**ISMST Congress 2019 Beijing, China**

**Abstract No. P45**

**B. Sharpe M.D., Georgia Urology, USA**

# First Report for Unfocused Li-eswt for Nocturia and Erectile Dysfunction.

**Introduction and Objective:**
Nearly 350 Shockwave Therapy (SWT) devices have been sold in the USA for Erectile Dysfunction (ED) since 2007 - with at least 250,000 patients treated. The vast majority of treatments have been performed with inexpensive radial/ballistic SWT devices by non-urologists (primarily by chiropractors). Annually, many millions of dollars have been spent on advertising (primarily AM radio) to recruit ED patients to these clinics. The fee for a series of 6 – 10 treatments by non-urologists averages $4000. During last year's ISSM Congress in Lisbon, invited speakers from the Mayo Clinic estimated the overall "success" rate for these ED clinics at "about 50%".

Monthly, our network of urology offices receive hundreds of inquiries from our patients regarding this technology (most inquiries driven by the frequent radio advertisements, at least 8 each hour on Atlanta's largest AM station). To respond to our patient's inquiries, and to answer our own questions, we initiated an IRB study to evaluate this technology. This is the first report for unfocused, electro-hydraulic SWT (or any form of shockwaves) for Nocturia and for ED. Multiple publications confirm that a primary mechanism of action of SWT for urologic and sexual health indications is a shockwave's unique ability to recruit a patient's own stem cells to the targeted/treated area (not yet proven for radial/ballistic acoustic pulse therapy). The objective of this study was to evaluate the effectiveness and safety of unfocused, electro-hydraulic SWT "SoftWaves" for ED. The results of this study, and a review of the literature, will determine whether we offer this technology to our patients through our network of 40 urologists and 30 offices.

**Methods**:
All patients (15) were consented per the IRB and evaluated to confirm the ED diagnosis and screened for prostate cancer (PSA or digital or ultrasound screening). Patient's ages ranged from 54 to 80 (64 average). Each patient was treated once a week. Utilizing the UroGold SWT device (Distributed by TRT, Woodstock, GA., www.trtllc.com; and manufactured by MTS Germany) - 6 treatments per patient were applied over an average of 8 weeks. The average treatment required 2000 pulses. SWT was evenly divided between 3 treatment sites on the patient's shaft, crura, and perineum. Treatment times averaged less than 15 minutes. After an average of 12 weeks from the first treatment, patients were asked to complete the post treatment questionnaire which asked the patient to report their % improvement on a scale of 0 to 100%, with 100% representing a return to normal erectile function. Patients paid $1500 each to participate in the study.

**Results:**
Average improvement for the ED group was 47% (range of 0 – 100%); 12/14 showed at least 40% improvement (86%); 14/15 showed some improvement. All patients reported that they wanted to continue the protocol and would pay for more treatments. No pain was reported. No numbing cream was utilized.

During the weekly evaluations of the ED patients, very interesting observations were made by multiple patients. As early as week 2, several patients reported that they urinated less frequently at night and attributed this improvement to the SWT. Post study, we collected data from all of the patients that complained of Nocturia who were enrolled in the study (11). We can report the first ever results for SWT and Nocturia. 8/11 (73%) patients reported the reduction in the number of night time urinations of at least 50%. Three (3) patients decreased bathroom visits from 6 to 1 times per night. The average decrease in bathroom visits was 64%. Most interesting, patients reported these improvements in the early weeks, whereas ED symptoms improved much later (average 3 vs. 10 weeks).

**Conclusions**: All results are statistically significant and no adverse events reported. Based on these results, an exhaustive review of the literature, and the recent FDA Clearance of the device; our practice has determined that we will offer this technology to our patients.