

## ORIGINAL RESEARCH

# Chinese herbal retention enema combined with magnetic vibration magneto-electric therapy: a promising therapeutic strategy for chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS)

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## Abstract

**Background:** Chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) is a common urological condition characterized by complex etiology, high incidence and limited treatment options. Despite extensive research, its pathogenesis remains poorly understood and high-quality, effective therapies are lacking. **Methods:** This propensity score-matched study assessed 92 patients by evaluating symptom scores, complications, and prognostic outcomes using the National Institutes of Health Chronic Prostatitis Symptom Index (NIH-CPSI), International Prostate Symptom Score (IPSS), and Hospital Anxiety and Depression Scale (HADS), with patients stratified based on baseline characteristics for outcome comparison. **Results:** The total clinical effective rate was significantly higher in the combination therapy group (91.30%) compared to the control group (76.09%,  $p < 0.05$ ); the treatment process was uneventful in both groups, and four weeks after treatment, the total NIH-CPSI score and its subscales were significantly lower in the combination therapy group ( $-17.24$  (6.84) vs.  $-12.54$  (7.18),  $p < 0.05$ ), with a more pronounced reduction in the IPSS score ( $-6.70$  (2.54) vs.  $-3.87$  (2.03),  $p < 0.05$ ) and superior improvements in both peak and average urine flow rates—especially the latter—while neither regimen produced a significant improvement in mood scores. **Conclusions:** The combination of Chinese herbal retention enema and magnetic vibration magneto-electric therapy is more effective than magnetic vibration magneto-electric therapy alone in alleviating the primary symptoms of CP/CPPS, suggesting significant potential for broader clinical application. **Clinical Trial registration:** This study was registered on [itmctr.ccebtcn.org.cn](https://www.clinicaltrials.gov/ct2/show/study?term=ITMCTR2024000191). And the registration number is ITMCTR2024000191.

## Keywords

Chronic prostatitis/chronic pelvic pain syndrome; Chinese herbal retention enema; Magnetic vibration magneto-electric therapy; Treatment effect; Combination therapy

## 1. Introduction

Chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) is a highly prevalent condition among adult males, characterized by persistent urinary discomfort, pelvic pain and sexual dysfunction. The etiology of CP/CPPS remains poorly understood, contributing to its recurrent and long-lasting nature, which significantly impairs patients' physical and mental health [1], as well as imposing a considerable economic burden on affected individuals and their families. The prevalence of CP/CPPS increases with age, and as the population transitions into an aging society, the burden of CP/CPPS is anticipated to rise, posing a growing public health challenge [2, 3]. Current treatment approaches include various clinical and rehabilitation strategies, such as anti-inflammatory agents

like levofloxacin and Chinese patent medicines. However, the therapeutic efficacy of these treatments is often limited due to the hepatic metabolism of drugs and the presence of the blood-prostate barrier, which restricts drug concentrations in prostate tissue [4]. Additionally, adverse effects such as gastrointestinal discomfort and drug resistance compromise patient compliance and therapeutic outcomes, and these challenges highlight the need for alternative or complementary treatment modalities.

Traditional Chinese herbal retention enemas have a long-standing history in disease management and are an established component of Chinese medicine. Clinical experience and a review of relevant literature [5] suggest that retention enemas have demonstrated favorable outcomes in the treatment of CP/CPPS. When integrated with Chinese and Western medical

practices, they form a valuable component of comprehensive CP/CPPS management.

Magnetic vibration magneto-electric therapy is a relatively novel treatment modality for CP/CPPS. It utilizes physical factors such as sound, light, electricity, heat and magnetism to act locally on prostate tissues, enhancing or restoring physiological function. However, relying on specialized personnel and equipment limits its accessibility and widespread adoption. Given the multifactorial nature of CP/CPPS, characterized by diverse etiologies and symptoms, single-treatment approaches are often insufficient.

Since February 2023, our hospital has initiated the combined use of Chinese herbal retention enemas and magnetic vibration magneto-electric therapy for CP/CPPS treatment. This protocol, applied to 46 patients, incorporates rectal retention enemas with proprietary Chinese medicines alongside magnetic vibration magneto-electric therapy over a two-week treatment period. The combination uses the strengths of both approaches, resulting in faster symptom relief and enhanced therapeutic efficacy. The following sections will detail the treatment protocol and its outcomes.

## 2. Methods

### 2.1 Design overview

This study utilized a propensity score-matched design and was conducted with approval from the Ethics Committee of the Second Affiliated Hospital of Zhejiang Chinese Medical University (approval No. 2023-LW-016-01). Written informed consent was obtained from all participants before their inclusion in the study.

### 2.2 Settings and participants

Participants were selected based on strict inclusion and exclusion criteria. The inclusion criteria were as follows: all participants met the diagnostic criteria for CP/CPPS, as defined by the 2020 edition of the Chinese Diagnostic and Therapeutic Guidelines for Urological Diseases [6], which included (1) the presence of urinary symptoms such as frequency, urgency, and a sensation of incomplete urination, accompanied by recurrent perineal or pelvic pain for over three months; (2) an NIH-CPSI score  $>10$ ; (3) type IIIA cases show in white blood cells (WBC)  $\geq 10$ /High Power field (HP) with reduced or absent lecithin bodies in prostate massage fluid microscopy, or type IIIB cases showing WBC  $< 10$ /HP with similar lecithin body changes; and (4) a negative bacterial culture of prostate massage fluid. Additionally, participants were required to be between 20 and 65 years old, have a disease course lasting longer than three months, must not have received physical or pharmacological interventions during the week preceding the study, and had agreed and signed the informed consent.

Exclusion criteria included individuals younger than 20 years or older than 65 years, those with acute urinary system diseases or sexually transmitted infections, and individuals with serious underlying diseases or mental health disorders. Cases involving metal implants, skin diseases, a history of severe allergies or intestinal inflammation or tumors that were contraindicated to the administration of enema were also

excluded.

According to Traditional Chinese Medicine diagnostic criteria, based on the Industry Standards for Traditional Chinese Medicine in the People's Republic of China [7], the participants were classified into two subtypes: Shi-Re-Yun-Jie and Yu-Xie-Zu-Luo.

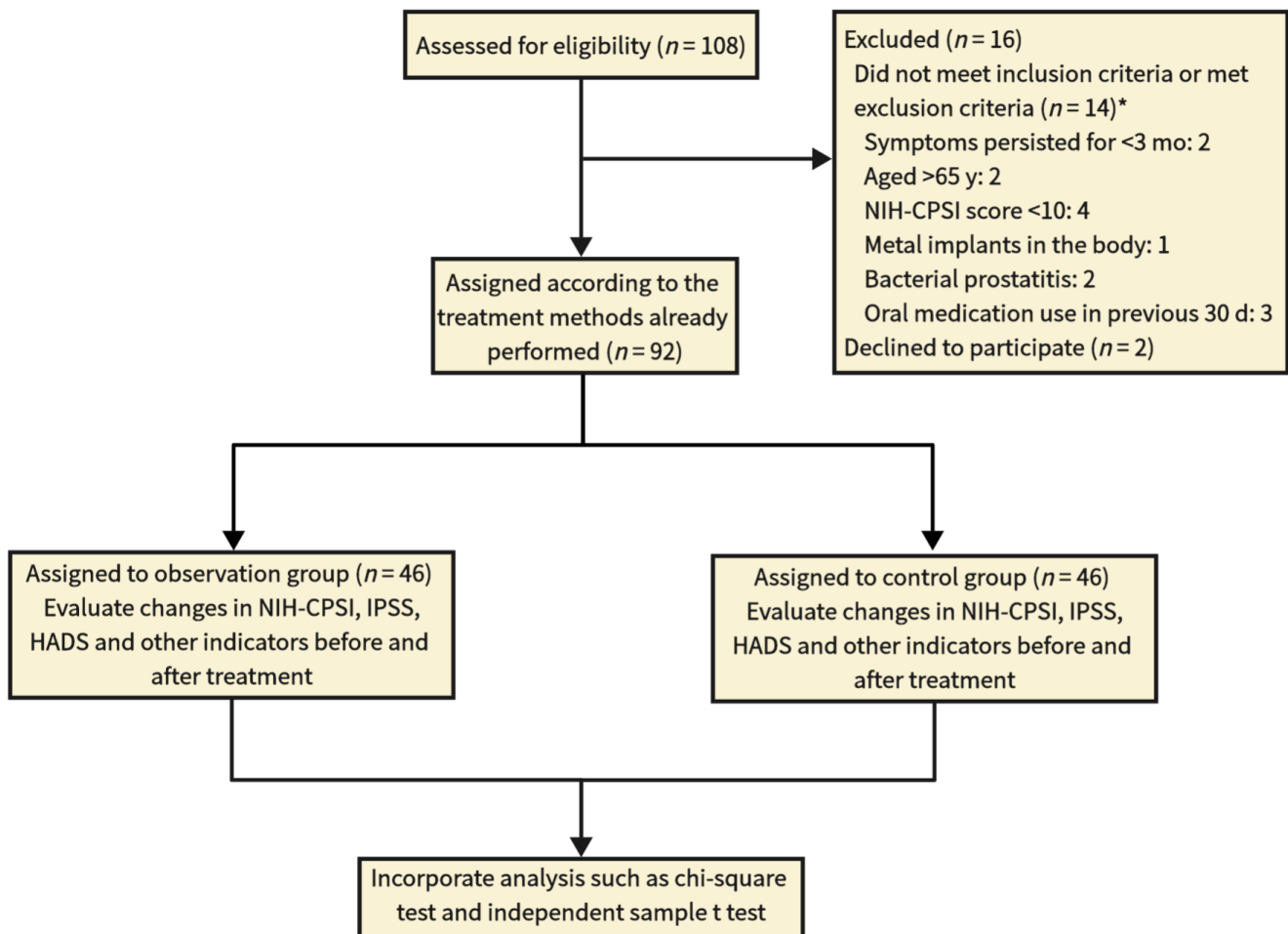
Between February 2023 and June 2024, 108 men with CP/CPPS who were treated at the Department of Urology of the Second Affiliated Hospital of Zhejiang Chinese Medical University were screened for eligibility (Fig. 1). Among them, 92 cases met all inclusion criteria and were classified into a control group and an observation group ( $n = 46$  participants/group). Baseline characteristics and diagnostic data, including general demographic variables and clinical measures, were statistically compared between the two groups (Tables 1 and 2). No statistically significant differences were observed between groups ( $p > 0.05$ ), confirming that they were comparable.

### 2.3 Treatment content

The control group received magnetic vibration magneto-electric therapy, while the observation group underwent a combination therapy of magnetic vibration magneto-electric therapy supplemented with Chinese herbal retention enema.

(1) Magnetic vibration magneto-electric therapy: This treatment utilized the RHY-CZCD-II S model from Zhengzhou Renhui Medical Equipment Co., Ltd (Zhengzhou, Henan, China). Patients were instructed to lie flat and relax during the procedure. Before treatment, the magnetic vibration treatment heads were disinfected with medical alcohol cotton balls. These treatment heads were positioned on the perineum and above the pubic symphysis, with disposable electrodes placed on the four magnetic vibration treatment heads. Electrodes were also attached to bilateral Zusanli and Sanyinjiao acupoints. The power supply was started, and the output current was gradually increased within adjustable settings to ensure the patient experienced a comfortable level of stimulation without excessive discomfort. Each session lasted for 30 minutes, conducted once daily for a total of 28 consecutive days.

(2) Chinese herbal retention enema: According to the diagnosis of Shi-Re-Yun-Jie type, the main Chinese medicines used were Banzhilian (*Scutellaria barbata*, 15 g), Huzhang (*Giant knotweed rhizome*, 15 g), Niuxi (*Radix Achyrantis Bidentatae*, 20 g), Chishao (*Radix Paeoniae Rubrae*, 15 g), Salt Cheqianzi (*Semen Plantaginis*, 30 g), Zelan (*Herba Lycopi*, 15 g), Qumai (*Herba Dianthi*, 20 g), Danggui (*Radix Angelicae Sinensis*, 30 g), Baijiangcao (*Herba Patriniae*, 30 g), Gancao (*Radix Glycyrrhizae*, 6 g), Dangshen (*Codonopsis pilosulae*, 30 g) and others. According to the diagnosis of Qi-Zhi-Xue-Yu type, the main Chinese medicines used were Huzhang (*Giant knotweed rhizome*, 15 g), Yejuhua (*Chrysanthemi Indici Flos*, 6 g), Baihuasheshicao (*Herba Hedyotis Diffusae*, 10 g), Wuyao (*Herba Linderae*, 10 g), Moyao (*Herba Myrrhae Vinigari*, 10 g), Baijiangcao (*Herba Patriniae*, 6 g), Honghua (*Flos Carthami*, 6 g), Huangbo (*Phellodendron chinense*, 6 g), etc. The herbal preparation involved decocting the ingredients in water, followed by removal of the residue to retain 100



**FIGURE 1. Study flow diagram.** \*: Some participants had more than one cause for exclusion. NIH-CPSI: National Institutes of Health Chronic Prostatitis Symptom Index; IPSS: International Prostate Symptom Score; HADS: Hospital Anxiety and Depression Scale.

mL of herbal solution, which was maintained at a temperature of 39–41 °C before use. For administration, the patient was positioned on their left side with their hips slightly elevated and knees bent, their anal canal was lubricated with paraffin oil to minimize the risk of mucosal injury during the procedure, and the enema device was then carefully inserted to a depth of 15–20 cm. After loading the enema device with the herbal solution, the liquid was administered slowly for 5–10 minutes, the enema was retained for 20–30 minutes before removal, and this procedure was conducted once daily for a total of 28 consecutive days.

(3) Combination therapy: This involved administering magnetic vibration magneto-electric therapy immediately after the Chinese herbal retention enema, during which the anal canal was retained in place, with the session lasting for 30 minutes.

## 2.4 Assessments methods

### 2.4.1 Measures

The primary assessment indicators included pain symptom scores, urinary symptom scores, quality of life scores and IPSS and HADS scores, which were evaluated for both groups at baseline and at 2 and 4 weeks after the initiation of treatment.

Comparisons were made both within and between groups to assess changes over time. The total NIH-CPSI score, calculated as the sum of pain, urinary symptom and quality of life scores, was also compared between the two groups at 4 weeks post-treatment. The overall treatment effectiveness rates were evaluated and compared at 4 weeks.

Secondary indicators included peak urinary flow rate and average urinary flow rate, measured during routine outpatient urodynamic examinations conducted at 2 and 4 weeks after treatment initiation. These data were statistically analyzed and compared within and between the two groups.

All symptom scores were provided by the participants using paper-based standardized scales, which were subsequently collected and analyzed, whereby higher scores indicated more severe disease manifestations. The standardized scales used were translated accurately, and the original scales are shown in the **Supplementary material** for reference.

### 2.4.2 Criteria for determination

Treatment effectiveness was assessed according to established criteria [8]. The outcomes were classified into the following categories: Cured: Complete resolution of clinical symptoms with a reduction of  $\geq 90\%$  in NIH-CPSI scores compared to

TABLE 1. General data baseline characteristics of the study population.

Characteristics <sup>a</sup>	Observation (n = 46)	Control (n = 46)	p value
Mean age (SD), yr	40.56 (10.71)	43.71 (10.43)	0.224
Race, n (%)			
Han	44 (95.7)	45 (97.8)	N/A
Other	2 (4.3)	1 (2.2)	N/A
Mean body mass index (SD), kg/m <sup>2</sup>	23.9 (6.6)	25.1 (4.7)	0.335
Married, n (%)	31 (67.4)	34 (73.9)	N/A
Median sexual frequency per week (range)	1.0 (1.0–2.0)	1.0 (1.0–3.0)	N/A
Education level, n (%)			
Primary education or less	1 (2.2)	2 (4.3)	N/A
Secondary education	20 (43.5)	21 (45.7)	N/A
Tertiary education	25 (54.3)	23 (50.0)	N/A
Current smoker, n (%)	15 (32.6)	17 (37.0)	N/A
Current drinker, n (%)	16 (34.8)	14 (30.4)	N/A
Eating preferences, n (%)			
Normal	32 (69.6)	33 (71.7)	N/A
Fast food	5 (10.9)	3 (6.5)	N/A
Light	4 (8.7)	4 (8.7)	N/A
Spicy	4 (8.7)	5 (10.9)	N/A
Tea/coffee	1 (2.1)	1 (2.1)	N/A
Habit of staying up late, n (%)	25 (54.3)	29 (63.0)	N/A
Sedentary lifestyle, n (%)	33 (71.7)	32 (69.6)	N/A
Previous treatments for CP/CPSP, n (%)			
Herbal medicine	12 (26.1)	10 (21.7)	N/A
Local treatments	8 (17.4)	5 (10.9)	N/A
Antibiotics	3 (6.5)	3 (6.5)	N/A
$\alpha$ -Blockers	10 (21.7)	11 (23.9)	N/A
Acupuncture	1 (2.2)	2 (4.3)	N/A
Physical therapy	2 (4.3)	6 (13.0)	N/A
5- $\alpha$ -Reductase inhibitors	8 (17.4)	9 (19.6)	N/A
Other	2 (4.3)	2 (4.3)	N/A

<sup>a</sup>Self-reported by participants. SD: Standard Deviation; N/A: Not Applicable; CP/CPSP: Chronic prostatitis/chronic pelvic pain syndrome.

baseline. Improved: A decrease of 70–89% in NIH-CPSI scores compared to baseline. Effective: A reduction of 30–69% in NIH-CPSI scores compared to baseline. Ineffective: A reduction of <30% in NIH-CPSI scores compared to baseline.

## 2.5 Statistical analysis

Statistical analyses were performed using SPSS version 27.0.1 (International Business Machines Corporation, Armonk, NY, USA). Continuous variables that followed a normal distribution were expressed as mean (Standard deviation, SD). A one-way Analysis of Variance (ANOVA) was used to compare scores within each group across different follow-up time points, evaluating changes before and after treatment initiation. For comparisons between groups at each follow-up time point

relative to the pre-treatment period, an independent samples *t*-test was applied. A *p*-value of < 0.05 was considered to indicate statistical significance.

## 3. Results and outcomes

This study comprised 46 participants in each group who underwent either magnetic vibration magneto-electric therapy alone or in combination with a Chinese herbal retention enema. All participants were treated at the Department of Urology, Second Affiliated Hospital of Zhejiang University of Chinese Medicine, between February 2023 and June 2024. The baseline characteristics of the two groups were comparable, as shown in Table 1. The mean age of participants was 42.47

**TABLE 2. Diagnostic relevant baseline characteristics of the study population.**

Characteristics <sup>a</sup>	Observation (n = 46)	Control (n = 46)	p value
Median CP/CPPS symptom duration (range), mon	8.70 (0.5–22.5)	9.65 (0.8–24.1)	0.390
Comorbidities, n (%)	3 (6.5)	5 (10.9)	N/A
Neck, waist or knee pain	1 (2.1)	1 (2.1)	N/A
Chronic gastritis	1 (2.1)	0	N/A
Anxiety and insomnia	2 (4.3)	2 (4.3)	N/A
Benign prostatic hyperplasia	0	1 (2.1)	N/A
Other	1 (2.1)	1 (2.1)	N/A
Mean IPSS score (SD) <sup>b</sup> (range, 0 to 35) <sup>b</sup>	17.87 (4.36)	17.35 (4.02)	0.553
Mean HADS score (SD) <sup>b</sup> (range, 0 to 42) <sup>b</sup>	12.93 (7.05)	13.52 (6.90)	0.687
Mean peak urinary flow rate (SD), mL/s	20.18 (2.86)	20.04 (3.07)	0.825
Mean average urinary flow rate (SD), mL/s	10.49 (2.37)	10.18 (2.75)	0.566
Median residual urinary volume (range), mL	5.5 (0–15)	5 (0–14)	N/A
Mean NIH-CPSI score (SD) <sup>b</sup>			
Mean pain symptom score (SD) (range, 0 to 21)	11.39 (2.37)	11.41 (2.42)	0.552
Mean urinary symptom score (SD) (range, 0 to 10)	5.98 (1.56)	6.35 (1.39)	0.336
Mean quality-of-life score (SD) (range, 0 to 12)	6.93 (1.37)	7.22 (1.62)	0.476
Mean NIH-CPSI total score (SD) (range, 0 to 43)	24.30 (4.04)	24.98 (3.04)	0.771
Syndrome of TCM			
Shi-Re-Yun-Jie, n (%)	27 (58.70)	25 (54.35) <sup>c</sup>	N/A
Qi-Zhi-Xue-Yu, n (%)	19 (41.30)	21 (45.65) <sup>c</sup>	N/A
Western Medicine diagnostic type			
IIIA, n (%)	8 (17.39)	7 (15.22)	N/A
IIIB, n (%)	38 (82.61)	39 (84.78)	N/A

<sup>a</sup>Cases participated in questionnaires and were evaluated by professional physicians.

<sup>b</sup>Higher scores on the IPSS, HADS and NIH-CPSI indicate worse symptoms.

<sup>c</sup>Due to the fact that cases in the control group did not undergo enema, the traditional Chinese medicine syndrome types are only displayed here.

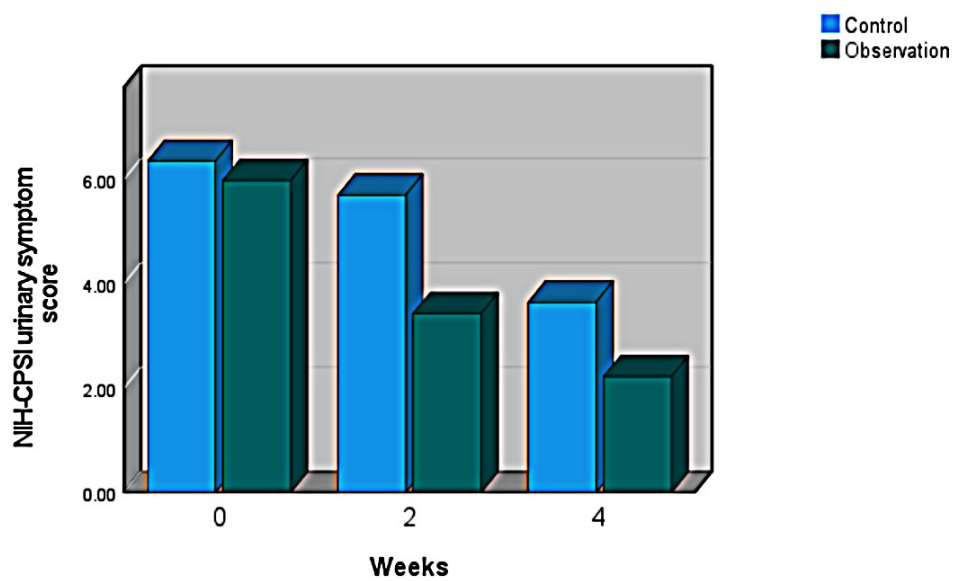
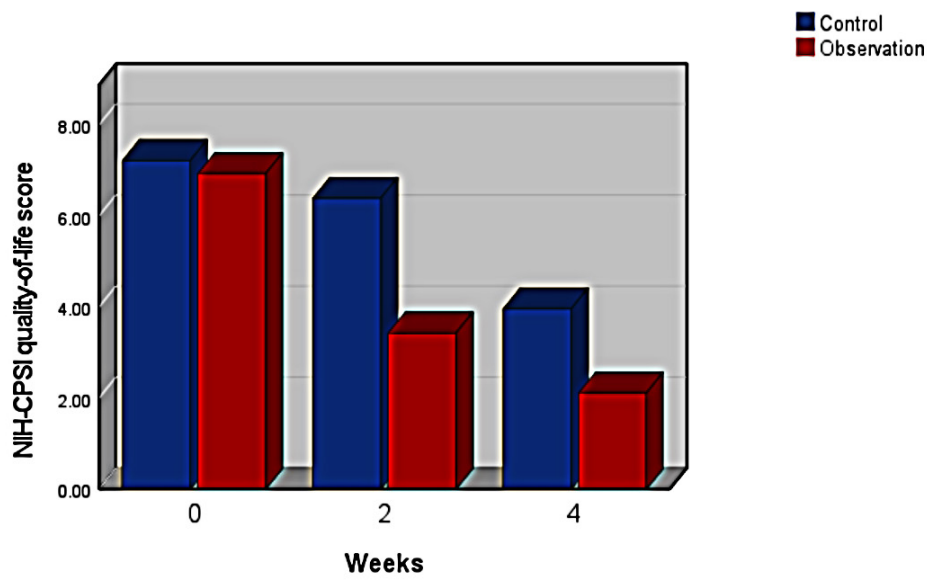
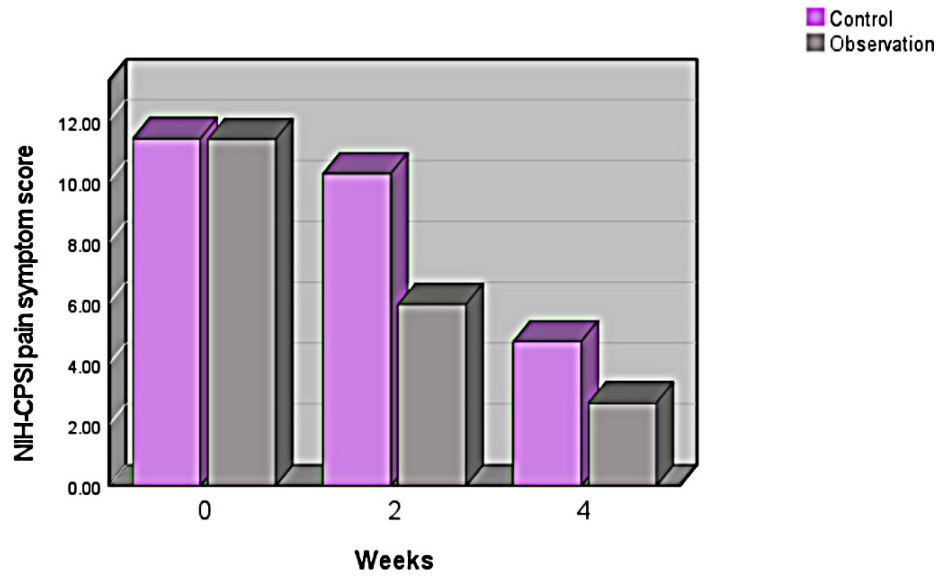
CP/CPPS: Chronic prostatitis/chronic pelvic pain syndrome; IPSS: International Prostate Symptom Score; SD: Standard Deviation; HADS: Hospital Anxiety and Depression Scale; NIH-CPSI: National Institutes of Health Chronic Prostatitis Symptom Index; TCM: Traditional Chinese Medicine; N/A: Not Applicable.

years, with a median duration of CP/CPPS symptoms of 9.15 months (range: 0.5 to 24.1 months). Given that significant symptom improvements in CP/CPPS are typically observed around one month after treatment initiation and most patients adhere to treatment for at least this period, two and four weeks were chosen as the observation points for treatment evaluation. Intra-group and inter-group comparisons were performed for NIH-CPSI, IPSS, HADS, peak urinary flow rate, average urinary flow rate, and other treatment-related indicators. As each group consisted of 46 cases, and the maximum and minimum values for each dataset were excluded after calculating the 95% confidence interval (CI). Confidence interval values for the study results are not described separately in this report.

No statistically significant differences were observed between the two groups in pain symptom scores, urinary symptom scores, quality of life scores, NIH-CPSI total scores or IPSS scores before treatment ( $p > 0.05$ ). In the control group,

the pain, urinary symptoms and quality of life scores mean value decrease ranged from 0.65 to 1.15 points at two weeks post-treatment (Fig. 2, bottom). The mean IPSS score decreased by 2.13 points, but none of these changes were statistically significant at two weeks post-treatment compared to baseline ( $p > 0.05$ ). By four weeks post-treatment, significant improvements were observed in all these scores compared to baseline ( $p < 0.05$ ). The NIH-CPSI total score decreased by an average of 12.54 points, and the IPSS score dropped by 3.87 points.

In the observation group, statistically significant improvements were observed in all scores at both two and four weeks post-treatment compared to baseline ( $p < 0.05$ ). Notably, significant improvements in the observation group were detected as early as two weeks post-treatment, earlier than in the control group. By four weeks post-treatment, the NIH-CPSI total score had decreased by an average of 17.24 points, and the IPSS score had dropped by 6.70 points. Comparisons between the



**FIGURE 2. Response on the NIH-CPSI over time.** NIH-CPSI: National Institutes of Health Chronic Prostatitis Symptom Index.

groups revealed a more significant reduction in NIH-CPSI total scores and a higher total effective rate in the observation group compared to the control group at four weeks post-treatment ( $p < 0.05$ ). The detailed data supporting these findings are shown in Table 3.

Urinary frequency and urgency are among the most common urinary symptoms in patients with CP/CPPS. To evaluate improvements in urination function, we compared changes in maximum urinary flow rate and average urinary flow rate between the two groups. The baseline maximum urinary flow rate values showed no significant differences between the groups before treatment. After 2 weeks of treatment, the average urinary flow rate in the observation group increased by 0.81 mL/s, while the control group demonstrated an increase of 0.37 mL/s. However, these changes were not statistically significant, either between or within the groups ( $p > 0.05$ ), suggesting that two weeks of treatment with Chinese herbal retention enema is not effective in improving maximum urinary flow rate.

After four weeks of treatment, the observation group exhibited a statistically significant improvement in maximum urinary flow rate, with an increase of 1.72 mL/s compared to baseline ( $p < 0.05$ ). In contrast, the control group showed an increase of 0.76 mL/s, which was not statistically significant ( $p > 0.05$ ). Comparisons between the groups at four weeks also showed no statistically significant differences ( $p > 0.05$ ), indicating that the combination therapy could not significantly enhance the maximum urinary flow rate compared to magnetic vibration magneto-electric therapy alone.

Regarding average urinary flow rate, there were no significant differences between the groups at baseline. After two weeks of treatment, the average urinary flow rate increased by 0.32 mL/s in the observation group and 0.16 mL/s in the control group. These changes were not statistically significant, either within or between the groups ( $p > 0.05$ ), indicating that two weeks of treatment with Chinese herbal retention enema did not improve the average urinary flow rate. After four weeks of treatment, the observation group showed a significant increase in average urinary flow rate of 1.03 mL/s compared to baseline ( $p < 0.05$ ), whereas the control group exhibited an increase of 0.29 mL/s, which was not statistically significant ( $p > 0.05$ ). Moreover, there was a statistically significant difference between the groups at four weeks ( $p < 0.05$ ), suggesting that the combination therapy for four weeks significantly improves the average urinary flow rate, with a greater effect compared to magnetic vibration magneto-electric therapy alone.

Furthermore, the emotional state of patients in both treatment groups was evaluated and compared. After two weeks of treatment, no statistically significant differences were observed within or between the groups regarding changes in HADS scores ( $p > 0.05$ ), indicating that enema therapy for two weeks did not significantly improve patients' emotional states. After four weeks of treatment, the observation group showed an average decrease in HADS score exceeding 2 points compared to baseline, while the control group demonstrated an average decrease exceeding 1.4 points. However, intragroup comparisons revealed no statistically significant differences in either group ( $p > 0.05$ ), suggesting that four weeks of treatment did not lead to a substantial improvement in the

emotional state within either group. In contrast, the intergroup comparison after four weeks showed a statistically significant difference ( $p < 0.05$ ), indicating that the improvement in emotional state in the observation group was slightly greater than in the control group.

In this study, the total effective rate of the observation group, which received Chinese herbal retention enema combined with magnetic vibration magneto-electric therapy, was 91.30% after four weeks of treatment. In comparison, the total effective rate for the control group, which received magnetic vibration magneto-electric therapy alone, was 76.09%. This difference was statistically significant ( $p < 0.05$ ), as detailed in Table 4. Adverse events were reported in both groups, with four cases (8.7%) in the observation group and two cases (4.3%) in the control group. All treatment-emergent adverse events were mild and transient, resolving without the need for additional intervention. Importantly, no serious adverse events occurred in either group, as shown in Table 5.

## 4. Discussion

CP/CPPS is a prevalent urological condition primarily affecting middle-aged and elderly men. Its etiology is multifactorial and poorly understood, making its treatment particularly challenging. Patients often present with symptoms such as pelvic pain in the perineal region, abnormal urinary function, and sexual dysfunction, which significantly diminish their quality of life and may adversely affect interpersonal relationships, particularly with their spouses [9]. Current evidence suggests that CP/CPPS arises from a complex interplay of multiple pathogenic factors. Interestingly, the severity of the condition appears to be independent of the presence or absence of inflammatory cells or pathogens in the prostatic fluid [4]. The blood-prostate barrier further complicates treatment, as it limits drug delivery to prostate tissue via oral administration. Consequently, the absorption of many medications is suboptimal, and the use of single-drug therapies often fails to achieve satisfactory therapeutic outcomes.

Magnetic vibration magneto-electric therapy represents a form of physical therapy that has been applied in clinical practice and shown promising therapeutic outcomes. This technology combines electricity, magnetism, sound and other physical stimuli to generate low- and medium-frequency pulsed currents. These currents enhance ion and molecule movement in local tissue cells, thereby stimulating metabolic activity and physiological processes that promote tissue repair and regeneration, and also facilitating the repair of damaged tissue and cellular structures. The magnetic component of the therapy utilizes an inhomogeneous unidirectional pulsed magnetic field, characterized by varying magnetic field strength. This variation enhances the vibration of molecular ions in local tissue cells, improving cellular metabolism and accelerating the recovery of damaged cell functions. In addition to its electromagnetic effects, the therapy generates acoustic waves, which induce a specific type of vibration that contributes to a dynamic yet harmonious environment. This state supports the patient's mental and emotional adaptation to chronic pain, urinary discomfort, anxiety and agitation, which are often associated with chronic urological conditions.

TABLE 3. Primary and secondary outcomes.

Outcome	Observation (n = 46)	Control (n = 46)	Adjusted Difference (95% CI)
Primary Outcomes <sup>a</sup>			
Adjusted mean change in NIH-CPSI pain symptom score (SD) (95% CI)			
Week 2	-5.43 (2.34)	-1.15 (1.07)	-4.28
Week 4	-8.67 (3.08)	-6.67 (3.65)	-2.00
Adjusted mean change in NIH-CPSI urinary symptom score (SD) (95% CI)			
Week 2	-2.54 (1.50)	-0.65 (0.85) <sup>a</sup>	-1.89
Week 4	-3.76 (2.79)	-2.70 (2.30)	-1.06
Adjusted mean change in NIH-CPSI quality-of-life score (SD) (95% CI)			
Week 2	-3.50 (1.71)	-0.83 (0.68)	-2.67
Week 4	-4.83 (2.03)	-3.26 (2.44)	-1.57
Adjusted mean change in NIH-CPSI total score (SD) (95% CI)			
Week 4	-17.24 (6.84)	-12.54 (7.18)	-4.70
Adjusted mean change in IPSS score (SD) (95% CI)			
Week 2	-3.15 (2.63)	-2.13 (1.39)	-1.02
Week 4	-6.70 (2.54)	-3.87 (2.03)	-2.83
Adjusted mean change in HADS score (SD) (95% CI)			
Week 2	-0.85 (2.03)	-0.39 (1.87)	-0.46
Week 4	-2.17 (1.42)	-1.46 (1.73)	-0.71
Secondary Outcomes			
Adjusted mean change in peak urinary flow rate (SD) (95% CI), mL/s			
Week 2	0.81 (0.86)	0.37 (0.67)	0.44
Week 4	1.72 (1.11)	0.76 (0.74)	0.96
Adjusted mean change in average urinary flow rate (SD) (95% CI), mL/s			
Week 2	0.32 (0.69)	0.16 (0.38)	0.15
Week 4	1.03 (1.02)	0.29 (0.32)	0.74
Use of other treatment for CP/CPPS during study, n (%)			
Herbal medicine	5 (10.9)	3 (6.5)	N/A
Antibiotics	1 (2.2)	2 (4.3)	N/A
Infrared therapy or moxibustion	0	0	N/A
$\alpha$ -Blockers or 5- $\alpha$ -reductase inhibitors	1 (2.2)	0	N/A
Hip bath	2 (4.3)	3 (6.5)	N/A
Sertraline	0 (0)	1 (2.2)	N/A

<sup>a</sup>Details on the definition of the primary outcomes are provided in Measures (Assessments Methods).

CI: Confidence Interval; NIH-CPSI: National Institutes of Health Chronic Prostatitis Symptom Index; IPSS: International Prostate Symptom Score; HADS: Hospital Anxiety and Depression Scale; TCM: Traditional Chinese Medicine; CP/CPPS: Chronic prostatitis/chronic pelvic pain syndrome; N/A: Not Applicable.



**TABLE 4. Comparison of the clinical efficacy of the two groups of cases (n (%)).**

Response rate	Observation (n = 46)	Control (n = 46)	$\chi^2$ value	p value	Adjusted Odds Ratio (95% CI)
Cured	12 (26.09)	7 (15.22)			
Improved	23 (50.00)	16 (34.78)			
Effective	7 (15.22)	12 (26.09)		N/A	
Ineffective	4 (8.70)	11 (23.91)			
Overall response rate <sup>a</sup>	42 (91.30)	35 (76.09)	3.903	0.048	3.301 <sup>b</sup>

<sup>a</sup>Details on the definitions of responder analyses at each visit are provided in *Criteria for determination (Assessments Methods)*.

<sup>b</sup>Odds ratios were based on the prespecified logistic generalized linear mixed model and adjusted for baseline NIH-CPSI total score.

CI: Confidence Interval; N/A: Not Applicable.

**TABLE 5. Adverse events related and unrelated to treatment<sup>a</sup>.**

Adverse Event	Observation (n = 46)	Control (n = 46)
Any	4 <sup>b</sup>	2
Serious	0	0
Related to treatment <sup>c</sup>		
Abdominal pain	1 (2.2)	0
Diarrhea, Emesis	1 (2.2)	0
Bloody stools	0	0
Intestinal perforation	0	0
Intestinal infection	0	0
Anaphylactic reaction	0	0
Unrelated to treatment <sup>c</sup>		
Cold	1 (2.2)	1 (2.2)
Fever	0	1 (2.2)
Tonsillitis	0	0
Fall	0	0
Pneumonia	1 (2.2)	0
Acute gastritis	0	0

<sup>a</sup>Data are numbers (percentages).

<sup>b</sup>Adverse events in this study were categorized based on their type rather than their frequency within individual participants. Different types of adverse events occurring in the same participant were considered independent adverse events. Conversely, an adverse event of the same type with multiple occurrences in a single participant was recorded as a single adverse event.

<sup>c</sup>A treatment-related adverse event was defined as any adverse event that was considered to be possibly, probably, or definitely related to the trial intervention as determined by urologists.

In this study, the magnetic vibration magneto-electric probe was positioned at the Zusanli and Sanyinjiao acupuncture points, as well as the local skin near the prostate gland, to combine magnetic vibration, mechanical stimulation, low-frequency acoustic waves and oscillating magnetic fields to target the perineum, pelvis, and surrounding regions, with the aim of stimulating the meridians, facilitating the flow of qi and blood, reducing mesenchymal edema, loosening adhesions caused by inflammation, and promoting the release

of analgesic factors. These effects contributed to decreased pressure within the ducts of the adenohypophysis and reduced excitability of sensory nerves, ultimately alleviating pelvic pain [10, 11].

In addition, the specific intensity of electromagnetic waves applied to the pelvic floor can stimulate local nerve activity, promoting bladder emptying and significantly improving urinary dysfunction [12, 13]. This method enhances the local microenvironment of the prostate by increasing blood flow,

expediting the clearance of metabolites and inflammatory factors, and thereby reducing pain and inflammation. In addition, it boosts cellular activity and vascular permeability, facilitating drug absorption. These effects are particularly significant in alleviating clinical symptoms and improving the overall therapeutic efficacy of pharmacological treatments.

According to Shaoying Yuan *et al.* [14], the total effective rate of the two-week treatment of CP/CPPS with magnetic vibration magneto-electric therapy alone was close to 80%. In the present study, the total effective rate of this therapy alone was 76.09%, aligning closely with the previous findings. Given the complex etiology and diverse symptomatology of CP/CPPS, the most effective management is likely to involve a combination of therapeutic approaches. This study innovatively modified traditional Chinese medicine (TCM) administration during magnetic vibration magneto-electric therapy by employing rectal retention enema to deliver the medication. The TCM etiology of CP/CPPS is characterized by patterns such as liver depression and qi stagnation, spleen deficiency with dampness, and disharmony between the liver and spleen. Certain traditional Chinese herbs, such as *Hericium erinaceus*, have demonstrated efficacy in alleviating CP symptoms, likely due to their antibacterial and anti-inflammatory properties [15]. In clinical practice, such treatments have shown effectiveness in managing pelvic inflammatory conditions, significantly improving pelvic floor muscle tenderness [15]. Furthermore, lower urinary tract symptoms associated with CP/CPPS may have an intestinal origin via the mechanism of pelvic cross-organ sensitization, and there is evidence suggesting that patients with inflammatory bowel disease are predisposed to lower urinary tract symptoms, likely due to a similar pathogenic mechanism [16]. In this study, the herbal retention enema formula used aimed to promote blood circulation, resolve tissue adhesions, move qi and alleviate pain. The rectal administration allowed rapid drug absorption through the intestinal mucosa, bypassing the first-pass effect of the liver and directly targeting the prostate gland. Despite this, the presence of the blood-prostate barrier remains a limiting factor for drug penetration into prostate tissue [17]. To address this limitation, magnetic vibration magneto-electric therapy was applied immediately after the herbal retention enema. This combination improved the vascular permeability of prostate tissue, reduced local tissue edema, and enhanced microcirculation. These effects compensated for the limited drug absorption within prostate tissue during the enema, and the two approaches worked synergistically, resulting in a rapid increase in local drug concentration, a fast therapeutic onset, and high safety [5].

This study demonstrates that cases in the control group showed improvement in NIH-CPSI and IPSS scores after 4 weeks of magnetic vibration magneto-electric therapy, although the changes were not statistically significant after two weeks of treatment ( $p > 0.05$ ). Conversely, the observation group showed significant improvements in all scores after both two and four weeks of treatment compared to baseline ( $p > 0.05$ ). These results indicate that while both magnetic vibration magneto-electric therapy alone and the combination therapy can alleviate the primary symptoms of CP/CPPS, the combination therapy has a faster onset and more

pronounced therapeutic effects, likely due to their synergistic mechanisms. Magnetic vibration magneto-electric therapy enhances local tissue responses and mitigates the restrictive effect of the blood-prostate barrier, thereby facilitating the delivery of therapeutic agents from the rectum into prostate tissue, contributing to a rapid and significant reduction in symptoms. After treatment, cases in the observation group exhibited notable improvements in all measured scores compared to both pre-treatment levels and corresponding follow-up scores in the control group. These differences were particularly evident at the two-week follow-up, underscoring the enhanced efficacy and rapid onset of the combination therapy. These findings highlight the ability of the combined approach to effectively alleviate symptoms of CP/CPPS and improve the quality of life for patients.

Statistical analysis of patient' peak and average urinary flow rates revealed that the 4-week combination therapy significantly improved the average urinary flow rate compared to magnetic vibration magneto-electric therapy alone. However, there was no notable improvement in the peak urinary flow rate, which may be attributed to the relatively short treatment duration. Comparative analysis of emotional state showed no significant differences between the observation and control groups after 2 weeks of treatment. By the 4th week, both groups exhibited some improvement in emotional state, with slightly better outcomes observed in the observation group. The study also highlighted that CP/CPPS is associated with increased levels of depression and anxiety, with substantial individual variability in mood regulation. It could be plausible that with larger sample sizes, extended treatment durations and more pronounced therapeutic effects, mood improvements may become more evident.

A previous study [14] reported the use of oral *Danhong-Tongjing-Fang* combined with magnetic vibration magneto-electric therapy for treating CP/CPPS, using a regimen of one-week treatment courses with two-week intervals between courses. After two courses of treatment, improvements were observed in pain and discomfort, urinary symptoms, quality of life, and NIH-CPSI total scores, yielding a total effective rate of 86.76%. In this present study, the observation group achieved a total effective rate of 91.30% after four weeks of treatment, while single magnetic vibration magneto-electric therapy alone achieved a total effective rate of 76.09%. These results suggest that the combination therapy utilized in this study demonstrated superior efficacy compared to the previously reported combination therapy and significantly outperformed magnetic vibration magneto-electric therapy alone. The combination of Chinese herbal retention enema with magnetic vibration magneto-electric therapy for CP/CPPS has been preliminarily shown to offer precise efficacy, rapid onset of action, mild adverse effects, and the ability to effectively alleviate symptoms of discomfort in the short term. Furthermore, this approach significantly enhances patients' confidence in recovery and improves long-term quality of life. These findings underscore the potential of this multidisciplinary approach for broader clinical application. However, the study is limited by the relatively small sample size and the absence of long-term efficacy follow-up. Future research will aim to address these limitations, providing a more comprehensive evaluation

of the therapy's sustained benefits and further exploring its mechanisms and applications.

## 5. Conclusions

The combination of Chinese herbal retention enema with magnetic vibration magneto-electric therapy demonstrates superior and faster efficacy compared to magnetic vibration magneto-electric therapy alone in alleviating pain and discomfort, improving voiding abnormalities, and enhancing the quality of life in patients with CP/CPPS. This approach offers notable advantages over the use of magnetic vibration magneto-electric therapy as a standalone treatment, making it a promising therapeutic option for this condition.

## ABBREVIATIONS

CP/CPPS, Chronic Prostatitis/Chronic Pelvic Pain Syndrome; IPSS, International Prostate Symptom Score; HADS, Hospital Anxiety and Depression Scale; NIH-CPSI, National Institutes of Health Chronic Prostatitis Symptom Index; TCM, Traditional Chinese Medicine; SD, Standard deviation; ANOVA, Analysis of Variance; WBC, white blood cells; HP, High Power field; CI, confidence interval.

## AVAILABILITY OF DATA AND MATERIALS

The data are contained within this article.

## AUTHOR CONTRIBUTIONS

YX and HZ—designed the research study; wrote the manuscript. YX, HZ and JTS—performed the research. WHZ, JTF, QYuZ, QYaZ and GC—provided help and advice on technical details. YX and JTS—analyzed the data. YD—offered funding support for research projects and provides guidance on the direction of research topics. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

## ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study was conducted with approval from the Ethics Committee of the Second Affiliated Hospital of Zhejiang Chinese Medical University (approval No. 2023-LW-016-01). Written informed consent was obtained from all participants before their inclusion in the study.

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## CONFLICT OF INTEREST

The authors declare no conflict of interest.

## SUPPLEMENTARY MATERIAL

Supplementary material associated with this article can be found, in the online version, at <https://oss.jomh.org/files/article/1905526443688771584/attachment/Supplementary%20material.docx>.

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