

Twelve-Month Efficacy and Safety of Low-Intensity Shockwave Therapy for Erectile Dysfunction in Patients Who Do Not Respond to Phosphodiesterase Type 5 Inhibitors.

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Author information

Abstract

INTRODUCTION: Low-intensity shockwave therapy (LISWT) has recently emerged as a promising method in the treatment of erectile dysfunction (ED).

AIM: To assess the long-term results of the effectiveness and safety of LISWT in patients with ED who are non-responders to phosphodiesterase type 5 inhibitor (PDE5i) treatment.

METHODS: This open-label, longitudinal, and observational study investigated an uncontrolled population of 50 consecutive patients whose ED was unresponsive to PDE5i treatment. Patients were treated with a four-session LISWT protocol. During active treatment and follow-up, all patients remained on their regular high on-demand or once-daily PDE5i dosing schedules.

MAIN OUTCOME MEASURES: Effectiveness was assessed according to the International Index of Erectile Function erectile function domain, questions 2 and 3 of the Sexual Encounter Profile, Erection Hardness Scale, and Global Assessment Question scores at baseline and at 3, 6, 9, and 12 months after treatment. Patients were considered responders whenever they showed improvement in erection parameters in all four assessments and responded positively to the Global Assessment Question. Adverse events were recorded. Statistical variables were applied and findings were considered statistically significant at a P value less than $< .05$.

RESULTS: Eighty percent (mean age = 64.8 years) completed the 12-month follow-up. Positive response rates were 60% of available subjects at the end of the study and 48% of the intent-to-treat population. After the 12-month follow-up, 91.7% of responders maintained their responses. No patient reported treatment-related adverse events.

CONCLUSION: LISWT in patients with ED unresponsive to PDE5i treatment was effective and safe in 60% of patients treated. The efficacy response was maintained for 12 months in most patients.

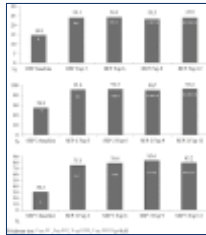
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KEYWORDS: Erectile Dysfunction; Low-Intensity Extracorporeal Shockwave Therapy; Phosphodiesterase Type 5 Inhibitor

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Phase	Visit	Procedure
SCREENING	1	Screening ECG, Physical Exam, Lab Tests
	2	Screening ECG, Physical Exam, Lab Tests
	3	Screening ECG, Physical Exam, Lab Tests
	4	Screening ECG, Physical Exam, Lab Tests
RANDOMIZED	1	Randomized ECG, Physical Exam, Lab Tests
	2	Randomized ECG, Physical Exam, Lab Tests
	3	Randomized ECG, Physical Exam, Lab Tests
	4	Randomized ECG, Physical Exam, Lab Tests



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