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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/mm^2; Group B received LiST three times a week with EFD of 0.05mJ/mm^2; Group C received LiST twice a week with EFD of 0.10mJ/mm^2; Group D received LiST three times a week with EFD of 0.10mJ/mm^2. 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/mm^2, 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/mm^2 appeared to be more efficacious than EFD of 0.05mJ/mm^2, 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/mm^2, without any break during treatment.

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