

Acupuncture for Chronic Prostatitis/Chronic Pelvic Pain Syndrome: A Randomized, Sham Acupuncture Controlled Trial

Zongshi Qin,* Zhiwei Zang,* Kehua Zhou, Jiani Wu, Jing Zhou, Joey S. W. Kwong and Zhishun Liu†

From the Department of Acupuncture, Guang'anmen Hospital, China Academy of Chinese Medical Sciences (JW, JZ, ZL) and School of Life Sciences, Beijing University of Chinese Medicine, Beijing (ZQ) and Department of Acupuncture, Yantai Hospital of Traditional Chinese Medicine (ZZ), Yantai, China, Catholic Health System Internal Medicine Training Program, Jacobs School of Medicine and Biomedical Sciences, University at Buffalo (KZ), Buffalo, New York, and Jockey Club School of Public Health and Primary Care, Faculty of Medicine, Chinese University of Hong Kong (JSWK), Hong Kong

Purpose: We investigated the effectiveness of acupuncture in patients with chronic prostatitis/chronic pelvic pain syndrome.

Materials and Methods: We performed this 32-week randomized, controlled trial with 8 weeks of treatment followed by 24 weeks of followup to compare acupuncture with sham acupuncture. Participants with chronic prostatitis/chronic pelvic pain syndrome were randomly assigned to acupuncture or noninvasive sham acupuncture. The primary outcome was the change in the NIH-CPSI (National Institutes of Health Chronic Prostatitis Symptom Index) total score from baseline to week 8. Secondary outcomes were the NIH-CPSI subscale scores, pain severity, the I-PSS (International Prostate Symptom Score), the global response rate and satisfaction assessment.

Results: A total of 68 participants 18 to 50 years old were enrolled and included in intent to treat analyses. Baseline characteristics were comparable in the 2 groups. The reduction in the NIH-CPSI total score differed significantly between the 2 groups at weeks 8, 20 and 32 with a difference of -5.7 (95% CI -7.8 — -3.7), -6.7 (95% CI -8.9 — -4.5) and -7.4 (95% CI -9.8 — -5.1), respectively (each $p < 0.001$). All differences were greater than the 4-point minimal clinically important difference. No significant difference was found between the groups in NIH-CPSI pain and quality of life subscale scores or in I-PSS at week 4 (each $p > 0.05$). For all other secondary outcomes the acupuncture group was statistically better than the sham acupuncture group.

Conclusions: Acupuncture showed clinical and long-lasting benefits compared with sham acupuncture for chronic prostatitis/chronic pelvic pain syndrome. Randomized controlled trials with larger sample sizes are needed in the future.

Key Words: prostate, prostatitis, pelvic pain, acupuncture therapy, patient reported outcome measures

CHRONIC prostatitis/chronic pelvic pain syndrome is defined as chronic pelvic pain and symptoms of prostate inflammation lasting at least 3 to 6 months in the absence of any detectable infection.¹ It is often associated

with negative cognitive, behavioral, sexual or emotional consequences as well as with symptoms suggestive of lower urinary tract and bowel dysfunctions.² The causes of CP/CPSS remain poorly understood and appear

Abbreviations and Acronyms

AE = adverse event
BL = bladder
CP/CPSS = chronic prostatitis/chronic pelvic pain syndrome
CPSI = Chronic Prostatitis Symptom Index
I-PSS = International Prostate Symptom Score
MCID = minimal clinically important difference
NIH = National Institutes of Health
SP = spleen

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* Equal study contribution.

† Correspondence: No. 5 Beixiange, Xicheng District, Beijing, China 100053 (telephone: +86-10-88002331; e-mail: liuzhishun@aliyun.com).

to encompass a wide array of heterogeneous conditions. Due to the lack of characteristic physical findings or diagnostic laboratory tests in patients with chronic prostatitis the 1999 version the prostatitis classification by the NIH (National Institutes of Health) remains widely used in clinical practice.³ Based on this classification CP/CPSP is considered in category III of prostatitis syndromes.

Prostatitis-like symptoms affect 9% to 16% males younger than 50 years.³⁻⁷ CP/CPSP accounts for 90% to 95% of prostatitis cases and it is associated with substantial health care costs.^{8,9} Compared with other urological disorders the diagnosis and treatment of CP/CPSP are difficult.¹⁰

CP/CPSP treatments include α -blockers, antimicrobial therapy and nonsteroidal anti-inflammatory drugs, of which all have been found to have moderate effects on CP/CPSP. However, the side effects of these pharmaceutical agents, such as gastrointestinal intolerance and hypotension, decrease patient compliance with treatment and must be considered upon long-term use.^{11,12}

In recent studies and systematic reviews researchers found that acupuncture was effective and safe for CP/CPSP.¹³⁻¹⁶ Acupuncture could relieve CP/CPSP symptoms and reduce total NIH-CPSI scores with minimal to no side effects.¹³⁻¹⁶ However, evidence of a long-lasting acupuncture effect for CP/CPSP remains insufficient. The main objective of this trial was to evaluate the effectiveness and safety of acupuncture in men with CP/CPSP.

METHODS

Study Design

This randomized, participant blinded, sham acupuncture controlled clinical trial was performed at Guang'anmen Hospital affiliated with China Academy of Chinese Medical Sciences and Yantai Hospital of Traditional Chinese Medicine (ClinicalTrials.gov NCT02588274). The study protocol¹⁷ was developed in accordance with the Declaration of Helsinki and the Chinese version of the ICH (International Conference on Harmonization) GCP (Good Clinical Practice) (supplementary material, <http://jurology.com/>).¹⁸ The institutional review boards at the 2 hospitals approved the study protocol before implementation.

Participants

Men with CP/CPSP were eligible for this study. CP/CPSP in this trial was defined as discomfort in the perineum and the suprapubic region with lower urinary tract symptoms without infection.³ The diagnosis was based on a detailed history, physical examination and laboratory workup. Study inclusion criteria were men 18 to 50 years old with a history of pain or discomfort perceived in the prostate region with no other lower urinary tract pathology for a minimum of 3 of the last 6 months, a CP/CPSP history greater than 1 year and a NIH-CPSI total score greater than 15.

Participants with any of certain conditions were excluded from analysis, including specific disease associated pelvic pain or discomfort caused by nonCP/CPSP diseases (eg acute prostatitis, bacterial prostatitis, benign prostatic hyperplasia, prostate cancer, urinary tuberculosis or urinary tract infection), the presence of a serious or an acute disease of the heart, liver, kidney or blood and receipt of acupuncture or medication treatment (α -blockers or pain killers) in the week before baseline assessment. All patients signed informed consent prior to enrollment.

Randomization and Blinding

A total of 68 eligible participants were randomly assigned with a 1:1 ratio to receive acupuncture or sham acupuncture treatment. The randomization sequence was generated at the Institute of Clinical Pharmacology affiliated with Guang'anmen Hospital of China Academy of Chinese Medical Sciences. Randomization numbers and group assignments were sealed in prepared opaque envelopes. Participants, outcome assessors, data collectors and statisticians were blinded to treatment allocation but acupuncturists were not blinded. To evaluate the blinding effect at week 4 outcome assessors asked participants in each group, "Do you think you received traditional acupuncture or sham acupuncture?" Answer options were traditional acupuncture, sham acupuncture or unclear.

Intervention

Hwato® disposable acupuncture needles (0.30 × 40 mm/0.30 × 75 mm) and pragmatic placebo needles (size 0.30 × 25 mm) were used. All acupuncturists had at least 5 years of acupuncture higher education, they were licensed to practice acupuncture and they had at least 2 years of clinical experience.

Participants in the acupuncture group received acupuncture at bilateral Zhongliao (BL33), Shenshu (BL23), Huiyang (BL35) and Sanyinjiao (SP6) (fig. 1). After skin disinfection sterile adhesive pads were placed on the acupoints. For bilateral BL33 acupuncture needles were inserted through the adhesive pads for approximately 50 to 60 mm at a 45-degree angle. For BL35 the needles were inserted to a depth of 50 to 60 mm in a slight superolateral direction. For BL23 and SP6 the needles were inserted vertically to a depth of 25 to 30 mm. Following needle insertion the acupuncturists twirled the needle handles back and forth to achieve the sensation of achiness, heaviness and numbness (known as de qi) at all acupoints except BL33.

Participants received 3 treatment sessions per week for 8 consecutive weeks for a total of 24 sessions. Each acupuncture session lasted 30 minutes and acupuncture needle manipulation was performed every 10 minutes to reach de qi.

Participants in the sham acupuncture group received sham acupuncture at the same acupoints (fig. 1). In the sham acupuncture group pragmatic placebo needles with a blunt tip were used, similar to the Streitberger needle design, but they could not penetrate the skin.¹⁹ Procedures and other treatment parameters were the same as in the acupuncture group but there was no acupuncture needle manipulation.

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