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Low-Intensity Shock Wave Therapy for Treatment of Vasculogenic Erectile Dysfunction: Phase 1 Results of the Dornier Aries in the First United States Clinical Trial

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Objective: Low-intensity shockwave therapy (Li-ESWT) is a promising therapy for vasculogenic erectile dysfunction (ED). The Dornier Aries is CE Marked and used in Europe for Li-ESWT of ED patients. This first US study investigates the safety and efficacy of the Dornier Aries in American patients.

Methods: This open-label single arm pilot study was approved by the ethics committee. 23 patients with International Index of Erectile Function-Erectile Function Domain (IIEF-ED) scores 11-25 (while on and off oral PDE5 inhibitors (PDE5i)) were recruited. After a 1 month PDE5i wash out period, patients were treated with weekly sessions of Li-ESWT (5000 shocks/session at energy flux density 0.051-0.062 mJ/mm²), for a total of 6 sessions. IIEF-ED, EHS, SEP, GAQ questionnaires were administered at screening, baseline, 1-month and 3-month follow up (FU) visits. Oral PDE5i intake was not allowed throughout the study. Penile hemodynamics during pharmacological erection were assessed by duplex Doppler at baseline and 3-month FU visits.

Results: IIEF-ED (mean \pm SD) was 15.5 \pm 3.0, 18.6 \pm 7.0 and 20.1 \pm 5.8 at baseline, 1-month FU and 3-month FU. Minimally clinically important difference (MCID) was achieved in 5 of 7 patients with mild ED (71%), and 7 of 16 patients with moderate ED (44%). 70% of subjects agreed that the treatment improved their ability to have sexual intercourse. Increases in IIEF-ED, EHS and SEP scores were all statistically significant. Gray-scale ultrasound did not show worsening of erectile tissue non-homogeneous echoes in any case. Cavernal artery peak systolic velocities (mean \pm SD, cm/s) increased from 24.5 \pm 9.4 (right) and 27.9 \pm 14.7 (left) at baseline, to 30.5 \pm 12.8 (right) and 35.2 \pm 19.6 (left) at 3-month FU. 10 treatment emergent adverse events were judged to be possibly, probably or definitely related to the study device. All 10 events involved pain or tenderness in the pelvic region, were of mild severity, and resolved spontaneously without sequelae. No ecchymoses, hematuria or hematoma were reported or observed.

Conclusions: Li-ESWT with the Dornier Aries device significantly improved erectile function in the study population, and was well tolerated with no serious adverse events and only a few minor transient side effects. Further studies are planned with a larger patient cohort.

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