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PILOT STUDY OF MED3000 FOR TREATMENT OF ERECTILE DYSFUNCTION AFTER BILATERAL NERVE-SPARING RADICAL PROSTATECTOMY

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INTRODUCTION AND OBJECTIVE: Erectile dysfunction (ED) is a common complication of radical prostatectomy, even with the application of anatomic nerve-sparing techniques. MED3000, a topical erectogenic gel that has shown promise in previous clinical trial data, may offer a novel, non-invasive intervention for ED in this patient population. This pilot study explored the safety and efficacy of MED3000 for treatment of ED in patients status-post bilateral nerve-sparing radical prostatectomy (bnsRP).

METHODS: MED3000 was tested on patients with ED, per the International Index of Erectile Function (IIEF), 1.5-4 years post-bnsRP in a 12-week open-label, non-randomized, single-arm trial. Patients had normal pre-surgical erectile function and had normal baseline testosterone at time of enrollment. Patients who received androgen deprivation therapy, had evidence of biochemical recurrence, or who were treated with radiation therapy were excluded. Patients first underwent a 4-week washout period from other erectogenic aids to establish functional baseline. Patients then received MED3000 monotherapy treatment for 12 weeks and were assessed at 4-week intervals. They were encouraged to attempt sexual intercourse at least four times per month. Interval assessment measures included the IIEF, Self-Esteem and Relationship (SEAR), Expanded Prostate Cancer Index Composite (EPIC), and degree of climacturia.

RESULTS: A cohort of 20 patients were initially enrolled. 19 patients (mean 64.6±4.6 years) completed at least one on-treatment questionnaire set and 17 patients completed the entire 12 week treatment phase. 17 patients were white/non-Hispanic and two patients were black/non-Hispanic. Baseline post-washout ED classification was 84% severe, 11% moderate, and 5% mild to moderate. Paired t-tests between baseline and 4, 8 and 12-week scores on the IIEF Total, IIEF-EF domain, SEAR, EPIC total, EPIC-sexual domain, and frequency of climacturia did not demonstrate statistically significant differences at any time points (Table 1). There were no adverse events reported.

CONCLUSIONS: In this pilot study, our findings show MED3000 was well tolerated but did not demonstrate efficacy in improving EF in post-bnsRP patients with predominantly severe ED.

Table 1. Questionnaire Results

	Mean change from baseline to 4 weeks	Mean change from baseline to 8 weeks	Mean change from baseline to 12 weeks
IIEF-EF	0.8 (p=0.2)	0.8 (p=0.4)	0.8 (p=0.4)
IIEF Total	0.7 (p=0.7)	-0.1 (p=0.9)	0.4 (p=0.9)
EPIC-Sexual domain	-0.3 (p=0.7)	-0.4 (p=0.4)	-0.1 (p=0.9)
SEAR	3.0 (p=0.5)	2.4 (p=0.5)	1.5 (p=0.3)

Source of Funding: Futura Medical supplied MED3000

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SHOCK WAVE THERAPY IN THE TREATMENT OF ERECTION DYSFUNCTION: HOW TO DEFINE REAL CLINICAL OUTCOMES? A BLINDED, SHAM-CONTROLLED TRIAL

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INTRODUCTION AND OBJECTIVE: The use of penile Doppler ultrasound under pharmaco induction in the evaluation of patients with vasculogenic erectile dysfunction has been proposed in several international guidelines. The erection hardness score (EHS) is also a clinical tool in the evaluation of these patients after pharmacoinduction.

However, there is a lack of evidence to determine which is the best clinical assessment tool for erectile dysfunction and also the response to shock wave therapy. The objective of this paper is to define the best tool for evaluating erectile dysfunction in patients undergoing low-intensity shock wave therapy (penile Doppler vs. EHS) using the international sexual function index in its summarized version as a control reference parameter.

METHODS: Twenty-one participants with purely vasculogenic erectile dysfunction were selected and randomized (2:1) to shock wave therapy (n=14) or sham (n=7). All patients underwent evaluation with IIEF-5, EHS, and penile Doppler ultrasound prior to and after shock wave therapy (1, 3, and 6 months). Patients with erectile dysfunction of non-vascular etiology (neurogenic, post-prostatectomy, endocrine disorders, or psychological causes) were excluded according to clinical history and results of laboratory tests.

RESULTS: Using the IIEF-5 as a control tool, we obtained a clinical response after 1 month, with a greater increase in the shock wave therapy arm of +3.21 points compared to the sham group of +0.57 points, a difference that was not statistically significant (case = +3.21 vs. control - sham=0.57, p=0.128). At six months after treatment, the treated group showed an average increase of 4.71 points compared to baseline (p=0.006), while those who received sham therapy had a decrease of 1.00 points (case = +4.71 points vs. sham control = -1.0, p=0.006). Based on this difference observed between the groups, we carried out a comparative analysis between the EHS and the penile Doppler ultrasound to observe whether the test results corroborated the IIEF-5 findings. The group that received the therapy had a 23% increase in EHS in the first month and 41.15% in 6 months, reaching an average of 3.43 points. In the evaluation by penile Doppler ultrasound, there was an increase in peak systolic velocity in the control group compared to the placebo group, but without statistical significance.

CONCLUSIONS: Low-intensity shock wave therapy proved to be effective in addressing vasculogenic erectile function, with results observed from 3 months being optimized at 6 months post-treatment. The use of the erection hardness score appears to offer a more reliable measurement of erectile dysfunction when compared to penile Doppler ultrasound.

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RESULTS OF PREDICTABLE UP TITRATION OF ORAL TESTOSTERONE UNDECANOATE IN A PHASE 3 RANDOMIZED TRIAL

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INTRODUCTION AND OBJECTIVE: >2.4 million US men have hypogonadism, defined as a serum testosterone (T) level <300 ng/dL with symptoms of T deficiency. Hypogonadism can result in the development of metabolic syndrome, increased risk of coronary artery disease, decreased libido, low bone mineral density, and muscle loss. While oral testosterone therapies provide a route of administration that may be more appropriate for some patients' needs, effective dose titration remains a key challenge for clinicians as they often need to titrate multiple times for patients to achieve target T levels which is labor-intensive. Herein, we present secondary analyses of post-titration changes in T levels from the phase 3 inTUNE study of oral titratable testosterone undecanoate (TU).

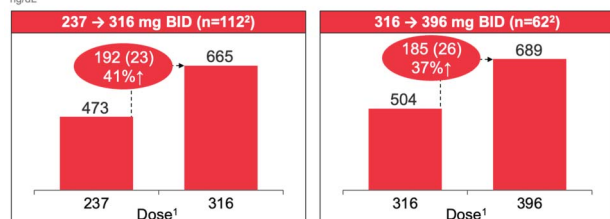
METHODS: A phase 3, randomized, active controlled, open-label study assessed the safety and efficacy of oral TU (approved in 158, 198, 237, 316, and 396 mg doses) in 166 hypogonadal men. The initial oral TU dose was 237 mg TU twice a day, which is the approved starting dose. Patients were allowed to titrate up on Days 35 and 70 if their 24-hr average T concentration on Days 21 and 56 was <350 ng/dL. Serum T measurements were taken before and after each titration adjustment (Days 21, 56 and 105, respectively) at 2, 4, 6, 9, 12, 14, 16, 18, 21 and 24 hours after the morning TU dose. Serum T at 4-hr post dose was analyzed in this secondary analysis.

RESULTS: A total of 116 patients required up-titration based on 24-hr average T levels below 350 ng/dL on the standard dosing of TU, resulting in 174 up-titration events. On average, up-titration from 237 to 316 mg and from 316 to 396 mg resulted in a mean of 192 and 185 ng/dL rise in T at the 4-hr post dose, respectively (Fig 1). 34% and 41% of patients required 1 and 2 titrations, respectively.

CONCLUSIONS: Patients observed a mean serum T increase of around 190 ng/dL with up-titrations from 237 to 316 mg and from 316 to 396 mg. Around 75% of patients required 1-2 titrations to reach therapeutic T levels. These results suggest it may be beneficial to start men at a higher starting dose of TU than the approved dosing regimen to minimize multiple time-intensive dose titrations and allow patients to reach therapeutic T levels in a more timely manner. Future studies should aim to evaluate patient-specific variables to determine which patients would benefit from starting at higher TU doses initially to guide clinician management of hypogonadism.

Fig 1: Mean T and Change in T with Increased Dose

Mean (SE) Serum T Before and After Dose¹ Increases (237, 316, 396) – 4 Hours Post Dose
ng/dL



1 All dosing is given twice daily (mg BID)

2 n is the number of up-titration events; Only patients with T values on all study days were included; T values for each patient are an average of Serum T values at hours 4 and 16 on Days 21, 56 or 105; 1 patient from 198 to 237 mg BID titration not included

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CLOMIPHENE CITRATE THERAPY EFFECTS ON LIPID PANELS IN MEN WITH HYPOGONADISM

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INTRODUCTION AND OBJECTIVE: Clomiphene citrate (CC) is a selective estrogen receptor modulator used to improve testosterone production in men with hypogonadism. CC is commonly used in Andrology clinics with known side effects such as elevated estradiol levels and gynecomastia. There are several case studies of severe hypertriglyceridemia in women on CC, but little data exists evaluating the impact of CC on lipid panels in men. This study aims to assess the impact of treatment with CC on lipid panels in hypogonadal men.

METHODS: A retrospective review was performed on patients presenting to a Men's Health clinic for hypogonadism from January 2020 - September 2024 that had complete lab panels pre- and post-CC treatment. Pre-treatment endocrine and lipid profiles were compared to panels collected 4 weeks after beginning treatment. Labs collected include total testosterone (TT), free testosterone (FT), estradiol (E2), hematocrit (Hct), hemoglobin (Hg), triglycerides (TG), total cholesterol (TC), high density lipoproteins (HDL) and low density lipoproteins (LDL). Labs were collected before 11am, fasting, using LCMS and equilibrium dialysis for the lipid panels.

RESULTS: 52 men with a mean age of 42.4 had complete lab data and were included in this study. Mean TT levels were 322 ng/dl pre-CC and 502 ng/dl post-CC treatment. Pre-CC TG, TC, HDL, and LDL means were 141.9, 172.4, 43.3, and 100.9, respectively. Post-CC TG, TC, HDL, and LDL means were 140.9, 171.5, 40.1, and 103.2, respectively. We found no statistically significant difference in the change of triglyceride ($p=0.903$, $SD=39.3$), total cholesterol ($p=0.783$, $SD=14.01$), and low-density lipoprotein ($p=0.447$, $SD=24.3$) lab values before and after treatment with CC. We did

however find a statistically significant decrease in high-density lipoprotein lab values ($p<0.001$, $SD=12.95$).

CONCLUSIONS: Men on CC therapy for hypogonadism showed a statistically significant decrease in HDL levels after 4 weeks on clomid. While many men remain on clomid for an indeterminate time frame this is an area that deserves further investigation with larger population samples to determine the significance of this finding and long-term outcomes of CC on lipid profiles.

	Pre-CC Mean \pm SD	Post-CC Mean \pm SD	Pre-CC Range	Post-CC Range	P-Value (n = 52)
Total Cholesterol (mg/dL)	172.4 \pm 33.6	171.5 \pm 33.8	89-253	99-247	0.783
Triglycerides (mg/dL)	142 \pm 71.2	141 \pm 77.5	41-330	44-380	0.903
HDL (mg/dL)	43.3 \pm 10.0	40.1 \pm 10.2	31-77	21-73	<0.001
LDL (mg/dL)	101 \pm 29.8	103 \pm 32.7	28-163	42-174	0.447
Total Testosterone (ng/dL)	320 \pm 233	501 \pm 207	23-1349	55-1024	<0.001
Free Testosterone (pg/mL)	60.0 \pm 35.2	98.4 \pm 50.5	4.7-216	6.4-213	<0.001
FSH (mIU/mL)	10.2 \pm 9.80	12.2 \pm 10.9	1.5-44.9	1.1-59.1	0.129
LH (mIU/mL)	6.11 \pm 4.13	8.71 \pm 7.00	1.3-22.3	1-37.2	0.00234
SHBG (nmol/L)	23.4 \pm 7.79	27.3 \pm 9.65	10-48	6-53	<0.001
Prolactin (ng/mL)	7.80 \pm 3.17	7.80 \pm 3.25	2-21.8	1.3-19.3	0.996
Estradiol (pg/mL)	29.7 \pm 23.8	42.4 \pm 28.5	10-164	15-214	<0.001
Hemoglobin (g/dL)	14.6 \pm 1.1	14.6 \pm 1.2	37.1-49.4	37.0-51.8	0.921
Hematocrit (%)	43.3 \pm 3.3	43.31 \pm 3.4	37.1-49.4	37-51.8	1
PSA (ng/dL)	0.717 \pm 0.570	0.824 \pm 0.700	0.008-3.5	0.008-3.96	0.023
HbA1c (%)	5.77 \pm 1.2	5.66 \pm 0.5	4.6-13.7	4.5-7	0.44

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IP10-29

MANAGEMENT OF PRIAPISM AND ITS IMPACT ON OUTCOMES: AN INTERNATIONAL REGISTER (MARS STUDY) &NDASH; THE FIRST INTERNATIONAL, MULTICENTER, OBSERVATIONAL STUDY REGARDING PRIAPISM

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INTRODUCTION AND OBJECTIVE: Priapism is a medical condition characterized by persistent and often painful erections that last more than 4 hours and that is not associated with sexual stimulation or sexual desire. As a relatively rare condition priapism affects 1.5 per 100,000 person-years. Despite different type of priapism requires targeted treatments, the goal is certainly to relieve the prolonged erection and prevent complications as irreversible damage of erectile tissue.

METHODS: This project has been conducted by the YAU-Sexual and Reproductive health group and the EAU-research foundation and aims to present the first international, multicenter, observational study regarding priapism, the MARS study. Actually, 16 centers from six countries are participating the study.

RESULTS: The study included 92 patients (median age of 41.9 years). 75% had ischemic priapism, 14.13% had hematological disorders, 19.56% reported using erectile medications and 16.30% recreational drugs, particularly cocaine (9.78%). About 35% initially tried conservative treatments with resolution of the condition in 28.26% of cases. Surgical approaches, such as shunt procedures, were used in 41.30% of cases. Only half received prosthesis implants with preference between delayed (7.60%) or immediate (7.60%) implantation, but a slight preference of inflatable prostheses (8.69%) over semirigid ones (6.52%). Corpora fibrosis (18.47%) and Erectile dysfunction (14.13%) were the most common complication at 3 months follow up, followed by corpora necrosis (1.1%) and penile curvature (1.1%). When analyzing priapism by subgroups—ischemic, non-ischemic, and stuttering, a statistically significant differences in IIEF-5 scores were observed in the ischemic group, declining from baseline to 3-month (20 vs. 16; $p=0.01$) and 6-month follow-ups (20 vs. 3; $p<0.01$). When analyzing the association between the use of conservative