

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.

Material and 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.

Disclosure:

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Low-intensity shockwave therapy for erectile dysfunction: the effect of energy flux density level and frequency of sessions per week

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Objective: Low-intensity shockwave therapy (LiST) is safe and efficacious in men with vasculogenic erectile dysfunction(ED). There is lack of data however, on the safety and efficacy of different energy levels and session frequency per week. This study compares the safety and efficacy of different LiST protocols for vasculogenic ED. Two different energy flux density (EFD) and two different session frequencies are investigated.

Material and Methods: 96 patients were randomized into 4 groups. All patients received a total of 12 LiST sessions: Group A received LiST twice a week with EFD of 0.05mJ/mm²; Group B received LiST three times a week with EFD of 0.05mJ/mm²; Group C received LiST twice a week with EFD of 0.10mJ/mm²; Group D received LiST three times a week with EFD of 0.10mJ/mm². Sessions were delivered within a 4 week (Groups B, D) or 6 week (Groups A, C) period, without any break in treatment. IIEF-EF domain score, Minimally Clinical Important Differences (MCID), and Sexual Encounter Profile question 3 (SEP3) assessed subjective erectile function; objective assessment of penile hemodynamics was based on Peak Systolic Velocity (PSV).

Results: 1-month and 3-month data are available from 80 and 75 patients respectively. IIEF-EF increased by 4.2, 3.8, 4.3, 4.7, and 4.6, 4.5, 5.4, 5.2 points for Groups A, B, C, D at 1-month and 3-month follow-up. MCID was achieved in 68%, 76%, 67%, 58%, and 73%, 86%, 94%, 67%, for Groups A, B, C, D at 1-month and 3-month follow-up. SEP3 "yes" answers increased by 24.9, 22.1, 29.2, 35.2, and 24.1, 28.2, 31.6, 37.0, for Groups A, B, C, D at 1-month and 3-month follow-up. Finally, PSV increased by 4.3, 4.8, 5.9 and 4.9cm/s for Groups A, B, C, D at 3-month follow-up. No adverse events were reported, even at the most intensive protocol (EFD 0.10 mJ/mm², three times per week).

Conclusion: This study provides for the first time, evidence that LiST can be safely and efficaciously applied up to 3 times per week. %MCID was lower in Group D, but this was due to a higher proportion of moderate and severe ED patients. EFD of

0.10mJ/mm² appeared to be more efficacious than EFD of 0.05mJ/mm², but difference was not statistically significant in this study. Pending confirmation in a larger study, our preliminary results suggest implementation of 12 sessions of LiST either 2 or 3 times per week at EFD 0.10mJ/mm², without any break during treatment.

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