

# The Effect of Low-Intensity Shock Wave Therapy on Moderate Erectile Dysfunction: A Double-Blind, Randomized, Sham-Controlled Clinical Trial.

Dimitrios Kalyvianakis , Ioannis Mykoniatis, Nikolaos Pyrgidis, Paraskeui Kapoteli, Filimon Zilotis, Agrippina Fournaraki, Dimitrios Hatzichristou

J Urol 2022 Aug;208(2):388-395

## **Abstract**

**Purpose:** We conducted the first double-blind, randomized, sham-controlled trial evaluating the efficacy and safety of low-intensity shock wave therapy (LiST) exclusively in patients with moderate erectile dysfunction.

**Materials and methods:** Seventy patients were randomized to 12 sessions of LiST (35) or sham therapy (35) twice weekly. Patients were evaluated at 1 and 3 months after completion of treatment. The proportion of participants attaining minimal clinically important difference (MCID) in the International Index of Erectile Function-Erectile Function (IIEF-EF) and the effect of LiST on erectile function, as well as on safety, were the study outcomes.

**Results:** At 3 months, MCID was attained by 27 (79%) patients in the LiST group compared to 0 patients in the sham group. The risk difference between the 2 groups was 79% (95% confidence interval [CI]: 66-93,  $p < 0.001$ ) and the baseline-adjusted mean between-group-difference in the IIEF-EF was 4.4 points (95% CI: 3.4-5.4,  $p < 0.001$ ). At 1 month, MCID was attained by 20 (59%) patients in the LiST group compared to 1 (2.9%) patient in the sham group. The risk difference between the 2 groups was 56% (95% CI: 38-73,  $p < 0.001$ ) and the baseline-adjusted mean between-group-difference in the IIEF-EF was 3.9 points (95% CI: 2.7-5.2,  $p < 0.001$ ).

**Conclusions:** Twelve sessions of LiST twice weekly for 6 weeks with a treatment protocol of 5,000 impulses, 0.096 mJ/mm<sup>2</sup> energy flux density and 5 Hz frequency are highly effective in patients with moderate erectile dysfunction. Still, further long-term randomized studies are warranted to corroborate our findings.

## **COMMENT (ENGLISH)**

This is a great randomized clinical trial, that analyzes the effects of LiST in moderate ED patients. The authors successfully demonstrated efficacy at both 1 and 3 months with a high statistical significance.

Despite previous several human studies demonstrating that LiST can improve erectile function, this is the first trial with a rigorous design, prospective, double-blinded, randomized, with adequate follow-up that reports objective changes in erectile function.

This study recruited a total of 70 patients, with 35 of them undergoing LiST, and the other half allocated to Sham Therapy with a previously designed device. After 12 sessions of LiST, twice weekly for 6 weeks, using a treatment protocol of 5,000 impulses, 0.096 mJ/mm<sup>2</sup> energy flux density and 5 hz of frequency using the ARIES 2 device, a significant improvement was identified at 1 and 3 months in patients with moderate vasculogenic erectile dysfunction and previous good or partial response to phosphodiesterase type 5 inhibitors. The patients were compared with a Sham therapy group, the improvement in the LiST group was demonstrated using the IIEF.

One of the major limitations of the study is that it is a single-center study, and the number of patients is small. Nonetheless, this study has set a solid background for further research on this field.

## **COMENTARIO (ESPAÑOL)**

Este es un notable ensayo clínico aleatorizado, que analiza los efectos de la terapia con ondas de choque de baja intensidad en pacientes con disfunción eréctil moderada. Los autores demostraron exitosamente la eficacia a los meses 1 y 3 con una significancia estadística alta.

A pesar de estudios previos que demuestran que la terapia con ondas de choque de baja intensidad puede ayudar a la función eréctil, este es el primer ensayo con un diseño riguroso, prospectivo, doble ciego, aleatorizado, y con un seguimiento adecuado que reporta cambios favorables objetivos en la función eréctil.

Este estudio reclutó un total de 70 pacientes, 35 de ellos fueron asignados al grupo de terapia de ondas de choque, y la otra mitad fue asignada a terapia con

el dispositivo suplantador, previamente diseñado. Luego de 12 sesiones de terapia de ondas de choque de baja intensidad, dos veces por semana, durante 6 semanas, usando un protocolo de 5,000 impulsos, 0.096ml/mm<sup>2</sup> de densidad de flujo de energía y una frecuencia de 5 Hz usando el dispositivo Aries 2, una mejoría significativa fue demostrada a los meses 1 y 3 en pacientes con disfunción eréctil vasculogénica moderada y respuesta a los inhibidores de la 5 fosfodiesterasa buena o parcial previamente. Los pacientes de ambos grupos fueron comparados, demostrando mejoría significativa en el índice internacional de la función eréctil.

Una de las principales limitantes de este estudio es que es un estudio realizado en centro único, y el grupo de pacientes es pequeño; sin embargo, este estudio ha sentado bases sólidas para investigación futura en esta área de la urología.



[Juan Ramón Torres Anguiano](#)

Urólogo Centro Médico Nacional Siglo XXI  
Fellowship en Cirugía Reconstructiva University of Toronto  
Actualmente en Baylor College of Medicine, Houston, TX, USA