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### **Development of an evidence-based protocol for the application of low-intensity shockwave therapy for erectile dysfunction: comparison of two treatment protocols and the impact of repeating treatment**

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**Objective:** There is lack of evidence-based protocol for Low-intensity Shockwave Therapy (LiST) for erectile dysfunction (ED). Furthermore, safety and efficacy of repeating shockwave therapy has not been explored. This 2-phase study a) compares the efficacy and safety of 6 and 12 treatment sessions within a 6-week treatment period and b) investigates the effect of re-treatment after 6 months period.

**Methods:** Patients with vasculogenic ED, responders to PDE5 inhibitors, were randomized into 2 groups: LiST sessions once (Group A) or twice (Group B) per week for 6 consecutive weeks (Phase 1). Patients who completed 6-month follow-up were offered 6 additional sessions (Phase 2); Group A received 2 sessions per week, and Group B received 1 session per week. Patients were then followed up for 6 months. IIEF-EF domain score, Minimally Clinical Important Differences (MCID), Sexual Encounter Profile (SEP) and triplex ultrasonography parameters were assessed.

**Results:** In Phase 1, both groups improved in IIEF-EF, MCID, SEP3 and mean peak systolic velocity (PSV) compared to baseline. MCID were achieved in 62% (Group A) and 71% (Group B), while SEP3 "Yes" response was 47% in Group A, and 65% in Group B (Group A vs Group B p-value = 0.02). Mean PSV at baseline and 3m-FU-1 were 29.5 and 33.4 cm/s for Group A and 29.6 and 35.4 cm/s for Group B (p = 0.06). In phase 2, Group A experienced a greater increase in SEP3 %Yes responses (Group A = +14.9; Group B = +0.3). When the impact of the total number of sessions received was examined, minimal clinically important difference (MCID) in IIEF-EF domain from baseline were achieved in 62%, 74% and 83% of patients after 6, 12 and 18 sessions, respectively. No treatment-related side-effects were reported.

**Conclusion:** Total number of LiST sessions impacts the efficacy of ED treatment. Retreating patients after 6 months may further improve erectile function, without side effects. 12 sessions may be delivered within 6 weeks without a 3-week break period. Patients may benefit more in sexual performance from 12 sessions, twice per week, compared to 6 sessions, once a week. It is meaningful and safe to repeat shockwave therapy, up to a total of 18 sessions.