

## Sexual Function/Dysfunction: Medical, Hormonal & Non-surgical Therapy II

### Podium 52

Sunday, May 5, 2024

3:30 PM-5:30 PM

#### PD52-01

#### A PHASE 2 RANDOMIZED, PLACEBO-CONTROLLED CROSSOVER TRIAL TO EVALUATE SAFETY AND EFFICACY OF PLATELET-RICH PLASMA INJECTIONS FOR PEYRONIE'S DISEASE: CLINICAL TRIAL UPDATE

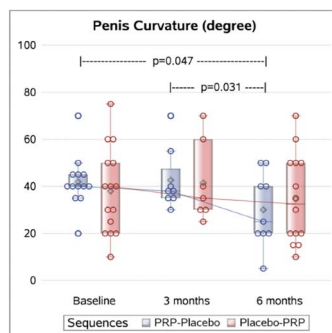
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**INTRODUCTION AND OBJECTIVE:** Peyronie's Disease (PD) is a condition characterized by localized inflammation leading to the formation of fibrotic plaques within the penile tunica albuginea, resulting in penile curvature and painful erections. Existing therapeutic options are limited. Platelet-Rich Plasma (PRP) may be a promising alternative due to its potential to modulate inflammatory processes. However, few placebo-controlled clinical trials exploring PRP's impact for PD exist. This study investigates the safety and efficacy of PRP injections in PD.

**METHODS:** We present an ongoing randomized, placebo-controlled, crossover study conducted at the University of Miami, aiming to evaluate the safety and potential benefits of intralesional PRP injections for PD. We have enrolled 52 subjects into two groups, PRP-placebo sequence (Group A) and placebo-PRP sequence (Group B). Each group receives two injections of PRP and two placebo injections (saline) over six months, with crossover at the midpoint. Immediate and follow-up assessments, including pain scale measurements, goniometer assessments, questionnaires, and curvature evaluations, were conducted at baseline, three months, and six months.

**RESULTS:** Interim analysis of 28 subjects who have completed the study shows PRP's safety and potential efficacy. No minor or major adverse events, such as penile bruising, swelling, edema, allergy, or penile fracture were reported. We also observed a 25% reduction in curvature (median of 10-degree reduction,  $p=0.047$ ) in Group A after six months compared to baseline.

**CONCLUSIONS:** Preliminary data show that PRP injections as safe and potentially effective for PD. These findings, although from a limited sample with complete data, are noteworthy for the absence of adverse events. Current research with extended follow-up aims to clarify the long-term therapeutic role of PRP in PD.



**Figure 1.** Boxplot for penis curvature (degree) with median values connected by sequence. There was a 25% reduction in curvature of median 10 degrees ( $p=0.047$ ) in the PRP-placebo sequence after six months compared to baseline. In the PRP-placebo sequence, the median curvature at baseline was 40 (IQR: 40, 45) and the median curvature at six months was 25 (IQR: 20, 40). There was no significant improvement in curvature observed in the placebo-PRP (Group B) sequence from baseline to six months.

**Source of Funding:** Supported by NIDDK grants R01 DK130991, UE5 DK137308, and Clinician Scientist Development Grant from American Cancer Society to RR

#### PD52-02

#### MULTICENTRE STUDY ON PREMATURE EJACULATION TREATMENT WITH PELVIC FLOOR MUSCLE REHABILITATION: ANALYSIS OF 5 YEARS RESULTS

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**INTRODUCTION AND OBJECTIVE:** The aim of the study was to evaluate the long-term results of pelvic floor muscle (PFM) rehabilitation in males suffering from lifelong and acquired premature ejaculation. To evaluate PE, patients were investigated with intravaginal ejaculatory latency time (IELT) and the self-report Premature Ejaculation Diagnostic Tool (PEDT). The primary outcomes endpoints were the IELT change, and the score reported at the PEDT.

**METHODS:** This retrospective study evaluated 273 subjects with PE diagnosis (lifelong 198 and acquired 75), and a total of 241 pts out of 273 (88%) completed the rehabilitative protocol, whereas 207 pts (75%) attended the follow-up of 5 years. At baseline, all participants reported an IELT  $\leq 60$  s and PEDT score  $>11$ . All Participants completed a 12-week program of PFM rehabilitation, including physio-kinesiotherapy treatment, electrostimulation, and biofeedback, with three sessions per week, with 20 min for each component completed at each session. The effectiveness of intervention was evaluated by comparing the geometric means of IELT times and PEDT scores observed from baseline, to 6, and 12 months during the intervention, and at 24, 36, 48, 60 months postintervention, using a paired sample 2-tailed t-test, including the associated 95% confidence intervals.

**RESULTS:** 241 out of 273 enrolled subjects completed the PFM rehabilitation protocol with 36 sessions of PFM. All patients reported a significant improvement of the ejaculatory time with a mean IELT of 185.4 s and PEDT score of 2.6 at the 12-week endpoint of the intervention ( $p<0.0001$ ). Of the 207 participants who completed the 60-month follow-up, 81%, 78%, 75%, and 66% maintained satisfactory and significant results (ejaculatory latency time and PEDT score) through the follow-up times at 24, 36, 48, and 60 months after the PFM training, respectively.

**CONCLUSIONS:** Our study is the first on PE treatment with a representative number of patients and long-term evaluation (5 years). The results observed are significant and were maintained through the entire follow-up time. PFM rehabilitation in premature ejaculation is an effective therapy with lasting results.

**Source of Funding:** Yaacov D, Nelinger G, Kalichman L. The Effect of Pelvic Floor Rehabilitation on Males with Sexual Dysfunction: A Narrative Review. Sex Med Rev. 2022 Jan;10(1): 162-167. doi: 10.1016/j.sxmr.2021.02.001. Epub 2021 Apr 27. PMID: 33931383

#### PD52-03

#### USE OF THE CNS AGENT BREMELANOTIDE IN MEN WITH SEXUAL DYSFUNCTION: RESULTS FROM A SEXUAL MEDICINE CLINIC

Sue W. Goldstein, Irwin Goldstein\*, San Diego, CA

**INTRODUCTION AND OBJECTIVE:** Bremelanotide is FDA approved for premenopausal women with generalized, acquired hypoactive sexual desire disorder (HSDD). It modulates dopaminergic pathways involved in sexual desire and arousal in men and women and has been reported to increase genital blood flow within hours of

subcutaneous administration. We have been prescribing bremelanotide off-label to men with sexual dysfunctions (SD) after undergoing a biopsychosocial evaluation. The aim was to better understand the use at our clinic of bremelanotide in men, evaluating improvements in sexual function, overall satisfaction, and side effects.

**METHODS:** Bremelanotide prescription dispensing data from our facility was compiled from September 2019 to June 30, 2023 and analyzed for prescribing patterns and refill rates. We performed a one-group study design for men with SD who were prescribed bremelanotide. Participants answered the Quality of Life Dimension of Sexual Quality of Life Questionnaire, Patient Global Impression of Improvement (PGI-I) and General Assessment Questions online. Participants completed a structured interview over the telephone with a single interviewer. Descriptive statistics characterized the study cohort. Adverse events were collected.

**RESULTS:** Over the 46-months, bremelanotide has been dispensed to men for SD 444 times; 65% of dispenses were refills. Over a recent 18 period, refill rates have been 73% (n=219). 25 men signed consent and 20 completed the online questionnaires. 75% of these men were more satisfied with their lovemaking and duration of lovemaking; 88% reported vaginal insertion was easier and 67% said it was easier to orgasm. Concerning feelings about initiating lovemaking, 80% were more at ease and 73% anticipated it would be more pleasurable and more carefree. 64% believed orgasm was more pleasurable and 69% said that lovemaking was more pleasurable while 73% reported that the partner's overall experience was more pleasurable. Using the PGI-I, 72% of participants felt that sexual function after using bremelanotide was a little better, much better, or very much better. Side effects included nausea (30%), flushing (22%), headache (13%), bothersome spontaneous erections without sexual stimulation for about 24 hours after injection (13%), and incontinence, cramping and abdominal burning (4% each). All adverse events were transient.

**CONCLUSIONS:** Bremelanotide acts centrally by raising dopamine, unlike PDE5 inhibitors that act peripherally. Our study showed that bremelanotide safely and effectively improved SD for some men.

**Source of Funding:** Investigator Initiated Research funded by Palatin Technologies

## PD52-04

### ORAL TESTOSTERONE UNDECANOATE (316 MG BID) QUICKLY AND EFFECTIVELY INCREASES SERUM TESTOSTERONE CONCENTRATIONS IN HYPOGONADAL MEN

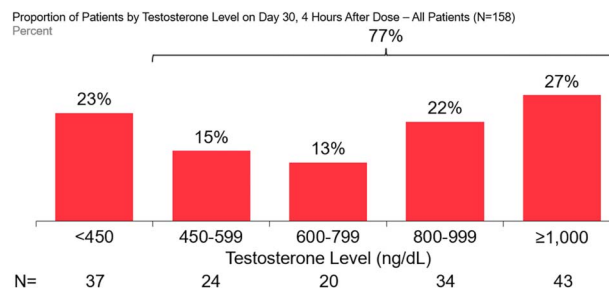
Mohit Khara\*, Houston, TX; Deborah M. Boldt-Houle, Rhea Daugherty, Stuart N. Atkinson, Buffalo Grove, IL

**INTRODUCTION AND OBJECTIVE:** Over 2.4 million US men have hypogonadism, defined as serum testosterone (T) levels <300 ng/dL. Negative effects associated with hypogonadism include development of metabolic syndrome, increased risk of coronary artery disease, decreased libido, low bone mineral density, and muscle loss. Oral T replacement therapies provide a route of administration that may be more appropriate for some patients' needs. We present secondary analyses of T data from a phase 3 study of testosterone undecanoate which is approved in 158, 198, 237, 316, and 396 mg doses, with the goal of demonstrating that a large proportion of patients quickly achieved normal serum T levels.

**METHODS:** A phase 3, randomized, 12-month study was conducted to assess the safety and efficacy of oral testosterone undecanoate (TU) in 325 hypogonadal men. Men  $\geq 18$  to  $\leq 75$  years with morning serum T  $\leq 300$  ng/dL twice in one week were eligible. Eligible patients were randomized to oral TU or transdermal T-gel from Days 0 to 42. The initial oral TU dose was 316 mg TU twice a day (BID) (two 158 mg capsules orally). On Day 30 $\pm$ 3 days, serum T sampling was done 4-6h after the morning dose. Serum T concentrations at Day 30 were evaluated for men treated with 316 mg TU BID.

**RESULTS:** 158 men had serum T data. For men achieving serum T <450 and  $\geq 450$  ng/dL on Day 30 after initial dosing, mean baseline T was 234.04 and 218.5, and mean baseline BMI was 30 and 30, respectively. Overall, mean serum T was 874 ng/dL, 91% achieved serum T  $\geq 300$  ng/dL, 77% achieved serum T  $\geq 450$  ng/dL (Figure 1). See Figure 1 for distribution of T levels achieved with initial 316 mg TU BID.

**CONCLUSIONS:** Overall, 316 mg TU BID quickly and effectively increased serum T concentrations above 450 ng/dL in 77% of hypogonadal men. The wide distribution of serum T concentrations for the same dose (e.g., 23% <450 ng/dL and 27%  $\geq 1000$  ng/dL) suggests that men likely respond differently to T replacement therapy. Future studies and investigations should evaluate patient factors that impact the magnitude of T increases allowing for more individualized titrations.



**Source of Funding:** Tolmar, Inc

## PD52-05

### ENERGY ABSORPTION SIMULATION DURING LOW INTENSITY SHOCKWAVE THERAPY

Irwin Goldstein\*, Alyssa Yee, San Diego, CA; Erich Theuer, Kirchberg, Germany; Nikolaus Hopfenzitz, Konstanz, Germany; John Warlick, Kennesaw, GA

**INTRODUCTION AND OBJECTIVE:** Low intensity shockwave therapy (LiSWT) induces tissue mechanotransduction; the greater the shockwave energy absorption (SWEA) in cavernosal erectile tissue, the greater the opportunity for mechanotransduction regenerative mechanisms to improve erectile function. Effectiveness of LiSWT depends, in part, on applied energy (mJ/mm<sup>2</sup>) and number of applications (total shocks). Although intensity of LiSWT energy cannot be arbitrarily increased due to side effects, SWEA may be improved by performing treatment to an erect versus flaccid penis. Intracavernosal pressure and penile volume are both determinants of velocity of the energy wave in tissue and therefore SWEA in that tissue. Intracavernosal penile pressure when erect is 16-fold higher than flaccid and blood volume when erect is >2 times more than flaccid, therefore LiSWT in the erect state should be associated with greater SWEA. The aim of this study was to perform a simulation of SWEA during LiSWT in both the flaccid and erect penis.

**METHODS:** This energy model used the MTS UroGold electrohydraulic shockwave device [Softwave TRT]. When sound waves pass through an interface between 2 media with different impedances, sound propagation can be significantly altered. Sound propagation in tissue can be illustrated via computer simulation by mathematically calculating the damping and deflection of the sound wave by different tissue structures. Finite Element Method (FEM) simulation models are particularly suitable for the mathematical description of complex processes of shockwave propagation, such as in the flaccid and erect penis. Based on results, a "prediction" of propagation of LiSWT in tissue is possible. This patient-specific procedure is based on consideration of individual anatomical structures: corporal lacunar spaces and physical-acoustic laws. For FEM modeling of LiSWT propagation, program systems ANSYS, MATLAB and PZ-FLEX/ONSCALE were used.

**RESULTS:** Using the FEM calculation model of the simulation analyses, the shockwave pulse is applied at the bottom edge of the