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Treatment of Vasculogenic Erectile Dysfunction with Piezowave^2 Device. Application of Low Intensity Shockwaves Using Novel Linear Shockwave Tissue Coverage (LSTC-ED®) Technique. A Prospective, Multicentric, Placebo-Controlled Study

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Abstract

Low intensity shockwave (LiSW) treatment is known to improve revascularization. The method has been evaluated and is used to treat vasculogenic erectile dysfunction (ED). The present study aimed to demonstrate the efficacy of a linear focused piezoelectric shockwave device (Richard Wolf/ELvationPiezowave^2) to treat patients with vasculogenic ED using a novel linear shockwave tissue coverage LSTC-ED® technique. A total of 75 patients were treated using the Piezowave^2 device and the LSTC-ED® technique. Patients' erectile function was evaluated using the modified IIEF-5 (International Index of Erectile Function) scale at the beginning of treatment and at 1 month post treatment; patients were additionally questioned using our own Treatment Satisfaction Questionnaire (TSQ). The study also included a group of 50 patients treated by placebo; the outcomes of both groups were compared. The average IIEF-5 score of patients in the treatment group increased from 14.4 at baseline to 18.6 at 1 month post treatment. According to the IIEF-5 scale, treatment was successful in 81.33% of patients (61/75). According to the Treatment Satisfaction Questionnaire (answers 1 to 3 of the TSQ), treatment was successful in 77.3% of patients

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(58/75). In the placebo group of 50 patients only 5 patients showed an improvement based on IIEF score, and 8 reported an improvement based on their answers to the TSQ. No significant adverse effects were observed during treatment or in the follow-up period. The Piezowave² device and the LSTC-ED® technique proved to be suitable and effective to treat erectile dysfunction.

Keywords

Piezowave², LSTC-ED®, Erectile Dysfunction, Extracorporeal Shockwaves, Low Intensity Shockwave Therapy

1. Introduction

Erectile dysfunction (ED) is defined as inability to achieve or maintain erection adequate for sexual intercourse. The association between vascular disease and erectile dysfunction has been recognized and well documented. Alterations in the vascular hemodynamics are believed to be the most common cause of organic erectile dysfunction .Vascular diseases such as diabetes mellitus or atherosclerotic vascular occlusive disease are present in up to 60% of ED patients.

It has been demonstrated that shockwaves can improve intrinsic angiogenic activity when used to treat ischemic heart disease [1]. Current methods for treating vasculogenic ED aim to reduce symptoms rather than reverse the cause of the disorder, which in most cases is due to disorders affecting arterial inflow, so the use of shockwaves to treat ED has been evaluated [2] [3] using a modified orthopedic device [4]. The present study aims to assess the safety and efficacy of a shockwave device, the Piezowave² device of Richard Wolf GmbH, which offers substantially superior treatment parameters and organ coverage using a new Linear Shockwave Tissue Coverage LSTC-ED® technique.

The study was conducted in accordance with the principles of the Helsinki Declaration, and approved by the Ministry of Health of the Czech Republic and by the 1st Faculty of Medicine, Charles University. The survey was administered anonymously by trained researchers under the supervision of Institute of Sexology, the 1st Faculty of Medicine, Charles University. All respondents gave consent to participate.

2. Patients and Methods

This study was a prospective, multicenter, placebo-controlled study. The study consisted of a screening phase, a treatment phase and follow-up at 1 month. In the screening phase, 157 patients arrived for physical examination and their medical history was recorded. Only heterosexual men aged between 36 and 71 years with vasculogenic ED for at least 6 months, an International Index of Erectile Function (IIEF-5) score of 7 to 21 while on PDE5-I, and in a stable heterosexual relationship since at least 6 months were recruited to the study.

Vasculogenic ED was assessed by measuring of Cardio-ankle vascular index (CAVI) which is an excellent indicator of arterial stiffness. CAVI has been widely applied clinically to assess arterial stiffness [5].

All 75 (+50 placebo group) recruited patients were responders to phosphodiesterase type 5 inhibitors (PDE5-I) and use PDE5-I prior to and during the treatment as usual.

Exclusion criteria were hormonal, neurological or psychological pathology; prior radical prostatectomy; unstable medical, psychiatric and/or spinal cord injury; penile abnormality; clinically significant chronic hematological disease; use of anti-androgens, treatment for cancer in the past 5 years; radiotherapy of the pelvic region.

All patients completed the baseline evaluation questionnaire which consisted of 5 questions from the modified IIEF-5.

This questionnaire consists of 5 questions on erectile function; the IIEF-5 scale ranges from 1 - 25 points, with some level of ED considered to be present for scores below 21 points.

The newly designed TSQ questionnaire comprised the 4 questions shown below. This questionnaire had been created by us to be able to evaluate treatment results and satisfaction more precisely and it proved to be very understandable for all patients.

Both questionnaires were also used to evaluate treatment one month after treatment had ended.

Treatment consisted of four weekly sessions using the LSTC-ED® technique. The technique covers the entire

organ and was developed and introduced in 2014 at our department based on our experiences with appropriate LiSW devices. In each session 4000 shocks of 0.16 mJ/mm^2 were applied. The wave focus penetration depth was set to 10 - 15 mm. Shocks were applied to the corpora cavernosa (2000) and the crus of the penis (2000). The treatment areas were the same in each session, so that by the end of the full course of treatment (4 sessions) the total number of applied shocks was 16,000. Each session lasted 8.3 minutes, and the total treatment time was 33 minutes, with the total energy applied amounting to 2560 mJ.

50 patients in the placebo group were given the same treatment regimen; however, the device was switched off and a typical shockwave sound recording (MP3 file) was played through external speakers. During treatment as well as during the first month following treatment, all patients took PDE5-I where necessary. Follow-up was done 1 month post treatment. The primary criterion of success was defined as an increase in IIEF-5 score from baseline to follow-up at 1 month after treatment, with the severity of symptoms graded according to the minimal clinically important differences in the erectile function domain of the International Index of Erectile Function scale (IIEF-5) [6], modified as shown in **Table 1**.

3. Assessed Device

The Piezowave^2 of Richard Wolf GmbH and Elvation Medical GmbH differs from other shockwave devices in that it offers full organ coverage and superior treatment parameters. The device uses piezoelectric elements (rather than electrohydraulic or electromagnetic principles) to generate shockwaves and linear double layer technology to apply shockwaves to the target area. In linear shockwave therapy (LSWT), the treatment area is 46 mm long and 4 mm wide with a penetration depth into the target organ of 5 - 20 mm. Shocks are delivered at a maximum rate of 480 PPM (8 Hz), resulting in shorter treatment sessions than with other shockwave devices.

These characteristics combined with the LSTC-ED® technique allowed sufficient energy to be applied to the whole penile area in a very short space of time.

4. Results

157 patients were initially examined before patient selection. Finally a total of 75 (+50) middle-aged men (mean age: 56.5 years, range: 35 - 70 years) with vasculogenic ED were recruited and finished the study. There were no drop-off patients.

71% of patients suffered from comorbidities such as diabetes (18%), hypertension (36%), dyslipidemia (21%) or coronary heart disease (3%). According to results obtained with the IIEF-5 scale, treatment was successful in 81.33 % of patients (61/75).

Our original TSQ questionnaire consisted of 4 questions:

Q1. I was: 1) very satisfied; 2) fairly satisfied; 3) satisfied; 4) rather unsatisfied; 5) unsatisfied with the effect of treatment;

Q2. Treatment was: 1) painless; 2) slightly uncomfortable; 3) neutral; 4) rather uncomfortable; 5) uncomfortable;

Q3. My sexual life after the treatment is: 1) much better; 2) substantially improved; 3) better; 4) not much improved; 5) not improved;

Q4. I would: 1) definitely recommend this treatment; 2) probably recommend this treatment; 3) recommend this treatment; 4) rather not recommend this treatment; 5) not recommend this treatment to other patients.

Based on the answers to these questions, 58 of 75 patients (77.3%) showed themselves to be satisfied or very

Table 1. The success criteria of this study-modified from: 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, European Urology, November 2011, 60(5): 1010-1016.

IIEF-5 Baseline Score	Success Factor
5 - 8	Improvement of 7 Points or More
9 - 14	Improvement of 5 Points or More
15 - 21	Improvement of 2 Points or More

satisfied with the treatment received (answers 1 - 3). No patient reported significant pain during treatment, and 82% of patients stated that they would recommend this treatment to others.

In the placebo group only 5 patients (10%) showed an improvement in IIEF-5 score; based on the TSQ only 8 patients (16%) reported greater satisfaction after placebo treatment.

There were no complications or side effects during the treatment.

5. Discussions

Given that the reported success rate after treating patients with other comorbidities and an initial IIEF-5 score of 6 - 8 points is only around 20%, selecting eligible patients with vasculogenic ED suitable for treatment is crucial.

We are currently working on the first unique algorithm which will allow us to customize treatment to each patient. The overall number of shocks applied will take factors into account that could influence the outcome of treatment (e.g., degree of erectile dysfunction, blood sugar and lipid levels, smoking, etc.). We believe that this "tailored" treatment is right pathway for the future evolution of this treatment because it would not only reduce costs but especially increase the efficacy.

The study is still ongoing, with more patients included and further follow-ups are planned to evaluate the long term duration of treatment efficacy as well as the long term safety and possibility of re-treatment

Patients will be evaluated after 3 and 6 months, than after 1 and 2 years. We expect the IIEF-5 score to have increased by 3 - 6 months post treatment as has been reported in previous studies.

6. Conclusion

The results of this study indicate that Piezowave^2 and the LSTC-ED® technique are effective to treat mild to moderate vasculogenic ED using low-intensity focused shockwaves. More studies are required to confirm the safety and efficacy of this treatment. Particularly, we believe that in the future it is the most important to focus on the unification of treatment parameters among different devices, techniques and to perform more multicentric, placebo-controlled studies on this harmonized basis as well as to evaluate results with respect to our new treatment algorithm developed for tailored treatment.

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