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Efficacy of Radial Extracorporeal Shock Wave Therapy for Chronic Pelvic Pain Syndrome: A Nonrandomized Controlled Trial

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Abstract

This study aims to determine the effect of radial extracorporeal shock wave therapy (rESWT) versus drug when treating chronic pelvic pain syndrome (CPPS; type III B chronic prostatitis). The study included 45 participants with CPPS, divided into two groups: Group I comprised 25 participants, who were treated with rESWT (3,000 pulses each; pressure: 1.8–2.0 bar; frequency: 10 Hz) once a week; Group II consisted of 20 participants who received a combination of an α-blocker and an anti-inflammatory agent. Participants were treated for 8 weeks. The assessments were done before treatment, after the fourth and eighth rESWT, and 3 months after the end of treatment by Visual Analogue Scale (VAS) for pain, National Institutes of Health-developed Chronic Prostatitis Symptom Index (NIH-CPSI), International Prostate Symptom Score (IPSS), quality of life (QoL), and International Index of Erectile Function-5 (IIEF-5). Both groups of participants showed statistically significant improvement in all the assessments ($p < .001$) after the treatment, with significantly better results in Group I in NIH-CPSI ($p < .001$). The recurrence rate of symptoms in Group I at 3 months after end of treatment was much lower than that in Group II (4% vs. 50%, $p < .001$). This prospectively nonrandomized, control study revealed perineal rESWT as a new therapy option for CPPS with statistically significant effects in comparison to drugs at least for 3 months after cessation of treatment.

Keywords

chronic pelvic pain syndrome, radial extracorporeal shock wave therapy, chronic prostatitis

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According to the National Institutes of Health (NIH) classification, chronic pelvic pain syndrome (CPPS) is characterized by lack of signs of infection in urine and sperm as well as by specific symptoms such as urinary and erectile dysfunction, pain focused in the prostate region, and perineal, inguinal, scrotal, and suprapubic pain. Depending on the presence or absence of inflammatory cells in the semen or prostatic fluid, CPPS is classified into either NIH IIIA or NIH IIIB prostatitis. CPPS is a common condition that affects nearly 8.2% of men (Magistro et al., 2016). As the disease prolongs, the patients may also have emotional disorders, such as depression, which will severely impact the quality of life. The complex and heterogeneous pathophysiology of CPPS is poorly understood.

By covering primary physiological etiologies, α-blockers and anti-inflammatories rather than monotherapy is often used for patients with type IIIB CPPS because of its convenience and good efficacy (Rees, Abrahams, Doble, Cooper, & Prostatitis Expert Reference Group, 2015). Although the drug treatment can quickly relieve the symptoms for most people, the signs often recur after

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withdrawal, and long-term medication often has side effects such as hypotension and liver and kidney function damage. Thus, numerous patients face frustration with the inadequate efficacy of drug treatment (Thakkinstian, Attia, Anothaisintawee, & Nickel, 2012). In addition, some physical therapy approaches have provided positive results, such as biofeedback, acupuncture, and transcutaneous electrical nerve stimulation (Rees et al., 2015).

Since the effectiveness of transperineal extracorporeal shock wave therapy (ESWT) was first investigated in CPPS patients in 2008, it has shown great potential (Guu et al., 2018). There are different mechanisms through which ESWT reduces pain: inducing neovascularization and anti-inflammation, nerve impulse interruption, reduce passive muscle tone, and influencing neuroplasticity of the pain memory (Al Edwan, Muheilan, & Atta, 2017; Guu et al., 2018). There are two forms of ESWT available, focused (fESWT) and radial (rESWT; Schmitz et al., 2015; Speed, 2014). As the second generation of ESWT, ESWT is the ballistic type in which stress waves are generated using a projectile impacting a solid surface. The energy is highest at the tip of the applicator and decreases peripherally by the square of the distance. Different from fESWT which focuses shock waves with a point of highest pressure at the desired target within diseased tissue, rESWT generates a diffused shock wave. The maximum frequency of the rESWT (21 Hz) is significantly higher than that of the fESWT (5 Hz). As the probe moves, the rESWT acts more evenly than the fESWT, and does not require imaging positioning to avoid damage to nerves and blood vessels. The therapeutic penetration depth is depending on the type of transmitter tip and the intensity parameter to meet different treatment needs. Several studies reported that fESWT is readily applicable by transperineal approach without side effects, achieving significant improvement of CPPS-related symptoms, particularly concerning pain (Al Edwan et al., 2017; Guu et al., 2018; Moayednia, Haghdani, Khosrawi, Yousefi, & Vahdatpour, 2014; Pajovic, Radojevic, Dimitrovski, & Vukovic, 2016; Vahdatpour et al., 2013; Zeng, Liang, & Ye, 2012; Zimmermann et al., 2008; Zimmermann, Cumpanas, Miclea, & Janetschek, 2009). The encouraging results of those studies remind us that rESWT should also be useful for CPPS.

This study compares the effects of transperineal rESWT versus drug (α-blocker and anti-inflammatory) for the treatment of noninflammatory CPPS (Category III B).

Methods

Study Design and Participants

The study participants were recruited from patients with type IIIB chronic prostatitis seeking treatment at the First Affiliated Hospital of China Medical University from June 2016 to September 2017. All participants were fully informed regarding the execution and goals of the study and provided written informed consent. All study procedures were approved by the Ethics Committee of the Chinese Clinical Trial Registry. The Clinical Trial Registry Number is ChiCTR-OPC-17013456. The inclusion criteria include no evidence of bacteria in urinary and seminal culture tests (standards according to NIH classification; National Institutes of Health Chronic Prostatitis Symptom Index, NIH-CPSI) >19, and a pain score of NIH-CPSI >3. The exclusion criteria included being under treatment by another method at the beginning of the study, urinary tract infections, cystitis, prostate cancer, urinary calculi, urinary tract tuberculosis, urethral stricture, coagulation abnormalities or oral anticoagulants, patients with a PSA level >4 ng/ml, and refusal to sign informed consent. The participants were provided with two options for treatment: rESWT (Group I) or drug (Group II).

Study Intervention

The participants who selected rESWT (Group I) received one transperineally applied rESWT treatment weekly (3,000 pulses each; pressure: 1.8–2.0 bar; frequency: 10 Hz) with the transducer head R15 (diameter: 15 mm) for 8 weeks. The pressure started at 1.8 bar and increased by 0.1 bar per week until 2.0 bar. According to preliminary tests, most patients can tolerate strengths up to 2.0 bar. In previous reports, fESWT was treated once a week for CPPS, and most other musculoskeletal diseases treated with rESWT were also once a week, so this treatment interval was chosen for this trial (Guu et al., 2018). The participants were asked to empty the bladder before the procedure and lie in lithotomic position. A standard commercial gel generally used for sonography was applied to the perineum. The device used for the study was a standard ballistic shock wave unit with a radial shock wave source (MASTERPULS® MP100, STORZ MEDICAL AG, Switzerland). The therapist informed the patient to avoid local hot compresses within 24 hr of treatment. The participants of Group II received the combination of an α-blocker (tamsulosin 0.2 mg/day) and an anti-inflammatory (celecoxib 200 mg/day) for 8 weeks and were followed up for 3 months after stopping the drugs.

Assessment

The follow-up assessments were done at the initiation, after the fourth and eighth rESWT, and 3 months after the end of treatment. Group II was evaluated at 4 and 8 weeks after commencement of medications and 3 months after drug withdrawal. Throughout the study, additional drug

Table 1. Differences in the Primary Criterion of Response Between Two Groups of Participants 8 Weeks After the Treatment Initiation.

	Group I			Group II		
	Response number	Total number	%	Response number	Total number	%
Primary criterion (A)	25	25	100	18	20	90
Primary criterion (B)	24	25	96	15	20	75

Note. The primary criterion (A) of response to therapy was scoring 2 or less on the NIH-CPSI QOL item after 8 weeks. The primary criterion (B) of response to therapy was a greater than 50% reduction in NIH-CPSI total score after 8 weeks.

intake was excluded. The degree of pain was evaluated using the Visual Analog Scale (VAS, 0–10) (Guu et al., 2018). CPPS-related complaints were investigated using the NIH-CPSI (0–43; Guu et al., 2018). NIH-CPSI addresses the three most important domains of chronic prostatitis, which are pain, urinary function, and quality of life (QoL, 0–6). Micturition conditions were examined using the International Prostate Symptom Score (IPSS, 0–35; Guu et al., 2018); the International Index of Erectile Function-5 (IIEF-5, 0–25) was applied for evaluating erectile dysfunction (Guu et al., 2018). The primary criterion responding to therapy was scoring 2 or less ("delighted-to-mostly satisfied") on the NIH-CPSI QoL item or more significant than a 50% reduction in total NIH-CPSI scale after 8 weeks of treatment (Pajovic et al., 2016). The secondary criterion of response to therapy was VAS, IPSS, and IIEF-5. During the 3-month follow-up, if the NIH-CPIS score is higher than 17 and the VAS score is higher than 3, it is defined as relapse of CPPS, and the participants can receive medication or rESWT as they wish.

Statistical Analysis

Data were analyzed using SPSS (version 22) and expressed as mean ± standard error of mean. The statistical analyses such as chi-square, paired *t*-test, and independent *t*-test were used. Statistical significance was set at $p < .05$.

Results

The study included 50 participants with type IIIB CPPS, 30 of whom underwent rESWT (mean age: 40 years, range: 22–64; mean duration: 37.4 months, range: 5–71 months); the other 20 participants received medication (mean age: 39 years, range: 27–61; mean duration: 36.1 months, range: 6–66 months). There was no significant difference in the basic conditions such as age ($p = .898$), duration of disease ($p = .657$), NIH-CPSI ($p = .668$), and pain VAS score ($p = 1.000$) between the two groups. Participants without an active sexual life do not apply to IIEF-5 scores. Five participants in Group I were removed because they did not follow the treatment plan. The rest of the participants completed the treatment and follow-ups. IIEF-5 was evaluated in 23 participants and 16 participants in Group I and Group II, respectively. No adverse effect associated with rESWT, such as hematuria, hemospermia, perineal pain, or ecchymosis, was seen in any of the participants.

Using the primary criterion, all the subjects (100%) responded in Group I compared to 18 of 20 (90%) in Group II. Whereas, 24 of 25 subjects (96%) responded in Group I compared to 15 of 20 (75%) in Group II (Table 1). Both groups showed statistically significant improvement ($p < .001$) in VAS, NIH-CPSI, QOL, IPSS, and IIEF-5 scores at 4 weeks and 8 weeks compared with baseline (Table 2). For between-group comparisons, NIH-CPSI ($p = .006$) and IIEF-5 ($p = .02$) scores demonstrated significant differences between the two groups at 8 weeks (Table 2).

During the follow-up period, 10 participants (50%) in the drug group relapsed and restarted medication. One patient in the rESWT group had a slight recurrence of symptoms and did not seek treatment. At the 3 months follow-up, except for the 10 participants (including nine participants with a sexual life) who relapsed and restarted medication in the drug group, the remaining maintained the efficacy and there was no significant difference in all the scores between the two groups (Table 2). The recurrence rates of the rESWT group and the drug group were 4% (1 out of 25) and 50% (10 out of 20), respectively, and the difference was statistically significant ($p < .001$; Table 3).

Discussion

In the current study, data reveal improvement in pain VAS, NIH-CPSI, QoL, IPSS, and IIEF-5 scores both in Group I and Group II after 4 weeks of treatment. After 8 weeks of treatment, the improvement of Group I was more visible in the NIH-CPSI score, indicating that the rESWT was more effective with the prolongation of treatment time. At the follow-up of 3 months after the end of treatment, it can be seen that the recurrence rate of Group II was significantly higher than that of Group I, meaning that the therapeutic effect of the rESWT was longer than that of the drugs. There was no significant difference in the

Table 2. Changes in NIH-CPSI, NIH-CPSI QOL, Pain VAS, IPSS, and IIEF-5 Scores in Both Groups of Participants.

	Baseline	4 weeks	p^a	8 weeks	p^a	3 months (*n*)	p^a
NIH-CPSI (*n*)							
Group I (25)	28.52 ± 4.07	19.12 ± 2.92	<.001	10.32 ± 2.70	<.001	10.44 ± 2.20 (25)	<.001
Group II (20)	28.05 ± 2.96	19.65 ± 2.76	<.001	13.00 ± 3.55	<.001	11.10 ± 1.73 (10)	<.001
p^b	.668	.539		.006		.403	
QOL (*n*)							
Group I (25)	4.72 ± 0.98	3.16 ± 1.03	<.001	1.48 ± 0.51	<.001	1.72 ± 0.74 (25)	<.001
Group II (20)	4.60 ± 0.99	3.00 ± 0.80	<.001	1.65 ± 0.67	<.001	1.80 ± 0.79 (10)	<.001
p^b	.687	.570		.339		.778	
VAS (*n*)							
Group I (25)	5.40 ± 0.82	3.24 ± 0.78	<.001	1.40 ± 0.58	<.001	1.32 ± 0.56 (25)	<.001
Group II (20)	5.40 ± 0.99	3.00 ± 0.80	<.001	1.75 ± 0.97	<.001	1.20 ± 0.42 (10)	<.001
p^b	1.000	.314		.139		.544	
IPSS (*n*)							
Group I (25)	21.80 ± 6.66	15.40 ± 5.19	<.001	8.72 ± 3.17	<.001	8.92 ± 2.89 (25)	<.001
Group II (20)	21.60 ± 6.14	15.45 ± 4.22	<.001	9.25 ± 3.14	<.001	9.90 ± 1.29 (10)	<.001
p^b	.918	.972		.579		.312	
IIEF-5 (*n*)							
Group I (20)	16.50 ± 2.50	19.35 ± 2.08	<.001	21.80 ± 1.47	<.001	21.60 ± 1.47 (20)	<.001
Group II (16)	16.25 ± 1.88	19.44 ± 2.34	<.001	19.56 ± 2.28	<.001	21.00 ± 1.53 (7)	.001
p^b	.742	.907		.002		.365	

Note. Data are mean ± *SD*. NIH-CPSI = National Institutes of Health Chronic Prostatitis Symptom Index; QOL= quality of life; VAS = Visual Analog Scale; IPSS = International Prostate Symptom Score; IIEF-5 = International Index of Erectile Function-5.
p^a: compared with baseline. p^b: comparison between groups.

Table 3. Three-Month Follow-Up of the Recurrence of the Two Groups.

	Total number	Relapse number	Relapse rate
Group I	25	1	4%
Group II	20	10	50%

NIH-CPSI score between the two groups at the 3-month follow-up mainly because the 10 relapsed patients in Group II did not count. Also, none of the participants reported any adverse effect associated with rESWT. No report on rESWT of CPPS has been found yet.

Two latest studies reviewed literature from 2008 to 2018 (Franco et al., 2018; Guu et al., 2018) on the positive results of fESWT in the improvement of CPPS. Four studies with 237 participants reported that fESWT reduced prostatitis symptoms compared to the sham control or no intervention control, measured by NIH-CPSI score at 12 weeks' follow-up (Pajovic et al., 2016; Vahdatpour et al., 2013; Zeng et al., 2012; Zimmermann et al., 2009). In most of the studies, the fESWT was applied once a week for four times, and the long-term effect of fESWT is still equivocal (Al Edwan et al., 2017; Moayednia et al., 2014). One of the studies reported sexual dysfunction and identified that fESWT probably reduced sexual dysfunction compared to control, measured by the IIEF scale at 12 weeks (Pajovic et al., 2016; Vahdatpour et al., 2013; Zeng et al., 2012; Zimmermann et al., 2009). In the current study, 8-week rESWT showed excellent effects both in NIH-CPSI and IIEF which last for 3 months. Because generators and protocols of fESWT are different in previous studies, the results are hard to compare.

An open-label, single-arm prospective study reported that for patients with severe CPPS who are nonresponsive to traditional 3-As therapy (antibiotics, α-blockers, and anti-inflammatories), fESWT has proved to be able to allow these patients to become responders (Zimmermann et al., 2008). The patients had concomitant α-blocker and anti-inflammatory drug use during and after fESWT. After 12 weeks of fESWT treatment, up to 72.7% of patients could taper 3-As medication and only 36.4% of patients still needed anti-inflammatory drugs. The conclusions of this study are consistent with their research, and rESWT may replace the drug treatment of CPPS. Therefore, it can circumvent many side effects of drugs, such as postural hypotension, palpitation, and gastrointestinal complaint. The study conducted by Pajovic et al. (2016) indicates that 12 weeks of a combination of triple therapy (α-blocker, anti-inflammatory agent, and muscle relaxant) and fESWT showed significantly better results than the triple therapy group in all aspects of NIH-CPSI

scores in the 24-week posttreatment follow-up. However, there are no reports on the comparison of ESWT and drugs. The 3-month follow-up results in this study suggested that the recurrence rate of the rESWT (4%) group is significantly lower than that of the drug group (50%), clearly indicating the advantage of the rESWT to the drugs.

A possible cause of CPPS might be neurogenic or immunogenic inflammation; this activates prostate-afferent nerves, and induces inflammation, prostate pain, and referred pain. Previous studies have reported that NGF and cytokines (IL-6, IL-10, INF-γ, TNF-α, and IL-1b,) that regulate inflammation might play a role in the pain symptoms experienced by patients with CPPS (Khan et al., 2017; Wang, Cheng, & Chuang, 2017). Previous studies have reported that ESWT has protective effects on inflammatory reaction, by downregulation NF-kB and NF-kB-dependent inflammatory genes, as well as lowering the expression of NGF, IL-6, IL-12, TNF-a, COX-2, and iNOS (Chen et al., 2014; Wang, Cheng, et al., 2017; Wang, Lee, Tyagi, Huang, & Chuang, 2017). These effects of ESWT might be used as a novel therapy in treating CPPS.

Another possible mechanism through which rESWT can improve CPPS may be partly mediated by the antispasm effect. CPPS is assumed to be the ultimate reflection of a smooth and skeletal neuromuscular disorder phenomenon in the perineum or pelvic floor (Khan et al., 2017; Vahdatpour et al., 2013). Abnormal activity of the perineum and pelvic floor muscles causes pain in the corresponding areas outside the prostate. The current guideline points out that, based on the antispasmodic effect of α-adrenergic antagonists, they may have a modest treatment effect regarding total, urinary symptom, pain, and QoL scores in CPPS and should be considered as an initial treatment option (Rees et al., 2015). There are also reductions in muscle tone and spasticity after applying ESWT in patients with upper arm hypertonia and hypertonic plantar flexor muscles caused by a stroke (Guo et al., 2017; Santamato et al., 2014). Several authors have concluded that the mechanism most likely linked to the reduction of spasticity could be related to a direct effect of shock waves improving the stiffness of connective tissue by directly acting on the rheological properties of the hypertonic muscles (Santamato et al., 2014; Sohn, Cho, Kim, & Hwang, 2011). ESWT could also recruit endogenous mesenchymal stem cells to promote angiogenesis, tissue repair, and nerve generation in a rat model of pelvic neurovascular injuries (Li et al., 2016), thereby improving muscle stiffness.

The current study has several limitations. First, it was a nonrandomized controlled trial, which is inevitably biased. Second, the participant number was limited; hence, a comparison of the efficacy of rESWT for different etiologies of CPPS is difficult. Third, the follow-up period was only 3 months; thus, the long-term effectiveness of rESWT could not be evaluated. Fourth, there was no sham rESWT group to eliminate the placebo effect.

CPPS is a frequently-occurring disease with poor drug efficacy and side effects, posing great challenges for clinicians. This study proved that rESWT is a comparable therapy without side effects for CPPS compared with the combination of an α-blocker and an anti-inflammatory agent, although it did not compare rESWT with fESWT. rESWT has a higher frequency than fESWT, and the same number of pulses takes less time. Although rESWT is not as convenient as a drug to be taken at home, it requires hospital treatment, but this noninvasive and convenient physical method provides a new and promising option for CPPS. It will be further explored whether shortening the treatment interval and increasing the intensity will improve the efficacy.

Declaration of Conflicting Interests

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