290

Efficacy of low-intensity shock wave therapy for the treatment of ED in diabetic patients : a Pooled analysis

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Objectives: Low-intensity shock wave therapy (LI–ESWT) has been shown to be effective as a non-invasive treatment for men suffering from vasculogenic erectile dysfunction (ED). Diabetes induced ED is more severe and more difficult to treat due to combined vasculopathy and peripheral neuropathy that both negatively affect the erectile mechanism. Our aim was to assess the efficacy of LI-ESWT specifically on diabetic ED patients.

Material and Methods: Analysis of pooled data from 4 double-blind, sham-controlled trials conducted in Israel, USA, Greece and India was performed. The analysis provided a cohort of 350 PDE5I responders with vasculogenic ED that underwent LI-ESWT therapy. We sub-analyzed the 61 diabetic patients that were part of this cohort. Of these, 44 had received LI-ESWT treatment and 17 underwent sham. The treatment protocol was identical in all 4 studies; LI-ESWT was applied to five sites on the corpora X2 weekly for 3 weeks and repeated after a 3 week rest period for a total of 12 treatment sessions. IIEF-EF domain scores were documented at baseline, at mid-treatment (MT-end of rest period); 1-month (FU1), 3-months (FU2), 6-months (FU3) and-12 months (FU4) post last treatment.

Results: The average baseline IIEF-EF scores were: 11.4±4 and 11.5±3.8 for the treated and sham group respectively. The mean change in IIEF-EF domain scores of the treated group from baseline to MT, FU1, FU2, FU3 and FU4 were 5.9(±4.6), 8(±5.5), 8.6(±5.3), 8.4(±5.0) and 5.9(±5.1); ($p < 0.001$) respectively. The difference between the treated and sham groups was significant ($p<0.05$) at all visits. Minimally clinical important difference (MCID; 2,5,7, points change for mild, moderate and severe ED, respectively) in IIEF-EF score was achieved in 50%, 79.5%, 72.7%, 77.3% and 65.9% of the subjects in the treated group in MT, FU1, FU2, FU3 and FU4 respectively. The sham group achieved MCID in 17.6%, 35.3%, 23.5%, 23.5% and 11.8% of the subjects in MT, FU1, FU2, FU3 and FU4, respectively. The difference between the groups was significant ($p<0.05$) at MT and all follow-up visits.

Conclusion: LI-ESWT was well tolerated and effective for the treatment of ED in patients suffering from DM; adverse events were mild, self-limited and resolved spontaneously. These results support

the use of LI-ESWT with the Omnispec model ED1000 applying the original treatment protocol for diabetes induced ED.

Disclosure:

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