Testosterone Replacement in Hypogonadal Men with Recent Coronary Artery Revascularization Improves Exercise Capacity

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Objectives: Current controversy regarding cardiovascular (CV) risk and testosterone replacement (TRT) exists. However, a robust scientific literature supports the fact that hypogonadism is a significant risk factor for CV disease (CVD). We sought to assess potential benefit of TRT in men with coronary artery disease (CAD) requiring revascularization in the past year. In this study we investigated the effect of TRT on exercise capacity and time to ischemic change on treadmill exercise testing.

Methods: Fifty-one subjects were enrolled in a randomized, double-blind, (Androgel) group analysis and t-tests changes (time to ST in seconds at baseline).

Results: In those observed treatment group at all-time points: month 1 (589.7 vs. 452.4), p=0.013, month 3 (607.6 vs. 472.1), p=0.035, and month 6 (614.0 vs. 470.0), p=0.087. Although there was improvement in time to ischemic change in the treatment group, it was not significant when compared to the placebo group. No serious adverse events (MI, stroke, death) occurred in either group.

Conclusion: Exercise capacity is an independent prognostic factor for CVD and mortality. In this study, exercise time on treadmill was used as a measure of exercise capacity. Those in the treatment group showed a significant improvement in exercise capacity at month 1 and 3, indicating the beneficial role of TRT in men to improve CV health. These results support the role of TRT in hypogonadal men with stable CAD.

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

Engineering of Corporal Tissue Constructs using Non-Human Primate and Human Corpus Cavernosal Smooth Muscle and Endothelial Cells for Clinical Applications

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**Objectives:** Numerous conditions exist, both congenital and acquired, that threaten male sexual health through changes in form and/or function. Efforts in penile reconstruction are often limited by poor availability of functionally intact penile tissue. We have previously demonstrated the ability to reconstruct functional corporal tissue via autologous cell-seeded collagen matrix in a rabbit model. In this study, we investigated the feasibility of engineering corporal constructs using cavernosal smooth muscle (SMCs) and endothelial cells (ECs) from humans and non-human primates (NHPs) seeded onto 3D acellular corporal collagen matrices.

**Materials and Methods:** Corpora cavernosa were isolated from NHPs and human donor penile tissue. These specimens were then subjected to an established decellularization process to create acellular corporal collagen matrices. Autologous corporal SMCs and ECs were isolated, expanded in vitro, and seeded onto matrices via a multistep static/dynamic procedure.

**Results:** Histologic and immunohistochemical analyses were performed. The corporal construct treated with the TritonX-100 protocol was effectively decellularized based on results of both DAPI (4',6-diamidino-2-phenylindole) staining and DNA assay (< 50 ng dsDNA/mg dry sample weight). Scanning electron microscopy demonstrated highly porous 3D structure and structural integrity. Evenly distributed cellular attachment and phenotype of corporal ECs and SMCs before/after dynamic culture conditioning were evaluated by immunohistochemical staining with anti-von Willebrand factor and anti-alpha smooth muscle actin.

**Conclusions:** We have demonstrated the feasibility of engineering viable and well-organized corpora cavernosa using tissue from NHPs and humans. This represents the next step toward clinical utility for humans. Such technology may have application for congenital anomalies, penile cancer, traumatic penile injury, and selected cases of erectile dysfunction and Peyronie’s 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.

003

**Novel Model of Ex-Vivo Mixed Lymphocyte Reaction to Assess the Effects of Rejection on Erectile Function in the Setting of Human Penile Transplantation**

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**Objective(s):** The use of penile transplantation may be a necessary alternative for genital reconstruction in severe cases of penile tissue loss, as seen in recent wartime injuries. It is expected that the rejection process will induce erectile dysfunction (ED). We used a novel model of ex-vivo mixed lymphocyte reaction (MLR) using human corporal tissues to assess the affects of rejection and tissue preservation on erectile function (EF).

**Material(s) and Method(s):** MLRs were prepared by mixing human corporal tissues obtained during penile prosthesis operations with autologous or allogeneic peripheral blood mononuclear cells (PBMCs) for 24 hours in serum-free media. Additional human tissues were also incubated in cold (4°C) or warm (37°C) organ preservation fluid for 24 hours. Immunofluorescent live imaging was used to assess tissue apoptosis by caspase-3/7 activation. Myograph was performed to evaluate tissue contraction in response to KCl, phenylephrine (PE), and electrical field stimulation (EFS) as well as relaxation in response to sodium nitroprusside (SNP) and EFS following PE-induced maximal contraction. All studies were approved by the local IRB.

**Results:** Imaging demonstrated increased caspase-3/7 activation in tissues incubated in warm preservation fluid and those exposed to allogeneic PBMCs. All tissues demonstrated relaxation in
response to both SNP and EFS following pre-contraction by PE. Tissues in cold preservation and autologous PBMCs demonstrated greater contraction than warm ischemia and tissues incubated with allogenic PBMCs, which is consistent with the increased apoptosis seen with live imaging.

**Conclusion(s):** The effects of rejection on EF can be investigated by myograph of human tissues that underwent MLR. This model can be used to further investigate pathogenesis of rejection, to evaluate erectogenic therapies, and to help optimize anti-rejection regimens in penile transplantation.

**Disclosure:**
Work supported by industry: no.

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**004**

**Post Finasteride Syndrome: Is dutasteride unfairly accused?**

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**Objectives:** Finasteride (FIN), a 5α−reductase inhibitor (5−ARI’s), is used to treat benign prostatic hyperplasia and alopecia. Controversial research has suggested that finasteride, can result in persistent sexual and nonsexual side effects known as post−finasteride syndrome (PFS). Because of a shared mechanism of action, dutasteride voluntarily underwent an FDA label change similar to that for FIN. The aim of this study was to evaluate adverse effects associated with dutasteride by examining an FDA Adverse Event Reporting Symptoms (FAERS) database. The aim of this report was to address PFS putatively induced by dutasteride by quantifying and summarizing these FAERS reports, create a demographic of patient reports, assess the cluster of PFS symptoms, and to correlate consistency of the PFS syndrome.

**Materials and Methods:** A FAERS database between 4/1/2011 and 10/29/2014 pertaining to all 5−ARI’s received was analyzed. Every reported case was coded according to date received, case type, whether it was reported by a health professional, outcomes, manufacturer, age of patient, country, product used, adverse events, and the suspected role of the reported drug.

**Results:** The FAERS database consisted of 3,295 cases (2,986 male and 305 either female or gender unreported). Of the 2,986 male cases, 31 were with the concomitant use of finasteride and dutasteride. There was only one reported case of dutasteride which caused “back pain.” Sexual dysfunction was reported in 16% of cases with a combination of finasteride and dutasteride. There was only one reported case of dutasteride which caused “back pain.” Sexual dysfunction was reported in 16% of cases with a combination of finasteride and dutasteride. Overall, 41% incidences of PFS symptoms were reported with finasteride alone and none with dutasteride alone.

**Conclusion:** Use of a FAERS database demonstrated that there were no persistent sexual side effects reported over a 3.5 year period associated with the use of dutasteride alone. Although the FAERS has limitations such as self-reported data, our findings suggest that dutasteride is not associated with PFS.

**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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**005**

**Impact of Diabetes on Erectile Function Recovery (EFR) after Radical Prostatectomy (RP)**

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Objectives: Diabetes (DM) is a known risk factor (RF) for erectile dysfunction, mediating erectile function (EF) through endothelial changes, arteriosclerosis, autonomic neuropathy and smooth muscle structural changes. Post-RP EFR rates are poorly defined in DM patients. The aim of this analysis was to assess the impact of DM on EFR after RP.

Materials and Methods: Using data from a prospective, quality of life (QOL) study evaluating men post-RP. Patients completed the IIEF EF domain (EFD) pre-RP and serially at 3, 6, 12, 18, 24, and 36 months after RP. Pearson correlation coefficients and chi-squared were used for univariate analyses and multiple linear regression was used for multivariable analysis to determine the effect of DM on EFR.

Results: 384 men with mean age = 58±7 years. Mean baseline and 24m EFD score = 26±5 and 21±8, respectively. 4% had DM. A greater percentage of men with DM were sexually inactive at 24m post RP compared to men without DM (47% vs. 26%, p=0.06, RR=1.8, 95%CI: 1.06-3.02). On univariate analyses, 24m EFD score was associated with age (r=-0.18, p=0.001), baseline EFD score (r=0.37, p=0.0001), nerve-sparing status (NSS) (r=-0.23, p=0.0001), and DM (r=-0.18, p=0.001). All these variables remained significant predictors on 24m EFD in multivariable analysis: age (beta=-0.10, p=0.05), baseline EFD (beta=0.33, p=0.0001), NSS (beta=-0.28, p=0.0001), and DM (beta=-0.12, p=0.01).

Conclusion: DM is a significant predictor for poorer EF recovery at 24 months after RP. The diabetic patient should be counseled about expectations for EFR after RP.

Disclosure:
Work supported by industry: no.

006

Simplified Interpretation of the Erectile Function Domain of the International Index of Erectile Function

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Objectives: The International Index of Erectile Function (IIEF) is a 15-item, validated, patient-reported questionnaire that is widely used for assessing male sexual function in clinical trials and clinical practice. The 6-item Erectile Function (EF) Domain of the IIEF is validated as a diagnostic tool for assessing the severity of erectile dysfunction and as a measure of treatment efficacy. The objective of this analysis is to simplify interpretation of IIEF EF Domain scores for better understanding by stakeholders (patients, clinicians, researchers, regulators, and policymakers).

Material and Methods: A post hoc analysis was conducted of IIEF data from a double-blind, placebo-controlled, flexible-dose trial of men with ED who were treated with sildenafil or placebo. For this analysis, the categorical responses for each question of the IIEF EF Domain (questions 1-5 with 6 response options and question 15 with 5 response options) were combined into 2 broader but distinct categories: “success” (the 2 most favorable responses) and “no success” for all other responses. Each question, with its binary response, was expressed as a function of the overall 6-item EF Domain score in a simple logistic regression model (with both the sildenafil and placebo treatment groups combined). The probability of success for each question was computed and plotted according to overall EF Domain scores (score range: 1–30).

Results: When the predicted probability of success for each question of the EF Domain was plotted according to overall EF Domain scores, each plot was an S-shaped curve. For an EF Domain score of ~22, the mean endpoint score in the sildenafil group, the probability of success for getting an erection was 81%; having an erection hard enough, 86%; being able to penetrate, 89%; being able to maintain, 67%; maintaining an erection to completion, 70%; and having confidence getting and keeping an erection, 32%. For an EF Domain score of ~16, the mean endpoint score in the placebo group, the corresponding
likelihoods of success were 22%, 4%, 20%, 4%, 22%, and 6%. Across both treatments, for an increase of 4 points in the EF Domain score (the minimal clinically important difference), the odds of success were 6.1, 29.2, 10.0, 12.8, 4.0, and 3.7 times as likely, respectively.

Conclusions: These results provide a substantive profile of success probabilities for facets of erectile function that can aid stakeholders with a simplified interpretation and clearer understanding of IIEF EF Domain scores.

Disclosure:
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A Review of Microorganisms Isolated at Salvage or Explant of IPPs: Are We Covering the Correct Bugs?

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Objective: Current AUA guidelines regarding IPP implantation dictate that the standard of care is to use antibiotics that cover Gram-positive and Gram-negative organisms. These guidelines are intended to prevent infection with skin flora (the most likely cause of infection per the literature) and urinary tract flora. A review of organisms cultured during IPP salvage or explant at our institutions indicates that fungi and anaerobes are prevalent isolates. These organisms are not covered by the recommended antibiotic regimens.

Material and Methods: This is a retrospective IRB-exempt multi-institution study of 119 patients with IPPs who presented with infections. These patients underwent either prosthesis explant or Mulcahy salvage procedure with device replacement. Patients’ operative notes and charts were extensively reviewed to compile study data. Antibiotics were recorded at implantation, immediately prior to infection-related surgery, and during infection-related surgery.

Results: Between 2002 and 2014, 128 total intraoperative cultures were obtained at the time of either salvage or explant. Antibiotic regimens for all patients at implantation were consistent with AUA guidelines. Gram-positive organisms were found in 55/128 cultures (43%) and Gram-negative in 15/128 (11.7%). No growth was found in 48/128 cultures (35.7%). Candida (11/128) and anaerobes (9/128) were found in 8.6% and 7% of total cultures respectively. Candida was present in 11.25% and anaerobes in 10% of 80 positive cultures.

Conclusions: Intraoperative cultures obtained from infected IPPs in this sample show an unexpected rate of microorganisms that are not covered by current AUA recommended antibiotic regimens. Candida and anaerobes comprised 21.2% of positive cultures in this series. Additionally, 37.5% of all cultures were negative at salvage or explant. We used these findings to devise a management protocol for salvage or explant of infected IPPs. Further correlation with data from other providers may verify if this trend persists more widely and indicates a need to broaden antifungal and antibiotic coverage at implantation, salvage, or explant.

Disclosure:
Submuscular Ectopic Inflatable Penile Prosthesis Reservoir Placement: A Cadaveric Study of Anatomic Location

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Objective: Ectopic submuscular placement of the inflatable penile prosthesis (IPP) reservoir via the inguinal canal has become popularized as an alternative to the traditional retropubic space of Retzius. Published results suggest minimal complications and high patient satisfaction. However, in our practice, we identified several patients presenting for IPP revision after submuscular ectopic placement who were found to have reservoirs within the peritoneal cavity. Given the potential for associated complications, we performed a cadaveric study to define the anatomic location of reservoirs placed in the high submuscular position via the inguinal canal.

Methods: We secured 10 fresh male cadavers (prior to the embalming process) without history of prior intra-abdominal surgery. Bilateral submuscular ectopic reservoir placement was performed using published techniques via the inguinal canal. After placement, an anatomic dissection was performed to identify the location within the abdominal wall layers. Cadaver specific data, surgical technique, and anatomic reservoir location were recorded.

Results: 20 separate IPP reservoirs were placed (10 AMS Conceal™ and 10 Coloplast Cloverleaf™). 16 reservoirs (80%) were located anterior to the transversalis fascia, including 6 (30%) located in the space just deep to the rectus muscle and 10 (50%) located deep to the external oblique fascia but anterior to the internal oblique and transversus abdominis muscles. 2 reservoirs (10%) were identified either within the peritoneal cavity (n=1; 5%) or within the immediate preperitoneal space (n=1; 5%). Additionally, 2 reservoirs (10%) were identified within the retroperitoneal space.

Conclusion: 10% of IPP reservoirs were located within potentially dangerous spaces, either within or immediately superficial to the peritoneal cavity. An additional 10% were located in a suboptimal location within the retroperitoneal space. These findings suggest an inconsistent positioning via the submuscular technique, and support the use of a cut-down at the time of reservoir placement to confirm placement and prevent the possibility of complications associated with intra-abdominal reservoirs.

Disclosure:
Work supported by industry: no.
**Material and methods:** A double-blind, placebo-controlled, randomized clinical trial of 12 month duration was conducted in postmenopausal women with Hypoactive Sexual Desire Disorder (HSDD). The diagnosis was based on the following: Self-reported dissatisfaction with the subject’s sexual life; confirmation that there has been a change in sexual function within the last 10 years and not less than 6 months prior to completion of the Medical History Questionnaire; Sexual Function Questionnaire (SFQ) (domain score of < 23 on the Desire Subscale for HSDD); personal distress needed to present based on a score ≥ 15 on the Female Sexual Distress Scale (FSDS); finally a Diagnostic Interview was conducted by a trained interviewer to confirm the diagnosis of HSDD. Postmenopausal women with a diagnosis of HSDD were randomized to one of three daily lasofoxifene doses (0.025, 0.25 or 0.5 mg) or placebo. The primary time point for analyses was at 6 months of treatment, and the outcome measures of interest included changes in: sexually satisfying events (SSEs), FSDS score, SFQ scores (arousal and desire domains).

**Results:** A total of 466 postmenopausal women were enrolled in the clinical trial. Baseline characteristics were comparable between treatment groups with a mean age ranging from 54.4 – 54.7 years and mean years postmenopausal ranging from 6.2 – 7.4 years. Mean number of satisfying sexual events/week at baseline ranged from 0.49 to 0.66, mean SFQ desire score ranged from 11.9 to 12.6, mean SFQ arousal score ranged from 11.7 to 12.1, and mean FSDS score ranged from 24.4 to 28.4. At Month 6 it was demonstrated that the 0.5 mg dose significantly differed from placebo on all outcome measures. The mean weekly change in SSEs increased by 0.27 (p=0.002), the mean SFQ desire domain score increased by 1.51 (p=0.007), the mean SFQ arousal domain score increased by 1.44 (p=0.02), while the mean FSDS decreased by -2.83 (p=0.034). No significant safety issues were identified; most common adverse events were hot flushes and unexpected benefit.

**Conclusion:** In this Phase 2 study, lasofoxifene at the 0.5 mg dose demonstrated efficacy and safety in postmenopausal women diagnosed with HSDD.

**Disclosure:**
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**Pregnancy and Sexual relationships Study Involving wOmen and meN (PASSION study)**

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**Objective:** To determine how relationship satisfaction and sexual function are impacted by the third trimester of pregnancy and describe the impact on women as compared to their male partners.

**Material and Methods:** We performed an observational study of heterosexual married/cohabitating men and pregnant women in their 3⁰ trimesters. The woman and her partner completed the Golombok-Rust Inventory of Sexual Satisfaction (GRISS) questionnaire with regard to their current status of sexual relationship exclusively. In addition we collected baseline demographic information. The female version produces a total GRISS female score as well as subscale scores for anorgasemia, vaginismus, non-communication, infrequency, avoidance, non-sexuality, and dissatisfaction. The male version produces a total GRISS male score as well as subscale scores for impotence, premature ejaculation, avoidance, non-sensuality, dissatisfaction, non-communication and infrequency. Total GRISS scores are transformed into a 1-9 score, with non-problematic relationships scoring between 1 and 4-5. The higher the transformed score the greater the sexual dysfunction. The Research Electronic Data Capture (REDCap) web application was used to manage data. The results for each of the seven subscales when possible were compared between women and men using a paired sample t-test.
Results: All couples were recruited after 35 weeks gestation. Nearly all those approached participated (30/31). Mean age was 28.5 and 30.5 years for women and men respectively. 57% of the cohort was Caucasian. 40% of couples were married. 16.6% women had a history of cesarean delivery. A significant difference was seen in mean avoidance scores between females and males (3.67 vs. 2.63; p = 0.01). There was also a significant difference in mean scores for overall sexual activity between females and males (2.43 vs. 3.10; p = 0.04). Partners reported more infrequency of intercourse during pregnancy than before pregnancy (M = 4.87). Vaginismus was more problematic during pregnancy than before (M = 4.67). A diagnostic profile for our cohort showed a non-problematic relationship.

Conclusion: Pregnant couples reported less frequency of intercourse and more female pain with intercourse. Females were more likely to avoid intercourse. Although a small study population, sexual satisfaction and function was overall non-problematic for these couples during pregnancy.

Disclosure: Work supported by industry: no.

Ultrasound Guided Treatment of Peyronie’s Disease with Plasma Rich Platelets (PRP) and Hyaluronic Acid (HA)

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Objectives: To evaluate the efficacy of a minimally invasive treatment of PD using injections of PRP+HA

Patients and Methods: 50 patients from 29 to 77 Y (mean 56.3) complaining of PD gave an informed consent to the treatment consisting in injections of PRP+HA after local anesthesia into diseased area of the albuginea visualized by US echography. Twelve ml of whole blood are collected in two vials (Cellular Matrix BCT-HA kit) containing separating gel and HA (2ml) and centrifuged during 5mn at 3000 rounds/mn to obtain 8ml of PRP mixed with HA, and immediately injected. Four to eight sessions were applied at fifteen days interval for the first four and monthly after. Prior to PRP and HA injections, plaques are punctured with a 25G needle. Changes of PDQ, IIEF-5, angulation, maximum thickness in mm were evaluated one month after the last session, as well as an auto evaluation of satisfaction in 5 items quoted from 5 to 25. Final results are stratified in Good if positive percent changes (PPC) are > to 30 % for at least two items and or final angulations’< 25° and a personal note (PN) >16; Negative if PPC are < 10 and PN <11; Partially Improved in between those values

Results: All patients completed at least 4 sessions with a mean follow up of 6 months. Average duration of PD was 21months (5 to 120), ED is present in 38%, localization of the disease is dorsal in 90%, calcified plaques in 10%. Average angulations (curvature or deformation) 47° (+/-37) were reduced by 38% ; average maximum thickness diminished from 4.4mm to 3.3, average PDQ bother from 10.5 to 5 . Final results show 26% Good, 58%, partially improved and 16% negative. Average IIEF-5 increased from 17.7 to 21.1.Superficial hematoma were observed in 10% of the injection sites. All patients of the partially improved group asked for continuation of the treatment

Discussion and Conclusions: PRP with HA demonstrate to be efficient in 84%, of this short unselected series of PD patients, without any severe complication. If confirmed in larger series, PRP with HA could range as a costless and effective minimally invasive treatment of PD. US is very helpful to localize and work diseased area and injecting precisely the material.

Disclosure: Work supported by industry: yes, by Regen Lab SA Switzerland (industry funding only - investigator initiated and executed study).
Initial Experience with Peyronie’s Plaque Excision and Grafting without Penile Degloving: An Update on the “Window” Technique

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Objective(s): Peyronie’s disease (PD) is a highly prevalent and potentially debilitating condition. In its most severe form, treatment is usually limited to surgical intervention with either penile plication or plaque excision and grafting as the preferred methods of management. These are typically performed following complete penile de-gloving however recent literature has discussed methods for plication without the need for the de-gloving portion of the surgery. We have previously reported a novel case of a plaque excision and grafting performed without de-gloving through a small incision along the penile shaft, entitled the ‘Window’ approach. We present an updated series of our results in men treated with this surgical technique.

Material and Method(s): An IRB approved prospective database was created including all patients undergoing Peyronie’s plaque excision and grafting without penile de-gloving from January 2014 to present. Patient demographics were recorded as well as pre-operative erectile function as measured by the Sexual Health Inventory for Men (SHIM). Degree, direction of curvature and location of plaque were elucidated via artificial erection. Intra-operative data was collected and post-operative patient factors were measured at 6-month follow up. Technical success was defined as improvement to < 15° of curvature on post-op evaluation.

Result(s): A total of five patients underwent plaque excision and grafting without penile de-gloving. Mean patient age was 61.8 years (SD = 10.8) and pre-operative degree of curvature was 88° (SD = 10.9). Angulation of curvature included lateral, dorsolateral, ventrolateral and ventral bends. Plaque location was proximal in 2 patients and mid-shaft in 2 patients. A fifth patient had a compound mid and proximal-shaft plaque. Mean graft size was 16.75 cm² (SD = 5.8). Technical success was achieved in 4 patients. The fifth required subsequent penile plication to reach our end-point. There was no significant difference between mean pre-operative and post-operative SHIM (16.6 vs. 15.2, p = 0.63). No complications were encountered. Cosmesis at 6 months was excellent in all cases.

Conclusion(s): Plaque excision and grafting through a penile shaft incision is a safe and effective method for the surgical management of PD. This approach obviates penile de-gloving and the potential associated post-operative morbidity.

Disclosure:
Work supported by industry: no.
Materials and Methods: We conducted a cross-sectional study between July 1 and September 30, 2014 at the Sickle Cell Unit (SCU), University of the West Indies, Jamaica. The electronic database of the SCU was searched and we recruited all male patients with SCD who had a recorded history of recurrent ischemic priapism (active or remitted) and had previous or active treatment with HU. All patients were contacted via telephone and the 12-item Priapism Impact Profile Questionnaire (PIP) was completed. Eight (8) Additional questions were asked relating to the relationship of priapism and HU treatment.

Results: Of the 16 male patients who fulfilled eligibility criteria, 12 males of mean age 28.5 ± 12.1 years consented for the study. The most frequent indication for HU use was prevention of recurrent painful crises (42%) and stroke (33%). The reported baseline frequency of priapism was varied with daily, alternate daily and once monthly episodes occurring in 25%, 17% and 17% of patients respectively. The baseline duration of the priapism episode was greater than 2 hours in 58% of those interviewed, with a third lasting over 5 hours. 17% of patients interviewed continued to have daily episodes of stuttering priapism while on HU, however 42% of patients had cessation of episodes while on HU therapy. Of the patients who continued to have priapism while on HU therapy, 4 patients had episodes lasting less than 30 min, 1 patient had episodes of average 1 hour duration and only 1 patient continued to have episodes lasting over 5 hours. 63% of patients thought that their priapism episodes had improved while on HU therapy.

Conclusion: HU appears to be beneficial in reducing the frequency of recurrent priapism. Further controlled studies are required to confirm these findings.

Disclosure: Work supported by industry: no.

014

Neuronal and Sonic Hedgehog Regulation of Collagen Abundance and Development in the Penis
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Objective: Cavernous nerve (CN) injury, which occurs during prostatectomy and in diabetes, decreases penile smooth muscle, leading to erectile dysfunction (ED). As smooth muscle decreases, collagen increases, through a largely undefined mechanism. We’ve shown in previous studies that the sonic hedgehog (SHH) pathway is critical for the response of the penis to denervation. It has recently been suggested that SHH may play a role in renal and pulmonary fibrosis and collagen production during lung embryogenesis. Our preliminary studies suggest that collagen production is responsive to SHH signaling and we hypothesize that SHH plays a role in collagen regulation in the penis.

Materials & Methods: Collagen abundance was quantified by trichrome stain with Image J analysis and hydroxyproline assay in human corpora cavernosal tissue (n=21) of prostatectomy, diabetic and control (Peyronnie’s) patients, and in rat penis (n=143) from: 1.) CN injured penis, 2.) SHH inhibited penis, 3.) CN injury/SHH treated penis by peptide amphiphile (PA), 4.) SHH inhibited pelvic ganglia (PG), 5.) SHH treated PG, and 6.) CN injury/SHH treated PG/CN by PA. The localization of collagen sub-types I-IV was examined in sham and CN injured rat penis. Collagen abundance and morphology were examined during postnatal development of the penis.

Results: Collagen increased 18% in prostatectomy and 19% in diabetic patients. In rats, SHH inhibition in the penis increased collagen 17% at 1-2 days and 21% at 4 days. SHH treatment of CN injured penis by PA prevented collagen induction by 19% at 2 days and 7% at 4 days. SHH inhibition in the PG for 2 days increased collagen 17% in the penis. SHH treatment of normal PG did not alter collagen, however SHH treatment of injured CN by PA decreased collagen 9%. Collagen growth increased throughout postnatal penile development.
Conclusions: SHH perturbation either directly in the penis or indirectly in the PG/CN has a selective impact on collagen abundance in the penis, with SHH treatment suppressing collagen induction in response to CN injury. These results suggest that SHH treatment has translational potential not only to prevent smooth muscle changes that occur with prostatectomy, but also to suppress collagen induction and remodelling, an irreversible component of ED development.

Disclosure:
Work supported by industry: no.

015

Sepiapterin Supplementation Fails to Ameliorate Diesel Exhaust Particle Exposure-Related Erectile and Coronary Artery Dysfunction in Young Lewis Rats

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Objectives: The influence of environmental exposures on erectile function has been noted for nearly 40 years. The environmental exposure can be involuntary or occupational and include air pollution. The health hazards linked to diesel exhaust particles (DEPs) are of particular interest as it is a major constituent of air pollution. The exposure to DEP is known to cause a myriad of vasculopathies through increased inflammation and oxidative stress including oxidation of the nitric oxide synthase (NOS) cofactor, tetrahydrobiopterin (BH₄) and uncoupling of the NOS complex. The effect of this combustion particle exposure on erectile response has not been explored. We hypothesized that: 1) Pulmonary instillation of DEPs would induce erectile and coronary vascular dysfunction. 2) The erectile dysfunction would manifest prior to coronary vascular dysfunction in a model of repeated exposure. 3) Increasing bioavailability of BH₄ would ameliorate DEP-induced dysfunction

Materials and Methods: Erectile function in young, vehicle control (14 weeks old; n=12) and groups of 1x, 2x, & 3x 125 µg DEP-instilled over 14 days (14 weeks old; n=3) male Lewis rats was assessed in situ by measuring the maximum intra-cavernosal pressure (ICP) and mean arterial pressure (MAP) in response to electrical field stimulation of the cavernosal nerve. Coronary artery and thoracic aorta segments were isolated and pharmacological contraction and relaxation responses were constructed using phenylephrine, acetylcholine, sodium nitroprusside and incubation with sepiapterin to improve NO availability.

Results: DEP exposed groups (1x and 3x) displayed depressed ICP levels at all voltages including a rightward shift in the EV₅₀. Erectile responses after intra-cavernosal injection of 10 µM sepiapterin, a BH₄ precursor were unaffected. In vitro coronary artery responses revealed impaired serotonin-dependent vasoconstriction and endothelium-dependent relaxation in all DEP exposed groups that was not relieved by sepiapterin treatment. The thoracic aorta did not reveal any significant response changes following DEP exposure.

Conclusions: Our conclusion based on the data was pulmonary instillation of DEP was associated with both significant coronary artery and erectile dysfunction with the same exposures. The extent of dysfunction was unrelieved by supplementation with sepiapterin to increase BH₄ bioavailability. This may suggest that the dysfunction that manifested may not be due to an uncoupling of nitric oxide synthase enzymes. Although, an oxidative burden may still contribute to dysfunction. Supported in part by a Sexual Medicine Society of North America fellowship to D.P.B., East Carolina University and NIH U19 ES 019525 to CJW.

Disclosure:
Work supported by industry: no.
Development of a High-Throughput, Cell-Based Assay for Anti-Myofibroblast Activity in Peyronie’s Disease
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Objectives: Peyronie’s disease (PD) is a fibrotic disorder characterised by the formation of plaques in the tunica albuginea (TA) of the penis, which can result in curvature, pain and erectile dysfunction. PD has been affecting a growing number of men worldwide; however, no method is available to quickly and inexpensively test a large number of potential new drugs, known as high throughput screening (HTS). The aim of this study was to develop and validate an HTS assay for the identification of compounds with anti-myofibroblast activity in cells established from tunica albuginea.

Methods: Fibroblasts cultures established from the TA of patients with and without PD were exposed to TGF-β1 in order to differentiate them into myofibroblasts. Alpha-smooth muscle actin (α-SMA) immunostaining was assessed using immunohistochemistry (IHC) and immunocytochemistry (ICC). The α-SMA mRNA levels were measured using real-time RT-PCR (RT-qPCR). In Cell Western (ICW) method was used to develop the HTS assay measuring α-SMA staining and cell numbers, in cells isolated from non-PD tissue and exposed to control conditions, TGF-β1 and 22 FDA approved drugs with potential anti-myofibroblast activity.

Results: IHC, ICC and RT-qPCR showed higher α-SMA-positive cells or α-SMA expression in fibroblasts derived from PD plaque tissue than from cells isolated from non-PD tissues. The ICW assay was able to effectively and reproducibly detect TGF-β1-induced myofibroblast transformation, obtaining an average Z’ of 0.84 with a CV of 6% in 96 well plates. Using the ICW assay, 5 of the 22 drugs were found to significantly inhibit TGF-β1-induced myofibroblast transformation. Full concentration response curves were constructed for all the five compounds, where an inverted sigmoid curve with an upper and lower plateau was observed and IC50 values could be calculated. DNA staining showed that the cell numbers were not significantly reduced by any of the five compounds.

Conclusions: The first assay amenable to HTS was developed for the detection of compounds with anti-myofibroblast activity in cells isolated from human non-PD tissue. The data presented herein suggests that this novel assay can potentially be used for identification of novel compounds or repositioning of approved drugs not only for PD but also for other fibrotic disorders. Funding: Partly funded by ESSM Research Grant to W.J.S.

Disclosure:
Work supported by industry: no.

Development of Gene Therapy for Erectile Dysfunction: Delivery to Corpus Cavernosa using Viral Vectors
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Objectives: Erectile dysfunction (ED) affects roughly 20% of all men, and existing therapeutic options fail to restore spontaneous and satisfactory erectile function in long-term fashion. Preliminary studies demonstrated improvement in erectile function with a lipid-based delivery of MaxiK channels to corporal smooth muscle cells (SMCs). This prior model, however, was neither efficient in delivering gene product
nor specific in infecting SMCs. Advancements in adeno-associated viruses (AAV) have generated serotypes that are specific in the tissue and cell type they infect. We aimed to demonstrate the feasibility and specificity of AAV vectors in delivering gene product to SMCs within the corpus cavernosa.

**Materials and Methods:** Using two different AAV serotypes (AAV6 and AAV6.3) expressing GFP, we performed intracavernosal injections of $10^9$ viral particles in a volume of 50 µL on 9 month old Sprague Dawley rats. Corpora were harvested 1 and 2 weeks following injection and were subjected to multispectral microscopy to identify SMCs and determine infection efficiency of SMCs for each vector. Groups of 3 rats were analyzed at each time point and compared to a control group injected with normal saline.

**Results:** No GFP expression was detected in the control group or at 1 week following injection with either vector. At 2 weeks, a significantly higher percentage of corporal SMCs in the AAV6 group expressed GFP compared to the AAV6.3 group (21 ± 7% vs 5.5 ± 2%).

**Conclusions:** Our data demonstrates the ability to infect a significant number of cavernosal SMCs using different AAV vectors. We achieved this level of expression of gene product quickly (within 2 weeks). Furthermore, we validated AAV6 as an excellent candidate for future work toward development of an effective gene therapy for ED. Future studies are needed to examine long term expression and clinical efficacy.

**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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**018**

**Mirabegron Elicits Smooth Muscle Relaxation of Human and Rat Corpus Cavernosum Tissues via Non Nitric Oxide-cGMP Pathways**

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**Objective:** The β3-adrenergic receptor (AR) subtype of the sympathetic nervous system has been well characterized at the structural and molecular levels. Stimulation of β3-ARs localized on smooth muscle cells may play a physiological role in mediating penile erection. Mirabegron, a selective β3-AR agonist, has been recently developed for the treatment of overactive bladder, and may offer an alternative pharmacological option for the treatment of erectile dysfunction (ED). We sought to examine the effects and mechanism of action of mirabegron in rat and human erectile tissues.

**Materials and Methods:** Human corpus cavernosum (CC) specimens were obtained from 17 patients with ED undergoing penile prosthesis implantation. Mirabegron-elicited relaxation responses ($10^{-8}$-$10^{-3}$ M) on phenylephrine (Phe)-induced contraction were performed using human and rat CC strips in the organ bath. The effects of inhibitors [NG-nitro-L-arginine methyl ester (L-NAME, 100µM), 1H-[1,2,4]-oxadiazolole-[4,3-a] quinoxalin-10one (ODQ, 30µM), methylene blue (20µM), SR59230A (β3-AR blocker, 1 µM), and fasudil (Rho-kinase-ROCK inhibitor, 0.1 µM)] on mirabegron-induced relaxation responses were evaluated. The mirabegron responses were compared with responses to isoprenaline and nebivolol. After drug exposure, immunohistochemistry was employed to localize β3-AR and Rho-kinase in CC smooth muscle cells and cGMP levels were measured by enzyme-linked immunosorbent assay.

**Results:** Mirabegron inhibited Phe-evoked CC contractions in a dose-dependent manner and SR59230A antagonized mirabegron-induced relaxations in human and rat CC. Inhibitors of L-NAME and ODQ as well as methylene blue did not affect the mirabegron-induced relaxation responses. Mirabegron responses (between 0.1 and 10µM) were enhanced by the ROCK inhibitor, fasudil. KCl-induced contractions in human and rat CC were partially inhibited by mirabegron. Although intracavernosal...
mirabegron (doses of 0.1 – 1 mg/kg) had a minor effect compared to the vehicle administerd alone on in vivo procedure, it decreased MAP. β3-ARs localized mostly to smooth muscle cells of human and rat CC. The inhibitory effects of mirabegron on contractile activity were independent of changes in tissue cGMP.

**Conclusion:** Mirabegron markedly relaxes isolated CC by activating β3-ARs independently of the NO-cGMP pathway. There is also evidence of the existence of a close functional link between β3-ARs and the RhoA/Rho-kinase pathway. These results may provide support for further clinical studies using combinations of mirabegron with ROCK and phosphodiesterase-5 inhibitors for the treatment of 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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**Vascular Endothelial Growth Factor and Antioxidants Improve Erectile Function in Diabetic Rats**

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**Objectives:** Despite pharmacological advances, diabetes mellitus is frequently associated with difficult to treat erectile dysfunction. It is well documented that vascular endothelial growth factor (VEGF) and vascular endothelial growth factor receptor-2 (VEGFR-2) are involved in tissue re-vascularization related to improvement of erectile function in diabetics. Oxidative stress is also an important etiological factor in diabetes-induced complications due to excessive production of reactive oxygen species. Our study evaluates the benefits of combining VEGF with an anti-oxidant on the improvement of endothelial function and recovery of erectile function in a diabetic animal model.

**Methods:** Twenty eight adult male Sprague Dawley rats with streptozotocin induced diabetes were analyzed. We sub-divided the rats into study groups of: diabetes with buffer; diabetes with VEGF (D+VF); diabetes with insulin and Vitamin E (DIVE); and DIVE + VEGF (DIVE+VF). Five age-matched healthy rats served as controls. Erectile function was assessed by cavernous nerve electro-stimulation and intracavernosal pressure (ICP). Penile tissues were analyzed with western blots and immunohistologic staining for VEGFR-2, the erectile function mediators nNOS and smooth muscle a-actin (SM a-actin), and endothelial cell integrity.

**Results:** A significant decrease in ICP was recorded in diabetic rats (56.0 ± 4.3cmH₂O) compared with control (97.3 ± 2.7cmH₂O). Rats in the VEGF (71.4 ± 4.6cmH₂O) or DIVE (70.84 ± 9.2cmH₂O) sub-groups showed improvement in ICP. DIVE+VF group achieved normal ICP levels (104.1±4.1 cmH₂O). The DIVE+VF group showed a statistically significant improvement in endothelial staining, as well as an increased nNOS, and SM a-actin content. VEGFR-2 was significantly decreased in Diab group and significantly increased in DIVE+VF.

**Conclusions:** In this study of diabetes-induced erectile dysfunction, VEGF enhanced the therapeutic effect of insulin and vitamin E through increasing the expression of VEGFR-2, nNOS and SM a-actin. Diabetic rats treated with VEGF, insulin, and vitamin E, regained normal or near-normal erectile function. This animal study supports the potential use of VEGF in combination with antioxidants in salvaging erectile function in the difficult to treat diabetic patient.

**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.
Regulation of Sphingosine-1-Phosphate (S1P) Signaling Pathway in Rats and Humans and Alterations in Response to Pathologically-Induced Erectile Dysfunction  
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Objectives: The bioactive lipid sphingosine-1-phosphate (S1P) regulates smooth muscle (SM) contractility and apoptosis in mammalians predominantly via three G protein-coupled receptors (S1P1, S1P2, S1P3). The major objectives of this study were to determine 1) S1P serum levels and expression of the S1P signaling pathway in the corpus cavernosum (CC) of normal rats and humans as well as disease states associated with erectile dysfunction (ED) and 2) the role of the S1P pathway in regulating in vivo erectile function.

Materials and Methods: Sprague-Dawley rats (270-300 g) were used as well as human CC obtained from men undergoing insertion of a penile prosthesis. Serum S1P levels were detected by high-performance liquid chromatography. The expressions of S1P1-3 receptors and sphingosine kinase-1 (SphK1) were determined by Real-Time RT-PCR and Western blot. \textit{In vitro} organ bath contractility and \textit{in vivo} intracavernous pressure (ICP) measurements were also performed. Heart and bladder tissues were used as internal expression comparators.

Results: Serum S1P levels were determined to be \textasciitilde250 nM in rat and \textasciitilde100 nM in healthy humans. However, in response to diabetes in Zucker Diabetic Fatty (ZDF) rats, S1P serum levels were increased 4-fold, while S1P levels in men with ED increased \textasciitilde50%. Human and rat CC expressed SphK1 and all S1P1-3 receptors. At the mRNA level, lower S1P2 and higher SphK1 were found in rat penis as compared to the heart. When normalized to bladder, S1P2 expression is significantly higher in rat CC. In humans, S1P3 and SphK1 are significantly increased by age. Exogenous S1P as well as the S1P1/S1P3 receptor agonist FTY720-P contracted, while the S1P2 antagonist JTE-013 relaxed, CCSM \textit{in vitro}. Meanwhile, force produced by S1P and FTY-720P could be almost completely blocked by the Rho-kinase (ROK) inhibitor H-1152 which was interestingly independent of nitric oxide, as L-NAME (NO inhibitor) did not abrogate JTE013 relaxant efficacy. Finally, knockdown of SphK1 increased by up to 2-fold the ICP increase in response to electrical stimulation of the cavernous nerve.

Conclusions: We provide novel data that S1P, possibly coupling with S1P2 and S1P3 receptors via the ROK pathway, mediates CCSM \textit{in vitro} and \textit{in vivo} contractility. Antagonizing S1P or its receptors induced CCSM relaxation and a pro-erectile effect. This study presents the first clear evidences that the S1P pathway is another key contractile machinery in CC and suggests this pathway as a potential therapeutic target for priapism and ED.

Disclosure:  
Work supported by industry: no.

SDF-1 Treatment Promotes Neurite Outgrowth from the Major Pelvic Ganglion by Upregulating Neurotrophins  
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Objective(s): Stromal Derived Factor 1 (SDF-1) is a potent chemoattractant with known endogenous angiogenic and neurogenic properties. Both of its receptors, CXCR4 and CXCR7 have been shown to have roles in nerve repair in the central nervous system. Its role in peripheral regeneration is unknown.
By using a major pelvic ganglion (MPG) explant model, we investigated the stem cell independent ability of SDF-1 to augment nerve regeneration.

**Material and Method(s):** MPGs were harvested from male Sprague-Dawley rats (300-350 g) and cultured in Matrigel with media or SDF-1 (500 ng/mL, n=5/group). Media and SDF-1 were changed every 24 hours. Neurite lengths were measured at 24, 48, and 72 hours after culture. MPGs were then processed for qPCR to evaluate gene expression of the SDF-1 axis (SDF-1, CXCR4, and CXCR7) and neurotrophins (brain derived neurotrophic factor (BDNF), nerve growth factor (NGF), and neurotrophin-3 (NTF3)). Additional MPGs were cultured as above for 72 hours, fixed and prepared for immunoflorescent imaging of neuronal nitric oxide synthase (nNOS), tyrosine hydroxylase (TH), and CXCR4.

**Result(s):** SDF-1 enhanced neurite outgrowth from the MPG. Significant (p<0.05) increases in neurite length with SDF-1 treatment compared to control were seen at 48 (746±45 uM vs. 575±34 uM) and 72 hours (1045±46 uM vs. 739±34 uM). Compared to controls, MPGs cultured with SDF-1 demonstrated a 3-fold increase in SDF-1 gene expression (p=0.048) but no difference in CXCR4 or CXCR7 expression. SDF-1 treatment was associated with 53% increase in BDNF (p=0.02) and a 73% increase in NGF (p=0.03), but no difference in NT3 expression. Immunofluorescence microscopy demonstrated nNOS, TH, and CXCR4 expression along regenerating neurites.

**Conclusion(s):** This study demonstrates that SDF-1 treatment facilitates neurite outgrowth from the MPG by utilizing positive feedback autocrine SDF-1 signaling and increasing neurotrophin expression. This study suggests that SDF-1 plays an important role in stem cell independent peripheral nerve regeneration and may provide a novel therapeutic target.

**Disclosure:**
Work supported by industry: no.

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**022**

**Matrix Metalloproteinases and Tissue Inhibitors of Matrix Metalloproteinases in the Pathogenesis of Peyronie's Disease**

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**Objectives:** Peyronie’s disease (PD) is a fibrotic condition of penile tunica albuginea (TA). The expanding role of medical management in PD mandates that we more fully elucidate the underlying causative pathophysiologic processes. The dense plaques identified in Peyronie’s disease result from abnormal wound healing caused by an imbalance of fibrosis and fibrinolysis. Matrix metalloproteinases (MMPs) and tissue inhibitors of matrix metalloproteinases (TIMPs) play a central role in the regulation of this dynamic process. To investigate the role of these proteins in Peyronie’s disease, we examined the concentrations of MMPs, TIMPs and inflammatory cytokines expressed in cell culture media of human PD cells compared to control TA cells.

**Methods:** Human tissue samples from PD plaques and normal TA where collected intraoperatively. The third passage of the primary cell cultures of PD and controls were sub-cultured on Bio Flex-Pro Nectin plates. Media obtained from these final cell cultures were collected and analyzed. We measured Interleukin-1 (IL-1) levels with aliquots of cell culture media using an enzyme-linked immunosorbent assay. The protein concentrations of MMP1, 2, 3, 7, 8, 9, 10, 11 and 12; TIMPS 1, 2, 3, and 4; and TGF β1, 2 and 3 were measured in the cell culture media using multiplexed immunoassay kits.

**Results:** Nine PD plaque cultures and six TA control cultures were analyzed. We found significantly higher concentrations of MMP2, MMP12 and MMP13 in PD cells compared to the controls. There were also significantly higher amounts of TIMP1, TIMP2, and TIMP3 in the PD plaque cells. No significant measureable differences were detected in TGF-B and IL-1 concentrations from the two groups.
Conclusions: MMPs are key regulators of extracellular matrix (ECM) turnover during normal and pathological processes. A fine balance between the levels of MMPs and TIMPs control the extent of local ECM degradation. Our data show higher concentrations of TIMPs and lower concentrations of MMPs in Peyronie’s disease, implying an imbalance in the healing equilibrium, such that mediators of fibrosis predominate. This information will be helpful in the development of specific immunologic based therapies for the treatment and prevention of Peyronie’s 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.

023

Harnessing the Role of Microtubules in Neural Regeneration to Improve Erectile Function Outcomes Following Cavernous Nerve Injury in a Rat Model of Radical Prostatectomy
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Objective: Growing evidence demonstrates that pharmacological stabilization of microtubules has the potential to promote neural regeneration. Recently we reported that local depletion of a newly discovered endogenous microtubule regulator called Fidgetin-like 2 (FL2) promotes the closure and regeneration of cutaneous wounds. In the studies reported here we investigated if depletion of FL2 at the site of cavernous nerve (CN) injury in a rat (a model of radical prostatectomy (RP)) might improve erectile function outcomes.

Material and Methods: Two rat models of CN injury were used; mild (a smooth clamp was applied for 2 minutes to the CN) and moderate (a serrated clamp was applied for 4 minutes to the CN). At the time of injury two formulations (nanoparticle or liposomal) for delivery of FL2-siRNA (experimental) or control-siRNA were applied. At several time points following injury (up to 4 weeks) erectile function was determined by measuring the intracorporal pressure/blood pressure ratio following electro-simulation of the CN.

Results: In both models of CN injury there was an improved erectile response in the FL2-siRNA treated animals compared to controls (indicated by a greater ICP/BP response at a particular level of electro-simulation of the CN. This improvement was significant two-three weeks following treatment.

Conclusion: This is the first ever demonstration that modulating microtubule processes can repair peripheral nerve damage, specifically CN injury. This study suggests the potential for depletion of FL2 in the recovery of erectile function in a rat model of RP and identifies novel molecular mechanisms involving the microtubule cytoskeleton that are responsible for this recovery.

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.

024

TNF-alpha Inhibits Neurite Outgrowth from the Major Pelvic Ganglion by Inducing Apoptosis of Nitrergic Neurons Ex Vivo
Matsui, H; Sopko, NA; Weyne, E; Reinhardt, AA; Kates, M; Lough, DM; Liu, X; Albersen, M; Hannan, JL; Bivalacqua, TJ

\textbf{Materials and Methods:} Two rat models of CN injury were used; mild (a smooth clamp was applied for 2 minutes to the CN) and moderate (a serrated clamp was applied for 4 minutes to the CN). At the time of injury two formulations (nanoparticle or liposomal) for delivery of FL2-siRNA (experimental) or control-siRNA were applied. At several time points following injury (up to 4 weeks) erectile function was determined by measuring the intracorporal pressure/blood pressure ratio following electro-simulation of the CN.

\textbf{Results:} In both models of CN injury there was an improved erectile response in the FL2-siRNA treated animals compared to controls (indicated by a greater ICP/BP response at a particular level of electro-simulation of the CN. This improvement was significant two-three weeks following treatment.

\textbf{Conclusion:} This is the first ever demonstration that modulating microtubule processes can repair peripheral nerve damage, specifically CN injury. This study suggests the potential for depletion of FL2 in the recovery of erectile function in a rat model of RP and identifies novel molecular mechanisms involving the microtubule cytoskeleton that are responsible for this recovery.

\textbf{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.
Objective(s): Cavernous nerve (CN) injury leads to erectile dysfunction (ED) following radical prostatectomy (RP). Previously, we demonstrated that TNF-α was increased in the major pelvic ganglion (MPG) following bilateral CN injury. Increase in TNF-α was shown to induce neuronal apoptosis following sciatic nerve injury. We hypothesized that TNF-α also induces neuronal apoptosis in the major pelvic ganglion (MPG). To test this hypothesis, we examined the effect of exogenous TNF-α (eTNF-α) on neurite outgrowth form the MPG ex vivo.

Material and Method(s): Whole MPGs were harvested from male Sprague-Dawley rats (300-350g) and cultured in Matrigel with eTNF-α in the concentrations of 0, 10, 20, 30 ng/mL (n=5/group). Media and eTNF-α were changed every 24 hours. Neurite lengths were measured at 72 hours after culture. MPGs were processed for qPCR to evaluate gene expression of neuronal nitric oxide synthase (nNOS), tyrosine hydroxylase (TH), and Caspase (CASP) -1, CASP3, and CASP9 (n=5/group). Additional MPGs were cultured in Matrigel with or without eTNF-α 20 ng/mL and fixed at 72 hours after culture to perform immunofluorescence for TH and nNOS.

Result(s): eTNF-α inhibited neurite outgrowth from the MPG in a dose-dependent fashion (neurite lengths: 586±20.5, 455±11.5, 408±28.7, 361±2.65 μm; eTNF-α 0, 10, 20, 30 ng/mL, respectively: p<0.01). eTNF-α groups demonstrated bimodal distribution in the histograms of neurite lengths, while control group demonstrated normal distribution. MPGs cultured with eTNF-α displayed increased gene expression of CASP1 (p=0.03) and decreased gene expression of nNOS (p<0.05). Gene expression of CASP3, CASP9, and TH remained unchanged (p>0.05). Immunofluorescence demonstrated that nNOS-positive neurites were shorter than TH-positive neurites in the MPGs cultured with eTNF-α 20 ng/mL, while nNOS-positive neurites were as long as TH-positive neurites in the control group.

Conclusion(s): This study demonstrated that eTNF-α impaired neurite outgrowth from the MPG in a dose-dependent fashion by upregulating gene expression of apoptosis marker. Furthermore, eTNF-α downregulated the gene expression of nNOS and inhibited neurite outgrowth of nNOS-positive neurites, indicating that eTNF-α selectively inhibited neurite outgrowth of nitricergic neurons. These results suggest that TNF-α antagonists may prevent post-RP ED by inhibiting apoptosis of nitricergic neurons.

Disclosure:
Work supported by industry: no.

New Methodology for Investigating Ejaculation Dysfunction: Measuring Intraluminal Seminal Vesicle Pressure in Rats with Telemetric Device
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Objective: Ejaculation dysfunction is the most common male sexual disorder. Despite its prevalence and adverse impact on patients, little attention has been given to investigating the ejaculation dysfunction. We introduce a new in vivo method for the evaluating ejaculation dysfunction in rats with telemetric device.

Materials and Methods: A pressure sensor (C40; Data Sciences) was surgically implanted in the seminal vesicles of 7-week-old male Sprague–Dawley rats. One week later, the rats were subcutaneously administered to tamsulosin (3 and 10 ug/kg), silodosin 1mg/kg or normal saline (control), respectively. And 30 minutes later, intraluminal seminal vesicle pressure (ISVP) was recorded in freely moving rats after apomorphine (80ug/kg). Sexual events were visually identified and recorded. Ejaculation was
confirmed by inspection of copulatory plug in the tip of penis. We compared the maximal ISVP and the area under the curve (AUC).

**Results:** The mean numbers of ejaculation during inspection time was 1.5±0.1. The maximal ISVP values in rats receiving 3ug/kg (30.0±5.2mmHg) tamsulosin and 10ug/kg (15.1±1.6 mmHg) tamsulosin, and silodosin 1mg/kg (12.9±2.2 mmHg) were significantly lower than that of control (61.4±13.4 mmHg P<0.05). The AUC of tamsulosin 3ug/kg (72.7±18.9mmHg*s) and 10ug/kg (23.5±6.1mmHg*s), and silodosin 1mg/kg (23.9±8.0mmHg*s) were also lower than that of control (162.6±34.3 mmHg*s, p<0.05).

**Conclusions:** The present report is the first to describe the use of telemetric device for measuring ISVP in rats. Telemetric ISVP is reliable and feasible for investigating ejaculation physiology in seminal vesicle.

**Disclosure:**
Work supported by industry: no.

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**026**

**The Effect of Dietary Iron Intake on Intratesticular Metal Concentrations**

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**Objective:** Genetic causes of severe iron overload and anemia are associated with decreased testosterone production and impaired spermatogenesis, suggesting a need for iron homeostasis in normal testicular function. While iron is required by all cells, few tissues express ferroportin, the only known iron export protein, and most of these tissues (e.g., duodenum, liver and macrophages) are linked to dietary iron uptake, storage and recycling. Interestingly, ferroportin is also expressed in the testis, further suggesting an important role for active iron regulation. While severe genetic iron overload is associated with iron deposition in the testes, it is unknown how dietary iron intake affects intratesticular iron levels under normal conditions. We sought to define the effect of dietary iron on intratesticular iron and other metal concentrations.

**Materials and Methods:** Male c57BL6 mice were fed an ultra-low (UL, 4 mg/kg), low-normal (LN, 35 mg/kg), high-normal (HN, 500 mg/kg) or high (H, 2000 mg/kg) iron diet for two months following weaning. Testes were harvested by orchietomy and extruded tubules from the right testis were digested in nitric acid. Metal concentrations (Fe, Ag, Co, Cd, Cu, Mg, Mn, Ni, Se, Zn) were analyzed by inductively-coupled plasma (ICP).

**Results:** Intratesticular iron concentrations were not significantly different with the LN and HN iron diets (0.037 ppm/ug vs. 0.036 ppm/ug, p=0.81), but were lower in the UL iron group compared to the LN and HN groups (0.025 ppm/ug, p=0.031 and p=0.016, respectively), and higher in the H group (0.053 ppm/ug, p=0.010 and p=0.003). No trends were seen in other metal concentrations.

**Conclusions:** These data indicate that dietary iron intake affects intratesticular iron concentrations in a murine model. While the mice were able to maintain stable tissue iron levels on both LN and HN diets, dietary intake outside this normal range had significant impact on intratesticular iron concentrations. These data suggest that dietary iron excess or insufficiency may influence proper testicular function.

**Disclosure:**
Work supported by industry: no.
Diagnostic Accuracy of a Single Serum Testosterone Measurement: The False Negative Rate

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¹: Eli Lilly and Company, USA

Objectives: To diagnose hypogonadism, evidence-based guidelines recommend, in addition to clinical signs and symptoms, a measurement of morning total testosterone (TT) level by a reliable assay followed by a repeated measurement of TT for confirmation. While at least two measurements are recommended for the diagnosis of hypogonadism, only one measurement of TT level is recommended 3 to 6 months after treatment initiation to determine if dose adjustment is needed. The aim of this post-hoc analysis was to evaluate the diagnostic accuracy of a single serum TT measurement in men receiving TT replacement therapy who had serum average concentration (C_avg) below normal range (<300 ng/dL).

Materials and Methods: Androgen-deficient men (N=155), enrolled in an open-label, multi-center, titration trial, were started on 60-mg daily morning dose of T solution 2% (Axiron®) applied to axillae (30 mg/axilla). On Days 15, 60, and 120, TT levels were measured at 2, 4, 8, 12, 16 and 20 hours post-dose and serum TT C_avg was determined. If necessary, dose was adjusted on days 45 and 90 to maintain C_avg in the normal range (300-1050 ng/dL). C_avg was determined to be below normal (<300 ng/dL) for 31 patients on day 15, 16 patients on Day 60, and 17 patients on Day 120; per protocol, these patients were titrated up at the next visit from the 60-mg dose to the 90-mg daily dose, or from the 90-mg dose to the 120-mg daily dose.

Results: In total, there were 64 instances when C_avg was determined to be below normal. However, 12 (40%) patients on Day 15, 10 (63%) patients on Day 60, and 6 (35%) patients on Day 120 with a C_avg below normal had a 2-hour serum TT determination within the normal range. The average percentage (across all days) of discordant results between C_avg and serum TT measurements, where TT was in the normal range, declined as the time from application increased, from 44% at 2 hours, to 38% at 4 hours, 22% at 8 hours to as low as 3% at 16 hours.

Conclusions: The diagnostic accuracy of a single TT measurement in men whose C_avg was below the normal range was as low as 56% at 2 hours, varying at different time points post-dose. In men receiving topical T therapy, whose C_avg is below normal, relying on a single TT determination could result in less than optimal dosing which may lead to discontinuation of therapy due to perceived lack of treatment effect.

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.
Objective: Successful testosterone (T) therapy relieves both hypogonadal symptoms and restores serum T levels to the physiological range. LPCN 1021 is a novel oral T undecanoate (TU) formulation, absorbed primarily via lymphatics bypassing the liver. LPCN 1021 was assessed in a Phase 3 SOAR trial that may avoid some undesirable attributes of topical gels/solutions and injectable formulations of T and oral methyl testosterone. In this study, we assessed the pharmacokinetics (PK) and efficacy of LPCN 1021 administered orally twice daily

Material and Methods: We report on a randomized active – controlled (Androgel® 1.62%), 2-arm, 12-month, open label, multicenter dose-titration trial that included hypogonadal T<300ng/dL on 2 separate days) men 18 – 80 years. Participants were randomized to either oral TU (n=210) or active control, Androgel® 1.62% (n=105). The individual subject dose was titrated up (e.g. if C_ave, 24h <300ng/dL) or down (e.g. if C_max was >1500 ng/dL) at weeks 4 and 8 based on 24 h PK for oral TU and per label for Androgel. Hypogonadal sexual function and mood changes were assessed by the Psychosexual Daily Questionnaire (PDQ) for the 7 days preceding visits at weeks 1, and 52/end of study (EOS) and quality of life (QoL) by SF-36 questionnaire on weeks 1, and 52/ EOS for both oral TU and Androgel arm.

Results: For oral TU (N=193), 87% had an average total T level between 300 – 1140 ng/dL with mean C_ave, 24h of 478 (± 197) ng/dL and mean C_max of 1255 ng/dL (± 607) at week 13. All PDQ scores increased significantly from baseline to EOS (p < 0.0001). Significantly more marked change from baseline were observed in “negative mood” (p < 0.05) and “maintained erections” (p < 0.1) when compared to that of Androgel. Significant improvements was observed in vitality (p < 0.001), social functioning (p < 0.05), mental health (p < 0.05), mental component summary (p < 0.001) and physical role (p < 0.05) components of the SF-36 after 52 weeks of treatment. Significantly larger improvements in change from baseline were observed in mental health (p < 0.05) and mental component summary (p < 0.01) when compared to that of Androgel.

Conclusion: These results indicate that twice daily administration of oral LPCN 1021 is an effective treatment for androgen replacement in hypogonadal men via restoring the serum T levels in physiological range and relieving hypogonadal symptoms both in sexual and QoL domains

Disclosure:
Work supported by industry: yes, by Lipocine, 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.
MSHQ-EjD-SF Bother item. Treatment differences were calculated from an analysis of covariance (ANCOVA).

**Results:** Overall, 715 men (mean age 55 years) were randomized to placebo (n=357) or T-sol 2% (n=358). Approximately 80% of the sexually-active men who reported IIEF scores had mild to severe Erectile Dysfunction (ED) (IIEF-EF score <26). Across all IIEF Domains, the observed change in score from baseline to endpoint reached statistical significance in favor of T-sol 2% versus placebo (Erectile Function: p<0.001; Orgasmic Function: p=0.003; Sexual Desire: p<0.001; Intercourse Satisfaction: p<0.001; Overall Satisfaction: p<0.001). Change in total MSHQ-EjD-SF scores from baseline to endpoint was also statistically significant between T-sol 2% and placebo (p<0.001). MSHQ-EjD-SF Bother item was not statistically significant between the treatment groups.

**Conclusions:** Testosterone therapy in hypogonadal men was associated with an improvement in all domains of sexual function, as assessed by IIEF and MSHQ-EjD-SF.

**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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**030**

Dose Titration and Safety of Oral Testosterone in Hypogonadal Men: Results from the SOAR Study

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1: Baylor College of Medicine, Houston, TX, USA; 2: Johns Hopkins University School of Medicine, Baltimore, MD, USA; 3: Harbor-UCLA Medical Center and Los Angeles Biomedical Research Institute, Torrance, CA, USA; 4: University Urology Associates, New York, NY; 5: Alvarado Hospital, San Diego, CA, USA; 6: St Joseph’s University, Philadelphia, PA & Lipocine, Inc. Salt Lake City, UT, USA; 7: Lipocine, Inc. Salt Lake City, UT; 8: Lipocine, Inc. Salt Lake City, UT, USA; 9: Brown University and the Miriam Hospital, Providence, RI, USA

**Objective:** LPCN 1021 is a novel oral T undecanoate (TU) formulation free of any potential inadvertent T transference that is absorbed primarily via lymphatics. Achievement of reliable restoration of T levels post dose adjustment with minimal or no titration is an important attribute of a patient-friendly TRT option. The purpose of this study was to assess the T levels and degree of dose titration required for LPCN 1021 and active control, Androgel® 1.62% as well as to assess associated adverse events (AEs) for LPCN 1021.

**Material and Methods:** Randomized active – controlled (Androgel® 1.62%), 2-arm, 12-month, open label, multi-centre dose-titration trial that included 18 – 80 years old hypogonadal (T<300ng/dL on 2 separate days) men. Participants were randomized to either oral TU (n=210) or active control, Androgel® 1.62% (n=105). The individual subject dose was titrated up (e.g. if C_ave, 24h <300ng/dL) or down (e.g. if C_{max} was >1500 ng/dL) at weeks 4 and 8 based on 24 h PK for oral TU and per label for Androgel. AEs were assessed and reported.

**Results:** LPCN 1021 subjects requiring no dose adjustment, 1 dose adjustment or 2 dose adjustments were 42%, 45%, and 13%, respectively. Androgel subjects requiring no dose adjustment, 1 dose adjustment or 2 dose adjustments were 2%, 35%, and 62%, respectively. 85% of LPCN 1021 and 37% of Androgel subjects required ≤1 dose adjustment. Post titration mean (SD) C_ave, 24h for LPCN 1021 150mg, 225mg, and 300mg was 441 (223) ng/dL, 486 (175) ng/dL, and 482 (183) ng/dL/d, respectively. Mean testosterone concentrations, 3 – 6 hours post dose for LPCN 1021 and Androgel subjects are 481 and 599 ng/dL at week 26, 543 and 469 ng/dL at week 39, and 530 and 459 ng/dL at week 52 respectively.
There was no drug or cardiac related serious AEs reported in LPCN 1021 subjects. Adverse drug reactions (ADRs) are reported for LPCN 1021 patients only. In addition polycythemia, prostatic symptoms, peripheral oedema were seen in less than 1% of men. None of the patients reported sleep apnea or oily skin while 2.9% of men reported drug related acne. Other ADRs included headache, weight gain, and hypertension in 1%, 2.4%, and 0.5% of subjects, respectively. **Conclusion:** 87% of LPCN 1021 and 37% of Androgel subjects requires minimal dose titration of ≤1 dose adjustment and 42% of LPCN 1021 and 2% of Androgel patients requiring no dose adjustment at all. LPCN 1021 was well tolerated with minimal AEs or androgenic adverse drug reactions.

**Disclosure:**
Work supported by industry: yes, by Lipocine, 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.

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**Effect of Testosterone Solution 2% on Testosterone Concentration, Sex Drive and Energy in Hypogonadal Men: Results of a Placebo-Controlled Study**

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¹: Department of Surgery, University of Western Ontario, Canada; 2: Eli Lilly and Company, USA; 3: University of Florence, Italy; 4: Seoul St. Mary’s Hospital, The Catholic University of Korea, Korea; 5: Hospital Infanta Leonor, Spain; 6: University Hospital Halle (Saale), Germany; 7: Quality of Life Medical & Research Center, USA; 8: Eli Lilly and Company, USA (Now retired)

**Objective(s):** We assessed the effect of testosterone solution 2% (Axiron®) on serum total testosterone (TT) concentration and on 2 common symptoms in hypogonadal men, decreased sex drive and energy level.

**Material and Method(s):** In this randomized, double-blind study, hypogonadal men ≥18 years (serum TT <300 ng/dL) were assigned testosterone or placebo for 12 weeks. The primary objective was to compare the effect of testosterone and placebo on the proportion of hypogonadal men with TT within the normal range (300-1050 ng/dL) at study completion. Secondary objectives were to assess the effect of testosterone on sexual drive and energy level using two new patient-reported outcome instruments, the Sexual Arousal, Interest, and Drive (SAID) Scale and the Hypogonadism Energy Diary (HED), respectively.

**Result(s):** TT levels were within the normal range after treatment for 217 men (73%) in the testosterone group versus 43 (15%) in placebo (p<0.001). SAID and HED findings are shown (table). There were no significant treatment group differences in reporting of adjudicated CV events (stroke, MI, unstable angina) (placebo, 2; testosterone, 0) or venous thromboembolic events (placebo, 1; testosterone, 0). Elevated PSA (>4ng/mL) was reported in 6 subjects assigned testosterone and 3 assigned placebo (p=0.51), and elevated hematocrit (>54%) was reported in 6 assigned testosterone and 1 assigned placebo (p=0.07).

**Conclusion(s):** Testosterone therapy resulted in TT concentration levels returning to the normal range in the majority of cases, and improvement in sex drive but not energy levels at the p<0.01 level. The safety findings are consistent with those of prior studies and no new safety concerns were identified.

**Table: Summary of SAID and HED findings**

<table>
<thead>
<tr>
<th></th>
<th>LS mean change (SE)¹</th>
<th>LS mean difference (95% CI)</th>
<th>Adjusted P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Placebo (N=357)</strong></td>
<td><strong>Testosterone (N=358)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SAID scale</td>
<td>6.3 (0.99)</td>
<td>11.4 (1.02)</td>
<td>5.1 (1.05, 9.07)</td>
</tr>
<tr>
<td>HED scale</td>
<td>7.5 (0.87)</td>
<td>10.5 (0.89)</td>
<td>2.9 (-0.59, 6.45)</td>
</tr>
</tbody>
</table>
Analysis of covariance was used to evaluate baseline-to-endpoint (12 week/LOCF). Not significant at pre-specified p < 0.01 level.

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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The Construct Validity of the Patient-Reported Outcome Instruments Sexual Arousal, Interest, and Drive Scale (SAID) and the Hypogonadism Energy Diary (HED)
Hayes, RP1; Ahn, TY2; Jones, TH3; Ni, X4; Knorr, J4; Iyengar, S4; Heiselman, D4
1: Eli Lilly and Company, USA (Now retired); 2: ASAN Medical Center, Korea; 3: Robert Hague Centre for Diabetes and Endocrinology, UK; 4: Eli Lilly and Company, USA

Objective: In a recent study, the content validity of two patient-reported outcome measures for sexual drive and energy (Sexual Arousal, Interest, and Drive Scale [SAID] and Hypogonadism Energy Diary [HED]) were established. Here, we explore the construct validity of the SAID and HED against similar instruments, the Psychosexual Daily Questionnaire (PDQ) and the International Index of Erectile Function Domain of Sexual Desire (IIEF- Sexual Desire Domain), among 694 hypogonadal men receiving placebo or testosterone solution 2% (T-sol) therapy in a multinational, randomized placebo-controlled trial, TSAT (NCT01816295).

Materials and Methods: Convergent validity was assessed for the SAID by correlating (Pearson’s correlation; a priori criterion for significance of >0.60) SAID total scores with the PDQ Sexual Desire item and IIEF Sexual Desire Domain scores at randomization and by correlating HED scores with the PDQ “Full of pep” (>0.60) and “Tired” (<-0.60) items’ scores at randomization. Placebo and T-sol patients were pooled for PDQ-related comparisons. Known-groups validity was assessed by comparing SAID and HED scores between men with (vs without) clinician-identified decreased sexual drive and energy, respectively, at randomization using a t-test.

Results: In men with decreased sexual drive (603/694) and/or decreased energy (620/694), strong associations were evident for all the convergent validity assessments: PDQ Sexual Desire item and IIEF-Domain of Sexual Desire and SAID total score [Coefficient [95% CI]: 0.68 [0.64, 0.73]], PDQ “Full of pep” score and HED total score (Coefficient [95% CI]: 0.76 [0.72, 0.79]), PDQ “Tired” score and HED total score (Coefficient [95% CI]: 0.66 [-0.71, -0.61]), IIEF-Domain of Sexual Desire and SAID (Coefficient [95% CI]: 0.64 [0.58, 0.69]). Mean (SD) SAID total scores were statistically significantly different between men with (vs without) decreased sexual drive at study entry (Decreased Sexual Drive: 34.5 [17.75], No Decreased Sexual Drive: 42.8 [17.88]; p<0.001). Similarly, mean (SD) HED total scores were statistically different between men with (vs without) decreased energy at study entry (Decreased Energy: 48.9 [15.57], No Decreased Energy: 60.2 [18.32]; p<0.001).

Conclusions: Findings here support the construct validity of SAID and HED that assess sexual drive and energy, respectively – substantiating the potential utility of the instruments for evaluating these frequently-reported symptoms of 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.
An Assessment Of The Impact Of Testosterone Supplementation Therapy On Hemoglobin A1C (HbA1C) Levels In Diabetic And Non-Diabetic Men.

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Objective: Hypogonadism (HG) has been shown to be associated with diabetes development and some data support the concept that testosterone (T) replacement therapy (TRT) may improve glycemic control. We aimed to assess the impact of TRT on HbA1C levels.

Material and Methods: The study group included men with (i) hypogonadism (HG) defined by two serum total T (TT) levels <300 ng/dl with symptoms (ii) a HbA1C level ≥5.8% at baseline and (iii) TRT for ≥6 months. Men had on-treatment TT and HbA1C levels measured every 6 months. Men had their HG treated using clomiphene citrate (CC), transdermal T (TDT), intramuscular T (IMT) or subcutaneous pellet (SCT). Predictors of ≥1% decrease in HbA1C were evaluated using multivariate analysis, including presence of DM, patient age, baseline HbA1C, BMI, type of TRT as potential factors.

Results: 127 patients were studied, 79 known diabetics (DM) and 48 men without a formal diagnosis of DM (NDM) but with elevated HbA1C, with mean ages of 62 years and 69 years respectively, p<0.05. Mean HbA1C levels were 7.2±3.9 (6.4-11.2)% (DM) and 6.2±0.6% (NDM), p<0.05. Mean baseline TT level was 238±83 ng/dl; mean on-treatment TT level was 502±190 ng/dl with no difference between DM and NDM groups for pre or post treatment TT levels. Mean decreases in HbA1C were 0.9±0.4% (DM) and 0.6±0.22% (NDM), p<0.05. The proportion of men with a HbA1C drop of ≥1% was 50% (DM) and 30% (NDM). Mean time to see nadir in HbA1C was 6±9 months (3-24) months. On multivariate analysis, predictors of HbA1C decrease of ≥1% were: diabetes presence (OR 4.1, 1.9-2.2, p<0.01), age ≥60 years (OR 2.2, 1.4-3.7, p<0.01), baseline HbA1C ≥7% (OR 3.1, 1.9-5.7, p<0.01), BMI >30 (OR 1.4, 1.2-4.4, p<0.05).

Conclusions: In men with HG and elevated HbA1C, TRT translated into improvement in glycemic control in 30-50% of men with greater likelihood of clinically meaningful changes in diabetics, men with poorer glycemic control, older and obese men.

Disclosure: Work supported by industry: no.

Diagnostic Accuracy of a Single Serum Testosterone Measurement

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1: Eli Lilly and Company, USA

Objectives: There are biological and technical difficulties in measuring serum total testosterone (TT) levels that may reduce the diagnostic accuracy of a single TT determination. Consequently, evidence-based guidelines suggest that although the measurement of morning TT level is the initial diagnostic test for hypogonadism (HG), repeating the TT measurement is recommended. While repeat measurements are recommended, a single TT determination is required for dose titration in HG men receiving T replacement therapy. This post-hoc study evaluated the diagnostic accuracy of a single serum TT measurement in men receiving T replacement therapy.

Material and Methods: In an open-label, multi-center, titration trial, androgen-deficient men (N=155) were started on a daily morning dose of a 60-mg T 2% solution (Axiron®) applied to axillae (30 mg/axilla). Serum testosterone average concentration (C_{avg}) was determined on Days 15, 60, and 120. If necessary,
the dose was adjusted to maintain C_{avg} in the normal range (300-1050 ng/dL). This analysis included subjects (n=85) with C_{avg} within the normal range on Days 15, 60, and 120. A generalized linear mixed model was fitted to assess the visit and hour effects with indicator of hourly concentration within the normal range as the outcome variable (assuming a Bernoulli distribution with a logit link function), including visit, hour, and visit-by-hour interaction as the fixed effects and subject as random effects in the model. Main outcome measures were the proportion of men with normal serum testosterone levels at 2, 4, 8, 12, 16, or 20 hours post-dose on Days 15, 60, and 120.

**Results:** Between 79% and 92% of subjects had testosterone serum levels within the normal range at 2, 4, 8, 12, 16, or 20 hours post-dose. No differences were found in the proportion of men whose TT levels were in the normal range in the samples obtained at the three different days, whereas there were significant hour effects on the diagnostic accuracy (p=0.01), with the accuracy peaking in the 4- to 8-hour window and tapering at around 16 hours.

**Conclusions:** The diagnostic accuracy of a single TT measurement in men whose C_{avg} was within the normal range was up to 93%, varying at different time points post-dose. Because all these men had a normal C_{avg} and required no dose adjustment, relying on a single TT determination would have resulted in an unnecessary dose adjustment in up to 20% of men.

**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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**035**

**Improvement of Endothelial Function Following Initiation of Testosterone Replacement Therapy**
Shoskes, D; Tucky, B; Dunlap, K
1: Cleveland Clinic, USA

**Objective:** Isolated recent studies have suggested an increased risk of heart attack as early as 3 months following testosterone replacement therapy (TRT) initiation. Such a rapid risk increase would likely require rapid deterioration of arterial endothelial function since atherosclerosis would be unlikely to develop so quickly de novo. Our goal was to assess arterial endothelial function in hypogonadal men prior to and at least 3 months after initiation of TRT.

**Methods:** Adult men were consented for the study if they had symptoms of hypogonadism, a total testosterone < 350 ng/dl, and planned to begin TRT. Endothelial function was non-invasively assessed using the Endo-PAT2000 machine, an FDA approved test of cardiac risk. We measured the Augmentation Index(AI) (normal < 3%), a measure of arterial stiffness and Reactive Hyperemia Index(RHI), a measure of endothelial vasodilation (normal > 1.69). Prior studies suggest that a 10% level of day to day test variability is expected. Topical gels or Testopel were used for TRT and target testosterone confirmed post therapy. Endothelial function was reassessed at the next clinic visit, between 3 and 6 months after treatment started if the patients were compliant with therapy. Changes in continuous variables were assessed with the paired t test and significance set at p<0.05

**Results:** 23 patients were consented with a mean age of 52.7 (range 34-68) and starting testosterone 196.9 ng/dl (range 35-339). There was a history of diabetes in 4, hypertension in 10 and coronary artery disease in 5 men. Mean RHI was 1.67 +/-0.37 (70% were abnormal) and mean AI was 2.57% +/-14.0 (39% were abnormal). No patient subsequently developed a clinical cardiac event. At first follow up 17 patients were compliant with therapy and retested. Mean total testosterone increased from 203 to 530 (p<0.0001). Mean RHI improved from 1.74 to 2.07 (p=0.03). Mean AI improved from 4.2% to -0.89% (p=0.01). In 4 men RHI worsened but in each case the decrease was less than the 10% error of the test (1.3-6.3%). No man had worsening of AI.
Conclusions: Men with symptomatic hypogonadism often have abnormal arterial endothelial function. Following TRT, this endothelial function either remains unchanged or improves. This improvement would be expected to reduce the risk of subsequent cardiac events.

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.

Assessment of Fasting and Varying Meal Fat Content on the Bioavailability of Oral Testosterone Undecanoate (LPCN 1021) in Hypogonadal Men

Khera, M1; Dobs, AS2; Miner, MM3; Wang, C4; Delconte, A5; Chidambaram, N6; Nachaegari, S6; Patel, M6
1: Baylor College of Medicine, Houston, TX, USA; 2: Johns Hopkins University School of Medicine, Baltimore, MD, USA; 3: Brown University and the Miriam Hospital, Providence, RI, USA; 4: Harbor-UCLA Medical Center and Los Angeles Biomedical Research Institute, Torrance, CA, USA; 5: St Joseph's University, Philadelphia, PA; & Lipocine, Inc. Salt Lake City, UT, USA; 6: Lipocine, Inc. Salt Lake City, UT, USA

Objective: To evaluate effects of fasting and varying food fat content on the pharmacokinetics of serum testosterone following administration of a single dose of 225 mg LPCN 1021 in hypogonadal men.

Methods: A single-center, open-label, randomized, single-dose, 4-way crossover study of LPCN 1021 in 13 hypogonadal (mean (SD) baseline testosterone 275(42) ng/dL) men was conducted. Men received 225 mg LPCN 1021 under fasted conditions as well as under the following 3 fed conditions: 800 to 1000 calorie meal with 15% of calories from fat, low fat meal (LFM i.e. 15g of fat), 30% calories from a standard fat meal (SFM, i.e. 30 gm of fat), and 50% calories from a high fat meal (HFM i.e. 50 gm of fat) with washout of 4 days between each period.

Results: The mean (% CV) of AUC0-t and Cmax after taking 225mg of LPCN in the fasting state were 7423 (19) ng.h/dL and 562 (26) ng/dL, respectively. The mean serum testosterone levels for men in the LFM, SFM, and HFM groups increased significantly with a mean (% CV) AUC0-t of 10429 (19) ng.h/dL, 10421 (16) ng.h/dL, and 11974 (18) ng.h/dL, respectively and a mean (% CV) Cmax of 1570(35) ng/dL, 1560(30) ng/dL, and 1680(44) ng/dL, respectively without significant difference between the three meals (p>0.05) with fat significantly different (p<0.001) when compared with the fasting state.

Conclusion: Under fasting condition, administration of LPCN 1021 resulted in low serum testosterone concentrations. Any fatty meal resulted in 60% more bioavailable serum testosterone levels compared to fasting state. Serum testosterone concentrations are not affected by the amount of fat (from 15gm to 50gm) content taken with LPCN 1021. Men ingesting a LFM with LPCN 1021 had similar serum testosterone levels as those men ingesting a SFM or HFM. Therefore, LPCN 1021 performance is consistent, predictable and oral absorption did not vary significantly with the fat content between 10 and 50 % of fat of the meal.

Disclosure:
Work supported by industry: yes, by Lipocine, 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.
Twice Weekly Dosing of Injectable Testosterone Associated with Increased Erythrocytosis

Ohlander, SJ\textsuperscript{1}; Varghese, B\textsuperscript{1}; Jones, M\textsuperscript{1}; Lindgren, MC\textsuperscript{1}; Herati, AS\textsuperscript{1}; Pastuszak, AW\textsuperscript{1}; Lipshultz, LI\textsuperscript{1}

\textsuperscript{1}: Baylor College of Medicine, USA

Objectives: The most common dose-limiting adverse effect of testosterone (T) therapy (TTh) is erythrocytosis, which may increase the risk for thromboembolic complications. We sought to determine if the incidence of erythrocytosis, as defined by a hematocrit (Hct) > 52\%, could be avoided by more frequent, lower dose T injections.

Materials and Methods: A sample of 55 men using injectable T (cypionate or enanthate) at a single dose and frequency was selected for analysis from The Baylor Men's Health Database. Age, T dose and frequency of administration, Hct and duration of TTh were extracted. Groups were divided into 27 men on 200 mg T once weekly (QW) and 28 men on 80-160 mg of T twice a week (BIW). BIW dosing was initiated in men in whom hypogonadal symptoms returned prior to administration of their next dose. Maximum Hct was determined for each patient and the cohort mean of these maxima calculated. Mann-Whitney U analysis was used to compare differences between numerical variables.

Results: Mean (range) ages were 43.2 (27-63) years and 40.6 (27-62) years for the QW and BIW cohorts, respectively (p=0.36). Maximum Hct (Interquartile Range) for the QW cohort was 49.2 \% (43.4, 54.6) with erythrocytosis occurring in 11\% of these men. In contrast, a maximum Hct of 51.4 \% (45.7, 56.9) was observed in the BIW cohort, with 29\% of men developing erythrocytosis (p=0.007) when comparing QW and BIW dosing). The time to developing erythrocytosis, defined as the number of days until maximum Hct while on testosterone, was comparable in both groups (p=0.18).

Conclusions: More frequent dosing of injectable T is associated with a higher maximum Hct and a higher incidence of erythrocytosis, although the rate at which erythrocytosis develops does not vary with the frequency of T dosing. These data suggest that dosing frequency, rather than total T dose, is an important factor in development of erythrocytosis in men on injectable TTh.

Disclosure:
Work supported by industry: no.

Validation of the Priapism Profile Impact Questionnaire

Morrison, B\textsuperscript{1}; Anele, U\textsuperscript{2}; Metzger, S\textsuperscript{3}; Madden, W\textsuperscript{1}; Burnett, AL\textsuperscript{3}

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Background and Objective: The priapism impact profile (PIP) questionnaire is the first validated instrument to assess adverse health impact in men with priapism across 3 domains: quality of life (QoL), sexual function (SF) and physical wellness (PW). Higher scores indicate greater dissatisfaction within each domain. Our objective was to perform a cross-sectional validation of the questionnaire in a sample of Jamaican men with Sickle Cell Disease (SCD).

Materials and Methods: Cross-sectional validation of the questionnaire was carried out in a sample of men attending the Sickle Cell Unit, University of West Indies, Kingston, Jamaica from May 1-August 3, 2015. Male patients with active priapism (most recent priapism episode within past year) or remitted
priapism (most recent priapism episode > 1 year) were included. All participants were required to complete the 12-item PIP questionnaire and rate each question for importance and clarity. The International Index of Erectile Function (IIEF), Sexual Health Inventory for Men (SHIM) and sexual activity log were also completed by all participants.

**Results:** Fifty-one (51) men, mean age 30.9 ± 9.8 years, completed the questionnaire. 61% of respondents had their first episode of priapism before age 18 years and 49% had active priapism. Men with active priapism (n=25) had higher QoL, SF and PW scores than those with remitted disease (n=26; p <0.005, p <0.005 and p < 0.04, respectively). Patients with active priapism had a mean SHIM score of 19.2 ± 5.9 compared to a mean score of 18.6 ± 8.3 in men with remitted priapism (p > 0.05). Total SHIM scores for men whose first episode of priapism occurred before 19 years, 19-30 years and over 30 years were 19.6 ± 6.8, 17.7± 7.3 and 21.5 ± 5.1 respectively.

**Conclusion:** The PIP questionnaire is a useful psychometric tool to evaluate the health impact in men with priapism. Its use was validated in Jamaican patients with priapism of SCD etiology.

**Disclosure:**
Work supported by industry: no.

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**A Retrospective Evaluation of the Safety and Effectiveness of a Silicone Block Implant for Elective Cosmetic Surgery of the Penis**

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**Objectives:** Elective cosmetic surgery is a common approach to correct or improve deformities or unattractive disfigurements, or to simply improve a patient’s self-confidence. Silicone blocks are simple devices that are often implanted sub-cutaneously to aid the surgeon in completing cosmetic procedures. Silicone blocks are viewed as safe and effective when used in many parts of the body, including the chest, arms, legs and buttocks; however, there is little information on their use in the penis. This study evaluates a large case series from a surgeon using a novel silicone block implant for the elective cosmetic surgery of the penis.

**Material and Method(s):** 526 patients underwent elective cosmetic surgery of the penis using a silicone block implant between January 1, 2009 and January 30, 2014. IRB approval was obtained for a retrospective analysis. Consent forms and an IRB-approved questionnaire were sent to all eligible patients. 400/526 (76%) consented to participate. A medical record review provided demographic information, an evaluation of adverse device effects (ADE) and device deficiencies, and an effectiveness measurement of self-confidence via a Likert scale administered immediately before the procedure and two months after the procedure. 307/400 (77%) of the consented subjects completed the long-term follow-up questionnaire that assessed current levels of self-confidence, satisfaction, and device deficiencies and adverse device effects not yet reported.

**Results:** The 400 consented men averaged 35.5 years old with an average BMI of 25.4, just slightly above the normal range, and were all circumcised. 12/400 patients (3%) experienced serious adverse device effects necessitating device removal. The causes included implant breakage with implant perforation and infection (4/400 patients (1%)); implant infection (4/400 patients (1%)); suture detachment (2/400 patients (0.5%)); implant breakage (1/400 (0.25%)); and hematoma (1/400 (0.25%)). The self-confidence options ranged from 1 (Low) to 4 (Very High). Post-surgery, 83.5% of respondents (334/400) reported at least a 2 category improvement in self-confidence. Long-term, 72.6% (223/307) reported at least a 2 category improvement in self-confidence (p < 0.001 for both) and 81.1% of subjects (249/307) reported high levels of satisfaction.
Conclusions: Retrospective analysis of 400 subjects electing surgical correction of the penis demonstrates the safety and effectiveness of the implantation of a novel silicone block. Device removals attributed to an adverse event are few, and subjects report improved self-confidence and high levels of long-term satisfaction.

Disclosure:
Work supported by industry: yes, by International Medical Devices, Inc. (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.

040

Surgical Management of Acquired Buried Penis: Experience from Two Institutions
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Objectives: Buried penis results in a penile shaft buried below the level of the prepubic fat. Surgical treatment options can include exhumation of the penile shaft, suspensory ligament release, suprapubic lipectomy, split-thickness skin grafting (STSG), and insertion of a penile prosthesis. However, optimal treatment and functional outcomes remain unknown. Here we present our experience with surgical management of buried penis in a series of men treated at two institutions.

Materials and Methods: A retrospective chart review was performed of 11 men who underwent reconstruction for adult acquired buried penis prior to 2014 at two institutions. Pre- and post-operative penile length, Sexual Health in Men (SHIM) questionnaire scores, the use of STSG and/or penile prosthesis placement, and postoperative complications were evaluated.

Results: Median (range) age at surgery was 55.8 (41-69) years, with men having a mean (±SD) BMI of 39.8 (±6.8) kg/m2. Seven patients underwent suprapubic lipectomy, three had suprapubic ligament release, five received a STSG, and three underwent penile prosthesis placement. One of the three patients who underwent penile prosthesis also received a split thickness skin graft. Mean (±SD) pre-op penile length was -1.67 (±2.0) cm, and the mean (±SD) increase in penile length after surgery was 7.7 (±1.7) cm. Postoperatively, two patients developed complications, including one surgical site infection following STSG and one hematoma after lipectomy. A significant improvement in SHIM scores was observed following repair with a mean (±SD) increase of 8.6 (±1.5) points (p<0.001).

Conclusion: Buried penis is an uncommon but surgically treatable condition with good erectile responses after surgery and few postoperative complications. Penile prosthesis insertion does not appear to increase the rate of complications. Long-term follow-up is required to determine the durability of the outcomes observed.

Disclosure:
Work supported by industry: no.

041

Use of Phenylephrine in the Treatment of Ischemic Priapism: 5 year Experience at a Single Institution
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Objective: To evaluate the use intracavernosal phenylephrine in the treatment of ischemic priapism and report associated changes in patient vital signs, symptoms, and complications.

Materials and Methods: A retrospective review was performed of patients identified by a clinical database to have presented to the Emergency Department from January 2010 to February 2015 with the diagnosis code of priapism associated with their hospital visit. Of the 92 patients identified with the diagnosis code of priapism, 61 patients underwent treatment with intracavernosal phenylephrine on 140 separate occasions. Phenylephrine dosing and vital signs were documented for each patient’s first experience receiving phenylephrine.

Results: Of the 140 cases of priapism treated with phenylephrine, there was no documentation of patients developing symptoms or complications related to phenylephrine. The median total dose of phenylephrine received was 1.5 mg, with a range of 0.1 mg to 12 mg. Vital signs at presentation and discharge from the Emergency Department were recorded and revealed a significant decrease in heart rate (6.8 +/- 3.5, 95%CI) and diastolic blood pressure (10.5 mmHg +/- 4.4, 95%CI), while changes in systolic blood pressure were insignificant. In 8 of the 61 patients, intracavernosal phenylephrine failed to achieve detumescence and surgical intervention was required.

Conclusions: In this single center study a wide range of phenylephrine dosing was utilized to treat ischemic priapism with minimal associated systemic side effects.

Disclosure:
Work supported by industry: no.

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042

Buccal Mucosal Grafting in Peyronie’s Disease. Still not the Best

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Objectives: The aim of the present study is to evaluate the functional outcome of plaque incision and buccal mucosal grafting in cases with severe penile curvature as a result of Peyronie’s disease (PD).

Materials and methods: We performed plaque incision and single buccal mucosal grafting on 15 patients with PD. All patients had preoperative good erections but failed to perform sexual intercourse due to the penile deformity. Age ranged from 45 to 68 years (mean 56.7 years), the angle of penile curvature during full erection ranged from 45 to 85 degrees (mean 65 >degrees). Mean preoperative penile length was 11.3 cm. Degree of satisfaction was reported 6 months after surgery.

Results: All patients underwent successful surgeries with minor complications including slight penile edema and ecchymosis, and mild oral tingling sensation. None of the fifteen patients reported excellent satisfaction after surgery revealing that the functional outcome of the surgery did not meet their expectations. Four patients encountered significant penile shortening >1 cm, and five patients encountered residual penile curvature >20 degrees. De novo erectile dysfunction was encountered in all patients. The mean postoperative IIEF-5 score after 6 months was 12.3, and the percentage of yes responses to GAQ2 (Did the treatment improve your ability to engage in sexual activity?) was only 13.3% where only two patients were just satisfied from the surgery.

Conclusion: Plaque incision and buccal mucosal grafting in patients with severe penile curvature due to PD did not prove to be a successful treatment alternative.

Disclosure:
Work supported by industry: no.

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Objectives: The Sexual Medicine Society of North America’s position statement on penile lengthening and girth enhancement states that there is “no peer-reviewed, objective or independently-monitored studies, or other data, which prove the safety or efficacy of penile lengthening and girth enhancement surgery.” Despite this position, men focused on maximizing penile size may ultimately resort to medically unsupervised treatments to “enhance” the appearance of their penis. This report uses a photo-documentary to highlight the complications and management following self-administered Vaseline injection into the penis to enhance girth and serves as a caution for endorsing similar practices.

Clinical Presentation: A 49 year-old Romanian male presented to the ER complaining of penile pain, swelling and skin breakdown. He reported a history of self-administered Vaseline injection into the penile skin to enhance girth approximately 4 years earlier. On examination the majority of the penile shaft skin was compromised demonstrating diffuse induration and thickening with patches of ulceration and skin necrosis. Penile ultrasound demonstrated the foreign material to be superficial to the corporal bodies and urethra. The patient was scheduled for urgent surgical debridement and removal of the foreign material with possible penile skin grafting (plastic surgeon on stand-by).

Surgical Findings: Under general anesthesia with penile block a circumcising incision was made below the coronal ridge. There was significant fixation of the Vaseline to the penile shaft skin and dartos muscle requiring extensive (approximately 80%) debridement and removal. The glans and immediate sub-coronal skin remained viable. A Foley catheter helped define the location of the urethra. Careful layer-by-layer scalpel-guided shaving of the caseating material off the corporal bodies and urethra was performed. Bucks fascia acted as a barrier to deeper penetration. Following complete removal of the foreign material, the dorsal neuro-vascular complex within Buck’s fascia appeared predominantly intact and options for skin coverage were considered. The capacity and compliance of the scrotal skin allowed for transposition and complete dorsal and ventral coverage of the penile shaft - negating the need for skin grafting or a staged procedure. The scrotal skin was tailored and contoured to recreate a natural penile and scrotal appearance. A Penrose drain was placed to facilitate fluid drainage of post-operatively. The surgery was performed as same-day surgery. The patient was discharged home after a 4-hour recovery.

Results: On post-operative day 7 the Foley catheter and Penrose drains were removed. The transposed scrotal skin remained viable. Over a 6-month period of follow-up, penile sensation was intact and the patient reported satisfactory erectile (SHIM 21), orgasmic and ejaculatory function. Cosmetically, the penis demonstrated good functional length with a capacious scrotum. The dorsal penile shaft suture line had largely resolved.

Conclusions: As highlighted in this report and consistent with the position of the SMSNA, penile girth and lengthening procedures should be approached with caution given their limited efficacy and real potential for both early and late complications. While challenging, single-stage surgery to remove foreign materials can be successful in preserving the functional and cosmetic appearance of the 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.

The Effect of Treatment for Priapism on Erectile Dysfunction

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Objective: Treatment for priapism can lead to erectile dysfunction. However, the extent of erectile dysfunction following aspiration and irrigation has not been evaluated. Our objective was to elucidate the effect of aspiration and irrigation for priapism on erectile dysfunction.

Material and Methods: After IRB approval, we retrospectively reviewed the records of all men presenting with low flow/ischemic priapism who required aspiration and irrigation from 2009 – 2015 at our institution. Sexual Health Inventory for Men surveys were completed.

Results: A total of 16 men underwent cavernous aspiration and irrigation with phenylephrine for treatment of priapism. The median age of the cohort was 24 years (IQR: 45-24). The most common causes of priapism among the cohort were sickle cell disease (n=6), intracavernosal injection therapy (n=4), or medication induced (n=3). Fifty percent (8 men) of the cohort underwent only 1 aspiration and irrigation treatment for priapism. Twelve men underwent 1-3 treatments and the remaining 4 men (25%) underwent > 3 treatments. A total of 5 men had both pretreatment and post-treatment SHIM scores. The median post treatment SHIM score for the cohort was 21 (IQR: 24-15.5). Surprisingly, men who had 3 or more treatments also had a similar SHIM score of 21 (IQR: 23-15.25).

Conclusions: The number of aspiration and irrigation treatments for recurrent priapism does not appear to affect erectile function. The small sample size limits the generalizability of the conclusions.

Disclosure: Work supported by industry: no.

045

Surgical Interventions for Priapism: The role of Penile Prostheses

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Objective: Men with ischemic priapism receive a variety of treatments including irrigation, shunts and penile prostheses. Receipt of care is institution specific.

Material and Methods: This is an IRB-approved retrospective review of a large publically available database of men with ischemic priapism (ICD-9 code 607.3) age 18-80 listed in the Nationwide Inpatient Sample from 2002-2011. The search was limited to men presenting to the emergency room and then stratified by treatment or no treatment. Treatments included insertion or replacement of semi-rigid prosthesis (64.95), insertion or replacement of inflatable prosthesis (64.97), and other operations on penis inclusive of irrigation of corpus cavernosum, corpora cavernosa-corpus spongiosum shunt, corpora-saphenous shunt (64.98). Comorbid diseases such as heart disease and sickle cell disease (SCD) were included. Time to intervention and length of stay were reviewed. Factors associated with insertion of a penile prosthesis were modeled.

Results: There were 21,284 cases of ischemic priapism between 2002-2011. 61% of men received no treatment, while 38% had irrigation or a shunt surgery, just 0.3% had an inflatable prosthesis placed and only 0.1% had a semi-rigid prosthesis placed. 28% of men had SCD and these men were less likely to have any surgical intervention (OR 0.37, p<0.01). Middle aged men, ages 41-50 and 51-65, were more likely to undergo intervention of some type (OR1.19 and 1.11, p<0.01) compared to the reference group ages 31-40. There were no racial differences in receipt of care.

Conclusions: Most men who present with ischemic priapism receive no treatment and 0.5% of all men received a penile prosthesis during their initial admission for priapism. There were no disparities in access to surgical intervention in this population.
Percutaneous Revision of a Testicular Prosthesis

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Objective: Traditional revision of a testicular implant requires surgical intervention, and while manufacturers recommend against adjustment of fill-volume post-operatively, the package insert indicates the injection port can be accessed up to 5 times with a 21-gauge needle. Additionally, percutaneous inflation has been successfully used in other devices to augment filled volume. Our patient wanted to avoid surgery and wished to pursue a nontraditional procedure. We herein describe a novel technique of an office-based percutaneous revision of a testicular prosthesis and its associated outcomes.

Material and Method: After receiving a testicular prosthesis filled to match the texture of his atrophic contralateral testicle, our patient was dissatisfied with the firmness of the implant. In an office setting, the prosthetic was infused with additional fluid via a percutaneous approach (figure 1). Evaluated outcomes included patient satisfaction, prosthesis size, recovery time, and cost savings.

Results: The patient was very satisfied with the cosmetic result, immediate recovery time, and low cost. More than one year since the procedure, there is no evidence of infection, leak, or complication. The initial surgery resulted in total hospital charges of $22,521.95 while the percutaneous, in-office procedure was performed within the global period resulting in no charges to the patient or his insurer. Office supplies needed to perform the procedure totaled $18.77.

Conclusion: Percutaneous adjustment of testicular prosthesis fill-volume can be safe, inexpensive, and result in good patient satisfaction.

Figure 1: Locate the inflation port (IP) and the suture tab (ST). Next, line up the needle to ensure that it is inserted in the center of the inflation port. This method is further facilitated if during the initial surgical implantation the IP is kept inferior and the prosthesis is secured with a purse-string at the superior aspect of the Dartos pouch (DP).

Disclosure: Work supported by industry: no.
Objective: Combined dorsal and ventral onlay grafts with a glans splitting technique for strictures of the fossa navicularis is a novel technique that creates a functional urethral channel while maintaining a cosmetically appealing glans penis. There is concern however that aggressive mobilization of the glans wings off the tips of the corpora might affect glans sensation and sexual function. Given this, we sought to describe sexual physiologic outcomes after utilizing this technique.

Material and Method: Three patients with recalcitrant strictures of the fossa navicularis and meatus underwent the above procedure. In brief, the procedure entails splitting the glans, excising the dysplastic urethral plate, preforming a dorsal onlay with buccal graft, a ventral onlay with a transverse island or circumferential pedicled skin flap, and lastly, reapproximation of the glans. As part of their routine pre and postop care, the patients were interviewed to describe their current glans and shaft sensation, ejaculatory status, penile length, and quality of glans engorgement.

Results: Postoperatively, all three patients reported normal glans and shaft sensation and denied having symptoms of cold glans or paresthesia. No changes in glans engorgement or ejaculatory function were found, and there was no loss of penile length.

Conclusion: Using dorsal and ventral onlay grafts with a glans splitting technique for strictures of the fossa navicularis utilizes a combination of several different reconstructive techniques that collectively have not been previously described. Our three patients had excellent sexual physiologic outcomes with preservation of glans sensation and engorgement, ejaculatory function, and penile length. Aggressive mobilization of the glans wings does not appear to affect glans sensation or sexual function and allows for an excellent cosmetic reconstruction.

Disclosure:
Work supported by industry: no.

048

Fertility Preservation in the Male to Female Transgender Patient: Role of Testis Sperm Extraction (TESE) and Testis Histology in Patients undergoing Gender Reassignment Surgery
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Objective: Patients undergoing gender reassignment surgery (GRS) from male to female may consider initiating future fertility. WPATH guidelines recommend discussion of fertility early in protocol prior to transition. Little is known regarding spermatogenesis potential in male transsexuals treated with estrogen supplementation therapy (EST). Since sperm production is highly androgen dependent, use of EST preoperatively may affect spermatogenesis and maturation. Furthermore, there is scant literature regarding the testicular changes associated with EST, and there is no published literature assessing the role of sperm retrieval at the time of GRS. The objective of this study is to review TESE and histology results in GRS patients and propose an algorithm for male fertility preservation.

Materials and Methods: Five male to female transsexual patients underwent either complete GRS or bilateral orchiectomy. One patient consented to testicular sperm extraction (TESE) after the patient was unable to produce an ejaculate. Testis histology was reviewed on all five patients. Patient age ranged from 24-54 years old. Two patients were not on EST due to history of stroke and personal preference respectively, and three patients were on EST up to 2 weeks prior to GRS/ or thru surgery.

Results: Patient 1 (no EST) had sertoli cell only (SCO) histology upon review of the orchiectomy specimens. Patient 2 (no EST), had normal spermatogenesis bilaterally. Two additional patients underwent GRS while undergoing EST. Patient 3 (EST) was found to have SCO histology, with early maturational arrest bilaterally. Patient 4 (EST) underwent a testicular sperm retrieval during GRS. Sperm was successfully cryopreserved, with normal spermatogenesis on histology. Pt 5 (EST) had mostly hypospermatogenesis, but full sperm present in biopsy. Histology was independently reviewed by the
Conclusions: The effect of estrogen on spermatogenesis is incompletely studied and poorly understood. The surprisingly wide range of histology findings prompts additional questions about the interaction between estrogen and testosterone in spermatogenesis. This is the first documented case report of successful testicular sperm retrieval at the time of GRS, and this provides evidence that TESE is a viable option if ejaculation is not possible or pre-operative semen analysis reveals azoospermia.

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.

Epidemiology of Penile Fractures in the Emergency Setting
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Objective. The epidemiology of penile fracture in the acute setting is not well described. This study aims to characterize the epidemiology, evaluation, management, and use of financial resources of patients with penile fracture. Given the acute nature of the condition, the study was based on data collected from emergency department (ED) encounters nationwide.

Methods. The National Emergency Department Sample (NEDS) for 2012 was used to identify and analyze patient encounters for penile fracture, identified by ICD-9 code. Confidence bounds were generated for each statistic using bootstrapped samples of the male portion of the database, and a Wald test was used to assess for significance. Mutual information was used as a clustering metric.

Results. A weighted population of 1,749 patient encounters for penile fracture were identified in 2012 in the National Emergency Department Sample. Urethral injury was diagnosed in 9.23% of patients with penile fracture. Mean age of patients with concurrent urethral injury was found to be significantly greater than patients without urethral injury (4.02 years, p < 0.0001). In patients with penile fracture, 59.8% were treated and discharged from the ED, and 30.5% were admitted as an inpatient. Notably, 59.4% of patients with urethral injury were admitted, whereas only 27.6% of patients without urethral injury were admitted. Cost of stay in the ED averaged $5,165, and inpatient hospital charges for admitted patients averaged $24,414. Urethral evaluation (cystoscopy or retrograde urethrogram) was performed on 27.6% of all comers and 43.8% of patients with urethral injury. Tobacco use was found to be significantly associated with urethral injury in patients with penile fracture.

Conclusions. Based on our results, penile fractures occur at greater incidence than previously suggested in the literature, and although uncommon, the impact on healthcare resources is not negligible. Concomitant urethral injury suggests a more serious penile fracture, requires urethral evaluation and more often results in inpatient admission. We propose greater index of suspicion for urethral injury in older patients and tobacco users, to better inform treatment and decrease patient morbidity.

Disclosure:
Work supported by industry: no.

Improved Recovery of Erectile Function in Younger Men after Radical Prostatectomy: Does it Justify Immediate Intervention in Low-Risk Patients?
Objectives: Younger patients with low-risk prostate cancer are often counseled to undergo immediate treatment on the grounds that recovery of erectile function (EF) declines with age. We investigated whether superior post-operative recovery of EF in younger men justifies immediate intervention for low-risk prostate cancer.

Materials and Methods: Baseline and post-operative IIEF-6 questionnaires for 1806 patients who underwent radical prostatectomy (RP) at our institution between 2008 and 2013 were reviewed. Patients with clinical features of high-risk disease (PSA ≥ 10, biopsy Gleason grades ≥ 4+3, > cT2b) were excluded from analysis (n=603). Scores were plotted over time to illustrate recovery of EF for a 55-year old patient with a baseline IIEF-6 score of 26 under two strategies: immediate RP and delayed RP following a period of surveillance. We then calculated average EF for a 10 and 15 year period after diagnosis.

Results: Functional recovery declined slightly with age. However, 10-year average EF following immediate RP for this patient was lower compared to intervention five years after diagnosis (21.2, difference of 2.0; 95% CI: 0.4 - 3.9). 15-year average IIEF-6 scores also favored delayed intervention (difference between mean scores - 1.6, 95% CI 0.2 - 3.8). Results were robust for different delays to definitive treatment. These findings underestimate the benefits of active surveillance because we assume that all men are treated within 5 to 10 years.

Conclusions: Small differences in recovery in younger men are offset by a longer period of time living with decreased post-operative function. Better functional recovery in younger men cannot be used to justify immediate intervention in young patients with low-risk prostate cancer.

Disclosure: Work supported by industry: no.

Impact of Anal Sex Role on the HIV Protective Effect of Circumcision in MSM

Objective: Voluntary medical male circumcision reduces the risk of HIV heterosexual transmission in men, but the impact of sexual position in male-to-male sexual transmission is uncertain. This study examined HIV prevalence in the men who have sex with men (MSM) population stratified by whether the subject had predominantly insertive, receptive, or versatile anal sexual intercourse.

Materials and Methods: 1155 MSM volunteers were recruited in Beijing, China. Among the participants at enrollment, there were 242 known seropositives and 913 with unknown HIV status. Serostatus of all participants was confirmed. Circumcision status was evaluated by genital examination and self-report; anal sexual role was assessed by questionnaire interview.

Results: Among MSM who predominantly practiced insertive anal sex, circumcised men had 62% lower odds of HIV infection than those who were uncircumcised (aOR, 0.38, 95%CI, 0.09-1.64). Among those whose anal sex position was predominantly receptive or versatile, circumcised men have 46% lower odds of HIV infection than did men who were not circumcised (aOR, 0.54, 95%CI, 0.25-1.14). Compared to uncircumcised men reporting versatile or predominantly receptive anal sex positioning, those who were circumcised and reported practicing insertive sex had an 85% lower risk (aOR, 0.15; 95%CI, 0.04-0.65).

Conclusion: Sexual position, whether practicing receptive or insertive anal intercourse, appears to have an important impact on HIV positivity and the protective effect of circumcision in our study population.
052

Testicular Torsion: Epidemiological Risk Factors for Orchiectomy in Pediatric and Adult Patients
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Objectives: Testicular torsion is known to be a significant cause of morbidity in pediatric patients but the burden of torsion in the adult population is poorly understood. We determined the incidence of testicular torsion and quantified risk factors for orchiectomy.

Materials and Methods: A cohort analysis of 785 males undergoing a surgical intervention for torsion was performed using the 2012 Healthcare Cost and Utilization Project Nationwide Emergency Departments Sample. Patient- and hospital-level factors were examined for influence on risk of orchiectomy vs. testicular salvage.

Results: The estimated yearly incidence of testicular torsion was 2.8 per 100,000 males one year of age or older. The incidence of testicular torsion exhibited a right-skewed distribution with respect to age, with a mean age of 20.4 +/- 0.2 years (median: 17, IQR 14 - 22 years). Among patients undergoing surgical intervention for torsion, orchiectomy was performed in 33.4%. The adjusted odds ratio for orchiectomy was highest in patients 1 - 11 years of age (OR 2.8, 95% CI 1.1 - 7.0) and patients 50 years of age or older (OR 8.0, 95% CI 2.7 - 23.3), corresponding to orchiectomy rates of 50.5% and 69.9% respectively. Additional associations with orchiectomy included Medicare insurance (OR 3.5, 95% CI 1.1 - 11) and lowest median household income quartile for the patient ZIP code (OR 1.9, 95% CI 1.1 - 3.3).

Conclusions: Testicular torsion is less common in the mature adult population, but the rate of orchiectomy is high. The youngest and most impoverished patients are also at increased risk for testicular loss.

Disclosure: Work supported by industry: no.

053

Evaluation of Doppler Parameters in Patients without Organic Erectile Dysfunction
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Objectives: Erectile Dysfunction (ED) can be non-invasively diagnosed by Color Duplex Doppler Ultrasound (CDDU) coupled with intravenous injection (ICI) of a penile vasoactive agent. The primary aim of the study was to characterize CDDU parameters for patients without organic erectile dysfunction.

Materials and Methods: A retrospective review was conducted to identify patients without organic ED who underwent office testing with intracavernous pharmacologic erection augmented by visual sexual stimulation and CDDU from January 2009 to January 2010. Patients were further characterized by age, BMI, sexual activity, degree of penile curvature, cardiovascular risk factors (smoking hypertension, hyperlipidemia), co-morbid diagnosis of Dupuytren’s contracture or hypogonadism, tunica plaque characteristics, Sexual Health Inventory for Men score, and prior prostate surgical history. CDDU characteristics including pre and post-visual stimulation ICI peak systolic velocity (PSV) and resistive index (RI) were also identified.
**Results:** 120 patients, with a mean age of 56, were found to have normal Doppler parameters (PSV>35, RI>.90) Average (Right and Left cavernosal artery) pre-visual stimulation PSV was 45.96, while average post-visual stimulation PSV was 57.21. Average (Right and Left) RI was 0.97. For patients under 50 years of age, average pre-visual stimulation PSV was 49.74 and post-visual stimulation PSV was 56.41, with average RI of .95; for patients over 50 years of age, average pre-visual stimulation PSV was 44.64 and post-visual stimulation PSV was 57.48 with an average RI of .97. Mean Doppler parameters were identified for ages 40-49, 50-59, 60-69, and above 70 with the following distribution (pre-visual stimulation PSV/post-visual stimulation PSV/RI): 49.24/53.15/.97, 46.01/56.77/.97, 45.45/59.99/.97, and 31.06/50.38/.98, respectively.

**Discussion:** No patients were diagnosed with arterial insufficiency or cavernous venous occlusive disease. There appears to be an age-related decline in pre-visual stimulation PSV. Characterization of Doppler parameters in patients without organic ED can be used to construct age-related cutoffs to define normalcy.

**Disclosure:**
Work supported by industry: no.

### 054

**Post Finasteride Syndrome: Guess Who-Demographics from FDA Database**

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**Objectives:** Post-finasteride syndrome (PFS) has recently been recognized as a cluster of sexual, physical, and psycho-neurologic symptoms associated with 5-alpha reductase inhibitor (5ARI) exposure with variable persistent symptoms despite cessation of drug use. Whether this is a true medical disorder remains controversial. Our aim was to help quantify PFS reports to help understand the demographics of the PFS syndrome.

**Methods:** We collected all 3,295 Food and Drug Administration Adverse Event Reporting System (FAERS) cases that were reported from April 2011 to October 2014 on all 5ARI’s. We then looked at single-dose 5ARI monotherapies and analysed these cases for overall incidence, age distribution, geographic representation, and health professional reports per dose frequency.

**Results:** A total of 3,295 FAERS cases were reported to the FDA over a 43 month period. Of these cases, 2,048 monotherapy cases using 5ARI’s were identified with 1581 cases of finasteride 1mg, 240 cases of finasteride 5mg, and 227 cases of finasteride of unreported doses. Over time, the FAERS database case volume at each time period increased. The median age of cases reported for finasteride 1mg use was 35y while the median age for finasteride 5mg was 61y (p<0.01). The USA reported the most cases for all finasteride doses. They reported 86% of 1mg finasteride use while Great Britain, the country with the second most cases, reported 4%. Over 19 countries reported use of <1% of finasteride 1mg compared to 11 countries of finasteride 5 mg. Regardless of the dose, cases were most often not reported by health care professionals but by patients. When health care professionals did make reports, finasteride 5mg (40%) was reported more often than finasteride 1mg (16.5%)(p<0.01).

**Conclusion:** Finasteride 1mg, the lower dose, appears to be affiliated with PFS-like symptoms in a younger population with a median age of 35 compared to the 5mg dose which had a median age of 61 by the FAERS data. The majority of reports of PFS-like symptoms from finasteride use were made from patients and not healthcare professionals. The United States reported the most finasteride cases and represents a significant portion of the FAERS data, especially finasteride 1mg. PFS findings require further exploration to discern its true existence, its putative cause(s), and 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.

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National Trends in the Diagnosis and Management of Psychogenic Erectile Dysfunction
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Objectives: To evaluate the demographic differences between men with psychogenic erectile dysfunction (ED) vs organic ED in a national database and the trends in the placement of penile prostheses (PP) in these men.

Materials and Methods: An analysis of the 5% Medicare Public Use Files from 2002 to 2010 was performed. Regression analysis was performed to identify factors associated with psychogenic ED and PP placement.

Results: From 2002 to 2010, the prevalence of ED in men with Medicare increased from 7.4% to 15.1%. The majority of the increase in ED was men with organic ED, which increased over 300%, from 46,740 in 2002 to 145,860 in 2010. The number of men diagnosed with psychogenic ED each year was relatively stable during the study period, ranging from 21,800 to 38,000. Due to the increase in all ED diagnoses, the percentage of ED due to psychogenic causes fell from 19.8% in 2002 to 8.8% in 2010. Men with psychogenic ED were more likely to be <65 years, more likely to be black, have a lower Charleston Comorbidty Index, more likely to live outside the Northeast, and less likely to have a PP placed. (Table). PPs were placed in 5% of psychogenic ED patients during the study period. The annual number placed decreased from 9.5% in 2002 to 1.3% in 2010. In multivariable analysis, years before 2007 and Midwest location predicted PP placement for psychogenic ED.

Conclusions: Although the prevalence of ED increased significantly from 2002 to 2010, the prevalence of psychogenic ED remained relatively stable. Additionally, there was progressive decline in number of men with psychogenic ED treated with PP. This may reflect better understanding of the complexity of sexual dysfunction and the increased use of pharmacologic management in men with psychogenic ED.

Table. Demographic Differences between Men with Psychogenic and Organic ED

<table>
<thead>
<tr>
<th>ED Type</th>
<th>Total</th>
<th>Age &lt;65 yrs</th>
<th>Black</th>
<th>South/Midwest</th>
<th>CCI&lt;2</th>
<th>PP Placed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychogenic</td>
<td>284,520</td>
<td>31.1%</td>
<td>18.8%</td>
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Disclosure:
Work supported by industry: no.

056

National Sex Survey in South Korea
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**Objective:** Limited data are available concerning sexual behavior of Korean men. This study aimed to perform the national sex survey and to collect the basic data for establishment of the prevention strategies of sexually transmitted infections (STIs) and HIV/AIDS.

**Material and method:** This is a national survey performed on a sample of 2,500 individuals (1,273 men and 1,227 women) aged 18-69 years old. The online surveys were carried out on a national scale in South Korea. Subjects were randomly selected from resident registration. A structured questionnaire was developed which elicited information concerning: demographic information, information on their sexual behavior, sexual identity, prostitution, experience of STIs, and experience of sex education.

**Results:** The majority of the subjects were either married or living with a partner. Mean number of sexual intercourse is 3.0±3.3 times a month. Mean sexual satisfaction score using visual analog scale is 63.2±24.6. Eighty-four percent had a fixed sex partner; 13.1% (22.6% of men; 2.5% of women) had experience through a speed dating or prostitution. 0.9% of men and 1.1% of women were sexually attracted to the same gender only, 1.5% of men and 2.0% of women were sexually attracted to both gender. 1.8% of participants had the experience of the STIs. Only 10.4% of the respondents had received sex education in the past year.

**Conclusion:** We performed the National Sex Survey according to the nationwide distribution of population. It would be useful for establishment of the prevention strategies of STIs and HIV/AIDS. To control STIs and HIV/AIDS, powerful policies containing sex education and medical services will be needed.

**Disclosure:**
Work supported by industry: no.

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**Changes in Erectile Dysfunction over Time by age: A Community-Based Population Study**

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**Objective:** The prevalence of erectile dysfunction (ED), and its association with age and other comorbidities, is well documented. However, few studies have assessed the rate of decline in erectile function based on disease comorbidity. Herein, we sought to evaluate changes in erectile function over time and identify any differences in the rate of change based on age and other medical comorbidities.

**Methods:** Brief Male Sexual Inventory (BMSI) surveys were administered to 1,306 randomly selected men age ≥ 50 years from Olmsted County in 2002, 2004, 2006, and 2009 as part of a large prospective cohort study. Other medical comorbidities including hypertension (HTN), diabetes (DM), cardiac disease (CAD), benign prostatic hyperplasia (BPH), and smoking history, as well as patient demographics were obtained. Patients with a history of pelvic or penile surgery were excluded, leaving 897 patients with at least 2 separate available BMSI scores available for review. Changes in the ED domain of the BMSI were evaluated, and statistical analysis was performed.

**Results:** Average BMSI ED domain scores decreased over time, and were significantly lower in older patients (p<0.0001). [Figure 1] The mean rate of BMSI decline (points per year) was 0.23 (SD 0.55). Overall, BMSI scores for each year were significantly lower in patients with a history of HTN, DM, CAD, BPH, and smoking compared to those without any comorbid disease process (P≤0.002). Surprisingly, there were no differences in the rate of BMSI decline when patients were stratified by decade of age, HTN, DM, CAD, BPH, or smoking.

**Conclusions:** Among those patients ≥ 50 years, older age, HTN, DM, CAD, BPH, and a smoking history were associated with lower BMSI score. Interestingly, the rate of decline in BMSI scores was similar among all men, regardless of age or comorbid conditions.
Disclosure:
Work supported by industry: no.

058

Safe Space: LGBTQ training at the University of Miami
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Objectives: In 2014, an online questionnaire was distributed to University of Miami (UM) medical students to assess the LGBTQ (lesbian, gay, transgender, bisexual, transsexual and/or questioning) campus climate. Based on the survey findings, UM implemented several educational initiatives targeting practicing physicians, residents, and medical students. One initiative was a ‘Safe Space’ interactive training program for administration, faculty and staff. The goal of such training is to improve knowledge about issues affecting the LGBTQ community and provide tools for participants to combat homophobia and heterosexism at UM.

Materials & Methods: To date, over 100 UM faculty and staff have participated in the Safe Space training. To assess program efficacy and impact on learners, we developed pre and post training
evaluation questionnaires that were modeled on existing instruments. While data analysis is still ongoing, in this abstract we present preliminary findings from the first 21 participants.

Results: The number of participants who believe that LGBTQ individuals are significantly impacted by discrimination increased from 4% to 65%; those who consider themselves knowledgeable of unique challenges faced by LGBTQ students increased from 19% to 70% and that those who felt able to respond to situations pertaining to sexual orientation or gender identity increased from 38% to 65%. All participants also expressed interest in changing their language and behavior after the training. Based on these preliminary findings, the Safe Space curriculum was also used to inform the LGBTQ cultural competency curriculum for medical residents and we are currently adapting Safe Space curriculum to be used to train medical students.

Conclusion: Within a one year period, it was feasible to develop and incorporate an effective LGBTQ sensitivity training program at UM. Preliminary data suggests that the Safe Space program increased participants’ knowledge of LGBTQ issues and enhanced their preparedness to provide guidance in situations involving sexual orientation or gender identity. This LGBTQ sensitivity training program has subsequently spawned additional training LGBTQ programs for future clinicians. Combined, these programs have the potential to improve the quality of care LGBTQ individuals receive from UM providers.

Disclosure:
Work supported by industry: no.

059

The Effect of Hypogonadism on Post-Prostatectomy Erectile Function in Men Treated with Penile Rehabilitation
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Objective: Preoperative hypogonadism has been associated with worse recovery of erectile function after radical prostatectomy in older series. We sought to determine whether hypogonadal status was associated with functional outcomes in a contemporary cohort treated with penile rehabilitation.

Materials and Methods: We reviewed the records of 121 men who underwent radical prostatectomy and had preoperative morning serum testosterone. Hypogonadal men were defined by 2014 ISSM criteria of serum total testosterone (eugonadal (EU) ≥346ng/dL, hypogonadal (HG) <231ng/dL, and borderline (BD). All men were recommended postoperative daily tadalafil 5 mg. Erectile function was assessed by question 2 of the SHIM. We evaluated erectile function at baseline, 3, 6, and 12 months.

Results: 17 (14%) were hypogonadal, 37 (21%) were borderline and 67 (55%) were eugonadal. Baseline clinical and pathologic characteristics were similar between the three groups, including baseline IIEF (HG 48.3 ±22.7 vs. BD 54.2 ±18.7 vs. EU 53.9 ±21.3), with the exception of body mass index being lower in eugonadal men. Follow up was available for 117 (97%) men at 3 months, 69 (57%) men at 6 months, and 52 (43%) men at 1 year. All three groups had similar erectile function at 3 months (HG 1.9 ±1.3 vs. BD 1.5 ±1.3 vs. EU 1.6 ±1.4, p=0.57). This was true at 6 months (HG 2.3 ±1.6 vs. BD 2.1 ±1.5 vs. EU 2.2 ±1.4, p=0.92), and 1 year (HG 3.1 ±1.3 vs. BD 2.8 ±1.5 vs. EU 2.8 ±1.1p=0.78). There was also no difference between the three groups patients when accounting for all time points with mixed ANOVA analysis (p=0.99).

Conclusions: In a contemporary series of men offered penile rehabilitation after robotic prostatectomy, there was no difference in erectile function after radical prostatectomy between eugonadal, borderline, and hypogondal men.

Disclosure:
Work supported by industry: no.
The Impact of Surgical Approach on Corporal Sizing for Inflatable Penile Prosthesis Insertion

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Objectives: Although true corporal length is considered an inflexible value in IPP placement, various aspects of surgical approach affect cylinder sizing, including corporotomy site, measurement technique, and ability of the corpora to fully expand during dilation. We retrospectively reviewed a single high-volume prosthetic surgeon’s experience utilizing two surgical approaches to compare mean differences in cylinder measurement and sizing.

Material and Methods: Infrapubic approach was used exclusively for all IPP placements 1/2012 to 1/2014, and subcoronal approach was used exclusively from 1/2014 to 4/2015. Data were recorded on total corporal length and base cylinder size. All cases utilized the Titan penile implant (Coloplast; Minneapolis, MN). Means were compared by student’s t-test (GraphPad Prism; La Jolla, CA). In addition, in two fresh-frozen cadaveric male pelvises IPP placement was performed via infrapubic approach into one corpus cavernosum and subcoronal approach on the contralateral corpus by two experienced surgeons blinded to the contralateral measurement.

Results: Mean corporal length was 20.4 ± 0.9 cm for infrapubic approach (n=170) and 22.1 ± 2.2 cm for subcoronal (n=200) (p<0.0001, Δ1.7cm, 95% CI 1.3-2.1cm). Corporal measurements in cadaver #1 were 20cm infrapubically vs 21.5cm subcoronally, and for cadaver #2 measurements were 22.5 vs 24 cm, respectively.

Conclusions: In a single high-volume surgeon cohort, adoption of a new surgical approach resulted in a highly statistically significant 1.7cm increase in mean corporal measurement, with similar results in cadaveric pilot study. Although we cannot rule out a true shift in corporal size in our patient population over time, we hypothesize that subcoronal approach may allow for an improved angle for corporal dilation as well as uninhibited corporal elasticity obtained by penile degloving. Further studies in other surgeon cohorts will be necessary to validate initial findings.

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.

The who, how and what of Real-World Penile Implants Patients in 2015: The propper (Prospective Registry of Outcomes with Penile Prosthesis for Erectile Restoration) Registry Baseline Data

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1: Regional Urology / LSU-S, USA; 2: El Camino Urology, USA; 3: U of Utah, USA; 4: U Centers of Alabama, USA; 5: The Urology Team, USA; 6: Baylor Urology, USA; 7: San Antonio Urology, USA; 8: SIU
**Introduction:** Heretofore, the published data on penile implant patients consisted generally of small series of single-surgeon, retrospective experiences rather than prospective or large, multicenter evaluations. This study establishes a baseline of data collection from PROPPER (Prospective Registry of Outcomes with Penile Prosthesis for Erectile Restoration). PROPPER is the first large, prospective, multicenter, multinational, monitored, and internal review board (IRB) -approved study of real-world outcomes for penile implant patients.

**Materials and Methods:** Data from the PROPPER study was examined to determine patient baseline characteristics and primary and secondary etiologies prior to ED treatment, to include: type and size of implant received; surgical steps/techniques utilized during implantation; and duration of hospital stay.

**Results:** Through June 22, 2015, a total of 1077 patients were enrolled in the study at 11 sites, with: 1039 patients implanted with AMS 700, 27 patients implanted with Ambicor, and 11 patients implanted with Spectra. Radical prostatectomy (RP) was the predominant etiology in 307 (28.5%) subjects. The other major contributing etiologies included: 230 subjects with diabetes (21.4%), 219 subjects with cardiovascular disease (20.3%), and 97 subjects with Peyronie’s disease (9%). Of those 307 RP patients, 301 (98%) received an AMS 700. Of these patients, 66.4% (200/301) had placement of the reservoir in the traditional retropubic space, versus 29.2% (88/301) in a submuscular location. Compared to those non-RP patients receiving an AMS 700, less patients underwent reservoir placement in the submuscular location 17.1% (126/737), versus 81.3% (599/737), p-value:<0.001. Moreover, length of procedure for RP patients 50 ± 30.5 minutes was not significant p = 0.192. AMS700 patient status in terms of hospital length of stay revealed that 531 patients (51.2%) remained under 24 hour observation, while 457 (44%) underwent same-day surgery discharge with 50 (4.8%) admitted for more than 24 hours.

**Conclusions:** This first-of-its-kind, large, prospective, multi-center study reveals most penile implant patients in North America receive an IPP and that radical prostatectomy is the most common primary etiology of penile implant surgery. Moreover, radical prostatectomy patients were more likely to have the reservoir placed in a submuscular location and may appear to require more OR time than other etiologies though the difference is not statistically significant.

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**062**

"Just the Tip" Closed Suction Drain Cultures after Implantation of Penile Prosthesis

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**Objective:** This study serves to perform analysis and present the culture results of our prolonged closed-suction drain series, with specimens taken at different distances from the skin, to assess for bacterial colonization as a source for infection in post operative IPP patients. This study aims to verify that use of prolonged closed-suction drains after penile prosthesis implantation is a sound post-operative technique to aid in hematoma prevention, and furthermore prove that this intervention does not increase the risk for infection.

**Materials and Methods:** This study is a conglomerate of previous series of post-operative drains analysis now totaling roughly 130 surgeries, of which cultures were obtained from both the distal tip and
the proximal end of each drain. The drains were left in for a “prolonged” timeframe: 48 or 72 hours. An alcohol pad was first used to cleanse the surrounding skin prior to removing the drain in the standard fashion. Care was taken not to contaminate the drain specimens as both the distal tip and a section 1 cm beneath the skin were collected. The two portions were then sent for anaerobic and aerobic culture and these results were analyzed.

**Results:** All 130 patients received a standardized regimen of pre- and post-operative antibiotics (usually Vancomycin/Gentamycin pre-op and Bactrim DS post-op). None of the surgical cases had any evidence of hematoma formation at the time of drain removal, which occurred 48-72 hours post-op. All distal drain tip cultures were negative for bacterial growth after the standard 48-hour incubation period. Only one of the 130 proximal sections (taken 1 cm beneath the level of the skin) grew bacteria. Of the 130 patients included in this update, none suffered prosthesis infection at the time of most recent follow-up.

**Conclusions:** Opponents of drain placement argue that there exists a hypothetical risk that longer drain placement is associated with a higher likelihood that bacteria may contaminate the surgical site and compromise the implant which would negate the benefit of decreased hematoma formation. Of the 130 patients in this series, there was no evidence of retrograde migration of bacteria over a 48-72 hour period of drain placement. We have only recorded 2 (1.5%) infections and 2 (1.5%) hematomas out of 130 patients to date. While drain placement is still a surgeon preference, this data further supports the safe use of prolonged closed-suction drains in penile prosthetic surgery for the prevention of hematoma formation.

**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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**Influential Factors for Penile Implant Patient Satisfaction at 1 year from the PROPPER Registry**

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1: Southern Illinois University SOM, USA; 2: Regional Urology, USA; 3: University of Ottawa, Canada; 4: U of Utah, USA; 5: St. Vincent’s, USA; 6: Lahey Clinic, USA; 7: Baylor College of Medicine, USA; 8: The Urology Team, USA; 9: Kaiser Permanente, USA; 10: Urology San Antonio Research, USA; 11: El Camino Urology, USA

**Introduction:** We previously reported an overall dissatisfaction rate of 12% for patients with penile prostheses from the PROPPER study of AMS penile implants. Here we further analyze which variables influence satisfaction.

**Methods:** This is a retrospective analysis of prospectively collected data as part of the PROPPER penile prosthesis patient registry. Men with at least 1-year patient satisfaction data were included. Univariable analyses were performed with ANOVA or Chi-square tests as indicated with significance set to a P-value ≤0.001 after Bonferroni correction. Stepwise Multivariable logistic regression analysis was then performed with variables with a P value <.05 retained in the model.

**Results:** As of June 2015, 615 subjects had at least 1 year of evaluable data. 84% were satisfied/very satisfied, 6% were neutral, and 10% were dissatisfied/very dissatisfied. Variables that did not influence satisfaction included age, ethnicity, implant model, surgical approach, concurrent curvature correction, primary ED category, duration of ED, baseline depression status, concomitant ED diagnoses such as peyronies or diabetes, anti-coagulant use, IIIEF baseline score or severity, UCLA sexual function bother or baseline, concurrent procedures, drain use, hospital admission status, Foley at time of discharge and reservoir type or placement approach. Factors that were associated with satisfaction included surgery type (virgin/salvage/revision), use of device at 1 year, device problem reported at 1 year, AUA SI total
score and baseline category, baseline UCLA bowel function and urinary bother. Data regarding baseline penile size largely did not influence patient satisfaction (total device length, pre-op penile flaccid and stretched length, penile length and girth difference between pre and post op, total length of RTE per cylinder), but penile length with device inflated trended toward significance (p=0.006). The stepwise logistic regression model selection indicated that only baseline UCLA bowel function, AUA SI total score, and penile length with device inflated were significantly associated with satisfaction.

**Conclusion:** Our data offers insight into potential predictors of satisfaction with noteworthy and somewhat unexpected predictors that included baseline voiding and bowel function and penile length characteristics.

**Disclosure:**
Work supported by industry: yes, by American Medical Systems (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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**064**

**Risk Factors for Surgical Revision after Penile Prosthesis Surgery**

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**Objective:** In this study, we seek to find what differences exist between patients who have a problem-free course after penile prosthesis implantation (PPI) and those patients who develop problems that require revision surgery.

**Material and Methods:** We retrospectively analyzed 148 consecutive patients seen in our institution between January 2012 and December 2013 for placement of penile prosthesis. Using follow up visits and telephone calls, we were able to reach 118 (80%) of these patients. Patient characteristics were tabulated: demographics, previous medical and surgical treatment of erectile dysfunction, comorbidities, and social history. Student’s t-test was used to compare the continuous variables, and Fisher’s exact test for the categorical variables.

**Results:** Of the 118 patients who were contacted, 20 developed problems requiring revision (16.9%), including: 6 infections, 2 erosions, 4 malposition of device, 1 chronic pain, 7 device malfunction. A total of 21 (18%) patients presented with a history of previous PPI. Of the 20 patients who required revision after our surgery, 7 (35%) had previously had prosthesis surgery. The average Body Mass Index (BMI) of patients who required revision was 32.3 compared to 28.8 (p = 0.005) in the no-revision group. Patients who were obese (BMI >30) had a revision rate of 32.6% compared to 5.8% in patients who are not obese (p= 0.0003). In the revision group, 70% of patients had previously used intra-corporal injections (ICI) compared to 44% in the no-revision group (p = 0.048). In the revision group, 35% of patients had previous PPI surgery compared to 14% in the no-revision group (p= 0.049). The revision group had a higher percentage of diabetics (35% versus 24%) but this was not significant. Age, hypertension, smoking history, hyperlipidemia, African-American race, Phosphodiesterase 5 Inhibitor use, vacuum erection device, and MUSE suppositories were found to have no significance.

**Conclusions:** When compared to patients who had a problem-free course after PPI, those who required revision surgery were more likely to have higher BMI, a history of use of ICI, and a history of previous PPI 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.
Erectile Function and Urinary Bother Following Radical Prostatectomy (RP)

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Introduction: Following RP, data suggest that men experience significant bother related to loss erectile function and difficulty with urinary incontinence. However, limited data exist which helps us understand which condition is most bothersome. These data may be important to best help men improve their quality of life following RP.

Materials and Methods: We assessed men pre-RP and then 6, 12, 18, 24, 36, and 48 months(m) post-RP. All men scheduled to have an RP were eligible. Men completed corresponding validated assessments of erectile function bother (EFB) and urinary bother (UB). Both assessments used 4 questions rated on the same Likert scale (total score range=4-20). The questions asked if the condition: limited activities, was considered a problem, caused embarrassment, or reduced life enjoyment. Means and standard deviation are reported for EFB and UB. Since these are different constructs, mean statistical comparisons are not appropriate. We calculated effect sizes (Cohen’s d) from baseline to the post-RP assessment points to quantify the clinical impact: d<0.2 negligible effect; d=0.2 minimal effect; d=0.5 moderate effect; d=0.8 large effect.

Results: 472 men had an average age at RP of 59±7 years. Mean EFB was consistently higher than UB from baseline to 48m post-RP. Both EFB and UB demonstrate statistically significant increase from baseline across all the time points (p<0.05). However, the effect sizes for EFB consistently show a moderate to large clinical effect as compared to the small and negligible effects sizes for UB.

Conclusion: While both EFB and UB statistically increase from baseline, EFB demonstrated a considerably larger effect suggesting EFB impacts men more consistently and to a greater degree than UB.

<table>
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<tr>
<th>Time Point</th>
<th>EFB Mean±SD</th>
<th>EFB Effect Size</th>
<th>UB Mean±SD</th>
<th>UB Effect Size</th>
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Disclosure:
Work supported by industry: no.
Introduction: One of the most common patient complaints after IPP (inflatable penile prosthesis) surgery is loss of penile length. We have employed a method of using new length measuring technique (NLMT) intraoperatively, coupled with a daily post-operative rehab protocol with maximum inflation of the IPP, to evaluate objective morphologic changes in penile measurements as well as to assess patient satisfaction in their penile length up to 2 years after Coloplast Titan placement.

Methods: A prospective, three-center, study of 40 patients who underwent IPP placement, with NLMT for erectile dysfunction with the Coloplast Titan IPP. Patient instructions were to inflate daily for 6 months and then inflate maximally for 1-2 hours daily for 6-24 months. Fifteen penile measurements were taken before and immediately after surgery and at follow-up visits.

Results: All 15 penile measurements were improved at 1 and 2 years from pre-implant status, and there was a statistically significant improvement in the objective measurements at year 2 compared to year 1. There was also statistically significant improvement in satisfaction of penile morphology at both year 1 and year 2 compared to pre-operative physical perception. At 2 years post-op, 67.8% of subjects were satisfied with their length and 77% had perceived penile length that was longer (30.8%) or the same (46.2%) as prior to the surgery. These 2 year values were an improvement from 1 year. Patient satisfaction profiles regarding penile size, use of IPP, and sexual performance with the IPP were all improved at 2 years compared to 1. At year 2, 96.4% of the patients reported being very satisfied or extremely satisfied in regards with the surgery fulfilling their expectations, versus 83.3% for the first year.

Conclusion: This study suggests using the Coloplast Titan with aggressive cylinder sizing and a post-operative penile rehabilitation inflation protocol may optimize patient satisfaction and erectile penile measurements, and provide sustained improvement with longer follow-up.

Disclosure:
Work supported by industry: yes, by 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.
plaques were identified by Doppler ultrasound preoperatively. Our technique has already been described, but briefly the penis was degloved through our subcoronal modified no touch technique, and an artificial erection was created. PD plaque and penile deformity, if present, is identified and marked. NVB mobilization begins lateral to the urethra. Following IPP placement any residual curvature was noted. Using relaxing incisions with cautery into the corpora or penile modeling, the curvature was addressed; no plicating stitches were used in any patients. The NYU group uses a graft material to cover corporal defect, while the CUMC does not. Patients were seen postoperatively and curvature and penile length was examined. Of note men from the NYU group did not suffer from PD, but had significant concern about their penile length.

**Results:** Preoperatively, patients demonstrated an average penile length was 11.9 cm (9.5-14); no statistical difference between institutions was noted. 68% of men had previous radical prostatectomy and 56% had PD, average curvature was 56.2° (41-68°); Mean operative time was 153 (95-201) minutes. Postoperative length increased by 2.4cm (1.5-4) when measured at 8mo and for the 75% of patients with follow-up over a year (average follow-up 14.2 months) and length was maintained. Curvature improved by 90-95% for the subset of men with PD. There was 4 complications of the MoST procedure at CUMC: specifically one partial necrosis of a suture line, two had contracture at the site of a PDP which required release and one hypermobile glans and 1 at NYU: partial necrosis of a suture line; none were infectious and no herniation of the prosthesis were noted.

**Conclusions:** Penile length loss and ED secondary to RP or PD and the subsequent penile curvature that results can be very concerning to men, our previously described MoST procedure allow for penile lengthening, IPP placement and simultaneous correction of penile deformities caused by Peyronie’s plaques through a single incision. Penile length increased by 2.4cm in this cohort and curvature improved by 95%; which was not lost in long term follow-up. This multi-intuitional analysis shows that our technique can be reproduced and maintains lasting results for men suffering from penile length loss.

**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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068

**Subcoronal IPP can be Performed under Local Anesthesia**

*Park, SSH1; Wilson, SK2; Valenzuela, RJ3*

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**Objective:** To report our results placing 3-piece inflatable penile prosthesis under local anesthesia occasionally supplemented with conscious sedation via a subcoronal incision.

**Material & Methods:** Retrospective review of 27 first time patients who had IPP performed via subcoronal incision under local anesthesia. Patient age was 63.78 ± 8.05 (Mean ± SD) and all had medical clearance for conscious sedation. Patients were followed up to 6 months.

**Technique:** Nursing professionals monitored airway, vital signs and pulse oximeter. Local anesthesia was obtained by injection of mean 23.52 ± 1.65 cc of 1:1 mixture of 1% lidocaine and 0.5% bupivacaine with 100 μg of fentanyl citrate. After bilateral pudendal block, the local was injected in base of the penis and the external inguinal ring with finger assistance. A subcoronal incision was used and reservoir placement was either in the retroperitoneal space (85%) or the high submuscular location (15%). Foley catheter and compressive scrotal dressing were utilized. Patients were given oral sedative prior to surgery and a single injection of intravenous etomidate if they were uncomfortable during reservoir placement.
Results: Mean procedure time was 66.33 ± 20.33 min (Mean ± SD). Mean pain scale at the time of surgery was 4.04 ± 2.12 (Mean ± SD). One scrotal hematoma was experienced which healed spontaneously.

Conclusion: IPP via subcoronal incision can be accomplished safely under local anesthesia.

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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069

Penile Intracavernosal Pillars: Lessons from Anatomy and Potential Implications for Penile Prosthesis Placement

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Objectives: Studies of penile anatomy have demonstrated that intracavernosal pillars radiate from the inner layer of the tunica albuginea. Although their role in providing geometric support during intercourse has been suggested, their implications during penile surgery are not well described. We sought to anatomically describe the relationship of these pillars to corporal dilation during penile prosthesis placement.

Material and Methods: Corpora cavernosa from 4 embalmed male cadavers were dissected and underwent probe dilation. Corpora were then cross-sectioned and examined for the gross presence and location of pillars and dilated spaces. A complete inflatable penile prosthesis insertion was performed via infrapubic approach on one fresh-frozen cadaveric male pelvis, followed by cross-sectioning of the tissue to examine the dilated space. A single live patient had intracavernosal pillars examined intraoperatively during surgery for Peyronie’s plaque excision and penile prosthesis insertion.

Results: Intracavernosal pillars were identified in all cadavers and one surgical patient, passing obliquely from the dorsolateral tunica albuginea across the sinusoidal space to the ventral intercorporal septum. This delineated each corpus into two potential compartments for dilation: dorsomedial and ventrolateral. Dorsomedial dilation seated instruments and prosthetics satisfactorily in the dorsal mid-glands and provided additional tissue coverage over weak ventral areas of the tunica albuginea, while ventrolateral dilation appeared to result in ventral seating and susceptibility to perforation. All findings were documented via illustration and/or photo images.

Conclusions: Intracavernosal pillars are an important anatomic consideration during corporal dilation for penile prosthesis placement. Dilation of the compartment on the dorsomedial side appears to result in improved distal seating of cylinder tips, which may be protective against tip malposition, perforation, or subsequent erosion.

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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070
Placement of Penile Prosthesis May Improve Metabolic Syndrome: Retrospective Cohort in a Single Site Institutional Experience
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1: USA

Objectives: The indications for penile prosthesis placement are for patients that have failed to achieve satisfying penile erections after attempting other treatment modalities for ED. The purpose of this article is to describe patients with erectile dysfunction that undergo penile prosthesis placement and objectively measure markers of metabolic syndrome to delineate if there is a physiologic improvement in subsequent clinic visits.

Methods: This is a retrospective cohort study of a single institution of patients from July 2008 until August 2012. A total of 200 patients were analysed, out of which 63 patients (31.5%) had documented diagnosis of diabetes mellitus and contained HbA1c recorded in the electronic chart.

Results:

<table>
<thead>
<tr>
<th></th>
<th>Pre-Implant</th>
<th>Post-Implant</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1C</td>
<td>9.3 +/-2.3</td>
<td>7.22+/-1.52</td>
<td>&lt;.05</td>
</tr>
<tr>
<td>BMI</td>
<td>30.7+/4.99</td>
<td>29.9+/5.2</td>
<td>&gt;.05</td>
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<tr>
<td>LDL</td>
<td>131+/45</td>
<td>81+/33</td>
<td>&lt;.05</td>
</tr>
<tr>
<td>HDL</td>
<td>41.3+/15</td>
<td>53.2+/20</td>
<td>&lt;.05</td>
</tr>
</tbody>
</table>

Conclusion: This is the first description of patients that undergo penile prosthesis placement whose metabolic profile is investigated. We were able to demonstrate that HbA1c level, a surrogate marker of diabetes mellitus is substantially altered for a positive effect. The clinical implication is that diabetic patients wishing to undergo semi-rigid prosthesis or inflatable penile prosthesis may be counselled that their metabolic parameters may improve.

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.

071

Post-Prostatectomy Penile Prosthesis Reservoir Placement with Radiographic Guidance
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Objectives: Inflatable penile prosthesis (IPP) implantation is a well-established low risk procedure for refractory erectile dysfunction. However, complications with traditional IPP reservoir placement can occur especially in patients who have had previous prostatectomy. Distorted anatomy can potentially lead to reservoir misplacement in undesirable locations. Intraabdominal reservoir placement can lead to vascular and visceral injuries, while more superficial placement can lead to a palpable reservoir. Here we describe a novel method of using intraoperative radiographs to guide IPP reservoir placement in the Space of Retzius (SOR) in post prostatectomy patients.

Material and Methods: From Dec 2014 to June 2015, we obtained intraoperative radiographs for 8 consecutive patients who had undergone laparoscopic, robotic assisted laparoscopic, or retropubic radical prostatectomy who underwent three-piece IPP placement. After dissection of the SOR, a 16 French Foley catheter is inserted, the catheter balloon is inflated with 10mL of sterile water, and 60-100
cc of contrast is injected into this space. Radiographs were obtained with a detector plate that was placed prior to the start of the procedure.

**Results:** All patients had standard dissection by a single surgeon with intention for reservoir placement in the SOR. No intraoperative complications or intraperitoneal placement were identified. Two distinct contrast patterns were seen that correlate with placement in the SOR (Fig 1A) or in spaces anterior to the transversalis fascia (Fig 1B). Follow up is limited, but all patients were seen at least one month from surgery without notable complications or palpable reservoirs.

**Conclusions:** Intraoperative radiographs is an easy method to aid in dissection of the SOR in post-prostatectomy patients. Ensuring appropriate reservoir placement in the SOR can avoid potential visceral and vascular injuries, or palpable reservoirs.

Figure 1A: Contrast forms in a spherical collection in the SOR defined by abundant preperitoneal fat tissue. Note no contrast is noted outlining visceral structures indicating extraperitoneal space.
PKA Agonist Colforsin Recovers Erectile Function and Promotes nNOS Signalling in the Penis in Cavernous Nerve Injury Rat Model
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Objectives: Neuronal nitric oxide synthase (nNOS) initiates and maintains penile erection. However, the mechanisms by which nNOS activity is regulated after bilateral cavernous nerve injury (BCNI) are poorly understood. We evaluated the effect of BCNI and cAMP-dependent protein kinase (PKA) agonist (Colforsin) treatment on the phosphorylation of nNOS, nNOS uncoupling, and erectile function (EF) status.

Materials and Methods: Male Sprague–Dawley rats were divided into BCNI and sham group. Each group included 2 subgroups; vehicle and Colforsin 0.1 mg/kg i.p. injection. After 3 days, erectile function (intracavernosal pressure) was measured and penes were collected for molecular analyses of P-nNOS (Ser-1412 and Ser-847), total nNOS, nNOS uncoupling (by Western blot) and oxidative stress (hydrogen peroxide [H2O2] and superoxide by microdialysis method).

Results: Erectile response to electrical stimulation of the cavernous nerve was decreased (p<0.05) after BCNI and increased (p<0.05) by Colforsin treatment. nNOS uncoupling and nNOS phosphorylation on both positive (Ser-1412) and negative (Ser-847) site were increased (p<0.05) after BCNI and normalized (p<0.05) by Colforsin treatment. nNOS protein expression was decreased (p<0.05) after BCNI and unaffected by Colforsin treatment. H2O2 and superoxide were elevated in BCNI group and normalized by Colforsin treatment.

Conclusion: BCNI inhibits nNOS function in the penis by causing its uncoupling and deranging its phosphorylation, and increasing oxidative stress, resulting in erectile dysfunction. PKA agonist reverses these molecular changes and preserves penile erection in the face of BCNI.

Disclosure: Work supported by industry: no.
neuroprotective M2) to examine whether increase in TNF-α enhances recruitment of neurotoxic M1 macrophages to MPGs following BCNI.

**Material and Method(s):** Male Sprague-Dawley rats (300-350 g) underwent sham surgery or BCNI. MPGs were harvested 48 hours, 7 days, 14 days after BCNI, and 48 hours after sham surgery. MPGs were processed for qPCR (n=5/group), Western blot (WB) (n=5/group), and immunofluorescence (n=5/group). We examined gene expression of Tnfa, macrophage markers (Cd11b and Cd68), M1 markers (Cd86, Nos2, Il1b) and M2 markers (Cd206, Arg1, Il10) by qPCR. WB was used to evaluate protein amount of TNF-α, inducible nitric oxide synthase (iNOS: M1 marker) and Arginase-1 (ARG1: M2 marker). We examined macrophage population in the MPG with immunofluorescence (IF) for TNF-α, CD68, iNOS, and ARG1.

**Result(s):** BCNI significantly increased gene expression of Tnfa, Cd11b, Cd68, Cd86, Nos2, Il1b, Cd206, and Arg1 (p<0.05). Maximal increase of Tnfa, Cd68, Cd86, Il1b, and Cd206 was at 48 hours. Maximal increase of Cd11b and Nos2 was at 7 days. Gene expression of Arg1 remained unchanged. BCNI significantly increased protein expression of TNF-α at 7 days and iNOS at 14 days after BCNI (p<0.05), while protein amount of ARG1 remained unchanged. IF demonstrated that CD68 positive cells are increased and surrounded by TNF-α in MPG following BCNI with maximal increase at 14 days. CD68 positive cells in MPG were mostly iNOS positive but ARG1 negative, indicating M1 macrophage phenotype.

**Conclusion(s):** This study demonstrated that BCNI increased gene and protein expression of TNF-α and M1 markers. Gene expression of M2 markers was increased but protein expression of M2 markers remained unchanged after BCNI. Furthermore, M1 macrophages were co-localized with TNF-α in MPG after BCNI. These results suggest that TNF-α antagonists may prevent post-RP ED by inhibiting recruitment of neurotoxic M1 macrophages to the MPG.

**Disclosure:**
Work supported by industry: no.

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**074**

**S-Nitrosoglutathione Reductase (GSNOR) Protects against Western Diet Induced Reactive Oxygen Species Production and Erectile Dysfunction**

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**Objectives:** Binding of nitric oxide (NO) to a cysteine thiol is termed S-nitrosylation, which is emerging as an important means of NO-mediated signal transduction independent of stimulation of soluble guanylate cyclase. However, the impact of S-nitrosylation on erectile function remains unclear. S-nitrosylation is a redox sensitive post-translational modification, which is thought to be promoted by reactive oxygen species (ROS). Protein S-nitrosylation levels are regulated in part by S-nitrosoglutathione reductase (GSNOR), which acts to de-nitrosylate protein thiols. The objectives of this study were to determine the role of GSNOR on maintenance of redox balance and erectile function in response to a Western diet (WD) high in fat and sugar.

**Materials and Methods:** Young male wild type (WT; n = 94) and GSNOR−/− (n = 92) mice were fed either a control diet or a WD ad libitum for 3, 6, 9, or 12 weeks. Following the dietary intervention, erectile function was assessed by measuring intracavernosal pressure (ICP) and mean arterial pressure (MAP) during cavernous nerve stimulation. In separate mice, in vivo ROS production was measured in the penis utilizing a novel microdialysis approach. Microdialysis probes were inserted into the penis of anesthetized mice and perfused with saline containing 100 uM Amplex Ultrared, 1 U/ml horseradish peroxidase, and 10 U/ml superoxide dismutase. ROS convert the reagents to a fluorescent byproduct resorufin, which was measured in the outflowing dialysate.
Results: Neither ROS generation (WT: 0.66 ± 0.09 vs. GSNOR−/− 0.96 ± 0.12 µM H₂O₂; p = 0.41) nor erectile function (WT: 8.44 ± 1.4 vs. GSNOR−/− 9.6 ± 1.6 ICP area/MAP; p = 0.97) were different between genotypes fed the control diet. However, ROS were elevated following just 3 weeks of WD consumption in GSNOR−/− mice (1.44 ± 0.19; p = 0.01), whereas ROS increased following 6 weeks of WD in WT mice (1.29 ± 0.19; p = 0.02). Subsequent to increases in ROS, ED was evident after 6 weeks of WD in GSNOR−/− mice (5.0 ± 1.1, p = 0.04) and after 12 weeks of WD in WT mice (3.1 ± 0.6, p = 0.02).

Conclusions: Mice lacking GSNOR demonstrated an impaired ability to maintain redox balance in the face of the pro-oxidant stimulus of the WD, prompting accelerated development of erectile dysfunction. These data implicate a protective role for GSNOR in the penis and suggest that excessive S-nitrosylation may negatively regulate erectile function.

Disclosure: Work supported by industry: no.

075

Protective Effect of Herbal Formulation in the Bladder of Androgen-Deprived Rat

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Objective(s): We hypothesized that positive effects of the herbal formulation on the urinary bladder would be attributable to its antioxidant effects or to an elevation in NO-cGMP activity. We investigated the protective effects on the bladder of androgen-deprived rats.

Material and Method(s): Male rats aged 8 weeks were randomly divided (n=8 in each): sham operation only (normal control), androgen-deprived only (androgen-deprived control), androgen-deprived followed by treatment with 200mg/kg, and 400mg/kg. After leuprorelin 0.5mg/kg was subcutaneously injected in androgen-deprived groups, oral administration of either distilled water (normal control, androgen-deprived control) or herbal formulation(treatment groups) was continued for 4 weeks. Serum testosterone level, RhoGEFs, nitric oxide (NO)-cyclic guanosine monophosphate (cGMP) related parameters, oxidative stress, and histologic change were evaluated after treatment.

Result(s): Treatment with the herbal formulation (1) increased the serum testosterone levels; (2) restored the expression of RhoGEFs, eNOS and nNOS; (3) increased the expression of superoxide dismutase; and (4) decreased bladder fibrosis.

Conclusion(s): Our results suggest that a positive influence on molecular change in the urinary bladder would be attributable to an antioxidant effect or to an elevation in NO-cGMP activity.

Disclosure:
Work supported by industry: no.

076

Correlation between Androgen Receptor CAG Repeat Length Polymorphism and Metabolic Syndrome, Late Onset Hypogonadism in Korean Male

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Objective: It is generally assumed that there is a negative linear association between androgen receptor (AR) sensitivity and the CAG repeat length. However, correlation between CAG repeat length and clinical
factors of metabolic syndrome, late onset hypogonadism is unclear. In this study we explored the relationship between androgen receptor (AR) CAG repeat length polymorphism and MS, late onset hypogonadism (LOH) in a Korean male population.

**Material and method:** The association between AR CAG repeat length polymorphism and MS was analyzed in 241 Korean men (20-90 years old). MS was diagnosed according to the NCEP criteria (any three or more of the following components were present: abdominal obesity (waist circumference (WC) > 102 cm), triglycerides > 150 mg/dL, HDL cholesterol < 40 mg/dL, fasting glucose > 110 mg/dL, or blood pressure of > 130/85 mmHg). LOH was diagnosed by serum testosterone level of <3.5ng/mL and androgen deficiency in the aging male questionnaire positive. AR CAG repeat length polymorphism was determined by microsatellite fragment sizing and association with clinical factors and questionnaire related with LOH (patient health questionnaire-9 (PHQ), aging male symptom scale (AMS), and international index of erectile function (IIEF)) were analyzed.

**Results:** Mean age of the patients was 56.9±11.2 years. Mean AR CAG repeat length and serum testosterone levels were 26.7±8.9 and 5.6±2.3ng/ml, respectively. A Total of 64 men (26.6%) were diagnosed with MS and 22 men were diagnosed with LOH. Men with MS showed no significant difference in AR CAG repeat length compared with men without MS (p=0.325). AR CAG repeat length was not associated with HDL, LDL, triglyceride (p=0.397, p=0.609, p=0.867), but showed significant association with HbA1c (r=0.103, p=0.029). Men with LOH showed no significant difference in AR CAG repeat length compared with men without LOH (p=0.665). However as CAG repeat length was increased, AMS and PHQ scores were decreased and IIEF score was increased, significantly (r=-0.118, r=-0.153, r=0.069)(p<0.01, p<0.01, p<0.01).

**Conclusion:** In conclusion, AR CAG repeat length seems to be associated with HbA1c and clinical symptoms of LOH in Korean male.

**Disclosure:**
Work supported by industry: yes, by by Basic Science Research Program through the National Research Foundation of Korea(NRF) funded by the Ministry of Education (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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077

**Protective Effect of KH-204 via ERK and Akt Pathways in LOH Rat Model**

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**Objective(s):** The present study was intended to assess that the herbal formulation, KH-204 could protect TM3 Leydig cells against oxidative stress in vitro; and restore testosterone production in androgen-deprived or aging male rats.

**Material and Method(s):** The survival rate of TM3 Leydig cells treated with KH-204 was measured based on oxidative stress. Androgen-deprivation was induced by s.c. injection of leuprolelin 0.5mg/kg. After daily intake of KH-204 for 4 weeks, the level of testosterone, oxidative stress, aromatase inhibition and apoptosis were measured in androgen-deprived or aging male rats.

**Result(s):** KH-204 protected TM3 cells from oxidative stress via activation of ERK and Akt pathways. The level of testosterone and activation of spermatogenesis in androgen-deprived or aging male rats were significantly enhanced, and germ cell apoptosis was reduced after treatment. In addition, KH-204 exhibited the aromatase inhibitory activities in a dose-dependent manner.

**Conclusion(s):** These results suggested that KH-204 may alleviate the oxidative stress via ERK and Akt pathways, and the aromatase inhibitory activity of KH-204 may contribute, to a different extent, to the improvement of serum testosterone levels.
Disclosure:
Work supported by industry: no.

078

Further Evidence for a Role of Human Growth Hormone (hGH) in the Control of Penile Erection in the Adult Male

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1: Hannover Medical School, Division of Surgery, Dept. of Urology, Hannover, Germany; 2: Ludwig Maximilians University, Faculty of Medicine, Dept. of Urology, Munich, Germany; 3: Osnabrück Municipal Hospital, Dept. of Urology, Osnabrück, Germany

Objective(s): Human growth hormone (GH) has been suggested to be involved in sexual maturation and play a role in male reproductive function. Treatment with recombinant GH in patients with GH-deficiency increases nitric oxide (NO) and cGMP. The purpose of our study was to examine the role of GH in the mechanism of penile erection in adult males.

Material and Method(s): The effects of GH were investigated on electrically (EFS)-induced relaxations of isolated HCC in the absence and in presence of the guanylyl cyclase inhibitor ODQ and NO synthase inhibitor L-NOARG (10 µM). Effects of GH on the production of cGMP in the absence and presence of ODQ and L-NOARG were also elucidated. In 35 healthy adult males and 45 ED patients, blood samples were drawn simultaneously from the corpus cavernosum penis (CC) and a cubital vein (P) during the penile conditions flaccidity, tumescence, rigidity (healthy subjects only) and detumescence. Serum levels of GH and IGF-1 (insulin-like growth factor) were determined by means of immunoradiometric assays.

Result(s): ODQ and L-NOARG abolished the relaxation of the tissue induced by EFS, whereas amplitudes were increased by GH (1 nM - 100 nM). The attenuation of EFS-induced amplitudes by L-NOARG but not ODQ was, in part, reversed by GH. The production of cGMP induced by 10 nM GH was abolished in the presence of 10 µM ODQ, the combination of GH (10 nM) + L-NOARG (10 µM) maintained cGMP-production significantly above baseline (0.68 versus 1.07 pmol cGMP/mg protein). In the healthy males, an increase in GH serum levels (ng/ml) was registered in the systemic circulation and the cavernous blood during tumescence (mean: 5.2 to 9.5). GH levels decreased from tumescence to rigidity (7.2) and detumescence (6.1). In the patients, mean GH levels were determined to be about 7-fold lower than in the blood of the healthy males, the increase in systemic and cavernous GH levels from flaccidity to tumescence was 5-fold weaker than in the healthy subjects. In a cohort of patients with ED (30 to 70 years of age), IGF-1 levels were significantly below the age-adapted reference values.

Conclusion(s): Our data provide evidence that GH may act on guanylyl cyclase activity via an NO-independent effect. We consider our data evidence that GH is of importance in the maintenance of male erectile capability.

Disclosure:
Work supported by industry: no.

079

Separate or Combined Treatments with Human Bone Marrow-Derived Stem Cells and Substance P of Erectile Dysfunction in a Rat Model of Diabetes

Song, GH1; Ryu, CM2; Ahn, TY2
Objective: To investigate the possibility of utilizing human bone marrow-derived stem cell (hBMSC) and substance P (SP) to treat diabetogenic erectile dysfunction (ED), we will establish a base to test potential clinical applications of this treatment using hBMSC and SP.

Materials and Methods: Forty 8 week old male Sprague-Dawley rats were injected with streptozocin (STZ) in order to induce type 1 DM, and 10 rats served as normal controls. Eight weeks later, rats were divided into five groups: nondiabetic controls (Con, n = 10); diabetic rats injected with PBS (diabetes mellitus [DM], PBS 60µL, n = 10,); diabetic rats transplanted with human BMSCs (hBMSC 5x10⁴ cells/60µL, n = 10); diabetic rats injected with Substance P (Substance P [SP] 0.5nmol/60µL) and diabetic rats in accordance with hBMSC and SP injection (hBMSC 5x10⁴ cells/60µL + SP 0.5nmol/60µL, n=10, [combine]). Body weight and blood glucose levels were measured and recorded weekly during this study. Four weeks after transplantation, all rats were analyzed for erectile function (the ratio between intracavernous pressure (ICP) and mean arterial pressure (MAP)) and immunofluorescence (α−smooth muscle actine marker, von Willebrand factor marker (vWF) and endothelial nitric oxide synthase (eNOS) in corpus cavernosum and neuronal nitric oxide synthase (nNOS) in dorsal nerve).

Results: After hBMSC and SP transplantation, the ICP/MAP ratio of the hBMSC, SP and combine groups were increased significantly compared with diabetic controls, but there was no significant differences of the ratio among hBMSC, SP and combine groups (0.68±0.07 vs 0.67±0.18 vs 0.75±0.14; p =0.18). The content of the smooth muscle and endothelium in the corporal cavernosum of experimental groups (hBMSC, SP and combine group) were also significantly higher in comparison with the diabetic controls. vWF were significantly increased in the experimental groups in comparison with the DM group. eNOS and nNOS were also significantly higher in the experimental groups in comparison with the DM group according to immunofluorescence and Western blot analyses. Although, combine group tend to increase on aSMA, vWF, eNOS and nNOS, there was no difference among hBMSC, SP and combine groups (all p>0.05).

Conclusions: Intracavernous transplantation of hBMSC and SP had beneficial effects on erectile function and histopathology of diabetic rats. We expected in our current study to demonstrate a dose reduction in using stem cells for therapy of ED. Although combine therapy tended to recovery on erectile function and histopathology in diabetic ED, we need further evaluation.

Disclosure: Work supported by industry: no.
whose corona of the glans could not be identified during vulvoscopy, despite vigorous retraction maneuvers. In these 8 clitorodynia patients, adjacent skin adhesions to the glans clitoris were identified and an oily waxy sebum material exuded through breaks in adhesions. Under magnification, keratin or epithelial pearls formed concentric layers approximately 0.5-2 mm in diameter under squamous skin epithelial adhesions. These 8 women underwent exploration, dorsal slit surgery and release of localized adjacent skin adhesions to the glans clitoris. In all, more than 50% of the glans was involved with balanitis noted below the adhesions above the corona. 2 of 8 also had lichen sclerosis, concomitantly managed with clobetasol. 6 of the 8 patients have significant improvement of clitoral pain at least 1 year postop. Of the 7 women who did not have closed compartment syndrome, 3 had clitoral priapism responding to adrenergic agonist treatment or shunt surgery, 2 suffered blunt perineal trauma, suspected of having pudendal neuropathy, and 2 had blunt perineal trauma and clitoral neuromata on surgical exploration.

Conclusions: Clitorodynia, although rare, appears most commonly to be caused by a closed compartment syndrome of adjacent skin adhesions to the glans clitoris. This leads to unrecognized balanitis, keratin pearl formation and chronic pain. If the corona of the glans clitoris cannot be visualized despite vigorous retraction, closed compartment syndrome should be suspected.

Disclosure:
Work supported by industry: no.

081

Sub-Urethral Sling Surgery For Stress Incontinence May Result In Orgasmic Dysfunction Through Direct Injury to Anterior Vaginal Wall, Peri-Urethral Prostatic Tissue

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Introduction: Over 200,000 surgical procedures are completed yearly for stress incontinence, mostly sub-urethral slings, TVT or TOT procedures. Peri-urethral tissues are contiguous with female prostate tissue, thus in women with stress incontinence, surgical placement of a sub-urethral sling may directly injure anterior vaginal wall, peri-urethral prostatic tissue. The integrity of anterior wall, peri-urethral prostatic tissue may play a critical role during vaginal orgasm. Motivated by distressed patients who lost orgasmic capabilities following TVT or TOT procedures, we studied the prevalence of orgasmic dysfunction after sub-urethral surgery for stress incontinence.

Materials and Methods: 23 manuscripts, 5 RCTs, 4 Retrospective Cohorts and 14 Prospective Cohorts, examined 2,350 women from 2002-2015. Follow-up ranged from 3 to 24 months postop. Most studies involved the TOT or TVT mid-urethral slings, few included the single incision type mid-urethral slings. In these manuscripts, sexual questionnaires included the FSFI and PISQ that include questions on orgasm outcome.

Results: Approximately 14-20% of women experienced worsening sexual function after mid-urethral sling placement. 30% reported statistically significant worsening of orgasm frequency and intensity. 2/3s of women showed statistically significant improvement in sexual satisfaction following the mid-urethral sling surgery. 33% of patients showed statistically significant improvement in orgasm. Concerning orgasm satisfaction, approximately 27% of women experienced worsening of orgasm satisfaction and 40% realized no change.

Conclusions: There was a large discrepancy noted in orgasm satisfaction versus overall sexual satisfaction following sub-urethral sling placement. It is hypothesized that women who were pre-operatively experiencing vaginal orgasm are at risk of developing orgasmic dysfunction secondary to
direct sub-urethral sling injury to anterior wall, peri-urethral prostatic tissue. Pre-operative identification of women with vaginal orgasm and development of surgical strategies that minimize direct injury to anterior vaginal wall, peri-urethral prostatic tissue may be keys to avoiding post-operative orgasmic dysfunction.

Disclosure:
Work supported by industry: no.

082

Responder Analyses Based on Minimum Clinically Important Differences Derived from Receiver Operating Characteristic Curves in Premenopausal Women Using Bremelanotide for Female Sexual Dysfunctions
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Objectives: Bremelanotide (BMT) is a novel cyclic heptapeptide known to act as a melanocortin-receptor-4 agonist. In a large Phase 2 study of its potential use to treat female sexual dysfunctions (FSDs), key efficacy outcomes were subjected to post hoc responder analyses anchored to minimum clinically important differences (MCIDs) derived from receiver operating characteristic (ROC) curves.

Material and Methods: All patients were premenopausal women with hypoactive sexual desire disorder and/or female sexual arousal disorder. After 4 weeks of single-blinded subcutaneous (SC) placebo self-dosing (baseline period), they were randomized to double-blind SC placebo or BMT 0.75, 1.25, or 1.75 mg for 12 weeks of at-home, as-needed self-dosing. Key efficacy endpoints included change from baseline to end of study (EOS) in the 4-week number of satisfying sexual events (SSEs) and in total score and desire subscore on the Female Sexual Function Index (FSFI) and the Female Sexual Distress Scale–Desire/Arousal/Orgasm (FSDS-DAO). At EOS, patients responded, on a 7-point Likert scale, to a questionnaire item asking: “To what degree do you think you benefited from taking the study drug?” From a ROC curve for each efficacy endpoint, an MCID was computed as the value simultaneously maximizing the endpoint’s sensitivity and specificity for predicting a Likert-scale rating of 5 to 7 (i.e., patient-reported global benefit). The MCIDs then served as anchors for responder analyses.

Results: 327 patients provided data (for SSEs, 324). The computed MCIDs were +1.0 for number of SSEs, +2.1 for FSFI total score, +0.6 for FSFI desire subscore, −7.0 for FSDS-DAO total score, and −1.0 for FSDS-DAO desire subscore. Using these cut-offs, the SSE responder rate was 37% for placebo vs 38%, 48%, and 55% for BMT 0.75, 1.25, and 1.75 mg respectively. The FSFI responder rate was 46% vs 45%, 61%, and 69% for total score and 53% vs 46%, 60%, and 77% for desire subscore. The FSDS-DAO responder rate was 45% vs 49%, 60%, and 69% for total score and 45% vs 48%, 57%, and 72% for distress subscore. For all five endpoints, the difference from placebo was statistically significant (P <0.05, Cochran-Mantel-Haenszel test) at 1.75 mg.

Conclusions: Self-administered SC BMT showed a clear, dose-dependent increase in responder rates defined by MCIDs for multiple widely used, clinically relevant FSD measures, attaining statistically significant separations from placebo at the BMT 1.75 mg dose.

Disclosure:
Work supported by industry: yes, by Palatin Technologies, 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.
Partner Prosthesis Panic
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Introduction: Approximately 300,000 penile implants are placed annually in the US. Female partners in relationships with men with ED considering implant surgery have expressed concern over reintroduction of an erect penis into their sexual lives. We define “Partner Prosthesis Panic” as the concerns of the female sexual partner who during pre- or post-operative interview openly described issues such as: her low sexual desire, reduced arousal, muted orgasm, and bothersome pain during penetration. These conditions may negatively influence the post-operative outcome and frequency of implant use. We examined prevalence of “Partner Prosthesis Panic” and management strategies of the distressed female partners of men undergoing IPP insertion.

Material and Methods: In the last fifty consecutive penile implant surgeries in men in monogamous heterosexual relationships, 11 (22%) female sexual partners were identified (mean age 57±11 years) who expressed “Partner Prosthesis Panic” and underwent management in our facility.

Results: Contemporary management of women with sexual dysfunction is biopsychosocial including judicious use of FDA-approved and non-approved treatments. 82% were menopausal and 18% were peri-menopausal. All had FSD >5 years prior to implant procedure. FSI (mean 18±4) and SDS (21±6) scores were abnormal in all. Psychologic interviews revealed findings consistent with a history of sexual trauma/abuse (27%) and mood issues: anxiety, depression, panic, use of mood-related medications (45%). Pelvic floor physical exams were abnormal in 73%. Vulvoscopic assessments revealed abnormalities such as clitoral atrophy, resorption of labia minora, erythema and tenderness of minor vestibular glands, limited robust peri-urethral tissue, urethral prolapse, limited gavial rugae, abnormal vaginal pH in all patients. Hormonal assessments of sex steroids were abnormal in all patients. Following sex therapy, physical therapy and biologic management, 8 of 11 experienced markedly improved sexual function that significantly facilitated couple satisfaction post-penile implantation.

Conclusions: With FDA approved treatments for women with FSD, management of women with sexual dysfunction, especially in monogamous heterosexual relationships with men with erectile dysfunction considering penile implant surgery will become more commonplace. To maximize satisfaction following penile implant insertion, sexual medicine care to both individual members of the couple should be offered and provided.

Disclosure:
Work supported by industry: no.

084

Have Related Between Female Sexual Function and Male Partners’ Erectile Function?
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Objective: Female sexual difficulty (FSD) with or without sexual distress is highly prevalent. Erectile dysfunction (ED) is one of the most common sexual dysfunction in men. Several epidemiological studies have shown that the sexual function of woman is affected in multiple domains when they perceive ED in their partner. Aim of this study was to evaluate the association between female sexual function (FSF) and the erectile function (EF) of their male partners.

Materials & Methods: The study was conducted in 2009-2011 among a convenience sample of the female employees and simultaneously among their male sexual partners. Study packages were distributed in total to 359 couples. The questionnaire for women included the 19-items, Female Sexual
Function Index (FSFI) and for men was composed of 22-items, which included the 15-items, International Index of Erectile Function (IIEF) and questions about demographic data, comorbidities, length of marriage, relationship with the partner and lower urinary tract symptoms, respectively.

Results: The couples have mean ages of 38.5±7.5Yr (range 18-70Yr) and 40.3±6.5Yr (range 23-75Yr) for female and male partners, respectively. The total and domain scores of the FSFI were lower for the female partners of men with ED than for those of men without ED, with effect sizes of $\eta^2=0.02-0.08$. After adjustment for female group, nearly all the FSFI and IIEF domains scores correlate significantly to a slight to moderate degree. On the basis of the FSFI and IIEF scores, 39.7% of the women reported sexual difficulty and 17.5% of men reported mild to moderate ED. The men with ED were older and more likely to report premature ejaculation, low libido than those without ED. ED of the male partner was still a significant risk factor for FSD as well as for sexual difficulty in the aspects of arousal, orgasm sexual satisfaction and sexual pain (OR=2.7-3.9).

Conclusion: Yes, the Female Sexual Function have a significant correlations with the male partners erectile function.

Disclosure:
Work supported by industry: no.

085

'A Rose By Any Other Name': Historical Insights into Restless Genital Syndrome (RGS)

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Objectives: To critique the common assertion that RGS is a newly discovered disease by analyzing the changes to its name over time, and to articulate the ways that the semantics of disease structure our understanding of sexual pathophysiology, epidemiology, diagnosis, and treatment.

Materials and Methods: Close reading and period contextualization of the relevant medical and historical literature, including texts describing the recently coined RGS, Persistent Genital Arousal Disorder (PGAD), and Persistent Sexual Arousal Syndrome (PSAS), as well as the now defunct, but previously commonplace, diagnoses of hysteria, nymphomania, and chlorosis.

Results: The collection of symptoms that are currently described as RGS are not a novelty, but rather have been considered characteristic of various diseases throughout the course of medical history, from the ancient world to the present day. In all of its guises, medical authors have consistently struggled to reconcile the psychosocial and somatic aspects of the condition, ultimately tending to privilege the latter.

Conclusions: Medical history has shown how disease constructs reflect and reaffirm the assumptions and prejudices of their eras. The evolution in disease nomenclature described above, from names that embrace the contributions of psyche and social relations and make explicit the eroticism of the condition, to the asexual RGS, represents both the increasing complexity of sexual science and a persistent discomfort with sexual discourse in a biomedical professional context.

Disclosure:
Work supported by industry: no.

086

The Impact of Testicular Loss on the Psychopathology of Young Patient in Korea: Population-based Analysis of 4 Million Examinees of Manpower Administration Database for 10 Years
Objective: Patients of hypogonadism have high risk of depression and anxiety with impaired quality of life. Although testicular loss is common morbidity, the psychopathological impact of testicular loss is rarely reported. We studied the impact of testicular loss on psychopathology.

Materials and Methods: The interview with urologist for the screening and the Military Multiphasic Personality Inventory (MMPI, consist of 9 domains, 365 questionnaires) for screening psychopathological disease are one of the routine exam. We retrospectively analysed 4 million cases of Manpower Administration (MA) database of last 10 years (from 2003 to 2012) for the evaluation of the psychopathological status of examinee of testicular loss. The examinees of testicular loss were defined at least 50% decrease of testicular volume at CT scan. The examinees without severe medical disability were classified as normal control group. The abnormal result of MPI scale was defined as a score more than one standard deviation.

Results: In this cross-sectional study, total 3932 unilateral testicular absent examinees (UTAE) and 203 bilateral testicular absent examinees (BTAE) were screened. After exclusion of examinees with abnormal response, total 3562 UTAEs and 171 BTAEs were included for final analysis. The abnormal rate of anxiety (15.5% vs. 9.5%), depression (18.3% vs. 10.6%), somatization (18.6% vs 8.7%) and personality disorder (16.8% vs. 13.7%) were higher in UTAE group than matched control. The abnormal rate of depression (18.3% vs. 15.8%) and somatization (18.6% vs. 12.6%) in UTAE group were even higher than in BTAE group.

Conclusions: Our population based study suggests young patients with testicular loss are psychopathological vulnerable condition. More active psychopathological screening is indicated for young testicular loss patients.

Disclosure:
Work supported by industry: no.

087

Sexual Behavior Seems to Influence Depression

Ramirez, F1; Nedley, N1
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Objectives(s): The present study assesses the relationship between sexual activity outside marriage and depression before and after an educational facilitator based depression program.

Material and Method(s): A medical clinic trains and certifies facilitators in 3 continents. Participants meet once a week for 2 hours for 8 weeks. The previously validated Nedley Depression and Anxiety Test (registration TX 7-398-022), a 75-item self-report tool, is taken at baseline and after 8-weeks. This tool assesses depression levels (using PHQ-9 [Patient Health Questionnaire]) and other mental health markers. Demographic data and sexual habits are also asked among other questions used to identify factors that may exacerbate or trigger depression. These factors were determined dichotomously using their answers on the test. The depression was classified according to the DSM-5 (The Diagnostic and Statistical Manual of Mental Disorders Volume 5) into 4 categories as none (0-6), mild (7-10), moderate (11-19) or severe (20 or more). The program teaches lifestyle interventions (nutrition, rest, exercise, etc) to participants.

Result(s): The questionnaire was administer to 5,621 individuals from 9 countries. Three percent (n=170) of participants from 5 countries recognized that they were involved in sexual relationships outside marriage before and after the program, at baseline their average PHQ-9 for depression was 14.2
(moderate) SD 7.3 and as a group 19% none, 16% mild, 35% Moderate, 30% Severe depression. Those that were not in sexual relationships outside marriage had a group average a PHQ-9 for depression 12.3 (moderate) SD 7.5 (28% none, 15% mild, 35% moderate, 21% severe). By the end of the 8-weeks those involved in extramarital sexual activities had on average a depression of 7.2 (mild) SD 6.4 (57% none, 15% mild, 22% moderate, 6% severe) while the rest of the group had a depression average of 6.5 (none) SD 6 (59% none, 18% mild, 19% moderate, 4% severe).

**Conclusion(s):** It seems sexual relationships outside of marriage are related to higher depression levels and severity even before the 8-week program. The program seems to benefit both groups but more improvement is seen in those not involved in the extramarital situations. Further follow up is recommended.

**Disclosure:**
Work supported by industry: no.

088

**Sexual Abuse Increases Risk of Addictive Behaviors**

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1: Nedley Clinic, USA

**Objective(s):** Using the data from a community based 8-week depression recovery program, the study assessed if there is a relationship between certain common addictions and the fact that someone had suffered sexual abuse in the past.

**Material and Method(s):** The 8-week depression educational program uses a previously validated depression and anxiety questionnaire, which consist of 75 questions. The tool is used to evaluate depression, anxiety, EQ and causes of depression. Questions are asked about past sexual history and current addictive behaviors. Data was used from all participants that finished the 8-week program (n=5621). The program teaches lifestyle changes.

**Result(s):** From the 5,621 participants, 25.5% (n=1437) acknowledge that they had suffered sexual abuse sometime in the past. From the group that suffered sexual abuse, 22% (n=316) disclosed that they had an alcohol drinking problem, 10% (n=147) disclosed that they were tobacco users, 27% (n=387) acknowledged that they were users of illegal drugs and/or controlled substances, 13.5% (n=194) acknowledged that they were using benzodiazepines and had a depression average of 13 (moderate), 7.5 SD at baseline. The group that did not suffer forced abuse, 11.3% (n=431) abused alcohol, 7.2% (n=274) used tobacco, 6.8% (n=261) abused illegal drugs and/or controlled substance, 9.5% (n=361) used benzodiazepines and had a depression average of 12 (moderate), 7.5 SD at baseline. The group that had the history of sexual abuse abused alcohol 48.2% more, used tobacco 29.5% more, abused illegal drugs and/or controlled substance 74.4% more, and used benzodiazepines 29.6% more. By the end of the 8-weeks the sexually abused group had a group average of depression of 7 (mild), SD 6 and the other group had a depression average of 6.4 (none), SD 6.

**Conclusion(s):** It seems that having a history of sexual abuse does increase the risk of various types of addictive habits. The 8-week program was also effective in improving depression even among those with a history of sexual abuse. Steps should be taken to prevent addictive behaviors in those that have suffered sexual abuse.

**Disclosure:**
Work supported by industry: no.
Emotional Intelligence in Persons Involved in Sexual Relationships Outside Marriage

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Objective: The purpose of this study was to determine if there is a correlation between sexual relations outside of marriage and a patient’s emotional intelligence (EQ) score before and after an educational 8-week facilitated depression and anxiety recovery program.

Methods and Patients: For the study, data from 9 countries (n=5621), of participants that completed the program was used. Average age was 52.6 [SD 15]. The community program meet once every week for two hours. Activities during the 2-hour program included 1 hour of lecture presented on DVD by a mental health professional, and 1 hour of discussion on a lifestyle topic. At the beginning and end of the program participants filled out a 75-item questionnaire, which measured depression level, anxiety, standardized mini EQ test, and demographics. The questionnaire included the question "Are you involved in sexual relations outside of marriage?".

Results: From the 5621 participants studied at baseline, 6% (n=340) were involved in sexual relations outside of marriage. The 340 that were involved had an initial average EQ score of 94.5 [SD 14.9], minimum of 54, maximum of 135, mode of 86 and median of 94. The rest of the group at baseline, that were not involved in sex outside marriage, had an EQ of 100.6 [SD 15.1], minimum of 50, maximum of 150, mode of 102 and median of 100. At the end of the 8-week program there were 5% (n=263) of the participants that reported that they were involved in sexual relations outside of marriage and 95% (n=5385) were not involved. Those who were involved had a final EQ score of 102.2 [SD 14.4], minimum of 60, maximum of 144, mode of 102 and median of 102. At the end those who were not involved in sex outside marriage had an EQ score of 109.2 [SD 14.3], minimum of 54, maximum of 150, mode of 110 and median of 110.

Conclusions: At the beginning of the program there was a clear difference between the scores of those involved in sex outside marriage and not involved. By the completion of the program there was still a marked difference but there was increase in both parties EQ scores. According to this data sex outside of marriage is related to lower EQ scores. The 8-week depression and anxiety program is effective in increasing the EQ scores of both, those involved and not involved, in sexual relations outside of marriage.

Disclosure:
Work supported by industry: no.

Vaginal Dilation: Current Use and Treatment Practices Vaginal Dilator Clinician Survey:
Preliminary Report Health Care Provider Insight

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Objective: Vaginal dilators are recommended and used for many clinical indications including but not limited to dyspareunia, pelvic floor hypertonus and vulvar vestibulitis. Online clinician and patient surveys were created to ascertain further information concerning dilators and their practical implications in clinical practice.

Methods: Two online clinical surveys were created in order to ascertain detailed information concerning practical and clinical information with respect to dilator use. Participants received a small financial
remuneration, $10 Starbucks gift card, for their time. We present the first 96 clinicians and 40 patients who completed the survey from July 2 to and including September 21, 2015.

**Results** The preliminary report consisted of 96 respondents (89 female; 7 male) who were in clinical practice for an average of 15.9 years. The majority were physical therapists (70.8%) 67/96; and 21 were medical doctors. The most common indication for prescribing dilators was for painful intercourse and vaginismus. Approximately 14% of those surveyed prescribed over 100 dilators per year whereas 16% prescribed approximately fifty. Health care professionals estimated their success rate as measure by painless penetration at 71% and that patients achieved success on average 4.7 months after starting their dilator program. Clinicians estimated that 80% of their patients had suffered from their medical conditions for 2 years or greater before seeking treatment with 20% suffering for 5 years or longer. Most HCP instruct patients to use dilators every other day and follow up is commonly 2-4 weeks with only 8.3% following up every 3 months. Half are instructed to use dilators at night and the other half are instructed to use them whenever they feel comfortable in their scheduling. In 80% of the time patients are taught mindfulness, 57% of the time meditation and more than half are instructed to listen to calming music during dilator exercises. The most common reasons for non-compliance is perceived to be – lack of privacy, pain during use, fatigue and dilators being cumbersome. HCP report patient commonly expressed emotions are anxiety, hopeful, empowered, embarrassed and frustration. 77% of HCP would consider selling dilators through their office.

**Conclusion:** Vaginal dilators are widely used in sexual medicine practice for a variety of health care conditions however largely remain an understudied and under appreciated sexual accessory. HCP perception of use and impression of emotional barriers to compliance are important facets to understand.

**Disclosure:**
Work supported by industry: yes, by The survey was funded by Materna Medical. 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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**091**

**Barriers to Sexual Activity after Treatment for Head and Neck Cancer: A Qualitative Approach**

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**Objective:** Patients treated for head and neck cancer (HNC) may face great disfigurement as well as a decline in physical function. These issues have the potential to uniquely impact survivors’ actual and perceived experience of sexual activity. As it is difficult to observe sexual activity in a research or clinical setting, it is imperative that self-report measures of sexual activity be available. There are no known HNC-specific self-report measures of sexual activity. Furthermore, no known studies have examined barriers to sexual activity after treatment for HNC. The purpose of this study was to examine barriers to sexual activity after treatment for HNC using a qualitative approach to obtain preliminary data for the development of a HNC-specific self-report measure.

**Materials and Methods:** Individuals age 21 years or older with a history of HNC were recruited to participate in a one-on-one semi-structured interview. Interviews were audio recorded and transcribed verbatim. Transcripts were then analyzed by two independent reviewers using ATLAS.ti software. Analysts triangulated findings and confirmed thematic categories. Descriptive statistics were used to describe the sample population.

**Results:** Ages of participants (n=11) ranged from 33 to 70 years with an average of 55 years. Participants were mostly male (64%), Caucasian (82%), and married (73%). Three themes that focused on barriers to sexual activity were identified. Themes included psychological challenges, physical impairment, and chemical problems. Psychological challenges included the subthemes of body image, interpersonal communication and desire. Physical impairment included the subthemes of general fatigue
and head and neck-specific challenges. Chemical problems included the subthemes of opiate usage and hormonal imbalances.

**Conclusions:** HNC survivors face disease-specific barriers to sexual activity. This qualitative study will aid researchers in identifying disease-specific elements that should be further explored for inclusion in a self-report measure of sexual activity after treatment for HNC. This study will also aid clinicians by identifying the multidimensional aspects of barriers to sexual activity in this population.

**Disclosure:**
Work supported by industry: no.

092

**A Comparison of Baseline Erectile Function after On-Demand 20 mg Tadalafil vs. Daily 5 mg Tadalafil in Men with Erectile Dysfunction and Diabetes: A Prospective, Observational 2-year Study**

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**Objectives:** We studied whether long-term use of 5 mg tadalafil once daily improved baseline erectile function or prevented erectile dysfunction (ED) in men with diabetes.

**Material and Methods:** Men with ED and diabetes who were naïve to PDE5 inhibitors were assigned to 20 mg tadalafil on-demand or 5 mg tadalafil once daily and asked to provide information about erectile function at the start of treatment and after 2 years. When men completed the questionnaire after 2 years of treatment, they also stopped the medication for 4 weeks to check their baseline erectile function. The primary efficacy variable was the IIEF-EF score. Secondary efficacy variables included a change in the scores IIEF Q3 and Q4 from baseline, changes in all domain scores on the IIEF from baseline, SEP2 and SEP3, and the GAQ. Rigiscan® measurements of nocturnal penile tumescence and rigidity (NPTR) were also carried out 2 years after treatment.

**Results:** The study enrolled 118 men (mean age: 56.2yrs) and most had mild to moderate ED (57.6%): 65 patients (55.1%) were prescribed 20 mg tadalafil on demand and 53 patients (44.9%) took 5 mg tadalafil once daily. After 2 years of treatment, the daily treatment group had a significantly greater change in the IIEF-EF domain score from baseline compared with the on-demand group (7.3 vs. 2.4, *P* < 0.0001). The changes in IIEF from baseline on Q3 (1.4 vs. 0.4, *P* < 0.0001) and Q4 (1.4 vs. 0.3, *P* < 0.0001) were higher in the daily group than in the on-demand group. Differences between the daily and on-demand groups were significant for SEP2 (53.8% vs. 32.3%, *P* = 0.0003) and SEP3 (56.6% vs. 15.4%, *P* < 0.0001). Normal EF domain scores (≥26) at the end of the study were achieved by 20.7% and 6.2% in the daily and on-demand groups, respectively (P = 0.0031). Normal patterns of NPTR at the end of the study were achieved by 13.2% only in the daily group.

**Conclusion:** Long-term use of 5 mg tadalafil once daily was more beneficial for improving baseline erectile function or preventing ED than the on-demand pattern in men with ED and diabetes.

**Disclosure:**
Work supported by industry: no.

093

**Prevalence of Sex Stimulants Abuse among Male Subjects in Calabar, Cross River State, Nigeria, Following Perceived Beneficial Effect in Increasing Genital Size**
Objectives: Erectile dysfunction (ED) is a multifactorial problem with psychological, biological and social ramifications. Over the years, the use of several sex stimulants to sustain erection even in the absence of any erectile disease has become a norm. This study was therefore embarked upon to ascertain the prevalence of ED, knowledge of the causes of ED, the use of various sex stimulants as well as the motivation surrounding the use of sex stimulants among male subjects in Calabar, Cross River State, Nigeria.

Material and Methods: Subjects with frequency of sexual activity less than 4 times a month were excluded from this study. Two thousand and ten male subjects resident in Calabar, aged 15 – 74 years were qualified based on the exclusion criteria and assessed in this study using a questionnaire.

Results: Out of the 2010 subjects, 1317 (65.5%) had at least secondary education, while 11 (0.5%) had no formal education. Forty five respondents (2.2%) were aware of the causes of ED, while 1965 (97.8%) had no idea about the causes of ED. Fifty one respondents (2.5%) were currently suffering ED, while 1959 respondents (97.5%) were not suffering ED as at the time of this study. Also, 41 respondents (2.0%) had no history of intake of sex stimulants, while 1969 (98%) had taken and were currently taking sex stimulants. There was a statistically significant (p<0.001) positive correlation between age and incidence of ED. One thousand seven hundred and forty five respondents (86.8%) took sex stimulants following their perceived beneficial effect in increasing genital size, of which 1622 (92.9%) were aged 15 – 34 years.

Conclusion: The likelihood of suffering ED increases with increasing age. However, the younger population indulged more in the use of sex stimulants, despite the low incidence of ED among them, in their quest for an increased genital size.

Disclosure:
Work supported by industry: no.

Relationship Between Age and Erectile Dysfunction Diagnosis or Treatment Using Real-World Observational Data in the United States

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Objectives: To assess the relationship between patient age and diagnosis or treatment of erectile dysfunction (ED) using real world observational data in the United States.

Material and Methods: This cross-sectional, non-interventional (NI) study used 7/1/2010–6/30/2014 de-identified claims data from the Truven Health MarketScan® Commercial and Medicare Supplemental Research Databases. Men with ED were defined as those with an ED diagnosis (organic and/or psychogenic origin; ICD-9-CM codes 607.84 or 302.72) or with a phosphodiesterase type 5 inhibitor (PDE5I) prescription. Inclusion criteria included men aged ≥18 y and 360-day continuous enrollment before index date. The prevalence of comorbid conditions (hypertension, other cardiovascular disease [CVD], diabetes mellitus [DM], depression, and benign prostatic hypertrophy [BPH]) was examined in men with ED and those without ED. Univariate analysis was conducted to assess the percentage of identified ED in the overall population and in age-by-decade subgroups. Additional analyses were conducted by stratifying each age subgroup with each comorbid condition.

Results: Of 19,833,939 men meeting inclusion criteria, 1,108,842 (5.6%) had an ED diagnosis or PDE5I prescription (mean [SD] age: 55.2 [11.2] years; median age: 56 years). The percentage of ED diagnosis
or treatment increased with each decade of age (18–29 y: 0.4%; 30–39 y: 2.1%; 40–49 y: 5.7%; 50–59 y: 10.0%) until the 6th decade (11.5%), and then decreased to 11.0%, 4.6%, and 0.9% in the 7th, 8th, and 9th decade, respectively. Men with ED had a higher prevalence of any comorbid condition (63.1%) versus men without ED (29.3%), including hypertension (45.0% vs 21.1%), other CVD (12.9% vs 7.1%), DM (19.9% vs 8.7%), depression (7.0% vs 4.2%), and BPH (16.2% vs 4.5%). Analyses of men with each comorbid condition showed a similar relationship of age with ED diagnosis or treatment as that of the overall population.

**Conclusions:** In the real-world setting, men in the United States with ED had higher prevalence of comorbid conditions than men without ED. After taking into consideration comorbid conditions, ED diagnosis or treatment increased with age, whereas very old age was associated with a decrease in ED diagnosis or treatment. Future studies may be warranted to better understand underlying factors contributing to the decreasing ED diagnosis or treatment among older men.

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**Efficacy and Safety of Sildenafil by Age in Men With Erectile Dysfunction**

**Goldstein, I; Tseng, L; Creanga, D; Stecher, V; Kaminetsky, JC**

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**Objectives:** Sildenafil, an oral phosphodiesterase type 5 inhibitor, has been extensively investigated for the treatment of erectile dysfunction (ED) in randomized controlled trials. However, published data are limited on the treatment response to sildenafil in men with ED according to age ≥65 years. We assessed the efficacy and safety of sildenafil versus placebo according to age subgroups (<65, 65–74, and ≥75 years) in 11,364 men with ED using pooled data from 48 randomized, double-blind, placebo-controlled, parallel-group, flexible-dose trials.

**Material and Methods:** Most trials had a 12-week treatment period. The starting sildenafil dose was 50 mg, taken 1 hour before sexual activity, with subsequent adjustment to 100 or 25 mg based on efficacy and safety. Men taking nitrate therapy/nitric oxide donors and men with severe cardiac failure, unstable angina, or recent stroke or myocardial infarction were excluded. Efficacy analyses included all subjects with baseline and ≥1 post-randomization evaluation. Safety analyses included all subjects who received study drug. The primary efficacy outcomes were the change from baseline to week 12 in International Index of Erectile Function (IIEF) scores and a Global Assessment Question (GAQ; "Did the treatment improve your erections?") at week 12.

**Results:** The age range in the overall population was 19–87 y in the sildenafil group and 18–89 y in the placebo group. Mean IIEF scores for question 3 (frequency of penetration), question 4 (maintenance of erections after penetration), and the Erectile Function Domain were statistically significantly improved with sildenafil versus placebo for each of the 3 age subgroups (all P < 0.001); Orgasmic Function, Intercourse Satisfaction, Sexual Desire, and Overall Satisfaction Domain scores also were statistically significantly improved with sildenafil versus placebo (all P < 0.001). The percentage of men reporting improved erections on the GAQ was statistically significantly higher with sildenafil versus placebo for all 3 age subgroups (P < 0.001); the percentage with sildenafil tended to decrease with increasing age (<65 y, 80%; 65–74 y, 69%; ≥75 y, 59%). The most common all-cause adverse events with sildenafil were headache (8%–12%) and flushing (8%–9%) for the 3 age subgroups. Discontinuation due to treatment-related adverse events was low (sildenafil: ≤1.5%; placebo: ≤0.9%).
Conclusions: Sildenafil is an effective and well-tolerated treatment for ED regardless of patient age. Sexual function can continue with aging for most sildenafil-treated men with ED, including men aged ≥75 years.

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.

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Penile Rehabilitation Adherence and Outcomes: The First 6 Months of Treatment
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Objectives: The aim of this descriptive, cross-sectional study is to determine compliance with and the impact of PDE-5 inhibitors and the vacuum constriction device (VCD) on preservation of pre-treatment erectile function in men after prostate cancer treatment.

Materials and Methods: This is a longitudinal study of men treated for prostate cancer with radical prostatectomy and/or radiation therapy who use PDE-5 inhibitors and the VCD for erectile dysfunction following prostate cancer treatment. The study uses a one-group pretest-posttest design to compare erectile function outcomes and quality of life before, 1, 3, 6, 12, and 24 months after initiation of treatment for erectile dysfunction in men who had prostate cancer treatment. Patients are asked to use the pills at least three times a week and if they are not getting hard enough with pills, to use the vacuum device daily for stretching.

Results: 48 men completed the 1 month survey, 36 completed 3 months, and 31 men completed 6 months. The average age was 58.2 (SD 6.9), the majority were Caucasian (85.7%), all but 3.6% had some college with most having a bachelor's degree or higher (81.9%), 91.1% had a robotic radical prostatectomy (the remaining were open), and all had nerve sparing (except one partial nerve sparing). The mean SHIM score pre-op was 22.2 (SD 2.5) and the mean erection hardness was 3.47/4 (SD 0.37). The mean use of pills was 2.5-2.8 (SD 0.8-1.5) times a week and the mean use of the vacuum device was 3.1-3.8 (SD 1.8) times per week. IIEF EF Domain scores improved from 6.54 (SD 4.8) initial, to 12.21 (SD 8.24) at 1 month, 15.26 (SD 8.13) at 3 months, and 18.45 (SD 9.38) at 6 months (p < 0.001).

Conclusions: Even though men were asked to use the vacuum device daily, they used it an average of 3-3.5 times a week. The men were asked to take the pills three times a week, but they took them an average of 2.4-2.8 times a week on average. Despite comprehensive instructions and follow-up, men do not use the vacuum device daily and take the pills only 2-3 times a week on average. Erectile function, penile stretched length, and sexual relationship satisfaction improved over the 6 months. Placebo controlled research is needed to determine efficacy of penile rehabilitation with the pills and/or vacuum device.
Disclosure:
Work supported by industry: no.

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Preservation of Nocturnal Penile Tumescense with Daily Low-Dose Sildenafil 6 Weeks after Nerve-Sparing Radical Prostatectomy is Correlated with Erectile Function Rehabilitation

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Objectives: Previous studies showed that daily low dose sildenafil leads to improvement of the preservation of nocturnal penile tumescence and rigidity (NPTR) 6 weeks after nerve-sparing radical prostatectomy (nsRP). Aim of this study was the evaluation of NPTR-preservation on further erectile function (EF) recovery.

Material and Methods: 24 sexual active patients were operated by nerve-sparing radical prostatectomy. An erectometer measurement of NPTR (Rigi-Scan®) was carried out on each patient after removal of the transurethral catheter and again 6 weeks after surgery. To maintain and support recovery of spontaneous erectile function 12 patients with preserved nocturnal erections detected during NPTR-recordings received sildenafil 25mg/d at night starting immediately one the day after catheter removal (group 1). A control of 12 patients underwent follow up without daily PDE-5-inhibitors (group 2). All patients completed an IIEF-5 questionnaire concerning erectile function preoperatively, 3, 6, and 12 months after surgery.

Results: Group 1 (daily 25mg sildenafil) showed 2-5 erections (mean 3.2 erections/night) during the first night after catheter removal. In the control (group 2) 1-5 erections (mean 3.1 erections/night) were recorded within this acute phase after nsRP. NPTR-recordings 6 weeks after nsRP showed a decline of nocturnal penile erections with only a slight decrease in group 1 (1-4 erections/night, mean 2.8 erections)
vs. group 2 (0-2 erections/night, mean 1.1 erections/night) (p<0.05). In the group of daily sildenafil the IIEF-5 score decreased from preoperative 22.4 mean score to 3.8 at 3 months, 12.4 at 6 months and 17.5 at 12 months after nsRP. In the control group preoperative IIEF-5 mean score 23.2 decreased to 2.6 at 3 months, 7.4 at 6 months, 9.3 at 12 months. Statistical evaluation showed a correlation of NPTR-preservation with a significant increase of IIEF-5 score and time to recovery of erectile function (p<0.05).

Conclusions: EF rehabilitation with daily low dose sildenafil leads to significant preservation of nocturnal penile tumescense 6 weeks after nsRP which correlates with a significant increase of erectile function recovery.

Disclosure:
Work supported by industry: no.

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Prevalence and Predictors of Erectile Dysfunction in Men Evaluated for Infertility
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Objective: We sought to describe the prevalence of erectile dysfunction (ED) in men presenting for infertility consultation and to identify clinical predictors of ED in this population.

Material and Methods: This was an IRB approved study. We retrospectively reviewed clinical data from men that presented to a single urologist for infertility consultation at a tertiary referral center between July 2012 and June 2015. Clinical data included medical comorbidities, presence or absence of testosterone deficiency syndrome (TDS) defined as total testosterone < 300 ng/dl or calculated free testosterone < 6.5 ng/dl, body mass index (BMI), and serum hormonal data. The rates of ED diagnoses and treatment initiation for ED were recorded. Univariate odds ratios (OR) of ED with 95% confidence intervals (CI) were calculated using Fischer’s exact test.

Results: The cohort was comprised of 523 infertile men (mean 37.8 years old, standard deviation 7.7 years). 30.7% were obese, 11.2% had a history of hypertension, 8.3% had mood disorders, 3.9% had diabetes mellitus, 0.6% had coronary artery disease, and 0.4% had BPH. Erectile dysfunction diagnoses were assigned to 96/523 men (18%), including 52/523 men (10%) who were not previously diagnosed with ED. 50/523 men (9.6%) initiated treatment with an oral phosphodiesterase-5 inhibitor after their initial consultation for infertility. Increased age (p <0.001), obesity (OR 4.6 CI 2.8-7.5), and hypertension (OR 3.6 CI 1.9-6.7) were associated with ED. We also found trends towards significance for the association between mood disorders and ED (OR 4.6 CI 2.8-7.5) and TDS and ED (OR 1.7 CI 0.96-2.93).

Conclusions: ED is prevalent in men that present for infertility consultation, affecting nearly 1 in 5 men. Older men, obese men, and men with hypertension are at particularly high risk. This represents an important opportunity for treatment that may facilitate reproduction and improve quality of life in infertile men.

Disclosure:
Work supported by industry: no.

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The Prevalence And Predictors Of Vasovagal Reactions In Men Being Trained In Penile Injection Therapy
Objectives: Penile injection therapy represents a major strategy in the treatment armamentarium for patients with erectile dysfunction (ED). Clinical experience has informed us that some men suffer from vasoovagal reactions (VVR) while using such injections. This analysis was conducted to define the incidence of this problem as well as making an attempt to determine predictors of VVR in this population.

Material and Methods: Men undergoing in-office penile injection training were evaluated during the training visits, two of which are standard at our center. VVR was defined as the presence of ≥2 of the following symptoms/signs: dizziness, syncope, drop in systolic pressure (SBP) ≥35mmHg, bradycardia (≤60 BPM). A multivariable model (MVA) was constructed using patient age, history of prior VVR, history of anxiety disorder and injection medication dose.

Results: 1762 injection training patients were analyzed. 96% of patients received trimix (papaverine, phentolamine, PGE1) as their injection agent. 17/1764 men had a VVR at their first injection visit (0.9%). Of the 16 who proceeded to a second visit, none had a repeat VVR. 14/17 had a prior history of VVR (10 during prior blood draws). 22/1745 (1.2%) men who did not experience VVR during injection training had a prior history of VVR. 11/17 had a history of anxiety (treated or untreated). Mean drop in SBP was 47±17mmHg (12/17 SBP ≤90mmHg). Mean pulse rate = 45±22 BPM (11/17 ≤60 BPM). On MVA, prior VVR history (OR 17.6, 7.9-33.6, p<0.001) and history of anxiety disorder (OR 9.2, 3.8-22.1, p<0.001) were the only predictors of VVR.

Conclusions: VVR is a rare occurrence in a penile injection training program and is most often seen in men with a history of prior VVR or anxiety disorder. Of note, no patient with an in-office VVR had a repeat VVR.

Disclosure: Work supported by industry: no.

End Diastolic Velocity versus Resistive Indices in Predicting Better Clinical Response Using Penile Doppler Ultrasound for Patients with Erectile Dysfunction
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Introduction: Erectile dysfunction (ED) is a common disorder affecting millions of men worldwide. Penile Doppler (PD) is a useful modality to assess the functional underlying cause of the ED. PD can be used for evaluating different parameters of an erection including peak systolic velocity (PSV), End diastolic velocity (EDV), Resistive Indices (RI) and cavernosal artery diameter (CAD). These measurements can aid the physician in diagnoses and treatment. The objective of this study was to determine whether RI or EDV better predicts clinical response on PD for erectile dysfunction evaluation.

Methods: Between July 2008 and February 2013, 472 consecutive patients were evaluated for ED with a PD ultrasound of which 465 patients had complete data. This cohort was then divided into three groups based on clinical response: 1) Clinical response 0 degrees (n=112, 24%), 2) Clinical response 0-45 degrees (n=226, 49%), 3) Clinical response greater than 45 degrees (n=127, 27%). Interquartile Range (IQR), Mean, median and Standard Deviation (SD) were then calculated for certain demographic data and PD parameters including EDV and RI (calculated (PSV-EDV)/PSV). Both parameters were calculated by best response regardless of cavernosal side. Demographic and PD ultrasound parameters between the groups were compared using descriptive statistics.

Results: The median age for Group 1 was 58 (IQR 20) years, 59 (IQR 16) years for Group 2 and 55 (IQR 18) years for Group 3 (p=0.06). Caucasians showed a significantly better clinical response when
compared to other races (p= 0.03). There was no significant difference between the groups for marital status (p=0.67). Patients in Group 3 had significantly improved EDV (0 ± 0 vs Group 1, 0.1 ± 3.2 vs Group 2, 0.9 ± 0.1) and RI (1.02 ± 0.16 vs Group 1, 0.99 ± 0.17 vs Group 2, 0.95 ± 0.19) values compared to the Group 1 and 2 (both p<0.0001).

**Conclusion:** EDV and RI can both be used to accurately predict clinical response of PD. However, using RI may be superior to EDV when reporting results, as it more accurately depicts overall vascular flow. This is likely secondary to RI considering both venous and arterial data, compared to EDV which only assesses the venous system.

**Disclosure:**
Work supported by industry: no.

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**Determining Factors Associated with Early Onset of Erectile Dysfunction (ED) in Men with Type 1 Diabetes**

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**Objective:** Erectile dysfunction (ED) has earlier onset and greater severity in men with type 1 diabetes (T1D) than in men from the general population. The objective of this study is to develop a comprehensive model of the predictors of ED onset.

**Material and Methods:** Longitudinal data from men in the Diabetes Control and Complications Trial (DCCT) and its follow-up Epidemiology of Diabetes Interventions and Complications (EDIC) study defined ED annually over 30 years as a “Yes” or “No” response to a single question querying the presence of “impotence” or report of pharmacologic therapy for ED. Men in DCCT were recruited in two cohorts (the primary cohort excluded people with diabetes-related complications, the secondary cohort required mild to moderate nonproliferative retinopathy and a urinary albumin excretion rate <200mg/day) and randomly assigned to conventional or intensive insulin treatment. A multivariable Cox proportional hazards model incorporating time-dependent covariates for factors that changed over the risk period (e.g., BMI and Hypertension) was used to determine the impact of demographic and clinical variables on age of onset of ED, with onset defined as the first year of at least 2 consecutive years reporting ED.

**Results:** We found 333 cases out of 616 men with T1D who have ED data from 5-30 years. The cases had mean age of onset of ED of 45.6 ± 7.0 years. Obesity (HR=1.39), HbA1c (HR=1.57), current smoking (HR=1.38), conventional insulin therapy during DCCT (HR=1.13), and Hypertension (HR=1.84) were all found to be associated with earlier onset of ED, while younger Diabetes onset (HR=0.36) and secondary cohort (HR=0.88) were found to have protective effects (all p<0.01).

**Conclusions:** Demographic and clinical variables are predictive of early onset ED in men with T1D. This knowledge will allow targeting of high-risk patients for intervention and prevention. Associations with other diabetes complications will be examined in future work.

**Disclosure:**
Work supported by industry: no.

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**Sex & Intimacy after Prostate Cancer Treatment: What Men and Partners Say**

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Objectives: The purpose of this qualitative study is to describe the real life experiences of men and their partners with sexual dysfunction after prostate cancer treatment.

Materials and Methods: Men with sexual dysfunction after prostate cancer treatment with either surgical removal or radiation therapy 1-5 years after prostate cancer treatment were invited to participate in this research study. They were recruited in the urology clinic and through prostate support/network groups. The study used a phenomenological design to determine the lived experience of men with sexual dysfunction. Open-ended questions about their cancer experience and treatment guided the interviews. Men reported demographic information and completed sexual health questionnaires.

Results: 27 men completed the study, mean age 61 years (SD = 8.0; range = 44-77 years). 9 partners of men who had previously been treated for prostate cancer were also interviewed, individually. Partners did not complete any forms. The majority of men (92.6%) had surgical treatment. The average time from treatment to completion of study was 23.5 months (SD = 11.7; range = 12-52 months). The majority of men did not report erectile dysfunction prior to prostate cancer (74.1%), however, men reported post-treatment erectile dysfunction with a mean IIEF EF Domain Score (0-30) of 16.1 (SD = 5.8) and a mean erection hardness score of 1.48 (SD = 1.18 on a 0-4 scale). Themes identified were frustration with lack of sexual function and the negative impact of that on men’s lives, importance of support and understanding from partner and other people, psychological ramifications (depression and anxiety) related to SD, importance of intimacy with partner, factors that impact treatment satisfaction/dissatisfaction, and education and comprehensive information about sex and intimacy before, during, and after prostate cancer treatment.

Conclusions: Prostate cancer survivors and their partners report a need for accurate information about sexual side effects before, during, and after prostate cancer treatment. Men and their partners want providers to be sensitive to their sexuality and assist them in finding appropriate help to deal with sexual dysfunction. Understanding the impact of the anticipated side effects, like erectile dysfunction, and assisting patients with treating erectile dysfunction, is imperative to treatment satisfaction.

Disclosure: Work supported by industry: no.
Results: A total of 248 men were surveyed with 127 (51%) male PCPs and 121 (49%) female PCPs identified. In total, 64 (26%) of the PCPs asked about sexual dysfunction during a routine visit in the previous year. Of the 64 PCPs addressing male sexual dysfunction 34 (53%) were male and 30 (46%) were female. No measure of statistical association was found to be significant. These findings suggest that the gender of the treating PCP is unrelated to the likelihood of inquiring about male sexual dysfunction.

Conclusions: Prior studies have shown a statistically significant difference between male and female physicians reporting their discomfort when discussing sexual dysfunction with male patients. Our study focused on PCP’s specifically and found no difference in the likelihood of inquiring about male sexual dysfunction in an at risk male patient population based on physician gender. In addition, our study shows that approximately 75% of PCPs are failing to address male sexual dysfunction during routine visits, a figure that is on par with previous studies, despite evidence that ED can be used as an early marker to identify men at a higher risk of cardiovascular disease.

Disclosure:
Work supported by industry: no.

Orgasm in Men on Androgen Deprivation Therapy (ADT) for Prostate Cancer
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Objective: Testosterone (T) is believed to be required for sexual desire, semen production, erectile tissue health and orgasm. There are no analyses assessing orgasm in men with castrate T levels. We aimed to define the prevalence and nature of orgasm in men on ADT.

Materials and Methods: Men presenting to a sexual medicine clinic who (i) were currently on ADT for prostate cancer (ii) had been on ADT for ≥3 months (iii) answered all questions regarding orgasm presence and nature (iv) completed the orgasm domain of the IIEF (v) had documented orgasm prior to ADT and (iv) castrate T levels while on ADT comprised the study group. Predictors were interrogated using a multivariable model. Factors assessed included: patient age, partner presence, ADT duration, type of therapy (1T vs other).

Results: 196 men were evaluated. 12 had ADT as monotherapy (1T), 120 had prior prostate radiation therapy (2T) while 64 had a prior radical prostatectomy plus radiation therapy (3T). Mean age 64±19 (42-79) years with no significant difference between the three groups. 78% of men were partnered. Mean duration of SADT at time of interview was 5 ±11 (3-26) months. 4% (n=8) experienced orgasm while on ADT. All of these 8 patients had a reduction in intensity and ease of achieving orgasm since ADT commenced. 7% (n=14) had retention of sexual desire, but only one half had visceral (biologic) desire, all 14 had intellectual (motivational) desire. On multivariable analysis, the only predictors of libido retention were partner presence (OR 2.2, 1.5-6.4, p<0.05) and any sexual desire retention (OR 11.6, 4.4-13.2, p<0.01).

Conclusions: Orgasm is a rare entity in men on ADT for prostate cancer. The chances of achieving orgasm are greatest in men with a partner and preservation of sexual desire.

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.
Daily Modafinil Treatment may be Beneficial for the Treatment of Lifelong Premature Ejaculation
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Objective: Modafinil is a wakefulness-promoting drug for oral administration. Although the precise mechanism of action is unknown, it interacts with norepinephrine, serotonin, dopamine and GABA containing neuronal systems. Premature ejaculation (PE) is a common but poorly understood disorder with both biological and psychological background. Pharmacotherapy for PE is limited to antidepressants and topical anesthetic agents. This study aims to evaluate the effects of modafinil on the intravaginal ejaculatory latency time (IELT) and patient reported outcomes (PROs) in patients with lifelong PE.

Material and Methods: Treatment naïve lifelong PE patients were included to this proof of concept study. Self-estimated intravaginal ejaculatory latency times (IELTs) of the patients were recorded and Premature Ejaculation Profile (PEP) was administered before the initiation of daily modafinil 100 mg treatment. At the end of the first month of treatment, self-estimated IELTs were recorded again, along with post-treatment PEP outcomes. Paired t-test was used for comparison of variables with normal distribution and Wilcoxon test for variables that were not distributed normally.

Results: Overall, 28 lifelong PE patients with a mean age of 38.86±9.34 (range 22 to 58) years were enrolled. Modafinil treatment significantly increased the mean IELT at the end of first month (26.96±12.12 vs. 34.11±15.87, p=0.002). Moreover, patients reported better control over ejaculation (0.86±0.65 vs. 1.21±0.88, p=0.008) and lesser distress (0.32±0.72 vs. 0.61±0.88, p=0.038) in the PEP questionnaire.

Conclusion: Modafinil prolongs the IELT and improves PRO measures in patients with lifelong PE. Future controlled clinical trials are necessary to confirm these findings.
Figure 1: Comparison of Premature Ejaculation Profile (PEP) questionnaire before and after modafinil treatment

* p=0.008; § p=0.038; ‡ p=0.006

Figure 2: Comparison of intravaginal ejaculatory latency time (IELT) before and after modafinil treatment

* p=0.002

Disclosure:
Work supported by industry: no.
The Significance of Testosterone Levels and the Efficacy of Tadalafil 5 mg Once Daily for Lower Urinary Tract Symptoms

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Objectives: Testosterone (T) regulates nitric oxide synthase and is necessary to achieve an optimum response to PDE5 inhibitors for erectile dysfunction. Recently, tadalafil was found to be effective for treating lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH). We studied the relative importance of the T level in patients with LUTS and determined whether the T level predicts the response to tadalafil 5 mg once daily for LUTS/BPH.

Material and Methods: After a 4-week washout period, 122 men older than 45 years without (n=62, T level ≥300 ng/dl) and with (n=60, T level <300 ng/dl) hypogonadism were given tadalafil 5 mg once daily for 12 weeks. We assessed its impact and the severity of LUTS/BPH using the International Prostate Symptom Score (IPSS) and BPH Impact Index (BII) and IPSS quality-of-life (IPSS-QoL) subscores. Safety was assessed using treatment-emergent adverse events.

Results: The severity of LUTS/BPH was similar in the men with and without hypogonadism. Tadalafil significantly reduced LUTS/BPH from baseline in both groups (IPSS –5.4 vs. –5.1, both p < 0.05; IPSS voiding subscore –3.4 vs. –3.4, both p < 0.05; IPSS storage subscore –2.0 vs. –1.7, both p < 0.05; without and with hypogonadism, respectively). Tadalafil also significantly improved the quality of life from baseline in both groups (IPSS-QoL –1.0 vs. –0.7, BII –1.3 vs. –1.2; both p < 0.05, without and with hypogonadism, respectively). Comparing the groups, the magnitude was significantly larger for the IPSS storage subscore and IPSS-QoL in men without hypogonadism. Tadalafil was safe and well tolerated.

Conclusion: Tadalafil 5 mg once daily improved LUTS/BPH in men with and without hypogonadism. However, the changes from baseline were more prominent in men without hypogonadism.

Disclosure:
Work supported by industry: no.

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Impact of Endogenous Hormonal Status on Successful Treatment of Sexual Dysfunction in Men Taking Once-Daily Tadalafil 5mg for LUTS/BPH

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Objective: Controversy exists as to whether erectile response to phosphodiesterase type 5 inhibitors (PDE5i) is compromised in men with low total testosterone (TT) levels. This is amplified by reports of improved response to PDE5i therapy following co-administration of testosterone replacement therapy in hypogonadal men unresponsive to PDE5i therapy. The purpose of this analysis was to determine if baseline TT and luteinizing hormone (LH) levels influence the efficacy of tadalafil at endpoint (12 weeks) for erectile dysfunction in men with concomitant lower urinary tract symptoms (LUTS)/benign prostatic hyperplasia (BPH).

Methods: This integrated analysis included 1076 men randomized to once-daily tadalafil 5 mg (n=540) or placebo (n=536) for 12 weeks in 3 prospective clinical trials. Subjects were categorized at baseline by low vs. normal TT (<300 ng/dL vs. ≥300 ng/dL) and normal vs. high LH levels (≤9.4 mIU/mL vs. >9.4 mIU/mL). Treatment-group differences (12-week mean changes) in International Index of Erectile Function (IIEF) domain scores by hormone subgroups were assessed using analysis of covariance (ANCOVA). The main outcome measure was change in the Erectile Function (EF) domain score.
Results: The study population was primarily comprised of Caucasian men (>87%) ranging in age from 60-80 years; 1049 men in the pooled studies with baseline TT levels were not receiving testosterone replacement therapy. Median baseline TT level in the overall population was 355 ng/dL; 32.4% were below the 300 ng/dL cutoff for normal. Men with low TT levels reported diabetes (21.8%), cardiovascular disease (54.1%), and hypertension (49.1%) more often than men with normal TT levels (10.6%, 43.2%, and 36.7%, respectively). Low TT and high LH levels were associated with numerically lower changes in 12-week EF domain scores than those with normal levels, although the differences did not reach statistical significance. ANCOVA models for individual changes in 12-week IIEF domain scores by hormone level found no significant treatment-by-baseline hormone subgroup interactions (all \( P \geq 0.10 \)).

Conclusions: Low TT levels and high LH levels at baseline did not influence erectile response to tadalafil in men with LUTS/BPH, suggesting that tadalafil can be used successfully for erectile dysfunction in all men, irrespective of their gonadal status.

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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Prostatic Urethral Lift: BPH Treatment for the Sexually Inclined
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Objective: To report the initial experience and surgical outcomes of the Prostatic Urethral Lift (PUL) procedure in men who desired to maintain maximal sexual function.

Material and Methods: The first 15 patients treated with PUL from two men's sexual health clinics in Tampa, FL were included in this study. Selected patients had medication-refractory lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH), and prioritized maintaining their baseline sexual function post-operatively. All patients demonstrated bilobar prostatic hypertrophy on pre-operative cystoscopy. A student's t-test was used to analyze the pre- and post-operative AUASS and SHIM scores in order to assess voiding and sexual function, respectively.

Results: The average age of the cohort was 63.3 years. Patients were followed for a median of 4 months (range 0.5-16). The median number of PUL implants was 4 (range 2-6). Of the 15 patients, 11 men reported significant improvement in their urinary function. The average post-operative AUASS (15.8, moderate) was significantly improved compared to the pre-operative values (24.2, severe, \( p=0.01 \)). No patient reported a decline in his erectile or ejaculatory function; there was no significant change in the average pre- and post-operative SHIM scores (\( p>0.05 \)). There were two adverse events: one patient experienced post-operative hematuria requiring approximately 24 hours of continuous bladder irrigation (CBI), while another case was complicated by a retained needle of the Urolift device, which required subsequent endoscopic removal.

Conclusions: PUL offers a safe and viable option in the treatment of bladder outlet obstruction secondary to BPH, with no significant impact on the patient’s erectile or ejaculatory function. Expanding the urologic armamentarium to include PUL will allow men's health centers to effectively counsel patients with BPH on treatment modalities that will improve their voiding symptoms while preserving their sexual activity.

Disclosure:
Work supported by industry: no.
The Effect of Hyaluronic Acid/Carboxymethylcellulose Instillation to Prevent Urethral Stricture after Transurethral Bladder Surgery

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Introduction and Objective: To evaluate the effects of hyaluronic acid/carboxymethylcellulose instillation on the occurrence of urethral stricture after transurethral bladder surgery.

Methods: From January 2011 to June 2014, we retrospectively investigated records of patients who underwent transurethral bladder tumor surgery in our hospital. Among 174 patient, 74 patients received hyaluronic acid/carboxymethylcellulose instillation (Group A) and 100 patient did not (Group B). Each patient was evaluated at preoperation, postoperative 12 weeks. Baseline characteristics were compared and the effectiveness of hyaluronic acid/carboxymethylcellulose was evaluated by the International Prostate Symptom Score (IPSS), uroflowmetry parameters.

Results: Baseline characteristics of two group were not significantly different. Urethral stricture occurrence were 2 (2.7%) in Group A and 11 (11.0%) in Group B and significantly different (p = 0.040) (Table 1). IPSS total, obstructive subscore, irritative subscore and Quality of life (QoL) were significantly increased at 12 weeks from baseline in Group B (p = 0.023, 0.030, 0.029 and 0.011, respectively). Maximal flow rate was significantly decreased at the same period (p = 0.018). However, univariate and multivariate logistic regression analysis showed that GUARDIX-SL instillation was not significant protective factor for urethral stricture occurrence (p = 0.057 and 0.057) (Table 2).

Conclusions: During transurethral bladder tumor surgery, hyaluronic acid/carboxymethylcellulose instillation decreased the occurrence of urethral stricture, however it was not significant protective factor. Further well designed studies are needed.

Disclosure:
Work supported by industry: no.

Relationship between Serum Testosterone and Nocturia in Men with Normal Prostate Size

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Background: The association between testosterone and nocturia has been the focus of several investigations, have shown sexual dimorphism. We supposed that the reason for the disparate findings between studies of male and female examining sex hormones in relation to nocturia include obstructive effect of benign prostate enlargement (BPE). We wonder about the relationship between testosterone and nocturia in men without BPE.

Objectives: To clarify the association between serum total testosterone (TT) and nocturia in male without enlarged prostate.

Material and methods: Among 1029 patients were visited our clinic for screening of male health from January 2010 to March 2014, 596 patients without BPE (prostate size ≤30mL) were analysed. To evaluate the effect of serum testosterone on nocturia, multivariate analyses were performed including the covariates of age, IPSS score, IIEF score, BMI, PSA, prostate volume and maximal urine flow rate.
**Results:** Mean prostate volume was 21.70±4.34mL. The multivariate regression analysis showed that Age, the total IPSS and testosterone levels were positively related to the occurrence of nocturia. However, no consistent association with the number of nocturia episodes was seen for testosterone after adjusting for relevant factors.

**Conclusions:** A higher testosterone level was significantly associated with nocturia in our study. Therefore, in men without enlarged prostate, testosterone seems to have an opposing role in etiologies of nocturia.

**Disclosure:**
Work supported by industry: no.

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**Post-Finasteride Syndrome - Outcomes of FDA Database**

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**Introduction/Aims:** Post-finasteride syndrome (PFS) is a cluster of sexual, physical, and psychoneurologic symptoms associated with 5-alpha reductase inhibitor (5ARI) exposure with variable persistent symptoms. Our aim was to help quantify the Food and Drug Administration’s (FDA) Adverse Event Reporting System (FAERS) data to help characterize the cohort and to determine the outcomes and symptoms of 5ARI use.

**Methods:** We collected all 3,295 5ARI cases reported to FAERS from April 2011 to October 2014. We used 38 discrete variables (date, age, outcome, symptoms, location, who made the report, and case type) that were compared to single-dose 5ARI monotherapies (1mg, 5mg, and dose unreported (UR)) for a total of over 77,824 individual data points. ANOVA and Turkey comparison statistics were performed.

**Results:** 2,048 monotherapy cases of finasteride were identified with the following breakdown: 1581 (1mg), 240 (5mg), and 227 unreported doses. After adjusting for dose, finasteride 1mg demonstrated more adverse events than the 5mg and/or the UR doses in the following areas: disability (p<0.001), hospitalizations (p=0.035), sexual dysfunction (p<0.001), libido decrease (p<0.001), ejaculation disorders (p<0.001), erectile dysfunction (p<0.001), testicular atrophy (p<0.001), hypogonadism (p<0.001), orgasmic disorder (p<0.015), skin anomalies (p<0.002), metabolic anomalies (p<0.003), self-harm (p=0.029), slow cognition (p<0.001), psychological pathologies (depression/anxiety) (p<0.001), emotional anhedonia (p=0.021), insomnia (p<0.015). Overall, UR finasteride doses were significant for other symptoms not included in PFS including (seizures, pallor, gastritis, etc.). Duration of symptoms were not analysed due to lack of collection in the FAERS data. Non-significant (p≥0.05) reports of 1mg finasteride were as follows: curvature of the penis, change in penis size, infertility, prostatitis, gynecomastia, fatigue, muscle weakness/pain, hearing defect/tinnitus, and memory impairment.

**Conclusion:** Finasteride 1mg has significant reports of PFS-like symptoms compared to 5mg and UR doses. This peculiar dose-response relationship is questionable, but may result from the publication, selection, reporting, and observer bias’s that are inherent in the FAERS database. Additional studies are needed to authenticate and evaluate why the 1mg dose seems to result in higher rates of PFS-like symptom reports compared to 5mg and UR doses.

**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.
The Effect of Duration of Daily Penile Traction in Patients Undergoing Intralesional Injection Therapy for Peyronie’s Disease

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Objective: The concomitant use of penile traction PT with intralesional injection of interferon alpha-2b (IFN) has been previously described. We present an update on our clinical experience to assess the benefit and duration of daily traction.

Materials and Methods: A retrospective review of patients who underwent IFN therapy between 2001 and 2012 with completed pre- and post-penile duplex Doppler studies was performed. Charts were reviewed and were collected regarding various patient demographics, vascular parameters, objective penile length and curvature measurements and use of PT. PT was further stratified according to duration of daily use.

Results: One-hundred and twelve patients underwent a median of 12 IFN injections (range 6-24). Daily use of PT was reported by 31% of patients. There were no differences in patient demographics, initial vascular status, pre-treatment stretched penile length (SPL), erect penile circumference and curvature between patients who followed a PT regimen and those who did not. Overall use of PT did not impact change in penile circumference (PT +3.2mm [SD 6.5] vs. no PT +2.1mm [SD 7.4], p=0.45), change in curvature (PT -8.1 degrees [SD 16.0] vs. no PT -9.9 degrees [SD 11.8], p=0.49), or change in SPL (PT +2.4mm [SD 0.9] vs. no PT +1.3mm [SD 0.8], p=0.56). Men who used PT ≥3 hours/day, however, gained significantly greater SPL compared to those not using PT (4.4mm [SD 0.5] vs. 1.3mm [SD 0.8], p=0.04).

Conclusions: Daily use of PT during intralesional therapy for PD may provide a small but subjectively meaningful improvement in SPL, without affecting curvature, if used for at least 3 hours a day.

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.

Penile Prosthesis Can Safely and Easily Be Inserted in Patients with Peyronie’s Disease: Results of the PROPPER Study

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Objective: Assess efficacy, safety, and overall satisfaction of AMS 700 penile prosthesis (PP) placement in men with Peyronie’s disease (PD) versus non-Peyronie’s disease (NPD) using the Prospective Registry of Outcomes with Penile Prosthesis for Erectile Restoration (PROPPER).

Material and Methods: The PROPPER registry prospectively evaluates outcomes in men undergoing penile prosthesis. Men complete questionnaires at baseline and annually out to 5 years.
Results: 1038 men underwent insertion of AMS 700 at 11 sites. This is an on-going study; one and two year data is available on 595 (57.3%) patients and 375 (36.1%), respectively. PD patients (n=223) were compared to NPD patients (n=815). Intra-operatively, patients with PD had significantly greater corporal fibrosis than NPD patients (53.2% vs 24.0% (p<0.001)). When operative times were reported there was a significant difference between PD and NPD patients (53.7±35.2 min vs 46.0±27.8 min (p=0.002)). PD patients (44.4%) were more likely to receive a CX cylinder compared to NPD patients (34.6%), while NPD patients (53.1%) were more likely to receive a LGX cylinder compared to PD patients (43.5%). At baseline, men with PD were more likely to report being depressed compared to NPD men (20.0% vs 13.8%, p=0.050). At one and two years follow-up, there was no difference in self reported depression between the two groups (p=0.277 and p=0.704, respectively). Over 75% of PD and NPD patients were satisfied or very satisfied at 1 and 2 year follow-up and there was no significant difference in satisfaction scores between these two groups. There were no differences between PD and NPD patient outcomes in terms of AE (7.2% vs 7.1% (p=0.976)), treatment related AE (6.3% vs 5.8% (p=0.774), device related AE (2.7% vs 3.9% (p=0.384)), device malfunction (1.3% vs 1.5% (p=0.888)), and revision surgery (1.3% vs 3.2% (p=0.139)).

Conclusion: AMS 700 can safely and easily be inserted in PD patients with no significant differences in overall outcomes, patient satisfaction, or adverse events when compared to NPD patients. While there is significantly greater corporal fibrosis in PD patients, this does not lead to greater surgical complications or operative times. Depressive symptoms appear to improve in PD patients following PP placement.

Disclosure:
Work supported by industry: yes, by AMS (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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Preliminary Data In A Longitudinal Analysis of the Psychological and Relationship Impact of Peyronie’s Disease (PD)
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Objectives: Individuals with PD often report psychological distress (manifested as anger, frustration, low self-esteem, negative body image and depression) which appears, based on cross sectional data, not to change significantly over time. The aim of this study is to use validated measures to screen and follow patients through treatment of PD for depression, low sexual self-esteem, and physical and psychological bother due to their symptoms.

Methods: Individuals with PD coming into our Sexual Medicine clinic are given three validated questionnaires at their first visit. Patients meeting predetermined scores in any of the three surveys will be referred to a psychologist specializing in psychosexual counseling. Patients will be given the same questionnaires following initiation and completion of treatment for PD. The questionnaires include: the Center for Epidemiologic Studies Depression Scale (CES-D); the Self-Esteem and Relationship Questionnaire (SEAR); the Peyronie’s Disease Questionnaire (PDQ).

Results: To date, 39 subjects have had an initial evaluation. Mean age was 55±12 years, mean PD duration was 21±23 months and mean penile curvature of 39±20 degrees. 28% percent of the sample had significant depressive symptoms (10% moderate and 18% severe), 38% had low sexual self-esteem, while 51% reported PD specific bother and distress as measured by the PDQ. The relationships among the predictor variables and distress outcome variables were weak and non-significant.
**Conclusion:** The study demonstrates a need for better psycho-sexual screening for patients with PD. Strengths of this approach consist of the use of validated instruments for measurement of psychological and relationship impact and medical expertise on progression and management of PD.

**Disclosure:**
Work supported by industry: yes, by SMSNA Young Investigator Award (industry funding only - investigator initiated and executed study).

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**Positive Results with Collagenase Clostridium histolyticum Treatment in Two Patients with Ventral Penile Curvature Due to Peyronie’s Disease**  
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1: Vanderbilt University, USA

**Objective:** Penile curvature in the ventral direction has the greatest impact on a patient’s ability to have intercourse. After considering the risks and alternatives, two patients elected to undergo a course of collagenase clostridium histolyticum (collagenase) injections into their discrete ventral Peyronie’s plaques. We report the results.

**Material and Methods:** Two patients with 45 and 35 degree ventral penile curvatures due to Peyronie’s Disease chose treatment with collagenase. Both had discrete Peyronie’s plaques involving the ventral surface of the corporal tunic that could be readily identified as separate from the urethra. Both underwent 4 treatment cycles of two injections each. These early results are based on lateral photographs taken the day before the 4'th series of injections.

**Results:** Patient one initially had a stable 45 degree ventral curvature 75% down the shaft that improved to 5 degree ventral curvature in the same location at the time of the 4'th cycle. Patient 2 had a stable 30 degree ventral curvature 60% down the shaft that improved to 5-10 degree ventral curvature in the same location at the time of the 4'th cycle. Both patients reported marked improvement. Neither patient experienced side effects other than local discomfort and minor bruising.

**Conclusion:** The two patients reported here achieved good initial results. Injection of a ventral Peyronie’s plaque is not without risk and currently is not consistent with FDA approved product indications. Nevertheless, Patients with disabling ventral penile curvature due to Peyronie’s plaque must weigh all potential risks when selecting treatment. From the perspective of the two patients reported here, the question was whether collagenase injection had greater risk than traditional surgical treatment.

**Disclosure:**
Work supported by industry: no.

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**Restoration of Penile Function and Patient Satisfaction with Intralesional Collagenase Clostridium Histolyticum Injection for Peyronie’s Disease**  
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1: Mayo Clinic Rochester, USA

**Objective:** Collagenase clostridium histolyticum (CCH) is approved for the treatment of Peyronie’s disease (PD). To date, no post-release study has evaluated patient perceived outcomes and satisfaction.
Therefore, we sought to evaluate patient perceived experience with CCH injection for PD in a clinical practice.

**Methods:** From March 2014 to July 2015, 66 patients underwent one to four series of CCH injections for PD at our institution. Objective changes in penile curvature as well as patient-reported functional outcomes and patient perceived curvature improvements were evaluated.

**Results:** In total, 27 (41%) patients completed four trials, 35 (53%) three trials, and 50 (76%) two trials. Subjective improvements in curvature increased with each series (Trial 1-14%, Trial 2-27%, Trial 3-33%, and Trial 4-40%, p<0.05). Among those completing therapy, 65% reported that CCH injections negated a need for surgery, and 66% reported restoration of penetration. Eighty percent of men perceived CCH treatment as meaningful, and 87% reported subjective improvements following four series of injections. Objective measures demonstrated a mean 22 degree curvature improvement (36%, p<0.0001). Six patients (9.1%) experienced penile hematomas and no patients experienced tunical rupture.

**Conclusion:** CCH injections reduced the need for surgery and restored penetration in the majority of patients completing four series of injections. Subjective improvements in curvature increased with each series of CCH injections, and the majority of patients felt that the therapy was worthwhile.

**Disclosure:**
Work supported by industry: no.

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**Penile Prosthesis Ventral Extrusion: An Unforeseen Consequence of Penile Modeling in Peyronie’s Disease**

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**Objective:** To determine complications arising from penile modeling with concomitant penile prosthesis insertion.

**Material and Methods:** A retrospective chart review was performed to identify complications on patients undergoing penile prosthesis insertion with concomitant modeling of Peyronie’s disease since 2010. All patients with tunical plication or grafting for Peyronie’s disease were excluded from analysis. Outcomes were assessed for adjunctive procedures, surgical revisions, and implant explantations.

**Results:** A total of seven patients were identified having ventral extrusion of the penile prosthesis. The mean preoperative curvature in this patient population was 21.7 degrees. Mean time to ventral extrusion was 18.9 months (range 3.6–17.4). The level of extrusion was variable: tunical thinning (n=3), tunical rupture (n=3), and skin extrusion (n=1). A variety of repairs were performed to correct the condition: distal corporalplasty (n=3), distal corporalplasty with grafting (n=3), unilateral cylinder explantation with urethrorrhaphy (n=1). Two patients required penile plication to perform curvature correction at the time of their ventral repair. Two patients required eventual explantation of their implants due to repeat extrusions. No implant infections occurred.

**Conclusion:** Ventral erosion of penile prosthesis can occur in a delayed fashion following penile prosthesis modeling. A variety of adjunctive repairs can be performed to salvage the penile prosthesis. However, approximately 29% of these repairs will result in explantation due to repeated erosion.

**Disclosure:**
Work supported by industry: no.
Peyronie's Disease Symptom Prevalence, Bother and Risk Factors in Dupuytren's Disease Patients  
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Objectives: Existing evidence suggests an association between Dupuytren’s Disease (DD) and Peyronie’s Disease (PD). In many cases PD may go undiagnosed due to lack of awareness or embarrassment. As many as 20% of men with PD have evidence of DD on examination. The prevalence of PD in men with DD has not been well characterized. We studied the prevalence of PD-like symptoms in a cohort of men with DD.

Material and Methods: Men greater than 18 years of age who were seen in our university’s orthopedics department for DD were invited to complete a 14 question survey; the survey assessed demographics, health factors, and specific items derived from the Erection Hardness Scale (EHS) and the Peyronie’s Disease Questionnaire (PDQ). Additional queries were included to detail willingness to pursue therapy for PD-like symptoms. Descriptive statistics were calculated; Fisher’s exact test was used to assess demographic variables and their association with PD-like symptoms.

Results: Fifty surveys have been completed to date. Median patient age was 65 years. Prevalence of PD-like symptoms was 22% (11/50). No demographic or health factors were clearly associated with prevalence of PD-like changes in this initial small cohort. 2/11 (17%) of men with PD-like symptoms reported EHS 4 erections compared to 19/39 (49%) of men without PD-like symptoms. The most common penile changes reported were new onset curvature, loss of length, and shaft narrowing in 82%, 46%, and 36% respectively. 7 of 11 (64%) of men with PD-like symptoms reported bother and 5/11 (46%) reported that they would be probably or definitely be interested in an office corrective procedure.

Conclusions: The prevalence of PD symptomatology amongst DD patients was similar to previously published data on the prevalence of DD in men with PD. Men with PD-like symptoms tend to have worse erections and are often interested in treatment options. Increasing awareness of PD amongst hand specialists and DD patients may foster recognition and the opportunity for intervention in patients bothered by penile deformity and/or erectile dysfunction.

Disclosure:  
Work supported by industry: no.

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Erectile and Non-erectile Sexual Dysfunction in Men with Peyronie's Disease  
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Objectives: Our primary objective was to evaluate the impact of Peyronie’s disease (PD) on erectile and non-erectile sexual function. Our secondary objective was to investigate associations of specific penile characteristics with domains of sexual function.

Methods: This was a retrospective review of clinical data and Male Sexual Health Questionnaire (MSHQ) responses of men evaluated for PD by a single urologist at a tertiary care center. 45 vasectomy-seeking healthy men who completed the MSHQ were identified as controls. The PD cohort was comprised of 114 men, including 60 otherwise healthy men without any comorbidities. Men with PD underwent pharmacologic erection induction; physical exam of the erect penis; measurement of curvature with a goniometer; and penile duplex Doppler ultrasound (PDDU). Differences in MSHQ erectile domain (EDSS), ejaculatory domain (EjDSS), and satisfaction domain (SDSS) sum scores between men with PD controls were analyzed by t-test. Associations between objectively measured clinical variables and MSHQ sum scores were assessed using the nonparametric Kruskal–Wallis test and multivariable analysis.
**Results:** Median curvature was 37° (STD 20°, range 5-97°). Deformity location was proximal, mid-shaft, and distal in 27, 41, and 32%, respectively. Curvature direction was dorsal, ventral, and lateral in 57, 13, and 30%, respectively. 42.1% had vasculogenic ED (VED) on PDDU. The PD group had lower EDSS (8.99 vs. 13.8, p<0.001), EjDSS (26.1 vs. 31.7, p<0.001), and SDSS (20.3 vs. 26.5, p<0.001) compared with controls. These differences remained highly significant when the subset of PD patients without any comorbidities was compared with controls. PDDU evidence of VED was associated with lower EDSS (p=0.005) and EjDSS (p=0.013). Men with proximal and mid-shaft deformities reported worse EjDSS (p=0.017), weaker force of ejaculation (p=0.007), and lower semen volume scores (p<0.001) than those with distal deformities. We did not observe associations of curvature direction, curvature severity, or other deformities with self-reported sexual function.

**Conclusion:** Men with PD suffer from complex, multifactorial deficits in sexual dysfunction. VED is associated with decreased erectile and ejaculatory function in men with PD. Men with proximal and mid-shaft penile deformities appear to be predisposed to ejaculatory dysfunction.

**Disclosure:** Work supported by industry: no.

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**Characterizing Peyronie’s Disease And Its Response To Intralesional Verapamil In Men Developing Peyronie’s Disease After Radical Prostatectomy**

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**Objectives:** Early data suggest that Peyronie’s Disease (PD) may be associated with Radical Prostatectomy (RP). Intralesional Verapamil (ILV) may be used to help stabilize acute PD. The goal of this project was to evaluate the efficacy of ILV treatment, as well as characterize post-RP deformity compared to idiopathic PD.

**Materials and Methods:** Men with a palpable penile plaque diagnosed with PD were included. Patients with PD were given the option of ILV (10 mg verapamil/5 ml saline) every 2 weeks for a total of 6-12 injections. All patients are evaluated with a curvature assessment with intracavernosal injection assistance. Improvement was defined as ≥10° reduction and worsening ≥10° increase. For multi-planar curvature, the largest initial curvature was analysed. Statistical analyses included: descriptive statistics, independent-measures t-test, chi-square, multiple regression, and logistic regression.

**Results:** 217 consecutive PD patients were analysed. 107 men (49%) had de novo PD (without RP) and 110 men (51%) after RP. Post-RP men were significantly older than de novo men, 57±6 and 51±11 years, respectively, p=0.001. More men with de novo PD were Caucasian (95%) compared to the RP men (85%, p=0.02). A higher percentage of the RP men (35%) had hypertension compared to the de novo men (19%, p=0.01). There was no difference between the groups in presence of diabetes (27%), high cholesterol (41%), coronary artery disease (4%), and smoking (5%). Mean duration of de novo PD was 13±60 months prior to ILV treatment, and post-RP PD was 7±20 months, p=0.35. There were no significant differences in types of curvature or deformity with 57% dorsal, 7% ventral and 36% lateral. Mean baseline curvature was 36±20° in de novo group and 33±17° in RP men. There was no significant difference in the percentage of those whose curvature worsened (de novo 22% vs. RP 25%), remained stable (de novo 49% vs. RP 46%), or improved (de novo 30% vs. RP 30%) (p=0.85). In multivariable analyses, controlling for age, duration of PD, ethnicity and comorbidities there remained no difference in change of curvature between the groups (p=0.96).

**Conclusions:** ILV is an effective treatment for PD which develops after RP, and can successfully be incorporated into treatment regimens to help stabilize the disease.
Assessing the Impact of Change in Penile Rigidity on Degree of Penile Curvature in Men with Peyronie’s Disease (PD)

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Objectives: The cornerstone of PD evaluation is curvature assessment (CA). This is best performed with the assistance of intracavernosal injection (ICI) of vasoactive agent. Not all patients respond with a rigid erection, which may impair the accuracy of the assessment. We analyzed the impact of repeat ICI as well the use of basal compression (BC) on documented magnitude of penile deformity.

Methods: Consecutive patients underwent CA by a single examiner with the assistance of ICI. Rigidity was evaluated using a 0-10 scale with 10 being maximal rigidity and degree of curvature was measured using a goniometer. Repeat ICI was used in men who failed to generate ≥8/10 in penile rigidity. A log was kept of penile rigidity and degree of curvature (DOC) with and without basal compression for each ICI dose.

Results: In 113 patients, the number of ICI used for CA: 113=1, 50=2, 7=3. Mean patient age = 55±10. Mean duration of PD = 22±26 months. Mean curvature at maximum rigidity = 40±22. BC after a single ICI increased mean rigidity by 28% (6.9±1.7 to 8.8±1.5, p=0.001) and also significantly changed mean DOC (33°±23 to 36°±23, p=0.04). In 50 subjects who received a second ICI, again BC improved rigidity (8.2±1.3 to 9.7±0.7, p=0.001) but failed to impact DOC (40°±25 to 42°±26, p=0.13). Compared to a single ICI (even with BC), giving a second injection (without BC) significantly increased rigidity (7.5±1.5 vs 8.2±1.3, p=0.01) as well as DOC (31°±26 vs 40°±25, p=0.002).

Conclusion: When assessing penile curvature, the use of BC to increase penile rigidity does not circumvent the need to give a second ICI. Maximal penile rigidity is necessary to properly assess penile curvature.

Disclosure: Work supported by industry: no.

A Preliminary Report on Xiaflex Therapy Outcomes for Peyronie’s Disease After a Year of Implementation at a Single REMS Institution

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Objectives: The penile curvature, focal pain, and plaque formation found in Peyronie’s disease (PD) carries a significant psychosocial impact for those afflicted. Many patients avoid seeking treatment due to embarrassment as well as fear about undergoing a surgical operation on the penis. Peyronie’s disease has always been considered a surgical disease, and the complications associated with these surgeries (i.e. Nesbitt, plication, excision/incision and patch grafting) caused a worrisome risk associated with loss of penile length, sensation and potency to name a few. Xiaflex, previously reserved for treatment
of Dupuytren’s contracture, was approved for nonsurgical treatment of Peyronie’s disease following a pair of 2013 clinical trials. There has been limited data from individual patient centers outside. Here, we examine the efficacy of Xiaflex in the treatment of Peyronie’s disease at our institution and present our results.

**Materials and Methods:** All patients who visited our institution were offered three categories of therapy once they have achieved the stable phase of their Peyronie’s disease: conservative medical management, Xiaflex, and surgical management. After IRB approval we performed a retrospective review of our patient charts over the past year. A total of 17 men underwent therapy with Xiaflex. The change in penile curvature (in degrees) was measured by a goniometer. The period of follow-up for each patient was 6 weeks after a cycle of Xiaflex. Twelve of the patients received only 1 cycle and 6 patients received 2 cycles.

**Results:** The mean percent change in curve for patients after one 6-week cycle was 15.73%, and over half saw results. The average change in degree of curvature was 8.61 degrees. For cycle 2, the change in degree for the 6 patients was 19.17 degrees. This value was a 33.28% improvement from baseline for these patients after a total of 12 weeks. Nearly 50% improvement in curvature was seen in 4 out of the 6 patients that underwent cycle 2. No patients reported significant swelling, bruising and pain. No reports of penile fracture.

**Conclusions:** The early data from this study supports the use of Xiaflex in the treatment of PD in patients with stable disease. The results mirror the success of the clinical trials and emphasize the potential of Xiaflex as another treatment option for the management of this very frustrating disease. The patient population who improved expressed great satisfaction with the procedure as well as the results of the injections for penile curve.

**Disclosure:**
Work supported by industry: no.

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**Dissecting the Peyronie’s Disease Questionnaire (PDQ): What Matters Most in the Initial Evaluation of Patients with Peyronie’s Disease ?**

**Bryson, C1; Lu, A2; Rosoff, J1; Su, J1; Honig, S1**

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**Objective:** The Peyronie’s Disease Questionnaire is a series of questions that evaluates patient bother as it relates to pain, psychological bother, bother with intercourse and bother with decreased frequency of intercourse. This validated questionnaire (PDQ) has been used for evaluation before and after treatment of PD with intrallesional collagenase. However, its value in the initial evaluation of ALL patients with PD is unclear. The purpose of this study is to evaluation individual questions of the PDQ to determine whether each question can predict total bother score.

**Methods:** 95 consecutive pts seen in a sexual dysfunction clinic were given the PDQ. Evaluation also included past history, PE, and duplex ultrasound. A total bother score was tabulated using four bother-related questions on the PDQ (0-4 for each question, maximum total score: 16). Scores were tabulated for total bother (0-16) and then individually for (1) bother with pain – question 10 (2), psychological bother- question 11, (3) bother with intercourse- question 13, (4) bother with frequency of intercourse-question 15.

**Results:**
The mean score of each of the questions is

Q10: 1.05  Q11: 2.72  Q13: 2.40  Q15: 2.40

Each of the questions Q11, Q13, Q15 also had higher r^2 values than Q10 for predicting total bother score, with Q13 having the strongest correlation with total bother (all p < 0.001)

Q10: r^2 = 0.23  Q11: r^2 = 0.48  Q13: r^2 = 0.67  Q15: r^2 = 0.62
Conclusions: Using the individual questions in the PDQ, bother with intercourse and bother with decreased frequency of intercourse had the closest correlation to total bother score.

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 Peyronie’s Disease Questionnaire Bother Scores do not Correlate with Degree of Penile Curvature in Patients with Peyronie’s Disease
Su, J1; Lu, A2; Bryson, C1; Rosoff, J3; Honig, S3
1: Yale Urology, USA; 2: Yale University, USA; 3: Yale Urology, USA

Objectives: Historically, the initial evaluation of patients with peyronie’s disease (PD) has been based on non-systematic collection of information regarding patient bother. Many pts have depression-related symptoms due to penile shortening, curvature, etc. The validated Peyronie’s disease questionnaire (PDQ) has been used for evaluation before and after treatment of PD with intralesional collagenase. However, its value in the initial evaluation of ALL patients with PD is unclear. The purpose of this study is to establish whether there is a correlation between patient bother and age and degree of curvature in the initial evaluation of patients with peyronie’s disease.

Methods: 95 consecutive pts seen in a sexual dysfunction clinic were given the PDQ. Evaluation also included past history, PE, and duplex ultrasound. A total bother score was tabulated using four bother-related questions on the PDQ (0-4 for each question, maximum total score:16).

Results: The mean pt age was 54.3 yrs and the median disease duration at initial evaluation was 12 mos. The median angle of curvature was 46.8 +/-16.0 degrees based on intracavernosal injection. Of the 82 patients, 24 (29%) were not having vaginal intercourse and were excluded. 55 of 58 patients had penile curvature measurements. Overall, the mean total bother score was 8.5. There was no significant difference in bother score when pts were grouped based on degree of curvature (see table below).

<table>
<thead>
<tr>
<th>Degree of Curvature (n)</th>
<th>Mean Bother Score (Range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-30 (n=11)</td>
<td>8.35</td>
</tr>
<tr>
<td>31-60 (n=37)</td>
<td>8.18</td>
</tr>
<tr>
<td>61-90 (n=7)</td>
<td>9.9</td>
</tr>
</tbody>
</table>

Conclusions: There was no statistically significant relationship between angle of curvature, and bother score on the PDQ. Nevertheless, the PDQ is useful as a validated tool for the initial and longitudinal evaluation of men with PD. Future questionnaires should include bother scores in patients who are not having vaginal intercourse.

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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Effects of Combination Therapy of Tamoxifen, L-carnitine and Daily PDE5 Inhibitors in the Peyronie’s Disease
Kim, JW1; Park, JJ1; Kang, JI1; Kim, JJ1; Moon, DG1
1: Korea University College of Medicine, Korea, South
**Objective:** This study was designed to evaluate the efficacy of combination therapy of Tamoxifen, L-carnitine and daily PDE5 inhibitors and to compare with Potassium para-aminobenzoate(Potaba) monotherapy in the medical treatment of Peyronie’s disease.

**Material and method:** From January 2011 to December 2014, a total of 104 patients with Peyronie’s disease enrolled in this study. Thirty-four patients were treated with Potassium para-aminobenzoate 12g daily (Group 1), while patients of Group 2 were treated with Tamoxifen 20mg and Acetyl L-carnitine 330mg twice a daily in addition to daily PDE5 inhibitors (Tadalafil 5mg once daily) combination therapy. Pain on erection, impossibility of intercourse, plaque size, penile curvature and IIEF-5 were assessed. Plaque volume was assessed by palpation and by ultrasonography.

**Results:** Both groups showed resolution of pain and intercourse satisfaction after treatment. The pretreatment plaque sizes of both groups were 16.97±5.02mm, 17.06 ± 7.19mm, respectively. After treatment, those parameters significantly reduced to 16.19 ± 5.33mm, 13.20 ± 5.61mm. The size of the plaque, penile curvature and IIEF were improved in monotherapy. However, no significant differences were observed. Combination therapy significantly improved the angle of penile curvature, plaque size, and IIEF (p-value < 0.05)

**Conclusion:** Statistically significant improvement in intercourse satisfaction, plaque size, degree of curvature and IIEF-5 was observed in combination therapy. Combination therapy may be the more effective than monotherapy in medical treatment of Pyerone’s disease.

**Disclosure:**
Work supported by industry: no.

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**High Dose Testosterone and Other Performance Enhancing Drug Use in Professional Male Bodybuilders Is Associated with Increased Mortality**

**Allison, A**¹; **Gwartney, D; Pastuszak, AW**¹; **Eisenberg, ML**²; **Canales, S; Stoll, WT**¹; **Lipshultz, LI**¹

¹: Baylor College of Medicine, USA; ²: Stanford University, USA

**Objective:** To assess mortality rates among professional bodybuilders, who frequently use high dose testosterone and other performance enhancing drugs, when compared to the general U.S. male population.

**Material and Methods:** An initial cohort of all 1,578 professional male bodybuilders who competed between 1948-2014 was identified, and complete mortality data were obtained on 597. Proof of life or death was compiled using data from public records, competition listings, bodybuilding websites, and social media venues. Mortality rates among bodybuilders were compared with CDC mortality rates for an age-matched male population.

**Results:** The mean age within the study cohort overall was 47.5 years (range 25.0-81.7) and mean age during bodybuilders’ competitive years was 24.6 years (range 18-47). Of the 597 professional bodybuilders, 58 (9.72%) were reported dead and 539 living. The mean age of death was 47.7 years (range 26.6-75.4). Only 40 deaths were expected in the population based on age-matched data, yielding a standardized mortality rate (95% confidence interval) of 1.45 (1.10-1.88) for these competitors.

**Conclusion:** Mortality rates among professional U.S. male bodybuilders are almost 50% greater than those in an age-matched general U.S. male population. The cause of this increased mortality remains unclear, but mimics a reported increased death rate in professional wrestlers. Current work is focused on determining cause of death by linkage to the National Death Index.

**Disclosure:**
Work supported by industry: no.
Testosterone Enanthate Administered Once-Weekly by Subcutaneous Auto Injector in Men with Hypogonadism: Pharmacokinetic and Safety Results from a Phase III Trial
Kaminetsky, JC; Jaffe, JS
1: University Urology Associates, USA; 2: Antares Pharma, USA

Objective: Pharmacokinetic and safety results from the phase III, double-blind, multicenter Subcutaneous Testosterone Efficacy and Safety in Adult Men Diagnosed with Hypogonadism (STEADY) trial of a novel, pre-filled auto injector (AI) are presented here.

Methods: 150 hypogonadal adult men with baseline testosterone (T) levels of <300 ng/dL received 75 mg of testosterone enanthate (TE) administered via the AI once-weekly for 6 weeks. At week 7, blinded dose adjustments were based on week-6 pre-dose blood levels. Complete PK profiles were obtained at week 12. Protocol success criteria required ≥75% of patients to achieve a C_avg within the range of 300–1100 ng/dL with a lower limit of a 95% 2-sided confidence interval (CI) ≥65%. Further, ≥85% of week-12 C_max values of <1500 ng/dL and no more than 5% of C_max values of >1800 ng/dL were required. Patients without a C_max determination at week 12 were assigned to the above 1500 ng/dL group.

Results: 150 patients received ≥1 dose; 137 patients completed all study procedures at 12 weeks. At week 12, C_avg was within the 300–1100 ng/dL range in 139/150 patients (92.7%) with 95% CI lower limit of 87.3%; C_max was <1500 ng/dL in 137/150 patients (91.3%); C_max was below 1800 ng/dL in all patients. Among the 137 completers at week 12, C_avg was within the 300–1100 ng/dL range in 135/137 patients (98.5%) with 95% CI lower limit of 94.8%; C_max was <1500 ng/dL in 137 patients (100%); and C_max was not >1800 ng/dL in any patients. 137 patients achieved a mean (± standard deviation) steady-state T concentration of 553.3±127.3 ng/dL at 12 weeks. No deaths have been reported. One serious adverse event (SAE) of hospitalization for worsening depression was reported. This patient received a single dose of SC TE. The SAE was not considered related to the study drug. The safety profile of SC TE AI is consistent with other T replacement therapies.

Conclusion: A starting dose of 75 mg TE via the auto injector was shown to achieve T levels within a pre-defined range when dosed once-weekly for 12 weeks in men with hypogonadism. Comparable numbers of patients had increases and decreases in dose based on blood level monitoring. Participants in the study will remain on SC TE AI and followed for an additional 40 weeks. Collection of safety data is ongoing.

Disclosure:
Work supported by industry: yes, by Antares Pharma (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.

Comparison of the Effects of Oral Enclomiphene Citrate and Topical Testosterone Gels Treatment on Serum Hormones, Erythrocytosis, Lipids, and Prostate Specific Antigen
Pastuszak, AW; Wiehle, RD; Fontenot, G; Podolski, J; Lipshultz, L
1: Baylor College of Medicine, USA; 2: Repros Therapeutics, USA

Objectives: To compare the effects of topical testosterone (T) gel and oral enclomiphene citrate in hypogonadal men on serum hormones, lipids, erythrocytosis, and prostate specific antigen (PSA).
**Materials and Methods:** Data from eleven prospective, randomized, blinded Phase 2 and 3 trials of oral enclomiphene citrate, placebo, and one of two topical T gels were analyzed. Men with secondary hypogonadism based on two morning serum evaluations for total T (TT) <300 ng/dL and low-to-normal LH were enrolled; 130 men on T gels, 290 on placebo, and 953 on enclomiphene citrate treatment completed the study protocols. TT, dihydrotestosterone (DHT), estradiol (E), hemoglobin (Hgb), hematocrit (Hct), PSA, total cholesterol (Tchol), triglycerides (TG), LDL-Chol, and HDL-Chol were evaluated at baseline and during follow-up for up to 1 year. Serum parameters were compared using a mixed model linear regression for repeated measures.

**Results:** Both T gels and enclomiphene raised serum TT, DHT and E levels, with a more significant increase in TT and E levels in men on enclomiphene, and a slower return to baseline after treatment was discontinued. In contrast, Hgb and Hct were higher in men on T gels than enclomiphene, although the rate of erythrocytosis (Hct >54%) was low. Small, clinically insignificant increases in PSA were observed with enclomiphene that were not observed in men on T gels. Decreases in TChol, HDL-Chol and LDL-Chol were observed with both enclomiphene and T gels, with more significant changes with enclomiphene. Effects on triglycerides were variable and inconsistent for both enclomiphene and T gels.

**Conclusions:** Enclomiphene therapy results in more significant and sustained increases in TT and E, as well as more significant and sustained decreases in TChol, HDL-Chol and LDL-Chol, than T gel therapy. Enclomiphene may represent an effective, low-risk treatment option for androgen deficient men with few adverse effects.

**Disclosure:**
Work supported by industry: yes, by Repros Therapeutics (industry funding only - investigator initiated and executed study).

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**Testosterone Inhibits the Growth of Prostate Cancer Xenografts in Nude Mice**

*Khera, M*; *Song, W*; *Soni, V*; *Soni, S*

*1: Baylor College of Medicine, USA*

**Objective:** Traditional beliefs of androgen’s stimulating effects on the growth of prostate cancer (PCa) have been challenged in recent years. Our previous *in vitro* study indicated that physiological normal levels of androgens inhibited the proliferation of PCa cells. In this *in vivo* study, the ability of testosterone (T) to inhibit PCa growth was assessed by testing the tumor incidence rate and tumor growth rate of PCa xenografts on nude mice.

**Materials and Methods:** Different serum testosterone levels were manipulated in male mice by orchiectomy or inserting different dosages of T pellets subcutaneously. Also, five million LNCaP cells were injected subcutaneously. Tumor incidence and growth were observed every two to three days for 12 weeks. Tumor incidence rate and growth rate were analyzed.

**Results:** The data demonstrated that low levels of serum T resulted in the highest PCa incidence rate (50%). This PCa incidence rate in mice with low T levels was significantly higher than in mice treated with higher doses of T (24%, P<0.01) and mice that underwent orchiectomy (8%, P<0.001). Mice that had low serum T levels had the shortest tumor volume doubling time (112 hours). This doubling time was significantly shorter than that in the high dose 5 mg T arm (158 hours, P<0.001) and in the orchiectomy arm (468 hours, P<0.001).

**Conclusions:** The results of this study indicated that the relationship of androgens and PCa growth possessed a biphasic pattern in animals. Castrate T levels were not sufficient to support PCa growth, low T levels were optimal for PCa growth, and higher T levels inhibited PCa growth.

**Disclosure:**
Age and Body Mass Index are Independent Predictors of Testosterone Deficiency in Men with Erectile Dysfunction

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1: Columbia University Medical Center, USA; 2: Columbia University Mailman School of Public Health, USA

Objective: To identify clinical predictors of testosterone deficiency syndrome (TDS) that are easily ascertained at initial consultation for men with erectile dysfunction (ED), thereby identifying subgroups that are most likely to benefit from targeted serum total testosterone (TT) measurement.

Material and Methods: Retrospective review was conducted of 498 men evaluated for ED between 1/2013 and 7/2014. Patients with history of prostate cancer or testosterone replacement were excluded. Early morning serum TT measurement (Elecsys 2010 immunoassay, Roche) was offered to all men, and abnormal results were repeated for confirmation. All men completed the self-administered Male Sexual Health Questionnaire (MSHQ). Univariable linear/logistic regression was conducted to analyze 19 demographic, clinical, and MSHQ variables for associations with TT, calculated free testosterone (cFT), and TDS (T < 300 ng/dL or cFT < 6.5 ng/dL). Variables significant on univariable analysis were included in multiple regression models.

Results: 225 men met inclusion criteria. Lower TT levels were associated with greater BMI, less frequent sexual activity, and absence of clinical depression on multiple regression analysis. TT decreased by 9.9 ng/dL for each 1 point increase in BMI. BMI and age were the only independent predictors of cFT levels on multivariable analysis. Overall 62 subjects (27.6%) met criteria for TDS. Only age (p=0.003, OR 1.06, 95% CI 1.02-1.10), BMI (p<0.001, OR 1.17, 95% CI 1.07-1.28), and frequency of sexual activity (p=0.039, OR 0.68, 95% CI 0.47-0.98) were independently associated with TDS on multiple regression. We observed a 2.2-fold increase in the odds of TDS for every 5 point increase in BMI, and a 1.8-fold increase for every 10 year increase in age. When patients were stratified by BMI, TDS was diagnosed in 13.6% of men with BMI < 25, 29.9% of overweight men, 28.0% of obese men, and 64.7% of morbidly obese men (p=0.0004).

Conclusions: Men with ED and comorbid obesity, advanced age, and/or infrequent sexual activity appear to be at high risk of TDS, and such patients represent excellent potential candidates for targeted serum TT testing. Among self-reported sexual domain scores we detected no association of TDS with level of erectile function, sexual satisfaction, or sexual desire; only frequency of sexual activity (inclusive of masturbation) was significant. This may represent a more specific means of assessing TDS-risk among men with 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.
Objective: To determine the availability and ease of purchase of anabolic androgenic steroids (AAS), testosterone (T), and anabolic supplements on the Internet.

Materials/Methods: A Google search was performed using “buy steroids.” The top 10 ranked sites were evaluated for content, and discussion forums and YouTube links were excluded. The availability of agents per site was stratified by AAS, T, anabolic supplements (naturally occurring extracts), and post-cycle recovery and erectile dysfunction medications. Purchase was simulated up to payment entry. Ease of purchase was evaluated by need for prescription, pharmacy location, and payment and delivery options. Supportive information and instruction was stratified by cycle recommendations, recovery information, and non-steroid alternatives.

Results: 8 sites remained after exclusion. The most commonly available synthetic AAS were Dianabol, Deca-Durabolin, Anadrol, Masteron, and Winstrol respectively, on 87% of sites, with 62% offering additional agents. Injectable T preparations including enanthate, cypionate, propionate, and T blends were available on 87% of sites. Only 12.5% offered anabolic supplements or alternatives. Recovery agents available included clomiphene citrate offered by 75% of sites, 62% offered tamoxifen and anastrozole, and 50% offered hCG and letrozole. PDE5 inhibitors were offered by 62% of sites, and one offered intracavernosal alprostadil. For ease of purchase, no site required a prescription, 71% accepted credit card/Paypal, 37% accepted Bitcoin, and all sites supplied international pharmacies shipping directly to home addresses with disclaimers that consumers are liable to local laws. For supportive information, 75% of sites had cycle recommendations, 62% provided post-cycle recovery information, and only one site provided non-steroid alternatives.

Conclusions: AAS and T are readily available and remarkably easy to purchase on the Internet without a prescription. It is of paramount importance that clinicians are aware of this considerable problem given the known significant detrimental effects these agents have on long-term fertility and sexual function.

Disclosure:
Work supported by industry: no.

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Female Post-Finasteride Syndrome: It’s Not Just A Man’s World
Fiuk, J1; Butcher, M1; Kohler, T1; McVary, K1
1: SIU School of Medicine, USA

Introduction: Post-Finasteride Syndrome (PFS) refers to sexual, neurological and physical adverse reactions that persist for at least three months in men who have taken the 5-alpha reductase type II inhibitor. No studies exist that examine this syndrome in finasteride–exposed women.

Materials and Methods: Under the Freedom of Information Act (FOIA), a list of all finasteride related adverse events from April 2011 to October 2014 were obtained from the FDA Adverse Event Reporting System (FAERS). Female cases were identified and reported outcomes were examined.

Results: Out of 3034 total reports, 105 women (3.5%) were identified with adverse events after taking finasteride. Mean age at time of reporting was 38.9 (18-84) years old. Thirty five women (33.3%) were taking Propecia (finasteride 1 mg), 20 were taking Proscar (19.0%), and 50 (47.6%) took finasteride of an unknown dose. Adverse effects are outlined in Table 1. Notably, they include an 8.6% renal failure rate, a 6.7% incidence of new breast cancer, and a 5.7% incidence of temporal lobe epilepsy.

Conclusions: Female PFS represents a small but real subset of finasteride-related long term adverse outcomes. Further investigation of etiology and potential treatment is crucial for this devastating syndrome.
<table>
<thead>
<tr>
<th>Adverse Event Type</th>
<th>Percent Total Affected</th>
<th>Affected Causes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Congenital birth defect</td>
<td>5</td>
<td>Phalangeal agenesis (1); Canavan disease (1); Fetal death (1); Unspecified (2)</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Disability</td>
<td>1</td>
<td>Unspecified (1)</td>
</tr>
<tr>
<td>Hospitalization</td>
<td>15</td>
<td>Renal Failure (9); Thrombocytopenia (1); Urosepsis (1); Breast Cancer (1); Unspecified (3)</td>
</tr>
<tr>
<td>Life threatening</td>
<td>4</td>
<td>Hemorrhagic diathesis (1); Unspecified (2); Breast Cancer (1)</td>
</tr>
<tr>
<td>Other</td>
<td>80</td>
<td>Blindness (7); Suicidal Ideation (2); Sleep Disturbances (2); Deafness (1); Vomiting (7); Dry eyes (3); Unspecified (58)</td>
</tr>
</tbody>
</table>

Disclosure:
Work supported by industry: no.

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A Critical Evaluation of the Readability, Credibility, and Quality of High Ranking Websites Proclaiming to Provide Patient Centered Information on Hypogonadism

McBride, JA1; Lyons, MD1; Vukina, J1; Carson, CC1; Coward, RM1
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Objective: To determine the readability, credibility, and overall quality of the most accessible, patient-centered, online information on hypogonadism.

Materials/Methods: The top 25 Google search results for “testosterone,” “testosterone therapy,” and “hypogonadism” were each separately evaluated and duplicates removed. Included sites contained apparently unbiased information directed to patients, and we excluded advertisements, physician education, pharmaceutical sites, non-medical periodicals, subscription-based sites, lawyer/litigation sites, and bodybuilding/fitness sites. Readability was assessed using Readability Studio™ (Oleander Software, Ltd; Vandalia, OH) to determine reading grade level. Credibility was assessed by site authorship, number of references, number of advertisements, and personal review for medical errors. Quality was assessed by number of educational resources/links per site, breadth of discussion and inclusion of treatment-associated risks.

Results: 20 websites met inclusion/exclusion criteria. 53-60% of included sites were initially within the Google top 10 depending on initial search term used. For readability, 70% of sites were determined to read at ≥ grade 15 or “professor” level. For credibility, 45% were neither authored nor reviewed by a physician, only 25% were Health on the Net Foundation (HON Code) certified, only 50% contained ≥1 reference, 55% had advertisement link(s), and only 1 site was associated with a major medical society (Endocrine Society). For quality assessment, 55% did not comprehensively discuss management of hypogonadism or mention treatment-associated risks.

Conclusions: Most patient-centered websites for testosterone deficiency and/or treatment are well above the average American reading level (7-8th grade) and are of questionable credibility and quality. Websites from the AUA and SMSNA were not represented within the search of the top 25 websites on Google. This work highlights the need for greater availability and accessibility of quality, patient-centered educational information on hypogonadism and treatment on the internet, particularly from the urology community.
Disclosure:
Work supported by industry: no.

Low Plasma Testosterone is Associated with Elevated Cardiovascular Disease Biomarkers
Pastuszak, AW¹; Lindgren, MC¹; Ohlander, SJ¹; Herati, AS¹; Estis, J²; Lipshultz, LI¹
¹: Baylor College of Medicine, USA; ²: Singulex Corporation, USA

Objectives: Few studies have assessed cardiovascular (CV) risk as a function of plasma testosterone (T) level using objective biomarkers. Here we evaluate the relationship between T levels and markers of CVD.

Material and Methods: 10,087 unique male patients were identified in the database of the Singulex® Clinical Laboratory (SCL), which specializes in high sensitivity CVD biomarker testing using SMC™ technology, with results for total T, hs-cardiac troponin I (cTnI), endothelin-1 (ET), N-terminal pro-B-type natriuretic peptide (NTproBNP), interleukin-6, (IL-6), tumor necrosis factor-α (TNF-α), and interleukin-17A (IL-17A). Patients were grouped by total T concentration and associations with the above biomarkers were determined.

Results: Median (interquartile range) age within the cohort was 58 (48-68) years, and plasma T level was 420 (304-565) ng/dL. An inverse relationship between plasma T level and the number of men with increased cardiovascular risk was observed for 6 of 7 cardiovascular markers (Table 1).

Table 1: Percent of patients with elevated CVD biomarkers grouped by T concentrations

<table>
<thead>
<tr>
<th>T Level (ng/dL)</th>
<th>IL-6 (%)</th>
<th>cTnI (%)</th>
<th>TNF-α (%)</th>
<th>IL-17A (%)</th>
<th>ET (%)</th>
<th>NTproBNP (%)</th>
<th>Leptin (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;200</td>
<td>10.8</td>
<td>9.5</td>
<td>14.3</td>
<td>2.4</td>
<td>15.1</td>
<td>23.7</td>
<td>27.3</td>
</tr>
<tr>
<td>200-299</td>
<td>6.2</td>
<td>6.7</td>
<td>11.8</td>
<td>1.8</td>
<td>7.2</td>
<td>15.4</td>
<td>16.1</td>
</tr>
<tr>
<td>300-399</td>
<td>4.8</td>
<td>6.4</td>
<td>9.0</td>
<td>1.4</td>
<td>6.5</td>
<td>15.6</td>
<td>9.4</td>
</tr>
<tr>
<td>400-499</td>
<td>3.6</td>
<td>6.6</td>
<td>7.7</td>
<td>1.2</td>
<td>5.4</td>
<td>15.8</td>
<td>5.6</td>
</tr>
<tr>
<td>&gt;499</td>
<td>3.3</td>
<td>6.1</td>
<td>8.8</td>
<td>1.5</td>
<td>6.0</td>
<td>13.8</td>
<td>2.5</td>
</tr>
</tbody>
</table>

p-value for trend: <0.0001 0.021 <0.0001 0.1031 0.0035 <0.0001 <0.0001

Risk Cutoff: 7.2 pg/mL 6.1 or 5.8 pg/mL 4.2 pg/mL 3.3 pg/mL 3.7 pg/mL 124 or 449 pg/mL 25.2 ng/mL

Conclusions: Our findings support prior published studies demonstrating increased CV risk in hypogonadal men.

Disclosure:
Work supported by industry: yes, by Singulex, Inc. (industry funding only - investigator initiated and executed study).
Testosterone Replacement Therapy in Adolescents with Sickle Cell Disease Reverses Hypogonadism without Promoting Priapism

Morrison, B; Madden, W; Gabay, L
1: University of the West Indies, Jamaica

Objective: Delayed puberty secondary to hypogonadism is commonly seen in sickle cell disease (SCD), affecting the normal growth and development as well as psychosocial status of affected adolescents. The condition is uncommonly treated in SCD for fear of inducing priapism episodes which is also commonly seen in this disorder. A causal association between testosterone replacement therapy (TRT) and priapism in SCD has never been proven, however affected adolescents suffer increased morbidity due to non-treatment. To our knowledge, this is the first report documenting the safety of TRT in adolescents with hypogonadism and SCD.

Materials and Methods: We present 2 case reports of Afro-Jamaican adolescent males at 16 years of age who presented to the Sickle Cell Unit, University of the West Indies, Kingston, Jamaica with symptoms and signs of delayed puberty. Endocrinological assessment revealed low serum total testosterone levels in both males (50 ng/dl; < 20 ng/dl). Serum follicle stimulating hormone, luteinizing hormone and cortisol levels were normal in both. Bone age corresponded to 10 and 11.5 years respectively. One patient reported recurrent ischemic priapism episodes occurring nightly. Both adolescents were treated monthly with 50 mg testosterone enanthate with increasing doses for 12 months. Both patients were monitored serially for changes in total testosterone levels and anthropometric measures.

Results: TRT resulted in increased serum total testosterone in both patients (210 ng/dl at 11 months; 141 ng/dl at 12 months). There was complete resolution of recurrent ischemic priapism episodes after 3 months of TRT in the single patient with a prior history of frequent episodes. No episodes of priapism were induced in the other patient. Both patients had improvement in anthropometric measures and early resolution of delayed puberty.

Conclusion: TRT improved symptoms of delayed puberty in adolescent males with SCD and hypogonadism. The treatment did not appear to promote priapism episodes. Future controlled studies investigating the role of androgens in hypogonadism in SCD are warranted.

Disclosure: Work supported by industry: no.

Low Dose Growth Hormone Releasing Peptide Treatment Does Not Increase Serum IGF-1 Levels in Men

Lindgren, MC; Ohlander, SJ; Sigalos, JT; Pastuszak, AW; Herati, AS; Lipshultz, LI
1: Baylor College of Medicine, USA

Objectives: Few studies have evaluated the effects of growth hormone releasing peptides (GHRPs), such as sermorelin (serm), GHRP-2 and GHRP-6, on growth hormone (GH) and insulin-like growth factor-1 (IGF-1) levels in humans. Here we present data to evaluate the impact of low dose GHRPs on IGF-1 levels as a surrogate marker for GH in men.

Material and Methods: Retrospective chart review was performed for 122 men prescribed either sermorelin 0.5 or 1 mg daily, sermorelin + GHRP-2 (serm/GHRP2) 0.1 or 0.2 mg 1-3 times daily, or sermorelin + GHRP-2 + GHRP-6 (serm/GHRP2/6) 0.1 or 0.2 mg 1-3 times daily. Serum IGF-1 levels, body weight, and body fat percentage were assessed as a function of GHRP prescribed; dose, duration of treatment and concomitant T therapy status were also analysed.
Results: Mean (SD) age within the cohort was 42.6 (21-68) years, and baseline serum IGF-1 level was 163.7 (50-308) ng/mL. Median (range) duration of continuous treatment was 499 (27-879) days. Within the cohort, 11 men were on GHRP therapy alone and the remaining 111 were on concomitant T therapy. Across the entire cohort, serum IGF-1 levels (p=0.21), body weight (p=0.44), and body fat percentage (p=0.89) did not significantly change during follow-up. However, subgroup analysis of men with pretreatment IGF-1 levels < 150 ng/mL yielded a trend towards a significant increase during GHRP therapy (p=0.08). When evaluating men on and off T therapy, no significantly changes in IGF-1 levels were observed. When men were grouped by serm, serm/GHRP2, and serm/GHRP2/6 and subdivided by dose, no significant changes in serum IGF-1 levels were observed.

Conclusions: Low-dose GHRP therapy does not increase IGF-1 levels using standard hormonal testing or changes in body weight or fat. To reach a significant clinical end point, men on GHRP therapy may require markedly increased dose adjustment or direct GH evaluation to better quantitate hormonal changes.

Disclosure:
Work supported by industry: no.

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Effect of Testosterone Solution on Total Testosterone, Sex Drive and Energy in Hypogonadal Men
Heiselman, D1; Dowsett, S
1: USA

Objective(s): We assessed the effect of testosterone solution 2% (Axiron®) on serum total testosterone (TT) concentration and on 2 common symptoms in hypogonadal men, decreased sex drive and energy level.

Material and Method(s): In this randomized, double-blind study, hypogonadal men ≥18 years (serum TT <300 ng/dL) were assigned testosterone or placebo for 12 weeks. The primary objective was to compare the effect of testosterone and placebo on the proportion of hypogonadal men with TT within the normal range (300-1050 ng/dL) at study completion. Secondary objectives were to assess the effect of testosterone on sexual drive and energy level using two new patient-reported outcome instruments, the Sexual Arousal, Interest, and Drive (SAID) Scale and the Hypogonadism Energy Diary (HED), respectively.

Result(s): TT levels were within the normal range after treatment for 217 men (73%) in the testosterone group versus 43 (15%) in placebo (p<0.001). SAID and HED findings are shown (table). There were no significant treatment group differences in reporting of adjudicated CV events (stroke, MI, unstable angina) (placebo, 2; testosterone, 0) or venous thromboembolic events (placebo, 1; testosterone, 0). Elevated PSA (>4ng/mL) was reported in 6 subjects assigned testosterone and 3 assigned placebo (p=0.51), and elevated hematocrit (>54%) was reported in 6 assigned testosterone and 1 assigned placebo (p=0.07).

Conclusion(s): Testosterone therapy resulted in TT concentration levels returning to the normal range in the majority of cases, and improvement in sex drive but not energy levels at the p<0.01 level. The safety findings are consistent with those of prior studies and no new safety concerns were identified.

Table: Summary of SAID and HED findings

<table>
<thead>
<tr>
<th></th>
<th>Placebo (N=357)</th>
<th>Testosterone (N=358)</th>
<th>LS mean difference (95% CI)</th>
<th>Adjusted P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAID scale</td>
<td>6.3 (0.99)</td>
<td>11.4 (1.02)</td>
<td>5.1 (1.05, 9.07)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>HED scale</td>
<td>7.5 (0.87)</td>
<td>10.5 (0.89)</td>
<td>2.9 (-0.59, 6.45)</td>
<td>0.019b</td>
</tr>
</tbody>
</table>

aAnalysis of covariance was used to evaluate baseline-to-endpoint (12 week/LOCF). bNot significant at pre-specified p < 0.01 level.
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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Complications of “Drained and Retained” Urologic Prosthetic Components
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1: University of Kansas Medical Center, USA; 2: University of Utah, USA

Objective: To determine the outcomes and complications of retained, de–functionalized penile implant and artificial urinary sphincter components left in situ following previous revision surgery.
Material and Methods: A retrospective chart review from 2010 to the present was performed to identify complications arising from patients undergoing revision penile prosthesis and artificial sphincter surgery with retained prosthetic components. Outcomes were assessed for adjunctive procedures, surgical revisions, implant explantations, and signs of implant infection.
Results: A total of six patients were identified having retained prosthetic components leading to complications. Complications occurred with both penile prosthesis (n=3) and artificial urinary sphincter (n=3) surgery. Components left behind include penile prosthesis reservoir (n=3), artificial urinary sphincter pressure regulating balloon (n=3), artificial sphincter tubing (n=1). Time to presentation ranged from 3 days to an estimated 10 years after procedure. Six of seven patients developed infectious related complications requiring explantation of the retained component and drainage of an abscess. Adjunctive surgical maneuvers performed in the infectious group include repair of bladder and fistulectomy. One patient had a reservoir migration into the peritoneum requiring exploratory laparotomy for treatment of a bowel obstruction.
Conclusion: Draining and retaining of urologic prosthetic components can cause rare but sometimes serious, delayed complications and tend to be infectious in nature.

Disclosure:
Work supported by industry: no.

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Penile Prosthesis Implantation in Patients with Severe Corporal Fibrosis After Mechanical Therapy
Levine, L¹; Chaus, F ¹; Tsambarlis, P¹
1: Rush University Medical Center, USA

Objectives: Penile prosthesis implantation (PPI) in men with severe corporal fibrosis is a surgical challenge. Vacuum erection device (VED) and traction therapy (TT) have been used for men before PP placement to restore lost shaft length due to corporal fibrosis. It appears that VED may restore cavernosal tissue integrity by drawing blood into the corporal space, which theoretically would facilitate subsequent penile prosthesis placement by softening the fibrotic tissue and allowing easier intracorporal dilation. Over the past 5 years, we have employed a pre-operative protocol of daily VED and TT for several months before PPI for men with severe corporal fibrosis following PP explantation for infection or priapism. Our goal was to assess the success of this approach.
Materials and Methods: We retrospectively reviewed all patients who had a PP implant at our institution between 2010 and 2015. Of these, 13 men had severe corporal fibrosis caused by prior PP infection (11/13) or priapism (2/13). VED was applied for 10-15 minutes 2-3 times daily, 4 men also applied TT for 2-4 hours daily for up to 4 months prior to PPI. Primary outcomes included ease of prosthesis placement and post-VED/TI stretched penile length (SPL) compared with baseline SPL. Patient satisfaction was assessed by the Quality of Life and Sexuality with Penile Prosthesis Questionnaire.

Results: 13 inflatable PP’s were placed with mean follow up of 24 months (range 6-54 months). There was one infection and one revision surgery. VED +/- TT were used for up to 4 months before surgery. Daily average use of VED was 20 minutes daily and for TT was 3 hours per day. Pre-implantation SPL increased 0.5-2cm. All patients had standard size cylinders implanted following local corporotomy scar excision and standard dilators to 12mm. Distal cylinder tips were routinely positioned symmetrically in the mid to proximal glans. Other techniques were unnecessary including corporal scar excavation and multiple or extended corporotomies.

Conclusions: The use of VED prior to surgery appears to result in softening of corporal fibrosis and facilitates implantation of a PP. TT also appears to help in recovery of lost penile length due to corporal fibrosis. Patients noted improved quality of life and sexuality after VED and TT. We strongly recommend preoperative corporal tissue rehabilitation with VED and if possible TT to improve surgical outcomes and diminish difficulty during PP implantation in men with corporal fibrosis.

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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Use of Dorsal Nerve Block with Bupivacaine Liposome Injectable Suspension (Exparel) for Pain Management Following Three-Piece Penile Prosthesis Surgery

King, SA1; Gonzalez, JR2; Goldstein, IP

1: San Diego Sexual Medicine, USA; 2: Southern California Men’s Medical Group, USA; 3: Alvarado Hospital, USA

Introduction: Optimizing postop pain control in men with three-piece penile implant surgery remains an important clinical challenge. Some men with ED experience significant pain and discomfort for several weeks post-op and require large doses of narcotic analgesics. In 2012, Raynor et al reported on the use of dorsal penile nerve block with 10 ml of both short-acting (lidocaine) and moderately-acting (bupivacaine) local anesthetics to provide effective anesthesia for post-op pain control. To the best of our knowledge, there has been limited reporting of use of dorsal penile nerve block with 20 ml of long-acting intra-operative bupivacaine liposome injectable suspension (Exparel) local anesthesia for post-op pain control. Our objective was to determine in a retrospective study based on post-op narcotic use, the effectiveness of an intra-operative long-acting local anesthetic administration as a dorsal nerve block would decrease the number of post-op intravenous morphine sulphate administrations and oral narcotic pain pills utilized in patients undergoing three-piece penile implantations.

Materials and Methods: 16 men who underwent three-piece penile implantations prior to 2011 at our facility served as historic controls. 28 men who underwent such surgery after 2012 received a dorsal nerve block with 20 ml subcutaneous administered long-acting intra-operative bupivacaine liposome injectable suspension (Exparel) local anesthesia as a dorsal penile nerve block for post-op pain control. All patients were prescribed intravenous morphine sulphate during the overnight stay in the hospital and oral narcotics thereafter following discharge. Patients were contacted and provided the estimated number of narcotic pills utilized.

Results: The mean number of total pain administrations taken by the study group over the 4-week post-
op period was 8.2 ± 5.7 compared with an average of 24.1 ± 4.5 (p < 0.001) in the control group. Study patients had significantly less post-op pain and ambulated earlier post-op. Several study patients used no pain medications after 1 week of surgery.

**Conclusions:** This single site retrospective trial has shown that a dorsal nerve block with a long acting bupivacaine liposome injectable suspension (Exparel) local anesthesia can significantly impact long-term post-op pain control. Additional prospective multi-site trials are needed.

**Disclosure:**
Work supported by industry: no.

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**Preoperative Local Anesthetic Block Reduces the Need for Narcotic Medications Following Penile Prosthesis Surgery**

*Weinberg, A¹; Pagano, M¹; Valenzuela, R²*

¹: Columbia University Medical Center, USA; ²: Washington Heights Urology, USA; Columbia University Medical Center, USA

**Objective:** Inflatable penile prosthesis (IPP) surgery plays a vital role in the treatment of erectile dysfunction (ED) and can be one of the most rewarding procedures for both patients and surgeons. Patient satisfaction is high regardless of surgical approach, however pain in the postoperative time period remains a concern for all parties. Often patients are discharged with narcotic based pain medication which can lead to nausea and constipation. The aim of this study was to evaluate the effectiveness and patient tolerance to local penile block anesthesia and postoperative pain for inflatable penile prosthesis surgery.

**Materials and Methods:** 56 men were treated for erectile dysfunction at our institution by IPP, following failure of medical management. The IPP was placed through our modified no touch technique, through a subcoronal incision (sclPP). Local anesthesia was administered using a 23-gauge needle. A total of 40cc of local anesthetic was injected into the pudendal space bilaterally, at the external inguinal ring and subcutaneous penile ring infiltration at the level of the penile root. We used a combination of 0.5% Ropivacane-20cc (Naropin) and 1.0% lidocaine (Xylocaine), without epinephrine, with the addition of sodium bicarbonate (2cc) and dexamethasone (4mg).

**Results:** All 56 men underwent sclPP with local block, 18 (32%) had general anesthesia (GA) and 38 (68%) had monitored anesthesia care (MAC) anesthesia with Propofol drip. The local block took a total of 4 min (3-4.5min). Mean age 63 years (range 39-89) and an average operative time of 38 minutes (range 32-66); there was no statistical difference between the groups. In patients with MAC sedation average total Propofol received was 247 mg, (range 207-465). Pain severity was examined by the Wong-Baker FACES Visual Analog Scale and was documented by nursing staff in the postoperative anesthesia care unit (PACU), and any additional pain medication was administered. Average FACES scale was 4.4 (0-6) for MAC group and 4.5 (0-5) for GA group. Average patient received 2 Percocet tablets (Oxycodone 5mg and Acetaminophen 325mg), prior to discharge. All postoperative patients were discharged with a prescription for NSAID (extra strength Acetaminophen or Ibuprofen) medication for pain control and antibiotics. All patient were evaluated in the office on POD 2 and nine patients (16%) required an additional narcotic prescription; however all patients were off narcotic medications and pain was controlled with NSAID at their second postoperative office visit (POD 7-10).

**Conclusion:** IPP placement continues to be a rewarding surgery for both patients and surgeons, however postoperative pain is a known concern and narcotic medications are known to lead to both nausea and constipation. We conclude that our local anesthesia block was quick to administer, safe and effective in reducing pain in men following penile prosthesis 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.

Medium-term Outcomes of the MINT Technique for IPP Surgery in 180 Consecutive Patients
Love, C; Katz, D
1: Men's Health Melbourne, Australia

Objectives: We have developed a new surgical approach for implantation of inflatable penile prostheses, with the aims of earlier use of the device by patients, avoidance of complications of reservoir placement, longer cylinder implantation, and reduced prosthetic infection rates.

Material and Methods: We have combined two previously described penile implantation techniques from Drs. Eid and Perito, to develop a Minimally Invasive, No-Touch (MINT) penile implant surgical technique. The steps of this procedure include artificial erection with local anesthesia and vaso-dilating medications, small incision and minimal dissection, complete occlusion of patient skin from operative field, and high sub-muscular placement of reservoir, with hernia mesh repair of external inguinal ring at time of reservoir placement. We have prospectively studied 180 consecutive non-selected patients presenting for elective first-time penile implant surgery and analyzed various outcome parameters.

Results: All patients have a minimum of three months post-operative follow-up. There are no infections in this group, including diabetic patients. The average implanted cylinder length is 21.11 cms, some 0.95 cm longer than a previous historical series of implants by the same surgeon. 75 % of patients are able to cycle their devices by 4 weeks post-operatively. Four patients required re-operation for pump related issues, and there were no reservoir complications or reservoir herniation. One patient developed penile glandular necrosis requiring urgent explantation.

Conclusion: Our surgical approach utilizing the MINT technique has met our stated objectives and has proven to be an easily reproducible and teachable approach to penile implant surgery with excellent patient outcomes and very low morbidity.

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.

Preop vs. Postop Penile Length/Girth Maintenance and Satisfaction Following AMS 700 LGX Inflatable Penile Prosthesis Implantation
Gross, M; Henry, GD; Wang, R
1: LSU Health Sciences Center - Shreveport, USA; 2: Regional Urology, USA; 3: UT Health Sciences Center - Houston, USA

Objective: Loss of penile length after IPP implantation is a concern for many patients with ED who choose surgical treatment. The purpose of the study was to evaluate the effectiveness of the American Medical Systems (Minnetonka, MN) 700™ LGX™ cylinders in maintaining penile length post-IPP implantation in patients treated for ED utilizing a modified method of cylinder sizing during implantation and a max-inflate technique after implantation. Success was defined as the distal length of a patient’s penis at 12 months post-implant being greater than the length of that patient’s penis at baseline pre-implant.
**Material and Methods:** A single armed, prospective, two-center study was conducted with patients selected from the existing population experiencing ED without previous prosthetic implantation. The patients were seen periodically between implant and the 24 month visit. The distal length of a patient’s penis at 12 months post-implant as measured using a paper ruler calibrated to the nearest 0.5 cm. Patient satisfaction was also captured on the Penile Prosthesis Patient Satisfaction Survey (PPPSS), and improvement in ED was measured using the International Index of Erectile Function (IIEF).

**Results:** All patients were implanted using the penoscrotal approach. Twenty-six patients, with a mean age of 60.3 ± 7.7, were enrolled. Increases in the width and the circumferences were observed for all the subjects (22/22, 100%) at the 12 month visit. A decrease was seen in stretched penile length (12.5cm to 11.2cm, p=0.0028). High or very high satisfaction was reported in 73% of the patients, 61.5% were satisfied with the length of their erection and 84.5% were satisfied with their ability to have intercourse. No surgical complications were reported.

**Conclusions:** The AMS LGX™ cylinders were able to maintain stretched penile length in 27.3% of patients with an increase in penile girth in 100% of patients. Defining a max-inflation protocol is essential for maintaining or increasing penile length. A scheduled max-inflation technique should be recommended to all patients soon after AMS LGX™ implantation to prevent loss of length.

**Disclosure:**
Work supported by industry: yes, by AMS (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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**A Contemporary Series of Penile Implant Complications Occurring at a Training Institution**

**Kohler, TS; Moore, A; Ring, J**

1: Southern Illinois University SOM, USA

**Objective:** We report on a contemporary series of complications occurring in a training institution necessitating revision surgery following implantation of inflatable penile prostheses.

**Material & Methods:** We retrospectively reviewed the medical records for a total of 240 patients who were treated at a single academic institution for erectile dysfunction with inflatable penile prostheses at two different hospitals from 2009 to 2015 by a single surgeon supervisor utilizing a penoscrotal approach. 200 cases were virgin cases and 40 cases were revision. Diabetes was present in about 30% of cases. The patient database was generated through queries of the hospital billing system using all CPT codes related to implant procedures.

**Results:** 140 patients received Coloplast implants and 100 AMS Implants. Device malfunction occurred in 11 patients (4.6%): 9 AMS vs. 2 Coloplast (p=.0092). AMS malfunctions: 5 “frozen” AMS MS pumps, 2 Conceal® reservoirs leaked, 1 AMS cylinder ruptured. 3 patients (2 Coloplast/1 AMS) developed device aneurysm. 8 (3.3%) patients became infected, in which 7 underwent salvage explanation of the IPP with malleable replacements. 4/7 were successful, with 3/7 requiring malleable explantation for recurrent infection. Of the 8 infected patients, 6 were diabetic (p=.0086) and 3 occurred in revision cases (p=.13). Other injuries consisted of 6 perforations (2.5%): 2 urethral lacerations in reinsertions into scarred corporal bodies, 2 distal urethral injuries with modeling of distal peyronie’s plaques, and 2 delayed bladder injuries after standard reservoir placement into the space of retzius in patients with history of robotic prostatectomy. 4 patients (1.7%) underwent re-operation for miscellaneous events such as pump repositioning (2), one for SST correction and 1 device removal for chronic pain. Overall, 27 patients required revision surgery (11.3%).

**Conclusions:** Our series demonstrates our contemporary results in a training institution with excellent patient retention and follow up. Mechanical failure was the most common reason for re-operation. As a
result of our experience, we prefer adjunct plication over modeling for Peyronies. We also no longer use the space of Retzius after robotic prostatectomy. Diabetes was a clear infectious risk factor in our series. We feel 2 of our 3 malleable salvage failures likely occurred because we failed to treat the local infection long enough with IV antibiotics prior to attempted salvage.

Disclosure:
Work supported by industry: no.

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HIV-Positive Status does not Increase Risk of Penile Prosthesis Infection

Davoudzadeh, N1; Stember, D1; Nagler, H1
1: Mount Sinai-Beth Israel, USA

Objectives: Infection of penile prostheses (PP) is a feared complication that necessitates device removal. Human immunodeficiency virus (HIV) is an immunosuppressive disorder that may raise concern related to increased infection risk following PP surgery. This study was performed to define the impact of HIV status on PP infection risk.

Materials and Methods: Patients that underwent PP surgery at one institution comprised the study population and were retrospectively analyzed. Patients were divided into groups based on presence or absence of HIV co-morbidity at the time of surgery. No patients in the study had acquired immune deficiency syndrome (AIDS).

Results: The analysis included a total of 221 men with a mean age of 64.0 years. Eight urologists performed at least 6 PP each. Of the patients without a diagnosis of HIV, 12/1209 (5.7%) had subsequent infection requiring explant. Among patients with documented HIV co-morbidity, a total of 1/12 (8.3%) developed infection. Fisher’s exact test confirmed absence of a statistically significant difference in infection rates between HIV-positive and negative men (p=0.4721).

Conclusions: HIV positive status is not associated with increased risk of PP infection.

Disclosure:
Work supported by industry: no.

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Treatment Satisfaction after Penile Prosthesis Surgery is Higher for Virgin Cases Compared to Revision Cases

Pineda, M1; Khurgin, J2; Anele, U3; Burnett, A4
1: Johns Hopkins Hospital, USA; 2: Maimonides Medical Center, USA; 3: Virginia Commonwealth University Medical Center, USA; 4: Johns Hopkins Hospital, USA

Objective: High satisfaction rates have been associated with penile prosthesis implantation (PPI). In this study, we compare satisfaction rates between patients undergoing virgin PPI and those undergoing revision PPI.

Material and Methods: We retrospectively analyzed 148 consecutive patients who were seen in our institution between January 2012 and December 2013 for PPI. Using telephone calls, we reached 102 (68%) patients. Of the 102 patients, 21 had previous PPI, and 81 were virgin cases. Patients completed the Erectile Dysfunction Inventory of Treatment Satisfaction (EDITs), the International Index of Erectile Function (IIEF) to assess their satisfaction, and the Centers for Disease Control and Prevention (CDC)
Health-Related Quality of Life (HRQOL) questionnaires. Student’s t-test was performed to compare the mean scores.

Results: Overall satisfaction (OS) of PPI as measured by EDITS was 73.25 for virgin implants versus 51 for revisions (p= 0.01). Patients with virgin PPI were more likely to continue using the device (p= 0.03), more satisfied with how quickly the device worked (p= 0.004), more satisfied with how long the device lasts (p= 0.0004) and more confident about their ability to engage in sexual activity (p=0.008). None of the questions for the IIEF had a significant difference in response between the groups, thus there was no difference in IIEF-Overall Satisfacion and IIEF-Intercourse Satisfaction score. Finally, the CDC-HRQOL, which assess the perception of general, physical and mental health, showed no difference between the groups.

Conclusion: Patients may be counseled that the history of a prior PPI may impact their satisfaction of subsequent PPI.

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 Wang Collar:” A Novel Post Operative Device after Inflatable Penile Prosthesis Placement

Benson, C1; Wang, R2
1: University of Texas at Houston, USA; 2: University of Texas at Houston/MD Anderson Cancer Center, USA

Objective: Since the introduction of inflatable penile prosthesis (IPP) into the United States in early 1970s, IPP has become the most effective treatment modality for erectile dysfunction (ED). However, IPP implantation is still not perfect with greatest complaint of penile shortening after the surgery. Penile rehabilitation after IPP implantation includes leaving the device partially inflated so as to preserve penile length and a method for hemostasis. We describe a novel additional post-operative device, ‘The Wang Collar.’ This device is intended to protect the penis in the early post-operative period when the penis is most sensitive with the partially inflated IPP.

Materials and Methods: Twenty-eight consecutive patients had the “The Wang Collar” included as part of their post-IPP management from August 1 to October 28, 2014. All patients underwent IPP implantation with three-piece IPPs through either penile-scutal or infrapubic incisions. The device devised from a polystyrene cup, which is cut and is then secured with tape over the previously dressed partially inflated penis. The device covers the penis in its entirety, with the urethral catheter emanating from the end of the collar if the Foley is placed. The device is kept in place until post-operative day two and removed along with the remainder of the dressings.

Results: The ‘Wang Collar’ is beneficial in the early post-operative care of our patients. It prevents the penis from rubbing on sheets and clothes, which is a source of discomfort in the first days following surgery. The operating room nurses and the recovery room staff appreciate the device because they no longer worry about manipulating or hurting the penis after initial IPP placement when they are caring for or moving the patients. Anecdotally, these patients commented on less discomfort in the first several days following surgery due to this added protection from clothes rubbing on the partially inflated penis when the penis is most sensitive.

Conclusion: We present a novel penile device after IPP placement, which we have found to improve patient satisfaction in the initial post-operative period. Additionally, it eases the care of the patient by the operating room and recovery room staff. It is now our routine to use this device after IPP surgery. A validated post-operative questionnaire will be developed to further characterize the benefit of this device in the care of our patients.
Subcutaneous Placement of Inflatable Penile Prosthesis Reservoirs
Garber, B¹; Bickell, M¹
¹: USA

Objective: To review our experience with subcutaneous inflatable penile prosthesis reservoir insertion in a large, single-surgeon series.

Materials and Methods: We carried out a retrospective review of 1000 consecutive Coloplast Titan inflatable penile implant procedures carried out by a single high-volume surgeon. Eight patients underwent subcutaneous reservoir placement (SRP), and are the subject of this review.

Results: Eight of our last 1000 patients underwent SRP. SRP was only employed in patients with a thick subcutaneous abdominal fat layer, which would be capable of concealing the reservoir. Seven patients recovered uneventfully, and none reported a palpable or visible reservoir. One patient, who had 5 prior penile implant procedures, developed peri-prosthetic infection, and required complete device removal. Reservoir removal in this obese patient was facilitated by its subcutaneous location.

Conclusions: SRP is a viable option for carefully selected obese patients. We suggest that this approach only be utilized in those with high BMI and a thick subcutaneous abdominal fat layer. In thinner patients the reservoir will be visible and/or palpable; we do not recommend subcutaneous placement under those circumstances.

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.

A Streamline Approach to Inflatable Penile Prosthesis Placement
Weinberg, A¹; Pagano, M¹; Valenzuela, R²
¹: Columbia University Medical Center, USA; ²: Washington Heights Urology, USA; Columbia University Medical Center, USA

Objective: Patients undergoing inflatable penile prosthesis (IPP) surgery often suffer from associated risk factors related to their chronic medical conditions including coronary artery disease, type two diabetes and peripheral vascular disease. General surgery is not without risk and this morbidity has been linked to the length of surgery. Being able to minimize operative time, general anesthesia (GA) and postoperative pain have direct effects on patient care. Spinal anesthesia is a safe alternative, but often prolongs discharge home for ambulatory centers. We have created a streamlined surgical protocol which reduces many "standard" steps that unnecessarily add time to the surgery; such as preoperative groin shaving, perioperative Foley placement and postoperative drain placement. Additionally men often have unknown penile curvature at the time of surgery and treatment may require multiple procedures and surgical incisions to correct this from the traditional IPP implantation techniques (infrapubic or scrotal). We report a prospective review of our surgical experience utilizing a streamlined approach and monitored anesthesia.
care (MAC) with a Propofol infusion, for IPP placement through our subcronal modified no touch technique (scIPP); by a high volume surgeon.

**Materials and Methods:** Prior to conducting this prospective project, we first retrospectively analyzed 20 men who underwent IPP with GA to calculate the time spent to complete what we define as the ten non-surgical “standard” steps that are required for IPP placement (Figure 1); we acknowledge some are out the control of the urologist (Anesthesia procedures and Room Cleanup/Room Setup), however others are unneeded and add to the overall length of surgery. Next we prospectively conducted a trial with a streamlined approach to scIPP placement under MAC (Figure 2): All men voided to maintain post void residual (PVR) of less than 50cc prior to entering the surgical suite, were started with a Propofol infusion and underwent a 10 min scrub of the penis and groin; followed by the administration of a local anesthesia bloc. All patients had scrotal model Titan (Coloplast) IPP placed through our scIPP technique. Following maximum inflation of the IPP the patient’s corpora were inspected for penile curvature or other abnormalities; and subsequently repaired. Patients were transferred to the postoperative anesthesia care unit (PACU) and discharged home when anesthesia criteria was met; patients did not have to void prior to discharge.

**Results:** Of the 38 men who had IPP placement, average age was 66 (55-78), total time (from entering to leaving room) was 54.3 min (40-74), 9 (24%) had penile curvature which was treated; these procedures added an extra 6.4 min (5-18). Mean total Propofol received was 247 mg, (range 207-465). Four men (10%) required conversion to general anesthesia. All patients were discharged home from the PACU after an average of 45 min (30-65). No patients required postoperative intervention for inability to void.

**Conclusion:** Total operative time and length of GA are significant risk factors for postoperative complications, and this effect is increased when patients have significant preoperative comorbidities. Many surgeons perform unneeded steps during IPP placement that can be eliminated, without jeopardizing outcomes. Offering men a safe alternative to general or spinal anesthesia helps to improve overall surgical flow in the hospital or ambulatory surgery center. We present an approach to streamline IPP surgery with the use of MAC anesthesia. However, as the need for booster sedation or GA exists, the procedure should be performed under monitored anesthetic care and pre-operative evaluation should be performed as for general anesthesia.
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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Synchronous Dual AUS/IPP Insertion through a Single Penoscrotal Incision
Yafi, FA1; Peak, T1; Mitchell, G1; Sangkum, P1; Hellstrom, WJG1
1: Tulane University School of Medicine, USA

Objective: Current gold standards of care for patients with significant post-prostatectomy erectile dysfunction (ED) and stress urinary incontinence (SUI) are the inflatable penile prosthesis (IPP) and the artificial urinary sphincter (AUS). We sought to report our experience with dual synchronous AUS/IPP insertion through a single penoscrotal incision.

Materials and methods: We retrospectively collected data on 33 patients who had synchronous dual insertion of AUS/IPP through a single penoscrotal incision between 2009 and 2014. Collected data included various patient, clinical, and surgical parameters. Post-surgical outcomes including erectile function, degree of incontinence, complications, and patient and partner satisfaction rates were also collected.

Results: The median age of the cohort was 64 (range 51-79). Co-morbidities included hypertension (67%), dyslipidemia (52%), coronary artery disease (30%), diabetes (24%), with 21% of the patients receiving post-prostatectomy radiotherapy. Distribution of AUS cuff sizes was 3.5cm (33%), 4.0cm (64%), and 4.5cm (3%). IPPs were 3-piece in 70% and 2-piece in 30%. At a median follow-up of 19 months (1-92), median SHIM score improved from 5 to 25 and median pads per day decreased from 6 to 1. Median patient and partner satisfaction rates were 9/10 and 10/10, respectively. Complications included 3 infections, 2 AUS cuff leaks, 2 AUS erosions and 1 IPP distal erosion, and occurred more commonly in patients with co-morbidities and/or previous radiotherapy.

Conclusions: Dual synchronous AUS/IPP insertion through a single penoscrotal incision is a safe procedure, which can yield excellent results. Diabetes mellitus and previous history of radiotherapy convey a higher risk of device infection and AUS erosion.
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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.