

## **Penile low intensity shock wave therapy for PDE5i non responders suffering long-term vasculogenic erectile dysfunction: A prospective, randomized, placebo-controlled study (2016)**

**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 was reported 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 long-term phosphodiesterase type 5 inhibitors (PDE5i) refractory erectile dysfunction.

**Methods:** Prospective, randomized, simple-blind, sham-controlled study. In total 58 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 mJ/mm<sup>2</sup> at 5 Hz, urogold100® MTS) 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 like the International Index of Erectile Function (IIEF-5) and the Sexual Encounter Profile (SEP). Demographic and clinical characteristics were recorded. Forty-one patients presented ED for 2-10 years; 22 in the active group and 19 in the sham group.

**Results:** 22 active-treated patients and 19 sham-treated patients, suffering from ED for 2-10 years were analyzed. There was no significant difference between the two groups in baseline characteristics. Baseline five-item version of the IIEF mean scores, in the active and sham groups, were  $10.0 \pm 4$  and  $9.9 \pm 4.6$ , respectively ( $p= 0.94$ ). At baseline, 14% of patients in the active group (3 of 22) and 10.5% of patients in the placebo group (2 of 19) had a positive answer to the SEP 3 question ( $p= 0.8$ ). One month after treatment IIEF-5 scores mean changes from baseline, in the active and placebo group, were  $2.2 \pm 4.9$  and  $0.25 \pm 4.4$ , respectively ( $p= 0.2$ ). After LIST, SEP 3 positive responders increased by 33% in the active group (7 of 22) and decreased by 5% the placebo group (1 of 19) ( $p=0.03$ ).

**Conclusion:** In this prospective study, a six week treatment with a moderate protocol of penile LIST led to partial recovery of erectile function at one-month follow up. SEP 3 positive responders significantly increased in the active treated group when compared to the placebo group. More studies with larger sample size and longer follow-up, comparing different lithotripters and shock wave protocols,

are imperative to define the real role of LIST in the treatment of erectile dysfunction.