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Original Article

Meta-analysis of the effectiveness and safety of magnetic stimulation for chronic pelvic pain

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Abstract: Objective: To systematically assess the effectiveness and safety of magnetic stimulation (MS) for treating chronic prostatitis (CP) and chronic pelvic pain syndrome (CPPS) through a meta-analysis. Methods: A comprehensive search of databases including PubMed, The Cochrane Library, EMbase, VIP, Web of Science, WanFang, China Biology Medicine disc (CBMdisc), and China National Knowledge Internet (CNKI) databases was conducted to retrieve randomized controlled trials (RCTs) on MS interventions for CPPS from inception to the present. The search employed keywords such as "MS", "CPPS", and "prostatitis". Data analysis was performed using RevMan 5.4 software, focusing on NIH-Chronic Prostatitis Symptom Index (NIH-CPSI), maximal urinary flow rate (Qmax), and international index of erectile function-5 (IIEF-5) score. Results: Eight RCTs involving 636 patients were included. Our meta-analysis revealed that extracorporeal MS significantly reduced NIH-CPSI scores [MD = -6.65; 95% CI (-8.15, -5.15), P < 0.00001] and improved Qmax [MD = 2.98; 95% CI (1.36, 4.59), P = 0.0003] compared to the control group. Although a trend toward improved IIEF-5 scores was observed [MD = 0.81; 95% CI (-0.34, 1.95), P = 0.17], the results were not significant. Conclusion: MS is effective in alleviating clinical symptoms and enhancing Qmax in patients with CP/CPPS.

Keywords: Magnetic field therapy, prostatitis, chronic pelvic pain syndrome, meta-analysis

Introduction

Chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS), classified as Type III prostatitis by the National Institutes of Health (NIH), is a prevalent condition encountered in urology clinics, accounting for approximately 2.2% to 16.0% of cases worldwide [1]. Notably, up to 50% of patients experience recurrent episodes, making CP/CPPS a significant urological concern [2]. The clinical manifestations typically include urinary symptoms like urgency, frequency, and pain, as well as discomfort in the pubic region [3]. These symptoms may be accompanied by male infertility, sexual dysfunction, and psychiatric issues such as anxiety and depression, garnering increasing attention. A 2019 survey [1] among Chinese men over 40 years of age revealed that up to 25.3% had been diagnosed with CP/CPPS. The etiology of CP/CPPS is complex, encompassing factors such as pathogenic infections, elevated oxidative stress, psychosomatic components, autoimmunity, neurogenic inflammation, and pelvic floor muscle spasms [4]. With advancing research, it is increasingly believed that CP/CPPS arises from the synergistic effect of multiple factors [5]. Pathologic changes are not confined to the prostate alone, but may be caused by damaged nerve endings and receptors, leading to pain, pelvic floor dysfunction, local chemical alterations, neurotransmitter imbalances, and perfusion disorders. The hallmark of CP/CPPS pathology is chronic/persistent pain in pelvic organs and structures, often accompanied by lower urinary tract symptoms. The diagnosis and management of CP/CPPS remain challenging for urologists due to the poorly understood pathogenesis, symptom heterogeneity, low cure rate, and high recurrence rate [6]. The primary objective in managing CP/CPPS is to alleviate symptoms, enhance patients' quality of life, and foster the restoration of functional and pathologic impairments.

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Current treatment modalities for CP/CPPS commonly encompass antibiotics, α-receptor blockers, anti-inflammatory and analgesic agents, as well as botanicals [7]. Nevertheless, these treatments are associated with adverse effects, high cost, and limited efficacy in improving patients' overall quality of life [8].

Extracorporeal magnetic stimulation (MS) emerges as a novel non-invasive physical therapy modality that utilizes magnetic fields to stimulate the nervous system. It has garnered widespread attention in the treatment of central nervous system disorders, such as depression, anxiety, and stroke, exhibiting promising clinical outcomes and a favorable safety profile [9]. MS leverages the principle of electromagnetic induction to generate a magnetic field through a closed coil, which interacts with the human body. This technique stimulates tissue cells by inducing currents that form within the tissue as a result of the non-contact spatial coupling of magnetic field changes. Consequently, it triggers physiological and biochemical alterations. MS effectively activates pelvic floor muscle cells, promoting muscle contraction without physical contact. This is achieved through inductive electricity generated by the magnetic field, ultimately achieving the desired therapeutic effect. Compared to electrical stimulation alone, MS offers deeper and wider stimulation of the pelvic floor, requiring neither undressing nor the use of an invasive vaginal probe. This enhances patient compliance and cooperation, leading to improved pelvic floor muscle tone, pain relief, and an enhanced clinical outcome. Recent studies have demonstrated that MS targeting sacral nerves or pelvic floor muscles can excite or inhibit nerve pathways, regulate abnormal reflex arcs, and enhance pelvic floor function [10]. MS has proven efficacious in improving bladder, rectal, and urethral functions, particularly in cases of urinary incontinence, overactive bladder, and constipation [11]. While pelvic floor muscle training and neuromodulation with MS have shown promise in alleviating CP/CPPS symptoms, the results remain inconsistent [12, 13].

Given this inconclusiveness, the current study aimed to conduct a meta-analysis to systematically evaluate the efficacy of MS in improving the NIH-CPSI, Qmax, and IIEF-5 scores among CP/CPPS patients.

Methods

Literature search

A systematic search was conducted across PubMed, Embase, China National Knowledge Internet (CNKI), The Cochrane Library, Wanfang, China Biology Medicine disc (CBM-disc), VIP database, and Web of Science to identify randomized controlled trials (RCTs) evaluating MS for the treatment of CP/CPPS. The search encompassed the time frame from the inception of these databases up to October 31, 2023. Two independent reviewers screened the literature, extracted relevant information, and assessed the risk of bias in the studies. Meta-analysis was performed using Reviewer Manager 5.4 (RevMan 5.4). Furthermore, a manual search of references was conducted to ensure a comprehensive and relevant literature review. The search strategy was as follows: #1: "chronic prostatitis" OR "CP/CPPS"; #2: "MS" OR "magnetic field therapies" OR "stimulation therapies"; #3: "RCT" OR "controlled" OR "randomized" OR "experimental"; #4: #1 AND #2 AND #3.

Inclusion and exclusion criteria

Inclusion criteria: (1) Study type: Published RCT research literature, both domestic and international, focusing on extracorporeal MS for CP/CPPS. The languages were limited to Chinese and English. (2) Study subjects: Patients meeting the diagnostic criteria for CP as established by the NIH in the United States, regardless of age. (3) Interventions: The use of MS, MS combined with drugs, or MS combined with electrical stimulation. The control group should have received conventional treatment or a placebo. (4) Endpoints: Primary outcomes should include the NIH-CPSI, Qmax, and IIEF-5 scores.

Exclusion criteria: (1) Studies from which relevant data could not be extracted. (2) Duplicate publications reporting the same research data. (3) Literature that is not in Chinese or English. (4) Non-human experimental studies, including animal models or in vitro experiments.

Data extraction and bias assessment

A standardized data extraction form was designed to capture pertinent information, including authors, publication year, region, sample size, intervention duration, and MS

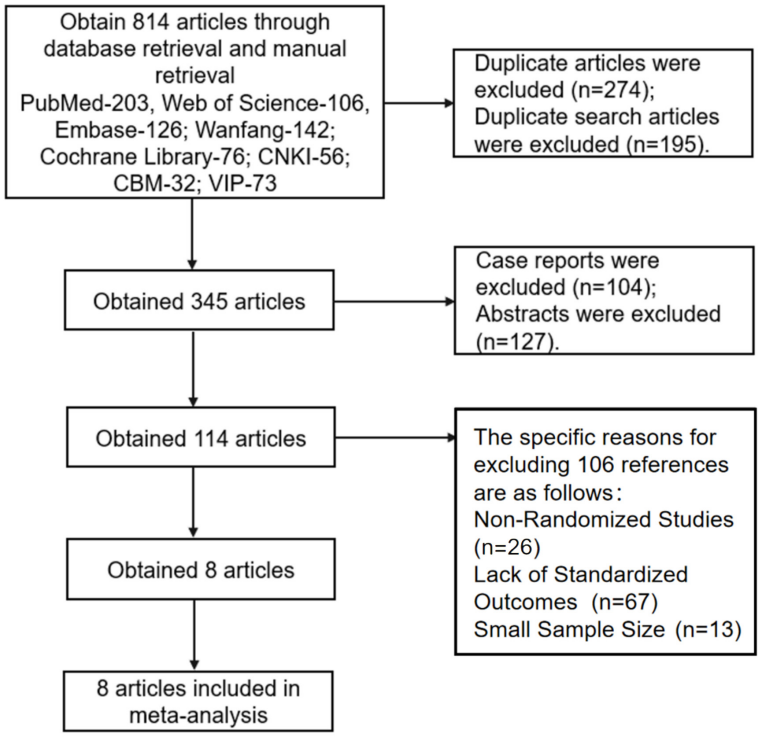

Figure 1. Literature search process and results.

parameters. This process was independently conducted by two experienced researchers, Jing Wu and Huixiang Li, who are also co-authors of this article. Any discrepancies were resolved through consensus within the research team. The extracted data were then entered into a predefined data extraction form, encompassing general information (author, publication date, title), sample size, intervention details, control group, and outcome indicators. The risk of bias in the included RCTs was assessed using the Cochrane Handbook Risk of Bias Assessment Tool.

Statistical analysis

Statistical analysis was conducted using RevMan 5.4 software. For continuous data, mean difference (MD) and 95% confidence intervals (CIs) were computed as measures of effect. Statistical significance was defined as $P < 0.05$. Heterogeneity among the study results was evaluated using the chi-square (χ^2) test, and the extent of heterogeneity was quantified using the I^2 statistic. In the absence of statistically significant heterogeneity, a fixed-effects model was employed for meta-analysis. Conversely, after excluding factors that significantly contributed to clinically meaningful heterogeneity, a random-effects model was adopted for meta-analysis.

Results

Results of literature search

A total of 814 articles were retrieved, ultimately resulting in the inclusion of 8 studies comprising 636 subjects. The detailed screening process and outcomes are depicted in **Figure 1**.

Literature quality and bias evaluation

To comprehensively understand the distribution and specifics of risk types in the included studies, the risk assessment results are presented in two formats (**Figure 2**).

Basic characteristics

Table 1 summarizes the general features of the studies. MS was the sole intervention employed in all studies, targeting either the pelvic floor muscles or the sacrococcygeal area.

Meta analysis of total NIH-CPSI score

Eight studies were incorporated in the analysis of the NIH-CPSI total score. Significant statistical heterogeneity was observed among the studies ($P < 0.00001$, $I^2 = 82\%$), necessitating the use of a random-effects model (**Figure 3**). The findings indicate a lower NIH-CPSI score in the experimental group compared to the control group [MD = -6.65; 95% CI (-8.15, -5.15), $P < 0.00001$]. Sensitivity analyses revealed a substantial reduction in heterogeneity following the exclusion of studies by Kessler, Paike, and Wang ($I^2 = 30\%$, $P = 0.22$).

Meta-analysis of NIH-CPSI pain score

Eight studies were analyzed for the NIH-CPSI pain score. Due to significant statistical heterogeneity ($P < 0.00001$, $I^2 = 84\%$), a random-effects model was employed (**Figure 4**). The

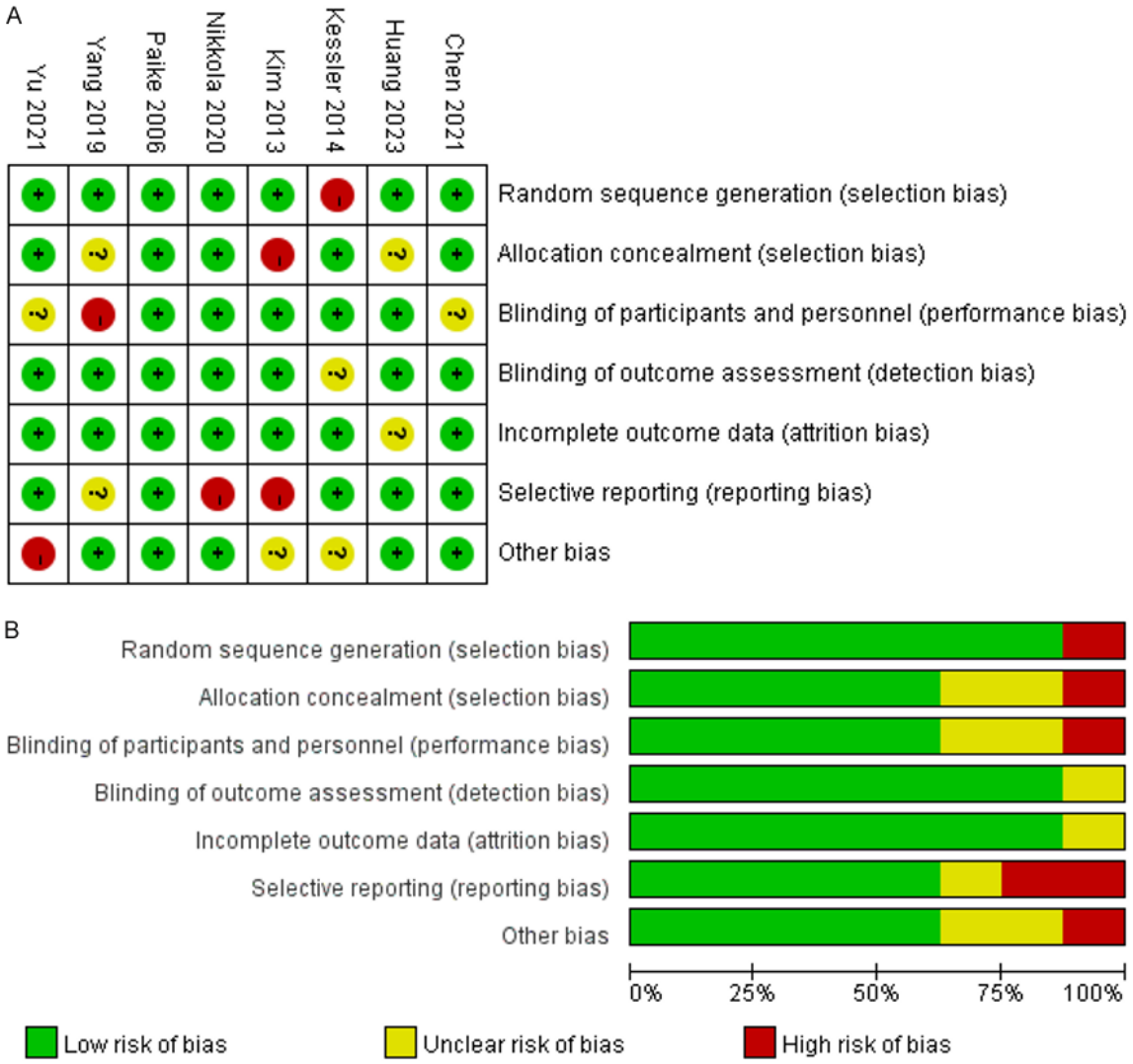

Figure 2. Results of risk of bias assessment. A: Risk of bias summary; B: Risk of bias graph.

findings revealed a lower NIH-CPSI pain score in the experimental group compared to the control group [MD = -2.78; 95% CI (-3.50, -2.06), P < 0.00001]. Sensitivity analysis confirmed the robustness of these results, as excluding any individual study did not alter the outcome.

Meta analysis of NIH-CPSI urinary symptoms

The analysis of urinary symptoms, encompassing eight studies, revealed statistical heterogeneity (P < 0.00001, I^2 = 84%). Consequently, a random-effects model was adopted (**Figure 5**). The experimental group exhibited a lower NIH-CPSI score for urinary symptoms compared to the control group [MD = -1.51; 95% CI (-2.06, -0.97), P < 0.00001]. Sensitivity analysis confirmed the reliability of these results, with no change observed upon excluding any study.

Meta analysis of NIH-CPSI quality of life

The assessment of quality of life, based on eight studies, was subject to significant statistical heterogeneity (P < 0.00001, I^2 = 87%). Therefore, a random-effects model was used (**Figure 6**). The experimental group demonstrated a lower NIH-CPSI score for quality of life than the control group [MD = -2.20; 95% CI (-2.80, -1.59), P < 0.00001]. Sensitivity analysis indicated a significant reduction in heterogeneity upon excluding the studies by Paike and Huang (I^2 = 14%, P = 0.32).

Meta analysis of Qmax

Four studies were analyzed for Qmax measurements. With moderate statistical heterogeneity (P = 0.08, I^2 = 55%), a random-effects model

Table 1. General characteristics of the included studies

Author	Year	Country	Study type	n	Patients	E	C	Total duration	Indicators
Chen [27]	2021	China	RCT	75 (50/25)	CP/CPPS	Magnetic stimulation	Conventional therapy	8 wk	(1) (3)
Huang [28]	2023	China	RCT	98 (49/49)	CP/CPPS	Magnetic stimulation	Conventional therapy	4 wk	(1) (2)
Kessler [29]	2014	Switzerland	RCT	60 (30/30)	CP/CPPS	Magnetic stimulation	Conventional therapy	6 wk	(1)
Kim [30]	2013	Korea	RCT	74 (37/37)	CP/CPPS	Magnetic stimulation	Conventional therapy	6 wk	(1)
Paike [31]	2006	Korea	RCT	40 (21/19)	CP/CPPS	Magnetic stimulation	Conventional therapy	5 wk	(1) (2)
Wang [32]	2020	China	RCT	100 (50/50)	CP/CPPS	Magnetic stimulation	Conventional therapy	4 wk	(1)
Yang [33]	2019	China	RCT	65 (33/32)	CP/CPPS	Magnetic stimulation	Conventional therapy	8 wk	(1) (2)
Yu [34]	2021	China	RCT	124 (62/62)	CP/CPPS	Magnetic stimulation	Conventional therapy	2 wk	(1) (2) (3)

Note: RCT, Randomized controlled trial; CS, cohort study; E, experimental group; C, control group; (1) NIH-CPSI; (2) Qmax; (3) IIEF-5. CP/CPPS, Chronic prostatitis/chronic pelvic pain syndrome; NIH-CPSI, NIH-Chronic Prostatitis Symptom Index; Qmax, maximum urine flow rate; IIEF-5, international index of erectile function-5.

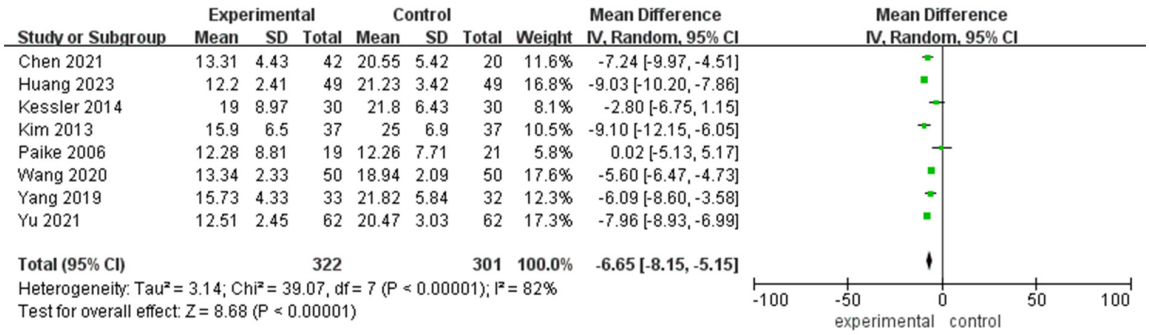

Figure 3. Forest plot of total NIH-CPSI score. NIH-CPSI, NIH-Chronic Prostatitis Symptom Index.

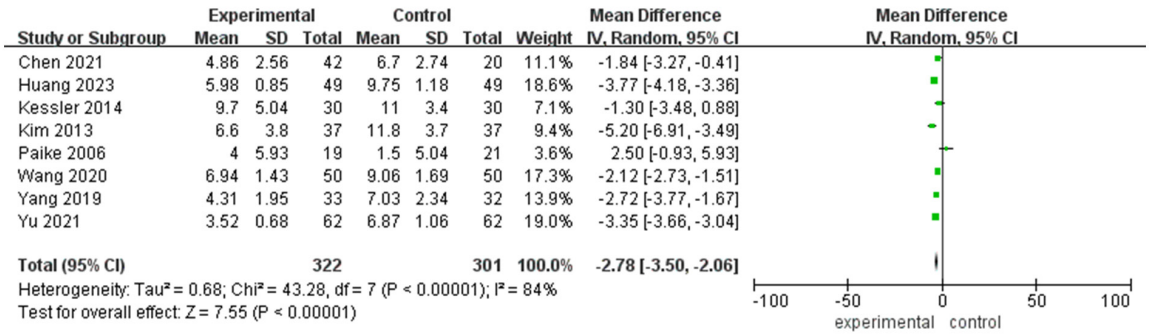

Figure 4. Forest plot of NIH-CPSI pain score. NIH-CPSI, NIH-Chronic Prostatitis Symptom Index.

was chosen (**Figure 7**). The results indicated a higher Qmax score in the experimental group compared to the control group [MD = 2.98; 95% CI (1.36, 4.59), P = 0.0003]. Sensitivity analyses revealed a substantial reduction in heterogeneity upon excluding the study by Yu (I^2 = 0%, P = 0.50).

Meta analysis of IIEF-5

The IIEF-5 scores were analyzed in two studies. Owing to the absence of statistical heterogeneity (P = 0.17, I^2 = 47%), a fixed-effects model was utilized (**Figure 8**). Our findings did not reveal a significant difference between the experimental and control groups [MD = 0.81; 95% CI (-0.34, 1.95), P = 0.17].

Published bias

The analysis of publication bias for NIH-CPSI results revealed an asymmetric distribution of the funnel plot due to the small sample size and inconsistent intervention parameters.

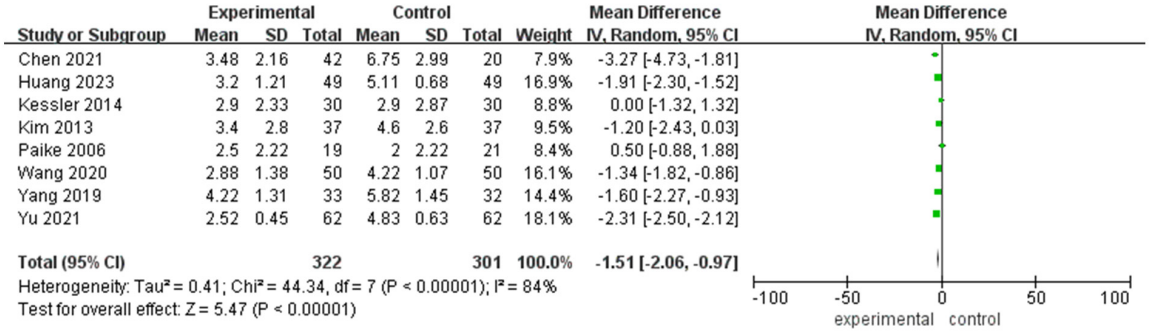

Figure 5. Forest plot of NIH-CPSI urinary symptoms. NIH-CPSI, NIH-Chronic Prostatitis Symptom Index.

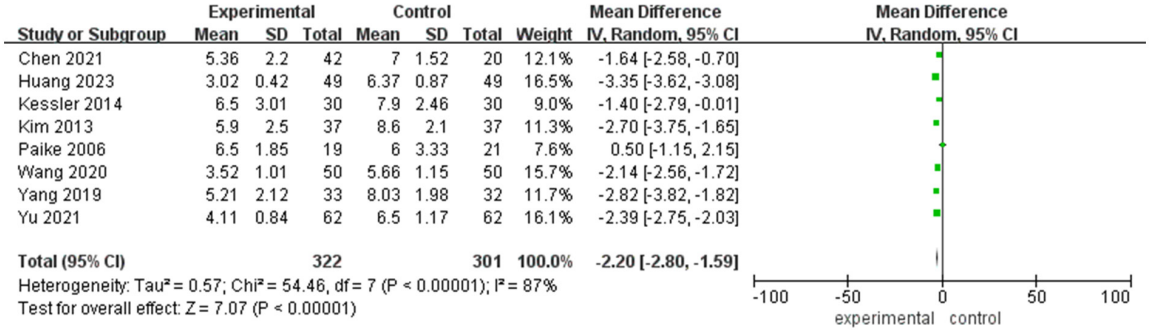

Figure 6. Forest plot of NIH-CPSI quality of life. NIH-CPSI, NIH-Chronic Prostatitis Symptom Index.

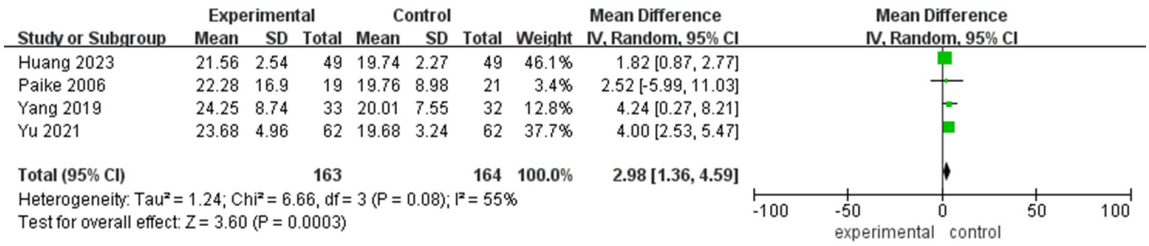

Figure 7. Forest plot of Qmax. Qmax, maximum urine flow rate.

Notably, the dropout points were observed outside the contour line (**Figure 9**), indicating possiblel publication bias.

Discussion

In China, the prevalence of CP among men aged 15-60 years stands at approximately 8.4% [14]. The NIH categorizes prostatitis into four types, where Types I and II are caused by identifiable prostatic infections, and Type IV is asymptomatic. Notably, the majority of symptomatic prostatitis cases fall under CP/CPPS, or Type III prostatitis [15]. Type III prostatitis accounts for over 90% of clinical prostatitis cases, characterized by complex etiology, recurrent episodes, and protracted healing difficulties. Specifically, Type IIIB prostatitis, known as non-bacterial, non-inflammatory prostatitis or chronic pelvic pain syndrome, is a prevalent subtype, presenting with urinary irritation and perineal pain or discomfort as the primary clinical manifestations.

Due to the unclear pathogenesis and pathophysiological changes of CP, clinical diagnosis and treatment remain challenging [16]. Traditional markers, such as leukocytes in prostatic fluid, are not significantly correlated with the primary symptoms of the disease, and even

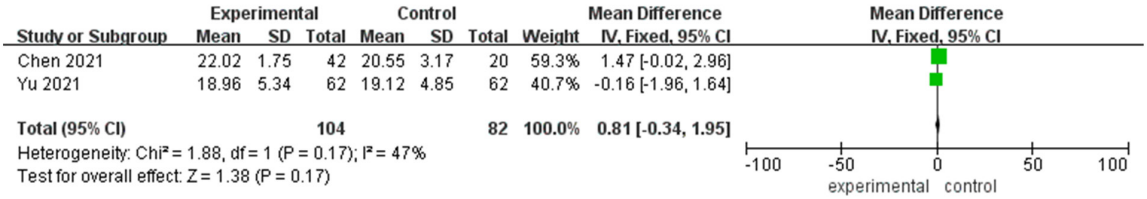

Figure 8. Forest plot of IIEF-5. IIEF-5, international index of erectile function-5.

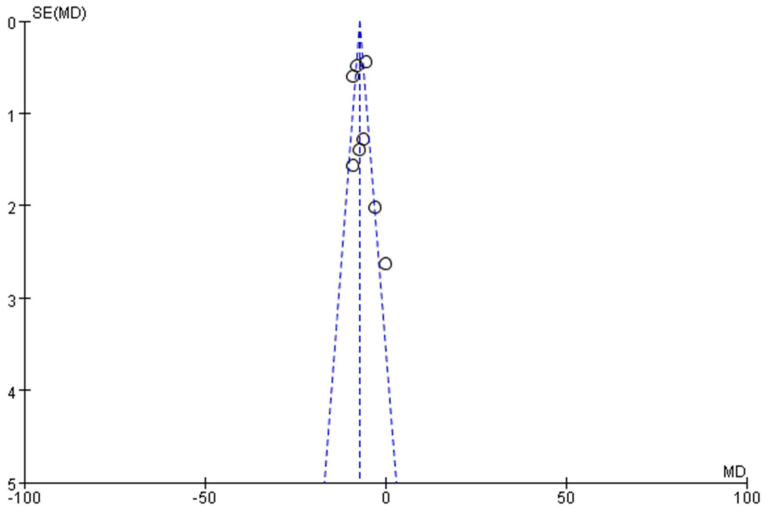

Figure 9. Funnel plot of NIH-CPSI score. NIH-CPSI, NIH-Chronic Prostatitis Symptom Index.

revealed that a significant proportion of patients (34.9%) were dissatisfied with their current treatment, primarily antibiotics. Additionally, while some physical therapies, such as prostate massage, heat therapy, and electrical stimulation, have shown some degree of effectiveness, they are associated with numerous adverse reactions, resulting in poor long-term patient compliance. Given these limitations, there is an urgent need for a novel, safe, and effective treatment approach to enhance clinical outcomes for patients with type IIIB prostatitis.

the prostate gland itself may not be the sole source of these symptoms. Possible risk factors for CP include genetics, infections, hormonal abnormalities and imbalances, voiding dysfunction, autoimmunity, and psychological factors [17]. Current conventional therapies encompass α-receptor blockers, antibiotics, anti-inflammatory drugs, and other medications like finasteride and phytotherapy [18]. However, the efficacy of traditional therapies for type IIIB prostatitis remains controversial. Recent research [19] suggests that the etiology of this subtype may not be rooted solely in the prostate gland, but instead may be triggered by neuromuscular dysfunction of the pelvic floor. Consequently, clinical treatments primarily focus on alleviating pelvic floor pain and discomfort, as well as addressing urinary dysfunction. Commonly administered drugs, including antibiotics, anti-inflammatory and analgesic medications, and α-blockers, have demonstrated unsatisfactory outcomes. A survey encompassing 2,498 prostatitis cases

Although the precise mechanism of CP remains elusive, numerous studies have highlighted pain and discomfort as the primary clinical manifestations of this condition. Some research further suggests that myofascial pain and neurogenic inflammation, accompanied by pelvic muscle spasms, may arise as secondary phenomena to localized infection or inflammation. Accumulating evidence indicates a potential association between CP and muscle dysfunction as well as nerve injuries in the pelvis and lower urinary tract [19, 20].

In recent years, external MS, an emerging physical therapy, has exhibited promising effects in alleviating CP/CPPS [21]. As a non-invasive technique, extracorporeal MS has gained widespread application in the treatment of urinary incontinence. MS uses magnetic fields to stimulate the central and peripheral nervous systems non-invasively, thereby enhancing the activity of enzymes that catalyze the hydrolysis of pain-inducing substances [22]. This action

contributes significantly to reducing the presence of these substances, thus mitigating pain and discomfort. Moreover, extracorporeal MS enhances blood circulation and blood flow, facilitating the release of analgesic factors, expulsion of pain-inducing and inflammatory mediators, and reducing the excitability of sensory nerves, ultimately leading to pain alleviation and resolution. By inducing vortex currents in the pelvic region or muscles, electromagnetic waves penetrate the pelvis, activating local nerves and inducing muscle excitation. This process involves pelvic movement and sensation, or innervation. Repeated MS of the pelvic floor can temporarily or permanently alleviate symptoms in patients with CP, particularly pain [23].

Furthermore, positioning magnetic coils at the sacral nerve roots significantly promotes bladder emptying. MS at this location stimulates the sacral nerve, inducing muscle contractions that trigger urination [24]. Because of its non-invasive nature and ability to penetrate high-resistance tissues such as bone, scalp, and fat, MS is a promising technique for stimulating bladder emptying. A 2019 meta-analysis encompassing 612 female patients with urinary incontinence revealed that MS significantly improved International Consultation on Incontinence Questionnaire-Short Form scores, voiding frequency, and patients' quality of life [25]. Since then, the application of MS in treating other prevalent urological conditions has been progressively explored [26]. Basic research has demonstrated that extracorporeal MS modulates macrophage regenerative phenotypes and enhances the synthesis of anti-inflammatory mediators, thereby mitigating inflammatory response. The potential mechanisms underlying EMS's therapeutic benefits in patients with CP/CPPS include: accelerating local blood circulation, reducing autonomic excitability, alleviating local pain, and relieving involuntary spasms of the prostate smooth muscle and pelvic floor muscles, ultimately achieving relaxation and coordinated muscular contractions.

Consequently, MS, as an innovative therapeutic modality, shows promise in alleviating clinical symptoms in CP/CPPS patients. This study encompassed eight RCTs with 636 patients. Through the analysis of the NIH-CPSI, Qmax, and IIEF-5 scores, we observed that extracorporeal MS significantly alleviated CP symptoms. Specifically, all three dimensions of the questionnaire - pain symptoms, urination symptoms, and quality of life - showed marked improvement. Additionally, the maximum urinary flow rate also enhanced. However, no significant enhancement was observed in the erectile function score among CP/CPPS patients receiving extracorporeal MS. This might be attributed to the fact that the two comparative studies employed positive controls, leading to a certain degree of improvement in IIEF-5 scores in the control group post-intervention.

This study has several limitations worth noting: (1) Due to the exclusion of studies not utilizing the NIH-CPSI as an endpoint outcome and non-randomized controlled trials, only eight papers were included, representing a relatively small dataset. (2) The study did not conduct subgroup analyses regarding stimulation frequency and intensity, thus it was unable to establish an optimal treatment protocol. (3) Variations in the experimental design of the included studies introduced inconsistencies in the meta-analysis results, introducing possible confounding bias.

In summary, this systematic review and meta-analysis of RCTs evaluating MS for CP/CPPS reveals that MS effectively ameliorates clinical symptoms and maximizes urinary flow rate. However, the paucity of rigorously designed RCTs with large sample sizes and the heterogeneity in treatment protocols and parameters hinder the elimination of selection biases and experimental protocol biases. Consequently, this study serves as a preliminary reference for the treatment of CP/CPPS using MS, necessitating further large-scale, multicenter RCTs to provide more clinically applicable evidence and optimize the MS therapy protocol.

Acknowledgements

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Disclosure of conflict of interest

None.

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