



Safety and efficacy of wrist-ankle acupuncture in treating catheter-related bladder discomfort after transurethral resection of the prostate: a double-blind randomized clinical trial

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Background: Benign prostatic hyperplasia (BPH) is an age-related condition and its prevalence has increased as China's population ages. Transurethral resection of the prostate (TURP) remains the gold standard for treating moderate to severe BPH. Routine placement of a urinary catheter after TURP is often associated with catheter-related bladder discomfort (CRBD). The development of CRBD is related to an increased synthesis of prostaglandin (PG), and wrist-ankle acupuncture (WAA) can inhibit the expression of PG at the site of inflammation, thus alleviating CRBD symptoms. Here we evaluated the efficacy of WAA in alleviating CRBD in patients undergoing TURP.

Methods: A total of 46 patients who underwent elective TURP in Hebei Provincial Hospital of Traditional Chinese Medicine from June 2022 to July 2022 were randomly divided into two groups according to the complete randomization method. The WAA group (n=23) and the control group (n=23). The WAA group received WAA, and the needles were retained for 24 h. The control group was treated with sham needles that did not penetrate the skin, and the needles were also retained for 24 h. At T₁ (0 h after entering the ward), T₂ (0.5 h after entering the ward), T₃ (6 h after entering the ward), and T₄ (24 h after entering the ward), CRBD severity score, visual analogue scale (VAS) and vital signs monitor were used for assessment. Accidents were recorded in the case report form. Graded data using Wilcoxon signed rank sum test, repeated measures using repeated measures analysis of variance.

Results: A total of 46 patients participated in this study, and 44 patients completed the experiment. At T₂, T₃, and T₄, the severity of CRBD in the WAA group was significantly lower than that in the control group (all P<0.05), and the VAS pain score was significantly lower in the WAA group than in the control group (all P<0.05). In contrast, the vital signs, including mean arterial pressure (MAP), heart rate (HR), and blood oxygen saturation, showed no statistical significance (all P>0.05). No accident occurred in both groups.

Conclusions: WAA can effectively relieve CRBD symptoms after TURP. WAA deserves further research and assessment for clinical practice.

Trial Registration: Chinese Clinical Trial Registry identifier: ChiCTR2200061525..

Keywords: Benign prostatic hyperplasia (BPH); wrist-ankle acupuncture (WAA); transurethral resection of the prostate (TURP); catheter-related bladder discomfort (CRBD); traditional Chinese medicine

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Introduction

Benign prostatic hyperplasia (BPH) is an age-related condition that usually develops in middle-aged and older men, and its prevalence has increased as China's population ages. The main clinical presentation of BPH is dysuria (1) and transurethral resection of the prostate (TURP) remains the gold standard for treating moderate to severe BPH (2). After surgery, routine placement of a urinary catheter is required for bladder irrigation, compression for hemostasis, urethral support, and urine drainage. However, the urinary catheter produces mechanical stimulation of the urethral mucosa, leading to suprapubic pain, a frequent urge to urinate, and a tingling/burning sensation during urination. Patients may experience agitation characterized by flailing limbs, strong verbal responses, and attempts to pull out the catheter during recovery. All of the above symptoms constitute catheter-related bladder discomfort (CRBD) (3-5). Surgical injury due to both qi and blood deficiency, qi stagnation and blood stasis, hot and humid disturbance, combined with indwelling catheter to stimulate urethral mucosa aggravate bladder discomfort related symptoms. CRBD occurs in 47–90% of patients after TURP (6-8) and may aggravate pain and prolong the hospital stay. Postoperative complications, such as bleeding and circulatory changes (e.g., arrhythmia), may occur in severe cases (9). Therefore, early postoperative remission of CRBD is clinically valuable. Although M-receptor antagonists, opioids, and other drugs can relieve CRBD symptoms, these drugs have side effects such as dry mouth, nausea, and blurred vision (4,10). Developed by Professor Xinshu Zhang in the 1970s, WAA only requires regional acupuncture on the wrist and ankle to achieve its purpose in treating systemic diseases (11). Subcutaneous shallow needling, linear stimulation of nerve endings, stimulate twelve skin meridian qi and defensive qi function, meridians, promote the operation of qi and blood, to achieve the purpose of 'Tong Ze Bu Tong' treatment of disease (12,13). Urethra, prostate and bladder are located in the middle line of the human body. According to the principle of acupuncture point selection, the lower 1, lower 2 and lower 3 areas should be taken. The direction of acupuncture in these 3 areas is consistent with the direction of the three yin meridians of the foot. Wrist-ankle acupuncture (WAA) has been widely used in treating pain,

insomnia, urinary retention, and many other diseases, with remarkable clinical effectiveness (14-17). Unfortunately, few studies have described its application in CRBD patients. We speculated that postoperative application of WAA might reduce the severity of CRBD. Here we evaluated the efficacy of WAA in alleviating CRBD in patients undergoing TURP. We present the following article in accordance with the CONSORT reporting checklist (available at <https://gs.amegroups.com/article/view/10.21037/gS-22-438/rc>).

Methods

Subjects and methods

This prospective, double-blind, single-center, two-parallel, randomized controlled study. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Ethics Committee of Hebei Provincial Hospital of Traditional Chinese Medicine (approval number: 2018-research-35) and informed consent was taken from all the patients.

Patients

A total of 46 patients who underwent TURP in Hebei Provincial Hospital of Traditional Chinese Medicine between June 2022 and July 2022 were enrolled. SAS software PROC PLAN was used to generate a random distribution table. Patients who met the inclusion and exclusion criteria were randomly treated with WAA or sham acupuncture according to the random distribution table. And allocation ratio is 1:1, with 23 cases in each group. The inclusion criteria were as follows: (I) a diagnosis of BPH in accordance with the *Guidelines for the Diagnosis and Treatment of Benign Prostatic Hyperplasia from the Perspective of Integrated Traditional Chinese and Western Medicine* (18); (II) aged ≥ 60 years (19); (III) an International Prostate Symptom Score (IPSS) score of ≥ 15 points (20); (IV) undergoing TURP; (V) the use of a 22 FR disposable sterile Foley catheter after surgery; (VI) acupuncture-naïve; (VII) attended the study voluntarily. The exclusion criteria included: (I) other severe cardiac, renal, or kidney diseases; (II) communication problems; (III) the presence of scars, wounds, or masses at the skin where the needle was

inserted, making acupuncture unsuitable; (IV) incomplete medical data; (V) drowsy or confused; (VI) history of prostate surgery and (VII) participation in other research.

WAA group

The patients were actively communicated with the patients before the operation to inform them that CRBD symptoms would occur in some patients with indwelling catheter after the operation. If this reaction occurred after the operation, WAA could be used to reduce the discomfort symptoms. At the same time, family members are encouraged to care for patients, help patients establish confidence and improve stress ability.

Upon the completion of the surgery, a 22 FR disposable sterile Foley catheter (UroCare, Malaysia; batch number: 20172660335) was inserted, and 40 mL of distilled water was injected into the balloon. The patient was returned to the ward after recovery from anesthesia.

After the patient entered the ward, the researchers immediately evaluated the symptoms of CRBD, and the operator immediately used WAA to intervene in patients with CRBD symptoms. The acupuncture site was approximately three transverse fingers above the inner malleolus and one loop around the ankle area, and the lower 1, 2, and 3 areas on both sides were used. The lower 1 area is located near the medial border of the Achilles tendon, the lower 2 area is located near the medial border of the tibia, and the lower 3 area is located 1 cm medially from the anterior crest tibia (11). The patient was asked to relax his body and mind before the acupuncture because fear and anxiety may undermine the effectiveness of the intervention. The patient was asked to take a supine position with the knees abducted and the soles of the feet facing upward. The local skin area was sterilized with 75% alcohol. The handle of the acupuncture needle was held with three fingers, and the needle (Hua Tuo brand, Suzhou Medical Products Co. Ltd.; size: 0.25 mm × 25 mm) was quickly inserted into the subcutaneous layer at a 30° angle. The needle body was held flat, and a 0.2-cm-sized skin mound was visible. The needle was then advanced in a straight line without lifting, inserting, or twirling. The needle body was kept at 0.2 mm and fixed with tape when the operator felt that the needle was moving smoothly without obvious resistance, and there was no feeling of soreness, numbness, swelling, or pain at the needling site. The time of acupuncture and the number of needles used was recorded. Inform patients of subcutaneous bleeding, faint needle and other unexpected

situations during needle retention and pull out WAA by nurses. All patients were continuously intervened for 24 hours and then the WAA was drawn.

After surgery, the necessity for bladder irrigation was explained to the patient. Normal saline with a core temperature of 35–37 °C was used for the bladder irrigation (21). Close attention was paid to any changes in the color of the irrigation fluid. The amount and speed of irrigation were adjusted as necessary, the irrigation input/output amount was accurately recorded, and the fixation of the urinary catheter was checked to ensure smooth drainage.

The patients' vital signs were closely monitored after surgery. Patients were educated to eat a proper diet and drink 2,000–3,000 mL of water daily to keep the stools soft. Ankle pump exercises were performed on the bed during bed rest. After the irrigation was stopped, the patient was asked to exercise near the bed at first and then gradually increased the amount of exercise to prevent the formation of venous thrombosis in the lower extremities.

Control group

Before the acupuncture, the 23-mm needle body was removed, and only the 0.2-mm needle body and the needle handle were kept. After the patient enters the ward, the researcher immediately evaluates the CRBD-related symptoms, and the operator immediately uses false intervention for patients with CRBD symptoms. Local skin was sterilized with 75% alcohol. Held by the right hand, the needle was used to prick the skin lightly (without piercing the subcutaneous layer). Subsequently, the needle handle was stuck onto the lower 1, 2, and 3 areas on both sides and fixed with tape. The time of acupuncture and the number of needles used was recorded. All patients were intervened for 24 hours before removing wrist ankle acupuncture. The remaining nursing steps were the same as in the WAA group.

Outcomes

The severity of CRBD, Visual Analog Scale (VAS) score, and vital signs were assessed and recorded at T₁ (0 h after entering the ward), T₂ (0.5 h after entering the ward), T₃ (6 h after entering the ward), and T₄ (24 h after entering the ward).

Primary indicator

The severity of CRBD (22) was measured as follows: grade 0 (absent): the patient did not report any urethral or bladder

discomfort on inquiry; grade 1 (mild): the patient complained of urethral discomfort only when asked, and the discomfort was tolerable; grade 2 (moderate): the patient complained of lower abdominal distention, urgency, and dysuria, which were tolerable and not accompanied by physical movements; and grade 3 (severe): the patient complained of severe lower abdominal distention, urgency, dysuria, and frequency, which were intolerable and accompanied by physical movements (swinging extremities, strong verbal responses, and attempts to pull out the catheter).

Secondary indicator

We used the VAS, which consists of a straight line 0–10 cm long. A score of 0= no pain, 3= normal sleep and tolerable pain, 5= inability to fall asleep and intolerable pain, 8= passive position and autonomic dysfunction, and 10= the most severe and unendurable pain. Patients were asked to mark a point on the line that best represented their pain.

Vital signs, including mean arterial pressure (MAP), heart rate (HR), and oxygen saturation (SPO₂), were monitored.

Accidents: this study uses case report forms to record the occurrence of accidents.

Randomization

In this study, the complete randomization method was adopted, and the PROC PLAN software was used to generate a random distribution table. Patients who met the inclusion and exclusion criteria were randomly treated with WAA or sham acupuncture according to the random distribution table. The patients were divided into the WAA group and the control group with 23 cases in each group. A sheet containing the treatment allocation and identification number was placed in an envelope, then sealed. An operator who had received professional training on WAA opened the envelope before needling. All the subjects were WAA-naïve and had no knowledge of acupuncture, and neither did they know the grouping status during the operation. After the procedure, the needle was fixed with opaque tape and retained for 24 hours each session. Trained researchers blind to the grouping information collected and processed the data.

Statistical analysis

In the pilot study, the incidence of bladder discomfort was 95% in the control group but dropped to 51% in the WAA group. The probability of type I error (α) was set at 0.05 (two-sided), and the probability of type II error (β) was set

at 0.1. Calculations by Power Analysis & Sample Size (PASS; version 15.0, NCSS, Kaysville, UT, USA) indicated that 20 patients were needed for each group. Considering the 15% dropout rate, we enrolled 46 patients. Normally distributed measurement data are presented as $\bar{x} \pm SD$ and were analyzed by independent sample *t*-tests. The non-normally distributed measurement data are presented as medians and interquartile ranges and were analyzed with the rank sum test. The count data are presented as frequencies and percentages and were compared using the chi-square test. The ranked data were analyzed using the non-parametric Wilcoxon rank sum test. The repeated measured data were analyzed using ANOVA with repeated measures. Data were analyzed by Per-Protocol (PP). Graphs were drawn with Graphpad Prism software (version 7.0, Graphpad Microsoft Corporation, San Diego, CA, USA). Data were analyzed with SPSS Statistics for Windows, Version 23.0 (IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp). A P value <0.05 was considered statistically significant.

Results

General data

A total of 56 patients underwent TURP in our center from June 2022 to July 2022. Eight patients were excluded because they did not meet the inclusion criteria, and two refused to participate. Two patients in the control group could not tolerate the intervention and switched to medical treatment. Wrist ankle acupuncture group 23 patients, control group 21 patients, a total of 44 patients entered the final analysis (Figure 1). The two groups were matched in age, prostate volume, IPSS score, and other general data (Table 1).

Severity of CRBD

The severity of CRBD was matched between the two groups at T₁ (P>0.05). However, it was significantly different at T₂, T₃, and T₄ (all P<0.05) (Table 2).

VAS

As shown by the repeated-measures ANOVA, VAS scores differed significantly between the WAA and control groups at T₂, T₃, and T₄ (group F =23.29, time F =11.03, group × time F =5.77, P<0.05). The VAS scores gradually declined in both groups. Pairwise comparisons at different time points showed that the difference between the two groups

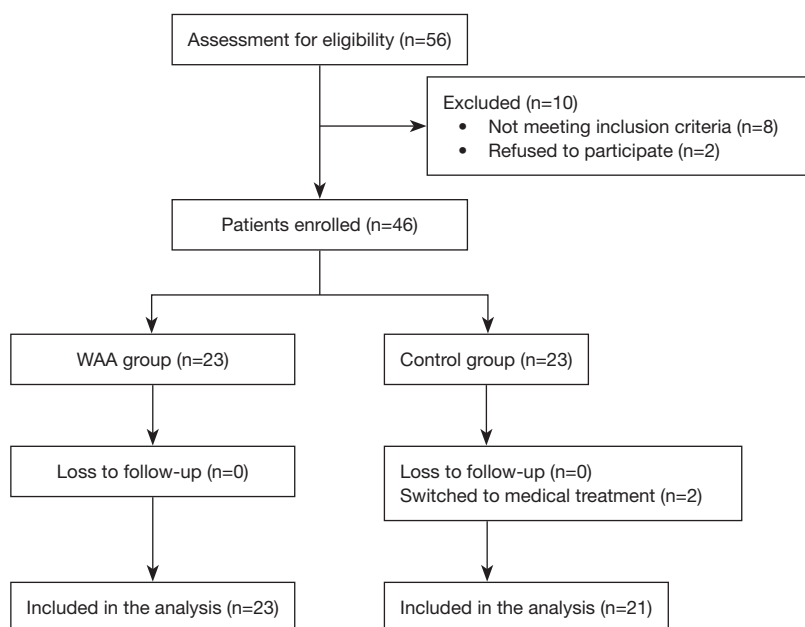


Figure 1 Flowchart of subject enrollment. WAA, wrist-ankle acupuncture.

Table 1 General data of the WAA and control groups

Group	Age (years), $\bar{x}\pm SD$	BMI (kg/m ²), $\bar{x}\pm SD$	IPSS score (points), $\bar{x}\pm SD$	Prostate volume (mL), M (Q)	Hypertension, (N)
WAA group (n=23)	73.09±7.35	22.66±3.06	28.09±3.52	86 (17.0)	8
Control group (n=21)	73.57±7.08	23.80±3.42	28.78±3.82	95 (54.0)	11
T/Z/c ²	0.23 ^a	1.19 ^a	0.64 ^a	0.28 ^b	0.81 ^c
P value	0.82	0.24	0.52	0.78	0.37

Note: ^a, F value; ^b, Z value; ^c, χ^2 value. WAA, wrist-ankle acupuncture; BMI, body mass index; IPSS, International Prostate Symptom Score.

Table 2 Comparison of the severity of CRBD between the WAA and control groups [n (%)]

Time	n	Group	Light	Moderate	Heavy	Overall incidence	Z	P value
T ₁	23	WAA group	8 (34.8%)	15 (65.2%)	0	100%	0.30	0.76
	23	Control group	9 (39.1%)	14 (60.9%)	0	100%		
T ₂	23	WAA group	7 (30.4%)	1 (4.3%)	0	34.8%	2.61	0.01
	21	Control group	6 (28.6%)	13 (61.9%)	2 (9.5%)	100%		
T ₃	23	WAA group	5 (21.7%)	0	0	21.7%	2.91	0.00
	21	Control group	5 (23.8%)	14 (66.7%)	1 (4.8%)	95.2%		
T ₄	23	WAA group	2 (8.7%)	0	0	8.7%	3.14	0.00
	21	Control group	11 (52.4%)	0	0	52.4%		

CRBD, catheter-related bladder discomfort; WAA, wrist-ankle acupuncture.

Table 3 Comparison of the VAS score between these two groups (n=44, $\bar{x}\pm SD$, points)

Group	T ₁	T ₂	T ₃	T ₄
WAA group	2.22±1.70	0.74±1.18	0.52±1.04	0.22±0.60
Control group	2.38±1.72	2.86±1.39	2.33±1.62	1.57±1.53
F	0.10	29.97	19.80	15.35
P value	0.75	*	*	*

Note: *, P<0.001. VAS, Visual Analog Scale; WAA, wrist-ankle acupuncture.

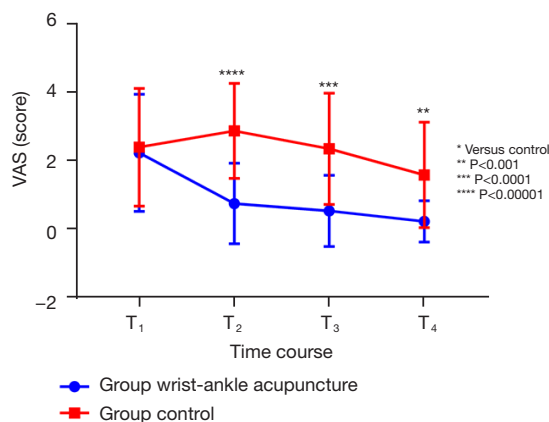


Figure 2 VAS scores at different time points. VAS, Visual Analog Scale.

was largest at T₂ and smallest at T₄ (Table 3, Figure 2).

Vital signs

As shown by the repeated-measures ANOVA, MAP (group F =1.33, time F =1.90, group × time F =4.43, P>0.05), HR (group F =0.08, time F =17.91, group × time F =0.34, P>0.05), and SPO₂ (group F =0.44, time F =27.15, group × time F =1.06, P>0.05) showed no significant differences between the two groups at T₂, T₃, and T₄ (Table 4).

Accident

No accident happened in both groups.

Discussion

WAA is an effective method for relieving CRBD symptoms after TURP. In this study, patients undergoing TURP were selected as the research subjects based on the following considerations: (I) males have a long urethra that contains three strictures and two curvatures, and urethral sphincter

contraction may be more likely to cause CRBD after the Foley catheter stimulates the urethral mucosa. (II) Male gender and postoperative indwelling urinary catheter size (>18 Fr) are two independent predictors of CRBD symptoms (23). (III) A concavity is formed locally after prostatectomy; in some patients, the Foley catheter water sac will move into the prostate concavity and stimulate the prostate wound, and the Foley catheter will stimulate the urethral mucosa. All three conditions together produce a stimulating effect. In this prospective, randomized, placebo-controlled study, the control group still experienced discomfort symptoms despite sham acupuncture, thus excluding the placebo effect of the acupuncture, as confirmed in a previous study (24). The operators who participated in the intervention had extensive experience in acupuncture, the research subjects were blind to the treatment assignment, and the data were collected and analyzed by different researchers. All data were subject to strict statistical analyses with scientific rigor.

In the present study, the lower 1, 2, and 3 areas were selected on both sides. These three areas roughly correspond to the same sites as the Kidney Meridian of Foot Shaoyin, the Liver Meridian of Foot Jueyin, and the Spleen Meridian of Foot Taiyin (25) “Where meridians pass, indications for acupoints of this meridian could be considered”. These three yin meridians travel to the urethra, prostate, and bladder, whereas the direction of acupuncture is consistent with the direction of the three yin meridians of the foot. The acupuncture conforms to the principle of “reinforcing and reducing by puncturing along and against the direction of meridians respectively” and works to regulate the zang-fu viscera, remove blood stasis, and promote menstruation. Therefore, WAA can alleviate CRBD symptoms caused by the Foley catheter. The development of CRBD is related to an increased synthesis of prostaglandin (PG) (26) and WAA can inhibit the expression of PG at the site of inflammation (27), thus alleviating CRBD symptoms.

Table 4 Comparisons of vital signs between the WAA and control groups (n=44, $\bar{x}\pm S$)

Parameters	Group	T ₁	T ₂	T ₃	T ₄
MAP (mmHg)	WAA group	97.26±10.11	93.61±7.37	93.30±5.95	92.78±5.74
	Control group	95.76±8.99	97.48±7.23	96.81±7.28	96.29±7.21
HR (f/min)	WAA group	78.61±10.70	79.04±9.47	73.83±7.01	72.39±6.39
	Control group	78.24±11.32	80.14±9.53	74.29±9.00	74.05±9.70
SPO ₂ (%)	WAA group	98.30±1.40	99.17±0.58	99.39±0.58	99.52±0.51
	Control group	98.24±1.48	98.71±0.96	99.43±0.60	99.48±0.60

WAA, wrist-ankle acupuncture; MAP, mean arterial pressure; HR, heart rate; SPO₂, oxygen saturation.

However, our study had some limitations. The results of this study were only applicable to patients with CRBD after TURP, and the role of WAA after other surgeries remains unknown. Relevant studies will be conducted on the basis of the present study.

In summary, with rapid and significant therapeutic effects, WAA can effectively relieve CRBD symptoms and achieve better control of inflammation and the need for pain medication. As a safe and easy-to-operate technique without apparent side effects, WAA deserves further research and assessment for clinical practice.

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Footnote

Reporting Checklist: The authors have completed the CONSORT reporting checklist. Available at <https://gs.amegroups.com/article/view/10.21037/ga-22-438/rc>

Trial Protocol: Available at <https://gs.amegroups.com/article/view/10.21037/ga-22-438/tp>

Data Sharing Statement: Available at <https://gs.amegroups.com/article/view/10.21037/ga-22-438/dss>

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at <https://gs.amegroups.com/article/view/10.21037/ga-22-438/coif>). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are

appropriately investigated and resolved. This prospective, double-blind, single-center, randomized controlled study has been approved by the Ethics Committee of Hebei Provincial Hospital of Traditional Chinese Medicine (approval number: 2018-research-35). All patients provided written informed consent before participating in the study. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013).

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