The Clinical Effect of Jindan Paishi Decoction on Ureteral Calculus with Damp-Heat Syndrome

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Abstract: Objective: This study aims to explore the clinical effect of Jindan Paishi (JDPS) decoction in treating patients of ureteral calculus with damp-heat syndrome. Methods: Total of 62 patients of ureteral calculus with damp-heat syndrome hospitalized in Pingyi County People's Hospital from Jan 2021 to Dec 2022 were randomly divided into the control group (n=31) orally given Shenshitong (SHST) granules and the treatment group (n=31) orally given SHST granules + JDPS decoction for 30 days continuously. The pain degrees of patients were evaluated according to World Health Organization Pain Grade Standard. The traditional Chinese medicine (TCM) syndromes, micturition frequency and urine volume were recorded according to the principles of Clinical Research Criteria of New Chinese Medicine. The number of WBC and RBC in urine, the number and classification of WBC in blood, the serum levels of creatinine (Cr) and urea nitrogen (BUN) were determined by biochemical assay. The size and number of ureteral calculus were detected by imaging examination, and at last the total effective rate of the two drugs was evaluated comprehensively. Results: (1) Comparison between before and after treatment in the two groups: After treatment, all the pain degree and pain time, the tongue coating color and pulse conditions, the size and number of ureteral calculus, the urine volume and frequency of patients were significantly improve than those before treatment respectively; the numbers of WBC and RBC in urine were significantly decreased than those before treatment; the serum levels of Cr and BUN were significantly decreased than those before treatment; the number of WBC and neutrophils in blood were significantly reduced than those before treatment, $P<0.01$. (2) Comparison between control and treatment groups after treatment: The pain degree and time of patients in treatment group were significantly decreased than those in control group, $P<0.05$; the number of WBC in urine, the serum levels of Cr and BUN, and the number of WBC and neutrophils in blood in treatment group were significantly lower than those in control group, $P<0.01$. (3) The total effective rate of patients in treatment group (90.32%) was significantly higher than that in control group (80.64%), $P<0.01$. Conclusions: JDPS decoction might improve clinical symptoms and renal function of patients of ureteral calculus with damp-heat syndrome.

Keywords: Jindan Paishi Decoction; Ureteral Calculus; Damp-Heat Syndrome; Clinical Effect

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1 Introduction

Ureteral stones are the most common upper urinary tract calculus which mostly occur in medium age men [1]. The incidence of urinary calculus increases [2] with age, the complication incidence was more than 10% and the recurrence rate around 50%. Ureteral calculus are closely related to diet, lifestyle habits and daily behaviors [3]. The treating therapy of calculus depends on the size and location of the calculus. When the calculus is greater than 5 mm or cannot be discharged, it can be treated by interventional surgery such as extracorporeal shock wave lithotripsy (ESWL) [4], but the postoperative recurrence rate is still about 50% [5], and ESWL can cause side effects such as renal injury or renal function disorder [6]. Upon to now, there are no satisfactory drugs for clinical treatment of ureteral calculus [7]. Traditional Chinese medicine (TCM) believes that the "damp-heat evils" in the body accumulate at "Xiajio" to boil urine and then the impurity in urine deposit as sand or gravel. Diuretics could eliminate the" evil heat" boiling urine to prevent the formation of calculus, and urine cleansing could promote the calculus discharging from the urinary tract [8]. Tu LR, et al. [9] prepared Paishi soup to treat wet-heat syndrome accumulated urinary calculi (diameter < 8 mm), and the cure rate reached 78%. Sheng MH [10] prepared Yiqi Huoxue Paishi soup to treat urinary calculi and also achieved significant effect. Sun T, et al. [11] applied compound *Lysimachia christinae* granules to assist ESWL and achieved good effect, so they prescribed Jindan Paishi (JDPS) decoction according to the principle of syndrome differentiation for the treatment of ureteral calculus damp-heat syndrome, but its efficacy and mechanism need to be further studied. This study designed a randomized controlled clinical trial to observe the clinical efficacy of JDPS decoction on ureteral calculus with damp-heat syndrome.

2 Information and Methods

2.1 Study Subjects

2.1.1 Case Source

Total of 62 patients of ureteral calculus with damp-heat syndrome were hospitalized in Pingyi County People's Hospital from Jan 2021 to Dec 2022, aged 18 to 70 years, 30 cases of upper ureteral calculi, 9 cases of middle calculi, 23 cases of lower calculi, and transverse diameter of 5-14 mm. This clinical trial was approved by the Ethics Committee of Pingyi County People's Hospital (PYYXLL-LW-2023-018). All the patients signed the informed consent form.

2.1.2 Diagnostic Criteria

According to the Guidelines for Diagnosis and Treatment of Urological Diseases in China (2007 Edition) [12], ureteral calculi were confirmed by imaging. According to the Principles of Clinical Research Criteria of New Chinese Medicine, all the patients met the damp-heat syndrome: recurrent ureteral calculus, lumbar and abdominal pain and radiation to the private parts (pudenda), lower abdomen falling and swelling, red-color tongue and yellow-color tongue coating, and rapid pulse.

2.1.3 Exclusion Criteria

According to the Chinese Guidelines for Diagnosis and Treatment of Urological Diseases (2007 edition) [12]: (1) the patient who is < 18 years or more than 70 years, pregnant and lactant women, and unable to tolerate the drug; (2) the patient with various basic metabolic diseases, cardiovascular and cerebrovascular diseases, hematopoietic diseases and mental disorders; (3) the patient did not take drugs according to this study protocol and incomplete clinical data. And the patient who is ureteral calculus complications such as severe urinary tract infection, male prostatic hyperplasia and urinary tract-related tumors.

2.1.4 Randomization

Total of 62 subjects were numbered according to the order of admission sequence, and the randomization scheme was kept with a shaded envelope, and then 31 subjects were respectively divided into control group (male 19, female 12) and treatment group (male 20, 11 female).

2.2 Jindan Paishi (JDPS) Decoction

2.2.1 JDPS decoction

It originated from Paishi soup and Sanjin Paishi soup recorded in "Ancient and Modern Prescription" [8-9]. According to the principle of TCM syndrome differentiation and clinical experience, the prescription was improved based on the original formula.

2.2.2 Prescription

Lygodium japonicum 30g, Corium stomachium galli 30g, Lysimachia christinae 30g, Dianthus superbus L. 15g, Taraxacum officnala 20g, Pyrrosia lingua 10g, Rhizoma alismatis 15g, Achyranthes bidintata 15g, Salvia miltiorrhiza 30g, Peach kerneltea 10g, Safflower 10g, Semen plantaginis 15g, White paeony root 20g, Dipsacus asperoides 10g, Eucommia ulmoides 10g, Rhizoma corydalis 20g, Pseudo-ginseng 30g.

2.2.3 Processing

JDPS decoction was made according to the quality standard of "Management Standards of Traditional Chinese Medicine Decocting Room in Medical Institutions" (No. [2009]3) [11]. The drug filtrate was concentrated into a liquid conforming to the national standard, fused and sealed in a high-temperature resistant plastic bag (125 mL/bag), cooled at room temperature, and stored at 2-8 ℃.

2.3 Treatment Plan

2.3.1 Control Group

According to the dose indicated in the instructions, the patients were give Shenshitong (SHST) granules (National Drug Approval No. Z22021933, Made in Xiuzheng Pharmaceutical Co. Ltd.), 1 bag (15g) each time, twice a day for 30 days continuously.

2.3.2 Treatment Group

SHST granules + JDPS decoction. Referring to domestic similar prescription [8-10] and combining clinical experience to determine the dose, JDPS decoction was given (Production batch No. P20201101) 125 mL twice a day for 30 days.

2.4 Observation Indexes

Before and after treatment, the following indexes were observed once time respectively.

2.4.1 Pain Degree

ccording to the World Health Organization (WHO) Pain Grade standard (ICD-11) [13]: Grade 0: painless pain; Grade 1: mild pain, intermittent pain, no medication; Grade 2: moderate pain, continuous pain, affecting rest; Grade 3: severe pain, persistent pain. The pain time is the cumulative daily pain time (min).

2.4.2 TCM Syndrome

The tongue coating colors and the pulse conditions were mainly observed.

2.4.3 Clinical Signs

The daily urine volume and urination frequency were mainly recorded.

2.4.4 Size and Number of Calculus

Measuring mainly the size (transverse diameter, mm) and number of calculus with Color B-scan Ultrasounography.

2.4.5 Urine Routine Test

Counting mainly the urinary red blood cells (RBC) and white blood cells (WBC) of patients.

2.4.6 Blood Routine Test

Detecting mainly the leukocyte number and classification of patient in the peripheral blood.

2.4.7 Renal Function Test

The serum levels of creatinine (Cr, μmol/L) and urea nitrogen (BUN, mmol/L) were detected by Automatic Biochemical Analyzer (AU 5811, Bekmann Co. Ltd. USA).

2.5 Efficacy Criteria

The efficacy criteria was evaluated according to the Guidelines for Diagnosis and Treatment of Urological Diseases in China (2014 edition) [12]:

2.5.1 Effective

Symptoms and signs of renal colic disappeared, B-scan ultrasound examination calculi disappeared, routine urine examination more than 2 consecutive times normal; ureter expansion improved, no red blood cells and white blood cells by urinary examination;

2.5.2 Obvious Effective

renal colic symptoms disappeared, some calculi discharged, B-scan ultrasound examination calculi falling down or hydronephrosis decreased; no significant improvement in urine routine;

2.5.3 Ineffective

clinical symptoms slightly relieved or no improvement, no change after B ultrasound examination calculi.

Total effective rate = (number of effective cases + effective cases) / total cases × 100%

2.6 Statistical Analysis

Statistical analysis was performed using the SPSS 20.0 software. Measurement data were conform to normal distribution by homogeneity of variance test and described as mean ± standard deviation. Within-group comparisons were performed by paired *t*-test before and after treatment, independent sample *t*-test, χ^2 test for count data, and two-sided for all statistical tests at $P<0.05$.

3 Results

3.1 Basic Information of Patients

There was no significant difference in age, sex and calculus transverse diameter between the two groups (Table 1).

Table 1 Basic information of patients between the two groups (n=31)

Groups	Sexual distinction		Age	Diameter of calculus
	male	female	year	mm
Control group	19	12	43.55±16.72	5.47±0.16
Treatment group	20	11	47.61±13.68	5.42±0.12
	χ^2=0.07		*t*=1.05	*t*=0.33
	P>0.05		*P*>0.05	*P*>0.05

3.2 Tongue Coating and Pulse Conditions

After treatment, the tongue coating color and pulse conditions improved significantly than those before treatment both in the two groups. After treatment, the tongue coating color and pulse conditions in the treatment group improved significantly than those in the control group (Table 2).

Table 2 Comparison of tongue coating and pulse conditions between the two groups (n=31)

Groups	Tongue coating		Pulse condition	
	Before treatment	After treatment	Before treatment	After treatment
Control group	Tongue red, yellow and greasy coating	Light red, greasy coating	Smooth and rapid	Smooth
Treatment group	Tongue red, yellow and greasy coating	Light red, white coating	Smooth and rapid	Sink

3.3 The Degree and Time of Pain

Before treatment, there was no significant difference in pain grade and pain time between the two groups. After treatment, the pain grade decreased and the pain time shorten significantly than those before treatment both in the two groups, and which in the treatment group were significantly lower than those in the control group (Table 3).

Table 3 Comparison of pain grade and time between the two groups (n=31)

Groups	Pain grade			Pain time (min)		
	Before treatment	After treatment	*t, P*	Before treatment	After treatment	*t, P*
Control group	2.71±0.59	1.68±0.94	5.15,<0.01	35.65±3.22	16.84±1.61	29.07,<0.01
Treatment group	2.81±0.54	1.23±0.96	8.01,<0.01	35.68±2.01	15.38±1.31	47.16,<0.01
t	0.67	3.23		0.05	3.89	
P	>0.05	<0.05		>0.05	<0.05	

3.4 Urine Volume and Urination Frequency

Before treatment, there was no statistical difference in the urine output and the number of urination between the two groups. After treatment, the urine volume increased while the number of urination decreased significantly than those before treatment both in the two groups. There was no significant difference in the urine output and number of urination between the two groups after treatment (Table 4).

Table 4 Comparison of urine volume and number of urination between the two groups (n=31)

Groups	Urine volume (L)			Urination frequency		
	Before treatment	After treatment	*t, P*	Before treatment	After treatment	*t, P*
Control group	1.35±0.05	1.75±0.15	17.07,<0.01	8.84±1.49	5.00±1.37	10.56,<0.01
Treatment group	1.36±0.05	1.66±0.14	23.16,<0.01	8.68±1.83	5.10±2.26	6.86,<0.01
t	0.26	1.79		0.38	0.21	
P	>0.05	<0.05		>0.05	>0.05	

3.5 The Size and Number of Calculus

Before treatment, there was no significant difference in the transverse diameter and the number of ureteral calculus between the two groups. After treatment, the transverse diameter the number of ureteral calculus decreased significantly than those before treatment both in the two groups, however, no significant difference existed in the transverse diameter and the number of ureteral calculus between the two groups after treatment (Table 5).

Table 5 Comparison of the size and number of ureteral calculus between the two groups (n=31)

Groups	Diameter of calculus (mm)			Number of calculus		
	Before treatment	After treatment	*t, P*	Before treatment	After treatment	*t, P*
Control group	5.47±0.16	2.18±0.16	9.37,<0.01	2.84±0.77	0.94±0.73	8.08,<0.01
Treatment group	5.42±0.12	2.32±0.39	4.13,<0.01	2.58±0.72	0.74±0.82	9.39<0.01
t	0.33	0.25		0.53	1.01	
P	>0.05	>0.05		>0.05	>0.05	

3.6 Urine Routine Test

Before treatment, there were no significant difference in the numbers of urinary WBC and RBC between the two groups. After treatment, the numbers of urinary WBC and RBC were decreased significantly than that before treatment both in the two groups, and which in the treatment group were significantly lower than those in the control group (Table 6).

Table 6 Comparison of the urine routine test results between the two groups (n=31)

Groups	WBC/μL			RBC/μL		
	Before treatment	After treatment	*t*-value, *P*-value	Before treatment	After treatment	*t, P*
Control group	38.58±3.28	13.73±1.89	58.27,<0.01	24.00±1.87	13.86±1.19	25.47,<0.01
Treatment group	37.41±2.56	6.11±1.67	103.01,<0.01	24.80±1.85	11.89±0.90	34.94,<0.01
t	0.53	32.97		1.69	7.35	
P	>0.05	<0.01		>0.05	<0.01	

3.7 Renal Function Test

Before treatment, there were no significant difference in serum levels of Cr and BUN between the two groups. After treatment, the serum levels of Cr and BUN were significantly decreased than those before treatment both in the two groups, and which in the treatment group were significantly lower than those in the control group (Table 7).

Table 7 Comparison of renal function test results between the two groups (n=31)

	Cr (μmol/L)			BUN (mmol/L)		
	Before treatment	After treatment	*t, P*	Before treatment	After treatment	*t, P*
Control group	133.33±5.92	98.74±8.33	36.18,<0.01	7.65±0.25	5.22±0.15	46.41,<0.01
Treatment group	132.43±3.64	88.86±5.75	7.06,<0.01	7.76±0.27	4.02±0.14	68.47,<0.01
t	0.83	11.14		1.69	32.56	
P	>0.05	<0.01		>0.05	<0.01	

3.8 Blood Routine Test

Before treatment, there were no significant difference in the numbers of WBC, neutrophil and lymphocyte between the

two groups. After treatment, the numbers of WBC, neutrophil were significantly lower those before treatment both in the two groups, and which in the treated group were significantly lower than those in the control group, while no significant difference existed in the number of lymphocyte between the two groups after treatment (Table 8).

Table 8 Comparison of blood routine test results between the two groups (n=31)

Groups	WBC (10^9/L)			Neutrophil (10^9/L)			Lymphocyte (10^9/L)		
	Before treatment	After treatment	*t, P*	Before treatment	After treatment	*t, P*	Before treatment	After treatment	*t, P*
Control group	10.68±1.45	7.90±0.64	7.87,<0.01	8.29±0.69	5.53±0.43	5.87,<0.01	2.07±0.19	2.12±0.21	0.72,>0.05
Treatment group	10.66±1.49	7.51±0.72	14.79,<0.01	8.23±0.66	5.31±0.41	4.79,<0.01	2.07±0.19	2.12±0.21	0.61,>0.05
t	0.07	3.45		1.21	2.95		1.55	1.34	
P	>0.05	<0.01		>0.05	<0.01		>0.05	>0.05	

3.9 Total Effective Rate

After treatment, the total effective rate of the treatment group was significantly higher than that of control group, $\chi^2 = 6.6$, $P < 0.01$ (Table 9).

Table 9 Comparison of total effective rates after treatment between the two groups (n=31)

Groups	Effective (case)	Obvious effective (case)	Ineffective (case)	Total effective rate (%)	χ^2, *P*
Control group	17	8	6	80.64	6.63
Treatment group	18	10	3	90.32	<0.01

4 Discussion

According to traditional Chinese medicine, urinary calculi occurred due to the "damp-heat evils" in the body to boiling urine over a long time, so that impurities in urine accumulated as gravels, and the TCM therapy is clearing heat and eliminating dampness. Diuresis therapy could not only guide and promote the "damp-heat evils" with drowning, eliminate "heat-evil" boiling urine, prevent the formation and development of calculi, but also promote the calculi discharge outside the body from the urinary tract by urinary flushing action. *Lysimachia christinae* in JDPS decoction belongs to Primulaceae, which medical property is sweet and salty, and "meridian tropism" belongs to the channels of liver, gallbladder and kidney bladder, so that it could benefit water and pour, clear heat and detoxify poison. Zou ZH, et al. [14] studied and proved that the flavone extracted from *Lysimachia christinae* could inhibit the formation of calcium oxalate crystals in the kidneys of rats with experimental hyperoxaluria. Hu LH, et al. [15] reported the extracts of *Lygodium japonicum* could significantly reduce the calcium, phosphorus and uric acid levels while raise the urine magnesium level in the urine of rats with renal calculus, and increase the urine output, so that reduced the contents of oxalate and calcium in renal tissue to inhibit the formation of calcium oxalate crystals in renal tissue.

The characteristics of tongue coating and pulse conditions of damp-heat syndrome with ureteral calculus are usually manifested as red tongue and yellow-greasy coating, smooth and rapid pulses. After 30 days of taking JDPS decoction, the tongue coating of patients in the treatment group gradually changed from red and greasy to pale-red and white color, while unchanged (still red tongue and coating greasy) significantly in the control group. The pulse conditions in the treatment group changed from smooth and rapid to deep pulse, while in the control group changed from smooth and rapid pulse to smooth pulse. After treatment, the tongue coating color and pulse conditions were significantly improved both in the two groups. The tongue coating color and pulse conditions were significantly improved than those in the control group, which suggested that the clinical effect of JDPS decoction was better than that of SHST granules [16].

The ureteral calculus mostly come from the kidney, which are common in the ureteropelvic junction, the site of ureter crossing iliac vessels, the female ureter through the basal part of broad ligament of uterus, the site of male ductus deferens across the ureter, and the ureterovesical junction including the ureter-opening in bladder. Simillar as the kidney calculus, the composition of ureteral calculus was mainly oxalate calculus, and secondary uric acid

calculus. The size and number of ureteral calculus can affect the drug efficacy. Most calculus with diameter less than 5 mm can be discharged naturally, and if the symptoms can be controlled, it can be cured by conservative drug treatment [17]. Recent studies [18] have proved that the average natural discharge time of calculus with diameter less than 4 mm is 1.6 weeks, and diameter 4-6 mm is 2.8 weeks, while which with diameter greater than 6 mm cannot be discharged naturally. The results of this study showed that after treatment, the size and number of ureteral calculus decreased significantly compared to before treatment both in the two groups, but no significant difference existed between the two groups. It shows that JDPS decoction and SHST granules have equal effects for discharging ureteral calculus.

The most important clinical reactions to ureteral calculus are low back pain on the one-side and microscopic hematuria. The pain is colic and could radiate to the ipsilateral lower abdomen and vulva area. Hematuria was mild, and most ones with only microscopic hematuria. Pain is an important symptom of ureteral calculus and seriously affects the quality of life [19]. The results of this study showed that the pain grade and pain time of patients were significantly lower lower than those before treatment both in the two groups, and which in the treatment group were significantly lower than those in the control group. It indicated that the analgestic effect of JDPS decoction was greater than that of SHST granules.

Increased urine volume is conducive to discharge calculus and avoid the formation of calculus [20]. Endogenous serum levels of Cr and BUN can reflect the glomerular filtration function [21]. The results of this study showed that urine volume increased significantly in the two groups, but no significant difference existed between the groups after treatment. After treatment, the serum levels of Cr and BUN were significantly reduced than those before treatment both in the two groups, and which in the treatment group were significantly lower than those in the control group. It indicated that JDPS decoction was more conducive to the recovery of renal function than that of SHST granules.

The mild elevation of blood leukocytes in the onset of renal colic is the stress response of the body, and the increasing of lymphocytes is more common in the recovery period of infection or inflammation [22]. Ureteral calculus and their triggered inflammation and infection could cause elevating urinary RBC and WBC [23]. The results of this study showed that after treatment, the numbers of WBC in urine and blood were significantly reduced than those before treatment both in the two groups, and which in the treatment group was significantly lower than those in the control group. After treatment, the numbers of WBC, neutrophil were significantly lower than those before treatment both in the two groups, and which in the treated group were significantly lower than those in the control group. This indicates that the anti-inflammatory and anti-infectious effect of JDPS decoction is stronger than that of SHST granules.

In conclusion, JDPS decoction has a good effect in treating damp-heat syndrome of ureteral calculus.

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Ethics Approval and Consent to Participate

All related experiments were approved by the Ethics Committee of Pingyi County People's Hospital (PYYXLL-LW-2023-018).

Conflicts of Interest Statement

The authors declare that there are no conflict of interest.

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