

# Linear Extracorporeal Shockwaves for Erectile Dysfunction Treatment: an Advanced Feasibility Study

Paolo Puppo, Antonio Casarico

Montallegro Clinic, Genova, Italy

## *Introduction*

Erectile dysfunction is associated with various comorbidities, including cardiovascular disease, advancing age, diabetes and hypertension (ref. 1).

Low intensity extracorporeal shockwaves treatment (LI-ESWT) has been shown to have a beneficial effect on erectile function in men with erectile dysfunction and cardiovascular risk factors in a randomized, double-blind, sham controlled study (ref. 2).

The encouraging results of previous studies have been followed by several trials that evaluated the efficacy of a new shockwave device, which was developed especially for the treatment of erectile dysfunction. As the new device enables excellent cover of the treated organ, superb results were obtained by applying it at the Crura and at the Corpora Cavernosa, at both sides each. At this study, a new treatment protocol was evaluated; a larger number of shocks were applied at the Crura in order to increase the therapeutic effect on the origin of the male sexual organ.

## *Materials and Methods*

This study was conducted on an outpatient basis in the Montallegro Clinic, Genoa. Eligible patients were those who have been suffering from Vasculogenic erectile dysfunction for at least 6 months, both PDE-5 inhibitors responders and non-responders. Patients with any kind of erectile dysfunction which does not origin from a vascular disease were excluded from the study. First, patients were evaluated by the International Index of Erectile Function (IIEF-6). Then, all patients were instructed not to use PDE-5 inhibitors from 3 weeks prior treatment and until the end of treatment. Treatment consisted of 4 weekly identical sessions, in which patients laid in a lithotomic position and the shockwave device ("Renova", Direx-Group Ltd.) was attached to 4 treated areas: left and right Crus and left and right Corpus Cavernosum. Each Crus received 1600 shocks and each Corpus Cavernosum received 900 shocks. At the end of the treatment, all patients who have been using PDE-5 inhibitors before being recruited to the study continued their old consumption habits. At 1 month post the end of treatment, patients came back to the clinic for a follow-up session, had a physical examination for adverse effects detection and answered several questionnaires for erectile function evaluation.

## *Results*

10 patients were included in this study and their mean age was  $62.4 \pm 9.8$  years (45-74). Patients arrived to receive a treatment after a mean duration of 5.6 years in which they have been suffering from Vasculogenic erectile dysfunction. Patients smoking habits in the past and in the present were reported; when referring to 'pack years', meaning the number of packs smoked per day x years as a smoker, the mean value of patients was

24.4 pack years. Patients were also suffering from background diseases, as described in the following table:

Cardiovascular	Diabetes	Hypertension	Cholesterol
40.0%	30.0%	40.0%	50.0%

At baseline evaluation, the mean IIEF of patients was  $19.5 \pm 3.9$ . At 1 month follow-up, patients mean IIEF was  $24.3 \pm 4.7$ , an increase of 4.8 points.

Patients have answered questions 2 and 3 of the Sexual Encounter Profile (SEP), before and at 1 month after treatment. These questions evaluate the ability to achieve a successful intercourse and the answers to those questions are either "Yes" or "No". At baseline evaluation, the number of patients that answered "Yes" to questions 2 and 3 were 8 and 6 respectively. At 1 month follow-up, the numbers increased to 10 and 8.

Patients have filled in the Erection Hardness Score at baseline evaluation and at 1 month follow-up. The mean score has risen from 2.5 at baseline to 3.2 at 1 month follow-up.

At the follow-up meeting, patients have also answered questions 1 and 2 of the Global Assessment Questions (GAQ). These questions evaluate the improvement in erectile function as a result of the treatment. As in the SEP, the answers to those questions are either "Yes" or "No". The number of patients that answered "Yes" to questions 2 and 3 were 8 and 7 respectively.

Patients did not report on any pain or discomfort during and after the treatment. Adverse events were not reported from any patient.

#### *Discussion and conclusion*

This study has shown the efficacy of linear shockwaves in the treatment of Vasculogenic erectile dysfunction. When determining the success of treatment according to the "Minimal Clinically Important Differences in the Erectile Function Domain of the International Index of Erectile Function Scale" (ref. 3), it appears that 7 out of 10 patients have succeeded in the treatment. In addition, one of the patients, 71 years old men who suffered from Vasculogenic erectile dysfunction in the past 2 years, was using PDE-5 inhibitors before treatment with an IIEF of 20, and after the treatment had very good erections and satisfactory sexual intercourses (IIEF 29) without any aid or medication. Since this report includes only 10 patients, it is too soon to compare the outcomes of the new treatment protocol with the old protocol.

#### *References*

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