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### Poster Session SD13

#### **Penile low intensity shock wave therapy for PDE5i non responders: A prospective, randomized, placebo-controlled study**

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**Background:** Several animal and human studies have evaluated the role of low-intensity extracorporeal shockwave therapy (LIST) in the management of multiple disorders such as chronic wounds, peripheral neuropathy and cardiac ischemic disease. LIST is thought to trigger a chain of events that releases angiogenic factors, recruits endothelial progenitor cells, induces neovascularization and enhances blood flow in treated areas. Recently, some studies with contradictory results have assessed the efficacy and safety of this therapy on patients suffering erectile dysfunction.

**Aim:** Investigate the effects of penile LIST on erectile function in patients suffering erectile dysfunction refractory to phosphodiesterase type 5 inhibitors (PDE5i).

**Methods:** Prospective, randomized, simple-blind, sham-controlled study. Fifty-eight patients with vasculogenic erectile dysfunction refractory to PDE5i were randomized into two groups. 30 were treated with electrohydraulic low intensity shock waves (1 session/week for 6 weeks; 1,500 pulses of  $0.10 \text{ mJ/mm}^2$  at 5 Hz) and 28 were treated with a sham probe. Eleven patients withdrew from the study and were lost to follow-up. All patients were evaluated at baseline and 1 month after the end of treatment using validated erectile dysfunction questionnaires. Demographic and clinical characteristics were recorded.

**Results:** 27 active-treated patients and 20 sham-treated patients completed the one-month follow-up. There was no significant difference between the two groups in baseline characteristics. Baseline five-item version of the International Index of Erectile Function (IIEF-5) mean scores, in the active and sham groups, were  $10.0 \pm 3.9$  and  $10.0 \pm 4.5$ , respectively ( $p=0.863$ ). At baseline, 48.1% of patients in the active group and 50.0% of patients in the placebo group had a positive answer to the Sexual Encounter Profile (SEP) 2 question ( $p=1.000$ ); 11.1% of patients in the active group and 10.0% of patients in the placebo group had a positive answer to the SEP 3 question ( $p=1.000$ ). One month after treatment IIEF-5 scores mean changes from baseline, in the active and placebo group, were  $1.6 \pm 4.7$  and  $0.5 \pm 4.4$ , respectively ( $p=0.478$ ). SEP 3 positive responders increased by 18.5% in the active group and by 0% in the placebo group ( $p=0.063$ ).

**Conclusion:** In this specific sample, electrohydraulic LIST produced non-significant changes in erectile function at one-month follow up, compared to sham treated patients. Type of energy, intensity, frequency of shockwaves and follow-up length, together with limited sample size, could be in part responsible for this finding. More studies with larger sample size and longer follow-up, comparing different lithotripters and shock wave protocols, are imperative to elucidate the real role of LIST in erectile dysfunction.