

EFFICACY OF EXTRACORPOREAL SHOCKWAVE THERAPY OF THE PERINEUM FOR CHRONIC PELVIC PAIN SYNDROME IN MALE PATIENTS: A PILOT STUDY

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ABSTRACT

Chronic pelvic pain syndrome (CPPS) is a complex, multifactorial condition that significantly impairs the quality of life. It is a challenging condition for urologists, as there are no established treatment options and it requires a multimodal approach. This single-arm, prospective study was conducted in a tertiary-level hospital. Men >18 years of age with pelvic discomfort for at least 3 months, without urological abnormalities, a National Institutes of Health Chronic Prostatitis Symptom Index (NIH-CPSI) total score >15, and failure of various pharmacological therapies were enrolled. All patients underwent eight sessions of perineal Low-Intensity Shockwave Therapy (LiSWT) over four weeks, with each session delivering 2400 impulses (frequency of 12 Hz). Treatment response was assessed using the NIH-CPSI score immediately after therapy and at 4, 8, and 12 weeks of follow-up. Twenty-one patients (mean age 42.8 ± 7.9 years) with a mean symptom duration of 12.8 ± 3.2 months, with baseline NIH-CPSI scores of 12 ± 1.58 for pain, 6.8 ± 1.5 for urinary symptoms, 9.35 ± 1.18 for quality of life, and 29.15 ± 2.94 in total. Clinical improvement was observed in 42.8% of patients at four weeks, increasing to 66.7% at eight weeks and 80.9% at twelve weeks. Urinary symptoms showed early improvement, while pain, quality-of-life, and total scores demonstrated improvement by eight and twelve weeks ($p < 0.05$). The perineal LiSWT is a safe, feasible, and potentially effective treatment option for patients with CPPS.

KEYWORDS

Chronic pelvic pain, chronic prostatitis, shockwave therapy

Received on: May 17, 2026

Accepted for publication: August 30, 2026

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DOI: <https://doi.org/10.3126/nmcj.v28i3.101259>

Cite this paper as: Ghimire S, Adhikari MB, Yadav DK *et al.* Efficacy of extracorporeal shockwave therapy of the perineum for chronic pelvic pain syndrome in male patients: a pilot study. *Nepal Med Coll J* 2026; 28: 236-9.

INTRODUCTION

Chronic pelvic pain syndrome (CPPS), also known as category III prostatitis or chronic non-bacterial prostatitis (CP), is a common urological condition, as up to 50.0% of men experience this entity in their lifetime.^{1,2} It is characterized by persistent pelvic pain and lower urinary tract symptoms (LUTS) in the absence of active infection, and a multifactorial etiology that potentially involves neurogenic inflammation, pelvic floor dysfunction, and impaired pelvic microcirculation, making it a diagnosis of exclusion.³ In 1999, the International Prostatitis Collaborative Network (IPCN) developed and validated the National Institute of Health Chronic Prostatitis Symptom Index (NIH-CPSI) for the diagnosis of CPPS, which has nine items that address the pain, urinary symptoms, and quality of life domains of these patients, and NIH-CPSI has been widely used globally for the diagnosis, management, and follow-up of patients.⁴ The standard pharmacological therapies (antibiotics, analgesics, or alpha blockers) provide only subclinical and short-lived benefit.⁵ The multimodal treatment strategy for CPPS incorporates the use of perineal Low Intensity Shock Wave Therapy (LiSWT), and the proposed biological effects of LiSWT are promotion of angiogenesis, modulation of nociceptive signaling, induction of nitric oxide synthesis, passive muscle tone decrease, and facilitation of tissue regeneration.⁶⁻⁸ Zimmerman *et al*⁹ did the first randomized controlled trial, and after that, there have been ample publications advocating the safety and efficacy of LiSWT in CPPS.^{10,11} This pilot study is the first study done in our country to evaluate the safety and efficacy of LiSWT in CPPS.

MATERIALS AND METHODS:

Study design: This single-arm prospective pilot study was done in the outpatient clinic of the Department of Urology of a tertiary-level institution from July 2024 to June 2025 after obtaining ethical approval from the Nepal Health Research Council (Ref. No.: 513/2023).

Patient selection: We included male patients aged more than 18 years complaining of pelvic discomfort, which was defined as pain in the groin, genital, bladder, perineal, or lower abdomen for ≥ 3 months, without urological abnormalities, with NIH CPSI total score >15 , with negative urine culture, and failure of various pharmacological therapies to alleviate the symptoms. Total enumerative purposive sampling was used; hence, during the one-year study period, all the patients fulfilling the aforementioned inclusion criteria were included.

Treatment protocol and response assessment: The low-intensity shockwave therapy was delivered to the perineum using the MEDISPEC ED 1000 machine with the handheld probe, with the patient in the supine position and hips abducted and knees flexed. During each session, 2,400 impulses were imparted to the perineum at the rate of 120 impulses per minute, and the sessions were given twice weekly for four weeks by the trained urology technicians. This method of shock-wave delivery was designed in reference to various publications on the use of LiSWT for CPPS.^{10,11} Treatment response was assessed subjectively using a yes-or-no question for improvement and objectively using the change in the baseline NIH-CPSI score at completion of therapy at four weeks and then at eight and twelve weeks of follow-up.

Statistical analysis: Statistical analysis was performed using SPSS-26. Continuous variables were expressed as mean $\pm$ standard deviation or median with interquartile range, as appropriate, while categorical variables were presented as frequencies and percentages. The normality of continuous variables was assessed using the Shapiro-Wilk test. Changes in clinical outcomes and NIH-CPSI scores before and after extracorporeal shockwave therapy were analyzed using the paired t-test. A two-sided p-value <0.05 was considered statistically significant. Given the pilot nature of the study, the findings were interpreted as exploratory.

RESULTS

Participant characteristics: During the study period, 21 patients met the inclusion criteria, and all of them completed the scheduled follow-up. The mean age of the patients was 42.8 years (range 31 to 64 years), and the mean symptom duration was 12.8 ± 3.2 months. Of all participants, diabetes was present in nine (42.8%) patients, but none of them were taking medicines for neuropathy. The baseline NIH-CPSI scores were 12 ± 1.6 for pain, 6.8 ± 1.5 for urinary symptoms, 9.3 ± 1.2 for quality of life, and 29.15 ± 2.9 for the total score.

Response: At the end of shockwave therapy, at four weeks, only eight patients (38.1%) reported subjective improvement in their symptoms. But by the eighth and twelfth week, the proportion rose to 71.4% (15 patients) and 80.9% (17 patients). The objective evaluation with change in NIH CPSI score is tabulated below (Table 1). As only eight patients reported improvement at the end of shock wave therapy, the change in NIH CPSI score was also similar, with only the pain domain showing a statistically significant decrease in score. The pain, quality of life, and total score decreased significantly by eight weeks, but the urinary symptom score took twelve weeks to decrease significantly.

Table 1: Paired-sample t-test analysis of the difference in NIH CPSI score in follow-up

Domain	Baseline	Four weeks	Eight weeks	Twelve weeks
Pain (0-21)	12 ± 1.6	8.8 ± 2.0 ^a	5.0 ± 1.9 ^a	3.5 ± 1.7 ^a
Urinary symptoms (0-10)	6.8 ± 1.5	6.2 ± 1.27	5.5 ± 1.3	4.1 ± 1.1 ^a
Quality of life impact (0-12)	9.4 ± 1.2	8.6 ± 1.5	5.8 ± 1.9 ^a	4.9 ± 2.0 ^a
Total Score (0-43)	23.2 ± 2.9	19.8 ± 3.5	14.3 ± 4.1^a	12.7 ± 3.8^a

*a denotes a significant P value <0.05

Tolerability and safety: All the participants tolerated the sessions. One patient developed transient self-remitting left testicular pain after the first session, but he could continue with subsequent sessions of the shock wave therapy. No major adverse events were noted.

DISCUSSION

The CPPS significantly affects patients' quality of life and is also challenging for treating urologists. The available treatment options include an exhaustive list of lifestyle modifications, pharmacotherapies, phytotherapeutics, cognitive-behavioral therapy, transcutaneous electrical nerve stimulation, acupuncture, and physical therapy.¹²

LiSWT is a non-invasive therapeutic modality that delivers focused acoustic waves to targeted tissues, believed to promote angiogenesis, enhance blood flow, and stimulate tissue regeneration, making it a promising option for conditions involving vascular or inflammatory pathophysiology.^{13,14} LiSWT was initially used for tendon and bone healing, and its domain has now broadened to various cardiovascular diseases, wound healing, neurological diseases, and various aspects of men's health, including CPPS.^{9,15-21} Recent AUA guidelines have mentioned that the LiSWT has a Grade A-level of evidence for its use in CPPS.¹²

This study was done to evaluate the efficacy and safety of LiSWT in CPPS. Among the twenty-one participants, the proportion of patients experiencing subjective improvement was among just eight patients at the end of the shockwave therapy sessions at the fourth week, but as time passed by, the improvement was seen in fifteen patients and seventeen patients at the eighth and twelfth weeks, respectively. There was a statistically significant decrease only in the score of the pain domain at the fourth week. But as time passed, at the eight-week mark, there was a further significant decrease in scores of the quality of life and total score. However, the score of the urinary symptoms decreased significantly only at the twelfth week. One patient developed transient self-remitting testicular pain, but none of the patients reported significant adverse events. Similarly, in their initial study, Zimmerman *et*

*al*⁹ also found a statistically significant decrease in the pain and quality of life score, but no significant decrease in the urinary symptoms score. The long time taken by the urinary symptoms domain to improve is another area of research.

In a similar pilot study from Singapore, done by Lee *et al*,¹⁰ including fourteen patients with CPPS, found improvement in the visual analogue score and NIH CPSI score till 20 weeks post shockwave therapy. So, the authors have concluded that LiESWT improved pain and quality of life of male patients with CPPS, and it can be a safe and effective treatment modality in the armamentarium of CPPS.

However, two randomized studies done by Vahdatpur *et al*²² and Zeng *et al*²³ showed an initial improvement in all the components of the NIH CPSI score with slight deterioration after 3 months of therapy.

A recent systematic review has concluded that ESWT appears to be a safe and effective treatment for CPPS, improving pain and quality-of-life outcomes across multiple trials. The authors have recommended larger randomized trials with longer follow-up to confirm findings and define optimal protocols.²⁴ Similarly, another systematic review has concluded that the LiSWT is an effective treatment modality for the improvement of pain and quality of life in patients with CPPS, and they have recommended LiSWT as a part of individualized treatment strategies in patients with CPPS.²⁵

Limitations: Small sample size, single-arm study without any comparison group, short follow-up period, and use of NIH CPSI score in a non-native language are the identified limitations of this study.

In conclusion, this pilot study suggests that perineal LiSWT is a safe, feasible, and potentially effective treatment option for patients with CPPS, as the majority of patients demonstrated notable symptomatic relief and improvement in the quality of life without significant adverse effects. Although it is not a universal care but can be a better noninvasive and non-pharmacological alternative intervention to exhaustive medical therapy. We would like to recommend a larger sham-controlled randomized study with longer follow-up to

validate efficacy, optimize treatment protocols, and establish the long-term role of ESWT in the management of CPPS.

Conflict of interest: None

Source of research fund: None

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