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*Original Article*

# The effect of Qianliekang tablets on the clinical efficacy, immune function, and inflammatory factor levels in the prostatic fluid of elderly chronic prostatitis patients

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**Abstract:** Purpose: To study the effect of Qianliekang tablets on the clinical efficacy, immune function, and inflammatory factor levels in the prostatic fluid of elderly chronic prostatitis (CP) patients. Methods: 106 elderly CP patients admitted to our hospital between June 2018 and June 2020 were recruited as the study cohort and randomly divided into a regular group and an observation group. The regular group was administered tamsulosin hydrochloride, and the observation group was administered a combination of tamsulosin hydrochloride and Qianliekang tablets. After a course of treatment, the clinical efficacy, the changes in the patients' symptoms, the function scores, the prostate ultrasound indicators, the changes in the T lymphocyte subsets, and the inflammatory factor expression levels in the prostatic fluid before and after the treatment were measured and compared in the two groups. The occurrence of adverse effects during the treatment was statistically analyzed. Results: The overall effectiveness rate in the observation group was superior to the overall effectiveness rate in the regular group (94.34% vs. 75.47%, $P < 0.05$). There were no significant differences in the patient clinical data before the treatment in the two groups ($P > 0.05$). After the treatment, the $CD_4^+/CD_8^+$ immune function indicators, the prostatic fluid inflammatory factor levels, the symptom function scores, and the prostate ultrasound indicators in the observation group were better than they were in the regular group (all $P < 0.05$). No significant differences were found in the incidence of adverse effects between the two groups ($P > 0.05$). Conclusion: Qianliekang tablets can improve the curative effect in elderly CP patients, enhance their immune function, and reduce the inflammatory factor expression levels in their prostatic fluid.

**Keywords:** Chronic prostatitis, elderly men, immune function, prostatic fluid, inflammatory factors

## Introduction

Chronic prostatitis (CP) is a series of inflammatory reactive lesions induced primarily by infections of the prostate and the peripheral tissues. It may trigger prostatic hyperplasia, especially among the elderly [1-3]. With the improvement in medical technology and the awareness of healthcare in China, the average life expectancy among the Chinese people continues to increase, and the proportion of the elderly in the population is increasing daily. The number of patients with CP has also increased and is of great concern because of its high incidence and its negative impact on the quality of life of elderly patients. Evidence suggests that increased inflammatory secretions are among the most important factors for CP patients. The abnormally elevated inflammatory factor levels in the prostatic fluid are associated with long-term local chronic inflammatory infiltration, leading to disease progression and recurrent persistence [4-6]. Elderly CP patients experience a natural decline in their autoimmune function, type 2 diabetes mellitus, decreased vascular endothelial function, and other pro-inflammatory factors, which further increases the expressions of the inflammatory factors in the prostatic fluid, making it easy for prostate hyperplasia to form over time. Conservative treatment with drugs is mainly used for the treatment of elderly CP patients in clinical practice. However, up to now, it has often been difficult to achieve the desired effect with a single

drug. The discovery of a combination regimen is greatly needed. But no uniform standard for a combination regimen has been adopted. Tamsulosin hydrochloride capsules, a regular medication used in CP therapy, can alleviate dysuria to some extent, but the recurrence rate remains high. Qianliekang tablets are a herbal preparation that reduces the edema of the urethral mucosa and the surrounding tissues in elderly CP patients with few adverse effects. It is suitable for combination therapy [7, 8]. The specific objective of this study was to evaluate the therapeutic effect of Qianliekang tablets on CP and their influence on the immune function and the expression levels of the inflammatory factors in elderly CP patients' prostatic fluid, thus providing scientific information for future clinical practice.

## Materials and methods

### *General data*

A total of 106 elderly CP patients admitted to our hospital between June 2018 and June 2020 were recruited as the study cohort. Diagnostic criteria: A diagnosis of CP was made according to the relevant criteria for chronic prostatitis established by the National Institutes of Health (NIH) [9], and the clinical symptoms were assessed according to the International Prostate Symptom Scale (IPSS) scores [10]. Specific criteria: ① dysuria, weakness, and an interruption of the urinary flow. ② Frequent urination, urinary retention, or urinary incontinence. ③ Medical imaging examinations such as B-ultrasound suggesting prostatic changes. ④ An IPSS score ≥ 12 points, a bladder residual urine (RU) ≥ 6 ml, and a maximum urinary flow rate (Qmax) < 15 ml/s at presentation. Inclusion criteria: ① Patients over 65 years old. ② Patients who met the diagnostic criteria for CP through a pathological diagnosis. ③ Patients whose course of disease was ≥ 3 months. ④ The patients and their families were well-informed, and they signed the relevant documents. Exclusion criteria: ① Patients with other prostatic lesions, urinary calculi, congenital physiological or anatomical abnormalities of the prostate. ② Patients with immune dysfunction or an immune disease. ③ Patients with other infectious diseases, inflammation, severe liver, kidney, or other organ lesions. ④ Patients in the acute phase of cardio-cerebral adverse events. ⑤ Patients who were within 14 days of experiencing surgery or trauma. ⑥ Patients with psychiatric diseases or cognitive dysfunction and who failed to cooperate with the treatment. ⑦ Patients used immune agents or hormones within the three months prior to their enrollment in the study. ⑧ Patients allergic to the study medication. The patients were randomly divided into the regular group (n = 53) or the observation group (n = 53) . The patients in the regular group ranged in age from 65 to 79 years old and were an average of (69.86±3.91) years old, had a disease duration of 8 to 42 months and an average disease duration of (26.79±8.26) months. The patients in the observation group ranged in age from 65 to 80 years old had an average age of (70.04±4.13) years old, had a disease duration 9 to 44 months, and an average disease duration of (27.12±8.57) months. The study was approved by our hospital's ethics committee. There were no significant differences in the patients' general clinical data between the two groups (P > 0.05).

### *Methods*

Both groups were administered an analgesic and antispasmodic treatment and nightly hot water baths, and they were required to abstain from smoking and drinking alcohol and to maintain a daily water intake of 800 ml. The patients in the regular group were treated with tamsulosin hydrochloride capsules (NMPA approval no. H20000681) administered orally at a dose of 0.2 mg qd before bedtime for every 3-month cycle. The patients in the observation group were treated with the combination of tamsulosin hydrochloride capsules and Qianliekang tablets (NMPA approval no. Z33020303) administered orally at a dose of 4 tablets (0.57 g × 4) tid in the morning, noon, and night for every 3-month cycle.

### *Observation indicators*

(1) Clinical efficacy. After the course of treatment, the clinical efficacy of the two groups was evaluated. The clinical effect was assessed with reference to the NIH-Chronic Prostatitis Symptom Index (NIH-CPSI) [12]. The treatment was viewed as apparently effective if the CP-related symptoms completely disappeared or were significantly improved, the NIH-CPSI score was 0 points or it decreased by > 25% compared with its pre-treatment level, the

**Table 1.** Comparison of the clinical effect [n (%)]

| Group | n | Apparent effect | Effective | Null effect | Overall effect |
|---|---|---|---|---|---|
| Regular group | 53 | 9 (16.98) | 31 (58.49) | 13 (24.53) | 40 (75.47) |
| Observation group | 53 | 17 (32.08) | 33 (62.26) | 3 (5.66) | 50 (94.34) |
| $Z/x^2$ | | | -2.751 | | 7.361 |
| *P* | | | 0.006 | | 0.007 |

white blood cell count in the prostatic fluid decreased by > 25% or met the normal standard. The treatment was regarded as effective if the CP-related symptoms improved, the NIH-CPSI score decreased by 25% compared with its pre-treatment level, the white blood cell count in the prostatic fluid decreased by 25% but did not meet the normal standard. The treatment was considered as having a null effect if it did not meet the above criteria or it was aggravated compared with its pre-treatment level. The total effect was the sum of the apparently effective and effective cases. (2) The IPSS scores, the urinary symptom bother (BS) scores, and the International Index of Erectile Function (IIEF-5) scores. There was a total of 7 sub-items in the IPSS, and the possible scores ranged from 0-35 points, with a higher score indicating more severe CP. The BS score ranged from 0-35 points, where a higher score indicates a patient more severely afflicted with CP symptoms. There are 5 sub-items on the IIEF-5, and the scores range from 0-25 points, with a higher score indicating more normal erectile function [11]. (3) Prostate ultrasound parameters: The ultrasound parameters, including the prostate volume (PV), RU, and Qmax were measured using transabdominal ultrasound before and after the treatment. (4) The changes in the T lymphocyte subset ($CD_3^+$, $CD_4^+$, $CD_4^+/CD_8^+$) levels and the inflammatory factor (Interleukin (IL) -2, IL-6, IL-8, TNF-α) levels in the prostate fluid. Before and after the treatment, 3 ml of cubital vein blood samples were collected from all the patients after they fasted, and their serum was obtained after centrifugation at 3000 r/min for 10 min with a centrifuge. The proportions of the immune cells were analyzed using monoclonal antibodies and flow cytometry to calculate the ratios. The prostatic fluid was obtained from all the patients using prostate massage before and after the treatment to ensure aseptic conditions. The inflammatory factor expression levels were measured using enzyme-linked immunosorbent assays (ELISA). (5) Adverse reactions. The occurrence of any adverse effects during the treatment was statistically analyzed.

*Statistical analysis*

The statistical analysis was performed using SPSS 21.0 software. The grade data were analyzed using rank-sum tests, and the enumeration data were analyzed using chi-square tests. These data were represented as n (%). The enumeration data were analyzed using t-tests and expressed as ($\bar{x}\pm s$). $P < 0.05$ indicated a statistically significant difference.

## Results

*Clinical effect*

The observation group had a higher overall effective rate (94.34%) than the regular group (75.47%) ($P < 0.05$), and the clinical effect in the observation group was superior to the clinical effect in the regular group ($P < 0.05$). This is shown in **Table 1**.

*Comparison of the immune function*

No statistical differences were observed in the $CD_3^+$ or the $CD_4^+$ levels before and after the treatment between the two groups ($P > 0.05$). No statistical differences were observed in the $CD_4^+/CD_8^+$ levels before the treatment between the two groups ($P > 0.05$). The $CD_4^+/CD_8^+$ levels after the treatment in the observation group were higher than they were in the regular group ($P < 0.05$). This is shown in **Table 2**.

*Comparison of the prostatic fluid inflammatory factor levels*

No statistical differences were noted in the inflammatory factor levels before the treatment in the two groups ($P > 0.05$). The post-treatment IL-2, IL-6, IL-8, and TNF-α levels in the observation group were lower than they were in the regular group ($P < 0.05$). This is shown in **Table 3**.

*Comparison of the symptoms and the function scores*

No significant differences were found in the IPSS, BS, or IIEF-5 scores before the treatment

**Table 2.** Comparison of the immune function indicators before and after the treatment between the two groups ($\bar{x}$±s)

| Group | n | Time | $CD_3^+$ (%) | $CD_4^+$ (%) | $CD_4^+/CD_8^+$ (valu e) |
|---|---|---|---|---|---|
| Regular group | 53 | Pre-treatment | 60.46±9.73 | 33.12±8.41 | 1.12±0.37 |
| | | Post-treatment | 61.64±5.97 | 36.62±8.82 | 1.29±0.35 |
| Observation group | 53 | Pre-treatment | 60.29±9.81 | 32.69±8.25 | 1.10±0.36 |
| | | Post-treatment | 62.29±5.69 | 39.24±9.07 | 1.55±0.33 |
| Pre-treatment | | *t* | 0.092 | 0.263 | 0.399 |
| | | *p* | 0.927 | 0.793 | 0.691 |
| Post-treatment | | *t* | 0.579 | 1.506 | 3.863 |
| | | *p* | 0.564 | 0.135 | < 0.001 |

**Table 3.** Comparison of the inflammatory factor levels in the prostatic fluid before and after the treatment in the two groups ($\bar{x}$±s, pg/ml)

| Group | n | Time | IL-2 | IL-6 | IL-8 | TNF-α |
|---|---|---|---|---|---|---|
| Regular group | 53 | Pre-treatment | 117.74±33.29 | 63.74±14.88 | 1037.33±211.49 | 213.62±17.88 |
| | | Post-treatment | 97.34±34.22 | 55.64±12.16 | 737.34±140.52 | 130.95±9.96 |
| Observation group | 53 | Pre-treatment | 118.46±32.01 | 63.83±14.19 | 1039.67±227.68 | 214.47±19.87 |
| | | Post-treatment | 83.22±27.55 | 47.38±11.94 | 526.28±129.48 | 90.37±7.68 |
| Pre-treatment | | *t* | 0.114 | 0.031 | 0.055 | 0.229 |
| | | *p* | 0.910 | 0.976 | 0.956 | 0.819 |
| Post-treatment | | *t* | 2.341 | 3.529 | 8.042 | 23.488 |
| | | *p* | 0.021 | < 0.001 | < 0.001 | < 0.001 |

between the two groups (P > 0.05). After treatment, the IPSS and BS scores in the observation group were lower than they were in the regular group (P < 0.05), but the IIEF-5 score in the observation group was higher than it was in the regular group (P > 0.05). This is shown in **Table 4**.

*Comparison of the prostate ultrasound indicators*

No significant differences were found in the prostate ultrasound indicators before the treatment between the two groups (P > 0.05). After the treatment, the PV and RU in the observation group were lower than they were in the regular group (P < 0.05), but the Qmax rates were higher than they were in the regular group (P < 0.05). This is shown in **Table 5**.

*Comparison of the adverse effects*

In the observation group, there was 1 patient with a mild headache, 2 with digestive system discomfort, and 1 with skin flushing during the treatment, for an adverse effects rate of 7.55% (4/53). In the regular group, there was 1 patient with a mild headache, 3 with digestive system discomfort, 2 with skin flushing, for an adverse effects rate of 11.32% (6/53). There was no significant difference in the incidences of adverse effects between the two groups ($\chi^2$ = 0.442, P = 0.506 > 0.05).

## Discussion

Along with the decline of the overall health of the elderly, the reduction of many of the body's functions, and the combination of other underlying diseases, it predisposes the elderly to develop CP, complications or CP secondary to prostatic hyperplasia, urinary tract infections, and other related diseases [13, 14]. CP has a high incidence among elderly patients, is difficult to heal, and easily relapses. In CP patients, inflammation occurs in the prostatic orifice and easily induces adhesions,, resulting in obstructions. Thus, it causes an accumulation of prostatic fluid in the glandular duct, leading to abnormally elevated inflammatory factors levels in the prostatic fluid, forming edema, or even hyperplasia when long-term infiltration occurs [15-17]. As a chronic inflammatory

**Table 4.** Comparisons of the symptoms and function scores before and after the treatment between the two groups ($\bar{x}\pm s$, points)

| Group | n | Time | IPSS | BS | IIEF-5 |
|---|---|---|---|---|---|
| Regular group | 53 | Pre-treatment | 22.33±3.64 | 3.79±0.83 | 11.41±2.30 |
| | | Post-treatment | 17.75±2.23 | 2.23±0.45 | 14.05±2.12 |
| Observation group | 53 | Pre-treatment | 22.66±3.18 | 3.81±0.76 | 11.25±2.36 |
| | | Post-treatment | 14.22±2.41 | 1.71±0.40 | 17.64±3.67 |
| Pre-treatment | | *T* | 0.493 | 0.172 | 0.349 |
| | | *P* | 0.623 | 0.864 | 0.728 |
| Post-treatment | | *T* | 7.825 | 6.332 | 6.167 |
| | | *P* | < 0.001 | < 0.001 | < 0.001 |

**Table 5.** Comparison of the prostate ultrasound indicators before and after the treatment between the two groups ($\bar{x}\pm s$)

| Group | n | Time | PV ($mm^3$) | RU (ml) | Qmax (ml/s) |
|---|---|---|---|---|---|
| Regular group | 53 | Pre-treatment | 36.42±3.67 | 37.92±4.42 | 9.89±1.05 |
| | | Post-treatment | 34.67±3.37 | 28.36±2.93 | 13.92±1.43 |
| Observation group | 53 | Pre-treatment | 37.19±3.85 | 38.20±5.81 | 9.82±0.86 |
| | | Post-treatment | 31.61±3.25 | 22.63±2.45 | 17.31±1.69 |
| Pre-treatment | | *T* | 1.054 | 0.280 | 0.395 |
| | | *P* | 0.294 | 0.780 | 0.693 |
| Post-treatment | | *T* | 4.754 | 10.945 | 11.160 |
| | | *P* | < 0.001 | < 0.001 | < 0.001 |

lesion, the treatment and progression of CP are closely related to the patients' immune function. Immune function mainly refers to the body's ability to defend itself against disease, including immune surveillance, immune defense, and immune homeostasis. If the patient's immune function performs well, it will facilitate recovery and reduce the recurrence rate. The $CD_4^+/CD_8^+$ ratio is an important indicator of human immune function and has a normal reference value of 1.4-2.0. A value lower than 1.4 indicates diminished immunity, and a value higher than 2.0 suggests the possibility of immune overload. IL-2 is a pro-inflammatory factor synthesized by activated T lymphocytes, and its expression level correlates with the immune response. In addition, it plays a vital role in mediating cellular immunity in the formation and development of CP. IL-6, a clinical indicator of inflammatory factors involving the regulation of pro-inflammatory, can promote inflammatory responses versus exacerbating the degree of inflammation. IL-8, along with IL-2 and IL-6, belongs to the interleukin family. It has a pro-inflammatory effect, exerting a major pro-inflammatory biological function locally in infections. TNF-α, an inflammatory cytokine that can induce a stimulated inflammatory response by stimulating prostaglandin E synthesis in large amounts, is associated with febrile symptoms in the inflammatory response.

The conventional treatment of CP using Western medicine has focused on relieving the CP-related symptoms. However, Western medicine is not effective at antagonizing the inflammatory response or enhancing immune function, so the disease is prone to recur after the drugs are discontinued. Previous research has established that Qianliekang tablets, a herbal preparation, can effectively reduce the edema of the urethral mucosa and surrounding tissues in CP patients [18]. It is now well established from a variety of studies that Qianliekang tablets can inhibit the androgen levels, enhance bladder contractions, and relax the urethral muscles. It plays the crucial role of shrinking the PV by improving the local edema, thus effectively relieving the symptoms of incomplete urination, improving the weaknesses in urination and urinary cut-off, reducing bladder RU, alleviating the inflammatory response, and

having the effect of enhancing patients' immune function [19]. In general, therefore, it has a positive effect on preventing recurrence.

This study has shown that the clinical effect in the observation group was superior to the clinical effect in the regular group, suggesting that Qianliekang can improve the clinical effect among elderly CP patients. The $CD_4^+/CD_8^+$ levels after the treatment in the observation group were higher than they were in the regular group, indicating that Qianliekang tablets may enhance the immune function of elderly CP patients. The inflammatory factors in the prostatic fluid in the observation group were lower than they were in the regular group after the treatment, indicating that Qianliekang tablets may improve the anti-inflammatory effect of the clinical therapy and antagonize the synthesis of various inflammatory factors. Thus it can reduce the local inflammatory infiltration of the prostate, which is important for relieving edema and weakening or blocking disease progression [20, 21]. Qianliekang tablets have the major advantage of reducing the PV and RU and increasing the Qmax rate as mentioned above. It was clear from the comparison that the symptoms and function scores in the observation group were better than symptoms and function scores in the regular group after the treatment, suggesting that Qianliekang tablets may improve the functions of elderly CP patients, restoring the normal physiological structure of the prostate, relieving their symptoms, and finally upgrading the clinical effect by enhancing the immune function of the elderly CP patients and further antagonizing the expression of the inflammatory factors in the prostatic fluid. The results of this study showed no significant difference in the occurrence of adverse effects between the two groups, suggesting that the combination of Qianliekang tablets and regular therapy in elderly CP patients is safe and feasible . However, the following limitations were identified in this study. It is a monocentric study with a small number of participants and a short follow-up. A multicenter, double-blind study with a large sample is needed to confirm this conclusion further.

To sum up, Qianliekang tablets are thought to improve the curative effect among elderly CP patients, enhance their immune function, and lower the inflammatory factor expression levels in their prostatic fluid.

## Disclosure of conflict of interest

None.

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