INPLASY

Optimizing the Use of Extracorporeal Shock Wave Therapy for CP/CPPS: A Modality-Based Systematic Review and Metaanalysis Comparing Focused and Radial Devices

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ADMINISTRATIVE INFORMATION

Support - Nil.

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 December 2025 and was last updated on 18 December 2025.

INTRODUCTION

Review question / Objective To evaluate the efficacy and safety of low-intensity extracorporeal shock wave therapy (Li-ESWT) for chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) and to determine whether stratifying trials by wave-generator modality (focused versus radial) resolves the substantial heterogeneity observed in prior meta-analyses. P (Population): Adult men with CP/CPPS (NIH Category IIIa/IIIb). I (Intervention): Li-ESWT (Focused, Radial, or Multifocal devices). C (Comparator): Sham procedure or standard pharmacologic therapy. O (Outcome): Total NIH-CPSI score, pain and urinary subscores, and adverse events. S (Study Design): Randomized controlled trials (RCTs).

Rationale CP/CPPS is a complex condition often refractory to standard pharmacological therapy. While Li-ESWT has emerged as a promising nonpharmacologic intervention, previous meta-analyses have reported inconsistent results and substantial heterogeneity ($I^2 > 50\%$). A critical limitation of prior reviews is the pooling of fundamentally different shock wave technologies (focused, radial, and multifocal) into a single intervention category. These modalities differ significantly in energy generation, focal depth, and tissue interaction. This systematic review hypothesizes that the observed heterogeneity is driven by inappropriate pooling and aims to provide precise, modality-specific evidence to guide clinical device selection.

Condition being studied Chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS), defined as National Institutes of Health (NIH) Category III prostatitis. It is characterized by persistent pelvic pain or discomfort lasting for at least 3 months within the previous 6 months, often accompanied by lower urinary tract symptoms (LUTS) and sexual dysfunction, in the absence of demonstrable uropathogenic bacteria. The pathophysiology is multifactorial, potentially involving neurogenic

inflammation, pelvic floor hypertonicity, and impaired local microcirculation.

METHODS

Search strategy A comprehensive search will be conducted in PubMed, Embase, Web of Science, and the Cochrane Library for records published from January 2015 to October 2025. Medical Subject Headings (MeSH) and free-text terms will include: ("prostatitis" OR "chronic pelvic pain syndrome" OR "CP/CPPS" OR "pelvic pain") AND ("extracorporeal shockwave therapy" OR "shock wave therapy" OR "Li-ESWT"). The search will be restricted to human studies published in English. Reference lists of relevant systematic reviews will be manually screened for additional eligible studies.

Participant or population Adult men diagnosed with CP/CPPS (NIH Category IIIa or IIIb) who have experienced symptoms for at least 3 months. Patients with active urinary tract infection, bacterial prostatitis (NIH Category I or II), or other identified organic causes of pelvic pain will be excluded.

Intervention Low-intensity extracorporeal shock wave therapy (Li-ESWT) administered as monotherapy or as an adjunct to standard pharmacotherapy. The review encompasses all wave-generator modalities, including focused (electrohydraulic, electromagnetic, piezoelectric), radial (pneumatic/ballistic), and multifocal devices.

Comparator Control groups receiving either a sham (placebo) procedure (e.g., using a probe with an energy-absorbing cap or minimal energy output) or standard pharmacologic therapy (e.g., α-blockers, antibiotics, or anti-inflammatory agents) alone.

Study designs to be included Randomized controlled trials (RCTs) only.

Eligibility criteria To evaluate the efficacy and safety of low-intensity extracorporeal shock wave therapy (Li-ESWT) for chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) and to determine whether stratifying trials by wave-generator modality (focused versus radial) resolves the substantial heterogeneity observed in prior meta-analyses.P (Population): Adult men with CP/CPPS (NIH Category IIIa/IIIb).I (Intervention): Li-ESWT (Focused, Radial, or Multifocal devices).C (Comparator): Sham procedure or standard pharmacologic therapy.O (Outcome): Total NIH-CPSI score, pain and urinary subscores, and adverse events.S (Study Design): Randomized controlled trials (RCTs).9. Rationale CP/CPPS is a complex condition often refractory to standard pharmacological therapy. While Li-ESWT has emerged as a promising nonpharmacologic intervention, previous meta-analyses have reported inconsistent results and substantial heterogeneity ($I^2 > 50\%$). A critical limitation of prior reviews is the pooling of fundamentally different shock wave technologies (focused, radial, and multifocal) into a single intervention category. These modalities differ significantly in energy generation, focal depth, and tissue interaction. This systematic review hypothesizes that the observed heterogeneity is driven by inappropriate pooling and aims to provide precise, modality-specific evidence to guide clinical device selection.10. Condition being studied Chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS), defined as National Institutes of Health (NIH) Category III prostatitis. It is characterized by persistent pelvic pain or discomfort lasting for at least 3 months within the previous 6 months, often accompanied by lower urinary tract symptoms (LUTS) and sexual dysfunction, in the absence of demonstrable uropathogenic bacteria. The pathophysiology is multifactorial, potentially involving neurogenic inflammation, pelvic floor hypertonicity, and impaired local microcirculation.11. Search strategy A comprehensive search will be conducted in PubMed, Embase, Web of Science, and the Cochrane Library for records published from January 2015 to October 2025. Medical Subject Headings (MeSH) and free-text terms will include: ("prostatitis" OR "chronic pelvic pain syndrome" OR "CP/CPPS" OR "pelvic pain") AND ("extracorporeal shockwave therapy" OR "shock wave therapy" OR "Li-ESWT"). The search will be restricted to human studies published in English. Reference lists of relevant systematic reviews will be manually screened for additional eligible studies.12. Patient, Participant, or population Adult men diagnosed with CP/CPPS (NIH Category IIIa or IIIb) who have experienced symptoms for at least 3 months. Patients with active urinary tract infection, bacterial prostatitis (NIH Category I or II), or other identified organic causes of pelvic pain will be excluded.13. Intervention Low-intensity extracorporeal shock wave therapy (Li-ESWT) administered as monotherapy or as an adjunct to standard pharmacotherapy. The review encompasses all wave-generator modalities, including focused (electrohydraulic, electromagnetic, piezoelectric), radial (pneumatic/ballistic), and multifocal devices.14. Comparator Control groups receiving either a sham (placebo) procedure (e.g., using a probe with an energy-absorbing cap or minimal energy output) or standard pharmacologic therapy (e.g., α-

blockers, antibiotics, or anti-inflammatory agents) alone.15. Study designs to be included Randomized controlled trials (RCTs) only.16. Eligibility criteria Inclusion criteria:Population: Men with CP/CPPS (NIH Category III).Intervention: Li-ESWT (any modality).Comparator: Sham or standard medical therapy.Outcome: Reported NIH-CPSI scores.Design: RCTs published between Jan 2015 and Oct 2025.Exclusion criteria:Non-randomized studies, retrospective cohorts, case series, reviews, and editorials.Studies involving animal models.Trials with unavailable or insufficient data for meta-analysis.Duplicate publications involving the same patient cohort (only the most complete dataset will be included).

Information sources Electronic databases including PubMed, Embase, Web of Science, and the Cochrane Library. Additionally, the reference lists of included RCTs and relevant systematic reviews will be hand-searched to identify further potential studies.

Main outcome(s) The primary outcome is the change in total National Institutes of Health Chronic Prostatitis Symptom Index (NIH-CPSI) score from baseline to the 12-week follow-up endpoint.

Additional outcome(s)
Secondary outcomes include:
NIH-CPSI subscores (Pain domain, Urinary domain, and Quality of Life domain).
Visual Analog Scale (VAS) for pain.
International Prostate Symptom Score (IPSS).
International Index of Erectile Function (IIEF).
Incidence of adverse events (safety profile).

Data management Data extraction will be performed independently by two reviewers (Wu and Chen) using a standardized, predefined data extraction form. Collected variables will include study characteristics (author, year, design), participant demographics, ESWT protocols (device type, energy flux density, impulses, sessions), and clinical outcomes. Discrepancies will be resolved through discussion and consensus.

Quality assessment / Risk of bias analysis The methodological quality of included RCTs will be assessed using the Cochrane Collaboration's Risk of Bias tool (RoB 2.0). Domains to be evaluated include random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other sources of bias. Assessments will be conducted independently by two reviewers.

Strategy of data synthesis Statistical analyses will be performed using Stata version 18.0. Continuous outcomes (e.g., NIH-CPSI) will be synthesized using standardized mean differences (SMDs) with 95% confidence intervals (CIs). Heterogeneity will be assessed using Cochran's Q test and the I2 statistic. A fixed-effects model will be used if heterogeneity is low (I2 50%).

Subgroup analysis To explore sources of heterogeneity, prespecified subgroup analyses will be conducted based on:
Wave-generator modality: Focused vs. Radial vs. Multifocal devices.
Comparator type: Sham control vs. Active pharmacologic control.

Sensitivity analysis Sensitivity analyses will be performed by sequentially omitting individual studies (leave-one-out method) to assess the stability of the pooled results and determine if any single trial disproportionately influences the overall effect size.

Language restriction English.

Country(ies) involved Taiwan.

Other relevant information None.

Keywords Chronic prostatitis; Chronic pelvic pain syndrome; Extracorporeal shock wave therapy; Li-ESWT; Meta-analysis.

Dissemination plans The results of this systematic review and meta-analysis will be submitted for publication in a peer-reviewed international medical journal. Findings may also be presented at relevant urological conferences.

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