



Actas Urológicas Españolas

www.elsevier.es/actasuro



CASUISTRY

Linear shock wave therapy in the treatment of erectile dysfunction[☆]

M. Pelayo-Nieto^{*}, E. Linden-Castro, A. Alias-Melgar, D. Espinosa-Pérez Grovas, F. Carreño-de la Rosa, F. Bertrand-Noriega, R. Cortez-Betancourt

Departamento de Urología, Centro Médico Nacional 20 de Noviembre, México Distrito Federal, Mexico

KEYWORDS

Erectile dysfunction;
Vasculogenic erectile dysfunction;
Linear shock wave;
Linear shock wave therapy

PALABRAS CLAVE

Disfunción eréctil;
Disfunción eréctil vasculogénica;
Ondas de Choque Lineal;
Terapia de Ondas de Choque Lineal

Abstract

Introduction: Linear shock wave therapy (LSWT) is a new noninvasive therapy that uses low-intensity shock waves to induce local angiogenesis promising modality in the treatment of erectile dysfunction (ED).

Objective: To evaluate the effectiveness of LSWT in men with vasculogenic erectile dysfunction (ED), in a Tertiary Care Center.

Material and methods: Included 15 men aged 45–70 years, sexually active with mild and moderate vascular ED evaluated with the International Index of Erectile Function (IIEF). The study was conducted in three stages: screening, treatment and results. Treatment stage: 4 weekly sessions LSWT (RENOVA[®]) 5000 waves (.09 mJ/mm²). Erectile function was assessed with IIEF-EF, SEP (Sexual Encounter Profile) and GAQ (Global Assessment Questions) at one and six months after treatment.

Results: The rate of success was 80% (12/15). Patients with mild ED (6/15) 40% and moderate ED (9/15) 60%. We found a positive association between IIEF-Basal (average 14.23 pts) and IIEF at one month and six months after therapy (19.69 pts) a difference of 5.46 pts ($p < .013$).

Conclusions: The feasibility and tolerability of this treatment, and rehabilitation potential features, make it this an attractive new treatment option for patients with ED.

© 2014 AEU. Published by Elsevier España, S.L.U. All rights reserved.

Terapia de ondas de choque lineales en el tratamiento de la disfunción eréctil

Resumen

Introducción: La terapia de ondas de choque lineales (LSWT) es una nueva terapia no invasiva que utiliza ondas de choque de baja intensidad para inducir la angiogénesis local controlada y mejorar significativamente la función eréctil.

Objetivo: Evaluar la eficacia de la LSWT en hombres con disfunción eréctil vasculogénica (DE) en un centro de atención de tercer nivel.

[☆] Please cite this article as: Pelayo-Nieto M, Linden-Castro E, Alias-Melgar A, Espinosa-Pérez Grovas D, Carreño-de la Rosa F, Bertrand-Noriega F, et al. Terapia de ondas de choque lineales en el tratamiento de la disfunción eréctil. Actas Urol Esp. 2015. <http://dx.doi.org/10.1016/j.acuro.2014.09.010>

^{*} Corresponding author.

E-mail address: marcelapelayo@hotmail.com (M. Pelayo-Nieto).

Material y métodos: Se incluyeron 15 hombres de edades comprendidas entre 45 y 70 años, sexualmente activos con DE vascular leve y moderada, evaluados con el índice internacional de función eréctil (IIEF). El estudio se realizó en 3 etapas: detección, tratamiento y seguimiento. Recibieron 4 sesiones de LSWT semanales (RENOVA®) 5.000 ondas (0,09 mJ/mm²). La función eréctil se evaluó con IIEFF-EF, Perfil del encuentro sexual (SEP) y Cuestionario de evaluación global (GAQ) al mes y a los 6 meses después del tratamiento.

Resultados: La tasa de éxito fue del 80% (12/15). Pacientes con DE leve 40% y DE moderada 60%. Se encontró una asociación positiva entre el IIEF-basal (promedio 14,23 pts) y IIEF un mes y 6 meses después del tratamiento (19,69 pts) una diferencia de 5,46 puntos ($p < 0,013$).

Conclusiones: La factibilidad y tolerabilidad de este tratamiento, y sus características potenciales de rehabilitación, hacen que pueda ser una nueva opción terapéutica atractiva para pacientes con DE.

© 2014 AEU. Publicado por Elsevier España, S.L.U. Todos los derechos reservados.

Introduction and clinical scenario

Erectile dysfunction (ED) is the persistent inability to achieve and maintain the erection sufficient to permit satisfactory sexual intercourse.¹ Vasculogenic ED is due to diseases such as diabetes mellitus, hypertension, hyperlipidemia, smoking, or vascular occlusive disease.^{2,3} Although ED is a benign disorder, it affects physical, mental, and social health and has a significant impact on quality of life of men and their partners.⁴ LSWT stimulates the expression of angiogenesis-related growth factors, such as endothelial nitric oxide synthase, vascular endothelial growth factor, and endothelial cell proliferation factors. Also LSWT induces neovascularization and cell proliferation.⁵ LSWT could improve penile blood flow and endothelial function by stimulating angiogenesis in the penis.⁶ This technology is becoming a new modality in the treatment of patients with ED.

Clinical cases

We evaluated 15 men, with vasculogenic ED, between 45 and 70 years of age sexually active (sexual activity with a partner or manual stimulation) with mild to moderate vasculogenic ED. Patients were assessed with the International Index of Erectile Function (IIEF-EF). The study was conducted in three stages, from June to December 2013. The first stage consisted of screening, including complete medical history and physical examination. The second stage was the treatment, which in turn was carried out in two phases, the first phase is called "physical therapy" in which all patients received 4 sessions with LSWT (RENOVA®) 5000 waves of 0.09 mJ/mm², 300 intensity waves/min (5 Hz), 40 mm deep, in four areas (cavernosum right, left waves on each side 900, and left and right crus waves 1600 on each side); each session lasting 20 min with an interval of one week between each session.

The treatment is performed on an outpatient basis without using any anesthetic. The second phase of treatment consisted of "rehabilitation" at home between sessions (sexual activity with a partner or manual stimulation); and finally, the third stage of the study, evaluating the clinical results using IIEF, EHS (Erection Hardness Score),

SEP (Sexual Encounter Profile), GAQ (Global Assessment Questions) at one month and six months after treatment.

We analyzed quantitative and qualitative variables such as age, body mass index (BMI), smoking history, diabetes mellitus, hypertension, ischemic heart disease, Basal IIEF (Grade ED), EHS, SEP, years with ED. The statistical analysis is done with GraphPad Prism 6.0 and SPSS 19 statistics using the following tests: Student *t* distribution (*t*), Pearson correlation (*r*), (*p*).

Results

Fifteen men with a mean age of 59.6 years (45–70) with mild to moderate ED were enrolled. 40% of patients (6/15) had mild ED, and 60% had moderate ED (9/15). Patients with mild ED had a basal IIEF-EF average of 18 points, and 13 points for patients with moderate ED. Treatment efficacy was evaluated with IIEF-EF, GAQ, and SEP.

Success of treatment was defined as an increase of >2 points and >5 points in groups of mild and moderate, respectively (9). No adverse effects occurred. The rate of success was 80%. We found a positive association between the basal IIEF (average 14.23 pts) and IIEF after one month and six months (19.69 pts) with a difference of 5.46 pts ($p < 0.013$) (Table 1).

Patients with mild ED 83% (5/6) had improvement >2 pts; and patients with moderate ED 78% (7/9) had an increase of >5 pts ($p < 0.56$).

We found no association between minor age (mean 59.6 years) and treatment success, (7/15) 46% of patients were >60 years, all these (7/7) had a positive response to treatment, and (8/15) 54% patients were <60 years in this group, 62% (5/8) were successful with the treatment ($p < 0.01$).

We observed that patients who had 1–5 years with ED 60% (9/15) showed an improvement of 4 points in 67% (6/9) of patients, ($p < 0.20$); and we did not find an association between the IPSS (average 9 points) and the success of treatment ($p = 0.0712$).

We analyzed the influence of the smoking index on the response to the treatment. Patients had a smoking index <20 and >20, and there is a negative association ($p < 0.05$) between these groups, 73% (11/15) of patients had a smoking index (SI) <20, 92% (10/11) of them were successful with

Table 1 Results of sexual function questionnaires before and 1 month after low-intensity extracorporeal shockwave therapy.

Test Score	Baseline Score	Score 1 mo after treatment	<i>p</i> value
IIEF	15 (11–18) pts	20 (11–23) pts	<i>p</i> < 0.013
EHS	2 (2–3) pts	4 (2–4) pts	<i>p</i> < 0.01
SEP III	7 patients	12 patients	<i>p</i> = 0.0013
GAQ	–	12 patients	

IIEF: International Index of Erectile Function 21–25 points = normal, 16–20 = mild erectile dysfunction, 11–15 = moderate erectile dysfunction, 5–10 = severe erectile dysfunction. EHS: 0 = the penis enlarges, 1 = the penis enlarges, but not flabby, 2 = the penis hardens, but not enough for penetration, 3 = the penis is hard enough for penetration but not completely hard, 4 = the penis is completely hard and stiff. SEP: Sexual Encounter Profile; GAQ: Global Assessment Questions.

the treatment, and only 50% (2/4) of patients with a SI >20 showed improvement.

There is no influence between obesity and treatment response in these patients, according to the BMI. Overweight 73% (11/15) and obese 27% (4/15) patients, in the obese patients group had 50% (2/4) success with the treatment, the trend is that there is no association between obesity and no improvement in IIEF (*p* = 0.15).

Diabetic patients were 53% (8/15), of which 62% (5/8) had a favorable response to treatment, and 47% (7/15) of non-diabetic patients were successful with the treatment.

During the study, we compared the strength of erection with baseline and post-treatment level, finding that 53% (8/15) of patients had EHS <2, and of these, 33% (3/8) showed improvement with treatment (*p* < 0.01) (Table 2).

In reviewing the responses on the GAQ, in our study we found that 80% (12/15) of patients responded “yes”, therefore we consider it a successful treatment for these patients (Table 1).

Discussion

All treatments available for ED improve sexual function and the quality of erections, but they are not curative. The search for a cure for ED is the next step, and it should be the goal in the coming years. Scientific evidence casts controversial results, so efficiency will be demonstrated in LSWT double-blind controlled studies.

We selected measurement tools validated and accepted as the IIEF and EHS, these questionnaires have a high degree of sensitivity and specificity for detecting changes in the mechanism of erection associated to the treatment.^{7–9}

The results in our study show that EHS was >3 in 80% of patients after LSWT. It is a remarkable improvement in patients, and it is noteworthy that it was achieved without using any medication. Subjective evaluation of erectile function coincides with the fact that LSWT has an effect on the mechanism of erection by improving blood flow to the penis.¹⁰ It is suggested that successful LSWT for mild to moderate ED is defined as an increase >2 and >5 points in the IIEF.¹¹

Table 2 Patient characteristics and the effect of low-intensity extracorporeal shockwave therapy on the International Index of Erectile Function score.

Patient characteristics	No. Patient that improve IIEF	<i>p</i> value
<i>ED grade</i>		
Mild	(5/6)	<i>p</i> < 0.56
Moderate	(7/9)	
<i>Age</i>		
<60 years	(5/8)	<i>p</i> < 0.01
>60 years	(7/7)	
<i>ED duration</i>		
>3 years	(6/6)	<i>p</i> < 0.20
<3 years	(6/9)	
<i>Smoking index</i>		
>20	(2/4)	<i>p</i> < 0.05
<20	(10/11)	
<i>Quality of life</i>		
QoL >15	(10/10)	<i>p</i> = 0.19
QoL <15	(2/5)	
<i>Body mass index</i>		
>30	(2/4)	<i>p</i> = 0.009
<30	(10/11)	
<i>Diabetes mellitus</i>		
Diabetic patients	(5/8)	<i>p</i> = 0.1
Non-diabetic Patients	(7/7)	
<i>Trust to achieve and maintain erection</i>		
Q15 >3	(10/10)	<i>p</i> = 0.19
Q15 <3	(2/5)	

SEP evaluates sexual encounters with two questions; SEP-2 in the past 4 weeks, were you able to penetrate your partner?, SEP-3 Have you had an erection long enough for you to have successful intercourse? The GAQ questionnaire evaluates treatment; GAQ-1 in the past 4 weeks, Has the treatment you have been following improved erectile function?, GAQ-2 if the response to GAQ-1 is YES, Has the treatment improved its ability to engage in sexual activity during the past 4 weeks? In reviewing the responses to these questionnaires, in our study we found that 80% of patients responded “yes”, so it is considered a successful treatment for these patients.

The initial trend indicators help us identify risk factors that contribute to negative results. We consider that monitoring should be extended to obtain long-term results, and so far there are no reports of long-term results.

Conclusions

Our short-term results are encouraging, but they demand a long-term evaluation. Based on our results, LSWT can be effective and safe for the treatment of vasculogenic ED. The feasibility and tolerability of this treatment make it an attractive new treatment option for patients with vasculogenic ED.

Conflict of interest

The authors declare that they have no conflict of interest.

References

1. Persu C, Cauni V, Gutue S, Albu ES, Jinga V, Geavlete P. Diagnosis and treatment of erectile dysfunction. *J Med Life*. 2009;2:394–400.
2. Robert C, Lue TF. Physiology of penile erection and pathophysiology of erectile dysfunction. *Urol Clin North Am*. 2005;32:379–403.
3. Wespes E, Amar E, Eardley I, Giuliano F, Hatzichristou D, Hatzimouratidis K, et al. Guía clínica sobre la disfunción sexual masculina: disfunción eréctil y eyaculación precoz. *Eur Urol*. 2010;5:846–99.
4. Johannes CB, Araujo AB, Feldman HA, Derby CA, Kleinman KP, McKinlay JB. Incidence of erectile dysfunction in men 40 to 69 years old: Longitudinal results from the Massachusetts Male Aging Study. *J Urol*. 2000;163:460–3.
5. Wang CJ, Wang FS, Yang KD, Weng LH, Hsu CC, Huang CS, et al. Shock wave therapy induces neovascularization at the tendon-bone junction: a study in rabbits. *J Orthop Res*. 2003;21:984–9.
6. Lei H, Liu J, Li H, Wang L, Xu Y, Tian W, et al. Low-intensity shock wave therapy and its application to erectile dysfunction. *World J Mens Health*. 2013;31:208–14.
7. Rosen RC, Cappelleri JC, Gendrano N 3rd. The International Index of Erectile function (IIEF): a state-of-the-science review. *Int J Impot Res*. 2002;14:226–30.
8. Rosen RC, Allen KR, Ni X, Araujo AB. Minimal clinically important differences in the erectile function domain of the International index of erectile function scale. *Eur Urol*. 2011;60:1010–6.
9. Vardi Y, Dayan L, Apple B, Gruenwald I, Ofer Y, Jacob G. Penile and systemic endothelial function in men with and without erectile dysfunction. *Eur Urol*. 2009;55:979–85.
10. Vardi Y, Appel B, Jacob G, Massarwi O, Gruenwald I. Can low-intensity extracorporeal shockwave therapy improve erectile function? A 6-month follow-up pilot study in patient with organic erectile dysfunction. *Eur Urol*. 2010;58:243–8.
11. Vardi Y, Appel B, Kilchevsky A, Gruenwald I. Does low intensity extracorporeal shock wave therapy have a physiological effect on erectile function? Short-term results of a randomized, double-blind, sham controlled study. *J Urol*. 2012;187:1769–75.