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Research Article

Extracorporeal shockwave therapy of the perineum for male patients with chronic pelvic pain syndrome: a pilot study



P R O S T A T

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A R T I C L E I N F O

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ABSTRACT

Background: Chronic pelvic pain syndrome (CPPS) is a complex condition that is often difficult to treat and may sometimes require a multidisciplinary team. Among the wide array of treatment options is extracorporeal shockwave therapy (ESWT). However, its role in CPPS remains controversial. The purpose of our study is to assess the efficacy and safety of ESWT of the perineum in male patients with CPPS.

Methods: Fourteen patients aged between 21 and 85 years were recruited in this single-center, singlearm prospective trial from October 2018 to October 2020. ESWT was delivered to the perineum weekly for up to 8 weeks. Assessment was done via International Index for Erectile Function, International Prostate Symptom Score, King's Health Questionnaire, National Institutes of Health – Chronic Prostatitis Symptom Index, Visual Analogue Scale, Analgesic Questionnaire, and UPOINT (urinary symptoms [U], psychosocial dysfunction [P], organ-specific symptoms [O], infection-related symptoms [I], neurological/ systemic conditions [N], tenderness of skeletal muscles [T]) phenotype system. The parameters are assessed before the start and end of treatment as well as at regular time points on follow-up appointments up to 20 weeks.

Results: Thirteen patients completed the study. There was improvement in the Visual Analogue Scale pain score, Tenderness domain on UPOINT, King's Health Questionnaire, and National Institutes of Health – Chronic Prostatitis Symptom Index scores. In terms of erectile function, improvement in the erectile function domain of International Index for Erectile Function was observed. There was also significant improvement in lower urinary tract symptoms assessed on International Prostate Symptom Score. There were no adverse events reported post treatment and during the follow-up period.

Conclusions: ESWT improved pain and quality of life of male patients with CPPS. It can be a safe and effective treatment modality in the armamentarium of CPPS.

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1. Introduction

Chronic pelvic pain syndrome (CPPS) type III is used to designate unexplained chronic pelvic pain in men. This pain is associated with irritative voiding symptoms and/or pain located in the groin, genitalia, or perineum, in the absence of pyuria and bacteriuria.¹ In patients with CPPS type III, no bacteria are detectable in prostatic secretions by Gram stain and culture. CPPS type III comprises 90% of CPPS patients, and current medical treatment (antibiotics, alpha blockers, anti-inflammatories) has variable effects often equal to placebo.² A recent study suggests that a short course of dutasteride may help with the symptoms.³

Although CPPS is also referred to as 'chronic prostatitis', there is increasing evidence that the etiology of CPPS type III does not involve the prostate. Instead, causative factors may be the other viscera, neurological, or musculoskeletal.⁴ In particular, studies have found musculoskeletal tenderness in more than half of CPPS patients, and pelvic floor therapy (trigger point therapy, massage and exercises) achieved a 64% patient satisfaction rate at 12 weeks

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follow-up.^{5,6} Pelvic floor ischemia in CPPS patients has been postulated as a cause for pain.

Extracorporeal shockwave therapy (ESWT) has been used in the clinic for myofascial trigger point therapy since the 1990s, and is reported to be effective for treatment of CPPS IIIb patients.⁷ ESWT is a well-documented therapy in the treatment of erectile dysfunction. The mode of action is by stimulating angiogenesis in the ischemic tissues by exposing them to low-intensity shockwayes. As pelvic floor ischemia is a problem implicated in CPPS, we hypothesize that similar dosages of low-intensity shockwaves to different zones in the pelvic floor can improve CPPS-related symptoms, particularly with regard to pain.

The primary objective of this study was to evaluate the efficacy and safety of ESWT of the perineum for male patients with CPPS.

2. Materials and methods

2.1. Study design

The study was a single-center single-arm prospective openlabel trial, and individuals were recruited between October 2018 and October 2020 from the National University Hospital, Singapore. Patients are evaluated using International Index of Erectile Function (IIEF), International Prostate Symptoms Score (IPSS), quality of life (QOL) using short form King's Health Questionnaire (KHQ), National Institutes of Health – Chronic Prostatitis Symptom Index (NIH-CPSI), Visual Analogues Scale (VAS) pain scale, Analgesic Questionnaires and UPOINT phenotype system (urinary symptoms [U], psychosocial dysfunction [P], organ-specific symptoms [O], infection-related symptoms [I], neurological/systemic conditions [N], tenderness of skeletal muscles [T]).^{8–12} The trial study was approved by our institutional review board, NHG DSRB Ref no. 2018/00182.

2.2. Patient selections

Male patients with CPPS and aged between 21 and 85 years were recruited. Inclusion criteria were as follows: (1) chronic pelvic pain for more than a 3-month duration and failed at least one course of systemic treatment; (2) no evidence of ongoing urinary treat infection and prostatic infection; and (3) patients should also have identifiable pelvic myofascial trigger points via digital rectal examination (DRE) (Fig. 1A), able to understand and complete the questionaries.

Exclusion criteria were as follows: identified nonmuscular cause of pelvic pain such as tumor, benign prostate hyperplasia, urinary stones, irritable bowel syndrome, multiple sclerosis, nerve impingement, and fibromvalgia. Patients are on anticoagulant medications or have blood coagulation disorder.

All patients provided written informed consent for involvement in the study.

2.3. Withdrawal criteria

Patients who find the therapy uncomfortable can choose to withdraw from the study. Patients will need minimum of 4 sessions of ESWT or they will be withdrawan from the study.

2.4. Medical device and treatment protocol

The ESWT will be performed using the Dornier Aries device (manufactured by Dornier MedTech). All treatments will be performed with the patient in the lithotomy position. A total of 6000 shockwave will be delivered to the perineum at a maximum energy level of 5-7 (0.06-0.10 mJ/mm²), over 5 treatment points in the urogenital triangle (Fig. 1B). ESWT will be delivered once a week over a duration of 15-20 minutes. All patients will receive 4 sessions of ESWT over 4 weeks and will be followed up at the 4th week and 12nd week after the 4th session. If the patient has residual pain symptoms (VAS pain score > 2) at the 4^{th} week's follow-up visit, he will be offered another 4 sessions of ESWT over 4 weeks, and followed up at the 4th week and 12nd week after the final treatment session.

2.5. Study assessment, follow-up, and end point

2.5.1. Screening/baseline visit

After giving consent, all patients will complete the IIEF-15, IPSS, KHQ, NIH-CPSI, VAS pain score, and Analgesic questionnaires and have a clinical review for UPOINT criteria. This includes clinical history as well as DRE of the pelvic floor muscles and the prostate. Location of any pelvic tender/trigger points will be recorded. Patients with identified trigger points will be offered ESWT.



Fig. 1. A: Identifiable pelvic myofascial trigger points. B: Area to deliver shockwave for the extracorporeal shockwave therapy.

A: Identifiable Pelvic Myofascial Trigger Points

2.5.2. Treatment visits

DRE will be performed to identify and assess pelvic trigger points. ESWT will be applied to the perineum as per the treatment protocol.

Adverse events and CPPS pain from the preceding week will be assessed at each treatment visit. Patients with a VAS Pain scale score of >2 at the 4th week follow-up visit will be offered 4 more sessions of ESWT. Patients who accept the 4 more ESWT sessions, the ESWT will be delivered once a week.

2.5.3. Follow-up visits after final ESWT

Patients with only 4 sessions of ESWT will complete the IIEF-15, IPSS, NIH-CPSI, KHQ, VAS pain score, and Analgesic questionnaires at week 4, week 8, and week 16.

Patients with 8 sessions of ESWT will complete the IIEF-15, IPSS, KHQ NIH-CPSI, VAS pain score, and Analgesic questionnaires at week 4, week 12, and week 20.

Clinical review for UPOINT criteria will be performed, including symptom evaluation and DRE for pelvic trigger points. Adverse events will be assessed at each follow-up visit.

2.6. Statistical methods

Differences in mean on the domains of IIEF-15, IPSS, KHQ NIH-CPSI, and VAS pain score between the baseline and on the last week of follow-up (after treatment) were compared using paired sample *t*-test, while the mean difference in UPOINT criteria between the baseline and on the last week of follow-up (after treatment) were compared using McNemar test. Post treatment, mean differences between patients with 2 or less trigger points versus those with more than 2 trigger points were compared using independent sample *t*-test for continuous variables and Pearson Chi-square for categorical variables. A *P* value of <0.05 is considered to be significant. All statistical evaluations were generated using STATA v. 14 assuming a two-sided test at the conventional 5% level of significance. The statistical analyses were performed according to the principle of intention-to-treat.

3. Results

A total of 14 patients were recruited for ESWT for CPPS between October 2018 and October 2020. Only 1 patient did not complete the minimal 4 sessions of ESWT and was removed from the study. In total, 13 patients completed the treatment and were available for the final analysis with 4 patients having 4 sessions of ESWT and 9 patients having 8 sessions of ESWT (Fig. 2). The study was affected by the COVID pandemic health measures started in February 2020 in Singapore.

3.1. Patient characteristics

Table 1 shows that the baseline characteristic of the patients with a mean age of 40.93, a mean duration of CPPS of 29.64 months, and a mean VAS pain score of 5.93. Between the two treatment groups (4 sessions of ESWT vs. 8 sessions of ESWT), only the weak-stream domain in the initial IPSS has significant difference (3.60 vs. 1.56, P = 0.014), while the rest of the demographic and clinical characteristics were comparable.

3.2. Outcomes and adverse events

Table 2 shows the post-treatment scores and mean difference of the scores.

A myriad of scores were utilized. Scores which reflected significant improvements in scoring post treatment are described in the following (VAS pain score, IIEF-15 score (erectile function domain), IPSS score (frequency, urgency, weak stream, straining and total score), KQH score (all domains), and NIH-CPSI score (all domains).

There was statistically significant mean reduction of the VAS pain score post treatment (2.923; 95% confidence interval [CI]: [1.835–4.011]), *P* < 0.001. For the IIEF-15 score, there was isolated significant difference/improvement with mean difference of -3.077 (95% CI: [-6.021 to -0.132], P = 0.042) post treatment for the erectile function domain. Significant differences/improvements with mean differences in the following domains of IPSS post treatment were also noted in terms of frequency 0.846 (95% CI: [0.072-1.620], P = 0.035, urgency: 1.000 (95% CI: [0.396-1.604], P = 0.004), weak stream: 1.077 (95% CI: [0.139–2.015], P = 0.028), straining: 1.000 (95% CI: [0.145–1.855], *P* = 0.025), and total score: 5.308 (95% CI: [1.789–8.826], *P* = 0.006). There were significance differences/improvements with mean differences in all domains of KQH post treatment and all domains of NIH-CPSI. There was, however, no significant difference in UPOINT domains except for the Tenderness domain from 12 patients to only 1 patient still complaining of tenderness post treatment (P = 0.001).

There was no case of reported adverse events.

Table 3 shows the subanalysis for patients with 2 or less trigger points versus those with more than 2 trigger points: All the patients with more than 2 trigger points will need 8 sessions of ESWT and



Fig. 2. Number of patients available for analysis.

Table 1Characteristic of the patients and pretreatment values.

	All patients	Patients with only 1 round of ESWT (4 Sessions)	Patients with 2 rounds of ESWT (8 Sessions)	P valve (1 session versus 2 sessions)	
Total number of patients	13	4	9	N.A.	
Age (mean (SD))	40.93 (12.003)	42.8 (14.394)	39.89 (11.274)	0.681	
Race:					
Chinese	7	2	5	0.331	
Malay	0	0	0		
Indian	4	2	2		
Caucasian	2	0	2		
BMI (mean (SD))	23.571 (5.1583)	24.00 (5.8434)	23.333 (5.0978)	0.827	
Diabetes:					
Yes	1	1	0	0.164	
No	12	3	9		
Duration of the CPPS in months (mean (SD)) History of UTI:	29.64 (28.52)	42 (45.695)	22.78 (11.377)	0.699	
Yes	8	3	5	0.360	
No	5	1	4		
History of physical trauma:					
Yes	1	0	1	0.439	
No	12	4	8	0.155	
History of psychological trauma:		-	-		
les	0	0	0	N.A.	
No	13	4	9	i v ./ l .	
nitial VAS pain score (mean [SD]):	5.93 (2.018)	4 5.80 (2.588)	6.00 (1.803)	0.890	
initially on painkiller	C	2	4	0 577	
Yes	6	2	4	0.577	
No	7	2	5		
UPOINT					
Urinary					
1. Yes	6	2	4	0.577	
2. No	7	2	5		
Psychosocial					
I. Yes	6	2	4	0.577	
2. No	7	2	5		
Drgan-specific					
1. Yes	2	1	1	0.207	
2. No	11	3	8		
nfection	••	2	5		
1. Yes	2	0	2	0.255	
2. No	11	4	7	0.233	
2. No Neurologic	11	7	,		
	5	1	1	0.070	
1. Yes	5	1	4	0.872	
2. No	8	3	5		
Tenderness	10	2	0	0.101	
1. Yes	12	3	9	0.164	
2. No	1	1	0		
Sexual dysfunction					
1. Yes	10	3	7	0.480	
2. No	3	1	2		
Fender point					
Prostate tenderness					
1. Yes	3	1	2	0.480	
2. No	10	3	7		
Muscle tone (number of patients)		-			
1 = Normal;	10	4	6	0.597	
2 = Hypertonic;	3	0	3	0.337	
3 = Hypotonic	0	0	0		
Number of patients with presence of trigger point	U	U	U		
1. Yes	12	4	8	0.303	
				0.303	
2. No	1	1	0	0.400	
Number of right anterior trigger point	1	0	1	0.439	
Number of left anterior trigger point	0	1	0	0.164	
Number of right middle lateral trigger point	3	0	3	0.145	
Number of right middle medial trigger point	9	4	5	0.590	
Number of left middle medial trigger point	7	1	6	0.334	
Number of left middle lateral trigger point	1	0	1	0.439	
Number of right posterior trigger point	4	1	3	0.725	
Number of left posterior trigger point	4	0	4	0.078	
Number of Anal Sphincter Trigger point	0	0	0	N.A.	
IEF	-	~	-	1 4.2 1.	
Erectile function (mean (SD))	13.43 (8.890)	15.20 (7.430)	12.44 (9.888)	0.160	
			. ,		
Orgasmic function (mean (SD))	5.07 (2.999)	5.80 (2.168)	4.67 (3.428)	0.638	
Sexual desire (mean (SD))	5.86 (2.507)	4.80 (1.483)	6.44 (2.833)	0.279	
Intercourse (mean (SD))	6.00 (4.540)	6.6 (3.050)	5.67 (5.339)	0.639	

Table 1 (continued)

	All patients	Patients with only 1 round of ESWT (4 Sessions)	Patients with 2 rounds of ESWT (8 Sessions)	P valve (1 session versus 2 sessions)
Overall satisfaction (mean (SD))	5.86 (1.834)	5.20 (1.643)	6.22 (1.922)	0.244
Total IIEF (mean (SD))	36.21 (18.230)	37.6 (14.450)	35.44 (20.827)	0.593
IPSS				
Incomplete empty (mean (SD))	1.86 (1.748)	2.60 (1.673)	1.44 (1.740)	0.193
Frequency (mean (SD))	2.07 (1.592)	2.00 (1.00)	2.11 (1.90)	0.945
Intermittency (mean (SD))	1.64 (1.447)	2.40 (1.517)	1.22 (1.302)	0.146
Urgency (mean (SD))	1.86 (1.460)	2.40 (1.517)	1.56 (1.424)	0.244
Weak stream (mean (SD))	2.29 (1.490)	3.60 (1.140)	1.56 (1.130)	0.014
Straining (mean (SD))	1.64 (1.646)	2.80 (2.168)	1.00 (0.866)	0.150
Nocturia (mean (SD))	1.43 (0.938)	1.40 (1.140)	1.44 (0.882)	0.888
Total IPSS (mean (SD))	12.79 (8.088)	17.2 (7.53)	10.33 (7.681)	0.109
Kings Health				
Job (mean (SD))	2.93 (0.997)	3.00 (1.00)	2.89 (1.054)	0.889
Travel (mean (SD))	2.50 (1.286)	2.80 (1.304)	2.33 (1.323)	0.530
Social (mean (SD))	2.50 (1.286)	2.80 (1.304)	2.33 (1.323)	0.485
Family (mean (SD))	2.71 (1.069)	3.00 (1.00)	2.56 (1.130)	0.490
Depressed (mean (SD))	3.00 (0.784)	3.20 (0.837)	2.89 (0.782)	0.477
Tired (mean (SD))	3.00 (0.679)	3.00 (0.707)	3.00 (0.707)	1.00
NIH-CPSI				
Total pain score (mean (SD))	11.79 (3.068)	10.60 (2.302)	12.44 (3.358)	0.345
Total urinary symptoms (mean (SD))	4.00 (3.234)	4.60 (3.209)	3.67 (3.391)	0.502
Total QOL and impact score (mean (SD))	9.71 (1.899)	9.60 (1.517)	9.78 (2.167)	0.577
Total overall score (mean (SD))	25.50 (6.595)	24.8 (5.675)	25.89 (7.356)	0.840

Abbreviations: ESWT, extracorporeal shockwave therapy; IIEF, International Index for Erectile Function; IPSS, International Prostate Symptom Score; NIH-CPSI, National Institutes of Health – Chronic Prostatitis Symptom Index; SD, standard deviation; UPOINT, urinary symptoms, psychosocial dysfunction, organ-specific symptoms, infection-related symptoms, neurological/systemic conditions, tenderness of skeletal muscles.

only half (4 out of 8) of the patients with 2 or less trigger points needed 8 sessions of ESWT, but it is not statistically significant (P = 0.057). The improvement in VAS score is more prominent in patients with more than 2 trigger points, 4.000 (standard deviation: 1.000) compared to 2.250 (standard deviation: 1.909), but it is not statistically significant (P = 0.054). The rest of the parameters were not statistically significant between the 2 groups.

4. Discussion

ESWT has been used in multiple medical disciplines for treatment including orthopedics and neurology. Specifically, to urology, it has been shown to be helpful mainly in the treatment of refractory erectile dysfunction as well as for pain relief for Peyronie's disease. Its role in CPPS is however not well understood.

In our paper, we demonstrated that ESWT results in improved VAS with a reduction in the score by almost half (improved from 5.93 to 2.92). With regards to UPOINT domains, there was an improvement across all domains, although they were not statistically significant. Only the Tenderness domain showed statistically significant improvement post treatment. This is likely mediated through several mechanisms including nociceptor hyperstimulation, nitric oxide synthesis induction, passive muscle tone decreases, interruption of nerve impulses, and rising of local microvascularization.^{13–15}

ESWT-improving IIEF has been postulated based off early studies in animals, showing how ESWT improves neovascularization, angiogenesis markers that subsequently remodel tissues.^{16,17} This regenerates the endothelium, smooth muscles and expression of nitric oxide synthase. The improvement in endothelial function then improves penile hemodynamics, which then improves erectile function, and consequently IIEF scores. A systematic review and meta-analysis by Calvijo showed that there was improvement in IIEF scores (6.40 vs. 1.65 points difference) versus sham therapy.¹⁸ In our study, the ESWT was not delivered to the penile region but the perineal, as such, the improvement in most domains of the IIEF are not significant except for the erectile function domain with a significant improvement with mean difference of -3.077. This warrants further study of ESWT not only to the penile region but also to the perineal region for treatment of erection dysfunction.

ESWT has been postulated to improve lower urinary tract symptoms. Some animal studies show that ESWT changes bladder wall composition and improves regeneration, contraction, and innervation while promoting urethral incontinence.¹⁹ In patients with CPSS, there have been promising results to show the improvement of IPSS after ESWT administration. Wu's paper shows that a pre-ESWT IPSS of 13.9 recorded a 27.1%, 38.0%, 42.0%, and 50.9% time-dependent improvement up to 1 year of result collection.²⁰ This was also concordant with Zimmerman's findings, which reported a 25% decrease in IPSS 3 months after ESWT.⁷ Our study also demonstrated significant improvements in the frequency, urgency, weak stream, straining, and total score domain of the IPSS. This suggests that ESWT can be a potential therapy for lower urinary tract symptoms.

In this study, analysis has shown that there were significant improvements on all the domains in NIH-CPSI and in four domains (job, travel, depressed, and tired) in the short-form KHQ. In addition to pain alleviation, it was demonstrated that ESWT significantly reduced urinary symptoms. This in turn resulted in a significant improvement in quality of life. These findings corroborate with the findings from Zimmerman et al, which reported a 17% decrease in NIH-CPSI, following the implementation of ESWT for CPPS.⁷

Our study has demonstrated that there was no significant difference between patients who needed 4 sessions versus those who needed 8 sessions of ESWT except for the weak-stream domain in IPSS. The results suggest that for some patients, 4 sessions may be enough for pain score to show improvement, but for some patients, it may take a longer treatment to get the same results.

Further studies on factors that may affect rate of improvement of CPPS such as chronicity of symptoms, hypertonicity of pelvic muscles will be useful in better patient prognostication.

The number of trigger points in each patient (2 or less trigger points versus more than 2 trigger points) does not account for the number of sessions of ESWT needed, and there was no significant difference in the post-treatment score.

Table 2

Post-treatment values.

	Post-treatment scores (last follow-up) for all patients	Mean difference (initial score minus post- treatment score for all patients)	P value for means difference
Final VAS pain score (mean (SD))	2.92 (2.431)	2.923 (1.801)	0.000
Amount of painkiller required (numbers of patient	, ,		
1. Increased	0		
2. Same amount	0	N.A.	N.A.
3. Reduced	3		
4. Stop all analgesia	4		
5. Never started	6		
UPOINT	C C		
Urinary			
1. Yes	5	N.A.	1.000
0. No	8		1000
Psychosocial	5		
1. Yes	1	N.A.	0.063
0. No	12	14.2 €.	0.005
Organ-specific	12		
	0	ΝΔ	1 000
1. Yes 0. No	13	N.A.	1.000
	15		
Infection	2	NI 4	1 000
1. Yes	0	N.A.	1.000
0. No	13		
Neurologic			
1. Yes	0	N.A.	1.000
0. No	13		
Tenderness			
1. Yes	1	N.A.	0.001
0. No	12		
Sexual dysfunction			
1. Yes	5	N.A.	0.180
0. No	8		
lief			
Erectile function (mean (SD))	16.46 (9.972)	-3.077 (4.873)	0.042
Orgasmic function (mean (SD))	5.38 (3.203)	-0.231 (2.743)	0.767
Sexual desire (mean (SD))	6.46 (2.537)	-0.538 (2.634)	0.475
Intercourse (mean (SD))	6.77 (4.567)	-0.769 (3.270)	0.413
Overall satisfaction (mean (SD))	6.54 (1.898)	-0.538 (1.561)	0.237
Total IIEF (mean (SD))	41.62 (20.714)	-5.154 (12.435)	0.161
IPSS			
Incomplete empty (mean (SD))	0.92 (1.188)	0.692 (1.316)	0.082
Freq (mean (SD))	1.15 (1.144)	0.846 (1.281)	0.035
Intermittency (mean (SD))	0.92 (1.256)	0.615 (1.044)	0.055
Urgency (mean (SD))	0.69 (1.109)	1.00 (1.000)	0.004
Weak stream (mean (SD))	1.08 (1.441)	1.077 (1.553)	0.028
Straining (mean (SD))	0.46 (1.198)	1.000 (1.414)	0.025
Nocturia (mean (SD))	1.31 (1.109)	0.077 (0.954)	0.776
Total IPSS (mean (SD))	6.54 (7.299)	5.308 (5.822)	0.006
Kings Health	0.01 (1.200)	0.000 (0.022)	0.000
ob (mean (SD))	1.69 (0.855)	1.154 (1.144)	0.003
Travel (mean (SD))	1.46 (0.776)	0.923 (1.382)	0.033
Social (mean (SD))	1.62 (0.650)	0.769 (1.362)	0.055
Family (mean (SD))	1.92 (1.038)	0.692 (1.316)	0.082
Depressed (mean (SD))	, ,	, ,	
1 (, , , , , , , , , , , , , , , , , ,	1.92 (0.862)	1.077 (0.760)	0.000
Tired (mean (SD))	1.69 (0.855)	1.308 (1.182)	0.002
NIH-CPSI	C 4C (4 CCC)	E E 20 (4 202)	0.004
Fotal pain score (mean (SD))	6.46 (4.666)	5.538 (4.390)	0.001
Total urinary symptoms (mean (SD))	1.92 (2.100)	1.692 (2.394)	0.026
Total QOL and impact score (mean (SD))	4.92 (2.900)	4.769 (2.891)	0.000
Total overall score (mean (SD))	13.31 (8.750)	12.00 (8.544)	0.000
Number of adverse events	0	N.A.	N.A.

Abbreviations: IIEF, International Index for Erectile Function; IPSS, International Prostate Symptom Score; NIH-CPSI, National Institutes of Health – Chronic Prostatitis Symptom Index; SD, standard deviation; UPOINT, urinary symptoms, psychosocial dysfunction, organ-specific symptoms, infection-related symptoms, neurological/systemic conditions, tenderness of skeletal muscles.

4.1. Limitations

A key limitation of this study was a small sample size prospective, open-label single-arm pilot trial, thus, lacking a control group for comparison and exclusion of placebo effect, and also lacking blinding to exclude possible bias. The slow recruitment and small sample size were indirectly due to the COVID pandemic health measures. The heterogeneity in the study with the presence of two treatment groups of 4 sessions of ESWT and 8 sessions of ESWT was also noted but overall demonstrated that ESWT was effective for the treatment of CPPS.

Overall, our study concluded that ESWT improved pain and quality of life of male patients with CPPS. ESWT to the perineal region may also provide potential treatments/improvements to

Table 3

Sub analysis for patients with 2 or less trigger points versus those with more than 2 trigger points.

	Patients with ≤ 2	Patients with >2	P value between
	trigger points	trigger points	groups
Number of patients	8	5	N.A.
Number of ESWT session:			
4 sessions	4	0	0.057
8 sessions	4	5	
Mean difference (initial score minus post-treatme	nt score for patients)		
VAS pain score (mean (SD))	2.250 (1.909)	4.000 (1.000)	0.054
lief			
Erectile function (mean (SD))	-2.625 (3.889)	-3.800 (6.6106)	0.731
Orgasmic function (mean (SD))	-0.125 (0.835)	-0.400 (4.615)	0.901
Sexual desire (mean (SD))	-0.750 (2.252)	-0.200 (3.421)	0.760
Intercourse (mean (SD))	-0.125 (2.588)	-1.800(4.266)	0.459
Overall satisfaction (mean (SD))	-0.625 (1.506)	-0.400 (1.817)	0.823
Total IIEF (mean (SD))	-4.25 (8.746)	-6.60 (18.050)	0.796
Final IPSS			
Incomplete empty (mean (SD))	1.125 (1.458)	0.000 (0.707)	0.091
Frequency (mean (SD))	0.875 (1.356)	0.800 (1.304)	0.923
Intermittency (mean (SD))	0.750 (1.282)	0.400 (0.548)	0.512
Urgency (mean (SD))	1.250 (0.707)	0.600 (1.342)	0.360
Weak stream (mean (SD))	1.500 (1.690)	0.400 (1.140)	0.189
Straining (mean (SD))	1.250 (1.753)	0.600 (0.548)	0.355
Nocturia (mean (SD))	0.125 (1.126)	0.000 (0.707)	0.810
Total IPSS (mean (SD))	6.875 (6.490)	2.800 (3.899)	0.185
Kings Health			
Job (mean (SD))	1.250 (1.282)	1.000 (1.000)	0.703
Travel (mean (SD))	1.000 (1.690)	0.800 (0.837)	0.782
Social (mean (SD))	1.000 (1.512)	0.400 (1.140)	0.435
Family (mean (SD))	1.000 (1.512)	0.200 (0.837)	0.246
Depressed (mean (SD))	1.250 (0.707)	0.800 (0.837)	0.348
Tired (mean (SD))	1.375 (1.188)	1.200 (1.304)	0.814
NIH-CPSI			
Total pain score (mean (SD))	6.125 (4.581)	4.600 (4.393)	0.564
Total Urinary symptoms (mean (SD))	2.000 (2.928)	1.200 (1.304)	0.515
Total QOL and impact score (mean (SD))	5.000 (3.251)	4.400 (2.510)	0.716
Total overall score (mean (SD))	13.125 (9.935)	10.200 (6.301)	0.529

Abbreviations: ESWT, extracorporeal shockwave therapy; IIEF, International Index for Erectile Function; IPSS, International Prostate Symptom Score; NIH-CPSI, National Institutes of Health – Chronic Prostatitis Symptom Index; SD, standard deviation.

erectile dysfunction and lower urinary tract symptoms. It can be a safe and effective treatment modality in the armamentarium of CPPS.

Author contributions

Lee JKC: conceived the study, participated in its design and coordination, help in the recruitment, reviewed the manuscript.

Law TYX: Analysis the data and drafting of the manuscript. Shen L: Performed the statistical analysis.

Pek GXW: Help in the recruitment and drafting of the manuscript.

Lim QY: Help in the recruitment and drafting of the manuscript. Tan YQ: Help in the recruitment and drafting of the manuscript. Chia JY: Help in the recruitment and drafting of the manuscript. Li MK: Provide advises and supervisor the study, reviewed the manuscript.

All authors read and approved the final manuscript.

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Conflicts of interest

Nil.

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Abbreviation

CPPS	Chronic	Pelvic	Pain	Syndrome
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- DRE Digital Rectal Examination
- ESWT Extracorporeal Shockwave Therapy
- IIEF Index of Erectile Function
- IPSS International Prostate Symptoms Score
- KHQ King's Health Questionnaire
- NIH-CPSI National Institutes of Health Chronic Prostatitis Symptom Index
- QOL Quality of life
- SD Standard Deviation
- VAS Visual Analogues Scale

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