



Effect of Tamsulosin on Lower Urinary Tract Symptoms in Elderly Patients with Benign Prostatic Hyperplasia

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ABSTRACT

The objective of this study was to investigate the effect of tamsulosin combined with ginger moxibustion on lower urinary tract symptoms in elderly patients with prostatic hyperplasia. It provides basis and new way for the research and treatment of BPH. A total of 80 elderly patients with BPH and lower urinary tract symptoms admitted from March 2021 to July 2022 in our hospital were selected for the study. The patients were separated into ginger moxibustion group (G) with 40 patients and combined group (J) with 40 patients. Among them, the patients in Group G were only treated with ginger, while oral tamsulosin sustained release capsule combined with ginger was used in Group J. The course of treatment of both groups is 1 month, and the treatment is in progress. The changes of IPSS, QOL, residual urine volume, bladder volume, TCM symptom score and SF-36 score of patients in Group G and Group J were compared. Compared with Group G, the total IPSS score, SSS score, QOL score, bladder residual urine volume and TCM symptom score of Group J were lower ($P < 0.05$) after treatment. The MFR, SF-36 score and the treatment efficiency in Group J were higher ($P < 0.05$). Compared with simple ginger moxibustion, tamsulosin combined with ginger moxibustion can effectively improve the lower urinary tract symptoms of elderly patients with benign prostatic hyperplasia.

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Authors' Contribution

MW and CW conducted the experiments in this study. They also contributed to the design and interpretation of the current study and wrote the article. Both authors read, revised, and approved the final manuscript.

Key words

Tamsulosin, Prostatic hyperplasia, Lower urinary tract symptoms, Braised with ginger

INTRODUCTION

In the elderly male population, benign prostatic hyperplasia (BPH) is a relatively common urological disease (Lerner *et al.*, 2021). Due to China's special national conditions, the aging of the population is more serious, and the incidence of BPH has also increased significantly (De Nunzio *et al.*, 2020; Haghpanah *et al.*, 2022). Some studies show that the incidence of BPH is large in China (Launer *et al.*, 2021). BPH can lead to bladder outlet obstruction, lower urinary tract structure and lower urinary tract function changes, resulting in dysuria (Knight *et al.*, 2021; Launer *et al.*, 2021). It is accompanied by a series of lower urinary tract symptoms (LUTS), such as urgent urination, endless urination, frequent urination, etc., which affects the physical, mental and life of patients (Abt *et al.*, 2021; Carnevale *et al.*, 2020).

Therefore, many scholars have studied and analyzed BPH.

Insausti *et al.* (2020) randomly divided the patients with BPH into two groups and treated them with prostate artery embolization and transurethral prostatectomy, respectively. Thus, the effects of prostate artery embolization and transurethral prostatectomy in the treatment of BPH were compared, which has reference and reference significance for the clinical treatment of BPH. Pisco *et al.* (2020) studied the effect of prostate artery embolization in the treatment of BPH. The long-term follow-up of patients with BPH who participated in the trial was also conducted to verify the persistence of the improvement of symptoms of patients with BPH after prostate artery embolization. Lerner *et al.* (2021) carried out preliminary examination and medical management of LUTS caused by BPH according to the standard treatment methods in the AUA guidelines. The intervention effect of this method on BPH with LUTS was verified in the experiment (Lerner *et al.*, 2021). Knight *et al.* (2021) used systematic retrospective analysis and meta-analysis to compare the application effects of two surgical methods in the treatment of BPH. The two surgical methods were prostate artery embolization and gold standard transurethral prostatectomy.

At present, the treatment of BPH is mainly surgery, but the operation will cause great damage to the body. However, the body function of the elderly is degraded and

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their physical quality is poor, which is not conducive to postoperative recovery. Ginger-separated moxibustion is a method combining the pharmacological effects of mugwort and ginger, which is common in the treatment of BPH. These methods have the advantages of low cost and high convenience (Parsons *et al.*, 2020; Bilhim *et al.*, 2022). However, the effect of single ginger-separated moxibustion in the treatment of BPH is not ideal. Therefore, a new treatment method of tamsulosin combined with ginger-separated moxibustion is proposed and its clinical effect is analyzed. The purpose is to verify tamsulosin's clinical efficacy, so as to improve the physical and mental health of BPH patients.

MATERIALS AND METHODS

A total of 80 elderly patients with BPH and lower urinary tract symptoms were selected in our hospital for the study. The admission time of the patients was from March 2021 to July 2022. The patients were separated into ginger moxibustion group (G) with 40 patients and combined group (J) with 40 patients. In the comparison of basic data, the difference was not significant ($P>0.05$). The inclusion criteria were age between 68 and 80 years old, meet the BPH diagnostic criteria, no major diseases such as cardio-cerebrovascular disease, no mental illness, able to communicate normally, no other drugs have been taken in the past 2 weeks, the patients and their families were informed of the experimental contents and signed the electronic informed consent form. The exclusion criteria were those whose age does not meet the criteria, LUTS patients caused by urinary calculus and renal function changes, patients with poor drug compliance, LUTS triggered by non-BPH, people who are allergic to moxa sticks. This study has been approved by the hospital ethics committee.

Research methods

For patients in Group G, only ginger was used for treatment.

For preparation of mugwort and ginger slices, moxa villi were kneaded until the moxa villi formed a small conical moxa pillar with a diameter of about 1.2cm and a height of 1.8cm. Fresh ginger were cut into slices, with a diameter of about 2.0 cm and a thickness of about 0.4 cm. Through a cotton swab, several small holes were made in the center of the ginger slices.

Specific operation of ginger roasting: refer to Acupuncture and Moxibustion for the location of acupoints, select Guan Yuan, Qihai, Zhongji, Shenque, Shenshu, Bladder Shu, Ciliao. On the treatment bed, the patient first used the lying position, and took the supine position when performing the operation for abdominal

acupoints. Prone position was taken when performing the manipulation of back acupuncture points. When burning, acupoints were first disinfected with alcohol and then smeared with ginger juice. The prepared ginger slices were placed above the acupuncture points, and then the prepared mugwort on the top of the ginger slices, and ignited the fire to make the mugwort ignite slowly. When the patient felt burning pain in the skin, the ash of wormwood replaced with a new wormwood pillar to rekindle the fire. At the above 7 acupoints, each acupoint was burnt with 5 pillars of wormwood. According to the degree of redness and wetness of the patient's local skin as the judgment basis, ginger roasting is performed every 1 day, and the abdominal and back acupoints are alternately performed every other day.

For patients in Group J, on the basis of the ginger-separated roasting operation adopted in Group G, Tamsulosin Hydrochloride sustained-release capsule (Astera Pharmaceutical (China) Co., Ltd., GYZZ H20000681) 0.2mg po qd was taken orally.

Both groups were treated for 1 month. The patients were instructed not to take other drugs that may affect the study. The patients were advised to work and rest regularly, prohibit drinking, and prohibit eating raw food, cold food, spicy food, and stimulating food. Patients had light diet and regular work and rest.

Observation indicators

During the treatment, indicators were used to evaluate the effectiveness of the two therapies. These included symptom score of urine storage period (SSS), international prostate symptom score (IPSS), quality of life (QOL), maximum urine flow rate (MFR), residual urine volume (RV), prostate volume (PV), TCM symptom score and SF-36 score. The changes of SSS, IPSS, QOL, maximum urine flow rate, residual urine volume, bladder volume, TCM symptom score and SF-36 score of patients in Group G and Group J were compared. These indicators can be used to evaluate the improvement effect of two treatment methods on the lower urinary tract symptoms of elderly patients with BPH.

Statistical analysis

During this study, software SPSS 22.0 was used to process the data. The measurement data, and conformed to normal distribution, and the variance is homogeneous, it was expressed by means of mean \pm standard deviation, and the test method was *t*-test. If the experimental data is counting data, it was expressed by rate and composition ratio, and χ^2 test was used. When $P<0.05$, the difference was significant. When $P<0.01$, the difference was highly significant.

RESULTS

During the treatment, the scores of all sub-items of IPSS and the total score of IPSS in Group G and Group J decreased significantly (Table I). Compared with Group G, except for Q1 and Q3, the scores of IPSS sub-items and its total score in Group J were lower ($P<0.05$). SSS scores of Group G and Group J decreased significantly compared with those before treatment (Table II). After 4 weeks of treatment, the SSS score of group J was lower than that of group G, and the difference was highly significant ($P<0.01$). QOL scores of Group G and Group J reduced after treatment ($P<0.01$). QOL score of Group J was lower than Group G (Table II). MFR in Group G and Group J improved after treatment (Table III). The improvement of MFR in Group J was better than Group G ($P<0.01$). The residual urine volume in Group G and Group J decreased significantly (Table III). After treatment, the residual urine volume of bladder in group J was lower ($P<0.05$). The prostate volume in Group G and Group J decreased to a certain extent, but there was no difference ($P>0.05$). The volume of prostate in Group J was slightly smaller than Group G after treatment, but there was no difference ($P>0.05$). After treatment, TCM symptom scores in Group G and Group J decreased significantly, and TCM symptoms scores in Group J was lower than Group G (Table IV). After 4 weeks of treatment, the SF-36 scores in Group G and Group J increased significantly, and SF-36 score of Group J was higher than Group G after treatment (Table IV).

Table I. IPSS score of group G and group J.

Group	IPSS score	Before treatment	After treatment	t	P
G	Q1	2.02±0.23	1.00±0.66	3.054	<0.05
	Q2	3.51±0.84	2.15±0.86	2.136	<0.05
	Q3	1.94±0.63	1.13±0.74	3.022	<0.05
	Q4	2.06±0.52	1.55±0.53	2.572	<0.05
	Q5	3.15±0.45	2.06±0.32	4.133	<0.05
	Q6	3.02±0.86	1.34±0.55	4.036	<0.05
	Q7	2.53±0.94	1.98±1.03	2.154	<0.05
	Total	17.58±3.06	11.62±3.20	7.031	<0.01
J	Q1	2.05±0.27	1.02±0.46	3.258	<0.05
	Q2	3.53±0.64	1.85±0.43*	4.102	<0.05
	Q3	2.02±0.55	0.95±0.14	3.432	<0.05
	Q4	2.10±0.34	1.12±0.35*	4.066	<0.05
	Q5	3.09±0.55	1.03±0.34*	6.853	<0.01
	Q6	2.98±0.47	0.88±0.42*	6.142	<0.01
	Q7	2.52±0.66	1.48±0.37*	2.031	<0.05
	Total	17.67±3.82	9.15±3.28**	8.744	<0.01

Group G, ginger moxibustion group; Group J, combined group.

Table II. SSS and QOL scores of group G and group J.

Treatment time (weeks)	G group	J group	t	P
SSS scores				
Before treatment	12.83±2.32	12.65±2.84	0.623	>0.05
1	11.45±2.05	10.14±3.18*	4.025	<0.05
2	10.32±1.46*	8.43±2.52**	6.463	<0.01
3	9.17±2.07**	6.17±1.62**	8.054	<0.01
4	8.28±2.58**	5.52±1.22**	9.640	<0.01
QOL score				
Before treatment	4.50±0.58	4.46±1.02	0.568	>0.05
1	3.14±0.37*	4.02±0.58*	3.146	<0.05
2	2.44±0.52**	3.64±0.82*	6.532	<0.01
3	1.84±0.25**	2.86±0.13**	8.174	<0.01
4	1.23±0.46**	2.48±0.53**	8.832	<0.01

Table III. MFR improvement in group G and group J.

Treatment time (weeks)	G group	J group	t	P
MFR (ml/s)				
Before treatment	9.52±2.18	9.46±2.25	0.563	>0.05
1	10.58±3.14	11.43±2.85	1.352	>0.05
2	11.14±2.30	13.44±3.16	4.907	<0.05
3	11.64±2.03	14.62±3.48	6.341	<0.01
4	12.22±3.67	15.13±4.28	7.417	<0.01
Residual urine volume (ml)				
1	45.65±6.33*	42.64±4.76*	2.315	<0.05
2	40.14±4.56*	38.54±6.32**	3.047	<0.05
3	37.35±6.72**	35.17±4.28**	1.872	<0.05
4	36.36±4.13**	34.13±3.53**	2.305	<0.05
Prostate volume (cm³)				
Before treatment	42.44±12.08	41.71±10.86	0.632	>0.05
1	42.01±10.94	41.06±12.35	0.350	>0.05
2	41.58±11.33	40.58±14.14	0.644	>0.05
3	41.14±12.36	40.37±11.28	0.315	>0.05
4	40.51±12.58	40.23±13.38	0.555	>0.05

According to the evaluation criteria of western medicine, the clinical efficacy is shown in Table V. Compared with Group G, in the evaluation criteria of western medicine, the number of significantly effective people in Group J was higher ($P<0.05$). The total effective rate of treatment in Group G was slightly lower ($P>0.05$).

Table IV. TCM symptom and SF-36 scores of group G and group J.

Treatment time (weeks)	G group	J group	t	P
TCM symptom score				
Before treatment	17.35±4.32	17.41±4.28	0.246	>0.05
1	16.12±3.22*	14.02±3.58**	3.705	<0.05
2	14.44±2.56**	11.02±2.84**	7.022	<0.01
3	12.14±3.18**	10.03±2.53**	7.593	<0.01
4	11.32±2.51**	8.07±2.33**	8.864	<0.01
SF-36 score				
Before treatment	54.36±12.08	55.14±13.12	0.532	>0.05
1	58.73±12.16*	63.95±13.61**	5.374	<0.05
2	64.74±13.07**	70.44±12.84**	7.582	<0.01
3	69.45±13.46**	79.63±13.48**	8.063	<0.01
4	72.46±13.34**	85.02±14.14**	8.416	<0.01

Table V. Clinical efficacy under the evaluation standard of western medicine.

Group	Significant effect (n, %)	Valid (n, %)	Invalid (n, %)	Efficiency (n, %)
G (n=40)	6 (15.0)	28 (70.0)	6 (15.0)	34 (85.0)
J (n=40)	10 (25.0)	25 (62.5)	5 (12.5)	35 (87.5)
χ^2	4.456	0.106	0.453	0.156
P	<0.05	>0.05	>0.05	>0.05

Table VI. Analysis of curative effect under the evaluation standard of traditional Chinese medicine.

Group	Cure (n, %)	Significant effect (n, %)	Valid (n, %)	Invalid (n, %)	Efficiency (n, %)
G (n=40)	0 (0)	5 (12.5)	30 (75.0)	5 (12.5)	35 (87.5)
J (n=40)	0(0)	12 (30)	26 (65.0)	2 (5.0)	38 (95.0)
χ^2	-	4.203	3.620	2.035	3.145
P	-	<0.05	<0.05	<0.05	<0.05

According to the evaluation standard of traditional Chinese medicine, the clinical efficacy of Group G and Group J is shown in Table VI. In the evaluation criteria of traditional Chinese medicine, there were no cured cases in Group G and Group J. Compared with Group G, the number of markedly effective and effective people in group J was higher ($P<0.05$). The number of invalid patients was less ($P<0.05$). The total effective rate of treatment in group G was lower ($P>0.05$).

DISCUSSION

After one month of treatment for patients in Group G, the total IPSS score, SSS score, QOL score, bladder residual urine volume and TCM symptom score of patients in Group G decreased significantly ($P<0.05$). MFR and SF-36 scores were enhanced ($P<0.05$). This shows that the symptoms of patients in Group G have been significantly improved. The data obtained during the study can confirm the above, so it also proves the therapeutic effect of ginger broiling in the elderly with BPH and LUTS.

The study referred to Acupuncture and Moxibustion during the operation of separating ginger. Seven acupoints including Guanyuan, Qihai, Zhongji, Shenque, Shenshu, Bladdershu and Ciliao were selected for the experiment. These acupoints belong to the abdominal Ren meridian acupoints and the back bladder meridian acupoints. Among them, Guan Yuan is three inches below the belly button of the human body. This acupoint has key role in the clinical application of urinary system diseases and reproductive system diseases. Some clinical studies show that acupuncture at this point can regulate the sympathetic nerves of patients. This regulates the detrusor and urethral sphincter of the patient, thereby improving the bladder storage and urination function of the patient. Burning this acupoint can replenish the spirit and make the patient's urine smooth. Qihai or Dantian, is 1.5 inches below the navel. In the theory of traditional Chinese medicine, this acupoint gathers the vitality of the human body. Therefore, burning this acupoint can increase the vitality of the human body, dredge the qi of the lower energizer, improve the bladder gasification function of the patient, and improve the urination function of the patient (Ottaiano *et al.*, 2022). The location of Zhongji point is in the lower abdomen, which is the intersection point of the three yin meridians of the foot. In the theory of traditional Chinese medicine, this point is the place where the gas of the bladder gathers. Some studies have shown that acupuncture at Zhongji can regulate the bladder tension of patients. Therefore, in clinical treatment, Zhongji is one of the most commonly used acupoints for the treatment of dysuria. In the theory of western medicine, the position of Zhongji point is controlled by T12-L1 spinal cord segment nerve, which also controls bladder and prostate. Therefore, stimulating Zhongji point with appropriate methods can also improve the bladder function and prostate function of patients, and thus improve the LUTS of patients (Morton *et al.*, 2020). Burning this acupoint can regulate the bladder function. The Shenque is located in the navel. This acupoint is the center of the human meridians, which can connect all the meridians. Burning this acupoint can warm and replenish the kidney yang, regulate the viscera function,

and improve the bladder gasification function of patients. Shenshu is located under the 2nd lumbar vertebra and is the site of kidney gas infusion. Bladder Shu is located under the second sacral spine, which has the effect of regulating the bladder. Ciliao is in the sacrococcygeal region, and its nerve stage basically coincides with the urination center (Bouhadana *et al.*, 2020). To sum up, the above acupuncture points are roasted with ginger, which can improve the bladder function and prostate function of patients. After treatment, MFR and bladder residual urine volume in group G were significantly improved ($P<0.01$). The volume of prostate decreased to a certain extent, consistent with the above content.

At present, the mechanism of LUTS caused by BPH is not completely clear in the research community. However, the bladder outlet obstruction and bladder detrusor dysfunction caused by BPH have been widely recognized in clinic. There are two main reasons for bladder outlet obstruction. The first is because the prostate volume increases. The second reason is that smooth muscle's tension in the prostate and bladder is increased. An α_{1A} receptor is widely distributed in the urethra, bladder and prostate. Some studies have shown that α_{1A} receptor blockers can inhibit this receptor, thus relaxing smooth muscle, relieving bladder outlet obstruction, and alleviating LUTS in BPH patients. Tamsulosin is a commonly used α_{1A} receptor blocker, which has high selectivity and blocking effect on α_{1A} receptor. This can improve the bladder function and prostate function of patients, thus improving the urination function of patients (Betschart *et al.*, 2020; Tsunemori and Sugimoto, 2021). Tamsulosin has the advantages of high selectivity and high safety, so it is more commonly used in the treatment of BPH (Madersbacher *et al.*, 2020). Aiming at the problem that the treatment effect of ginger-separated broiling on BPH is not ideal, a treatment method of tamsulosin combined with ginger-separated broiling was proposed. This method combines the advantages of the two treatment methods, and makes up for the shortcomings of both sides, so as to improve the treatment effect. Compared with Group G, except for Q1 and Q3, the scores of IPSS sub-items in Group J were lower after treatment ($P<0.05$). The total score of IPSS in group J was lower ($P<0.01$). The SSS score of group J was lower ($P<0.01$). The QOL score of group J was lower ($P<0.01$). The improvement of MFR in group J was better ($P<0.01$). The residual urine volume of bladder in group J was lower ($P<0.05$). The score of TCM symptoms in group J was lower ($P<0.01$). The SF-36 score of group J was higher ($P<0.01$). In the evaluation criteria of traditional Chinese medicine, the number of significantly effective and effective people in Group J was higher ($P<0.05$). The number of invalid patients was less

($P<0.05$). The total effective rate of treatment in group G was lower ($P<0.05$). During the experiment, there were no adverse reactions or scalds or burns in patients in Group G and Group J. The data obtained from the experiment are consistent with the previous literature. This also verified the efficacy and safety of tamsulosin combined with ginger broiling in the treatment of elderly BPH with LUTS.

CONCLUSION

Tamsulosin combined with ginger roasting has a better therapeutic effect on the elderly patients with BPH and LUTS. This can more effectively alleviate the symptoms of patients, thus improving their physical and mental health. The experimental time of the study is short, and only the short-term clinical efficacy of this method has been observed and analyzed. Therefore, it needs observe and analyze the long-term effect of this method in the follow-up study to provide more ways for the clinical treatment of LUTS.

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IRB approval

This research was carried out with the approval of Research Guidance Workshop Committee (Affiliated Hospital, Inner Mongolia Minzu University).

Ethical approval

The study was carried out in compliance with guidelines issued by ethical review board committee of Inner Mongolia Minzu University, Tongliao, 028000, China. The official letter would be available on fair request to corresponding author.

Statement of conflict of interest

The authors have declared no conflict of interest.

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