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The clinical research of modified chailing paste treated small volume prostatic hyperplasia with chronic prostatitis patients after TURP about LUTS and bladder neck contracture

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Abstract

Objective To explore the clinical effect and safety of modified Chailing paste on improving postoperative lower urinary tract symptoms (LUTS) and bladder neck contracture in patients with small-volume prostatic hyperplasia (SBPH) complicated with chronic prostatitis after transurethral resection of the prostate (TURP). **Methods** A total of 145 patients with SBPH were enrolled in a randomized double-blind placebo-controlled study and randomly divided into three groups. Group A (49 patients) underwent simple TURP, Group B (48 patients) underwent TURP combined with postoperative Tamsulosin, and Group C (48 patients) underwent TURP combined with modified Chailing paste. Tissue specimens from all patients were sent for pathological examination. Data were analyzed using SPSS22.0 statistical software. **Results** The study followed up 141 patients. The detection rate of histological prostatitis (HP) was 92.91%. Significant improvements in residual urine volume (PVR), International Prostate Symptom Score (IPSS), quality of life (QOL) score, and maximum urine flow rate (Qmax) were observed in all groups before and 3 months after surgery ($P < 0.01$). Group C showed statistically significant improvement compared to Groups A and B ($P < 0.05$). The incidence of bladder neck contracture 12 months post-operation was significantly lower in Group C compared to Groups A and B ($P < 0.05$). **Conclusion** Modified Chailing paste significantly improves postoperative LUTS symptoms and quality of life and reduces the incidence of bladder neck contracture in patients with SBPH complicated with chronic prostatitis after TURP.

Keywords modified chailing paste; small volume prostatic hyperplasia; chronic prostatitis; LUTS; bladder neck contracture

Benign prostatic hyperplasia (BPH) is one of the main causes of lower urinary tract symptoms (LUTS) in elderly men. It mainly manifests as bladder irritation, bladder outlet obstruction symptoms, and related complications.

Patients with BPH who have a small prostate size but serious lower urinary tract symptoms are often encountered in the clinic. This type of BPH, which has obvious lower urinary tract symptoms but not an obvious increase in prostate size, is called small-volume prostatic hyperplasia (small-volume BPH)[1].

Currently, the results of treating small-volume prostatic hyperplasia with medication alone or surgery alone are not satisfactory. Most patients still have obvious LUTS and a high incidence of bladder neck contracture after surgery.

The efficacy of Traditional Chinese Medicine (TCM) in treating BPH and relieving the symptoms of LUTS is well established and has been reported in the literature. However, the efficacy of TCM treatment in preventing postoperative bladder neck contracture after TURP has not yet been reported, as there are differing views on the transportation and dispensing of medicines.

It has been reported that intraoperative injection of combined steroids into the bladder neck orifice during TURP can prevent bladder neck contracture, but the side effects are significant.

Chai Ling Ling Cream has a glucocorticoid-like effect, which not only exerts anti-inflammatory effects through multiple mechanisms but also improves the body's autoimmunity. It effectively prevents the excessive proliferation of fibroblasts and scar tissues in the traumatic area of the bladder neck after prostatectomy, reduces the LUTS symptoms after TURP, and also reduces the incidence of BNC.

In this study, we used a randomized controlled design to evaluate the clinical efficacy of adding Chai Ling Ling Cream to improve postoperative LUTS and bladder neck contracture in patients with small-volume prostatic hyperplasia combined with chronic prostatitis.

1 Methods

1.1 General Information

A total of 145 SBPH patients with a mean age of 63.9±4.6 years who attended Shouguang Hospital of Traditional Chinese Medicine from March 2016 to March 2022 were selected. All patients were randomly divided into three groups according to their treatment methods: Group A had 49 cases of simple TURP surgery, Group B had 48 cases of TURP surgery and postoperative treatment with tamsulosin, and Group C had 48 cases of TURP surgery and postoperative treatment with Traditional Chinese Medicine. Tissue specimens of all patients were sent for pathological examination after surgery. The differences in age, preoperative prostate volume (PV), PVR, prostate-specific antigen (PSA), IPSS, QOL, and Qmax among patients in Groups A, B, and C were not statistically significant ($P > 0.05$).

1.2 Diagnostic Criteria

1.2.1 Western Medicine Diagnostic Criteria

The diagnostic criteria for Western medicine refer to "Wu Jieping Urology"[2]:

Table 1 Comparison of age, preoperative PV, PVR, PSA, IPSS, QOL, and Qmax in each group（$\bar{X}$ ±S）

Group	n	Age	PV(cm^{3})	PVR(ml)	PSA(ug/L)	IPSS(分)	QOL(分)	Qmax(ml/s)
A	49	63.8±4.6$^{\Delta}$	24.1±3.2$^{\Delta}$	102.3±27.9Δ	4.97±1.79$^{\Delta}$	26.1±3.4$^{\Delta}$	4.9±0.7$^{\Delta}$	8.3±3.1$^{\Delta}$
B	48	64.1±4.1*	23.6±4.1*	98.9±33.2*	5.24±2.32*	25.3±4.2*	4.5±0.7*	8.6±3.7*
C	48	63.6±3.9$^{\&}$	23.3±3.9$^{\&}$	101.4±31.9$^{\&}$	5.79±2.52$^{\&}$	24.5±4.9$^{\&}$	4.7±0.5$^{\&}$	7.7±3.8$^{\&}$
t		0.79	0.58	1.32	0.91	0.89	0.56	0.85

$^{\Delta,*,\&}$P>0.05，Two-by-two comparisons between the three groups：$^{\Delta:*}$P>0.05; $^{\Delta:\&}$P>0.05; $^{*:\&}$P>0.05

1. Patients with lower urinary tract symptoms such as frequent urination, increased nocturia, and progressive difficulty urinating;
2. Digital rectal examination: Mild prostate hyperplasia with a slightly hard texture;
3. Ultrasound indicating benign prostatic hyperplasia with a volume less than 30 ml;
4. Perform urodynamic examination to determine bladder outlet obstruction, excluding neurogenic bladder, low urine flow rate, high urethral resistance, and no significant elongation of prostate length.

1.2.2 Traditional Chinese Medicine Diagnostic Criteria

According to the "Diagnostic and Therapeutic Efficacy Standards for Traditional Chinese Medicine Diseases"[3], the diagnostic and therapeutic efficacy standards for traditional Chinese medicine in the People's Republic of China ZY/T0011.1-94 are determined as follows:

Dialectical: Qi deficiency, blood stasis, damp heat.

Symptoms: Difficulty urinating due to low volume, dribbling down, or even poor flow, bloating in the lower abdomen, dry mouth and reluctance to drink, and constipation in bowel movements. The tongue is red or purple, the coating is white or yellow and greasy, and the veins are deep and thin.

1.2.3 Inclusion Criteria

The inclusion criteria are as follows:

1. Meet the diagnostic criteria of Chinese and Western medicine;
2. The course of the disease is more than three months;
3. Maximum urine flow rate <15 ml/s or average urine flow rate <10 ml/s;
4. Cease α-receptor blockers for at least 1 month or 5 months, α-reductase inhibitors, and traditional Chinese medicine for more than 3 months;
5. Age $\geq$ 50 and $\leq$ 80 years old;
6. The patient has informed consent and is willing to undergo the trial.

1.3 Therapeutic Method

1.3.1 Surgical Treatment

The surgical treatment was performed using lumbar anesthesia combined with epidural anesthesia. The Olympus prostate electrocautery was used with a cutting power of 200 W and a coagulation power of 180 W. The outer sheath of the electrocautery was F27, equipped with a 30° eyepiece and a circular electrocautery loop. The infusion solution used was physiological saline, with a flushing pressure of 40-60 cm H_2O (1 cm H_2O = 0.098 kPa). The surgery was divided into the following steps:

(1) Retrograde search for the surgical capsule. Short cut the tips of both leaves near the seminal vesicle and the mucosa of the middle lobe before the seminal vesicle. Press down on the tip of the outer sheath to press against the mucosal fissure in front of the seminal vesicle, and make a small continuous arc pushing along the fissure from the middle lobe to the lateral lobe from the front to the lower part. Imitate the action of using fingers to "pick" the prostate during open surgery, slightly peel off a small amount of hypertrophic gland, and then pry the gland inward and upward to find a dense and smooth surgical capsule with slightly strong reflection and occasional parallel passage of small blood vessels. If there is adhesion between the proliferative gland and the surgical capsule surface, the adhesive tissue can be incised or the normal surgical capsule surface can be found around this area. Then, the gland can be pried towards the adhesive area to sharply remove the adhesive tissue. Peel off before the 3-9 o'clock plane, generally speaking, this area is easier to find the surgical capsule. Clear plane, capable of 360° surface peeling; otherwise, stop in time.

(2) Remove the narrow ring at the neck opening. Perform a 360° excision of the cervical mucosal layer, with a deeper incision possible at points 3-9, but without the need for flattening or cutting.

(3) Remove the proliferative glandular tissue. Apply a surgical capsule at 5 and 7 o'clock to pry and peel off the proliferative glands until the separation surface crosses the narrow ring of the neck and penetrates into the bladder. Using this plane as a reference, quickly remove the hyperplasia and cervical tissue.

(4) Strengthen peripheral band resection. After the first three steps, the prostate fossa forms a trumpet-shaped structure, with most of the wound consisting of dense and white fibrous tissue. Using the seminal vesicle as a reference, continue deep electrocautery at 4-5 and 7-8 points on both sides of the prostatic fossa until milky white prostatic fluid overflows or loose reticular tissue appears. At this point, both sides of the seminal vesicle appear as shallow spoon-shaped depressions. Use an Ellik aspirator to extract tissue fragments, re-examine the wound and stop bleeding, check that the external sphincter is normal, observe that the prostate urethra is unobstructed, place an F20 three-chamber catheter for drainage, and inject 30 ml of water into the balloon. Perform continuous bladder irrigation with saline solution for 1-3 days after surgery, and remove the catheter 5-7 days after surgery.

1.3.2 Postoperative Medication Method

Group B received tamsulosin after surgery. Group C took modified Chailing paste after surgery. The formula of Jiawei Chailing paste consists of 20g radix bupleuri, 10g Scutellaria baicalensis, 6g Ginseng, 10g Pinellia ternata, 6g Licorice, 10g Ginger, 20g pinellia ternata, 20g Poria cocos, 20g Alisma orientalis, 12g Cinnamomum cassia, 15g Atractylodes macrocephala, 15g Angelica sinensis, 15g Red peony, and 15g Plantago seed. Starting from the second day after surgery,

take one dose daily, warm in the morning and evening after meals, for one month as a course of treatment. Stop taking the medication for one month in the middle and take another course of treatment.

1.4 Follow-up and Observation Indicators

Visit the hospital for examination and follow-up at 1, 3, 6, and 12 months after taking medication, and evaluate the therapeutic effect at 3, 6, and 12 months. The main observation is the improvement of LUTS symptoms (IPSS score, QOL score, maximum urine flow rate, residual urine volume) and the incidence of bladder neck contracture in patients with small-volume benign prostatic hyperplasia complicated with chronic prostatitis after TURP surgery.

1.5 Data Processing

All data were statistically processed using the SPSS 22.0 software package, and all values were expressed as $(\bar{x} \pm s)$. Chi-square test was used for count data, t-test was used for metric data, and $P < 0.05$ was considered statistically significant.

2 Results

2.1 Detection Rate of SBPH Combined with Histological Inflammation

Among the 141 SBPH patients in this group, 131 cases showed infiltration of inflammatory cells, mainly lymphocytes. Among them, there were 10 cases of grade 0 (7.09%), 16 cases of grade 1 (11.35%), 69 cases of grade 2 (48.94%), and 46 cases of grade 3 (32.62%). The detection rate of SBPH combined with HP in this study was 92.91%, with moderate to severe inflammation infiltration accounting for 81.56%.

2.2 Comparison of LUTS-related Indicators Before and 3 Months After Surgery

There were statistically significant differences in PVR, IPSS, QOL, and Qmax among each group before and 3 months after surgery ($P < 0.01$), and there were statistically significant differences between Group C, Group A, and Group B at 3 months after surgery ($P < 0.05$). There was no statistically significant difference between Group A and Group B ($P > 0.05$), as shown in Table 2.

Table 2 Comparison of PVR, IPSS, QOL, and Qmax before and 3 months after surgery in each group（$\overline{X}$ ±S）

Group	n	PVR(ml)		IPSS(s)		QOL(s)		Qmax(ml/s)	
		Preoperative	Postoperative	Preoperative	Postoperative	Preoperative	Postoperative	Preoperative	Postoperative
A	48	101.3±27.9	17.9±3.6$^{\Delta}$	25.6±4.2	11.9±2.3$^{\Delta}$	4.8±0.6	3.1±1.1$^{\Delta}$	8.1±3.6	17.1±2.9$^{\Delta}$
B	46	99.1±33.4	18.1±4.1*	23.8±5.3	12.7±2.6*	4.7±0.9	2.9±1.3*	8.5±2.9	16.7±3.7*
C	47	102.1±31.4	9.8±5.2$^{\&}$	24.1±4.9	6.51±3.6$^{\&}$	4.5±0.7	1.3±1.4$^{\&}$	7.7±4.2	21.9±2.3$^{\&}$

$^{\Delta,*,\&}$P<0.01 compared to preoperative; Pairwise comparison between groups at 3 months after surgery $^{\Delta:*}$P<0.05; $^{\Delta:\&}$P<0.01; $^{*:\&}$P<0.05

2.3 Comparison of Postoperative Complications and Incidence of Bladder Neck Contracture

All 141 surgeries were successful without severe complications such as major bleeding, urethral rectal injury, and TURS. Follow-up for 12 months after surgery. The number of cases of bladder neck contracture in Group A, Group B, and Group C was 6, 5, and 1, respectively. Urinary improvement was achieved after TURP. Two cases in Group A and Group B each experienced urethral stricture after surgery, and urinary patency was achieved after urethral dilation; Six cases in Group A and three cases in Group B experienced transient urinary incontinence, and urination was normal after anal lifting exercise; There were no complications in Group C. The incidence of bladder neck contracture at 12 months after surgery showed statistically significant differences ($P < 0.05$) between Group C, Group A, and Group B. However, there was no statistically significant difference ($P > 0.05$) between Group A and Group B, as shown in Table 3.

Table 3 Comparison of the incidence of postoperative bladder neck contracture among different groups

Group	n	Number of cases of postoperative bladder neck contracture			The incidence of bladder neck contracture（%）
		3 month	6 month	12 month	
A	48	2	3	1	12.50
B	46	2	2	1	10.87
C	47	1	0	0	2.13

3 Discussion

3.1 Impact of LUTS on Quality of Life

Lower Urinary Tract Symptoms (LUTS) caused by benign prostatic hyperplasia directly affect the quality of life of patients and can lead to damage to bladder and kidney function in the later stages. The degree of LUTS is not directly proportional to the volume of the prostate, and small-volume benign prostatic hyperplasia can also lead to severe LUTS and bladder outlet obstruction (BOO).

3.2 Treatment Challenges and Complications

There are various treatment methods for small-volume benign prostatic hyperplasia, but the efficacy is poor, and there are many postoperative complications. Bladder neck contracture (BNC), as a postoperative complication of BPH, is prone to occur in small-volume prostate. Compared to the poor blood supply of small-volume prostate, the relatively high power of electrocautery and electrocoagulation during surgery is related to severe thermal damage to the wound. The circular fibrous tissue of the bladder neck is prone to re-proliferation, leading to scar healing and bladder neck contracture[4-6]. Prostatitis is also a risk factor for bladder neck contracture after PKRP surgery.

3.3 Prostatitis as a Risk Factor

Kaynar et al.[7] conducted a retrospective analysis and found that histopathological examination results of 340 specimens of bladder neck contracture showed that 338 cases of BPH had varying degrees of inflammation and fibrosis, indicating that prostatitis and fibrosis can increase the incidence of bladder neck contracture after electrocautery. Research by Gu Hongbing et al.[8] suggests that prostate volume ($\leq$ 30 ml), combined with prostatitis, low age surgical patients, unit time resection weight ($\leq$ 0.5 g/min), and postoperative urinary balloon injection volume (>40 ml) are the main risk factors for bladder neck contracture after PKRP surgery.

3.4 Controversies in Treatment Approaches

At present, there is controversy over the treatment of recurrent BNC after failed endoscopic resection. Some scholars have attempted to use steroid drugs such as methylprednisolone and triamcinolone acetonide to inhibit bladder neck scar hyperplasia and have achieved good results[9-10]. KRAVCHICK et al.[9] reported the therapeutic effect of methylprednisolone injection, and performed endoscopic guided injection of 2-4 ml methylprednisolone (40 mg/ml) into the bladder neck in 14 patients with recurrent BNC. The overall success rate after surgery was 93%. Liu Sheng et al.[10] injected triamcinolone acetonide after scar tissue removal in 92 patients with BNC after prostatectomy, 95.7% of patients did not relapse during follow-up and no adverse reactions related to triamcinolone acetonide were found. Corticosteroids can alleviate the inflammatory process of wounds, inhibit the chemotaxis of inflammatory cells towards the wound site, and reduce the release of local pro-fibrotic cytokines, inhibit the proliferation of fibroblasts, reduce the synthesis of extracellular matrix such as collagen, and thus inhibit scar formation[11].

3.5 Limitations of Current Treatments

At present, the use of medication alone or surgery alone for the treatment of small-volume benign prostatic hyperplasia is not ideal, and postoperative LUTS is still relatively obvious in most patients, with a high incidence of bladder neck contracture. The efficacy of traditional Chinese medicine in relieving LUTS symptoms and other aspects of BPH treatment has been confirmed, and there are many literature reports. However, there are different opinions on the use of prescriptions and medication, and the efficacy varies. There have been no reports on traditional Chinese medicine treatment for preventing bladder neck contracture after TURP surgery.

3.6 Pathogenesis and Treatment Rationale

Based on the basic theories of traditional Chinese and Western medicine, combined with years of clinical experience, we believe that the pathogenesis of LUTS and bladder neck contracture in patients with small-volume benign prostatic hyperplasia complicated by chronic prostatitis after TURP surgery is not singular, often coexisting as a disease. Qi deficiency, blood stasis, dampness, and heat are common. The initial cause of small-volume benign prostatic hyperplasia is dampness and heat, which cannot be cured for a long time and may recur repeatedly. Overuse of cold and cool can make the kidneys and bladder unable to gasify, leading to liver depression, dampness stagnation, three jiao, poor qi circulation, phlegm and blood stasis, resulting in abnormal fluid and body fluids being unable to gasify normally, abnormal distribution, and many adverse symptoms

of urination. The basic pathogenesis is deficiency of kidney qi, weakness of the three jiao qi, loss of bladder qi, accumulation of dampness and heat, liver depression, and deficiency of qi and blood stasis. According to reports, the combination of steroid drugs injected into the bladder neck during TURP surgery can prevent bladder neck contracture, but with significant side effects.

3.7 Benefits of Chailing Paste

Chailing paste has a glucocorticoid-like effect, which not only exerts anti-inflammatory effects through multiple mechanisms but also enhances the body's own immunity, effectively preventing excessive proliferation of fibroblasts and scar tissue in the bladder neck wound after prostatectomy. It can not only alleviate LUTS symptoms after TURP surgery, but also reduce the incidence of BNC. This project involves first performing TURP surgery to relieve mechanical obstruction at the bladder outlet, reducing fiber tension in the bladder neck, and then taking modified Chailing paste after surgery to improve detrusor dysfunction and coordination of detrusor bladder neck function by unblocking the three jiao qi mechanism, strengthening bladder gasification, and promoting liver and blood circulation, clearing heat and dampness, as well as the glucocorticoid-like and anti-fibrotic effects of Chailing paste. Multiple mechanisms play an anti-inflammatory and anti-fibrotic role, improving congestion, edema, inflammatory cell infiltration, and excessive proliferation of fibroblasts and scar tissue in the bladder neck and prostate tissue. This improves LUTS symptoms in patients with small-volume prostate hyperplasia after TURP surgery and reduces the incidence of postoperative bladder neck contracture.

3.8 Clinical Findings

This study showed that the TURP combined with modified Chailing paste group had a significantly better clinical effect on improving postoperative LUTS in small-volume benign prostatic hyperplasia complicated with chronic prostatitis compared to the TURP group alone and the TURP+tamsulosin group, with no postoperative complications. In the comparison between the TURP+tamsulosin group and the TURP group alone, PVR, IPSS, and QOL were lower than those in the TURP group alone, and Qmax was higher than those in the TURP group alone, but the difference was not statistically significant. At the same time, the clinical effect of the TURP combined with modified Chailing paste group on reducing the incidence of bladder neck contracture after TURP surgery for small-volume benign prostatic hyperplasia combined with chronic prostatitis was significantly better than that of the TURP alone group and the TURP+tamsulosin group, and the difference was statistically significant.

3.9 Conclusion

In summary, Jiawei Chailing paste can significantly improve the postoperative LUTS symptoms of patients with small-volume benign prostatic hyperplasia combined with chronic prostatitis after TURP, significantly improve their quality of life, and reduce the incidence of postoperative bladder neck contracture. The effect is satisfactory. TURP combined with modified Chailing paste is an effective method for treating patients with small-volume benign prostatic hyperplasia combined with chronic prostatitis.

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