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P-01-046. **Low intensity extracorporeal shock wave therapy in patients with vasculogenic erectile dysfunction: A placebo-controlled cross-over study in oral PDE5i non-responders**

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Objective
Low-intensity extracorporeal shock wave therapy (Li-ESWT) shows encouraging results in patients with vasculogenic erectile dysfunction (ED). This single-arm cross-over study investigated Li-ESWT efficacy in ED patients who were non-responders to oral phosphodiesterase type 5 inhibitors (PDE5i), with each patient serving as his own sham control.

Methods
The Dornier Aries device was used on ED patients with multiple cardiovascular risk factors, IIEF-ED score ≤ 15, and who were non-responsive to oral PDE5i. After 1-month washout without oral PDE5i, patients received 5 once-a-week sessions with a sham applicator. After 1-week break, they received 5 once-a-week sessions with an active applicator. During active treatment, a total of 5000 shockwaves (energy flux density 0.051 mJ/mm2) were applied at the penile shaft and crus. Patients were not informed that the first 5 sessions were with a sham. IIEF-ED and penile hemodynamics were assessed at baseline, after sham treatment, and 1 and 3 months after active treatment. Patients were allowed to resume oral PDE5i after the 1-month follow-up (FU) assessment.

Results
All patients (n=15) completed the study without side effects. IIEF-ED scores (mean ± SD) were 10.4 ± 2.8 at baseline, 10.5 ± 2.7 after sham, 17.7 ± 4.9 at 1-month FU, and 18.1 ± 6.8 at 3-month FU. Treatment success (increase in IIEF-ED ≥ 7 at 1-month FU) was achieved in all 7 patients with moderate ED, and 4 of 8 patients with severe ED. Cavernosal artery peak systolic velocities (mean ± SD, cm/s) were 12.0 ± 2.9 at baseline, 11.9 ± 3.1 after sham, 21.1 ± 6.6 at 1-month FU, and 23.0 ± 8.4 at 3-month FU.

Conclusion
Li-ESWT using the Dornier Aries significantly improved erectile function and penile hemodynamics over sham treatment, in this cohort of moderate-severe ED patients who were non-responsive to oral PDE5i.