gel, using a prefilled syringe system. Patients were instructed how to properly insert to promote absorption and maximize outcomes.

Rsults: Comparing pre-BMG and post-BMG Sexual Health Inventory for Men (SHIM) scores, the average was 7.02 (range 0-20) and 15.78 (range 0-25), respectively. The pre-BMG scores represent patients potentially being on some other form of ED therapy. Patients responded favorably, and all positively responded regarding the medication's efficacy. Favorite aspect of the therapy was its needle-free drug delivery system. No adverse events were reported. Most common complaint was some burning with application.

Conclusions: As another weapon in the urologists' armamentarium, BMG may have several advantages over both phosphodiesterase inhibitors (PDE5-I) and traditional, ICI. We showed a change in average SHIM score of 8.76, comparable to other treatment modalities. BMG can be stored at room temperature (although refrigeration still recommended) and provides greater stability (versus ICI). This needle-free option for Bimix is an important addition in sexual medicine, as patients require alternatives for ED care. These follow up results with BMG are favorable, yet further clinical data will help solidify it amongst the other treatment modalities for ED.

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RETROSPECTIVE REVIEW OF IMPROVEMENT OF ERECTILE FUNCTION AFTER LOW INTENSITY SHOCKWAVE TREATMENT WITH UROGOLD 100^{TM}

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Introduction: Erectile dysfunction (ED) can result from insufficient arterial blood inflow and/or from veno-occlusive dysfunction from reduced erectile tissue expandability secondary to erectile tissue fibrosis. Non-surgical strategies to manage ED in the United States (US) are primarily symptomatic-based, such as PDE5 inhibitors and/or intracavernosal injections. In Europe, disease modification strategies such as Low Intensity Shockwave Treatment (LiSWT) using energy levels 0.09 − 0.12 mJ/mm^2 have shown, in multiple sham-controlled prospective studies, significant improvement in both ED outcome measures and blood inflow. The European Urological Association lists Li-SWT as a recognized ED treatment. The Urogold 100^{TM} is an electrohydraulic shockwave device that generates energy levels such as 0.09 − 0.12 mJ/mm^2 with a unique parabolic reflector. It is FDA-cleared for improved blood flow and connective tissue activation as non-significant risk in humans.

Objectives: The objective was to perform a single site retrospective chart review of the outcome of ED treatment with the Urogold 100^{TM} shockwave device.

Methods: Patients presenting with ED were offered the opportunity to receive shock wave therapy as a potential treatment for their ED as part of patient care or in a clinical trial. As standard of care, patients at baseline completed the International Index of Erectile Function (IIEF), the sexual distress scale (SDS), and Grayscale and Doppler ultrasound. LiSWT treatment protocol involved 6 treatment sessions of 5000 total shocks each (500 right/left hilum, 1000 right/left penile shaft, and 1000 right/left crus), frequency 4/sec, membrane level 1. The energy varied from 0.10 − 0.12 mJ/mm^2, based on patient toleration. Patients were asked in follow-up about their response, recorded as Patient Global Impression of Improvement (PGI-I), on a scale of 1 − 7 with clinically relevant improvement expressed by scores of 1 − 3.

Results: To date, data have been collected on 40 ED patients, mean age 45 years (range 25 − 72). Baseline IIEF domain scores for Erectile Function, Orgasm, Desire, Intercourse Satisfaction and Sexual Satisfaction were 14.5, 6.2, 6.6, 7.1, and 4.2 respectively. Baseline mean sexual distress scale score was 30.7/52. Baseline Grayscale ultrasound, used to assess erectile tissue homogeneity in the proximal, mid-shaft and distal aspects of the penile shaft, revealed minimal (<25% cross sectional area), moderate (>25%-50%) and severe (>50%) erectile tissue inhomogeneity in 22/40 (55%), 13/40 (33%) and 5/40 (12%), respectively. Post-treatment, 25/40 (63%) of patients reported a PGI-I of 1 − 3. These patients had baseline erectile tissue homogeneity of 18/25 (72%), 6/25 (24%) and 1/25 (4%), respectively. No treatment related side effects were noted.

Conclusions: In this US-based LiSWT retrospective study, the Urogold 100^{TM} shockwave device has shown clinically relevant improvement in 63% of men with ED, based on self-report. Preliminary studies show that minimal erectile tissue homogeneity has a higher likelihood of positive treatment outcome with shockwave therapy. Only 1 patient with severe inhomogeneity showed improvement. An IRB approved sham-controlled prospective 2 arm 40-week clinical trial using Urogold 100^{TM} shockwave device with all subjects undergoing baseline and post-treatment Grayscale and Doppler ultrasound to assess objective erectile function changes is currently underway.

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PREDICTING INTRACAVERNOSAL INJECTION THERAPY FAILURE BY EVALUATING MEDICAL RISK FACTORS IN MEN WITH ERECTILE DYSFUNCTION

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Introduction: Erectile dysfunction (ED) is a debilitating condition for many men with significant implications on overall physical and emotional health. There are a substantial number of organic disease processes that impact treatment options and their efficacy. All too often, men fail more conservative treatments, specifically intracavernosal injection therapy (ICI) and, after shared decision-making with their urologist, either opt for intrapenile prosthesis (IPP) or abandon further treatment.

Objective: Our primary aim was to identify medical risk factors associated with ICI failure resulting in progression to IPP.

Methods: We included 339 patients with erectile dysfunction who were initiated on ICI in our practice from 2013 through 2018. We assessed each patient's medical risk factors which included body mass index (BMI) ≥30, history of PDE-5 failure, smoking history, history of myocardial infarction (MI), congestive heart failure (CHF), coronary artery disease (CAD), history of coronary artery stent (CAS), chronic obstructive pulmonary disease (COPD), diabetes mellitus (DM), hypertension (HTN), hyperlipidemia (HLD), history of prostatectomy regardless of approach, and history of organ transplantation. Our primary outcome measure was ICI failure, which was defined as progression to IPP. Associations of each risk factor with ICI failure were statistically explored using single variable logistic regression. The number of risk factors was categorized based on the sample median. All statistical tests were two-sided. Statistical analyses were performed using SAS (version 9.4M5; SAS Institute Inc., Cary, North Carolina).

Results: Among 339 patients with ED who were initiated on ICI, 5.6% eventually failed therapy. Of those, 1.5% had 0 risk factors, 9.7% had 1 risk factor, 18% had 2 risk factors, 20.9% had 3 risk factors, 20.4% had 4 risk factors, 15.6% had 5 risk factors 9.4% had 6 risk factors, 3.5% had 7 risk factors, and 0.9% had 8 risk factors. The individual risk factors most strongly associated with ICI failure included smoking history, robotic prostatectomy, history of PDE-5 failure, COPD, and HLD with COPD having the strongest association (OR=3.50). When taken individually, none of the risk factors were statistically significant predictors of ICI failure (all p≥0.11). However, having ≥4 risk factors demonstrated a statistically significant risk of ICI failure (p=0.04).

Conclusion: In our study, 5.6% of patients had ICI failure. We did not find a statistically significant association between individual risk factors and ICI