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.

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PD52-04

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

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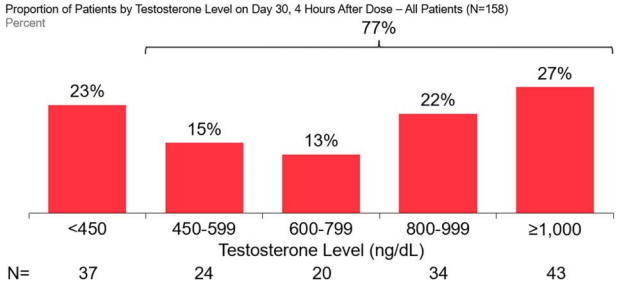
INTRODUCTION AND OBJECTIVE: Over 2.4 million US men have hypogonadism, defined as serum testosterone (T) levels <300 ng/dL. Negative effects associated with hypogonadism include development of metabolic syndrome, increased risk of coronary artery disease, decreased libido, low bone mineral density, and 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 ≥18 to ≤75 years with morning serum T ≤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±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 ≥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 ≥300 ng/dL, 77% achieved serum T ≥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% ≥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.



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PD52-05

ENERGY ABSORPTION SIMULATION DURING LOW INTENSITY SHOCKWAVE THERAPY

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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^2) 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 PZFLEX/ONSCALE were used.

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