

Effect of Qianlietongyu Capsule Combined with Tamsulosin Hydrochloride in the Treatment of Prostatitis Complicated with Premature Ejaculation

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Yin *et al.*: Combined Effect of Qianlietongyu Capsule and Tamsulosin Hydrochloride

To discuss the clinical effect of Qianlietongyu capsule combined with tamsulosin hydrochloride in the treatment of prostatitis complicated with premature ejaculation and its impact on the sexual life of patients. We selected 70 patients with prostatitis complicated with premature ejaculation untreated in our hospital from July 2020 to July 2021 and divided them into control group (35 cases) and observation group (35 cases). Treated control group with compound lidocaine cream, after receiving the same treatment as control group, treated observation group with tamsulosin hydrochloride and Qianlietongyu capsule. After 1 mo treatment, observation group possessed lower National Institutes of Health chronic prostatitis symptom index score than control group, but it possessed higher intravaginal ejaculation latency time than control group ($p < 0.05$); after treatment, observation group possessed lower interleukin 8 and tumor necrosis factor alpha levels, higher maximum urinary flow rate and lower bladder residual urine volume than control group ($p < 0.05$). After treatment, the total clinical effective rate and sexual life satisfaction of observation group were 94.29 % (33/35) and 88.57 % (31/35) respectively, those in control group were 77.1 % (27/35) and 68.57 % (24/35) respectively, the differences possessed statistical significance ($p < 0.05$). In clinical treatment of patients with prostatitis complicated with premature ejaculation, tamsulosin hydrochloride combined with Qianlietongyu capsule can significantly improve the effect of patients' clinical symptoms and related biochemical indicators, improve the overall clinical treatment effect and promote patients to obtain more ideal sexual life satisfaction after treatment.

Key words: Prostatitis, premature ejaculation, tamsulosin hydrochloride, Qianlietongyu capsule

Chronic prostatitis is one type common disease in urology clinical diagnosis, which frequently occurs in young and middle-aged men and their incidence rate is about 15 %^[1]. The main clinical symptoms of chronic prostatitis are urinary urgency, frequent urination, dysuria etc., and most patients will be accompanied by certain functional disorders. Premature ejaculation is a typical symptom of functional impairment in chronic prostatitis patients^[2]. Patients with chronic prostatitis and premature ejaculation have a complex condition, easy to repeat and difficult to treat, which seriously affects their physical and mental health and quality of life. Tamsulosin hydrochloride is a selective α_1 receptor blocker that is widely used in clinical practice. It has obvious effects in improving urination symptoms and delaying ejaculation^[3]. Qianlietongyu

capsule has good effects such as reducing swelling and pain, promoting blood circulation and removing blood stasis and it has shown good results in treating benign prostatic hyperplasia and prostatitis in clinic^[4]. This study mainly discusses the clinical effect and value of Qianlietongyu capsule combined with tamsulosin hydrochloride in the treatment of patients with prostatitis and premature ejaculation. The report is as follows. Selected 70 patients with prostatitis^[5] complicated with premature ejaculation untreated in our hospital from July 2020 to July 2021, according to random number table method, we divided them into two groups. Control group has 35 cases, ages were from 27 to 48 y old, average were about (34.52±2.19) y old, course of disease were from 2 to 20 mo, average were about (5.35±1.36) mo; observation group has 35 cases,

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ages were from 25 to 49 y old, average were about (34.58±3.53) y old, course of disease were from 2 to 12 mo, average were about (5.38±1.56) mo. Compared the general information such as course of disease, age, the differences of both groups possessed no statistical significance ($p>0.05$). The hospital ethics committee approved this study. Inclusion criteria meet the chronic prostatitis diagnostic criteria of 'Chinese Guidelines in the Diagnosis of Urologic Diseases (2011 edition)' and was diagnosed with premature ejaculation, meet the damp-heat stasis type criteria of 'Guidance for Diagnosis and Treatment of Chronic Prostatitis by Integrative Medicine', main symptoms were urgent urination and frequent micturition; the lower abdomen, perineum or lumbosacral part has obvious swelling pain; incessant urine; dark purple tongue, or ecchymosis, petechiae, or yellow fur, astringent pulse, slippery pulse; the secondary symptom are damp scrotum, urethral burning, prostate tenderness or inflammatory nodules, if there are two main symptom and one secondary symptom, dialectical judgment can be established; normal erectile function and fixed sexual partner; no other drug treatment within the last 30 d and voluntary participation and signed informed consent under the premise of informed research methods and objectives^[6]. Exclusion criteria with viral myocarditis, congenital heart disease, disease of hematopoietic system, severe cardiovascular and cerebrovascular disease, prostate tumor and systemic immune disease; with benign prostatic hyperplasia, genitourinary malformation, urinary tract infection, severe pneumonia, nephritis and hepatitis B; decreased libido; cognitive impairment and mental illness. Applied compound lidocaine cream (Tongfang Pharmaceutical, National License Medical Number H20063466) locally for control group treatment. Applied the drug evenly to the glans penis, coronal sulcus, frenulum 15-20 min before intercourse, wiped off residual cream. After receiving the same treatment as control group, treat observation group with tamsulosin (Zhejiang hailisheng Pharmaceutical Co., Ltd, National License Medical Number H20020623) and Qianlietongyu capsule (Zhuhai Xingguang pharmaceutical, National License Medical Number Z19990060). Tamsulosin should be used as follows: The patient took orally 0.2 mg/time, once a day. Qianlietongyu capsule should be used as follows: The patient took orally 5 capsules/time, 3 times/d, after meals. Both groups continued to use the corresponding drugs for 1 mo to evaluate the effect. Meanwhile, all patients were instructed to avoid prolonged cycling, sedentary, etc. during treatment, maintain good living habits and laws of life and avoid excessive fatigue.

As for the diet, eat less spicy food, drink less alcohol, strong tea, strong coffee, cola, etc. Instruct the patient to appropriately increase the amount of water to drink as to increase the amount of urine and ensure that the urethra is effectively flushed. Meanwhile, it also strengthened psychological counseling for patients, help them relieve tension, anxiety and other emotions caused by illness and guide them to maintain a good attitude in the face of disease treatment. Adopted National Institutes of Health Chronic Prostatitis Symptom Index (NIH-CPSI) to evaluate severe symptoms of prostatitis before and after treatment, divided them into 3 levels, scores from 1 to 14 is classified as mild, scores from 15 to 29 as moderate, scores exceeded 30 as severe. Meanwhile, measured the patient's Intravaginal Ejaculation Latency Time (IVELT). IVELT refers to the measurement of the time from the insertion of the patient's penis into the vagina to the beginning of ejaculation. Carried out a total of 3 measurements and took the average value as the final value, classified them according to time, which is divided into three levels, 0-2 min, 2-5 min and >5 min. Anti-inflammatory effect evaluation was done by drawing 3 ml of patient's venous blood, applied centrifugation, took the upper serum, detected the related inflammatory factors by enzyme-linked immunosorbent assay before and after treatment. The detected indexes were Interleukin-8 (IL-8) and Tumor Necrosis Factor alpha (TNF- α). Urodynamic index evaluation was done by detecting Maximum Urinary Flow Rate (MFR) and Residual Volume of Urine (RVU) before and after treatment. Overall efficacy assessment^[7] after treatment, basic or complete of patient-related clinical symptoms disappeared, NIH-CPSI scores dropped >90 % compared before treatment, marked as markedly effective; patient-related clinical symptoms improved remarkably after treatment, NIH-CPSI scores dropped 50 % to 89 % compared before treatment, marked as effective; patient-related clinical symptoms had no significant improvement, NIH-CPSI scores dropped <40 % compared before treatment, marked as ineffective.

Total effective rate=(Effective+markedly effective)/total cases×100 %

The patient's ejaculation latency was remarkably longer than before treatment, significant improvement in prostatitis symptoms, both husband and wife were satisfied with their sexual life, marked as satisfied^[8]; the patient's ejaculation latency was obviously longer than before treatment, obvious improvement in prostatitis symptoms, one of the couple was satisfied with their sexual life, marked as basically satisfied; the patient's

ejaculation latency had no remarkable changes compared before treatment, no significant improvement in prostatitis symptoms or worse, both husband and wife were not satisfied with their sexual life.

Degree of satisfaction=(Basically satisfied+satisfied)/total cases×100 %

Adopted Statistical Package for the Social Sciences (SPSS) 25.0 to process and analyze data. Expressed the counting data by percent (%) and compared by Chi-square (χ^2) test, rank data by rank sum test. Expressed the measurement data by ($\bar{x}\pm s$), compared by t test, compared intra-group and inter-group by paired and independent sample t-tests, respectively. $p<0.05$, indicating that the divergence possessed statistical significance. Compared both groups on NIH-CPSI scores and IVELT before treatment, the divergence possessed no statistical significance ($p>0.05$). After 1 mo treatment with the corresponding drug, NIH-CPSI scores of both groups were lower than treatment before, IVELT was longer than treatment before, observation group possessed lower NIH-CPSI scores and longer IVELT than control group, the divergence possessed statistical significance ($p<0.05$) as shown in Table 1. Before treatment IL-8 and TNF- α determination results had no remarkable difference ($p>0.05$). After 1 mo of treatment, IL-8 and TNF- α levels of both groups were lower than treatment before, observation group possessed lower IL-8 and TNF- α levels than control group, the divergence possessed statistical significance ($p<0.05$) as shown in Table 2. After receiving the related treatment for 4 w, observation group possessed higher total clinical efficacy and sexual life satisfaction than control group, the divergence possessed statistical significance ($p<0.05$) as shown in Table 3. The etiology of prostatitis is complex, abnormal immunity, pathogen infection, pelvic floor muscle activity and inflammation etc., have close relationship with its occurrence. Prostatitis patients mainly have symptoms such as increased nocturia, urgency, frequent urination and dysuria. Chronic prostatitis patients are prone to repeated illness, difficult to cure and have a long course of disease, which has a serious impact on the patient's physical and mental health. Premature ejaculation is an ejaculation disorder caused by the disorder of ejaculation reflexes involved in reproductive organs, neuroendocrine and other systems, the incidence rate is between 35 % and 50 %^[9]. After the occurrence of prostatitis, if the patient fails to receive effective treatment in time, with the aggravation of the disease, anxiety, premature ejaculation, insomnia, sexual

dysfunction, etc. are often complicated, among which premature ejaculation is a common complication. Chronic prostatitis and premature ejaculation are the cause and effect of each other, the coexistence of the two will greatly increase the difficulty for disease treatment, seriously affect the patient's urodynamic status and quality of sexual life. Tamsulosin is currently a commonly used and effective drug for treating prostatitis patients. It is a selective $\alpha 1$ receptor blocker, it can selectively block $\alpha 1$ adrenergic receptors in the prostate during application, promotes effective relaxation of prostate smooth muscle, effectively relieve the spasm of the internal urethral sphincter and then relieve urethral hypertension and improve uroflow laminar flow, reduce urine reflux inside the prostate and promote the improvement of symptoms such as pain in urination and dysuria. Some studies have shown that the application of tamsulosin hydrochloride can significantly improve the stability of the detrusor muscle in some patients, thereby relieving the symptoms of urgency and frequency^[10]. Tamsulosin hydrochloride, as an adrenergic receptor blocker, has been widely used in treating benign prostatic hyperplasia in clinic, it can selectively block $\alpha 1$ adrenergic receptors in prostate, relax prostate smooth muscle, thereby improve prostate disease^[11]. But the condition of patients with prostatitis complicated with premature ejaculation is complicated. When only tamsulosin hydrochloride is used for treatment, there are obvious limitations in symptom improvement and clinical effect. Zhang *et al.*^[12] showed that tamsulosin hydrochloride capsules combined with other drug regimens were used to treat patients with chronic prostatitis, it can effectively enhance the efficacy of the drug, improve patients' symptoms and signs, and the overall curative effect is more ideal. In traditional Chinese medicine, prostatitis is included in the category of 'dysuria' and 'stranguria'. Traditional Chinese medicine believes that the pathogenesis of chronic prostatitis is mainly manifested as blood stasis, and damp heat causes bladder and orifice obstruction, thereby leads to disease^[13]. Therefore, from the perspective of traditional Chinese medicine, prostatitis treatment should follow the principle of removing blood stasis and dispersing knots, clearing away heat and removing dampness, in order to achieve the effect of promoting inflammation absorption and improving blood circulation. Currently, there are many traditional Chinese medicines and methods for treating premature ejaculation in clinic. The traditional Chinese medicine treatment of the disease mainly follows the principles of Zi yin Qian yang, invigorating the kidney and

stopping emission, promoting blood circulation and removing blood stasis, clearing the liver and regulating Qi, tranquilizing the mind and so on. Qianlietongyu capsule selected in this study belongs to traditional Chinese medicine preparation commonly used in clinic, its main pharmaceutical components are *Paeoniae radix rubra* the root of common peony, *Cyathula* root, *Ligusticum wallichii*, golden cypress, *Sparganii rhizoma*, *Angelica sinensis*, *Verbena*, licorice, *Bupleurum chinense* and so on. *Ligusticum wallichii* has the effect of dispelling wind and relieving pain, promoting blood circulation and Qi circulation etc.; *Paeoniae radix rubra* the root of common peony has the effect of dispersing blood stasis and relieving pain, clearing heat and cooling blood; *Cyathula* root has the effect of promoting diuresis and relieving stranguria; *Angelica sinensis* has the effect on enrichment of blood, promoting blood circulation; Golden cypress has the effect of heat-clearing and damp-drying; *Verbena* has the effect of cooling blood and relieving itching, clearing away heat and toxic material and so on; *Sparganii rhizoma* has the effect of breaking blood and promoting Qi, removing stagnation food and alleviating pain and so on; licorice has the effect of clearing heat, coordinating the drug actions of a prescription; *Bupleurum chinense* has the effect of soothing liver and relieving depression, raising yang and lifting prolapsed zang-fu organs and so on^[14]. All drug complications has the effect of removing blood stasis and dispersing knot, relieving pain, clearing heat and draining dampness and so on. Modern pharmacological research shows that *Paeoniae radix rubra* the root of common peony and *Ligusticum wallichii* have a good microcirculation improvement effect; *Bupleurum chinense*, *Verbena*, *Cyathula* root have good effect of relieving pain,

antibiosis, antiinflammatory etc., *Angelica sinensis* has the effect of inhibiting platelet aggregation, free radical scavenger etc., it also promote body immunity significantly enhanced^[15]. We adopted Qianlietongyu capsule combined with tamsulosin hydrochloride in treating 35 cases prostatitis complicated with premature ejaculation, this group possessed lower NIH-CPSI scores, IL-8 and TNF- α levels than control group, but in urodynamic parameters, it possessed higher MFR and greater RVU than control group, the divergence possessed statistical significance. It can be seen that the combined drug regimen used for observation group treatment can effectively make up for the limitations of single drug, play a synergistic effect and improve drug efficacy, thereby it can significantly improve the clinical symptoms and inflammatory response control effect of patients, promote the effective improvement of the overall treatment. In our study, after receiving the related treatment for 1 mo, observation groups possessed higher total clinical efficacy and sexual life satisfaction than control group. It can be seen that combination of the above two drugs for treating patients with prostatitis and premature ejaculation, can obtain more ideal clinical efficacy, help to improve the quality of sexual life of patients and enhance the total clinical efficacy. In conclusion, combined application of tamsulosin hydrochloride and Qianlietongyu capsule for the treatment of patients with prostatitis and premature ejaculation, it can promote better improvement of patients' clinical symptoms and related biochemical indicators, effectively improve the effectiveness of clinical treatment and improve patient satisfaction with sexual life.

TABLE 1: COMPARISON OF NIH-CPSI SCORES AND IVELT BETWEEN BOTH GROUPS ($\bar{x}\pm s$)

Group	n	NIH-CPSI score (point)				IVELT (min)			
		Before treatment	After treatment	t	p	Before treatment	After treatment	t	p
Control group	35	28.64 \pm 3.11	16.78 \pm 3.54	19.223	<0.001	0.87 \pm 0.14	2.10 \pm 1.03	4.410	<0.001
Observation group	35	28.60 \pm 2.85	11.94 \pm 2.64	23.301	<0.001	0.85 \pm 0.16	3.88 \pm 1.24	14.574	<0.001
t	-	0.056	6.484			0.557	6.533		
p	-	0.955	<0.001			0.580	<0.001		

TABLE 2: COMPARISON OF IL-8 AND TNF- α LEVELS BETWEEN BOTH GROUPS ($\bar{x}\pm s$)

Group	Period	IL-8 (pg/ml)	TNF- α (pg/ml)	MFR (ml/s)	RVU (ml)
Control group	Before Treatment	325.51 \pm 45.87	126.87 \pm 52.26	11.30 \pm 2.04	20.36 \pm 3.21
	After treatment	272.46 \pm 42.19	99.24 \pm 18.55	15.62 \pm 3.20	11.15 \pm 2.01
	t	7.535	6.912	9.644	20.561
	p	<0.001	<0.001	<0.001	<0.001
Observation group	Before Treatment	330.19 \pm 48.64	128.19 \pm 53.64	11.36 \pm 3.21	20.40 \pm 4.25
	After treatment	231.61 \pm 43.45	76.62 \pm 16.50	19.59 \pm 3.95	7.12 \pm 1.34
	t	14.497	13.134	15.074	24.323
	p	<0.001	<0.001	<0.001	<0.001
	t ₁	0.414	0.104	0.093	0.044
	p ₁	0.680	0.917		0.965
	t ₂	3.990	5.390	4.620	9.869
	p ₂	<0.001	<0.001	<0.001	<0.001

Note: t₁, p₁: Comparison between groups before treatment and t₂, p₂: comparison between groups after treatment

TABLE 3: COMPARISON OF TOTAL CLINICAL EFFICACY AND SEXUAL LIFE SATISFACTION BETWEEN BOTH GROUPS [cases (%)]

Group	n	Overall response			Sexual life satisfaction				
		Markedly effective	Effective	Ineffective	Total efficacy	Satisfied	Basically satisfied	Dissatisfied	Degree of satisfaction
Control group	35	12 (34.29)	15 (42.86)	8 (22.86)	77.14 %	11 (31.43)	13 (37.14)	11 (31.43)	68.57 %
Observation group	35	22 (62.86)	11 (31.43)	2 (5.71)	94.29 %	16 (45.71)	15 (42.86)	4 (11.43)	88.57 %
χ^2	-				4.200				4.158
p	-				0.040				0.041

Conflict of interests:

The authors declared no conflicts of interest.

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