- Thursday, October 24, 2019, 03:35 p.m. - 04:00 p.m., Location: Broadway Ballroom Foyer - E-poster Station 3
  E-poster Session 3 - Erectile Dysfunction Medical 1

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Retrospective Review of Improvement of Erectile Function after Low Intensity Shockwave Treatment with Urogold 100™

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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™ 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™ 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™ 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™ shockwave device with all subjects undergoing baseline and post-treatment Grayscale and Doppler ultrasound to assess objective erectile function changes is currently underway.

Disclosure:

Work supported by industry: no.