METHODS: After institutional review board approval, a retrospective review was performed on 121 men who received 25-50 milligrams of CC daily and 137 who received transdermal TRT for the treatment of hypogonadism from 2008 to 2013. Potential increased cardiovascular risk was defined as the presence of any of the following: HDL<40, LDL>130, total cholesterol>240, triglycerides>200.

RESULTS: Overall, the median age was 39 years (IQR 33-48) and men underwent CC therapy for a median of 13 months (IQR 7.1-25.4) and TRT therapy for a median of 32.6 months (IQR 10.5-53.2). At baseline, there were no differences in the median BMI ($p=0.57$), and the BMI following treatment did not significantly change for either CC or TRT ($p>0.05$). Within 3 months of therapy, both TRT and CC have significantly higher levels of estradiol compared to baseline (20 to 30 for TRT, 22 to 42 for CC, both $p<0.01$), however the increase is much larger for those on CC than TRT ($p<0.01$). The median total testosterone increased to 508, 522, and 463 after 3, 6, and 12 months on TRT from a baseline of 272 ($p<0.01$), while the median total testosterone increased to 507, 647, and 481 from a baseline of 306 ($p<0.01$). Two-hundred one (77.9%) of the men had at least one cardiovascular risk factor at baseline; after one and two years of therapy, the rate remained above 70%. There were no significant changes noticed in total cholesterol, LDL, HDL, or triglyceride levels with either CC or TRT therapy (all $p>0.05$). There were also no significant differences noted in the level of fasting serum glucose, HgB A1c levels, or IGF-1 levels (all $p>0.05$).

CONCLUSIONS: Neither CC nor TRT therapy significantly altered BMI, cholesterol levels, or glycemic control in hypogonadal men. However, a high percentage of men in this population had significant cardiovascular risk factors because of increased cholesterol at baseline, which did not improve with CC treatment. Prospective trials will be needed to validate these findings and can be used to help counsel patients and guide management.

Source of Funding: none

PD45-09

SCROTOX: SALVAGE PERI-SPERMATIC CORD BOTULINUM-A TOXIN INJECTIONS FOR PATIENTS WITH REFRACTORY CHRONIC SCROTAL CONTENT PAIN AFTER MICROSURGICAL DENERVATION OF THE SPERMATIC CORD.

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INTRODUCTION AND OBJECTIVES: Botulinum-A toxin (Botox) has been shown to modulate the release of neuropeptides leading to inhibition of neurogenic inflammation and chronic pain. This provides an antinociceptive effect. Chronic scrotal content pain is a difficult condition to treat. Microsurgical denervation of the spermatic cord (MDSC) is one surgical treatment option with success rates published in the 60-85% range. However, patients who fail MDSC have limited options. Our goal was to assess the use of peri-spermatic cord Botox injections (Scrotox) to provide prolonged pain relief in men with refractory chronic scrotal content pain after MDSC.

METHODS: Retrospective review of 25 patients who underwent Scrotox (29 procedures: 4 bilateral, 10 right side, 11 left side) from July 2013 to July 2014. All patients had failed prior MDSC. 100 units of Botox diluted in 10cc of saline was injected medial and lateral to the spermatic cord at the level of the external inguinal ring to ablate branches of the genitofemoral, ilioinguinal and inferior hypogastric nerves. The primary outcome measure was the level of pain. Pain was assessed preoperatively and postoperatively using two assessment tools: a) the subjective visual analog scale (VAS) and b) an objective standardized externally validated pain assessment tool (PIQ-6, QualityMetric Inc., Lincoln, RI).

RESULTS: Median age was 43 years. Median duration of pain prior to the procedure was 10 years. Median operative duration was 15 minutes. Median follow up post procedure was 8 months. Subjective VAS patient pain outcomes: 70% significant reduction in pain (14% complete resolution, 56% reported a greater than 50% reduction in pain). Objective PIQ-6 outcomes: significant reduction in pain in 40% of patients at 6 months and 20% at 1 year post-op. There were no complications in our small cohort.

CONCLUSIONS: Scrotox is a potentially safe and viable treatment option for the salvage management of persistent chronic scrotal content pain in patients who have failed MDSC. Further studies are warranted to better understand the long-term durability of this treatment modality.

Source of Funding: none

PD45-10

THE SAFETY AND EFFICACY OF LI-ESWT IN 604 PATIENTS FOR ERECTILE DYSFUNCTION: SUMMARY OF CURRENT AND EVOLVING EVIDENCE

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INTRODUCTION AND OBJECTIVES: Low intensity shock wave therapy (Li-ESWT) is currently approved in over 20 countries and available at over 200 clinics worldwide. A US multicenter study has been completed and the data are currently under FDA review. Herein we provide an overview of the clinical experience to date on the safety and efficacy of Li-ESWT for the treatment of erectile dysfunction. Studies were conducted in men with ED considered responders and in men considered poor responders to PDE5i. We report pooled data from 5 randomized, placebo-controlled studies (USA, Israel, Greece and India) and 3 single-arm open label studies (Israel, Japan). Li-ESWT for ED has been recently included in the European Association of Urology guideline 2013 for male sexual dysfunction

METHODS: The database included men (N=604) using the same treatment protocol with Li-ESWT (ED1000 Medispec applicator; Active Rx N=440; Sham Rx N=164).; Li-ESWT was applied to the corpora 2X weekly for 3 weeks and repeated after a 3 week rest period for a total of 12 Rx sessions. Changes in IIEF-EF domain were assessed at baseline and at mid-treatment; 1 month (FU1), 3 months (3M), 6 months (FU2) 12 (FU3) and 24 months (FU4) post treatment. Objective measurements of efficacy were assessed by various measures including penile US Doppler (Greece, penile triplex), Flow Mediated Dilation (FMD, Israel) and nocturnal penile tumescence (NPT, USA). Incidence and severity of adverse events were recorded.

RESULTS: Results of pooled data revealed that 55%, 61%, 65% and 71% of the subjects achieved a minimally clinical important difference (MCID) in their −IIEF-EF score from baseline at midterm, FU1, FU2 and FU3 and FU4 respectively. The mean change in IIEF-EF from baseline was 5, 6.8, 6.2 and 7 points at midterm, FU1, FU2 and FU3 and FU4 respectively.

Li-ESWT applied via the ED-1000 was well tolerated; reported AEs were mild and resolved spontaneously. Results from selected studies in which objective measures were assessed are presented in table 1.

CONCLUSIONS: In these pooled data analyses, Li-ESWT was demonstrated to be safe and effective for the treatment of ED in men considered responders as well as non-responders to PDE5i therapy. Li-ESWT was well tolerated, adverse events were mild, self-limited and resolved spontaneously. These results support the role of Li-ESWT in the management of men with ED.

Table 1 Results from selected studies in which objective measures were assessed

Country	USA	Greece	Israel	Israel	Israel
	RCT	RCT	RCT1	†Group D	††RCT2
Response to PDE5i prior to Li-ESWT	Responders	Responders	Responders	Responders	Poor responders
‡MCID II-EF EF domain	62% vs. 37.5% in treatment vs. placebo group, p=0.025	58.6% vs.12.5% in treatment vs. placebo group, p=0.003	49.3% vs. 9.1% in treatment vs. placebo group, p<0.01	45.8% vs. 12.5% in treatment vs. placebo group, p=0.021	40.5% vs. 0% in treatment vs. placebo group, p=0.001
IIEF-EF mean change from baseline	6.1 vs.2.5 points in treatment vs. placebo group, p=0.02	4.6 vs.1.4 points in treatment vs. placebo group, p<0.001	5.3 vs. 0.2 in treatment vs. placebo group, p<0.001	5.5 vs. -0.1 points in treatment vs. placebo group, p<0.001	5.4 vs. 0.1 points in treatment vs. placebo group, p<0.001
US Doppler	NA	PSV increased by 4.5 vs. 0.6 cm/sec in treatment vs. placebo, p<0.001	NA	NA	NA

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Country	USA	Greece	Israel	Israel	Israel
	RCT	RCT	RCT1	†Group D	††RCT2
FMD	NA	NA	Mean AUC difference, treatment vs. placebo, 361.3 p=0.002	Mean AUC difference, treatment vs. placebo, 316.9 p=0.002	Mean AUC difference, treatment vs. placebo, 276.2 p=0.001
NPT	Mean difference treatment vs. placebo, 0.52 p=0.016	NA	NA	NA	NA
Population	103 pt. (treatment-84, placebo-40)	46 pt. (treatment-31, placebo-15)	89 pt. (treatment-59, placebo-30)	24 pt.	55 pt. (treatment-37, placebo-18)

†Group D-Subjects from the placebo group of the RCT study, who did not demonstrated significant improvement in their IIEF-EF domain score, received an additional treatment course with an active shockwave applicator. The treatment protocol those subjects received was identical to the original study protocol.††RCT-Subjects that were poor responders to PDE5i prior to Li-ESWT, were allowed PDE5i use at baseline and following last treatment until FU1 assessment (all pt. achieved erection hardness score $\leq$2 at baseline, and EHS$\geq$3 in 62% at FU1 . Population pilot study included).‡MCID (Rosen)-Success define as: an increase in the IIEF-EF Domain score $\geq$2 points from baseline for mild ED, $\geq$5 points for moderate ED, and $\geq$7 points for severe ED. ED Severity define as : Mild ED: IIEF-EF score 17-22 ,Moderate ED: IIEF-EF score 11-16, Severe ED: IIEF-EF score 0-10.

Source of Funding: Medispec Ltd.

PD45-11

SEVERE OBSTRUCTIVE SLEEP APNOEA SYNDROME AND ERECTILE DYSFUNCTION: A PROSPECTIVE RANDOMISED STUDY TO COMPARE SILDENAFIL VS. NASAL CONTINUOUS POSITIVE AIRWAY PRESSURE

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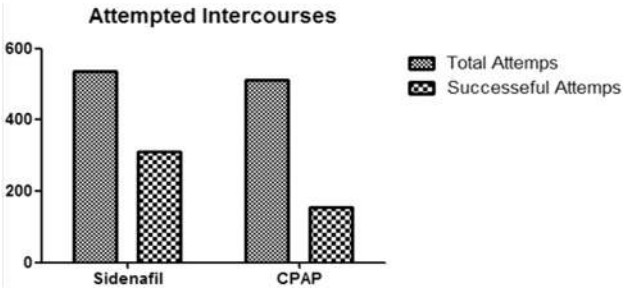
INTRODUCTION AND OBJECTIVES: A high incidence of erectile dysfunction (ED) among patients with obstructive sleep apnoea syndrome (OSAS) has been reported, with a strong correlation between obstructive sleep apnoea, ED, and quality of life (QOL), and it has been estimated that 10−60% of patients with OSAS suffer from ED. In this prospective randomised controlled trial, we investigated 82 men with ED consecutively who were referred to the outpatient clinic for sleep disorders and had severe OSAS(AHI$>$ 30 events/h) without any other comorbidities as a possible cause of ED. The aim of this study was to evaluate and compare the efficacy of sildenafil vs. continuous positive airway pressure (CPAP) in men with ED and severe OSAS.

METHODS: Eighty-two patients were randomised to two main treatment groups: group 1 patients (n = 41) were treated with 100-mg sildenafil 1 h before sexual intercourse without CPAP, and group 2 patients (n = 41 men) were treated with only nasal CPAP during night time sleep. Both groups were evaluated with the same questionnaire (International Index of Erectile Function-EF domain; Sex Encounter Profile; Erectile Dysfunction Inventory Treatment Satisfaction) 12 weeks after treatment.

RESULTS: In patients receiving sildenafil treatment, 58.2% of those who attempted sexual intercourses were successful compared to 30.4% in the CPAP group. The mean number of successful attempts per week was significantly higher in the sildenafil group compared with the CPAP group (2.9 vs. 1.7, respectively; $p < 0.0001$). The mean IIEF-EF domain scores were significantly higher in the sildenafil group compared with the CPAP group ($p < 0.0001$). The overall satisfaction rate was 68% with sildenafil treatment and 29% with CPAP treatment.

CONCLUSIONS: This study confirms that severe OSAS is strongly associated with erectile dysfunction. CPAP and sildenafil (100 mg) are safe and effective therapies for OSAS-related ED patients. In the present study sildenafil was more effective than CPAP in treating ED associated with OSAS, as indicated by a significantly higher rate of successful attempts at intercourse and higher IIEF-EF domain scores. Our study, to date, is the only that has investigated sildenafil in patients with severe OSAS.



Source of Funding: None

PD45-12

AVANAFIL EFFICACY WITHIN 15 MINUTES OF DOSING IN MEN WITH MILD TO SEVERE ERECTILE DYSFUNCTION BY DEMOGRAPHIC AND BASELINE CLINICAL CHARACTERISTICS

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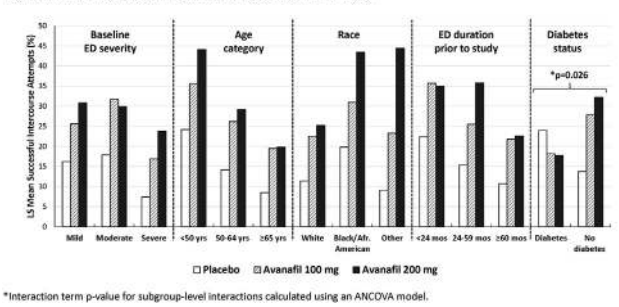
INTRODUCTION AND OBJECTIVES: We examined the efficacy of avanafil, a phosphodiesterase type 5 (PDE5) inhibitor approved for the treatment of erectile dysfunction (ED), within 15 minutes of dosing in subgroups of study subjects defined by: baseline ED severity (mild [International Index of Erectile Function (IIEF)-EF domain score 17-25], moderate, [IIEF score 11-16], severe [IIEF score $\leq$10]); age category ($<$50 years, 50-64 years, $\geq$65 years); race (White, Black/African American, Other); ED duration prior to study entry ($<$24 months, 24-59 months, $\geq$60 months); and diabetes status (diabetes, no diabetes).

METHODS: This double-blind, phase 4 study randomized 440 men $\geq$18 years old with a history of mild to severe ED of $\geq$6 months' duration, to placebo, avanafil 100 mg, or avanafil 200 mg (1:1:1). The primary efficacy variable was the per-subject proportion of all sexual attempts within the 8-week treatment period in which subjects obtained an erection sufficient for vaginal penetration within approximately 15 minutes after dosing ($\leq$17 minutes and 59 seconds) and that enabled successful completion of sexual intercourse. Treatment by subgroup-level interactions were tested for the primary efficacy variable using an ANCOVA model.

RESULTS: No significant interactions between treatment groups and subgroup levels were observed for baseline ED severity, age category, race, or duration of ED prior to study entry. Least squares mean per-subject percentages (model-adjusted) of successful intercourse attempts within 15 minutes after dosing for the placebo, avanafil 100 mg, and avanafil 200 mg groups were: 24.0, 18.2, and 17.8, respectively, for subjects with diabetes, and 13.8, 27.9, 32.2, respectively for subjects without (interaction term p value = 0.026; **Figure**). The 3 most common treatment-emergent adverse events overall were headache, upper respiratory tract infection, and nasal congestion.

CONCLUSIONS: The effects of avanafil treatment were not impacted by baseline ED severity, age category, race, or duration of ED prior to study entry. The significant interaction between treatment effect and diabetes status may have been driven by a greater placebo response in subjects with vs without diabetes and was likely due to chance.

Figure. Per-subject proportion of all sexual attempts during the 8-week treatment period in which subjects obtained an erection within the 15 minute period of dose administration that enabled successful intercourse



*Interaction term p-value for subgroup-level interactions calculated using an ANCOVA model.

Source of Funding: Auxilium Pharmaceuticals Inc. and Vivus, Inc.