Exploring the number of low intensity shock wave treatment (LiSWT) sessions needed in patients with vasculogenic erectile dysfunction (ED): 6 vs 12 sessions in a 6 weeks period

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Objective
Despite several reports on the efficacy of LiSWT for vasculogenic ED, no data exist in order to determine the ideal treatment protocol. The purpose of the present study was to compare, for the first time, the efficacy and safety of two treatment protocols.

Methods
This is a randomized, 2 parallel arms clinical study. Patients with IIEF ED domain 7-24 and vasculogenic ED, responders to PDE5 inhibitors were included. After 4 weeks wash-out period, patients were randomized into 2 groups. Group A received one session/week for 6 weeks, while Group B received 2 sessions/week (12 sessions within 6 weeks). All patients were treated using the ARIES® device (Dornier MedTech, Germany). IIEF and SEP were assessed at baseline, 1, 3 and 6 months follow up. Triplex ultrasonography was conducted by the same investigator, at baseline and at 3 months follow-up visit.

Results
Forty-two patients (mean age 59±1.5) were included. Mean IIEF-ED domain score was 16.19, 19.54, 19.0, 19.33 for the group A (n=21) and 15.38, 20.57, 20.61 and 20.52 for the group B (n=21) at baseline, 1, 3 and 6 months respectively (p<0.001). Mean peak systolic velocity was 30.52 and 34.45 cm/sec for the group A and 30.57 and 35.91 for the group B, at baseline and 3 months respectively (p<0.001). A tendency for better erectile function was noticed in Group B (IIEF score and triplex parameters). SEP3 “yes” responses however, clearly demonstrated the additional benefit offered by 12 sessions (36.84%, 52%, 46% and 50% for Group A, and 41.71%, 70.24%, 68.42% and 65.14% for Group B at baseline, 1, 3 and 6 months follow-up, respectively). Side-effects were absent in both groups.

Conclusion
LiSWT may improve erectile function in a session-dependent manner. Treatment sessions may apply either once or twice/week, without intervals. Future studies will determine possible saturation effect.