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Comparison of two low-intensity ESWT protocols in patients with erectile dysfunction

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Objective: We compared the efficacy and safety of two focused low-intensity extracorporeal shock wave therapy (Li-ESWT) protocols for the treatment of erectile dysfunction (ED) in this study.

Materials and Methods:This is a randomized, experimental, non-inferiority clinical trial. Two Li-ESWT protocols were evaluated in adult patients with primary ED for more than 3 months in over 50% of sexual intercourses, EHS score under or equal to 3, IIEF-5 score under or equal to 21. We excluded patients with

bladder, prostate or colon cancer, Psychogenic ED, psychiatric pathologies, spinal cord injury, clinically suspected hypogonadism, active infections, lesions on the penis or pubic area. Protocol 1 consisted of five weekly sessions, each with 3000 pulses at 0.15 mJ/mm² and 4 Hz frequency. Protocol 2 consisted of six sessions, two per week, each with 1500 pulses at 0.10 mJ/mm² and 4 Hz frequency. All patients were treated with the Duolith SD 1, Storz Medical AG. The primary outcome was the EHS score at 1 month after completing each protocol; secondary outcomes were: IIEF-5 at 1, 3 and 6 months after completing each protocol. Clinical trial register NCT02683044.

Results: 178 patients were recruited, 110 received protocol 1 and 68 protocol 2. Age, comorbidities, and ED duration were similar in both groups. The baseline scores of group 1 and 2 were: EHS 2.3 vs. 2.4; IIEF-5 13.1 vs. 13.6. A significant improvement was observed in the EHS score at one month of follow-up in both protocols ($p < 0.001$ protocol 1, $p = 0.003$ protocol 2). There were no statistically significant differences between the groups in the improvement of the EHS score (48.4% protocol 1 vs 43.5% protocol 2, $p = 0.6324$). The medians of IIEF-5 scores were similar between the intervention groups at 1, 3 and 6 months follow-up (value $p= 0.5221$, 0.6650 and 0.3868, respectively). There were no serious adverse events/adverse events during the study.

Conclusions: The results suggest that there is no difference in the efficacy between the two protocols of 5 and 6 sessions.

Disclosure:

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