

Evaluation of SWT efficiency in alleviation of chronic prostate inflammation

Preliminary clinical study report

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Abstract

Aim: The purpose of the study is to investigate the effectiveness of extracorporeal shock wave therapy (ESWT) for symptoms alleviation in patients with chronic pelvic pain syndrome (CPPS).

Design: A prospective single/center, open label clinical study.

Participants: 29 patients with symptoms of chronic pelvic pain syndrome.

Methods: Extracorporeal shock wave therapy device BTL-6000 SWT.

Outcome measures: Symptom scale score (pain and urinary symptoms) and total scale score (pain, urinary and quality of life symptoms).

Results: 24 patients had observed 50% or better alleviation of the pelvic pain and urinary syndroms. Mean symptom alleviation through all 29 patients was 68%. All patients tolerated treatment well and no adverse effects were reported.

Conclusion: The results of the study show that the radial SWT device BTL-6000 SWT is safe and efficacious for reducing chronic pelvic pain and urinary symptoms.

Background:

Extracorporeal shock wave therapy is effectively used to reverse the process of development of kidney stones, cystitis, kidney diseases (pyelonephritis), etc. and also in case of chronic prostatitis and benign prostate hyperplasia. Chronic prostatitis is an inflammation of the prostate gland. The main cause of the disease is an invasion of the gland by an infectious agent. BPH is a benign hyperplasia of the prostate. It is a benign tumor arising from growth of prostate tissue. It is one of the most common urogenital diseases in men. We work with the positive effect of swt on local neovascularization, reversal of chronic inflammation. These long-term mechanism are also supported with intense local vasodilatation and immediate pain suppression.

Technology:

Radial shock wave therapy device BTL-6000 SWT (manufacturer: BTL industries, UK) is a portable device enabling the application of therapy by using non-invasive shockwaves.

Shockwaves are acoustic waves with an extremely high energy. A shockwave differs from ultrasound by its large pressure amplitude up to 25MPa. Additionally, shockwave uses a single pulse for therapy effect. The term “shockwave therapy” refers to the mechanical pressure pulses that expand as a wave within the human body. 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 causes microscopic interstitial and extracellular biological effects which result in tissue regeneration. The BTL-6000 SWT device consists of the main pneumatic compressor unit and handheld applicator.

Materials and methods:

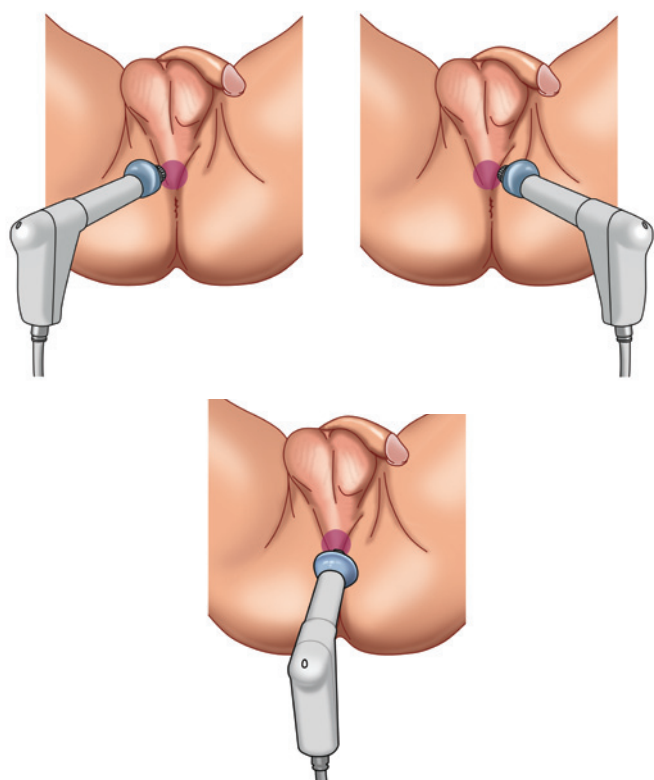
A prospective single/center, open label clinical study of the Shock Wave device was intended for treatment of 30 patients with symptoms of chronic pelvic pain syndrome (CPPS). Patients suffering

from chronic pelvic pain for more than 3 months and having no addiction to drugs or narcotics were chosen for the study. Patients were examined prior to the first treatment, when symptom scale score (pain and urinary symptoms) and total scale score (pain, urinary and quality of life symptoms) were inquired. An anticipated duration of each subject's treatment cycle was 4 months, with standardized follow-up performed after the last treatment, 30 and 90 days following the therapy.

The study was performed on 29 patients. The therapy was administered in contact manner using direct application above the target area, with 15mm diameter focused applicator and the contact area fully covered by sufficient amount of transmission gel. The application pressure was set to 3 bars and frequency to 8 Hz. If the therapy was well tolerated, the pressure was progressively increased up to 5 bars.

First 500 pulses were applied with the applicator positioned with approximately 30° angle deviation to the left side. Next 500 pulses were applied on opposite 30° angle deviation to the right side, last 1500 pulses in the central position of the applicator. Starting from the second therapy session the number of the pulses was increased to 2000 in the last therapy phase (central applicator position). Total numbers of the pulses were 3000 per one session.

Patients were positioned on the urological chair.



Patients underwent 4 treatments in weekly period. Symptom Scale Score (pain and urinary symptoms) ranging from 0 to 31, where Mild stands for 0-9, Moderate 10-18, Severe 19-31; and Total Score (pain, urinary and quality of life symptoms) ranging from 0 to 43 were evaluated, according to The National Institutes of Health Chronic Prostatitis Symptoms Index (NIH-CPSI). The patients' symptoms were questioned before the first treatment and after the last treatment.

Results:

The study was performed on 29 patients. Subjects' age ranged from 27 to 70 years with the mean age of 42.51 ± 10.12 years. All subjects in the study received 4 weekly treatments. After the last ESWT treatment, the total scores and sub-domain scores (Symptom scale score) were evaluated.

Significantly decrease in Symptom scale score (pain and urinary symptoms), QOL (Quality of life), and total NIH-CPSI was observed after last treatment. 24 patients had observed 50% or better alleviation of the pelvic pain and urinary syndroms. Mean symptom alleviation through all 29 patients was 68%.

5 patients, noticed only small symptoms alleviation (less then 50%). The second group of 15 patients had ESWT treatment allowed to reduce the chronic pelvic pain symptoms up to 80%. 9 patients had symptoms alleviation >80%.

Decreases in quality of life (QOL) scores were also significant (mean 78%). At the end-point of treatment, the improvement in mean of total NIH-CPSI compared with the results before treatment was 57% (12.7 points decrease). All patients tolerated treatment well and no adverse effects were reported.

Conclusion:

The goal of the study was to investigate the effectiveness of extracorporeal shock wave therapy (ESWT) for symptoms alleviation in patients with chronic pelvic pain syndrome (CPPS). The results of the study show that the ESWT device BTL-6000 SWT is safe and efficacious for reducing chronic pelvic pain and urinary symptoms. Patients tolerate the treatment sessions nicely. The device and methodology, evaluation methods, patient's selection and management are adequate for a larger study.