INPLASY PROTOCOL

To cite: Li et al. Efficacy of radial extracorporeal shock wave therapy for chronic prostatitis/chronic pelvic pain syndrome: a protocol for systematic review. Inplasy protocol 202090076. doi: 10.37766/inplasy2020.9.0076

Received: 21 September 2020

Published: 21 September 2020

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Support: **QNXZ2019013.**

Review Stage at time of this submission: **The review has not yet started.**

Conflicts of interest:
The authors report no conflicts of interest in this work.

Efficacy of radial extracorporeal shock wave therapy for chronic prostatitis/chronic pelvic pain syndrome: a protocol for systematic review

Li, G[1]; Chang, D[2]; Chen, D[3]; Zhang, P[4]; You, Y[5]; Huang, X[6]; Cai, J[7]; Yang, X[8].

Review question / Objective: **The purpose of this study is to further evaluate the efficacy and safety of radial extracorporeal shock wave therapy in the treatment of CP/CPPS. The results will provide urologists and andrologists with clinical decisions.**
Condition being studied: **Prostatitis is a common urogenital system disease in men which affects 5%-9% of adult men worldwide and accounts for approximately 8% of visits to urologists. In the past years, its pathogenesis is complicated and the classification of it is not clear, so the effect of treatment measures is not significant. Recently, the treatment of CP/CPPS includes nonsteroidal anti-inflammatory drugs, phytotherapy, hormonal therapy, alpha-blockers, anti-anxiolytic, and acupuncture, which provide more choice for the urologist. But there still are some limitations. scholars. Many studies suggest radial extracorporeal shock wave therapy may be the better option in the treatment of CP/CPPS. However, the efficacy and safety of it still lack solid evidence.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 21 September 2020 and was last updated on 21 September 2020 (registration number INPLASY202090076).

INTRODUCTION

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Rationale: **Prostatitis is a common urogenital system disease in men which affects 5%-9% of adult men worldwide and accounts for approximately 8% of visits to**

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METHODS

Participant or population: Inclusion criteria: ·NIH-CPSI >19, and a pain score of NIH-CPSI >3. ·Pain in penis, testicles, perineum, or lumbosacral region. ·Voiding symptoms, such as dysuria, frequency, and sense of incomplete urination. ·The minimum duration of these symptoms for inclusion in the study was 3 months. Exclusion criteria: ·Patients with a past medical history for urinary tract infections. ·Patients with urethral malformation, stricture, urinary calculi, and cystitis. ·Patients with BPH, prostate cancer, epididymitis, urinary tract tuberculosis, and spermatic cord disease. ·Patients with mental illness.

Intervention: The patients in the treatment group received rESWT.

Comparator: The control group could gain a NSAIDs, phytotherapy, hormonal therapy, alpha-blockers, anti-anxiolytics, acupuncture, or guideline-recommended conventional treatment.

Study designs to be included: All the RCTs of rESWT for patients with CP/CPPS will be included without publication status restriction or writing language letters to editors, review articles, case reports, conference abstracts, cross-sectional studies, and all observational studies will be excluded.

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Information sources: The electronic databases of MEDLINE, PubMed, Web of Science, EMBASE, Cochrane Library, Clinicaltrials.org, China National Knowledge Infrastructure Database (CNKI), Wan fang Database, China Biology Medicine Database (CBM), VIP Science Technology Periodical Database, Chinese Clinical Trial Registry will be retrieved. They will be searched until JUNE 2021 to recognize related studies. The search strategy that will be run in the PubMed and adjusted to fit the other database when necessary.

Main outcome(s): 1) NIH-CPSI.

Additional outcome(s): 1) Visual Analog Scale (VAS, 0–10) 2) Micturition conditions were examined using the International Prostate Symptom Score (IPSS, 0–35) 3) The International Index of Erectile Function-5 (IIEF-5, 0–25) was applied for evaluating erectile dysfunction.

Quality assessment / Risk of bias analysis: We will evaluate selection bias, detection bias, attrition bias, performance bias, and

other bias based on the Cochrane Collaboration Network Risk Assessment Tool. The tool assesses the risk of bias mainly in the following 7 aspects: random sequence generation, allocation concealment, the blinding method for patients, researchers and outcomes assessors, incomplete result data, and selective reports. As recommended by the Cochrane manual, the risk of bias in each of these areas will be assessed as low or high depending on whether the criteria were met or not met, and the lack of information will be recorded as unclear. The risk of bias will be checked by two review authors. Discrepancies between review authors on the risk of bias will be resolved through discussion with a third review author.

Strategy of data synthesis: The RevMan5.3 software will be used to conduct the meta-analysis (If feasible). Descriptive analysis or systematic narrative synthesis will be performed to summarize and explain the characteristics and findings of the included studies and provide the information in the texts and tables. For dichotomous data (e.g., effective and ineffective), we will calculate risk ratio (RR) and 95% confidence intervals (CIs). For continuous data, which will be pooled as mean difference (MD).

Subgroup analysis: If necessary, we will identify the source of heterogeneity through subgroup analysis and manage the heterogeneity: 1) The duration and severity of CP/CPPS. 2) whether with other complications. 3) demographic characteristics of the patients: age, marital and family status, region, race. 4) follow-up time.

Sensibility analysis: Sensitivity analysis will be used to test the reliability and stability of the meta-analysis results, and to assess the source of heterogeneity. We will compare the results before and after by excluding trials with a high risk of bias or eliminating each study individually one study each time and then pooling the remaining studies.

Language: English.

Country(ies) involved: China.

Keywords: radial extracorporeal shock wave therapy; chronic prostatitis/chronic pelvic pain syndrome; protocol.

Contributions of each author:
Author 1 - Guangsen Li drafted the manuscript.
Author 2 - Degui Chang provided statistical expertise.
Author 3 - Di'ang Chen contributed to the development of the selection criteria.
Author 4 - Peihai Zhang contributed to the risk of bias assessment strategy.
Author 5 - Yaodong You read, provided feedback and approved the final manuscript.
Author 6 - Xiaopeng Huang use the software to analysis the data.
Author 7 - Jian Cai write the original draft.
Author 8 - Xuesong Yang review and edit the manuscript.