

Evaluation of SWT efficiency in treatment of Erectile Dysfunction

Preliminary case report

Authors:

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Summary:

The main objective of the study was to investigate and prove the effectiveness and safety of radial shock wave therapy (RSWT) in treatment of erectile dysfunction (ED) caused by vascular disorders.

Key words: extracorporeal shockwave therapy, erectile dysfunction, pneumatic shockwave system

Background

Erectile dysfunction (ED) is a common problem which affects large population of men especially in 40-70 years of age. The most common cause of erectile dysfunction is poor cavernosal arterial blood flow in the penis - vasculogenic ED. Our study aimed to prove that inducing neovascularization by extracorporeal shock wave therapy could potentially improve cavernosal arterial flow which will lead to improved erectile function.

Shockwave therapy is a non-invasive, non-pharmacological therapy which triggers a natural mechanism in treated area and may allow restoration of penile function and sexual spontaneity without need for ongoing treatment

Technology

The term “shockwave therapy” refers to the mechanical pressure pulses that expand as a wave within the human body. In 1980, the shockwave method was used for the first time to disintegrate kidney stones in a patient (Journal of Urology, 1982). During the past two decades, this method has become the standard treatment in many other fields including rehabilitation, orthopaedic surgery and non-invasive urology. In these fields extracorporeal shock wave therapy (in contrast to lithotripsy) is not used to disintegrate tissues,

but rather cause microscopic interstitial and extracellular biological effects which result in tissue regeneration. In urology we expect positive effect of shock wave therapy on local neovascularization and reversal of chronic inflammation. These long-term mechanism are also supported with intense local vasodilatation and pain suppression following immediately the swt application.

BTL-6000 SWT is a radial shockwave therapy device enabling the application of therapy by using handheld pneumatic applicator. (Pic. 1)



Pic. 1. BTL 6000 SWT

Materials and methods

This was a prospective single/center, open label clinical study of the radial shockwave therapy system (BTL-6000 Topline, manufacturer: BTL Industries ltd.) intended for treatment patients with symptoms of erectile dysfunction (ED).

The patients were enrolled to the study according following inclusion criteria: Erectile dysfunction existence for more than 6 months; metabolic syndrome; Hypertension; Diabetes; Positive results of fosfomonoestherasis-5; Normal level of testosterone.

Assessment of erectile function was performed at screening, after the last treatment and at the 3- and 6-month follow-up examinations using the International Index of Erectile Function (IIEF) questionnaire.

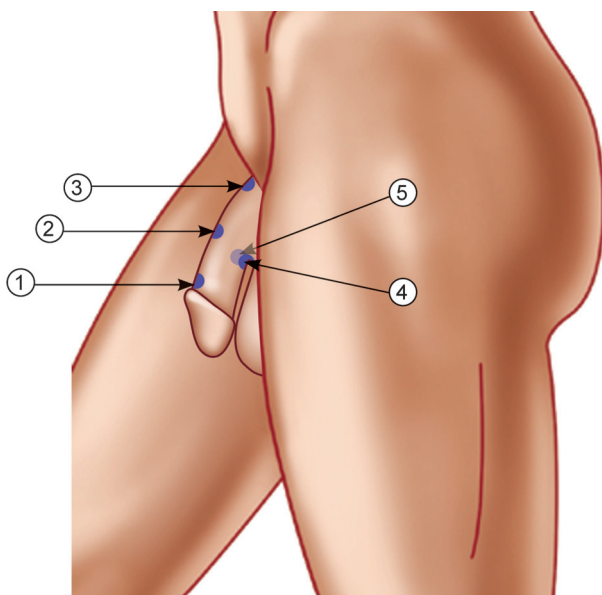
Safety assessments were based on complications and reported adverse events.

Patients underwent 8 treatments on every 3 – 4 days.

The therapy was administered in contact manner using direct application onto the treated area.

The therapy started outside the most painful area and then after few dozens of pulses moved on directly above the pathologic area.

The application pressure was set to 1,5 bars and frequency to 12 Hz. If the therapy was well tolerated, the pressure was progressively increased up to 2 bars.



Pic. 2. Treatment areas

The therapy was performed in 5 consequent steps/ areas with 600 pulses applied in each step/area using static application. (Pic.2) Starting from the first therapy session the total number of the pulses was 3000 per one session.

Results

We treated 8 middle-aged men (average age: 55.5 ± 6.3 yr.) with vasculogenic ED. After the last treatment, significant increases in IIEF domain scores were recorded in all subjects (average 57.6 ± 11.6 vs 37.2 ± 13.5). More than 10 points improvement in IIEF domain score was noted in 3 patients, and by more than 20 points in 4 patients. Only one subject had IIEF total score increased with less than 10 points.

These results remained unchanged at 30 and 90-day examination.

A significant increase in the duration of erection and penile rigidity were reported. It was observed a genuine physiological and psychological effect on the erectile mechanism.

No adverse events were reported during the sessions and follow-ups.

Patient tolerance of the treatments was excellent, none of the subjects reported treatment-associated pain during or after the treatment.

Conclusion

The main object of the study was to investigate the effectiveness and safety of extracorporeal shock wave therapy (ESWT)) in treatment of erectile dysfunction (ED) caused by vascular disorders. The results of the study show that the ESWT device BTL-6000 SWT is safe and efficacious to improve erectile function. Patients tolerate the treatment sessions well.

ESWT is a new treatment option for erectile dysfunction, enabling the patient to achieve and maintain dependable erections.

In view of these very successful preliminary results, further extensive research is essential and adequate.