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UROLOGY - REVIEW

Efficacy of acupuncture in the treatment of chronic prostatitis-chronic pelvic pain syndrome: a review of the literature

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Abstract

Among one of the four category prostatitis, chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) is the disease with unknown etiology and having 90–95% prevalence in prostatitis. CP/CPPS poses adverse psychological effects and weakens the quality of life (QoL) of the patients. Due to its multifactorial etiology, various types of treatment are available with different management efficacies. The conventional treatment like anti-inflammatory medications, antibiotics, and alpha-blockers have given the lack of verified efficacy that has turned the patients to alternative therapies such as acupuncture because of its efficacy, safety, and high compliance. Acupuncture is an alternative management accepted in several countries and is commonly used in traditional Chinese medicine for chronic pain. Acupuncture had the effect of immune modulation, anti-inflammatory, and neuromodulation. For chronic prostatitis, acupuncture can improve pain symptoms and can bring better results about National Institutes of Health Chronic Prostatitis Symptom Index (NIH-CPSI), and QoL. This review will discuss the efficacy of acupuncture in the treatment of CP/CPPS and effect of acupuncture on NIH-CPSI total score and its domains: pain, voiding, and QoL, as well as its effect on different biomarkers of CPPS.

Keyword Chronic prostatitis · Chronic pelvic pain syndrome · Acupuncture · NIH-CPSI scores · Quality of life

Introduction

Chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) also called NIH Category III Prostatitis is a discomfort or urologic pain lasting for at least 3 months in the pelvic region related to voiding symptoms. NIH category III prostatitis is a highly extensive condition affecting men having a wide age range and impairing severely quality of life (QoL) [1]. As the most prevalent type of prostatitis, almost 90–95% of men have CP/CPPS with symptoms of chronic prostatitis [2]. Presently, etiology and pathophysiology are not well-known. Many scholars believe that it might be related to pathogen infection, mental and psychological factors, neuroendocrine, immune function, and oxidative stress [3]. Currently, there are no established treatments to alleviate symptoms for CPPS. The therapeutic interventions for CP/CPPS mainly include alpha-blockers, antibiotics, pain medications, and multimodal therapy [4]. Though antibiotics and alpha-blockers exert only moderate, although substantial, favorable effects. Additionally, adverse effects, such as nausea, dizziness, gastrointestinal complaints, and postural hypotension, also reduce the compliance of the patients to treatment,

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which possibly will affect the usefulness of the treatment [5]. Recently, there is growing evidence that acupuncture treatment could help men having CP/CPPS. Acupuncture is alternative management accepted in several countries and is commonly used in traditional Chinese medicine for chronic pain.

The acupuncture is one of the oldest standardized neuromodulatory remedies available in traditional Chinese medicine. Acupuncture is commonly thought to have originated in China, is first mentioned in documents dating from a few 100 years leading up to the Common Era. The bones and sharpened stones have been thought as apparatuses for acupuncture treatment that date from about 6000 BCE [6, 7], but they may simply have been used for puncturing abscesses or drawing blood as surgical instruments [8]. The Yellow Emperor's Classic of Internal Medicine dating from about 100 BCE is the first text clearly describing a structured system of diagnosis and treatment, which is recognized as acupuncture [9]. Acupuncture continued to be advanced and classified in texts over the following centuries and progressively became one of the standard treatments used in China, besides massage, diet, herbs, and moxibustion (heat). The Great Compendium of Acupuncture and Moxibustion, was published during the Ming Dynasty (1368–1644), which forms the basis of modern acupuncture. It has clear descriptions of the full set of 365 points that represent openings to the channels through which needles could be inserted to modify the flow of Qi energy [10].

The method of acupuncture treatment involves the insertion of fine, single-use, sterile needles in acupuncture points. Acupuncture points, according to classical Chinese theory, are connected in a network of "meridians" running longitudinally along the surface of the body [11]. The acupuncture meridians are a system of non-physical energy channels or pathways that run like map lines throughout the body. The general theory of acupuncture is based on the principle that there are patterns of energy flow (Qi) through the body using meridians channels that are vital for health. It is believed that for the disease, the disruptions of this flow is responsible. Acupuncture at detectable points close to the skin may correct imbalances of flow [12].

Some researchers reported that acupuncture had the effect of immune modulation, anti-inflammatory, and neuromodulation [13]. For chronic prostatitis, acupuncture can improve pain symptoms and can bring better results about National Institutes of Health Chronic Prostatitis Symptom Index (NIH-CPSI), and QoL. Based on these facts, it is evitable to examine the efficacy of acupuncture for the CP/CPPS based on available reports.

Previous systemic reviews and meta-analysis found evidence of the effectiveness of acupuncture in CP/CPPS patients [14–16]. In this article, we review the results of recent clinical and experimental studies using acupuncture as a tool to reveals its efficacy for CP/CPPS, and to know its effect on different biomarkers of CP/CPPS as well as the possible mechanisms of acupuncture in CP/CPPS.

Search strategy

The following databases were searched from their inception until 31 March 2019: PubMed, Web of Science, Google Scholar, MEDLINE, CENTRAL, EMBASE, CBM, CNKI, JCRM, CiNii, and Wang-Fang Database. The search terms related to acupuncture, electroacupuncture, auricular acupuncture, chronic prostatitis, chronic pelvic pain syndrome, CPPS treatments, animal studies, and clinical trials. No language barriers were imposed. We also examined the reference list of articles identified by this search strategy and selected those we judged relevant, according to our keywords. Several studies were located that were published in Chinese with English language abstracts. We included studies where we could not extract sufficient data from the English abstract since our resources did include translation from Chinese. Considering the volume of literature, we did not perform a formal quality assessment.

Types of acupuncture

Since acupuncture has spread from its basic origin across the world, in addition to classical body acupuncture, different acupuncture styles have been established. The main types of acupuncture include; TCM, auricular, scalp, hand, and non-insertion acupuncture.

Traditional Chinese Medicine (TCM) is the most common practice of acupuncture. It is a combination of the traditional acupuncture with herbal medicine theory. It is a method that has developed point prescriptions for use with specific differentiations and allows for adjustment of the point prescription. Based on the analysis, management can include, nutrition, moxibustion, herbs, electro-acupuncture cupping, and gua sha.

Auricular acupuncture involves treatment in the ear as it is seen as the main part of the body with points that connect to major organs. These may be stimulated using very fine, minute steel needles. This method is frequently used in combination with other acupuncture styles.

Scalp acupuncture involves treating the scalp by inserting fine needles into precise trigger points. It is a style that uses specific locations on the scalp to treat problems of the body.

Hand acupuncture also called Korean acupuncture, focuses on targeting specific points in the hand that can treat the entire body. It also uses the basic meridian systems with all the points on the hands. It, therefore, can use point prescriptions from TCM by just placing needles on the hands.

Non-insertion acupuncture is great for people who do not particularly like needles as it uses blunt needles made of silver or platinum that stimulates trigger points on the body just by touching them.

This is by no means a full accounting of all the available acupuncture styles. It seems that even though some areas of the world focus on just a few styles, it is the acupuncturists that eventually find the style that fits their perspectives and personalities.

Acupuncture method for the patients of CP/CPPS

During the session of acupuncture for CP/CPPS, the patient with the exposed intended sites of needle insertion lies prone or supine on a bed. Disposable steel needles of fine diameter (0.25–0.3 mm) and length (25–70 mm) are commonly used with a number of needles (2–15) and depth of needle insertion (25–60 mm). The needles could be stimulated by the practitioner manually to produce soreness, fullness, ache, numbness, or the warm sensation that is termed De qi, as well as a tugging sensation observed by the acupuncturist. To stimulate the needles, moxibustion, electrical current, or heat could be applied. Traditional manual acupuncture consists of inserting and manipulating needles into the acupuncture points, while small electrical currents with low frequency (1–5 Hz) and tolerable intensity is applied to needles inserted at acupuncture points in electroacupuncture treatment. In traditional medicine theory, based on physical examination, individualized selection of acupuncture points for each patient would be recommended. According to the traditional Chinese medicine theory [17] and WHO standard acupuncture point location [18], the location and needling methods of common acupoints used for the CP/CPPS patients are listed in Table 1.

Acupuncture rationale and possible mechanism for CP/CPPS

About the therapeutic effect of medical acupuncture, several theories exist. Acupuncture has been found to motivate the secretion of endogenous opioids, which indicates a neural pathway exists that may also cause the release of other neurotransmitters [19]. However, for the exact mechanism of acupuncture, there is no unified theory, but rather only several hypotheses and models for different clinical applications are available. Acupuncture can be seen as having effects through the nervous system in the comprehensive categories of local, segmental, extrasegmental and central effects and direct mechanical effects on myofascial trigger points [20]. Local needling in acupuncture treatment may recover tissue healing and give rise to local pain relief through axon reflexes, the release of neuropeptides and local endorphins. The common acupoints used for CP/CPPS, CV1 (Huiyin), CV3 (Zhongji) and CV4 located in the pelvic floor muscle and lower abdominal could relieve the local pain and muscle spasm around the penis, testicle, perineum, rectum and groin in the patients having CP/CPPS. The local endorphins and their receptors gather after a few days at the injury site [21, 22]. The insertion of acupuncture needles brings small-tissue injuries; thus, in some instances, after a few days, there may be an increase in local endorphins, which may lead to peripheral opioid analgesia some days after an acupuncture session. Regional needling might relieve pain from the somatic afferent nerves stimulation and propriospinal neurons inhibition by afferent stimulation [20]. The gate-control theory gave a hypothetical outline for explaining the perceived pain relief resulting from stimulation of somatic afferent nerves [23]. The acupoints BL32 (Ciliao) and BL33 (Zhongliao) commonly used for CP/CPPS located on the posterior ramus of the sacral nerve could inhibit segmental area pain, stimulate the sacral afferent nerves and

Table 1 Acupoints commonly used for treating CP/CPPS

Acupoint name	Location	Needling method
Shenshu (BL23)	1.5 cun lateral to the posterior midline, on the level of the lower border of the spinous process of the 2nd lumbar vertebra	Vertically or obliquely 0.5–1.5 cun
Ciliao (BL32)	On second sacral foramen	Vertically 0.7–1.5 cun
Zhongliao (BL33)	On third sacral foramen	Vertically 0.7–1.5 cun
Huiyang (BL35)	0.5 cun lateral to the posterior midline, on the level of the tip of the coccyx	Vertically 1–1.5 cun
Huiyin (CV1)	In the center of the perineum	Vertically 0.5–1 cun
Zhongji (CV3)	On the anterior midline, 1 cun superior to the upper border of the pubic symphysis	Vertically 0.5–1 cun
Guanyuan (CV4)	On the anterior midline, 3 cun inferior to the umbilicus	Vertically 0.5–1.2 cun
Sanyinjiao (SP6)	3 cun proximal to the highest prominence of the medial malleolus, on the posterior border of the medial crest of the tibia	Vertically or obliquely 1–2 cun
Yinlingquan (SP9)	On the lower border of the medial condyle of the tibia, in the depression on the medial border of the tibia	Vertically 1–1.5 cun

improve the urinary symptoms in CP/CPPS patients [20]. Acupuncture for the CP/CPPS by the distal, regional, and some local needling could stimulate the descending pain inhibitory tracts in the spinal cord and release the endogenous opioids which could bring improvement in pain and QoL of CP/CPPS patients. This mechanism can be achieved by the activation of descending pain inhibitory system and by endorphinergic systems that could be activated by acupuncture needling [24].

Effect of acupuncture for CP/CPPS

The etiology of this disease is poorly understood, so there is no gold standard diagnostic test for CP/CPPS. Thus, diagnosis usually based on exclusion [25]. The NIH-CPSI was developed in 1999 and has been commonly used to evaluate the severity of CP/CPPS symptoms. The questionnaire NIH-CPSI has three domains of a most important symptom: assessing pain, urinary symptoms, and QoL, which can provide a complete and authentic valuation [26, 27]. Acupuncture appears to be a safe and potentially effective treatment in relieving pain symptoms and improving the QoL of men clinically diagnosed with CP/CPPS. Previous studies have shown that acupuncture treatment for CPPS can decrease NIH-CPSI total score and its three domains, including, pain, urinary, and QoL. The study of Chen and Nickel [28] reported a significant decrease in NIH-CPSI in 12 CPPS men after 6 weeks of treatment, who were intractable to standard treatment. After the follow-up of an average 33 weeks, the result showed the total NIH-CPSI score from 28.2 ± 4.8 to 8.5 ± 8.6, pain score from 14.1 ± 2.2 to 4.8 ± 5.2, urinary from 5.2 ± 2.5 to 1.3 ± 1.9, and in QoL score from 8.8 ± 2.3 to 2.3 ± 2.6 decreased significantly. In another study, Honjo et al. [29] evaluated the effect of acupuncture on BL33 acupoint to ten patients with CP/CPPS. In this study, the NIH-CPSI scores were not reported, but after the acupuncture treatment, the three domains of NIH-CPSI were decreased significantly. NIH-CPSI pain score decreased from 11.6 ± 4.5 to 8.8 ± 6.3, urinary symptoms from 3.2 ± 3.0 to 2.8 ± 3.7, and QoL score from 7.6 ± 2.5 to 4.3 ± 3.6. Capodice et al. [30] studied 6-week full-body acupuncture in 10 men with CP/CPPS having lower urinary tract symptoms for more than 6 months. After 6 weeks of follow up the decrease in NIH-CPSI total score was 25.1 ± 6.6 to 6.6 ± 4.3, pain 9.9 ± 3.1 to 2.1 ± 2.0, urinary 5.7 ± 3.3 to 1.6 ± 1.2 and QoL 9.5 ± 2.0 to 2.9 ± 2.0. Tugcu et al. [31] also reported that acupuncture could recover the pain, urinary symptoms, and QoL after 6-week treatment in 97 patients having CP/CPPS. After 12 weeks of follow-up considerable decrease was noted in the NIH-CPSI total score 26.6 ± 2.9 to 10.6 ± 5.4, pain 11.6 ± 2.2 to 5.9 ± 2.4, urinary 5.0 ± 1.3 to 2.1 ± 2.2, and QoL 9.9 ± 1.3 to 2.5 ± 2.1.

The study of Bahia A. Ohlsen [32] reported the adjuvant therapy of acupuncture with Chinese medicine in a 35-year-old man having CPPS. The patient indicated severe symptoms of pain, voiding, and QoL, which scored 38 out of 43 on the NIH/CPSI. After 8-weeks acupuncture treatment and daily use of Chinese medicine *Ba Zheng San* and *Yi Guan Jian,* the patient scored his symptoms 9 on the NIH/CPSI. The patient was then put on a supplement regimen of green tea. 4 months later the patient scored symptoms 4 on the NIH/CPSI, 2 on 8 months later, and 1 year later the score was 0 on the NIH/CPSI. The results confirmed that the patient had long-term relief from CPPS after acupuncture treatment with Chinese medicine.

To check the therapeutic effect of the long-needle acupuncture for CP/CPPS. A traditional randomized, controlled single-blind study of acupuncture was conducted in 77 patients [33]. In this study, the patients were randomly divided into long-needle acupuncture (LA) and traditional acupuncture (TA) groups. After six sessions of acupuncture treatment for 2 weeks, the NIH-CPSI total and scores of its domains were reduced notably in both groups. After 22 weeks follow up in the LA group, the total NIH-CPSI, pain, urination, and QoL scores were improved significantly as compared to the TA group.

In CPPS patients to explore the effect of pharmacopuncture, the combination of acupuncture and injection of herbal medicine to the acupoints. K.M. Seong et al. [34] conducted research to compare the effect of Chinese herbal solution *Hwanglyunhaedok* through electroacupuncture. In this study, 63 patients were divided into HP (Hwanglyunhaedok Pharmacopuncture) and normal saline injection (Saline Pharmacopuncture, SP) group. HP group were treated with electroacupuncture and injected with 1 ml of herbal solution, and SP group treated with electroacupuncture and injected with 1 ml saline. After 4 weeks of treatment, in both groups, the total NIH-CPSI and pain scores reduced significantly, while the scores of voiding and QoL reduced significantly in the HP group only. There was no significant difference between both groups in NIH-CPSI scores. The studies reported acupuncture treatment in CP/CPPS are listed in Table 2.

Acupuncture versus sham acupuncture

Acupuncture has been proved almost twice as effective as sham acupuncture for treating CP/CPPS [35]. Sham acupuncture usually involves needle placement [36]. In contrast to acupuncture, such sham needles are usually placed superficially away from true acupuncture points, and needles are not stimulated. For the comparison of acupuncture with sham acupuncture for CP/CPPS, Lee et al. reported the first randomized, blinded study [37]. This study was aimed to examine whether 10 weeks' acupuncture, relieve CP/CPPS

Table 2 Studies reported the acupuncture treatment for CP/CPPS

Reduction in NIH-CSPI scores, no. of cases, method and acupoints							
Study	NIH-CPSI total	Pain	Urinary	QoL	No. of cases	Method	Acupoints
Chen and Nickel [28]	28.2 ± 4.8 to 8.5 ± 8.6	14.1 ± 2.2 to 4.8 ± 5.2	5.2 ± 2.5 to 1.3 ± 1.9	8.8 ± 2.3 to 2.3 ± 2.6	12	Needle acupuncture	CV1 (Huiyin), CV4 (GuanYuan), SP6 (Sanyinjiao), SP9 (Yinlinquan)
Honjo et al. [29]	11.6 ± 4.5 to 8.8 ± 6.3	7.6 ± 2.5 to 4.3 ± 3.6	3.2 ± 3.0 to 2.8 ± 3	7.6 ± 2.5 to 4.3 ± 3.6	10	Needle acupuncture	Bilaterally BL33 (Ciliao),
Capodice et al. [30]	25.1 ± 6.6 to 6.6 ± 4.3	9.9 ± 3.1 to 2.1 ± 2.0	5.7 ± 3.3 to 1.6 ± 1.2	9.5 ± 2.0 to 2.9 ± 2.0	10	Needle acupuncture	SJ5 (Waiguan) GB41 (Zulinqi), LR3 (Taichong), LI4 (Hegu), SP8 (Diji), SP6 (Sanyinjiao)
Tugcu et al. [31]	26.6 ± 2.9 to 10.6 ± 5.4	11.6 ± 2.2 to 5.9 ± 2.4	5.0 ± 1.3 to 2.1 ± 2.2	9.9 ± 1.3 to 2.5 ± 2.1	97	Needle acupuncture	Bilaterally BL32(Zhongliao),
Zhou et al. [33]	TA: 26.7 ± 4.9 to 17.3 ± 9.1 LA: 26.6 ± 5.8 to 9.4 ± 8.6	TA: 11.1 ± 2.8 to 6.6 ± 4.0 LA: 11.1 ± 3.1 to 3.3 ± 3.8	TA: 5.8 ± 2.8 to 3.8 ± 3.1 LA: 5.4 ± 3.3 to 2.1 ± 2.6	TA: 4.9 ± 1.2 to 3.5 ± 1.7 LA: 4.9 ± 1.1 to 2.0 ± 1.6	77	Needle acupuncture/ long needle acupuncture	BL30 (BaiHuanShu), BL35 (Huiyang)
Seong et al. [34]	HP: 17.9 ± 7.71 to 14.4 ± 7.02 SP: 19.91 ± 6.0 to 16.0 ± 6.46	HP: 7.6 ± 4.89 to 4.7 ± 3.55 SP: 7.1 ± 4.28 to 4.3 ± 3.38	HP: 3.9 ± 2.67 to 3.3 ± 2.22 SP: 4.7 ± 2.67 to 4.6 ± 2.44	HP: 4.2 ± 1.11 to 3.1 ± 1.27 SP: 4.2 ± 1.04 to 3.9 ± 1.33	60	Pharmacopuncture	CV1 (Huiyin)

*TA*traditional acupuncture group, *LA* long needling acupuncture group, *HP* Hwanglyunhaedok Pharmacopuncture group, *SP* Saline Pharmacopuncture group, *QoL* quality of life

related symptoms. 90 patients were randomized into the acupuncture and sham acupuncture group. Sham acupuncture involved the same type, number of needles, frequency of sessions, and duration as the acupuncture group at non acupoints. At the end of 10 weeks' treatment, in the acupuncture group, 73% were NIH-CPSI responders compared with 47% in the sham group. In the acupuncture group the total NIH-CPSI score reduced from 24.8 to 14.5, pain 11.4–7.0, urinary 4.1–0, and QoL 9.3–3.5, and in sham acupuncture group the NIH-CPSI scores reduced as; total score 25.2–19.0, pain 11.5–8.0, urinary 4.3–2.0, QoL 9.4–8.0. In the acupuncture group, the NIH-CPSI total score improved 4.5 points than the sham group. After the follow-up of 24 weeks, the NIH-CPSI responses in the acupuncture group were 32% and 13% were in the sham group. In another study Lee and Lee [38] randomized 39 patients in the three-arm single-blind study, into exercise and advice plus electroacupuncture (EA) group; exercise, and advice plus sham EA group; exercise and advice alone group. These patients received twice 20-min treatment for 6 weeks. After the 6 weeks treatment, a significant decrease was observed in the NIH CPSI total score (-9.5 ± 3.7) of electroacupuncture group as compared with sham electroacupuncture (-3.7 ± 3.6; $P < 0.01$) and exercise and advice alone group (-3.5 ± 2.4; $P < 0.01$). No significant differences were observed in the urinary and QoL score among the treatment groups. In this study, the effect of electroacupuncture was explained by an improvement in the pain score rather than QoL and urinary symptoms. At the end of the therapy in the electroacupuncture group, NIH-CPSI responders were 100%, while the sham group and advice only group were 16.7% and 25.0%, respectively. Sahin et al. also reported a blind randomized, comparison of acupuncture with sham acupuncture [39]. In this study, 100 CPPS patients were randomly divided into acupuncture and sham acupuncture groups, 50 patients in each group. After 6 weeks of treatment, the NIH-CPSI baseline of the total score was decreased in both groups. After 8 weeks, 92% of participants in the acupuncture group were NIH-CPSI responders while in the sham group the responders were 48%. At the end of follow-up of 24 weeks, 74% of patients in the acupuncture group were responders, whereas only 30% of participants in the sham group were NIH-CPSI responders. The pain, urinary, and QoL subscores were decreased considerably in both groups while after the follow-up of 24 weeks the decline in the acupuncture group was significantly greater than the sham acupuncture group. In one recent study, Qin et al. [35] investigated the effect of acupuncture compared with sham acupuncture in 68 CPPS patients. The patients received 8 weeks acupuncture treatment, and after the follow up of 24 weeks, NIH-CPSI total score and pain, urinary and QoL subscores were decreased significantly in the acupuncture group compared with sham

acupuncture. The studies comparing the acupuncture with sham acupuncture in the treatment of CP/CPPS are summarized in Table 3.

Acupuncture versus western medicine

In the first controlled study conducted by Hong and Zhang [40], 87 CP/CPPS patients were randomly divided into acupuncture ($n=44$) and western medication group ($n=43$). The patients in both groups received 1-month treatment. The acupuncture was given daily on the abdominal 9 points while oral administration of Prostat tablets were prescribed to the medication group. The NIH-CPSI scores were not described, but the therapeutic rate was 100% in the patients receiving acupuncture, while the effective rate was 69.8% in the western medication group ($P<0.01$). In another clinical trial to check the therapeutic effect of 1-month electroacupuncture in comparison with western medicine in CPPS patients Zhang et al. [41] randomized 48 patients into electroacupuncture and western medicine group. The electroacupuncture group was treated by electroacupuncture while oral Sparfloxacin tablets and Prostat tablets were given to the patients in western medicine group. After the treatment, a significant decrease in the NIH-CPSI scores were observed in both treatment groups. The NIH-CPSI total and its subscores in the electroacupuncture group were significantly lower than that of western medicine group ($P<0.05$). In the electroacupuncture group, the total effective rate was 87.5%, while 62.5% was in western medicine group. Ma et al. [42] also conducted a study to compare the efficacy difference between acupoint catgut embedding therapy and western medication in the treatment of 70 CPPS patients. These patients were randomized into the catgut embedding group

Table 3 Comparison of the NIH-CPSI, between acupuncture and sham acupuncture groups

Study	NIH-CPSI A/S	Follow-up NIH-CPSI A/S	No. of cases	Method	Acupoints
Lee et al. [37]	24.8 ± 6.2/25.2 ± 5.8	14.5 ± 8.7/19.0 ± 10.3	90	Needle acupuncture	CV1 (Huiyin), CV4 (GuanYuan), SP6 (Saninjiao), SP9 (Yinlinquan)
Lee and Lee [38]	26.9 ± 5.2/25.5 ± 3.6	− 9.5 ± 3.7/− 3.5 ± 3.6	39	Electroacupuncture	Bilaterally BL32 (Zhongliao), BL33 (Ciliao), GB30 (Huantiao)
Sahin et al. [39]	27.0 ± 3.5/26.5 ± 3.7	11.06 ± 1.88/17.08 ± 6.7 (8 weeks) 12.22 ± 2.3/18.35 ± 6.54 (16 weeks) 13.6 ± 3.37/20.96 ± 8.22 (24 weeks)	100	Needle acupuncture	BL33 (Zhongliao), BL34 (Xialiao), BL54 (Zhibian), CV1 (Huiyin), CV4 (Guanyuan), SP6 (Sanyinjiao), SP9 (Yinlingquan)
Qin et al. [35]	28.0 ± 4.8/26.0 ± 3.7	15.3 ± 3.4/19.3 ± 3.4 (8 weeks) 15.0 ± 3.6/20.1 ± 3.3 (20 weeks) 14.6 ± 3.7/20.4 ± 3.7 (32 weeks)	68	Needle acupuncture	Bilateral Zhongliao (BL33), Shenshu (BL23), Huiyang (BL35), Sanyinjiao (SP6)

Study	Pain (A/S)	Follow-up pain (A/S)	Urinary (A/S)	Follow-up Urinary (A/S)	QoL (A/S)	Follow-up QoL (A/S)
Lee et al. [37]	11.4 ± 3.4/11.5 ± 2.9	7.0 ± 4.5/8.0 ± 4.8	4.1 ± 3.7/4.3 ± 3.7	0 ± 2.9/2.0 ± 3.2	9.3 ± 1.6/9.4 ± 1.8	3.5 ± 5.5/8.0 ± 3.8
Lee and Lee [38]	12.2 ± 2.5/11.8 ± 2.7	− 3.7 ± 2.6/− 1.4 ± 2.0 (3 weeks) − 5.2 ± 1.9/− 1.6 ± 1.8 (6 weeks)	5.3 ± 3.0/3.8 ± 2.8	− 1.2 ± 1.4/− 0.7 ± 1.2 (3 weeks) − 1.8 ± 1.5/− 0.7 ± 1.4 (6 weeks)	9.4 ± 1.8/9.8 ± 1.6	− 2.2 ± 2.0/− 1.1 ± 1.6 (3 weeks) − 2.6 ± 2.4/− 1.3 ± 1.8 (6 weeks)
Sahin et al. [39]	13.2 ± 2.3/13.0 ± 2.2	6.14 ± 1.49/8.16 ± 3.17 (6 weeks) 6.31 ± 1.42/8.59 ± 3.23 (8 weeks) 6.74 ± 1.56/9.13 ± 3.14 (16 weeks) 7.16 ± 1.81/10.41 ± 3.71 (24 weeks)	4.6 ± 1.2/4.5 ± 1.4	2.22 ± 0.89/3.46 ± 1.2 (6 weeks) 2.24 ± 0.78/3.67 ± 1.25 (8 weeks) 2.63 ± 0.65/3.92 ± 1.2 (16 weeks) 2.98 ± 0.94/4 ± 1.51 (24 weeks)	9.1 ± 1.5/8.9 ± 1.4	2.48 ± 0.79/4.58 ± 2.81 (6 weeks) 2.51 ± 0.79/4.8 ± 2.72 (8 weeks) 2.85 ± 0.87/5.31 ± 2.75 (16 weeks) 3.47 ± 1.29/6.54 ± 3.46 (24 weeks)
Qin et al. [35]	12.4 ± 2.8/11.4 ± 2.1	6.0 ± 1.8/7.7 ± 1.8 (8 weeks) 6.0 ± 1.7/8.3 ± 1.8 (20 weeks) 5.9 ± 1.8/8.4 ± 1.8 (32 weeks)	6.1 ± 1.1/5.6 ± 1.0	3.0 ± 0.9/4.3 ± 1.0 (8 weeks) 2.8 ± 1.0/4.3 ± 1.0 (20 weeks) 2.8 ± 1.0/4.4 ± 1.0 (32 weeks)	9.5 ± 1.5/8.9 ± 1.1	8.1 ± 1.0/7.1 ± 0.9 (8 w) 6.0 ± 1.0/7.2 ± 1.0 (20 w) 5.6 ± 1.2/7.5 ± 1.1 (32 w)

A/S acupuncture group versus sham acupuncture group, *QoL* quality of life

Table 4 Comparison of the NIH-CPSI, between acupuncture and western medicine groups

Study	NIH-CPSI (A/W)	Follow-up NIH-CPSI (A/W)	No. of cases	Method	Acupoints
Hong and Zhang [40]	Not reported	Not reported	87	Cluster-needling	CV 3 (Zhongji), LV3 (Taichong), KI3 (TaiXi), SP6 (Sanyinjiao)
Zhang et al. [41]	28.8 ± 5.7/26.5 ± 6.4	15.9 ± 7.6/19.2 ± 6.8	48	Electroacupuncture/prostat tablets	CV4 (Guanyuan), CV 3 (Zhongji), BL32 (Ciliao), BL35 (Huiyang)
Ma et al. [42]	22.07 ± 6.12/21.82 ± 5.04	10.86 ± 4.49/15.87 ± 3.78	70	Catgut embedding therapy/Sparfloxacin tablets and Prostat tablets	SP6 (Sanyinjiao), LI11 (Quchi), CV1 (Huiyin), ST36 (Zusanli), CV3 (Zhongji), BL23 (Shenshu)
Kucuk et al. [43]	20.36 ± 7.35/22.92 ± 7.36	− 12.54 ± 4.95/− 6.43 ± 4.95	54	Electroacupuncture/levofloxacin and ibuprofen	BL28 (Pangguangshu), GB41 (Zulinqi), LV3 (Taichong), LI4 (Hegu), SP6 (Sanyinjiao), SP8 (Diji)

Study	Pain (A/W)	Follow-up pain (A/W)	Urinary (A/W)	Follow-up urinary (A/W)	QoL (A/W)	Follow-up QoL (A/W)
Hong and Zhang [40]	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported
Zhang et al. [41]	14.6 ± 1.5/13.7 ± 1.8	7.8 ± 2.9/9.2 ± 2.6	7.4 ± 1.9/7.8 ± 2.0	4.5 ± 2.4/6.2 ± 2.1	6.7 ± 2.1/6.6 ± 1.9	3.6 ± 1.5/4.7 ± 1.4
Ma et al. [42]	9.56 ± 2.88/9.60 ± 2.65	3.46 ± 1.44/5.99 ± 1.97	Not reported	Not reported	Not reported	Not reported
Kucuk et al. [43]	11.07 ± 3.58/11.6 ± 4.5	− 6.65 ± 3.73/− 3.89 ± 2.97	2.89 ± 2.72/3.77 ± 3.06	− 1.77 ± 2.45/− 0.82 ± 1.44	6.39 ± 2.79/7.50 ± 2.33	− 5.50 ± 2.37/ − 4.32 ± 2.67

A/W acupuncture group versus western medicine group, *QoL* quality of life

(40 cases) and a western medication group (30 cases). In the catgut embedding group, the patients received the therapy to the SP6, LI11, CV1, ST36, CV3, and BL23 acupoints. The treatment was given once every two weeks, the treatment for 4 weeks was as one session, and totally two sessions were given. The western medication group was treated with oral tamsulosin hydrochloride capsules and indometacin sustained-release tablets. After the treatment, the total therapeutic rate in the catgut embedding group was 91.9% while in the western medication group, the rate was 86.2%. The effectiveness of the catgut embedding group was significantly better than the western medication group ($P < 0.05$). In this study, only NIH-CPSI total score and pain score were reported, which were improved after the treatment in both group, but the catgut embedding group was statistically superior to the western medication group.

Kucuk et al. [43] conducted a randomized control study to compare the acupuncture and medical treatment (antibiotic and NSAID) on pain management, voiding symptoms and QoL of 54 CP/CPPS patients. Patients were randomized into the acupuncture and medical treatment group. Acupuncture group was treated twice a week for 7 weeks with acupuncture, while the medical group was prescribed with daily 500 mg levofloxacin and twice a day 200 mg ibuprofen for 6 weeks. In the NIH-CPSI scores, no statistical difference was shown in both groups before the treatment. After the treatment in the acupuncture group, the reduction in the total NIH-CPSI score and pain score were significantly decreased compared to the medical group ($P < 0.01$). However, the urinary and QoL scores were decreased more in the acupuncture group than the medical group, but there was no statistical difference among both groups. The NIH-CPSI responders in the acupuncture group were 89.3% (25 patients). The improvement in total NIH-CPSI scores and pain were significant with electroacupuncture treatment compared to treatment with antibiotics and NSAID. Results from the previous studies showed that compared to medicine, acupuncture leads to a significant decrease in the total NIH-CPSI scores and pain symptom subscale score; in terms of urinary symptoms and QoL improvement, acupuncture was as effective as a medicine. The studies comparing the acupuncture with western medicine for CP/CPPS are summarized in Table 4.

Acupuncture plus medicine versus western medicine

Chen [44] designed a three-arm study to observe the therapeutic effect of daily 1-month warm needle moxibustion and acupuncture group compared with only acupuncture or Western medication group in men with CP/CPPS. After 1 month of treatment, NIH-CPSI total score decreased from 22.56 ± 7.52 to 11.92 ± 7.11 in the warm needle moxibustion and acupuncture group, from 21.97 ± 8.65 to 16.08 ± 6.83 in the acupuncture group, and from 22.89 ± 7.06 to 15.66 ± 6.94 in the western medication group. The scores of the warm needle moxibustion and acupuncture group were significantly lower than that of the acupuncture and western medication group.

In another study to compare the combined treatment of acupuncture and isolated-ginger moxibustion with western medicine for the CPPS Wu et al. [45] randomly divided 110 patients into acupuncture and moxibustion group and medicine group. In the acupuncture and moxibustion group, the combined treatment of acupuncture and isolated-ginger moxibustion was given for 1 month, while the medicine group was treated with oral tamsulosin for 1 month. After the treatment, NIH-CPSI scores were significantly reduced in both groups; however, the improvements in the acupuncture and moxibustion group were greater than that of the medicine group. At the end of follow-up of 3 months, the acupuncture and moxibustion group showed a significant reduction in the NIH-CPSI scores as compared to the medicine group ($P < 0.05$). This study concluded that the combined treatment of acupuncture and isolated-ginger moxibustion for CP/CPPS patients could bring better results in the relieving the symptoms compared to the tamsulosin and also achieves long term efficacy.

Chen et al. [46] also reported the comparison study of acupuncture, acupuncture combined with western medicine and western medicine for 90 CP/CPPS patients. The patients were randomly divided into the acupuncture group, acupuncture with western medicine group and western medicine group. The acupuncture group received 30 min of acupuncture treatment daily for 24 days. In the combined group, the same acupuncture treatment along with oral administration of 0.2 g twice/day levofloxacin and once-daily 0.2 mg tamsulosin were given. The western medicine group was treated with the same dose of western medicine as in the combined group. The NIH-CPSI total score and pain score among all the groups were analyzed before and after the treatment. After the treatment, NIH-CPSI total score and pain score in all the treatment groups were reduced significantly as compared to those before the treatment ($P < 0.01$). The total NIH-CPSI score in the combined group was decreased significantly compared to the acupuncture and the western medicine group. In the pain score, no significant difference was shown in the combined group and acupuncture group, but both groups were significantly better than the western medicine group. The combined acupuncture with western medicine showed superior efficacy in the improvement of symptoms of the CP/CPPS than that of acupuncture alone and western medicine alone.

To investigate the therapeutic effect of triple acupuncture as an adjuvant therapy with western medicine at the CV2

Table 5 Comparison of the NIH-CPSI, between acupuncture plus medicine and western medicine groups

Reduction in NIH-CSPI scores, no. of cases, method and acupoints							
Study	NIH-CPSI total	Pain	Urinary	QoL	No. of cases	Method	Acupoints
Chen [44]	Warm needle moxibustion: 22.56 ± 7.52 to 11.92 ± 7.11 Acupuncture: 21.97 ± 8.65 to 16.08 ± 6.83 Western medicine: 22.89 ± 7.06 to 15.66 ± 5.88	Not reported	Not reported	Not reported	125	Warm needle moxibustion/acupuncture/prostat tablets	BL23 (Shenshu), BL18 (Ganshu), BL54 (Zhibian), CV4 (Guanyuan), CV3 (Zhongji), SP9 (Yinlingquan), SP6 (Sanyinjiao)
Wu et al. [45]	[a]Reduction in acupuncture and moxibustion were significant than tamsulosin group	Not reported	Not reported	Not reported	110	Acupuncture and moxibustion/tamsulosin	CV4 (Guanyuan), CV2 (Qugu), SP6 (Sanyinjiao), GV3 (Yaoyangguan), BL28 (Pangguangshu), BL54 (Zhibian)
Chen et al. [46]	[a]Reduction in needle-acupuncture were significant than acupuncture and medicine group	[a]Reduction in acupuncture group were significant than needle-acupuncture and medicine group	Not reported	Not reported	90	Needle acupuncture/levofloxacin and tamsulosin	GV24 (Shenting), GV22 (Xinhui), GV21 (Qianding), GV20 (Baihui), BL6 (Chengguang), BL7 (Tongtian), CV3 (Zhongji), CV4 (Guanyuan), BL28 (Pangguangshu), BL32 (Ciliao)
Zhang et al. [47]	Not reported	C: −8.6 ± 2.12[b] T: −6.2 ± 2.25[b]	C: −5.8 ± 1.22[b] T: −3.1 ± 1.10[b]	C: −6.0 ± 1.33[b] T: −3.4 ± 1.71[b]	90	Adjuvant acupuncture plus levofloxacin mesylate + terazosin hydrochloride	CV2 (Qugu)

C control group, *T* treatment group

[a]Value were not reported

[b]Value were not reported before treatment

Table 6 Effect of acupuncture on different biomarkers of CP/CPPS

References	Biomarker	Result	Treatment method	Acupoints used
Lee and Lee [38]	Prostaglandin E2	Decreased	Electroacupuncture	BL32 (Ciliao), BL33 (Zhongliao), GB30 (HuanTiao)
	β-Endorphin	No change		
Lee et al. [56]	Cortisol	No change	Needle acupuncture	CV1 (Huiyin), CV4 (GuanYuan), SP6 (Saninjiao), SP9 (Yinlinquan)
	β-Endorphin	Increased		
	Leucine-enkephalin	Increased		
Lee et al. [60]	NK lymphocyte	Increased	Needle acupuncture	CV1 (Huiyin), CV4 (GuanYuan), SP6 (Saninjiao), SP9 (Yinlinquan)
Yuan et al. [62]	IL-8, IL-10 and TNF-α	Decreased	Electroacupuncture	CV3 (Zhongji), ST29 (GuiLai), SP9 (Yinlinquan), SP6 (Saninjiao), CV4 (GuanYuan), ST28 (ShuiDao), SP10 (XueHai), LR3 (TaiChong)
Liu et al. [64]	CD4+, CD4+/CD8+ ratio	Increased	Electroacupuncture	Sanyin acupoints
Ma et al. [57]	Lecithin body	Increased	Catgut embedding therapy	CV2 (Qugu), BL23 (Shenshu), BL54 (ZhiBian), CV1 (Huiyin), SP6 (Saninjiao)
	Plasma substance P	Decreased		
	β-Endorphin	Increased		
Shilin et al. [63]	IL-1β, TNF-α	Decreased	Needle acupuncture	N/A

acupoint in CP/CPPS patients, Zhang et al. [47] randomized the patients into control and treatment group. The patients in both groups were prescribed with levofloxacin mesylate tablets and terazosin hydrochloride capsules for 4 weeks. At the same time for adjuvant therapy, the treatment group received twice a week triple acupuncture at the CV2 acupoint. After the 4 weeks of follow-up, NIH-CPSI scores and time and rate of recurrence were noted. In the NIH-CPSI scores, the treatment group showed a significant decline compared to the control group ($P < 0.05$), NIH-CPSI pain score 8.6 ± 2.12 vs 6.2 ± 2.25, urinary 5.8 ± 1.22 vs 3.1 ± 1.10, and QoL score 6.0 ± 1.33 vs 3.4 ± 1.71. The recurrence rate was remarkably lower while in the treatment group, the recurrence time was considerably longer than the control group. This study showed that the triple acupuncture at the CV2 acupoint as an adjunctive therapy can improve the clinical symptoms, lower the recurrence rate, extend the recurrence time and enhance the curative effect of antibacterials in the treatment of CP/CPPS. The summary of comparison studies between the combined acupuncture with medicine/western medicine and western medicine for CP/CPPS are listed in the Table 5.

Effect of acupuncture on different biomarkers of CPPS

Laboratory biomarkers such as a prostaglandin E2, leu-enkephalin, β-endorphin, lecithin body, natural killer cell, plasma substance P, cytokines, and T-lymphocytes play an essential role in CP/CPPS [13]. The studies reported the effect of acupuncture on different biomarkers of CPPS are summarized in Table 6.

Prostaglandin E2

In the biological functions, such as blood pressure, gastrointestinal integrity regulation of immune responses, and fertility PGE2 has a role of vital mediator [48]. PGE2 is of specific interest in inflammation, its involvement in various processes leading to the common signs of redness, inflammation, pain, and swelling [49]. A higher prostaglandin E2 were present in the prostatic fluid of the men diagnosed with CP/CPPS [50]. The EA effect might relieve the hyperalgesia condition by inhibition of local prostaglandin E2 secretion in neuropathic pain [51]. For chronic prostatitis/chronic pelvic pain syndrome to investigate the clinical effect of electroacupuncture on the levels of β-endorphin and Prostaglandin E2, Lee et al. [38] randomized 39 patients into exercise and advice plus EA group, exercise, and advice plus sham EA group, exercise, and advice alone group. These patients received the treatment for 6 weeks. After the treatment, ELISA was used to analyze the levels of Prostaglandin E2 and β-endorphin in post-massage urine samples. The level of Prostaglandin E2 in the exercise and advice plus EA group were decreased significantly, while there was no considerable change in the level of β-endorphin.

Endogenous opiates, substance P, lecithin bodies

The patients with some urological diseases have shown β-endorphin in their seminal plasma [52]. The substantial evidence suggests that immune cells such as monocytes and lymphocytes, give rise to the production of β-endorphin at the spot of inflammation to bring a decline in the pain. Increased post-treatment β-endorphin were evaluated by

Shahed, A.R., and D.A. Shoskes in CPPS patients [50]. The release of many endogenous opioid peptides especially endorphin and encephalin is the main pathway to give the analgesic effect of acupuncture [53]; though different stimulation methods and acupoints may produce variance effects in the release of endogenous opioid peptides [54]. In the previous studies, it has been reported that acupuncture can increase the concentration of β-endorphin in the cerebrospinal fluid [55]. To check whether acupuncture can have an effect on the level of β-endorphin and leu-enkephalin in patients having CP/CPPS, a double-blind, randomized trial was conducted to determine the sham acupuncture and acupuncture 10 weeks treatment for CP/CPPS. β-Endorphin, leu-enkephalin, and cortisol levels were analyzed in both groups after the treatment. At the end of the treatment, both β-endorphin and leu-enkephalin levels were increased in the acupuncture group, while after the treatment, there was no significant difference in the levels of cortisol [56]. In one another study to observe the acupuncture effect on β-endorphin, substance P, and lecithin bodies. Ma et al. [57] conducted a study of catgut embedding therapy. One hundred and eighty CPPS patients were randomly divided into catgut embedding and a western medication group. The acupoint catgut embedding therapy was applied in the catgut embedding group, and in the medication group, tamsulosin and indomethacin were prescribed. After the treatment, β-endorphin, substance P, and lecithin bodies were observed in both group. β-Endorphin and lecithin bodies were high in both groups; however, in the catgut embedding group, the levels were significantly increased than the western medication group. The SP level after the treatment was lower in both groups, but the catgut embedding group showed lower SP levels than the western medication group. Previous studies have shown that EA can considerably reduce the content of substance P by inhibiting the noxious nerve stimulation [58].

Immune mediators

In previous studies, the activity of splenic natural killer (NK) cells in mice was enhanced after long term EA (electroacupuncture) [59]. In CP/CPPS patients to investigate the effect of acupuncture in comparison with sham acupuncture on cellular immunity, a randomized clinical trial was conducted [60]. After the treatment of 10 weeks, the NK lymphocytes were increased more in the acupuncture group as compared to the sham acupuncture group. Moreover, in the acupuncture group, the total white cell values were decreased more than the sham acupuncture group, with no statistical difference.

Cytokines are well known for its role in the pathogenesis of CP/CPPS, and in previous studies, acupuncture has shown its effect on the cytokines [61]. For CP/CPPS to explore the effect of acupuncture on cytokines Yuan et al. [62] treated 40 CPPS patients with electroacupuncture. After the treatment, the levels of TNF-α, IL-8, and IL-10 were analyzed. The result of this study showed a significant decrease in the levels of TNF-α, IL-8, and IL-10 as compared to those before treatment [62]. In one another study to check the efficacy of Chinese herbal medicine in combination with acupuncture on proinflammatory cytokines in 160 patients with CP/CPPS. Shilin et al. [63] randomized the patients in the Chinese medicine group, western medicine group, and acupuncture group plus the Chinese medicine group. Tamsulosin and Celecoxib tablets were used in western medicine group. Chinese medicine group was treated with Qingzhuo Qudu Pills, and the combined group was treated with Qingzhuo Qudu Pills plus acupuncture. After 30 days of treatment, the TNF-α, IL-1β levels were decreased in all groups, while the combined group showed a significant difference than the other groups. To examine the effect of electroacupuncture on cellular immune function in rats Liu et al. [64] randomly divided 40 rats into the normal, model, medication, and EA group. The model was made by the injection of an equal ratio of allogeneic prostatein purification liquid plus CFA and pertussis, diphtheria, tetanus (DPT) vaccine. Medication group was treated with Cernilton with oral administration, while EA group received electroacupuncture. After the treatment, the CD4+ and CD8+ plasma levels were analyzed with flow cytometry. The levels of plasma CD4+ in both treatment groups were significantly increased compared to the model group, while the EA group was significantly higher than that of the medication group. The CD4+/CD8+ ratio was significantly high in the EA group than the model group. However, the plasma CD8+ levels showed no remarkable difference among the groups.

Future directions/research

A large body of evidence reported that acupuncture treatment for CP/CPPS is superior to common care. However, acupuncture treatment is, at most, only marginally more effective than sham acupuncture, which, when compared to no treatment, is associated with larger effect sizes than when conventional placebos are compared to no treatment. These lead to a hypothesis that acupuncture may be a placebo intervention, which is just needling into the skin at any positions of the body. However, the truth is that acupuncture is a complex intervention with the placebo effect, non-specific physiological effects to needle insertion, and specific effect. It is very important to perform a blind control study in an acupuncture practice. Most trials about acupuncture in the treatment of CP/CPPS are single-blind, while the reported double-blind studies usually refer to the

subjects and evaluators being blinded instead of acupuncturists. Even though explicit and rigorous blinding remains necessary in practice. The future acupuncture research not only needs to highlight acupoint effective specificity but also needs to identify key physiological and psychological non-needle components of acupuncture treatment to minimize specific non-needle effects in sham treatment. The translational medicine in acupuncture research means the future researches need to make a bridge connecting the laboratory mechanism with the clinical outcomes. The various needling parameters, such as depth, frequency, angle, and twirling, have a great impact on the acupuncture effect. The acupuncture also could influence numerous biomarkers testified in the laboratory. Biomarkers tested from the laboratory could also be brought into TCM outcome criteria, which could better reflect the acupuncture effect. Together, all these could improve the correlations between the needling parameters, biomarker changes, and clinical outcomes. Further, there are many very important issues surrounding acupuncture research, such as underlying mechanisms of acupuncture needling, acupoint specificity, and understanding how individual factors of acupuncture treatment interact and translate into physiological and clinical outcome, that need to be solved before maximizing clinical beneficial of acupuncture treatment for the CP/CPPS.

Conclusion

To some extent, the standard pharmacotherapy management can relieve the syndrome. However, due to their adverse events, patients are looking for the effective and safer measure. Chronic prostatitis/chronic pelvic pain syndrome, which is still not fully known for its cause. CP/CPPS is a disease having multi-factors, such as genetic predisposition, intraprostatic ductal reflux, autoimmunity, infection, and neuromuscular problem. Acupuncture is multi-function therapy and had the effect of immune modulation, anti-inflammatory, and neuromodulation. In the present study, a complete and thorough picture of acupuncture effect in CPPS, its comparison with sham acupuncture and western medicine, and its effect on biomarkers of CP/CPPS is drawn so that one can easily understand it in a single glance without looking into the literature for each study. For the future perspective, further research studies should be carried out to confirm the effectiveness of acupuncture as a complementary therapy for CPPS patients.

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Compliance with ethical standards

Conflict of interest All authors declare no conflict of interest.

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