Urology Research, 2024, Volume 2, Issue 4
https://ojs.bbwpublisher.com/index.php/UR
Online ISSN: 2981-8230

Clinical Efficacy of Tamsulosin Combined with Huang'e Capsules in Improving Type III Prostatitis

Qiang Ren, Hankai Chen*, Jinfeng Yu, Junbiao Zheng, Yumin Li, Dong Li

Jiashan First People's Hospital, Jiaxing 314100, Zhejiang Province, China

***Corresponding author:** Hankai Chen, 576531703@qq.com

Abstract: *Objective:* To explore the clinical efficacy and safety of tamsulosin combined with Huang'e capsules in treating type III prostatitis. *Methods:* A total of 74 patients from the Department of Urology at Jiaxing University Affiliated Jiashan Hospital were selected and randomly divided into treatment group and control group by double-blind method, with 37 cases in each group. The treatment group was given tamsulosin combined with Huang'e capsules, and the control group was given tamsulosin alone. The NIH-CPSI, IIEF-5, and EPS-WBC scores and the incidence of adverse reactions in the two groups were compared before treatment as well as 15 and 30 days after treatment. *Results:* The treatment group showed statistically significant differences compared to the control group in terms of pain or discomfort, urinary symptoms, quality of life, NIH-CPSI, and EPS-WBC after treatment ($P < 0.05$). There was no statistically significant difference in IIEF-5 scores between the two groups ($P > 0.05$). No major adverse reactions occurred in either group during the treatment. *Conclusion:* Tamsulosin combined with Huang'e capsules can effectively improve the clinical symptoms of patients with type III prostatitis, enhance the quality of life, and has good safety.

Keywords: Type III prostatitis; Tamsulosin; Huang'e capsule; NIH-CPSI; EPS-WBC; IIEF-5

Online publication: January 8, 2025

1. Introduction

Chronic prostatitis is one of the most common disorders in the urinary system, with type III prostatitis being particularly prevalent [1]. In recent years, the incidence of the disease has shown a gradual upward trend. Clinically, it presents with symptoms such as pain (in the perineum, testicles, pubic area, etc.), urinary storage and voiding symptoms, and sexual dysfunction, significantly affecting the quality of life and physical and mental health of men. Epidemiologically, prostatitis patients account for 8% to 25% of urology outpatient visits, with the reported prevalence in China ranging from 6.0% to 32.9% [2]. Huang'e capsules, developed by Professor Jinming Jia and his team in China, contain 12 traditional Chinese medicinal ingredients: astragalus, peach kernel, curcuma, motherwort, selfheal, rhubarb, earthworm, coix seed, cinnamon, pueraria, platycodon, and epimedium.

Current studies show that Huang'e capsules can alleviate symptoms such as difficulty urinating, frequent urination, urgency, and lower abdominal discomfort by reducing the tension of the urethral sphincter, improving microcirculation, and exerting anti-inflammatory effects [3,4]. This study aims to investigate the efficacy and safety of tamsulosin combined with Huang'e capsules in patients with type III prostatitis.

2. General information and methods

2.1. General information

A total of 74 patients diagnosed with type III prostatitis between May 2022 and December 2023 were selected and randomly divided into a treatment group and a control group, with 37 patients in each group. The subjects' age ranged from 30 to 65 years old, and the course of the disease ranged from 1 to 60 months. None of the patients had underlying diseases.

2.2. Inclusion and exclusion criteria

Inclusion criteria: (1) Meet the diagnostic criteria for type III prostatitis according to the "2019 Edition of Chinese Urological Disease Diagnosis and Treatment Guidelines"; (2) Have not received other drug treatments or methods in the 15 days prior to treatment; (3) Have agreed to participate in the study through informed consent. Exclusion criteria: (1) Cases that have received other related treatments; (2) Cases with interfering diseases such as other prostate disorders, cystitis, urethritis, etc.; (3) Cases with severe underlying diseases; (4) Cases with mental disorders; (5) Cases where complete information cannot be collected due to personal reasons such as withdrawal in the middle of the study. This study has been reviewed and approved by the ethics committee of our hospital, and all subjects have been informed and signed informed consent forms.

2.3. Methods

The treatment group took Huang'e capsules (manufacturer: Zhejiang Kang En Bei Pharmaceutical Co., Ltd., specification: 0.4 g/capsule), 1.6 g per dose, three times a day; and tamsulosin capsules (manufacturer: Zhejiang Qianyuan Hailisheng Pharmaceutical Co., Ltd., specification: 0.2 mg/capsule), 0.2 mg per dose, once at night.

The control group took tamsulosin capsules (manufacturer: Zhejiang Qianyuan Hailisheng Pharmaceutical Co., Ltd., specification: 0.2 mg/capsule), 0.2 mg per dose, once at night.

Assessments were conducted 15 and 30 days after starting treatment.

2.4. Evaluation metrics

(1) National Institutes of Health Chronic Prostatitis Symptom Index (NIH-CPSI): This scale consists of three parts: pain symptoms, urinary symptoms, and the impact of symptoms on quality of life. The total score ranges from 1 to 14 for mild, 15 to 29 for moderate, and 30 to 43 for severe. A higher score indicates more severe clinical symptoms.

(2) International Index of Erectile Function (IIEF-5): A score of less than 7 indicates severe erectile dysfunction, 8–11 indicates moderate erectile dysfunction, and 12–21 indicates mild erectile dysfunction.

(3) White Blood Cell Count in Prostatic Fluid (EPS-WBC): Prostatic fluid was obtained through prostate massage and sent to the hospital's laboratory for leukocyte counting under high magnification.

2.5. Statistical methods

Data analysis was performed using SPSS26.0 software. Categorical data are expressed as percentages (%) and

analyzed using the chi-square test. Quantitative data are expressed as mean ± standard deviation (SD) and analyzed using the *t*-test. A *P*-value less than 0.05 was considered statistically significant.

3. Results

3.1. Comparison of basic information

The comparison results showed no statistically significant differences in age, disease duration, body mass index (BMI), and underlying diseases between the two groups of patients, indicating that the subjects were comparable (**Table 1**).

Table 1. Comparison of basic patient information (mean ± SD)

Basic information	Age	Disease duration (months)	BMI
Treatment group	48.32 ± 9.45	15.38 ± 10.82	23.89 ± 2.38
Control group	48.32 ± 9.01	14.16 ± 9.76	23.42 ± 2.38

Note: Compared with the control group, $P > 0.05$

3.2. Comparison of NIH-CPSI scores

Before treatment, there were no statistically significant differences in pain or discomfort, urinary symptoms, quality of life, and total scores between the two groups ($P > 0.05$). After treatment, the scores for pain or discomfort, urinary symptoms, and quality of life in the treatment group were significantly reduced; the difference between the treatment group and the control group was statistically significant ($P < 0.05$). The results are shown in **Table 2**.

Table 2. Comparison of NIH-CPSI scores before and after treatment in both groups (mean ± SD)

Group	Treatment group			Control group		
	Pre-treatment	15 days after treatment	30 days after treatment	Pre-treatment	15 days after treatment	30 days after treatment
Pain or discomfort	8.72 ± 3.54	6.54 ± 2.06	4.17 ± 2.38a	9.02 ± 2.54	7.87 ± 2.56	7.12 ± 2.78a
Urinary symptoms	7.63 ± 1.94	4.16 ± 1.18	2.01 ± 1.04b	7.48 ± 1.78	6.08 ± 1.79	5.57 ± 1.06b
Quality of life	9.05 ± 0.92	5.72 ± 1.54	3.23 ± 1.67c	9.76 ± 1.08	7.33 ± 2.35	6.78 ± 1.97c
Total score	24.75 ± 3.01	16.78 ± 1.98	12.51 ± 1.06[d]	25.45 ± 3.64	19.06 ± 1.98	18.98 ± 1.98[d]

Note: For between-group comparisons, $P < 0.05$; compared with the control group, [a]P, [b]P, [c]P, and [d]P are all less than 0.05.

3.3. Comparison of IIEF-5 scores

Based on **Table 3**, there was no significant difference in erectile dysfunction between the two groups before and after treatment, and the difference was not statistically significant ($P > 0.05$).

Table 3. Comparison of IIEF-5 scores before and after treatment in both groups (mean ± SD)

Group	Treatment group		Control group	
	Pre-treatment	30 days after treatment	Pre-treatment	30 days after treatment
IIEF-5 score	13.45 ± 1.57	13.98 ± 1.64[a]	12.33 ± 1.78	12.01 ± 1.61[a]

Note: Compared with the control group, $P > 0.05$

3.4. Comparison of EPS-WBC

There was no significant difference in white blood cell count in prostatic fluid between the two groups before treatment, and the difference was not statistically significant ($P > 0.05$). After treatment, the white blood cell count in prostatic fluid of the treatment group decreased significantly; compared with the control group, the difference was statistically significant ($P < 0.05$), as presented in **Table 4**.

Table 4. Comparison of EPS-WBC changes before and after treatment in both groups (mean ± SD)

Group	Treatment group		Control group	
	Pre-treatment	30 days after treatment	Pre-treatment	30 days after treatment
EPS-WBC	24.49 ± 3.78	6.37 ± 2.05	23.57 ± 3.08	18.78 ± 3.12

Note: Comparison between groups, $P < 0.05$; compared with the control group, $P < 0.05$

3.5. Comparison of adverse reaction incidence

During the treatment process, only one case of nausea was reported in the treatment group, and no other adverse reactions occurred (**Table 5**). The *P*-value between the two groups was greater than 0.05, indicating no statistical significance.

Table 5. Incidence of adverse reactions in both groups ($n = 37$, %)

Group	Nausea	Dizziness	Allergic reaction	Other	Total incidence
Treatment group	1/37	0/37	0/37	0/37	2.70
Control group	0/37	0/37	0/37	0/37	0

Note: Compared with the control group, the total incidence of adverse reactions was $P > 0.05$

4. Discussion

Chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) is the most common, symptomatically complex, and difficult-to-treat type of prostatitis, with an unclear etiology. Current clinical treatment typically involves α-receptor blockers, plant-based formulations, nonsteroidal anti-inflammatory analgesics, and M-receptor blockers to alleviate symptoms. Cognitive-behavioral education [5], acupuncture [1], and other methods have also demonstrated clinical effectiveness. Huang'e capsule, formulated with a combination of 12 traditional Chinese medicinal herbs based on the principles of Chinese medicine, primarily works by tonifying qi and invigorating blood to improve urinary symptoms. It has been shown to antagonize α1-receptor adrenal receptors [6], regulating prostate smooth muscle tone and urethral pressure, thus reducing urinary resistance. It can also decrease the activity of 5α-reductase in the prostate interstitial cells [7], lowering dihydrotestosterone levels and shrinking prostate volume. Additionally, Huang'e capsule has been reported to improve microcirculation [8] and exhibit anti-inflammatory effects [9], providing a strong theoretical basis for its use in treating type III prostatitis.

Tamsulosin sustained-release capsules are a selective α1-adrenergic receptor blocker that relaxes prostate smooth muscle to alleviate urinary symptoms, and they are commonly used in patients with prostatitis and urinary disorders. The "Jun-Chen-Zuo-Shi" method, originating from the *Shennong Bencao Jing*, outlines the roles of the ingredients in the formulation: the Jun (emperor) drug is the primary tonic; the Chen (minister) drug supports the

main tonic; and the Zuo-Shi (assistant) drug treats the disease. In Huang'e capsule, the Jun drugs are astragalus and peach kernel. Modern pharmacology shows that astragalus contains polysaccharides, saponins, flavonoids, folic acid, and riboflavin [10], with properties such as antibacterial, anti-inflammatory, immune regulation, antioxidant, and diuretic effects [10-12]. Peach kernel is traditionally used in Chinese medicine to promote blood circulation and remove blood stasis [13]. This study selected 74 patients with type III prostatitis, and the results demonstrated significant differences in urinary pain or discomfort, urinary symptoms, quality of life scores, total NIH-CPSI scores, and EPS-WBC between the treatment group and the control group. These findings confirm the clinical efficacy of Huang'e capsule in treating type III prostatitis. Previous studies by Yang *et al.* [14], Geng *et al.* [15], and others have also reported similar outcomes.

Although Huang'e capsule has theoretical support and research evidence for improving urinary symptoms and quality of life in type III prostatitis patients, there have been no clinical reports on its effect on erectile dysfunction in these patients. During the study, we also assessed patients with lower urinary tract symptoms and concurrent erectile dysfunction, and found significant improvement in urinary symptoms, but minimal improvement in erectile dysfunction. Factors such as the patient's condition, emotions, lifestyle, and sexual psychology can affect erectile dysfunction [16] and may have interfered with the research data. The adverse reactions were monitored, with one case of nausea reported in the treatment group, but no major adverse effects were observed.

5. Conclusion

In conclusion, the combination of tamsulosin sustained-release capsules and Huang'e capsule is effective and safe for treating type III prostatitis. However, the study's limitation lies in the small sample size. Future research should expand the sample size and include multi-center collaboration to obtain more reliable clinical data.

Disclosure statement

The authors declare no conflict of interest.

References

[1] Qin Z, Liu Y, Zhou K, et al., 2017, Acupuncture for Chronic Prostatitis/Chronic Pelvic Pain Syndrome: Study Protocol for a Randomized Controlled Trial. Trials, 18(1): 616.

[2] Zhang M, Chang D, Bin B, et al., 2023, Guidelines for the Diagnosis and Treatment of Chronic Prostatitis with Integrated Traditional Chinese and western Medicine. Chinese Journal of Andrology, 37(01): 3–17.

[3] Ma W, Jia J, Jiao Y, et al., 2008, Effects of Longbixiao Capsule on the Expression of *TGF-β1* and *Smoothelin* Genes in Human Prostatic Hyperplasia Stromal Cells Cultured *In Vitro*. Chinese Journal of Andrology, (05): 466–470.

[4] Jia J, Ma C, Wang L, et al., 2002, The Effect of the Traditional Chinese Medicine "Xiaolong Tongbi" on NOS Nerves in Prostatic Smooth Muscle. Chinese Journal of Integrated Traditional and Western Medicine in Surgery, (05): 22–24.

[5] Lackner JM, Jaccard J, Quigley BM, et al., 2022, Study Protocol and Methods for Easing Pelvic Pain Interventions Clinical Research Program (EPPIC): A Randomized Clinical Trial of Brief, Low-Intensity, Transdiagnostic Cognitive Behavioral Therapy vs Education/Support for Urologic Chronic Pelvic Pain Syndrome (UCPPS). Trials, 23(1): 651.

[6] Jia J, Sun L, Ma C, et al., 2000, The Antagonistic Effect of "Xiaolong Tongbi" on α1 Adrenergic Receptors in the Cerebral Cortex of Dogs. Modern Urology, (01): 1–3.

[7] Jia J, Liu Y, Li Y, et al., 2007, Study on the Mechanism of Traditional Chinese Medicine Xiaolong Tongbi Improving Urination Difficulty and Reducing Prostate Volume. Journal of Medical Research, (09): 59.

[8] Jia J, Sun L, Wang L, et al., 1999, The Effect of Xiaolong Tongbi on the Expression of Basic Fibroblast Growth Factor in Rat Prostate Tissue. Chinese Journal of Integrated Traditional and Western Medicine in Surgery, (02): 5–7.

[9] Dong J, Jia J, 2008, Research Progress on the Role of FGFs and TGF-βs in the Pathogenesis of Benign Prostatic Hyperplasia. Modern Urology, (06): 490–492.

[10] Wu J, Tong F, 2024, Chemical Components, Pharmacological Effects, and Clinical Applications of Astragalus Membranaceus. Journal of Binzhou Medical University, 47(01): 68–75.

[11] Li CX, Liu Y, Zhang YZ, et al., 2022, Astragalus Polysaccharide: A Review of Its Immunomodulatory Effect. Archives of Pharmacal Research, 45(6): 367–389.

[12] Zhang Q, Xing Y, 2024, Reflections on the Absence of Astragalus Membranaceus in Zhang Zhongjing's "Treatise on Febrile and Miscellaneous Diseases." Chinese Ethnic Medicine and Ethnomedicine, 33(04): 95–97.

[13] Yang L, Chen J, 2020, A Review of the Research on Chinese Medicinal Persicae Semen. China Journal of Pharmaceutical Economics, 15(05): 118–121.

[14] Yang L, Wang Y, Song C, 2022, Observation on the Therapeutic Effect of Huang'e Capsule in Treating Chronic Prostatitis/Chronic Pelvic Pain Syndrome. Modern Chinese Doctor, 60(23): 88–90 + 98.

[15] Geng Q, Chen S, Li Z, et al., 2023, Clinical Observation of Huang'e Capsule in Treating Damp-Heat and Blood Stasis Type Chronic Prostatitis/Chronic Pelvic Pain Syndrome. Chinese Journal of Andrology, 37(06): 101–104 + 109.

[16] Chinese Expert Consensus, 2021, Chinese Expert Consensus on the Diagnosis and Treatment of Comorbid Premature Ejaculation and Erectile Dysfunction. Chinese Journal of Andrology, 27(05): 461–466.