

The Impact of Combined Traditional Chinese Medicine and Finasteride on the Morphology of the Posterior Urethra in Patients with Benign Prostatic Hyperplasia

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Abstract: Objective: This study aims to evaluate the effects of a six-month treatment combining traditional Chinese medicine derived from oilseed rape pollen with finasteride on the mean curvature of the prostatic urethra (UMCP), urethral length of the prostate (ULP), thickness of the prostate and bladder neck (TPBN), testosterone/estradiol ratio (T/E), and International Prostate Symptom Score (IPSS) in patients with benign prostatic hyperplasia (BPH). The goal is to determine whether the oilseed rape pollen preparation enhances the alleviation of urinary obstruction symptoms. Methods: Sixtytwo patients with urinary obstruction due to prostatic hyperplasia, who met the study's inclusion criteria and were treated at Tongxiang Municipal Hospital of Traditional Chinese Medicine, were selected. They were randomly divided into two groups: one receiving the oilseed rape pollen preparation in combination with finasteride and the other receiving finasteride alone. Relevant indicators were measured and recorded at baseline and six months after treatment. Data were analyzed using appropriate statistical methods. Results: The combined therapy with oilseed rape pollen did not significantly reduce the mean curvature of the prostatic urethra but effectively delayed its further increase. Patients in the experimental group showed a greater increase in urethral length compared to the control group. Additionally, the thickening of the prostate and bladder neck was significantly inhibited in the experimental group. Both groups exhibited a significant increase in T/ E, with no notable difference between them. IPSS scores improved significantly in both groups, with a more pronounced reduction in the experimental group. Conclusion: The combination of oilseed rape pollen-based traditional Chinese medicine and finasteride for BPH treatment can help improve posterior prostatic urethral morphology, regulate hormone levels, and enhance symptom relief. This combined approach provides notable benefits for patients with BPH.

Keywords: Benign prostatic hyperplasia; Urethral morphology; Oilseed rape pollen preparation

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1. Introduction

Benign prostatic hyperplasia (BPH) is a common and frequently occurring disease that affects the quality of life of elderly men and the final dignity of terminal patients in the context of the increasingly serious aging population in China ^[1]. BPH is a disease with extremely complex pathological mechanisms. The currently known pathological mechanisms include sex hormones, polypeptide growth factors, inflammatory signal transduction, apoptosis, oxidative stress, and smooth muscle, and their mechanisms in the pathogenesis have not been fully elucidated ^[2]. Literature indicates that sex hormones and their receptors, as well as oxidative stress, play important roles in the pathogenesis of BPH ^[3-5] and are currently important keys to clinical drug treatment. Among them, the representative Western medicine is 5α -reductase inhibitor, and the representative Chinese medicine is oilseed rape pollen preparation. Their common goal is to control the continued proliferation of the gland to improve the disease prognosis. Currently, the main treatment methods for improving urination symptoms in BPH patients are drug therapy and transurethral surgery. Some patients cannot undergo surgical treatment due to advanced age, bedridden status, or multiple underlying diseases and can only solve urination problems through bladder fistulization. This method changes the natural urination path, causes great pain, and affects patients' self-esteem. Therefore, it is crucial to select effective drug treatment to improve prognosis as early and quickly as possible.

2. Materials and methods

2.1. Clinical data

We selected 62 patients for follow-up observation from those with benign prostatic hyperplasia who visited Tongxiang Traditional Chinese Medicine Hospital from January 2022 to February 2023, based on the inclusion and exclusion criteria designed for the experiment.

Inclusion criteria: (a) $Q_{max} \le 15$ ml/s in both measurements when urine volume is ≥ 200 ml; (b) IPSS score ≥ 20 (severe); (c) Prostate-specific antigen (PSA) < 10 ng/ml, and those with PSA between 4–10 ng/ml have been diagnosed with BPH by prostate biopsy 10 weeks later; (d) Patients and their families explicitly refuse surgery and request medical treatment.

Exclusion criteria: (a) Patients with PSA between 4–10 ng/ml but cannot rule out prostate cancer; (b) Presence of other conditions that affect the detection of testosterone, estradiol, PSA, and other indicators; (c) Patients with contraindications for MRI examination; (d) Patients who develop acute urinary retention and urgently need other treatment methods; (e) Recurrence after prostate hyperplasia surgery; (f) Diseases caused by various reasons such as urethral stenosis, bladder, bladder neck, etc., that affect the interpretation of results; (g) Patients who have used other Chinese medicine preparations before enrollment; (h) Patients who are randomly included in the experimental group and indicate that they cannot adhere to Chinese medicine treatment for six months.

Withdrawal criteria: (a) Patients who experience adverse drug reactions, develop other serious diseases during medication, and need to withdraw from the experiment; (b) Patients who change the treatment plan, refuse to take, or miss multiple administrations of the treatment drug; (c) Patients who request to terminate the experiment or are lost to follow-up and automatically withdrawn.

2.2. Experimental methods

The control group received treatment with 5α -reductase inhibitor finasteride for BPH. The experimental group received combined therapy with a representative Chinese herbal medicine, oilseed rape pollen preparation, on the basis of the control group's treatment. Patients were randomly assigned to the two groups using a random number

table. This experimental design strictly followed the ethical review requirements of the ethics committee.

The control group received oral administration of 5α -reductase inhibitor finasteride at a dose of 5 mg once daily. The experimental group received additional oral administration of oilseed rape pollen preparation at a dose of 2 g three times daily on the basis of the control group's treatment. The treatment duration was six months for both groups.

2.3. Observation and follow-up indicators

This study innovatively observed three types of indicators: morphological changes in the prostatic urethra (including the mean curvature of the prostatic urethra [UMCP], urethral length of the prostate [ULP], thickness of the prostate and bladder neck [TPBN]), changes in testosterone/estradiol levels (T/E), and improvement in urinary symptoms assessed using the International Prostate Symptom Score (IPSS). These indicators reflected the effects of combined therapy on prostate stromal cell proliferation, androgen/estrogen balance, and symptom improvement, respectively.

Among these indicators, the thickness of the prostate at the bladder neck was measured as a line segment representing the anteroposterior diameter of the prostate at the bladder neck on MRI images in the sagittal plane of the urethral bladder entrance axis. The urethral length of the prostate was defined as the length from the bladder urethral opening to the tip of the prostate on MRI images in the sagittal plane of the urethral axis. The urethral mean curvature of the prostate was calculated as the ratio of the angle between the tangents at both ends of the prostatic urethra to the arc length of the urethra. Morphological indicators were observed for changes after six months of treatment.

2.4. Statistical methods

Data were processed and charted using GraphPad Prism9 statistical software. All measurement data passed the normality test. One-way ANOVA was used for statistical analysis, with a significance level of $\alpha = 0.05$. A *P*-value of ≤ 0.05 was considered statistically significant.

3. Results

3.1. Morphological changes in the prostatic urethra

There was no significant difference in the average UMCP between the experimental group and the control group at the beginning of the experiment. The curvature in the experimental group remained at the initial level after six months of treatment. The curvature in the control group increased at the end of the experiment compared to the beginning, and that of the experimental group at six months, with *P*-values of 0.0053 and 0.0033, respectively, indicating significant differences. There was no significant difference in the ULP between the experimental group and the control group at the beginning of the experiment. The experimental group showed a slight increase in ULP after six months of medication compared to the beginning (P = 0.0390), while the control group showed no significant difference. There was no significant difference in the TPBN between the experimental group and the control group at the beginning of the experiment. The TPBN in the experimental group remained stable after six months of medication. The control group showed a significant increase in this value (P = 0.0004), resulting in a significant difference from the experimental group after six months (P < 0.0001) (**Table 1**) (**Figures 1** to **3**).

3.2. Changes in androgen/estrogen levels

Testosterone/estradiol levels were consistent and showed no significant difference between the experimental group and the control group at the beginning of the experiment. Both groups showed significant increases in T/E levels before and after the experiment, with mean differences of -53.15 and -45.41, respectively, and *P*-values less than 0.0001. There was no significant difference in the results between the experimental group and the control group after six months of medication (**Table 1**) (**Figure 4**).

3.3. Improvement in urination symptoms indicated by the International Prostate Symptom Score (IPSS)

The experimental group and the control group maintained good consistency in IPSS at the beginning of the experiment. Both groups showed significant improvement in IPSS within the group at the end of the experiment (P < 0.0001), and the improvement in IPSS in the experimental group was significantly better than that in the control group (P = 0.0011) (**Table 1**) (**Figure 5**).

	UMCP		ULP		TPBN		T/E		IPSS	
	Mean diff.	Р	Mean diff.	Р	Mean diff.	Р	Mean diff.	Р	Mean diff.	Р
Experimental group before vs six months after treatment	0.1219	0.1756	-8.109	0.0390	4.593	0.0516	-53.15	< 0.0001	13.42	< 0.0001
Control group before vs six months after treatment	-0.1883	0.0053	4.137	0.9614	-7.161	0.0004	-45.41	< 0.0001	11.26	< 0.0001
Experimental group vs control group before treatment	0.1140	0.2475	-1.342	> 0.9999	0.2948	> 0.9999	-8.732	> 0.9999	-0.2258	> 0.9999
Experimental group vs control group six months after treatment	-0.1962	0.0033	10.90	0.0018	-11.46	< 0.0001	-0.9903	> 0.9999	-2.387	0.0011

Table 1. One-way ANOVA results of the efficacy of finasteride alone or combined with oilseed rape pollen in
the treatment of BPH

4. Discussion and conclusion

Based on the analysis of the results in this study, it is concluded that the combination therapy of finasteride and traditional Chinese medicine with oilseed rape pollen as the main ingredient can relieve obstructive urination symptoms faster than monotherapy in the treatment of BPH.

Combination therapy more effectively preserves the morphology of the prostatic urethra without significant changes. In the finasteride monotherapy group, the curvature of the prostatic urethra continued to increase, and the thickness of the prostate-bladder junction also showed progressive thickening. Although combination therapy did not demonstrate a significant advantage in terms of hormonal level changes, it provided a clear benefit in improving IPSS scores, which reflect symptom relief. According to the fundamental principles of fluid dynamics, when fluid passes through a channel with greater curvature, resistance is significantly higher compared to a channel with less curvature. In this study, the combination therapy group exhibited a delayed progression of prostatic urethral curvature compared to the monotherapy group, which may be a key morphological factor

前列腺部尿道平均曲率(UMCP)

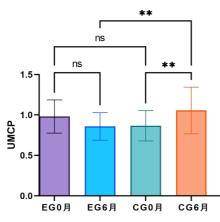


Figure 1. UMCP before and after six months of treatment in the experimental group (EG) and the control group (CG)

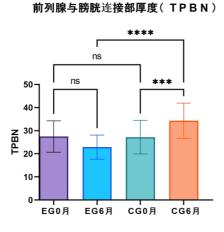
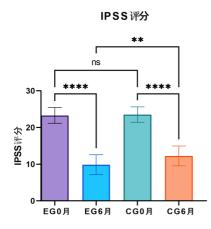


Figure 3. TPBN before and after six months of treatment in the experimental group (EG) and the control group (CG)



前列腺部尿道长度(ULP)

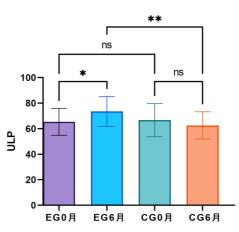


Figure 2. ULP before and after six months of treatment in the experimental group (EG) and the control group (CG)

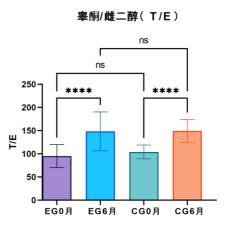


Figure 4. T/E before and after six months of treatment in the experimental group (EG) and the control group (CG)

Figure 5. IPSS before and after six months of treatment in the experimental group (EG) and the control group (CG)

contributing to the improvement or stabilization of urination difficulty symptoms. Additionally, regarding the thickness of the prostate-bladder junction, the combination therapy group demonstrated the ability to stabilize prostate morphology and prevent further progression, whereas the monotherapy group continued to show thickening at the bladder entrance.

This study selected prostate thickness at the bladder-prostate junction as an indicator of urine flow obstruction. During the trial, it was observed that some patients with severe urination difficulties exhibited significant enlargement of the anterior lobe of the prostate, even protruding above the internal urethral orifice, resembling a dam obstructing the urethral opening. Others displayed pronounced hyperplasia of the posterior lobe, which pushed the urethra forward from behind the internal urethral orifice or blocked the urethral opening in a similar manner. These morphological changes appeared to exacerbate urination difficulties. Since measuring only the thickness of the anterior or posterior lobe or the extent of protrusion into the bladder would not provide a comprehensive assessment, this study instead examined prostate thickness at the urethral orifice to reflect the overall progression of prostate hyperplasia. The experimental results aligned with observed changes in urethral curvature and IPSS scores, suggesting that this indicator holds potential for further investigation in subsequent observational studies.

Another morphological indicator selected in this experiment is the length of the prostatic urethra. According to the general principles of fluid dynamics, the longer a fluid travels, the greater the resistance it encounters, leading to increased velocity loss. However, experimental results indicate that combination therapy actually prolonged the prostatic urethral length, whereas the monotherapy group better preserved the original local urethral length. Upon further discussion, we found that morphological indicators such as total urethral length, minimum urethral width, and the length and number of stenotic segments have a greater impact on urine flow than the velocity loss associated with prostatic urethral length. The total urethral length may be unrelated to, or even inversely correlated with, changes in prostatic urethral length. Additionally, the urethra is a muscular tube, with the spongy segment being particularly variable. Its thickness and length are challenging to measure accurately, and the velocity loss caused by urethral length may be negligible compared to other obstructive factors. Rather than analyzing every individual fluid dynamics factor separately, it may be more practical to focus on significant and easily measurable physical parameters that can effectively explain real-world phenomena.

This experiment also recorded changes in the testosterone-to-estradiol (T/E) ratio. The data indicated that although both testosterone and estradiol levels decreased, estrogen declined at a faster rate, leading to an increase in the T/E ratio. No significant difference in efficacy was observed between the experimental and control groups in this regard. This indicator was selected because, while individual hormone baselines vary significantly, their ratios tend to remain relatively stable. Existing research has demonstrated that androgens are the primary drivers of prostatic acinar hyperplasia, with most estrogens being converted from testosterone or androstenedione. Finasteride acts as an enzyme inhibitor in the metabolic pathway that converts testosterone into the more potent dihydrotestosterone (DHT). By reducing DHT levels in both the bloodstream and the prostate, finasteride helps slow the progression of hyperplasia. It is well established that finasteride does not affect circulating estradiol levels. Short-term use of the drug can increase testosterone levels in the prostate without disrupting the pituitary-testicular axis.

The Chinese herbal medicine oilseed rape pollen extract contains long-chain fatty acids, flavonoids, alkaloids, and cerebrosides—compounds known for their effectiveness in combating BPH ^[6-8]. Among these, flavonoid extracts are the primary active substances responsible for the antioxidant properties of oilseed rape pollen, while

long-chain fatty acids exhibit significant activity in hormone regulation and anti-inflammatory effects ^[9,10]. Additionally, oilseed rape pollen polysaccharides exert antitumor effects by increasing the expression of IL-2 and TNF- α mRNA in the body ^[11]. Some discrepancies were observed between the hormonal changes recorded in this experiment and established theories. We speculate that clinical tests may not precisely measure circulating and tissue levels of DHT, testosterone (T), estradiol (E), follicle-stimulating hormone (FSH), luteinizing hormone (LH), and other hormonal fluctuations across various stages of the gonadal axis is necessary to accurately determine the positive or negative feedback effects of these drugs and to elucidate their pharmacological mechanisms convincingly.

Finally, both the experimental and control groups showed significant improvements in IPSS, with high patient satisfaction reported for both treatments. The combined medication group outperformed the control group, demonstrating that combination therapy can more effectively and rapidly alleviate urinary discomfort. This approach offers hope for continued conservative treatment in patients with severe obstruction who are ineligible for surgery. By alleviating the distress associated with bladder fistulization, it also enhances patients' quality of life.

Finally, after discussion, this experiment identified certain deficiencies in research indicators, providing a valuable foundation for more detailed studies on the relationship between posterior urethral morphology and urinary tract obstruction. The findings highlight the need for further research to exclude physical variables related to fluid mechanics, which are complex, highly variable, difficult to measure accurately, and influenced by multiple interfering factors in the human body. Additionally, the study should account for functional and molecular biological factors, such as bladder contractility, the gonadal hormone axis, and target organ hormone concentrations, as they may impact experimental results. Moreover, the small sample size limits the ability to fully capture the true pharmacological effects. Therefore, further research should incorporate regular observations on a smaller scale to refine and expand the research indicators.

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Disclosure statement

The authors declare no conflict of interest

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