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Low intensity shockwave (LiSW) treatment is known to improve revascularization. The method has been evaluated and is used to treat erectile dysfunction (ED). The present study aimed to demonstrate the efficacy of a linear focused piezoelectric shockwave device (Richard Wolf/ELvation Piezowave²) 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 Piezowave² 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 10 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 (58/75). In the placebo group of 10 patients only 1 patient showed an improvement based on IIEF score, and 2 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.

Key words: Piezowave², LSTC-ED®, erectile dysfunction, extracorporeal shockwaves, low intensity shockwave therapy

Introduction

Vasculogenic erectile dysfunction (ED) is defined as an inability to achieve or maintain erection adequate for sexual intercourse. Vascular diseases such as diabetes mellitus or atherosclerotic vascular occlusive disease are present in up to 60% of ED patients. 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. It has been demonstrated that shockwaves can improve intrinsic angiogenic activity when used to treat ischemic heart disease [1]. The use of shockwaves to
treat ED has also been evaluated [2, 3] using a modified orthopedic device [4]. The present study aimed 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.

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, patients arrived for physical examination and their medical history was recorded. Only heterosexual men aged between 36 and 71 years with vascular 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. Recruited patients were at least partial responders to phosphodiesterase type 5 inhibitors (PDE5-I). 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 used PDE5-I in the 4 weeks prior to starting treatment. All patients completed the baseline evaluation questionnaire, which consisted of 5 questions from the modified IIEF-5 and our own TSQ (4 questions). Both questionnaires were also used to evaluate treatment one month after treatment had ended. IIEF-5 is widely accepted as the best method to identify ED. It 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 TSQ questionnaire comprised the 4 questions shown below. Treatment consisted of four weekly treatment sessions using the LSTC-ED® technique. The technique covers the entire organ and was developed by us based on our experiences with appropriate LiSW devices. In each session 4000 shocks of 0.16 mJ/mm² 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 16000. Each session lasted 8.3 minutes, and the total treatment time was 33 minutes, with the total energy applied amounting to 2560 mJ. 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) [5], modified as shown in Table1.
**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, 2011 Nov;60(5):1010-6*

<table>
<thead>
<tr>
<th>IIEF-5 Baseline Score</th>
<th>Success Factor</th>
</tr>
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<tbody>
<tr>
<td>5-8</td>
<td>improvement of 7 points or more</td>
</tr>
<tr>
<td>9-14</td>
<td>improvement of 5 points or more</td>
</tr>
<tr>
<td>15-21</td>
<td>improvement of 2 points or more</td>
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**Assessed device**

The Piezowave² 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.

**Results**

A total of 75 middle-aged men (mean age: 56.5 years, range: 35-70 years) with vasculogenic ED were recruited into the study. 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 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 1 patient showed an improvement in IIEF-5
score; based on the TSQ only 2 patients reported greater satisfaction after placebo treatment.

Conclusions

The results of this study indicate that Piezowave² and the LSTC-ED® technique are very effective to treat mild to severe ED using low-intensity shockwaves. 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 will not only reduce costs but also increase the efficacy of treatment. The study is still ongoing, with more patients included and further follow-ups planned to evaluate the duration of treatment efficacy. We expect the IIEF- 5 score to have increased by 3-6 months post treatment as has been reported in similar studies. More studies are required to confirm the safety and efficacy of this approach, and to evaluate the effect of changes in the treatment protocol with respect to our new algorithm.

References