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**INTRODUCTION & OBJECTIVES:** To evaluate the safety and efficacy of Low-intensity extracorporeal shock wave therapy (LI-SWT) on patients with severe erectile dysfunction (ED) who are poor responders to phosphodiesterase type-5 inhibitors treatment (PR-PDE5I).

**MATERIAL & METHODS:** An open label, prospective study was conducted and included 53 consecutive patients with severe vasculogenic ED who are PR-PDE5I (International index of erectile function–erectile function domain  $<10$  and erection hardness score  $\leq 2$ ). All patients received 12 sessions of penile LI-SWT (2 sessions/week for 3 weeks, then 3 weeks free of treatment, then 2 sessions/week for another 3 weeks). The shock waves were delivered to the distal, mid and proximal penile shaft, and the left and right crura using a specialized focused shock wave probe (Dornier MedTech System, GmbH, Wessling, Germany). The 300 shocks at an energy density of  $0.09 \text{ mJ/mm}^2$  and a frequency of 120 shocks per minute were delivered at each of the 5 treatment points with frequency of 4 Hz. Each treatment session was 15 minutes and no local or systemic analgesia was needed. Patients were followed-up after the 1st month of treatment (FU1), 3 months (FU2) and 6 months (FU3) intervals. Effectiveness was assessed by International index of erectile function questionnaire (IIEF) and erection hardness score (EHS). Success was defined as patients who achieved erection hard enough for vaginal penetration (IIEF-EF domain  $\geq 26$  and EHS  $\geq 3$ ). During the active treatment and till FU1, all patients stopped any regular or on demand intake of PDE5I. After FU1 patients were classified into complete responders to LI-SWT and were followed up at 3 and 6 months, and poor responders (IIEF-EF domain  $<26$  and EHS  $\leq 2$ ) who received 50 mg daily dose of sildenafil citrate for 2 months, and then reevaluated at 3 months for further subdivision into: responders (PDE5I converter) and non PDE5I converters who will be offered penile prosthesis.

**RESULTS:** Mean age was  $52 \pm 11.4$  years and all 53 patients completed the 6 months follow-up program. Hypertension, diabetes mellitus and coronary ischemia were present in 11 (20.8%), 24 (45.3%) and 11 (20.8%) patients, respectively. There were no patients reporting treatment-related adverse events. The mean (SD) EF-domain and EHS significantly improved after treatment across the follow up period ( $p < 0.001$ ). Pretreatment, all patients had severe ED, At FU1, 16 (30.2%) had normal erectile function, 21 (39.6%) had improvement in IIEF score but still have mild to moderate ED (IIEF-EF domain 11-25 and EHS  $\leq 2$ ) and 16 (30.2%) had no response to treatment.

During FU2, 7 out of the 16 patients with normal EF at FU1 developed mild ED at FU2 and required oral PDE5i with good response which is maintained at FU3, while patients with no response at FU1 showed also no response to oral PDE5I at FU2 and FU3. Out of the 21 patients with mild to moderate ED at FU1, 10 patients showed good response to oral PDE5I at FU2 till FU3. While 11 patients reported good response to oral PDE5I at FU2 then poor response at FU3.

**CONCLUSIONS:** LI-SWT for men with severe ED and PR-PDE5I is safe and effective. Normal erection was achieved and maintained at 6 months in 9 patients (17%) and restoring PDE5I response was obtained and maintained in 17 patients (32%). A large-scale with longer follow up study is required to determine the value of this treatment for ED.