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## Penile Low Intensity Shock Wave Treatment is Able to Shift PDE5i Nonresponders to Responders: A Double-Blind, Sham Controlled Study.

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## **Abstract**

**PURPOSE**: We performed sham controlled evaluation of penile low intensity shock wave treatment effect in patients unable to achieve sexual intercourse using PDE5i (phosphodiesterase type 5 inhibitor).

MATERIALS AND METHODS: This prospective, randomized, double-blind, sham controlled study was done in patients with vasculogenic erectile dysfunction who stopped using PDE5i due to no efficacy. All patients had an erection hardness score of 2 or less with PDE5i. A total of 58 patients were randomized, including 37 treated with low intensity shock waves (12 sessions of 1,500 pulses of 0.09 mJ/mm(2) at 120 shock waves per minute) and 18 treated with a sham probe. In the sham group 16 patients underwent low intensity shock wave treatment 1 month after sham treatment. All patients were evaluated at baseline and 1 month after the end of treatment using validated erectile dysfunction questionnaires and the flow mediated dilatation technique for penile endothelial function. Erectile function was evaluated while patients were receiving PDE5i.

**RESULTS:** In the low intensity shock wave treatment group and the sham group 54.1% and 0% of patients, respectively, achieved erection hard enough for vaginal penetration, that is an EHS (Erection Hardness Score) of 3 (p <0.0001). According to changes in the IIEF-EF (International Index of Erectile Function-Erectile Function) score treatment was effective in 40.5% of men who received low intensity shock wave treatment but in none in the sham group (p = 0.001). Of patients treated with shock waves after sham treatment 56.3% achieved erection hard enough for penetration (p <0.005).

**CONCLUSIONS:** Low intensity shock wave treatment is effective even in patients with severe erectile dysfunction who are PDE5i nonresponders. After treatment about half of them were able to achieve erection hard enough for penetration with PDE5i. Longer followup is needed to establish the place of low intensity shock wave treatment in these challenging cases.

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