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Original Article

Effect of radial shock wave on chronic pelvic pain syndrome/chronic prostatitis

Amr B. Salama, PhD[1, 2)*], Walid A. Abouelnaga, PhD[2)]

[1)] *Department of Physical Therapy, College of Applied Medical Sciences, Najran University, Saudi Arabia*
[2)] *Department of Physical Therapy for Surgery, Faculty of Physical Therapy, Cairo University: Giza, Egypt*

Abstract. [Purpose] This study aimed to evaluate the effect of radial extracorporeal shock wave therapy (rESWT) on patients with chronic pelvic pain syndrome (CPPS). [Participants and Methods] Forty male CPPS patients were randomly assigned into either an rESWT group or a control group. The first group was treated with rESWT two times per week for four weeks with a protocol 3,000 pulse, 12 Hz at 3 to 5 bar. The control group was treated with the same protocol, but the device's probe had been turned off. The follow-up assessment was done using the National Institutes of Health-developed Chronic Prostatitis Symptom Index (NIH-CPSI) before treatment, as well as one week, four weeks, and 8 weeks after treatment. [Results] No significant difference was found in terms of age, sub-domain, or the total score of the NIH-CPSI between the rESWT group and the control group at the baseline. A statistically significant decrease was determined in the pain domain, urine score, quality of life, and the total NIH-CPSI score of the rESWT group at all post-treatment time points. All domains and the total score of the NIH-CPSI at all three follow-up time points decreased more significantly in the rESWT group as compared to the control group. [Conclusion] The findings of this study confirmed that rESWT is an effective method for treating CPPS.
Key words: Radial shock wave, Chronic pelvic pain syndrome, Prostatitis

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INTRODUCTION

Chronic pelvic pain syndrome (CPPS) or chronic prostatitis (CP) is a common urological disorder[1)]. It has adverse effects on the patient's quality of life. It is increasing in prevalence, affecting about 15% of the adult male population[2)]. Chronic non-bacterial prostatitis is the main etiology of chronic pelvic pain syndrome[3)].

CPPS is diagnosed if pelvic pain persists for more than three months with no infection present. CPPS causes pain in the perianal region; it also causes a problem with voiding[4)].

The pathophysiology of CP/CPPS has not yet been fully explained. Neuropathy, inflammation, pelvic floor muscle dysfunction, and neurobehavioral disorder are the most common hypothesized etiologies[5)].

Medical treatment such as anti-inflammatory agents, antibiotics, analgesics, α-receptor blockers, and 5α-reductase inhibitors are used. Recently, alternative therapy has been used, such as physiotherapy, hyperthermia, acupuncture, balloon dilatation, laser coagulation, intra-prostatic injection of botulinum toxin A, and invasive neuromodulation[6–8)].

Shock waves are a sequence of single sound pulses, characterized by high point of pressure reach up to 100 MPa (but most often 50–80 MPa), fast reach of pressure for a short period of less than 10ns, short duration (10 μs), followed by a variable negative pressure that can affect cavitation and a frequency of 16–20 Hz[9)].

Shock wave therapy has been used successfully in the treatment of certain chronic conditions such as diabetic wounds,

*Corresponding Author. Amr B. Salama (E-mail: amrpt81@yahoo.com)

tendinitis, planter fasciitis, and epicondylitis[10, 11]. Recently, ESWT has been investigated in CPPS due to its anti-inflammatory, analgesic, and anti-spastic effects. The previous studies showed that ESWT is an effective modality and is safe for the treatment of CPPS[12–17].

ESWT can be classified into two types: focused ESWT and radial ESWT. The radial wave is less painful and covers a larger area than the focal shock wave[18].

No previous study has been conducted to evaluate the effect of radial shock waves on CPPS, as the previous studies investigated focused ESWT. Therefore, this study evaluated the efficacy of radial shock waves on CPPS.

PARTICIPANTS AND METHODS

From December 2015 to November 2017, in Najran University campus, we conducted a 12-week, randomized, single-blinded study to assess the effect of radial shock waves on patients with CPPS of type IIIB. Based on the National Institute of Health (NIH) classification, it is characterized by a lack of signs of infection in the urine and semen, with a total score of greater than 15. The diagnosis of CPPS was based on history, signs, symptoms, the NIH-CPSI questioner, prostatic transrectal ultrasonography, urine analysis, uroflowmetry with residual urine measurement, four-glass test, and a semen culture. All participants signed an informed consent.

The selected patients maintained the following inclusion criteria: above 18 and less than 50 years old; suffering from pelvic pain or discomfort in the lower abdomen, genitalia, groin, bladder, and/or perianal area without abnormalities and with persistence of at least three months; and with a NIH-CPSI total score of more than 15 and pain greater than 4.

The study excluded patients receiving treatment using alternative methods or who had alternate diagnoses, such as prostate cancer.

This study was approved by the ethics committee of Najran University. The patients were randomly allocated into the rESWT group or the control group.

The randomization process was performed using closed envelopes. The investigator prepared 40 closed envelopes, each of which contained a card labeled either "rESWT group" or "control group." Each patient was asked to select a closed envelope that stated whether the patient was allocated to the rESWT group or the control group. The patients were randomly allocated to either the rESWT group (n=20) or the control group (n=20). All the patients did not receive any drugs or medication within four weeks prior to enrollment and through the study.

In the rESWT group, the patients were treated by radial shock waves twice a week for a period of four weeks, receiving 3,000 impulses per session; continuous type of the shocks, frequency with12 Hz was delivered at the intensity of 3 to 5 bar, according to the patient's tolerance, the intensity was increased gradually until reaching the tolerable level of pain.

The patient was asked to lie down in the supine position, with the hip abducted and flexed. The probe of the shock wave device (Shockmaster MP200, pneumatic-mechanical radial shock wave device, Storz Medical®, Switzerland) was applied with ultrasound gel perpendicular to the perineal region targeting the painful area.

The patients in the control group were treated using a sham rESWT, as the device's probe was turned off.

To avoid the infection, the area of treatment and the probe of the device were cleaned and sterilized before and after the application. Every patient was asked to remove the hair in the area of application, 2 days before starting of the treatment.

The follow-up evaluation to detect the efficacy of radial shock waves was done by Arabic version of the NIH-CPSI which is an index developed to assess symptoms and quality of life in men with CPPS. It is consist of three subscales addressing pain, urinary symptoms, and quality of life (QOL). It has demonstrated good validity and reliability, and it has been used as the primary outcome variable in multiple large-scale studies of CPPS treatments. It has also been translated into several languages as Arabic version which used in this study[19].

The evaluation performed before the treatment (pre-treatment), one week after the initiation of the treatment (post-1), four weeks after the initiation of the treatment (post-2), and eight weeks after the end of treatment (post-3).

Participant characteristics were compared between both groups using a t-test. A mixed MANOVA was conducted to compare the mean values of the pain domain, urinary score, quality of life, and total score of NIH-CPS between the treatment and control groups and among the four time periods (pre-treatment, post 1, post 2, and post 3) in each group. The level of significance for all statistical tests was set at $p<0.05$. All statistical analysis was conducted using SPSS (Statistical Package for Social Version 19 for Windows [IBM SPSS, Chicago, IL, USA]).

RESULTS

Forty patients with CPPS participated in and completed this study. The mean ages of the patients in the treatment (rESWT) and control groups were 37.6 ± 7.89 and 35.1 ± 7.59 years, respectively with no statistical different between them ($p>0.05$). The symptom duration means of treatment group and control group were 11.75 ± 2.69 and 12.80 ± 3.20 months, respectively with no statistical different between them ($p>0.05$).

The baseline evaluation for the means of the pain score, urinary score, quality of life, and total score of NIH-CPSI between the treatment (rESWT) group and control group were not statistically different ($p>0.05$) (table 1).

In terms of a within-group comparison, in the treatment (rESWT) group, the means of all four domains of the NIH-CPSI

Table 1. Comparison of pain, urine score, quality of life, and total score of NIH-CPSI within groups and between groups

Variables		rESWT group	Control group	Mean difference
		Mean ± SD	Mean ± SD	
Pain	Pre	12 ± 1.58	12.75 ± 2.19	−0.75
	Post-1	7.75 ± 2.02	10.65 ± 1.78*	−2.9
	Post-2	3.05 ± 1.95	10.7 ± 2.51*	−7.65
	Post-3	2.45 ± 1.73	10.65 ± 2.58*	−8.2
Urine score	Pre	5.8 ± 1.5	5.1 ± 1.58	0.7
	Post-1	3.5 ± 1.27	4.05 ± 1.76	−0.55
	Post-2	1.45 ± 1.27	4.45 ± 1.9*	−3
	Post-3	1.4 ± 1.09	4.3 ± 2*	−2.9
Quality of life	Pre	8.35 ± 1.18	8.15 ± 1.69	0.2
	Post-1	4.55 ± 1.5	6.8 ± 1.47*	−2.25
	Post-2	1.75 ± 1.86	6.65 ± 1.84*	−4.9
	Post-3	1.85 ± 2.03	6.8 ± 2.26*	−4.95
Total NIH-CPSI score	Pre	26.15 ± 2.94	26 ± 3.62	0.15
	Post-1	15.8 ± 3.54	21.5 ± 3.15*	−5.7
	Post-2	6.25 ± 4.11	21.8 ± 4.16*	−15.55
	Post-3	5.7 ± 3.81	21.75 ± 5.22*	−16.05

*Significant ($p<0.05$) difference between rESWT and control group. SD: Standard deviation; NIH-CPSI: National Institutes of Health-developed Chronic Prostatitis Symptom Index.

score significantly decreased in post-1, post-2, and post-3 from the baseline ($p<0.05$). also, there was significant decrease in post-2 and post-3 as compared to post-1 ($p<0.05$). However, no significant differences were found in all four domains between post-2 and post-3 ($p>0.05$). In the control group, there was a significant decrease in all four domains of the NIH-CPSI score in post-1 as compared to the baseline ($p<0.05$), but there was no significant difference in post-2 and post-3 as compared to the previous reading ($p<0.05$). In the control group's urinary score, there was deterioration in post 2 and post 3 compared to the post-1. In terms of QOLm there was deterioration in post 3 as compared to post-1 but with no statistical different (Table 1).

In terms of a between-groups comparison, in post 1 there was a significant difference between the treatment group and the control group in the pain domain, QOL, and total score of the NIH-CPSI, but no significant difference in urinary score. In post 2 and post 3 there was a significant difference between the treatment group and the control group in all four domains of the NIH-CPSI. The result also showed that improvement in all four domains of the NIH-CPSI score of the treatment group was significantly better than that of the control group (Table 1).

DISCUSSION

CPPS is a common disorder in urology. Its diagnosis stems from symptoms such as pain or discomfort in the perineal area, pelvis, and suprapubic area, with ejaculatory and voiding problems. The disease has no established pathophysiology[20].

Shock waves have been used to treat chronic conditions such as orthopedic problems, diabetic wounds, burns, and spasticity[9, 10]. Recently, the clinical effect of ESWT on CPPS has received attention, and several studies have applied ESWT as an alternative means of management for the treatment of CPPS[12–17].

ESWT is classified into focused ESWT (fESWT) and radial ESWT (rESWT) based on the reflector for its pressure field and energy. The characteristic of rESWT are less painful, less penetration depth, less focus of the energy on the targeted spot, and relatively lower intensity as compared to fESWT[18].

According to our literature review, no previous studies discussed the efficacy of radial ESWT on CPPS; all the previous studies were about focused ESWT.

This study showed an improvement in pain, urinary score, quality of life, and the total score of the NIH-CPSI in both groups, however significantly more so for the rESWT group as compared to the control group. At the end of the study, the percentage of improvement in NIH-CPSI score for the rESWT group was 78.6%, while it was 19% in the control group.

Previous studies of focused ESWT showed similar results. Zimmermann et al. conducted two studies; in the first one, they showed significant statistical improvement in pain and QOL in the shock wave group; urinary conditions improved, but with no statistical significance. In the second study, they showed significant statistical improvement in pain and QOL in the shock wave group[13, 14].

In a randomized study with CPPS patients, Zeng et al. reported that pain, QOL, and NIH-CPSI scores significantly improved in the ESWT group. The 12-week follow-up showed an exacerbation of pain, symptoms, and NIH-CPSI score in both groups[10].

In a randomized study on CPPS, Vahdatpur et al. showed an improvement in pain, QOL, urinary score, and NIH-CPSI score with a slight deterioration in all variables during the 12-week follow-up[15].

In another study, Moayednia et al. randomized 40 patients with CPPS into treatment and control groups. In a short-term follow-up, they found ESWT to be a safe and effective therapy for CPPS[16].

Al Edwan et al. evaluated the long-term effect and safety of extracorporeal shock wave therapy (CPPS). They showed significant statistical improvement in pain level, CPPS-related complaints, micturition, QOL, and potency, with maintenance of the effect without any significant side effects over the 12 months following treatment with ESWT[17].

The mechanism of rESWT on CPPS remains unclear. There are some explanations that ESWT modulates pain signal transmission through the gate control theory. Shock waves produce extracellular cavitation, which may damage the nerve ending[11, 21]. Other considerations are reduction in muscle tone, interruption of the nerve impulse flow, and nociceptors' hyperstimulation, influencing pain memory neuroplasticity[22]. Shock waves may induce nitric oxide (NO) synthesis, NO is involved in neuromuscular junction formation in peripheral nervous system including neurotransmission and synaptic plasticity. NO synthesis may be one of the important mechanisms to explain the effectiveness of shock waves as antiinfiammatory[23].

Shock waves produce neovascularization with release of angiogenesis-mediating growth and proliferating factors, including endothelial nitric oxide synthase, vascular endothelial growth factor, and proliferating cell antinuclear antigen, all of which lead to improved blood supply and tissue regeneration[24].

In this study, the dose of rESWT increased from previous studies by increasing the number of shocks per session, the number of sessions, and the duration of treatment, as rESWT is less painful and less intense than fESWT. This study noted no significant side effects during the treatment.

The importance of this study is that it is the first to evaluate the effect of radial shock waves, as previous studies evaluated focused shock waves. The patients included in our study failed to achieve improvement with traditional treatment options such as anti-inflammatories, antibiotics, and alpha blockers.

The weakness of this study is the lack of long-term follow-up for the patient and the limited number of participating patients.

This study revealed that radial shock waves are effective and safe modalities in the treatment of CPPS cases with respect to a short-term follow-up.

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Conflict of interest

None.

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