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001

PATIENTS' UNDERSTANDING OF COMMON TERMS USED IN SELF-REPORTED MEASURES OF SEXUAL FUNCTION

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Objectives: Patient reported outcome measures may use terms that can be challenging for respondents with low literacy. As part of the development of the PROMIS® Sexual Function measure, we tested comprehension of words and phrases typically used in sexual function measures. **Material and Methods:** We conducted cognitive interviews among a diverse set of participants with respect to sex, age, race, ethnicity, education, health, and sexual orientation. We assessed participants' reading level using the Wide Range Achievement Test (WRAT). In the first round of cognitive interviews, each survey item was reviewed by 5 or more people, at least 2 of whom had less than a 9th grade reading level (low literacy). Patient feedback was incorporated into a revised version of the items. In the second round of interviews, an additional 3 or more people (at least 1 with low literacy) reviewed each revised item. **Results:** Twenty male and 28 female participants ranged in age from 21 to 70 years. Half were of non-white race, 3 were of Hispanic or Latino ethnicity, and 6 self-identified as gay, lesbian, or bisexual. Seventeen participants were classified as low literacy, some despite having greater than 9th grade education. Participants with low literacy had difficulty comprehending important terms including *aroused*, *orgasm*, *erection*, *ejaculation*, *incontinence*, and *vaginal penetration*. Many women, not only those with low literacy, had difficulty with clinical terms like *labia* (7/11 women) and *clitoris* (5/18 women). We modified unclear terms to include parenthetical descriptors or slang equivalents. For example, in the item, "How difficult was it to get an erection when you wanted to?" a participant misread or misunderstood the term *erection* to mean *ejaculation*. We added the parenthetical (*get hard*) after the term *erection* and found no misunderstanding in the second round of testing. Such revisions improved clarity with rare exceptions. For example, an item on how much *incontinence* has affected satisfaction with sex life was revised to include a descriptive parenthetical, but was still misunderstood by one patient to mean *intercourse*. **Conclusion:** Common words and phrases used across measures of self-reported sexual function are not universally understood. The use of parenthetical descriptors or colloquial terms yielded a higher overall understanding of survey items. Some items may remain unclear to participants with low literacy. Researchers should appreciate these misunderstandings as a potential source of error in studies using self-reported measures of sexual function.

Disclosure:

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002

MALE DYSPAREUNIA: A 4 YEARS PROSPECTIVE STUDY

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Defined by the occurrence of pain exclusively provoked by sexual intercourse, male dyspareunia is very rarely reported in medical literature. **Objective:** to analyze prospectively its frequency in our uro-andrological consultation from November 2004 to August 2008.

Method: The main clinical features (age, aetiology and treatment) of men consulting only for this reason (painful ejaculations excluded) have been noted. **Results:** 183 cases of a mean age 48 (17–81) of varied aetiology: a) 74 painful **La Peyronie's diseases** all treated by intracavernous corticotherapy; b) 49 **post-traumatic**: 38 partial or complete ruptures of glans fraenum (surgical treatment), 5 partial cavernous ruptures and 6 superficial cutaneous scratches (medical treatment); c) 28 **dermatological**: 22 scleroatrophic lichens, 5 chronic balanitis, 1 dorsal penile lymphangitis (medical or surgical treatment); d) 12 **mechanical**: 9 primary phimosis in young men, 2 penile ventral curvatures (1 congenital, 1 La Peyronie's disease) surgically treated, 1 chronic paraphimosis (posthectomy); e) 10 **post-surgical iatrogenic**: 2 medical (post-PGE1 intracavernous injection) and 8 surgical including: 1 distal pain after inflatable prosthesis implantation (removed), 3 after conservative surgery for La Peyronie's disease (2 ablations of non resorbable threads, 1 posthectomy), 2 painful fraenum scars (Z plasty) and 2 painful post-posthectomy scar (Z plasty); f) 10 **idiopathic** but in a particular context of both hyper sensitivity of glans and primary sexual difficulties in 7 young men (sexological approach and anesthetic cream), diabetic neuropathy (1), "chronic" priapism (1) and 1 without any detectable anomalies (oral or local analgesic before sexual intercourse). **Conclusions:** In spite of our bias of recruitment, male dyspareunia is likely underestimated because it is not a rare condition for consulting (mean : 4 per month in our experience). As it is often the revealing symptom of La Peyronie's disease or foreskin pathology, it should be systematically researched in this etiological context. Our clinical analysis shows that its medical or surgical management gives good results without difficulties for almost all cases. According to its severity, it may impair (personal / couple) sexual life with often a psychological suffering as for female dyspareunia. Like any chronic pain, male dyspareunia (and also any sexual pains) is not a minor symptom. This functional and common sexual trouble must be included in any standard evaluation of sexual health of both male and female.

Disclosure:

Work supported by industry: no.

003

SOMATIC CO-MORBIDITY AND CROSS-SEX HORMONE TREATMENT IN TRANSGENDER SUBJECTS

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Objective: To describe side effects and somatic co-morbidity in transgender subjects receiving cross-sex hormone treatment (CSHT) and the management of CSHT in those cases.

Material and Methods: Based on published papers, small unpublished studies (MtF > 50 years of age starting CSHT), and >30 years of the authors' experience in the field with >3000 subjects treated.

Results: Major side effect in estrogen-treated male-to-female (MtF) subjects are: venous thromboembolism and cerebrovascular disease, and probably cardiovascular death. These are more frequent with ongoing ethinyl estradiol or oral contraceptive use. The effect of CSHT on diabetes, hyperlipidemia and hypertension are not well studied but some indirect negative effects, such as weight gain, are probable.

Except for hormone-dependent neoplasms, there was no increased total mortality related to malignancy. A decrease in colon cancer-

observed elsewhere in postmenopausal women on estrogen- and an increased number of hematological malignancies have been reported. Many minor side effects were noted, which can be managed by adapting CSHT. Age and unhealthy life style (including smoking, obesity) may be important contributing factors to the occurrence of side effects, particularly in MtF persons.

In female-to-male (FtM) subjects, who average significantly younger than MtF persons when starting CSHT, acne (20%) and weight increases (>10% weight gain in 17% of subjects) are the most frequent side effects of testosterone therapy. Modifying androgen therapy and life style interventions can be of benefit.

Conclusions: Cross-sex hormone treatment of transgender persons carries certain health risks but these are largely preventable and manageable.

Disclosure:

Work supported by industry: no.

004

CHARACTERIZATION OF HYPOACTIVE SEXUAL DESIRE DISORDER (HSDD) IN MEN

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OBJECTIVES: Hypoactive Sexual Desire Disorder (HSDD) is the most common sexual dysfunction in women, however little is known about HSDD in men. Established patient-reported outcomes (PROs) and new PROs developed with U.S. Food and Drug Administration guidelines were used to develop the first comprehensive characterization of men diagnosed with HSDD (Diagnostic and Statistical Manual of Mental Disorders, 4th Edition, Text Revision [DSM-IV-TR]).

MATERIALS AND METHODS: A total of 200 men with or without symptoms of low sexual desire and related distress were recruited for this 4-week non-treatment study. Exclusions included erectile dysfunction, serum testosterone <300 ng/dL, and depression. Men completed assessments of sexual desire and sex-related distress and underwent structured clinical interviews for the diagnosis of HSDD. Scores on the Sexual Desire Inventory (SDI), Male Desire Scale (MDS), Sexual Concerns Inventory-Male (SCI-M), and Sexual Desire Relationship Distress Scale (SDRDS) on day 28, as well as University of California, Los Angeles (UCLA) Psychosexual Diary on days 21–27 served as primary endpoints. Scores are presented as median (interquartile range).

RESULTS: Of the 200 men enrolled in this study, 109 were diagnosed with HSDD and 91 were without HSDD. There were no clinically relevant differences in age, serum testosterone, depressive symptomatology, erectile function, concomitant illness, or medication use between the two groups. Clinically meaningful differences between men with and without HSDD, however, were observed in sexual desire according to the SDI score (40.0 [21.0] vs. 65.0 [25.0]) and the MDS sexual desire domain score (18.0 [8.0] vs. 31.0 [13.0]), in sex-related distress according to the SCI-M score (22.0 [12.0] vs. 6.0 [12.0]) and the SDRDS score (36.0 [17.0] vs. 10.0 [16.0]), and in the UCLA Psychosexual Diary sexual activity domain score (2.6 [2.7] vs. 4.9 [3.9]) ($P < 0.0001$, for all).

CONCLUSIONS: Men with and without HSDD as determined by a brief structured interview, diagnosis according to DSM-IV-TR criteria for HSDD, were comparable in age, serum testosterone, concomitant illness and medication use. Their experience of sexual desire and distress associated with low desire was, however, different. These controlled data characterize HSDD in men as a distinct sexual dysfunction.

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005

OUTCOME AND RISK FACTORS FOR VAGINECTOMY IN FEMALE-TO-MALE TRASEXUALS

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Objective(s): To determine outcome and risk factors for vaginectomy in female-to-male (FTM) transsexuals undergoing sex reassignment surgery.

Patients and Method(s): 89 FTM patients underwent mucosal vaginectomy between April 2004 and October 2011. This was performed as sole procedure in 15 (16.9%) and as a combined procedure in 74 (83.1%). Tranexamic acid 1 g was given at the end of surgery in 68 (76.4%) to reduce bleeding and all patients had a drain. All patients were discharged with either an urethral or a suprapubic catheter for at least 3 weeks in case of bladder hypotonia. Non-parametric Mann-Whitney tests were used to evaluate the data.

Result(s): Median operative blood loss was 700 ml (mean 762, range 100–3000); median post-operative blood loss was 200 ml (mean 261, range 20–1490); median blood transfusion was 0 units (mean 0.5, range 0–7) and 20 (22%) were transfused. Operative complications include 3 bladder perforations and 2 urethral injuries both treated with immediate primary repair with no future consequence. Post-operative complications included wound infection (n = 11, 12.3%), UTI (n = 5, 5.6%), wound bleeding (n = 13, 14.6%) and vaginal haematoma/abscess (n = 6, 6.7%) of which 5 were re-explored. Median catheter removal was 28 days (range 21–73) and 23 days (range 17–99) for urethral and suprapubic respectively. Post-op LUTS occurred in 10 (11.2%) patients. 4 patients with hypotonic bladder (2 pre-existing) were successfully managed with prolonged catheterisation and 6 with overactive bladder were treated with anti-cholinergics. There was 1 (1.1%) posterior urethral (vaginal) fistula and 1 (1.1%) urethral stricture directly related to the vaginectomy. There was a significant increase in total bleeding and complications with long vaginas ($p < 0.001$). Tranexamic acid appeared to make no difference to post-op bleeding ($p = 0.48$). There was no correlation of post-op LUTS with vagina length.

Conclusion(s): Urological complications are few and are easily manageable. Most complications are related to bleeding which appears to be related to vagina length.

Disclosure:

Work supported by industry: no.

006

WITHDRAWN

007

EFFECT OF BOTULINIUM-A TOXIN INJECTION INTO BULBOSPONGIOSUS MUSCLE ON EJACULATORY LATENCY TIME IN MALE RATS

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Objective: A variety of pharmacotherapeutic strategies have been employed to treat men suffering with lifelong PE. Given that the bulbospongiosus muscle (BSM) is involved in ejaculation and that local administration of the Botulinum-A Toxin (Btx-A) has been shown to impact muscle contractions, the current study was conducted to examine the effect of Btx-A injection into the BSM on the ejaculation latency of male rats.

Materials and Methods: After confirming sexual behavior in 33 male Long-Evans rats with sexually receptive females, those that exhibited

the entire repertoire of sexual behaviors received an additional 4 sexual experiences over the course of the following week in which all sexual behaviors were recorded by trained observers. On the day after their last experience, rats were lightly anesthetized, and received an injection of either 0.5 ($n = 11$), or 1 unit ($n = 11$) of Btx-A, or saline vehicle ($n = 11$). Btx-A was delivered bilaterally in 0.1 ml of saline vehicle injected percutaneously into the BSM. Two days after treatment, sexual behaviors were re-examined over the course of the following week on 4 separate occasions. The latency to first achieve first mount, intromission, ejaculation, the post-ejaculatory interval, the frequency of mounting behaviors and the number of intromissions were recorded by trained observers blind to the conditions.

Results: Relative to pre-treatment ejaculation latencies, bilateral injection of saline into the BSM did not impact ejaculation latencies (402.3 ± 220.1 sec vs. 453.8 ± 275.2 sec, $p = 0.53$); however, rats treated with either 0.5 or 1 unit Btx-A exhibited significantly longer latencies to achieve ejaculation relative to pre-treatment performance (357.9 ± 237.3 sec vs. 590.2 ± 306 sec, $P = 0.04$ and 302.8 ± 171.0 sec vs. 668.0 ± 376.8 sec, $P = 0.013$, respectively). Importantly, Btx-A did not impact the ability to achieve mount or intromission.

Conclusions: These results demonstrate that Btx-A injection into the BSM is a safe and effective treatment which can lengthen the latency time to ejaculate in rats without suppressing sexual behavior. Further studies are required to evaluate the therapeutic concept of this drug in PE patients.

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008

REDUCED GENITAL BLOOD FLOW IN A RAT MODEL TO SIMULATE AUTONOMIC DYSFUNCTION AFTER NERVE SPARING RADICAL HYSTERECTOMY

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Objectives: Radical hysterectomy (RH) causes sexual dysfunctions. Nerve-sparing RH (NSRH) may improve this morbidity but longterm studies are scarce and preclinical models in this field are not available. Our aim was to develop a model to study the impact of autonomic neuropathia on genital blood flow in female rats.

Materials and Methods: After ethical approval, female Sprague Dawley rats (250 g) were subjected to unilateral pelvic nerve (PN) crush (3×15 sec.; PNC; $n = 9$) or unilateral crush of the PN and nerves of the pelvic plexus supplying the vagina and bladder (clock-nerve crush; CNC; $n = 9$). During anesthesia, mean arterial blood pressure (MAP) was monitored and clitoral and vaginal bloodflows were registered by Doppler (tissue perfusion units; TPU) during stimulation (2.5–7.5 V; 20 Hz) of the PN at 3 and 10 days after nerve crush. Expressions of collagen III or neuronal nitric oxide synthase (NOS) were studied in genital tissues of rats subjected to bilateral PNC ($n = 5$) or sham operation ($n = 5$). T-test and ANOVA was used for comparisons.

Results: Rats exhibited voltage-dependent increases in vaginal and clitoral blood flows to activation of the intact (control) or crushed PN. At 3 and 10 days after surgery, stimulations of the PN caused vaginal blood flows of 0.09–0.32 TPU/MAP (control), 0.05–0.13 TPU/MAP (CNC; $p < 0.05$), and 0.04–0.15 TPU/MAP (PNC; $p < 0.05$), respectively. At any time, vaginal blood flows corresponded to 36–51% (CNC) and 39–51% (PNC) of control responses ($p < 0.01$ – 0.05). Similar findings were recorded at 3 and 10 days for clitoral blood flows that amounted to 0.05–0.20 TPU/MAP (control), 0.03–0.06 TPU/MAP (CNC; $p < 0.05$), and 0.02–0.06 TPU/MAP (PNC; $p < 0.05$),

respectively. Clitoral blood flows corresponded to 41–60% (CNC) and 35–51% (PNC) of control responses ($p < 0.05$). Vagina and clitoris from bilateral PNC rats expressed more collagen III and genital nerves contained less NOS-expressing fibers than sham-operated rats ($p < 0.05$).

Conclusions: Crush of pelvic nerves causes autonomic neuropathia that is recorded as genital blood flow dysfunction. Damage to pelvic nerves increases fibrosis and reduces NOS expression in vasoregulatory nerves in genital tissues. In analogy to the male rat model for cavernous nerve injury, the above models are proposed as relevant for the study of neuropathia associated with NSRH and will forward understanding of etiologies and development of novel therapeutic strategies for associated urogenital dysfunctions.

Disclosure:

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009

MINERALIZATION AND MECHANICAL TESTING OF PEYRONIE'S DISEASE TISSUES

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Objective: The primary purpose of this study was to investigate the biomechanical properties of plaque tissue recovered from surgical correction of patients with Peyronie's Disease (PD) relative to their mineral content.

Material and Methods: Tissue specimens were collected from Peyronie's Disease patients after surgical correction for PD with patients' consent and institutional approval. Specimens were stored at -80°C in Dulbecco's Modified Eagles Medium until testing was performed. Tensile tests were performed on 2×12 mm tissue strips. Indentation testing was performed with a Tissue Diagnostic Instrument using both a flat and a needle probe. Mineral foci in the tissues were first detected on x-ray films and then analyzed by scanning electron microscopy (SEM) and energy dispersive x-ray spectroscopy (EDX).

Results: Mechanical testing showed that low mineral regions had an elastic modulus ranging from 10–15.5 MPa by both testing methods. High mineral regions demonstrated an elastic modulus ranging from 21–25 MPa. SEM of the mineral-tissue interface revealed abundant collagen fibers which became embedded in dense mineral deposits. Surprisingly the collagen-rich fibrous regions adjacent to the heavily mineralized areas showed elevated levels of silicon. The concentration of silicon detected by EDX in the PD plaque ranged from 0.37–4.85 dry weight %. This observation was consistent in the apparently non-mineralized regions of all PD specimens examined whether these tissues contained no mineral, low mineral or high mineral content as detected by x-ray film.

Conclusions: Deposition of mineral as calcium phosphate in PD plaque tissues increases both the tensile and compressive elastic modulus and makes the dense collagenous tissues stiffer as would be expected. Surprisingly the highly mineralized tissue exhibits an elastic modulus only twice that of minimally mineralized tissue in other PD plaques. One possible reason for this observation is that the least mineralized regions of the PD plaques already contain elevated levels of silicates which begin to stiffen the dense collagen matrix before heavy calcium phosphate deposition. To our knowledge these are the first reports of the mechanical properties of PD plaques and the first demonstration of silicon deposition in PD plaques. Methods to detect and prevent silicon deposition in PD plaques may represent a new therapeutic approach to help prevent or reverse Peyronie's Disease.

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010

PELVIC NERVE INJURY LEADS TO AUGMENTED VAGINAL VASOREACTIVITY IN VITRO AND INCREASED FIBROSIS OF THE DISTAL VAGINA

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Objectives: Hysterectomy is the second most common surgery performed in women in the United States and frequently results in sexual dysfunction. Female sexual responses rely on innervations from the pelvic plexus which may become damaged during radical hysterectomies. The purpose of this study is to characterize the physiological and morphological end organ changes that take place following bilateral pelvic nerve injury (BPNI) in female rats. We hypothesize that there will be a decrease in neurogenic-mediated vaginal blood flow, decreased vaginal contraction to adrenergic stimuli and increased collagen in the vaginal wall.

Methods: Female Sprague-Dawley rats (8–10 wks) were divided into sham or BPNI groups. BPNI was performed by crushing nerves from the pelvic plexus innervating the vagina and bladder. *In vivo* pelvic nerve stimulated vaginal blood flow was assessed. Distal vaginal strips were mounted in a myograph and contractile responses to increasing concentrations of the alpha agonist, phenylephrine or frequencies of electrical field stimulation (EFS) were measured in the presence or absence of nitric oxide synthase (NOS) inhibitor L-NAME. Vaginal segments were also formalin-fixed and stained with Masson's trichrome to assess collagen content.

Results: *In vivo* vaginal blood flow was markedly decreased ($p < 0.05$) in BPNI compared to sham. In the distal vagina, there were no differences in contractile responses between the sham and BPNI rats when stimulated with an alpha-agonist, phenylephrine, or EFS. However, in the presence of L-NAME, the injured vaginal strips had a significantly greater ($p < 0.05$) contraction to EFS while there was no increase in sham strips indicating that the BPNI vagina may have a deficiency in NOS. Following crush injury, there is a significant increase ($p < 0.05$) in collagen within the vaginal wall and a decrease in vaginal epithelium.

Conclusions: The results in this study demonstrate that injury to the pelvic nerves will lead to impaired genital blood flow, augmented NOS-dependent smooth muscle reactivity, and fibrosis in the vaginal wall. These findings parallel the phenotype demonstrated in the male cavernous nerve injury model and provide us with a female counterpart to study the mechanisms of neuropraxia-induced female sexual dysfunction.

Disclosure:

Work supported by industry: no.

011

INTERVAL HYPOXIA TRAINING PRESERVES NORMAL ERECTILE FUNCTION IN THE AGING MALE SPONTANEOUSLY HYPERTENSIVE RAT

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Background: Interval hypoxia training (IHT), also known as altitude training, has cardiovascular and performance benefits in athletes, although the full impact on chronic diseases with cardiovascular elements like hypertension and erectile dysfunction are less well defined. The benefits of normobaric IHT on sexual function and cardiovascular health in spontaneously hypertensive rats (SHR) were evaluated in this study.

Methods: 12 week-old male SHRs received control (CON) or IHT (12 hours of 12.5% O₂ daily, 7/grp). Blood was taken for complete blood counts (CBCs). Erections (ER) and yawns (Y) were assessed by

a standardized apomorphine assay (80 ug/kg, s.c., 30 min). After 2 weeks of IHT (14–16 wks), both groups underwent telemeter implantation surgery to enable measurement of heart rate and blood pressure. IHT continued until week 24, but was then suspended to be resumed at week 30. Results are mean \pm st. dev. * = $P < 0.05$, Student's t test.

Results: As expected, CBC values in the control group were similar throughout the study. In contrast, IHT rats had sustained increases in hematocrit (25%*), red blood cells (20%*), and hemoglobin (25%*) after 2 weeks of treatment. Platelet and white blood cell counts were unaffected. Pre-IHT (13 wks), erectile responses were similar. In controls, erectile function declined from a peak at 15 weeks (3.0 \pm 1.2 ER) to less than 1 (0.8 \pm 0.5 ER at 23 wks, 0.8 \pm 0.7 ER at 37 wks). In contrast, at 23 weeks, the IHT group had significantly more erections (2.1 \pm 1.2* ER), despite significantly reduced apomorphine-induced yawns (11.4 \pm 4.9 CON vs. 2.9 \pm 1.2*** IHT Y). Six weeks after IHT was stopped (week 30), the benefit on erections and other parameters was lost (0.71 \pm 0.64), but was regained after resuming IHT. Specifically, at 33 weeks, increases in hematocrit (29%*), red blood cells (27%*), and hemoglobin (21%*) returned, and yawns reduced (9.5 \pm 4.2 CON vs. 1.0 \pm 0.7* IHT). At 33 weeks, total erectile responses in IHT rats had not achieved significance (1.8 \pm 1.2 IHT vs. 0.8 \pm 0.5 CON), but by week 37 full erectile function was regained with IHT therapy (2.8 \pm 1.9* ER).

Discussion: This study reveals that IHT can preserve normal erectile function in the aging SHR. Evaluating the clinical potential of treatment modalities, such as simulated "altitude training", will require further investigation, but appears to be promising. Funding: Federal Economic Development Agency for Southern Ontario, CMP: Queen's Dept. of Medicine.

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012

GGF2 IS NEUROPROTECTIVE IN A RAT MODEL OF CAVERNOUS NERVE INJURY-INDUCED ERECTILE DYSFUNCTION

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Objective: Erectile dysfunction (ED) is a common complication following radical prostatectomy. It is acknowledged to be due to penile neuropathy; however, there is no effective treatment. Glial growth factor 2 (GGF2) is a member of the neuregulin family of growth factors that has been demonstrated to protect neurons from injury and stimulate their growth in a range of animal models of neuropathy. Our previous data suggests that GGF2 delivered subcutaneously (sc) may be a viable therapy for cavernous nerve (CN) injury. In this study, we aimed to test the effective dose range of GGF2 to recover erectile function (EF) and examined its effect on CN survival.

Material and Methods: Adult male rats underwent bilateral CN crush injury (BCI) or sham surgery (Control) and were divided into the following groups (n = 10–12/group): Control+vehicle; Control+GGF2 (15 mg/kg); BCI + vehicle; BCI + GGF2 (5 mg/kg); BCI + GGF2 (15 mg/kg). GGF2 was administered sc 24 h before, 24 h after and once weekly until study end 5 weeks after BCI or sham surgery. At the end of the treatment, EF was examined by monitoring intracavernous pressure responses to electrical stimulation of CN at 0.3, 1 and 4 volts. CN were processed for electron microscopic analysis and quantitation of unmyelinated nerve fibers.

Results: EF was significantly decreased in BCI+vehicle and BCI+GGF2 (15 mg/kg) groups ($p < 0.05$) but not in BCI+GGF2 (5 mg/kg) group ($p > 0.05$) compared with Control+vehicle at 0.3 and 1 volt. At 4 volts, EF was significantly increased in both BCI+GGF2 (5 and 15 mg/kg) groups compared to BCI+vehicle ($p > 0.05$) and did not differ from Control+vehicle ($p > 0.05$). In BCI+GGF2 (5 mg/kg) group, the number of denervated Schwann cells without unmyelinated

fibers was significantly lower than BCI+vehicle group ($p < 0.05$), and unmyelinated nerve fiber histogram demonstrated a rightward shift, indicating an increase in number of unmyelinated axons per Schwann cell.

Conclusion: Treatment with GGF2 at 5 mg/kg, sc effectively preserved EF in rats following CN crush injury with an increase in the number of surviving unmyelinated nerve fibers. Our results suggest that GGF2 is a potent neuroprotective agent in penile innervation and provides a new therapeutic approach to treat or prevent ED following prostate surgery.

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013

GALANIN IS UPREGULATED IN THE RAT MAJOR PELVIC GANGLION FOLLOWING CAVERNOUS NERVE INJURY: A NOVEL TARGET IN ERECTILE FUNCTION RECOVERY FOLLOWING RADICAL PROSTATECTOMY?

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Objectives: In a recent micro-array on the regulation of 44K genes in the major pelvic ganglion (MPG) of cavernous nerve injured (CNI) rats at 48 hours following injury, the neuropeptide Galanin was upregulated compared to sham operated rats. Galanin has been proposed as an endogenous neurotrophic peptide and may therefore play a role in the neuroregenerative response to CNI. This study was designed to gain a further insight in the expression and temporal regulation of galanin and galanin receptor 2 (GalR2) in the MPG following CNI. **Material and Methods:** After ethical approval, 30 rats were subjected to bilateral CNI under anesthesia. The MPGs were harvested at 2, 7, 14, 30 and 60 days following injury in 5 rats per time-point. Sham operated rats ($n = 5$) served as controls. MPGs were lysed and RNA was isolated, followed by reverse transcription and qPCR for Galanin and GalR2 expression. Furthermore, we evaluated the expression of GalR1, 2, and 3 and Galanin in the MPG of sham rats by IHC. Data are given as mean \pm SEM.

Results: Galanin, and its receptors GalR1 and GalR2 are expressed in the MPG, and are located in the neuronal population of the ganglion. GalR3 was detected at the adventitial side of the vasa nervorum and in pelvic resistance arteries close to the MPG. Galanin expression significantly increased acutely after CNI and gradually started to decrease after 14 days (2d: 231,4 \pm 63,3; 7d: 251 \pm 55; 14d: 128,9 \pm 94,8; 30d: 28,6 \pm 9,1; 60d: 10,2 \pm 3,8. Data are fold regulation of sham). GalR2 expression showed a gradual decrease following CNI (2d: 0,68 \pm 0,16; 7d: 0,55 \pm 0,04; 14d: 1,05 \pm 0,26; 30d: 0,49 \pm 0,04; 60d: 0,39 \pm 0,02).

Conclusions: Galanin is upregulated in the MPG in the early phase after CNI after which it gradually decreases. GalR2 expression slowly decreases after injury which is may be a result of apoptosis of neurons expressing this receptor. Previously it has been shown that Galanin expression is regulated by nerve growth factor in autonomic ganglion neurons (Liu et al 2010), and autonomic ganglia from knock-out mice for GalR2 show impaired neuroregeneration in-vitro (Hobson et al. 2006). Based on these data and our results we hypothesize that Galanin upregulation is an important factor in the endogenous neuroregenerative response to CNI. Modulation of this peptide and its receptors represents an interesting new avenue in the setting of erectile function recovery following CNI.

Disclosure:

Work supported by industry: no.

014

COMPLETE RECOVERY OF ERECTILE FUNCTION BY COMBINED INTRACAVERNOUS BONE MARROW-DERIVED MESENCHYMAL STEM CELL THERAPY AND ORAL TADALAFIL ADMINISTRATION AFTER CAVERNOUS NERVE INJURY IN RATS

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Objective: To evaluate the efficacy of dual targeted strategy to promote cavernosal tissue preservation using systemic PDE5 inhibition and local stem-cell therapy in a rat model of cavernous nerve (CN) injury. **Material and Methods:** Bilateral CN crush injury (BCNI) was produced in anesthetized male Wistar rats.

Tadalafil was orally administered at 5 mg/kg/day dose. Bone marrow-derived mesenchymal stem cells (BMSC) were obtained from donor rats and in vitro expanded and characterized before intracavernosal implantation by means of an automated microinjector pump. Erectile responses to CN electrical stimulation (CNES) and ex vivo function of corpus cavernosum (CC) were evaluated 4 weeks after BCNI.

Treatment group	n	% of response to CNES in Sham (20 Hz)
SHAM	7	100.0 \pm 9.1
BCNI	9	39.2 \pm 5.2***
BCNI+TAD	5	64.2 \pm 6.3*
BCNI+BMSC	4	46.0 \pm 17.5**
BCNI+TAD+BMSC	4	92.1 \pm 4.9††

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$ vs SHAM, †† $p < 0.01$ vs BCNI.

Results: BCNI resulted in marked reduction of erectile responses to CNES which were partially recovered by treatment with tadalafil or by intracavernosal implantation of BMSC. The complete recovery of erectile function was only achieved when both treatments were combined (Table). Relaxations of CC to carbachol or sodium nitropruside were not altered by BCNI or any of the treatments. In contrast, nitroergic relaxations were almost abolished in CC from BCNI rats and improved by tadalafil, BMSC or combined strategy.

Conclusions: BCNI did not impair endothelial or smooth muscle relaxation of CC but blunted neurogenic (nitroergic) relaxation which was improved by oral tadalafil and intracavernosal BMSC individually but only the combination of both therapies recovered erectile function. These results support the use of dual therapeutic approaches, cell therapy and oral PDE5 inhibitors, for recovering erectile function in patients undergoing radical prostatectomy.

Disclosure:

Work supported by industry: no.

015

ACTIVATION OF MU AND DELTA OPIOID RECEPTORS IN THE LUMBAR SPINAL CORD IS CRITICAL FOR EJACULATION

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Objective: Ejaculation is controlled by a spinal ejaculation generator located in the lumbosacral spinal cord, consisting of a population of lumbar spinothalamic (LSt) cells. LSt cells regulate ejaculation via inter-spinal projections to autonomic and motor centers, and co-express several neuropeptides, including enkephalin, galanin and gastrin releasing peptide (GRP). We hypothesize that the neuropeptide enkephalin plays a critical role in the control of ejaculation by acting on mu or delta opioid receptors in LSt target areas.

Materials and Methods: Adult male rats were anesthetized and spinalized and received intrathecal infusions of saline, mu receptor antagonist CTOP (0.3 or 3 nmol), delta antagonist (TIPP (0.4, 4 or 40 nmol), mu agonist DAMGO (0.1 or 10 nmol) or delta agonist deltorphin (1.3 or 13 nmol). Ejaculatory reflexes were triggered by stimulation of the dorsal penile nerve (DPN) and seminal vesicle pressure (SVP) and rhythmic contractions of the bulbocavernosus muscle (BCM) were analysed.

Results: First, intrathecal infusion of mu or delta receptor antagonists, but not saline, effectively blocked ejaculatory reflexes induced by DPN stimulation. Second, we tested if mu or delta agonist infusions trigger ejaculatory reflexes in the absence of DPN stimulation or following sub threshold stimulation that does not trigger ejaculation in control conditions. Intrathecal infusion of DAMGO, but not deltorphin, triggered ejaculation in absence of DPN stimulation in a subset (75%) of animals. Both mu and delta agonists facilitated ejaculatory reflexes induced by sub threshold DPN stimulation in all animals.

Conclusions: Overall, these results support the hypothesis that enkephalin plays a critical role in the control of ejaculatory reflexes in male rats, by acting on mu and delta opioid receptors in LSt target areas in the lumbosacral spinal cord. Opioid receptor activation is required for ejaculation, and mu activation is sufficient to trigger ejaculation in the absence of sensory stimulation. Previously, we showed a similar critical role for GRP, a neuropeptide that is completely and exclusively expressed by LSt cells. Together these findings suggest a complex balance between the actions of these co-expressed neuropeptides, where co-release of multiple neuropeptides may be required to trigger ejaculation, but inhibition of each one alone may disrupt ejaculation. Finally, these findings suggest that opiates may serve as a treatment option for ejaculatory disorders.

Disclosure:

Work supported by industry: no.

016

EVALUATION OF SEXUAL FUNCTION IN FEMALE POST-CYSTECTOMY PATIENTS USING CURRENT HRQOL TOOLS

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Objectives: We hypothesized that validated bladder cancer Health-Related Quality of Life Questionnaires (HRQOL) in female cystectomy patients do not fully capture sexual function compared to the FSFI.

Materials and Methods: We isolated the sexual function questions from the Bladder Cancer Index (BCI), European Organization for Research and Treatment of Cancer Quality of Life – Bladder Cancer Superficial/Muscle Invasive (EORTC QLQ-BLS24/BLM30), Functional Assessment of Cancer Therapy-Bladder Cancer (FACT-BL), and the Functional Assessment of Cancer Therapy-Vanderbilt Cystectomy Index (FACT-VCI). These questions were then categorized into the six domains present in the FSFI.

Results: The BCI covers four domains out of the six utilized on the FSFI. Lubrication and satisfaction are not addressed. The EORTC

Table 1: Bladder Cancer HRQOL instrument and No. of items correlating with FSFI domains*

FSFI DOMAIN	BCI	EORTC QLQ-		
		BLS24/BLM30	FACT-BL	FACT-VCI
Desire	2	1	1	1
Arousal	1			
Lubrication		1		
Orgasm	2	**2	**1	**1
Satisfaction		1	1	
Pain	1			

* No. indicates no. of items tied to particular FSFI domain within specific HRQOL instrument.

** Pertains to erectile function in men only - N/A to study.

QLQ-BLS24/BLM30, FACT-BL, FACT-VCI include questions directed at three, two, and one of the six FSFI domains respectively.

Conclusions: Current bladder cancer HRQOL tools do not fully capture sexual function. Revising the instruments or supplementing current HRQOL tools with the FSFI will better evaluate women after cystectomy.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

017

THE RELATIONSHIP BETWEEN SEXUAL FUNCTION AND CARDIOVASCULAR HEALTH IN WOMEN: A PRELIMINARY STUDY

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Objectives: Erectile dysfunction is a known predictor of cardiovascular disease (CVD) in men, and CVD is the leading cause of death in the United States. Despite similarities in vascular engorgement during sexual arousal in men and women, little is known about CVD and female sexual arousal. A paucity of studies have found lower sexual function in women with CVD, but no study to date has directly studied the relationship between genital sexual responses and CVD in women. We used objective measures of vascular health and genital engorgement during sexual arousal to identify associations between these measures.

Material and Methods: Eight healthy pre-menopausal women between 25 and 45, not on hormonal birth control, were studied during their luteal phase. Vaginal pulse amplitude (VPA), a measure of genital sexual arousal, was measured by vaginal photoplethysmography during exposure to audio/visual sexual stimuli. Vascular measures included flow mediated vasodilation, pulse wave velocity (PWV), an index of vascular stiffness, both of which were measured in two different vascular beds using non-invasive ultrasound approaches. Vascular compliance was estimated by the relationship of cardiac output to stroke volume (SV) and peripheral pulse pressure (PP).

Results: Preliminary results (n = 4) suggest that VPA is associated with vascular function. Half of the subjects exhibited normal change in VPA from baseline (responders) and half demonstrated <20% change in VPA from baseline (non-responders) in response to sexual stimuli. Although the sample is too small for statistical analyses, results were in line with expectations: For the non-responders, PP, systolic blood pressure, mean arterial pressure, and PWV values were higher and SV/PP was lower than for the responders. Data collection is ongoing and results will be updated as they become available.

Conclusions: The association between VPA and vascular function is in line with studies on men and provides the first direct evidence that problems in genital sexual arousal could predict CVD. If these results are confirmed by a larger sample, future studies should focus on symptoms associated with impaired genital sexual responses that can be identified by patients. Patient-identifiable symptoms could provide an opportunity for early detection of vascular dysfunction.

Disclosure:

Work supported by industry: no.

018

CARDIOMETABOLIC RISK AND FEMALE SEXUAL HEALTH: THE PRINCETON III SUMMARY

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OBJECTIVES: The first two Princeton Consensus Conferences focused on relationships between sexual function and cardiovascular

health in men, and the development of guidelines for management of erectile dysfunction in men with cardiovascular disease. The 3rd Princeton Consensus Conference updated recommendations and assessed, for the first time, the association between female sexual dysfunction (FSD) and systemic vascular endothelial dysfunction and its consequences in women. Female sexual function is dependent, in part, upon normal endothelial function within the genital arterial vascular bed. The 3rd Princeton Consensus Conference reports on the association between cardiometabolic risk factors and female sexual health.

MATERIALS AND METHODS: Associations between some cardiometabolic risks and women's sexual health was reviewed by a panel of experts. These risk factors included hypertension, dyslipidemia and/or hyperlipidemia, cigarette smoking, diabetes mellitus, and metabolic syndrome/obesity. In addition, the literature concerning associations between FSD and presence or absence of cardiovascular disease, predictive association of FSD with cardiovascular events, and the possibility of vascular risk factor treatment modifying FSD was reviewed. Main outcome measures used were cardiometabolic risk factors and female sexual health, specifically genital arousal.

RESULTS: Women treated for hypertension have more FSD than their normotensive counterparts. Women with hyperlipidemia but without cardiovascular disease have more FSD than women without hyperlipidemia. Women with metabolic syndrome/obesity have more FSD than those without. Cardiometabolic risk factors, diabetes, and coronary heart disease are associated with increased FSD. Treating the metabolic syndrome/obesity is associated with less FSD. At present there are no data to support the hypothesis that FSD is a predictor of future cardiovascular events, as it is in men.

CONCLUSION: Female sexual health is complex. Subjective and objective aspects of arousal and desire, with their numerous contributions from hormonal, psychological, interpersonal, and social factors, are relatively independent. Based on limited current data, there appears to be an association between female sexual health and the vascular risk factors hypertension, hyperlipidemia, metabolic syndrome/obesity, diabetes, and coronary heart disease, however more research is needed.

Disclosure:

Work supported by industry: no.

019

UPDATED ANALYSES OF A RANDOMIZED, DOUBLE-BLIND, PHASE 3 STUDY OF FEMPROX®[®], A TOPICAL ALPROSTADIL CREAM WITH A NOVEL TRANSDERMAL DELIVERY TECHNOLOGY (NEXACT®) FOR THE TREATMENT OF FEMALE SEXUAL AROUSAL DISORDER (FSAD)

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Objectives: Female sexual arousal disorder (FSAD) is the second most common sexual health concern affecting 26% of adult women. Approximately one fifth of these women (5.4% of all adult women) are distressed by their FSAD. A randomized, double-blind, placebo-controlled Phase 3 trial was performed in pre- and post-menopausal women with FSAD using Femprox®[®], a topical alprostadil 0.4% cream with the skin penetration enhancer DDAIP, an ester of N, N-dimethylalanine and dodecanol. After publication of key results, the weighted FSFI scores have been re-analyzed providing new analyses of efficacy and safety.

Material and Methods: After screening and undergoing a 4-week non-treatment baseline period, a total of 387 women received up to 10 identical premeasured doses during 8 weeks of active treatment. Each subject received five doses of either placebo or active drug for each 4-week treatment period with the same alprostadil dose. The primary efficacy endpoint was Satisfactory Sexual Events (SSEs). Secondary endpoints included the Female Sexual Function Index (FSFI),

Global Assessment Questionnaire (GAQ), and the Female Sexual Distress Scale (FSDS).

Results: The percentage improvement in SSEs at the end of the total evaluation period in the Intent-To-Treat population (n = 374) was 33.1%, 46.3% (p = 0.0161), 43.5% (p = 0.0400), and 53.9% (p = 0.0002) for placebo, 500, 700, and 900 mcg alprostadil groups, respectively. There was a clear dose response with respect to improvements in FSFI score. The 900 mcg dose showed a statistically significant reduction in all FSFI domains, with a baseline value of 14.65 and post-treatment value of 23.19 vs. placebo at 14.85 and 20.30 respectively (p = 0.0017). The 900 mcg dose was also statistically significantly superior to placebo in the GAQ and FSDS assessments.

Conclusions: The 900 mcg dose of Femprox®[®], topical alprostadil 0.4% cream, appears to be safe and efficacious for the treatment of FSAD, however, more research is needed.

Disclosure:

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020

COMPARISON BETWEEN PERINEAL EXERCISES AND SEXUAL EXERCISES AS PHYSIOTHERAPEUTIC TREATMENT METHOD IN FEMALE ORGASMIC DYSFUNCTION

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Objectives: The main objective of study is to compare the perineal exercises and sexual exercises as a physiotherapeutic treatment method in female orgasmic dysfunction.

Methods: Fourteen women patients were randomized and compared in a descriptive study divided in two groups: sexual exercises (SE - five patients) and sexual and perineal exercises (SPE - nine patients). The groups were analyzed through personal information, personal history, and information about sexual life. The pelvic floor muscle functions were evaluated using by bidigital palpation and the scales AFA and PERFECT Scheme. The questionnaire "Sexual Quotient - Female Version" (SQF) was used to evaluate the sexual function. The patients in group SE received an explanatory booklet with information and exercises to facilitate the obtaining orgasm and were instructed to follow the guidelines of the booklet three times a day. The patients in the SPE received the same instructions given to the SE group and underwent two perineal exercises protocols, once a week in the clinic and another daily in their house. After ten weeks of perineal exercises, the patient ability to achieve orgasm were evaluated using "SQ-F" questionnaire and went through a final evaluation of the pelvic floor.

Results: Our findings showed that 80% of patients in the SE group were able to achieve orgasm only through masturbation. Moreover, 40% of patients of this group (SE) were able to achieve orgasm through masturbation with the presence of the partner, and only 22.2% in the SPE group. The results showed an improvement, evidenced by the AFA and PERFECT scales pre and post intervention and the mean scores of the "SQ-F".

Conclusions: Sex education is important in the treatment of anorgasmia. The rehabilitation program improves the pelvic floor perineal muscle strength, sensitivity and awareness perineal, and genital pleasure during intercourse, and sexual quality, evidenced by the "SQ-F".

Disclosure:

Work supported by industry: no.

021

LAXITY OF THE VAGINAL INTROITUS AFTER CHILDBIRTH: CLINICAL EVALUATION OF NONSURGICAL VAGINAL TISSUE RESTORATION WITH RADIOFREQUENCY IN JAPANESE WOMEN

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Objective: Decreased genital sensation of the vaginal tissue associated with childbirth has the potential to negatively impact sexual satisfaction of many women. The study objective was to demonstrate the effect of low energy radiofrequency (RF) on vaginal laxity and subsequent sexual satisfaction in women with a complaint of increased vaginal laxity and decreased genital sensation as a result of childbirth.

Material and Methods: The Viveve System (Viveve, Inc., Sunnyvale, CA USA) is a RF device that uses surface cooling with low energy delivery (90 J/cm²) to restore collagen found in the submucosal vaginal tissue. Thirty pre-menopausal Japanese women were treated in this single-arm study. Self-reported levels of vaginal laxity and sexual satisfaction were measured before treatment, and at one, three, and six months post-treatment.

Patients were assessed using two Likert-type visual analog scale self-report questionnaires for scoring patient-reported vaginal laxity/tightness and sexual satisfaction. Two standard sexual function questionnaires were also administered, the FSFI and FSDS-R.

Results: Patients were on average age of 42.9 years (range 30–52; median 43) and average parity of 2.2 (range 1–4). Because of the variability in the subjects' pretreatment vaginal laxity (VLQ scores) and sexual satisfaction (SSQ), each subject's pretreatment scores was set to zero to serve as her own control, and post-treatment scores were reported as changes relative to that baseline. Subjects' perceived vaginal tightness improved by a mean score of 1.37 at month 1 ($p < 0.001$) to 1.77 at month 6 ($p < 0.001$) levels from baseline.

At screening, 17 of 30 (57 %) subjects reported a decrease in sexual satisfaction compared prior to childbirth. For these subjects, significant improvements in sexual satisfaction were reported at each follow-up assessments, mean score of 0.88 at month 1 ($P = 0.017$) increased to 1.41 at month 6 ($P = 0.001$) post-treatment. FSFI and FSDS-R scores were also significantly improved after treatment. The FSFI total scores improved from a mean of 22.4 pre-treatment to 26.0 ($P = 0.005$) 6-months post-treatment. The FSDS-R scores improved significantly from 15.8 to 9.9 at month 6 ($P = 0.001$). Adverse events, consisting of one case each of vaginal leukorrhea, abdominal discomfort and vaginitis, were mild and self limited.

Conclusion: These results indicate RF treatment at the vaginal introitus is safe and well-tolerated office based procedure, and offers a nonsurgical modality to treat distressing vaginal laxity. Significantly improved self-reported sexual satisfaction, as well as improved sexual function and decreased sexual distress, were observed at 6 months following a single treatment.

Disclosure:

Work supported by industry: no.

022

RESULTS FROM THE HEALTHY WOMEN SURVEY: VAGINAL SYMPTOMS OF MENOPAUSE

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Introduction: To help better understand postmenopausal women's knowledge and attitudes towards the vaginal and sexual symptoms of menopause, particularly vaginal dryness and painful intercourse and

their impact on women's sexual health. **Methods:** An online custom research survey administered to 1,043 postmenopausal women 40+ years of age who reside in the US. Online interviews averaged 13 minutes and took place April 19–May 3, 2011. Participants were not compensated. **Results:** Respondents' age ranged from 40 to 84 years, with an average age of 58.9, and the majority (55%) reported having their last period within the past 10 years. The majority of women who responded to the survey (73%) reported they are in a committed relationship, and 50% of those have had sex in the past six months. More than half of the postmenopausal women surveyed (56%) indicated they have experienced vaginal dryness. Among those women who reported experiencing vaginal dryness, 82% reported that their vaginal dryness bothers them a little to a great deal, with 20% reporting that their vaginal dryness bothers them either a lot or a great deal. Only 17% of women reported that their vaginal dryness did not bother them at all. Of the postmenopausal women surveyed, half of those who reported experiencing vaginal dryness (50%) and two-thirds of those who reported experiencing painful intercourse (66%) agreed* with the statement, "Vaginal dryness/painful intercourse makes me not want to have intercourse anymore." Almost all of the postmenopausal women surveyed who reported experiencing painful intercourse (93%) indicated they still engage in intercourse even though it is painful, with 40% engaging in intercourse at least once a week. Of the postmenopausal women surveyed who reported engaging in intercourse even though it is painful, almost three-quarters (73%) said they engage in painful intercourse because of their partner. Among the postmenopausal women surveyed who reported speaking to their health care professional, nearly two-in-five who reported experiencing painful intercourse (39%) and 27% who reported experiencing vaginal dryness indicated they waited more than two years before they spoke to their health care professional about their condition. **Conclusions:** There continues to be a lack of awareness concerning menopausal vaginal dryness and dyspareunia. Women continue to face barriers to candid communication with their health care professional and barriers to safe effective treatment exist.

Disclosure:

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023

THE IMPACT OF THE SELF-ESTEEM IN THE FEMALE SEXUALITY

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Objective: Evaluate the effects of self-esteem in the female sexuality in a population of women with sexual dysfunction.

Material and Methods: The sample was composed by 139 women who looked for the Project Afrodite – Female sexuality ambulatory of Unifesp – São Paulo, Brazil, in the period from April 2011 to April 2012 complaining of sexual dysfunction. Each participant answered to two questionnaires previously validated. The first, the Rosenberg's Self-Esteem Scale is composed of 10 Likert type affirmative sentences which evaluate the global self-esteem and which was adapted and validated to the Brazilian population by C. Hutz. The second, Female Sexual Quotient (FSQ) was created and validated in Brazil by C. Abdo. It is a questionnaire composed of 10 questions whose options vary from 0 to 5 and evaluate all the phases of the cycle of sexual response.

Results: The results showed it exists significant relation ($\chi^2 = 33,54$ s.1%) between the self-esteem and the level of sexual satisfaction, pointing out the importance of high levels of self-esteem to the good performance in sexual life. It is confirmed the relation between the level of sexual satisfaction and the age ($\chi^2 = 10,74$ s.5%), but in a different sense of the expected, because instead of prevailing the sexual difficulties in the menopause, the difficulties were noticed in the period from 31 to 45 years old. When the questions of the FSQ were evalu-

ated separately and compared to the self-esteem, it was certified significant relation ($z = 2,38$ s.5%) to the spontaneous thinking, also significant ($z = 2,38$ s.5%) to the disposition to participate of the sexual intercourse and ($z = 7,5$ s.1%) to the concentration in the sexual act as well. It was also known that the self-esteem is associated to the importance attributed to the foreplay, with significant differences between high self-esteem and sexual arousal ($z = 3,1$ s.5%) just like the sexual harmony ($z = 3,25$ s.5%) the only significant difference was between women of high and medium self-esteem.

Conclusion: It is concluded that the self-esteem interferes in the performance of the sexual activity, exercising greater influence in the matters related to desire and to the importance attributed to the foreplay.

Disclosure:

Work supported by industry: no.

024

THE ASSOCIATION BETWEEN BODY MASS INDEX, STUNKARD FIGURE RATING SCALE AND SEXUALITY IN YOUNG ITALIAN FEMALES

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Objective: To evaluate (in the follicular phase) in young, eumenorrheic women, the role of body weight and perceived body image in the sexual behavior.

Material and Methods: Ninety Italian women were recruited in the study and underwent to ultrasonographic measurement of the clitoral body volume and color Doppler evaluation of the clitoral and ophthalmic arteries. Moreover, subjects were asked to fill in the two-factor Italian McCoy female sexuality questionnaire (MFSQ), the Stunkard Figure Rating Scale and the Beck's Depression Inventory questionnaire (BDI). Fasting blood samples were drawn to test hormonal (estradiol and testosterone) and biochemical (sex hormone binding globulin, lipids, glucose, insulin) parameters.

Results: All women completed the study and were divided into: lean (Group I; $n = 47$); overweight (Group II; $n = 22$); and obese (Group III; $n = 21$). At the level of ophthalmic artery, the Doppler analysis showed significant lower resistances in lean (Pulsatility Index $-PI: 1.72 \pm 0.39$) in comparison with overweight ($PI = 1.99 \pm 0.30$; $p = 0.041$) and obese women ($PI = 2.08 \pm 0.19$; $p = 0.003$). In addition, the obese subjects presented the worst clitoral vascularization.

He MFSQ for sexuality was higher in lean (45.8 ± 11.8) than in overweight (36.4 ± 15.0 ; $p = 0.038$) and obese (36.1 ± 10.8 ; $p = 0.031$) women. The incidence of sexual dysfunction (MFSQ < 35) was lower in lean (12%) than in obese subjects (42%; $p < 0.05$). The number of intercourse/week was significantly higher in lean (2.2 ± 1.4) than in overweight (1.3 ± 0.7 ; $p = 0.049$) and obese women (1.2 ± 0.4 ; $p = 0.020$). The percentage of anorgasmic women was significantly higher in obese (23%) than in lean subjects (6%; $p < 0.05$). The Stunkard Figure Rating Scale evidenced that the lean subjects represented themselves with a mean value (3.5 ± 1.0) lower than overweight (4.8 ± 0.7 ; $p < 0.0001$) and obese women (5.9 ± 0.6 ; $p < 0.0001$). The figure that represented their own ideal was significantly higher in obese (4.0 ± 0.4) than in overweight (3.3 ± 0.5 ; $p = 0.008$) and lean (2.9 ± 0.7 ; $p < 0.0001$) subjects. Similar differences were observed in relation to the figure they considered most feminine and to that they considered most attractive for their partner. The actual and ideal weight was not different among lean subjects. On the contrary it was significantly different for the other two groups. The obese women were satisfied of their own body and felt good because of their own silhouette significantly lesser than the lean subjects.

Conclusions: obesity might impair the quality of sexual life inducing genital and general vascular stiffness, body image distortion and emotional distress.

Disclosure:

Work supported by industry: no.

025

IMPACT OF PRIMARY ED ETIOLOGY ON DEVICE DURABILITY FOR CONTEMPORARY INFLATABLE PENILE PROSTHESES: OUTCOMES FROM 1,882 PATIENTS WITH, AND 23,032 PATIENTS WITHOUT, PEYRONIE'S DISEASE

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Objective: Recent reports suggest an increased rate of device-related complications for 3-piece inflatable penile prostheses (IPPs) as treatment for combined refractory erectile dysfunction and Peyronie's disease (PD). IPPs are an essential option for these patients, resulting in improved erectile function and quality of life. Current series are limited by small patient numbers, lack of multi-institutional cohorts, and may not reflect contemporary surgical practice or devices. We present a large series of patients treated with IPPs for PD in order to better define implant durability in these patients.

Materials and Methods: Patient Information Form (PIF) database records for AMS 700 prostheses implanted between May 1, 2001 and December 31, 2008 were retrospectively reviewed to compare device revisions reported for patients with and without PD as their single recorded etiology of ED. Reasons for IPP revisions were categorized as mechanical malfunction, fluid loss, dissatisfaction, infection, erosion and other. Life table survival analysis was used to estimate device survival from revisions for any reason in men with PD vs. other etiologies, and between CX and LGX/Ultrex cylinders within the subgroup of men with PD. Log-rank p-values < 0.05 were statistically significant.

Results: No appreciable differences in device survival from revision for any reason was demonstrated for 1,882 men with PD vs. 23,032 with other recorded etiologies, including diabetes, organic, prostatectomy, vascular, or others ($p = 0.3529$). In the men with PD, revisions were reported at any time throughout follow-up for 113 (6.97%) of 1,621 patients with CX, and for 5 (3.31%) of 151 with LGX/Ultrex cylinders; mean follow-up was 45 months for CX and 32 months for LGX/Ultrex cylinders. Survival from revision for any reason in men with PD at up to 7.7 years of follow-up was 90.96% for CX implants, vs. 93.36% for LGX/Ultrex implants ($p = 0.2154$).

Conclusions: This series of PD patients treated with modern IPPs, the largest reported to date, demonstrates that device survival over more than 7 years post-implantation exceeds 90% and is not significantly different than in patients with non-PD primary causes of ED. Further, the cylinders that allow for limited length and girth expansion do not appear to have reduced durability when used in men with PD than the cylinders allowing for only girth expansion.

Disclosure:

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026

SALVAGE REPLACEMENT OF PENILE PROSTHESIS WITH NORMAL SALINE WASHOUT

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Objectives: Successful salvage of infected penile prosthesis (IPP) operations has previously shown a benefit with complete implant removal along with a regimented salvage irrigation protocol. This paradigm is widely utilized for the management of prosthesis infections. During revision surgery for infected penile prosthesis, we investigated the use of normal saline washout of the implant space followed by immediate replacement of prosthesis.

Materials and Methods: All patients presenting with prosthesis infection between 2002 and 2011 were considered for salvage surgery as

part of a dual institution study. These patients underwent a standard 10-minute skin preparation with povidone-iodine scrub followed by an alcohol solution, and standard preoperative antibiotics for prosthesis surgery. The 3-piece inflatable prosthesis was removed including the cylinders, scrotal pump and reservoir in all cases. Intra-operative wound culturing was performed including specific culturing of the prosthesis components. The corpora, scrotal cavity, and reservoir pockets were then copiously irrigated with 10 to 12 liters of normal saline using a Simpulse™ irrigator. Gloves were frequently changed. All implants were replaced with a semi-rigid implant and 4 penrose drains were placed. All patients were admitted for IV antibiotics until drains were removed, and then discharged with 4–6 weeks of culture-specific antibiotics. We waited 3 months after the salvage operation before removing and replacing the semi-rigid implant with an IPP.

Results: 2515 patients underwent insertion of a 3-piece inflatable penile prosthesis, of which 27 (1.1%) presented with prosthesis infection, and 18 underwent salvage surgery with placement of a semi-rigid implant. The median follow up was 12 months. None of these patients required reoperation for infection. 100% of patients reported use of their replacement implant and no patient had any further complications. 6 (33%) patients with semi-rigid reimplants went on to have replacements with inflatable prostheses.

Conclusions: Salvage replacement of infected prosthesis with normal saline lavage is safe and effective in maintaining sexual function and preventing recurrence of infection. Contrary to prior paradigms, aggressive washout rather than specificity of irrigant along with meticulous sterile technique may contribute to an even lower post-salvage infection and re-operation rate.

Disclosure:

Work supported by industry: no.

027

PERTINENT ANATOMICAL MEASUREMENTS OF THE RETROPUBIC SPACE: A GUIDE FOR INFLATABLE PENILE PROSTHESIS RESERVOIR PLACEMENT SHOWS THAT THE EXTERNAL ILIAC VEIN IS MUCH CLOSER THAN THOUGHT

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Introduction and Objective: The number one worry for many prosthetic urology surgeons in the surgical placement of a three-piece inflatable penile prosthesis (IPP) is “blind reservoir placement.” There are multiple reports in the literature about bladder, bowel, vascular, and different types of hernial complications occurring while attempting to place the reservoir into the retropubic space. Despite this problem, there appears to be no published literature on the important anatomical measurements of the retropubic space relating to reservoir placement. We evaluate the pertinent anatomical measurements of the retropubic space to better aid in the safe placement of the reservoir.

Methods: A total of 15 cadaver bodies at 4 different surgical training courses were used for a total of 30 possible sides to measure. If during inspection or dissection of the cadavers, any signs of surgery / fibrosis in the area or difficultly in the exposure was encountered, that side was not included in the study. All measurements were taken from the ipsilateral inguinal ring to the bladder (both decompressed, and if possible to catheterize the bladder, with 200 cc of fluid in it) and the external iliac vein. Moreover, the degrees medial (for the bladder) and lateral (for the vein) were determined using the ipsilateral inguinal ring at the pubic tubercle as the baseline.

Results: Of the 15 cadavers, 3 were excluded due to signs of major pelvic surgery, and an additional 6 sides were excluded due to unilateral fibrosis / surgery or difficultly in exposure. Distance to the decom-

pressed bladder was 5.3 to 8 cm (average 6.75 cm) at a 15 to 30 (22.5) degree medial measurement from the inguinal ring. The filled bladder was 2 to 4 cm (average 2.64 cm) from the inguinal ring. The external iliac vein distance from the inguinal ring was 2.5 to 4 cm (average 3.16 cm) at a 25 to 60 (36.9) degrees lateral measurement from the inguinal ring.

Conclusions: These anatomical measurements of the retropubic space show the importance of having the bladder decompressed and to avoid going deep lateral to the inguinal ring, as the external iliac vein was much closer than expected.

Disclosure:

Work supported by industry: yes, by American Medical Systems (industry funding only - investigator initiated and executed study). The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

028

PENILE PROSTHESIS INSERTION IN PATIENTS WITH REFRACTORY ISCHEMIC PRIAPISM: IMMEDIATE VERSUS DELAYED IMPLANTATION

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Objectives: Ischaemic priapism is a urological emergency. Prolonged ischaemia within the corpus cavernosum results in the development of irreversible smooth muscle dysfunction followed by corporal fibrosis. The patients may end up with severe erectile dysfunction requiring insertion of penile prosthesis.

In our study we present our series with the long-term results of immediate and delayed insertion of penile prosthesis in patients with refractory low flow priapism.

Materials and Methods: A penile prosthesis was inserted in 95 patients with refractory ischemic priapism. Immediate insertion was carried out in 68 patients (mean age 42 yrs; range 26–73) within a mean of 171 hours (24–408) from the onset of the priapic episode, while delayed implantation was offered to the remainder 27 patients (mean age 45 yrs; range 28–69) after a median of 5 months (range 2–14) from the initial management of the priapic episode. All patients had failed aspiration and instillation of alpha-agonists and 28 patients had had unsuccessful shunt surgery performed prior to referral. The diagnosis was confirmed by cavernosal blood-gas-analysis, colour-Doppler-ultrasonography and cavernosal smooth muscle biopsy in 54 patients.

Results: The aetiology of the priapism was related to antipsychotic agents (n = 27), haemoglobinopathy (n = 39) and idiopathic (n = 29). In the immediate insertion group, a malleable prosthesis was inserted in 64 patients and 4 patients had a 3-piece-inflatable prosthesis implanted. Dilatation of the corpora has been easy in all cases, with minor distal fibrosis encountered in 6 patients. After a mean follow-up of 17 months, 6 patients needed revision surgery due to infection (n = 5) and curvature (n = 1). Overall the satisfaction rate was 96% without penile shortening.

In the delayed implantation group, corporal dilatation was difficult in all cases due to dense fibrosis and as a result of that a second distal corporal incision was required in 80% of patients. A malleable penile implant was inserted in 12 patients and inflatable in 15 patients, but downsized cylinders were required in 22 cases. After a mean follow-up of 21 months, 7 patients required revision surgery due to infection (n = 5), erosion (n = 1) and mechanical failure. Overall, 25 patients are currently able to engage in sexual intercourse but dissatisfaction rate is 40% due to significant penile shortening.

Conclusions: Patients with refractory ischemic priapism should be offered immediate implantation of a penile prosthesis as this is simpler than delayed implantation, yields superior functional results and allows the preservation of penile length.

Disclosure:

Work supported by industry: no.

029

COMPARISON BETWEEN AMS 700™ CX AND COLOPLAST™ TITAN INFLATABLE PENILE PROSTHESIS FOR PEYRONIE'S DISEASE TREATMENT AND REMODELLING: CLINICAL OUTCOMES AND PATIENT SATISFACTION

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Introduction and objective:

Inflatable penile prosthesis (IPP) is indicated in men with Peyronie's disease (PD) and concomitant medically-refractory erectile dysfunction (ED). To date, there is no published literature comparing AMS 700™ CX and the newer Coloplast™ Titan IPP. This study evaluates the clinical outcomes and patient satisfaction following the 2 different IPPs implantation with penile remodelling.

Materials and methods:

A retrospective review of clinical database and prospective telephone survey were conducted in all men with PD who underwent IPP between Jan 2006 and Nov 2010. The main outcome measures include patient demographics, type of IPP, clinical outcomes, post-implant sexual characteristics and overall patient satisfaction.

Results:

A total of 138 patients with an average age of 57.7 (32 to 80) underwent AMS 700 CX (88 patients) and Coloplast Titans (50 patients) IPP implantation during the 5-year period. The majority of patients (91%) had only one IPP implantation. The IPP clinical outcomes include 8 (6%) revision surgery for device malfunction and 3 (2%) device explantation for prosthesis infection. While there was no statistically significance in device survival between the 2 devices, the trend favoured AMS700 CX over Titan (5-year Kaplan-Meier estimates of mechanical survival were 91% vs. 87%, $p < 0.05$) and both IPPs provided similar penile straightening without the need for revision surgery. Most men (79%) reported great satisfaction following CX or Titan implants with greater than two thirds of men reported greater self-confidence and 82% of patients would undergo the same operation again.

Conclusion:

AMS 700™ CX and Coloplast™ Titan IPP implantation and penile remodelling appeared to provide permanent penile straightening and high patient satisfaction without an increase risk of revision surgery.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

030

VIRTUAL CAVERNOSCOPY -UTILITY FOR PENILE REVASCULARIZATION SURGERY-

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Objective: Variations in penile arterial anatomy are important when individualizing penile revascularization procedures. However, previous modalities visualize arteries based on arterial blood flow, and therefore have an insufficient detection rate of arteries with decreased blood flow inside the corpus cavernosum. Recent developments in digital technology have allowed for reconstruction of virtual endoscopic images. The utility of virtual cavernoscopy in detecting arteries inside the corpus cavernosum was evaluated.

Material and Method: The study subjects were 70 patients who visited our clinic for an erectile dysfunction examination and underwent 3D-CT cavernosography. Virtual cavernoscopic images were reconstructed from previous 3D-CT cavernosographic image data. A Zio-station System 1000 (version 1.17t) and a volume analyzer Synapse Vincent (Fujifilm Medical, Japan) were used to reconstruct the images. Using virtual cavernoscopy, the artery inside the corpus cavernosum

was visualized. The visualization rate of the artery was evaluated by PSV values.

Result: The artery was visualized in 135 out of 140 corpus cavernosal lumen. The cavernous artery was shown as the main artery in 73 lumen. The penetrating artery of the penile dorsal artery was shown as the main artery in 52 lumen, and the branch of the cavernous artery to the other side of the corpus cavernosum was shown in 10. The visualization rate of the artery with virtual cavernoscopy was consistent at any PSV value.

Conclusion: Compared with conventional modalities, virtual cavernoscopy is able to visualize arteries independent of arterial blood flow, showing potential for it to be used as a more appropriate method for evaluation of the artery inside the corpus cavernosum.

Disclosure:

Work supported by industry: no.

031

THE EFFICACY OF LOW INTENSITY SHOCK WAVE THERAPY TO THE PENIS FOR VASCULOGENIC ERECTILE DYSFUNCTION-A RANDOMIZED SHAM-CONTROLLED DOUBLE BLIND STUDY

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Objective: In two previous studies we have shown that Low Intensity Shock Wave Therapy (LI-ESWT) is effective for treating ED. The aim of this study was to re-establish and validate these results on a larger group of ED patients responding to PDE5i's in a randomized double-blind sham-controlled fashion.

Methods: Sixty vasculogenic ED patients were eligible for final evaluation. Their mean age was 56.5 ± 10 and at screening had an IIEF-ED Domain ≤ 19 (without PDE5i treatment). After a one-month washout, they underwent a baseline assessment of erectile function using validated questionnaires and objective local endothelial function testing using the penile flow mediated dilatation technique (FMD). At this visit a blinded randomization to treatment (2/3) and sham (1/3) was performed. The average IIEF-ED at baseline was 12.3 ± 4.1 (SEM) with no statistical significant difference between the placebo and treatment groups. The treatment protocol included 12 sessions of LI-ESWT, twice a week for 3 weeks, repeated after a 3-week no-treatment interval. During the whole study period no PDE5i was allowed and re-evaluation of erectile function was performed one-month post treatment. For those who did not sufficiently respond to the treatment (IIEF-ED an increase of less than 5 points) an additional 12 session shock wave treatment was offered.

Results: The average increase in IIEF-ED score between baseline and one month post treatment follow up was 6.7 ± 0.8 for the treatment group vs. 2.9 ± 1.43 for the sham ($P = 0.0098$). Sixty five percent of the treated group had an increase of ≥ 5 points compared to 25% of the sham, $P = 0.0003$. All the penile hemodynamic parameters significantly increased only in the treatment group ($P = 0.0009$). No adverse events were reported. All other evaluated parameters showed similar results. Twenty three subjects underwent a second shock wave treatment, 16 were from the placebo group (80%). One Month after the end of the second treatment session, the IIEF - ED score of these 16 patients increased from an average of 11.8 ± 1.9 to 16.6 ± 1.2 , $p = 0.007$.

Conclusions: This first randomized sham controlled double blind study we demonstrated that LI-ESWT applied directly to the penis has a clinical significant effect on the erectile mechanism and hemodynamics. This study requires further investigation in a larger scale of ED population and needs more basic science research in order to fully understand its mechanism of action.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

032

TADALAFIL IMPROVES EJACULATORY FUNCTION AND SEXUAL SATISFACTION IN MEN WITH LOWER URINARY TRACT SYMPTOMS SUGGESTIVE OF BENIGN PROSTATIC HYPERPLASIA (LUTS/BPH) AND ERECTILE DYSFUNCTION (ED): RESULTS FROM A PLACEBO- AND TAMSULOSIN-CONTROLLED 12-WEEK DOUBLE-BLIND STUDY

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Objective: To assess the effects of tadalafil 5 mg or tamsulosin 0.4 mg once daily compared to placebo on ejaculation and orgasm as well as on sexual satisfaction in men with LUTS/BPH and ED.

Material and Methods: Following a 4-week placebo lead-in, 511 men at least 45 years of age with moderate to severe LUTS/BPH (International Prostate Symptom Score ≥ 13 and Qmax ≥ 4 – ≤ 15 mL/s) were randomized to tadalafil 5 mg, tamsulosin 0.4 mg, or placebo; 309 reported ED at baseline and intended to remain sexually active (placebo, N = 105; tadalafil 5 mg, N = 106; tamsulosin 0.4 mg, N = 98). The study was not powered for direct comparison between active treatments. The International Index of Erectile Function (IIEF) Intercourse Satisfaction (IS) and Overall Satisfaction (OS) domains were pre-specified analyses. The Orgasmic Function (OF) domain and its constituent questions 9 and 10 (during sexual stimulation, the proportion of attempts achieving ejaculation [Q9] and orgasm [Q10] were post hoc analyses). The IIEF was administered at baseline, 4, 8, and 12 weeks, and was analyzed using analysis of covariance as change from baseline (randomization) to endpoint (or last measurement) compared to placebo. The percentages of men with improvements (increases) from baseline in IIEF scores were compared using chi-square tests.

Results: Compared with placebo, tadalafil significantly improved the IIEF OF domain (0.8, $p = 0.048$) and IIEF-Q9 (0.4, $p = 0.045$) but not IIEF-Q10 (0.3, $p = 0.10$); response with tamsulosin was significantly less than placebo in these domains (OF: -1.1 , $p = 0.006$; Q9: -0.5 , $p = 0.011$; Q10: -0.6 , $p = 0.009$). The percentage of men with improvement in ejaculation (IIEF-Q9) was 24.0% with placebo, 39.8% with tadalafil ($p = 0.016$ vs placebo), and 18.3% with tamsulosin ($p = 0.333$ vs placebo); orgasmic function (IIEF-Q10) improved for 26.0% with placebo, 40.8% with tadalafil ($p = 0.026$ vs placebo), and 19.4% with tamsulosin ($p = 0.273$ vs placebo). Compared with placebo, tadalafil significantly improved the IIEF IS (1.5, $p < 0.001$) and OS (0.9, $p < 0.001$) domains; responses in the tamsulosin group were less than placebo in these IIEF domains (IS: -0.6 , $p = 0.18$; OS: -0.7 , $p = 0.009$).

Conclusions: In men with LUTS/BPH and ED, tadalafil 5 mg once daily significantly improved the IIEF OF domain compared with placebo, including ejaculatory function, and improved sexual satisfaction; the opposite effects were observed for tamsulosin 0.4 mg once daily.

Disclosure:

Work supported by industry: yes, by Eli Lilly and Company, Lilly Research Laboratories, Indianapolis, USA (industry initiated, executed and funded study). The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

033

ERECTILE HEMODYNAMICS ASSESSMENT IN MEN WITH PERSISTENT ERECTILE DYSFUNCTION AFTER 5-ALPHA REDUCTASE INHIBITOR USE

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Objective: There has been tremendous interest recently in the concept that 5-alpha reductase inhibitors (5-ARI) are associated with persistent sexual side effects after cessation of these medications. While there is animal evidence supporting structural and functional changes in erectile tissue and some human evidence supporting alterations in neurosteroid production, there does not yet exist any formal objective erectile function assessment in such patients. This analysis was conducted to define the erectile hemodynamic profiles of men presenting with this condition.

Methods: Study population consisted of: (i) men presenting with the complaint of erectile dysfunction (ED) only after commencement of 5-ARI (ii) presentation to sexual medicine clinic ≥ 6 months (m) after cessation of 5-ARI and (iii) at least 3 months use of 5-ARI (finasteride, dutasteride). Demographic data, comorbidity parameters and treatment history were recorded. All patients underwent duplex Doppler penile ultrasound (DUS) in a vasoactive agent re-dosing fashion. Criteria for normal erectile hemodynamics were PSV > 30 cm/s and EDV < 5 cm/s.

Results: 39 men had a mean age = 34 ± 16 years (y). 31 had used Propecia (Group A) for alopecia prevention. 8 had used 5-ARI (Proscar 5, Avodart 3) for benign prostate hyperplasia (BPH) (Group B). Mean ages in these groups = 25 ± 8 y, 48 ± 11 y respectively. Median vascular risk factor (VRF) number: A 1 (0–2); B 2 (0–4). Duration of 5-ARI exposure: A 22 ± 18 months (m); B 18 ± 22 m. Duration off 5-ARI at presentation: A 11 ± 9 (6–24)m; B 11 ± 10 (6–37)m. None had ED prior to 5-ARI use. Overall, mean PSV and EDV values = 60 ± 18 cm/s and 1.5 ± 1.5 cm/s respectively. 2/35 DUS demonstrated impaired cavernosal artery inflow with mean PSV = 24 (22–26) cm/s. Both these men were in Group B, were ≥ 50 y old and both had ≥ 2 VRF.

Conclusions: In this group of men complaining of ED onset after 5-ARI use, erectile hemodynamics were normal in Propecia users. 2/8 men with ED onset after use of 5-ARI for BPH had abnormal DUS although it is plausible that these changes are related to VRF-associated vascular changes rather than the 5-ARI exposure.

Disclosure:

Work supported by industry: no.

034

NINE MONTHS TREATMENT WITH ALPROSTADIL CREAM (VITAROS[®]) RESULTS IN SUSTAINED IMPROVEMENT OF ERECTILE FUNCTION IN MALES SUFFERING FROM ERECTILE DYSFUNCTION

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1: CETPARP; 2: Apricus Biosciences; 3: NexMed (USA); 4: WebbWrites LLC

Objective: Vitaros[®] is an erectile dysfunction (ED) drug approved in Canada. In a flexible dose extension study (MED-006), a subpopulation of subjects treated for 3 months (M3) with placebo, 100 mcg, 200 mcg or 300 mcg during the two pivotal studies were assessed for their erectile function progress over a 6 months treatment prolongation with Vitaros[®].

Material and Methods: MED-006 was an open label dose titration efficacy and safety study. A subpopulation of 119 patients who were treated for 1 month with 200 mcg and elected the 300 mcg for 5 months were assessed for their clinical efficacy and safety at M6. The

primary (IIEF-ED domain score) and secondary (SEP-2, SEP-3 and Global Assessment Question-GAQ) endpoints, as well as their safety profile were assessed and compared to their corresponding endpoints at inclusion (M0) and (M3).

Results: At M6, 94/119 patients (79%) showed clinically significant improvement with alprostadil cream (IIEF-EF score change from baseline ≥ 4) versus 45% at M3. 39/119 (33%) had a normal IIEF-ED (score > 25) at M6. The mean change from baseline in the rate of Yes responses to SEP-2 and SEP-3 questions were 6.2 and 4.8 % at M6 and 3.7 and 2.4% at M3, respectively. The rate of positive responses to GAQ was of 91% at M6 compared to 46% at M3.

Conclusions: Vitaros[®] at the dose of 300 mcg demonstrated gradual and sustained improvement of erectile function over a period of nine months treatment in ED patients. The drug was safe and well tolerated.

Disclosure:

Work supported by industry: yes, by NexMed (USA) (industry initiated, executed and funded study). The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

035

AVANAFIL FOR ON-DEMAND TREATMENT OF ERECTILE DYSFUNCTION (ED): AN ANALYSIS OF PATIENTS ATTEMPTING SEXUAL INTERCOURSE WITHIN 15 MINUTES OF DOSING

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Objective: Avanafil, a rapidly absorbed ($T_{max} = 30-45$ minutes), highly specific PDE5 inhibitor is the first ED drug to receive FDA approval (April 2012) in nearly a decade. Participants in the randomized, placebo-controlled studies were instructed to dose approximately 30 minutes prior to sexual activity, however 277 patients (18.3%) recorded intercourse attempts within 15 minutes of dosing with avanafil. The objective of this study was to evaluate the per-patient success rates (SEP 3) at less than or equal 15 minutes from dosing.

Material/Methods: Patients with (n = 85) and without (n = 391) diabetes in addition to patients who had undergone bilateral, nerve sparing radical prostatectomy (n = 121) were included in the analysis. To evaluate successful intercourse by time interval from dose administration to attempt, mean individual patient success rates were calculated and compared to baseline.

Results: For the integrated analysis of subjects making sexual attempts within 15 minutes of dosing, treatment comparisons between each avanafil dose and placebo were statistically significant ($P < 0.05$). On a per-attempt basis, 59.7% (237/397) of diabetic and non-diabetic patients and 36.4% (38/77) of post-prostatectomy patients experienced one or more successful attempt at ≤ 15 minutes from dosing with avanafil compared with 27.6% (34/123; $P \leq 0.0001$) and 4.5% (2/44; $P \leq 0.0005$) for placebo, respectively.

Conclusion: A rapid onset of action (≤ 15 minutes) suggests avanafil is well-suited for on-demand treatment of men with mild to severe erectile dysfunction.

Disclosure:

Work supported by industry: yes, by Vivus, Inc (industry initiated, executed and funded study). The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

036

INITIAL EXPERIENCE OF LOW-INTENSITY SHOCK WAVE THERAPY FOR THE ED PATIENTS IN JAPAN

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Objective: Phosphodiesterase type 5 inhibitors (PDE5i) revolutionized the treatment of erectile dysfunction (ED). However, even in vasculogenic ED patients, one fifth of them showed poor response to PDE5i. Vardi et al. recently reported the beneficial effects of low-intensity shock wave therapy (LI-ESWT) on mild and moderate ED. We report our initial experience of LI-ESWT (ED1000TM) for ED patients in Japan.

Methods: This study included patients with ED history for more than 6 months, sexual health inventory for men (SHIM) score of ≤ 12 without PDE5 inhibitor, EHS grade 1 or 2, mean penile circumferential change (MPCC) by erectometer of < 25 mm, and non-neurological pathology. Patients were treated by a low energy shockwaves generator (ED1000, MEDISPEC, MD, USA); 3-minute application of 300 shock waves (intensity of 0.09 mJ/mm²) in 5 different anatomical sites of penis. After the baseline assessment, treatment was done twice a week for 3 weeks (6 times), no treatment for 3 weeks, and twice a week for 3 weeks (6 times) again. Total of 12 shock wave treatments were applied.

Results: Of 35 patients who assigned for the LI-ESWT trial, we analyzed the 14 patients whose data were available at 4 weeks after treatment. Median age was 61 years (range; 39–83). Median duration of ED was 3 years (range; 0.5–18). Median SHIM score was 5 (range; 1–12). Median MPCC was 14 mm (range; 6.7–28.3). One experienced mild pain on the penis during the procedure. SHIM after treatment was significantly increased from 5 to 10 ($p = 0.041$, Wilcoxon signed-rank test). Baseline EHS was 0 in 4, 1 in 2, and 2 in 3 patients, and EHS after LI-ESWT was 2 in 4 and 3 in 5 patients. Mean MPCC was increased from 12.83 mm to 24.17 mm after LI-ESWT ($p = 0.029$).

Conclusions: We reported the pilot study of LI-ESWT for ED in Japan. This study showed the safety and feasibility of the low energy shockwaves treatment for Japanese ED patients.

Disclosure:

Work supported by industry: yes, by Meditec Far East Inc. (no industry support in study design or execution).

037

A QUALITATIVE AND QUANTITATIVE STUDY TO INVESTIGATE PATIENT PERCEPTIONS WITH A NEW FORMULATION OF SILDENAFIL CITRATE IN CHEWABLE FORM (VIAGRA JET) COMPARED WITH THE STANDARD ORAL TABLET (VIAGRA)

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1: Asociacion Mexicana Para La Salud Sexual, A.C. (AMSSAC)

Objectives: 1. To gather qualitative information on using a new chewable formulation of sildenafil for ED, compared to the traditional tablet. 2. To compare erectile function, as measured by the IIEF-EF, and erection hardness perception, as measured by EHS. 3. To evaluate treatment preference.

Material and Methods: A comparative randomized cross-over 2X2 open label trial. Patients started with 100 mg sildenafil and in need reduced to 50 mg. Participants were assigned to in-depth interview or a focus group.

Results: 61 men were enrolled. Mean (s.d.) age was 52.42 (9.59). 32.2 % had mild to moderate ED, 42.37% moderate and 22.03% severe. The following perceptions were reported for the chewable formulation in comparison with the traditional oral tablet: A) Positive: greater efficacy, higher speed in onset of action, longer duration of therapeutic effect, more prolonged erections, and rapid absorption; it was considered convenient, easy to administer and discrete, some participants reported less adverse effects and it was considered a solution for those with problems swallowing tablets. B) Negative: the flavor was unpleasant for some participants as it was the perception of this flavor by the couple. Some disadvantages were reported by some individuals, the need to drink water, the blue coloration of the tongue, the big size of the tablet, and the remaining pieces in the mouth after chewing. The efficacy comparisons resulted in statistically significant improvements of both IIEF-EF and EHS in both formulations (baseline measurements vs. end of treatment) for IIEF-EF from 13.98 mean (12.781–15.183 95 % CI) to 24.24 (22.797–25.676) $p < 0.001$ for oral; and 13.96 (12.775–15.142) to 25.05 (23.993–26.152) $p < 0.001$ for chewable and for EHS from 1.89 (1.732–2.050) to 3.15 (2.964–3.327) $p < 0.001$ for oral tablets; and 1.89 (1.732–2.050) to 3.18 (3.003–3.361) $p < 0.001$ for chewable. The comparisons of both IIEF-EF and EHS at the end points resulted in non-significant differences. The preference was 54 % for the oral and 46 % for the chewable, not statistically significant.

Conclusions: The chewable formulation of sildenafil represents an alternative that offers some eventual advantages to patients including the perception of more effectiveness and higher speed in onset of action. The quantitative measurements revealed no differences in efficacy between the two formulations and a significant change when comparing basal and end of study measurements.

Disclosure:

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038

TADALAFIL ONCE DAILY FOLLOWING PRN PHOSPHODIESTERASE TYPE 5 INHIBITOR TREATMENT, AN ASSESSMENT OF RETURN TO NORMAL ERECTILE FUNCTION

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Objective: To determine if men who did not achieve normal erectile function (IIEF-EF domain score ≥ 26) with the maximum dose of a PRN PDE5 inhibitor have: a) a significantly greater probability of return to normal erectile function; b) significant improvement in the change from baseline in IIEF-EF domain score and; c) significant improvement from baseline in the percentage of successful intercourse as measured by Sexual Encounter Profile question 3 (SEP3), when treated with tadalafil once daily compared to placebo.

Material and Methods: Two identical double-blind, randomized, placebo-controlled studies were conducted in which men following a 1 month maximum dose PRN PDE5 treatment and 1 month nondrug lead periods were randomized to once daily therapy with tadalafil 2.5 mg to 5 mg, tadalafil 5 mg, or placebo for 12 weeks. Combined results of the 2 studies are reported.

Results: In men with ED (n = 590), average age of 58 years, erectile function was significantly improved with tadalafil once daily compared to placebo. A significantly higher percentage of men treated with tadalafil 2.5 to 5 mg (39%) and tadalafil 5 mg (40%) had an IIEF-EF

domain score ≥ 26 at endpoint compared to placebo (12%) (both $p < .001$). An 8-point improvement from a baseline IIEF-EF domain score of 14 was observed for both tadalafil groups, compared to 2 points for the placebo ($p < .001$). Significant improvement was also seen in change from baseline in SEP3 with tadalafil 2.5 to 5 mg of 38% (endpoint 68) and tadalafil 5 mg of 40% (endpoint 69) compared to 12% (endpoint 43) for placebo (both $p < .001$). Tadalafil was generally well tolerated and adverse reactions observed were consistent with previous reports of tadalafil once daily.

Conclusions: Approximately 40% of men who did not achieve normal IIEF-EF domain score when using the maximum dose of a PRN PDE5I were able achieve normal scores when treated with tadalafil once daily. Treatment with tadalafil once daily may be a viable option for men with ED that could help restore normal erectile function.

Disclosure:

Work supported by industry: yes, by Eli Lilly and Company (industry initiated, executed and funded study). The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

039

TIME-TO-EVENT MODELING OF SUCCESSFUL SEXUAL INTERCOURSE IN A SILDENAFIL TRIAL

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Objectives: Patients may prematurely discontinue effective treatment if they have unmet expectations for the time required to experience improvement (or sustained improvement) with treatment. We assessed median time to successful sexual intercourse (SSI) with sildenafil and placebo.

Material and Methods: SSI was assessed in an 8-week, double-blind, placebo-controlled trial of sildenafil treatment in men with erectile dysfunction. For each episode of sexual activity, SSI was based on patient report and defined by 2 jointly occurring events: (1) the subject attempted sexual intercourse and (2) the subject had an erection lasting long enough for successful intercourse. The Kaplan-Meier method was used to estimate median time to SSI for 2 types of events: (1) the first SSI (transient event) and (2) the beginning of stable SSI (defined as $\geq 50\%$ of attempts of sexual intercourse being successful until study end, after the initial SSI episode). Log-rank tests compared time-to-event curves between treatment groups.

Results: Of 288 men enrolled, 95, 99, and 94 received placebo, sildenafil 100 mg, or sildenafil 50 mg, respectively. Median time from the start of the study to achieve initial SSI was 3 days (95% CI, 2 to 5 days) for sildenafil 50 mg and 3 days (95% CI, 2 to 3 days) for sildenafil 100 mg, compared with 13 days for placebo-treated patients (95% CI, 6 to 22 days; $P < 0.001$). (Not everyone attempted sexual intercourse on the first day of treatment.) Median time to achieve stable SSI was 5 days (95% CI, 3 to 11 days; 50 mg) and 3 days (95% CI, 2 to 5 days; 100 mg) for sildenafil-treated patients versus 55 days for placebo-treated patients (95% CI, 41 to >56 days).

Conclusions: Time frames for when patients can expect to see initial and then stable improvements with sildenafil treatment may be derived from this novel application of time-to-event analysis. Median times to sustained SSI were numerically shorter for men receiving 100-mg sildenafil vs 50-mg sildenafil.

Disclosure:

Work supported by industry: yes, by Pfizer Inc (industry initiated, executed and funded study). The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

040

ADJUVANT RADIOTHERAPY NEGATIVELY IMPACTS ON THE LONG-TERM RECOVERY OF NORMAL SEXUAL FUNCTION IN TESTICULAR GERM-CELL CANCER SURVIVORS

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OBJECTIVES. To assess predictors of long-term normal sexual function recovery in testicular germ-cell cancer (TGCC) survivors.

MATERIAL AND METHODS. A cohort of 448 consecutive patients who underwent uni- or bilateral orchiectomy for TGCC was used. Patients were comprehensively assessed with a detailed medical history, thus including any oncologic treatment following TGCC diagnosis. Patients' comorbidities were scored with the Charlson Comorbidity Index (CCI) according to the ICD-9-CM codes. Likewise, patients completed the IIEF domains and a semi-structured interview including specific questions on sexual function. Descriptive statistics and cox regression models tested the association between predictors [including age at surgery (according to age quartiles), body mass index [BMI], CCI, pathologic classification (seminoma vs. non seminoma) and adjuvant therapy [either chemotherapy (CT, any combination) or radiotherapy (RT) and/or retroperitoneal lymph node dissection (RPLND)] and the long-term recovery of normal sexual function [defined as IIEF-EF \geq 26, and sexual desire (SD), intercourse satisfaction (IS) orgasmic function (OF) and overall satisfaction (OS) domain scores in the upper tertiles].

RESULTS. Psychometric complete data collection was available for 143 (31.9%) cancer survivors at a 71 mo median follow-up. Of these, 78 (54.5%) patients had a seminoma and 65 (45.5%) a non-seminoma. Of 143 patients, 66 (46.2%) received CT, 47 (32.9%) RT, and 30 (21%) RPLND. At survey, CCI was 0, 1, and 2+ in 118 (82.5%), 20 (14%), and 5 (3.5%) patients, respectively. Mean IIEF domain scores were: IIEF-EF: 24.1 (range 0-30); SD: 7.7 (2-10); IS: 10.2 (0-15); OF: 7.8 (0-10), and OS: 7.7 (2-10). IIEF-EF domains scores were suggestive for normal EF, mild, mild-to-moderate, moderate, and severe erectile dysfunction in 108 (75.5%), 9 (6.3%), 6 (4.2%), 4 (28) and 16 (11.2%) patients, respectively. Cox regression analyses showed that having a seminoma (HR: 0.57; p = 0.04) and adjuvant RT (HR: 0.42; p = 0.001) negatively impacted on normal EF recovery at a 71 mo median follow-up. Likewise, having a seminoma (HR: 0.41; p = 0.02) and adjuvant RT (HR: 0.43; p = 0.02) negatively impacted on the recovery of a normal IIEF-SD. Conversely, none of the other predictors was significantly associated with both IIEF-EF \geq 26 or normal IIEF-SD recovery. In contrast, none of the analyzed predictors emerged as an independent predictor for the other IIEF domains.

CONCLUSIONS. Adjuvant RT emerged as the only negative predictor of long-term recovery of normal erectile function and sexual desire in TGCC survivors.

Disclosure:

Work supported by industry: no.

041

STANDARD VS ENHANCED EDUCATION TO IMPROVE VAGINAL DILATOR ADHERENCE AFTER VAGINAL BRACHYTHERAPY FOR ENDOMETRIAL CANCER

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Objectives: Endometrial cancer is the most common gynecological malignancy in the US, with 68% to 83% of women treated with adjuvant vaginal brachytherapy (VBT) for Stage II or III disease surviving

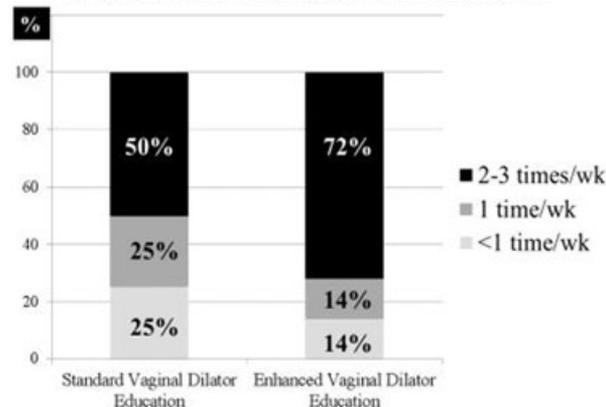
5-yrs. Vaginal shortening may occur in up to 65% of patients treated with VBT and interfere with sexual function. Prescription of vaginal dilators, smooth plastic instruments used to break up adhesions and stretch the skin in an effort to promote new epithelial growth is common, if not standard of care in the U.S. Canada, Europe and Australia. We have shown in a previous retrospective review that dilator use of 2-3times/wk helps prevent decline in vaginal length post VBT however, with standard education (one page written instructions and a dilator) any adherence is only 67%, 41%, 34%, and 29% at 6-mos, 1-, 2-, and 5-yrs, respectively. This pilot study is assessing the feasibility of recruiting women to participate in and test a method to increase adherence with dilators

Material and Methods: Two NCI-designated cancer centers' institutional nurse delivered standard education was compared to trained nurses' delivery of enhanced dilator education based on the information-motivation-behavioural skills model of behaviour change.

Results: Of 54 women treated with VBT for endometrial cancer screened for this ongoing pilot study: 2 were ineligible, 7 refused, 45 consented, 8 withdrew (5 changed their minds and 3 had disease progression) and 37 (69%) were retained. 23/50 women, mean age 61, have completed the 6 mo endpoint. As per the Figure an increase in vaginal dilator use adherence to the prescribed 2-3/times per week was 50% in the standard education arm vs 72% in the experimental arm.

Conclusions: Preliminary findings show recruitment and retention to be high and enhanced education to improve adherence and will provide the groundwork for a Phase III trial of dilator use that could have clinical implications for behavioral and device interventions to maintain sexual health after cancer therapy.

Fig. Average Weekly Dilator Use Difference at 6 Mos Between Methods of Patient Education



Disclosure:

Work supported by industry: no.

042

EVALUATION OF THE ASSOCIATION OF PROSTATE CANCER-SPECIFIC ANXIETY WITH SEXUAL FUNCTION, DEPRESSION AND CANCER AGGRESSIVENESS IN MEN ONE YEAR FOLLOWING SURGICAL TREATMENT FOR LOCALIZED PROSTATE CANCER

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Objective: Cancer-specific anxiety (CSA) can affect treatment decisions and is common in men following surgery for prostate cancer (PCa). We hypothesized that CSA is also associated with factors affecting quality-of-life. Herein, we examine the association of CSA with

psychosocial factors and PCa aggressiveness in a cohort of men one year after prostatectomy for localized PCa.

Materials and Methods: From our prospective PCa Registry, we identified 365 men who underwent prostatectomy for localized PCa who completed the Memorial Anxiety Scale for Prostate Cancer (MAX-PC) and Expanded Prostate Cancer Index (EPIC) at one year follow-up. We evaluated the association of scores on the MAX-PC with demographics, clinico-pathologic features, sexual function, and depression scores using Wilcoxon Rank Sum and Kendall's Tau correlation tests.

Results: Higher scores on the MAX-PC (i.e. higher anxiety) are associated with younger age ($p < .001$) and non-Caucasian race ($p = 0.006$). Men with higher MAX-PC scores also reported poor sexual satisfaction/function ($p = .006$) and increasing depressive symptoms ($p < 0.001$). Finally, while higher anxiety is associated with several pathologic features of aggressiveness (stage, positive margins, PSA at one-year; all p -values < 0.01), we noted several men with clinically indolent disease who reported significant anxiety.

Conclusions: Our data suggest that higher levels of CSA are associated with poor sexual function and increased depressive symptoms one year after prostatectomy. Moreover, we noted demographic and pathologic features associated with higher CSA as well. If confirmed, our data support development of models to predict men at high risk of CSA following PCa surgery and targeted referral for additional counseling.

Disclosure:

Work supported by industry: no.

043

VAGINAL LENGTH AFTER VAGINAL BRACHYTHERAPY FOR ENDOMETRIAL CANCER

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Objectives: Five year survival for women treated for Stage II or III endometrial cancer (the most common gynecological malignancy in the US), with adjuvant vaginal brachytherapy (VBT) is 83% and 68%, respectively. Survival is marked by treatment related vaginal changes including significant decrease in vaginal length (VL) which may interfere with sexual function. We and others have documented significant decline in VL compared to norms (nml non-irritated VL is 6.5–12.5 cm) in the 2 years following VBT, with some suggestion that most decline occurs in the first year following treatment. This pilot study is assessing changes in VL from pre- to post-VBT in women prescribed vaginal dilators, smooth plastic instruments used to break up adhesions and stretch the skin in an effort to maintain VL and ultimately sexual function.

Material and Methods: Two NCI-designated cancer centers participated in this study. VBT was delivered either alone or as a boost after external beam RT. VBT was delivered with a vaginal cylinder using standard technique. All patients received high-dose-rate fractionated treatment based on the American VBT Society recommendations. The dose was prescribed to either the vaginal mucosa or 0.5 cm from the vaginal mucosa to the upper 3–5 cm of the vagina. For patient receiving primary VBT the prescribed dose was delivered in 3–5 applications. For VBT after 45 Gy of external beam RT the prescribed dose was delivered in 2–3 fractions with additional boost dose after 50.4 Gy of external beam RT permitted of 6 Gy X 2. Vaginal dilators were prescribed to be used 2–3 times per week. VL was measured in cm following the bi-manual pelvic exam by a validated instrument, the Vaginal Sound, while the physician taking the measurement was blinded to dilator compliance.

Results: 23/50 women, mean age 61, had VL data pre and 6 mos post VBT. PreVBT VL was 8.7 cm (SD + 1.51) and 6 mos PostVBT VL was 8.8 cm (SD + 1.58). Dilator compliance was variable at 6 mos with 22% using the dilator < 1 time/wk; 22% using the dilator 1 time/week; and 56% using the dilator 2–3 times/wk.

Conclusions: Preliminary findings show no difference in VL from before to 6 mos after VBT for the treatment of endometrial cancer. This is contrary to previous reports showing decline in VL within the first year post brachytherapy, however, dilator use was higher in this study than previous reports.

Disclosure:

Work supported by industry: no.

044

IN THEIR OWN WORDS: AN EXAMINATION OF THE EXPERIENCE OF SEXUALITY IN INDIVIDUALS WHO HAVE UNDERGONE HEMATOPOIETIC STEM CELL TRANSPLANTATION

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Objective: The primary objective of this study was to identify patients' experience of sexuality following autologous or allogeneic hematopoietic stem cell transplantation (HSCT).

Materials and Methods: This study utilized a concurrent, mixed qualitative-quantitative design. Participants completed the Functional Assessment of Chronic Illness Therapy-BMT (FACT-BMT) as well as underwent semi-structured interviews.

Results: Eleven individuals participated in the study. The mean age at time of transplant was 43 years (range: 17–62) and mean number of months from transplant to time of study participation was 29 (range: 2–86). Participants scored relatively high on the FACT-BMT (mean 106 [range: 56–134] out of a possible 148), where higher scores indicate better quality of life. Despite the high FACT-BMT scores, the majority of participants indicated some level of dissatisfaction with his/her sex life. Regarding sexual function, the most common changes experienced by the participants were: decreased libido (67% of female participants; 63% of male participants), difficulties with erectile function (88% of male participants), dyspareunia (67% of female participants), vaginal dryness (100% of female participants) and not feeling desirable (33% of female participants; 38% of male participants). Analysis of the qualitative data obtained from the interviews revealed several themes pertaining to sexuality and HSCT including: changes in sexual function, coping with impaired fertility, the impact of the disease/treatment on the transplant recipients' relationships, the experience of discussing sexuality with health care providers, and recommendations for potential strategies that may make it easier for patients to discuss sexuality with health care providers. Interview responses provided context for the participants' FACT-BMT scores and perspectives on each individual's experience with sexuality throughout the illness and treatment trajectory.

Conclusions: In this study, 100% of participants experienced changes in sexuality following HSCT. While many participants encountered changes in sexual function, the interview component of this study revealed that sexuality, as a broader concept, went beyond the physical realm. The study findings have been used to inform the development of a survivorship clinic for individuals who have undergone HSCT. Further study is planned with a view to involve a larger cohort of transplant recipients and to include the participants' partners or spouses.

Disclosure:

Work supported by industry: no.

045

CHARACTERISTICS AND NEEDS OF FEMALE CANCER PATIENTS/SURVIVORS SEEKING TREATMENT AT A FEMALE SEXUAL MEDICINE PROGRAM

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Objectives: The Female Sexual Medicine (FSM) program at Memorial Sloan-Kettering Cancer Center was established to address the consequences of cancer treatment on vaginal health and sexuality. The objectives of this study were to characterize those seeking treatment at the FSM program, to examine the severity of patients' sexual health issues and concerns, and to identify patterns of referrals to FSM Program, in order to assist in patient outreach efforts and help to tailor clinical interventions to meet the needs of women diagnosed with cancer.

Methods: A Limited Waiver of Authorization was obtained to evaluate new-visit patients from within year 1 of the FSM Program. Data were analyzed from 121 patients from FSM Program who completed an initial visit. Each patient was asked to complete a Clinical Assessment Form, consisting of: Sexual Activity Questionnaire [SAQ], Sexual Self-Schema Scale [SSS], Female Sexual Function Index [FSFI], and exploratory items. Descriptive statistics were performed.

Results: The majority of the women had a diagnosis of breast (65.3%) or gynecologic (23.9%) cancer. Other sites of disease included colorectal, bone, melanoma, and thyroid cancer patients (11%). FSM program attendees were predominantly married or having an intimate relationship with someone (80%), and were Caucasian (82%), with a median age of 52 years (range, 26–72 years). Ninety-six percent (n = 116) of FSM attendees completed the FSM clinical assessment. Over half (54.5%) reported being sexually active with a partner. Eighty-eight percent (n = 106) indicated that they were somewhat to very concerned about their sexual function/vaginal health. Confidence about future sexual activity was only reported by 51.4% of these women. Sexual self-schemas (or a woman's perception of her sexual self) appeared to be equally positive or negative among FSM attendees and 91% (n = 110) scored 26 or less on FSFI, reflective of sexual dysfunction.

Conclusions: Our preliminary investigation of the characteristics and needs of women receiving care at the FSM Program suggests that predominantly breast and gynecologic cancer patients are seeking or being identified for referral to the FSM program. Our attendees indicated significant concerns about their sexuality and vaginal health, with only half feeling confident about future sexual activity. Not surprising, they exhibited sexual dysfunction, as per FSFI. Future FSM program evaluation will prospectively examine long-term outcomes and compliance with sexual and vaginal health promotion strategies. Primary goals for the FSM program are to directly improve vaginal and sexual health concerns of female cancer patients/survivors while simultaneously promoting evidence-based research.

Disclosure:

Work supported by industry: no.

046

DISPARATE LEVELS OF CIRCULATING VON WILLEBRAND FACTOR IN WOMEN AND MEN WITH SEXUAL DYSFUNCTION

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1: Queens University, Canada

Introduction: Von Willebrand Factor (VWF) is a biomarker of endothelial function that, when elevated, has been associated with cardiovascular disease (CVD). Although there are strong associations between CVD and sexual dysfunction (SD) in men, the link in women

has not yet been elucidated. Our study sought to examine the link between VWF and SD in both women and men who are overweight or obese.

Methods: A cross-sectional analysis of overweight and obese men (N = 19, 34–67 yrs) and women (N = 29, 35–64 yrs) was performed. Male sexual function was determined via IIEF questionnaires (scores ≤25 reflect SD). Females received FSFI questionnaires (scores ≤26 reflect SD). BMI, waist circumference and circulating osteoprotegerin (OPG), C reactive protein (CRP), VWF propeptide (VWFpp) and VWF antigen (VWF:Ag) were measured.

Results: In women without SD their VWF levels (U/dl) were: VWF:Ag 127.5 ± 38.1 and VWFpp 140.4 ± 24.4.

The VWFpp was significantly lower in women with SD (114.3 ± 26.8), while the VWF:Ag was not (97.5 ± 40.1). In males without SD, VWF levels (U/dl) were: VWF:Ag 98.3 ± 24.9 and VWFpp 115.0 ± 14.6. In contrast to the women, VWF levels in men with SD were significantly elevated: VWF:Ag 124.0 ± 22.0 and VWFpp 131.8 ± 16.4. There were no significant differences in body weight, BMI, waist circumference or other biomarkers between SD and no SD groups. Data are presented as mean ± SD, p < 0.05.

Conclusions: It has been proposed that the vascular mechanisms underlying SD in men and women are dissimilar. These findings support that notion, in that levels of VWF, an endothelial biomarker, were disparate between men and women. The decrease in VWFpp in women suggests that vascular mechanisms may not be the major role behind SD in this population. Interestingly, other conventional biomarkers such as OPG and CRP were not significantly different between groups (no SD v.s. SD). (Funds:H&SC, CIHR, MTM: CIHR-DRA CP:Queen's Dept.Med-PDF).

Disclosure:

Work supported by industry: no.

047

THE NATIONAL HEALTH AND WELLNESS SURVEY IN 5 EUROPEAN NATIONS PROVIDES A NEW IDENTIKIT OF THE ED PATIENT AND IDENTIFIES HIS UNMET NEEDS

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Objectives: To identify the unmet needs and characteristics of patients suffering from Erectile Dysfunction (ED) in big 5 EU nations (France, Germany, Italy, Spain, and UK).

Materials and Methods: The survey was conducted in 2011 (when the new vardenafil orodispersible tablet (ODT) was available for a short time only) on a population of 28,511 adult men and was focused on patients (5,184) who self-reported ED. Data were collected from the National-Health and Wellness-Survey (Kantar Health, February 2012, National Health and Wellness Survey, 2011 [EU Big 5], Princeton, NJ). The presence of ED was classified by asking if in the past six months, males have had difficulty achieving/maintaining an erection, quality of life (QoL) and work productivity was explored by the SF-12v2 and WPAI validated psychometric tools, respectively.

Results: One in every 20 young (in the age range 19–39 yrs, so far not studied in large surveys) Europeans experienced ED (defined as scale point 3- 5 of the Likert scale) in the past 6 months. About half the men [2702/5184; (52%)] with ED, across all ages, did not discuss their condition with their physician. Interestingly, among men who spoke of ED to the doctor, 68% (1,668/2465) do not currently use drugs. These findings were more evident in the age group 18–39 years. Only 48% (2,524/5,184) had a closer relationship with their physician, suggesting that this quality of relationship may be unsatisfying. Apart from the well-known ED-comorbidities, ED patients compared with controls have a higher intrapsychic and relational psychopathological comorbid burden (phobia, Obsessive-Compulsive Disorder, social anxiety, bipolar disorder) (p < 0.05). Finally, ED patients show relevant

decrease in QoL with a higher impairment on work productivity and activity.

Conclusions: Data suggest that ED is still an under-diagnosed and under-treated condition; despite the possibility of several treatments, men with ED were unsatisfied about their relationship with their physician and with the available drugs. Psychopathological comorbidities seem to be a major problem in these subjects. All together, these data suggest that there was a need for a new therapeutic paradigm in ED treatment. Hence, drugs such as the new vardenafil ODT tablet may offer a unique discreet treatment of ED, thereby possibly reducing the psychological and social impact of this disease.

Disclosure:

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048

MULTIPLE SCLEROSIS AND SEXUALITY - HOW A NEUROLOGICAL DISEASE AFFECTS FEMALE SEXUAL DYSFUNCTION

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Objective: Sexual concerns of patients suffering from multiple sclerosis (MS) are common but still remain poorly understood in clinical practice. MS afflicts usually young and active people, has unclear etiology and unexpected progress. It is more frequent in women, however, more intensive research on sexual dysfunction (SD) was dedicated to men. The aim of this research was to assess accurately sexual functioning of women with MS in order to create proper treatment strategies.

Material and Method: A literature search on the topic compared with authors' experience based on the study of 137 female patients with definite MS. Our patients were assessed during clinical interview, physical examination (using Expanded Disability Status Scale) and completed questionnaires (Female Sexual Function Questionnaire SFQ28, Beck Depression Inventory).

Results: The literature on SD in women with MS is scant and rely predominantly on small groups or unclear methodology. SD are thought to be caused by demyelination and atrophy of nerve fibers that impact sexual response (primary SD), fatigue and physical disability (especially spasticity) related with MS (secondary SD), and finally psychological and sociocultural aspects of a chronic disease. In our research, at least one sexual dysfunction could be found in 82.5% of patients, that is higher in comparison with majority of other studies. Most common were hypoactive sexual desire, arousal dysfunction, and orgasmic dysfunction. Only 2.2% of patients had ever discussed their sexual concerns with a physician. Interestingly, psychological factors and relationship issues were the stronger predictors of sexual health and satisfaction than neurological status and duration of the disease. More than half of the patients did not perceived neurological impairment as directly deteriorating their sexual function.

Conclusion: SD is highly prevalent in women with MS. Most of the patients have a very limited access to professional care dedicated to their sexual problems. Psychological and relational factors might be much underestimated in women with MS suffering from SD. Treatment strategies (prophylaxis, sexual rehabilitation) should be therefore integrative. We propose a complex diagnostic and therapeutic approach designed for patients with MS.

Disclosure:

Work supported by industry: no.

049

ANALYSIS OF SELECTIVE INHIBITOR OF PHOSPHODIESTERASE TYPE 5 (PDE5I) USE IN THE UC DAVIS MEDICAL SYSTEM IN PATIENTS WITH AND WITHOUT A DIAGNOSIS OF ERECTILE DYSFUNCTION

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Objectives: Phosphodiesterase inhibitors (PDE5-I) have revolutionized management of ED; unfortunately, PDE5-I have also been used for recreational purposes and/or to facilitate high risk sexual behaviors. We hypothesized that within our health system a sizable contingent of men without ED diagnosis had been prescribed PDE5-I; we further hypothesized that this group would differ in meaningful ways from men prescribed PDE5-I with an ED diagnosis.

Materials and Methods: We reviewed an electronic database of adult male patients prescribed PDE5-I within the UC Davis Health System (UCDHS). We gathered data on presence of organic or psychogenic ED (ICD9 codes 607.84 and 302.7, respectively), demographic, and health factors (including pulmonary hypertension) to further investigate prescribing patterns. The main outcome measure was presence of organic ED diagnosis (ICD9 607.84). T test, chi square, and both univariable and multivariable logistic regression was performed to test for association between ED diagnosis and demographic/health factors. **Results:** 12,230 male patients over age 18 had been prescribed a PDE-I, of whom 47% carried the organic ED diagnosis. Subjects with a diagnosis of organic ED were older, more likely to have diabetes mellitus, low testosterone, high cholesterol, tobacco-use history, hypertension, MI, CAD, Peyronie's disease, and history of radical prostatectomy ($p < 0.05$). African Americans (AA) were more likely to have a diagnosis of ED. Multiple logistic regression analysis was performed to determine the probability of an ED diagnosis by subject characteristics. Subjects older than 50 had a higher probability of being diagnosed with ED compared to those less than 50 (OR 1.30). AA had a higher probability of being diagnosed than Caucasians (OR 1.50). Greater odds of ED diagnosis were also seen in men with the following diagnoses; low testosterone (OR 1.52), high cholesterol (OR 1.69), BPH (OR 1.53) and Peyronie's disease (OR 1.54). Races other than AA had a lower probability of ED diagnosis compared to Caucasians (OR 0.81).

Conclusions: Among patients prescribed a PDE5I at a large health care system in Northern California, over half of the men prescribed PDE5I did not carry the diagnosis of organic ED. Certain ethnic and health related variables were more common in those men prescribed PDE5I with the ED diagnosis. Whether this discrepancy represents incomplete coding or recreational prescription of PDE5I to men without ED is unclear. Further attention to appropriate coding and/or patient selection in the prescription of PDE5I is warranted.

Disclosure:

Work supported by industry: no.

050

HYPOALBUMINEMIA IN CIRRHOTIC PATIENTS AS AN INDEPENDENT PROGNOSTIC FACTOR FOR ERECTILE DYSFUNCTION

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Objective: To show a correlation between hypoalbuminemia and erectile dysfunction severity in patients with hepatic cirrhosis.

Material and Methods: An exploratory observational cross-sectional study was planned. The IIEF-5 questionnaire was individually answered by patients with HC and stable treatment in our Liver Clinic.

We included demographic, biochemical and clinical characteristics for the statistical analysis. We analyzed the correlation between the IIEF-5 score, serum albumin levels, Child-Pugh (C-P) classification and MELD (Model for End Liver Disease) score. A multivariate regression analysis between prognostic variables and the IIEF-5 was done.

Results: The questionnaire was applied to 36 patients and 2 were excluded because of lack of sexual activity. Thirty-four patients were analyzed. They had a mean age of 50.85 ± 11.39 years (range 30 to 72 years). Patients were classified by ED severity according to the IIEF-5 score as healthy, mild, mild-moderate, moderate and severe ED with 7, 11, 10, 3 and 3 patients respectively. They were also classified according to C-P as A, B and C, with 11, 13 and 10 patients respectively. Mean MELD score was 13.85 ± 5.72 (range 6 to 31). MELD score and CP classification had a non significant correlation with ED. The average serum albumin per ED severity group was: 4.04 ± 0.37, 3.52 ± 0.61, 3.1 ± 0.65, 2.93 ± 0.95 and 2.7 ± 1.32 g/dl, respectively (p = 0.037). Albumin had a significant correlation (p = 0.001) with the degree of ED according to the IIEF-5. We found a significant correlation between serum albumin and normal erectile function (p = 0.005) and severity of ED (p = 0.001). Albumin level less than 3 g/dl was significantly correlated with severity of ED (p = 0.001). After a logistic regression analysis we found that serum albumin is an independent predictor of mild to moderate (p = 0.032, OR 0.083, CI 0.009–0.812), moderate (p = 0.037, OR 0.053 (IC .003–.840), and severe ED (p = 0.024, OR 0.045 (IC 0.003–0.664).

Conclusions: A correlation between albumin and ED in patients with HC was demonstrated. Hypoalbuminemia is an independent predictor of ED severity controlled by MELD and C-P classification.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

051

CLINICAL AND BIOPSYCHOSOCIAL PREDICTORS OF PROGRESSION AND REMISSION OF MALE SEXUAL DYSFUNCTIONS

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Objective(s): There are limited data describing the natural history of male sexual dysfunction. We aimed to determine the progression and remission of erectile dysfunction (ED) and low libido, and their related factors, over a five-year period in a randomly selected community based cohort of middle-aged to elderly men.

Materials and Method(s): Data from the Florey Adelaide Male Aging Study, a multi-disciplinary prospective cohort study of men aged 35–80 years at recruitment, were used to assess erectile dysfunction (IIEF-EF) and dyadic and solitary sexual desire (SDI-II), together with information on socio-demographic, lifestyle and clinical factors, at baseline (n = 1068; 2002–5) and follow-up (n = 862; 2007–10) clinic visits. Men with prostate cancer, orchidectomies, or taking confounding medications were excluded from the analysis.

Result(s): At 5-year follow-up, the prevalence of ED, low dyadic and solitary sexual desire increased to 25.0 % (cf. 18.1% at baseline), 32.1% (28.0%), and 16.4% (12.6%), respectively. Overall ED, low dyadic and solitary sexual desire progressed in 30.4% (n = 348), 36.9% (n = 308), and 21.8% (n = 250) respectively, of all men, while 23.4% (n = 268), 32.3% (n = 256), and 15.8% (n = 181) of all men reported improvements. In final adjusted regression models, increasing age, abdominal fat mass, obstructive sleep apnea (OSA) risk, and the absence of a regular partner at baseline were independently associated with ED progression. Sufficient physical activity (PA), moderate alcohol consumption, higher income and no hypertension or voiding LUTS at baseline were associated with ED improvement. Depression, anxiety or insomnia at baseline was associated with progression of both low

dyadic and solitary sexual desire. Higher post-school qualification and plasma testosterone were associated with improvement in dyadic sexual desire, whereas lower education and income, unemployment and migration were associated with progression of low solitary sexual desire. The presence of a regular partner and lower OSA risk at baseline was associated with improvement in both dyadic and solitary sexual desire at follow-up.

Conclusion(s): While sexual function generally declines with age, a significant proportion of these community-dwelling men showed improvement in both ED and libido. Many of the identified predictors of sexual function (e.g. fat mass, OSA, PA, alcohol consumption, diabetes) are modifiable, and should be addressed in order to optimize outcomes.

Disclosure:

Work supported by industry: no.

052

THE HISTORY OF TUNICAL GRAFTING FOR PEYRONIE'S DISEASE

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OBJECTIVES: Plaque incision/excision and grafting (PG) was first described in 1950 and has undergone various modifications. Currently, there is no standard procedure or universal graft material and multiple techniques are employed by specialists in the field. This abstract outlines the history behind the evolution of PG.

MATERIALS AND METHODS: A thorough review pubmed and textbooks.

RESULTS: In 1950, Lowsley and Boyce used a fat graft on 33 men and cured 20 patients (61%). The no-graft control group had a cure rate of 53%. Fat grafting however resulted in a high incidence of ED and the focus over the next 2 decades was finding a more impermeable graft. Using plastic surgical principles, Brystom (1972) and Devine (1974) had success with dermal grafting with only 1/6 developing ED. Melman (1978) attempted to replicate Devine's success but most of his patients experienced ED. This prompted Lowe (1982) to try a Dacron graft in 4 patients and all were subsequently "capable of intercourse". In an attempt to use non-synthetic graft material, lyophilized human dura (Collins,1998) and temporalis fascia (Gelbard,1991) grafts were tried. The former having minimal success but Gelbard's description of 100% post-operative potency rate in 12 patients encouraged the author to continue using this technique. In 1992, 2 papers (Jordan, Dalkin) described some success using venous ligation and dermal grafting. Also in 1992 Brock's animal work with femoral vein grafting inspired several centers to use venous grafting (usually saphenous) in humans. Ganabathhi 1995 paper described success in selected patients having Gore-Tex grafts. Despite some encouraging results from Teloken's (2000) description of using tunical grafting and Knoll's (2001) xenographic porcine small intestinal submucosal graft, neither of these techniques were widely adapted. It was Helstrom's sentinel paper (2001) describing his long term experience with cadaveric pericardium graft which prompted many authors to trial this graft material. The benefit of an "off the shelf" allograft has had much wider appeal and is now incorporated by many surgeons.

CONCLUSIONS: Grafting materials used in PD surgery have changed dramatically since their first description in 1950. Autologous, xenographic, allografts and synthetic materials have all been tried with varying degrees of success and reproducibility.

Disclosure:

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053

A NATURAL LUBRICANT SUPERFICIAL ZONE PROTEIN IS ENHANCED BY TGF β TREATMENT OF CELL CULTURES DERIVED FROM PEYRONIE'S DISEASE PATIENTS

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Objective: Transforming Growth Factor- β (TGF β) stimulates collagen and elastin deposition in human tunica albuginea-derived cells from Peyronie's Disease (PD) patients. Animal models which mimic many features of PD can be induced by the injection of TGF β into the tunica albuginea of rats. In other collagen-rich connective tissues subjected to shear forces, including the surface of articular cartilage, tendons gliding in tendon sheaths, and the meniscus, lubrication is provided by a mucin-like glycoprotein called superficial zone protein (SZP) also known as lubricin. SZP is a mechano-sensitive macromolecule induced by shear forces through the biochemical actions of TGF β . The purpose of this study was to investigate the potential of cells from PD plaques to synthesize SZP in the presence or absence of TGF β .

Materials and Methods: Cells were isolated from fibrotic plaque tissues removed from patients undergoing surgical correction for PD. Cells were isolated by bacterial collagenase digestion. They were maintained in monolayer culture in DME/F12 medium with 10% fetal calf serum. Some cultures were supplemented with 10 ng/ml of TGF β . The SZP content in the culture medium was analyzed by ELISA, and the proportion of SZP positive cells in the cultures measured by immunohistochemistry with a SZP-specific monoclonal antibody (S6.79).

Results: Cell cultures derived from PD plaques synthesized low levels of SZP. However treatment of the cell cultures with 10 ng/ml of TGF β for 48 hours increased the synthesis of SZP dramatically. The majority of the SZP was secreted into the culture medium. Cell cultures derived from 4 different PD patients synthesized SZP at 1.30, 1.79, 2.11 and 2.17 ug SZP per million cells. Some PD-derived cell cultures were treated with TGF β and also with monensin to inhibit the secretion of the SZP. Immunohistochemistry with an antibody specific for SZP showed TGF β treatment caused an increase in the number of cells which stained positive for SZP.

Conclusions: TGF β increased the synthesis of the lubricating glycoprotein SZP in cells from PD plaque tissues. SZP may serve as a useful marker to detect active TGF β in PD tissues, and may help define cell subpopulations in PD plaques.

Disclosure:

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054

PREDICTORS OF DEFORMITY STABILIZATION AND PROGRESSION IN PEYRONIE'S DISEASE

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Objective: Only a small percentage of patients with early Peyronie's disease (PD) improve over time. This analysis was conducted to define if predictors of the natural history of PD could be defined.

Methods: Study population consisted of patients with PD defined by a palpable plaque and penile deformity who (i) had uniplanar curvature (ii) underwent a baseline deformity assessment (DA) in combination with a penile ultrasound (US) (iii) pursued no PD treatment and (iv) who had a repeat (DA) greater ≥ 12 months after initial presentation. Demographic, comorbidity and PD data were analyzed. Patients were subdivided into different groups based on time to presentation after PD onset (TTP): ≤ 6 months (A), 7–12 m (B), 13–18 m (C). Stabilization was defined as no change between DAs ($\pm 5^\circ$), while improvement/

progression were defined as $\geq 10^\circ$ change. ANOVA was used to define differences in stabilization and progression rates between TTP groups. Multivariable analysis (MVA) was performed to define predictors.

Results: 176 men met inclusion criteria. Mean age = 54 ± 27 years. Mean PD duration = 9 ± 12 m. Mean curvature = 42 ± 27 degrees. Mean duration between DAs = 15 ± 5 m. Distribution of patients based on TTP was: A n = 56, B n = 84, C 36. Mean group ages = 47 ± 11 y, 52 ± 16 y, 58 ± 12 y ($p = 0.07$). Mean group curvature degrees = $40 \pm 20^\circ$, $46 \pm 16^\circ$, $44 \pm 19^\circ$ ($p = 0.15$). 67% of the entire population had no change in deformity over time, 12% improved, 21% worsened. Proportion who were stable = A 43%, B 70%, C 95% ($p < 0.001$). Improvement rates = A 27%, B 7%, C 5% ($p < 0.01$). Progression rates = A 30%, B 23% C 0% ($p = 0.08$ A vs B; $p < 0.01$ A vs C). On MVA, predictors of stabilization included: TTP > 6 m (OR = 2.4, $p < 0.01$), per decade increase in age (OR = 1.5, $p < 0.05$), age ($r = 0.32$, $p < 0.05$). Predictors of improvement included: TTP ≤ 6 m (OR = 4.1, $p < 0.001$), per decade decrease in age (OR = 2.1, $p < 0.01$).

Conclusions: In men with uniplanar curvature, PD stabilization and improvement rates change with TTP and patient age. Patients presenting > 6 m and older patients were most likely to be stable at presentation. Those presenting early and younger patients were the most likely to improve over time. These data may be useful in counseling patients.

Disclosure:

Work supported by industry: no.

055

EFFECTIVENESS OF INTRALESIONAL VERAPAMIL FOR THE TREATMENT OF SEVERE PEYRONIE'S DISEASE

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Introduction: The incidence of symptomatic Peyronie's Disease (PD) is approximately 1%. Whereas treatments for PD range from oral medications to surgical intervention, no cure currently exists, and many treatments have varied outcomes. We sought to review our outcomes from intralesional verapamil injections (ILVI) in men with PD.

Materials and Methods: A retrospective review of 80 consecutive men with PD treated using ILVI at our institution from January 2010 to January 2012 was performed. Data collected included age, length of symptoms prior to treatment, use of oral PD medications, presence of pain with erection, history of penile trauma, time on oral medications prior to ILVI, presence of ED, current use of PDE5i's, penile curvature, and number of ILVI. Penile curvature was determined after induction of erection via intracavernosal trimix, but prior to ILVI. Verapamil (20 mg) was injected directly into the Peyronie's plaque after penile block. Six injections were given per cycle.

Results: The mean \pm SD age and length of symptoms were 56.2 ± 9.3 years and 23 ± 40 months, respectively. Seventy-five (93%) patients took oral medications for an average of 4 months prior to ILVI. Twenty three (28%) patients had pain with erection and a history of known penile trauma. Fifty three (66%) had ED and 60 (75%) were on PDE5i's. The mean \pm SD number of ILVI was 10.25 ± 5.5 (mode of 12, range 1–31). Seventy (81.5%) patients had recorded curvature with ICI prior to IVLI with a mean of $45.5 \pm 29.1^\circ$. Ten patients did not complete the first cycle. The number of patients returning for curvature measurements after 1, 2, 3, or 4 treatment cycles was 58(72.5%), 27(33.7%), 9(11.2%), 1(1.25%) with mean curvatures of $39.3 \pm 22.6^\circ$, $41.4 \pm 21.8^\circ$, $43.1 \pm 22.0^\circ$, and 30° , respectively, after each cycle. The mean difference in curvature after each treatment cycle from baseline was $-7.5 \pm 21.4^\circ$ ($p = 0.37$), $-2.8 \pm 21.8^\circ$, ($p = 0.47$), $-13.2 \pm 24.8^\circ$, ($p = 0.79$), and -60° (single value). When patients were grouped based on severity of initial curvature using a cutoff of 45° , the mean improvement in curvature was significantly higher in men with pre-ILVI curvature $> 45^\circ$ after both the first and second treatment cycles (Cycle 1: mean difference $< 45^\circ$ $0.07 \pm 13.6^\circ$ vs. $> 45^\circ$ $17.5 \pm 25.9^\circ$, $p = 0.003$; Cycle 2: $< 45^\circ$ $-3.7 \pm 20.4^\circ$ vs. $> 45^\circ$ $14.9 \pm 19.9^\circ$, $p = 0.05$).

Conclusions: Use of ILVI for treatment of penile curvature results in improvement of curvature more significantly in men with curvature $>45^\circ$. While men with curvature of $<45^\circ$ also benefit, the benefits are more modest. Further prospective studies are needed to better define success rates and which patients will most benefit.

Disclosure:

Work supported by industry: no.

056

RELATIONSHIP OF BASELINE PENILE CURVATURE DEFORMITY SEVERITY AND SYMPTOM BOTHER OBSERVED IN PATIENTS WITH PEYRONIE'S DISEASE

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Objective: Collagenase clostridium histolyticum is an investigational, in-office, injectable treatment for Peyronie's disease (PD) that selectively lyses collagen and is currently being studied in 2 double-blind, placebo-controlled phase 3 trials. The relationship between baseline penile curvature (PC) deformity severity and bother associated with PD was examined in this patient population.

Materials and Methods: The subjects included in the phase 3 studies were ≥ 18 years of age with PD symptoms for ≥ 12 months and PC deformity between 30° and 90° . Data collected during screening included demographics, disease history, and clinical assessments of PD, including a specific, validated PD questionnaire (PDQ).

Results: A total of 832 subjects were enrolled from 64 sites across the US and Australia in the 2 phase 3 studies. In these 2 studies, 643 subjects (77.3%) had baseline PC deformity of 30° - 60° (mean curvature = $44.3^\circ \pm 9.2^\circ$) and 189 subjects (22.7%) had PC deformity of 60° - 90° (mean curvature = $71.7^\circ \pm 7.8^\circ$). The mean duration of PD for subjects with baseline PC deformity of 30° - 60° or 60° - 90° was 4.28 ± 4.7 and 3.36 ± 2.7 years, respectively. Mean scores from the PD Bother domain of the PDQ were 7.47 ± 3.56 for patients with PC deformity of 30° - 60° and 8.17 ± 3.47 for patients with PC deformity of 60° - 90° , with lower bother scores associated with a lower degree of curvature ($r = 0.13$; $p = 0.0005$). However, responses from the PD Bother domain also demonstrated that 58% (314/540) of subjects with PC deformity of 30° - 60° and 72% (98/137) of subjects with PC deformity of 60° - 90° were "very bothered" or "extremely bothered" the last time they looked at their erect penis. A high level of patient-reported moderate to severe distress over PD was also noted among subjects with PC deformity of 30° - 60° or 60° - 90° (80.6% and 90.5%, respectively).

Conclusions: While there is statistically significant evidence that higher curvature results in increased bother, over half of the patients with PC deformity of 30° - 60° still experienced high levels of bother and distress associated with PD. This suggests that measuring curvature alone does not represent the full impact of disease and consideration of the psychosexual components will be important when managing patients with PD.

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057

PSD502 HAS SIMILAR EFFICACY IN LIFELONG AND ACQUIRED PREMATURE EJACULATION

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Objective: PSD502 is an aerosolised eutectic-like mixture of lidocaine and prilocaine that has been shown to be effective in two phase III studies in premature ejaculation (PE) (Carson C & Wyllie M. J Sex Med. 2010; 7(9):3179; Dinsmore W & Wyllie M. BJU International. 2009; 103(7):940-9). As the entry criteria were based on the ISSM definition, only patients with lifelong PE were included in the analysis. One of the primary endpoints was intra-vaginal ejaculatory latency time (IELT) although there was good concordance with data captured from the index of premature ejaculation (IPE) questionnaire. It is expected that the majority of patients presenting to the physicians' offices will have lifelong (LL) PE, but a substantial number are likely to have acquired (Acq) PE; it is obviously important that the impact of any novel potential therapeutic is evaluated in this patient sub-set.

Materials and Methods: In a preparatory study, data from a small number of patients with acquired PE was captured and has now been analysed.

Results: At baseline the IELT (seconds) was similar for all groups (Placebo LL 29.4; Acq 34.3; PSD502 LL 31.4; Acq 40.2). Likewise, at 3 months the IELT observed in both subsets was similar for both placebo (LL 43.6; Acq 38.9) and active (LL 111.7; Acq 104.6). Quantitatively similar changes in the domains of the IPE were also noted for PSD502 with placebo only producing marginal changes.

Conclusions: It can be concluded that in both lifelong and acquired PE, placebo produced only marginal changes in IELT whereas in both forms of PE, PSD502 produced clinically significant changes in IELT. In general the changes in IELT were mirrored in the changes in the satisfaction, control and distress domains of the IPE. Overall, it is likely that the response to PSD502 will be similar in men with lifelong or acquired PE. This would be consistent with the proposed mechanism of action of reducing penile hypersensitivity while leaving the "normal" ejaculatory reflex intact (Wyllie M & Hellstrom W. BJU International. 2011; 107(3):452-7).

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058

COMPARISON BETWEEN ON-DEMAND DOSING OF DAPOXETINE ALONE AND DAPOXETINE PLUS MIRODENAFIL IN PATIENTS WITH PREMATURE EJACULATION; PROSPECTIVE, RANDOMIZED, DOUBLE-BLIND, AND PLACEBO-CONTROLLED

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Objective: There are no clinical trial results about PDE5i combined with dapoxetine, although dapoxetine is only approved drug for PE. Hence, we compared on-demand dosing of dapoxetine alone and combined with mirodenafil in patients with PE.

Materials and Methods: A total of 118 patients with PE were enrolled in this study, which had a normal erectile function. The patients were divided into 2 groups; dapoxetine 30 mg plus placebo (group A, n = 56) and dapoxetine 30 mg plus mirodenafil 50 mg (group B, n = 62). Pretreatment evaluations included a medical history, physical examination and Premature Ejaculation Profile (PEP) questionnaire. Intra-vaginal ejaculatory latency time (IELT) and the time from foreplay to

beginning intercourse (FTIT) with a stopwatch were also evaluated. During 12 weeks, dapoxetine and mirodenafil (or placebo) were simultaneously taken at 1 hours before intended sexual intercourse with a steady partner once a week. IELT, FTIT, PEP, and any adverse events were recorded.

Figure 1. Comparison of parameters for premature ejaculation between two groups.

Duration	Variables	Group A	Group B	p value
4 weeks	IELT change	2.28 ± 4.34 min	4.55 ± 6.92 min	0.173
	IELT increase	158.8%	303.7%	0.040
12 weeks	IELT change	2.94 ± 5.23 min	7.09 ± 9.41 min	0.016
	IELT increase	186.1%	470.3%	0.009
4 weeks	FTIT change	1.27 ± 6.82 min	2.69 ± 6.44 min	0.601
	FTIT increase	132.0%	84.2%	0.706
12 weeks	FTIT change	1.18 ± 4.41 min	2.27 ± 5.14 min	0.310
	FTIT increase	53.9%	95.6%	0.330
4 weeks	FTIT & IELT change	3.57 ± 7.81 min	7.23 ± 10.92 min	0.153
	FTIT & IELT increase	88.0%	119.4%	0.128
12 weeks	FTIT & IELT change	4.16 ± 7.10 min	9.45 ± 10.60 min	0.043
	FTIT & IELT increase	77.3%	181.0%	0.033
4 weeks	PEP change	-1.9 ± 4.1	-1.6 ± 4.1	0.684
	PEP increase	-16.8%	-12.4%	0.601
12 weeks	PEP change	-4.8 ± 5.8	-3.2 ± 5.0	0.121
	PEP increase	-46.6%	-29.2%	0.094

Results: The mean age of group A and B were 51.5 and 50.0 years, respectively ($p = 0.248$). At baseline, both groups were alike with respect to IELT ($p = 0.278$), FTIT ($p = 0.516$), FTIT plus IELT ($p = 0.929$), and PEP score ($p = 0.837$). IELT increasingly improved in group B as compared with group A ($p < 0.05$, figure 1). However, there were no statistically differences between two groups with respect to improvement of FTIT and PEP score ($p > 0.05$, figure 1). Two groups were not significantly different in the improvement of FTIT plus IELT at 4 weeks ($p > 0.05$, figure 1), but improvement in group B was significantly higher than it in group A at 12 weeks ($p < 0.05$, figure 1). Adverse events included nausea in 6 (10.7%) and 5 (8.1%), diarrhea in 2 (3.6%) and 3 (4.8%), headache in 3 (5.4%) and 8 (12.9%), dizziness in 5 (8.9%) and 6 (9.7%), palpitation in 1 (1.8%) and 4 (6.5%), and facial flushing in 1 (1.8%) and 2 (3.2%), in group A and B respectively. There were no differences in adverse events between two groups ($p > 0.05$), and were no treatment-emergent adverse events in all patients. **Conclusions:** Dapoxetine combined with mirodenafil showed increasingly better results for the treatment of PE, as the number of times being taken the medication was increased, compared with dapoxetine alone. Our results support the suggestion the PDE5Is have a potential role in the treatment of PE without ED.

Disclosure:

Work supported by industry: no.

059

EFFECTS OF SILODOSIN FOR PREMATURE EJACULATION

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Objective: Premature ejaculation (PE) is a common sexual problem as is erectile dysfunction. We evaluated silodosin, a highly selective α 1A-adrenoceptor antagonist, as a new treatment option for PE. α 1-adrenoceptor antagonists are widely used for lower urinary tract symptoms (LUTS), and clinical studies on silodosin demonstrated excellent clinical efficacy for LUTS. However, compared to other α 1-adrenoceptor antagonists, silodosin appeared to suppress ejaculation in a relatively higher percent of trial participants. This suppression

of ejaculation by silodosin suggested its potential for treating PE. Consequently, we evaluated the feasibility of off-label silodosin as a new treatment option for PE.

Material and Method: Eight patients suffering PE were treated with silodosin. Silodosin (4 mg) was administered 2 hours before sexual intercourse. Intravaginal ejaculatory latency time (IELT), premature ejaculation profile (PEP) item, clinical global impression change (CGIC) in PE, and systemic adverse events were recorded.

Results: 1) IELT and Satisfaction rate: IELT was significantly prolonged (from 3.4 minutes to 10.1 minutes, $p = 0.003$). All patients answered better (much better) or slightly better for their own PE problem compared to pre-treatment condition in the CGIC.

2) Premature ejaculation profile: Premature ejaculation profile also significantly improved. Ejaculation control: No patients reported "Good" or "very good" as baseline ejaculation control. All patients answered "Good" or "very good" after treatment. Ejaculation control was significantly improved ($p = 0.003$).

Satisfaction with sexual intercourse: Six patients (75%) reported "very poor" or "Poor" satisfaction with intercourse at baseline. Six patients (75%) reported "Good" and "Very good" after treatment. Satisfaction with sexual intercourse was significantly improved ($p = 0.017$).

3) Orgasm and ejaculatory discomfort: Two (25%), three (37.5%) and seven patients (87.5%) experienced an ejaculation, reduced semen volume and discomfort during orgasm, respectively. However, these problems were not of major concern for the participants.

4) Systemic adverse events: No systemic adverse effects were reported.

Conclusion: This preliminary study demonstrates the potential of off-label silodosin as a new treatment option for PE. Our primary finding was the alleviation of PE in all patients with "on demand" use of silodosin. All patients responded with better (much better) or slightly better for their PE problem compared to pre-treatment status in the CGIC. IELT and premature ejaculation profile also significantly improved. In accord with these improved parameters, PE related distress was significantly reduced. Our current results support the possible use of silodosin as a new treatment option for PE. A Controlled study is in progress.

Disclosure:

Work supported by industry: no.

060

WITHDRAWN

061

TESTOSTERONE TREATMENT IN ELDERLY HYPOGONADAL MEN FOR UP TO 5 YEARS IS EFFICACIOUS IN WEIGHT REDUCTION

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Objectives: Obesity and testosterone deficiency form a vicious cycle. This study analysed the effects of normalization of serum testosterone in mainly elderly, hypogonadal men on body composition.

Material and Methods: Open-label, single-center, cumulative, prospective registry study of 255 men (aged 38–83 years, mean 60.6 ± 8.0 years), with testosterone levels between 1.7–3.5 ng/mL (mean: 2.87 ± 0.4). Cut-off point for testosterone treatment was serum testosterone ≤ 3.5 ng/mL). 215 men were studied for at least 2 years, 182 for 3 years, 148 for 4 and 116 for at least 5 years. They received parenteral testosterone undecanoate 1000 mg/12 weeks after an initial interval of 6 weeks.

Results: After 5 years the following changes were observed: weight (kg) decreased from 106.22 ± 16.93 (minimum: 70, maximum: 139) to 90.07 ± 9.51 (min 74.00, max 115). The statistical significance was $p < 0.0001$ vs baseline and vs the previous year over 5 years indicating a continuous weight loss over the full observation period. Waist

circumference (cm) declined from 107.24 ± 9.14 (min 86, max 129) to 98.46 ± 7.39 (min 84, max 117) ($p < 0.0001$ vs baseline and vs the previous year over 5 years). Body mass index (BMI, m/kg^2) declined from 33.93 ± 5.54 (min 21.91, max 46.51) to 29.17 ± 3.09 (min 22.7; max 36.71) ($p < 0.0001$ vs baseline and vs the previous year over 5 years). The mean per cent weight loss after 1 year was $4.12 \pm 3.48\%$, after 2 years $7.47 \pm 5.01\%$, after 3 years $9.01 \pm 6.5\%$, after 4 years $11.26 \pm 6.76\%$ and after 5 years $13.21 \pm 7.24\%$.

Conclusion: Normalizing serum testosterone in hypogonadal elderly men resulted in loss of body weight, waist circumference and BMI. These improvements were progressive over the full 5 years of the study.

Disclosure:

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062

METABOLIC AND SYMPTOMATIC RESPONSE TO TESTOSTERONE UNDECANOATE IN MEN WITH TYPE 2 DIABETES AND HYPOGONADISM TAKES 12 TO 18 MONTHS TO MAXIMUM EFFECT

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Objective: Men with type 2 diabetes have a high prevalence of symptomatic hypogonadism as well as depression. This is the first double blind placebo controlled study in an exclusively type 2 diabetes population to determine whether testosterone therapy improves HbA1c, other parameters of diabetes, and symptoms of mood and sexual function.

Methods: The primary care populations of 8 general practices were screened for morning testosterone levels to define 211 patients (Mean age 61.6) for a double blind placebo controlled 30 week study with 106 men continuing in a 52 open label follow on phase. Depot Testosterone Undecanoate (TU) as NEBIDO[®] or matching placebo was administered at week 0, 6 and 18. Patients were assessed for BMI, weight, waist circumference, AMSS, IIEF, HADS Anxiety and depression, global efficacy question, and blood was taken for HbA1c, HOMA, CRP, lipids, PSA and haematocrit as week 6, 18 and 30.

Results: Due to the double blind nature of the study, the interval injection was 12 weeks was used according to the SPC of the drug and this produced modest trough levels of testosterone by 30 weeks especially in the more obese patients. The testosterone levels improved markedly in the 12 month open label period. TU significantly reduced HbA1c at 18 weeks and the reduction was 0.42% in the poorly controlled patients and 0.72% after 52 weeks open label medication. There was also significant improvement in weight (1.3 kg), BMI 0.7 Kg/m^2 , waist circumference (3.7 cm), total cholesterol (0.72 mmol/l), AMSS (6.44) and all domains in the IIEF, especially the EF domain of 7.75 points by the end of the 52 weeks open label phase. There was a 25–30 per cent increase in PSA by 30 weeks but no rise thereafter. There was only 1 case of prostate cancer, in the placebo cohort.

Conclusion: Metabolic responses to TU in men with type 2 diabetes may take 12 to 18 months to achieve maximal effect, especially improvement in erectile function, which continued to improve at 18 months in associated with favourable changes in body (and presumably penile) composition. Current guidelines suggesting 3–6 month trials of testosterone may result in many men with type 2 diabetes failing to achieve maximal benefit.

Disclosure:

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063

ANALYSIS OF THE SAFETY AND EFFICACY OF TESTOSTERONE SUPPLEMENTATION FOLLOWING RADICAL PROSTATECTOMY

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Objective: Substantial controversy exists in the literature regarding testosterone (T) replacement therapy (TRT) in patients with a diagnosis of prostate cancer. Most current data suggests that TRT post radical prostatectomy (RP) is safe, at least in the short term. This study describes our experience with TRT in men post-RP.

Methods: Using a prospectively constructed database, we reviewed all patients treated with TRT after RP. TRT was generally confined to men (i) with organ confined disease (ii) with favorable progression free probability (PFP) based on nomograms (iii) who had 2 serum total T (TT) levels < 300 ng/dl and (iv) who were also symptomatic and/or had abnormal bone densitometry. T dose was titrated to achieve a serum T level of 500–600 ng/dL . Patient demographics, pathological parameters, T levels and PSA data were collected. Descriptive statistical analyses using a rank sum analyses presented.

Results: 71 men, median age (interquartile range: IQR) 62 (55, 68) years, initiated TRT following RP. Median (IQR) pre-RP PSA levels was 4.5 (3.5, 6.3) ng/dL . Post-RP, pre-TRT PSA levels were undetectable for all patients. Median Gleason sum on RP specimen was 7. Median 10-year PFP was 97 (95, 97) %. Pathologic stage: $\leq T2$, T3a, T3b, surgical margins +, and lymph node + were observed in 84%, 13%, 3%, 4% and 0%, respectively. Men received initial TRT at a median of 18 (6, 34) months after RP. Median follow-up was 19 (9, 35) months after starting TRT. Median baseline TT was 235 (206, 281) ng/dL . During TRT, a statistically significant increase in TT was seen; median 615 (461, 782) ng/dL , $p < 0.001$. Biochemical recurrence (BCR) occurred in 1 patient, 33 months post-RP, 15 months after starting TRT. Of the 71 patients, 17 had > 3 years follow-up after starting TRT. For this long-term follow-up cohort, median follow-up was 49 (42, 75) months following TRT commencement. There was no BCR in the long-term group.

Conclusions: Based on our experience, TRT has long-term safety and efficacy in the treatment of the hypogonadal patient post-RP, with only a single high-risk patient experiencing BCR. This recurrence rate is likely no higher than that expected for this cohort of RP patients.

Disclosure:

Work supported by industry: no.

064

ANDROGEN RECEPTOR CAG REPEAT LENGTH CORRELATES WITH SEXUAL FUNCTION AND HYPOGONADAL SYMPTOMS IN MEN

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Introduction and Objectives: The number of cytosine-adenine-guanine (CAG) repeats in the N-terminus of the androgen receptor (AR) affects activity, with fewer repeats increasing the AR's activity and more repeats decreasing it. Testosterone plays an integral role in male sexual function, with higher testosterone levels generally resulting in improved sexual function. Here we present an association between CAG repeat number and sexual function as well as hypogonadal symptoms, implicating AR activity in the modulation of sexual function.

Methods: A review of medical records for 96 men presenting to our clinic was performed, and demographic information, serum testosterone (T), free T (FT), body mass index (BMI), and number of CAG repeats were obtained for each patient. All patients completed the International Index of Erectile Function (IIEF), Androgen Decline in the Aging Male (ADAM) and quantitative ADAM (qADAM) questionnaires, validated metrics for the evaluation of sexual function and

hypogonadism in men, and responses were correlated to CAG repeat number using Spearman's rank correlation.

Results: Mean \pm SD subject age was 50.7 ± 14.7 years, serum T 391.5 ± 249.0 ng/dL, FT 9.0 ± 7.0 pg/mL and CAG repeat number 21.2 ± 2.8 . Men were grouped based on BMI $<$ or >25 . Significant positive correlations were observed between CAG repeat number and the IIEF Orgasmic Function domain ($\rho = 0.559$, $p = 0.030$), as well as the individual question "How often do you orgasm?" ($\rho = 0.588$, $p = 0.021$) in men with BMI < 25 . Significant positive correlations were also observed between CAG repeat number and Deterioration in Sports Ability ($\rho = 0.674$, $p = 0.006$) and Positive ADAM ($\rho = 0.524$, $p = 0.045$), with a trend towards significance for Deterioration in Work Performance ($\rho = 0.484$, $p = 0.067$), also in men with BMI < 25 . Men with BMI < 25 also demonstrated a significant negative correlation between CAG repeat number and the Sports Ability Rating ($\rho = -0.608$, $p = 0.016$), and a trend towards significance with Total qADAM Score ($\rho = -0.470$, $p = 0.077$). Of note, no significant differences in T, FT, or CAG repeat number were observed between BMI subgroups.

Conclusions: Androgen receptor CAG repeat number is directly correlated with male sexual function and inversely correlated with hypogonadal symptoms assessed using validated questionnaires. These data suggest that the sensitivity of the AR may play a role in the male sexual response, and further highlighting the complexity of the sexual response pathway.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

065

THE ENTERO-LYMPHATIC ABSORPTION AND PHARMACOKINETICS OF A NOVEL ORALLY BIOAVAILABLE TESTOSTERONE FORMULATION

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1: Clarus Therapeutics

Unbound testosterone (T) is ineffective when administered orally due to extensive first pass metabolism by the liver. Methylated T administered orally may cause significant liver toxicity. We describe the entero-lymphatic absorption, physiology and pharmacokinetics of a new, oral, self-emulsifying drug delivery system (SEDDS) formulation of testosterone undecanoate (TU) in hypogonadal men.

Oral is the preferred route of administration for most drugs that require long term or chronic administration but is a challenge for compounds with low aqueous solubility. Entero-lymphatic absorption is a pathway through which fat soluble molecules can access the systemic circulation with favourable bioavailability and also avoid first pass hepatic metabolism. SEDDS formulations consist of a drug – lipid–surfactant matrix leading to the formation of dispersed drug emulsions that are preferentially absorbed through the intestinal lymphatic circulation.

A novel formulation of oral TU incorporating a SEDDS platform has been developed. Two Phase 2 studies in hypogonadal men have been completed. With BID dosing, 24 hour T levels (Cavg) within the eugonadal range have been achieved in both P2 studies. Administered with a normal fat (10%–30%) meal, $>75\%$ of men (N = 41) were able to achieve T levels within the FDA reference range for efficacy at 7 and 28 days.

Study	N	Serum T Cavg (ng/dL) \pm SD	% With T in Normal Range (300–1000 ng/dL)
7-Day Repeat Dose*	26	518 \pm 223	77% of subjects
28-Day Repeat Dose*	15	516 \pm 226	87% of subjects

*All subject received 200 mg T (as TU) BID with meals.

This novel SEDDS formulation of TU has been well tolerated; no TE SAEs or LFT abnormalities have been reported to date.

An orally bioavailable formulation of TU has been developed and is currently in clinical testing. The SEDDS TU formulation is designed to promote absorption by the entero-lymphatic circulation, minimize first pass hepatic exposure and maintain eugonadal T levels. A Phase 3 active controlled study is underway to further assess the safety and efficacy of this novel formulation for TRT in hypogonadal men.

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066

IMPROVEMENT IN SEXUAL FUNCTION AND MOOD AS A FUNCTION OF TESTOSTERONE LEVEL IN HYPOGONADAL MEN RECEIVING TESTOSTERONE REPLACEMENT THERAPY

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1: Eli Lilly and Company

Objective: This post-hoc analysis was undertaken to gain insights into symptomatic improvement in hypogonadal men on testosterone replacement therapy (TRT) based on whether they reached the pre-specified threshold of serum testosterone (T) of 300 ng/dL.

Material and Methods: Data was from an open-label trial that enrolled 155 testosterone-deficient (T $<$ 300 ng/dL) men given an initial daily dose of T 60 mg in a topical solution applied to the axillae. Dose was adjusted on days 45 and 90 when necessary to maintain T within the physiological range (300–1050 ng/dL). Sexual function and mood changes were assessed for 7 days preceding visits on days 1, 15, 60, and 120 by the Psychosexual Daily Questionnaire (PDQ). Subjects were divided into two groups (T $<$ 300 and ≥ 300 ng/dL) based on their T level during therapy. Analysis of covariance (ANCOVA) with adjustments for baseline PDQ scores, age, and body mass index (BMI) was used to evaluate change in PDQ scores from baseline (pre-day1) to pre-day15 and pre-day 120 (with last-observation-carried-forward for dropouts) both within and between the groups.

Results: As early as day 15, numerical improvement was observed in all PDQ scores (sexual desire, sexual activity, percent full erection, erection maintained, and positive and negative mood) for both groups. Within-group improvement was significant ($p < 0.05$) for all parameters except positive mood in group T $<$ 300. Improvement in PDQ scores was maintained or increased on day 120. For example, sexual desire changes on day 15 for the T $<$ 300 and ≥ 300 ng/dL groups were 1.1 (0.2) and 0.8 (0.1) (least square means [standard error]) respectively; on day 120 values were 1.1 (0.3) and 1.5 (0.1) respectively. On day 120, changes in PDQ scores were numerically greater in the T ≥ 300 ng/dL group than in the T $<$ 300 ng/dL group, although the between-group difference was not significant ($p > 0.05$).

Conclusion: These data show that symptoms in hypogonadal men receiving TRT improved by day 15 and continued until day 120 even in men with T $<$ 300 ng/dL after treatment. Study limitations include lack of a placebo control group, small number of patients reaching the threshold after treatment, and basing the analysis groupings (T groups) on post-baseline efficacy results. Additional research is needed to better understand the thresholds at which patients and physicians can expect symptoms of hypogonadism to improve.

Disclosure:

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067

CHANGES IN MEN'S SEXUAL, EMOTIONAL, AND COGNITIVE FUNCTIONING AFTER TAKING FINASTERIDE FOR HAIR LOSS: A CHART REVIEW

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Objective: Patterns of persistent bothersome and distressful cognitive, emotional, and sexual changes are being observed in a subset of young men after use of the 5 alpha reductase inhibitor (5-ARI) finasteride for treatment of hair loss. Since there is a dearth of information regarding persistent symptoms in such post-finasteride users, more research is needed to help clinicians better identify, diagnose and treat these young individuals.

Material & Methods: A retrospective review was conducted on charts of men seen by a sex therapist and sexual medicine physician at a sexual medicine practice August 2010-April 2012. Inclusion criteria included: men over 18 years; used finasteride for hair loss; presented with sexual dysfunction as well as with emotional, physical and/or cognitive symptoms; symptoms began while using or after discontinuation of finasteride. Of 43 charts reviewed from the 20-month time frame 13 patients met eligibility requirements. Eligible charts were analyzed qualitatively for themes across patients.

Results: Mean age was 33.6 years (range 25–42 years); 54% were from the United States; 31% were married or in a monogamous relationship. Length of use of finasteride ranged from 10 days to 11 years; sexual, emotional and/or cognitive symptoms persisted from 3 months to 10 years. Sexual symptoms commonly reported included lowered sexual drive (77%), erectile dysfunction (73%), decreased penile sensitivity (54%), loss of morning erections (31%), and muted orgasm (23%). The majority of men also reported emotional symptoms including depression and anxiety (77%) and emotional numbness (69%). Common physical symptoms included fatigue (54%) and sleeping difficulties (38%) but some men (23%) also reported symptoms such as chest pain, headaches, and “sweats.” Cognitive changes (46%) included brain fog and short-term memory problems.

Conclusions: Several theories have been proposed for the emotional, cognitive, and sexual side effects persisting long-term after finasteride is discontinued. In this subset of finasteride users, 5-ARI may lead to diminished synthesis of critical centrally-acting neurosteroids, and/or increased synthesis of androgen receptor with subsequent androgen receptor insensitivity. Clinicians prescribing 5-ARIs for hair loss or benign prostatic hypertrophy should inform patients of possible persistent emotional, cognitive, and sexual side effects resulting from finasteride use. This research was supported by a SMSNA Trainee Grant.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

068

TESTOSTERONE REPLACEMENT THERAPY DOES NOT PROMOTE PRIAPISM IN HYPOGONADAL MEN WITH SICKLE CELL DISEASE: ONE YEAR SAFETY MONITORING

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Objective: Hypogonadism, which is highly prevalent in males with sickle cell disease (SCD), affects quality of life and causes great morbidity. The safety of testosterone replacement therapy (TRT) in SCD in relation to priapism episodes is relatively unknown. Our aim was to monitor the safety of TRT in a small cohort of men with SCD over a 1 year duration of follow-up.

Materials and Methods: Testosterone undecanoate (Nebido®) 1 g was administered intramuscularly to seven men with hypogonadism and SCD for 1 year. Hypogonadism was defined as a total testosterone <12.0 nMol/L with reference lab range of 12.5–38.1 nMol/L. Baseline PSA, total testosterone, hematocrit, cholesterol, renal and liver function tests and serum glucose were done. Serum total testosterone, blood viscosity and hematocrit were measured for every patient at each visit. The occurrence of adverse drug effects was investigated. WHO-QOL, IIEF and ADAM questionnaires were administered at baseline and at follow-up. Prior episodes of priapism and new episodes while on TRT were noted.

Results: Seven men with a mean age of 34.4 years were treated. Case 4 demised after 9 months of follow-up due to acute chest syndrome. Case 1 abandoned treatment after 9 months due to azoospermia and a desire for fertility. Mean total testosterone increased from 10.2 ± 1.3 nMol/L to 12.9 ± 5.4 nMol/L (p = 0.2). All other laboratory indices remained stable. Injection site pain was the most frequently reported adverse effect, with no increases in painful crises, hypersensitivity or edema. Three patients had no prior history of priapism. At baseline, four patients reported priapism experiences with 2 patients having active stuttering episodes of frequency of 1 and 5 times monthly and the other 2 having lifetime episodes of 5 and >20 episodes. After TRT, there was no evidence of increased priapism frequency in these patients, including those with stuttering episodes. One patient reported an episode of priapism lasting for 4 hours which resolved spontaneously. Questionnaire scores from baseline to follow-up were increased for the IIEF (38 ± 24 to 61 ± 19, p = 0.01), reduced for ADAM (5 ± 2, 2 ± 1, p = 0.01), and unchanged for WHO-QOL (96 ± 12 to 99 ± 8, p = 0.16).

Conclusion: TRT using testosterone undecanoate with eugonadal intent for hypogonadism appears to be safe in men with SCD. With respect to sexual dysfunction specifically, this treatment does not appear to promote priapism occurrences and rather it possibly improves erectile ability. Future prospective evaluations in larger groups of SCD men with hypogonadism are necessary to confirm these findings.

Disclosure:

Work supported by industry: no.

069

CHANGES IN PROSTATE-SPECIFIC ANTIGEN AND PERCENT FREE PROSTATE-SPECIFIC ANTIGEN IN MEN TREATED WITH TESTOSTERONE REPLACEMENT THERAPY

Morgentaler, A.¹; Kaufman, J.M.²; Denes, B.S.³; Miller, M.G.³; Benesh, J.A.³; Kan-Dobrosky, N.³

1: Harvard Medical School with Men's Health Boston/USA; 2: Urology Research Options/USA; 3: Abbott/USA

Objective: To investigate total and free (f) PSA changes in hypogonadal (HGN) men receiving 1.62% testosterone gel (T-Gel) for 6 months (mo).

Material and Methods: A 6 mo (182-day) placebo-controlled study in HGN males (T < 300 ng/dL) randomized 6:1 (T-Gel:PLB). During a 42-day titration phase, doses were adjusted to eugonadal T levels (300–1000 ng/dL). Baseline (BL) and 6 mo PSA and fPSA changes were included in the safety evaluation. Subjects discontinued (DC) if the mean of two follow-up PSA results was >4 ng/mL and/or increased from BL > 0.75 ng/mL. Changes in PSA and fPSA% in subjects with BL fPSA% <20% (Group 1) and ≥20% (Group 2) were also assessed. **Results:** Of 274 subjects randomized (234 T-Gel, 40 PLB), 209 and 207 in the T-Gel group had post-BL PSA and fPSA assessments, respectively; mean age: 53.5 (range, 26–79). Mean BL and 6 mo T levels were 244 and 497 ng/dL, respectively. Overall, a small statistically significant increase in PSA, from 0.9 to 1.0 ng/mL, was observed at 6 mo. Higher changes from BL for PSA were observed in older men, in men with lower BL testosterone and fPSA < 20%. Seventeen men DC due to increased PSA. One subject receiving 1.62% T-Gel

(BL fPSA > 20%) with a palpable nodule but without a rise in PSA was diagnosed with prostate cancer after 6 mo.

Conclusions: In this study, HGN men receiving TRT had a slight increase in PSA at 6 mo, which was primarily seen in older men with BL fPSA % <20%. Clinical implications of these findings may need further investigation.

Variable	PSA, $\mu\text{g/L}$			fPSA, %		
	n	Mean (SD)	P-value*	n	Mean (SD)	P-value*
Baseline (BL)	209	0.91 (0.64)		207	24.03 (11.28)	
Δ at 6 months Group 1; N = 82	209	0.14 (0.63)	0.0012	207	1.85 (11.85)	0.0259
PSA, Δ at 6 months Group 2; N = 150	76	0.25 (0.71)	0.0027	76	2.45 (5.98)	0.0006
PSA, Δ at 6 months	131	0.08 (0.57)	0.1184	131	1.49 (14.19)	0.2319

*P-Value: change from BL.

Disclosure:

Work supported by industry: yes, by Abbott (industry initiated, executed and funded study). The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

070

NATIONWIDE EMERGENCY DEPARTMENT VISITS FOR PRIAPISM IN THE USA

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Introduction and Objectives: The true prevalence of priapism is not well characterized. A small number of studies based on inpatient data or small population samples have estimated a prevalence ranging from 0.34 to 1.5 cases per 100,000 males. We set forth to estimate the current epidemiology and impact on resource utilization of priapism in the United States (US).

Methods: Emergency department (ED) visits for priapism were analyzed using discharge data from the Nationwide Emergency Department Sample (NEDS), Healthcare Cost and Utilization Project (HCUP), which contains over 25 million ED records per year, representing a 20% stratified sample of US hospital ED visits. Priapism encounters were identified by ICD9 code and analyzed with patient and hospital characteristics, hospital charge, and length of stay (LOS) if admitted. Established weighting in the sample was used to calculate nationwide estimates.

Results: 4,175 ED encounters for priapism were identified between 2007 and 2008 in the NEDS. This translated to an estimated 18,969 encounters for 2007 and 2008 out of a total of 247,277,003 ED visits, or 7.67 per 100,000 ED visits [95% confidence interval (CI) 6.52–8.05]. Assuming that all men with priapism would present to an ED, this would estimate a national prevalence of 6.35 encounters per 100,000 male population.

The mean age was 36.4 years old. 19.9% of patients had a concurrent diagnosis of sickle cell disease (SCD). 71.6% of all patients were discharged home from the ED, while only 48.8% of patients with SCD were discharged home. Concurrent diagnosis of SCD was associated with an odds ratio (OR) of 3.18 [95% CI of 2.35–4.32] for admission to the hospital when controlling for age, region, hospital and payer type. The mean hospital charge was \$1,776 per encounter if discharged home and \$44,118 per encounter if admitted.

Conclusions: Approximately three-fourths of all ED presentations for priapism were discharged home from the ED. Concurrent SCD was associated with a 3-fold likelihood of inpatient admission. As expected, inpatient admission was associated with a significantly higher cost.

Compared to prior reports on priapism, the current research found a significantly higher prevalence of priapism, and a lower concurrence rate with SCD.

Disclosure:

Work supported by industry: no.

071

DEVELOPMENT AND VALIDATION OF THE PROMIS SEXUAL FUNCTION MEASURE

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Objective: To develop a customizable self-report measure of sexual function (SxF) as part of the U.S. National Institutes of Health PROMIS® Network. **Material and Methods:** We developed the measure in two rounds, with evaluation in cancer patients and in targeted health groups (diabetes, heart disease, anxiety, depression, age >65, lesbian, gay, or bisexual). We identified extant SxF items (>2100), categorized similar items by domain, and selected clinically relevant items for further review. Concurrently, we conducted 26 focus groups with patients and 10 discussions with clinicians to ensure content validity and wrote new items based on the results. Candidate items were then evaluated for comprehension in 87 cognitive interviews with patients. Items were administered to 819 cancer patients. Items were calibrated using item response theory and released as version 1.0. We conducted a diary study in 200 men and women to examine the validity of the 30-day recall period and test-retest reliability. In May 2012, new and revised items will be administered to 3875 US adults and psychometrically evaluated for version 2.0. **Results:** The PROMIS Sexual Function (SxF) measure version 1.0 includes 79 items in 11 domains: interest in sexual activity, lubrication, vaginal discomfort, erectile function, global satisfaction with sex life, orgasm, anal discomfort, therapeutic aids, sexual activities, interfering factors, and screener questions. In addition to content validity (patients indicate that items cover important aspects of SxF) and face validity (patients indicate that items measure SxF), the measure shows evidence for discriminant validity (domains discriminate between patients who had and had not talked to a doctor or nurse about problems with their sex lives), convergent validity (strong correlations between scores on PROMIS and scores on accepted measures of sexual function), as well as favourable test-retest reliability among people not expected to change (inter-class correlations from 30-day diary study). Qualitative work in round 2 resulted in additional domains to be tested including oral discomfort, vulvar discomfort, and subjective arousal. **Conclusions:** The PROMIS SxF offers researchers a reliable and valid tool to measure self-reported sexual function and satisfaction among diverse men and women. The measure is customizable; researchers can select the relevant SxF domains and items comprising those domains for their study. PROMIS SxF version 2.0 will expand content and provide normed scores that correspond to a representative sample of English-speaking, sexually-active US adults.

Disclosure:

Work supported by industry: no.

072

REASONS FOR SEXUAL INACTIVITY: RESULTS FROM A NATIONAL SURVEY

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Objective: Efforts to quantify the effects of poor health on sexual function often fail to distinguish between lack of sexual activity and poor function. To remedy this as part of the PROMIS Sexual Function measure, we developed an assessment of reasons for sexual inactivity. The objective of this study is to estimate the prevalence of such reasons among U.S. adults. **Material and Methods:** In May 2012, we will survey a representative sample of 3875 English-speaking US adults, capturing sociodemographic and clinical characteristics and validated sexual function measures. The survey includes a set of items aimed to address the possible reasons respondents may not have participated in sexual activity in the past month. The items stem states, "There are many reasons why people may not have had sexual activity with a partner during the month. What are the reasons why you did not have sexual activity with a partner in the past 30 days? Please check every reason that applies to you, even if it happened only one time during the past 30 days." Response options were generated from extant items, patient focus groups, and expert input. They include: lack of interest in sexual activity, lack of enjoyment of sexual activity, lack of partner, personal or partner's sexual dysfunction (erectile dysfunction, vaginal dryness or pain, difficulties with orgasm), practical considerations (lack of privacy, time), social concerns (friends, children, or other family members wouldn't approve), lack of attraction to partner, fear of transmitting or contracting sexually transmitted infections, avoiding pregnancy, personal or partner's health (health condition, effects of medication, pain, anxiety, depression, feeling tired), and religious beliefs. Also included is an option to write in other reasons not included among the response options. The survey will be administered online by Knowledge Networks, which obtains its panel through a random sample of postal addresses and provides a computer and internet connection to its panel members who are otherwise without access to the internet. **Results:** We will describe the prevalence of self-reported reasons for sexual inactivity and explore associations between reasons for inactivity and patient sociodemographic and clinical characteristics. We will also explore associations between reasons for inactivity and self-reported overall satisfaction with sex life. **Conclusions:** With new, representative data from a large sample of US adults, we will be able to understand why people are not participating in sexual activity, including reasons related to health and sexual dysfunction.

Disclosure:

Work supported by industry: no.

073

LACK OF PREDICTIVE CORRELATION BETWEEN PERIPHERAL ARTERIAL TONE AND COLOR FLOW DOPPLER PARAMETERS IN MEN WITH ERECTILE DYSFUNCTION

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Introduction and Objectives: Erectile Dysfunction (ED) is associated with systemic cardiovascular disease. Many patients have reduction in penile arterial inflow and venous occlusion as measured by color flow penile Doppler. Peripheral arterial tone (PAT) abnormalities, measured non-invasively in the upper extremity, correlate with cardiac disease and mortality. We wished to study whether penile hemodynamics correlated with PAT and whether the less invasive PAT could reliably predict the results of penile Doppler in men with ED.

Materials and Methods: 50 men presenting to an ED clinic who requested etiologic evaluation were tested with an Endo-PAT2000 machine which assessed the Augmentation Index(AI) (normal <3%), a

measure of arterial stiffness and Reactive Hyperemia Index(RHI) (normal > 1.8), a measure of endothelial vasodilation. Penile hemodynamics were measured following pharmacologic erection with prostaglandin E1 using color flow Doppler. Arterial insufficiency was defined as peak systolic velocity (PSV) <30 cm/s and venous insufficiency as end diastolic velocity (EDV) >3 cm/s. Comorbidities were recorded and degree of ED assessed by the International Index of Erectile Function (IIEF). Between-group comparisons were done using Wilcoxon rank-sum test for continuous variables and chi-square test for categorical variables. Simple and multivariable logistic regression analyses were used for analysis of both Doppler measures.

Results: Patients ranged in age from 21 to 74 (mean 51.1) and had a mean IIEF of 28.0. By Doppler, 58% had decreased arterial inflow and 48% had venous insufficiency. By Endopat, 54% had decreased endothelial relaxation and 44% had increased arterial stiffness. By univariate logistic regression, increased arterial stiffness was marginally associated with arterial insufficiency (p = 0,0656), while only increasing age (p = 0.0025) was associated with venous insufficiency; RHI was not correlated with PSV or EDV. The closest association was between low AI and low PSV, with a sensitivity of 0.55 and specificity of 0.71.

Conclusions: In our ED patient cohort, peripheral arterial tone did not reliably predict arterial or venous findings on penile color flow Doppler. These tests appear to measure different although potentially complementary aspects of the local and systemic vasculature.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

074

FEMALE SEXUAL DYSFUNCTION, DEPRESSION, AND ANXIETY: A BRAZILIAN STUDY

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Objectives: It is well known that depression and anxiety are more frequent in women and that they are commonly associated with sexual dysfunction. However, these associations are seldom characterized and unknown for Brazilian women. This work reports the preliminary results of a research to characterize the interactions between female sexual dysfunction and both depression and anxiety in a Brazilian sample.

Material and Methods: A sample of 110 patients with stable relationships and no chronic diseases (age: 18–61; average: 38.5) was taken from the Gynecological Clinic of a University Hospital. The variables under study were then assessed through the Female Sexual Quotient, FSQ (Abdo, 2006), the Beck Depression Inventory, BDI (Beck, 1996), and the Beck Anxiety Inventory, BAI (Beck, 1996). Exploratory data analyses were conducted using the chi-square test, Cramer's V and Student's t test.

Results: Significant relationships were found between female sexual dysfunction and both depression (p < 0.001; V = 0.43) and anxiety (p < 0.001; V = 0.38). In both cases, the majority of women with no sexual dysfunction were found to present mild depression (69%) or mild anxiety (68%) levels, while most of those presenting some dysfunction had moderate to severe depression (44%) and moderate to severe anxiety (49%). In order to corroborate these observations, a t-test was performed on the groups presenting (n = 39) or not (n = 71) sexual dysfunction. The former group scored on average 8.9 and 8.3 points higher in the BDI and BAI, respectively. These differences were found to be significant (p < 0.001), showing large effect sizes (d = 0.94 for depression and d = 0.74 for anxiety).

Conclusions: This study showed the strong association on female sexual dysfunction versus depression and anxiety. Moderate to severe manifestations of these conditions were prevalent in patients with sexual dysfunction, while only mild levels were common in other patients.

Disclosure:

Work supported by industry: no.

075

ANDROGEN PATTERN AND ERECTILE FUNCTION IN NEWLY DIAGNOSED TYPE 2 DIABETES

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Objective: To assess pattern of androgen and erectile function in patients with newly diagnosed type 2 diabetes mellitus (DM).

Materials and Methods: A total of 176 newly diagnosed type 2 DM male patients were enrolled in this study. Erectile function was assessed using the International Index of Erectile Function (IIEF). At the time of assessment, patients were also interviewed and assessed for socio-demographic data. Patients underwent routine laboratory investigations, in addition to total testosterone (tT), sex hormone binding globulin (SHBG), prolactin and insulin assessment. Calculated free (fT) and bioavailable (bT) testosterone were also assessed.

Result: The mean age \pm SD of the study population was 48.2 ± 8.9 years. Of the patients 75.6% were overweight or obese and 42% were former or current smokers. Of the patients 21.6% and 48.3% had low tT and erectile dysfunction (ED) respectively. In hypogonadal men there were significant decrease in means of EF-domain, tT, fT, bT and increase in BMI in comparison to Eugonadal men. There were significant associations between increase number of patients with low level of tT or severe ED and high level of fasting blood sugar (FBS) (≥ 200 mg/dl), poor control of diabetes (HbA1c $> 7\%$) and dyslipidemia ($p < 0.01$ for each). There were significant associations between decrease of EF-domain and increasing of age, BMI, FBS, HbA1c ($p < 0.01$ for each). After adjusting for confounders; age, BMI, FBS, cholesterol, triglyceride, LDL, HDL, the relation between decreased tT as a dependent variable and increase HbA1c as a predictor was significant ($p < 0.05$).

Conclusion: This study clearly demonstrated that ED and hypogonadism are prevalent among newly diagnosed type 2 DM. Severe ED and hypogonadism had significant associations with high level of FBS and HbA1c at the time of DM diagnosis.

Disclosure:

Work supported by industry: no.

076

THE GLOBAL ONLINE SEXUALITY SURVEY: ERECTILE DYSFUNCTION IN USA

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Objectives: The Global Online Sexuality Survey (GOSS) is a worldwide epidemiologic study of sexuality and sexual disorders. The age adjusted prevalence of male and female sexual disorders is estimated around the world, and so are the predisposing risk factors, anatomical variations, sexual preferences and unique habits for each and every culture. GOSS is deployed over the internet to the general population regardless surfing and web search inclinations, the only prerequisite being above 18 years of age. The first reports out of GOSS came from the Middle East, in the year 2010, results of which were published in 2011. This study reports GOSS data in the domain of erectile dysfunction (ED) in USA, and compares it to GOSS results from the Middle East.

Material and Methods: GOSS was randomly offered to English-speaking male web surfers in the United States of America between August and October 2011. GOSS was offered via paid advertising on Facebook® based on validated questionnaires in addition to general questions.

Result: Two thousand and twenty two males participated. Mean age was 52.38 years ± 14.5 , median 54. Based on the abbreviated version of the International Index of Erectile Function (IIEF-5), 37.7% demonstrated various degrees of erectile dysfunction. Classic risk factors

for ED were evaluated for their effect, as well as novel ones such as penile size concerns, premature ejaculation, narcotic use and ethnic differences, among others.

Conclusion: The prevalence of ED in USA as of 2011 could be evaluated and objectively compared in a homogenous way and in the same period of time to its prevalence in the Middle East. Most of the classical risk factors for ED play the same role in USA and the World. New risk factors emerge including concerns over genital size and premature ejaculation.

Disclosure:

Work supported by industry: no.

077

STUDY ON FEMALE SEXUAL DYSFUNCTION AND ITS RISK FACTORS AMONG INFERTILE WOMEN IN CHINESE RURAL AREAS

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Objectives: To find out the occurrence rate of female sexual dysfunction (FSD) and its risk factors among infertile women in rural areas in China. **Methods:** We used the method of clinic-based descriptive epidemiological study to conduct face to face survey on infertile women by using questionnaires in Dengfeng city in Henan province, China. At the stage of data analysis, we used the method of case – control study. We considered the women with FSD as case group and considered the women without FSD as control group. **Results:** Among 260 infertile women investigated, the mean of age is 30.13 years, minimal age is 24 years and maximal age is 44 years. As regards educational level, 51.2% women are with senior high school, and 31.9% are with junior high school. 7.7% women have history of pelvic inflammatory diseases (PID). 9.6% suffered from reproductive tract infections (RTI). Only 33.5% women satisfied with sexual life. 11.5% women considered the sexual behavior as a ribald thing. Only 17.7% women thought that women should enjoy sexual pleasure. 4.2% women have history of masturbation. Among 260 infertile women, 66 women suffered from FSD. The occurrence rate of FSD is 25.4%. In comparison with control group, the case group (a group of women with FSD) has following 5 higher rates and 3 lower rate. The five higher rates among case group are as follows: higher rate of poor general health status (62.1% vs 42.8%, $P < 0.01$, OR = 2.19), higher rate of masturbation (10.6% vs 2.1%, $P < 0.01$, OR = 5.64), higher rate of history of induced abortion (28.8% vs 12.9%, $P < 0.01$, OR = 2.73), higher rate of PID (19.7% vs 3.6%, $P < 0.01$, OR = 6.55), and higher rate of premature ejaculation of her husband (15.2% vs 9.7%, $P < 0.01$, OR = 3.29). The three lower rates are as follows: lower rate of women who considered the sexual life as important (30.3% vs 49.5%, $P < 0.01$, OR = 0.44), lower rate of women who satisfied with sexual life (60.6% vs 93.8%, $P < 0.01$, OR = 0.27) and lower rate of women who considered that they had sufficient knowledge of sex (72.7% vs 85.1%, $P < 0.05$, OR = 0.49). **Conclusions:** There are higher occurrence rate of FSD among rural infertile women. The major risk factors related to FSD includes PID, masturbation, and induced abortion as well as sex knowledge, sex attitude and satisfaction of sexual life.

Disclosure:

Work supported by industry: no.

078

FEMALE SEXUAL COUNSELING ON THE INTERNET IN JAPAN

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Objective: Female sexual dysfunction (FSD) is a prevalent problem that can be detrimental to quality of life at any age. However, Japanese

women seldom consult physicians for sexual problems due to embarrassment or humiliation. The aim of this study is to investigate patients' potential needs and concerns when seeking sexual counseling on the internet.

Materials and Methods: Data was taken from 139 online consultations with female patients for sexual problems between January 2010 and November 2011. All counseling requests were answered by the same physician. Outcome measures included: age, marital status, stable partner, children and counseling content. We conducted descriptive analysis of all data.

Results: 58% of the clients were the 30 to 39 years old. 69% had a marital relationship, 94% had a stable partner and 20% had children. Desire Disorders accounted for 47% of the complaints, consultation on partner for 17%, Sexual Pain Disorder for 16%, Orgasmic Disorder for 7%. Marital status and the presence or absence of children affected the content of the consultation. Orgasmic Disorder and Sexual Pain Disorder were more prevalent in unmarried patients. Consultations about partners and those for Desire Disorders were more common among married patients. Among patients without children, there were increased instances of Sexual Pain Disorder and consultations on partners. Among patients with children, there was a significant increase in Desire Disorders.

Conclusion: Desire Disorders were the most common reason patients sought online counseling. Our results suggest that advice for sufferers of FSD focused on the male partner's ailments and attitudes.

Disclosure:

Work supported by industry: no.

079

WITHDRAWN

080

A STUDY EXPLORING SEXUAL SELF-SCHEMA OF WOMEN WITH CANCER-RELATED INFERTILITY

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Objectives: The purpose of this study was to determine if a gynecologic cancer survivor's view of her sexual self (sexual self-schema) impacts her level of grief and sexual functioning following cancer-related infertility. Our hypothesis was that a positive sexual self-schema may buffer or moderate grief and sexual concerns (e.g., decreased desire, arousal, and satisfaction) associated with infertility secondary to cancer treatment.

Methods: This study was part of an Institutional Review Board-approved study examining the psychosexual impact of cancer-related infertility (n = 41). Data were analyzed from 36 gynecologic cancer survivors experiencing the loss of ability to conceive and/or carry a pregnancy to term following cancer treatment. The study survey consisted of: Sexual Self-Schema Scale (SSS), Modified Inventory of Traumatic Grief of Infertility (MITGI), Female Sexual Function Index (FSFI), and Menopausal Symptom Checklist (SCL). Descriptive statistics conducted for the sample and Pearson correlations were performed between SSS, MITGI, FSFI, and SCL.

Results: Thirty-six gynecologic cancer survivors (ovarian, cervical, endometrial, gestational trophoblastic disease, vulvar) were enrolled on study. Median age was 41.5 (range, 27–50 yrs) and 60% (n = 19) were married or living with someone. Twenty-eight (73.7%) reported undergoing surgical removal of their ovaries. A significant negative correlation was observed between SSS and MITGI (–.500, p < 0.01). The Embarrassment/Conservative factor of the SSS scale was positively associated with grief (.396, p < 0.05), while the “Loving/Romantic” and “Direct/Open” factors were marginally significant, p < 0.05 level (–.291 and –.289 respectively). No associations were observed between FSFI and MITGI. Interactions between SSS and FSFI domains of desire (.430, p < 0.01), arousal (.391, p < 0.05), orgasm

(.373, p < 0.05), and satisfaction (.412, p < 0.05) were noted. A positive self-schema was associated with higher FSFI scores (or better sexual function). SSS was not associated with menopausal symptoms, but grief was a significant predictor (.599, p < 0.01).

Conclusions: Our findings suggest that a positive sexual self-schema may be protective for women emotionally coping with loss of fertility due to cancer. Alternatively, a negative SSS appeared to place our sample at greater risk for grief, sexual difficulties, and menopausal symptoms. As female cancer survivors begin their lives post-treatment, reproductive loss and sexual concerns may impact overall well-being and relationships. Future research is needed to prospectively examine the challenges associated with a negative sexual self-view and to develop clinical interventions to address emotional and physical risks for these women. Strategies to facilitate physician-patient communication about potential reproductive and sexual health effects of cancer should also be explored.

Disclosure:

Work supported by industry: no.

081

NERVE SPARING SCORE AND ERECTILE FUNCTION RECOVERY AFTER RADICAL PROSTATECTOMY: ASSESSMENT OF INTERSURGEON VARIABILITY

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Objectives: Increasing attention is focusing on nerve sparing scoring (NSS) during radical prostatectomy (RP). Prior work has shown good correlation between the use of such nerve sparing scores and long-term EF recovery. This analysis was conducted to define to what degree this correlation was dependent upon individual surgeons.

Material and Methods: We reviewed a prospective database of patients who underwent RP. EF was assessed prior to surgery and between 24 months (m) and 30 m after surgery (24 m EF). EF was graded on a validated 5-point patient-reported scale: 1 fully rigid, 2 diminished rigidity, capable of penetration, 3 occasionally satisfactory for intercourse, 4 tumescent, incapable of intercourse, and 5 no tumescence. EFR was defined as an EF score of 1 or 2. Only men with an EF of 1 or 2 pre-RP were included. The nerve sparing score (NSS) was assigned by the surgeon using a 4-point grading system. The NSS was assigned to each nerve where: 1 = fully preserved, 2 = partially preserved, 3 = minimally preserved, and 4 = resected. Thus, the NSS range = 2–8.

Results: 561 men had a mean age of 58 ± 7 years. Distribution of patients for each NSS score was: 2 = 369, 3 = 122, 4 = 70. Five surgeons were analyzed. Mean surgeon volume was 112 ± 89 (range 22–238). Mean baseline and 24 m EF scores were 1.1 ± 0.4 and 2.2 ± 1.4. No differences existed in mean patient age between surgeons and as such, age was not controlled for in further analyses. There were no significant differences in mean 24 m EF scores between surgeons based on NSS categories as follows: overall NSS 2–4: range 2.44–2.59 (p = 0.9); NSS 2 (1+1): range 2.03–2.53 (p = 0.7); NSS 3 (1+2): range 2.5–3.16 (p = 0.11); NSS 4 (2+2 only), range 2.86–3.61 (p = 0.7). In terms of the amount of inter-surgeon variability, the mean inter-surgeon variability in 24 m EF scores significantly increased with NSS 2, 3 and 4 (p = 0.02).

Conclusions: Despite the subjective nature of a NSS, there was no significant variability in EF recovery between surgeons when adjusted for nerve sparing score. The tightest concordance between surgeons was seen for the highest grade of nerve sparing. These data support the use of an institution-wide nerve sparing scoring system.

Disclosure:

Work supported by industry: no.

082

DETERMINING THE OPTIMAL ERECTILE FUNCTION DOMAIN SCORE CUTOFF AFTER RADICAL PROSTATECTOMY (RP)

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Objectives: The International Index of Erectile Function (IIEF) is the gold standard instrument for defining erectile function and its response to treatment. The Erectile Function Domain (EFD) contains 6 questions (score range 0–30), and an EFD score of 26 is considered as representing “no ED.” Various EFD scores have been used to define functional erections, most recently 22 (REINVENT study), without assessing the impact of these cut-offs on sexual satisfaction. This study was conducted to define which EFD score is the optimal cut-off when anchored against sexual satisfaction.

Material and Methods: We assessed men 24 months (m) post-RP with the EFD and Intercourse Satisfaction Domain (ISD) of the IIEF. We used two questions (Q) from the ISD to classify intercourse satisfaction (IS; range 0–10), one Q on satisfaction (0–5) and one Q on enjoyment (0–5). The sexual frequency Q of the ISD was excluded. We tested the following classifications of IS: IS = 10; IS ≥8; both Qs of IS ≥4. We used a receiver operating characteristic (ROC) curve to determine the optimal EFD score cut-off that predicts IS. The Youden index was used to determine the optimal cut-off maximizing both sensitivity and specificity.

Results: 178 men had an average age at RP of 58 ± 7 years and a 24 m EFD = 20 ± 9. The ROC curves produced the following areas under curve (AUC): IS = 10, AUC = 0.80, p < 0.001; IS ≥8, AUC = 0.85, p < 0.001; both IS Qs ≥4, AUC = 0.86, p < 0.001. Using IS criterion of both ISD Qs ≥4 (highest AUC), the EFD score of 25 produced the optimal sensitive/specificity. The sensitivity/specificity values for EFD scores were: 22 = 0.89/0.66, 23 = 0.78/0.71, 24 = 0.78/0.80, 25 = 0.77/0.82, 26 = 0.73/0.85.

Conclusions: A score of 25 represents the EFD score with optimal prediction of intercourse satisfaction. These data may be important when defining successful recovery of erectile function after treatments such as radical prostatectomy and for defining inclusion criteria and treatment end-points for ED trials.

Disclosure:

Work supported by industry: no.

083

BASELINE ERECTILE FUNCTION AS A DECIDING FACTOR FOR PERFORMING NERVE SPARING DURING RADICAL PROSTATECTOMY: IS THERE SURGEON VARIABILITY?

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Objectives: It has previously been shown that baseline erectile function (EF) is an independent predictor of the decision to perform nerve sparing during radical prostatectomy (RP). We conducted this analysis to determine whether there is inter-surgeon variability regarding this decision-making paradigm.

Material and Methods: We reviewed data on men who underwent RP. EF was graded on a validated 5-point patient-reported scale: 1 fully rigid, 2 diminished rigidity, capable of penetration, 3 occasionally satisfactory for intercourse, 4 tumescent, incapable of intercourse, and 5 no tumescence. EF was dichotomized into penetration hardness erections (PHE) (EF = 1 or 2) and non-PHE (EF = 3, 4, 5). The nerve sparing score (NSS) was assigned at the completion of the operation by the surgeon using a 4-point grading system. The NSS was assigned to each nerve where: 1 = fully preserved, 2 = partially preserved, 3 = minimally preserved and 4 = resected. Nerve sparing surgery was

defined as NSS ≤ 4, and non-nerve sparing was defined as NSS ≥ 5. Only surgeons with more than 50 cases were included.

Results: 875 men who underwent RP had a mean age of 60 ± 7 years. 81% of the total sample had NSS. Five surgeons were analyzed. Mean surgeon volume = 175 ± 134 (range 50–382). Mean baseline EF scores = 1.7 ± 1.1. No differences existed in mean patient age between surgeons and as such, age was not controlled for in further analyses. For patients with PHE, 86% had nerve-sparing surgery. For patients with non-PHE at baseline, 61% had nerve-sparing surgery. This difference was statistically significant (p = .01). There were no significant differences in the percentage of nerve sparing operations between surgeons based on baseline EF categories: PHE: range 80%–89% (p = 0.3) and non-PHE: range 50%–75% (p = 0.4).

Conclusions: There was a significant difference in nerve sparing rates between patients with PHE and those without PHE preoperatively. However, there were no significant differences between surgeons in the use of nerve sparing surgery for patients with or without baseline PHE.

Disclosure:

Work supported by industry: no.

084

ASSESSMENT OF SEXUAL DYSFUNCTION IN MEDICALLY UNDERSERVED PATIENTS WITH GYNECOLOGIC CANCERS

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Objective: Sexual dysfunctions are prevalent in women with cancer. The Female Sexual Function Index (FSFI) has been validated recently for use in oncology populations. However, medically underserved women are underrepresented in studies of cancer and sexual function, and the performance of validated assessment instruments in this population is unknown. The objective of this study was to evaluate the feasibility of questionnaire-based assessment of sexual function in a sample of gynecologic cancer patients in a public safety net health system.

Material and Methods: Consecutive English- and Spanish-speaking gynecologic cancer patients (n = 168) at a county hospital in Houston, Texas, US agreed to complete the FSFI in their language of choice. They also completed questionnaires establishing possible risk factors for sexual problems, including the Hospital Anxiety and Depression Scale (HADS) and a survey inquiring about age, marital status, type of cancer, history of depression or anxiety, and prior sexual abuse. Reasons for non-participation were documented. We calculated missing data rates and compared these between the FSFI and HADS. Predictors of missing data on both instruments were examined as function of demographic and psychosocial variables.

Results: The most common reason for non-participation was due to problems with literacy. A significantly higher proportion of patients missed or skipped items on the FSFI compared to the HADS (P < .001), with the highest rates of missing data occurring for the Pain and Satisfaction subscales. Age (OR = 1.08, P = .01) and availability of a partner (OR = 0.12, P < .001) were associated with missing 1 or more items on the Satisfaction subscale but were not systematically related to missing data (20% or more items) on the full FSFI or the HADS.

Conclusion: Use of the FSFI in our study sample was limited by low literacy, a high rate of missing data, and a large proportion of women without sexual partners. We caution against routine use of the FSFI in populations that are likely to have similar characteristics.

Disclosure:

Work supported by industry: no.

085

CANCER AND SEXUALITY: A SPECIFIC SURVEY IN 320 HEALTH CARE PROFESSIONALS IN ORDER TO SPECIFY THE PERCEIVED NEEDS FOR INFORMATION OR TRAINING

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If preservation or recovering of sexual health / intimate life is often a real parameter for the quality of life of patients and couples in case of cancer, both perceptions and attitudes of health care professionals remain badly-known contrary to the demands and expectations of patients. **Objective:** to analyze and evaluate: a) their personal and professional awareness concerning this specific dimension, b) attitudes and skills for listening and treating it. **Material and Method:** use of a validated questionnaire (7 closed questions quoted 0, 1 or 2 and 2 open questions) for identifying the needs of information and training; survey done with 320 French health care professionals all in contact with cancer patients: a) 161 various health professionals from our general hospital (58 physicians, 68 non-physicians) and a private hospital (3 physicians, 32 non-physicians), b) 76 residents (urology, oncology or radiotherapy) and 83 urologists from other institutions. **Results:** (number = mean): A) **Frequency:** a) personal awareness: higher in urologists (1.7) and hospital professionals (1.6) than residents (1); b) professional confrontation with the sexual complaint: usual for urologists (1.8), less in our hospital (1.4), in private hospital and for residents (1.2); c) attitude if patient demand: urologists (1.7) and residents (1.3) are more reactive than both hospital professionals (1.1). Urologists have a more proactive attitude (1.7) than residents (0.8) or in both hospitals (0.5). B) **Seriousness:** to be listening (1.9) and reactive (1.8) to both sexual complaint and demand is very important for all except for residents (1.3). C) **Problems:** theoretical knowledge: insufficient in both hospitals (0.3), better for residents (1) and good for urologists (1.6); technical skills: very low (0.1) in both hospitals, better for residents (1.1) and good for urologists (1.6); relational skills: globally better in both hospitals (1), for residents (1.2) and mainly for urologists (1.5) likely reflecting empathy qualities. These different insufficiencies explain the reported importance (1.8 in both hospitals, 1.7 for urologists, 1.1 for residents) to know how to inform and where to send. **Conclusion:** The very good survey acceptance points up a high awareness and a usual confrontation with the oncosexual problem. However, the response (listening and care) appears too insufficient in our selected samples except for urologists. The rarity of the double skill (oncology and sexual medicine) explains the strong demand for: a) better information, b) real visibility of this specific health care offer for all, c) specific guidelines and training for the most concerned and motivated.

Disclosure:

Work supported by industry: no.

086

MALE CANCERS AND SPECIFIC REQUESTS FOR SEXUAL CARE: LESSONS FOR DAILY PRACTICE BASED ON 3 PROSPECTIVE SURVEYS IN AN OUTPATIENT UROLOGY CLINIC IN PUBLIC HOSPITAL

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In order to better specify our needs in oncosexuality, prospective investigations were made among three successive cancer male outpatient populations (n = 983): first all cancers then only prostate cancer (PC) consulting in urology whatever the stage, treatment or follow-up. **Material and Method:** **All cancers:** investigation of exclusive patient requests followed by a specific treatment for sexual problems among

615 successive male outpatients with cancer. Five analyzed parameters: age, sexual problems, cancers and concerned treatments, effected sexual treatments, referral physician. **PC:** proactive analysis of: a) erectile capacity (Hardness Erectile Score: HES), b) eventual demand for treatment, c) survey well-founded in successive 246 all ages patients (mean age: 70.6) then only in 122 ageing (>74 years) ones. **Results:** **All cancer:** sexual troubles treatment: only for 126 patients (20.5%) i.e. 114 erectile dysfunction (ED), 5 lowering of desire and 7 miscellaneous; concerned cancers: only 8% non urological; specific treatment: mainly pharmacological using oral PDE5 inhibitors (PDE5i) (n = 50), PGE1 intracavernous injections (ICI) (n = 48) or associations (n = 10); referral physicians: only 10% patients specifically sent by other physicians. **PC:** a) all age: 18% no ED (mean HES 3.7) vs. 82% ED (HES score < 3); treatment demand = 48% (43 PDE5i, 42 ICI, 12 other); survey approval = 95%; b) ageing: 7% no ED vs. 93% ED; treatment demand (9%) or already treated (19%); survey approval (99%). In our 368 unselected PC outpatients, 20% have no ED problem, 40% ask for or are treated. If 40% are not interested in a treatment, 95% agree to be questioned and informed about the potential impact of PC treatments on sexual health and intimacy. **Conclusion:** In spite of several limitations, our observational investigations show 5 facts: 1) a minority (20.5%) of our all cancers patients benefits from specific care concerning mainly ED (90%), PC (79%) and pharmacological treatments (89%), 2) the low number of non urological cancers (8%) reflects a real inequality of access to oncosexual care, 3) 82% of our all ages PC patients have ED but only half is treated, 4) when proactively asked, 95% wanted specific information or treatment even the older ones proving a contrast between both "sexual" interest and survey approval and ED treatment demand, d) a paradoxical situation in CP group: overestimation of ED negative impact in youngest population vs. underestimation of sexual interest in oldest one.

Disclosure:

Work supported by industry: no.

087

PROSTATE CANCER DIAGNOSIS IS ASSOCIATED WITH AN INCREASED RISK OF ERECTILE DYSFUNCTION FOLLOWING PROSTATE BIOPSY

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Objectives: To prospectively evaluate the characteristics, erectile function, and LUTS of men undergoing PNBx.

Material and Methods: From 2008–2011, 134 men were prospectively administered the International Index of Erectile Function (IIEF), American Urologic Association Symptom Index (AUASI), and Quality of Life (QoL) questionnaires before and after undergoing a single 12-core PNBx. Comparisons of IIEF and AUASI scores based upon baseline characteristics and prostate cancer (PCa) diagnosis were performed. Univariable and multivariable logistic regression models characterized predictors of change in IIEF scores.

Results: In the 85 men who fulfilled inclusion criteria, there were no significant differences between the mean total pre-biopsy (57.8 ± 12.9) and post-biopsy (54.3 ± 17.2) IIEF scores. Subgroup analysis of men who were found to have biopsy-proven PCa had significantly greater changes in their post-biopsy IIEF scores compared to men without (-10.1 vs. 1.0; p < 0.001). Specific analyses of the IIEF domains in these groups demonstrated significant decreases in every domain, including erectile function (p = 0.01). On multivariate analyses, only PCa diagnosis was associated with a significant change in IIEF (OR 7.2; p = 0.003). There were no differences in AUA-SI or QoL scores in the overall population or in subgroups.

Conclusions: Cancer diagnosis appears to have an adverse effect on the erectile function of men undergoing PNBx but no effect on LUTS. This study highlights a potential negative psychologic con-

founder that may influence erectile function prior to the treatment of PCa. Additional prospective trials evaluating these relationships are warranted.

Disclosure:

Work supported by industry: no.

088

BREAST RECONSTRUCTION WITH NIPPLE AREOLA COMPLEX CONSERVATION AND TEMPORARILY NIPPLE BANKING: DOES IT OUTWEIGH THE SEXUAL COSTS?

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Breast - and nipple reconstruction after mastectomy has become an integral part of breast cancer treatment and is generally believed to improve women's quality of life. The effects of psychological and psychosexual factors on quality of life after reconstruction have scarcely been investigated.

Skin-sparing mastectomy followed by immediate reconstruction has been advocated as an effective treatment option for early stage breast cancer patients, provided it is oncologically safe. However, removal of the nipples and areola complex (NAC) may have negative consequences for affected women. For mutilation reduction purpose, NAC conservation can be advocated. Temporarily grafting of the NAC in the groin ("nipple banking") before placing it to the reconstructed breast, is performed in the Netherlands Cancer Institute (NKI) since 2005. We aimed (1) to investigate the psychological, psychosexual and motivational experiences of women undergoing direct breast reconstruction, and (2) to assess whether benefits of temporarily banking nipples outweigh the psychological/ psychosexual costs. This abstract is focused on sexuality data.

Material and Method: For questionnaire development, first 15 women with nipple banking were interviewed in focus groups on relevant nipple reconstruction-themes. The refined self-report questionnaire was sent to all women in the NKI who had a direct breast reconstruction after mastectomy during December 2004-June 2008 (481). Questions posed were on psychological distress, satisfaction with reconstruction, motivation and sexuality.

Results: In total, 318 of the 479 eligible women (66%) completed our questionnaire. Of these, 58 (18%) had undergone nipple banking, 167 (53%) had chosen for tattoos/flap, and 93 women (29%) declined reconstruction.

No significant psychological and psychosexual differences between these three groups were found. Most patients were satisfied with the offer and choice of nipple banking, though they experienced more medical complications. They were motivated to conserve their own nipples. Interestingly, women with nipple banking did not significantly worry more about oncological safety. Nipple banking had a major impact on sexual activity. During the banking period, two-third of women was not at all/less sexually active (embarrassment, discomfort with partner).

Conclusions: With pre-operative preparation on sexual functioning issues, nipple banking can be offered as an oncologically safe, valuable finishing touch of direct breast reconstructive surgery in early stage breast cancer patients. However, the benefits of nipple banking (keeping own nipple) should be carefully weighed against the costs (more medical complications, less sexual activity during banking time, shame).

Disclosure:

Work supported by industry: no.

089

BASELINE POTENCY AND DESIRE TO PRESERVE SEXUAL ACTIVITY: AN ASSESSMENT OF CHINESE PATIENTS FOR RADICAL RETROPUBIC PROSTATECTOMY

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Objectives: Erectile dysfunction (ED) is one of the commonest complications and significantly impacts on quality of life in patients treated with radical retropubic prostatectomy(RRP). There is no knowledge about baseline potency and desire to preserve sexual activity in Chinese patients undergoing RRP. These were both significantly important as they might influence surgeons' judgments about treatment decisions. This study was to assess the baseline potency and desire to preserve sexual function after RRP in Chinese patients with prostate cancer(PCa).

Material and Methods: A comprehensive medical and sexual history of 187 evaluable PCa patients for RRP was obtained on hospital admission the day prior to surgery. Baseline potency was assessed with the abridged 5-item version of International Index of Erectile Function(IIEF-5). The desire to preserve sexual activity and interests to see a doctor when diagnosed with ED after RRP were described and compared.

Results: Mean age was 65.6 years (range 48-79 years). Of all patients, 75.4% (N = 141) were sexually active before RRP. 26.2% (N = 37) were potent, 34.8% (N = 49) reported mild, 27% (N = 38) mild to moderate, 9.2% (N = 13) moderate, and 2.8% (N = 4) severe ED. 65.2% (N = 122) and 42.8% (N = 80) patients had desire to preserve sexual activity and interests to see a doctor when diagnosed with ED after RRP, respectively. Patients with ED were significantly older (P < 0.05), had no desire to persevere sexual activity (P < 0.05) and no interests to see a doctor (P < 0.001).

Conclusions: Nearly 3/4 Chinese patients diagnosed with PCa experiences some degree of baseline ED before RRP. However, quite a few patients are still interested to preserve sexual activity and to see a doctor when diagnosed with ED after RRP.

Disclosure:

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090

PENILE LENGTH AND GIRTH RESTORATION IN SEVERE PEYRONIE'S DISEASE BASED ON CIRCULAR AND LONGITUDINAL GRAFTS

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Objective: Penile prosthesis implantation for Patients with Peyronie's disease should be discussed in cases of severe erectile dysfunction, complex anatomical deformities and massive penile shortening. In up to 50% of cases patients are dissatisfied with their postoperative penile length after penile prosthesis implantation. We report our experience with a novel method for penile length and girth restoration with circular and longitudinal grafting during penile prosthesis implantation.

Patients and Methods: Between November 2006 and November 2011, 105 patients with disabling Peyronie's disease and associated erectile dysfunction underwent our surgical approach for penile length and girth restoration with concomitant penile prosthesis implantation. The technique consists of a straightening procedure based on the Egidio technique and circular as well as longitudinal grafting for maximum length and girth restoration.

Results: After an average of 18.2 months (range, 6-46 months) of follow-up all patients except of one (n = 104; 99.0%), who developed a post-operative wound infection with subsequent prosthesis removal were able to have sexual intercourse. The mean functional penile length gain was 3.6 cm (2-5 cm). It was clearly shown, that the acquisition or the recovery of the ability to perform sexual intercourse

brought major relief and high rates of satisfaction and self-esteem. Glans sensitivity, orgasmic ability and ejaculation were preserved in all patients.

Conclusion: Our technique resulted in a maximum length and girth restoration with excellent functional outcome. Patient satisfaction was very high. Not only the ability to perform sexual intercourse again after surgery, but also length and girth restoration are very important for recovering self-esteem and patient satisfaction.

Disclosure:

Work supported by industry: no.

091

THE PREVALENCE OF PEYRONIE'S DISEASE IN JAPAN: A STUDY IN MEN UNDERGOING MAINTENANCE HEMODIALYSIS AND ROUTINE HEALTH CHECKS

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Objective: The incidence of Peyronie's disease (PD) in the general population is believed to be as high as 20%. However, most of the data concerning the prevalence of PD have been obtained from Caucasian populations. Moreover, comorbidities, such as diabetes and hypertension have been proposed as risk factors. To our knowledge, no epidemiological data on the prevalence of PD in Asia or among men undergoing hemodialysis have been reported.

Materials and Methods: A total of 1090 men who received a routine health check (control group) as well as 130 male patients undergoing maintenance hemodialysis were enrolled in this study. The diagnosis of PD was based on a palpable penile plaque. Hemodialysis patients were asked about their sexual activity (frequency of sexual intercourse and masturbation) and completed the IIEF-5 questionnaires. The differences between patients' factors (age, frequency of sexual intercourse or masturbation, IIEF-5 responses, smoking status), hemodialysis-associated factors (dry weight, hemodialysis duration, and the type of dialysate, dialysis membrane, anti-coagulant), comorbidities and medications were statistically assessed for patients with and without PD.

Results: The mean \pm SD ages of the patients were 57.3 \pm 9.7 years (range: 39-71) and 59.2 \pm 11.2 years (range: 41-78) for the control group and the hemodialysis patients, respectively. The prevalence of PD was significantly increased among hemodialysis patients (12 patients: 9.2%) relative to the control group (6 men: 0.6%) ($p < 0.0001$, odds ratio: 18.4). In the hemodialysis patients, 1 patient underwent plication surgery, and the plaque of 1 patient spontaneously resolved following renal transplantation. In the hemodialysis patients with PD (12 patients), the frequency of masturbation ($p < 0.05$, odds ratio: 4.1) and the incidence of moderate or severe erectile dysfunction ($p < 0.01$, odds ratio: 14.9) were significantly higher than those among hemodialysis patients without PD (118 patients). In comparison to patients without PD, the number of acetate dialysate users was significantly higher among patients with PD ($p < 0.05$, odds ratio: 4.5), and none of the PD patients used angiotensin-converting enzyme inhibitors or angiotensin receptor blockers ($p < 0.05$, odds ratio: 4.5).

Conclusions: The prevalence of PD in healthy Japanese men is low (0.6%), which suggests the existence of racial differences in the prevalence of PD. Moreover, these results indicate that hemodialysis increases the incidence of PD. The differences in the characteristics between male hemodialysis patients with and without PD provide new insights into the pathophysiology and therapeutic window of PD.

Disclosure:

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092

DOES CALCIFICATION OF PEYRONIE'S DISEASE PLAQUE PREDICT PROGRESSION TO SURGICAL INTERVENTION?

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Introduction and Objective: Peyronie's Disease (PD) is a connective tissue disorder of the penis in which a fibrous scar or plaque in the tunica albuginea can result in multiple deformities of the penis including curvature, indention, and loss of penile length. Current clinical opinion holds that patients with calcified Peyronie's plaques are less responsive to non-surgical therapies. We investigated whether stratification of calcification based on severity seen on ultrasound findings, rather than presence or absence alone, would serve as a predictor of surgery.

Material and Methods: Retrospective review of 792 men presenting with PD from 1993 to 2009. N = 98 were found to have plaque calcification noted on ultrasound. We reviewed the intake PD questionnaire, history, physical, ultrasound images, and evidence of plaque calcification. Degree of calcification was recorded by a single urologist (LAL) conducting the ultrasounds. Calcification of the plaque was graded as: grade 1 (<0.3 cm), grade 2 (>0.3 cm, <1.5 cm), grade 3 (>1.5 cm; or ≥ 2 plaques >1.0 cm). Progression through treatment from non invasive to surgical was also reviewed (medical, traction, and injection therapies vs. surgery). A control group with non calcified plaques (n = 236) matched for age, disease duration, date of presentation, and mean curvature was selected for comparison.

Results: Mean age was 56 (25-73), 41% were found to have grade 1, 28% were grade 2, and 32% were grade 3. Overall, 34% elected to undergo surgical correction. When analyzed by grade and subsequent progression to surgery, 23% of grade 1, 32% of grade 2, and 55% of grade 3 patients ultimately had surgery. In the matched control group, 34% progressed to surgery. Patients with grade 3 calcification were more likely to elect surgical intervention for PD (OR 2.28 95% CI 1.07-4.86). Presence of calcification alone was not a predictor for progression to surgery (OR 0.95, 95% CI 0.58-1.57).

Conclusions: Men with a calcified PD plaque are likely to undergo surgery. Calcified PD plaques are not uncommon: and those men with severe grade 3 plaques have an increased likelihood of progression to surgical intervention.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

093

THREE-DIMENSIONAL IMAGING TO DOCUMENT IMPROVEMENT IN PENILE CURVATURE DEFORMITY IN PATIENTS WITH PEYRONIE'S DISEASE TREATED IN A PHASE III STUDY WITH COLLAGENASE CLOSTRIDIUM HISTOLYTICUM

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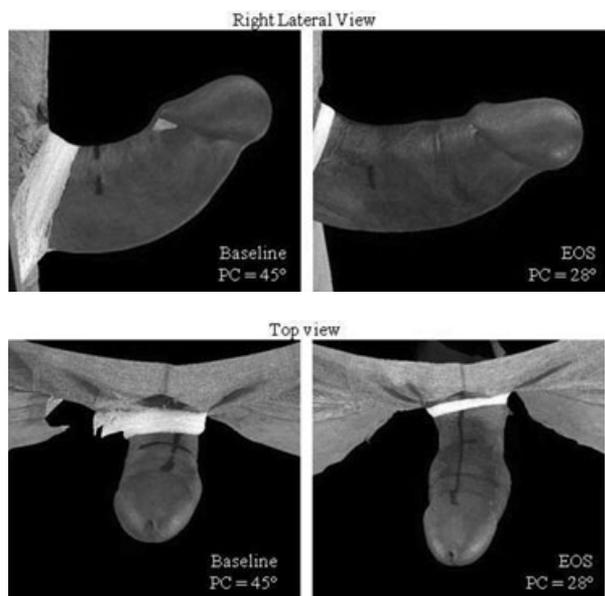
1: Maimonides Medical Center, USA; 2: Urology of Virginia, PLLC; 3: Auxilium Pharmaceuticals, Inc.

Objective: 3-D photography has never before been used to assess penile curvature (PC) deformity in patients (pts) with Peyronie's Disease (PD). As part of an open-label phase 3 study of collagenase clostridium histolyticum (CCH), an investigational, in-office injectable treatment for PD that selectively lyses collagen, a 3-D photography sub-study was conducted.

Materials and Methods: Pts (N = 10) in the sub-study were from 2 US sites utilizing the VECTRA[®] 3-D digital photographic system. Eligible pts were male ≥ 18 yrs of age with PD ≥ 12 months with a PC deformity between 30° and 90°. Pts received intralesional injections of 2 doses of CCH (0.58 mg) 24 to 72 hrs apart for up to 4 treatment

cycles, each 6 wks apart with penile plaque modeling. Pts were followed for 36 weeks and PC deformity was 3-D photographed prior to each cycle and at the end of the study (EOS; 36 weeks).

Results: Examples of two different views captured are shown below. A 37.8% improvement in PC deformity was demonstrated by EOS. This subject was not sexually active at baseline, but became so by EOS.



Conclusions: 3-D photography enables visualization of the PC deformity from any angle, including that of the patient. By capturing the PC deformity following each CCH treatment cycle, it is possible to time-lapse the correction demonstrating visually the impact of each treatment cycle on the reduction in PC deformity for pts with PD.

Disclosure:

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094

PEYRONIE'S DISEASE AMONG MEN WHO HAVE SEX WITH MEN: CHARACTERISTICS, TREATMENT, AND PSYCHOSOCIAL FACTORS

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Objectives: This study investigated the characteristics, treatment, and psychosocial factors of men with Peyronie's disease (PD) who have sex with men (MSM).

Materials and Methods: We identified 25 MSM with PD presenting from 2004 to 2010 through a retrospective chart review. MSM PD patients were matched one-to-one with non-MSM PD patients by age and duration of disease. A prospective non-validated questionnaire was given to MSM PD patients.

Results: No differences in comorbidities between groups: DM, HTN, cholesterolemia, CAD, radical prostatectomy, tobacco use ($p > 0.05$). Most common recognized activator of PD was coitus in each group ($p > 0.05$). Curvature, shortening were the most common presenting symptoms ($p > 0.05$). No differences in other presenting symptoms: pain, lump, ED, deformity, loss of length, indentation, hourglass, hinge, distal softening ($p > 0.05$). MSM had greater pre-treatment girth ($p = 0.01$), no difference in pre-treatment stretch length, plaque location, measured erect curvature, hinge, calcification ($p > 0.05$). PD affected emotional status (88% MSM, 80% non-MSM), intimate relationships (45% MSM, 64% non-MSM) ($p > 0.05$). 92% of MSM, 80%

of non-MSM had non-surgical treatment ($p > 0.05$). Surgery performed in 24% of MSM, 20% of non-MSM ($p > 0.05$). More MSM received oral therapy ($p = 0.02$), no difference in injection or topical therapy use ($p > 0.05$). No difference in traction therapy or VCD ($p > 0.05$). Plication, IPP, and grafting were equally utilized ($p > 0.05$). Our non-validated questionnaire was completed by 56% of MSM patients. Of the 71% of MSM engaging in anal sex, 40% reported anal sex as recognized activator of PD. Following PD onset, 29% of MSM experienced decreased libido, 50% decreased frequency of sexual activity. 11 (79%) had prior evaluation: 36% took vitamin E, 27% were referred, 27% had no treatment offered. 11 (79%) were satisfied with treatment, including 67% of those in surgery cohort. 11 (92%) agreed they would undergo treatment again, including 100% of those in surgery cohort. 8 (57%) agreed that their sex life improved following treatment, including 100% of those in surgery cohort.

Conclusions: In the limited population of this study, few differences exist in the clinical presentation and treatments used between MSM and non-MSM PD patients. There was evidence of emotional distress in both groups – consideration for psychosexual therapy may be useful.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

095

INITIAL EXPERIENCE WITH SURGICAL STRAIGHTENING FOR PEYRONIE'S DISEASE FOLLOWING XIAFLEX® INTRALESIONAL INJECTION

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Objectives: Peyronie's Disease (PD) is a physically deforming and psychologically devastating condition for which many men seek the care of a urologist. The success of non-surgical treatment options including oral, injection, and mechanical is well reported and modest at best making surgical correction the gold standard treatment for PD. Phase 2b and 3 trials of Xiaflex®, an injectable clostridial collagenase, have recently been completed in the USA. We reviewed our experience with men who completed the Xiaflex® study protocol and received active drug who subsequently underwent surgical straightening.

Materials and Methods: We performed a retrospective chart review of 7 patients who had completed the Xiaflex® study protocol who had persistent curvature and progressed to surgical straightening.

Results: Five men underwent partial plaque excision and grafting (PEG) and 2 required tunica albuginea plication (TAP) all reporting virtually complete straightness post-op with no reported added anatomical difficulties during surgery secondary to the effects of the Xiaflex® injection. The average age was 56 years with an average duration of disease prior to surgery of 2.26 years (SD 0.62). The average pre and post-injection curvature was 59° and 58° respectively ($p = 0.375$). The average time from last injection to surgery was 182 days (SD 118). Mean pre and post-operative erectile rigidity was 8.14/10 and 8.89/10, respectively. Mean pre and post-operative stretched penile length (SPL) as measured from pubis to corona was 10.3 and 11.1 ($p = 0.122$), respectively, with 6/7 patients reporting using post-operative traction therapy. One patient developed a sub-plant hematoma requiring drainage.

Conclusion: The results of the Phase 3 Xiaflex® clinical trial is currently undergoing review. For those men who do not have a satisfactory response to this treatment it appears that surgical correction with plication or grafting can be performed successfully without added technical difficulty due to the effects of the collagenase on the penile tissues.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

096

VALIDITY OF PREMATURE EJACULATION DIAGNOSTIC TOOL (PEDT) IN FOUR SUBGROUPS OF PREMATURE EJACULATION SYNDROME: DATA FROM THE KOREAN INTERNET SEXUALITY SURVEY

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Objective(s): Premature ejaculation diagnostic tool (PEDT) is a brief, multidimensional validated instrument for diagnosis of premature ejaculation (PE). However, evidence of clinical validity of this questionnaire and its capability of differentiating subgroups of PE is insufficient. We employed and compared PEDT score in Waldinger's 4 subgroups of PE (Lifelong, Acquired, Natural variable, and Premature like dysfunction) to identify validity of PEDT score for diagnosis of subgroups of PE.

Material and Method(s): E-mails were sent to population based sample of males aged 20–59. Participants were asked to complete a questionnaire requesting detailed medical and sexual histories, which included questions from PEDT, and Medical Outcome Study Short-form 36-Item Health Survey (SF-36). Self-reported PE and 4 subgroups were defined and classified by self-assessment. PEDT-PE was defined with cutoff score of 11.

Result(s): E-mails were opened by 1,206 recipient and a total of 443 subjects with mean age of 39.3 ± 10.1 years were included, a response rate of 36.7%. Incidence of PE and their mean PEDT score were; self-reported PE (20.5%, 11.2), Lifelong PE (2.9%, 15.5), Acquired PE (7.0%, 11.2), Natural variable PE (7.4%, 10.4), and Premature like dysfunction (3.2%, 9.0). PEDT scores were significantly higher in Lifelong PE than in other PE subgroups of PE (p < 0.001). Premature like dysfunction group showed the lowest PEDT score and their physical and mental component score of SF-36 were similar to that of non-PE subjects. In the ROC curve analysis, sensitivity and specificity for diagnosis of Lifelong PE by PEDT was 91.3% and 93.8%, respectively. PEDT-PE incidence was 14.6% and its risk factors were erectile dysfunction, nondrinking, and low health related self-perception.

Conclusion(s): This population-based cross-sectional survey shows validity of PEDT as a useful tool for diagnosis of self-reported PE and, especially of Lifelong PE.

Disclosure:

Work supported by industry: no.

097

PSYCHOSOCIAL ASPECTS OF PREMATURE EJACULATION

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Objectives: Premature ejaculation (PE) is the most common sexual dysfunction among men and affects both partners. Little qualitative data is available to understand why patients seek treatment. The objective of this study was to assess the impact of PE from the perspective of men who suffer from PE.

Material and Methods: We evaluated patients with the complaint of lifelong PE. All patients underwent general and urological physical examinations and medical history was obtained with special attention to sexual problems. If the man was ≥18 years, in a stable monogamous relationship for ≥6 months, ejaculated <1 minute in more than half of his intercourse attempts ≥6 months, had an International Index of Erectile Function (EF) domain score ≥26, he was enrolled in this study. The question “What is PE for you?” was asked to all patients and the following answers provided;

- a. Ejaculation suddenly or shortly after penetration
- b. Ejaculation without having enough satisfaction/pleasure
- c. Ejaculation without satisfaction/orgasm for his partner

Results: Forty patients with lifelong PE enrolled in this study with a mean age of 35.5 ± 7.6 (range 26–52) years. Twenty (50%) patients chose at least one answer related to pleasure or sexual satisfaction (for both of male and female) and 17 (85%) of them had concern about their partners satisfaction. Surprisingly, only 7 (35%) patients had concern about their own satisfaction or pleasure (P = 0.003).

Conclusions: Men with PE have more anxiety about their partner's sexual satisfaction instead of their own sexual satisfaction. Patients with PE need to be evaluated with their partners.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

098

PREMATURE EJACULATION: A NEW TREATMENT USING A STIMULATING DEVICE IN CONJUNCTION WITH THE START- STOP TECHNIQUE

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Premature ejaculation (PE) is a common condition estimated to afflict around 30% of sexually active men. The Start- Stop technique (SST) in conjunction with Psychosexual Therapy (PST) is considered to be the treatment of choice for PE. Other treatments include SSRIs such as Dapoxetine and Paroxetine as well topical local anaesthetic agents. The new treatment postulated that SST used in conjunction with a new, small, specifically designed, hand held stimulating device reduces sensitization and prolongs latency to ejaculation.

Method: A 6 patient case series was carried out as an initial step to study the merits of proceeding with a Randomised Controlled Trial (RCT). This was followed by an RCT of 52 subject comparing PST with SST versus the prototype of device with the SST, with 26 subjects in each group. The power of the study was 80%.

Results: The case series showed an average 5 fold improvement in latency period for the prototype device-SST treated subjects. Benefit was noted at week 1 and was maximal by the end of week 6. The RCT showed an average 11 fold improvement in latency period in 61% of subjects for the prototype device-SST group compared to a 3 fold improvement in 40% of the subjects for the PST-SST group. There were no side effects associated with the use of the device and the benefit achieved at the end of week 6 was maintained in both groups at 3 months after discontinuation of treatment.

Conclusion: This novel treatment is effective, affordable, and can be combined with any treatment modality currently used for PE. It proved to be side effect free and overcomes the traditional barriers associated with the treatment of PE including cost, side effects, barriers to access of care, and mass delivery of an effective treatment for a very common condition.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

099

BULBOSPONGIOSUS MUSCLE ELECTROMYOGRAPHY: A NOVEL DIAGNOSTIC TOOL FOR LIFELONG PREMATURE EJACULATION

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Introduction: Ejaculation is a reflex which is constituted by emission and expulsion phases. Premature ejaculation (PE) is thought to be due to hyperexcitable ejaculatory reflex. The aim of this study is to compare the electromyographic (EMG) activity of bulbospongiosus muscle (BSM) in lifelong PE patients and healthy volunteers.

Materials and Methods: Between January-May 2012, 10 lifelong PE patients and 5 healthy volunteers without PE complaints have been included. The EMG activity of BSM was recorded by concentric EMG needle electrode during masturbation with audio-visual stimulation. The EMG activity was displayed on the oscilloscope of a standard EMG apparatus until ejaculation occurs. The initiation time of the different electrical activity patterns and their frequencies have been compared along with the ejaculatory latency time.

Results: The mean age of the patients and controls were 34.7 ± 4.3 and 32.4 ± 5.6 , respectively ($p = 0.393$). Mean self-estimated intravaginal ejaculatory latency time was significantly shorter in PE patients (39.4 ± 13.3 sec vs. 386.8 ± 140.2 , $P = 0.005$). The time of initiation of both intermittent (36.7 ± 18 sec vs. 128.6 ± 11.4 sec, $P < 0.001$) and sustained (289.3 ± 37.4 sec vs. 481.8 ± 14.3 , $P < 0.001$) electromyographic activity was significantly shorter in lifelong PE patients. Similarly the frequency of intermittent and sustained activity were higher in lifelong PE patients (2.7 ± 1.2 Hz vs. 1.8 ± 0.5 Hz, $p = 0.12$ and 9.3 ± 2.8 vs. 2.6 ± 0.6 , $P < 0.001$).

Conclusions: Electromyographic activity of BSM is greater in lifelong PE patients during masturbation. This assessment has the potential of being used in diagnosis of lifelong PE. Further studies are required to establish the cut off frequency and time thresholds.

Disclosure:

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THE INCIDENCE AND TYPES OF SEXUAL DYSFUNCTION AMONG PROSTATE CANCER PATIENTS

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Objective: Although the incidence and treatment options for erectile dysfunction (ED) has been reported among prostate cancer patients, little attention has been focused on the other domains of sexual function, such as ejaculatory dysfunction and loss of libido. The aim of this study is to assess the incidence and types of sexual dysfunction among prostate cancer patients.

Materials and Methods: Between July 2011 and May January 2012, patients who were diagnosed with prostate cancer included into the study. After taking a careful medical and sexual history, the patients were instructed to complete Male Sexual Health Questionnaire (MSHQ) to assess their pre-treatment sexual function. Answers to the questions of MSHQ were analyzed and patients who scored 0–2 points from each question accepted to be symptomatic. Erection, Ejaculation, Satisfaction, Sexual Activity and Desire scales were separately evaluated.

Results: A total of 60 patients who were recently diagnosed with prostate cancer were studied. The mean age were 60.28 ± 6.25 (range

44–73) and 13.8% reported no sexual activity within the previous month (Q19). Erectile problems, especially getting an erection (13.6%, Q1), were common. Ejaculatory dysfunction was also highly prevalent and bothersome in men with prostate cancer, with decreased force of ejaculation (13.2%), diminished volume of ejaculate (18.5%) and decreased pleasure with ejaculation (20.4%) being the most commonly reported symptoms. Approximately, 31.5% of patients were unsatisfied with their sex activity (Q15).

Conclusion: The incidence of sexual dysfunction is high among prostate cancer patients. These problems need to be considered when discussing treatment options with prostate cancer patients.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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MEN'S EXPERIENCE WITH PENILE REHABILITATION FOLLOWING RADICAL PROSTATECTOMY: A QUALITATIVE STUDY

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Objectives: Erectile rehabilitation post-radical prostatectomy (RP) is important to help men regain erectile functioning. This qualitative study explored men's experience with erectile dysfunction (ED) and ED treatments with the goal to inform a psychological intervention designed to help men consistently adhere to erectile rehabilitation post RP.

Material and Methods: 35 men post RP took part in one of four focus groups to discuss their experience with ED, ED treatments, and provide suggestions to improve compliance with an erectile rehabilitation program. Thematic analysis was used to analyze these qualitative data.

Results: The primary themes that emerged from the qualitative analysis included: frustration over the lack of information provide pre-surgery about ED post-surgery; frustration/embarrassment about ED; anxiety/fear of entering into a sexual situation when not confident in erections; avoidance to using ED treatments and engaging in sexual relations; lack of spontaneity with sex; battling with the relationship between surviving cancer and quality of life after treatment; and openness to an intervention to address these issues. From these themes, we delineated a cycle of avoidance with the following stages: 1) the experience of frustration/shame in a sexual situation if having difficulty with erections, 2) increased anxiety/fear about entering into another sexual situation, 3) avoidance of sexual situations and intimate contact potentially leading to relationship conflict, 4) increased frustration/distress/depression.

Conclusions: Men's frustration and embarrassment about ED after prostate cancer surgery can result in avoidance of the use of ED treatments and engaging in a sexual rehabilitation program. Interventions should specifically target this avoidance.

Disclosure:

Work supported by industry: no.

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DECREASE IN INTERCOURSE SATISFACTION IN MEN WHO RECOVER ERECTIONS AFTER RADICAL PROSTATECTOMY

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Objectives: It is assumed that if a man "recovers" erections post-radical prostatectomy (RP), intercourse satisfaction (IS) will return to pre-RP levels. We explored if IS returned to baseline levels for men post-RP.

Material and Methods: We assessed 166 men pre-RP and 24 months (m) post-RP. Erectile function domain (EFD) and intercourse satisfaction domain (ISD) of the international index of erectile function (IIEF) were recorded. Patients answered a single question on PDE5i use. Those with penetration hardness erections (PHE) at baseline (EFD ≥ 24) were included. Erection recovery was defined in 2 ways at 24m (i) PHE (ii) EFD back to baseline (BTB) (score within 1 point or higher of baseline). Repeated measure t-tests tested for ISD change. Effect size (d) was calculated: d = 0.20 small; d = 0.50 medium; d = 0.80 large. Univariate associations (UVA) were tested with correlation coefficients, and multiple regression was used for multivariable analyses (MVA).

Results: Mean age = 58 \pm 7 years. Mean baseline and 24m EFD = 29 \pm 2, 19.7 \pm 10 (p < 0.01). Overall, ISD decreased (12 to 8.3, p < 0.01, d = 0.87), even for men with PHE at 24m (12.3 to 11.3, p < 0.01, d = 0.50). This was true for men not using PDE5i (12.1 to 10.8, p < 0.01, d = 0.61), and for men using PDE5i (12.5 to 11.7, p < 0.01, d = 0.42). UVA with 24m ISD for men with PHE at 24m were: age (r = -0.23, p = 0.05), baseline EFD (r = 0.25, p = 0.03), baseline ISD (r = 0.56, p < 0.001), and 24m EFD (r = 0.36, p < 0.01). Nerve sparing status (NSS) was not significant. On MVA, baseline ISD (beta = 0.46, p < 0.01) and 24m EFD (beta = 0.23, p = 0.04) were predictors of 24m ISD. For men who returned BTB at 24m, ISD also decreased (12.4 to 11.7, p = 0.02, d = 0.35). When considering decreases based on PDE5i use for the BTB group, these did not reach significance. UVA with 24m ISD for BTB were: baseline EFD (r = 0.45, p = 0.01), baseline ISD (r = 0.63, p < 0.01), and 24m EFD (r = 0.35, p = 0.01). On multivariable MVA, only baseline ISD (beta = 0.49, p = 0.01) remained a predictor of 24m ISD.

Conclusions: IS will decrease for most men post-RP, even for those men who achieve functional erections and even those achieving BTB erections post-RP. These data may assist clinicians in counseling patients pre-RP.

Disclosure:

Work supported by industry: no.

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PATIENT SATISFACTION OF VACUUM ERECTION DEVICE (VED) USE AFTER PROSTATE CANCER TREATMENT: THREE AND SIX MONTH OUTCOMES FROM A VED REGISTRY

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Introduction: Vacuum Erection Devices (VEDs) are commonly used following prostate cancer treatment to minimize the impact of radical prostatectomy (RP) or radiation therapy (XRT) on sexual function. We report three and six month data collected within an IRB approved VED registry for patients who have undergone either RP or XRT and prescribed a VED.

Methods: Patients were sent questionnaires to be completed upon receipt of their VED (baseline), 3, 6 and 12 months afterwards. They included Sexual Health Inventory for Men (SHIM) and satisfaction rates.

Results: A total of 291 questionnaires were returned from patients: 225 baseline, 47 three-month, and 19 six-month. 83% of the RPs were performed robotically. SHIM scores in the RP and XRT groups at baseline were 8.9 \pm 9.6 and 13.94 \pm 9.22, respectively. The SHIM scores in the RP increased to 11.2 \pm 8.6 and 15.1 \pm 8.0 at 3 and 6 months. The SHIM scores in the XRT group decreased to 8.6 \pm 4.98 and 8.67 \pm 3.51 at 3 and 6 months. Only one patient in the RP group reported a decrease in penile length after using the VED.

Conclusion: Significant improvements in SHIM scores were observed in patients after RP at 3 and 6 months. Conversely, SHIM scores in the XRT group decreased over time. Patient assessed penile length is preserved with VED use.

Disclosure:

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THE DESIRE OF PENILE REHABILITATION AFTER RADICAL PROSTATECTOMY IN JAPANESE MEN

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Objective: Penile rehabilitation is now widely used to recover erectile dysfunction (ED) after radical prostatectomy (RP), however, there is no conclusive optimal method. We performed a questionnaire survey of patients' opinions about ED after RP.

Materials and Method: This questionnaire survey was based on the International Index of Erectile Dysfunction (IIEF) in 153 prostate cancer patients treated with RP between 2009 and 2010 at three facilities. The response rate to the questionnaire was 74.5%, and 114 patients were analyzed. The mean age of the subjects was 68 years (range 50–76), and no one had received postoperative radiation or androgen deprivation therapy.

Results: Since only one quarter of patients had received nerve-sparing RP, most of them had severe ED. The impression of patients regarding postoperative ED varied: "Uneventful" was cited by 59.6%, and "Unexpectedly serious condition" by 20.2%. About half of the patients (47.4%) wished to receive penile rehabilitation, especially those patients treated with nerve-sparing RP or higher IIEF score. Regarding treatment method, 77.8% of patients preferred "oral medicine on demand", and 48.1% preferred "topical ointment on demand", and tended to avoid more invasive modalities. As to problems, 74.1% of patients reported "pain" and "high cost".

Conclusion: About half of patients wished to receive penile rehabilitation. Oral medicine on demand such as PDE5 inhibitors seemed to be the most acceptable for penile rehabilitation in Japanese men.

Disclosure:

Work supported by industry: no.

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WHAT IS THE VALUE OF NERVE SPARING PROSTATECTOMIES WITH PRE-PROSTATECTOMY POOR ERECTILE FUNCTION?

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Objective: Despite advances in diagnosis resulting in early case finding and improvements in surgical technique, significant morbidity associated with radical prostate surgery remains. Postprostatectomy erectile dysfunction is a frequent complication and a source of distress for many men despite modifications in surgical technique. While nerve-sparing prostatectomy has been demonstrated to preserve erectile function in the majority of men with good erectile function pre-operatively, the question remains whether the preservation of the cavernous nerves in men with poor erectile function is a worthwhile endeavour.

Methods: This is a retrospective analysis of prospectively collected data of 1160 patients operated on by two surgeons with a single technique for each surgeon comparing pre-operative poor IIEF scores to post-operative scores with 2 years of follow-up. Post-operative intracavernosal injection therapy, radiation or hormonal therapy excluded patients from the study as did pre-op IIEF > 12. Only bilateral nerve sparing (BNS, n = 21) versus non-nerve sparing (NNS, n = 26) procedures were compared. Sexual Health Inventory for Men – International Index of Erectile Function 5 (SHIM-IIEF-5) questionnaire was

used for assessment of erectile dysfunction pre-operatively and post-operatively at 6 months, 1 year and 2 years via self administration. All men were offered penile rehabilitation therapy post-operatively. The data included the learning curves for both surgeons (EDM laparoscopic RP and SEP robotic prostatectomy).

Results: Average pre-operative IIEF-5 scores were 5.2 (BNS) and 4.9 (NNS) and not statistically significant. At 2 years, the average post op IIEF scores were 5.6 (BNS) and 2.3 (NNS). This was a statistically significant decline in the NNS group. Most erectile function was recovered by 1 year. Positive surgical margins were not statistically significant between groups.

Conclusions: Although a small retrospective analysis, this study does seem to show that nerve sparing appears to be a worthwhile endeavour in men with poor pre-operative IIEF as they return to baseline, and oncologic outcomes are not compromised. The decision for a non-nerve sparing procedure should not be made on the patient's pre-operative erectile function or dysfunction, but made on the merits of other oncologic clinical indicators such as high risk Gleason scoring or advanced clinical stage.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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THE IMPACT OF PENILE CANCER TREATMENT ON SEXUAL RELATIONSHIPS: A QUALITATIVE ENQUIRY

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Background: Penile cancer is a rare but highly treatable condition. Current guidance recommends the use of a surgical procedure to excise the primary tumour (and a margin of normal penile tissue). Whilst treatment can be effective, treatment often has a significant impact on a patient's sexual and urinary function, and physical and mental wellbeing. The objective of this study was to explore the impact of treatment for penile cancer on sexual function and relationships.

Methods: Qualitative data was collected via narrative video interviews. Maximum variation sampling was used to acquire the widest possible range of experiences. All interviews were recorded using either a digital video recorder or digital audio recorder, transcribed. A method of constant comparison analysis was used to illicit themes and outliers.

Results: Twenty seven men were interviewed; mean age at diagnosis = 63 (range = 41–82); Mean number of years post-surgery = 3 (range = 0–15 years) 15 men were married, a further two were in a committed relationship, the remaining 10 were single/widowed. All men had received surgical treatment ranging from circumcision to total penectomy. Just two men had attended any form of psychological therapy.

The impact of treatment varied considerably. The majority of men talked about still being able to experience arousal and sexual pleasure in some way. However, for many, penetrative sex was awkward and less gratifying than before treatment. One man who had received a total penectomy was surprised to experience a form of orgasm after surgery. For a number of men, the impact of treatment on their ability to satisfy their sexual partners was a key concern. Men who were able to openly talk with their partners about sex and the impact of the treatment on sexual practice found this a great comfort.

Conclusion: The significance of sex for a man can differ considerably between individuals; relationship status, age and life stage are all likely to have a bearing on the role that sex plays in a man life. A diagnosis of cancer can also affect how a man (and his partner) views sex and the level of importance which he attaches to it. For men who are sexually active prior to treatment, surgery will undoubtedly result in changes to sexual practice, however, treatment does not have to result in sexual abstinence.

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Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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EVALUATION OF BASELINE BIOAVAILABLE TESTOSTERONE LEVELS, PROSTATE CANCER AGGRESSIVENESS, DEPRESSION, AND ERECTILE DYSFUNCTION IN MEN UNDERGOING TREATMENT FOR LOCALIZED PROSTATE CANCER

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Objective: Low levels of bioavailable testosterone (bT) have been associated with erectile dysfunction (ED); however, this association has not been adequately explored in men with localized prostate cancer (PCa). Motivated by this, we evaluated the association of serum bT levels and questionnaire-based measures of ED in PCa men prior to prostatectomy. Moreover, we examined whether bT levels are associated with pathologic features of PCa aggressiveness.

Materials and Methods: We prospectively identified 134 men scheduled to undergo prostatectomy for clinically localized PCa at our institution between August 2009 and March 2012 who agreed to provide a fasting blood sample prior to surgery. Of these, 88 (67%) provided baseline responses to question 3 (i.e., "how often are you able to penetrate your partner?") and question 4 (i.e., "how often are you able to maintain your erection after penetration?") on the International Index of Erectile Function (IIEF) survey as well as question 28 ("... how often have you felt depressed?") and question 31d (i.e., "how big a problem ... has feeling depressed been?") of the EPIC. Following surgery, we abstracted pathologic features from the medical record. We employed Kendall's tau rank correlation to evaluate the association of bT with IIEF responses and pathologic features of aggressiveness.

Results: Interestingly, we observed no association between bT and Gleason score (p = 0.26), pT stage (p = 0.71), PSA (p = 0.74) or extracapsular involvement (p = 0.79). Older men with lower bT reported higher frequency (p = 0.001) and a bigger problem of depression (p = 0.01) on questions 28 and 31d of the EPIC. Men with lower bT also reported a trend toward poorer erectile function based on responses to IIEF questions; these associations remained apparent after adjustment for age.

Conclusion: Our data suggest that low bT is associated with greater prevalence of depression and poorer sexual function among men with newly diagnosed PCa. In contrast, bT levels are not associated with more aggressive PCa. If confirmed, these data support further exploration of testosterone replacement in men with PCa who experience ED.

Disclosure:

Work supported by industry: no.

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RADICAL CYSTECTOMY IN PATIENTS WITH INTRA-ABDOMINAL PENILE PROSTHESIS RESERVOIRS-A CASE SERIES

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Objective: To present the outcomes of 4 patients with pre-existing inflatable penile prostheses (IPP) with reservoirs within the space of Retzius who were subsequently treated with radical cystectomy for bladder cancer management.

Material & Methods: The demographic, clinical and pathologic data were reviewed on 1,045 patients in the Johns Hopkins Cystectomy Database who underwent radical cystectomy for bladder cancer from

1994 to 2012. A case series of 4 patients is presented who had a pre-existing IPP and their post-operative course and long-term outcomes are reviewed.

Results: 2 patients had BCG-refractory urothelial carcinoma, and the other 2 had muscle-invasive bladder cancer. 1 patient had erectile dysfunction (ED) as a result of a previous radical retropubic prostatectomy, while the other 3 had organic ED. All had 3-piece IPPs. In 2 cases, the reservoir had to be removed prior to the bladder dissection as there was evidence of dense adherence to the bladder and scarring in the pelvis, which rendered bladder dissection and pelvic lymphadenectomy difficult. A new reservoir was subsequently replaced prior to the termination of the procedure. The reservoir was separated from the urinary diversion with an omental flap. In the third case the reservoir was separated from the bladder with a well-developed pseudocapsule. In these cases, the IPP was tested intraoperatively to verify functionality, and the patients reported functionality on follow-up. In the final case, as the patient was not sexually active, the reservoir was removed and the tubing capped. No infections in this case-series were observed.

Conclusion: As ED is more commonly being diagnosed and treated with IPP insertion at younger ages, surgeons will increasingly encounter pre-placed abdominal reservoirs when performing pelvic surgery. This case series of 4 patients undergoing radical cystectomy with prior-placed IPPs reveals that the functionality of the IPP can be preserved while still performing oncologically sound extirpative procedures.

Disclosure:

Work supported by industry: no.

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WITHDRAWN

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SYNERGISTIC EFFECTS OF BAY-604552 AND VARDENAFIL ON RELAXATION OF CORPUS CAVERNOSUM TISSUE OF PATIENTS WITH ERECTILE DYSFUNCTION AND CLINICAL PHOSPHODIESTERASE 5-INHIBITOR FAILURE

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Objectives: Overall efficacy rates of phosphodiesterase 5 inhibitors (PDE5i) for erectile dysfunction (ED) are 60–70%. Currently, non-responders to PDE5i have to resort to invasive treatment options for restoration of erectile function. The aims of this study were 1) to assess changes in the nitric oxide-cyclic (NO)/cyclic guanosine monophosphate (cGMP)/protein kinase G (PKG) pathway in human corpus cavernosum (HCC) of PDE5i nonresponders compared to healthy controls, and 2) to evaluate the effects of BAY 60–4552, a soluble guanylate cyclase (sGC) stimulator, and vardenafil either applied alone or in combination on relaxation of HCC strips from PDE5i non-responders.

Material and Methods: Specimen of HCC were harvested after consent from individuals undergoing penile prosthesis implantation (patients) and potent control subjects undergoing transurethral surgery (healthy controls, needle biopsy). Tissues of patients were compared to those of healthy controls for the expression of mRNA coding for various targets in the NO/cGMP/PKG pathway by qPCR. The respective proteins were localized using immunofluorescence. Tissue strips of patients were precontracted in an organ bath with phenylephrine followed by incubation with 1 μM of either vardenafil or BAY 60–4552, or both simultaneously.

Results: PDE5A, eNOS, PKGα1, PKG2, sGCα1, sGCα2, and sGCβ1 were significantly downregulated in PDE5-i nonresponders. sGCβ2 and nNOS expressions were below the detection limit in both

groups. The pathway was morphologically located to HCC smooth muscle (except for eNOS: endothelium). BAY-604552 (82,5 ± 5,0%) and Vardenafil (72,6 ± 2,3%) both induced relaxation of precontracted HCC strips. When both compounds were administered simultaneously, synergistic effects (44,7 ± 4,2%, P < 0.05 vs. each compound alone) on relaxation of HCC of PDE5i treatment failures were observed.

Conclusions: A downregulation of various effectors in the NO/cGMP/PKG pathway in corpus cavernosum smooth muscle of severe ED patients is responsible for decreased or absent responses to PDE5-i treatment. Despite this downregulation, combining the sGC stimulator BAY 60–4552 with Vardenafil significantly enhanced relaxation of corpus cavernosum tissue strips of patients not responding to PDE5i. Thus, combining sGC stimulators and PDE5i may become a new oral pharmacological treatment option for PDE5i nonresponders.

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Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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THE MECHANISMS OF ADIPOSE DERIVED STEM CELLS WITH COX1–10AA-PGIS GENE IMPROVE ERECTILE FUNCTION AFTER CAVERNOUS NERVE INJURY

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Objective: We previously reported Adipose Derived Stem Cells (ADSCs) with Cox1–10aa-PGIS Gene therapy improved erectile function in the rat model with bilateral cavernous nerve crush (BCNC). The present study was designed to look at the underlying mechanisms of ADSCs with Cox1–10aa-PGIS gene improving erectile function after BCNC.

Material and Methods: Sprague Dawley (SD) rats were randomly assigned into four groups: 1. sham surgery; 2. BCNC; 3. BCNC + ADSCs intracavernous injection; 4. BCNC + ADSCs with COX1–10aa-PGIS gene intracavernous injection. 28 days later, intracavernous pressure (ICP) was recorded under cavernous nerve stimulation. At the end of the measurement, the penis was harvested and urine was collected for 1, Neuronal nitric oxide synthase (nNOS), α-smooth muscle actin (αSMA), Vascular endothelial growth factor (VEGF) and Transforming growth factor beta-1 (TGFβ1); 2, Western blot for COX1–10aa-PGIS, TGFβ1, ASMA and Hypoxia-inducible factor 1-alpha (HIF-1α); 3, Liquid chromatography-quadrupole mass spectrometer (LC-MS/MS) of 6-keto-PGF1α; 4, Terminal deoxynucleotidyl transferase dUTP nick end labeling assay (TUNEL) for apoptosis.

Results: ADSCs with COX1–10aa-PGIS gene therapy improved erectile function in rats after BCNC injury.

ADSCs with COX1–10aa-PGIS upregulated nNOS, αSMA and VEGF expression level in Corpus cavernosum.

ADSCs with COX1–10aa-PGIS downregulated TGFβ1 and HIF-1α expression level in corpus cavernosum.

ADSCs with COX1–10aa-PGIS prevented cell apoptosis after cavernous nerve injury

Conclusion: Our data showed that ADSCs with COX1–10aa-PGIS gene therapy protected erectile function after cavernous nerve injury through anti-hypoxia, anti-fibrosis and anti-apoptotic combining with the paracrine secretion of ADSCs.

Disclosure:

Work supported by industry: no.

CONNEXIN 43 DENSITY AND DISTRIBUTION IN CORPUS CAVERNOSUM TISSUE FROM DIABETIC OR HYPOGONADAL PATIENTS WITH ERECTILE DYSFUNCTION

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Background: Vasoactive agents, prostaglandin E1, phenolamine and papaverine are used as direct cavernosal injection therapy for erectile dysfunction of patients who do not benefit from oral phosphodiesterase inhibitor therapy. The rapid onset of initiation of erection induced by these vasoactive agents is attributed to relaxation of the trabeculae in the corpus cavernosum. It is believed that the fast dissemination of the electrochemical signals and second messengers produced by the action of the vasoactive agents involves transport of small signaling molecules and chemical messengers between smooth muscle cells of the trabeculae via gap junctions.

Aim: Altered expression of connexin 43 (Cx43) has been associated with the development and progression of various diseases including erectile dysfunction in an animal model of diabetes. However, it is currently unclear whether Cx43 level in smooth muscle cells of corpus cavernosum is altered in human diabetes or hypogonadism and contributes to erectile dysfunction. The aim of this study is to determine whether distribution and density of Cx43 is altered in smooth muscle cells of human corpus cavernosal tissue samples derived from diabetic or hypogonadal patients with erectile dysfunction compared to those of normal subjects.

Methods: To assess the distribution pattern and relative density of Cx43 in corporal cavernosal smooth muscle cells, immunostaining for Cx43 was performed in tissue sections derived from normal, diabetic and hypogonadal subjects. Corpus cavernosal tissue biopsies were fixed in 4% formaldehyde and embedded in paraffin, and the tissue sectioned at 3–4 micrometer intervals. For immunostaining, tissue sections were fixed in ice-cold methanol, exposed to 2% BSA, and incubated overnight at 4°C in a moist chamber with a monoclonal mouse anti-rat Cx43 antibody. After several washes with phosphate buffered saline (PBS), the sections were incubated with rhodamine-conjugated goat anti-mouse IgG, washed with PBS, and mounted in Slow-Fade. The sections were viewed under immunofluorescence microscopy, and images digitally captured and analyzed for Cx43 plaque counts. Connexin density was expressed as the cumulative number of gap junction plaques per unit area of tissue corrected for number of DAPI-labeled smooth muscle cells (dots/unit area corrected for number of cells).

Results: The distribution of Cx43 plaques in smooth muscle cells was not affected in corpus cavernosal tissues derived from diabetic or hypogonadal subjects with erectile dysfunction compared to those of normal nondiabetic subjects. However, the number of Cx43 plaques was significantly reduced in cells of corpus cavernosal tissue derived from diabetic or hypogonadal subjects ($73 \pm 8\%$ of normal, $p < 0.05$; $68 \pm 11\%$ of normal, $p < 0.05$, respectively) indicating reduced Cx43 gap junctions in diabetic and hypogonadal subjects with erectile dysfunction.

Conclusions: Cx43 density in human corpus cavernosum is diminished in tissue samples derived from diabetic or hypogonadal patients with erectile dysfunction as compared to tissue samples from normal nondiabetic subjects. This marked decrease in connexin 43 gap junction channels may contribute to attenuated gap junction function and to dysfunction in erectile physiology.

Disclosure:

Work supported by industry: no.

CHRONIC SILDENAFIL TREATMENT REVERSES ENOS UNCOUPLING AND OXIDATIVE STRESS IN THE SICKLE CELL MOUSE PENIS

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Objectives: Sickle cell disease (SCD) is a state of chronic vasculopathy characterized by endothelial dysfunction and increased oxidative stress. These changes may also be associated with SCD-associated priapism, but evidence in this regard is lacking. Preliminary clinical trials show that chronic treatment with PDE5 inhibitors decreases priapic activity in patients with SCD, but the mechanism for this effect remains unclear. One mechanism of sildenafil action in the vasculature is to decrease formation of reactive oxygen species (ROS) and to activate eNOS. In our previous report we presented data which demonstrated that chronic treatment of SCD mice with sildenafil improved eNOS function and downregulated protein expression of gp91phox subunit of ROS-producing enzyme NADPH oxidase in the penis. Here we evaluated the effect of chronic treatment with sildenafil on eNOS uncoupling, another source of ROS, and 4-hydroxy-2-nonenal [HNE], a product of lipid peroxidation and a marker of oxidative stress, in the penis of SCD mice.

Materials and Methods: 7 month old homozygote SCD (sickle) and WT mice were treated with sildenafil citrate (100 mg/kg per day in rodent chow) or vehicle. After 3 weeks penes were collected for measurements of eNOS uncoupling and 4-HNE by Western blot.

Results: Relative to WT mice, SCD induced ($P < 0.05$) eNOS uncoupling and increased ($P < 0.05$) protein expression of 4-HNE in the penis. Sildenafil treatment of sickle mice prevented ($P < 0.05$) eNOS uncoupling and prevented ($P < 0.05$) increases in oxidative stress. Sildenafil did not affect measurements in the penis of WT mice.

Conclusion: Sildenafil maintains nitric oxide/redox balance in the penis of SCD mice. This effect of sildenafil may provide a molecular basis for the therapeutic benefit of PDE5 inhibitors for treatment of priapism.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

NITRIC OXIDE-RELEASING POLYMERIC MICROSPHERES AS A THERAPY FOR ERECTILE DYSFUNCTION

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OBJECTIVE: We have used a long-acting NO-releasing polymer to develop injectable biodegradable microspheres capable of sustained, localized NO release over prolonged periods of time. Our aim was evaluate the therapeutic potential of these microspheres for ED secondary to diabetes in the rat model.

MATERIALS/METHODS: NO-releasing microspheres were incubated in buffer under physiologic conditions and *in vitro* NO release was measured using the Griess assay. To ensure no migration, microspheres were fluorescently tagged and injected into the corpus cavernosum of adult rats and fluorescence imaging was performed weekly for 4 weeks, at which point the rats were sacrificed. To assess physiologic efficacy, diabetes was induced in 40 adult rats using streptozotocin (STZ) and glucose was monitored over 8 weeks, while 10 rats were kept as age-matched controls. Diabetic rats were divided into four experimental arms: no treatment, sildenafil, NO-releasing microspheres, and combination therapy. For each rat, the cavernosal nerve (CN) was stimulated at various voltages for 1-minute intervals, and intracavernosal pressure (ICP) and mean arterial pressure (MAP) were measured by catheterizing the corpus cavernosum and carotid artery,

respectively. Long-term efficacy studies were then carried out by injecting rats with NO-releasing microspheres 8 weeks following STZ injection and measuring erectile response up to 5 weeks after microsphere injection.

RESULTS: Under physiologic conditions *in vitro*, the microspheres released NO for up to 4 weeks. On fluorescence imaging, no fluorescent signal was detected in tissues other than cavernosal tissue at 4 weeks post-injection. Upon CN stimulation, we found the peak ICP/MAP ratio and area under curve of diabetic rats improved significantly ($p < 0.05$) in the NO-releasing microsphere and combination therapy arms, as compared to the no treatment and sildenafil arms, and were virtually equivalent to control rats. Long-term efficacy studies demonstrated that the microspheres significantly augmented the effect of sildenafil for up to 3–4 weeks following injection ($p < 0.05$).

CONCLUSION: These NO-releasing polymeric microspheres demonstrated the ability to significantly improve the erectile response of diabetic rats for up to 3–4 weeks, and hence offer a promising novel approach to therapy for ED, either as monotherapy or in combination with oral medications.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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INSULIN RESISTANCE INDUCES DECREASED ANDROGEN RECEPTOR EXPRESSION THROUGH METHYLATION OF THE PROMOTER IN THE PENILE CAVERNOSAL SMOOTH MUSCLE

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Objectives: Population studies have suggested association between diabetes and symptoms of testosterone deficiency. Recently, the androgen receptor (AR) has shown decreased expression in diabetic patients. Furthermore, diabetes has been shown to induce global methylation. In this study, we investigated whether a diabetic animal model shows increased methylation of the AR promoter, and whether these changes are associated with decreased expression of AR in the penile cavernosal smooth muscle tissue.

Materials and Methods: Twenty C57BL/6 J mice were divided into two groups, receiving either high (Diabetic group) or low (Mature Control) caloric meals for 14 weeks. Another ten mice were sacrificed at 1 week (Young Control). Methylation status of 22 CpG sites within a CpG island surrounding the promoter was investigated by pyrosequencing. AR mRNA and protein were assessed, as well as serum testosterone, insulin and glucose.

Results: Testosterone levels were decreased, but not statistically significant, in the diabetic group. No significant methylation was observed in the promoter region CpG island (–85 to +339) in both control groups, while significant methylation was observed at +185 and +200 in the diabetic group. These changes were associated with increased HOMA-IR and decreased penile mass, as well as AR mRNA and protein expression.

Conclusion: We conclude that insulin resistance in these animals increased methylation of the GC rich regions of AR promoter, leading to decreased AR expression.

Disclosure:

Work supported by industry: no.

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MARKED NEOINTIMAL FORMATION AND VASCULAR REMODELING IN CORONARY AND INTERNAL PUDENDAL ARTERIES FROM AGED MALE CADAVERS WITH CARDIOVASCULAR DISEASE

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Objectives: With advancing age the incidence of cardiovascular disease and erectile dysfunction increases. Erectile dysfunction is known to be a harbinger of cardiovascular disease. The pudendal is a key artery for erections as it contributes to 70% of the total penile vascular resistance. The present study morphometrically characterized the coronary and pudendal arteries from male cadavers with cardiovascular disease.

Methods: Eight formalin fixed adult (57–86 years) male cadavers were dissected to assess the morphology of the internal pudendal and coronary arteries. All men suffered from cardiovascular disease. Pudendal sections were taken distally before the artery branches into the penis and proximally above the rectal artery branch, and the coronary section from the middle of the artery. Arterial segments were fixed in formalin, embedded in paraffin, sectioned, stained with Masson's trichrome, and morphometrically assessed using light microscopy. Lumen diameter, wall thickness, wall-to-lumen ratio and cross-sectional area were measured.

Results: All coronary and pudendal arteries had the presence of a neointimal layer. Their smooth muscle layers were unorganized with a significant population of round synthetic-like cells. The coronary arteries had a larger lumen diameter than the pudendal arteries which tapered as they travelled distally towards the penis (9.5 ± 0.9 ; 6.9 ± 1.1 ; 5.2 ± 0.8 mm; respectively). The wall thickness was similar between all three arterial segments (1.8–2.4 mm). The wall-to-lumen percentage was drastically increased in the distal ($53 \pm 19\%$) and proximal ($40 \pm 8\%$) pudendal arteries compared to the coronary artery ($22 \pm 5\%$). Additionally, one of the distal pudendal arteries was 90% occluded with a remarkable wall-to-lumen percentage of 186%. This is direct evidence that the penile bed undergoes more drastic remodeling prior to severe changes in the coronary arteries.

Conclusions: In all aged males examined, coronary and pudendal arteries were found to have marked vascular remodeling. Striking intimal thickening and plaques significantly decreased lumen diameter and occluded flow. This is the first study to characterize the morphological changes in both the coronary and pudendal arteries in male cadavers and provides further evidence of a causative role of vascular structural changes in aging-induced ED.

Disclosure:

Work supported by industry: no.

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ADENOSINE SIGNALING IN PRIAPISM AND NOVEL THERAPIES

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Objective: Priapism is abnormal prolonged penile erection occurring without sexual interest. The condition is prevalent among men with sickle cell disease (SCD). Priapism is a urological emergency which needs early intervention to avoid the risks of penile fibrosis and eventual erectile dysfunction. Due to poorly understood pathogenesis of priapism no effective approaches to manage the disorder. Recent studies have revealed excess adenosine (Ado) in priapism via Ado A2B receptor (ADORA2B), suggesting novel therapeutic possibilities. Here, we aim to conduct preclinical studies to assess the efficacy and safety of Ado-based therapy in priapism.

Materials and Methods: ADA-deficient mice (ADA^{-/-}) and SCD Berkeley mice are two independent priapism animal models. We treated both mice with polyethylene glycol-modified ADA (PEG-ADA) to lower penile adenosine level or PSB1115, a selective ADORA2B antagonist. The erectile function are measured by the changes of intracavernous pressure (ICP) induced by cavernous nerve stimulation (CNS). Penile fibrosis is evaluated by histological studies and RT-PCR analysis of fibrotic marker gene. *In vitro* human microvascular endothelial cells (HMECs) were used to determine mechanism underlying ADORA2B-induced priapism.

Results: Both ADA^{-/-} and SCD mice with elevated Ado levels in penile tissue displayed priapic feature defined by prolonged and heightened erectile in response to CNS. Chronic reduction of accumulation of penile Ado levels by PEG-ADA enzyme therapy or PSB1115 corrected the priapic feature in both priapic animal models and further prevented progression of penile fibrosis. Significantly, both HIF-1 α and eNOS mRNA level were elevated but reversed by PSB1115 treatment in penile tissues of ADA^{-/-} mice and SCD mice. Finally, we provide *in vitro* direct evidence that PSB1115 treatment or siRNA knockdown HIF-1 α in HMECs significantly reduced Ado-induced eNOS mRNA, implicating that ADORA2B-mediated HIF- α induction contributes to elevated eNOS mRNA and underlies Ado-mediated priapism.

Conclusions: PEG-ADA and PSB1115 are effective and safe to treat priapism and exacerbation of the disease by decreasing penile Ado levels or interfering its signaling. This study provides direct preclinical evidence for the novel and general utility of PEG-ADA enzyme therapy or ADORA2B antagonists for priapism and sets up a solid foundation for future clinical trials to assess the usefulness of Ado-based therapeutics to treat priapism.

Disclosure:

Work supported by industry: no.

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IS THE MORE PRESERVATION OF ERECTILE FUNCTION ABLE TO BE EXPECTED USING MESCENCHYMAL STEM CELLS MIXED WITH CELL CARRIER IN THE NERVE-SPARING RADICAL PROSTATECTOMY ANIMAL MODEL?

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Objectives: After administration with mesenchymal stem cells (MSCs), we cannot always obtain the expected results because of the spread-out of MSCs to the adjacent tissue. And bilateral cavernous nerve crushing injury model is a representative animal model of nerve-sparing radical prostatectomy and has been used widely in this research area. Therefore, we evaluate the effect of MSCs and MSCs mixed with Matrixen as a cell carrier which can promote the retention ability of MSCs on the erectile dysfunction by bilateral cavernous nerve crushing injury.

Materials and Methods: Rats were divided into 4 groups: control group (n = 5), Bilateral cavernous nerve crushing group (n = 10, BCNC group), BCNC administered with Matrixen group (n = 10, 20 μ l), BCNC administered with MSCs group (n = 10, 1 \times 10⁶ in 20 μ l) and BCNC administered with MSCs/Matrixen group (n = 10, 1 \times 10⁶ in 20 μ l). After 4 weeks, Functional examination was done. After functional examination, major pelvic ganglion (MPG) and penile tissue were collected. Immunofluorescent staining of MPG was performed with PKH26 and Tuj1. Masson Trichrome staining and western blot analysis of endothelial nitric oxide synthase (eNOS) and neuronal nitric oxide synthase (nNOS) were done in corpus cavernosum.

Results: Intracavernous pressure (ICP)/mean arterial pressure (MAP) ratios of BCNC with MSCs and MSCs/Matrixen groups were significantly increased compared with BCNC group (p < 0.05). Moreover,

ICP/MAP ratios of MSCs/Matrixen group was significantly increased compared with BCNC with MSCs group (p < 0.05). In MPG, the more implantation of MSCs and increased expression of nerve cells were observed in MSCs/Matrixen group under immunofluorescent staining with PKH26 and Tuj1. More restoration of smooth muscle was also observed in BCNC with MSCs/Matrixen group by Masson Trichrome staining. Western blot analysis showed significant increase expression of neuronal nitric oxide synthase (nNOS) in BCNC with MSCs/Matrixen group.

Conclusions: MSCs/Matrixen group showed more functional and histological restoration compared with the single injection with MSCs in the rats of bilateral cavernous nerve crushing injury. Therefore, we considered that the use of transplant cell carrier such as Matrixen may help the implantation of MSCs and improve the therapeutic effect of MSCs.

Disclosure:

Work supported by industry: no.

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OPIORPHINS ARE UP-REGULATED IN CORPORAL TISSUE IN SICKLE CELL MICE PRIOR TO THE ONSET OF PRIAPISM

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Objectives: Patients with sickle cell disease have a high propensity for ischemic priapism. Priapic episodes lead to fibrosis of the corporal tissue and permanent erectile dysfunction. We have investigated the role that opiorphins (endogenous inhibitors of neutral endopeptidase (NEP)) and the polyamine synthetic pathway play in the development of priapism in a mouse sickle cell model of priapism. The objective of this work is to identify potential targets for prevention or treatment of priapism.

Material and Methods: Sickle cell mice were studied at 5, 10 and 15 weeks of age, representing time points where the mice are pre-priapic, priapic and post-priapic. Quantitative RT-PCR and western blotting was used to determine expression of the mouse opiorphin homologues and proteins of the polyamine synthetic pathway in the corpora and several other tissues of sickle cell mice and age-matched controls. Peptides were synthesized based on the mouse opiorphin genes and their ability to inhibit NEP determined.

Results: The two mouse homologues of opiorphin, SMR2 and SM3a, were detectable at high levels in the corpora, prostate and submandibular gland (but not other tissues). In the sickle cell mice of 5 weeks age (pre-priapic) there was a significant 13.5-fold increase in SMR3 in corporal tissue. At this time point there was no change in expression of genes involved in the polyamine synthetic pathway. At subsequent time points (priapic or post-priapic mice) the level of the mouse opiorphin homologues remained elevated compared to controls, and there was increased expression of key enzymes in the polyamine synthetic pathways. Similar to human opiorphin the peptides of the mouse homologues acted as NEP inhibitors.

Conclusions: Elevation of mouse opiorphin homologues occurs in the corpora of sickle cell mice at a time point before the onset of priapism. We have previously shown in the rat that overexpression of opiorphin results in a priapic-like condition. Therefore opiorphin expression is a potential target for preventing the development of priapism.

Disclosure:

Work supported by industry: no.

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PATIENTS' UNDERSTANDING OF INTEREST, DESIRE, AND AROUSAL

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Objective: The terms *desire* and *sexual interest* are often used interchangeably and may overlap with *arousal*. As part of development of the PROMIS Sexual Function measure, we explored patient understanding and perceptions of terms in targeted health groups. **Material and Methods:** We conducted 11 focus groups with 59 men and women recruited from health clinics and the local community. Groups were conducted with people who had diabetes, heart disease, depression or anxiety, people aged 65 years or older, and those who self-identified as gay, lesbian, or bisexual. All groups were separated by sex and facilitated by a moderator of the same sex as participants. Our discussion guide covered multiple topics related to health and sexual function. For each of 6 terms (desire, turned on, interest, excited, horny, aroused), the moderator asked participants what the term meant, whether the term carried positive or negative connotations, and whether it was different from the other terms. Group discussions were recorded, transcribed, and analyzed for content. **Results:** Participants perceived positive connotations of most terms. All terms were understood to have a mental or psychological component to them, especially the term interest. Interest was also seen as most distinct from the other terms (e.g., "interest is mental" and "interest seems to be more in my head.") For men, the term aroused was described as "something more" than erection. There were different opinions about whether desire was more like interest or more like arousal, but most often it was considered to be "stronger" than interest. Aroused and turned on were judged to be the same, and excited was close to these but was thought to more easily have a non-sexual meaning. Participants felt that horny had physical implications, closest to having intercourse, and some felt it was a juvenile term that would be inappropriate on a formal survey. **Conclusions:** The PROMIS Sexual Function measure started with a single domain called Desire; these qualitative results suggested evidence for two distinct domains: Interest in Sexual Activity (a conscious awareness of wanting to engage in sexual activity) and Subjective Arousal (the extent to which a person feels turned on in anticipation of sexual activity). Our next step will be to quantitatively test how these domains are distinct from each other and from the physical domains of Lubrication (women) and Erectile Function (men) using forthcoming data from a large, national sample. These findings have implications for conceptualizations of the sexual function domains of desire and arousal.

Disclosure:

Work supported by industry: no.

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ADULTERATION OF PURPORTED HERBAL AND NATURAL SEXUAL PERFORMANCE ENHANCEMENT DIETARY SUPPLEMENTS WITH SYNTHETIC PHOSPHODIESTERASE TYPE 5 INHIBITORS

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Objectives: This study assessed the availability, cost, contents, and origin of purported "all natural" or "herbal" over-the-counter dietary supplement products claiming to naturally enhance sexual performance, and examined whether they were adulterated with active pharmaceutical ingredients (APIs) of approved, prescription-only

phosphodiesterase type 5 (PDE5) inhibitors (eg, sildenafil citrate) or their unapproved analogues.

Material and Methods: A spot survey of uncontrolled, purported "all natural" or "herbal" dietary supplements available (without prescription) to the general public in convenience stores and filling stations was conducted in 2 US metropolitan areas (n = 54 distinct locations in Atlanta, GA and Baltimore, MD); 7 samples from US Customs seizures were also included. Procured samples were examined using liquid chromatography–mass spectrometry for adulteration with synthetic APIs of common, prescription-only PDE5 inhibitors.

Results: Samples were readily available; prices ranged from \$2.99 to \$17.99. In total, 91 samples (1 product included 2 different dosages) were evaluated; samples were labelled as 58 distinct products. Although no samples claimed to include synthetic substances, 74 (81%) contained synthetic PDE5 inhibitor APIs or analogues; 10 samples appeared to contain entirely herbal ingredients. Tadalafil or sildenafil was the primary API in 32 samples, while an additional 8 samples contained both APIs; 34 samples had APIs that were known PDE5i analogues (ex: dimethylsildenafil). Eleven samples contained caffeine and 1 contained the vasodilator phenolamine. Heterogeneity within individual products indicated minimal quality control during manufacture. Of samples labelled in English, 62 claimed to be of US affiliation or manufacture, whereas an additional 14 did not clearly identify a US origin; 15 samples were of apparent Asian manufacture (Tokyo, n = 4; Tibet, n = 3; Hong Kong, n = 3; Taiwan, n = 2; China, n = 2; unknown, n = 1). Only 14 samples included a warning against concomitant use with nitrates.

Conclusions: The majority (81%) of the tested "herbal" and "natural" products claiming to enhance sexual performance were found to be adulterated with synthetic PDE5 inhibitors or analogues. Patients unknowingly risk their health by using these products, which often come without important safety warnings and lack quality control during manufacture.

Disclosure:

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NOVEL TECHNIQUE TO EVALUATE ENDOTHELIAL FUNCTION AND MICROCIRCULATION IN THE PENIS

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Objective(s): This study was aimed to evaluate the hypothesis "Endothelial function in penis being affected earlier than the endothelial function in other capillary beds" by comparing reactive hyperemia response following a brachial artery and cavernosal artery occlusion in flaccid state.

Material and Method(s): A randomized prospective study was done on 5 Erectile Dysfunction (ED) patients and 5 normal subjects. We used O2C device from Lea Medizintechnik based on the principle of Micro light guide tissue photo spectrometry to non invasively assess real time blood flow in capillaries, oxygen saturation and hemoglobin filling on the venous side combined with a modified penile pressure cuff for occlusion and reactive hyperemia response. Endothelial function on dorsal hypothenar surface of hand was assessed first, following a 5 minute suprasystolic brachial artery occlusion and Endothelial Function Index (EFI) was calculated by software. A probe with 15 mm penetration depth used for hypothenar surface was placed on left lateral dorsal surface of penis with penile cuff placed proximally around the base of penis. Flow measurements for 30 seconds prior to occlusion and then with a 5 minute occlusion at 200 mm Hg were taken and reactive hyperemia response measured 1 minute later. A 5 minute repeat measurement at constant temperature was done.

Result(s): Controls displayed good endothelial function in hand and penis with a rise in blood flow and EFI being similar on repeat testing. 3 ED subjects showed poor response both in hypothenar area and penis suggesting a generalized endothelial dysfunction at both places. But, 2 ED subjects showed good endothelial response in hypothenar area with poor endothelial response in penis possibly suggesting earlier endothelial derangement only in penis. All subjects showed good retest repeatability.

Conclusion(s): Flaccid state study is independent of subject's arousal state allowing quantification of endothelial function in penis. This test for the first time opens up the possibility to predict the future onset of ED and indirectly assess the efficacy of various treatments to treat ED. In this limited pilot study, we have confirmed our descriptive hypothesis that endothelial function in hand and penis need not be identical, which till date had no direct evidence. A repeatable and normal EFI in controls and repeatable normal and abnormal EFI in ED subjects establishes the accuracy of the device to assess endothelial function in flaccid penis.

Disclosure:

Work supported by industry: no.

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A CONSERVATIVE APPROACH TO PENILE ENLARGEMENT: A PROSPECTIVE, PLACEBO-CONTROLLED PARALLEL-GROUP TRIAL

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Objective: The penis is central to cultural concepts of masculinity; its length, and performance are frequently considered to be indicators of masculinity. Equating penis size to masculinity makes under-endowed men worry about the size of their penis. To our knowledge all approaches for medical penile enlargement are not scientifically validated or have not been successful.

Material and Methods: In this prospective multicenter placebo-controlled parallel-group trial, 238 patients with a history of shortening of their penis, (mild or mild-moderate) erectile dysfunction and hypogonadism (Testosterone (T) <3.5 ng/ml) were screened and 198 patients were eligible for this study and were randomized to take.

A: PDE-5-Inhibitors (PDE-5-I): Riginan[®] evaluation to evaluate which PDE-5-I and dose would be the best to take nocte. B: Testosterone-substitution (target range T 7–8 ng/ml). C: A special mixture of supplements. D: Vacuum constriction device (VCD) training. E: The combination of a special mixture of supplements (see C), Testosterone-substitution (see B), VCD training (see D) and a PDE-5-Inhibitor nocte (as evaluated under A). F: Control group: placebo every night. The patients had to carry all medical cost themselves, which is uncommon in Germany.

Penile length and girth was measured before and after the initiation of therapy (6, 12 and 24 months). Patients who were unsatisfied with their results dropped out of the study and were treated according to F.

Efficacy responses were assessed by 1. Penile length and girth measurement, 2. global assessment question (GAQ) pertaining to penile length and girth improvement. Additionally the following parameters were assessed: 3. International Index of Erectile Function (IIEF) domain scores, 4. Aging Male Symptom Scale (AMS) 5. T-blood-levels.

Results: Of the 198 patients randomized, 50 patients (25.2%) dropped out during the first 12 months. After 24 months, 98 patients (49.5%) were still enrolled in the study. After 12 and 24 months, group E showed significant positive results: improvement of erectile function ($p < 0.05$) and penile length and girth enlargement ($p < 0.05$). Group A and B showed significant positive results: improvement of erectile function ($p < 0.05$) while there was only a tendency (not statistical significant) in penile length and girth enlargement.

Conclusion: Men with a history of shortening of their penis, who have mild or mild-moderate erectile dysfunction and hypogonadism can enlarge penile length and girth by taking a special mixture of supplements, undergo testosterone-substitution, perform VCD training and take a selected PDE-5-Inhibitor nocte for more than 12 months.

Disclosure:

Work supported by industry: no.

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PREDICTORS OF PARTNER ATTENDANCE AT MALE SEXUAL MEDICINE CONSULTATION

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OBJECTIVES: For the partnered man, optimal sexual medicine consultation is best conducted when the partner is present. Little data exists on how often a partner does not attend and what reasons contribute to such absence.

The aim of this study was to determine the rate of partner attendance and factors predicting this.

MATERIALS and METHODS: We prospectively administered a questionnaire to men partnered by a female presenting for their initial sexual medicine interview asking about reasons for partner presence or absence. A list of reasons were presented and patients were permitted to select more than one reason. Statistical analysis included descriptive statistics, correlations and Chi-square for univariate (UVA) analysis, and logistic regression for multivariable analysis (MVA) including factors such as patient age, ethnicity, relationship duration, sexual orientation, primary diagnosis and duration of condition.

RESULTS: 270 questionnaires are analyzed. Mean patient and partner age = 59 ± 10 and 55 ± 11 years (y). Mean relationship duration = 23 ± 15 y. The chief complaints were: erectile dysfunction (ED) 76%, 10% penile curvature, 7% ejaculation problems, 7% orgasm problems, 13% low testosterone and 16% other. Race: 74% White, 11% Hispanic, 9%, Black, 4% Asian, 2% other. 96% heterosexual, 1% gay, 4% declined to identify. 37% attended with partner. Reasons for partner presence were: to learn about the condition 77%, patient preference 68%, relationship problems 16%, at suggestion of referring doctor 10%, other 5%, no reason 5%. Reasons for absence: work conflict 40%, patient preference 9%, child care issues 7%, travel time 10%, partner was unaware of visit 5%, partner not interested in sexual activity 2%, 19% other, 10% no reason. On UVA, partner presence was related to race (White vs other) (41% vs 26%, RR = 1.59, $p = 0.03$), low patient libido ($r = -0.15$, $p = 0.02$) and ED as primary diagnoses (34% vs 47%, RR = 0.72, $p = 0.06$). Partner presence was not associated with patient age ($p = 0.8$), partner age ($p = 0.19$), age discrepancy ($p = 0.9$), sexual activity ($p = 0.4$), or erectile function ($p = 0.5$). On MVA, only patient libido remained a significant predictor (OR = 0.91, 95% CI: 0.83–0.99, $p = 0.04$).

CONCLUSIONS: Only about one third of partnered men present with their partner for initial sexual medicine consultation. The strongest predictor of partner attendance was low patient libido, indicating the significant negative impact a man's withdrawal from intimacy has on his partner.

Disclosure:

Work supported by industry: no.

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SEXUAL HEALTH EDUCATION - WHERE DO MEN GET THEIR INFORMATION?

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Objectives: Patients gain health information from a variety of sources. For conditions such as erectile dysfunction (ED) and testosterone deficiency syndrome (TDS), which affect sexual health, men may specifically seek information from sources that have questionable accuracy

or bias due to embarrassment or other factors. Understanding where men receive education about their health is important for creating meaningful interactions in the clinical setting.

Methods: A total of 75 men at two primary care clinics, representing a private community practice and county hospital-based practice, respectively, participated in a self-administered survey concerning men's health issues. The survey included socio-demographic items, validated instruments and independently developed questions regarding men's knowledge and attitudes about ED, TDS, and male infertility. Data were analyzed and differences measured by Pearson's chi-squared test using statistical significance at the 0.05 level. Information regarding men's sources of health information was reviewed.

Results: A majority of men (85%, 64/75) were high school graduates and 57% (43/75) were over the age of 50. Men reported an average of two distinct sources for information on ED (median = 2) and TDS (median = 2) from a list of potential options; some patients reported "no source of information" for ED (12%) and TDS (13%). For both private and county-based clinics, television was cited nearly twice as much as any other source (ED 67%; TDS 55%). A minority of men reported physicians as a source of information (ED 28%; TDS 23%) with no difference between sites. Additionally, men in the county-based clinic cited friends as an education source for ED (31%) and TDS (31%) considerably more than the private clinic men (ED 4%; TDS 9%) [$p = 0.01$; $p = 0.04$, respectively]. The internet was less commonly cited as a source of information for county-based clinic patients (19%) than for private clinic patients (43%) for TDS [$p = 0.04$].

Conclusion: Only about 1 in 4 men gain information about ED and TDS directly from physicians, and there were no significant differences in men from private community vs. county-based clinics, suggesting low rates of communication on these issues regardless of setting. Men from both sites listed television as the most common source of information, with friends being a significantly more important source for county-based clinic patients.

Disclosure:

Work supported by industry: no.

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HELEN SINGER KAPLAN'S LEGACY AND THE FUTURE OF SEXUAL MEDICINE

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Objective: Recognize Kaplan's legacy and its importance to sexual medicine.

Method: Literature review.

Results: Masters and Johnson's success attracted many to the field they pioneered, but their failure to recognize sexual desire, as a distinct and critical aspect of sexual response was noteworthy. That omission, although currently controversial once again, was rectified when Kaplan updated her "biphasic" model to a "triphasic" one (desire, arousal, orgasm), influencing (as did Lief independently, 1977) all clinicians who followed. Yet, it was Kaplan's first book, *The New Sex Therapy* (1974), which had the greatest effect on society, by impacting where and how people were treated for sexual disorders around the world. Kaplan adapted Masters and Johnson's two-week intensive residential program into an outpatient treatment, and her book became the standard text for most clinicians and institutions. She founded the Human Sexuality Program at the NY Hospital, Cornell University; the first medical school based clinic of its kind, anticipating many of today's programs. In 1974 (prior to other multidisciplinary sexual medicine journals) she, along with Sager and Lear established *The Journal of Sex and Marital Therapy*. Both a psychologist and psychiatrist by training, Kaplan recognized and brought to sexual medicine a respect for multi-determinism, multilevel causality and multidisciplinary participation. Kaplan's typology recommended the clinician modify the "immediate causes," and only directly address (although remaining mindful of) the "remote causes," when "resistance" to progress occurred. Kaplan's therapeutic eclecticism sometimes incorporated strategic use of medication, a combination treatment model. Although rarely recognized,

Kaplan's 8th and last book *The Sexual Desire Disorders* (1995), foreshadowed noted psychiatrist Bancroft's (Bancroft and Jansen, 1999) dual-control model of arousal. Kaplan described the "dual control elements of human sexual motivation," and identified sexual "inciters" and "suppressors" to sexual desire dysregulation. Subsequent dual-control biopsychosocial-cultural models have provided a conceptual framework for understanding the complex and dynamic intrapersonal and interpersonal variability of both sexual function and dysfunction. These models can be used to illustrate how sexual counselling can be integrated with current and future medical/surgical treatments to provide optimized risk/benefit for patients suffering from sexual disorders (Perelman, 2005, 2009).

Conclusion: Kaplan left a most important and critical legacy, in being one of the first clinicians to both conceptualize and utilize a treatment that combined the use of pharmaceuticals and sexual counselling, all within an approach that recognized the value of multispecialty cooperation. This is an elegant paradigm that should guide the future of sexual medicine.

Disclosure:

Work supported by industry: no.

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THE GAY MEN SEX STUDIES: ANODYSPAREUNIA AMONG BELGIAN GAY MEN

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Introduction: Anal intercourse is commonly associated with male homosexuality, but not all gay males engage in anal sex and it is becoming increasingly prevalent in heterosexual relationships. Although pain related to receptive anal intercourse is not uncommon, little is known about its phenomenology.

Aim: This study aims to determine the prevalence of anodyspareunia (AD) in a sample of the Belgian Men who have Sex with Men (MSM) population, and to assess the relevance of major predictors such as age, relationship and sexual behaviour.

Methods: An internet-based survey on sexual behaviour and sexual dysfunctions, called **Gay Men Sex StudieS** (GAMESSS), was administered to MSM, aged 18 yr or older, between the months of April and December 2008. A part of the questionnaire was focusing on anal eroticism. The participants, who self-reported being HIV-positive or indicating not having anal intercourse, were excluded for this part of the survey.

Results: Of the 1190 participants, who practice anal sex, 59 % indicated having some degree of anal pain during and after sexual intercourse. Mild AD was reported by 32,7% of the participants, 17,2% had mild to moderate AD, 4 % had moderate AD and 1,8 % had severe AD.

Independent predictors for the presence of AD were: age (Odds ratio [OR] = 0.99, 95% Confidence Interval [CI] 0.98–1.00, $p = 0.006$), having a steady relationship (OR = 1.30, 95% CI 1.03–1.65, $p = 0.029$), frequency of sex with their partner (OR = 1.14, 95% CI 1.03–1.27, $p = 0.011$), number of sex partners (OR = 0.88, 95% CI 0.82–0.94, $p < 0.0001$), the number of sex partners at the same time (OR = 0.91, 95% CI 0.85–0.98, $p = 0.008$) and the massage of the anal sphincter before anal sex (OR = 1.18, 95% CI 1.03–1.35, $p = 0.02$). The prevalence and the severity of AD among MSM decreased by age as they get more experienced. Participants rated inadequate lubrication and lack of oral or digitoproct stimulation prior to penetration as the most important factors predicting pain. Barebacking, without the use of a condom for anal sex, was performed by 28,2% of the participants.

Conclusion: 59% of participating Belgian MSM reported some degree of AD. These findings highlight the need for more information and education about anal eroticism and safe sex.

Disclosure:

Work supported by industry: no.

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THE SELF-ESTIMATION INDEX OF
ERECTILE FUNCTION-NO SEXUAL
INTERCOURSE (SIEF-NS): A
MULTIDIMENSIONAL SCALE FOR ERECTILE
DYSFUNCTION-NO SEXUAL INTERCOURSE

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Objective: Erectile Dysfunction-no sexual intercourse (ED-NS), defined as the inability to have enough erection hardness and duration so as to have enough confidence in attempting sexual intercourse, is an important new definition correspond to the well-known ED, which differs in whether or not sexual intercourse. Indeed, many males who complained of decline of erectile function (EF) can be diagnosed as ED-NS, including single males, patients after fracture of pelvic or lumbar vertebra, patients after radical prostatectomy, total cystectomy, and so on.

Our aim was to develop a brief, reliable, self-administered measure of erectile function that is psychometrically sound, with the sensitivity and specificity for detecting treatment-related changes in patients with ED-NS.

Material and Methods: Self-estimation Index of erectile function-No sexual life (SIEF-NS) was established, which included five dimensions, such as sexual libido, general EF, nocturnal penile erection, EF during audio-video sexual stimulation and EF during foreplay with potential sexual partner (PSP) without sexual intercourse. Relevant domains of sexual function without sexual intercourse were identified with components analysis. The SIEF-NS was examined for sensitivity, specificity, reliability, discrimination and construct validity.

Results: A principal components analysis identified two factors (that is, EF by oneself and EF with PSP) with eigenvalues greater than 1.0. High degrees of internal consistency were observed for two domains and for the total scale (Cronbach's alpha values: for 10 items 0.871, for Factor 1 0.840, for Factor 2 0.823). The SIEF-NS demonstrated adequate construct validity, and two domains showed a high degree of sensitivity and specificity to the effects of treatment. Significant ($P < 0.05$) changes between baseline and post-treatment scores were observed across ten items and two domains in ED-NS patients. For 405 men without sexual intercourse (212 with ED-NS, 193 controls) analyzed, a receiver operating characteristic curve indicated that the SIEF-NS is an excellent diagnostic test. Based on equal misclassification rates of ED-NS and no ED-NS, a cutoff score of 30 (range of scores, 10–50) discriminated best (sensitivity = 0.94, specificity = 0.82).
Conclusion: ED-NS is an important and useful new conception, especially for those who complained of decline of erectile function, but could not diagnosed as ED with traditional ED definition.

The SIEF-NS addresses the relevant domains of male sexual function and is psychometrically sound. This questionnaire can distinguish ED-NS and no ED-NS easily, which is readily self-administered in research or clinical settings. The SIEF-NS demonstrates the sensitivity and specificity for detecting treatment-related changes in patients with ED-NS.

Disclosure:

Work supported by industry: no.

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WITHDRAWN

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WITHDRAWN

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IMPAIRED ADENOSINE SIGNALING
CONTRIBUTES TO ERECTILE
DYSFUNCTION

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Objective: Erectile dysfunction (ED) affects billions worldwide and is characterized by the inability to develop or maintain an erection sufficient to permit satisfactory sexual intercourse. Despite intensive research, the molecular basis responsible for ED remains largely undefined. A considerable amount of evidence indicates that adenosine (Ado), as a signalling nucleoside, plays a significant role in cavernosal smooth muscle relaxation. However, the specific role of Ado and its receptors in ED is not fully understood. Here we sought to identify the potential role of Ado signaling in ED and underlying mechanisms.

Material and Methods: CD73-deficient mice (CD73^{-/-}), Ado receptor A1 (ADORA1)-deficient mice (ADORA1^{-/-}), and wild type (WT) mice were used. Some WT mice were treated with α,β -methylene ADP (APCP), a CD73 specific inhibitor. Erectile function was monitored by measuring the intracavernosal pressure in response to cavernosal nerve stimulation (CNS). HPLC was used to measure mouse penile Ado levels and ELISA was used to measure the norepinephrine (NE) levels. Immunostaining was used to localize penile CD73 and ADORA1 expression. Western blot analysis was used to measure myosin light chain (MLC) phosphorylation.

Results: We found that endogenous Ado levels were elevated in the erected state induced by CNS compared to the flaccid state in WT mice but not in CD73^{-/-} mice, indicating that CD73 was responsible for intrinsic Ado production during penile erection. At cellular levels, we identified that CD73 and ADORA1 were highly expressed in the neuron cells of mouse penile tissues. Functionally, we showed that CD73^{-/-} mice, ADORA1^{-/-} mice and APCP-treated WT mice displayed impaired erectile function featured with significantly decreased initiation and maintenance of penile erection. Mechanistically, we revealed that during penile erection, ADORA1^{-/-} mice exhibited a higher level of NE plasma concentration in the penis than WT mice. And WT mice had a significantly greater reduction in MLC phosphorylation compared to Adora1^{-/-} mice.

Conclusion: Our findings demonstrate that CD73-dependent production of intrinsic Ado signalling via ADORA1 signaling plays an important role in penile erection. Reduced endogenous Ado production or deficiency of inhibitory regulation of ADORA1 in neuronal NE release leads to impaired erectile function by increasing MLC phosphorylation and suggest that this signaling pathway may be a therapeutic target for ED.

Disclosure:

Work supported by industry: no.

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TREATMENT WITH CB2 AGONIST JWH-133
REDUCES OXIDATIVE STRESS AND FIBROSIS
IN PENIS FROM APOE^{-/-} MICE

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Objectives: Hypercholesterolemia is one of the most important risk factor for the development of erectile dysfunction (ED) in men, mostly due increasing oxidative stress and impairing endothelial function in the penis. The cannabinoids receptors (CB₁ and CB₂) are located in the penis of rodents and primates, suggesting a peripheral mechanism for cannabis-related sexual function. In the present study, we evaluated the effects of chronic CB₂ activation with the selective agonist JWH-133 on corpus cavernosum oxidative stress levels and fibrosis

development in hypercholesterolemic (Apolipoprotein [Apo] E^{-/-}) mice.

Methods: ApoE^{-/-} mice fed with a Western-type diet for 11 weeks were treated with the selective CB₂ agonist, JWH-133, or vehicle for the last 3 weeks. The expression and localization of CB₂ receptor within the penis was analyzed by immunohistochemistry and Western blotting. Reactive oxygen species (ROS) content within the corpus cavernosum was evaluated by dihydroethidium (DHE) staining. Total serum nitrite/nitrate was measured by Griess assay. Protein expression of endothelial nitric oxide synthase (eNOS), NADPH subunit p47-phox (p47) in the penis was assessed by Western blotting. Collagen content was evaluated by Sirius red staining.

Results: The CB₂ receptor was expressed in endothelial and smooth muscle cells of corpus cavernosum and vessels from the ApoE^{-/-} mice. Treatment with JWH-133 reduced ROS release and p47 protein expression in the corpus cavernosum. JWH-133 increased serum nitrite/nitrate levels and eNOS protein expression in the corpus cavernosum. The improvement of oxidative stress levels was associated with a reduction in corpus cavernosum and dorsal vessels collagen content.

Conclusions: Selective CB₂ activation decreases oxidative stress levels and fibrosis content in corpus cavernosum of hypercholesterolemic mice. Importantly, these results suggest that CB₂ agonist might have significant therapeutic benefits for the treatment of erectile dysfunction.

Disclosure:

Work supported by industry: no.

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UPREGULATION OF GP91PHOX SUBUNIT OF NADPH OXIDASE CONTRIBUTES TO ERECTILE DYSFUNCTION IN MIDDLE-AGED RATS: REVERSAL OF ERECTILE DYSFUNCTION BY APOCYNIN TREATMENT

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Objective: Erectile dysfunction (ED) is highly associated with aging, which has been related to an imbalance between reactive-oxygen species (ROS) production and antioxidant capacity of tissues. However, few studies have investigated the ED in middle-age and the importance of oxidative stress in corpus cavernosum. Therefore, we have undertaken functional and molecular studies to evaluate the importance of superoxide anion in ED of middle-aged rats.

Material and Methods: Male Wistar rats were divided into two groups, namely young and middle-aged rats (2.5 and 10 months, respectively). The erectile function was assessed by measuring the intracavernous pressure (ICP) following cavernous nerve electrical stimulation. Rat corpus cavernosum (RCC) relaxations induced by acetylcholine (ACh), sodium nitroprusside (SNP) and electrical field stimulation (EFS) in phenylephrine (10 µM)-pre-contracted tissues, as well as mRNA expression for gp91^{phox} and SOD-1 in RCC were evaluated.

Results: A significant decrease in ICP was observed in middle-aged compared with young rats (6 Hz: 15.6 ± 3 and 25.8 ± 3 mmHg, respectively; P < 0.05). The maximal relaxant response (E_{max}) elicited by ACh, SNP and EFS (32 Hz) were significantly lower in middle-aged RCC (E_{max}: 37 ± 2%, 88 ± 2% and 36 ± 3%, respectively, P < 0.05) compared with young rats (E_{max}: 70 ± 1%, 103 ± 2% and 53 ± 1%, respectively). Pre-incubation of RCC with the NADPH oxidase inhibitor apocynin (100 µM) fully restored the relaxant responses elicited by ACh, SNP and EFS in middle-aged RCC with no changes in the RCC relaxations in young rats (n = 5–8). In separate groups, young and middle-aged rats were treated orally with apocynin, given in tap water for 4 weeks. This treatment also restored the relaxant responses elicited by ACh, SNP and EFS in middle-aged RCC, without changing the relaxations

in young rats (n = 5–8). The mRNA expression for gp91^{phox} in cavernosal tissues was increased by approximately 64% in middle-aged group compared with young group, whereas no changes in the mRNA expression for SOD-1 were.

Conclusion: Our findings that apocynin treatment ameliorates the ED in middle-aged rats and that mRNA expression for gp91^{phox} is increased in RCC indicate that increased generation of superoxide anion greatly contributes to this disorder.

Disclosure:

Work supported by industry: no.

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ACTIVATION OF EXTRACELLULAR SIGNAL-REGULATED KINASE 1/2 (ERK1/2) CONTRIBUTES TO ERECTILE DYSFUNCTION IN ANGIOTENSIN II-INFUSED RATS

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Objective: Increased angiotensin II (AngII) levels cause hypertension, which is an important risk factor for erectile dysfunction (ED). Studies have shown that increased AngII levels in penile tissue are associated with ED. Data from our laboratory shows that AngII infusion leads to increased contractility in the corpus cavernosum with an increased phosphorylation of ERK1/2 in penile tissue. The goal of this study was to test the hypothesis that AngII induces ED by means of increased pudendal artery (PA) contractility via an increase in ERK1/2 activity.

Methods: Male Sprague-Dawley rats were implanted with miniosmotic pumps containing saline or AngII (70 ng/min, 28 days). Erectile function was examined, *in vivo*, via electrical stimulation of the pelvic ganglion and measuring changes in the ratio of intracavernosal pressure to mean arterial pressure (ICP/MAP). Pudendal artery contraction and relaxation was assessed.

Results: AngII-infused rats displayed ED which was associated with increased phenylephrine (PE)-mediated contraction in PA (% of the U-46619 contraction) from AngII-infused rats compared to sham (E_{max} = 519.4% ± 27.18 in AngII vs. E_{max} = 230.3% ± 5.20 in sham). Incubation with the ERK1/2 inhibitor (PD98059) did not affect contraction in PA from sham rats (E_{max} = 228% ± 5.91). However, ERK1/2 inhibitor significantly decreased PE-mediated contraction in PA from AngII rats (E_{max} = 387.8% ± 18.20). There were no observed differences in endothelium dependent and independent relaxation responses in PA from AngII-infused rats as compared to sham.

Conclusion: Infusion of AngII leads to increased mean arterial pressure and ED. The pudendal artery from AngII-infused rats exhibited an increased contractility which was significantly decreased when inhibiting ERK1/2. These results suggest that increased contractility in PA resulted from an activation of the ERK1/2, leading to a decrease of blood flow to the penis, resulting in ED.

Disclosure:

Work supported by industry: no.

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EFFECT OF LDD175, A NOVEL BENZOFUROINDOLE COMPOUND, ON THE MODULATION OF CORPORAL SMOOTH MUSCLES TONE

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Objectives: BK_{Ca} channel is a key modulator of smooth muscle tone and serve as a potential therapeutic target for the treatment of various

urological diseases. LDD175 is a product of synthetic chemistry and has been shown to inhibit contraction of the bladder and uterine by activation of the BK_{Ca} channel. In this study, we investigated whether LDD175 relaxes rabbit corpus cavernosum (CC) via BK_{Ca} channel activation.

Materials and Methods: Isolated rabbit corporal strips were mounted in an organ bath system, and the effects of LDD 175 were evaluated in endothelium-intact and endothelium-denuded strips after pre-contraction with PE (10⁻⁶ M). The effect of LDD175 to relax PE-induced CC tone was compared with udenafil, a PDE5 inhibitor. For the electrophysiological studies, the whole-cell patch clamp recording technique was used to record the changes in BK_{Ca} currents in short-term cultured smooth muscle cells of the human corpus cavernosum.

Results: LDD175 caused an endothelium independent relaxation of CC, and the effect was abolished by pretreatment with 200 nM iberiotoxin (IbTX), selective inhibitor of BK_{Ca} channels. The relaxation effect of LDD175 (10⁻⁴ M) was more potent than that of udenafil (10⁻⁶ M) (42.8 ± 6.2%, n = 8 vs. 34.5 ± 3.9%, n = 6, p < 0.05). In patch clamp recordings, LDD175 increased K⁺ currents in a dose-dependent manner, and washout of LDD175 or blockade of BK_{Ca} channel with IbTX or TEA fully reversed the increase. The activation threshold of BK channel currents were shifted to more negative voltages, which is close to the resting potential of the cells. The potency and efficacy of LDD175 were significantly higher than that of NS1619, a selective BK_{Ca} channel opener (at -40 mV, NS1619: 1.3 fold, LDD175: 42.8 fold vs. control).

Conclusions: LDD175 leads to an endothelium independent relaxation of CC primarily through opening BK_{Ca} channels. LDD175, a novel Benzofuroindole compound, could be new candidate for ED treatment depending upon further studies.

Disclosure:

Work supported by industry: no.

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BLADDER AND ERECTILE DYSFUNCTIONS IN THE TYPE 2 DIABETIC GOTO-KAKIZAKI RAT

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Objectives: Urological functional complications such as bladder and erectile dysfunctions (ED) significantly impact the quality of life of diabetic patients. Most of experimental in vivo studies of ED/bladder dysfunction caused by diabetes have used type 1 diabetes models. A robust model for type 2 diabetes urological complications is lacking. Bladder and erectile function in the Goto-Kakizaki (GK) rat model for type 2 diabetes and their respective responses to standard-of-care treatments for each disorder have been assessed.

Materials and Methods: Male GK rats (n = 20, GK/Par colony) and age-matched Wistar rats (n = 19), previously characterized for their metabolic parameters, were used at 18 weeks of age. Bladder function was assessed by cystometry in conscious rat treated by acute intravenous (i.v) solifenacin (1 mg/kg) or vehicle. Subsequently, erectile function was assessed in the same rat under urethane anaesthesia following electrical stimulation of the cavernous nerve at different frequencies and the acute effects of i.v sildenafil (0.3 mg/kg) or vehicle were evaluated.

Results: GK rats displayed detrusor overactivity characterized by a significant increase in the frequency (+374.1%, p < 0.001) and the amplitude (+63.3%, p < 0.001) of non-voiding contractions (NVC) and a significant decrease in the volume threshold to elicit NVC (-29.3%, p < 0.001) compared to Wistar rats. The intercontraction interval, the voided volume and the maximal pressure and the AUC of micturition contraction were significantly increased in GK rats compared to Wistar rats (+67.5%, p < 0.001; +71.7%, p < 0.01; +14.0%, p < 0.05 and +67.1%, p < 0.001 respectively). The bladder baseline pressure

and the pressure threshold necessary to elicit the micturition contraction were unchanged. Solifenacin significantly decreased the maximal pressure and the AUC of voiding contractions in both Wistar and GK rats.

Erectile function in GK rats compared to age-matched Wistar rats was markedly impaired. The ratio of intracavernosal pressure/mean arterial pressure was decreased by 46% (p < 0.001) in GK vs Wistar. Sildenafil significantly improved erectile function in GK and Wistar rats.

Conclusions: GK rats display both diabetic bladder dysfunction characterized by detrusor overactivity and ED characterized by a decrease in intracavernosal pressure. Furthermore, standard of care treatments for both disorders are effective in GK rats. Thus, GK rats represent a suitable and validated model to investigate the pathophysiology of type 2 diabetes-associated bladder and erectile complications and to assess efficacy of new therapeutic agents targeting diabetic bladder and/or ED.

Disclosure:

Work supported by industry: no.

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EFFECT OF THE SELECTIVE OXYTOCIN RECEPTOR ANTAGONIST GSK557296 ON PHARMACOLOGICALLY-INDUCED EJACULATION IN ANAESTHETISED RATEJACULATION

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Objectives: The neuropeptide oxytocin (OT) plays a major role in the control of male sexual responses. Notably, blockade of OT receptors has been reported to inhibit ejaculation in animals. The study aimed to investigate the action of the highly selective, non-peptide OT antagonist GSK557296 in a model of ejaculation in anaesthetised rats. The site of action of GSK557296 was assessed by investigating the effects of different delivery routes.

Material and Methods: Sexually naive male Wistar rats were anaesthetised with urethane and implanted with a cerebral ventricle cannula for intracerebroventricular (icv) injections, and with a subdural catheter for intrathecal (it) injections. Occurrence of seminal plug expulsion (i.e. ejaculation), was noted following iv 7-OH-DPAT, a dopamine D3 receptor agonist eliciting ejaculation in anaesthetised rat. In addition, seminal vesicle pressures (SVP) and bulbospongiosus muscle (BS) electromyograms (EMG) were recorded as physiological markers of emission and expulsion phases of ejaculation respectively. Doses (3 to 12 mg/kg) of GSK557296 were delivered iv. Doses (3.5 to 35 microg/rat) were administered icv or it (13th thoracic (T13) or 6th lumbar (L6) spinal segments) 10 min prior to 7-OH-DPAT and measurements were performed continuously over 20 min following 7-OH-DPAT. Animal studies were ethically reviewed and carried out in accordance with European Directive 86/609/EEC and the GSK Policy on the Care, Welfare and Treatment of Animals.

Results: In control groups receiving vehicle, 7-OH-DPAT elicited abrupt SVP increases and intense BS rhythmic activity, which were associated with expulsion of seminal plug. The 12 mg/kg dose of iv GSK557296 reduced occurrence of ejaculation and SVP increases but had no effect on BS EMG. Icv GSK557296 dose-dependently inhibited ejaculation, SVP increases and BS activity. Injected at T13 spinal level, GSK557296 dose-dependently inhibited ejaculation and SVP increases but BS activity was impaired only with the 35microg dose. Injected at L6 spinal level, GSK557296 dose-dependently inhibited ejaculation, SVP increases and BS activity.

Conclusions: In the 7-OH-DPAT model, GSK557296 acts in periphery and CNS to inhibit ejaculation with different modalities. Blockade of brain OT receptors appears to be the most effective mechanism of action of GSK557296. Targeting central OT receptors with highly selective antagonist may be a promising approach for the treatment of premature ejaculation.

Disclosure:

Work supported by industry: yes, by GSK (industry funding only - investigator initiated and executed study).

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NOVEL NITRIC OXIDE (NO) RELEASING COMPOUND CORRECTS DYSREGULATED NO SIGNALING IN SICKLE CELL DISEASE MOUSE PENIS

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Objectives: Recent investigations in transgenic sickle cell disease (SCD) mouse models have suggested that priapism arises from chronically impaired NO bioavailability causing a defect in NO and phosphodiesterase 5 (PDE5) signaling in the penis. Previously, we showed lowered PDE5 expression in the penis of mice with combined endothelial and neuronal NO synthase (NOS) gene deletion (dNOS^{-/-}), another mouse model of priapism, which was restored with treatment of a novel sustained NO releasing compound C6. For the purpose of this study, we explored the efficacy of this compound in regulating PDE5, phospho (p-) VASP (a downstream marker of NO signaling integrity) and p-eNOS (Ser1177) activity in the penis of SCD mice.

Materials and Methods: Adult male homozygous SCD mice (9–12 months old) and age matched heterozygous (hetero) mice were treated with 10 mg of C6 (an NO releasing compound) or C6 (an inactive compound) by depot administration beneath the bulbospongiosus muscle at the base of the penis. At one week, penes were collected for western blot analysis of PDE5, p-VASP, total VASP, p-eNOS and total eNOS expressions.

Results: PDE5 ($p < 0.01$), p-VASP/VASP ($p < 0.01$) and p-eNOS/eNOS ($p < 0.05$) expressions were significantly lower in the penis of SCD mice treated with C6 compared to hetero mice treated with C6. C6 treatment significantly increased both p-VASP ($p < 0.05$) and p-eNOS ($p < 0.05$) expressions. PDE5 expression with C6 treatment (0.8 ± 0.05) was increased compared to C6 treatment (0.64 ± 0.1) but was not significant.

Conclusions: Local penile administration of C6 restored p-VASP and p-eNOS expressions in the penis of SCD mice. These results suggest that sustained NO releasing compounds may be beneficial in treating erectile disorders related to dysregulated NO bioavailability and signaling.

Disclosure:

Work supported by industry: no.

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THE ROLE OF BILATERAL MAJOR PELVIC GANGLIA IN THE NEURAL PATHWAY OF ELECTRICAL STIMULATION OF LESSER SPLANCHNIC NERVE-INDUCED SEMINAL VESICAL PRESSURE INCREASE IN THE RAT

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Objectives: Lesser splanchnic nerve (LSN) is a sympathetic nerve. The results of our previous study suggested that electrical stimulation of the LSN or major pelvic ganglion (MPG) may elicit a simultaneous significant increase of seminal vesical pressures (SVP) on each side seminal vesicle in the rat. The purpose of this study was to investigate the role of bilateral major pelvic ganglia (MPG) in the neural pathway of electrical stimulation of LSN-induced SVP increase in the rat.

Materials and Methods: Male adult Sprague-Dawley rats were used. A PE-50 tube was inserted into left and right seminal vesicle (SV), respectively to simultaneously monitor SVP on each side SV. The MPG and LSN were electrically stimulated with stimulus parameters (10 V, 40 Hz, 1 ms, 60 seconds), respectively. Then the right MPG

was resected and the LSN was electrically stimulated. Following resection of right MPG, the left MPG was also resected and the LSN was electrically stimulated again. The amount of SVP increase was calculated by subtracting resting SVP from peak SVP. The amount of SVP increase between left and right side was compared with Mann-Whitney *U* test.

Results: There was an equivalent amount of SVP increase at left and right side after electrical stimulation of right MPG (left 60.3 ± 8.2 mmHg and right 61.1 ± 6.3 mmHg, respectively, $p = 0.818$) and LSN (56.4 ± 9.8 mmHg and 44.7 ± 8.5 mmHg, respectively, $p = 0.310$), respectively. After resection of right MPG followed by electrical stimulation of LSN, again there was a comparable amount of SVP increase at left and right side (55.5 ± 7.1 mmHg and 34.7 ± 3.3 mmHg, respectively, $p = 0.065$). However, there was no change of SVP at each side of seminal vesicle (resting SVP 3.3 ± 0.7 mmHg vs. peak SVP 3.3 ± 0.7 mmHg at left side; resting SVP 7.7 ± 2.1 mmHg vs. peak SVP 7.7 ± 2.1 mmHg at right side, respectively) after resection of bilateral MPG followed by electrical stimulation of LSN.

Conclusions: The results suggest that electrical stimulation of the MPG and LSN may induce a simultaneous significant, comparable amount of SVP increase on the left and right side seminal vesicle in the rat. This electrical stimulation of LSN-induced bilateral SVP increase is eliminated after resection of bilateral MPG. This implies that the neural pathway of electrical stimulation of LSN-induced SVP increase is through at least one side MPG in the rat.

Disclosure:

Work supported by industry: no.

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AN ORALLY-ACTIVE FORMULATION OF ANGIOTENSIN-(1-7) REDUCES PENILE FIBROSIS BY ATTENUATION OF OXIDATIVE STRESS

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Objectives: The renin angiotensin system (RAS) plays a crucial role in erectile function. It has been shown that elevated angiotensin II levels contribute to the development of erectile dysfunction. Oppositely, the heptapeptide angiotensin-(1-7) [Ang-(1-7)] appears to mediate penile erection by activation of receptor Mas. We have shown that the erectil function of Mas gene-deleted mice was substantially reduced, which was associated with a marked increase in fibrous tissue in the corpus cavernosum. Recently we have developed a formulation based on Ang-(1-7) inclusion in cyclodextrin (CyD) [Ang-(1-7)-CyD], which allow the oral administration of Ang-(1-7). CyDs are pharmaceutical tools which may enhancement of drug stability, absorption across biological barriers and gastric protection. In the present study we evaluated the effects of the Ang-(1-7)-CyD in hypercholesterolemic (Apolipoprotein [Apo] E^{-/-}) mice.

Methods: ApoE^{-/-} mice fed with a Western-type diet for 11 weeks were treated orally with Ang-(1-7)-CyD or vehicle for the last 3 weeks. The corpus cavernosum collagen content was evaluated by Sirius red staining. Reactive oxygen species (ROS) production within the corpus cavernosum was evaluated by dihydroethidium (DHE) staining. Protein expression of neuronal (nNOS) and endothelial (eNOS) nitric oxide synthase, NADPH subunit p67-phox (p67) and Mas receptor in the penis was assessed by Western blotting. Using Griess assay, nitrite (NO₂) and nitrate (NO₃) were measured as an indirect measurement of nitric oxide (NO) content in the mice serum.

Results: Three weeks of Ang-(1-7)-CyD treatment reduced collagen content into corpus cavernosum of ApoE^{-/-} mice. Interestingly, this effect was associated with an attenuation of ROS production into the corpus cavernosum and a diminished expression of p67 protein. In addition, Ang-(1-7)-CyD increased serum nitrite/nitrate levels and the protein expression of nNOS and eNOS into the penis. Furthermore, Ang-(1-7)-CyD increased the protein expression of Mas receptor.

Conclusion: We observed that oral treatment with Ang-(1-7)-CyD reduces penile fibrosis by attenuation of oxidative stress in hypercholesterolemic mice. Importantly, these results suggest that Ang-(1-7)-CyD might have significant therapeutic benefits for the treatment of erectile dysfunction.

Disclosure:

Work supported by industry: no.

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BETA ENDORPHIN (β -ENDORPHIN): AN ENDOGENOUS ANTAGONIST OF THE NORMAL MALE SEXUAL RESPONSE?

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Objectives: β -Endorphin, composed of 31 amino acids, belongs to a family of endogenous neuropeptides resembling an opioidergic structure and is known to mediate various body functions, including the control of pain perception and the mental state. Although it has been suggested that β -endorphin might facilitate the inhibition of the male sexual response including penile erection, its role and function in the control of the penile erectile tissue is only poorly understood. The aim of our study was to evaluate the course of β -endorphin plasma levels through different stages of sexual arousal in the systemic and cavernous blood of healthy male subjects.

Material & Methods: Thirty (30) healthy adult males (mean age 26 years) were exposed to erotic stimuli in order to elicit penile tumescence and rigidity. Whole blood was simultaneously aspirated from the corpus cavernosum (CC) and a cubital vein (CV) during the penile conditions flaccidity (Fl) ($n = 21/25$), tumescence (Tu) ($n = 25/28$), rigidity (Ri) ($n = 29/27$), and detumescence (Det) ($n = 18/27$). Plasma levels of β -endorphin (pmol/L) were determined by means of a radioimmunoassay (RIA). In addition, the effects of β -endorphin on the tension of isolated human penile erectile tissue were evaluated using the organ bath technique.

Results: β -endorphin in concentrations from 1 pmol - 1 μ M did not induce a contractile response of the cavernous tissue or reverse the tonic contraction induced by norepinephrine ($R_{max} = 24\%$). β -Endorphin plasma levels decreased with the beginning of sexual arousal, when the flaccid penis became tumescent and rigid. (Fl = 56 pmol/L, Tu = 47 pmol/L, Ri = 33 pmol/L) and again increased in the phase of detumescence (Det = 53,4 pmol/L). In the cavernous blood, no alterations in β -endorphin plasma concentrations were registered.

Conclusion: The findings are not in support for a direct action of β -endorphin on the penile erectile tissue. However, the apparent drop in β -endorphin observed in the systemic circulation during the phases of Tu and Det may reflect the inhibition of the opioidergic input with the beginning of sexual arousal.

Disclosure:

Work supported by industry: no.

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INFLUENCE OF BARIATRIC SURGERY ON THE MORPHOLOGIC AND BIOCHEMICAL CHARACTERISTICS OF CORPUS CAVERNOSUM IN THE TYPE 2 DIABETES RAT

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Objectives: The incidence of erectile dysfunction (ED) induced by type 2 diabetes mellitus (T2DM) has been growing as the increasing

number of people with T2DM caused by insulin resistance which is related with obesity. Therefore, lifestyle modification like weight loss and glycemic control is important to treat ED induced by T2DM as well as using the conventional therapy of ED. Recently, bariatric surgery was introduced one of the effective treatment options for obesity related T2DM and there are increasing evidences about the good outcomes. However, studies about the influence of bariatric surgery on the erectile function were lacking. Therefore, we studied about the morphologic and biochemical characteristic of corpus cavernosum in T2DM rat after bariatric surgery.

Materials and Methods: Otsuka Long Evans Tokushima Fatty (OLETF, $n = 15$) male rats were assigned to 2 groups: Group I (OLETF rats undergone sham operation, $n = 5$) and Group II (OLETF undergone gastric bypass surgery, $n = 10$). At 4-week operation, intraperitoneal glucose tolerance test (IPGTT) was performed. Histologic evaluation of corpus cavernosum was done by H&E and masson's trichrome staining at 4-week operation. In addition, western blot analysis of endothelial nitric oxide synthase (eNOS), neuronal nitric oxide synthase (nNOS), and Rho kinase were done in corpus cavernosum. To evaluate oxidative stress related with ED in T2DM the level of 8-hydroxy-2-deoxyguanosine (8-OHdG) was measured in corpus cavernosum.

Results: After 10-week gastric bypass surgery, the body weight of Group II was lower than Group I, however, there was no significance. The IPGTT of Group II was also lower than Group I and the significant differences were observed only at 120 minutes after intraperitoneal glucose injection (222.5 ± 66.4 mg/dl vs 149.5 ± 10.9 mg/dl, $p < 0.05$). Significant higher smooth muscle/collagen ratio was observed in corpus cavernosum of Group II ($18.1 \pm 15\%$) than Group I ($39.1 \pm 24\%$) ($p < 0.05$). The significant increased expressions of eNOS and nNOS were observed in Group II than Group I ($p < 0.05$). Significant decreased expression of Rho kinase was observed in Group II compared with Group I. The 8-OHdG level of Group II was significantly decreased than Group I ($p < 0.05$).

Conclusions: In this study, the body weight loss and improvement of blood glucose level were observed in T2DM rats after bariatric surgery. In addition, the morphologic and biochemical improvement was observed in corpus cavernosum after operation. From these results, we suppose that ED associated T2DM can be restored with the help of bariatric surgery as well as conventional ED management.

Disclosure:

Work supported by industry: no.

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PENILE FIBROTIC SIGNALING IN POST-PROSTATECTOMY PATIENTS WITH ERECTILE DYSFUNCTION

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Objective: Erectile dysfunction (ED) following radical prostatectomy (RP) is associated with atrophic and fibrotic changes leading to collagen infiltration and corporal smooth muscle deterioration. Although the mechanism is poorly understood and has not been extensively investigated in human penile tissue (HPT), animal studies suggest the role of transforming growth factor beta1 (TGF beta1) and related downstream signaling pathways in penile fibrosis. This study evaluated fibrotic signaling in a large cohort of HPT samples.

Materials and Methods: HPT was collected from patients who underwent penile prosthesis implantation (PPI) due to ED and partial penectomy due to penile cancer and divided into 3 groups: RP-ED: Post-RP ED ($n = 57$); MF-ED: Multifactorial ED ($n = 30$); CON: Control, no ED ($n = 6$). Western blot was performed to investigate changes in expression of TGF beta1; thrombospondin1 (TSP1) an activator of TGF beta1; Smad2, phospho(p)Smad2 [Ser 465/467], Smad3, pSmad3 [Ser 423/425], a family of transcriptional factors activated by TGF beta1 and fibronectin (FN), an extracellular matrix glycoprotein induced by TGF beta1. The protein expressions were analyzed using the Li-Cor® system.

Results: Groups were similar for age ($p = 0.960$) [RP-ED: 63.4 yr; MF-ED: 61.3 yr; CON: 61.5 yr] and body mass index ($p = 0.894$) [RP-ED: 27.8; MF-ED: 29.7; CON: 30.5]. Prevalence of diabetes was significantly higher in MF-ED ($p = 0.001$) patients compare to RP-ED and CON. There was no difference between the groups for prevalence of hypertension ($p = 0.889$), hypercholesterolemia ($p = 0.463$) and tobacco use ($p = 0.880$). Patients in RP-ED had a mean pre-RP SHIM score of 21.3, a post-RP SHIM score of 3.4 and mean time between RP and PPI of 54.1 mo. MF-ED patients had an average SHIM score of 3.9. Expression of TGF beta1 and TSP1 were significantly higher in both RP-ED ($p < 0.05$) and MF-ED ($p < 0.05$) compared to CON, and was not different between the two ED groups. Expression of Smad2, pSmad2, Smad3, pSmad3 and FN were similar in all groups.

Conclusion: Our results demonstrate that proteins involved in the initiation of fibrotic signals are increased in HPT from RP-ED and MF-ED, suggesting that this could be the main pathway responsible for changes leading to ED following RP. The unchanged expression of the transcriptional factors may be justified by a Smad independent downstream signaling pathway transmitting TGF beta1 signals.

Disclosure:

Work supported by industry: no.

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EFFECTS OF OVARIECTOMY AND PRASTERONE ON VAGINAL INNERVATION IN THE RAT

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Objective: It is known that prasterone (dehydroepiandrosterone, DHEA) exerts modulatory effects on vaginal tissue by a strictly local action. The goal of this study was to determine if prasterone could modify innervation in the rat vagina, thus providing an explanation for the improvement of the four domains of sexual dysfunction in postmenopausal women following intravaginal administration of the precursor of sex steroids.

Methods: The innervation of the rat vagina was examined 9 months after ovariectomy (OVX) compared to intact animals and treatment of OVX animals with prasterone (80 mg/kg applied on dorsal skin daily). Four sections from the central region of each vagina were immunostained using antisera against protein gene product 9.5 (PGP 9.5), a panneuronal marker, and tyrosine hydroxylase (TH), a sympathetic nerve fiber marker. The areas were measured by stereological analysis using the stereo investigator software (MicroBrightField).

Results: In OVX animals, the lamina propria area was decreased to 44% of the intact value ($p < 0.001$), an effect which was reversed by prasterone to 69% of the intact value ($p < 0.001$). OVX also caused a 59% decrease in the area of PGP 9.5 fibers, an effect which was completely prevented by prasterone, thus showing a 68% ($p < 0.01$) stimulatory effect of prasterone on the density of PGP 9.5 fibers in the lamina propria compared to OVX animals. Following OVX, the area of the muscular layer was decreased by 61% ($p < 0.001$), an effect which was reversed by 34% ($p < 0.001$) by prasterone. Ovariectomy, on the other hand, had no significant effect on the area of TH-positive fibers in the muscular layer while prasterone treatment induced 118% ($p < 0.01$) and 71% ($p < 0.05$) increases of TH fiber area above OVX and intact animals, respectively. When looking at the density of TH-positive fibers, prasterone treatment caused a 182% ($p < 0.01$) increase above intact controls.

Conclusion: The relatively potent stimulatory effect of prasterone on intravaginal nerve fiber density provides a possible explanation for the beneficial effects of intravaginal prasterone on sexual dysfunction observed in postmenopausal women treated by a low intravaginal dose

of prasterone with no significant change in circulating estradiol or testosterone, thus excluding systemic effects.

Disclosure:

Work supported by industry: no.

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EFFECTS OF ANDROGEN REPLACEMENT THERAPY FOR ERECTILE FUNCTION OF OLETF METABOLIC SYNDROME RATS

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Objective(s): Although metabolic syndrome (METS) is associated with androgen deficiency and ED, few basic research of androgen replacement therapy for METS animals was performed. Otsuka Long Evans Tokushima Fatty (OLETF) rat is a model that exhibits METS due to overeating. We investigated the erectile function in OLETF rats and examined how ART is effect for METS induced ED.

Material and Method(s): We examined in male OLETF rats and their counterpart Long Evans Tokushima Otsuka (LETO) rats. OLETF rats were injected testosterone propionate (3 mg/kg/day) for 5 weeks; ART group. At the age of 25 weeks, rats underwent erectile function testing in vivo by measuring intracavernosal pressure (ICP) upon electrical stimulation of the cavernous nerve. Relaxing and contractile responses of corpus cavernosum were measured by isometric tension study. Measurement of serum sex hormones was performed with LC-MS/MS. For structural analyses rat penis were harvested. Masson's trichrome staining was used to calculate the smooth muscle (SM) / collagen ratio using computer image analysis. NOS gene expression in the corpus cavernosum was determined by RT-PCR and NOS protein expression was determined by western blotting.

Result(s): Testosterone was decreased in OLETF rats, and ART effectively increased testosterone levels in ART group. OLETF rats were higher than LETO rats in body weight, blood glucose and triglyceride. ART did not reduce those parameters of OLETF rats. However, ICP/MAP ratio was 0.78 ± 0.03 in LETO group, 0.49 ± 0.03 in OLETF ($p < 0.01$ vs. LETO group) group and 0.73 ± 0.07 in ART group ($p < 0.01$ vs. OLETF group). SM / collagen ratio was $14.6 \pm 0.8\%$ in LETO group, $13.4 \pm 0.8\%$ in OLETF ($p < 0.05$ vs. LETO group) group and $17.3 \pm 0.6\%$ in ART group ($p < 0.01$ vs. OLETF group). Although relaxing responses induced by acetylcholine was decreased in OLETF rats compared to in LETO rats, it was increased in ART group compared to in OLETF rats.

Conclusion(s): METS caused endothelial dysfunction, but ART prevented the tissue damage and recovered erectile function of OLETF rats. We think that ART would be effective for METS patients.

Disclosure:

Work supported by industry: no.

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CHRONIC TREATMENT WITH ANTI-TLR4 ANTIBODY AMELIORATES IMPAIRED CAVERNOSAL RELAXATION IN ANGIIL-INFUSED MICE

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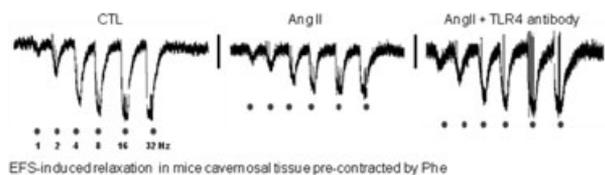
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Objective: Angiotensin-II (AngII) signaling and cytokines, specifically TNF-alpha, may mediate endothelial dysfunction associated with erectile dysfunction (ED). Recent evidence suggests that both AngII and TNF-alpha are linked with Toll-like receptor 4 (TLR4) upregulation. We hypothesized that chronic treatment with anti-TLR4 antibody ameliorates the impaired cavernosal relaxation in AngII-infused mice.

Methods: C57BL6 mice were infused with AngII (90 ng/min) for 28 days and treated with anti-TLR4 antibody (0.1 ug/daily, i.p. injection) for the last 14 days. Functional responses and protein expression were assessed in cavernosal tissue.

Results: Cavernosal strips from AngII-infused mice exhibited increased contraction to phenylephrine (PE, 10^{-8} to 10^{-4} M) and electrical field stimulation (EFS, 1–32 Hz), as well as decreased relaxation to acetylcholine (Ach, 10^{-9} to 10^{-5} M) compared to control (CTL). These effects were attenuated by chronic treatment with anti-TLR4, which also enhanced nitric oxide-induced relaxation in penile tissue from AngII-infused mice. Additionally, expression of TLR4 and TNF- α was increased in these mice penile tissue. Anti-TLR4 treatment prevented the decrease in eNOS expression and augmented TNF- α levels in cavernosal tissue from AngII-infused mice.

Conclusion: These results suggest that TLR4 contributes to impaired penile relaxation by decreased NO availability and increased TNF- α in response to upregulation of AngII.



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Disclosure:

Work supported by industry: no.

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EXPRESSIONS OF SK3 IN CAVERNOUS TISSUE OF DIABETES MELLITUS RAT

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Objective: Endothelium derived hyperpolarizing factor (EDHF) is the important vasodilator, Type of small conductance Calcium dependent potassium channels of SK3 is a key material in the EDHF pathway. In the study, We investigate the expression of SK3 in cavernous tissue of rat with diabetes mellitus and discussed the possible mechanism of damage to EDHF pathway and SK3 expression in diabetic mellitus erectile dysfunction (DMED).

Material and Method: All of 60 male Sprague-Dawley rats were divided into 2 groups: control group (n = 10) and diabetic group (n = 50). The diabetes mellitus model was established by the injection of streptozocin (STZ, 60 mg/kg). The rat of failing diabetes model in diabetic group set up to STZ group (n = 15). After 8 weeks erection function was examined by apomorphine (APO) injection. The expressions of SK3 mRNA and protein were measured by reverse transcription-polymerase chain reaction (RT-PCR) and Western blot, respectively.

Results: There were 9 rats deaths in the DM group, no death in the NDM group and STZ group. DM group (26) of 14 rats penile erection, erection rate was 54%, STZ group (15) and NDM (10) group rats full erection, erectile erection rate were 100%. SK3 mRNA expressions in DM group (0.50 ± 0.09) was significantly lower than STZ group (1.15 ± 0.03) and the NDM group (1.21 ± 0.04) ($P < 0.05$). SK3 protein expressions in DM group (0.65 ± 0.06) and the STZ group (1.28 ± 0.039) and NDM groups (1.34 ± 0.047) compared with significant difference ($P < 0.05$). STZ group and between the NDM group of rat penile erection and SK3 mRNA and protein expression was no difference ($P > 0.05$).

Conclusion: Diabetes can be significantly reduced erectile function in rats, and this may be related to decreased SK3 expressions in rat corpus cavernosum, and lead a new treatment for DMED in the future.

Disclosure:

Work supported by industry: no.

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IDENTIFICATION AND LOCALIZATION OF ENDOTHELIAL PROGENITOR CELLS IN THE RAT CORPUS CAVERNOSUM

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Objectives: Endothelial progenitor cells (EPCs) play an important role in the endothelial regeneration and maintenance. The purpose of this study is to identify and localize the cavernosal EPCs in the rat penis.

Materials and Methods: Corpora cavernosa were obtained from male Sprague-Dawley rats (12 weeks old, n = 20). To identify EPC in corpus cavernosa, we followed the single cell isolation protocol and analyzed the amount of EPC markers positive cells using flow cytometry. The expression of EPC specific markers (CD34, VE-cadherin, VEGFR-2) were evaluated by confocal immunofluorescence and immunocytochemistry.

Results: The EPC markers were mainly expressed in the vascular and sinusoidal endothelia by the confocal immunofluorescence and immunocytochemistry. The EPC markers positive cells were noted about 3 % in the corpus cavernosum by flow cytometric analysis.

Conclusion: The results revealed the existence of endothelial progenitor cells in the corpus cavernosum, and also showed the measurement of the endothelial progenitor cells in the rat model. It implies that the resident vascular progenitor cells may have a role in the maintenance of erectile function.

Disclosure:

Work supported by industry: no.

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WITHDRAWN

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WITHDRAWN

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CORPORAL “SNAKE” SURGICAL MANEUVER FOR THE TREATMENT OF ISCHEMIC PRIAPISM: LONG-TERM FOLLOW-UP

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Objective: To evaluate a modification of the Al-Ghorab distal penile corporoglandular shunt surgery for treating ischemic priapism.

Material & Methods: Retrospective review of all patients surgically treated for ischemic priapism refractory to clinical management at the Johns Hopkins Hospital from January 2008 to April 2012. We focused on patients specifically treated with the Al-Ghorab distal penile corporoglandular shunt wherein the corporal “Snake” maneuver (retrograde insertion of a size 7/8 Hegar dilator into each corporal body through the transected corporal tip and advanced proximally, with subsequent blood evacuation through the surgically formed channel by manual penile compression) was employed. A total of 10 patients were analyzed.

Results: Mean follow-up time was 6.6 months (range 0–17). The etiologies for the priapism were: idiopathic (3); trazodone (3); trazodone & cocaine (2); intracavernosal injection of trimix (1); spinal cord injury (1). 6 patients had previously undergone unsuccessful surgical attempts at priapism decompression, and mean priapism duration was 75 hours (range 24–288). 8/10 men achieved successful resolution of priapism with no recurrences. 2 men, who had recurrent priapism refractory to all management were definitively treated with insertion of an inflatable penile prosthesis. 6/9 men treated with the Snake

modification had normal erectile function pre-operatively. Of those, 2 (33%) achieved at least partial erectile function post-operatively and were able to engage in satisfactory sexual intercourse. 2 men sustained complications: one man developed a wound infection with skin necrosis, and the other sustained an intra-operative urethral injury, with subsequent urethrocutaneous fistula formation treated with prolonged catheterization, as well as a wound infection with skin necrosis.

Conclusion: The modified Al-Ghorab corporoglanular shunt is highly successful in resolving ischemic priapism, particularly for cases refractory to first-line management.

Disclosure:

Work supported by industry: no.

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EFFECT OF THE DEEP VEIN COMPLEX BUNCHING ON THE PENILE VENOUS DRAINAGE PATHWAY

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Objective: cavernous veins are the main venous drainage in both men with normal veno-occlusive function and men with venous leakage. Anatomically, cavernous veins originate at the area of cavernous body bifurcation, and flow into the prostatic plexus. Proper treatment for cavernous vein leakage has not yet been obtained. To establish the optimum ED treatment for venous leakage via cavernous veins, we studied the penile venous drainage pathway after laparoscopic radical prostatectomy(LRP). During LRP, the deep dorsal vein complex (DVC) is bunched, and then cut off to control bleeding. This procedure was developed by Dr. Myers in 1989 as a longitudinal bunching technique for open radical retropubic prostatectomies. This procedure has since been modified and is still performed in LRPs today. We performed three dimensional cavernosography in patients post LRP and studied the characteristics of their penile venous drainage pathways.

Material and Method: Study subjects were 10 ED patients who had previously undergone LRP for prostate cancer. 50 ED patients who had not undergone pelvic surgery were assigned as a control group. During all LRP cases, the procedure used was DVC bunching with 2-0 VICRYL followed by cutting off the DVC. There were three cases with unilateral nerve preservation. After obtaining written informed consent, we performed pharmaco-dynamic infusion cavernosometry and cavernosography using 20 micro grams of prostaglandin E1. Cavernosography was performed at 90 mmHg of intracavernous pressure using a multi-slice CT scan system (Aquilion 64, Toshiba Medical, Japan). 3D images were reconstructed with computer software (Aquarius Net Station, ver.2). This study was carried out with the permission of the ethical committee at our hospital.

Results: Cavernous veins were completely interrupted near their origins. Compared with the control group, post-LRP patients showed characteristic findings in prostatic plexus. In all patients with LRP, there was a portion of disappearance in the two-third ventral of the prostate plexus. Yet, veins inflowing to the obturator vein and the internal pudendal veins were depicted at the same ratio to that of the control group.

Conclusion: DVC bunching in LRP completely interrupted the cavernous vein near the origin. Deep vein bunching blocked the penile venous drainage pathway partially, however, veins which branch off from behind the levator ani muscle were not blocked. Further study examination of the three dimensional cavernosographic images of patients with post-LRP would deepen our knowledge about the penile venous drainage system, and give better insight into treatments of ED.

Disclosure:

Work supported by industry: no.

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INFLATABLE PENILE PROSTHESIS AND LOWER URINARY TRACT SYMPTOMS (LUTS)

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Objective: Placement of an inflatable penile prosthesis (IPP) for erectile dysfunction is a common urologic procedure. Many men with erectile dysfunction have concomitant lower urinary tract symptoms secondary to benign prostatic hyperplasia (BPH). The effect of IPP placement on a patient's LUTS has not been reported. We evaluated the change in bothersome LUTS before and after placement of an IPP.

Materials and Methods: We reviewed the medical records of patients who underwent placement of an IPP treated at Northwestern Memorial Hospital (NMH) from 1998 to 2011. To evaluate LUTS, all patients undergoing IPP completed American Urological Association Symptom Index (AUASI) surveys and post-void residuals (PVR) before and after prosthesis placement. The averages of all preoperative and postoperative AUASI scores were calculated. Incomplete AUA questionnaires were scored and prorated if the patient answered at least 5 items. Available data for urodynamic studies and changes in medications for LUTS were reviewed. Statistical analysis was completed by calculating mean scores using student T-test analysis with SAS 9.2 software.

Results: Forty-nine patients were identified with placement of an IPP for erectile dysfunction from the NMH database. The mean patient's age was 59.5 years old (range 35-84 years). The postoperative follow up period ranged from 12 days to 11 years. The mean follow up period was 473 days. Thirty patients (61%) had mild (0-7) preoperative LUTS, 16 patients (33%) had moderate (8-19), and 3 patients (6%) had severe (20-35) symptom scores. There was no significant difference between the pre and postoperative AUASI scores. The mean preoperative AUASI score was 7.86 (range 0-26, standard deviation 6.4) and the mean postoperative AUASI score was 7.42 (range 0-24, standard deviation 6.2). There were no differences in results of post-void residuals, pressure-flow studies, and medications pre and postoperatively.

Conclusions: A high prevalence of men with erectile dysfunction undergoing IPP have concomitant LUTS. Placement of an IPP for erectile dysfunction did not result in a change in LUTS scores, PVR results, and pressure-flow studies.

Disclosure:

Work supported by industry: no.

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COMBINED INFLATABLE PENILE PROSTHESIS AND MALE SLING OPERATIONS DO NOT INCREASE THE RISK OF SURGICAL INFECTION COMPARED WITH THE INFECTION RATES FOR THOSE OPERATIONS PERFORMED INDEPENDENTLY

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Objective: Combination implantation of artificial urinary sphincter/ inflatable penile prosthesis (IPP) is a safe and effective way to treat post-prostatectomy incontinence and erectile dysfunction. Male urethral sling has recently been shown to be an effective alternative for the treatment of post-prostatectomy incontinence ; however, no data exists on the safety and efficacy of combination implantation of male urethral sling/inflatable penile prosthesis. Herein, we report results from our series of combination implantation of male urethral sling/ inflatable penile prosthesis.

Material and Methods: Between January, 2006, and December, 2011, we performed combined sexual rehabilitation surgery with IPP implantation and urinary continence rehabilitation with implantation

of a male sling in 80 patients. During that time frame we performed a total of 551 IPP's and 271 male slings. All patients had been diagnosed with erectile dysfunction and stress urinary incontinence (SUI) for more than 12 months. The penile prostheses implanted included the American Medical Systems (AMS), CX, and the Coloplast Titan. The male slings included the InVance (AMS), bone anchored slings, AdvVance (AMS), transobturator slings and Virtue (Coloplast) male slings. The IPP was implanted through a transverse scrotal approach and the sling was implanted through a midline perineal incision. The operations were all done by the same two surgeons working in sequence through incisions during the same anesthetic.

Results: No infections were identified during the combined IPP and sling group. One surgical infection was identified in the IPP only group (0.18%). Two superficial wound infections were identified in the male sling only group (0.74%).

Conclusion: IPP and male slings can be safely implanted under the same anesthetic through two incisions with no increased risk of surgical infection.

Disclosure:

Work supported by industry: no.

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THE USE OF AN INTRACORPORAL ANTIBIOTIC CAST WITH SYNTHETIC HIGH PURITY CASO₄ DURING THE TREATMENT OF INFECTED PENILE IMPLANT

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Introduction: The surgical treatment of infected penile prostheses is complete removal and either an immediate salvage procedure or a delayed implant. Salvage procedures prevent corporal space fibrosis, however carry a significant infection risk. With delayed implantation the risk of infection is lower, but the patient loses penile length and width due to corporal fibrosis, which in turn can make the surgery technically challenging. We present our experience with the use of a novel temporary synthetic high purity calcium sulfate (SHPCaSO₄) component that acts as a "spacer" at the time of removal of an infected prosthesis while providing constant delivery of local antibiotic elution to the infected area.

Materials and Methods: 2 patients (Patient A (A) and B (B)) presented with pain and erythema and were found to have an eroded malleable implant and an infected malleable penile implant respectively. (A) suffered from a right distal erosion with visible prosthetic material. He underwent removal of right cylinder through a subcoronal incision. (B) was complicated by a failed previous salvage procedure and had purulent drainage from his penoscrotal wound. Both of his malleable cylinders were removed through this same approach. Removed implants were sent for tissue culture. The SHPCaSO₄ was mixed with vancomycin and tobramycin, allowed to set up for 5 minutes, and then injected into the corporal space (right only for A and bilateral corpora for B). The corporal incisions were then closed with 2-0 Vicryl sutures with a watertight closure. No drains were left in place. The injected SHPCaSO₄ was palpable in the penile shaft both proximally and distally, as an "intracorporal casts." Both were discharged on post-operative day one with oral antibiotic therapy for 7 days.

Results: Patients denied pain postoperatively and both did well clinically. Intra-operative cultures from A grew out some gram positive bacteria and B grew out candida albicans. Delayed implantation occurred at 6 weeks. Patients have had no infection after delayed implantation.

Discussion: Our initial experience demonstrates that the use of the novel completely dissolvable material, SHPCaSO₄, that acts as a space holder while locally treating the infected tissue at the time of infected penile prosthesis removal is an innovative way to bridge the gap between extrication of an inflatable penile implant and delayed reimplantation.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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3-PIECE INFLATABLE PENILE PROSTHESIS INSERTION POST DISTAL T-SHUNT FOR PRIAPISM WITH DILATION/CORPORAL SNAKE MANEUVER AND COMPARISON TO POST AL-GHORAB SHUNT IPP OUTCOMES

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Objectives: The distal T-shunt/corporal snake maneuver has redefined treatment-resistant priapism management by accessing the corpora cavernosa via the glans followed by instrumental dilation to the proximal corpora (entire corporal length). Potential erectile function return even after 24-72 hrs of priapism is described by Lue's and Burnett's groups. However, there remains a possibility that definitive management will include inflatable penile prosthesis, performed on a deferred basis. We present the first cumulative experience of IPP placement in post-T shunt patients, as well as comparative results to IPP following distal tunical excision (Al-Ghorab). **Materials and Methods:** 7 pts post T-shunt required IPP placement due to refractory erectile dysfunction. Color duplex ultrasound was performed prior to IPP by the operating surgeon in all cases. Comparison was made to post-Al-Ghorab IPP results from separate institutions.

Results: IPP surgery (penoscrotal access), at approximately 3 mths post T-shunt, was complicated in all cases by dense distal fibrosis, requiring a second small (<3 cm) ventral incision to allow for direct dissection into the corporal, excision of non-dilatable scar tissue, and dilation (proximally and distally) to establish continuum with the standard penoscrotal corporal dilation compromised by intracavernous fibrosis. The rate of second ventral corporotomy incision for non-priapism pts undergoing IPP, but including Peyronie's disease in the practice is 6.6%. There were no device infections or second procedures, EHS scores were 4 at six months, and IIEF-5 increased over 17 points (mean) from baseline. IPP post Al-Ghorab demonstrate similar device viability, but complementary technical complications. No erosions or early mechanical failures were noted in either group. **Conclusions:** In order to minimize iatrogenic injuries, including urethral perforation, a second ventral distal incision allows bilateral access to the corpora, and direct vision incision/dilation. These maneuvers added little to overall surgical times, did not confer additional morbidity, and are a valuable approach in the post T-shunt pt with dilation/corporal snake patient requiring IPP reconstruction. Although distal tunica is compromised at priapism management, no erosion was noted at medium-term follow-up.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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ANTICOAGULATIVE THERAPY IS NOT A CONTRAINDICATION FOR PENILE PROSTHESIS IMPLANTATION

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Introduction: Inflatable penile prostheses (IPP) represent the most effective treatment option for erectile dysfunction (ED) when con-

servative measures are unsuccessful or contraindicated. Many patients require anticoagulation therapy (AAT) for pre-existing conditions. Discontinuation of these medications may lead to life-threatening complications. Historically, these men were not candidates for IPP implantation. The objective of this study is to report perioperative outcomes in men undergoing IPP on AAT.

Material/Methods: Men undergoing IPP placement between 2009 and 2012 by a single surgeon were reviewed. Patient demographics, co-morbidities, and peri-operative parameters were evaluated. AAT included Aggrenox, Coumadin, Lovenox, Plavix, and/or Aspirin.

Results: 91 patients constitute the study population. 11 patients continued AAT during surgery. There was no significant difference in age between men on anticoagulation and men who were not, 62.54 vs. 59.18 years. Co-morbidities included diabetes (12%), HTN (60%), hyperlipidemia (45%), and CAD (55%). There were no significant differences analyzed in length of hospital stay [3.2 vs. 1.1 days; $p = 0.21$], duration of ED [7.91 vs. 4.90 years; $p = 0.15$], EBL [127.27 vs. 124.50 mL; $p = 0.90$], operative time [155.9 vs. 168.7 min; $p = 0.08$], INR [1.6 vs. 1.02; $p = 0.14$], and PTT [30.3 vs. 30.28; $p = 0.98$]. One patient on ASA had MI POD#1. No bleeding complications or transfusions occurred.

Conclusion: No significant differences in perioperative outcomes were observed in men undergoing IPP surgery on or off anticoagulant medication. IPP implantation may be safely completed in the setting of AAT without increased blood loss, hospital stay, or complication rate. Furthermore, this patient group might benefit from continuation of anticoagulation for pre-existing disease.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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MEN UNDERGOING PENILE PROSTHESIS HAVE SIMILAR MEASURED FLACCID PENILE LENGTH VIA STRETCH COMPARED TO PHARMACOLOGICALLY INDUCED ERECT PENILE LENGTH

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Objective: To compare the flaccid penile length on stretch versus penile length following intracavernosal injection (ICI) in men prior to undergoing first-time penile prosthesis surgery.

Material and Methods: 24 men pre-operatively underwent flaccid penile length measurements prior device implantation. Length was measured from the pubic bone to meatus along the dorsum of the shaft. Patients with Peyronie's disease were excluded from this analysis. We compared the stretched flaccid penile length to length measured following ICI of PDE1 inhibitor. Baseline characteristics including age, history of hypertension, diabetes and prior radical prostatectomy were reviewed for any discrepancy (>1 cm) between flaccid penile stretch versus ICI. Wilcoxon rank-sum and chi-squared tests were used for statistical analysis.

Results: The median \pm IQR of penile length ICI was similar (14 ± 1 cm) to a stretched flaccid penile length (13 ± 1 cm), $p > 0.05$. Median SHIM score was 10 ± 3 . Of all baseline characteristics measured between 6 men who had a discrepancy (>1 cm) between flaccid penile stretch lengths versus ICI – only age was significant (58 ± 2 years versus 68 ± 4 years; $p = 0.006$). There were no differences noted between penile lengths in men who were diabetic (38%), hypertensive (25%) or those who had prior radical prostatectomy (46%).

Conclusions: Stretched penile flaccid length is comparable to erect length following ICI, however younger men could have a shorter length following ICI. Whether length measured with and without ICI more closely resembles length measured following penile prosthesis remains to be determined. Such information may aid in preoperative

counselling and setting patient expectations prior to undergoing penile prosthesis surgery.

Disclosure:

Work supported by industry: no.

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SINGLE CENTER EXPERIENCE WITH RECONSTRUCTIVE SURGERY FOR ADULT - ACQUIRED BURIED PENIS: MEASUREMENTS OF ERECTILE FUNCTION, DEPRESSION, AND QUALITY OF LIFE

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Introduction and Objective: Management of adult acquired buried penis is a difficult problem for both the patient and surgeon. It has a strong association with morbid obesity and is currently thought to be exacerbated by the chronic infection, inflammation, skin breakdown, that leads to scar contracture and ultimately to a buried or trapped penis. The trapped penis has been associated with significant erectile and voiding dysfunction, depression, and overall poor QOL. This study assessed patient outcomes following reconstructive surgery with release of buried penis, escutcheonectomy, and circumcision with or without skin grafting based on previously published methods.

Materials and Methods: Retrospective chart review from our database of reconstructive surgery between 2007 and 2011. We identified 11 patients ages 44–69; complete data review was available on all 11. All patients were treated by a single surgeon (LAL). Validated EORTC 15 QOL, CES-D, and IIEF surveys assessed patient quality of life, depression, and erectile function pre and postoperatively.

Results: Mean BMI was 48.8 (42.4–64.6). Mean operative time was 191 min (139–272). Mean length of stay was 2.1 days. Mean EBL was 170 ml. 10/11 required phallic skin grafting. There was 1 peri-operative complication resulting in respiratory failure and overnight stay in ICU. Wound complications were seen in 2/11 patients, 1 needed surgical debridement for superficial wound infection. Excellent skin graft take was seen in 100% of patients. 91% of patients noted significant improvement in voiding postoperatively. 81% of patients reported significant erectile dysfunction preoperatively. Subsequently, IIEF scores were improved post surgery with 62% of men reporting erections. Clinical depression was noted to be decreased in 7/11 patients preoperatively to 2/11 based on CES-D surveys. QOL improved significantly in 10/11 compared to preoperative baseline, however many patients noted significant difficulties based on their weight and other comorbidities.

Conclusions: Management of adult acquired buried penis is a challenging, yet correctable problem. In our series it appears that using previously published surgical techniques can be beneficial in patient outcomes. Furthermore, it can improve erectile function, voiding, hygiene, and can improve QOL and CES-D scores.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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INITIAL EVALUATIONS FOR ENHANCED COLOPLAST TITAN INFLATABLE PENILE PROSTHESIS: RESULTS OF A MULTICENTER QUESTIONNAIRE

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Objectives: We evaluate physician opinion of Coloplast's latest enhancements of the Titan penile prosthesis that incorporates 0-degree tubing angle exit at the proximal base of the cylinders, and a soft silicone molded distal tip and the cloverleaf reservoir. These new implant features were designed for ease of physician usage and increased patient satisfaction.

Material and Methods: Thirty-four high volume prosthetic surgeons completed a standardized questionnaire regarding the enhanced Coloplast Titan as compared to previous Titan and competitive products. A total of 136 enhanced Titans and questionnaires were completed from March 7, 2012 through April 25, 2012.

Results: The 34 physicians implanted via both peno-scrotal 68% (n = 93) and infrapubic 32% (n = 43) approaches. The surgeons felt that 100% of the new cylinders were properly seated proximally. Ease of insertion of the 0° base was rated as very easy (85%) and moderately easy (12%). In comparison to other implants on the market, proximal insertion was rated much easier (67%), slightly easier (27%) or the same (5%). Most (75%) implanters believed the new cylinder design might lessen difficulty of dilatation and cylinder insertion in a fibrotic patient. The new soft, silicone molded distal tip was described as easy to seat and properly filled out the glans in 97% of the questionnaires. In regard to distal tip "feeling" for the patient, 94% of cases were considered better. Ectopic placement of the Titan CL reservoir was completed 20 times (15%), all of which were described as not noticeable after placement. History of robotic prostatectomy did not dissuade the majority of implanters from utilizing the space of Retzius for reservoir placement

Conclusions: Initial surgeon feedback for the enhanced Coloplast Titan penile prosthesis indicates easier implantation for the surgeon and predicts improved patient satisfaction by lessening palpation of the device. Future studies are needed to quantify patient opinions and document improvement in facilitating cylinder insertion into fibrotic corpora.

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THE EFFECT OF TESTOSTERONE REPLACEMENT IN MEN WITH TESTOSTERONE DEFICIENCY SYNDROME ON COGNITIVE PERFORMANCE AND DEPRESSION

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Purpose: Testosterone levels decline as men age, as does cognitive function. Testosterone may play a role in regulating moods. Symptoms

of testosterone deficiency syndrome (TDS) include diminished muscle mass and strength, decreased bone mineral density, anorexia, decreased libido, fatigue, dysphoria, and irritability. Some of these symptoms overlap with those of depressive illness. The aim of the present study was to evaluate the effect of testosterone replacement therapy (TRT) on cognitive function and depression in men with TDS.

Materials and Methods: A prospective, placebo-controlled, single-blind trial involving 68 men with TDS (calculated total testosterone <3.3 ng/ml with symptoms of hypogonadism) was carried out. The patients were divided into group A (TRT, n = 44) and group B (control, n = 22). The patients of group A were injected with 1000 mg of testosterone undecanoate and those of group B were advised to modify of lifestyle. We compared the data at baseline and 6 months using the serum levels of total testosterone and prostate specific antigen (PSA), the Aging Males' Symptoms (AMS) scale, the 5-item International Index of Erectile Function (IIEF-5), the Korean Mini-Mental State Examination (K-MMSE), the Beck Depression Inventory (BDI).

Results: The mean age of group A and B were 56.7 ± 12.6 and 57.8 ± 11.4 years old, respectively (p > 0.05). There were no statistically significant differences in serum testosterone, PSA level, AMS, IIEF-5, K-MMSE and BDI scores between the two groups at baseline. Serum testosterone, IIEF-5 and BDI scores were significantly increased in group A (p < 0.05). AMS scores were significantly decreased in the group A (p < 0.05). K-MMSE scores were not significantly increased in the two groups but significantly increased of patients with cognitive impairment (K-MMSE scores <25) in the group A. A total of 3 patients with serum PSA level greater than 4 ng/ml after TRT underwent a prostate biopsy but no patients were found to have prostate carcinoma. No significantly differences were observed in the group B (p > 0.05).

Conclusion: TRT effectively improved serum testosterone, AMS, IIEF-5, K-MMSE and BDI scores in men with TDS. TRT may improve some aspects of cognitive ability and depression in men with TDS. For men with both cognitive impairment or depressed men and low testosterone, TRT may be considered. Large long-term studies are required to evaluate the effects of TRT on cognitive function and depression in TDS.

Disclosure:

Work supported by industry: no.

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TESTOSTERONE TREATMENT WITH INJECTABLE TESTOSTERONE UNDECANOATE SUSTAINABLY IMPROVES ERECTILE FUNCTION, URINARY FUNCTION AND QUALITY OF LIFE IN ELDERLY HYPOGONADAL PATIENTS

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Objectives: Hypogonadism is often associated with erectile dysfunction (ED) and lower urinary tract symptoms (LUTS) and impaired Quality of Life. We studied long-term effects of testosterone treatment in elderly hypogonadal men treated with parenteral testosterone undecanoate.

Material and Methods: A cumulative registry study of 255 men (mean age: 60.6 ± 8.0 years) with testosterone levels ≤ 3.50 ng/mL were treated with injectable testosterone undecanoate for up to 60 months. Injections were administered with an initial 6-week interval (loading dose) followed by 12-week intervals.

Results: The International Index of Erectile Function (IIEF) increased from 21.13 ± 4.63 at baseline to 24.83 ± 3.8 after 60 months, most pronounced over the first 24 months but still slowly progressive thereafter. The International Prostate Symptoms Score (IPSS) improved from 6.73 ± 4.21 to 2.83 ± 1.25 (p < 0.0001 vs baseline with significant changes over the previous year up to 48 months). As an objective measurement, residual bladder volume decreased from 46.61 ± 22.74 mL to 19.74 ± 6.25 mL (p < 0.0001 vs baseline with significant changes over the previous year up to 48 months). Quality of life was

assessed by the Aging Males' Symptoms score (AMS). AMS improved from 55.01 ± 10.2 to 17.35 ± 0.55 (p < 0.0001 vs baseline) reaching a plateau after 24 months.

Inflammation plays a role in both erectile and urinary function. As measures of inflammation, highly sensitive C-reactive protein (hsCRP) and leukocyte count were assessed. hsCRP decreased from 6.29 ± 7.96 mg/L to 1.03 ± 1.87 (p < 0.0001 vs baseline) with a plateau after 36 months. Leukocyte count decreased from 8.06 ± 2.98 ×10⁹/L to 5.74 ± 0.81 (p < 0.0001 vs baseline).

Conclusion: Normalizing testosterone levels in hypogonadal men for up to 5 years resulted in sustainable and progressive improvement of erectile and urinary function.

Disclosure:

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15 YEARS OF EXPERIENCE WITH INTRAMUSCULAR TESTOSTERONE UNDECANOATE FOR SUBSTITUTION IN MALE HYPOGONADISM - BENEFICIAL EFFECTS ON THE METABOLIC SYNDROME AND HIGH SAFETY PROFILE

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Background: A reliable form of androgen substitution therapy in terms of favorable kinetics and tolerance as well as effective restoration of androgenicity is paramount for hypogonadal men. The intramuscular injection of the long-acting ester testosterone undecanoate (TU) offers a convenient modality for testosterone substitution.

Methods: We report data from 334 patients (147 with primary [including 38 Klinefelter patients], 100 with secondary hypogonadism and 87 with late-onset ("mixed" or "metabolic" hypogonadism) aged 15 to 72 years (mean 42 ± 15 years) receiving altogether 6596 intramuscular injections of 1000 mg of TU during a maximal treatment time of 15 years, overall corresponding to 1403 treatment years.

Components of the metabolic syndrome were assessed in 269 men receiving 4296 injections.

Results: Individual dosing intervals ranged from 10 to 14 weeks Serum T concentrations increased from 5.8 to stable 16.1 nmol within the first year of treatment. The proportion of men fulfilling the new Harmonized Criteria for definition of the Metabolic Syndrome decreased from initially 88% to 52% within 2 years (Chi-square for trend: p < 0.001). During the maximal duration of treatment, an overall favorable change from baseline was visible for a multitude of parameters related to androgen effects/metabolic risk (see Table). Prostate size increased from 16.1 ± 5.2 to 21.1 ± 5.2 ml (p < 0.001), whilst PSA levels moderately (1.8 ± 0.4 to 1.9 ± 0.4 µg/l, p = 0.001). No case of prostate cancer was observed. Hematocrit was significantly elevated during treatment but remained within the normal range (40.9 ± 2.1 to 46.2 ± 2.5%, p < 0.001), except for occasional measurements (maximal

value 56.6%). One patient suffered from deep vein thrombosis, one from stroke. No case of prostate cancer was observed.

Conclusion: Intramuscular injections of testosterone undecanoate represent a feasible, safe and well tolerated modality of androgen substitution in hypogonadal men of a wide age-range, substantiated by more than one decade of experience, facilitating a decrement of metabolic/cardiovascular risk factors.

Disclosure:

Work supported by industry: yes, by Bayer Health Care (no industry support in study design or execution).

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MEDICATION ADHERENCE AND PERSISTENCE FOR HYPOGONADAL PATIENTS TREATED WITH TOPICAL TESTOSTERONE THERAPY: A RETROSPECTIVE CLAIMS ANALYSIS

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Objectives: The diagnosis of hypogonadism is established in symptomatic men with consistently low levels of serum testosterone, whether due to specific diagnoses, such as Klinefelter syndrome, or non-specific diagnoses, which often occur with aging. In most cases, hypogonadism requires long term testosterone replacement therapy (TRT). Testosterone gels are the most common form of testosterone replacement therapy for hypogonadism in the US, but little is known about patient adherence and persistence with therapy. We hypothesized that men with specific hypogonadal diagnoses would be younger, more adherent, and more persistent than men with non specific diagnoses,

Materials and Methods: The type of hypogonadism (specific versus non-specific) was classified using either ICD-9-CM diagnostic codes in the Thomson Reuters MarketScan® Database in 2009. Medication persistence was defined as the length of therapy (LOT) from the index date to the earliest ending date of the last prescription, defined as either the date of the first gap of >30 days between prescriptions or the end of study period (12 months). Medication adherence was measured by medication possession ratio (MPR) in the 6 months follow-up period. Adherence rate was defined as percent of MPR ≥0.8. LOT, MPR and adherence rate were calculated by diagnostic code and age group and compared using t-test or chi-square test.

Results: 91,200 men met study criteria for hypogonadism: 11.1% with specific and 89.9% with non-specific diagnostic codes. The mean LOT was 196 days and 178 days, respectively (p < 0.0001). MPR and adherence rates were similar between men with specific (0.4 and 8.6%, respectively) and non-specific (0.4 and 9.0%, respectively) diagnoses. LOT, MPR and adherence rate were numerically similar across all age groups.

Conclusion: Unexpectedly, adherence and persistence with topical gel TRT agents were found to be similarly low among men with specific and non-specific hypogonadal diagnoses.

These findings are important for clinicians who prescribe topical TRT as they may affect needed follow-up plans for patients. Unexplored factors that might provide more sensitivity include other testosterone application methods, hypogonadal symptom severity, and ascertainment of testosterone levels.

Disclosure:

Work supported by industry: yes, by Eli Lilly and Company (industry initiated, executed and funded study). The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

Parameter	Unit	Baseline	Endpoint: 15 years	p for ANOVA, last observation carried forward
Body Mass Index	kgxm ²	31.8 ± 5.2	24.4 ± 3.2	<0.001
Waist circumference	cm	114 ± 10.5	94.1 ± 8.7	<0.001
Weight	kg	103.0 ± 16.3	79.1 ± 12.6	<0.001
LDL-Cholesterol	mg/dl	157 ± 29	110 ± 19	<0.001
HDL-Cholesterol	mg/dl	38.4 ± 9.7	53.6 ± 11.7	<0.001
Triglycerides	mg/dl	198 ± 33	145 ± 21	<0.001
Fasting glucose	mg/dl	118.1 ± 29.7	91.2 ± 15.2	<0.001
RR systolic	mmHg	148 ± 14	128 ± 11	<0.001
RR diastolic	mmHg	98 ± 11	81 ± 10	<0.001
Pulse	bpm	89 ± 9	75 ± 8	<0.001

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TOPICAL TESTOSTERONE GEL TREATMENT PATTERNS AMONG HYPOGONADAL MEN IN A LARGE RETROSPECTIVE CLAIMS DATABASE

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Introduction: Symptomatic hypogonadal men with low testosterone levels may find symptom relief when given topical testosterone gel (T) replacement therapy (TRT). We previously found that men initiate TRT at various doses, including the recommended starting dosage in the T product labels. It is possible that continuation of TRT would be mediated by starting dose, since symptom improvement may occur once a threshold level of testosterone is achieved. This study sought to understand whether higher starting doses (vs. the recommended starting dose) of topical TRT were associated with lower discontinuation rates.

Materials and Methods: Hypogonadism was identified using either the appropriate ICD-9-CM diagnostic codes or the testosterone prescription codes in the cross-sectional MarketScan Commercial and Medicare claims databases for commercially insured men age 18–64 and Medicare-insured men over 65 from 2009. Patients were followed for the first 6 prescriptions. Medication discontinuation was defined as no further prescription within 45 days after the last supply day of last prescription.

Results: In 2009, 25,205 met entry criteria. 11.0% had an initial dose of <50 mg/day, 80.3% had an initial dose of 50 mg/day, the recommended starting dose, and 8.7% had an initial dose of >50 mg/day. Attrition rates were numerically high; for example, 63.3% of patients received a second prescription and only 13.2% received six prescriptions. Disproportionately and numerically, patients in the highest category remained on therapy, with nearly 34% of patients in the highest category receiving six prescriptions.

Discussion: Patients who initiated therapy at the recommended starting dose discontinued use at a numerically higher rate than those initiating therapy on a higher dose. It is possible that more patients initiating therapy on the higher starting dose achieved testosterone levels within the normal range and thus, more likely to have improvement in symptoms, discontinuing at a lower rate than those at the recommended starting dose; however this premise could not be directly tested, since T Levels could not be evaluated in this study. Other factors may affect discontinuation, including cost of therapy, co-morbid conditions, and benefit/risk expectations with TRT.

Disclosure:

Work supported by industry: yes, by Eli Lilly and Company (industry initiated, executed and funded study). The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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DEPRESSION SIGNIFICANTLY REDUCES THE RESPONSE TO TESTOSTERONE THERAPY IN MEN WITH TYPE 2 DIABETES AND HYPOGONADISM

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Objective: Men with type 2 diabetes have a high prevalence of symptomatic hypogonadism as well as depression. This is the first double blind placebo controlled study in an exclusively type 2 diabetes population to determine whether testosterone therapy improves HbA1c, other parameters of diabetes, and symptoms of mood and sexual function.

Methods: The primary care populations of 8 general practices were screened for morning testosterone levels to define 211 patients (Mean age 61.6) with a total testosterone of less than 12 nmol/l for a double

blind placebo controlled 30 week study with 106 men continuing in a 52 open label follow on phase. Depot Testosterone Undecanoate (TU) as NEBIDO[®] or matching placebo was administered at week 0, 6 and 18. Patients were assessed for BMI, weight, waist circumference, AMSS, IIEF, HADS Anxiety and depression, global efficacy question, and blood was taken for HbA1c, HOMA, CRP, lipids, PSA and haematocrit as week 6, 18 and 30.

Results: The prevalence of hypogonadism in the male type 2 diabetes population was 50%. Depression as defined by a HADS score of 11 or greater was 25%. Men with depression were younger and more obese. TU significantly reduced HbA1c at 18 weeks and the reduction was 0.42% in the poorly controlled patients and 0.72% after 52 weeks open label medication. There were significant reductions in weight, BMI, waist circumference, lipids, AMSS, HADS Anxiety score and all domains of the IIEF in the non-depressed group but not in the cohort with depression. There was a trend for improvement in depression after 52 weeks of open labels medication. There was a 25–30 per cent increase in PSA by 30 weeks but no rise thereafter. There was only 1 case of prostate cancer, in the placebo cohort.

Conclusion: Depression is common in men with type 2 diabetes and especially those with hypogonadism. Response to testosterone was markedly reduced in men with depression. It is recommended that hypogonadal men with and without diabetes should be screened for depression and considered for concomitant treatment of the depression in addition to testosterone therapy.

Disclosure:

Work supported by industry: yes, by Bayer (industry funding only - investigator initiated and executed study).

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EFFECTS OF BASELINE TESTOSTERONE LEVELS ON SYMPTOM IMPROVEMENT IN HYPOGONADAL MEN RECEIVING TESTOSTERONE REPLACEMENT THERAPY

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1: Eli Lilly and Company

Objective: Symptom improvement may be affected by baseline testosterone (T) level in men receiving testosterone replacement therapy (TRT). We performed a post-hoc analysis to evaluate the effects of baseline T level on changes in sexual function and mood in hypogonadal men receiving 2% testosterone in a topical solution applied daily to the axillae.

Material and Methods: Data was from an open-label trial in 155 androgen-deficient men started on daily 60 mg T. Dose was adjusted on days 45 and 90 based on average serum T on days 15 and 60, respectively, to maintain T in the physiologic range (300–1050 ng/dL). Sexual desire and activity, positive and negative mood, percent full erection and erection maintained were assessed by the Psychosexual Daily Questionnaire (PDQ) for 7 days preceding visits at days 1, 15, 60 and 120. Subjects were divided into 4 subgroups depending on baseline (pre-day 1) total serum testosterone (TT) < 100, 100 < 200, 200 < 300 and >300 ng/dL. For each PDQ parameter, change from baseline to days 15, 60 and 120 was analyzed using repeated measures analysis of covariance (ANCOVA) adjusted for TT group, age, body mass index (BMI) and visit, with baseline TT subgroup effect assessed by the type III test of fixed effects.

Results: All PDQ domains showed significant ($p < 0.05$) improvement for subjects in all TT subgroups. In subgroup comparisons, T levels at baseline did not appear to affect the magnitude of improvement; $p > 0.05$ for all PDQ domains. The lowest TT group (TT < 100 ng/dL) seemed to have the greatest numerical improvement in sexual desire, sexual activity, percent full erection, and erection maintained after adjustments. The least squares means of the TT groups for sexual desire were 1.70, 1.15, 1.13 and 0.97 for the TT < 100, < 200, 200 < 300, and ≥ 300 ng/dL groups respectively (trend not seen in positive and negative mood domains). Limitations include lack of placebo control group and relatively small number of patients with very low serum T levels at baseline. While adjustments were made for age and

BMI, other confounders may have affected patients' response to therapy.

Conclusion(s): Subjects in all TT subgroups showed significant ($p < 0.05$) improvement in all PDQ domains but T levels at baseline did not appear to affect the magnitude of improvement. Additional research is needed to better understand the effects of TRT on symptom improvement in men with hypogonadism.

Disclosure:

Work supported by industry: yes, by Eli Lilly and Company (industry initiated, executed and funded study). The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

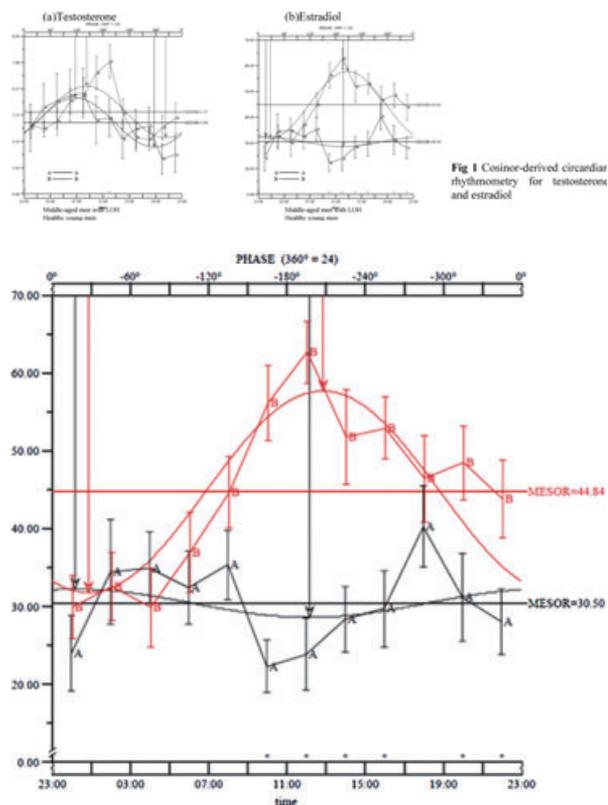
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COMPARISONS OF SERUM LEVELS AND CIRCADIAN RHYTHMS OF ESTRADIOL, TESTOSTERONE AND OTHER SEX HORMONES BETWEEN HEALTHY YOUNG MEN AND MIDDLE-AGED MEN WITH LATE ONSET HYPOGONADISM

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Objective: There is a lack of data exploring the associations between circadian rhythms of sex hormones including estradiol (E2) and late-onset hypogonadism (LOH) in aging male. This study was aimed to compare the differences of the serum levels and circadian rhythms of E2, testosterone (T) and other sex hormones between healthy young men and middle-aged men with LOH symptoms.

Material and Method: Ten healthy young men, aged 20–25 years, and 10 middle-aged men who had LOH symptoms were enrolled. Blood samples were collected every 2 hour for next consecutive 24hours and serum levels of E2, T, sex hormone-binding globulin (SHBG), luteinized hormone (LH) were measured. We analysed and



compare the serum levels and the circadian rhythms of E2, T, and other sex hormones between the 2 groups utilizing 24 hr cosinor regression analysis.

Result: In the middle-aged men, T was slightly decreased but not significant and the circadian rhythm was well maintained comparing with the young men (500 ng/dl vs. 537 ng/dl, $p = 0.25$). E2 showed significant diurnal cosinor rhythm in young men, but the rhythm was not observed and the E2 was significantly decreased (30.5 pg/ml vs. 40.84 pg/ml, $p = 0.02$) in middle-aged men. SHBG and LH were higher in middle-aged men (49.8 vs. 23.1, $p < 0.01$ and 6.5 vs. 4.0, $p < 0.01$, respectively) (Fig. 1).

Conclusion: These findings suggest that the serum level and circadian rhythm of E2 have correlations with LOH symptoms and the changes of E2 occurred earlier than the changes of T in middle-aged men with LOH symptoms. Further investigations are needed to identify how the attenuation of the diurnal rhythm of estradiol could affect symptoms of LOH in aging males.

Disclosure:

Work supported by industry: no.

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EFFECT OF TESTOSTERONE GEL ON SYMPTOM BURDEN AND MEDICATION USE IN PATIENTS WITH HYPOGONADISM: A RETROSPECTIVE COHORT STUDY

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Objectives - To compare differences in the reason for physician visits and medication use of hypogonadism patients consistently treated versus not consistently treated with testosterone gel.

Material and Methods - A cross-sectional retrospective study was conducted using the GE Centricity EMR Database (2000–2010). This database contains de-identified patient clinical information, from a nationally representative patient population. As of December 2010, there were more than 18 million patients in the database. Subjects were males, ≥ 18 years of age with an ICD-9 coding indicative of hypogonadism who were new users of testosterone gel. Subjects were defined as “consistently treated” if their EMR medication possession ratio (EMPR) was $\geq 80\%$. EMPR was defined as % of months with an active prescription of testosterone gel during the 24-months following the initial prescription. Outcomes evaluated included reason for visit and concomitant medications (drug class). Analyses were conducted as Chi-square tests on proportions of patients with symptoms of interest.

Results - The average age of consistent ($n = 1,337$) and non-consistent ($n = 1,419$) users were 54.3 and 55.1 years ($p > .05$), respectively. Consistently treated patients had significantly less occurrence of all studied reasons for visit compared to the non-consistently treated group ($p < .05$). These include fatigue (7.4% vs. 10.7%, $p = .006$), sleep disturbance (1.4% vs. 2.7%, $p = .029$), sexual dysfunction (1.2% vs. 2.2%, $p = .041$), depressed mood (5.5% vs. 7.5%, $p = .045$), and other non-specific symptoms (1.4% vs. 2.7%, $p = .029$). The consistently treated patients also had a lower utilization of anti-depressant medications (25.1% vs. 31.6%, $p < .001$). There was also a significantly lower proportion of co-morbid hypertension (53.1% vs. 56.9%, $p = .042$) and a trend toward lower use of anti-hypertensives (37.4% vs. 40.8%, $p = .066$) in consistently treated patients.

Conclusion - Hypogonadism patients consistently treated with testosterone gel had a lower symptom burden, lower use of anti-depressant medication and a lower rate of hypertension compared to those who are not consistently treated. The current study was cross-sectional in nature and hence does not allow causative inferences to be drawn.

Disclosure:

Work supported by industry: yes, by Abbott Laboratories (industry initiated, executed and funded study). The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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TOTAL PHALLIC CONSTRUCTION IN PATIENTS PREVIOUSLY TREATED FOR BLADDER/CLOACAL EXSTROPHY AND MICROPENIS/EPISPADIA

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Objectives: Our 8-year experience of total phallic construction with the radial-artery-free-flap (RAFF) in patients with bladder/cloacal exstrophy and micropenis-epispadias (BEME) is reported.

Material and Methods: Patients had already undergone a median of 12 surgical procedures (range 9–42) for the correction of BEME at the time of the phalloplasty and 7 had a closed bladder neck and were voiding through a Mitrofanoff. The technique, carried out in three separate stages, was similar to the one used for patients following penectomy. However, an adequate epigastric artery was missing in 8 patients and therefore the radial artery was anastomosed to the superficial femoral artery with the interposition of a saphenous graft. The previously reconstructed penile urethra was primarily anastomosed to the phallic one in all patients to allow ejaculation from the phallic tip.

Results: After an average follow-up of 20.5 months (range: 2–38), 8 patients have completed the 3 stages of the process with the implantation of an inflatable penile prosthesis. Acute arterial thrombosis at the level of the saphenous graft had occurred in one patient (6%). Although immediate exploration of the anastomosis and thrombolysis allowed to save the phallus, delayed necrosis of its distal third occurred, and therefore the patient required delayed salvage phalloplasty with an anterolateral thigh flap. Fistulas occurred in 5 patients (31%), typically at the junction between the penile and phallic urethra, and were all repaired during stage 2. Of the patients who have already undergone penile prosthesis implantation, 2 have required revision surgery due to mechanical failure of the device (24%) and 3 are engaging in penetrative sex (37%).

Conclusions: Although complication rates are higher than in patients who underwent penile amputation because a competent epigastric artery is frequently missing and the proximal reconstructed urethra has a poor blood supply, RAFF phalloplasty still represents the solution of choice in patients with BEME.

Disclosure:

Work supported by industry: no.

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PENILE AUGMENTATION SURGERY USING ACCELLULAR DERMAL MATRIX ALLOGRAFT

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Objective: Many grafts have been used for penile augmentation surgery. There may be a difference in effects and onset of complications according to the grafts as well as in the surgical technique. In the past, autologous dermal-fat has traditionally been used for the surgery, but an allograft is sometimes used these days. Recently, the safety of allograft has been improved and surgical techniques have been developed. This paper aims to report the clinical results of penile augmentation surgery using allograft.

Material and Methods: Acellular dermal matrix (AllodermTM, MegadermTM, CGdermTM) was mainly used for allograft surgery. The thickness of the augmented graft was about 2.3–5 mm. The material was designed 3–4 cm in width and 6–7 cm in length along the penile axis according to the size of the penis and then grafted. In the penile skin of the dorsal area, 1–2 cm from the subglans was incised at a length of 3 to 5 cm in a transverse direction with depth sufficient to expose the Buck's fascia and was then dissected up to the prepubic junction. Thereafter, enhancement tissue was placed between the dartos fascia and Buck's fascia and fixed to the Buck's fascia. In order for the graft

surgery to succeed and thereby enhance augmentation, multiple slits or separations were conducted between grafts.

Results: The surgery was conducted on 97 patients who had small penile complexes from March 2011 to January 2012. The average augmented effect in circumference was 33.6%. As for complications, wound problem cases occurred in 3 cases. There were temporal symptoms of curvature of the penis after surgery, but there was recovery. Such complications were not as frequent compared to those of autologous dermal-fat grafts.

Conclusions: Compared with the autologous dermal-fat grafts that have been used many times to date for penile augmentation, the acellular dermal matrix allograft showed positive results in terms of safety and surgical effectiveness. In that sense, it is regarded to be a safe method for penile augmentation surgery.

Disclosure:

Work supported by industry: no.

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EARLY OPERATIVE EXPERIENCE WITH THE AMERICAN MEDICAL SYSTEMS CONCEAL® RESERVOIR

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Objectives: The American Medical Systems Conceal® reservoir for inflatable penile prostheses (IPP) is a flat low profile reservoir that can be placed retropubically or ectopically depending on the needs of the patient. Herein, we describe our initial experience with primary implantation of the Conceal® reservoir.

Materials and Methods: We retrospectively identified patients who have undergone primary implantation of IPPs with the Conceal® reservoir from 2010 to March 2012. Sixty-five patients met study criteria. Four techniques were utilized for reservoir placement depending on surgeon preference and patient anatomy: 1) traditional retropubic placement through the external ring, 2) beneath Scarpa's fascia, 3) under the rectus muscle through a separate midline incision and 4) through the external inguinal ring over transversalis fascia. Data were collected on surgical technique for reservoir placement, operative time, estimated blood loss (EBL), complications and postoperative results.

Results: Of the 65 patients, 61.5% (40/65) had traditional placement, 13.8% (9/65) had placement beneath Scarpa's, 20.0% (13/65) under rectus, and 4.6% (3/65) through ring/over transversalis. There was no significant difference in EBL between the groups. However, the mean operative time to place the reservoir beneath the rectus (136.8 ± 21.22 minutes) was significantly longer ($p < 0.05$) than for other techniques. At a median follow up of 101 days (range 31–479) there were 4 reservoir related complications, none requiring surgical revision. One patient who underwent traditional placement had herniation of the reservoir into the inguinal region. The patient did not desire revision; the IPP functioned well. In 3 patients, the reservoir was palpable on examination. Two had the reservoir placed beneath Scarpa's fascia and one placed through the external inguinal ring/over transversalis. None of these patients expressed discomfort or concern for aesthetic appearance, and the IPPs functioned well.

Conclusions: We conclude that Conceal® reservoir can be placed safely using standard techniques for reservoir implantation, but placement of the reservoir through a separate midline incision will increase operative time. In addition, patients undergoing ectopic placement should be informed preoperatively that they may be able to palpate the reservoir postoperatively.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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REVIEW OF PENILE PROSTHETIC RESERVOIR: COMPLICATIONS AND PRESENTATION OF A MODIFIED RESERVOIR PLACEMENT TECHNIQUE

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Introduction: Multiple modifications have been made to the inflatable penile prosthesis (IPP) since its inception in the 1970s. These modifications have made reservoir-related mechanical malfunctions highly unlikely in current IPP models. Although these complications are rare, it would be incumbent upon the implanting surgeon to be aware of these potential complications, how they present, how they are best treated, and how to prevent them from occurring.

Objectives: To present our experience with complications associated with penile prosthesis reservoirs, perform a review of the literature regarding reservoir-related complications, and present our modified technique to place the reservoir into the space of Retzius.

Materials and Methods: We retrospectively reviewed our experience with penile prosthesis reservoir complications or procedures requiring an alternative implantation approach at our center over the past ten years where over 400 devices were implanted. We also review reservoir-related complications published in the English literature since the 1980s.

Results: While exceedingly rare, reservoir complications do occur. Six cases from our institution are presented including one reservoir herniation, one postoperative direct inguinal hernia, one bladder laceration during revision surgery, one ectopic reservoir placement due to morbid obesity, one iliac vein compression syndrome, and one vascular laceration during reservoir revision. Reported reservoir complications include inguinal herniation, erosion into the bladder or bowel, intraperitoneal reservoir placement with subsequent injury to the ureter or bowel, vascular injury, autoinflation, and infection.

Conclusion: Penile prosthesis reservoirs rarely fail mechanically but are associated with a variety of complications or may require alternate implantation technique. In our experience the Jorgensen scissors technique allows safe entry into the space of Retzius with diminished risk of hernia as well as vascular, bladder, or bowel injury.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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MANUFACTURERS DATA BASES YIELD INTERESTING DEMOGRAPHICS OF PENILE PROSTHESIS USAGE

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Objectives: We review modern trends of global penile prosthesis usage in regard to geography, volume implanted, surgical approach, erectile dysfunction (ED) etiology and measured corporal/cylinder size.

Material and Methods: This was a blinded retrospective review of the two major manufacturers' databases. Coloplast data was available on 19,039 first time implants performed between 1/2005–2/2011. American Medical Systems (AMS) implants numbered 39,430 between 1/2006–12/2010.

Results: Penile implant surgery increased annually by an average of 8% between 2005 and 2011. The highest surgical volume occurred in the US (81%) >>> Germany (2%) > United Kingdom > Italy > Spain > Canada > South Korea > Holland for countries in which at least 500 total implants were performed. 81% of implants utilized the penoscrotal approach. In the US inflatable implants were used 94% versus 76% outside of the US. Etiologies for ED listed were "organic" (23%),

prostatectomy (21%), diabetes (15%), vascular disease (15%) Peyronie's Disease (7%), radical pelvic surgery (3%), spinal cord injury (1%), other (5%), and unknown (29%). A yearly incremental, statistically significant increase in mean implant size was noted from 2006: 19.4 cm to 2010: 19.7 cm ($p < 0.0001$) for AMS implants. For Coloplast implants, device lengths implanted increased from 19.4 to 20.3 cm secondary to significantly decreased usage of 16 cm cylinders and increased usage of 20 and 22 cm cylinders. Mean measurement difference of corpora for AMS was insignificant and finding corporal disparity (≥ 1 cm) was $< 5\%$ in the Coloplast database. Patients with Peyronie's disease or a radical surgery history had statistically meaningful shorter corporal measurements (> 5 mms loss of length).

Conclusions: This massive amount of data indicates penile implantation frequency continues to rise yearly in the USA. Most implants are placed penoscrotally and the usual diagnosis is organic or post-prostatectomy ED. Average implanted device length rose over the study period. Radical pelvic surgery and Peyronie's disease result in shorter corporal measurements when compared to other etiologies of ED.

Disclosure:

Work supported by industry: yes, by AMS & Coloplast (industry funding only - investigator initiated and executed study). The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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THE USE OF PELVICOL IN PENILE AUGMENTATION IN KSA

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Introduction: Requests for penile girth enhancement in patients with a small size penis (SSP) is not uncommon in andrology clinics; many synthetic and natural materials such as fat, gels and dermis have been used but morbidity is high and patient satisfaction low. Pelvicol (Bard) acellular collagen matrix is used successfully in the fields of reconstructive and penile surgery and this study assesses the its use in penile girth enhancement.

Materials & Methods: Between June to December 2011, 18 patients were subjected to penile augmentation with Pelvicol. The mean age was 24 yrs (range 19–38) and mean penile circumference was 9.2 cm (range 7–13 cm) They were randomly divided into 2 groups: the first group of 10 patients had a 8 x 12 cm Pelvicol sheet inserted through a V-Y suprapubic incision and wrapped around the shaft in a bilayer under the Dartos but not covering the urethra. The second group of 8 patients had the 8 x 12 cm Pelvicol inserted through subcoronal degloving incision and placed in one layer fashion.

Results: The mean increase in circumference was 2.8 cm (2–3, 2 cm) in group 1 and 1.7 cm (1, 2–2 cm) in group 2. The patient satisfaction was: Group 1 - highly satisfied 2 (20%), moderately satisfied 4 (40%), unsatisfied 4 (40%).

Group 2- moderately satisfied 3 (37,5%), unsatisfied 5 (62,5%).

Complications were common in both groups with 5 patients in group 1 and 3 patients in group 2 developing severe penile oedema and ischaemic shaft ulcers. Removal of the graft was needed in 2 patients in each group.

Conclusion: this pilot study shows that Pelvicol is not an ideal option for penile girth enhancement and the method of placement did not influence the result.

Disclosure:

Work supported by industry: no.

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UPDATE ON COMPARISON OF CONCEAL (TM) VERSUS REGULAR SUB-SCARPA'S FASCIA RESERVOIR PLACEMENT FOR HIGH-RISK PATIENTS RECEIVING INFLATABLE PENILE PROSTHESIS IMPLANTATION

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Introduction: Placement of an inflatable penile prosthesis (IPP) reservoir in a patient with multiple lower abdominal/pelvic surgeries is a challenge. The Conceal^(TM) Low Profile Reservoir is a new one-size-fits-all designed for ease of placement, volume flexibility and eliminating the need to size the reservoir.

Objective: This study is to compare the sub-Scarpa's fascia (SSF) placement of Conceal versus regular reservoir in high-risk patients.

Material and Methods: Following IRB approval, prospective IPP database was reviewed. The 3-piece IPP implantation was performed through either a penoscrotal or an infrapubic incision with SSF placement of either a Conceal^(TM) or regular reservoir. During placement of reservoir, the rectus fascia or the external oblique aponeurosis/muscle at the external inguinal ring was identified. A space was created in the SSF towards the ipsilateral shoulder in either the right or the left lower abdomen for the reservoir placement.

Results: From January 2007 to March, 2012 a total of 42 patients received SSF reservoir placement: 16 regular reservoirs and 26 Conceal reservoirs at a single institution. Etiology for ED and reasons for SSF placement include: 2 each with severe pelvic trauma with multiple lower abdominal surgeries and post radical prostatectomy with severe obesity; 3 pelvic sarcoma surgeries; 5 salvage radical prostatectomy after XRT and 30 post radical cystectomy. Mean age was 55 years (range 39–72) and mean duration of follow-up was 6 months (range 2–24). No patient complained of discomfort at reservoir area or reported auto-inflation on follow up. The palpable reservoirs were seen in 5 patients who received regular reservoirs, but none in patients with Conceal reservoir.

Conclusion: Both regular and Conceal SSF reservoir placements are a safe and effective in high-risk patients. However, the conceal reservoir is cosmetically more acceptable.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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A STUDY OF DEEP DORSAL VEIN BY 3D-CT CAVERNOSOGRAPHY FROM A VIEW POINT OF PENILE REVASCULARIZATION SURGERY

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Objective: The deep dorsal vein (DDV) of the penis have been paid attention in the surgical treatment of erectile dysfunction (ED). Specifically, ligation of the deep dorsal vein for the treatment of venous ED, and DDVA for arterial ED. At present, since the introduction of PDE5-inhibitors, the need for such operations has diminished. Meanwhile, imaging technology has developed remarkably. DICC has developed into high-resolution three-dimensional imaging. We evaluated the DDV utilizing this newly developed DICC technology with regard to the surgical treatment of ED.

Material and Method: Study subjects were 128 ED patients. Cavernosography was performed using a multi-slice CT scan system while maintaining 90 mmHg of intracavernous pressure. 3D images were reconstructed using industry standard software. For the purpose of this

study, we used the maximum intensity projection (MIP) image of the deep dorsal vein as a substitute for conventional cavernosography.

Results: The deep dorsal vein was the most frequently visualized by both modes of imaging. In all cases, 3D-CT revealed the leak site via the deep dorsal more precisely. However, detection was impossible through MIP imaging. In 3D-CT cavernosography, the deep dorsal veins of 101 cases (79%) were filled with contrast medium. 20 (16%) out of the 101 cases had actual deep dorsal vein leakage. 43 (39%) showed the narrowing of the diameter of the deep dorsal vein at the base of the penis, and 38 (30%) showed complete blockage.

Conclusion: Arterio-arterial anastomosis is ideal for penile revascularization surgery. However, arterio-arterial surgery is sometimes made difficult by the narrowing or occlusion of the penile artery. So, there are currently various patterns of DDVA. In visualizing the DDV, especially visualization at the base of the penis, 3D-CT cavernosography is useful. We believe that only 3D-CT cavernosography is appropriate to be used in the diagnosis of candidates for surgery. Venous surgery and penile arterialization surgery using DDV should be tailor-made to the specific and individual characteristics of a patient's DDV.

Disclosure:

Work supported by industry: no.

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TOLERABILITY AND EFFICACY OF NEWLY DEVELOPED PENILE INJECTION OF CROSS-LINKED DEXTRAN AND POLYMETHYLMETHACRYLATE MIXTURE ON PENILE ENHANCEMENT: 1-YEAR FOLLOW-UP

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Objective: Cross-linked dextran and polymethylmethacrylate (PMMA) mixture (Lipen-10®) is a newly developed tissue filler for soft tissue augmentation. The purpose of this study was to evaluate efficacy and tolerability of cross-linked dextran and PMMA mixture on penile enhancement.

Materials and Methods: A total 20 adult males who wanted penile enhancement were enrolled at 2 centers. Mean patients age were 44.4years(20–70). Lipen-10® was injected into the subcutaneous tissue of the penile shaft, between Dartos fascia and Buck's fascia, using the fanning technique. The penile girth and length were measured with a caliper in the flaccid state, before and 3, 6 and 12 months after the injection. Any adverse events were also recorded during the trial.

Results: Mean injected volume of Lipen-10® was 23.73 ml (range 17 to 30 ml). The circumference increased by 3.7 cm (50.5 %, p < 0.0001) at penile base, 4.2 cm (59.2 %, p < 0.001) at mid-shaft, and 3.8 ± 1.0 cm (53.8 %, p < 0.0001) at distal shaft, and the length by 3.0 cm (83.3 %, p < 0.001). There was no significant difference in 3 circumferences between 6 and 12 months post-treatment (p-values of 0.796, 0.498, and 0.6 for penile base, mid-shaft and distal shaft, respectively). A 5 mm-sized palpable nodule on penile shaft and a mild asymmetry of penile shape were observed as complication. There were no clinically significant adverse events in all subjects.

Conclusions: Penile injection of cross-linked dextran and PMMA mixture led to a significant increase in penile size, showed a good durability, and was well tolerated, without serious adverse events. These results suggest that penile injection of cross-linked dextran and PMMA mixture may be a new effective method for penile enhancement.

Disclosure:

Work supported by industry: no.

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INTERNAL CORRECTION OF PEYRONIE'S PLAQUE DURING INFLATABLE PENILE PROSTHESIS PLACEMENT: A VIABLE ALTERNATIVE

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Objective(s): To describe a unique approach to correct Peyronie's defects encountered during inflatable penile prosthesis (IPP) placement.

Material and Method(s): Retrospective review of 234 patients (1/10–3/12) with simultaneous modification of Peyronie's curvature during implantation of IPP. All IPP were Coloplast Titan; all implanted by one surgeon. All patients were first-time (virgin) implants with intra corporal fracture/incision of plaque conducted before IPP cylinders placed. Immediately before surgery, patients received pseudo-erection by injecting lidocaine/saline that identified penile abnormalities. Infrapubic incision employed and limited mechanical dilation conducted (only Furlow passage with or without 12 mm Hegar). Insert long nasal speculum into affected corpora; spread to fracture plaque laterally. Linear releasing "incisions" can be made with either a #12 blade or a Metzenbaum scissors (depending on surgeon comfort level). After plaque disruption, IPP components are implanted.

Result(s): Plaque incision with concomitant IPP was performed in n = 234 virgin patients with mean age 65.5 yrs (range 35–84 yrs). Mean cylinder length 18.7 cm (range 12–24 cm). Technique was utilized on all penile curvatures (range 25°–120°) and all cases were corrected to < 20°. No patients experienced infection, neural injury or sensory loss. Correction was durable over time as no patients required adjunctive modelling to achieve better curve resolution.

Conclusion(s): This technique to disrupt Peyronie's plaque during penile prosthesis implantation is quick and efficacious with minimal complications. Post-operative outcomes mirror clinical literature of other Peyronie's correction options performed in association with IPP.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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CHANGES IN METHODOLOGY AND OUTCOMES OF DISTAL CORPOROPLASTY

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Objective(s): As implant patients age, we've experienced increased cases of penile prosthesis lateral extrusion, which represents an uncommon, yet distressing problem. Previously, tertiary centers utilized the distal corporoplasty (Mulcahy) to correct this prosthetic defect. A similar, yet novel advancement to the approach was utilized in 22 patients. Recent publications regarding potential effect of biofilm on revision implants (Wilson, et al) questions whether the entire implant should be exchanged at the time of corporoplasty.

Material and Method(s): Retrospective review of 22 distal corporoplasty patients (1/10–3/12). Procedure: Hemi-circumcising subcoronal incision. Lateral corporotomy is made proximally over the cylinder, exposing the cylinder, allowing it to be retracted proximally. The back wall of the capsule is incised transversely. Using Metzenbaum scissors, a new plane of dissection is developed (distally) through spongy tissue, behind the sheath to the glans. The cylinder is introduced into the new cavity. Close the defect and any redundant tunica tissue with imbricating 3-0 PDS sutures.

Result(s): Corporoplasty cylinders included: Alpha-one (7), Titan (6), AMS 700 (6) and Ambicor (3). A satisfactory result was achieved in all 22 patients. No simultaneous procedures were conducted upon these patients. Incidence of infection at the time of the procedure was 0/22, however one patient developed an infection of a previously

placed prosthesis (culture: Corynebacterium Smegmata and implant was removed). Lateral extrusion has not recurred for any patient (13 month mean f/u).

Conclusion(s): The corporoplasty used to repair lateral extrusion of penile prosthesis is safe and efficacious. Consistent with the literature, it appears that with minimal manipulation of the pre-existing implant we avoid activation of the biofilm and preclude the need to exchange the entire implant although more cases should be accrued.

Disclosure:

Work supported by industry: no.

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A RANDOMIZED, DOUBLE-BLINDED, PLACEBO-CONTROLLED STUDY COMPARING THE EFFECTS OF HYPERBARIC OXYGEN THERAPY TO ROOM AIR IN POST-PROSTATECTOMY MEN UNDERGOING PENILE REHABILITATION

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Objective: Penile rehabilitation has become the standard of care to aid the return of erections after radical prostatectomy, however, there is need for improvement regarding patient outcomes. Hyperbaric Oxygen Therapy (HBOT) has been shown to augment wound healing and promote neovascularization, and we hypothesized that the addition of HBOT to medical penile rehabilitation would further improve the erectile function of men taking daily phosphodiesterase-5i (PDE-5i) after radical prostatectomy.

Methods: After IRB and FDA approval, all potent men meeting inclusion criteria undergoing robotic radical prostatectomy at a single site were offered enrollment. Exclusion criteria included adjuvant treatment, non bilateral nerve-sparing surgery, medical comorbidities such as diabetes, or inability to tolerate the hyperbaric chamber or daily PDE-5i. All participants were provided 50 mg sildenafil daily to begin post-op day fifteen and completed the International Index of Erectile Function survey (IIEF) pre- and post-operatively. The design called for 100 patients to be randomized to five or ten daily two-hour dives at 2.2 atmosphere absolute starting post-op week one with either room air (RA) or 100% inspired oxygen (HBOT) in a double-blinded fashion.

Results: To date, 111 men have been enrolled and 34 excluded post enrollment. Of the remaining 77, 50 have completed 12 months of post-operative follow-up and outcomes data are available for 46. Twenty-two received RA and 24 HBOT. There were no differences in age (mean 55 years) or pre-operative erectile function domain of the IIEF (25) between the two groups. At 12 months follow-up, there were no statistically significant differences in the erectile function domain of the IIEF between RA (19) and HBOT (15) groups, and no differences in ability to penetrate or maintain an erection (questions 3 and 4 of the IIEF).

Conclusions: These are interim data only and thus under-powered. In addition, it is possible that the limited follow-up may preclude true assessment of any difference in outcomes between the two groups; however, we continue to accrue participants and extend follow-up. Nevertheless, we feel that this level one evidence, despite thus far showing no difference in treatment, contributes important information to the field of iatrogenic sexual dysfunction.

Disclosure:

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EFFICACY OF SAFETY OF TADALAFIL 5 MG ADMINISTERED ONCE DAILY IN MEN WITH ERECTILE DYSFUNCTION AND LOWER URINARY TRACT SYMPTOMS: COMPARATIVE STUDY BETWEEN METABOLIC SYNDROME PATIENTS AND NON-METABOLIC SYNDROME PATIENTS

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Objective: Metabolic syndrome is one of the key pathogenetic factors for erectile dysfunction (ED) and Lower urinary tract symptoms (LUTS). The aim of this study was to compare the effect of tadalafil 5 mg administered once daily in men with metabolic syndrome (MS) and non-metabolic syndrome (NMS) regarding the treatment effect of the ED and LUTS.

Methods: 60 men who complained of ED and LUTS has participated in this comparative prospective study and were given tadalafil 5 mg once daily for twelve weeks between September 2009 and august 2011. The metabolic syndrome was diagnosed by using the modified NCEP definition with the Asian-specific waist circumference cutoff (>90 cm for men). The International Prostate Symptom Score (IPSS) and the questionnaire information of the International Index of Erectile Function (IIEF) were obtained prior to treatment (V1), 4 weeks (V2) and 12 weeks (V3) after the treatment. To see the improvement of LUTS, the patients whose IPSS was lower than eight were excluded from IPSS results analysis. Differences between MS group and NMS group at different times were calculated with unpaired samples t-test. Between-group differences in change from baseline to 4 and 12 weeks were evaluated with linear mixed model.

Results: In total, 33 patients (55%) were diagnosed as MS according to the modified NCEP definition. There were no statistically significant differences in mean age, and IIEF, IPSS pre-treatment between the two groups. After treatment, IIEF and IPSS showed significant improvement in both group. In MS group, IIEF values were 22.06 ± 11.80 (V1), 32.94 ± 19.6 (V2), and 32.68 ± 20.12 (V3), with significant improvement (V1 vs. V3, p = 0.001) and the IPSS results were 19.38 ± 5.95 (V1), 17.09 ± 7.32 (V2), and 14.82 ± 8.04 (V3), with significant improvement (V1 vs. V3, p = 0.006). However, we found a between-group significant difference from baseline to 12 weeks in the following: (i) IIEF (MS: +10.62, NMS:+21.90, p = 0.015); (ii) IPSS (MS: -5.84, NMS: -4.56, p = 0.036); (iii) IPSS storage scores (MS: -1.35, NMS: -3.70, p = 0.002). Only three patients (5%) of the MS group were reported to suffer the adverse effects, i.e. two patients have experienced facial flushing and one patient had mild chest discomfort.

Conclusions: Treatment using Tadalafil 5 mg once daily was beneficial for both ED and LUTS regardless of the presence of MS. However, metabolic syndrome patients tadalafil 5 mg once daily effects of ED and storage symptom have decreased compared to non-metabolic syndrome patients.

Disclosure:

Work supported by industry: no.

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ADHERENCE TO INITIAL PDE-5 INHIBITOR TREATMENT: RANDOMIZED OPEN-LABEL STUDY COMPARING TADALAFIL ONCE A DAY, TADALAFIL ON DEMAND AND SILDENAFIL CITRATE ON DEMAND IN PATIENTS WITH ERECTILE DYSFUNCTION

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Objective: To compare the impact of initiating treatment with tadalafil once a day (Tad OaD) or tadalafil as needed (Tad PRN) vs. sildenafil citrate PRN (Sil PRN) on time to discontinuation of the randomized treatment in men with erectile dysfunction (ED) who are naive to PDE5 inhibitors.

Materials and Methods: In this multicenter, open-label study (NCT01122264), PDE5 inhibitor-naive men (≥18 years) with ED were randomized (1:1:1 ratio) to receive Tad 5 mg OaD or 10 mg PRN or Sil 50 mg PRN. A 4-week treatment-free run-in-period was followed by 8 weeks on randomized treatment (allowing dose adjustment), and a pragmatic period of 16 weeks, in which patients (pts) were allowed to switch according to efficacy, tolerability and personal preference. Time to discontinuation of initial treatment (any cause) was measured in days from randomization until the day the patient discontinued treatment and estimated using Kaplan-Meier product-limit method. Differences between groups were estimated as hazard ratios (Cox's proportional hazards model). Secondary measures included International Index of Erectile Function (IIEF) Erectile Function (EF) domain score and adverse events (AEs).

Results: 770 pts (mean age 53 yrs) were randomized to Tad OaD (257), PRN (252) and Sil PRN (261). 52.2%, 42% and 66.7% of pts discontinued randomized treatment (Kaplan-Meier estimates). Time to discontinuation (median, days) of randomized treatment was significantly longer for pts randomized to either Tad OaD (130) or PRN (> 168, < 50% discontinued during study period) compared to Sil PRN (67) (hazard ratio [97.3% CI] 0.66 [0.51, 0.85] and 0.49 [0.37, 0.65] respectively; p < 0.001). The main reason for discontinuation was "lack of efficacy (hardness of erection)" (18–21% in all groups), followed by preference for another dosing scheme PRN/OaD (8–11%). No between-group differences were found in IIEF-EF change from baseline to end of randomized treatment (least squares mean (SE): Tad OaD 9.41 (0.38), Tad PRN 9.55 (0.38), Sil PRN 10.04 (0.38); p = 0.359). Three pts (1.2%) in the Tad OaD, four (1.6%) in the Tad PRN, and four (1.5%) in the Sil PRN group discontinued the study due to AEs. The most common AE (≥5% in any group) was headache.

Conclusion: ED patients adhered to initial treatment with tadalafil OaD or PRN significantly longer compared to pts assigned to sildenafil PRN.

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THE EFFECT OF LOW INTENSITY SHOCK WAVES FOR THE TREATMENT OF VARIOUS DEGREES OF ERECTILE DYSFUNCTION SEVERITY: 6-MONTH FOLLOW UP

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Objective: Our aim was to evaluate the overall mid-term efficacy (6 months) of penile Low Intensity Shock Wave therapy (LI-ESWT) in

patients who participated in different studies regardless of ED severity, response to PDE5i, and etiology of ED.

Methods: During the past 30 months we have followed and evaluated the efficacy of LI-ESWT on 124 ED patients who at baseline were either responders or non-responders to PDE5i therapy. For responders evaluation at baseline and at followup was done without PDE5i therapy while for the non-responders evaluation was done under PDE5i therapy. These subjects were mainly cardiovascular and diabetic ED patients and represent various degrees of ED severity. They participated in different trials but all received the same treatment protocol. Follow-up data was collected at 6 months and their follow-up IIEF-ED scores were compared to their baseline scores.

Results: Mean age was $54.6y \pm 10$ years. Based on changes in IIEF-ED Domain scoring, 61% of all males had a significant clinical improvement 6 months after therapy. When sub-dividing them to severe, moderate and mild ED groups, we found that 52, 65 and 79 percent improved respectively according to the newly defined minimal clinical improvement criteria (Rosen et al. ...). Thirty two percent of the mild group reached normalization, while 24% and 15% of the moderate and severe group reached normalization respectively. Of these cardiovascular patients, 50 (40%) were diabetic of which 56% had a significant clinical improvement. Of these- 48%, 56% and 78% improved for severe, moderate and mild ED respectively.

Conclusions: In this study we have demonstrated that applying LI-ESWT directly to the penis has a significant clinical effect for all ED severities, for cardiovascular and diabetic patients as well as for either responders or non-responders to PDE5i therapy. This study requires further follow up in a larger scale of ED population in order to fully evaluate the long term or permanent effect of this treatment modality.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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TREATMENT PATTERNS AND PATIENT CHARACTERISTICS OF MEN INITIATING ALPHA BLOCKER THERAPY FOR BENIGN PROSTATIC HYPERPLASIA WITH OR WITHOUT CO-OCCURRING ERECTILE DYSFUNCTION

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Objectives: This study examines treatment patterns and patient characteristics of men initiating alpha blocker therapy (ABT) for benign prostatic hyperplasia (BPH) with and without co-occurring erectile dysfunction (ED).

Materials and Methods: The 2009 Thomson Reuters MarketScan® Database was used to identify ABT initiators, defined as men ≥ 40 years with continuous medical and pharmacy coverage for 12 months before and after ABT initiation, with no ABT or 5-alpha-reductase inhibitors in the previous year, and with ≥ 1 BPH diagnosis within 1 month before and 6 months after ABT initiation. Co-occurring ED was identified by diagnostic code or PDE5 inhibitor use. We analyzed patient demographics, clinical characteristics, type of ABT (selective or non-selective), persistence (total days from ABT initiation until first 60-day gap or end of follow-up), adherence (percent of men achieving medication possession ratio [MPR] ≥ 0.8), restarting the same ABT after discontinuation, and switching to another BPH medication. T-tests and chi-square tests compared differences at the 5% significance level.

Results: 13,474 men met inclusion criteria with mean age 63.1. Co-occurring ED was seen in 15.5% of the men. Persistence for men with and without ED at 6 months was 112.6 and 111.4 respectively; at 12

months, 176.7 and 177.6 respectively. For selective vs. non-selective ABTs, persistence at 6 months was 110.8 versus 117.3 ($p < 0.01$); at 12 months, 175.9 versus 188.0 ($p < 0.01$). Adherence for men with and without ED at 6 months was 37.2% and 39.1% respectively; at 12 months, 28.9% and 31.4% respectively. Adherence for selective vs. non-selective ABTs at 6 months was 38.1% versus 43.3% ($p < 0.01$); at 12 months, 30.5% versus 34.4% ($p < 0.01$). Two-thirds of BPH patients discontinued ABT in the 12-month period. Among discontinued patients, ABT patterns (restart, switch) at one year were numerically similar across cohorts.

Conclusions: Discontinuation rates were high across all cohorts, with a degree of restarting and switching that did not differ by cohort. Persistence and adherence were independent of ED co-occurrence. While there was statistical significance by selectivity of ABT, the numerical differences were slight, and likely not clinically relevant. There are other factors that might affect adherence and persistence, including baseline BPH symptom severity and change in treatment, such as surgery, which were not available in this claims database. However, consistent with the broader literature on chronic diseases and adherence, men with BPH with or without co-occurring ED are at a high risk of discontinuing ABT. Understanding reasons for ABT discontinuation is necessary.

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A RANDOMIZED, PLACEBO CONTROLLED, DOUBLE BLIND, MULTICENTER THERAPEUTIC EXPLORATORY CLINICAL STUDY FOR THE EVALUATION OF THE EFFICACY AND SAFETY OF AVANAFIL IN THE PATIENTS WITH ERECTILE DYSFUNCTION

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Objective: Avanafil is a newly developed selective PDE5 inhibitor for the treatment of ED. The aim of this exploratory clinical study is to evaluate the efficacy and safety of avanafil in the treatment of ED in Korean men.

Material and Method: 158 patients with ED were participated in a placebo controlled, double blind, multicenter trial and randomized to receive placebo, 50 mg, 100 mg or 200 mg of avanafil for 8 weeks. The primary efficacy variable was the change of IIEF-EF domain score. The secondary efficacy measures included the response to SEP Q2-3, the change of score in IIEF Q3-4, GEAQ and normal erectile function rate (IIEF EF domain score ≥ 26).

Result: The change in EF domain scores of each dosage was statistically significant. In multiple comparisons, all dosage groups except for avanafil 50 mg showed significant difference compared to placebo. In SEP Q2 and Q3, the change in success rate of each dosage group was statistically significant. However, avanafil 50 mg did not show a significant difference compared to placebo. The change in score of IIEF Q3 and Q4 of each dosage group was statistically significant. In multiple comparisons, all dosage groups of avanafil showed significant difference compared to placebo in IIEF Q3. However, only avanafil 200 mg showed significant difference compared to placebo in IIEF Q4. All dosage groups except for avanafil 50 mg showed significant difference compared to placebo in GEAQ. Ratio of

normal erectile function of each dosage was significant, and avanafil 200 mg showed significant difference compared to placebo. Most treatment-emergent adverse event was of mild intensity, recovering spontaneously.

Conclusion: Avanafil at 100 mg and 200 mg was an effective and well tolerated in the treatment for the ED in Korea men.

Disclosure:

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VIAGRA (SILDENAFIL CITRATE) ORDERED VIA THE INTERNET IS RARELY GENUINE

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Objectives: Counterfeit medication is a growing problem, amplified by Internet purchasing. This study assessed the requirement for prescription, cost, origin, and content of medication sold via the Internet and purporting to be the phosphodiesterase type 5 inhibitor Viagra (sildenafil), approved for the treatment of erectile dysfunction.

Material and Methods: Pfizer Global Security monitored top search results for the phrase 'buy Viagra' on the 2 leading Internet search engines in March 2011. Orders were placed from 22 unique websites claiming to sell Viagra manufactured by Pfizer. Tablets received were assessed for chemical composition.

Results: No website examined required a prescription for purchase or a health screening survey; 90% offered illegal "generic Viagra." Cost per tablet ranged from \$3.28–\$33.00. Postal origins of purchases were most commonly Hong Kong (n = 11), the United States (n = 6), and the United Kingdom (n = 2), as well as Canada, China, and India (n = 1 each). Notably, the 4 Internet pharmacies claiming to be Canadian did not ship medication from Canada. Of 22 sample tablets examined, 17 (77%) were counterfeit, 4 (18%) were authentic, and 1 (5%) was an illegal generic. Two of the 6 US shipments contained authentic medication, as did 2/2 of the UK shipments, which were diverted from their original market. The spectral match for the illegal generic sample was < 80% compared with genuine Viagra; counterfeit tablets showed spectral match between 25% and 55% vs genuine Viagra. Counterfeit tablets were analyzed for sildenafil citrate, the active pharmaceutical ingredient (API) of Viagra, and contents varied between 30% and 50% (averaging 35%) of the label claim. Counterfeits lacked product information leaflets and each counterfeit lacked the genuine Viagra formulation.

Conclusions: Internet sites claiming to sell authentic Viagra medication shipped counterfeit medication 77% of the time; counterfeits usually came from non-US addresses and had 30% to 50% (averaging 35%) of the labeled API claim. Caution is warranted when purchasing Viagra via the Internet.

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ONSET OF ACTION OF AVANAFIL, A NEXT-GENERATION PHOSPHODIESTERASE TYPE 5 INHIBITOR, IN MEN WITH MILD TO SEVERE ERECTILE DYSFUNCTION: DATA FROM AN INTEGRATED ANALYSIS OF THE PHASE 2 (TA-05) AND PHASE 3 (TA-301-AND TA-302) STUDIES

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Objective: Avanafil is a rapidly absorbed ($T_{max} = 30-45$ minutes), highly specific PDE5 inhibitor with a relatively short (3–5 hours) half-life. The objective of this study was to evaluate the onset of action of avanafil from an integrated analysis of non-diabetic and diabetic men.

Material/Methods: Avanafil doses were 50 mg (n = 210), 100 mg (n = 343), and 200 mg (n = 338); 337 patients were randomized to placebo. To evaluate successful intercourse (SEP3) by time interval from dosing, individual patient success rates as well as an aggregate of all attempts were analyzed.

Results: Mean age was 56.6 years (range 23–88); 31.2% of patients had severe ED, 31% had a history of diabetes. For all time intervals from dose to attempt, treatment comparisons between each avanafil dose and placebo for intercourse success rate were statistically significant ($P < 0.01$). When data was analyzed by patient success rate and attempt, 61% (113/186) and 60% (237/397) of patients attempting sexual intercourse ≤ 15 minutes of dosing were successful across all doses of avanafil, compared with 46% (25/54) and 28% (34/123; $P < 0.01$) for placebo, respectively. In patients with ≥ 1 attempt ≤ 15 or > 15 minutes of dosing, the overall incidence of treatment-emergent adverse events (TEAEs) were 32% and 34.9%, respectively.

Conclusion: A rapid onset of action (≤ 15 minutes) and low adverse event rate suggests avanafil is well-suited for on-demand treatment of men with mild to severe erectile dysfunction.

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IS THE TADALAFIL EFFECT ON LOWER URINARY TRACT SYMPTOMS (LUTS) RELATED TO SEVERITY OF ERECTILE DYSFUNCTION (ED) AND IS THE TADALAFIL EFFECT ON ED RELATED TO SEVERITY OF LUTS?

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Objective: Lower urinary tract symptoms suggestive of BPH (BPH-LUTS) and ED often co-exist. The aim of this post-hoc integrated analysis was to assess the relationship between the severity of ED or BPH-LUTS and response to tadalafil, a phosphodiesterase type 5 inhibitor, in men with co-existing BPH-LUTS and ED. The impact of prostate size (per PSA) was also assessed.

Material and Methods: Sexually active men with ED from 3 placebo-controlled clinical trials who had a total IPSS ≥ 13 and maximum urinary flow (Qmax) 4 to 15 mL/s were analyzed. Following a 4-week placebo run-in, men were randomized to 12 weeks of double-blinded

therapy with placebo (N = 400) or tadalafil 5 mg (N = 415) once daily. Changes from baseline (randomization) to endpoint (Week 12 or last postbaseline observation) were compared to placebo via analysis of covariance.

Results: Baseline characteristics were generally similar between the placebo and tadalafil groups, including mean age (63.2 and 62.8 years, respectively), PSA (both 1.9 ng/mL), IIEF-EF domain score (16.3 and 15.7, respectively), IPSS (17.4 and 17.7, respectively) and Qmax (10.4 and 10.7 mL/s, respectively). Baseline total IPSS and IIEF EF scores were weakly correlated ($r = -0.09$). IPSS improvements in men with mild, moderate, or severe ED at baseline were statistically significant versus placebo (all $p < 0.05$) and comparable across groups (treatment-by-baseline ED severity interaction $p = 0.672$). IIEF improvements in men with mild-moderate or severe LUTS at baseline were significant versus placebo (both $p < 0.001$) and comparable across groups (treatment-by-baseline LUTS severity interaction $p = 0.706$). Improvements were also significant for both IPSS and IIEF-EF when assessed in men with baseline PSA $<$ or $> = 2$ ng/mL (all $p < 0.01$) and were comparable across the PSA subgroups (treatment-by-baseline PSA interaction $p = 0.116$ for IPSS and $p = 0.321$ for IIEF EF).

Conclusions: Tadalafil 5 mg significantly improved BPH-LUTS independent of ED severity and significantly improved ED independent of BPH-LUTS severity.

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A 6-MONTH PROSPECTIVE OBSERVATIONAL STUDY OF PDE5 INHIBITOR TREATMENT PERSISTENCE AND ADHERENCE IN MIDDLE EASTERN AND NORTH AFRICAN MEN WITH ERECTILE DYSFUNCTION: THE PROMCEED STUDY

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Objectives: To assess treatment persistence and adherence over 6 months to on-demand PDE5 inhibitors among Middle East and North African (MENA) men with ED in a prospective, non-interventional, observational study.

Materials and Methods: Men were ≥ 18 years old with mild, moderate, or severe ED of any etiology (psychogenic, organic, mixed), were PDE5 inhibitor-naïve, and expected to be sexually active in a stable relationship with a female partner. Men took PDE5 inhibitors on-demand, selected per routine clinical practice of the physician, and provided treatment information at baseline and at 1, 3, and 6 months post-enrollment at a physician visit or by telephone or postal questionnaire. Patients were defined as persistent at a follow-up visit if they used ≥ 1 dose of their originally-prescribed PDE5 inhibitor within 4 weeks of the visit. Persistence at 6 months was defined as persistence at all prior follow-up visits. Patients were adherent if they used their most recent dose of originally prescribed PDE5 inhibitor as directed by their physician. Multivariate logistic regression models were used to identify factors ($\alpha = 0.10$) associated with persistence and adherence.

Results: Patients (n = 493) had a mean age of 49.8 years, mean BMI of 29.3, and most (n = 354, 71.8%) were from Saudi Arabia. A majority had moderate (52.6%) or severe (31.5%) ED of mixed (34.8%) or organic (39.6%) etiology. Most patients were treated with tadalafil (69.6%), versus sildenafil (15.4%), or vardenafil (15.0%). At 6 months,

64.9% of patients were treatment-persistent; persistence was highest with tadalafil (68.8%) followed by sildenafil (65.8%) and vardenafil (45.9%). Treatment adherence was 59.6% at 6 months. The overall mean time to non-persistence was 3.1 months. Factors significantly predictive ($p < 0.05$) of persistence at 6 months included age, employment status, and ED severity; those predictive of adherence were age, employment status, and duration of ED. All treatments were efficacious in improving ED. Patients' Erectile Function mean scores improved from moderate to mild and Erection Hardness Score improved from 1.8 at baseline to 3.5 at 6 months.

Conclusions: At 6 months, treatment-persistence was highest with tadalafil, followed by sildenafil. In this study, age, employment status, ED severity, and duration of ED were patient factors associated with persistence and/or adherence to PDE5 inhibitors in MENA men. These results will help physicians identify patients at risk for becoming non-persistent or non-adherent with their on-demand PDE5 inhibitor therapy.

Disclosure:

Work supported by industry: yes, by Eli Lilly and Company, Lilly Research Laboratories, Indianapolis, USA (industry initiated, executed and funded study). The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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EFFECTS OF KOREAN GINSENG BERRY EXTRACT ON SEXUAL FUNCTION IN MEN WITH ERECTILE DYSFUNCTION: A MULTICENTER, PLACEBO-CONTROLLED, DOUBLE-BLIND CLINICAL STUDY

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Objects: Ginseng is beneficial for many aspects of human physiology, including sexual function. In this study, we have evaluated the efficacy and safety of an extract of Ginseng berry, which has a ginsenoside profile distinct from other parts of the plant, on sexual function in men with erectile dysfunction.

Methods: One hundred nineteen men with mild to moderate erectile dysfunction participated in a multicenter, randomized, double-blind, parallel, placebo-controlled clinical study. They were administered 4 tablets of either Standardized Korean Ginseng Berry (SKGB, 350 mg ginseng berry extract per tablet), or placebo, daily, for 8 weeks. Efficacy was assessed with the International index of erectile function (IIEF)-15 and premature ejaculation diagnostic tool (PEDT) and safety markers including hormone and lipid in the blood at the end of the 4th and 8th week.

Results: One hundred eighteen participants completed the entire evaluation in the 8-week study. Their mean age, baseline IIEF-5 score, and erectile dysfunction duration in years were 57.49, 14.36, and 4.67 respectively in the SKGB group, and 57.32, 14.36, and 4.31 respectively in the placebo group. We observed that total IIEF-15 scores increased significantly from 40.95 ± 7.05 to 46.19 ± 12.69 ($P = 0.002$) after 8 weeks of SKGB treatment compared to the placebo ($P > 0.05$) and each of the individual domain scores of IIEF-15 increased significantly in the SKGB by the 8th week ($p < 0.05$). In addition, PEDT scores improved from 9.14 ± 4.57 to 7.97 ± 4.4 and 7.53 ± 4.26 in the SKGB group after 4 and 8 weeks of treatment respectively, showing a statistically significant change ($P < 0.05$).

Conclusions: Oral administration of the standardized Korean ginseng berry extract improved all domains of sexual function, including erection and ejaculation. It can be used as an alternative medicine to improve sexual life in men with sexual dysfunction.

Disclosure:

Work supported by industry: yes, by Amorepacific Corporation (industry funding only - investigator initiated and executed study).

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HYDRODISSECTION FOR IMPROVED MICROSURGICAL DENERVATION OF THE SPERMATIC CORD: PROSPECTIVE RANDOMIZED CONTROL TRIAL IN A RAT MODEL

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Objectives: Microsurgical denervation of the spermatic cord (MDSC) may provide a 70–85% success rate in eliminating pain in patients with chronic orchialgia who have failed conservative treatment options. Failures in MDSC could be due to small diameter nerves (≤ 1 mm) left behind on the arteries and veins in the cord based on previous studies. Our goal was to assess if hydrodissection (HD) of the spermatic cord after MDSC would decrease the number of residual nerve fibers without compromising blood flow.

Materials and Methods: Prospective blinded randomized control trial: bilateral MDSC was performed on 22 adult rats (44 cords). Hydrodissection of the spermatic cord was performed on one side of each rat (side randomized) using the ERBEJET2 (ERBE Inc, Atlanta, GA). The contralateral cord (with no HD) was the control for each animal. Blood flow through the vessels was monitored using a micro Doppler probe. After completion of MDSC with or without HD, the animal was euthanized and a cross section of the residual cord sent to pathology (pathologist blinded to technique) for H&E staining and evaluation for small nerve (≤ 1 mm) density and signs of structural damage.

Results: The cord with HD had a significantly lower total median residual nerve count of 5 (0–10), compared to 8 (2–12) on the non-HD side ($p = 0.007$). No structural damage was seen in the vessels in the cord with HD (gross exam and histology). Blood flow had been maintained in the vessels when the ERBEJET2 was set to 87psi (based on a separate dose titration study on 2 similar rats 4 MDSC procedures).

Conclusion: Hydrodissection of the spermatic cord at 87psi after microsurgical denervation of the spermatic cord significantly decreases residual nerve density without compromising vascular integrity in a rat model.

Disclosure:

Work supported by industry: no.

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TARGETED MICROSURGICAL DENERVATION OF THE SPERMATIC CORD: OUTCOMES OF 378 ROBOTIC ASSISTED CASES

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Objectives: Previous groups have shown microsurgical denervation of the spermatic cord (MDSC) as a possible treatment option for chronic orchialgia. Pathology and anatomical studies have identified specific nerve bundles within the spermatic cord that may be responsible for chronic pain in these men. This study presents outcomes for a robotic assisted targeted MDSC approach (RMDSC) utilizing a mapped nerve protocol to maximize preservation of vessels and lymphatics.

Materials and Methods: This study was a prospective outcomes database study. A five-arm RMDSC technique was developed utilizing the daVinci Si high definition robotic system (Intuitive Surgical, Sunnyvale, CA) with a simultaneous dual 16–18x optical high magnification view (VITOM, Karl Storz Inc, Tuttlingen, Germany). Analysis of 378 RMDSC cases from Oct'08–Apr'12 was performed (median follow up 22 months: 1 to 42). Selection criteria for RMDSC was: chronic testicular pain (>3 months), failed all other standard pain management treatments and negative urologic workup. Pre and post-operative pain was assessed utilizing a standardized externally validated pain assessment tool - PIQ-6 (QualityMetric Inc., Lincoln, RI). Pain scores

where recorded preoperatively and then postoperatively at 1, 3, 6, 9 & 12 months. Microsurgical operative duration was also measured.

Results: 86.5% (327/378) of the patients had a significant decrease in their pain. This was defined as complete elimination of pain (73.8%) or a greater than 50% reduction in pain score (an additional 12.7%) by 6 months post-op. The procedure failed to provide pain relief in 52 patients. Median operative duration was 15 min (5–150). Complications were: 1 testicular ischemia, 9 hematomas, 2 seromas. There were two testicular artery and one vasal injury: these were repaired intra-operatively with robotic assisted microsurgical techniques without any further sequela. The 4th robotic arm allowed the surgeon to control one additional instrument (micro Doppler) leading to less reliance on the microsurgical assistant.

Conclusion: Targeted robotic assisted microsurgical denervation of the spermatic cord is safe and feasible. Longer follow up and further evaluation is warranted. The five-arm robotic approach provides a dual focal length view to the microsurgeon thus improving surgical efficiency (no need to zoom in and out).

Disclosure:

Work supported by industry: no.

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PROSPECTIVE DATABASE COHORT TRIAL OF A NEUROPROTECTIVE WRAP FOR THE SPERMATIC CORD AFTER DENERVATION FOR CHRONIC ORCHIALGIA

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Objectives: Return or persistence of pain after microsurgical denervation of the spermatic cord for chronic orchialgia is quite disappointing for patients. One cause for this phenomenon could be neuroma formation or irritation of the ligated ends of the nerve fibers in the spermatic cord. Neuroprotective wraps have been safely and successfully utilized in peripheral nerve repair procedures to minimize such neuroma or scar formation. This study evaluates the impact of a neuroprotective wrap placed around the spermatic cord after the denervation procedure.

Materials and Methods: Prospective database cohort trial: 6 patients with similar bilateral chronic orchialgia who underwent bilateral robotic assisted microsurgical denervation of the spermatic cord by a single surgeon were selected. A neuroprotective wrap (bio-inert matrix derived from porcine gut: Axoguard, Axogen Inc., Gainesville, FL) was placed around the spermatic cord on one randomly selected side of each patient after completion of the denervation procedure. The contra-lateral side (with no wrap) was the control for each patient. Pain was assessed preoperatively and post-operatively at 1, 3, 6 and 12 months using an externally validated pain impact questionnaire (PIQ-6, QualityMetric Inc, Lincoln, RI). We also evaluated PIQ-6 scores of 98 consecutive patients whose spermatic cord were wrapped after robotic microsurgical denervation procedure.

Results: The median pain scores were less on both sides after surgery compared to pre-op (median pre-op score = 77). Median PIQ-6 scores on the wrap side were: 52, 40, 50 and 59 at 1, 3, 6 and 12 months post-op respectively. The median scores on the non-wrap side were: 59, 56, 60 and 68 respectively. The median pain scores on the side with the wrap were significantly less than the non-wrap side (a score change of 5 is significant: $p = 0.05$).

Conclusion: This study despite its small sample size seems to indicate a possible benefit to using a neuroprotective wrap around the spermatic cord after denervation procedures for chronic orchialgia. Further evaluation is needed.

Disclosure:

Work supported by industry: no.

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NOVEL MICRO-ULTRASOUND PROBE TO IDENTIFY MICROVESSELS IN THE SPERMATIC CORD

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Objectives: Previous studies have shown the benefit of real-time intra-operative audio Doppler identification of testicular arteries during microscopic subinguinal varicocelectomy. This minimizes the risk of inadvertent testicular artery injury. This study evaluates the use of a novel micro-ultrasound probe for the detailed localization of the testicular arteries during such procedures.

Materials and Methods: Prospective database study: A new micro-ultrasound probe (Aloka-Hitachi Ltd., Tokyo, Japan) was utilized to localize the testicular arteries real-time during three robotic assisted sub-inguinal microsurgical varicocelectomy cases. The ultrasound image was fed into the TilePro (Intuitive Surgical, Sunnyvale, CA) surgeon console platform to provide three simultaneous real-time video images to the microsurgeon during the procedure: 1) a 12–15x 3D image via the HD robotic camera, 2) a 16–18x optical high magnification view via the VITOM camera (Karl Storz Inc., Tuttlingen, Germany) and 3) a real time visual ultrasound image from the new micro-ultrasound probe. Localization of the testicular arteries was validated against the current standard - audio Doppler mapping using a micro Doppler probe (Vascular Technology Inc., Nashua, NH).

Results: In all cases, the new ultrasound probe was able to identify all arteries in the spermatic cord (testicular artery & deferential artery). The probe also allowed visualization of small posterior varicose veins (1–2 mm diameter) that are sometimes easy to miss on visual examination. No arteries were missed by the micro-ultrasound probe based on the additional Doppler scanning.

Conclusion: The new micro-ultrasound probe appears to be effective in micro-vessel localization in this preliminary study.

Disclosure:

Work supported by industry: no.

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SIDE EFFECT PROFILE OF LONG-TERM TREATMENT OF ELDERLY HYPOGONADAL MEN WITH TESTOSTERONE UNDECANOATE

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Objectives: Testosterone therapy for hypogonadal men has been used for decades. However, there are still concerns regarding the safety of this treatment, particularly in elderly men. We studied long-term effects of testosterone treatment in elderly hypogonadal men treated with testosterone undecanoate (TU).

Material and Methods: Cumulative registry study of 255 men (mean age 60.6 ± 8.0 years), with testosterone levels ≤ 3.5 ng/ml. They received injections of TU 1000 mg at day 1, week 6 and every 12 weeks for up to 5 years.

Results: Erythropoiesis: haemoglobin increased from 14.44 ± 0.72 to 14.99 ± 0.45 g/dl (p < 0.0001 vs baseline). Haematocrit increased from 43.22 ± 2.84 to 48.78 ± 1.7% (p < 0.0001 vs baseline). Four patients had haematocrit levels > 52% which resolved without intervention. Prostate: PSA increased from 1.77 ± 0.96 to 1.82 ± 0.96 ng/ml (p < 0.0001 vs baseline) with a plateau after 24 months. Prostate volume increased from 28.51 ± 11.2 to 30.23 ± 12.4 ml (p < 0.0001 vs baseline). 3/255 patients were diagnosed with prostate cancer following elevated PSA (<4 ng/mL) at 18 weeks of treatment. Tumour grade was T2 in all three and Gleason score 3 + 3 in two and 3 + 2 in one patient, resp. They all underwent radical prostatectomy. The proportion was 1.18% with an incidence of 30.334 per 10,000 patient years. For comparison: in the PLCO trial with a 7-year follow-up, the proportion of prostate

cancer was 7.35% with an incidence of 116 per 10,000 patient years [1]. – The International Prostate Symptom score (IPSS) improved from 6.73 ± 4.21 to 2.83 ± 1.25 (p < 0.0001). Liver enzymes: aspartate transaminase (AST) decreased from 43.05 ± 17.29 to 20.16 ± 3.21 U/L (p < 0.0001 vs baseline), alanine transaminase (ALT) from 43.89 ± 18.11 to 20.54 ± 3.92 U/L (p < 0.0001 vs baseline).

Conclusion: The incidence of 3/255 patients with prostate cancer does not suggest an increased risk of prostate cancer. Long-term treatment with testosterone undecanoate with proper monitoring is acceptably safe.

Disclosure:

Work supported by industry: yes, by Bayer Pharma AG (industry funding only - investigator initiated and executed study). The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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THE MEDTRONIC ZOTAROLIMUS-ELUTING PERIPHERAL STENT SYSTEM FOR THE TREATMENT OF ERECTILE DYSFUNCTION IN MALES WITH SUB-OPTIMAL RESPONSE TO PDE5 INHIBITORS - 6 MONTH RESULTS

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Objectives: Erectile dysfunction (ED) represents a significant unmet medical need that persists despite the advent of phosphodiesterase type-5 inhibitors (PDE5i) and mechanical devices. Organic ED is largely vasculogenic in origin and has been shown to predate coronary artery disease (CAD) symptoms by approximately three years. In addition up to 75 percent of men with CAD have ED. Prior research evaluating men with ED poorly responsive to PDE5i revealed flow-limiting lesions with 50% blockages in one or both internal pudendal arteries (Rogers, et al. Cath Cardio Interv. 2010). The objective of this study was to evaluate the safety and feasibility of the Medtronic Zotarolimus-Eluting Peripheral Stent System (ZEPS) to improve erectile function in males with a sub-optimal response to PDE5i and atherosclerotic lesions of the internal iliac and/or internal pudendal arteries. Zotarolimus is a cytostatic limus drug minimizing growth of restenotic cells and preserving healthy endothelial cells lining a cobalt chromium stent.

Materials & Methods: Men > 18 years with ED and sub-optimal response to PDE5i with atherosclerotic lesion(s) of the internal iliac and/or internal pudendal arteries were treated unilaterally or bilaterally with ZEPS. Subjects were identified after undergoing a duplex Doppler ultrasound study during pharmacologic induced erection to confirm inflow limitations and exclude venous insufficiency. The target reference vessel diameter was >2.25 mm and <4.20 mm and lesion length <27 mm by visual estimate.

Results: The primary feasibility endpoint for this study is increase in erectile function as measured by the improvement of IIEF EF domain score by ≥4 points. The 3 and 6 month data show that 68.2% and 69.6%, respectively, of the subjects treated per protocol experienced improved erectile function. There were no instances of stent fracture through 6 months and study patients experienced no major adverse events, implying the treatment's short-term safety.

Conclusions: While the early results of this feasibility study are promising, more research is needed to determine whether pelvic artery stenting could become a viable adjunctive treatment option for those with sub-optimal response to PDE5i and vasculogenic ED.

Disclosure:

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COMBINED ACUPOINT THERAPY FOR PATIENTS WITH PELVIC PAIN AND SECONDARY ERECTILE DYSFUNCTION

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Objective(s): The benefits of combining the common acupoints for chronic pelvic pain and sexual dysfunction to treat pain-related sexual dysfunction.

Material and Method(s): Two patients with chronic pelvic pain associated with sexual dysfunction who did not respond to conventional treatment were given a course of acupuncture. They were assessed using Global Pain Score and IIEF-5 before, mid-way and at the end of treatment course of 10 weekly sessions. Sterile single use disposable acupuncture needles of various sizes were used, namely 13 mm x 0.25 mm, 25 mm x 0.25 mm and 40 mm x 0.25 mm.

Each session is scheduled for 30 minutes of acupuncture. After achieving the arrival of Qi at the acupoints, intermittent electrical stimulation at 10 Hz for 15 minutes was applied to various acupoints. Simultaneously, heat application was also applied to various acupoints for 10 minutes. The acupoints used were those from the WHO Standard Acupuncture Point Locations in the Western Pacific Region (2009): namely Ren 3 and 4, Du 4, Spleen 6 and 9, Kidney 3 and 12, Bladder 23 and 52, Large Intestine 4 and 11. These are the common acupoints used to treat male sexual dysfunction and pain.

Result(s): Both patients reported symptoms improvement whilst on acupuncture treatment by 5th session. Both completed 10 sessions. 1 patient pain scored before therapy was 7 out of 10 and reduced to 3 after 10 sessions. 1 patient had pain score of 8 out of 10 before therapy and after 10 sessions, had 0 score and his IIEF-5 improved from an initial total of 8 out of 25 to 20 out of 25 after 10 sessions.

Conclusion(s): Commonly used acupoints for various conditions can be combined to benefit those with pain-related sexual dysfunction when conventional therapy fails.

Disclosure:

Work supported by industry: no.

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THE GLOBAL ONLINE SEXUALITY SURVEY: UTILIZATION TRENDS FOR PHOSPHODIESTERASE INHIBITORS IN USA

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Objectives: The Global Online Sexuality Survey (GOSS) is a worldwide epidemiologic study of sexuality and sexual disorders. The age adjusted prevalence of male and female sexual disorders is estimated around the world, and so are the predisposing risk factors, anatomical variations, sexual preferences and unique habits for each and every culture. GOSS is deployed over the internet to the general population regardless surfing and web search inclinations, the only prerequisite being above 18 years of age. The first reports out of GOSS came from the Middle East, in the year 2010, results of which were published in 2011. This report investigates the trends towards utility of phosphodiesterase inhibitors (PDEi's) in USA and compares it to other cultures.

Material and Methods: GOSS was randomly offered to English-speaking male web surfers in the United States of America between August and October 2011. GOSS was offered via paid advertising on Facebook®.

Result: Participants used phosphodiesterase inhibitors (PDEi's) on more consistent basis in 23.7%, increasing progressively with age. Participants diagnosed with erectile dysfunction (ED) used PDEi's in 37.5%, while those without ED used them in 15.6%; recreational use, the motivation for which was analysed. PDEi's were mostly utilized on prescription basis, and so was the choice for the brand of PDEi. PDEi's were mostly purchased from pharmacies (72.7%), followed by online

purchase (16.5%). However, 5.3% of pharmacy sales of PDEi's were without prescription, and 9.6% of those utilizing PDEi's without prescription happened to have coronary heart disease. Efficacy of PDEi's, experienced and theoretical side effects were also reported, with unrealistic concerns over safety detected.

Conclusion: In the United States of America, as of the year 2011, PDEi's are better accepted than they are in the Middle East. Preference for particular PDEi's over the others is primarily dictated by health care providers. Online and over the counter sales of PDEi's are not uncommon, and can expose a subset of users to health risks. Recreational use of PDEi's is an important entity that needs to be considered by the medical community.

Disclosure:

Work supported by industry: no.

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EARLY EXPERIENCE AND LESSONS LEARNED OF A YOUNG PENILE IMPLANTER

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Objectives: We review the initial one hundred first time penile prosthesis insertions of a single surgeon

Material and Methods: Retrospective chart review was performed of the first 100 penile prosthesis insertions supervised by a single surgeon (TSK) in a teaching center. Cause of ED, device brand and length, operative time, intra-operative complications, drain outputs, and post-operative complications were reviewed. All cases were performed via a peno-scrotal approach, utilized a compressive scrotal dressing, and a short term closed suction drain. Scrotoplasty was performed in all patients with a scrotal web (61%). Ectopic reservoir placement was used when the space of Retzius could not be easily accessed (21%).

Results: Average patient age was 61 years. Cause of ED was radical pelvic surgery (25%), vasculogenic (24%), diabetes (23%), Peyronies disease (20%), radiation (5%), and other (3%). 50 Coloplast and 50 AMS implants were utilized. Average cylinder length was 18.1 cm, average rear tip extender length was 2.8 cm, and average total length was 20.9 cm. Average operative time for implant only was 69 minutes (n = 15). Operative time increased with scrotoplasty by 11 mins (n = 61), ectopic reservoir placement 12 mins (n = 21), and penile modeling by 18 mins (n = 20). Operative time decreased by 21 minutes (30%) after the first year in practice. Average drain output was 86 ml. There were two intraoperative proximal perforations that were treated with rear tip extender slings. Minor wound separation occurred in 12% of which ¾ had undergone scrotoplasty. 10/12 of these patients did well with observation (n = 8) or a stitch placed in the clinic (n = 2). 6 patients required a second IPP related procedure/revision: 3 explants (1 infection after clinic stitch and 2 distal perforations), 3 mechanical (device failure, reservoir migration, pump malposition). Other complications were urinary retention (4%) and delayed hematoma (2%).

Conclusions: Our contemporary series is illustrative of the learning curve of an academic surgeon. Operative times and complications decreased dramatically with experience and changes in operative technique. Drain outputs were surprisingly high despite compressive dressings.

Disclosure:

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THE MISSING DISCOURSE OF FEMALE MASTURBATION

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The gender gap between many sexual behaviors is diminishing, yet gender differences in masturbation persist. This study researched how

young women learn and feel about masturbation and examined the missing discourse on female masturbation. Utilizing semi-structured qualitative interviews conducted over instant messaging programs, the interview guide included questions pertaining to masturbation information and masturbatory behaviors. Participants were women between 18–24 years old and predominately lived within the Southwestern United States. Data analysis showed women learned about masturbation during preadolescent ages through peers' sexual jokes, books, pornography, the Internet, and/or self-exploration. Feeling uncertain if masturbating was "normal" led to negative feelings and participants also noted a sexual gendered double standard with masturbation. Masturbation is a natural, pleasurable sexual behavior where the silence and stigma surrounding it creates a missing discourse of female masturbation. To normalize masturbation, a positive discourse must be established to empower female sexual agency and pleasure.

Disclosure:

Work supported by industry: no.

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A CASE OF POST-COITAL GROSS HEMATURIA ASSOCIATED WITH BLADDER NECK POLYP: USEFULNESS OF DOPPLER TRANSRECTAL ULTRASONOGRAPHY

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Objective: Post-coital hematuria is a symptom to be rarely experienced. It is often confused with hematospermia, and the cause of the disease is not often identified. Due to the rarity of the disease, standardization in the diagnosis and treatment are lacking. We experienced a post-coital gross hematuria associated with hyperplastic polyp diagnosed by Doppler transrectal ultrasonography (TRUS).

Material and Method: A 42-year-old man presented to our office having experienced post-coital gross hematuria for two years. Although the patient has had a series of urological examinations, the cause of hematuria has not been specified in the other hospitals. We had him do masturbation under Doppler TRUS observation.

Result: Doppler TRUS revealed that blood flow increased in his prostate and that bleeding from bladder neck was observed at several times just before an ejaculation, suggesting that bleeding was originated from bladder neck. We also found a small polyp with coagulation clot in the bladder neck by urethroscopy just after a masturbation. The patient had transurethral resection of the polyp. The post-coital gross hematuria improved after the operation.

Conclusion: We determined the origin of post-coital gross hematuria by Doppler TRUS under masturbation. Doppler TRUS might be an useful diagnostic tool for this disease. Transurethral resection of bladder neck polyp might be a good procedure for patients with post-coital hematuria associated with hyperplastic polyp.

Disclosure:

Work supported by industry: no.

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THE EFFECT OF DAILY EJACULATION ON SEMEN PARAMETERS AND SPERM DNA DAMAGE IN NORMAL MEN

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Objective: Poor semen quality and sperm DNA damage have been associated with deleterious effects on male reproductive potential, including decreased fertility rates and increased rates of miscarriage. Although increased days of abstinence may have a negative effect on semen quality, the effects of increased frequency of ejaculation on semen quality have not been extensively studied. Here we assessed the

effects of 14 days of daily ejaculation on standard semen parameters and sperm DNA damage in normal men.

Design: Prospective study with subject as his own control.

Materials and Methods: Nineteen healthy men, without history of smoking or infertility and mean age 25, underwent daily ejaculations for 14 consecutive days after a 3–5 day abstinence period. Semen samples were collected on Days 1, 3, 7 and 14. Standard semen parameters were assessed as well as: 1) DNA fragmentation index (DFI) and high DNA stainability (HDS) using flow cytometry/acridine orange (SDFA) test, and 2) reactive oxygen species damage, oxidative stress adduct (OSA) test.

Results: All 19 men began the study with normal standard semen parameters. Semen volume for all time points and total motile count for days 3, 7 and 14 decreased with respect to day 1 ($p < 0.001$). There was a significant increase in DFI and OSA on Day 14 compared to Day 1 ($p < 0.05$). No significant changes were observed in other parameters including: motility, morphology and HDS. Two of the 7 men with DFI's above 15%, showed 40% and 48% reduction (improvement) in DFI by day 14.

Conclusions: This study represents one of the most extensive examinations of parameters of semen health with daily ejaculation in normal men. Daily ejaculation for up to 14 days produced expected reductions in semen volume and total motile concentration. There was a significant worsening of parameters of semen health including DNA integrity and end damage from reactive oxygen species although these differences may be of minimal clinical relevance in this healthy population. Future studies will focus on oligospermic men with sperm with high DNA damage and the effects of frequent ejaculation.

Disclosure:

Work supported by industry: yes, by ReproSource Fertility Diagnostics (industry funding only - investigator initiated and executed study).

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FORMICOPHILIA: A CASE REPORT AND LITERATURE REVIEW

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Objective: Assess an uncommon case of zoophilia (formicophilia) of a 53 years old single man, with primary school education, catholic, coming from rural areas.

Material and Method: Patient (JCC) case report with discussion, correlating theory and therapy administered.

Results: Patient relates that at age 14, he observed an ice cream stick covered with ants. He had been curious about how it would be if your penis was in place of the stick. Then this practice was initiated, giving him excitement and sometimes orgasm. Despite not having completed elementary school, the patient does not have intellectual deficits. Retired, he serves as a secretary in the church and has good social and familial relationship, being adapted to the social environment. He also refers attraction and sex practice with dogs and goats, and he has even been licked and penetrated by a dog. These behaviors regressed in 2005. The practices persist with ants, especially those known in our midst as fire ant (genus - *Solenopsis*), that build large anthills and whose sting is particularly painful. As he lives far from the attention center, he was unable to undergo psychotherapy weekly, but only to psychiatric consultations monthly with focus on sexual counseling. He received paroxetine 20 mg/day, which reduced the zoophilic symptoms. During the treatment, the dose administered ranged according to the higher or lower symptoms degree and also due to adverse events such as nausea and sleepiness. Six months ago, divalproex sodium (250 mg/day) was associated with paroxetine, which provides higher stability to control the symptoms.

Conclusion: Drug treatment associated to a warm therapeutic environment was only partially satisfactory to control formicophilic symptoms, suggesting that it can not dispense other types of monitoring, for example psychotherapy.

Disclosure:

Work supported by industry: no.

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MULTIPHOTON LASER IMAGING AND ABLATION OF RAT AND HUMAN SPERMATIC CORD NERVES FOR THE TREATMENT OF CHRONIC ORCHIALGIA

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Objectives: We used multiphoton microscopy (MPM), a novel laser imaging technology, to identify and selectively ablate the spermatic cord nerves in the rat. We studied MPM as both a single modality, and as an augmentation to microsurgical denervation of spermatic cord (MDSC) for nerve ablation in a rodent model. We also imaged and ablated human spermatic cord nerves.

Material and Methods: We performed MDSC of 10 adult male Sprague-Dawley rats. Of the 10 rats, we performed MPM imaging and ablation of any remaining nerves in 5 rats. We determined the precision of nerve ablation, preservation of surrounding structures and efficacy of this intervention (all nerves ablated) with histologic analysis. We also imaged and ablated nerves in 3 human spermatic cords from ex vivo radical orchiectomy specimens.

Results: Following MDSC on 10 spermatic cords, we identified 6 (IQR 0–18.75) intact nerves on histology. When we used MDSC in combination with MPM imaging, we identified 2 (IQR 1.25–2.75) nerves. Following, MPM laser ablation of the nerves, we saw 0 (IQR 0–1.75) intact nerves on histology. The efficacy of nerve destruction with MDSC vs. MDSC + MPM laser ablation was 75% vs. 100% ($p = .03$). MPM imaging of human spermatic cords demonstrated 22 nerves. The median diameter of identified nerves was 400 μm and time of ablation of all nerves was 45 minutes.

Conclusions: MPM can identify and ablate nerves selectively *in vivo* in the rat following MDSC. MPM can potentially be used for spermatic cord denervation for the treatment of chronic orchialgia, and could be used to augment the efficacy of MDSC.

Disclosure:

Work supported by industry: no.

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EFFICACY AND SAFETY OF VIBERECT® VIBRATORY DEVICE IN COMPARISON TO INTRACAVERNOSAL PGE-1 FOR INDUCING ERECTION IN MEN WITH ERECTILE DYSFUNCTION - AN OBJECTIVE EVALUATION BY PENILE DUPLEX DOPPLER BLOOD FLOW ANALYSIS

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Introduction: Penile erection is a neurovascular event. Genital afferents activate spinal nuclei and higher centers responsible for sexual function. Viberect® is a new FDA-cleared medical device for inducing penile erection and treating an ejaculation in spinal cord injured men. We report a comparative evaluation of blood flow measurements in men with Peyronie's disease (PD) with or without erectile dysfunction (ED) by Viberect® (a non-invasive tool) versus the well-established intracavernosal injection (ICI) of PGE-1 using color duplex Doppler ultrasound (CDDU) technology.

Patients and Methods: Eighteen PD patients with or without ED were first instructed to properly pre-stretch the penis and correctly use the Viberect®. Viberect® stimulation was performed by the patient at 70–100 Hz for 10 minutes prior to performing CDDU as per standard

protocol. The patient was then rested until the penis was fully flaccid. An ICI of PGE1 at a dose of 7–15 mcg was administered and CDDU repeated. Settings and visual sexual stimulation were similar for both CDDU evaluations.

Results: Six men showed similar peak systolic velocity measurements (mean \pm SEM of 56.0 \pm 9.0 cm/sec with Viberect® and 59.6 \pm 5.0 cm/sec with PGE1 and Chi-square value of 0.05 ($P = 0.999$)) and erection responses (90% tumescence and 60 to 70 % rigidity) for both CDDU evaluations. Eight patients showed borderline peak systolic velocity of 27.3 \pm 2.9 cm/sec and 80% tumescence and 30% rigidity with Viberect® and good results (54.5 \pm 4.2 cm/sec) with PGE1 with Chi-square value of 13.6 ($p = 0.06$). Four patients (called “non-responders” to Viberect®) showed peak systolic velocity of 15.5 \pm 3.2 cm/sec with Viberect® and no erection response, although showed good velocity (53.2 \pm 6.4 cm/sec) and 90% tumescence and 60% rigidity with PGE1 and Chi-square value of 26.7 ($p > 0.01$). This suggests that Viberect can induce blood flow responses and mimic results as seen with standard ICI in majority of patients undergoing CDDU and only non-responders show significantly different peak systolic values. No complaints or adverse events were reported with Viberect® and two patients reported impending ejaculation. **Conclusions:** This preliminary study favors Viberect® that stimulates bulbocavernosus reflex over routine ICI as a safe, convenient, well-tolerated modality for diagnostic purposes. Randomized prospective multicenter trials will be needed to further validate these results and the concept of stimulating bulbocavernosus reflex with Viberect® for ED diagnosis and treatment.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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A NEW SURGICAL METHOD FOR THE CORRECTION OF CONGENITAL PENILE CURVATURE BASED ON GEOMETRIC PRINCIPLES AND SUPERFICIAL TUNICA ALBUGINEA EXCISIONS

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Objective: Congenital penile curvature can have detrimental effects on the life of patients. Surgical correction of a congenital penile deviation is associated with several side effects such as loss of penile length and formation of “dog ears”. We report our experience with a new technique for the correction of congenital penile curvature based on geometric principles.

Patients and Methods: Between January 2006 and March 2011, 211 men with congenital penile curvature underwent our modified Nesbit technique. The technique consists of an objectivation of the degree of curvature and distribution of the bending force by multiple, small, superficial, elliptical excisions of the tunica albuginea.

Results: Overall success rate was 99.1%. Residual curvature of less than 20 degrees was reported in 5% ($n = 11$) of the cases, none of those patients opted for further surgical correction. Residual curvature of up to 30 degrees was observed in 0.9% ($n = 2$), these patients underwent a re-operation. It was clearly shown, that the acquisition or the recovery of the ability to perform sexual intercourse brought major relief and high rates of satisfaction and self-esteem. No recurrence of a ventral curvature occurred.

Conclusion: Our modified Nesbit technique, consisting of superficial tunica albuginea excision according to the geometric principles of the Egidio technique leads to rapid and excellent results due to an objectification of the curvature. It is a safe and valid alternative for the treatment of congenital ventral or ventro-lateral penile deviation.

Disclosure:

Work supported by industry: no.

208

TRUE PENILE AUGMENTATION - PRELIMINARY REPORT

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Objectives: Penile augmentation surgery might be necessary for some patient with micro-penis and those whom are victim of penile trauma-tism although it is controversial. Among varied methods either a true girth expansion or a length increase of the corpora cavernosa is in paucity so far, herein we report a method with a true augmentation. **Materials and Methods:** From March 2010 to Nov 2011 5 males, aged at 50, 33, 25 29 and 23 respectively, with micro penis or ventral curvature associated with erectile dysfunction underwent our varied methods of penile augmentation with autologous tissues. It entailed a careful stripping and preserving of the deep dorsal vein, cavernosal vein and/or internal spermatic veins which were then fashioned to the inner layer of the tunica albuginea (TA) after being de-tubularized and spliced with 6-0 nylon suture. Similarly the aponeurosis of the external oblique muscle is fashioned to the outer tunical layer of the corporotomy with its longitudinal fiber parallel to the penile shaft. The wound is closed with 5-0 chromic catgut sutures. The international index of the erectile function (IIEF), cavernosography and penile dimension measurement were used for follow up. All these procedures are made under an acupuncture-aid pure local anesthesia on true out-patient basis.

Results: The operation varied from 8.5 to 13.0 hours. The follow-up period ranged from 3 months to 1.50 years. The IIEF-5 score was from 9 to 24, 11 to 21, 15 to 25, 10 to 17 and 15 to 25 respectively. The penile erectile length was preoperative 9.1, 8.9 and 7.8 cm to postoperative 12.0, 11.7 and 9.5 cm in three men respectively and the penile girth was from 7.8 to 9.2 cm, 7.5 to 10.5 cm in the remaining two males.

Conclusion: These innovative penile augmentation methods may be promising although they are technically challenging and a more men with longer time follow is deemed mandatory.

Disclosure:

Work supported by industry: no.

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MECHANICAL RELIABILITY AND CLINICAL OUTCOMES BETWEEN AMS 700 ULTREX AND LGX CYLINDERS: A SINGLE CENTRE OUTCOME STUDY WITH A MINIMUM OF 2 YEARS FOLLOW UP ON THE AMERICAN MEDICAL SYSTEMS INFLATABLE PENILE PROSTHESIS IMPLANTATION

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Introduction: Numerous technological advancements have been made to the American Medical Systems (AMS) 700 inflatable penile prosthesis (IPP) implant. AMS 700 Ultrex cylinder was first introduced in 1990 while LGX cylinder was later conceived in 2007 to replace Ultrex cylinder. To date there is no prospective study comparing the 2 types of penile prostheses implant. We evaluate the outcomes of Ultrex and LGX cylinders in terms of mechanical failure and infection rates in a single centre.

Materials and Methods: Prospective data collection of all consecutive patients who underwent IPP implantation for erectile dysfunction (ED) between December 2007 and December 2009 was reviewed. All patients have failed medical therapy and received appropriate counselling. The patients were randomised to receive either AMS 700 Ultrex or LGX devices. Using telephone interviews and review of clinical database, all patients were followed up for a minimum of 24 months post IPP implantation. The Ultrex and LGX groups were

compared with regard to: 1) intra-operative complication, 2) mechanical failure caused by device malfunction, 3) device explants for infection and/or erosion, and 4) patient satisfaction.

Results: A total of 67 (38 Ultrex and 29 LGX) IPP was implanted in the 2-year period. There was no statistical difference in patient age and causes of ED between the 2 groups. The main cause of ED was post prostatectomy (35%). The mean follow up for Ultrex group and LGX group were 35.1 (24-47) and 36.8 (28-47) months. There was one intra-operative complication documented in the LGX group. There were two mechanical failures (1 Ultrex and 1 LGX) but no device explant for infective and/or eroded penile prosthesis. The overall satisfaction on a 5-point scale was 4.8 in both groups with the majority of patients willing to undergo the same operation again.

Conclusions: There is no difference in the mechanical failure, prosthesis infection and patient satisfaction rates between AMS 700 Ultrex and LGX cylinders in the short term.

Disclosure:

Work supported by industry: no.

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THE EFFECT OF FAMILY PLANNING AND REPRODUCTIVE HEALTH PROGRAM AMONG YOUNG MALE ADULTS' SEXUAL RISK PERCEPTIONS

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STIs continue to be a major public health concern in both industrialized and developing countries and all sexually transmitted diseases (STDs) are attributed to unsafe sex. According to WHO, unsafe sex is the second leading risk factor among ten risk factors that increase the burden of disease.

Objective: In this study, it is aimed to identify the effect of Family Planning and Reproductive Health (FPRH) education among young male adults' sexual risk perceptions.

Material and Method: The research was conducted in Gulhane Military Medical Academy during April 2010-May 2011. Research group consisted of 874 participants who agreed to participate. Data were collected within the Sexual Risk Scale (SRS) developed by Dana DeHart (1997). In statistical analysis, numbers, frequencies, percentages, and mean \pm standard deviation depictions were utilized. Compliance with normal distribution was evaluated by one-sample Kolmogorov-Smirnov test and ANOVA, t-test, Mann-Whitney U and Kruskal-Vallis tests were used to compare groups. In order to determine the reliability of the SRS, item-total correlations and internal consistency analysis (Cronbach's alpha) were used. For all the analysis, 0.05 was considered to be statistically significant.

Results: According to the results obtained from the research; though SRS total score of the respondents whose educational status were primary school or lower and had Family Planning and Reproductive Health education (348) were higher than the ones who didn't receive (526), however only SRS total score ($p = 0.03$) and "perceived susceptibility to HIV" subscale was statistically different ($p = 0.002$).

In addition, SRS total score and subscale scores of "Intention to practice safer sex", "Attitudes toward safer sex" of the participants who attend high school and higher education and had FPRH education were statistically higher than the ones who didn't receive ($p = 0.001$, $p = 0.001$, $p = 0.001$).

Conclusion: As a result; FPRH education was found to be more effective on the participants with high school or higher educational status. It is recommended to emphasize the educations about risky sexual behaviors and especially condom use for the participants with lower educational status.

Disclosure:

Work supported by industry: no.

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SONIC HEDGEHOG REGULATES BRAIN DERIVED NEUROTROPHIC FACTOR IN THE CAVERNOUS NERVE

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Objective: Understanding the mechanisms that regulate cavernous nerve (CN) regeneration are critical for development of novel therapies for erectile dysfunction (ED). Sonic hedgehog (SHH) is an essential regulator of CN morphology and regeneration. The mechanism of how SHH promotes regeneration is unknown but likely involves signaling through several pathways critical for morphogenesis. Brain derived neurotrophic factor (BDNF) facilitates recovery of nNOS containing fibers and erectile function after injury and *Bdnf* mRNA is upregulated in the sciatic nerve in response to SHH. In this study we propose that BDNF is a target of SHH signaling during CN regeneration. We examined this hypothesis in a bilateral CN crush rat model and with targeted inhibition of SHH and BDNF signaling.

Materials and Methods: Sprague Dawley rats underwent one of four treatments: 1. SHH or BSA in the pelvic ganglia (PG/CN), 2. 5E1 SHH inhibitor or mouse IgG in the PG/CN, 3. Bilateral CN crush and SHH or BSA treatment, and 4. Bilateral CN crush with SHH or with SHH and BDNF inhibition (n = 4 in each group). BDNF and glial fibrillary acidic protein (GFAP) were quantified in CN/PG tissue by Western analysis.

Results: Inhibition of SHH signaling in the CN significantly decreased BDNF protein. CN crush with SHH treatment significantly increased BDNF protein 93%. BDNF inhibition decreases SHH induced CN regeneration. BDNF increases in the penis in response to SHH treatment of the penis.

Conclusions: These results show that BDNF is one of several factors/pathways that are regulated by SHH in the CN and that are required to promote regeneration and thus provide an opportunity to manipulate the nerve microenvironment and improve regeneration strategies.

Disclosure:

Work supported by industry: no.

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HORMONAL EVALUATION IN PREMATURE EJACULATION CASES: PRELIMINARY REPORT

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Objectives: There are some studies regarding the relation between thyroid hormones and premature ejaculation (PE). Our aim was to investigate whether any hormonal shift accord in PE cases.

Material & Methods: We had evaluated 31 pure PE cases. The patients were divided in two group as life-long and acquired PE. Prolactin (PRL), total testosterone, free testosterone, follicle stimulating hormone (FSH), luteinizing hormone (LH), free thyroxine 3 (FT3), free thyroxine 4 (FT4), thyroid-stimulating hormone (TSH) values were investigated. Combined cases of Erectil Dysfunction cases and PE were not included in this study.

Results: The mean age of cases was 35 (26–51). The mean TSH, FT3, FT4, , free testosterone, total testosterone, , FSH, LH, PRL values were detected 2.02 (0.4–5), 3.3 (3–3.6), 1.23 (0.8–2.4), 14.5 (4–39), 585 (291–1168), 2.92 (1.2–5.8), 3.44 (1–6.5) and 11.69 (4.3–18) respectively. The patients were evaluated with the validated version of PE questionnaire to state them all life-long or aquired PE. Life-long and acquired PE cases were found as 65% and 35% in our series.

Conclusions: According to our preliminary results we did not find any relation between thyroid hormones and FSH, LH, Total Testosteron, free Testosteron, Prolaktin with PE. Further double blind

placebo controlled studies will be needed to reveal more scientific result.

Disclosure:

Work supported by industry: no.

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3D RECONSTRUCTION OF THE CORPUS CAVERNOSUM WITH COMPARATIVE 3D ANALYSIS OF THE INFLATABLE PENILE PROSTHESIS

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Introduction: The intricate anatomy of the corpus cavernosum in both the flaccid and tumescent state has not been fully elucidated. Conventional CT and MRI images are limited by deformation artifacts and lack of fine detail. We report our experience using a three dimensional scanner to reconstruct cadaveric casts to reconstruct the anatomic shape of the corpus cavernosum. We used this data in combination three-dimension scanning with reconstruction of the inflatable penile prosthesis to fully elucidate the anatomy of the prosthesis in comparison to the native corpora.

Methods: Two different model Titan Coloplast® inflatable penile prosthesis were analyzed using a three dimensional scanner. One was the standard model and the second was a newer model with a blunter silicone tip. Two cadaveric phalluses with ages ranging from 71 to 81 years were harvested with the use of intra-corporal casts. A 16-gauge needle was used to inject the side of both corporal bodies with Smooth-Cast® 300Q polyurethane molding. After allowing for the material to harden, the molds were excised and then soaked in sodium hydroxide to remove all of the surrounding tissue. A FlexScan HDI Advanced R2 three-dimensional scanner was used to scan the cadaveric phalluses and the two prosthesis. Leios Mesh software was used for analysis to compare corporal anatomy.

Results: Analysis of an interpolated curve was generated from the 3D scans and the data was used measure a spherical radius of curvature near the tip. This demonstrated the average human corporal radii at the tip to be 36.51 (36.01–37.0) mm. The old Titan penile prosthesis spherical radius was 202.52 mm while the new silicone tip prosthesis had a radius of 139.33 mm. It was observed that the trajectory of the cavernosa appeared curvilinear and the distal ends appeared blunt. The new Titan® penile prosthesis silicone tip appears to better conform to the tip of the human corpora.

Conclusions: The use of cadaveric cavernosal molds in combination with the three-dimensional scanner allowed us first time to accurately image the corpus cavernosum. Our scans of both the human corpora and the inflatable penile prosthesis give us a greater understanding of this device. Our findings suggest that anatomically accurate corporal tips appear to be relatively blunt and that the new Titan® silicone tip penile prosthesis more closely resembles the human corporal tip.

Disclosure:

Work supported by industry: yes, by Coloplast (industry funding only - investigator initiated and executed study).

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PENILE ANGINA: INACCURATE TERM BUT USEFUL CONCEPT

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Erectile dysfunction (ED) being a potential precursor of acute cardiovascular (CV) problems, the concept of penile angina (PA) has been proposed (Prog.Urol.2005). This specific clinical form of ED is characterized by: a) occurrence in young men (35–60 years old), b) often significant ED, c) significant cardio-vascular (CV) risk, d) absence of

non CV obvious aetiology. **Objective:** As ED is often but not always a vascular marker, our aim was to analyze the reality and accuracy of PA concept by comparing its physiopathological mechanisms and its clinical usefulness with the pectoris angina. **Material and Method:** to analyze the PA concept through three real clinical cases. **Case 1:** 52 years old, high mountain guide consults for a penile pain and cyanosis occurring exclusively during physical stress in specific cold climatic conditions since 1 year, disappearing when he stops its effort and climbs down in hotter climatic conditions. Penile and CV check-up are normal. Preventive treatment using 5 mg daily tadalafil improved by 80% this ischemic penile problem (confirmed by a portable Doppler made in high altitude during pain occurrence). The use of specific alpinist warmer underwear fully resolves the problem (2 years follow-up). **Case 2:** 42 years old consults for painful erections since 20 hours. He reports similar episodes since 10 months spontaneously resolved. Cavernous gas analysis confirms an ischemic priapism successfully treated by decompressive puncture and etilefrine intracavernous injection without erectile sequels. **Case 3:** 46 years old consults for progressive ED (EHS = 2) since 18 months. The health check-up reveals a high CV risk and a coronary insufficiency requiring stent dilation. ED was successful treated with iPDE5 on demand and life style improvement. **Conclusions:** physiologically, the true PA is the rare ischemic priapism. *Stricto sensu*, the occurrence of penile vascular pain is only possible in case of erection excess (i.e. priapism) or of non erectile vascular spasm (as in 1st case induced by cold). But, this exceptional "Raynaud-like disease" is not related to erection but only to stress. For daily practice, the false PA, i.e. the frequent isolated vascular ED, is semantically inaccurate but very useful because as for the pectoris angina, it points up: a) the links between ED and CV diseases, b) the benefit of an opportunist ED screening in CV risk populations. Thus, it can prevent or reduce the morbidity / mortality of numerous men unaware of their underlying CV disease / risk owing to its potential role of saving life through a simple and inexpensive question about their erectile capacity.

Disclosure:

Work supported by industry: no.

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A PILOT STUDY TO DETERMINE PENILE OXYGEN SATURATION BEFORE AND AFTER VACUUM THERAPY IN PATIENTS WITH ERECTILE DYSFUNCTION AFTER RADICAL PROSTATECTOMY

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Objective: Provide a physiologic rationale for the use of a Vacuum Erection Device (VED) in penile rehabilitation protocols.

Methods: Twenty men between 2 and 24 months following Radical Prostatectomy (RP) were enrolled. Under supervision, each man cycled the Obson Erecaid Vacuum Therapy System to achieve full erection 10 consecutive times over a period of approximately 2 minutes. No constriction ring was used. Penile oximetries were immediately measured using the Vioptix Odissey oximeter at five marked sites: the right thigh, right corpora, glans penis, left corpora, and left thigh. At least 5 measurements were made at each site. Additional measurements were captured over the course of an hour.

Results: Mean age and time from surgery was 58.2 years and 12.6 months respectively, and the average SHIM score was 7. Right and left oximetry measurements were averaged. The use of a Vacuum Erection Device significantly ($p < 0.001$) increased corporal and glanular oximetry relative to the respective baseline value for the entire 60 minutes measured during the study.

Conclusion: This is the first study demonstrating that a single, brief application of the VED without a constriction ring results in significant improvement in both corporal and glandular oxygen saturation. The use of a VED has significant benefits for patients both with regard to cost and invasiveness when compared to other penile rehabilitation protocols. This study provides a physiologic rationale for VED use in

penile rehabilitation and supports incorporation of the VED in post-prostatectomy penile rehabilitation protocols.

Disclosure:

Work supported by industry: no.

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CELL PHONE USAGE AND MALE ERECTILE FUNCTION

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1: Canada; 2: Austria

Objective: This pilot study aims to report initial findings on the effect of cell phone usage on erectile function (EF).

Methods: We recruited 20 consecutive men complaining of erectile dysfunction (ED) for at least 6 months (Group A). Group B included another 10 healthy men with no complaint of ED. Full history taking, basic laboratory investigations and clinical examination was done. All men completed the German version of the SHIM for evaluation of the IIEF. Another designed questionnaire of the subjects' cell phone usage habits was given.

Results: There was no significant difference between both groups regarding total, free testosterone and SHBG levels. The SHIM scores of group A were significantly lower than that of group B, 11.2 ± 5 and 24.2 ± 2.3 , respectively. Total time spent talking on the cell phone per week was not significantly higher in group A over B, 17.6 ± 11.1 vs 12.5 ± 7 hours. Men with ED carried their switched on cell phones significantly longer time than men with no ED, 4.4 ± 3.6 vs 1.8 ± 1 hours per day.

Conclusions: There is a potential for cell phone usage to negatively impact EF. Further large-scale studies confirming our initial data and exploring mechanisms involved in this phenomenon are recommended.

Disclosure:

Work supported by industry: no.

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SONIC HEDGEHOG SIGNALING IN THE CAVERNOUS NERVE

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1: Northwestern University, USA; 2: RICE University, USA

Objective: The cavernous nerve (CN) is a peripheral nerve that is commonly injured during prostate cancer treatment, resulting in erectile dysfunction (ED). Although peripheral nerves have a limited ability to regenerate, a return of function typically does not occur due to irreversible down stream morphological changes in the penis. We have shown in previous studies that sonic hedgehog (SHH) is critical for maintaining homeostasis of the CN. In this study we examined SHH signaling in CN crushed and regenerating CN's in order to understand the mechanisms that underlay regeneration.

Material and Methods: SHH pathway was examined in normal pelvic ganglia (PG) via immunohistochemistry and in situ ($n = 5$). Sprague Dawley rats underwent bilateral CN crush ($n = 36$) and SHH and glial fibrillary acidic protein were quantified by western analysis of the CN at 1, 2, 4, 7 and 14 days. TUNEL was measured in the CN crushed penis. SHH ($n = 8$) was quantified by western in the CN with blockade of anterograde and retrograde transport ($n = 8$). Bolus SHH delivery versus extended release was examined on CN regeneration ($n = 12$).

Results: SHH pathway is localized in an intriguing pattern in neurons of the PG. SHH protein is decreased in the CN after crush injury. SHH treatment is neuroprotective in the crushed CN, bolus delivery is sufficient to promote regeneration, and signals from the PG and the penis are required to maintain SHH in the CN.

Conclusions: There is a window of opportunity immediately after nerve insult in which manipulation of the nerve microenvironment can affect long-term regeneration outcome.

Disclosure:

Work supported by industry: no.

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CLINICAL EVALUATION OF THE LIFELONG PREMATURE EJACULATION THAT EJACULATES LESS THAN ONE-MINUTE INTRAVAGINAL EJACULATION LATENCY TIME(IELT)

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Objective: This study aims to analyze sexual activity patterns and the results of clinical laboratory studies of the patients with lifelong premature ejaculation of less than 1 minute IELT.

Materials and Method: The subjects were those who ejaculated within 1 minute, did not have any other disease history, and no other sexual dysfunction. In this study, their sexual activity patterns were researched, penile sensitivity test, blood test, and prostatitis test were conducted.

Results: The number of subjects were 122. The threshold of biothesiometry was 5.1 ± 1.6 and 32(26.2 %) of them showed less than 4 threshold level. All were normal in the prostatitis test. Their thyroid hormone levels were T3 1.1 ± 0.3 ng/ml, and T4 8.3 ± 1.7 µg/dl, respectively. 6(4.9%) of them showed hypothyroidism while 3(2.5%) of them showed hyperthyroidism. The level of total testosterone and free testosterone was 514 ± 193 ng/dl and 12.6 ± 5.2 pg/ml, respectively. 4(3.3%) of them had increased level of testosterone. Their leptine level was 3.9 ± 3.9 ng/mL and 75.5% of the subjects showed prolongation of the ejaculatory latency after using anesthetic cream. As for the question about the reason of their premature ejaculation, 54.5% responded that it was due to penile hypersensitivity.

Conclusion: In case of consulting the patients with lifelong premature ejaculation of less than 1 minute IELT, it may be considered to take thyroid function test, testosterone hormone test and biothesiometry as a selective test. As for treatment, along with the generally-used drug therapy such as SSRIs and behavioral therapy, it is recommended to use penile sensitivity approach.

Disclosure:

Work supported by industry: no.

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MALLEABLE PROSTHESIS INSERTION THROUGH SUBCORONAL INCISION MAY BE PRONE TO INCORRECT MEASUREMENT AND TEMPORARY HYPESTHESIA OF THE GLANS

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Introduction: Penile prosthesis implantation has the highest patient satisfaction among treatment choices for erectile dysfunction. Malleable penile implants are cost effective and yield acceptable patient satisfaction. The AMS Spectra® is a unique malleable prosthesis because of its "string of pearls" construction. It has been described as best implanted through a subcoronal incision because its unique construction requires a very long corporotomy if implanted via penoscrotal incision. Using the subcoronal incision, we noted difficulty dilating, incorrect measuring, and patient complaints about loss of sensation of the glans penis.

Material and Methods: Thirty-four patients were implanted with Spectra penile prosthesis from 2/2011 to 3/2012 All were placed via subcoronal incision. Patients were followed from 3 to 12 months and complaints of numbness of the glans occurred immediately post OP in 14 (41%). Three (8.8%) complained of an annoying cracking sound

during intercourse. Five (14.7%) noted floppy glans from too short cylinders. Two patients were bothered by inadequate girth.

Results: 10 patients had removal of the Spectra via penoscrotal incision for reasons of too short cylinders, (5) noisy prosthesis (3) and poor girth (2). All were replaced with Coloplast Titan and gained 1.5–3 cm in length of cylinder. All patients were satisfied with the replacement prosthesis. The numbness of the glans resolved in all patients.

Conclusion: In our hands subcoronal placement of the Spectra prosthesis has high rate of mismeasurement of the corpora resulting in placement of too short and too narrow cylinders. While the glans sensation returned, temporary hypesthesia is another reason to abandon this surgical incision.

Disclosure:

Work supported by industry: no.

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INCREASED AWARENESS BUT LACK OF KNOWLEDGE ABOUT TESTOSTERONE DEFICIENCY SYNDROME AND ITS TREATMENT IN A PRIMARY CARE UNITED STATE POPULATION

Gerhard, R.S.¹; Ritenour, C.W.M.¹; Hsiao, W.H.¹

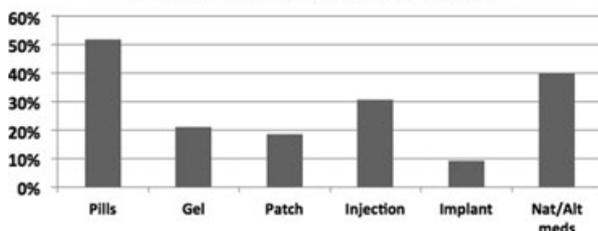
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Objectives: Testosterone deficiency syndrome (TDS) has received increased attention in the medical community, however patients awareness and knowledge of this condition are not well understood.

Materials: A total of 75 men at two primary care clinics (a private university practice and a county hospital-based practice) completed a self-administered survey concerning men's health issues. The survey included socio-demographic items, validated instruments, and independently developed questions about men's knowledge and attitudes surrounding erectile dysfunction, TDS, and male infertility. Awareness and knowledge items were assessed with closed ended Yes/No, Likert scale, and multiple-choice answer formats.

Results: A majority of men (85%, 64/75) were high school graduates. 46% (35/75) reported some familiarity with TDS, though 72% (54/75) of men said they had heard of the condition. 55% of men identified the correct definition from a list of four choices. 31% (23/75) of men did not recognize a single currently used therapy for low T. "Pills" were most frequently cited by patients (52%, 39/75) as a treatment for TDS. 40% (30/75) cited "natural or alternative medicines" as a treatment choice, while knowledge of gels, transdermal patch, and testosterone pellets was less than 21%. 39% (29/75) of men were able to recognize two of fewer signs of TDS from a list of 8 signs (Figure 1). ADAM scores in this cohort of patients showed 57% (43/75) scored positive.

Figure 1. Patient awareness of treatments for TDS



Conclusions: Overall, men's self reported awareness of TDS is moderate. However, knowledge of currently used treatment options, manifestations, and the definition of TDS is poor. Men who don't recognize symptoms or know available treatment options may be less likely to seek care for this condition. More patient education for TDS is needed.

Disclosure:

Work supported by industry: no.

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SERUM OSTEOCALCIN LEVELS CORRELATE WITH HYPOGONADAL SYMPTOMS IN MEN

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Introduction and Objectives: Osteocalcin is secreted by osteoblasts and is a marker of bone formation commonly used to assess the efficacy of drugs that enhance bone growth. One of the most significant sequelae of hypogonadism is loss of bone mineral density (BMD), the effects of which can lead to osteoporosis and ultimately pathologic fracture. The diagnosis of hypogonadism currently relies on evaluation of serum testosterone (T) and free T levels, as well as hypogonadal symptoms. However, the value of osteocalcin as a marker for hypogonadism is unclear. Here we evaluate the correlation between serum osteocalcin levels and the symptoms of hypogonadism.

Methods: A retrospective review of 92 men presenting to our clinic was performed, and demographic information, serum T and osteocalcin levels were obtained for each patient. All patients completed the quantitative Androgen Decline in the Aging Male (qADAM) questionnaire, a metric for the evaluation of hypogonadal symptoms, and responses were correlated to osteocalcin levels using Spearman's rank correlation.

Results: Mean \pm SD subject age was 51.2 ± 12.9 years, serum T 390.48 ± 253.12 ng/dL, and osteocalcin 3.70 ± 2.73 ng/mL. Significant negative correlations were observed between osteocalcin and total qADAM score ($\rho = -0.211$, $p = 0.045$), as well as individual qADAM questions including falling asleep after dinner ($\rho = -0.213$, $p = 0.043$). We then separated men by total qADAM score into 0–20 (severe hypogonadism), 21–30 (moderate hypogonadism), and > 30 (minimal/no hypogonadism). No differences in serum T were observed between subgroups, and no impact on qADAM score or osteocalcin level was observed as a function of whether men were on testosterone replacement therapy. Men with severe hypogonadism had mean osteocalcin levels of 4.1 ± 3.0 ng/mL ($n = 19$), moderate hypogonadism 3.7 ± 2.8 ng/mL ($n = 63$), and minimal/no hypogonadism 2.9 ± 1.4 ng/mL ($n = 10$) ($p = 0.52$). While these differences were not statistically significant, an overall trend towards higher osteocalcin levels in men with more severe hypogonadal symptoms was observed.

Conclusions: Serum osteocalcin levels are inversely correlated with hypogonadal symptoms, suggesting that osteocalcin may be useful as a serum marker for hypogonadism. Future work to further validate these conclusions using a larger dataset, as well as bone densitometry and more extensive evaluation of the interplay of serum and symptomatic parameters, will further elucidate the utility of osteocalcin as a serum marker for hypogonadism.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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SEXUAL FUNCTION, QUALITY OF LIFE AND SEX HORMONES IN MALE RECIPIENTS OF UNCOMPLICATED ORTHOTOPIC LIVER TRANSPLANTATION

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Objectives: Men with post orthotopic liver transplantation (OLT) report mild to moderate sexual dysfunction. We set out to evaluate sexual function, sex hormones and quality of life in male OLT recipients.

Material and Methods: Married male recipient patients of OLT were recruited. Patients with significant postoperative complications, unstable liver function or transplanted less than 4 months were excluded.

All patients underwent morning hormonal assays and blood chemistry. All patients were interviewed using the International Index of Erectile Function (IIEF-15) and Chronic Liver Disease Questionnaire (CLDQ-29). Patients were grouped into 3 groups; severe erectile dysfunction (ED), mild to moderate ED and no ED. Group comparisons were conducted using one way ANOVA and Post Hoc analysis. Median \pm interquartile range values are reported. P value is considered significant if <0.05 .

Results: We evaluated 37 men $895 \pm (2221)$ days post OLT with an age of 58.4 ± 13.1 years. A total of 22 patients (59.5%) received a cadaveric OLT while 15 patients had live related donor OLT. Median values were within normal for serum estradiol (114 ± 65 pmol/L), testosterone (13.4 ± 6.8 nmol/L), prolactin, FSH, LH, ALT, total bilirubin and creatinine. The erectile function domain score of the IIEF (26 ± 18) and orgasmic domain score (10 ± 6) were normal. The sexual desire (8 ± 6), intercourse satisfaction (10 ± 8) and overall satisfaction (7 ± 8) domain scores of the IIEF indicated mild dysfunction. Eight patients (21.6%) had severe ED, 10 (27%) had mild to moderate ED and 19 (51.4%) had no ED (including 3 patients on intracavernous injection with PgE1). There was no significant difference among groups in age, duration of transplantation, medical co-morbidities and laboratory values. There were significantly lower scores in the severe ED group in orgasmic function, sexual desire, intercourse satisfaction and overall satisfaction. There was significantly lower score in CLDQ-Abdominal Symptoms, CLDQ-Systemic Symptoms, CLDQ-Activity, CLDQ-Emotional Function associated with ED. No difference was observed with CLDQ-Fatigue and CLDQ-Worry.

Conclusions: Nearly half of the men who underwent OLT have normal erection. Patients with ED did not show difference in hormonal milieu or serum chemistry values. ED is associated with impaired orgasm, desire, sexual satisfaction and lower quality of life scores.

Disclosure:

Work supported by industry: no.

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MINIMALLY INVASIVE MODIFICATION OF THE DOT PPLICATION TECHNIQUE UTILIZING ABSORBABLE SUTURES

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Objective: Plication of the tunica albuginea is an established technique for the treatment of penile curvature resulting from Peyronie's disease. Classically, this utilizes a degloving incision with permanent suture for the plication of the tunica. One of the known pitfalls is the potential for the patient to feel the suture knots and resulting pain. We proposed the modification of this technique, using absorbable sutures rather than the standard permanent sutures as well as a minimally invasive longitudinal incision. Here we present our updated series in patients undergoing penile plication with the utilization of absorbable, 3 month lifespan, Biosyn™ suture.

Material and Methods: Nine patients with stable Peyronie's disease presented for consideration of surgical treatment. These patients were noted to have mild to moderate degree curvatures, ranging from 20 to 95 degrees with good erectile function. They reported a significant compromise of their sexual function and elected to proceed with penile plication. An artificial erection was induced and longitudinal penile incisions were made opposite the location of the curvature. The tunica albuginea was marked initially in an 8 dot technique. The tunica was then plicated utilizing absorbable monofilament 3-0 Biosyn™ sutures. Additional sutures were added as necessary for correction of the curvature, with a maximum of 20 dots in one patient.

Results: Nine patients underwent plication procedures for Peyronie's disease. These patients had correction of their curvature at the time of operation. There were no intraoperative complications reported. With a mean follow up of 11 months, and a range of 5–19 months, the patients reported no postoperative discomfort, and minimal residual curvature. There are no reports of palpable abnormalities along the suture line or chronic penile pain. There was minimal, 0 to 10 degree, recurrence of curvature during this follow up period. No

patients in our series reported a significant change in penile length. All patients reported satisfaction with the procedure.

Conclusion: Plication of the tunica albuginea utilizing absorbable sutures is a potentially viable alternative to the classic technique of permanent sutures. This series demonstrates that absorbable sutures of adequate duration allow for the reconfiguration of the tunica into the new, straight orientation, which persists long after the life span of the suture. A minimally invasive, longitudinal incision may be utilized, rather than a formal degloving approach with a satisfactory cosmetic result and rapid wound healing with minimal postoperative complications.

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BODY DISSATISFACTION AND SEXUAL DYSFUNCTION AMONG BRAZILIAN GYNECOLOGICAL PATIENTS

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Objectives: Investigations on the relationship between the way a woman perceives her body and measures of sexual response are scarce. The present study aims to evaluate the association between body dissatisfaction and female sexual dysfunction, reporting the parts of the body that bothers women the most.

Material and Methods: A sample of 110 sexually active Brazilian women aging from 18 to 61 (mean 38.5 and standard deviation 9.7) from the Gynecological Clinic of a University Hospital completed a questionnaire on sexual function (Female Sexual Quotient, FSQ) (Abdo, 2006). The body dissatisfaction also was assessed through the question "Is there something in your body that bothers you?". The patients were asked to specify her dissatisfactions. Cramer's V and the Fischer's exact test were used to assess the association between the variables.

Results: A total of 35.45% (n = 39) presented sexual dysfunction. The domains of sexual activity affected were desire and sexual interest (29,9%), preliminaries (29,9%), orgasm and sexual satisfaction (21,8%), personal excitement and sexual harmony with the partner (12,7%) and comfort (8,2%). Of the sexually dysfunctional women 82.05% (n = 32) reported having some body dissatisfaction, the most common being belly (48,18%), excess weight (26,36%), breasts (19,09%) and legs and/or buttock (10%). A significant association was found between sexual dysfunction and body dissatisfaction (V = 0.3; p = 0.002).

Conclusions: The responses about dissatisfaction with body parts are associated with perception of sexual difficulties. The findings of this study emphasize the need of considering body satisfaction as an important dimension of woman's sexual performance.

Disclosure:

Work supported by industry: no.

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SEXUAL HEALTH DISCUSSION IN CURRENT DAY U.S PRIMARY CARE CLINICS

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Introduction: Previous data show that many patients do not discuss sexual health with their healthcare providers and, likewise, many providers do not ask patients about their sexual health. Nonetheless, open dialogue between patients and their caregivers is important for optimal treatment of disease. Despite the introduction of convenient and effective oral medications over a decade ago, many men with erectile dysfunction (ED) are not receiving treatment. Understanding the barriers for treating sexual health concerns remains important.

Methods: A total of 75 men at two primary care clinics (a private community practice and a county hospital-based practice) completed

a self-administered survey concerning men's health issues. The survey included socio-demographic items, validated instruments, and independently developed questions about men's knowledge and attitudes surrounding ED, testosterone deficiency syndrome, and male infertility. Questions were closed-ended with yes/no/not sure and Likert scale response formats. Data were analyzed and clinic sites were compared by Pearson's chi squared test using statistical significance at the 0.05 level.

Results: A majority (45/75; 61%) of patients either strongly agreed or agreed with the statement that "It is important for doctors to routinely ask men about their sexual function." However, less than one-third (22/75; 29%) of men reported that their doctor inquired about sexual concerns during a routine visit in the past three years. A similar small number (19/75; 25%) reported asking the doctor themselves about sexual difficulties, yet most men (59/75; 78%) do not agree with the statement, "I feel uncomfortable talking to the doctor about my sexual function." Overall, less than one in three men (22/75; 29%) agree that their doctor has taken care of any concerns they may have about sexual function. There were no significant differences between men at the private community practice and those at the county-based hospital clinic.

Conclusion: Despite the majority of men agreeing that physicians should ask patients about sexual function, only about 30% of men reported that physicians actually did so. Similarly, only about 1 in 4 patients reported asking the physician about such concerns. There remain opportunities for better dialogue between patients and physicians even in the time of better treatments for ED.

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LAPAROSCOPIC CORRECTION OF INGUINAL HERNIA AFTER PENILE REVASCULARIZATION SURGERY

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Objective: Penile revascularization surgery is the only effective treatment for traumatic arteriogenic erectile dysfunction(ED). The inferior epigastric artery (IEA) is used as a neo-arterial blood flow source.

In this surgery, IEA is harvested carefully and passed through the inguinal canal to the base of the penis.

This procedure may cause a certain degree of damage to the inguinal canal, and may lead to the development inguinal hernia. In regard to the surgical treatment of inguinal hernia, there are several methods, including the Mesh-Plug method and Prolene hernia system (PHS) method. In case with post penile revascularization, maximum attention must be paid to avoid damaging the grafted IEA, which runs through the inguinal canal.

For the purpose of both completely curing inguinal hernia and maintaining erectile function restored by penile revascularization, a laparoscopic mesh patch method was chosen.

Material and Method: Subjects were 2 patients aged 36 and 38 years. They were patients with prior traumatic arteriogenic ED and had undergone penile revascularization surgery. Their erectile function had been restored completely by the penile revascularization surgery. They noticed their inguinal mass by themselves 10 years and 6 months after initial surgery. Ultrasonography showed the inguinal hernia and the patency of the donor vessel.

Laparoscopic inguinal hernioplasty was the method chosen. One 10-mm subumbilical port and 2 5-mm ports were placed approximately 5-7 cm apart. At first, the hernia orifice and the grafted IEA locations were carefully confirmed, and then Bard Composix Mesh was sheathed over the hernia orifice. It was then fixed with hernia staples. There were no adverse events, and the hospital stay was three days in each case.

Result: There were no significant changes observed in the postoperative ultrasonography and nocturnal penile tumescence monitoring. Furthermore, both patients reported no subjective change in erectile function postoperatively at 2 months and 3 years respectively.

Conclusion: After examining 2 cases of inguinal hernia in patients who underwent penile revascularization surgery, laparoscopic hernioplasty, using a mesh patch, is shown to treat inguinal hernia lower the risk of damage to the grafted vessel, specifically in cases with a history of penile revascularization.

Disclosure:

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A NOVEL THERAPY, COMBINATION OF L-CITRULLINE AND VARDENAFIL, FOR ERECTILE DYSFUNCTION WITH HYPOGONADISM IN RAT STUDY

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Objectives: L-citrulline (L-Cit) is converted into L-arginine in kidney and then known to augment nitric oxide (NO)-dependent signalling. Previously, we found oral L-Cit supplementation was effective for erectile function in castrated rats that NO production was known to decrease. In this study, we examined whether the combination of vardenafil (Var) and L-Cit supplementation was more effective than only Var treatment.

Materials and Methods: 15 weeks-old male Wistar-ST rats were divided into 4 groups: (1) Control, (2) surgical castration (Cast), (3) cast with acute Var treatment (Cast+Var), (4) Cast with oral L-Cit supplementation and acute Var treatment (Cast+L-Cit and Var). 2% L-Cit water was given for 4 weeks from the day of surgery. Var (8 mg/kg) was given at 1 hour before the measurement of erectile function. At 4 weeks after surgery, we evaluate erectile function. Erectile function was assessed based on changes in intracavernous pressure (ICP) by electrical stimulation of cavernous nerve and calculated maximum ICP/mean arterial pressure (MAP). Penises of rats in Control, Cast and Cast+L-Cit and Var groups were extracted and examine smooth muscle (SM)/collagen ratio by masson-trichrome staining. Serum NOx and available testosterone levels in all groups were measured by HPLC and LC-MS/MS. Bonferroni's multiple t-test was used as statistical analysis.

Results: ICP/MAP in Cast group was significantly decreased compared with that in Control group ($P < 0.01$). ICP/MAP in Cast+Var group was not enough improved compared with that in Cast group. In addition, interestingly, combination treatment of Var and L-Cit significantly increased ICP/MAP compared with Cast group ($P < 0.01$) and the ratio was almost equal to that of Control group. SM/collagen ratio in Cast group was significantly decreased compared with that in Control group ($P < 0.05$). The ratio in Cast+L-Cit and Var group was significantly increased compared with that in Cast group ($P < 0.05$). Serum NOx levels were lower in Cast group than Control group. The NOx levels were higher in Cast+L-Cit and Var group than in Cast group. Available testosterone levels in all rats with castration were significantly lower than those in Control rats.

Conclusions: The combination of L-Cit and phosphodiesterase-5 (PDE-5) inhibitor may be more effective therapy for ED with hypogonadism than only PDE-5 inhibitor treatment.

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EVALUATION OF ANKLE BRACHIAL INDEX AS A MARKER OF SUBCLINICAL ATHEROSCLEROSIS IN MALES WITH VASCULOGENIC ERECTILE DYSFUNCTION

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Objective: To evaluate the ankle brachial index test (ABI) as a marker of subclinical atherosclerosis in males with vasculogenic erectile dysfunction (ED).

Patients and Methods: The study was carried out as a case control study on Department of Dermatology and Andrology, Andrology unit, and cardiology department, Suez Canal University Hospitals, Ismailia, Egypt. We investigated 74 married males' patients with arteriogenic ED, older than 35 years who Involved in a stable heterosexual relationship for 6 months or longer (study group) and 74 volunteers males without ED matching the age of the study group (as a control group). Self-administered questionnaire (IIEF-5) was used for diagnosis of ED and its severity. Penile Duplex parameters were performed for patients with ED using a10-MHz linear array transducer (AU 5, Ezaoty, Italy). All Participants were evaluated for subclinical atherosclerosis parameters. For Ankle brachial index (ABI) measurement, a standard sphygmomanometer and a continuous-wave Doppler ultrasound device, with an 8-MHz probe was used. Exercise stress test and echocardiography were done for all subjects.

Results: The main finding in the present study is that the prevalence and extent of asymptomatic peripheral arterial disease (PDA), as detected by ABI (ABI < 0.9), is significantly higher among patients with ED (case) group than in (control) group (36.5% Vs 13.5%, $p < 0.01$), (OR: 2.7, CI: 1.18 < OR < 6.22).

There were 5 positive stress ECG for induced ischemia in cases with statistically significant difference between the two groups ($p < 0.05$). LV mass index was significantly higher in cases than in control group ($p < 0.05$). In patients with very low Framingham risk score there were 33 participants had PAD (ABI < 0.09), 6 participants of low Framingham risk score had PAD, and the only participant with moderate risk Framingham score found to have PAD.

Conclusion: A significant low (< 0.9) ABI value can detect subclinical atherosclerosis. Erectile dysfunction is an independent predictor of PAD as determined by screening ABI test.

Disclosure:

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A COMPARISON BETWEEN CITALOPRAM AND ESCITALOPRAM IN TREATMENT OF PATIENTS WITH PREMATURE EJACULATION: A DOUBLE-BLIND CONTROLLED CLINICAL STUDY

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Objective: to compare of efficacy of citalopram and escitalopram in treatment of patients with premature ejaculation (PE).

Material and Methods: Patients with PE (n = 60) were randomly divided into two treatment groups: a group receiving escitalopram 10 mg daily for 6 weeks (n = 30); and a group receiving citalopram 20 mg daily for 6 weeks (n = 30). The Chinese Index of Sexual Function for PE was used for patient evaluation at pre-treatment, at 2 weeks intervals after start of treatment for 6 weeks, and at 3 months after stopping treatment.

Results: The mean of total scores in the escitalopram group at initial pre-treatment evaluation and at 2, 4 and 6 weeks of treatment and at 3 months after stop of treatment (21.66 ± 1.80, 29.63 ± 1.47,

36.83 ± 1.64, 43.76 ± 1.27 and 41.40 ± 1.07; respectively) were not significantly different from those in the citalopram group (21.86 ± 1.22, 29.30 ± 0.91, 37.13 ± 0.50, 43.90 ± 0.54 and 41.70 ± 0.59; respectively) (P value = 0.51, 0.27, 0.27, 0.32 and 0.10 respectively).

Conclusion: Daily administrations of 10 mg of escitalopram or 20 mg citalopram for 6 weeks were found to be equally effective for treatment of patients with PE. Both drugs have the potential to provide long term control over ejaculation.

Disclosure:

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PENILE VENOUS STRIPPING PROCEDURE FOR PATIENTS WITH ERECTILE DYSFUNCTION: A PHYSIOLOGICAL APPROACH

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Purpose: A refined technique of penile venous stripping surgery (PVS), has been a viable option for treating erectile dysfunction (ED) in our practice for the past two decades. We present a physiological approach for patients with ED secondary to veno-occlusive dysfunction (VOD), performed in an outpatient environment and purely under an acupuncture-assisted local anesthetic.

Materials and Methods: From February 2002 to December 2005, 98 patients diagnosed with ED secondary to VOD and refractory to medical treatment were assigned to the circumferential (35), semi-circumferential (32), and control groups (31). The first two groups received PVS and the third was only followed up. After degloving the preputial tissues superficial to Colles' fascia, the deep dorsal vein (DDV) and cavernosal veins (CVs) were stripped and ligated with 6-0 nylon sutures, whilst the para-arterial veins (PAVs) were only segmentally ligated. A median longitudinal pubic incision was created to continue the stripping of the DDVs and CVs proximal to the infrapubic angle. The pubic and circumferential wounds were then closed in layers.

Results: Within the surgical group, operative times were 2.4 ± 0.2 vs 3.1 ± 0.4 hours and postoperative frenulum edema was 3.2 ± 1.6 vs 11.9 ± 2.1 days respectively. Follow-up ranged 3.2–7.2 years with an average of 5.4 ± 1.3 years. The operative time and satisfaction rate of the surgical course was significantly different ($p < 0.01$) in favor of the circumferential approach, although no difference was noted in post-operative infection. Differences in erectile function were significant ($p < 0.001$) between the groups of surgery and control in terms of preoperative IIEF-5 (9.8 ± 2.3 and 9.6 ± 2.1) scores compared to postoperative (21.6 ± 2.5 and 20.8 ± 2.7) ones. There was no difference between the 2 surgical approaches. Overall, 90.4% of the surgery group (51/67) reported improvements whilst the control group had worsening IIEF-5 scores during the same period of follow-up.

Conclusions: A circumferential and median longitudinal pubic incision appears to be a valid physiological approach which achieves favorable outcomes with negligible morbidity for treating ED secondary to VOD.

Disclosure:

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SIMULTANEOUS CIRCUMCISION WITH PENILE PROSTHESIS IMPLANTATION DOES NOT INCREASE THE RISK OF INFECTION

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Introduction: Early study reported that simultaneous circumcision with penile prosthesis implantation increased the risk of infection. However, there is no report to look at this association after the introduction of hydrophilic device and antibiotic coated prosthesis. This study was designed to look at the incidence of infection associated with simultaneous circumcision with inflatable penile prosthesis (IPP) implantation.

Methods: The IPP data base from 2007 to 2011 by a single surgeon was reviewed. The IPP types, the surgical approaches for IPP, etiologies of erectile dysfunction (ED) and reasons for circumcision were recorded. The incidence of infection was the main outcome.

Results: From January, 2007 to December, 2011 a total of 327 IPP surgeries by a single surgeon were included in this study. Of those 327 surgeries, 13 patients had circumcisions for phimosis/redundant foreskin at the same time of the IPP implantation. All patients received the 3-piece IPP with either hydrophilic devices or antibiotic coated implants through either penile-scrotal or infrapubic incisions. The follow up was from 3 months to 3 years. Two implant infections occurred with one related to sphincter cuff erosion that affected penile implant (3 years after the IPP and the artificial urinary sphincter implantation) and one patient with penile implant pump infection one year after the IPP without any obvious reason. No patient developed infection from the simultaneous circumcision. The post-operative scores of Sexual Health Inventory for Men are similar in patients with simultaneous circumcision compared to patients with IPP placement only.

Conclusion: Simultaneous circumcision with the hydrophilic and antibiotic coated IPP are safe and effective for the treatment of ED and phimosis/redundant foreskin. There is no increased risk for infection.

Disclosure:

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DOES PENTOXIFYLLINE ENHANCE THE RECOVERY OF ERECTILE FUNCTION FOLLOWING T SHUNT PROCEDURE FOR PROLONGED ISCHEMIC PRIAPISM? A PROSPECTIVE RANDOMIZED PLACEBO CONTROLLED TRIAL

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Objective: The aim of this study is to evaluate the role of using oral pentoxifylline for enhancing recovery of erectile function in patients who underwent T shunt procedures. **Materials & Methods:** This prospective randomized study was conducted on 40 patients with prolonged ischemic priapism (1–4 days) treated with T shunt. Patients were randomly divided into two groups. Group A received oral Pentoxifylline from the second post-operative day for 3 months. Group B received placebo. Patients were followed for 18 months patients were then evaluated objectively using the sexual health inventory scoring system (SHIM). **Results:** Resolution of pain occurred in all patients. Recovery of erectile function occurred in 15 patients in group A and 10 patients in group B within 3 months. All patients but 3 had recovery of erectile function within 18 months of follow up. Six patients had recovery of erectile functions by using on demand 50 mg sildenafil. The 3 patients who did not recover erectile function underwent penile prosthesis implantation after the end of the study. **Conclusion:**

Pentoxifylline did not show significant effect as regard potency recovery following T shunt procedure, however a larger study population (double blinded) is required for more accurate assessment of beneficial effect of pentoxifylline after T shunt procedures.

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KINETICS OF INTRACELLULAR SILDENAFIL UPTAKE AND RETENTION IN CULTURED HUMAN PENILE CAVERNOSAL CELLS

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Objectives: To determine the kinetics of cellular uptake and retention for the PDE5 inhibitor sildenafil (SIL) and its duration of efficacy in cultured human corpus cavernosum cells.

Methods: Penile cavernosal tissue from consenting human donors was minced and incubated with 0.5% collagenase A to dissociate stromal cells (SC). For uptake studies, cells were incubated with 400 ng/ml of SIL (plasma C_{max} after ingestion of 50–100 mg tablet) for varying times. Retention studies were performed by incubating cells with SIL for 30 min and then exchanging with fresh medium without SIL. Cells were then harvested at varying times after medium exchange. All incubations were terminated on ice and cells were quickly washed, harvested, and homogenized. The cytosolic fractions were extracted with a mixture of diethylether: dichloromethane (3:2), dried under N₂ gas, and analyzed by LC-MS/MS. In separate experiments, cGMP was measured by ELISA for uptake and retention time courses. PDE5 enzyme activity and protein expression were also assessed in cells incubated with SIL.

Results: SIL uptake occurred rapidly and plateaued by 20 min (85 ± 15 ng/10⁶ cells). In retention studies, 85% of intracellular SIL was lost within the first 5 min. The remaining 15% was retained within the cells through 30 min. The mean basal cGMP level was 10.4 ± 2.7 fmol/μg DNA. Through 30 min, SIL uptake did not significantly change these levels. Upon stimulation with 1 μM nitroprusside, cGMP levels increased 2.2-fold in the absence of SIL and 7.9-fold after 30 min of SIL uptake. In retention studies, cGMP levels increased 3.7-fold after stimulation with nitroprusside, suggesting that the remnant intracellular SIL concentration could effectively inhibit PDE5. Enzyme activity studies demonstrated that cGMP hydrolysis remains significantly suppressed even after cell washing, homogenization and significant dilution (500 - 1000 fold). PDE5 protein levels (Western blots) did not change in response to high concentrations (0.1–1 μM) or prolonged incubations (24 h) with SIL.

Conclusions: SIL is transported rapidly into penile SC and apparently remains tightly associated with PDE5 even after significant loss of intracellular drug or cell disruption and significant dilution. These findings are consistent with previously published data on SIL binding to PDE5 and provide a mechanistic basis for both the onset and duration of action of SIL at clinically relevant doses.

Disclosure:

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EXPLORING CLITORAL COMPLEX SEXUAL AROUSAL STATES WITH FUNCTIONAL ULTRASONOGRAPHY

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Introduction: Low sexual arousability is a critical issue for many women. However there is still no standard physiological measure of

female sexual arousal. In view of this, sonography could be a good tool for scoring arousal.

Aim: The aim of the study is to explore with ultrasounds the clitoral complex before and during sexual arousal.

Method: We recruited 8 healthy women without any sexual dysfunction (age range 26–46). They elicited a subjective arousal by external clitoral masturbation (arousal 1–4, Likert Scale). We practiced sonographic measurements of the quiescent and aroused clitoral complex.

Main Outcomes Measures: On a two-dimensional ultrasonographic transversal plane, we measured cavernous bodies circumferences at their junction. On a parasagittal plane, we measured with Doppler Ultrasound systolic and diastolic velocities, Resistive Index measurement of the cavernous artery. On a sagittal plane we measured the thickness of the urethra lumen at different stages.

Results: This study revealed changes in the clitoral complex: bodies circumferences, systolic and diastolic velocities increased, resistive Index decreased. In most cases, the thickness of the urethra lumen increased, probably due to fluid secretion.

Conclusion(s): Ultrasonography might easily demonstrate the changes of the clitoral complex during arousal. With further methodological refinements and larger studies, this suggests that it could be feasible to create a sonographic arousal score. It could become a standard measure for comparing subjective perception and objective measurement of female sexual arousal, for evaluating women with sexual dysfunction, for assessing the effects of a range of treatments on arousal (local, hormonal, antidepressants, etc.)

Disclosure:

Work supported by industry: no.

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THE EXPRESSION OF CSE BUT NOT CBS IN CORPUS CAVERNOSUM IS ENHANCED BY ENOS GENE DEFICIENCY

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Objectives: Recently, hydrogen sulfide (H₂S) has been identified as a gasotransmitter endowed with physiological and pathological functions much as another gasotransmitter- nitric oxide (NO). H₂S is synthesized from L-cysteine mainly by cystathionine-γ-lyase (CSE) and cystathionine-β-synthase (CBS) while NO is derived from L-arginine through nitric oxide synthase (NOS) isoforms. The cross-talk between H₂S and NO has been addressed in the recent years *in vitro* or *in vivo* through pharmacological treatments; however, conflicting observations have been reported partly due to the limitations of experimental techniques. In this pioneering study, we used endothelial-NOS (eNOS) deficiency mice to investigate the precise influence of NO on H₂S in the physiological condition.

Materials and Methods: Wild-type (C57BL/6J) and eNOS gene knockout (eNOS^{-/-}) male mice (5mo, n = 20 each), were procured for this study. Corpus cavernosum (CC), left ventricle and liver tissues from eNOS^{-/-} or wild-type (control) mice were homogenized for RNA and protein extraction. Reverse transcription, real-time quantitative PCR (RT-qPCR) and western blot analyses were performed to compare the mRNA and protein expression of CSE and CBS in these tissues.

Results: RT-qPCR analysis showed a significant (36%) up-regulation of CSE but not CBS mRNA expression in CC after eNOS gene knockout. Consistent with the transcription analysis, CBS protein expression in CC was not significantly altered in the condition of eNOS gene deficiency; however, CSE protein was also not detectable in our experimental condition. Interestingly, although eNOS gene deficiency caused a significant increase of CSE expression in corpus cavernosum, this was not observed in other CSE-abundant tissues such as left ventricle and liver. Consistent with CC, the CBS expression in heart and liver were not changed after eNOS gene knockout.

Conclusions: Taken together, we ascertain that the deficiency of eNOS gene enhanced the expression of CSE in a tissue-specific

manner, suggesting the specific role of this cross-talk between the two gasotransmitters in erectile physiology.

Disclosure:

Work supported by industry: no.

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ARE PILOT CAVERNOSOGRAMS INFORMATIVE IN PHARMACO-CAVERNOSOGRAPHY?

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Objective: Pharmacocavernosography (PC) whilst useful in documenting veno-occlusive dysfunction (VOD), is not informative for venous anatomy. We aim to develop a more informative method.

Materials and Methods: From March to December 2011, 96 consecutive men with erectile dysfunction (ED), aged 20 to 75 years, underwent dynamic PC. All patients self delivered two sets of 60 mL 50% Omnipaque solution via a 19-gauge needle inserted into the corpora cavernosa of the penis. Pilot cavernosograms were taken at two, five, ten, twenty and thirty seconds. PC was done in the same fashion within 30 minutes after injection of 20 µg prostaglandin E1. Well-demonstrated veins in the pilot and PC were compared in terms of venous numbers and presentation percentage. Each patient then had their pilot cavernosograms explained to them.

Results: There was a statistically significant difference ($P < 0.001$) between the presentation percentage of DDV (97.47%, 60.33%), CVs (38.91, 57.06%) and PAVs (29.34%, 19.08%) between the pilot cavernosograms and PC. The presentation of the aforementioned veins is consistently overwhelming in the pilot cavernosograms.

Conclusion: Pilot cavernosograms are capable of demonstrating more detailed penile venous anatomy than PC. This is relevant in formulating treatment and for the patients' understanding. We therefore may conclude that pilot cavernosograms are an essential phase of PC.

Disclosure:

Work supported by industry: no.

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DOT PLICATION FOR PEYRONIE'S DISEASE: THE USF EXPERIENCE

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1: USF Urology

Introduction: Penile plication of the tunica albuginea is a well-established technique for the treatment of penile curvature. It involves shortening of the convex side of the penile curve without excising the tunica. The dot plication involves no dissection of the tunica or the urethra and straightens the penis. This technique classically utilizes permanent sutures for the plication of the tunica. Major drawbacks include that patient's may feel the knots subcutaneously and report pain with erections.

Materials and Methods: Eight patients with stable Peyronie's Disease presented for consideration of surgical treatment. These patients were noted to have curves ranging from 20 to 95 degrees with good erectile function. After a discussion specific to therapy with these patients including other surgical options they chose to undergo penile plication. After an erection was pharmacologically induced, a paramedian longitudinal penile incision was made opposite the location of the curvature. The tunica was marked initially utilizing either a 8, 16, 20 or 24 dot technique. The tunica was then plicated utilizing absorbable monofilament 3-0 Biosyn® sutures.

Results: Eight patients underwent plication procedures for Peyronie's Disease. With a mean follow up of 5 months, the patients reported

mild post-operative discomfort from the incision, and minimal residual curvature of an average of less than 5 (2.5–8) degrees. After a 4 month follow up period, patient's denied feeling the knots subcutaneously.

Conclusion: Plication of the tunica albuginea utilizing a paramedian incision bypasses the need for formal de-gloving of the penis. Here we demonstrate our technique using a longitudinal incision with the use of absorbable synthetic sutures rather than the standard permanent sutures. Absorbable sutures provide the potential advantage of avoiding permanent palpable sutures and/or pain with erection secondary to retained sutures. We feel this combination of approach and suture selection has optimized both surgical outcomes and recovery.

Disclosure:

Work supported by industry: no.

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THE EFFECT OF DAILY SILDENAFIL ON PATIENTS WITH ABSENT NOCTURNAL ERECTIONS DUE TO PELVIC FRACTURE URETHRAL DISRUPTION: A SINGLE-CENTER EXPERIENCE

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1: Peking University First Hospital

Objective: Erectile dysfunction (ED) is a common sequel of pelvic fracture urethral disruption (PFUD). Those patients with nocturnal erections may respond favorably to sildenafil, however, little is known about the response to sildenafil in patients with absent nocturnal erections. In this prospective study we evaluated the response to the treatment of sildenafil 50 mg taken once daily in the patients with absent nocturnal erections due to PFUD.

Material and Methods: From Jan 2009 to Dec 2011, a total of 28 patients with absent nocturnal erections due to PFUD were evaluated prospectively and all reported normal erectile function before injuries. The International Index of Erectile Function-5 was used as an evaluation tool. Assessments were made before and after treatment of daily sildenafil. We recorded nocturnal penile tumescence and rigidity with an erectometer, and if nocturnal erections were absent for 3 nights, patients were administered sildenafil 100 mg at bedtime and tested again at the forth night. Penile duplex ultrasound with intracavernous injection was performed to define the causes. All patients received a daily dose of sildenafil 50 mg for 12 weeks. Response to sildenafil treatment was defined as sustained erectile allowing vaginal penetration and intercourse.

Results: 23 (78%) patients completed the daily sildenafil treatment and followup was available. The nocturnal erections at the forth night in 13 patients (46.4%) were improved. 6 of 13 patients (46.2%) with neurogenic ED and 2 of 10 (20%) with arterial ED who had nocturnal erections induced by bedtime sildenafil showed response to the daily treatment and reported successful intercourse.

Conclusions: Patients with absent nocturnal erections might respond to sildenafil taken daily, the improvement of nocturnal erections induced by sildenafil taken at bedtime might predict the response to sildenafil taken daily.

Disclosure:

Work supported by industry: no.

239

A NEW REPAIR SURGERY FOR PENILE VASELINOMA

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Objective: To introduce a new repair technique for penile paraffinoma without necrosis of the ventral skin anastomosed.

Materials and Methods: Between March 2009 and July 2011, 11 patients underwent penile paraffinoma repair using bilateral scrotal flap with a new technique. Two circumferential incisions were made, one at the skin just proximal to the corona of the penis and other at the penoscrotal junction. Complete removal of involved skin and subcutaneous tissue including paraffinoma was performed. Both scrotal skins were drawn to the dorsal glandular skin after scrotal skin was incised appropriately and sutured with T style anastomosis between coronal skin and scrotal skin. The ventral skin was anastomosed with end to end technique to avoid T style anastomosis like dorsal anastomosis. We made inverted V incision 1 cm below from the anastomosis site. The scrotal flaps were sutured layer by layer.

Results: All 16 flaps completely survived without the necrosis of ventral skin and there reconstructed penis had immediate postoperative tactile sensibility. The result were successful and without any major complications.

Conclusions: Penile resurfacing without T style anastomosis at ventral skin of the penis with bilateral scrotal flaps is new technique for repair or penile vasinoma. It can be an effective and reliable method, especially for saving ventral skin of the penis.

Disclosure:

Work supported by industry: no.

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COMPARISON OF CHARACTERISTICS OF LIFELONG AND ACQUIRED PREMATURE EJACULATORS: IS SMOKING A RISK FACTOR FOR ACQUIRED PREMATURE EJACULATION?

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Objectives: Patients with premature ejaculation (PE) can be subdivided into lifelong (PE since the beginning of their sexual lives), and acquired (developed the condition after years of satisfactory sexual functioning). However data on the different of characteristics between lifelong and acquired PE patients are limited.

Material and Methods: We evaluated all urology clinic patients with the complaint of PE. All patients underwent general and urologic physical examinations and medical history was obtained with special attention to sexual problems. If the man was ≥18 years, in a stable monogamous relationship for ≥6 months, ejaculated <1 minute in more than half of his intercourse attempts ≥6 months, had an International Index of Erectile Function (EF) domain score ≥26, he was enrolled in our study.

Results: Of the 46 PE patients that met all the specified criteria, 17 (36.9%) had acquired and 29(63.1%) had lifelong PE. Baseline characteristics except for age and smoking were similar. The mean age of the lifelong PE patients was 32.2 ± 5.5 (range 26–48) years and in acquired PE 41.1 ± 7.9 (range 28–54) years (P < 0.001). Among men with acquired PE, twelve (70.6%) were smokers, while 10 (34.5%) of lifelong PE patients were smokers (P = 0.031).

Conclusions: Smoking is more common in acquired PE patients compared to lifelong PE patients. Smoking is a risk factor for acquired PE. Further studies are needed to elucidate this possible link.

Disclosure:

Work supported by industry: no.

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PROFILING CHARACTERISTICS OF MEN WHO USE PHOSPHODIESTERASE TYPE-5 INHIBITOR BASED ON PURCHASING PATTERNS: DATA FROM THE NATIONWIDE JAPANESE POPULATION

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Objectives: Phosphodiesterase type-5 inhibitor (PDE5i) is commonly used in Japan for erectile dysfunction (ED). One problem seen worldwide is that certain subsets of men purchase PDE5i from uncontrolled sources, bypassing health care provider (HCP) interactions. In the present study, our aim is to stratify men who are PDE5i users based on their purchasing patterns and investigate the characteristics between these groups.

Material and Methods: A web-based observational study, conducted by Pfizer, was performed between March and June 2009 in Japan. Of 7710 total participants, 1144 men (14.8%) with mean age of 46.7 years reported PDE5i use within the past year. These men were asked to classify their PDE5i purchasing patterns. We stratified the reported purchasing patterns into three categories: men who had a prescription for PDE5i from their HCP, those who obtained PDE5i from friends, and those who obtained PDE5i via internet. Logistic regressions were conducted to determine independent predictors for purchasing patterns of PDE5i based on the aforementioned stratifications.

Results: Of 1144 men, 625 men (54.6%) obtained PDE5i from HCP, whereas 267 men (23.4%) obtained it from friends and 252 men (22.0%) obtained it via the internet. In a multivariable regression analyses, men purchasing PDE5i from HCP were more likely to live in a northern area of Japan (OR 0.98, P = 0.008), have a lower rate of cigarette smoking (OR 0.77, P < 0.001), and have higher awareness of ED (OR 3.04, P < 0.001). In contrast, men who obtained PDE5i from friends were more likely to live in a southern area (OR 1.02, P = 0.027), have higher alcohol intake (OR 1.20, P = 0.004), smoke more frequently (OR 1.45, P < 0.001), have a higher erection hardness score (OR 1.25, P = 0.038), and have a lower frequency of masturbation (OR 0.89, P = 0.015). Men obtaining PDE5i via internet were more likely to have lower awareness of ED (OR 0.62, P = 0.025) and to consider themselves to be in worse health (OR 0.85, P = 0.040).

Conclusions: Approximately half of men in Japan were found to bypass HCP interactions in order to obtain PDE5i. Our results could help HCPs identify men who may be likely to bypass HCP interactions and encourage these men to have their health checked appropriately. These predictors could also aid in the targeting of public service announcements designed to encourage men in at-risk populations to consult with a HCP regarding ED.

Disclosure:

Work supported by industry: yes, by Pfizer Japan Inc (no industry support in study design or execution).

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KNOWLEDGE AND ATTITUDES OF UROLOGISTS AND NON-UROLOGISTS TOWARD ERECTILE DYSFUNCTION AND PDE-5 INHIBITORS IN KOREA

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Purpose: In Korea, there are four phosphodiesterase type 5 (PDE-5) inhibitors (sildenafil, tadalafil, vardenafil and udenafil) for oral treatment of erectile dysfunction (ED) which has been marketed for more than four years. We compared the understanding of PDE-5 inhibitors between urologists and non-urologists (from department of internal

medicine and family medicine) who had prescribed phosphodiesterase-5 (PDE-5) inhibitors for more than 4 years in Korea.

Materials & Methods: Between July and September 2011, a 20-item questionnaire, designed to assess knowledge and attitudes toward PDE-5 inhibitors, was sent to 320 randomly sampled members of urologists and non-urologists in Daegu and Gyeongbuk area, Korea. To assess opinions associated with PDE-5 inhibitors, data were analyzed by cross analysis using chi-square test.

Results: Seventy six urologists and 74 non-urologists completed the questionnaire. Non-urologists had less active attitude toward treatment of ED ($p < 0.05$), meaning that they didn't tend to recommend salvage therapies in PDE-5 inhibitor non-responders ($p < 0.05$) and they had poor understandings about testosterone replacement therapy in late onset hypogonadism ($p < 0.05$). The prescription preferences (Urologists/Non-urologists) were 60.4%/60.3%, 27.1%/26.3%, 2.1%/2.7% and 10.4%/10.7% for sildenafil, tadalafil, vardenafil and udenafil, respectively. All participants had precise knowledge of contraindications for PDE-5 inhibitors.

Conclusions: The finding that general physicians had poor knowledge and a negative view toward PDE-5 inhibitors suggest a continuous need for comprehensive education programs focused on the various treatments for erectile dysfunction.

Disclosure:

Work supported by industry: no.

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SEXUAL BALANCE: THE UNIVERSAL VERSATILITY OF THE SEXUAL TIPPING POINT® MODEL

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Objective: Towards the end of the 20th century, the worldwide media seemed exclusively focused on promoting the “robust” efficacy of sexual pharmaceuticals. It seemed critical to advance a theoretical model that would help professionals and the public alike, appreciate that sexual function and dysfunction are always both “mental and physical”.

Method: A graphic artist was commissioned to create cartoons, which could be used interchangeably to illustrate different etiological factors, with differing valences.

Results: The Sexual Tipping Point (STP) Model® arose from approximately two decades of collaboration with Kaplan, at NY Weill Cornell Medical Center. Kaplan (1995) had described a “psychosomatic” dual-control model of sexual motivation emphasizing “inhibition/excitation” processes. An artist by training, Kaplan published a sketched cartoon that foreshadowed the current digital graphics independently developed for use in the STP model, which illustrate these mind/body concepts (that underlay all psycho-physiological phenomena). “Mental” factors can “turn you on” as well as “turn you off”; the same is true of the “physical” factors. Although presented earlier, STP gained a larger audience with the JSM (2006) publication of “The Sexual Tipping Point” abstract describing this new way of modeling etiology. The STP model complemented the seminal work of Bancroft and later Jansen, Graham, & Sanders who provided erudite articulation of “dual-control” theory, psychometrics, and comprehensive research. However, the STP model provides an extremely convenient heuristic device to illustrate both intra and inter-individual variability, which is key to appreciating concepts of psychosocial-cultural and biological predispositions and thresholds. STP has additional capacity to integrate and model an individual's placement on a population distribution curve, whether skewed or normal. The STP also allows for modeling of a variety of combination treatments, including future medical and surgical interventions, even those not yet discovered! All of these digitized illustrations are available gratis to any sexual health care professional for their own teaching, research or clinical use upon request from this author.

Conclusion: The STP model can illustrate all etiological permutations including “normal” sexual balance, and is particularly useful for

modeling combination treatment in an easily understood manner that can be used to explain risk/benefit for patients with sexual disorders.

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Disclosure:

Work supported by industry: no.

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ROBOTIC ASSISTED LEGO® CONSTRUCTION AS A MODEL FOR ROBOTIC MICROSURGERY SKILLS TRAINING

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Objectives: The application of robotic assisted microsurgery has been expanding. However, there are no structured training protocols for robotic microsurgical skill development. The existing training models (rodent, cadaver or synthetic) are also quite tedious and expensive. Our goal was to assess the use of robotic assisted Lego construction for robotic microsurgical skills training and compare it to our current standard.

Materials and Methods: 10 robot naïve trainees (6 medical students and 4 urology residents) were enrolled in the study and then randomized into two arms. The test group performed 5 sessions: 1 robotic assisted microsurgical vasovasostomy (RAMV) on a synthetic vas deferens model (anastomosis with 4 double armed 10-0 nylon sutures using microdot technique) – this was the pre-training test procedure, 3 training sessions where the trainee built a 77 piece Empire State Building Lego® set to completion with robotic assistance using all 3 instrument arms, and then a final test session RAMV. The control group also performed 5 sessions: they performed 5 successive RAMV procedures on the vas deferens model – an initial pre-training test anastomosis, 3 training RAMV sessions and then a final test anastomosis. The pre-training RAMV was then compared to the post-training RAMV for all trainees: duration, number of sutures used, suture breaks, needle bends, distance between suture placement and microdot where compared (a scoring methodology was developed).

Results: The mean pre-training RAMV measures did not differ significantly between the Lego® and control arms. Mean duration of the RAMV before and after training was: 62 min and 28 min for the Lego® test group; 89 min and 34 min for the control group, respectively. Mean number of sutures used, needle bends and suture breaks significantly decreased after training in both arms. The mean quantitative quality scores of the first test anastomosis were 2 (Lego® group) and 0.5 (control group). These scores improved after training to 11.5 (Lego® group) and 5.5 (control group). The score improvement after training did not differ significantly between the Lego group and the control group ($p = 0.27$).

Conclusion: Although this is a small sample size, this preliminary study appears to indicate that robotic assisted Lego® construction may provide a comparable training model to standard successive exercises in developing robotic assisted microsurgical skills.

Disclosure:

Work supported by industry: no.

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DOES TESTOSTERONE DEFICIENCY EXAGGERATE THE CLINICAL SYMPTOMS OF PEYRONIE'S DISEASE?

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Objective: Serum testosterone (T) influences wound healing and levels are decreased in the age group at risk of Peyronie's disease (PD). The aim of the present study was to evaluate the severity of penile deformity in men with PD in relation to T levels.

Material and Method: One-hundred and six patients with PD and T deficiency (serum T < 3.5 ng/mL; Group 1) and those with normal T levels (Group 2) were compared according to the duration of PD, the size and location of the plaques, penile curvature, pain on erection, and the severity of erectile dysfunction.

Result: The mean degree of penile curvature in Group 1 was significantly greater than in Group 2 (32.0 ± 15.9 vs 21.8 ± 15.4, respectively). The mean Group 1 score on the International Index of Erectile Function (IIEF)-5 was lower than the score for Group 2 (7.4 ± 3.7 vs 10.8 ± 4.8, respectively). The percentage of patients who complained of pain on erection did not differ between the two groups. Plaque size in Group 1 was larger than in Group 2 (3.0 ± 1.2 vs 2.0 ± 1.2 cm, respectively), whereas there was no significant difference in plaque location. Although there was a lower percentage of responders to medical treatment in Group 1, there were no differences in surgical outcomes between the two groups.

Conclusion: These findings suggest that the presence of T deficiency in patients with PD exaggerates the severity of PD by affecting penile deformity, plaque size, and erectile dysfunction. Further studies are needed to confirm this relationship.

Disclosure:

Work supported by industry: no.

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EGG (MASTURBATION DEVICE) AS A NEW PENILE REHABILITATION TOOL: A PILOT STUDY

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Introduction and Objective: Erectile dysfunction following radical prostatectomy (RP) is still significant burden as a post-operative morbidity, despite advancing of nerve-sparing technique and penile rehabilitation program. Phosphodiesterase Type 5 Inhibitors (PDE5-I) is frequently used for penile rehabilitation. However, during recovery period, patients cannot always achieve adequate penile erection for sexual intercourse even they used PDE5-I. In term of these situations, masturbation is a practical and reasonable way to confirm own erectile capacity and for penile rehabilitation. Using masturbation device may enhance erectile response and enjoyment of penile rehabilitation. Therefore we adopt masturbation device "EGG" in penile rehabilitation program for non-responder of PDE5-I. "EGG" is made of soft and stretch material in the shape of egg with special inner structure (<http://www.tenga-global.com/products/egg/index.php>). The EGG is worn over the penis and patients can stimulate penis using the EGG. As the first step of this trial, we compared erectile response in penile rehabilitation session (masturbation) with or without EGG-stimulation in non-responders for PDE5-I following RP.

Methods: Nigh non-responders for PDE5-I who underwent retropubic RP were enrolled. Patients' median age was 71(range 59-77 years old) Nerve sparing (NS) status were bilateral NS: 2patients, unilateral lateral NS: 4patients and No NS: 3patients. No patients received adjuvant therapy for prostate cancer. The patients' erectile response in penile rehabilitation session (masturbation) with PDE5-Is alone and PDE5-Is + the EGG-stimulation were evaluated by EHS score. Changes of self-esteem and motivation for penile rehabilitation were

assessed by the self-esteem domain of the SERS and ad-hoc questionnaire.

Results: In all, six patients reported better erectile response when using PDE5-I + EGG-stimulation compared to PDE5-I alone. Two patients showed no improvement of erectile response. One patient could not try EGG for family reasons. Mean EHS score is significantly increased (PDE5-I alone: 1.3 ± 1.0 mean ± S.D. PDE5-I and EGG: 2.1 ± 1.5 p = 0.006 by paired t-test). There was no significant difference in scores of self-esteem domain of SERS between after penile rehabilitation session with PDE5-I alone and PDE5-I+EGG-stimulation. However the good responders for EGG answered higher motivation for further penile rehabilitation.

Conclusions: PDE5-Is + the EGG-stimulation improved erectile response in post RP patients. Better responders showed better motivation for further PR. Penile rehabilitation protocol using masturbation device "EGG" may have a potential for keeping motivation and to realize own maximum erectile capacity.

Disclosure:

Work supported by industry: no.

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EFFECTS OF PHOSPHODIESTERASE-5 INHIBITOR TADALAFIL ON TRANSIENT CEREBRAL ISCHEMIA IN GERBILS: IMPLICATIONS FOR A NEW TREATMENT STRATEGY

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Objective: Cerebral ischemia is caused by a restriction in blood supply, generally due to factors in the blood vessels, with resultant damage or dysfunction of tissue. The main problem associated with cerebral ischemia is impairment of dopamine function. Tadalafil (Cialis®) is a long-acting phosphodiesterase type-5 (PDE-5) inhibitor used to treat erectile dysfunction. Tadalafil is known to ameliorate neurologic impairment induced by various brain insults. In this study, we investigated the effects of tadalafil on cyclic guanosine monophosphate (cGMP) and dopamine function following cerebral-ischemia in gerbils.

Material and Methods: Adult male Mongolian gerbils were used and randomly divided into five groups (n = 8 in each group): Sham-operation group, cerebral ischemia-induced group, cerebral ischemia-induced and 0.1 mg/kg tadalafil-treated group, cerebral ischemia-induced and 1 mg/kg tadalafil-treated group, and cerebral ischemia-induced and 10 mg/kg tadalafil-treated group. The gerbils were sacrificed immediately after the last injection of tadalafil (7 days after inducing ischemia). As the modalities of analyses, cGMP assay, immunohistochemistry for tyrosine hydroxylase (TH), and western blot for dopamine D2 receptor were performed.

Results: Cerebral ischemic insult suppressed cGMP level and decreased dopamine D2 receptor expression in the striatum and substantia nigra (SN), whereas tadalafil treatment significantly increased cGMP level and enhanced cerebral ischemia-induced dopamine D2 receptor expression as dose-dependently (p < 0.05). Cerebral ischemic injury also increased TH-immunoreactive fibers in the striatum and SN, whereas tadalafil treatment significantly suppressed cerebral ischemia-induced TH-immunoreactive fibers as dose-dependently (p < 0.05).

Conclusions: The present results showed that decreased cGMP level induced by cerebral ischemia was associated with decreased dopamine D2 receptor expression and excessive increment of TH expression in the striatum and SN region. Tadalafil treatment suppressed TH expression by enhanced cGMP expression and increasing dopamine D2 receptor in the striatum and SN. PDE-5 inhibitor, tadalafil, can overcome cerebral ischemia-induced over-expression of dopamine, thus facilitates recovery following cerebral ischemic injury.

Disclosure:

Work supported by industry: no.

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AROMATASE INHIBITOR PROLONGS THE EFFICACY OF LONG ACTING TESTOSTERONE PELLETS

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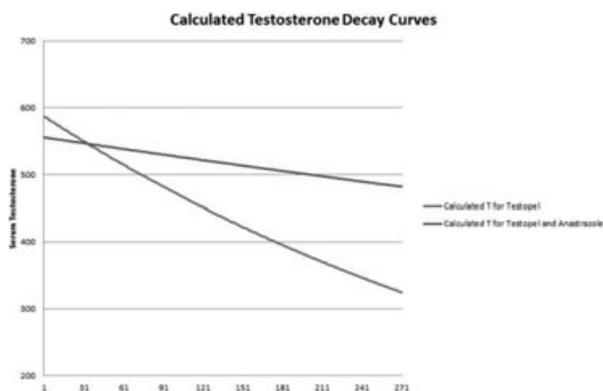
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Objective(s): Testosterone (T) replacement with Testosterone pellets (TP) is increasingly popular. TP insertion has a small risk of bleeding, infection, pain, and extrusion. Anastrozole (AZ) (an aromatase inhibitor) has been used in men for the treatment of hypogonadism. AZ use in men has been shown to increase gonadotropin and T levels. Exogenous T therapy uniformly suppresses GT levels. We hypothesized that the concomitant use of AZ at the time of TP insertion would increase the interval between pellet insertions.

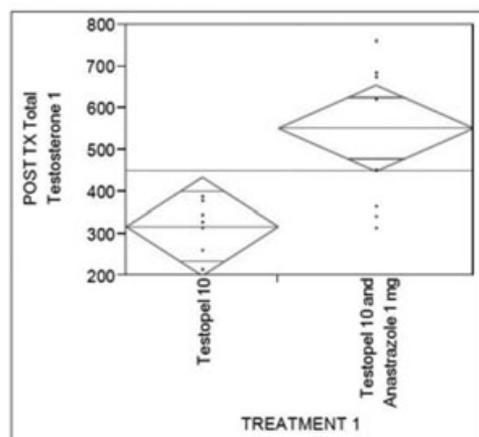
Material and Methods(s): The records of men who underwent TP insertion alone or in combination with AZ were reviewed from 2011–2012. T levels were obtained prior to T replacement therapy and then at approximately 1 and 4 months. Data were analyzed with linear regression and ANOVA.

Result(s): 29 subjects were included in the study. The concomitant use of AZ with TP resulted in a slower decrease in T level after implantation (see graphs). At greater than 120 days the T levels were significantly higher in the AZ with TP group vs. TP ($p < 0.01$). The average time to re-implantation for the TP group was 114 days (12 vs. 177 days (62) with 30% of men in TP/AZ not requiring further implantation.

Conclusion(s): The addition of AZ to TP insertion significantly increased the interval between TP implantations.



Testosterone Levels >120 Days After Pellet Implantation



$P < 0.01$

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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THE IMPACT OF TESTOSTERONE REPLACEMENT THERAPY ON LOWER URINARY TRACT SYMPTOMS

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Introduction: The impact of testosterone replacement therapy (TRT) on the lower urinary tract is unclear, though there is concern that exogenous testosterone(T) can worsen lower urinary tract symptoms (LUTS) because it stimulates prostate growth. Here we examine the impact of TRT on LUTS using validated questionnaires.

Methods: Retrospective review of 63 men was performed. Demographic information, T, free T(FT), estradiol(E), and responses to the International Prostate Symptom Score (IPSS) questionnaire on sequential visits at least 25 days apart were assessed. Men were separated into NewTRT (n = 28), PriorTRT (n = 13), and NoTRT (n = 22) groups. Men in the NewTRT group had started TRT within 2 weeks of the first questionnaire, whereas men in the PriorTRT group had started TRT at least one month before the first questionnaire. IPSS scores and hormone levels were compared between groups.

Results: No significant differences in age, hormone levels, number of men with benign prostatic hypertrophy (BPH), overactive bladder (OAB), or men on 5-alpha reductase inhibitors were observed between groups at baseline. Mean baseline total IPSS questionnaire scores for NewTRT, PriorTRT, and NoTRT groups were: 6.5 ± 5.5 , 8.3 ± 9.0 , and 7.7 ± 8.6 , respectively ($p = 0.764$). Of note, a significant difference in "overall urinary condition" was observed at baseline (1.9 ± 1.2 , 1.7 ± 1.6 , and 2.8 ± 1.4 ($P = 0.029$)). The mean follow-up periods between questionnaires for each group were 81.9 ± 64.8 days (NewTRT), 113.5 ± 75.5 days (PriorTRT), and 105.7 ± 81.5 days (NoTRT). No significant differences in IPSS scores were observed between groups at follow-up. However, a trend towards significantly higher second questionnaire scores was observed in the NoTRT group; mean IPSS score decreased by 0.5 ± 3.9 points in the NewTRT group and 1.9 ± 5.0 points in the PriorTRT group, but increased by 1.8 ± 4.0 points in the No TRT group ($p = 0.066$).

Conclusions: Over a term of approximately 3 months, LUTS in men on TRT do not worsen, whereas LUTS in men not on TRT do. Further work with longer follow-up will help clarify the relationship between TRT and LUTS.

Table 1. Mean differences between IPSS scores in two consecutive surveys

IPSS Question	NewTRT	PriorTRT	NoTRT	P-value*
Incomplete Emptying	-0.17 + 0.76	-0.18 + 0.66	0.23 + 0.60	0.181
Frequency	-0.14 + 1.18	-0.27 + 1.20	0.46 + 1.13	0.190
Intermittency	0.14 + 0.80	-0.27 + 1.35	0.54 + 1.20	0.110
Urgency	0.11 + 1.10	-0.09 + 1.63	-0.15 + 0.80	0.780
Weak Stream	-0.43 + 1.20	-0.27 + 0.94	0.38 + 1.89	0.174
Straining	0.036 + 0.51	-0.41 + 1.56	0.46 + 1.05	0.076
Nocturia	-0.07 + 0.94	-0.36 + 1.33	-0.15 + 1.34	0.679
Urinary Condition	-0.29 + 0.98	0.27 + 0.77	-0.31 + 0.85	0.061
Total Score	-0.50 + 3.88	-1.86 + 5.05	1.77 + 4.00	0.066

*P-value calculated using 3-way ANOVA.

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Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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CIRCADIAN RHYTHM PROFILES IN TESTOSTERONE PRODUCTION IN OLDER MEN

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Objectives: Conventional wisdom suggests that serum testosterone (T) level measurement is best conducted in the early morning (AM) as T levels decrease in the afternoon (PM) due to the circadian rhythm in T secretion. Furthermore, it is suggested that this variation is blunted in older men. This study aimed to define the magnitude of the difference between morning and afternoon T levels and to assess the impact of aging on this.

Materials & Methods: We reviewed our institutional database for all men who had both am (before 10am) and pm (after 2pm) total T (TT) levels within 3 months of each other. We excluded patients with a prior orchiectomy, with T levels < 100 ng/dL and those using androgen deprivation therapy. The differences in TT level between AM and PM were measured and was stratified by decade age increase (<50 years, 51-60 y, 61-70 y, 71-80 y, >80 y). Statistical analysis included descriptive statistics, repeated measure t-test, ANOVA, and Chi-square.

Results: 110 men with mean age of 64 ± 13 y had an age distribution of: 13% < 50 y, 21% 50-59 y, 31% 60-69 y, 28% 70-79 y, 7% ≥80 y. In the entire cohort, there were no differences between mean AM and PM TT levels (305 ± 196 vs 311 ± 199, p = 0.8). Mean AM TT levels decreased with age: 350 ± 172, 388 ± 214, 299 ± 168, 256 ± 205, 207 ± 186 respectively (p = 0.06). This was not true for PM levels: 328 ± 203, 351 ± 166, 284 ± 158, 318 ± 265, and 264 ± 163 respectively (p = 0.7). There were no significant differences in mean difference between AM and PM levels between groups: -22, -37, -15, +62 and +57 respectively (p = 0.9). While 57% of men had no significant difference (-100 to +100) between AM and PM levels, 9% had a > 200 ng/dl decrease, 16% 100-200 ng/dl decrease, 4% 100-200 ng/dl increase and 15% > 200 ng/dl increase. There were no differences in the percentage of men with these TT level changes when grouped by age (p = 0.8).

Conclusions: While mean AM TT levels decreased with age, this study did not detect a significant circadian variation in TT levels based on aging. However, 14 % had a significant difference between AM and PM levels (≥200 decrease or increase) while the PM TT levels did not decrease with age. With the minority of patients in this study being < 50 y of age, this study may reflect the circadian rhythm blunting that occurs in older men and may not be reflective of circadian T level changes in younger men.

Disclosure:

Work supported by industry: no.

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IMPACT OF ASSOCIATION BETWEEN ELEVATED ESTRADIOL AND LOW TESTOSTERONE LEVELS ON SEVERITY OF ERECTILE DYSFUNCTION

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Objective: To assess the impact of association between elevated Estradiol (E2) and low testosterone (T) levels on erectile dysfunction (ED) severity.

Materials and Methods: A total of 614 male patients with ED in association with normal or low T level and/or elevated E2 levels were enrolled. Patients underwent routine laboratory investigations, total T, total E2, FSH, LH and prolactin. We compared the responses to erectile function domain, Q3 (achieving erection), Q4 (maintaining erection) of IIEF score and ED duration in patients with: normal T and E2 levels, low T level, low T plus elevated E2 levels and elevated E2 level.

Results: Mean age plus or minus standard deviation for the study sample was 56.6 ± 11.4 years. Of the patients, 36.6% were below 50 yrs, 78.7% were overweight or obese, and 29.5% were current or ex-smokers. 87.1% of the patients with less than 50 yrs of age and 86.6% of patients with no risk factors had normal hormonal pattern. The percentage of patients with lower body mass index and no smoking were significantly higher in the group of patients with normal hormonal pattern in comparison to the group with low T plus high E2. Of the patients, 449 (73.1%), 110 (17.9%), 36 (5.9%) and 19 (3.1%) had normal T and E2 levels, low T level, low T and elevated E2 levels, and elevated E2 level respectively. There were significant associations between low T, elevated E2, both low T and elevated E2 levels and increased ED severity (*p* < 0.01 for each). The means of EF-domain, Q3 and Q4 were significantly lower in patients with both low T and elevated E2 levels than patients with any of the conditions alone. **Conclusion:** Low T and elevated E2 levels solely and together are associated with increase severity of ED. Low T level demonstrated the principal effect; however, existence of concomitant elevated E2 level adds to the severity of erectile dysfunction in patients with Low T level.

Disclosure:

Work supported by industry: no.

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ELEVATED DIHYDROTESTOSTERONE IS ASSOCIATED WITH TESTOSTERONE-INDUCED ERYTHROCYTOSIS

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OBJECTIVE: Contemporary literature has refuted the traditional believe of erythropoietin as the main mediator of erythrocytosis followed testosterone replacement therapy (TRT). We examined putative risk factors for erythrocytosis and lipid dysfunction associated with TRT.

METHODS: A prospective study was conducted in a single andrology clinic and 145 hypogonadal patients were recruited. Patients were placed on TRT for hypogonadism and pre- and post-treatment dihydrotestosterone(DHT), total T(TT), free T(FT), FSH, LH, hematocrit(Hct), and lipid panels were obtained. Erythrocytosis was defined as Hct > 50%, and non-parametric analysis of the variables between baseline and follow-up was performed using SPSS.

RESULTS: Mean ± SD age in the cohort was 51.2 ± 13.8 years and mean follow-up after TRT initiation was 5 months. Mean baseline lab values were: TT 266.0 ± 101.6 ng/dL, FT 7.4 ± 23.5 pg/mL, DHT 202.0 ± 109.2 pg/mL, FSH 7.0 ± 8.6 mIU/mL, LH 4.2 ± 4.5 mIU/mL, Hct 44.4 ± 3.0%, HDL 46.2 ± 11.3 mmol/L, LDL102.2 ± 34.9 mmol/L. Sixty-five men were placed on topical and 75 on injectable T formulations, and 5 on subcutaneous T implants. The incidence of erythrocytosis within the cohort was 24%(35/145), and of these patients 68% were treated with injectable T, 26% with gels, and 6% with T pellets. Mean DHT levels at follow-up in men who did and did not develop erythrocytosis were 852.7 ± 429.9 pg/mL and 549.0 ± 391.4 pg/mL(p = 0.0005), respectively. Spearman's correlation analysis between cohort variables yielded significant correlations between changes in lipid and Hct and pre- and post-treatment TT and DHT indicating a meaningful relationship between these variables. Notably, a stronger correlation was observed between the change in hematocrit from baseline for DHT (p = 0.303, p < 0.0001) than T (p = 0.204, p = 0.015) at follow-up, and no significant relationship between FT and Hct was observed.

CONCLUSION: DHT is more strongly correlated with T-induced erythrocytosis than TT or FT during TRT. A trend toward T-induced decreased in HDL and DHT is also observed. Data from animal research support a role for DHT in the pathophysiology of cardiovascular side effects resulting from TRT. Therefore, hypogonadal men with elevated Hct on TRT should be screened for elevated DHT levels, and 5α-reductase inhibitors may be a novel therapy for T-induced erythrocytosis.

Disclosure:

Work supported by industry: no.

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REFINED PENILE VENOUS STRIPPING SURGERY FOR PATIENTS WITH ERECTILE DYSFUNCTION: CLINICAL EXPERIENCE FROM ONE SINGLE INSTITUTION

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Objectives: With the discovery that the majority of patients with erectile dysfunction (ED) have veno-occlusive dysfunction (VOD), there has been resurgence in penile venous surgery. However, there is controversy about its effectiveness because of disappointing functional outcome and unacceptable penile deformity. We report long-term results of the refined penile venous stripping surgery on patients with VOD.

Materials and Methods: Between Jan. 2006 and Jan. 2011, 47 patients aged 25 to 71 years (mean age 47.2 years) underwent penile venous stripping surgery for VOD documented by cavernosography and color duplex Doppler ultrasonography. Before cavernosography each patient received a standard evaluation to rule out causes of ED other than VOD. Investigation included a thorough history and physical examination as well as serum testosterone determination. Patients who had suffered an untreated chronic systemic disease were excluded from this study, as were those who had undergone previous penile surgery in other institutions. Among them two patients had a history of prostatic cancer status post laparoscopic radical prostatectomy. 41 were available for long-term follow-up employing the sexual health inventory for men (SHIM) scoring system.

Results: The operation time was from 3.2 to 5.5 hours. The follow-up period ranged from 1.4 to 5.4 years with an average of 3.7 ± 1.2 years. There was significant difference ($p < 0.01$) between the preoperative SHIM (9.8 ± 5.4) and postoperative (17.4 ± 5.9) scores. Overall 33 of 41 patients (80.5%) reported improvements to resume satisfactory intercourse following surgery. In retrospect, 35 of 41 patients (85.4%) would undergo the procedure again, and 36 patients (87.8%) would recommend this procedure to other patients. Complications seem minor and negligible.

Conclusion: Introducing the refined penile venous stripping procedure allowed a trained urologist to achieve favourable results. In this regard, far from being experimental, the procedure finds a surgical niche and is a viable alternative for treatment of ED patients with VOD.

Disclosure:

Work supported by industry: no.

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EXPRESSION AND DISTRIBUTION OF THE TRANSIENT RECEPTOR POTENTIAL CATIONIC CHANNEL A1 (TRPA1) IN THE HUMAN SEMINAL VESICLES

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Objectives: The transient receptor potential cationic channel ankyrin 1 (TRPA1), a channel protein permeable to most divalent cations, has been suggested to play a role in mechano-afferent/efferent signalling (including the release of neurotransmitters) in the human urinary tract, such as the bladder, prostate, and urethra. Up until today, a few studies only have addressed the expression of this receptor in male and female genital and reproductive tissues. The present study aimed to evaluate

in human seminal vesicle (SV) tissue the localization of TRPA1 in relation to the endothelial and neuronal nitric oxide synthases (eNOS, nNOS), and neuropeptides vasoactive intestinal polypeptide (VIP) and calcitonin gene-related peptide (CGRP).

Material & Methods: Human SV tissue was obtained from 5 male subjects who had undergone pelvic surgery due to malignancies of the prostate or urinary bladder. Using immunohistochemical methods (double-labelling technique, laser fluorescence microscopy), the distribution of TRPA1 in relation to eNOS, nNOS, VIP, and CGRP was examined.

Results: Immunoreactivity specific for TRPA1 was located in nerves running through the smooth muscle portion of the SV sections. Here, the protein was only in part co-localized with nNOS and CGRP, whereas no co-localization with VIP was observed. Dot-like signals specific for TRPA1 were observed in the cytoplasm of epithelial cells lining the lumen of glandular spaces of the SV. The epithelial layer also presented staining for eNOS. Both the vascular and non-vascular smooth muscle appeared free of immunosignals related to TRPA1.

Conclusions: The distribution of TRPA1 in human SV tissue indicates that the protein is, to a certain degree, involved in the mechanism of the cyclic GMP-mediated signalling.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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PENILE DUPLEX DOPPLER ULTRASOUND: SURVEY RESULTS OF SEXUAL MEDICINE SOCIETY OF NORTH AMERICA PHYSICIAN UTILIZATION

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Objectives: The penile Duplex Doppler Ultrasound (DDUS) can be used to evaluate the vascular status and anatomy of patients with erectile dysfunction (ED) and Peyronie's Disease (PD). It is well-known that ultrasound is highly operator dependent, and methodology to induce maximal erectile rigidity with intracavernosal agents is variable. Intracavernosal injection (ICI) with a vasoactive agent is another non-standardized step in DDUS, and the choice of agent(s) as well as dosing are subject to the discretion of the urologist. The results of DDUS are often published and used as outcome measures in the literature, leading to comparison of the results of multiple DDUS protocols. Since there are currently no guidelines for specific indications or parameters of DDUS, the purpose of this study was to question Sexual Medicine Society of North America (SMSNA) members regarding their utilization of and method for performing DDUS.

Methods: A ten question electronic survey was sent to all members of the SMSNA querying their use of DDUS.

Results: 116 members completed the survey. 15% never use DDUS in their evaluation of any patient. The indications for DDUS were varied but was used most commonly for patients who want to know their vascular status (72%), to evaluate a patient with Peyronie's Disease (70%), and in young patients without risk factors for ED (64%), 62% of responders exclusively perform the ICI themselves, and 44% exclusively perform the DDUS. Most members used either prostaglandin-E1 (39%) or a mixture of prostaglandin-E1, papaverine, and phentolamine (38%). Only 58% of clinicians redose patients who do not achieve maximal rigidity after one injection, and 74% vary their initial dose and/or medication choice based on patient age or indication for DDUS. 61% check flow parameters every five minutes, and peak systolic velocity, end diastolic velocity, and resistive indices were the most common parameters reported. Only 31% of respondents offer patients visual sexual stimulation in order to aid in achieving maximal erectile rigidity.

Conclusions: There is a wide range of variations in the indications and techniques utilized for DDUS. Because DDUS is a valuable and widely used tool in evaluating patients with ED and PD, it has gained

a role in the literature. Currently, physicians are forced to compare DDUS results of widely divergent protocols. Further studies are necessary to allow for standardization of DDUS to enable better comparison of study groups.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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THE GLOBAL ONLINE SEXUALITY SURVEY (GOSS): THE USA OF AMERICA IN 2011 CHAPTER V: HETEROSEXUALITY, POLYGAMY AND CONTRACEPTION AMONG ENGLISH-SPEAKING MALES

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Objectives: The Global Online Sexuality Survey (GOSS) is a worldwide epidemiologic study of sexuality and sexual disorders, investigating cultural characteristics and uniqueness, and comparing sexuality across cultures and races, launched in the Middle East in 2010, and USA in 2011. The current report investigates trends in marriage, multiplicity of partners, polygamy, coital frequency, sexual positions and contraception

Material and Methods: GOSS was randomly offered to English-speaking male web surfers in the United States of America between August and October 2011. GOSS was offered via paid advertising on Facebook® based on validated questionnaires in addition to general questions.

Result: 63.4% of participants were married, mostly among the 50–59 age group (40.5%). Longer duration of coital relationship (DCR) was associated with higher prevalence of PE. Utility of PDEi's despite normal erectile function (recreational use) was most common among the married (69.5%). Monthly coital frequency declined with age from a median of 10 in the 18–39 years group to 4 in the above 60 age group. The most preferred and practiced sexual position was the missionary, with other positions preferred much more than practiced. 52% reported having had more than one partner in parallel (informal polygamy). 39.3% reported never using condoms on casual sexual encounters. 28.8% reported the use of one or more contraceptive measure for birth control. The most frequently used was condom, though least preferred. Vasectomy and female contraceptive measures were the most favored.

Conclusion: Couples with a longer DCR should be educated about PE and its management options. The data herein may be informative for female partners as to the preferences of males in coital positions, normal coital frequency and contraceptive measures. Prevention of sexually transmitted diseases requires more efforts in the domains of abstinence, monogamy and safe sex.

Disclosure:

Work supported by industry: no.

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DEVELOPMENT OF A CONTENT-VALIDATED, NURSE-DELIVERED STANDARDIZED PATIENT EDUCATION TEACHING TOOL (SPETT) REGARDING POST-RADICAL PROSTATECTOMY SEXUAL DYSFUNCTION

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Objectives: A major side effect of a radical prostatectomy (RP) is sexual dysfunction (SD). No research exists on the nature and impact

of pre-operative patient education by nurses addressing post-RP sexual dysfunction. As part of a doctorate in nursing practice program, an initiative to improve nursing knowledge on post-RP SD was implemented, which lead to the development of a content-validated SPETT for nurses to review with patients.

Material and Methods: Urological surgical nurses attended a 60-minute educational program to improve their knowledge and assess confidence and comfort in discussing and management of post-RP SD. The nurses completed a pre and post-program questionnaire developed for this study and reviewed by experts in sexual medicine and urology. The questionnaire assessed knowledge of post-RP SD, and confidence and comfort in discussing SD with patients. Survey findings supported the development of a SPETT reviewed by a multidisciplinary group of 6 clinical experts in medicine/surgery, nursing, and psychology for content validation.

Results: There were 23 nurses who attended one of 8 educational program sessions. Mean knowledge scores (range, 0–17; 0 low, 17 high) improved from baseline (11.60 ± 2.8) to post-program (16.61 ± 0.9, p < 0.01). An improvement in mean nurse confidence scores (range 1–5; 1 strong agreement, 5 strong disagreement) was also noted (pre = 3.04 ± 1.2; post = 2.39 ± 1.1, p < 0.05) with no change in mean nurse comfort scores (range 1–5; 1 strong agreement, 5 strong disagreement) (pre = 2.65 ± 1.2; post = 2.22 ± 1.0, p = ns). A content validation index (CVI) for relevancy and clarity of the 13 items on the SPETT was established (relevancy CVI [range = 0.88–1]) and clarity CVI [range = 0.96–1]) and relevancy of the tool as a whole CVI = 0.96. A CVI ≥ 0.83 defined content validity.

Conclusions: The findings demonstrate improved nursing education about post-RP sexual dysfunction from a continuing education program and supported the development of a content-validated SPETT by clinical experts. Future research will involve the implementation of the SPETT and evaluation of patient and nurse satisfaction.

Disclosure:

Work supported by industry: no.

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EXPLORING THE FACTORS INFLUENCE A MAN'S CONFIDENCE IN HIS ABILITY TO SATISFY A PARTNER DURING INTERCOURSE -DATA FROM WEB-BASED 7710 JAPANESE COHORT-

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Objectives: Confidence in the ability to satisfy a partner during sexual intercourse is an important issue for men. Higher erectile function (EF) seems to have a strong relationship with sexual self-confidence. Phosphodiesterase-5 inhibitor (PDE5i) was reported to improve confidence in men with erectile dysfunction (ED). However, it is not fully understood what factors correlate with increased confidence in the ability to satisfy a partner. In this study, we aim to investigate factors associated with higher sexual self-confidence in a Japanese population nationwide web-based data.

Material and Methods: We analyzed data from 7710 Japanese men who voluntary replied to a web-based questionnaire, conducted by Pfizer, between March and June 2009. In the present cohort, mean age was 39.3 years. Men were asked to indicate whether or not they were confident that their partners were satisfied during sexual intercourse. Several confounders were analyzed, including demographics, medical characteristics, sexual behaviors, EF and motivation for future treatment. Logistic regression analyses were conducted to determine independent predictors of a man's confidence in his partner's sexual satisfaction.

Results: Of 7710 men, 3172 (41.1%) men were confident that they satisfied their partners, whereas 4538 (58.9%) were not confident. In a multivariable logistic regression model, the sexual confidence was associated with older age (OR 1.01, P < 0.001), awareness of better

health (OR 1.16, $P < 0.001$), confidence of higher EF (OR 2.81, $P < 0.001$), higher erection hardness score (OR 1.75, $P < 0.001$), higher frequency of sexual intercourse (OR 1.51, $P < 0.001$), higher frequency of masturbation (OR 1.05, $P = 0.023$), lower awareness of ED (OR 0.76, $P < 0.001$), positive motivation of future clinic visit for ED treatment (OR 1.17, $P = 0.006$), and experience of PDE5i use (OR 1.35, $P < 0.001$). In contrast, marital status, presence of offspring, living location in Japan, lifestyle choices, such as cigarette smoking and alcohol drinking, metabolic syndrome, and comorbidities were not strongly correlated with sexual confidence.

Conclusions: Among those men who were confident, we found that confidence in partner satisfaction was correlated to not only EF but also to several of the aforementioned factors. Further study is needed to identify whether male confidence reflects female satisfaction in sexual intercourse.

Disclosure:

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COLOPLAST TITAN CL CLOVERLEAF RESERVOIR AND ZERO DEGREE/SOFT TIP CYLINDERS: INITIAL RESULTS

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Objectives: Coloplast Corp. has recently introduced modifications to their inflatable penile prosthesis (IPP) cylinders and reservoir. This abstract will report our initial experience with these new components.

Material and Methods: We carried out a retrospective review of 10 patients implanted with Titan Zero Degree/Soft Tip cylinders, and 20 patients implanted with the Titan CL cloverleaf reservoir.

Results: The CL reservoir has a different shape, stiffness, footprint, and insertion method than the prior reservoir. The recommended method for reservoir placement will be demonstrated. The Zero Degree/Soft Tip cylinders have decreased tubing angle-of-entry into the cylinder, facilitating proximal corporal insertion. The silicone cylinder tip cover presents a softer sub-glanular tip, which may improve patient and partner comfort. Both components functioned as specified by the manufacturer. With short-term follow-up, no complications were seen with either component.

Conclusions: The Titan Zero Degree/Soft Tip cylinders and CL cloverleaf reservoir are new components designed to improve on the functionality and ease of insertion of the Titan IPP. Our initial series revealed no complications related to either component. A larger series and longer follow-up is being accrued, to confirm these initial positive results.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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TADALAFIL TREATMENT OF ED IN DIFFERENT FORMS OF CHRONIC PROSTATITIS

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Objectives: About 30% with chronic prostatitis are suffering from ED. Due to demographic indices in the country it is a highly pressing problem. The aim of the study to compare the efficacy of tadalafil in patients with chronic bacterial prostatitis and nonbacterial prostatitis after the long time conservative treatment ED.

Material & Methods: 98 patients suffering from ED at the 3 year follow-up were treated with tadalafil. Statistical proved 51 patient with chronic bacterial prostatitis and 47 patients with nonbacterial prostatitis Age 23–35. Tadalafil was administrated once a week 20 mg. All patients and their partners were investigated once in 3 month using computerized generated random number list. All patients before starting treatment were examined by DRI, penil doplerografy, ultrasound, UTI EPS and abridged 5-item version of IIEF.

Results: Vascular insufficiency was assessed in 31(60,78%) in first group and 38(80,85%) in the second group of patients. IIEF score show several ED- 16(31,37%), moderate ED - 12(23,53%), mild ED - (15,69%) in first group and several ED- 19(40,43%), moderate ED- 8(17,02%), mild ED- 5(10,64%) in second group After treatment vascular insufficiency in first group was 12(23,52%) and 18(38,29%) in second group respectively. IIEF score show several ED- 9(17,65%), moderate ED-10(19,61%) mild ED-17(33,33%) in first group and findings 12(25,53%), 10(21,28%), 10(21,28%) in second group. Assessment of men partners before treatment in first group was excellent 8(15,69%), good 11(21,57%) pure 23(45,10%), in the second group 7(14,89%), 9(19,15%), 19(40,43%) respectively. After treatment results show excellent - 3(45,10%) good - 12(23,53%), and poor - 9(17,65%) in first group and excellent -12(25,53%), good - 11(23,40%), and poor - 7(14,89%) in second group. At the long term observation 31(60,78%) in first group and 26 {55,32%} patients in second group were still engaging in sexual intercourse ,when 7(13,73%) in first group and 8(17,02%) in the second group did not received a tumescence able to intercourse. Improvement of spontaneous erections were reported in 36(70,59%) in first group and 23(48,94%) in second group.

Conclusions: 1. Tadalafil treatment significantly helps in different forms of chronic prostatitis patients. 2. Tadalafil treatment options consider good effect on patients and partners satisfaction. 3. Tadalafil treatment successful improve the quality of life for patients partners.

Disclosure:

Work supported by industry: no.

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ELECTROANALGRAM

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Objective: To value the status of the pelvic muscles surrounding the anus in rapid ejaculation.

Material and Methods: Using a Perineometer we have been able to value the status of the pelvic muscles surrounding the anus. The evaluation we called Electroanalgram.

The Electroanalgram has the following parts: base line (BL), contraction, hold and relax (CHR), contraction, hold and relax five times (CH5R), contraction, hold x 10 second and relax two times (CHTR2), Contraction, hold steadily as much as you can (CHR), termination base line (TBL).

20 males with satisfactory ejaculatory time were comparing with 20 males with Rapid Ejaculation.

Results: A significant weakness was found in males with Rapid Ejaculation

Conclusion: The Electroanalgram have prove to be helpful in the diagnosis of weakness of muscles surrounding the anus, which is a main feature present in male's Rapid Ejaculation.

Disclosure:

Work supported by industry: no.

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TREATMENT DISPARITIES IN ERECTILE DYSFUNCTION: BELIEFS IN AN URBAN USA PRIMARY CARE POPULATION.

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Objectives: Racial and socio-economic disparities have been described in erectile dysfunction (ED). Men's beliefs about ED and treatment may be contributing factors, however this remains understudied.

Methods: A total of 75 men at two primary care clinics (a private university practice and a county hospital-based practice) completed a self-administered survey concerning men's health issues. The survey included socio-demographic items, the 15 item International Index of Erectile Function (IIEF), and independently developed questions about men's knowledge and attitudes surrounding ED, testosterone deficiency, and male infertility. Pearson's chi-squared test using significance at the 0.05 level was used to compare clinic sites.

Results: Significant socio-demographic differences existed between clinic sites (Table 1). Men's perceptions of ED and ED treatment, measured by Likert scale, were similar at both sites. A statistically significant difference was only found for "I am concerned about ED" which more county men agreed with. IIEF scores were significantly better in men at the private community clinic for three of five domains.

Conclusions: The two clinic sites differed considerably in racial and socio-economic background. However, beliefs about ED and treatment were similar in both groups of men. Men in the county clinic may be experiencing a greater burden of sexual and erectile difficulties based on IIEF score and they also report being more concerned about ED compared to men at the private clinic.

Table: Differences in beliefs, demographics, and IIEF scores between two clinic sites

	Public (n=52)		Private (n=23)		p-value
	n	%	n	%	
Age >50	28	54%	15	65%	0.45
Race					
Black	48	92%	3	13%	<.001
White	2	4%	19	83%	
Highest education					
HS graduate	27	52%	1	4%	<.001
Some college or more	13	25%	21	91%	
Beliefs (% agree or strongly agree)					
ED is a treatable condition	39	75%	19	83%	0.22
Treatments for ED are dangerous	10	19%	3	13%	0.56
Embarrassed to take medication for ED	9	17%	2	9%	0.48
ED is a serious condition	31	60%	10	43%	0.22
Erections are important to my overall health	36	69%	16	70%	0.85
I am concerned about ED	30	58%	7	30%	0.03*
IIEF Scores	mean	SD	mean	SD	p-value
Erectile function (1-30)	16.9	10.0	21.6	9.1	0.05
Orgasmic function (0-10)	4.9	3.5	8.2	2.7	<.001
Sexual desire (2-10)	6.0	2.5	7.5	1.7	0.006
Intercourse satisfaction (0-15)	6.8	4.7	8.9	5.2	0.1
Overall satisfaction (2-10)	5.9	3.0	6.8	2.5	0.18

Disclosure:

Work supported by industry: no.

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SONIC HEDGEHOG PATHWAY IS ACTIVE IN HUMAN PENIS

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Objective: Smooth muscle apoptosis is a major contributing factor to development of erectile dysfunction (ED) in prostatectomy and diabetic patients and animal models. A critical regulator of penile smooth muscle and apoptosis is the secreted protein sonic hedgehog (SHH). SHH protein is decreased in cavernous nerve (CN) injury and diabetic rat ED models and SHH treatment of CN injured rats prevents smooth muscle apoptosis and promotes regeneration of erectile function. We propose that the SHH pathway is active in human penis and

that decreased SHH protein plays a significant role in the development of ED in patients. In this study, we quantify SHH protein and corpora cavernosal morphology in penis from control, prostatectomy and diabetic patients.

Materials and Methods: Human corpora cavernosal tissue was obtained from patients undergoing penile implant to treat ED in prostatectomy (n = 17), diabetic (n = 22) and Peyronnie's (control, n = 11) patients. Quantification of SHH protein was performed by Western analysis. SHH localization was examined by immunohistochemical analysis and insitu hybridization. Smooth muscle and apoptosis were examined by quantifying α -ACTIN, trichrome stain and TUNEL assay.

Results: SHH protein and RNA were identified in human corpora cavernosal smooth muscle. Trichrome stain showed decreased smooth muscle in prostatectomy patients and intermediate staining in the diabetic.

Conclusions: These results identify that the SHH signaling pathway is active in human penis.

Disclosure:

Work supported by industry: no.

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THE GLOBAL ONLINE SEXUALITY SURVEY: PENILE SIZE AND STRAIGHTNESS IN USA

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Objectives: The Global Online Sexuality Survey (GOSS) is a worldwide epidemiologic study of sexuality and sexual disorders. The age adjusted prevalence of male and female sexual disorders is estimated around the world, and so are the predisposing risk factors, anatomical variations, sexual preferences and unique habits for each and every culture. GOSS is deployed over the internet to the general population regardless surfing and web search inclinations, the only prerequisite being above 18 years of age. The first reports out of GOSS came from the Middle East, in the year 2010, results of which were published in 2011. This report investigates self-measured penile size and anatomic variations in USA, correlates those findings to sexual function and compares the data obtained from reports from other populations.

Material and Methods: GOSS was randomly offered to English-speaking male web surfers in the United States of America between August and October 2011. GOSS was offered via paid advertising on Facebook®. Various aspects of sexuality and sexual function were inquired upon. In addition, penile size and straightness, as well as satisfaction with size were reported upon. Illustrations were provided along descriptive text to inform participants upon the method they are required to measure size with.

Result: Two hundred and twelve participants reported self-measured penile size. Median Erect visible length was 15 cm, while median flaccid non-stretched visible length was 7 cm. Median erect girth was 13.8 cm. Other penile dimensions were subjectively measured and reported. Minor ethnic variations were detected. Dissatisfaction with penile size was evaluated and correlated with erectile dysfunction (ED). Penile curvature in the erect state was reported by 49.5%, very severe in 1.3%, severe in 1.9%, slight in 28.9% and very slight in 17.4%.

Conclusion: Penile dimensions and straightness in USA were evaluated. Concern over genital size –and not an undersized penis per se– is a major risk factor for ED.

Disclosure:

Work supported by industry: no.

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MORPHOLOGICAL ASSESSMENT OF CORPORA CAVERNOSA TISSUE IN DIABETIC AND NON-DIABETIC PATIENTS WITH ERECTILE DYSFUNCTION

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Objective: Is to compare histopathological changes in corpora cavernosa (CC) tissues of diabetic with non-diabetic patients with erectile dysfunction (ED).

Materials and Methods: The study group consisted of 40 men with ED, consecutively scheduled for penile implant insertion at Assuit University Hospital. Biopsies from CC were obtained during penile implant insertion. Paraffin embedded sections from each specimen were stained with (1) conventional H&E for general assessment of the tissue and any pathological alteration (2) Masson Trichrome for identification and assessment of smooth muscle (SM) fibers and collagen and with (3) Verhoeff's elastic van Gieson stain for assessment of elastic fibers. SM was assessed for cell-thickness/bundle, shape and percentage from trabecular tissue thickness. Elastic fibers were assessed for shape (longitudinal wavy fibers versus frayed fibers) and percentage from trabecular tissue. Arteries and venous sinuses were assessed for presence of subendothelial fibrosis.

Results: Patients included in the study were divided into two groups; diabetic and non-diabetic. Histopathological assessment revealed no SM cell thickness difference between two groups. However, SM in diabetic group showed higher degree of shape abnormality in the form of frayed fibers ($p = 0.001$) and more fibrosis within the muscle bundles ($p = 0.011$). The collagen fibers percentage of trabecular tissue ranged from 10–100%. The percentage of collagen fibers in trabecular tissue was significantly higher in diabetic patients ($p = 0.015$). The elastic fibers percentage of the trabecular tissue ranged from 10%–60% and was significantly reduced in diabetic patients ($p = 0.003$). Elastic fibers shape was also altered in the form of frayed fibers but was not statistically significant ($p = 0.556$). Subendothelial fibrosis within arteries/arterioles and venous sinuses was higher in diabetic group however both were not statistically different $p = 0.052$ and $p = 0.072$ respectively.

Conclusions: The major structural changes within the CC tissue in diabetic patients were reduction of the SM, presence of fibrosis within SM bundles, increased collagen fibers and reduction of elastic fibers. These changes may play a role in prevention of appropriate SM relaxation and interference with proper sinus filling. Identification of histopathological changes in cavernosal tissue is essential not only for understanding the mechanisms of ED in diabetic men but also for proper management of each patient.

Disclosure:

Work supported by industry: no.

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MELD SCORE AS A PREDICTOR FOR ERECTILE DYSFUNCTION IN PATIENTS WITH HEPATIC CIRRHOSIS

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Objective: Estimated prevalence of Erectile Dysfunction (ED) in patients with Hepatic Cirrhosis (HC) is 50–93%. There are very few studies that analyze and explain this association. The aim of this study is to evaluate ED according to the International Index of Erectile Function (IIEF) questionnaire in patients with HC. We also analyze the relationship between the grade of ED and MELD (Model for End Liver Disease) and Child-Pugh (C-P) classification.

Material and Methods: This is an observational cross-sectional study. IIEF questionnaire was applied to identify the severity of ED in

patients with HC with a stable treatment, during their follow up in the Liver Diseases Clinic at our institution. Patients were classified according to the Child-Pugh and their MELD score. We tried to find a correlation between those scores and ED severity depending on IIEF scores.

Results: The study includes 31 men, with a mean age of 51.42 ± 11.8 years. IIEF total score was 48.87 ± 19.6 and an IIEF-5 score of 15.58 ± 6.3 . In accordance to the C-P classification there were 8, 14 and 9 patients in class A, B, and C, respectively. Mean MELD score was 13.9 ± 4.7 . In the initial analysis of the study no significant correlation was found between MELD and C-P with IIEF scores. After a ROC (receiver operating characteristic) curve analysis we found a cut-off point for MELD ≥ 15 to be the most sensitive predictor for ED. There was a significant correlation between MELD ≥ 15 and IIEF score ($p = 0.048$), IIEF-5 ($p = 0.045$) and IIEF categorized in 4 levels of severity ($p = 0.035$). Patients with a MELD score ≥ 15 had a substantial lower score in IIEF ($p = 0.05$), IIEF-5 ($p = 0.048$) and severe category of IIEF ($p = 0.037$). C-P classification was not significantly different.

Conclusions: Hepatic Cirrhosis has a positive correlation with Erectile Dysfunction using the IIEF questionnaire. The MELD score has a direct relationship with ED. MELD ≥ 15 identifies patients with severe ED.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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PREVALENCE OF MAJOR CARDIOVASCULAR RISK FACTORS IN MEN WITH ERECTILE DYSFUNCTION

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Objective: Greater than 80% of erectile dysfunction (ED) is considered to be of primarily organic etiology. Recent studies have demonstrated that ED precedes cardiovascular disease by 2–10 years. Therefore, a window of opportunity exists to detect modifiable risk factors in patients with ED and potentially prevent major cardiovascular events in the future. The purpose of our study was to determine the frequency of modifiable risk factors in men presenting with ED.

Materials and Methods: This was a retrospective study of 96 new patients who presented with ED over a 6-month period between January 1st and June 31st 2011. ED was defined subjectively by patients and based on IIEF score < 21 . All patients had height, weight and blood pressure measured on initial exam and completed the 15-item International Index of Erectile Function (IIEF) Questionnaire. Levels of total testosterone (TT), hemoglobin A1c (HBA1c) and lipid profile (total cholesterol, LDL-C, HDL-C, triglycerides) were also obtained in the majority of patients. Data are presented as mean \pm SD.

Results: Average age of patients was 55 ± 15.5 years. Almost half of all patients (37/77, 48%) were overweight (BMI 25.0–29.9 kg/m²), whereas 36% (28/77) were obese (BMI 30.0 kg/m² and above). Total testosterone level was measured in 92 patients. Thirty-three (30/92) percent of patients were hypogonadal (TT < 300 ng/dl), and TT level was inversely correlated with BMI ($r = -0.37$; $p = 0.001$). Hemoglobin A1c was determined in 63 patients. Thirty five percent of these patients (22/63) had prediabetes based on HBA1c between 5.7 and 6.4%, whereas 21% had diabetes (HBA1c 6.5% and above). Lipid profile was determined in 91 patients. More than half of all patients (52/91, 57%) had LDL-C level above 100 ng/dl on initial visit, whereas 22% (20/91) of patients had HDL-C levels below 40 ng/dl. Fifty-one percent (45/88) of all patients had uncontrolled systolic (>130 mm Hg) or diastolic (>80 mm Hg) blood pressure on initial exam.

Conclusions: More than half of men presenting with ED have at least one of the major cardiovascular risk factors including hypertension,

diabetes and dyslipidemia. Physicians should routinely screen for these conditions as part of the initial evaluation in any patient presenting with ED. Prompt correction of these factors may prevent major cardiovascular events in the future.

Disclosure:

Work supported by industry: no.

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PENILE FRACTURE: OUTCOMES OF IMMEDIATE SURGICAL INTERVENTION

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Objective: Penile fracture is a rare urologic emergency. Immediate surgical repair rather than conservative management is widely accepted as the therapy of choice. Patient outcomes with respect to erectile function and voiding symptoms are poorly defined. Preponderance of published studies attribute the mechanism of penile fracture to forcefully bending the erect penis to achieve detumescence. Few studies from Western societies have been reported where the primary mechanism of fracture is sexual intercourse. Medical records of patients with penile fracture were reviewed. The preoperative evaluation, surgical repair, and long term outcome were assessed.

Materials and Methods: Medical records of patients with penile fracture treated at Northwestern Memorial Hospital and Oregon Health & Science University from 2002 to 2011 were reviewed. Clinical presentation, preoperative evaluation, time from injury, mechanism and site of injury, and presence of urethral injury were assessed. Post-operative outcomes including erectile dysfunction, penile curvature, and voiding symptoms were evaluated using history and physical examination, American Urological Association Symptom Index (AUASI) scores and International Index of Erectile Function (IIEF) scores.

Results: Thirty-three patients were identified with penile fracture from the databases. The mean patient age was 44 years old (range 19–59 years). All patients presented to the emergency room with a history and physical examination consistent with penile fracture (penile buckling, a “pop”, rapid detumescence). The mean time from injury was 14.3 hours (range 0.75–54 hours). The mechanism of injury was sexual intercourse in 29 of the 33 patients with the others attributed to masturbation and “rolling over”. Immediate surgical repair was offered to all patients. Two patients refused surgery and elected conservative management and never followed up in clinic. The 31 surgical patients underwent flexible cystourethroscopy and surgical exploration with a degloving circumferential incision or at the site of injury. A urethral injury was noted in 5 of the 33 patients at the same level of the tunica albuginea tear. The site of fracture was at the proximal shaft in 15 of the 31 patients and at the mid shaft in 16 of the 31 patients. The mean follow up period was 3.6 months (range 1–11 months) with 2 of 33 patients not returning for assessment. Six patients reported new mild erectile dysfunction; 4 patient reported mild penile curvature (20 to 30 degree dorsal curve). One patient reported new post-operative irritative voiding symptoms (AUASI score 22).

Conclusions: Penile fracture is an uncommon but urgent urologic injury. The most common mechanism of injury in our study was from sexual intercourse. The frequency of concomitant urethral injury was low. Immediate surgical repair was associated with recovery of sexual function and minimal irritative voiding symptoms.

Disclosure:

Work supported by industry: no.

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ARE VIDEOS VALUABLE IN COUPLES RELATIONSHIP THERAPY?

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Objectives: To evaluate whether or not the use of a self-help video compared to usual care improves outcomes in couples with relationship problems.

Design: Randomized controlled trial.

Setting: Specialist out patient service in Sheffield.

Participants: 18 couples referred to a couples and sexual problems clinic.

Interventions: A project developed two culturally sensitive self-help videos for couples with relationship problems. These were evaluated against a no treatment 12 week waiting list for couples referred to a couples and sexual problems clinic.

Outcomes: GRIMM (primary), GRISS, BDI, and DAS collected at baseline and 12 weeks post randomisation.

Results: 8 couples were randomised to the video group and 10 to the no video control group. Recruitment was extremely difficult from natural referrals to the clinic as well as from primary care practices despite the opportunity of rapid access to self help materials. The study was suspended due to low recruitment numbers. We calculated the average baseline and follow-up scores and used these in the subsequent analysis. There were no statistically significant differences between the video and control groups at baseline or at follow-up. Even by adjusting for the baseline score there were still no statistically significant differences between the video and control groups at follow-up.

Conclusions: Although the results suggest that use of self help visual instructional material did not produce any significant differences, this may have been due to low recruitment alone as only 8 couples were randomised to video. A number of key learning points were identified and suggestions are presented for future studies of a similar nature. These include the opportunity of making the materials more easily accessible to couples using smart phone technology and via internet access as well as providing support through telephone and internet technologies to improve recruitment and participation.

Funding: Marriage & Relationship Support Grant Programme.

Disclosure:

Work supported by industry: no.

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MEASUREMENTS OF THE TOTAL TESTOSTERONE CANNOT USE A DIAGNOSIS AS TESTOSTERONE DEFICIENCY SYNDROME IN JAPANESE POPULATION

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Objectives: The International Society of Andrology (ISA), the International Society for the Study of the Aging Male (ISSAM), and the European Association of Urology (EAU) recommended the measurement of serum total testosterone for diagnosing as the presence of hypogonadism. However, Japanese Urological association and JSSAM recommended the measurement of analogue free testosterone (aFT) instead of total testosterone (TT). This discrepancy is due to a difference in TT value with aging. The aim of the study was to evaluate the TT value in Japanese population using liquid chromatography tandem mass spectrometry (LC MSMS) and to assess an application of measurement of aFT value instead of TT value.

Patients and Methods: This study is a part of the Longevity Sciences (H19-CHOJU-003, 1900000) from the Ministry of Health, Labour and Welfare, Japan. The study included 503 subjects. The age range was 39–90 (mean 60.6 ± 27.4, median 54). TT was measured using LC

MSMS and SHBG using an immunofluorometric assay (Delfia-Wallac), and FT was calculated (cFT). The aFT was measured by Commercial electrochemiluminescence immunoassay.

Results: The range of serum TT, SHBG, cFT and aFT were 21 to 1378 ng/dL (mean 437 ± 163, median 427), 234 to 10.7 nmol/L (mean 65.2 ± 38.2, median 53.3), 15.1 to 2.72 pg/ml (mean 5.84 ± 27.3, median 6.11), and 21.6 to 0.6 pg/mL (mean 8.20 ± 27.3, median 8.6), respectively. TT showed almost constant with age ($y = -0.0253x + 438.6$, $R^2 = 4E-06$). SHBG value increased ($y = 1.1928x - 6.943$, $R^2 = 0.2528$) and cFT value decreased ($y = -0.7753x + 105.4$, $R^2 = 0.2413$) with aging. There was significantly correlation between cTF and aFT ($P < 0.005$, $y = 0.1027x + 2.2019$, $R^2 = 0.5121$).

Conclusion: Although TT value in Japanese population is almost constant with aging, FT value decreases. This findings raises the possibility that a relatively high increased formation of SHBG with aging may show constant in TT value. Therefore, aFT is a suitable indicator in Japanese population.

Disclosure:

Work supported by industry: no.

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IS TOTAL TESTOSTERONE A TRULY DECISIVE MARKER FOR THE NEED FOR TESTOSTERONE SUPPLEMENTATION? A REPORT OF TWO EUGONADAL MEN

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Introduction: It is common practice to use total testosterone levels to determine whether a man should receive testosterone replacement therapy. However, men with normal total testosterone levels can still experience symptoms of hypogonadism due to deficiencies in bioavailable testosterone or genetic influences on androgen sensitivity.

We report two cases of men who had normal age-adjusted testosterone levels with symptoms of hypogonadism who benefited from testosterone supplementation therapy.

Materials and Method: We performed subjective measures of sexual functioning (International Index of Erectile Function (IIEF) domain score and Aging Male's Symptom (AMS) score) and objective measures of nocturnal penile activity (RigiScan®) before and after six months of intramuscular testosterone undecanoate injections.

Results: Both cases experienced a subjective improvement in sexual functioning as shown by a reduced AMS score and an increased IIEF domain score. Both cases experienced an objective and statistically significant improvement in penile rigidity as measured by RigiScan®.

Conclusion: We propose some men can and should receive testosterone supplementation if they present with symptoms of hypogonadism even though they are eugonadal.

Disclosure:

Work supported by industry: no.

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FEMALE SEXUAL DYSFUNCTION IN MENOPAUSAL SYMPTOMS SUCH AS SOCIAL REPRESENTATION OF WOMEN IN THE CLINIC OF MENOPAUSAL TRANSITION FEDERAL UNIVERSITY OF SAO PAULO

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Objective: To understand and identify the social representations built on perimenopause and menopause.

Material and Method: In a cross-sectional, exploratory, grounded in social psychological view were evaluated 162 patients over 40 years, the clinic Menopausal Transition, Climacteric sector, the Department of Gynecological Endocrinology, Department of Gynecology of UNIFESP-EPM. Through a questionnaire was used the technique of free association words (FAW). To apply this technique, after completing the demographic data were presented with two issues, a and b. In both, should be answered in order of importance of the feeling evoked, any word or phrase that came to mind. Question: a) When you say the word menopause, which the first words that come to mind? Question: b) What comes to mind when I say the word menopause? Specific questionnaire was applied on Quality of Life - abbreviated version (WHOQOL-BREF) and a list of 20 items related to symptoms of menopausal syndrome. The collected data were entered and analyzed electronically by the Statistical Package for Social Sciences for Personal Computer (SPSS-PC) for Windows version 18.0.

Results: Of 162 participants, most (93.2%) were post-menopausal, 110 reported one or more of these symptoms: vaginal dryness: 77.3%; dyspareunia: 39.1%, decrease in sexual desire: 70.9% and 42.7% to avoid intimate contact and fondling to intercourse. The words generated for menopause related to sexuality were: "lack of libido," "chilling," "unloving," "impotence," "just my sex life," "do not feel like sex," "lack of libido" "lack of sexual desire," "decreased libido", and 78.8% attributed the symptoms they experience the event of menopause. In evaluating the quality of life scores were related to sexual satisfaction: 18.5% very dissatisfied 19.8% dissatisfied, 25.3% neither satisfied nor dissatisfied, 25.3% and 11.1% very satisfied indicating that only 36.4% feel satisfaction.

Conclusion: The women in this sample postmenopausal negatively evaluate this phase with respect to the impact on their sexuality, crediting the menopausal symptoms and sexual dysfunction present.

Disclosure:

Work supported by industry: no.

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EFFECT OF THE ETHANOL ON THE ERECTILE FUNCTION IN THE RAT

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Purpose: Alcohol consumption is associated with the erectile function. However, the effect of ethanol (ETOH) on penile tissue is not fully understood. We investigated the acute and chronic effects of ETOH on corporal tissue in the rat.

Materials and Methods: To examine the acute effect of ETOH, the rats were divided into a control group and four experimental groups (1 hour, 2 hours, 4 hours and 6 hours after injected the ETOH). To examine the chronic effect of ETOH, the rats were divided into a control group (oral intake normal saline, 3 g/Kg, 4 weeks) and experimental groups (oral intake 15% ETOH, 3 g/kg, 4 weeks). The intracavernosal pressure/ blood pressure (ICP/BP) response to cavernosal nerve stimulation was assessed in all groups. And the concentration of released cGMP and cAMP were measured. In chronic ETOH group, serial sections of the penis were used to perform Masson's trichrome stain. We analyzed the expression of eNOS concentration in the isolated corpus cavernosum by western blotting.

Results: In acute ETOH study, the percentage of ICP/BP of the normal control group was 71.6 ± 4.8 (N = 7), the four experimental groups (1 hour, 2 hours, 4 hours and 6 hours after injected the ETOH) were 79.3 ± 8.3 (N = 7), 86.6 ± 7.6 (N = 7), 74.6 ± 7.3 (N = 7), 75.1 ± 5.2 (N = 7). The percentage of ICP/BP of experimental group (2 hours) only was statistically higher than the control group ($P < 0.05$). The concentration of cAMP of experimental group (2 hours) was statistically higher than the control group (control group N = 6, 4.56 ± 1.14 pmol/ml Vs. 2 hours 13.30 ± 4.92 pmol/ml) ($P < 0.05$). In chronic ETOH study, the percentage of ICP/BP of the normal control group was 84.0 ± 4.0 (N = 6), the experimental group was 88.5 ± 6.5 (N = 6) ($P > 0.05$). The concentration of cAMP and cGMP were not statistically higher than the control group ($P > 0.05$). In the chronic ETOH group, the immunoreactivity of eNOS decreased in the

smooth muscle and fibroblasts. The protein expression of eNOS was decreased in the chronic alcohol group ($p < 0.05$).

Conclusion: Acute effect of ETOH was improved the erectile function due to increased cAMP concentration in the rat. A chronic effect of ETOH significantly decreased the expression of eNOS in the rat. It can be one of the mechanisms for erectile function after alcohol drinking.

Disclosure:

Work supported by industry: no.

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EFFECTS OF COMBINED USE OF PHOSPHODIESTERASE 5 INHIBITOR AND MEDICATIONS FOR HYPERTENSION, LOWER URINARY TRACT SYMPTOMS AND DYSLIPIDEMIA ON TONE OF CORPORAL TISSUE

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Objective: To establish theoretical basis of choosing an appropriate medication for erectile dysfunction (ED) and concomitant disease, we examined the effects of combination Phosphodiesterase 5 inhibitor (PDE5I) with drug for ED comorbidities (hypertension, lower urinary tract symptoms, and dyslipidemia) on relaxation of rabbit corpus cavernosum (CC).

Methods: Contractility of CC strips was studied in organ baths. Concentration-response curves to mirodenafil were generated on phenylephrine (PE) (10^{-5} M)-precontracted strips before and after preincubation of losartan (10^{-5} , 10^{-4} M), amlodipine (10^{-7} , 10^{-6} M), nifedipine (10^{-7} , 10^{-6} M), enalapril (10^{-6} , 10^{-5} M), doxazosin (10^{-8} , 10^{-7} M), tamsulosin (10^{-10} , 10^{-9} M), or simvastatin (10^{-6} , 10^{-5} M). Another organ bath studies were done to determine the losartan/nitric oxide interaction on CC smooth muscle function.

Results: The effect of mirodenafil to relax PE-induced CC tone was significantly enhanced by preincubation of losartan, nifedipine, amlodipine, tamsulosin and doxazosin. The maximal effect was $35.8 \pm 2.0\%$ of inhibition of PE-induced tone for mirodenafil alone vs. $47.2 \pm 3.8\%$ for preincubation of 10^{-4} M losartan, $57.6 \pm 2.6\%$ for 10^{-6} M nifedipine, $64 \pm 3.7\%$ for 10^{-6} M amlodipine, $76.1 \pm 5.7\%$ for 10^{-7} M doxazosin, and $71.7 \pm 5.4\%$ for 10^{-9} M tamsulosin. But enalapril and simvastatin had no additional effect. Relaxation of CC smooth muscle induced by the nitric oxide donor sodium nitroprusside (SNP) was potentiated by losartan ($p < 0.05$). The maximal responses to SNP alone ($39.0 \pm 4.0\%$) were significantly enhanced in the presence of the 10^{-4} M losartan ($66.0 \pm 6.0\%$). Nonselective K⁺ inhibitor tetraethylammonium (1 mM) significantly inhibited enhancement effect of tamsulosin or doxazosin on mirodenafil-induced relaxation.

Conclusion: Amlodipine, nifedipine, losartan, doxazosin, and tamsulosin enhanced relaxation effect of mirodenafil in CC. Combination of PDE5I with these medications could be a possible pharmacologic strategy to simultaneously treat erectile dysfunction and its comorbidities and to increase response rate to PDE5I.

Disclosure:

Work supported by industry: no.

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EFFECTS OF DAILY ADMINISTRATION OF PHOSPHODIESTERASE TYPE 5 INHIBITOR ON ENDOTHELIAL DAMAGE IN ATHEROSCLEROTIC RAT MODEL

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Objectives: To evaluate the effects of chronic daily administration of phosphodiesterase type 5 inhibitor (PDE5I) on atherosclerosis-induced endothelial damage developed by 1% hypercholesterol-diet in rat model.

Material and Methods: Sprague-Dawley rats divided into 7 groups, that were 6 week-normal diet group, 10 week-normal diet group, 6 week-hypercholesterol diet group, 10 week-hypercholesterol diet group, 10 week-hypercholesterol diet and daily PDE5I administrated group, 6 week-hypercholesterol diet followed by 4 week normal diet group and 6 week-hypercholesterol diet followed by 4 week normal diet and PDE5I-administration group. For developing the definite endothelial damage & atherosclerosis, water mixed with 1 mg/ml L-NAME was supplied to rats for first 2 weeks. PDE5I (Vardenafil) was administered transperitoneally 1 mg/Kg/day since 2 weeks after 1% cholesterol diet. Serum cholesterol for hypercholesterolemia and endothelin-1, HIF-1 α , TGF- β 1 and eNOS for endothelial damage were measured.

Results: Cholesterol diet increased in expression of HIF-1 α , endothelin1 and TGF- β 1 but decreased in expression of eNOS, which was demonstrating endothelial damage. In hypercholesterolemic rat, normal diet only did not recover hypercholesterolemia, which might mean need exercise for endothelial recovery. Regular daily administration of PDE5I was partly helpful to recover endothelial damage by hypercholesterolemia even if it did not affect on serum cholesterol level.

Conclusion: Endothelial dysfunction of corpus cavernosum induced by hypercholesterolemia is not improved enough by control diet only. However, chronic daily administration of PDE5I and diet control might improve or prevent endothelial damage induced by hypercholesterolemia.

Disclosure:

Work supported by industry: no.

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PROLONGED CLOSED-SUCTION DRAINAGE AFTER PENILE PROSTHETIC SURGERY

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Introduction: An estimated 15,000 implants are placed each year in the United States. Complications from implants include swelling, hematoma, and the devastating infection. Drains are often used to minimize complication rates, however with a theoretical risk of infection. The general rates of infection are quoted from 2–5%. Sadeghi-Nejad et al have shown that short-term use of drains, 12–24 hours have not been shown to increase complication rates, with a quoted infection rate of 3.3%. In our small series we have shown that prolonged (up to 72 hours) use of closed suction drainage in a select patient population does not affect complication rate.

Materials and Methods: A total of six patients underwent placement of a three-piece inflatable penile prosthesis. The patients had a number 10 round drain placed at time of surgery. The patients all maintained the drain for approximately 72 hours. They presented to the clinic for removal.

Results: A total of 6 patients underwent placement of three-piece inflatable penile prosthesis. The average surgical time was 68 minutes. The average blood loss was 30 mL. All patients were given antibiotics prior to induction and were given a short course of post-operative

antibiotics. There was one patient on plavix for coronary artery disease. There were no post-operative complications. All patients maintained closed suction drainage for 72 hours and drains were removed without incident. There were no infections in our series.

Conclusion: There have been studies in the literature showing short-term drain placement doesn't significantly affect post-operative outcomes in penile prosthetic surgery. Our series shows that there is no significant increase in complications from prolonged placement of drain(72 hours) in a select patient population. This small group may indicate some degree of efficacy and safety for the few patients needing prolonged use of closed suction drainage after prosthetic surgery. Further larger prospective analysis is warranted.

Disclosure:

Work supported by industry: no.

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ARE PATIENTS WILLING TO COMPLETE THE IIEF-5 FORM IN THE PROSTATE ASSESSMENT CLINIC (PAC)?

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Objective: The association between ED and LUTS is well established. Patients are usually reluctant to disclose their sexual history. Using the IIEF-5 questionnaire to assess ED at PAC depends on the patients' attitude towards completing the form.

Material and Method: Patients who attended our Prostate Assessment Clinic were given the choice to complete the IIEF-5 form along with the IPSS chart before undergoing further evaluation. A total of 275 cases were reviewed and divided into two groups completed and declined.

Results: The percentages of completed and declined groups were 57% and 43% respectively. There was inverse proportion between the increasing age and the percent of completion (Table 1) as follow: 30-39 (100%); 40-49 (66%); 50-59 (80%); 60-69 (63%); 70-79 (39%), and 80-89 (23%). There was a higher percentage of severe LUTS in the completed group (44%) compared with the declined group (36%). The two groups were comparable when it comes to the effect of LUTS on the quality of life.

Conclusion:

The majority of the patients completed the IIEF-5 form, which provides a simple and convenient tool for both patients and clinicians to assess ED in PAC.

Disclosure:

Work supported by industry: no.

Table 1

Age	total	filled	declined
30-39	3	3	
40-49	18	12	6
50-59	50	40	10
60-69	110	69	41
70-79	72	28	44
80-89	22	5	17
	275	157	118

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KNOWLEDGE AND AWARENESS OF ERECTILE DYSFUNCTION IN U.S PRIMARY CARE CLINICS

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Objectives: Previous studies have suggested that men's knowledge of erectile dysfunction (ED) is poor. We report on the awareness and knowledge of ED in a primary care clinic population.

Methods: A total of 75 men at two primary care clinics (a private community practice and a county hospital-based practice) completed a self-administered survey concerning men's health issues. Knowledge and awareness of ED were assessed with closed ended yes/no/not sure and multiple-choice answer formats. Men were presented a set of questions that contained 8 correct risk factors, 8 correct causes, and 6 available treatment options and checked yes/no/not sure for each item. Men were asked to estimate the prevalence and treatment effectiveness in open answer format.

Results: 85% (64/75) of men were high school graduates. A large majority of men (81%, 61/75) report that they have heard of ED. Additionally 65% (49/75) of men answered that they were "very" or "somewhat" familiar with ED and 44% (33/75) with ED treatments. 69% (52/75) of men correctly identified the definition of ED from a list of 4 choices. Of the 8 causes presented, men recognized an average of 5.1 ± 2.9 with medications being the most commonly recognized cause (71%, 53/75). Of the 8 risk factors presented, men recognized an average of 4.4 ± 2.6 with "aging" being the most commonly cited (64%, 48/75). Men recognized an average of 2.6 ± 1.6 of the 6 treatment options for ED. Oral medication was most commonly cited (77%, 58/75), however "natural and alternative medicines" was the second cited treatment option (56%, 42/75). Nearly half of men (49%, 37/75) indicated that "speaking with a counselor or psychologist" was a treatment for ED. Men estimated that $48.3\% \pm 21$ of men between ages 40-70 have some form of ED and that $59\% \pm 23.7$ of men with ED would be able to "successfully have intercourse" with oral medication

Conclusions: Most men report having heard of ED, however one in three don't feel they are familiar with the condition or it's treatment. Overall knowledge was modest with men recognizing over half of the 22 presented causes, risk factors, and treatment items. Men's estimates of ED prevalence and treatment effectiveness for oral medication is consistent with published research indicating that men may understand how common this condition is in the general public and how effective current medications are.

Disclosure:

Work supported by industry: no.

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PROSTATIC URETHRAL LIFT: NOVEL TREATMENT FOR LUTS THAT MAY PRESERVE SEXUAL FUNCTION

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Objective: The Prostatic Urethral Lift is a novel, minimally invasive treatment for lower urinary tract symptoms (LUTS) caused by benign prostatic hyperplasia. Because of the importance of maintaining sexual function in men seeking treatment for LUTS, we sought to determine the effect of this procedure on erectile and ejaculatory function.

Materials and Method: Between 2005 and 2010, 64 men received the Prostatic Urethral Lift. The procedure employs small metallic implants that are delivered transurethral to endoscopically determined areas of obstruction. The implants are positioned such that the lateral lobes are lifted away from the urethral lumen, thereby increasing the voiding diameter and reducing obstruction. Patients were evaluated via symptom and sexual function assessment.

Results: Treatment allowed for rapid relief of LUTS and did not compromise sexual function. Erectile function, as assessed by the average SHIM score, was stable or slightly increased at all intervals. Similarly, ejaculatory function, as demonstrated by MSHQ-EjD score, was not compromised in these patients. No patient reported an adverse event of retrograde ejaculation at any follow up visit.

Conclusions: The Prostatic Urethral Lift procedure preserves erectile and ejaculatory function which offering relief of LUTS. This proce-

MRI imaging in Flaccid State: MRI imaging after Intracavernosal injection:

Type of ED	Time to Peak(s)	Intensity(rel)	Pattern of Run Off	Time to Peak(s)	Intensity(rel)	Pattern of Run Off
Arteriogenic	>120	<1000	Slow Decline	>120	>1000 <1500	Slow Decline
Venogenic	<120	>1000 <1500	Rapid Decline	<120	>1500	Rapid Decline
Neurogenic	<120	>1500	Rapid Decline	<120	>2500	Rapid Decline
Psychogenic	>120	>1000 <1500	Slow Decline	>120	>1500 <2000	Slow Decline
Normal	<120	>1000	Slow Decline	<120	>2000 <3000	Slow Raise

sure is a new option for the many patients who seek a minimally invasive alternative to current therapies and consider sexual function an important aspect of quality of life.

Disclosure:

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MANAGEMENT OF THE ADULT BURIED PENIS: A TEAM APPROACH

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Introduction: The syndrome of a buried penis in adult men is uncommon and can be challenging to manage. Although buried penis can be congenital in children it is often secondary to exogenous factors in adults including lymph edema, obesity, and loss of genital skin for any reason. At our institution, the surgical management of a buried penis utilized a team approach between Urology and Plastic Surgery. The specific techniques used in each reconstruction are tailored to the individual patient.

Methods: Between 2010 and 2012, 4 cases of buried penis were conjointly performed between Plastic Surgery and Urology. After panniculectomy, lipectomy or subtotal scrotoectomy with circumcision, tacking sutures were typically used on the penis. These permanent tacking sutures were placed on the proximal tunica albuginea tacking it to the rectus fascia or pubic periosteum dorsally and penoscrotal junction ventrally. This prevented the penis from retracting into the pubis and scrotum and maintaining the forward projection. Once sutures were placed, the abdominoplasty incision was re-approximated and closed suction drains are placed. A standard split-thickness skin grafting technique is used to cover the penile shaft.

Results: One of the cases of buried penis was secondary to severe scrotal lymph edema while the other three were the consequence of morbid obesity. Average age was 49 with ranges of 46–56 years. Flaccid penile lengths ranged from –2 cm to –4 cm preoperatively and an average of + 4.5 cm post operatively. Mean follow up is 18 months; all patients tolerated the procedure well with one complication of a post-operative seroma that required drain placement. All patients reported improved quality of life and return of sexual function in three with normal erections and ejaculation. Average increase in SHIM score was 6 (2–10).

Conclusions: The syndrome of a buried penis may become an increasingly prevalent condition in part due because of growing rates of obesity. Due to its challenging nature we recommend a team approach so that one can tailor care individually.

Disclosure:

Work supported by industry: no.

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MR IMAGING OF PENIS: FOR EXPLICIT MANAGEMENT OF ERECTILE DYSFUNCTION

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Objective(s): MR imaging as a diagnostic tool in the evaluation of erectile dysfunction(ED) has never been studied. We studied patients with ED to find the relevance of MRI, its evaluation and applicability.

Material and Method(s): We conducted a nonrandomized, prospective, descriptive study on 25 patients diagnosed to have ED. All Patients had IIEF- ED Domain score recorded, underwent NPT and Penile Doppler. Based on the above results, the patients were divided into 5 groups with 5 patients in each group. GroupI- Arteriogenic ED, GroupII- Venogenic ED, GroupIII- Neurogenic ED, GroupIV- Psychogenic ED, Group V- normal (Control). Study was approved by the institutional review board.

Result(s): The Graphic plots in each group had specific pattern and we were able to define particular criterias which proved to differentiate and classify the various types of erectile dysfunction. We were also able to quantify the degree of dysfunction based on the intensity of enhancement in corporal tissue after contrast injection and also establish the rigidity scaling which correlated clinically.

Conclusion(s): Our study of MR Imaging of the penis has provided clear objective definition of the various categories of ED which seems to be consistently reproducible. It gives valuable information on various aspects of erectile function. It defines the anatomy, physiology and mechanism of erection and its dysfunction. It categorises patients based on degree of rigidity and also on type of dysfunction. It also quantifies the dysfunction with numerical values based on which further management and follow up can be planned. There is massive information gathered from this single study which opens a new paradigm in understanding and treating ED.

Disclosure:

Work supported by industry: no.

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TESTOSTERONE LEVELS DECREASE WITH INCREASING NOCTURIA INDEPENDENT OF AGE

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Objective: Sleep regulation has been shown to be closely associated with diurnal changes in serum testosterone. Recent experimental studies have shown paradoxical sleep deprivation decreased testosterone secretion. One of the primary factors of sleep fragmentation in the LUTS patients is nocturia. In the clinical setting, nocturia is a significant stressor of daily life. We propose to identify whether nocturia is decreased testosterone levels independent of age.

Material and Methods: Patients visiting the outpatient department with complains of nocturia were recruited for this study from October 2011 to March 2012. Patients were asked to perform a three day frequency volume chart and sampled for serum testosterone and free testosterone. The association between nocturia and testosterone was assessed with age functioning as a covariate.

Results: Seventy patients were enrolled in this study. The mean age was 58.27 ± 11.66 years. Mean testosterone levels were 4.87 ± 1.70 ng/dl, and median nocturia episodes were 2 (range 0–6). Correlation analysis showed that the number of nocturia episodes was negatively correlated with serum testosterone (-0.28 , $R^2 = 0.19$) and free testosterone (-0.17 , $R^2 = 0.17$). A general linear model estimating for testosterone with nocturia episodes and age showed significant correlation ($p = 0.002$ for nocturia, $p = 0.0005$ for age), with no significant interaction between age and nocturia ($p = 0.06$).

Conclusion: Nocturia was negatively associated with serum testosterone and free testosterone levels. These correlations were shown to be independent of age, indicating significant effect of sleep disturbance associated with decreasing sex hormone levels.

Disclosure:

Work supported by industry: no.

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THE GLOBAL ONLINE SEXUALITY SURVEY: PREMATURE EJACULATION IN USA

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Objectives: The Global Online Sexuality Survey (GOSS) is a worldwide epidemiologic study of sexuality and sexual disorders. The age adjusted prevalence of male and female sexual disorders is estimated around the world, and so are the predisposing risk factors, anatomical variations, sexual preferences and unique habits for each and every culture. GOSS is deployed over the internet to the general population regardless surfing and web search inclinations, the only prerequisite being above 18 years of age. The first reports out of GOSS came from the Middle East, in the year 2010, results of which were published in 2011. This report investigates the general and age adjusted prevalence of premature ejaculation (PE) in USA, its predisposing risk factors, treatment trends and compares the data collected to other reports around the world.

Material and Methods: GOSS was randomly offered to English-speaking male web surfers in the United States of America between August and October 2011. GOSS was offered via paid advertising on Facebook® based on validated questionnaires in addition to general questions.

Result: 49.6% of the population surveyed was diagnosed with PE as per the Premature Ejaculation Diagnostic Tool (PEDT). Prevalence varied with alternative diagnostic tools. Approximate and exact intravaginal ejaculatory latency time (IELT) was recorded. Ailments confirmed as risk factors for PE included erectile dysfunction, genital size concerns, irregular coitus, interpersonal distress, diabetes, hypertension under treatment and subjectively reported obesity. On the other hand, factors such as masturbation, low desire, circumcision, dysuria, smoking, alcoholic beverages, narcotic drugs and depression did not have a statistically significant relationship with the prevalence of PE. Characteristics of life-long PE were discriminated from acquired PE.

Conclusion: The prevalence of PE in USA as of 2011 surpasses that of ED. Possible risk factors for PE could be pointed out, others denied.

Disclosure:

Work supported by industry: no.

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EARLY REVERSAL OF ERECTIONS FOLLOWING DIAGNOSTIC PENILE INJECTION: DON'T WAIT!

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Objective: Erections induced via intra-cavernous injection for office diagnostic procedures are associated with a significant risk of prolonged erection, and each practice needs to be prepared to handle these patients on-site in a timely fashion. Pharmacologically induced erections via direct intra-cavernous injection are associated with a significant risk of prolonged erection and priapism (5–35%). At our institution, color duplex Doppler ultrasound assessments are done on men with specific referral diagnoses. We retrospectively examined our office protocol of early reversal of erections induced via penile injection.

Material and Methods: Office records were reviewed from 2008–2011; 243 men were found who had pharmacologic erection reversal initiated 1–2 hours after diagnostic injection. Patients received either PGE1 or Tri-mix (papaverine, phentolamine, alprostadil) for penile Doppler testing. Pharmacologic reversal was initiated at one hour with a standard intra-cavernous dose of 200 mcg phenylephrine. Repeat doses were given every 5 minutes until detumescence was achieved.

Results: Early reversal was initiated in 243 patients. Mean patient age was 52 years (range 24–88 yrs). The majority of men were injected with Alprostadil; mean PGE1 dose was 11.7 mcg (range 10–24 mcg). Of all 243 patients receiving early reversal, 86% were detumescenced with a single 200 mcg dose of intra-cavernous phenylephrine and 14% of patients achieved detumescence with a second dosage. There were no significant side effects of hypertension or tachycardia, and no patient during this interval of study returned to the emergency department or required surgical shunting.

Conclusions: Expedient pharmacologic reversal at 1–2 hours is safe, effective practice that prevents priapism, minimizes patient discomfort and embarrassment and improves practice efficiency.

Disclosure:

Work supported by industry: no.

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LH SUPPRESSION PROFILES IN MEN TREATED WITH EXOGENOUS TESTOSTERONE

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Objective: Due to the negative feedback mechanism, testosterone replacement therapy (TRT) may result in suppression of luteinizing hormone (LH) secretion. Despite this, clinical experience demonstrates that not all men have LH suppression on TRT. We sought to define the prevalence of LH suppression in men on TRT.

Methods: Patient demographic and clinical data including were collected on patients with hypogonadism (HG) treated with TRT. Baseline serum total testosterone (TT) and LH levels and after ≥ 3 months (m) of TRT were recorded. LH suppression was defined as serum LH level < 1.0 IU/ml. Repeated measures t-test and correlation were used for univariate analyses, and logistic regression was used to test multivariable relationships.

Results: 53 patients with mean age = 63 ± 8 years (y). Mean TT level pre and post-TRT were 232 ± 47 ng/dl and 686 ± 282 ng/dl ($p < 0.001$). Route of T supplementation (subjects had multiple treatments): 96% transdermal T, 10% intramuscular T. The mean duration of TRT was 23 ± 21 m. The mean LH levels pre and post-TRT were 3.99 ± 2 and 2.6 ± 5 , $p = 0.01$. The percent of men who had a LH level above 1 IU/ml pre and post-TRT was 96% and 32%, ($p < 0.001$), thus 68% of men had suppressed LH levels on TRT. On TRT, LH

levels were distributed as follows: 72% ≤ 2 IU/ml, 9% 2–4, 19% ≥ 4 . 92% of patients had < 2 IU/ml drop, 4% 2–4 IU/ml drop and 4% > 4 IU/ml drop in LH on TRT. On univariate analysis, baseline LH ($r = -0.42$, $p = 0.03$) and change in TT level on TRT ($r = 0.35$, $p = 0.01$) significantly predicted LH suppression. Age ($p = 0.6$) and baseline TT ($p = 0.4$) were not significant. On multivariable analyses predicting LH suppression, none of the variables remained significant most likely due to low sample size, however the same two variables did produce meaningful odds ratios (OR): baseline LH level (OR = 0.63, 95% CI: 0.35–1.14, $p = 0.13$) and rise in T levels (by 100 ng/dl increments) (OR = 1.31; 95% CI: 0.85–2.01, $p = 0.2$).

Conclusions: On TRT, over two thirds of men experienced significant LH suppression. Predictors of this suppression include low pre-treatment LH level and large elevations in TT level on TRT. However, of note, age was not such a predictor.

Disclosure:

Work supported by industry: no.

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IN VITRO AND IN VIVO RELAXATION EFFECTS OF KOREAN GINSENG BERRY EXTRACT (GB0710) ON CORPUS CAVERNOSUM SMOOTH MUSCLE

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Objectives: Korean red ginseng (KRG; *Panax ginseng*) can be used to treat male erectile dysfunction, and it has been suggested that Korean ginseng berry (KGB) extract may have similar effects on male functioning. The effects of KGB extract on corpus cavernosum smooth muscle (CCSM) were evaluated both *in vitro* and *in vivo*.

Methods: In the *in vitro* experiments, strips of rabbit CCSM were prepared and precontracted by phenylephrine in an isotonic chamber, and various extracts of KRG and KGB were administered to evaluate their relaxation effects. In the *in vivo* experiments, KGB extract was orally administered to rats, and the intracavernosal pressure (ICP) was measured after stimulation of cavernous nerves. In addition, intracellular nitric oxide (NO) production was evaluated after treatment with KGB extract both in smooth muscle cell cultures and in *in vitro* experiments.

Results: It was found that various forms and constituents of KRG extract and KGB extract had dose-dependent relaxation effects on precontracted rabbit CCSM. The KGB extract GB0710 had the most potent relaxation effect of the tested extracts. Furthermore, administration of GB0710 increased ICP in a rat *in vivo* model in both a dose- and duration-dependent manner. Intracellular NO production in human microvascular endothelial cells was induced by GB0710 and was inhibited by NG-monomethyl-L-arginine (L-NMMA).

Conclusion: GB0710 had a greater relaxation effect on rabbit CCSM than did KRG extract, and it increased ICP in a rat model in both a dose- and duration-dependent manner. This relaxing effect might be mediated by NO production.

Disclosure:

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SHOCK WAVE THERAPY IN PATIENTS WITH PEYRONIE'S DISEASE – OUR EXPERIENCE

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Objectives: Retrospective assessment of success rate of the shock wave therapy to fibrous plaques in patients with Peyronie's disease.

Methods: Retrospective assessment of 40 patients treated between 2010 and 2012 at the Department of Urology, First Faculty of Medicine, Charles University and General University Hospital in Prague, Czech Republic. Parameters assessed: patient's age, duration of the disease, type of primary treatment, plaque size and its change following shock wave therapy, disease symptoms, number of sessions and shock delivered and length of follow-up. Dornier Compact Delta II machine was used, contact pressure 2, energy level C, shocks frequency 120–150/min, average number of shocks was 1350 (range 1200–1500). Therapy was performed on outpatient basis, with no anesthesia, ultrasound or manual focusing. Plaque size was measured by ultrasound before and after therapy (minimum of 10 sessions). Penile pain and angulation was assessed by patients.

Results: Mean patient's age was 58 years (range 31–74), mean disease duration was 22 months, medical therapy preceded in all patients (tamoxifen, vitamin E, intraplaque verapamil) and one patient underwent treatment with laser combined with an ultrasound. Mean number of sessions was 15.2 (5–34), follow-up period was 4–20 months (mean of 12.6 months). All 25 patients reporting plaque pain before therapy had complete resolution (100%), reduction in plaque size was reported in 19 patients (47.5%) and there was an improvement in only 6 out of 30 patients (20%) with various degree of penile angulation. There 5 minor complications (1 hematoma, 4 cases of lasting penile skin petechiae).

Conclusions: Shock wave therapy to fibrous plaques in Peyronie's disease is safe and applicable in patient with failed medical therapy. There is the fastest effect on subjective pain symptoms, with minimal change in plaques size. Penile angulation is the least changing parameter.

Disclosure:

Work supported by industry: no.

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LOWER URINARY TRACT SYMPTOMS AND SEXUAL DYSFUNCTION IN PATIENTS WITH LIVER CIRRHOSIS

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Introduction: Chronic liver disease and liver cirrhosis is a common finding in men, however, data concerning urinary symptoms and sexual function in this group of patients is still scarce. The aim of the present study was to evaluate the prevalence of lower urinary tract symptoms (LUTS) and erectile dysfunction (ED) in a population of patients with chronic liver disease and to identify underlying causes and risk factors.

Materials and Methods: 120 male patients with known chronic liver disease were asked to fill out the validated IPSS and IIEF-5 questionnaire. Child Pugh Score, hormone levels including testosterone, luteinizing hormone (LH), follicle stimulating hormone (FSH), sexual hormone binding globuline (SHBG), and prolactin (PRL), were measured.

Results: Mean age of patients was 55 ± 9 years. Mild (IPSS < 8), moderate (IPSS 8–19) and severe (IPSS 20–35) LUTS were found in 59%, 32%, and 9% of chronic liver disease patients, respectively. ED (IIEF-5 score < 22) was found in 81% of them. IIEF-5 scores were not significantly different between Child Pugh Score (CPS) groups A,

B, C, ($p > 0.05$). From CPS A to CPS C mean T levels (free and bound) were decreasing, prolactin levels were increasing (all $p < 0.05$).

Conclusions: LUTS and ED are common findings in male patients with chronic liver disease. Accurate diagnosis and therapy strategies are warranted to ameliorate the quality of life of these patients.

Disclosure:

Work supported by industry: no.

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REIMBURSED TREATMENT FOR ERECTILE DYSFUNCTION. A PECULIARLY BRITISH PROBLEM!

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Introduction: The United Kingdom is unusual in that a significant proportion of patients with ED have their treatment fully reimbursed by the National Health Service. This may have consequences for the choice of treatment and for compliance with treatment. We report the experience of a single hospital unit within the UK with respect to switching, compliance and costs of therapy.

Methods: Basic demographics and data on ED management for patients treated from January 2000 to April 2011 were obtained from a prospectively accrued database. We reviewed drug usage and switching between drugs. Patients were given the choice of all available therapies and were followed up annually.

Results: 2159 patients qualified for reimbursed therapy. 226 patients were excluded from further analysis owing to missing data. Patients were followed up on an annual basis. The mean patient age was 60.2 years (min 23, max 90) and mean follow up was 50.8 months (min 1, max 127). 696 were started on sildenafil, 990 on tadalafil, 163 on vardenafil and 84 on intracavernosal alprostadil. 18.0% patients initially started on the scheme stopped medication unilaterally. 12.3% patients changed their medication during follow up. The cost of drugs increased year on year from £257,100 in 2007 to £352,519 in 2011.

Conclusion: Our real-life observational study shows that in our institution, drop out from therapy is unusual. We hypothesise that this reflects, in part, the reimbursement issue. We also found that switching between drugs was unusual, although there are several possible explanations for that. Although this is a successful system for the patients, the hospital, which bears the costs of medication, is finding this an increasing economic drain.

Disclosure:

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STORE OPERATED CALCIUM CHANNEL ACTIVATION INCREASES APOPTOTIC MARKERS AND DECREASES NEURITE OUTGROWTH FROM THE MAJOR PELVIC GANGLION FOLLOWING CAVERNOUS NERVE INJURY

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Objectives: With advancing age the incidence of cardiovascular disease and erectile dysfunction increases. Erectile dysfunction is known to be a harbinger of cardiovascular disease. The pudendal is a key artery for erections as it contributes to 70% of the total penile vascular resistance. The present study morphometrically characterized the coronary and pudendal arteries from male cadavers with cardiovascular disease.

Methods: Eight formalin fixed adult (57–86 years) male cadavers were dissected to assess the morphology of the internal pudendal and coronary arteries. All men suffered from cardiovascular disease. Pudendal sections were taken distally before the artery branches into the penis and proximally above the rectal artery branch, and the coronary section from the middle of the artery. Arterial segments were fixed in formalin, embedded in paraffin, sectioned, stained with Masson's trichrome, and morphometrically assessed using light microscopy. Lumen diameter, wall thickness, wall-to-lumen ratio and cross-sectional area were measured.

Results: All coronary and pudendal arteries had the presence of a neointimal layer. Their smooth muscle layers were unorganized with a significant population of round synthetic-like cells. The coronary arteries had a larger lumen diameter than the pudendal arteries which tapered as they travelled distally towards the penis (9.5 ± 0.9 ; 6.9 ± 1.1 ; 5.2 ± 0.8 mm, respectively). The wall thickness was similar between all three arterial segments (1.8–2.4 mm). The wall-to-lumen percentage was drastically increased in the distal ($53 \pm 19\%$) and proximal ($40 \pm 8\%$) pudendal arteries compared to the coronary artery ($22 \pm 5\%$). Additionally, one of the distal pudendal arteries was 90% occluded with a remarkable wall-to-lumen percentage of 186%. This is direct evidence that the penile bed undergoes more drastic remodeling prior to severe changes in the coronary arteries.

Conclusions: In all aged males examined, coronary and pudendal arteries were found to have marked vascular remodeling. Striking intimal thickening and plaques significantly decreased lumen diameter and occluded flow. This is the first study to characterize the morphological changes in both the coronary and pudendal arteries in male cadavers and provides further evidence of a causative role of vascular structural changes in aging-induced ED.

Disclosure:

Work supported by industry: no.

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EFFECT OF INTRAMUSCULAR TESTOSTERONE REPLACEMENT ON INSULIN RESISTANCE IN JAPANESE MEN WITH LATE-ONSET HYPOGONADISM

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Objective: Low levels of testosterone in men have been shown to be associated with type 2 diabetes, visceral obesity, dyslipidemia and metabolic syndrome (MetS). We investigated the effect of testosterone replacement therapy (TRT) on insulin resistance and risk factors of MetS in men with symptomatic late-onset hypogonadism (LOH).

Materials and Method: This was a retrospective study in 28 men with LOH over the age of 40 years. Patients were treated with intramuscular testosterone 250 mg every 3 or 4 weeks for 6 months (range 3–12). The primary outcomes were mean changes from baseline in homeostasis model assessment of insulin resistance (HOMA-IR). The secondary outcomes were changes in body mass index, waist circumference, body fat, dyslipidemia and blood pressure.

Result: HOMA-IR decreased beyond 30% from baseline in only 6/28 (21.4%) of patients. Overall, TRT did not reduce HOMA-IR, fasting glucose or insulin. Also, no significant changes were observed of body composition, fasting lipids and blood pressure. There were individual differences in changes of HOMA-IR after TRT, therefore, we analyzed the background factors of TRT responders. However, no factors were observed in this study.

Conclusion: Over a 3-month period, intramuscular TRT in LOH patients did not improve insulin resistance, body composition, or risk factors of MetS. We need to identify the background factors of these patients whose insulin resistance was improved by TRT.

Disclosure:

Work supported by industry: no.

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EVALUATION OF THE PATIENTS WITH EJACULATION THAT ALWAYS OCCURS PRIOR TO OR WITHIN 10 SECONDS OF VAGINAL PENETRATION

Kim, J.Y.¹; Kim, B.M.P.¹

1: Philip and Paul Medical institute, Korea, South

Objective: Few clinical researches has been done on lifelong premature ejaculation that ejaculates before or immediate after the insertion. This study reports clinical characteristics of the patients who have severe lifelong premature ejaculation.

Material and Methods: The subjects were those who repeated ejaculation before or immediate after (less than 10 seconds) the insertion. Their sexual behavioral patterns were researched, penile sensitivity test, blood test, and prostatitis test.

Results: The study was conducted on 39 patients. The threshold of biothesiometry was 4.75 ± 1.2 and 14(36.8%) of them showed less than 4. In the prostatitis test, they were all turned out to be negative. The average PSA was 0.93 ng/ml. Their thyroid hormone levels were T3 1.2 ± 0.2 ng/ml, and T4 8.2 ± 1.3 µg/dl. 1(2.6%) showed hypothyroidism while 1(2.6%) showed hyperthyroidism. The total testosterone and free testosterone were 489 ± 132 ng/dl and 12.7 ± 4.7 pg/ml. 1(2.6%) of them showed increase in testosterone. The leptine was 3.1 ± 1.98 ng/mL. 73.7% of the patient responded that they had prolongation of the ejaculatory latency after applying anesthetic cream. On the question asking "What do you think of the reason of your premature ejaculation?", 55% responded to penile hypersensitivity

Conclusion: Though the patients group was small in number, this study was meaningful for reference in treating patients with very severe premature ejaculation. Not only the neurobiological access using SSRIs drug, but also the method to decrease penile sensitivity can be considered for treating the patients with severe premature ejaculation.

Disclosure:

Work supported by industry: no.

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CLINICAL EFFECTIVENESS OF PENILE VENOUS SURGERY IN ERECTION

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Objectives: According to the American Urological Association clinical guidelines panel penile venous surgery is not justified for routine use. However, in most nonsurgical cases these treatment modalities are insufficient to produce adequate erection. Although penile venous surgery has almost been abandoned and the venous factor eliminated as a contributing factor to erectile dysfunction, new concepts of erection related veins has recently been described and reported in literature. We are to report clinical result of venous ligation surgery.

Material and Methods: They were evaluated using the International Index of Erectile Function(IIEF-5) scoring system. In the dorsal area of penis, 1-2 cm from the subglans was incised at a length of 3 to 5 cm in a transverse direction with depth sufficient to expose the Buck's fascia and was then bluntly dissected up to the prepubic area. The incised area was widened with a retractor, so that the prepubic area could be seen. We ligated deep deep dorsal vein, cavernosal veins and para-arterial veins.

Results: Retrospective investigation was done for this study with 13 cases from January 2007 to September 2010. Median patient age at surgery was 45.2 years (range 22 to 54) and mean follow up was 13 months (range 2 to 39). Pre-operation average IIEF-5 score was 11 and post-operation average IIEF-5 score was 17. 1 case of infection was reported.

Conclusion: Though the patients group was small in number, this venous drainage reduction surgery as the modified venous ligation surgery appears to deliver reasonable positive results with low morbid-

ity. Patients showed improvement of IIEF-5 score by this surgery. The results obtained in this limited number of patients are promising and justify trials in larger groups

Disclosure:

Work supported by industry: no.

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SPECIAL CASE SCENARIO UTILIZING A HYBRID PENILE PROSTHESIS

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Objective: Penile prosthetic surgery at times can be complicated and technically difficult, especially in patients who have undergone multiple procedures. New and innovative techniques are necessary to treat this subset of patients, and intraoperative improvisation is sometimes necessary to provide a useable implant that is capable of coitus. We present the case of a hybrid penile implant with two different cylinders, one a Coloplast Titan® complete with pump and reservoir, the other a Coloplast Genesis®.

Materials and Methods: A 77-year-old male referred from an outside urologist with impending bilateral distal erosion of his implant and persistent left aneurysmal distal defect. He has a history of two previous implant surgeries, one requiring bilateral distal corporoplasty in addition to left distal shaft reduction corporoplasty of the aneurysmal tunica. He was taken to the operating room and underwent removal of the left Coloplast Titan® cylinder. It was noted that a large, left, lateral corporal aneurysmal defect was present secondary to hypoplasia of the corpora. A new path was tunneled more medially through a capsulotomy, and a semi-rigid Coloplast Genesis® cylinder was placed to prevent recurrence of this aneurysmal defect.

Results: Routine postoperative care was provided, and during his 4-week follow up visit, there was no evidence of recurrence of the corporal defect. By his 6-week postoperative visit, he had reported successful coitus, and no recurrence. He pumps the right cylinder to have intercourse, and is not bothered by the left semi-rigid cylinder. He does not feel the need to proceed with replacement to a full inflatable penile prosthetic.

Conclusions: Many different factors come into play during penile implant surgery that makes every case different. No one penis is the same, hence neither should every implant. This represents a novel modification were two different products from the same company were utilized. Sometimes, as urologist we are faced with complex situations, that require nontraditional and hybrid modifications to ensure the satisfaction of our customers. Although we had planned on replacing this patient's implant to a more traditional three-piece inflatable penile prosthesis, he is currently happy with his hybrid penis.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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ONCOSEXOLOGY: ASSESSMENT AND POTENTIAL ROLE FOR THE MAJOR FRENCH CANCER SURVIVORS ASSOCIATION LCC (LA LIGUE CONTRE LE CANCER)

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1: General hospital, France; 2: Rosa association, France

The cancer survivor associations have an increasing place and role particularly in the field of quality of life that includes sexual life and intimacy. In our knowledge, no survey has concerned this specific topic among cancer survivor associations. **Objective:** to analyse the current situation and recognize the "oncosexological" needs / demands of the major French cancer survivor association LCC (League against Cancer) with 727 918 members. **Material and Method:** The survey

has included: a) dispatch to the 101 French counties Committees of a questionnaire (4 closed + 8 semi-direct questions and free comments) approved by the LLC national Committee, b) telephone interviews (95 Committees) analyzing 5 parameters: 1) reality of patient demands, 2) perceived health professionals awareness, 3) awareness of voluntary helpers, 4) dedicated care availability, 5) League against cancer available strategy at the county, regional and national levels. **Results:** The survey was much more difficult than anticipated (5 reminders). Two years were necessary to obtain 70% (n = 71) of responses due to: a) major structural heterogeneity of counties Committees, b) finding of the relevant speaker(s), c) reluctance to discuss this topic. If a strong majority is not or little confronted to this particular demand, this problem appears very important (92% yes / rather) reflecting a real hiatus between the voluntary helpers perception and the demand reality. For 75%, the appropriation of sexual health and its dysfunctions by the carers is still not realized. 65% consider that physicians are not or little aware and that nurses appear as the best health care professional for touching on. The only organized response relies on very useful written League documents ("Male / female cancer and sexuality") and rare Committee dependant responses according to specific local offers or knowledgeable members. To know where to direct patients is a real challenge for Committees (26% without available addresses). However, motivation is strong since for 96%, the League appears as a valid relay for informing and directing patients which explains their strong wish to be more involved. **Conclusion:** This "audit" points up: a) the importance of oncosexual dimension for cancer survivors, b) a low patient demand despite a high voluntary helper awareness / motivation, b) the feeling of disappointing response due to a major lack of information and absence of organized response, c) the need of a better offer visibility and a more active Committee response, d) not a real lake of listening but a double problem of validated process and know-how.

Disclosure:

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PENILE REHABILITATION FOLLOWING RADICAL PROSTATECTOMY: PRACTICE PATTERNS AMONG JAPANESE UROLOGICAL ASSOCIATION MEMBERS

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Objectives: Despite the fact that the benefits are still unclear, penile rehabilitation after radical prostatectomy (RP) has become the standard of care for many urologists. Given the lack of definitive proof regarding the benefits, however, a standard program or optimal algorithm does not exist. Furthermore, financial, insurance, and cultural considerations might cause regional differences in the practice of penile rehabilitation. We sought to explore contemporary trends in penile rehabilitation practice patterns of Japanese Urological Association (JUA) members.

Materials & Methods: The proprietary questionnaire was comprised of 35 questions that addressed practitioner demographic factors and current practice status regarding rehabilitation. The questionnaire was mailed to all the representatives of urology departments authorized by the JUA.

Results: 376 physicians completed the questionnaire, representing a response rate of 31%. Twenty percent of the responders were members of the Japanese Society for Sexual Medicine (JSSM), 10% had formal sexual medicine specialty training, 68% were urologic oncology specialists, and 91% performed RP. Of the responders, 47% were not aware of the concept of penile rehabilitation and 29% performed some form of rehabilitation. As part of the primary rehabilitation strategy, 97% used phosphodiesterase type 5 inhibitors (PDE5i), 8% used a vacuum device, 13% used intracavernosal injections, and 2% used intra-urethral prostaglandin. Twenty percent commenced rehabilitation immediately after urethral catheter removal, and 36% within the

first three months after RP. 37%, 21%, and 18% ceased rehabilitation at ≤12, 13–18, and 19–24 months, respectively. Six percent rehabilitate all RP patients, 94% only do it with selected patients. For 76%, selection for rehabilitation was dependent upon patient age, 72% upon nerve-sparing status, 70% upon preoperative erectile function, and 39% upon comorbidity. With regard to the primary reason for not performing rehabilitation: 52% said they were not familiar with the concept; 22% said patients could not afford it, and 22% gave another reason. Performing rehabilitation was positively associated with being a member of JSSM ($P < 0.001$), seeing post-RP patients ($P < 0.001$), sexual medicine specialty training ($P < 0.001$), being a urologic oncologist ($P = 0.01$), performing RP ($P = 0.034$), and surgeons using the laparoscopic or robotic-assisted approach ($P < 0.001$).

Conclusions: Among the respondents, penile rehabilitation is not common. The most commonly employed strategy is PDE5i use and intracavernosal injections were not in common use. Clinicians who are engaged in the field of sexual medicine and see a lot of such patients are more likely to use rehabilitation practice.

Disclosure:

Work supported by industry: no.

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DELAYED PRESENTATION OF CONGENITAL PENILE CURVATURE WITH UNCONSUMMATED MARRIAGE: SINGLE CENTER EXPERIENCE

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Objective(s): Middle East countries are considered conservative societies with delayed age of marriage and the majority of the newly married couples are virgins with no previous sexual experience. Inability to achieve a successful sexual intercourse due to congenital penile curvature (CPC) in this group of newly married couples is infrequent; however it usually results in marked stress, frustration hostility, and even divorce. We describe our experience in the management of CPC that causes failure of penile penetration to the vagina at time of marriage.

Materials and Method(s): We retrospectively reviewed 30 patients who presented to our clinic with CPC causing failure of vaginal penetration in newly married couples. They were treated surgically by plication using the 16 dot technique. All patients were followed up for 6 months postoperatively.

Result(s): All patients were presented by unconsummated marriage due to CPC after 1 to 6 months of marriage. Average age of presentation was 32 years (ranging from 24 to 38 years), average penile curvature angle was 55 degrees (ranging from 22 to 73 degrees), average penile length was 19.5 cm (ranging from 14.3 to 23.2 cm). Of the 30 patients, 21 patients had ventral curvature, 1 had dorsal curvature, 5 had curvature to the right and 3 had curvature to the left. All patients underwent successful surgical correction using the 16 dot plication technique. Penile shortening was the main surgical drawback; however it did not interfere with successful vaginal penetration. Erectile function was preserved in all the 30 patients. The IIEF-5 score showed an increase from an average score 19 preoperative to an average score 23 postoperative with a principle increase in the scoring of the 5th question "when you attempted sexual intercourse, how often was it satisfactory for you?". 29 patients succeeded in consummating the marriage and only one patient failed due to female problem as a result of vaginismus and they were referred to psychiatrist.

Conclusion(s): Unconsummated marriage due to CPC is infrequent; however it can be successfully treated with plication achieving good results with increased satisfaction scoring.

Disclosure:

Work supported by industry: no.

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ESTABLISHING THE FIRST POST RADICAL PROSTATECTOMY REHAB PROGRAM IN ISRAEL - LESSONS LEARNED

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Objective: Penile rehabilitation after radical prostatectomy (RP) is a common practice in leading uro-oncology centers, yet, many institutions do not offer rehab care. This study was aimed to depict the establishment of the first structured rehab program in Israel, its contribution to sexual health and lessons learned, to assist sexual medicine (SM) professionals in establishing post-RP rehab program.

Materials and Methods: A rehab program was structured in 2009 by a SM fellowship-trained urologist. The program was based on providing information on the possible benefits of early intervention to RP surgeons, oncologists, urologists, oncology/urology nurses, patients and spouses. SM care data were collected by medical chart review and a proprietary questionnaire. Post-RP SM care quality in the years 2008 and 2010 was compared, before and after the rehab program establishment.

Results: 55 men had RP in 2008 and 47 in 2010. Both groups were similar in their demographic and surgical characteristics (age, marital status, nerve sparing, hospital stay, catheter bearing duration). Proportion of men who had pre-RP SM consultation increased from 3.6 to 10.6%, proportion of men who had post-RP SM care increased from 56.4 to 74.5% (p = 0.04) and median time to first post-op SM consultation decreased from 16.4 to 1.6 months (p = 0.001). Proportion of men trying PDE5i increased from 61 to 75% and median time to first trial decreased from 12 to 2 months (p = 0.03). Intracavernosal injections (ICI) utilization increased non-significantly from 27 to 29%, time to achieve first post op penetration rigidity erection decreased non-significantly from 9 to 7 months. PDE5i response rate (52%) and ICI response rate (75%) at 12 months were also similar in both groups. Patient satisfaction (very satisfied/satisfied) increased from 36% in 2008 to 79% in 2010, (p = 0.001).

Conclusions: SM education of professionals providing prostate cancer care, patients and spouses leads to marked improvement in post-RP SM care parameters, including patient satisfaction. ICI training was the bottle-neck in our rehab program. Ultimately, early after RP most patients need ICI to achieve functional erections, therefore, resources for early ICI training are mandatory to achieve the goal of post-RP rehab.

Disclosure:

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COMPARISON OF RATES AND TIMING OF ERYTHROCYTOSIS BETWEEN TESTOSTERONE GELS, INJECTIONS AND PELLETS - A SINGLE-INSTITUTION EXPERIENCE

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Introduction: The increased number of testosterone(T) formulations provides many choices for both physicians and patients. However, while effective in raising serum T and ameliorating hypogonadal symptoms, the side effect profiles of each class of T formulation are incompletely understood. Here we present single-institution data of the effects of T gels, injections and pellets on erythrocytosis.

Methods: Retrospective review of hypogonadal men treated with a single T formulation was performed and 49 men on T gels, 62 on injectable T, and 47 on T pellets were identified. Demographics, total T, free T(FT), estradiol(E), hemoglobin(Hgb), hematocrit(Hct), and prostate specific antigen(PSA) were evaluated at baseline and every 3

months. Serum parameters were compared between each T formulation group.

Results: Mean \pm SD follow-up for T gels 328 ± 84 days, T injections 307 ± 100 days, and T pellets 355 ± 78 days; men were followed up to 15 months. At baseline, men in the injectable T group were younger (43.0 ± 12.1 years) than in the gel or pellet groups (54 ± 9.6 and 56 ± 13.6 years, respectively, $p < 0.0001$), and FT (7.7 ± 5.2 pg/ml), Hgb (15.6 ± 1.3 g/dL) and Hct ($45.9 \pm 3.7\%$) were higher in this group than in the gel or pellet groups (FT 5.9 ± 1.6 and 6.0 ± 4.1 pg/mL, $p = 0.050$; Hgb 15.0 ± 1.0 and 14.7 ± 1.2 g/dL, $p = 0.002$; Hct 44.5 ± 3.1 and $43.6 \pm 3.3\%$, $p = 0.006$). No significant differences were observed in other serum parameters or prostate cancer rates at baseline. Increases in TT and FT levels were observed at 1–3 months and persisted throughout follow-up in all groups. Increases in E were observed only in the injectables group beginning at 1–3 months and persisting throughout. No significant increases in PSA were observed in any group. Significant increases in Hgb (16.4 ± 1.4 g/dL, $p = 0.04$) and Hct ($48.5 \pm 3.6\%$, $p = 0.008$) were observed in the T injectables group beginning at 1–3 months and persisting throughout follow-up. In contrast, significant increases in Hgb and Hct were only observed at 6–9 months follow-up in gel (15.8 ± 1.1 g/dL, $p = 0.008$; $46.8 \pm 3.0\%$, $p = 0.003$) and pellet (15.4 ± 1.5 g/dL, $p = 0.04$; $45.9 \pm 3.9\%$, $p = 0.02$). Using a cutoff of Hct $> 53\%$, 12% of men on T injectables developed erythrocytosis, in comparison with 6% of men on pellets ($p = 0.100$) and 2% of men on gels ($p = 0.006$) during 15 months of follow-up.

Conclusions: All T formulations increase serum T and FT over the short and long terms. However, the time to a significant rise in Hgb and Hct is shortest and the levels highest in the injectable T formulation group. Thus, care should be taken in selecting T formulations, keeping in mind the side effect profiles of each class.

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SEXUAL PRACTICE OF MALAYSIAN YOUNG MEN: SHARING THE EXPERIENCE OF UNIVERSITY STUDENTS

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Objectives: Socio-cultural changes have affected the sexual and intimate relationships of Malaysian citizens by the changing attitudes, behaviours and expectations of the new generation in male-female relationships. In most health and development programs, when compared with girls, young boys have seldom been the focus. In the area of sexual and reproductive health, boys and men have been left out while they are more likely to involve in risk taking behaviours. This paper reports on data from a larger qualitative research whose overall aim was preparing a counseling module for sexuality and romantic relationship of young people in Malaysia.

Material and Methods: This qualitative study utilized in-depth interviews with 36 Malaysian male university students aged 18–30 representing a range of sexual practices. This research involved three Malaysian largest ethnic groups (Malay, Chinese and Indian). Thematic analysis approach was used.

Results: The findings revealed that the concept of sex is seen only within a heterosexual relationship. Almost half of the participants expressed previous experience of sexual intercourse, and the rest had explored with foreplay and masturbation. Almost all of the younger guys (18–24) have had pre-marital sex. The reasons for having sex were: making love, to have fun, a natural and physiological need, and to gain experience for future marital relationship. Reasons for those who never had sex were: concerning about Sexually Transmitted Diseases, pregnancy, and religious beliefs. Having fear of mal-performance was reported by inexperienced respondents due to a common concept regarding the acknowledgment of highly masculine

behaviours. Most of them did not view oral sex and foreplay as sexual practice, but enjoyed more with oral sex. Condom use was not a "must" among sexually experienced participants. Some participants stated they lacked dating and communicating skills.

Conclusions: Pre-marital sex is common among younger men. Lack of information on sexual issues and communication skills was revealed. Misconceptions regarding the highly masculine behaviours and traditional myths require a gender specific education. A sexuality education program containing materials for improving protection, performance and communication skills is warranted.

Disclosure:

Work supported by industry: no.

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THE RESILIENCE OF A MALE'S PHALLUS

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Objective: Erectile function rigid enough for coitus, albeit any erectile function following removal of an Inflatable Penile Prosthesis (IPP) is rare. We present the case of a patient who achieved erections sufficient enough for anal penetration after suffering multiple insults to his erectile tissue. These events include an episode of ischemic priapism followed by placement of an inflatable penile prosthesis (IPP), post operative infection, and subsequent explantation of the IPP.

Materials and Methods: 52-year-old male, with a history of multiple insults to his erectile tissue, reports erectile function substantial enough for anal penetration during sexual intercourse. He initially presented with ischemic priapism (for >24 hours) status post penile shunt in 2005. This was followed by IPP placement in 2006 with evidence of corporal fibrosis noted intraoperatively. Subsequent removal of the device was performed in 2009 secondary to infection.

Results: An objective evaluation of the patient's current erectile function revealed an IIEF-5 score of 20/25 with occasional usage of Alprostadil urethral suppositories. Penile Doppler following 10 mcg injection of Trimix revealed numerous perforating vessels from the corpora spongiosum providing collateral blood flow to the corpora cavernosa. The patient obtained approximately a 60–70% rigid erection, no penile curvature noted.

Conclusions: Erectile function significant enough to take part in sexual intercourse and penetration after removal of a three-piece IPP, in a patient with multiple insults to their erectile tissue, is a rare phenomenon. Priapism and infection causes tissue necrosis as well as fibrosis of the corpora. The normal anatomy of the erectile tissue that allows for cavernosal arteriole vasodilation and increased blood flow into the corpora is typically disrupted upon placement of an IPP, with compression of the smooth muscle against the wall of the tunica albuginea. Theoretically, the remaining smooth muscle tissue may retain some of its physiologic function, adding some additional girth to the penis with an already activated IPP during sexual intercourse. Despite multiple insults to his erectile tissue, he reports unassisted erections rigid enough and sustainable enough for the entirety of intercourse, including anal penetration, demonstrated with penile doppler and objective patient questionnaire. He is not interested in further therapy, being content with the function of his resilient phallus.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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ONE-SIDE PENILE PROSTHESIS FOR SPINAL CORD INJURED PATIENTS

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1: Spinal Injuries Center

Objective: To find the usefulness of one-side penile prosthesis in spinal cord injured patients.

Patients: Two patients, who underwent penile prosthesis surgery at our institution and lost one-side prosthesis, are presented.

Results: Case 1 is a 47-year old paraplegic patient who underwent AMS 700 CXM inflatable penile prosthesis insertion in 1988 for the purpose of sexual activity and clean intermittent catheterization (CIC). Right side prosthesis went out of order in 1994. He refused to undergo re-insertion of new prostheses because of high cost (approximately ten thousand US dollars). Since then he operates one-side prosthesis and can perform CIC easily as he did so with two active prostheses.

Case 2 is a 45-year old paraplegic patient who underwent malleable silicone prosthesis (Koken in Japan) insertion in 1990 for the attachment of urinary appliance to his penis. Left side prosthesis slipped out 10 months later. He refused to undergo re-insertion of new prostheses because of high cost. Since then he can attach the urinary appliance to his penis easily as he did so with two prostheses.

Conclusion: Penile prosthesis is used not only to facilitate sexual activity but also to make urinary management easier for spinal cord injured patients. Our results suggest that one-side prosthesis is as useful as with intact both-side prosthesis for the urinary management in spinal cord injured patients.

Disclosure:

Work supported by industry: no.

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ERECTILE FUNCTION AFTER NERVE-SPARING RADICAL PROSTATECTOMY - CONCEPTS FOR REHABILITATION IN GERMANY: WHAT ARE WE DOING?

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Objectives: Despite objective data regarding rehabilitation of erectile function (EF) after nerve-sparing radical prostatectomy (nsRP) the „gold-standard“-treatment is still under debate. The aim of this study was to evaluate the distribution of the different treatment options in Germany.

Material and Methods: Between 10/2010 and 12/2011 we performed a questionnaire sent to all urologist (outpatient/general and university hospitals/rehabilitation hospitals) in Germany. The survey consists of different questions, e.g. if and what kind of therapy the urologist choose to support rehabilitation of EF after nsRP. Further questions dealt with the frequency, duration and "optimal" start of the chosen therapy.

Results: Until today 188 urologists completed and returned the questionnaire. The distribution was: urologists in hospitals n = 79, outpatient/ambulatory n = 106, with 24% performing surgical treatment, and urologist in rehabilitation hospitals n = 3. Overall 50% of the urologists are performing radical prostatectomy on a regular basis. The question about the "rehabilitation concept" showed 39 different treatments within this group. To increase EF after nsRP PDE5-inhibitors were mostly administered (88%): 45% „on demand" vs. 55% on a daily or regular basis ≥ 3 times/week. The use of penile injection therapy, MUSE or VCD was 32%, 6% and 30% respectively. In 56% the treatment started within the first weeks after surgery and was performed until the patient regained potency in 46%. Only 14% of the urologists didn't chose any "active" kind of rehabilitation treatment for EF recovery after nsRP.

Conclusions: Lots of different therapeutic concepts are currently performed in Germany to increase EF recovery after nsRP. The use of PDE5-inhibitors is the most chosen treatment option. Despite the published data regarding effectiveness the optimal treatment seems to be still unknown.

Disclosure:

Work supported by industry: no.

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THE SETTING UP OF ONCOSEXOLOGY IN THE CANCER CARE CONTINUUM: LESSONS FROM A PILOT EXPERIENCE

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1: General Hospital, France; 2: ROSA Association

In daily practice, the request for care for sexual difficulties related to cancer or to its treatment is mainly center or physician dependant. As cancer is increasingly a chronic disease, sexual health troubles should be taken into account without the problem of health care access. For this reason, the pilot plan ROSA has been set up. **Objective:** to analyze the different problems observed during the period of setting up from 2006 to 2010. **Material and Method:** ROSA included successively: a) a proximity care response whatever the stage, treatment or topography of cancer, thanks to a dedicated (patient/couple) consultation, b) a regional response by structuring our cancer network (5 millions of inhabitants), c) an ongoing national response by diffusing a specific guideline for health care professional. **Results: 2006–2008** has pointed up 3 main points: 1) the awareness of both health professional and institutions is real, mandatory but not sufficient; 2) the strong demand for a better offer visibility necessitates giving a structure to the oncosexological health care chain; 3) the large gaps (knowledge and skills) concerning this specific topic require a careful effort to inform and to educate all health professionals. **2009–2010** has specified six additional main points: 1) this care demand must be neither over nor under-estimated; 2) both information and training must be adapted to different health professionals; 3) the “sexual” demands often change according to time, 4) the structuring of regional/national offer requires a transversal approach for identifying all the potential targets i.e.: institutional (as supportive care, patients associations ...), all health professionals in contact with cancer patients either physicians or not (mainly nurses) and “sexological” resources (human / tools / teaching aids ...). To build up a regional directory of sexual health competences is a mandatory stage; 5) the place of nurses, GPs and patients associations appears as very efficient and well-adapted relays; 6) the helpful (but difficult) role of partner even if there are clear differences between men and women. **Conclusions:** for optimizing the oncosexological care, our experience shows 3 main points: 1) the structuring must be progressive by creating locally dedicated consultations, then to inform / train the numerous involved health professionals / structures on this specific topic; 2) the approach must be pragmatic, multidisciplinary and transversal using the numerous human/institutional local/regional/national resources; c) the supportive health care play a key role in establishing specific links between the separated worlds of oncology and sexual medicine.

Disclosure:

Work supported by industry: no.

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DIAGNOSTIC MANUAL OF SEXOLOGY III (DMS III)

Bianco, F.J.¹; Hernandez, R.²; Cabello Santa Maria, F.³

1: WAMS, Venezuela; 2: FLASSES, Venezuela; 3: IAMS, Espana

Objective: to present the english version of the third edition of the Diagnostic Manual of Sexology (DMS III) approved by the Latin-American Federation of Sexological and Sex Education Societies (FLASSES) in 1994; endorse by The World Association of Medical Sexology (WAMS) in 2009 and by the International Academic for Medical Sexology (AIMS) in 2010.

Material and Methods: several committees have been working in the third edition of the Manual. The Classification of Sex and Sexual Disorders is approached. Each nosological entity is described.

Result: The Diagnostic Manual of Sexology third edition (DMS III). A manuscript full of Symptoms, Signs and Syndromes.

Conclusions: Medical Sexology as a new Specialty in the field of Medicine, present its own classification of Sex and Sexual Function

disorders. Tights with the Diagnostic Manual for Mental Disease (DSM Series) done by American Psychiatry Association (APA) must be cut.

It is important that the International Diseases Classification (IDC) study the MDS III in order to adjust their Classification.

Disclosure:

Work supported by industry: no.

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ANTINUCLEAR ANTIBODY TITRES IN PEYRONIE'S DISEASE

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Objective: The aim of this study was to evaluate any relationship between the antinuclear antibody and Peyronie's disease (PyD).

Methods: We recruited 120 consecutive patients diagnosed with PyD by clinical and ultrasound examinations (group A). Another 30 healthy individuals who had no curvature of the penis, congenital or acquired, and who offered no history of trauma, served as the control group (group B). Basic laboratory investigations were obtained. Antinuclear antibody titres (ANA) together with serum total testosterone (TT), free testosterone (FT), and sex hormone binding globulin (SHBG) were all obtained.

Results: Serum TT and FT were significantly lower in group A than group B. No similar findings were obtained regarding SHBG. The normal titer of ANA is 1:40 or less. Higher titers are indicative of an autoimmune disease. ANA antibody may positive in 5% of individuals. Only 8% and 10% of patients had positive ANA positive titres in groups A and B, respectively. Those patients expressed a speckled pattern in their positive ANA titres.

Conclusions: We have not found any significant association of the ANA titres in patients with PyD. Low testosterone blood levels may be associated with PyD.

Disclosure:

Work supported by industry: no.

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A PIONEERING NON SURGICAL ALTERNATIVE FOR VAGINAL REJUVENATION USING HYALURONIC ACID VOLUMIZING FILLER (JUVÉDERM® VOLUMA™)

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2: Atlantic Clinical Consultants, London, ON, Canada

Objectives: A woman's self-image and sexual satisfaction are increasingly being recognized as important for overall well-being. As women become more comfortable with surgical procedures to enhance their self-image an increase in procedures to improve vaginal characteristics and sexual function have likewise increased. Surgical procedures have an increased risk of side effects, thus we performed here a pioneering pilot study to assess the safety and efficacy of hyaluronic acid volumizing filler (Juvéderm® Voluma™) injections to enhance vaginal tightness and sexual satisfaction.

Materials & Methods: Eight sexually active females with a vaginal dilator size between 3 and 4 (1.25" and 1.5", respectively) and who reported being finished childbearing, were enrolled in this study. Within 1 month of screening, subjects received 4 introital injections (4–6 mL total) of Voluma™ (Allergan Inc., Markham, Canada). If at 4 weeks post-injection a dilator size of 2 (1.06") was not achieved, patients were retreated at this visit. Dilator size measurements and questionnaires relating to vaginal tightness and sexual satisfaction were performed at 4, 8 and 12 weeks.

Results: As many subjects did not attend each post-treatment visit, values at baseline and the last available visit were compared. At the 4

week follow-up visit, 3 of 7 patients had achieved an introital dilator size of 2 (data not obtained for 1 subject), whereas all 7 of the subjects had achieved a size of 2 at 8 or 12 post-treatment weeks (1 subject was lost to follow-up after 4 weeks). All subjects reported an increased satisfaction with their vaginal tightness and during sexual activities/intercourse. Six of the 8 subjects reported an increased satisfaction in the quality of their vaginal sensitivity/orgasms and 2 reported no change.

Conclusion: Surgical and laser procedures for vaginal rejuvenation have gained increasing attention in recent years, however the risk of post-treatment complications remain. Here we show that vaginal introital injections of Voluma™ may be one alternative to invasive surgical procedures. Although the small sample size and issues with patient retention are limitations of this study, improvements in vaginal and sexual satisfaction were reported by the majority of patients. This positive interim results provides a rationale for performing larger controlled studies on the safety and efficacy of Voluma™ dermal filler for vaginal rejuvenation.

Disclosure:

Work supported by industry: yes, by Allergan, Inc. (industry funding only - investigator initiated and executed study).

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EFFECT AND MECHANISM OF ACTION OF A TRIBULUS TERRESTRIS EXTRACT ON PENILE ERECTION

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Objective: *Tribulus terrestris* has been used as an aphrodisiac. However, little is known about the effects and mechanism of action of *T. terrestris* on penile erection. Therefore, the effect of a *T. terrestris* extract and the mechanism of action of the extract on relaxation of the corpus cavernosum (CC) were investigated. The erectogenic effects of an oral preparation of the extract were also assessed.

Materials and Methods: The relaxation effects and mechanism of action of the *T. terrestris* extract on rabbit CC were investigated in an organ bath. The intracavernous pressure (ICP) was calculated after oral administration of the extract for 1 month to evaluate whether the relaxation response of the CC shown in the organ bath occurs *in vivo*. Additionally, cAMP and cGMP were measured in the CC using an immunoassay. Smooth muscle relaxation was expressed as the percent decrease in precontraction induced by phenylephrine. The ICP was assessed in rats after oral administration of the extract for 1 month, and changes in the cGMP and cAMP concentrations were monitored.

Results: Concentration-dependent relaxation effects of the extract on the CC were detected in the organ bath study. Relaxation of the CC by the *T. terrestris* extract was inhibited in both an endothelium-removed group and an L-NAME pretreatment group. The ICP measured after oral administration of the *T. terrestris* extract for 1 month was higher than that measured in the control group, and a significant increase in cAMP was observed in the *T. terrestris* extract group.

Conclusions: The *T. terrestris* extract induced concentration-dependent relaxation of the CC in an organ bath. The mechanism included a reaction involving the nitric oxide/nitric oxide synthase pathway and endothelium of the CC. Moreover, an *in vivo* study, *T. terrestris* extract showed a significant concentration-dependent increase in ICP. Accordingly, the *T. terrestris* extract showed satisfactory clinical treatment effects for erectile dysfunction.

Disclosure:

Work supported by industry: no.

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THE EFFECT OF AROMATASE INHIBITORS ON ESTROGEN LEVELS IN MEN RECEIVING TESTOSTERONE PELLETS

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Objective(s): To evaluate the effect of aromatase inhibitors on estrogen levels in men undergoing long acting testosterone replacement.

Material and Methods(s): The records of 62 hypogonadal men who were on either the aromatase inhibitor anastrozole (AZ), testosterone pellets (TP), or combination therapy (TP/AZ) were reviewed. Testosterone (T) and Estrogen (E) levels were obtained prior to the initiation of therapy and then examined in 60 month time intervals (A = 0-60, B = 60-120, C > 150). All men were treated with 750 mg of T, 1 mg of AZ daily, or combined therapy. Data were analyzed with linear regression and ANOVA.

Result(s):

Testosterone Levels

	Baseline	0-60 days	60-120 days	120-150 days
AZ	278 (90)	463 (141)	521 (142)	598 (131)
TP	220 (90)	615 (268)	475 (121)	350 (59)
TP/AZ	226 (90)	681 (188)	447 (129)	580 (59)

Estrogen Levels

	Baseline	0-60 days	60-120 days	120-150 days
AZ	32 (17)	23 (8)	27 (6)	16 (5)
TP	32 (13)	45 (19)*	38 (4)*	26 (3)*
TP/AZ	26 (5)	15 (11)	17 (4)	16 (3)

*p < 0.05

Conclusion(s): AZ prevents the increase in E seen with long acting T replacement therapy.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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VIRTUAL SEX OBSESSIVE DISORDER - DIAGNOSTICS AND TREATMENT

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Objective: Sex in third millennium does not always have to be with real person, object or alone. More and more people have sex with some help of internet. The most common forms are: 1. Use of erotic and pornographic stimuli; 2. Performing erotic chat; 3. Publishing and/or sharing sexually explicit materials about him/herself. Combining is frequent.

The extent of use of internet in the person's sexual life often exceeds the limits, which are positive and the behavior can be perceived merely as obsessive-compulsive than sexual one and such people and their partners demand the treatment. Therefore the author performed an anonymous study of active users the most popular central European amateur web site to compare the behavior of clients in virtual setting with real life findings, especially from the point of view of time spent in real/virtual sexual activities. Several case studies from the clinical practice illustrate the problem. The suggestion of therapeutic approach comes out from OCD treatment combined with couple and/or individual psychotherapy.

Material and Method: Relatively small random sample of 100 men and 100 women was selected during 2 months period from active participants in so called "chat rooms". Each person's statistical data were grouped and evaluated.

Results: The use of such most active site is dominated by male, but women tend to spend nearly twice as much time online and are also much more adherent to the special site (have been using it for a longer period). About 10 hours weekly spent by women and 6 hours by men compared with time dedicated to real sex with average frequency 2,5 per week shows 4 to 7 times higher preference of virtuality to reality. **Conclusions:** The clinical implications suggest that we perceive such disorder as a border-line between dependency (craving), OCD (neurosis and anxiety) and problem of sexual behavior (different activities from “real life” preferences). From psychopharmacological point of view influencing of dopamine - the reward transmitter - metabolism in the brain might be useful. But the basic obstacle seems to be a low motivation for treatment. As internet sex abuse leads often to evaporation of interest in real partner (if exists), the Coolidge effect (often described) is dubious.

Disclosure:

Work supported by industry: no.

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HORMONAL CONTRACEPTION AND FEMALE SEXUAL FUNCTION: A NON SYSTEMATIC REVIEW

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Objective: To evaluate the published of hormonal contraception's impact on female sexual function (FSF)

Material and Method: A non systematic review of articles crossing use of hormonal contraception and FSF was conducted on pubmed published until March 2012. The Key Words used on the search were: hormonal contraception, sexual dysfunction, combined oral contraceptive(COC), vaginal ring, contraceptive patch, progesterone only pill, hormonal intrauterine devices (HID), injectable contraceptive, transdermal implant, side effects, sexual desire, arousal, orgasm, sexual pain, androgens. The articles were classified as: positive, negative or non-effect on FSF.

Results: 49 articles were screened and 28 were included. The 28 clinical trials analysed etynilestradiol dose, progestin type, and routes of administration. Positive effect was found in 4 publications, negative effects in 5, and no effects in the others 19. There was a heterogeneity in the questionnaire used to evaluate FSF across publications.

Conclusion: The impact of hormonal contraception on feminine sexuality is still controversial. The different methodologies used to evaluate FSF are a limitation for adequate comparison of results between clinical trials. 19 out of 28 publications showed that hormonal contraception do not affect FSF no matter etynilestradiol dose, progestin type or route of administration.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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TESTOSTERONE REPLACEMENT THERAPY ALONG WITH CIRCADIAN RHYTHM BY LOW DOSE OF TESTOSTERONE OINTMENT FOR LATE-ONSET HYPOGONADISM

Amano, T.¹; Iwamoto, T.²; Sato, Y.³; Imao, T.¹; Takemae, K.¹

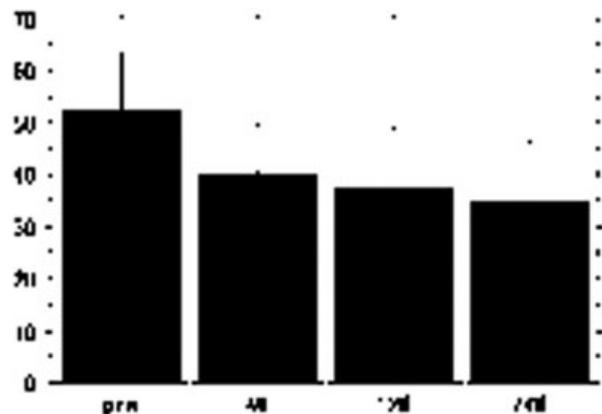
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Objectives: Testosterone replacement therapy (TRT) has been applied for the treatment of late-onset hypogonadism (LOH).Our previous report revealed that 3 mg of a short-acting testosterone ointment (Glowmin: GL) twice daily alleviated the various symptom of LOH patients (J Sex Med 2008; 5:1727). It is well known a loss of circadian rhythm in blood testosterone levels with aging, thus circa-

dian rhythm must be important for anti-aging and LOH treatments. The aim of this study was to clarify clinical efficacy of GL once every morning, which would enhance a circadian rhythm of testosterone.

Material and Methods: Seventeen LOH patients received 3 mg of GL once daily in the morning on scrotal skin and the clinical efficacy of GL were estimated by aging male symptoms (AMS) score at 4, 12 and 24 weeks after GL administration.

Results: Patients ages ranged from 44 to 63 years (mean 53.2 +/- 5.5). Total AMS scores before treatments were from 30 to 64 (mean 52.4 +/- 10.7). Total AMS scores at 4, 12 and 24 weeks after GL treatments significantly decreased to 39.9 +/- 10.1, 37.2 +/- 12.0 and 34.5 +/- 11.8, respectively (Figure).



The results of sub-analysis of AMS, including psychological, physical and sexual factors also significantly improved after GL treatments. One patient stopped administration of GL because he could not feel the efficacy of GL after 4 weeks, however no adverse reactions or abnormal laboratory data have reported. (Figure; Total AMS scores significantly improved at 4, 12 and 24 weeks after GL treatments)

Conclusions: TRT for LOH is an effective treatment; however, contemporary TRTs are performed without any considerations for circadian rhythm of testosterone. Loss of circadian rhythm of testosterone is one of the most important phenomenon in aging male. Although a role of testosterone circadian rhythm is unclear, TRT being consistent with testosterone circadian rhythm for LOH seems to be physiological. According to our preliminary data, low dose GL treatment supporting testosterone circadian rhythm is considered to be an effective and safe therapy with lower cost for LOH.

Disclosure:

Work supported by industry: no.

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THE TIME-LESS UROLOGIC QUESTION, “NOW WHY WOULD YOU DO THAT?” A CASE SERIES AND LITERATURE REVIEW OF SELF-INSERTED URETHRAL FOREIGN BODIES

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Objective: Self-inserted urethral foreign bodies are uncommon, with few cases reported in the literature. Urethral sounding may result in a retained urethral foreign body, and most commonly occurs in men as a form of masturbation. Although rare, it is a problem that many practicing urologists will encounter at some point in their career. We present a retrospective case review from a single facility over an 8-month period, discuss the limited literature available, etiology and rationale, and management of self-inserted urethral foreign bodies.

Material and Methods: In an 8 month limited period (3/2011 - 11/2011) there were 8 reported cases of intentional self-inserted

urethral foreign bodies, involving 3 different patients, all males. The patient characteristics varied with age (20–40 years old), race (Caucasian, African American and Hispanic), and type of foreign body (2 pen springs, 2 speaker wires, 2 pen tips, 1 pen cap and 1 pencil eraser). The reasons for placement also varied, with sexual gratification being most common. All 3 patients had a diagnosis of schizophrenia. All patients presented to the emergency department in a delayed fashion secondary to embarrassment and with difficulty voiding, pain and hematuria. Diagnosis was made using clinical history, physical examination, imaging studies, and/or endoscopic visualization of the foreign body. **Results:** All 8 cases were successfully treated via minimally invasive procedures, either with endoscopic removal or by manual expression of the foreign body out of the urethra. None of the 8 required open surgery, and most were treated successfully at the bedside in the emergency room (2 required anesthesia). After removal, all of the patients were able void without difficulty, and underwent psychiatric evaluation prior to discharge.

Conclusion: Urethral foreign bodies can be a result of sexual foreplay in the form of urethral sounding, which has been reported in up to 10% of males in certain populations. They to carry a concomitant psychiatric diagnosis and may be involved in other risky behaviors, such as substance abuse. A minimally invasive approach should always be attempted, but often time's surgical removal is necessary. Although rare, self-inserted urethral foreign bodies should be on the differential diagnosis of every urologist when evaluating a patient with voiding symptoms, especially if the patient has a history of substance abuse, psychiatric illness, mental retardation or dementia. Once discovered, the urologist can then ask their time-less question, "Now why would you do that?"

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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PENILE PLETHYSMOGRAPHY – USE OF THE METHOD IN THE 21ST. CENTURY

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Objectives: The main goal of this paper is to show the possibilities of usage of this method and help understanding of the results

Material and Method: Penile plethysmography as a diagnostic tool was first time introduced in Prague 1957. After half a century the technical part was very much improved from the first cumbersome volumetric gauge to these days computerized close-to-polygraph tool. Although the technical progress made the tool very accurate, still some questions arise.

Some scientists have doubt about psychometric bases of PPG assessments, speaking about dubious value of test procedure. Many sexologists – on the other hand - still appreciate its diagnostic potential.

Author wants to discuss the use of penile plethysmography and give some impulse to agreement of use in 21st. century. The results evaluation can be discussed as an important part of the diagnostic process in the forensic sexology. Another important issue concerns the ethical aspects, which have led to guidelines not always accepted, e.g., that "the PPG test should be carried out only in the context of an appropriate range of other assessment and treatment procedures or in the course of research that has been professionally and ethically approved by the relevant body". Because of author's 20 years of experience in the field, sharing some of his findings in the diagnostics and care especially of paraphiliac sex offenders seems to be valuable. Illustrated with some typical findings can give an idea of value of an assessment and interpretation of results in few brief case studies demonstrating the impact of an assessment even with cathamnetic findings. Appropriate focus will be given to stimuli and its impact.

Results: Especially when combined with other, merely psychological approach, penile plethysmography still gives results, which can help in not only forensic sexology.

Conclusions: Accepting certain limitations (especially speaking about different validity in different diagnoses) claims that use of PPG preferably as diagnostic tools in daily practice as well as in forensic sexology still has its place and can help the client with the treatment and so increase the protection of his social environment.

Disclosure:

Work supported by industry: no.

315

CLINICAL RESULTS OF PENILE REAUGMENTATION SURGERY USING BOVINE COLLAGEN IMPLANT

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Objective: Since the 1990s when penile augmentation surgery using autologous dermal-fat and fat injection were introduced, surgical techniques utilizing diverse kinds of augmentation materials have been conducted, such as allografts, xenografts, and chemical fillers. Such diverse surgical techniques have brought sexual satisfaction and self-esteem to those with a small penis complex. However, in some cases when the patient has a higher expectation or when shape improvement is required, secondary reaumentation may be necessary. This study reports on the use of a type I collagen implant as a xenograft material in penile reaumentation surgery

Material and Methods: The reaumentation surgery was conducted by using xenogrfts. For the xenogenic implant, type I collagen was used as the graft material. It was extracted from bovine pericardium. Through a transverse incision of 4–6 cm at the distal penis, girth enhancement was performed. After separating the existing grafted area from the Buck's fascia and obtained a widened space to the prepubic junction. Then, the prepared graft was anchored and sutured to the Buck's fascia on the distal, proximal, and lateral part of the penis using absorbable suture material.

Results: Retrospective analysis was conducted on penile reaumentation procedures performed between July 2005 and July 2009 using xenogenic type I collagen. This study included 67 patients with the following first augmentation surgery in the past: autologous dermal fat graft(29 cases, 43.3 %); silicon injection(18 cases, 26.9 %); xenograft such as bovine collagen(9 cases, 13.4 %); autologous fat graft(5 cases, 7.5 %); allograft(3 cases, 4.5 %); hyaluronic acid injection(2 cases, 3.0 %); restorative scaffold(poly lactic-co-glycolic acid) insertion(1 case, 1.5 %). An increase in diameter was observed using ultrasonography, and it was found that the diameter of the penis had increased by 5.6 ± 1.2 mm after surgery. Common postsurgical complications were temporary swelling and rubefaction, but these symptoms were relieved conservative treatment. Active treatment was required in 2 cases(3 %): removal of the graft because of infection.

Conclusions: Penile reaumentation surgery with xenogenic type I collagen has the advantages of being a simple surgical procedure and fewer complications. For the patient group that received penile augmentation surgery with diverse materials in the past, The use of xenogenic type I collagen in this procedure also demonstrated a effective profile. It can therefore be recommended as a favorable surgical method for use in future penile reaumentation surgery.

Disclosure:

Work supported by industry: no.

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ELECTROVAGINOGRAM

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1: CIPPSV, Venezuela

Objective: To value the status of the pelvic muscles surrounding the vagina in Orgasmic Dysfunction.

Material and Methods: Using the Perineometer we have been able to value the status of the pelvis muscles surrounding the vagina. The evaluation we called Electrovaginogram.

The Electrovaginogram has the following parts: base line (BL), contraction, hold and relax (CHR), contraction, hold and relax five times (CH5R), contraction, hold x 10 second and relax two times (CHTR2), Contraction, hold steadily as much as you can (CHR), termination base line (TBL).

20 women with satisfactory orgasmic response were comparing with 20 women with Orgasmic Dysfunction.

Results: A significant weakness was found in females with Orgasmic Dysfunction.

Conclusions: The Electrovaginogram have proved to be helpful in the diagnoses of the weakness of Pubococcygeal muscles, which is a main feature present in female's complaint of Orgasmic Dysfunction.

Disclosure:

Work supported by industry: no.

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EFFICACIOUS PLACEMENT OF AN INFLATABLE PENILE PROSTHESIS IMMEDIATELY AFTER REPAIR OF A SYNCHRONOUS IATROGENIC URETHRAL INJURY

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1: University of South Florida, USA

Objective: A urethral injury at time of placement of an inflatable penile prosthesis (IPP) has traditionally been an indication to abort placement of the implant, secondary to the presumed increased risk of infection. We propose that in the right setting, the urethral injury can be primarily repaired in concert with safe placement of the IPP. This represents the case of a successfully placed IPP despite intraoperative iatrogenic urethral injury.

Materials and Methods: A 65 year-old male with organic erectile dysfunction had failed multiple modalities of medical therapy and was subsequently scheduled for placement of an IPP. A peno-scrotal approach was utilized and inadvertently while dissecting the left corpora a urethral injury was visualization with exposure of the foley catheter. The urethra was mobilized for better exposure and a 1 cm longitudinal urethral laceration was noted. This was also evaluated cystoscopically and it was determined that the defect could be repaired primarily with using 3-0 monocryl sutures in a running fashion. This was reinforced with a second layer and tunica. Repeat flexible cystoscopy was performed confirming the watertight repair. A 16F foley catheter was replaced. Copious irrigation with antibiotic solution of the incision was performed followed by an otherwise uneventful placement of a 24 cm Coloplast® Titan IPP with 1 cm rear tip extenders bilaterally, and 75cc reservoir on the right. Postoperatively, the patient was discharged following routine protocol plus the foley catheter.

Results: The foley catheter was removed after a normal retrograde urethrogram (RUG) at post-operative week 2. To further evaluate the repair a flexible cystoscopy was performed at post-op week 4, at which time the repaired area was completely healed and could not even be identified. On postop week 6 the patient was able to have successful coitus with his IPP.

Conclusion: With the urethral repair being watertight and no previous violation of the corpora, it was determined that it was safe and in the patient's best interest to move forward with the placement of the IPP. The patient also had a negative preoperative urine culture, further minimizing the risk of infection. Although not recommended in all cases, we challenge the notion that all urethral injuries mandate that an IPP case be abandoned. In select situations, when a urethral injury is identified and immediately repaired in a watertight multi-layered fashion, proceeding with the placement of an IPP can be done efficaciously and safe.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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CONSIDERATION OF THE METHODS TO MANAGE THE PATIENT WHO HAVE DELAYED RECOVERY FOLLOWING PENILE ENHANCEMENT SURGERY

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Objective: Many penile enhancement surgeries have been performed to men who want an improved outer appearance and sexual performance. We aim to report our experiences to manage postoperative courses following the penile enhancement surgeries.

Material and Methods: We performed and followed up 520 penile enhancement surgeries for at least 6months. We adopted the pre-pubic incision, insertion of cadaveric dermal graft and multilayer suturing lengthening procedure. Following the surgery the patients reported several discomforts or questions concerning a delayed recovery. Among them, temporary penile shortening is the most frequent (442 cases, 85%). Dullness of the penile shaft and the glans is second most frequent symptom (317 cases, 61%). There were abnormal sensations including tingling and sharp pain (291cases, 56%) and a sense of hardness of inserted graft material (125 cases, 24%). 62 cases(12%) wanted to get treatment due to the Irregular shape of the penis skin. After following up for 5months, we applied triamcinolone injection on pre-pubic granuloma and hyaluronic acid on penile shaft to fix temporary penile shortening on erect state and accelerate the recovery of painful sensations and hardness of inserted graft. To reduce the recovery time, we recommend taking the pentoxifylline. And to fix the irregular skin shape, we used a hyaluronic acid injection.

Results: Within 5 months after penile enhancement surgeries, 97% of patients had completely recovered without any additional treatment. 3% were treated with triamcinolone injection or hyaluronic acid injection. All cases fully recovered.

Conclusion: In penile enhancement surgery, we have experienced several kinds of delayed recovery cases. All these cases were successfully treated with our follow up procedure.

Disclosure:

Work supported by industry: no.

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IS NONINVASIVE CONSERVATIVE THERAPY FOR IATROGENIC PRIAPISM WORTHWHILE?

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1: Elaj Medical Centers; 2: Urology section, KAMC

Subject: Iatrogenic priapism is a common complication following intracavernosal injection in the management of erectile dysfunction. The classic initial treatment is invasive in nature (aspiration and irrigation with sympathomimetic drugs). Noninvasive therapy can be used to treat priapism, and this study is investigating its success as the first treatment measure for that condition **Materials and Methods:** In a prospective manner, 56 consecutive patients with iatrogenic priapism were started on noninvasive therapy in the form of exercise (by walking up and down the stairs as long as tolerated, 30 minutes maximum), followed by oral Salbutamol tablets, for non responders, early (3 hours) after persistent erection. Patients were monitored for side effects and all vital signs were recorded periodically. **Results:** 37.5% of all patients had flaccid penis after exercise alone, and another 32.5% of patients had detumescence after Salbutamol therapy. No complications were recorded following the above conservative measures. The rest of patients (n = 17, 30%) needed invasive therapy with intracavernosal sympathomimetic irrigation **Conclusion:** It is worthwhile to try conservative therapy early in iatrogenic priapism before proceeding to invasive therapy, with reasonable success rate in more than two thirds of patients. Such simple measures should be included in the management scheme of iatrogenic priapism as first step, as it may save significant group of patients from the stressful and painful invasive therapy measures, currently considered initial management step.

Disclosure:

Work supported by industry: no.

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NORMAL VARIATION OF SEX HORMONE BINDING GLOBULIN (SHBG) UNDERMINES ACCURATE DIAGNOSIS OF HYPOGONADISM

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Objectives: We sought to assess the accuracy of total testosterone for determining hypogonadism compared to calculated free testosterone levels using Sex Hormone Binding Globulin (SHBG) levels.

Methods: Retrospective database review of patients seen in a male fertility clinic over the last 2 years for which a.m. testosterone, SHBG, and physical exam findings were available. Classification functions of total testosterone (sensitivity and specificity) were determined using calculated bioavailable testosterone levels of definitively low (< 156 ng/dL) and borderline (157–210 ng/dL) as the normal reference values.

Results: Data from 170 patients revealed the sensitivity, specificity, positive predictive value and negative predictive value of total testosterone to be 81%, 83%, 81%, and 82% respectively. Providers using only total testosterone to evaluate for hypogonadism may miss up to 20% of patients with a calculated bioavailable testosterone below 156 ng/dL, and as many as 40% of patients with levels below 210 ng/dL.

Conclusions: A significant portion of patients seen for infertility with a total testosterone above 300 ng/dL are hypoandrogenic if the bioavailable testosterone is calculated. Given the large variation in SHBG, clinicians should consider including SHBG for the calculation of bioavailable testosterone in the evaluation of men with symptoms of hypogonadism or infertility.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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MANAGEMENT OF PEYRONIE'S DISEASE WITHIN THE NCSAUA AS ASSESSED BY EMAIL SURVEY

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Objective: Practice patterns for management of Peyronie's disease (PD) by members of the North Central Section of the American Urological Association (NCSAUA) were assessed by email survey with regards to use of oral medication, intralesional injections, traction devices, surgery, and imaging.

Material and Methods: An email containing a link to the study survey and the subject heading "Peyronie's Disease Survey" was sent to 1,221 members of the NCSAUA. Responses were assessed 4 days after the survey was sent.

Results: Seventy-seven physicians completed the survey (response rate 6.3%). Sixty-three (81.8%) of respondents treat men with PD themselves, while 14 (18.2%) refer these men to another urologist. Forty-five of these 63 urologists (71.4%) treat patients with oral therapy, with Vitamin E being the most commonly used oral treatment. Intralesional injections are performed by 30/63 (47.6%), with verapamil being utilized 96.6% of the time. Thirty-eight of the 63 (60.3%) use vacuum erection devices, penile traction, or both in the management of PD. Surgery is performed by 48/63 (76.1%), and the majority of these urologists offer tunicoplication, grafting procedures, and penile prosthesis implantation. Only 12/63 (19.0%) order any imaging studies for patients with PD.

Conclusions: An email survey assessment of practice patterns for management of PD by members of the NCSAUA reveals that the majority treat these men themselves instead of referring to another urologist. Vitamin E remains a frequently-used treatment, and intralesional injections are performed by fewer than half of respondents.

Multiple surgical options are offered by a significant proportion of urologists treating PD. The low response rate for the survey raises concern for a lack of enthusiasm or confidence in the treatment of men with PD.

Disclosure:

Work supported by industry: no.

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HIGH RISK PENILE IMPLANTATION WITH MALLEABLE PENILE IMPLANTS VIA A SUBCORONAL INCISION

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Introduction: Patient's who are a high bleeding risk and fail medical management continue to be problematic when considering definitive management of erectile dysfunction with placement of penile implant. The risks include but are not limited to hematoma, increased incidence of infection, and exposure of the operative team to blood borne pathogens. The Subcoronal approach to placement of a malleable penile prostheses allows for easy and direct placement of prosthesis, limits intraoperative and postoperative bleeding, has only a small area of exposure during surgery, and a low maintenance recovery period.

Materials and Methods: One patient who had failed both oral and injection therapy, who was HIV positive and carried the diagnosis of idiopathic thrombocytopenia (ITP) was cleared medically for surgery insertion of a penile implant. In relation to his ITP he kept a baseline platelet count of approximately 4000. Acknowledging the risks of surgery, he chose to proceed. After a foley catheter was placed, a 3 cm subcoronal transverse incision was made. The incision was carried down to expose the bilateral corpora cavernosa while taking care to avoid the corpora spongiosum. After placing 2-0 vicryl stay stitches, bilateral corporotomies were made and routine dilation was accomplished using brooks dilators. A Genesis® implant measuring 13 millimeter in diameter and 21 cm in length was placed. The incision was closed in 3 layers.

Results: Estimated blood loss was 25cc. The patient was admitted overnight for observation. He was discharged post-operative day 1 and followed up in 2 weeks without evidence of hematoma or infection. He denied pain.

Conclusion: Subcoronal placement of a malleable implant is an effective treatment option for those patients who are high risk for intraoperative and postoperative bleeding. It also minimizes the operative team's exposure to blood borne pathogens. This approach is not as frequently utilized such as the infrapubic or penoscrotal but provides advantages especially in patients with certain complicating comorbid conditions.

Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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WHAT DO TURKISH YOUNG ADULT MEN KNOW ABOUT HPV: A CROSS SECTIONAL STUDY IN MILITARY

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Human papillomavirus (HPV) is common throughout the world and estimated to cause about half a million new cancers every year, most of them affecting women in developing countries. Over 6 million people acquire HPV each year and most of them do not develop symptoms. Although there is no treatment or cure for HPV, there are several ways to lower chance of getting HPV; like adopting safer sexual behaviors.

Objective: In this study, it is aimed to identify the knowledge level of young male adults about HPV.

Material and Method: The research was conducted in Gulhane Military Medical Academy in Ankara during April 2010-May 2011. Research group consisted of 874 private participants who agreed to participate. Data were collected with a form developed by the researchers including socio-demographic characteristics and knowledge level about HPV. In statistical analysis; frequencies and chi-square tests were utilized. For all the analysis, 0.05 was considered to be statistically significant.

Results: Participants had an average age of 23.3 ± 2.9 and the average age of first sexual intercourse was 17.6 ± 2.2 . Three quarters of the participants (70.9%) didn't hear HPV, 71.2% didn't know that sexual partner can spread HPV without warts and 70% didn't know that HPV causes cervical cancer in women and penile cancer in men. However, 5.8% of the respondents stated to have genital warts at any one time. Although half of the respondents (53.7%) stated that HPV spread through sexual intercourse, 12.9% chose "contact" as the most important transmission way for HPV. On the other hand, more than a quarter of the participants (28.5%) marked "blood transmission" as the route of transmission for HPV which is in fact not a transmission way. Almost one of every five respondents (17.6%) stated that they did not know whether they had HPV suspected sexual partners.

Conclusion: As a result, knowledge level of the respondents was found to be quite low and three of every four respondents were found to have no idea about HPV. In this context, nurses are believed to have an important role in informing young male adults about HPV.

Disclosure:

Work supported by industry: no.

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PREVENTION OF PITUITARY GONADOTROPIN SUPPRESSION DURING EXOGENOUS TESTOSTERONE REPLACEMENT BY CONCOMITTENT AROMATASE INHIBITOR ADMINISTRATION

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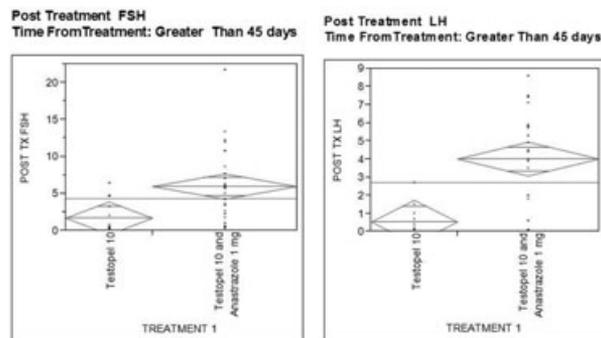
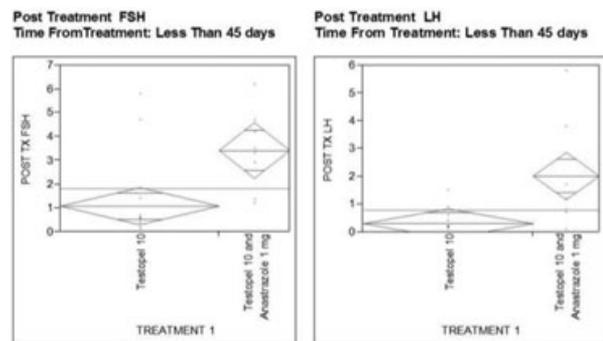
1: Albany Medical College, USA

Objective(s): We investigated the effect of aromatase inhibition with anastrozole (AZ) on pituitary gonadotropin levels in men receiving testosterone pellets (TP) for the treatment of hypogonadism.

Methods: The gonadotropin levels were retrospectively examined in 56 treatments of 29 hypogonadal men undergoing testosterone replacement with exogenous TPs. Men were offered the addition of AZ therapy after their first pellet insertion as a way of decreasing the frequency of pellet insertion. The days after treatment and serum determinations were recorded. Data was analyzed with linear regression and ANOVA with a categorical analysis of time from treatment less than or greater than 45 days.

Result(s): Gonadotropins were significantly higher with combination therapy at both time points, $p < 0.05$. (See graphs)

Conclusion(s): The suppression of pituitary gonadotropins (LH and FSH) with exogenous testosterone replacement is prevented by the concomitant administration of an aromatase inhibitor.



Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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PROFILE AND MAIN ETIOLOGIES OF WOMEN WITH VAGINISMUS ASSISTED ON A FEMALE SEXUAL HEALTH CENTER

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1: Federal University of Sao Paulo, Brazil

Objective: To evaluate the average of age, bond time and the main etiologies presented on women with the diagnosis of vaginismus assisted on the Feminine Sexual Department of the Federal University of Sao Paulo- UNIFESP.

Materials and Methods: That's a retrospective study, where medical records were analyzed from January/2005 until March/2012. The data were tabulated and allocated on the following criteria: age, being or not on a relationship; bond time, dysfunction time and the possible etiologies: repressive and/or rigid education; religion; dispareunia or sexual trauma.

Results: Were analyzed 83 medical records with the following data: the mean age was 35,5years, the mean of bond time was 8,8 years and the mean time of vaginismus was 12 years. From those 83 women, 44 (54%) were married and 38 (46%) single but with a stable union, only 6 (16%) were without partner. The etiologies that could justify the presence of vaginismus had the following order of incidence: 46 (56%) had Vaginismus probably because of a repressive and/or rigid education, 24 (29%) for conservative religions, 5 (6%) because of a progression of dispareunia and 8 (10%) for sexual trauma.

Conclusions: With the analysis of data we can conclude that there is an expressive incidence of vaginismus in younger women, no one woman was on menopause. The majority had a stable and long union; this is an interesting finding when we presume that the sex with vaginal penetration it's very important for the men. We can also observe that the main etiologies of this sexual dysfunction found in our patients are related with rigid and conservatives education and religions, where the virginity is generally required. The presence of vaginismus in our basis caused by a sexual trauma was minor than found in the literature. However there are few publications that address the characteristics of the woman with vaginismus.

Disclosure:

Work supported by industry: no.

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CONSIDERATION OF THE SAFEST SURGICAL METHOD FOR UNCIRCUMCISED MEN IN PENILE ENHANCEMENT SURGERY

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Objective: In many uncircumcised men who wish to have penile enhancement surgery, we have performed penile enhancement surgery by different surgical procedures. We aim to report the safest and most effective method in uncircumcised patients who want to get penile augmentation surgery.

Material & Methods: We have performed 480 penile enhancement surgeries in uncircumcised men with pre-pubic incision, cadaveric dermal graft insertion and multi-layer transverse suture lengthening procedure. We divided 2 groups according to the penis skin state after the preoperative consultation. Group 1 (435 cases) was characterized by uncircumcised men without narrowed skin band. Group 2 (45 cases) was defined as the uncircumcised patients having narrowed skin band. In group 2, we recommend the circumcision surgery first and then penile enhancement surgery after 6months. All patients in group 1 were performed with penile enhancement surgery first. In group 1, penile enhancement surgeries alone were done in 383 cases (79.8%) and 41 cases (8.5%) were performed by 2nd circumcision surgery after 1month to 5months and 11 (2.3%) were performed by circumcision surgery within postoperative 10 day due to skin banding and ulceration. We never adopted the circumcision incision in penile enhancement surgery to prevent inserted dermal graft infection. We followed up from 1 month to 12 months. Average follow up period was 5.3 months.

Results: Wound dehiscence was occurred in 10 cases (2.3%) in group 1 and 1 cases (2.2%) in group 2 in penile enhancement surgery. At the time of circumcision surgery, wound dehiscence was occurred in 1 cases (2.2%) in group 2 and 3cases (5.7%) in group 1. All cases were safely fixed within at least 3weeks. There was no disfigurement of the penis during the follow up time.

Conclusion: To perform the safest penile enhancement surgery in uncircumcised men, we have to consider the adequate timing of circumcision surgery following or prior to the penile enhancement surgery.

Disclosure:

Work supported by industry: no.

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IDENTIFYING THE EFFECT OF FAMILY PLANNING AND REPRODUCTIVE HEALTH PROGRAM AMONG YOUNG MALE ADULTS' ATTITUDES ON CONDOM USE

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Sexually transmitted infections (STIs) continue to be a major public health concern in both industrialized and developing countries and all STIs are attributed to unsafe sex. Use of condoms, monogamy, and sexual abstinence is recommended in preventing STIs.

Objective: It is aimed to assess the effect of Family Planning and Reproductive Health (FPRH) education among young male adults' condom use.

Material and Method: The research was conducted to 874 participants in Gulhane Military Medical Academy in April 2010-May 2011. Data were collected with a form developed by the researchers questioning socio-demographic characteristics and condom use attitudes. Chi-square test was utilized for the group comparison.

Results: 89.3 % of the participants were single, 77.7% had sexual experience and average age of first sexual intercourse was found to be 17.6 + 2.2. Half of the respondents (49.3%) had sexual intercourse with his girlfriend and 16.9% of them paid for sex. While a quarter of the

participants (29.1%) stated they always used condoms in their relations, 11.2% stated they never use it. In addition, when the reasons for condom use is examined, a statistically significant difference is found ($p < 0.05$).

One of every three respondents stated that they used condoms incorrectly. The participants who had FPRH education used condoms more correctly. As condom use behaviors; looking at the expiration date ($p > 0.05$), checking the post hole after sexual intercourse ($p < 0.05$), using only once ($p > 0.05$) drainage of the space before using ($p < 0.05$) behaviors are compared.

Conclusion: It is considered that FPRH education increases the knowledge level of condom use.

Disclosure:

Work supported by industry: no.

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COMBINED INTRACAVERNOUS INJECTION AND STIMULATION (CIS) THERAPY OF ED AFTER RADICAL PROSTATECTOMY

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Objective: Erectile dysfunction (ED) can develop after radical prostatectomy (RP) for prostate cancer. Nerve-sparing surgical procedures and postoperative erectile rehabilitation have been used to address this complication; however, nerve-sparing surgery is not indicated for all patients. In addition, some patients develop ED even after nerve-sparing procedures. We investigated the safety and effectiveness of Combined Intracavernous Injection and Stimulation (CIS) therapy for ED after RP.

Material and Methods: At our center, erection was induced by CIS using 20 µg prostaglandin E1 (PGE1) among patients for whom phosphodiesterase-5 inhibitor (PDE5I) therapy was ineffective or contraindicated. A Grade 3 or Grade 4 was classified as effective, as indicated by the Erection Hardness Score (EHS), and a self-injection regimen was begun. The study was approved by the Ethics Committee of Toho University Omori Hospital, and all patients provided written informed consent for inclusion in the study. A total of 54 patients with ED after RP were tested with an CIS using 20 µg PGE1, excluding those for whom the test was done for diagnostic purposes. Average age was 65.5 years. Nine patients had undergone nerve-sparing surgery and 30 had undergone non-nerve-sparing surgery. The surgical procedure could not be determined in 15 cases.

Results: The response was Grade 1 or 2 in 7 cases, Grade 3 in 9 cases, Grade 4 in 37 cases, and priapism in 1 case. The effectiveness rate was 85.2%. Penile self-injection therapy was selected by 5 patients with Grade 3 and 32 patients with Grade 4 (68.5%). There was 1 case of priapism, and 6 patients developed 2-hour prolonged erections, which were treated by phenylephrine injection. Ultimately, they were able to use low-dose PGE1 to obtain satisfactory erections, without adverse drug reactions. In our center, the effectiveness rate was 44% for CIS using PGE1 therapy among nonoperative ED patients for which PDE5I was not indicated. The effectiveness rate was significantly higher for operative patients than for nonoperative patients.

Conclusion: PGE1 self-injection was safe and effective for treatment of ED.

Disclosure:

Work supported by industry: no.

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IS INCREASING BMI AN INDEPENDENT RISK FACTOR FOR LOW SERUM TESTOSTERONE IN ADULT MALES?

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1: Elaj medical centers

Objectives: Obesity and increased weight were recognized in many studies as risk factors in decreasing serum testosterone, but most of the work done was studying multifaceted factors; we investigated the increase in body mass index (BMI) as independent risk factor in decreasing serum testosterone.

Material and Methods: Prospectively 664 patients were selected from our outpatients' Andrology clinic with standardization of any other contributing factor which might affect serum testosterone, and their BMI was calculated, then an early morning blood sample was taken for serum testosterone. Statistical analysis was performed with comparative statistical tables and graphs.

Results: An obvious inverse correlation between increasing BMI and decreasing serum testosterone was gained from statistical analysis.

Conclusion: Increasing BMI is an independent risk factor in lowering serum testosterone.

Disclosure:

Work supported by industry: no.

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POSTCOITAL VAGINAL RUPTURE IN A YOUNG WOMAN WITH NO PRIOR PELVIC SURGERY

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Introduction: Reports of postcoital vaginal rupture in the literature are limited to cases involving women who are postmenopausal, have recently undergone pelvic surgery, or have suffered genitourinary trauma.

Objective: We report a case of postcoital vaginal rupture in a 23-year-old woman with no prior surgical history who complained of acute onset, severe vaginal pain after consensual intercourse.

Results: Examination under anesthesia revealed a 6-cm laceration of the posterior fornix, which extended into the abdominal cavity. The laceration was repaired using a combined vaginal and laparoscopic approach.

Conclusions: Coitus-induced vaginal rupture in a reproductive aged woman with no prior pelvic surgery or other risk factors is a rare clinical presentation. Prior reports of rupture in premenopausal women have recommended repair via laparotomy. This case documents successful transvaginal and laparoscopic repair, and reviews the etiological mechanisms for coitus-induced injury.

Disclosure:

Work supported by industry: no.

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POSTGRADUATE TRAINING IN MEDICAL SEXOLOGY

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1: CIPPSV, Venezuela

Objective: To describe the Postgraduate Training in Medical Sexology.

Material and Methods: The Postgraduate Training in Medical Sexology started in 1985, is three-year program which has six academic semester and full time clinical training. During the first year the objective is to learn to make a Medical Sexology History, syndromatic diagnoses and diagnostics procedures. During the Second Year emphasis are done in the different Therapeutic approaches and the learning

of the Fundamental Therapeutic Program applied to Medical Sexology. During the third year a teaching experience in gain given lectures and class in the Postgraduate Training Program in Sexual Counseling. Skill in Promotion of Sex and Sexual Health, Prevention and Anticipation of sex and sexual diseases are taught. During the entire Residency Program a full exposure to research in mandatory and a final thesis is a requisite for getting the degree of Master in Science mention Medical Sexology.

Clinical rotations include: Psychiatry, Urology, Gynecology, Rehabilitation and Family Medicine.

Results: Since 1985 to present 54 Medical Doctors has being trained. Doctors from Ecuador, Colombia and Espana had taken our Program. The Venezuelan's Public Health System so far has opened 10 positions in seven different hospitals were a Medical Sexology Unit has been created. Five of them are University related.

Conclusions: the development of Medical Sexology in Venezuela has a direct relationship with the success of the Postgraduate Training in Medical Sexology.

Disclosure:

Work supported by industry: no.

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PHALLOPLASTY SURGERY BY ALLOGENIC DERMAL FILLERS

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1: Philip and Paul Medical institute, Korea, South

Objectives: Penile augmentation surgery with tissue grafts through incision so far has been performed with; however, there might be adverse effects such as a wound problem, a scar, pain, prolonged recovery time. Another augmentation method is the injection of chemical filler or fat into the penis but there is the disadvantage of histological instability, migration and a high reabsorption rate of the material. As a result, current penile augmentation surgery has been pursued for rapid recovery using a simple technique and natural appearance without any scars. We are to introduce new methods for penile augmentation using acellular human dermal tissue with injection.

Material & Methods: Being human derived, allogenic collagen does not require skin testing. The surgery was done for men with a small penis complex. Under the local anesthesia, according to the size of the penis and the augmentation size the patient desired, about 3–6cc of dried acellular particulate dermal matrix combined with 1.5–1.8cc of lidocaine and 0.3cc of gentamicin per 1cc of the tissue were injected into the subcutaneous tissue.

Results: Retrospective investigation was done for this study with 126 cases from December 2007 to Jan 2012. 4cc of acellular micronized dermal tissues on average were used for a one-time injection and the average surgery time was 20 minutes. 2 cases of local skin necrosis was reported but it was treated through the conservatory treatment. No other adverse reaction was occurred. There was little migration of the injected tissues after the graft.

Conclusions: This surgical method as a minimally invasive tissue graft has several advantages compared to preexisting techniques. It does not require an incision and resulting in short operation and rapid recovery time. There are few side effects. Therefore, for the men who experienced difficulty with penile augmentation surgery with the preexisting techniques, for example, those who had physical health problems, or were of an older age, or were on special medications, this surgical method could be recommended. It also may be considered a new technique that can be applied for partial augmentation, correction of deformity, and reconstructive surgery as well.

Disclosure:

Work supported by industry: no.

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TESTOSTERONE PELLETS (TESTOPELÂ®) INSERTION RESULTS IN REVERSIBLE SUPPRESSION OF PITUITARY GONADOTROPINS (GT)

Aggarwal, H.¹; Frankel, J.¹; Welliver, C.¹; Mecklin, C.¹; Armstrong, M.¹; McCullough, A.¹

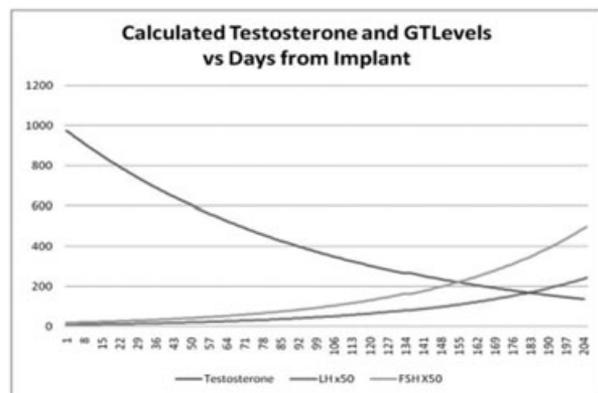
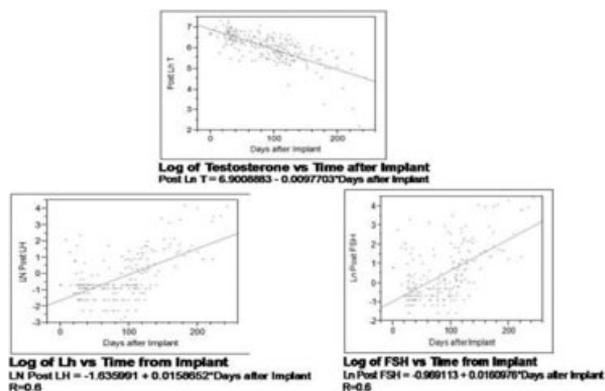
1: Albany Medical Center, Albany, NY, USA

Purpose: Luteinizing Hormone and Follicle Stimulating Hormone levels have been shown to decrease with all forms of testosterone (T) replacement. Long acting T pellets (TP) result in persistently elevated T levels resulting in suppression of GT and endogenous production of T. We examined the onset and the longitudinal effect of long acting TP on GT levels.

Methods: Data was retrospectively analyzed on 157 patients from two major academic institutions. Serum T, LH and FSH were measured pre-insertion of TP and at variable time points thereafter. Data was analyzed using JMP 9.0 statistic software. For comparisons with outcome variables the ANOVA test was used for continuous data while the Chi squared test was used for categorical data.

Results: Data were available on 157 patients (Table-1). LH and FSH levels were consistently suppressed for up to 4-5 months. GT suppression was maximized by second month regardless of the number of pellets inserted. There was 10-20 fold decrease in GT levels at nadir. As T level decreased the LH and FSH levels increased over time (Figure-1). As testosterone levels return to baseline the LH and FSH levels start rising to baseline in 4-5 months (Figure-2). It is probable that during the period of GT suppression the measured T is from exogenous replacement.

Conclusions: Long acting T pellets result in rapid suppression of pituitary GT followed by a return to baseline levels over a 4-5 month period.



Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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WITHDRAWN

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WITHDRAWN

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EXPRESSION OF AQUAPORIN PROTEINS IN VAGINA OF DIABETES MELLITUS RATS

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Objective: To investigate the expression of Aquaporin1-3 (AQP1-3) in vaginal tissue of diabetes mellitus rats.

Methods: Female Sprague-Dawley rats (n = 20) were divided into 4-week diabetes mellitus rats group (n = 5), 8-week diabetes mellitus rats group (n = 5) and control group (n = 10). Vaginal secretion was measured by fluid weight absorbed by cotton swabs after pelvic nerve electro-stimulation and anterior vaginal tissue was dissected for determining the expression of AQP1-3 by immunohistochemical study and Western blot.

Results: No significant difference in serum estradiol concentrations of rats among these groups (P > 0.05). Vaginal secretion was significantly lower in diabetics group than in control group (P < 0.05), respectively. The protein expressions of AQP1-3 were significantly lower in diabetics group than in control group (P < 0.05), respectively.

Conclusions: Decreased vaginal secretion in diabetes mellitus rats after electro-stimulation may be partly due to estrogen-independent decreases of AQP1-3 in vaginal tissue.

Disclosure:

Work supported by industry: no.

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THE PHARMACODYNAMICS AND PHARMACOKINETICS OF ENCLOMIPHENE CITRATE IN MEN WITH SECONDARY HYPOGONADISM SHOWS RESTORATION OF NORMAL HPA FUNCTION

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Objective: To determine the PD of serum testosterone (TT) and luteinizing hormone (LH) in men with secondary hypogonadism comparing AndroGel to daily oral doses of enclomiphene citrate (enCC or Androxal™).

Methods and Subjects: This was a randomized, single blind, two-center phase II study to evaluate three doses of enCC and AndroGel on 24-hour LH and TT in men with secondary hypogonadism. Sixty men were screened, 48 were enrolled in the trial and 44 were eligible to complete both PD arms. All subjects enrolled had TT in the low range (<350 ng/dL) and had low to normal LH (<12) on at least two occasions. The PD was over 24 hours and examined the effects of treatment with 6.25 mg, 12.5 mg and 25 mg enCC versus treatment with AndroGel. The initial PD profiles, was contrasted to that seen after six weeks of continuous daily oral or topical treatment (PD pt 2). The PK of enCC was also done. TT was assessed one week after treatments were discontinued.

Results: enCC raised TT initially only slightly in terms of TT_{0hr} , TT_{avg} , TT_{max} and TT_{min} . AndroGel was more effective initially. After six weeks of continuous use, the mean concentration of TT at time 0, C_{0hrTT} , was $604 + 160$ ng/dL for men taking 25 mg of enCC and $500 + 278$ ng/dL for those men on AndroGel. These values were higher than baseline values but not different from each other. All three doses of enCC were effective in increasing TT_{0hr} , TT_{avg} , TT_{maxT} , TT_{min} and TT_{range} . AndroGel was effective but variable. The pattern of TT in men on enCC in PD pt2 fitted a non-linear second order polynomial with a morning elevation, mid-day trough and rising night-time levels. enCC was associated with elevations of FSH; AndroGel decreased LH and FSH.

Conclusions: Effects of enCC on TT occurred with along with increases in serum LH without a temporal association between the peak of serum enCC and the peak of TT. The TT, LH, and FSH were elevated consistently into the normal range. We infer that enCC provokes an effect through pituitary hormones that results in a restoration of normal gonadotropin activity consistent with normalization of LH and FSH as well as TT. This restoration may persists or be sustainable for at least one week after drug treatment stops.

Disclosure:

Work supported by industry: yes, by Repros Therapeutics (industry funding only - investigator initiated and executed study). The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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WITHDRAWN

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SEX ADDICTION: MYTH OR REALITY

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2: Beth Israel Medical Center

Objective: To determine whether hypersexual behavior can appropriately be characterized as an addiction, or rather, a symptom or manifestation of a co-existing Axis I or Axis II Disorder.

Design and Methods: A literature review is being conducted to explore these opposing viewpoints. Articles published from the year 2000 to present relating to the topic of sex addiction/ hypersexuality/ sexual compulsivity/ impulsivity are reviewed.

Results: The concept of sexual addiction was introduced in the 1970's. Two schools of thought have. Proponents of sex "addiction" argue that the neurochemical changes associated with hypersexual behavior are quite similar to that of drug addiction. They argued that sex "addicts" can experience a psychological withdrawal as experienced by those addicted to drugs of abuse. Some proponents of sex addiction even advise a 12-step treatment program. Critics of sex addiction argue that increased sexual activity is a way of alleviating affective symptoms, or is reflective of the impulsivity, associated with concomitant Axis I or Axis II pathology. They postulate that treating the underlying psychiatric disorder would ameliorate hypersexual behavior.

Discussion: Despite standard, and even increasing use of the term "sex addiction" in media and popular culture, mental health professionals remain divided in regards to this subject. The proposed inclusion and subsequent rejection of hypersexual disorder in DSM-V highlights this existing debate. The notion of hypersexual behavior as an addiction warrants further exploration, especially since how it is defined may dictate treatment modality.

Disclosure:

Work supported by industry: no.

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THE COMBINATION OF ENILE REVASCULARIZATION SURGERY WITH PENILE CORRECTIVE TECHNIQUES IN PATIENTS WITH PEYRONIE'S DISEASE HAVING ERECTILE DYSFUNCTION AS AN ALTERNATIVE TO PROSTHESIS IMPLANTATION: PRELIMINARY RESULTS

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Objective: This study aimed to investigate the surgical results of the combination of complex corrective techniques with the penile revascularization in patients with Peyronie's disease those having ertcile dysfunction as an alternative to penile prosthesis implantation as a first study in the literature.

Materials and Methods: Between 2008 and 2011,the combination of penile revascularization surgery with penile corrective techniques were performed in 8 patients with Peyronie's disease having erectile dysfunction.Preoperative urologic evaluation was performed with penile color doppler ultrasonography,electromyography of corpus cavernosum(CC-EMG) and cavernosometry.The degree of penile angulation was $> 60^\circ$ in all t patients and none had hourglass deformity. All the patients were asked to answer a 15-item questionnaire 'International Index of Erectile Function'(IIEF) and five-item version of the IIEF(IIEF-5) preoperatively and during the postoperative follow-up. The efficacy of the operation was assessed as improvement or failure according to the change in the five-item version of the IIEF (IIEF-5).

Results: The mean age of the patients was 51.4 ± 4.2 (range:47-57) years.The mean follow up period was 18 (12-26) months. None of the patients had reported complications after surgery.Complete penile straightening was achieved in all the patients. However, 2 (13.3%) patients reported penile shortening without expressing any dissatisfaction about it.All of the patients were satisfied with the final surgical results.The mean IIEF-5 score was 9.8 ± 3.1 before the operation,and it was reported to be 22.03 ± 2.4 at the end of the follow up ($p < 0.05$). Preoperatively,the mean erectile function domain score was 12.6 ± 3.7 , and it was 24.09 ± 3.9 at the end of the follow-up ($p < 0.05$).

Conclusions: We reached statistically significant improvements by using the IIEF questionnaires and with this satisfactory preliminary results suggested that this combination could be an alternative to penil prosthesis implantation in highly selected patients with Peyronie's disease those having erectile dysfunction and further studies are needed to clarify this statement.

Disclosure:

Work supported by industry: no.

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PREVALENCE AND PROFILE OF MALE SEXUAL DYSFUNCTION ACCORDING TO IIEF IN TYPE 2 DIABETIC MALES"

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Objective(s): Male sexual dysfunction is widely prevalent in Type 2 Diabetic Males who suffer not only from erectile dysfunction but also low self esteem because of feeling of being unable to perform well during sexual activity. Despite this, health care providers often do not specifically ask their male diabetic patients about sexual function. This results in considerable under diagnosis because patients are often reluctant or embarrassed to initiate discussion of these issues them-

selves. The aim of this study was to understand the prevalence and score the symptoms as per International Index of Erectile Function Questionnaire (IIEF).

Material and Method(s): The study was conducted on 1000 patients of Type 2 Diabetes reporting to the consultation. They were selected from the routine weekly diabetes clinic. The patients were given the IIEF questionnaire and were assisted in filling up the form. The age range of these subjects was between 25 years and 50 years. The duration of diabetes was noted, weight recorded in kg, BMI calculated, the frequency and daily dosage of insulin noted with glycaemic control assessed by the mean of three HbA1c values over the previous 12 months.

Result(s): High percentage, of the subjects reported some form of sexual dysfunction and the prevalence did not vary with the level of control of diabetic status. Hypertension, microalbuminuria, retinopathy and a higher cardiovascular risk score were associated with ED. ED may be a predictor of subsequent cardiovascular disease. ED can have a marked effect on quality of life thus ED should be inquired of with sensitivity in appropriate privacy within the consultation. This clinical study also stressed that, OAS is more common in patients who are addicted to smoking and drinking (alcohol).

Conclusion(s): ED is a common complication of diabetes that affects patients' quality of life. While the etiology of this complication may be multifactorial in nature, it is clear that it usually has a strong organic component. Because it is important that providers encourage them to maintain good glycemic, blood pressure, and lipid control to minimize their risk of developing this complication. Patients tend to underreport ED when questioned directly by their providers.³ Therefore, the use of validated questionnaires that are either self-administered in an anonymous, neutral setting or administered by an objective third-party interviewer are preferred. For diabetic men who suffer from ED, there are numerous effective therapies available. Providers, therefore, should specifically inquire about erectile function when treating their diabetic male patients and offer treatment as needed.

Disclosure:

Work supported by industry: no.

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SEXUAL FUNCTION IN SCHIZOPHRENIA

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Objective: This study surveys patients with schizophrenia or schizoaffective disorder, to understand the relationship between sexual function and treatment with antipsychotic medication. The study compares patients on single versus multiple antipsychotics as well differences between first and second generation agents.

Design and Methods: Patients diagnosed with schizophrenia or schizoaffective disorder at Beth Israel Medical Center are eligible. Once patients are evaluated to ensure they meet enrollment criteria and are consented, they are administered the Positive and Negative Syndrome Scale (PANSS), Abnormal Involuntary Movement Scale (AIMS), and either the International Index of Erectile Function for men, or the Female Sexual Function Index for women. Inclusion criteria include age 18–65, able to participate in a structured interview, fulfill DSM-IV criteria for Schizophrenia or Schizoaffective disorder, and on stable doses of one or more antipsychotic medications for at least six weeks. Exclusion Criteria include patients taking Selective Serotonin Reuptake Inhibitors (SSRIs), and inability to provide informed consent.

Results: Presently, data suggests sexual function is impaired secondary to antipsychotic use. Further extrapolation of data is pending further enrollment.

Conclusions: Preliminary results point to better sexual function with certain second generation antipsychotics. It also appears that patients on single antipsychotic may have better sexual function than patients on multiple agents.

Disclosure:

Work supported by industry: no.

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INTEGRATING SEXOLOGY EDUCATION INTO PSYCHIATRY RESIDENCY TRAINING

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Objective: The presentation will focus on how psychosexual medicine and sexology education can be integrated into psychiatry residency training.

Design and Methods: The Psychosexual Medicine Program currently being implemented at Beth Israel Medical Center, Department of Psychiatry and Behavioral Sciences in New York, NY will be described.

Results: The positive impact on the training program and overwhelming support from faculty and residents of the program will be discussed.

Discussion: An argument will be made why it is important to teach sexual medicine in psychiatry residency training and how psychiatrists are uniquely positioned to be good sexologists. It will be recommended that sexual medicine education become an integrated part of psychiatry residency training everywhere in the USA.

Disclosure:

Work supported by industry: no.