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Analysis of the positive influence of Qianlie Shutong capsule combined with tamsulosin on prostate health of patients with prostatitis

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Abstract: Chronic prostatitis (CP) is one of the most common health issues in the male urinary system. In this study, we included 110 patients with CP as research subjects and divided them into a research group receiving Qianlie Shutong Capsule (QLSTC) combined with tamsulosin and a control group receiving tamsulosin monotherapy. Comparing their clinical efficacy, we found that the total effective rate of treatment in the research group was higher than that in the control group ($P<0.05$) and the clinical symptoms of CP were more significantly improved. Meanwhile, comparing the prostate function between the two groups, it was also seen that the small particle of lecithin (SBC) in the prostate fluid of the research group increased significantly after treatment ($P<0.05$). In addition, comparing the nutritional status of the two groups, we also found that the research group had better nutritional status after treatment. As for safety, there was no significant difference between the two groups ($P>0.05$). It can be seen that QLSTC combined with tamsulosin has extremely high clinical application value in the treatment of CP and is recommended to be used clinically.

Keywords: Nutritional status; prostate; prostatitis; Qianlie Shutong capsule; Tamsulosin

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INTRODUCTION

Prostatitis, a prevalent and complex disease in the male urinary system, afflicts over 50% of men at least once in their lifetime, with chronic prostatitis (CP) being the most common (Yebes *et al.*, 2023). Statistics show that the current global prevalence of CP is about 1.8-8.2% (Holt *et al.*, 2016). In recent years, the incidence of CP has shown an increasing trend from year to year (Moryousef *et al.*, 2022). The pathogenesis of CP is not fully understood and various factors such as trauma and immunity are believed to be the main triggers inducing CP in clinical practice (Brehm *et al.*, 2023). Currently, CP can usually be cured with aggressive drug therapy (e.g., tamsulosin hydrochloride, doxazosin mesylate, ciprofloxacin hydrochloride, etc.) without obvious sequelae (Liu *et al.*, 2020). However, there are various clinical treatment options, each with its own advantages and disadvantages, with no unified standardized medication guide (Maeda *et al.*, 2023). Because of this, researchers have devoted themselves to finding the optimal CP treatment scheme.

Tamsulosin hydrochloride is currently the basic drug for CP treatment. As an α-receptor blocker, Tamsulosin can relax the prostate and bladder smooth muscle and relieve lower urinary tract symptoms. However, the improvement effect of a single medication is limited (Zhao *et al.*, 2019). Recently, combined Chinese and Western medicine treatment programs have become more common in clinical practice. Among them, QLSTC is a very common Chinese patent medicine for prostate diseases, which is made of a variety of natural compounds (Zhang *et al.*, 2021). Meanwhile, natural compounds such as Glabrous greenbrier rhizome and radix bupleuri contained in QLSTC have been shown to help regulate the basic nutritional status of the human body, improve immune and metabolic functions (Zhao *et al.*, 2018) and lay a more reliable foundation for the therapeutic effect of CP.

In recent years, there have been many clinical reports in China mentioning that QLSTC combined with Tamsulosin has excellent results in the treatment of CP, but QLSTC is still not a commonly used drug in the international arena. In this study, we analyzed the therapeutic efficacy of QLSTC combined tamsulosin in CP, with the aim of promoting the use of QLSTC in clinical settings.

MATERIALS AND METHODS

Sample size calculation

This study was conducted at The Second Affiliated Hospital of Bengbu Medical College, Bengbu, Anhui. Sample size formula: $N=Z^2\times[P\times(1-P)]/E^2$ (Dong *et al.*, 2023). In the calculation, we set Z (statistic) to 1.96 (with a confidence level of 95%), E (error) to 10% and P (probability) to 0.5.After the calculation, N=96, which is the minimum sample size needed for this study.

Research population

One hundred and ten outpatient CP patients who visited our hospital from May 2020 to April 2023 were selected and using the random number table method they were divided into a research group (n=55) and a control group (n=55) that were treated with QLSTC + Tamsulosin and Tamsulosin monotherapy, respectively. This study was conducted in strict accordance with the Declaration of

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Helsinki and approved by The Second Affiliated Hospital of Bengbu Medical College's ethics committee (Approval No. 2023-279). All the study subjects signed an informed consent form.

Eligibility and exclusion criteria

Inclusion criteria: All the patients met the clinical diagnostic criteria for prostatitis (Pena *et al.*, 2021) and were diagnosed as CP after examination in our hospital, with intact medical records, no recent use of other drugs for prostatitis and no coagulation dysfunction or immune system diseases. Exclusion criteria: Those complicated with other urinary diseases, cardio-cerebrovascular diseases such as hypertension and heart disease, epilepsy, mental disorders, or history of drug allergies, patients with malignant tumors who were in the chemotherapy stage, as well as those who withdrew from the study, were excluded.

METHODS

Control group: Tamsulosin Hydrochloride Capsules (Jiangsu Hengrui Pharmaceuticals Co., Ltd., H20050392, 0.2 mg/capsule) were given orally before bedtime, 1 capsule/time, once a day. In addition, give oral levofloxacin tablets (pharmaceutical co., LTD., Beijing tayloe China H20000655, 0.1 g/tablets), 2 tablets/time, 2 times/d. Research group: In addition to the above treatment, patients in the research group were given QLSTC (Baoding Tianhao Pharmaceutical Co., Ltd., Z20027140, 0.4 g/capsule) orally after meals, 3 capsules/time, 3 times/d. The treatment lasted for 4 weeks in both groups.

Clinical efficacy evaluation

Clinical efficacy was judged as follows by referring to the National Institutes of Health Chronic Prostatitis Symptom Index (NIH-CPSI) (Kildegaard *et al.*, 2019): cure (disappeared symptoms and the NIH-CPSI ≤14), markedly effective (improved symptoms with an NIH-CPSI score range of 15-20), effective (reduced symptoms with an NIH-CPSI score of 20-29) and ineffective (no improvement in symptoms with an NIH-CPSI score of 30-43). Total effective rate = (cured +markedly effective +effective) cases / total number of people ×100%; excellent and good rate = (cured +markedly effective) cases / total case number ×100%.

Endpoints

(1) Clinical efficacy. (2) The frequencies of nocturia, urgent urination and urination in patients after treatment were counted. (3) Prostatic fluid was collected before and after treatment for routine examination of white blood cell count (WBC) and small particle of lecithin (SBC) count. Prostate fluid was applied directly to the slide and WBC and SBC were counted microscopically. The percentage of SBC is 25%, 50%, 75% is marked as "+", "++", "+++" respectively. The number of WBC was 0-10, 10-20, > 20 were labeled as "+", "++" and "++++" respectively. (4) Patients' malnutrition risk levels were assessed before and after treatment using the Patient-Generated Subjective Global Assessment (PG-SGA) (De Groot *et al.*, 2020), the survey included changes in body weight, daily diet, clinical symptoms and ability to perform daily activities, with a total score of 9, with 0-1 being no risk of malnutrition, 2-3 being mildly malnourished, 4-8 being moderately malnourished and 9 being severely malnourished. (5) Adverse reactions during treatment, such as allergies and gastrointestinal symptoms, were recorded and the total incidence was calculated.

Ethical approval

This study was approved by the Ethics Committee of The Second Affiliated Hospital of Bengbu Medical College (approval number: 2023-279) and was performed in accordance with the principles of the Declaration of Helsinki. All eligible participants signed an informed consent form.

STATISTICAL ANALYSIS

Statistical analysis was conducted using SPSS 24.0 software (IBM, Armonk, New York, USA). The comparison of count data [n (%)] was performed using the chi square test and that of measurement data ($\bar{\chi}$±s) was conducted using the independent sample t-test and paired t-test. Differences were considered statistically significant when $P<0.05$.

RESULTS

Comparison of clinical data

There was no difference in age, disease duration, body mass index (BMI) and family history between the two groups ($P>0.05$, table 1), confirming that the two groups of patients are comparable.

Higher clinical efficacy is determined in the research group compared with the control group

The inter-group comparison revealed higher total effective rate and excellent and good rate in the research group ($P<0.05$, table 2).

The micturition is better in the research group than in the control group

According to statistics, the frequencies of nocturia, urgent urination and urination in the research group were (1.09±0.29) times/d (fig 1A), (2.78±1.08) times/d (fig 1B) and (6.95±2.57) times/d (fig 1C), respectively, all of which were reduced compared to the control group ($P<0.05$).

The research group shows better prostate function than the control group

No statistical inter-group difference was found in the detection results of prostate function indexes before treatment ($P>0.05$). After treatment, there were more WBC0~+ and SBC++~+++ in the research group than in the control group ($P<0.05$, table 3).

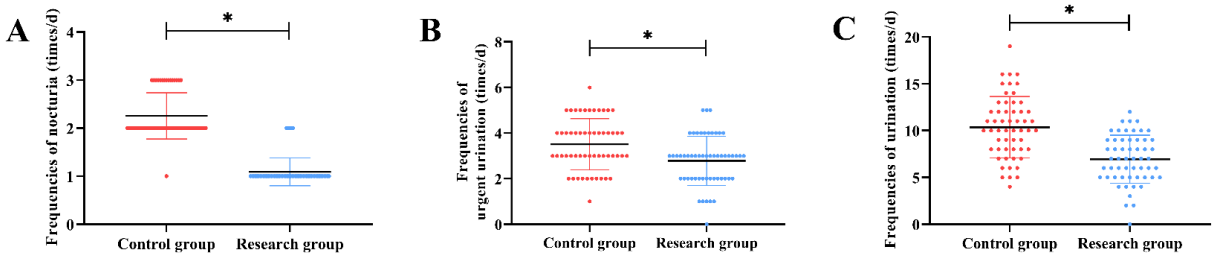

Fig. 1: Comparison of urination. A) Frequencies of nocturia, B) Frequencies of urgent urination, C) Frequencies of urination. *P<0.05.

Table 1: Comparison of general information

Groups	Age <45	Age≥45	Duration of disease (months)	BMI (kg/m^2)	Family history of disease	No family history of disease	Chronic smoker	Non-smoking
Control (n=55)	22 (40.00%)	33 (60.00%)	6.31±2.05	22.27±1.96	10 (18.18%)	45 (81.82%)	30 (54.55%)	25 (45.45%)
Research (n=55)	27 (49.09%)	28 (50.91%)	6.73±1.46	22.45±1.77	14 (25.45%)	41 (74.55%)	26 (47.57%)	29 (52.73%)
t or (χ^2)	0.920		1.231	0.512	0.853		0.582	
P	0.338		0.221	0.610	0.356		0.446	

Table 2: Comparison of clinical efficacy

Groups	Cured	Markedly effective	Effective	Ineffective	Excellent and good rate	Total effective rate
Control (n=55)	12 (21.82%)	13 (23.64%)	17 (30.91%)	13 (23.64%)	45.45%	76.36%
Research (n=55)	16 (29.09%)	20 (36.36%)	14 (25.45%)	5 (9.09%)	65.45%	90.91%
χ^2					4.453	4.251
P					0.035	0.039

Table 3: Comparison of prostate function

Timing	Inspection program	Control (n=55)	Research (n=55)	χ^2	P
Before treatment	WBC0~+	2 (3.64%)	4 (7.27%)	0.705	0.840
	WBC+~++	34 (61.82%)	30 (54.55%)	0.598	0.439
	WBC++~+++	19 (34.55%)	21 (38.18%)	0.157	0.692
	SBC0~+	22 (40.00%)	25 (45.45%)	0.334	0.563
	SBC+~++	26 (47.27%)	23 (41.82%)	0.331	0.565
	SBC++~+++	7 (12.73%)	7 (12.73%)	1.000	1.000
After treatment	WBC0~+	26 (47.27%)*	38 (69.09%)*	5.380	0.020
	WBC+~++	20 (36.36%)*	11 (20.00%)*	3.638	0.057
	WBC++~+++	9 (16.36%)*	6 (10.91%)*	0.695	0.405
	SBC0~+	16 (29.09%)	8 (14.55%)*	3.411	0.065
	SBC+~++	16 (29.09%)*	9 (16.36%)*	2.536	0.111
	SBC++~+++	23 (41.82%)*	38 (69.09%)*	8.280	0.004

Note: * indicates P<0.05 compared to before treatment.

Table 4: Comparison of risk levels for malnutrition

Timing	Degree of risk	Control (n=55)	Research (n=55)	χ^2	P
Before treatment	None	4 (7.27%)	5 (9.09%)	0.121	0.728
	Mild	19 (34.55%)	21 (38.18%)	0.157	0.692
	Moderate	25 (45.45%)	24 (43.64%)	0.037	0.848
	Severely	7 (12.73%)	5 (9.09%)	0.374	0.541
After treatment	None	9 (16.36%)	11 (20.00%)	0.244	0.621
	Mild	28 (50.91%)	39 (70.91%)*	4.620	0.032
	Moderate	17 (30.91%)	5 (9.09%)*	8.182	0.004
	Severely	1 (1.82%)*	0 (0.00%)*	1.009	0.315

Table 5: Comparison of adverse reactions

Groups	Skin allergies	Abdominal pain and diarrhea	Dizziness and headache	Nausea and vomiting	Total incidence
Control (n=55)	2 (3.64%)	3 (5.45%)	1 (1.82%)	2 (3.64%)	14.55%
Research (n=55)	1 (1.82%)	2 (3.64%)	2 (3.64%)	2 (3.64%)	12.73%
χ^2					0.077
P					0.781

The research group shows better nutritional status than the control group

The PG-SGA survey showed no significant difference in nutritional status between the two groups (P>0.05).

After treatment, more people in the research group were mildly malnourished and fewer were moderately malnourished (P<0.05, table 4).

There is no difference in adverse reactions between the two groups

According to statistics, there was no difference in the incidence of adverse reactions between the study group and the control group (P>0.05, table 5).

DISCUSSION

First of all, we found that the research group had higher total effective rate and excellent and good rate than the control group, suggesting that QLSTC + Tamsulosin is more effective in improving the condition of CP with higher clinical application value. CP belongs to the category of "turbid semen" and "stranguria", which is mostly correlated with the downward flow of damp-heat, liver-qi stagnation, as well as ejaculation and ejaculatory duct obstruction. Dampness-heat accumulation in the lower energizer further disturbs the essence chamber, resulting in obstruction of qi and blood circulation after transforming chronic diseases to collaterals and finally obstructing the operation of qi and blood and causing the disease (Zhang *et al.*, 2023). In this regard, the therapeutic principles should be based on clearing away heat, removing blood stasis, reducing swelling and resolving hard mass (Xue *et al.*, 2019). QLSTC is prepared from Chinese herbal medicines such as Cortex Phellodendri Chinensis, Radix Angelicae Sinensis, Radix Paeoniae Rubra, Radix Bupleuri, Glabrous greenbrier rhizome, Rhizoma Chuanxiong, Rhizoma Sparganii, Alisma orientalis, *Verbena officinalis L.,* Herba Portulacae, *Saxifraga stolonifera*, Radix Cyathulae and Glycyrrhiza. Among them, Cortex Phellodendri Chinensis and Radix Angelicae Sinensis have the effects of replenishing blood, promoting blood circulation and reinforcing kidney to replenish essence; radix bupleuri, glabrous greenbrier rhizome and Saxifraga stolonifera can detoxify, dehumidify and disperse stagnated liver qi to relieve depression; and the combination of Radix paeoniae rubra, *Verbena officinalis L.* and Herba Portulacae, effective medicines for removing blood stasis and resolving hard mass, inducing diuresis and reducing swelling, as well as the harmonization and compatibility of the drugs with the addition of licorice, enables the formula to play the role of blood-activating and heat-clearing, removing blood stasis and dispersing phlegm (Zheng *et al.*, 2021). Similarly, in the investigation of urination and prostate function, the frequencies of nocturia, urgent urination and urination were notably lower in the research group compared with the control group after treatment and the WBC and SBC were reduced, which can support our view and confirm the excellent application effect of QLSTC combined with Tamsulosin for CP. We believe that Tamsulosin can play a therapeutic role by ameliorating micturition symptoms, whereas QLSTC has the effect of promoting blood circulation. The two drugs have different mechanisms and therapeutic targets and their combined application can give full play to their synergistic effect, thus improving the prostate function of patients more effectively. Similarly, Zhang *et al*. found that the use of QLSTC can improve clinical outcomes in CP patients (Zhang *et al*., 2021), similar to our conclusions. This is also related to the anti-inflammatory effect of Herba Portulacae, Glabrous greenbrier rhizome and other pharmaceutical components in QLSTC (Li *et al.*, 2021), as well as the alleviated inflammation in patients by the combined treatment with Tamsulosin hydrochloride.

Moreover, the nutritional status of the body is one of the key points not to be ignored in CP. For example, protein is one of the important raw materials for the prostate to form semen (Cai *et al.*, 2021). Selenium, with excellent anti-bacterial ability, is concentrated in the prostate in men (Applegate *et al.*, 2021). These results fully demonstrate that the stability of one's nutritional status may not only be one of the potential triggers for CP, but also the basis for further improving therapeutic efficacy. In our survey, mild to moderate malnutrition was predominant in both groups before treatment, suggesting a potential link between nutritional status and the onset of CP. After treatment, more patients with mild malnutrition were found in the research group, which shows that QLSTC combined with Tamsulosin also helps improve the nutritional status of CP patients and lays a more reliable foundation for their rehabilitation. We believe that this is mainly attributed to the positive effects of various natural compounds in QLSTC on human trace elements. For example, radix bupleuri helps to regulate human intestinal microecology (Liu *et al.*, 2022) and Rhizoma Chuanxiong can improve human calcium ion metabolism (Wang H *al.*, 2010).

Finally, the safety of patients in both groups consistently confirmed the high clinical drug safety and great application value of QLSTC combined with Tamsulosin. As a natural Chinese medicine prescription, the drug safety of QLSTC has been repeatedly demonstrated (Franco *et al.*, 2019; Yany *et al.*, 2017), so the result is also in line with our expectations.

However, this study also shows some shortcomings, such as a small sample size, a short research duration and large individual differences among patients. Therefore, in the later research, the above shortcomings should be addressed to ensure the accuracy of the research results. Meanwhile, other comparative indexes, such as patient prognosis and disease recurrence, can be analyzed.

CONCLUSION

QLSTC combined with Tamsulosin has an obvious effect and high safety in the treatment of CP, which can effectively improve patients' prostate health and enhance their nutritional status.

Conflict of interest

The authors report no conflict of interest.

REFERENCES

Applegate CC, Lowerison MR, Hambley E, Song P, Wallig MA and Erdman JW Jr (2021). Dietary tomato inhibits angiogenesis in TRAMP prostate cancer but is not protective with a Western-style diet in this pilot study. *Sci. Rep.*, **11**(1): 18548.

Brehm TJ, Trautner BW and Kulkarni PA (2023). Acute and chronic infectious prostatitis in older adults. *Infect. Dis. Clin. North Am.*, **37**(1): 175-194.

Cai T, Gallelli L, Cione E, Perletti G, Ciarleglio F, Malossini G, De Pretis G, Palmieri A, Mirone V, Bartoletti R and Johansen TEB (2021). The use of *Lactobacillus casei* DG(R) prevents symptomatic episodes and reduces the antibiotic use in patients affected by chronic bacterial prostatitis: Results from a phase IV study. *World J. Urol.*, **39**(9): 3433-3440.

De Groot LM, Lee G, Ackerie A and van der Meij BS (2020). Malnutrition screening and assessment in the cancer care ambulatory setting: Mortality predictability and validity of the patient-generated subjective global assessment short form (PG-SGA SF) and the GLIM criteria. *Nutrients.*, **12**(8).

Dong Z, Li M, Zhang Y, Liu H and Cui Y (2023). Combined detection of vitamin D, CRP and TNF-alpha has high predictive value for osteoporosis in elderly men. *Am. J. Transl. Res.*, **15**(8): 5536-5542.

Franco JV, Turk T, Jung JH, Xiao YT, Iakhno S, Tirapegui FI, Garrote V and Vietto V (2019). Pharmacological interventions for treating chronic prostatitis/chronic pelvic pain syndrome. *Cochrane Database Syst. Rev.*, **10**(10): CD012552.

Holt JD, Garrett WA, McCurry TK and Teichman JM (2016). Common questions about chronic prostatitis. *Am. Fam. Physician.*, **93**(4): 290-296.

Kildegaard D, Graugaard-Jensen C andersen K and Thorlund JB (2019). Danish version of the National Institutes of Health-Chronic Prostatitis Symptom Index (NIH-CPSI) questionnaire: A linguistic translation, cross-cultural adaptation and test-re-test reliability study. *Scand. J. Urol.*, **53**(1): 62-68.

Li C, Xu L, Lin X, Li Q, Ye P, Wu L, Wang M, Li L, Li L, Zhang Y, Li H and Qin G (2021). Effectiveness and safety of acupuncture combined with traditional Chinese medicine in the treatment of chronic prostatitis: A systematic review and meta-analysis. *Medicine (Baltimore)*, **100**(49): e28163.

Liu L, Lu Y, Xu C, Chen H, Wang X, Wang Y, Cai B, Li B, Verstrepen L, Ghyselinck J, Marzorati M and Yao Q (2022). The modulation of chaihu shugan formula on microbiota composition in the simulator of the human intestinal microbial ecosystem technology platform and its influence on gut barrier and intestinal immunity in Caco-2/THP1-Blue Cell Co-Culture Model. *Front Pharmacol.*, **13**: 820543.

Liu Y, Mikrani R, Xie D, Wazir J, Shrestha S, Ullah R, Baig M, Ahmed A, Srivastava PK, Thapa KB and Zhou X (2020). Chronic prostatitis/chronic pelvic pain syndrome and prostate cancer: Study of immune cells and cytokines. *Fundam Clin. Pharmacol.*, **34**(2): 160-172.

Maeda K, Shigemura K and Fujisawa M (2023). A review of current treatments for chronic prostatitis/chronic pelvic pain syndrome under the UPOINTS system. *Int. J. Urol.*, **30**(5): 431-436.

Moryousef J, Blankstein U, Curtis Nickel J, Krakowsky Y, Gilron I and Jarvi K (2022). Overview of seminal fluid biomarkers for the evaluation of chronic prostatitis: A scoping review. *Prostate Cancer Prostatic Dis.*, **25**(4): 627-640.

Pena VN, Engel N, Gabrielson AT, Rabinowitz MJ and Herati AS (2021). Diagnostic and management strategies for patients with chronic prostatitis and chronic pelvic pain syndrome. *Drugs Aging.*, **38**(10): 845-886.

Wang H, Tang Y, Guo J, Ding A, Li W, Jiang W and Duan J (2010). Antidysmenorrheic effects of Radix angelica and Rhizoma Chuanxiong with different proportions and preparation methods on dysmenorrhea model mice. *Zhongguo Zhong Yao Za Zhi*., **35**(7):892-895.

Xue Y, Duan Y, Gong X, Zheng W and Li Y (2019). Traditional Chinese medicine on treating chronic prostatitis/chronic pelvic pain syndrome: A systematic review and meta-analysis. *Medicine (Baltimore).*, **98**(26): e16136.

Yany XZ, Guo Y, Xiong W, Li J, Chang DG, Zhang PH, Wang Y, Wang X and Dai XH (2017). Traditional Chinese medicine fumigation combined with Levofloxacin for type – A prostatitis with the symptoms of damp heat and blood stasis. *Zhonghua Nan Ke Xue.*, **23**(2): 173-177.

Yebes A, Toribio-Vazquez C, Martinez-Perez S, Quesada-Olarte JM, Rodriguez-Serrano A, Alvarez-Maestro M and Martinez-Pineiro L (2023). Prostatitis: A review. *Curr. Urol. Rep.*, **24**(5): 241-251.

Zhang K, Zhang Y, Hong S, Cao Y and Liu C (2023). Comparative analysis of efficacy of different combination therapies of alpha-receptor blockers and traditional Chinese medicine external therapy in the treatment of chronic prostatitis/chronic pelvic pain syndrome: Bayesian network meta-analysis. *PLoS One.*, **18**(4): e0280821.

Zhang Y, Ma H, Nan T, Li Y, Zheng W, Zhou Z and Gong X (2021). Comparative efficacy of oral chinese patent medicine for chronic prostatitis/chronic pelvic pain syndrome with sexual dysfunction: A bayesian network meta-analysis of randomized controlled trials. *Front Pharmacol.*, **12**: 649470.

Zhao F, Zhang CH, Yan JF, Li YF, Yang YJ and Sun D (2018). Effects of qianlie tongqiao capsule on bladder weight and growth factors in bladder tissue of rats with testosterone-induced benign prostatic hyperplasia. *Evid. Based Complement Alternat. Med.*, **2018**: 5059267.

Zhao L, Tian R, Liang C, Zhang L, Song W, Zhao J, Wang Z, Ji Z, Xia S and Li Z (2019). Beneficial effect of tamsulosin combined with dapoxetine in management of type III prostatitis with premature ejaculation. *Andrologia.*, **51**(8): e13319.

Zheng X, Yan Z, Wang W, Mao W, Wang Y, Zhao Y and Zhong Z (2021). Efficacy of acupuncture combined with traditional Chinese medicine on chronic prostatitis: A protocol for systematic review and meta-analysis. *Medicine (Baltimore).*, **100**(46): e27678.