Urology CHEAT SHEETS
IJIR Your Sexual Medicine Journal

Low-intensity shockwave therapy in Peyronie's disease: long-term results from a prospective, randomized, sham-controlled trial

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https://doi.org/10.1038/s41443-021-00447-2

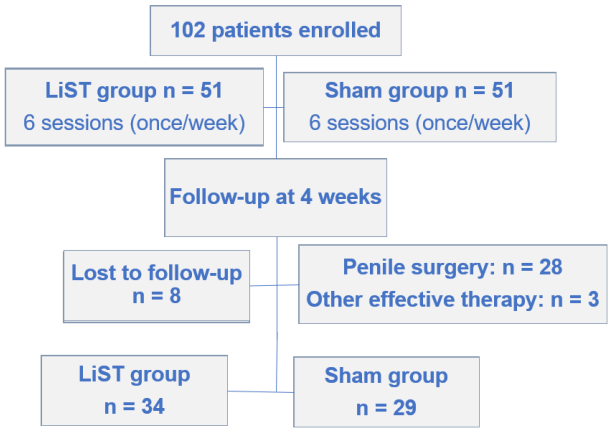
INTRODUCTION

In patients at the early stage of Peyronie's disease (PD) or in patients unwilling to undergo surgery, low-intensity shockwave therapy (LiST) has emerged as a safe and effective conservative treatment modality for short-term pain reduction.
The available randomized controlled trials on LiST report beneficial outcomes in terms of pain relief, but the efficacy of LiST on penile curvature and the ability to perform sexual intercourse remains controversial.

MATERIAL AND METHODS

Trial design	**Prospective, single-blind, randomized, sham-controlled trial**
Intervention	**LiST arm:** six sessions (once/week). Protocol of 2000 shockwaves per session and frequency of 3 Hz **Sham therapy:** same protocol, but a plastic membrane was placed within the transducer to prevent the delivery of shockwaves
Primary outcome	**Reduction of pain at 3 years vs baseline and at 3 years vs 4 weeks after protocol completion**
Secondary outcomes	**Changes in penile curvature, sexual function and safety**
Inclusion criteria	**Male patients ≥18 years old; PD lasting for ≥12 months; presence of penile plaque or pain at erection or curvature; previous unsuccessful oral PD therapy; stable symptoms for ≥3 months.**
Exclusion criteria	**Prior penile surgery or LiST; ED not responding to phosphodiesterase-type five inhibitors or intracavernosal injections; unwillingness or inability to provide informed consent.**
Follow up	**Baseline- 4 weeks- 3 years**

RESULTS



At the baseline evaluation, 32 (50.8%) participants with penile pain, and 47 (74.6%) were able to perform sexual intercourse. All patients presented with a plaque, while 60 (95.2%) with penile curvature.

Improvement of pain was reported in 23 participants (LiST = 16, sham = 7, p = 0.005) at 4 weeks and in 22 (LiST = 15, sham = 7, p = 0.031) at 3 years.

Mean difference of 2.2 points (95% CI: 0.9–3.5, p = 0.002) in the visual analog pain scale at 4 weeks and a mean difference of 2.5 points (95%CI: 1–4, p = 0.002) at 3 years between the two groups. No statistically significant difference between the two groups was observed at 4 weeks compared to 3 years (mean difference: 0.3, 95% CI: −0.7 to 1.4, p = 0.521).

No treatment-related complications occurred during the sessions or the follow-up period.

Regarding the improvement of penile curvature or sexual function, no significant differences between the two groups were observed.

CONCLUSION

In patients with PD, LiST may be a safe and effective long-term treatment modality for the improvement of pain symptoms. Given that penile curvature and the subsequent inability to perform sexual intercourse are the most bothersome symptoms, LiST should not be recommended for individuals with PD suffering predominantly from these symptoms. Regarding the natural history of the stable phase of the PD, symptoms persist or may even worsen despite conservative treatment with on-demand phosphodiesterase type 5 inhibitors or non-steroidal anti-inflammatory drugs. It should be highlighted that LiST constitutes an easily applied, indolent, and repeatable on an outpatient basis therapeutic approach that may improve pain in patients with PD both in the short- and in the long-term without any treatment-related complications.