



EDSWT

Erectile Dysfunction Shockwave
Therapy

Compendium of selected clinical trials
based on EDSWT

August 2013



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Peer Review - Clinical



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Sexual Medicine

Can Low-Intensity Extracorporeal Shockwave Therapy Improve Erectile Function? A 6-Month Follow-up Pilot Study in Patients with Organic Erectile Dysfunction

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Abstract

Background: Low-intensity extracorporeal shockwave therapy (LI-ESWT) is currently under investigation regarding its ability to promote neovascularization in different organs.

Objective: To evaluate the effect of LI-ESWT on men with erectile dysfunction (ED) who have previously responded to oral phosphodiesterase type 5 inhibitors (PDE5-I).

Design, setting, and participants: We screened 20 men with vasculogenic ED who had International Index of Erectile Function ED (IIEF-ED) domain scores between 5–19 (average: 13.5) and abnormal nocturnal penile tumescence (NPT) parameters. Shockwave therapy comprised two treatment sessions per week for 3 wk, which were repeated after a 3-wk no-treatment interval.

Intervention: LI-ESWT was applied to the penile shaft and crura at five different sites.

Measurements: Assessment of erectile function was performed at screening and at 1 mo after the end of the two treatment sessions using validated sexual function questionnaires, NPT parameters, and penile and systemic endothelial function testing. The IIEF-ED questionnaire was answered at the 3- and 6-mo follow-up examinations.

Results and limitations: We treated 20 middle-aged men (average age: 56.1 yr) with vasculogenic ED (mean duration: 34.7 mo). Eighteen had cardiovascular risk factors. At 1 mo follow-up, significant increases in IIEF-ED domain scores were recorded in all men (20.9 ± 5.8 vs 13.5 ± 4.1 , $p < 0.001$); these remained unchanged at 6 mo. Moreover, significant increases in the duration of erection and penile rigidity, and significant improvement in penile endothelial function were demonstrated. Ten men did not require any PDE5-I therapy after 6-mo follow-up. No pain was reported from the treatment and no adverse events were noted during follow-up.

Conclusions: This is the first study that assessed the efficacy of LI-ESWT for ED. This approach was tolerable and effective, suggesting a physiologic impact on cavernosal hemodynamics. Its main advantages are the potential to improve erectile function and to contribute to penile rehabilitation without pharmacotherapy. The short-term results are promising, yet demand further evaluation with larger sham-control cohorts and longer follow-up.

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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

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Purpose: We investigated the clinical and physiological effect of low intensity extracorporeal shock wave therapy on men with organic erectile dysfunction who are phosphodiesterase type 5 inhibitor responders.

Materials and Methods: After a 1-month phosphodiesterase type 5 inhibitor washout period, 67 men were randomized in a 2:1 ratio to receive 12 sessions of low intensity extracorporeal shock wave therapy or sham therapy. Erectile function and penile hemodynamics were assessed before the first treatment (visit 1) and 1 month after the final treatment (followup 1) using validated sexual function questionnaires and venoocclusive strain gauge plethysmography.

Results: Clinically we found a significantly greater increase in the International Index of Erectile Function-Erectile Function domain score from visit 1 to followup 1 in the treated group than in the sham treated group (mean \pm SEM 6.7 ± 0.9 vs 3.0 ± 1.4 , $p = 0.0322$). There were 19 men in the treated group who were initially unable to achieve erections hard enough for penetration (Erection Hardness Score 2 or less) who were able to achieve erections sufficiently firm for penetration (Erection Hardness Score 3 or greater) after low intensity extracorporeal shock wave therapy, compared to none in the sham group. Physiologically penile hemodynamics significantly improved in the treated group but not in the sham group (maximal post-ischemic penile blood flow 8.2 vs 0.1 ml per minute per dl, $p < 0.0001$). None of the men experienced discomfort or reported any adverse effects from the treatment.

Conclusions: This is the first randomized, double-blind, sham controlled study to our knowledge that shows that low intensity extracorporeal shock wave therapy has a positive short-term clinical and physiological effect on the erectile function of men who respond to oral phosphodiesterase type 5 inhibitor therapy. The feasibility and tolerability of this treatment, coupled with its potential rehabilitative characteristics, make it an attractive new therapeutic option for men with erectile dysfunction.

Key Words: erectile dysfunction, high-energy shock waves, penis, hemodynamics

NUMEROUS therapeutic strategies exist for improving erectile function. While these therapies have been proven to be safe and effective, they are limited for use before the sexual act and do not modify the physiological mecha-

nism of penile erection.¹ Gene and stem cell therapies are current examples of treatment strategies whose therapeutic goals are to restore erectile function as part of the present trend to shift the field of ED treat-

Abbreviations and Acronyms

ED	= erectile dysfunction
EHS	= Erection Hardness Score
FMD	= flow mediated dilatation
FU1	= followup 1
FU2	= followup 2
IIEF	= International Index of Erectile Function
IIEF-EF	= International Index of Erectile Function-Erectile Function domain score
LI-ESWT	= low intensity extracorporeal shock wave therapy
PDE5i	= phosphodiesterase type 5 inhibitors
V1	= visit 1

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 Study received institutional ethics review board approval.

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Low-Intensity Extracorporeal Shock Wave Therapy—A Novel Effective Treatment for Erectile Dysfunction in Severe ED Patients Who Respond Poorly to PDE5 Inhibitor Therapy

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ABSTRACT

Introduction. Low-intensity shock wave therapy (LI-ESWT) has been reported as an effective treatment in men with mild and moderate erectile dysfunction (ED).

Aim. The aim of this study is to determine the efficacy of LI-ESWT in severe ED patients who were poor responders to phosphodiesterase type 5 inhibitor (PDE5i) therapy.

Methods. This was an open-label single-arm prospective study on ED patients with an erection hardness score (EHS) ≤ 2 at baseline. The protocol comprised two treatment sessions per week for 3 weeks, which were repeated after a 3-week no-treatment interval. Patients were followed at 1 month (FU1), and only then an active PDE5i medication was provided for an additional month until final follow-up visit (FU2).

At each treatment session, LI-ESWT was applied on the penile shaft and crus at five different anatomical sites (300 shocks, 0.09 mJ/mm² intensity at 120 shocks/min).

Each subject underwent a full baseline assessment of erectile function using validated questionnaires and objective penile hemodynamic testing before and after LI-ESWT.

Main Outcome Measures. Outcome measures used are changes in the International Index of Erectile Function—erectile function domain (IIEF-ED) scores, the EHS measurement, and the three parameters of penile hemodynamics and endothelial function.

Results. Twenty-nine men (mean age of 61.3) completed the study. Their mean IIEF-ED scores increased from 8.8 ± 1 (baseline) to 12.3 ± 1 at FU1 ($P = 0.035$). At FU2 (on active PDE5i treatment), their IIEF-ED further increased to 18.8 ± 1 ($P < 0.0001$), and 72.4% ($P < 0.0001$) reached an EHS of ≥ 3 (allowing full sexual intercourse). A significant improvement ($P = 0.0001$) in penile hemodynamics was detected after treatment and this improvement significantly correlated with increases in the IIEF-ED ($P < 0.05$). No noteworthy adverse events were reported.

Conclusions. Penile LI-ESWT is a new modality that has the potential to treat a subgroup of severe ED patients. These preliminary data need to be reconfirmed by multicenter sham control studies in a larger group of ED patients.

Gruenwald I, Appel B, and Vardi Y. Low-intensity extracorporeal shock wave therapy—A novel effective treatment for erectile dysfunction in severe ED patients who respond poorly to PDE5 inhibitor therapy. J Sex Med 2012;9:259–264.

Key Words. Low Intensity Extracorporeal Shock Wave Therapy; Erectile Dysfunction; Penis

Introduction

Erectile dysfunction (ED) is one of the most common disorders of middle-aged men that profoundly affect their quality of life [1]. Although tremendous advances for treating this disorder

have been made in the past decade, most currently available treatment modalities still rely on an “on demand” regime, of which up to 35% are unsuccessful [2–4]. From our experience, ED patients who were treated with a phosphodiesterase type 5 inhibitor (PDE5i) tend to search for an alternative

Low-Intensity Extracorporeal Shock Wave Therapy in Vascular Disease and Erectile Dysfunction: Theory and Outcomes

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DOI: 10.1002/smrv.9



ABSTRACT

Introduction. Low-intensity extracorporeal shock wave therapy (LI-ESWT) to the penis has recently emerged as a new and promising modality in the treatment of erectile dysfunction (ED).

Aim. To review the published literature on the mechanism of action of LI-ESWT; and to report our clinical data on its efficacy in men with vasculogenic ED.

Methods. A Medline search using the relevant keywords on this topic has been done.

Results. From the results of numerous preclinical and animal studies that have been done to date, sufficient evidence shows that the underlying mechanism of action of LI-ESWT is probably neovascularization. Therefore, local application of LI-ESWT to the corpora cavernosa may potentially act in the same mechanism and increase corporal blood flow. We found that the application of LI-ESWT to patients who responded to oral therapy (PDE5i) eliminated their dependence on PDE5i and they were able to successfully achieve erections and vaginal penetration (60–75%). Furthermore, PDE5i non-responders became responders and capable of vaginal penetration (72%). Additionally, LI-ESWT resulted in long-term improvement of the erectile mechanism.

Conclusions. LI-ESWT has the potential to improve and permanently restore erectile function by reinstating the penile blood flow. Although these results on LI-ESWT are promising, further multi-centered studies with longer follow-up are needed to confirm these findings. **Gruenwald I, Kitrey ND, Appel B, and Vardi Y. Stem low-intensity extracorporeal shock wave therapy in vascular disease and erectile dysfunction: Theory and outcomes. Sex Med Rev 2013;1:83–90.**

Key Words. Low-Intensity Extracorporeal Shock Waves; Erectile Dysfunction; Therapy

Introduction

Throughout the ages, masculinity and sexual function have always been strongly linked. Erectile dysfunction (ED) is considered a sign of weakness and vulnerability, and men with ED see themselves as impotent in the wide sense of the word. Hence, the impact of ED on self-esteem and self-confidence is enormous and adversely affects quality of life [1]. From a medical standpoint, improving erectile function has always been fundamental to treating these stigmata. Fortunately, the quest for improving erectile function has been quite successful. The discovery in the mid-1980s that nitric oxide (NO) production by penile nerve terminals and vascular endothelium is essential for

normal erection improved our understanding of the pathophysiological processes that underlie ED [2]. This discovery also provided an explanation for the link between penile endothelial dysfunction and poor penile blood flow that occurs in atherosclerosis, diabetic vasculopathy, and diabetic neuropathy. This discovery also led to the improvement and development of therapies that specifically targeted penile endothelial cells, such as intracorporal injection of vasodilators and phosphodiesterase-5 inhibitors (PDE5is) [3]. Even so, none of these treatments addressed the problem of impaired blood supply to the corpora, and none of these therapies are curative because they do not restore corporal blood flow and/or endothelial function. Hence, the challenge in ED

Shockwave treatment of erectile dysfunction

Ilan Gruenwald, Boaz Appel, Noam D. Kitrey and Yoram Vardi

Abstract: Low-intensity extracorporeal shock wave therapy (LI-ESWT) is a novel modality that has recently been developed for treating erectile dysfunction (ED). Unlike other current treatment options for ED, all of which are palliative in nature, LI-ESWT is unique in that it aims to restore the erectile mechanism in order to enable natural or spontaneous erections. Results from basic science experiments have provided evidence that LI-ESWT induces cellular microtrauma, which in turn stimulates the release of angiogenic factors and the subsequent neovascularization of the treated tissue. Extracorporeal shock wave therapy (ESWT) has been clinically investigated and applied in several medical fields with various degrees of success. High-intensity shock wave therapy is used for lithotripsy because of its focused mechanical destructive nature, and medium-intensity shock waves have been shown to have anti-inflammatory properties and are used for treating a wide array of orthopedic conditions, such as non-union fractures, tendonitis, and bursitis. In contrast, LI-ESWT has angiogenetic properties and is therefore used in the management of chronic wounds, peripheral neuropathy, and in cardiac neovascularization. As a result of these characteristics we initiated a series of experiments evaluating the effect of LI-ESWT on the cavernosal tissue of patients with vasculogenic ED. The results of our studies, which also included a double-blind randomized control trial, confirm that LI-ESWT generates a significant clinical improvement of erectile function and a significant improvement in penile hemodynamics without any adverse effects. Although further extensive research is needed, LI-ESWT may create a new standard of care for men with vasculogenic ED.

Keywords: erectile dysfunction, male impotence, shockwaves, therapy

Introduction

The current nonsurgical treatment modalities in the management of erectile dysfunction (ED) mainly consist of oral phosphodiesterase type 5 inhibitors (PDE5is) and/or intracavernosal injections of vasodilating agents. These treatments are very effective and are reasonably safe with rare unwanted or adverse effects. However, they all share the same major drawback: they do not alter the underlying pathophysiology of the erectile mechanism. These treatments are usually taken on demand, prior to the sexual act, and their effect is essentially time limited. Although daily administration of a PDE5i instead of on-demand treatment does address some of these problems, it still does not modify the pathophysiology of the erectile process. Moreover, the evidence that its effect on the erectile tissue is long-lasting is very limited. Presently, only a small number of men with ED can be offered treatment that would restore their spontaneous erectile function. This group includes those who would benefit from various lifestyle or

drug regimen modifications, those who can be treated for relevant endocrine disorders, or those with vasculogenic ED who would benefit from microvascular surgery. Most patients with ED rely on their treatment in order to maintain their sexual function; providing a treatment for men with ED that is rehabilitative or even curative and enables them to regain spontaneous sexual activity with normal intimacy and without adverse effects is an unmet medical goal. Recently, data from several studies have accumulated that this goal could probably be met by low-intensity extracorporeal shockwave therapy (LI-ESWT) of the corpora cavernosa. This review intends to summarize the scientific background underlying the effect of this energy as well as recent clinical evidence of its effect in patients with vasculogenic ED.

Background

Shockwaves (SWs) are acoustic waves that carry energy and when propagating through a medium,

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Peer Review - Animal



Effects of Low-Energy Shockwave Therapy on the Erectile Function and Tissue of a Diabetic Rat Model

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DOI: 10.1111/jsm.12024

ABSTRACT

Introduction. Low-energy shockwave therapy (LESWT) has been shown to improve erectile function in patients suffering from diabetes mellitus (DM)-associated erectile dysfunction (ED). However, the underlying mechanism remains unknown.

Aim. The aim of this study is to investigate whether LESWT can ameliorate DM-associated ED in a rat model and examine the associated changes in the erectile tissues.

Methods. Newborn male rats were intraperitoneally injected with 5-ethynyl-2-deoxyuridine (EdU; 50 mg/kg) for the purpose of tracking endogenous mesenchymal stem cells (MSCs). Eight weeks later, eight of these rats were randomly chosen to serve as normal control (N group). The remaining rats were injected intraperitoneally with 60 mg/kg of streptozotocin (STZ) to induce DM. Eight of these rats were randomly chosen to serve as DM control (DM group), whereas another eight rats were subject to shockwave (SW) treatment (DM+SW group). Each rat in the DM+SW group received 300 shocks at energy level of 0.1 mJ/mm² and frequency of 120/minute. This procedure was repeated three times a week for 2 weeks. Another 2 weeks later, all 24 rats were evaluated for erectile function by intracavernous pressure (ICP) measurement. Afterward, their penile tissues were examined by histology.

Main Outcome Measures. Erectile function was measured by ICP. Neuronal nitric oxide synthase (nNOS)-positive nerves and the endothelium were examined by immunofluorescence staining. Smooth muscle and MSCs were examined by phalloidin and EdU staining, respectively.

Results. STZ treatment caused a significant decrease in erectile function and in the number of nNOS-positive nerves and in endothelial and smooth muscle contents. These DM-associated deficits were all partially but significantly reversed by LESWT. MSCs (EdU-positive cells) were significantly more numerous in DM+SW than in DM rats.

Conclusion. LESWT can partially ameliorate DM-associated ED by promoting regeneration of nNOS-positive nerves, endothelium, and smooth muscle in the penis. These beneficial effects appear to be mediated by recruitment of endogenous MSCs. **Qiu X, Lin G, Xin Z, Ferretti L, Zhang H, Lue TF, and Lin C-S. Effects of low-energy shockwave therapy on the erectile function and tissue of a diabetic rat model. J Sex Med **;**;**–**.**

Key Words. Low-Energy Shockwave; Diabetes Mellitus; Erectile Dysfunction

Introduction

Erectile dysfunction (ED) is a prevailing health problem that seriously impacts the quality of life of men and their spouses or partners [1]. Although the majority of ED patients can be sat-

isfactorily treated with phosphodiesterase type 5 inhibitors (PDE5), a substantial population (30–40%) cannot [2]. This includes patients who are intolerant to PDE5 inhibitors' side effects, taking nitrate medication for angina, or having certain types of ED refractory to PDE5 inhibitors. In particular, diabetes mellitus (DM) and surgery-induced cavernous nerve injuries (mainly due to radical prostatectomy) are currently the most

^{*}These authors contributed equally to this study.



Article

Evaluation of the Effect of Different Doses of Low Energy Shock Wave Therapy on the Erectile Function of Streptozotocin (STZ)-Induced Diabetic Rats

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Abstract: To investigate the therapeutic effect of different doses of low energy shock wave therapy (LESWT) on the erectile dysfunction (ED) in streptozotocin (STZ) induced diabetic rats. SD rats ($n = 75$) were randomly divided into 5 groups (normal control, diabetic control, 3 different dose LESWT treated diabetic groups). Diabetic rats were induced by intra-peritoneal injection of STZ (60 mg/kg) and rats with fasting blood glucose ≥ 300 mg/dL were selected as diabetic models. Twelve weeks later, different doses of LESWT (100, 200 and 300 shocks each time) treatment on penises were used to treat ED (7.33 MPa, 2 shocks/s) three times a week for two weeks. The erectile function was evaluated by intracavernous pressure (ICP) after 1 week washout period. Then the penises were harvested for histological study. The results showed LESWT could significantly improve the erectile function of diabetic rats, increase smooth muscle and endothelial contents, up-regulate the expression of α -SMA, vWF, nNOS and VEGF, and down-regulate

Abstracts from Congresses



The effect of Low Intensity Shock Waves on Erectile Dysfunction:



6-month follow up

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Objective:

To evaluate the overall efficacy of penile Low Intensity Shock Wave therapy (LI-ESWT) after 6 months in all our patients who participated in different studies.

Methods:

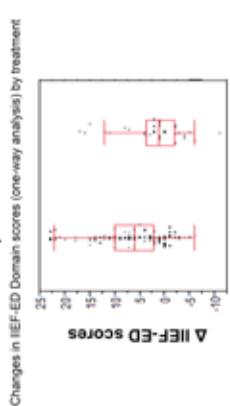
During the past 30 months we have followed up and evaluated the efficacy of LI-ESWT on 191 ED patients (155 treated and 36 Sham). These subjects represent various degrees of ED severity and response to PDE5i therapy. All received the same treatment protocol but they participated in different trials. Follow-up data were collected at the 6 month period after end of treatment and were compared to the patients' baseline scores before treatment.

Results:

- Mean age was 59 ± 10.3
- Mean ED Duration was 65.1 months.
- 86.4% were cardiovascular patients, 61 (40%) were diabetic of which 50.81% had a significant clinical improvement.
- Mean initial IIEF-ED domain scores: 11.0 (Treated-10.98, Sham 11.31)
- Mean initial Total IIEF score: 34.48 .
- No significant differences between sham and treatment regarding medical risk factors
- Based on changes in IIEF-ED Domain scores, 57.4% of all males had a significant clinical improvement 6 months after therapy.

Change in the IIEF-ED domain scores before and after treatment:

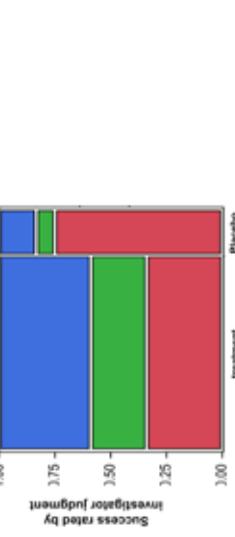
Comparison to Sham



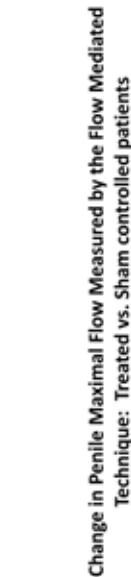
Treated (n=155) - Median score change 6, mean change 6.44
Placebo (n=36) - Median score change 1, mean change 1.77 ($P < 0.0001$)

Investigator Judgment

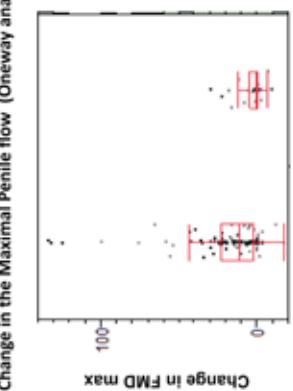
Contingency Analysis of Success By Treatment: Mosaic Plot



	No response	Partial response	Good response
Treated (%)	34.19	25.16	40.65
Placebo (%)	75.00	8.33	16.67



Change in the Maximal Penile flow (One way analysis)



Treatment (n=110): median change 0.56 ($p<0.0001$)
Sham (n=29): median change 0.56 ($p<0.0001$)

Conclusions:

In this study we have demonstrated that still after 6 months, applying LI-ESWT directly to the penis has a significant clinical effect for all ED severities, for cardiovascular and diabetic patients and for either responders or non-responders to PDE5i therapy. Further follow up in a larger scale of ED population is needed to fully evaluate the long term effect of this treatment modality.

Treatment (n=110): median change 0.56 ($p<0.0001$)
Sham (n=29): median change 0.56 ($p<0.0001$)

P-01-087

A MID-TERM ANALYSIS (6 MONTHS) OF THE EFFECT OF PENILE LOW INTENSITY SHOCK-WAVE THERAPY FOR PATIENTS OF VARYING ED ETIOLOGIES AND DIFFERENT DEGREES OF ED SEVERITY

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Objective: To evaluate the overall efficacy of penile Low Intensity Shock Wave therapy (LI-ESWT) after 6 months in patients with a variety of ED etiologies, a range of ED severities and with different responses to PDE5i's.

Methods: During the past 32 months we have followed up and evaluated the efficacy of LI-ESWT on 191 ED patients (155 treated and 36 Sham). These subjects represent a heterogeneous group of ED patients with regard to ED severity and etiology. All received the same treatment protocol but participated in different trials. Follow-up of subjective parameters using validated questionnaires (IIEF-ED Domain score, clinical judgment) was performed 6 months after end of treatment and compared to the patients' baseline scores.

Results: Mean age was 59 ± 10 years, 86% were cardiovascular patients, 50 (40%) were diabetics. Based on changes in IIEF-ED Domain scores, 57.4% of all patients had a significant clinical improvement 6 months after therapy (mean change of 6.44 points in the IIEF-ED Domain score). When sub-dividing the patients to initial severe, moderate and mild ED groups, we found that 46, 72 and 46 percent improved respectively according to minimal clinical improvement criteria. Nineteen percent of the entire group reached normalization.

Conclusion: In this study we have demonstrated that still after 6 months, applying LI-ESWT directly to the penis has a significant clinical effect for all ED severities, for cardiovascular and diabetic patients and for either responders or non-responders to PDE5i therapy.

Policy of full disclosure: an unrestricted grant was provided for this study by medispec.

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THE EFFECT OF A SECOND COURSE OF LOW INTENSITY SHOCK WAVES FOR ED IN PARTIAL OR NON-RESPONDERS TO ONE TREATMENT COURSE

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Objective: To evaluate the added effect of a second treatment course (2nd round) of penile Low Intensity Shock Wave therapy (LI-ESWT) in patients who underwent an unsuccessful or non-satisfactory 1st course.

Methods: During the past 15 months we treated 84 ED patients of various degrees of ED severity and different etiologies, all received the same treatment protocol. They were offered a 2nd round if the first one was unsatisfactory or if endpoint criteria for success were unmet. These included subjective measures (IIEF-ED Domain scores, clinical judgment) and objective hemodynamic parameters measured by Flow Mediated Dilatation (FMD) test. Evaluation of differences in changes from baseline (V1), one-month after first treatment course (FU1) and one-month after the 2nd round (FU2) was performed with non-parametric Wilcoxon tests.

Results: Twenty-two patients were included, fifteen (68%) had severe ED, mean age 59 y ± 10. After the 2nd round 7/22 (31.8%) achieved an increase of ≥5 points in IIEF-ED Domain score. This positive impact was further supported by the overall improvement in median IIEF-ED Domain scores (from 9.5 at FU1 to 13 at FU2). This 3.5 point-increase at FU2 was significant compared to the poor increase of only 0.5 at FU1 ($P = 0.0235$). According to the investigators' Clinical Global Impression of Change (CGIC) 12/22 (54.5%) improved, resulting in 6 more successful patients at FU2. According to FMD parameters, an additional significant increase of 4.24 ml/mm² tissue in maximal penile blood flow was recorded ($P = 0.0029$).

Conclusion: We have demonstrated that a 2nd round of LI-ESWT to the penis is beneficial in difficult cases of partial or unsatisfactory response to one round. A larger scale of ED patients who failed LI-ESWT is needed in order to fully evaluate the effect of the 2nd round.

Policy of full disclosure: None.

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Initial Experience of Low Intensity Shock Wave Therapy for the ED Patients in Japan

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Objective:

Phosphodiesterase type 5 inhibitors (PDE5i) revolutionized the treatment of erectile dysfunction (ED). However, even in vasculogenic ED patients, one fifth of them showed poor response to PDE5i. Vardi et al. recently reported the beneficial effects of low-intensity shock wave therapy (LI-ESWT) on mild and moderate ED. We report our initial experience of LI-ESWT (ED1000TM) for ED patients in Japan.

Methods:

This study included patients with ED history for more than 6 months, sexual health inventory for men (SHIM) score of ≤ 12 without PDE5 inhibitor, EHS grade 1 or 2, mean penile circumferential change (MPCC) by erectometer of <25 mm, and non-neurological pathology. Patients were treated by a low energy shockwaves generator (ED1000, MEDISPEC, MD, USA); 3-minute application of 300 shock waves (intensity of 0.09 mJ/mm²) in 5 different anatomical sites of penis. After the baseline assessment, treatment was done twice a week for 3 weeks (6 times), no treatment for 3 weeks, and twice a week for 3 weeks (6 times) again. Total of 12 shock wave treatments were applied.

Results:

Of 35 patients who assigned for the LI-ESWT trial, we analyzed the 14 patients whose data were available at 4 weeks after treatment. Median age was 61 years (range; 39-83). Median duration of ED was 3 years (range; 0.5-18). Median SHIM score was 5 (range; 1-12). Median MPCC was 14 mm (range; 6.7-28.3). One experienced mild pain on the penis during the procedure. SHIM after treatment was significantly increased from 5 to 10 ($p=0.041$, Wilcoxon signed-rank test). Baseline EHS was 0 in 4, 1 in 2, and 2 in 3 patients, and EHS after LI-ESWT was 2 in 4 and 3 in 5 patients. Mean MPCC was increased from 12.83 mm to 24.17 mm after LI-ESWT ($p=0.029$).

Conclusions:

We reported the pilot study of LI-ESWT for ED in Japan. This study showed the safety and feasibility of the low energy shockwaves treatment for Japanese ED patients.