### Original Article Clinical effect of ultrasound-guided extracorporeal shock wave lithotripsy in the treatment of uncomplicated ureteral stones and the influencing factors

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Abstract: Objective: This study aimed to explore the clinical effect of ultrasound-guided extracorporeal shock wave lithotripsy (ESWL) in the treatment of uncomplicated ureteral stones and the influencing factors. Methods: We randomly assigned 207 patients with uncomplicated ureteral stones to receive either conventional ESWL (the control group) or ultrasound-guided ESWL (the observation group). The detection rate, rate of missed diagnosis, misdiagnosis rate, treatment effectiveness, surgery situation (the operation time, intraoperative blood loss, and the length of hospital stay), and postoperative complications were compared between the two groups. Factors influencing the efficacy of ultrasound-guided ESWL for treating ureteral stones were analyzed. Results: The observation group had a markedly higher detection rate (P = 0.000) and markedly lower rates of misdiagnosis and missed diagnosis (P = 0.000, P = 0.001) than the control group. The overall response rate was markedly higher in the observation group than in the control group (94.29% vs. 84.31%, P = 0.020). Compared with the control group, the observation group had remarkably shorter operation time (P < 0.05) and a lower incidence of complications (P = 0.006). The course of disease, stone size, and the position of the stone could affect the treatment effect (all P < 0.05). Middle ureteral stones, lower ureteral stones, a stone size of  $\geq$  10 mm, and a course of disease of  $\geq$  60 d were identified as independent dent risk factors affecting the treatment outcome (all P < 0.05). Conclusion: Ultrasound-guided ESWL is markedly effective in the treatment of uncomplicated ureteral stones. The stone size, the course of disease, and the position of the stone can affect the treatment outcome.

**Keywords:** Ultrasound-guided extracorporeal shock wave lithotripsy, uncomplicated ureteral stones, treatment effect, univariate analysis of influencing factors

#### Introduction

Ureteral stone, a common acute illness in urology, is characterized by recurrent attacks. Patients with ureteral stones often experience severe abdominal pain, nausea and vomiting, and in severe cases, perineal pain and hematuria [1-3]. Untreated ureteral stones can cause hydronephrosis and perihepatic effusion, which damage the renal function and endanger the life and health of patients. Clinical researchers have been seeking for treatment methods with simple procedures, significant effect, and few complications for ureteral stones [4, 5]. Ultrasound-guided extracorporeal shock wave lithotripsy (ESWL), a new technology to treat ureteral stones, uses high-energy shock waves to break the stones so that the stone fragments can be excluded from the body, with a high accuracy in detecting and locating the stone under ultrasound guidance [6, 7]. Clinically, there is neither comprehensive analysis nor sufficient data on the clinical efficacy and influencing factors of this technology. Here we explored the clinical treatment effect of ultrasound-guided ESWL in patients with uncomplicated ureteral stones and analyzed factors affecting the treatment outcome.

#### Materials and methods

#### General clinical data

Totally 207 patients with uncomplicated ureteral stones admitted to The First Hospital of Yulin from January 2018 to December 2019 were included into this study and randomly assigned to the control group (102 patients, with an average age of  $48.8 \pm 8.7$  years) and the observation group (105 patients, with an average age of  $49.1 \pm 9.1$  years). The two groups were comparable since they were not significantly different in sex ratio, age, and the course of disease. All patients signed the written informed consent. This study was approved by the Ethics Committee of The First Hospital of Yulin.

Inclusion criteria: Patients meeting the diagnostic criteria for uncomplicated ureteral stones [8]; patients with good compliance to actively cooperate with medical staff; patients with no serious damage in important organs such as heart, liver, and kidneys.

Exclusion criteria: Patients with mental disorders; patients during pregnancy or lactation; patients with hepatorenal, cardiovascular, or hematopoietic diseases; patients with bilateral ureteral stones, multiple stones, or comorbid kidney stones; patients with distal ureteral obstruction.

#### Methods

Patients in the control group were treated with conventional SWL. Patients had normal blood pressure, renal function, and expression levels of routine hematuria markers before surgery. In the evening before the operation, patients were required to take 10 g of senna after mixing it with water to clean the intestines and eliminate intestinal gas. We checked the ureter, three anatomic sites of narrowing, and the severity of hydronephrosis to make sure there was no organic ureteral stenosis. We selected appropriate surgical positions for patients according to the position of the stone to better locate the stone, and then we employed the ESWL machine to perform the treatment.

Patients in the observation group were treated with ultrasound-guided ESWL. We selected appropriate surgical positions for patients: a supine position for patients with upper ureteral stones and a prone position for patients with

middle or lower ureteral stones. We used a convex array transducer (3.8 MHZ) combined with an ultrasound instrument to identify the position of the stone and made sure the midline of the positioning mark just passed the stone. Then we measured the distance between the stone and the skin and marked the position of the stone on the body surface. The operating voltage and shock frequency of the WSWL instrument were set at 8-14 KV and 1,600-2,700, which were adjusted according to the actual surgery situation of the patient [9, 10]. We closely monitored the occurrence of adverse reactions after surgery in all patients and provided conventional anti-inflammatory, analgesic, hemostatic, and antispasmodic drugs.

#### Outcome measures and efficacy evaluation

A marked response refers to basically disappeared clinical symptoms after surgery and totally disappeared stone shadow according to the X-ray or ultrasound examination, requiring no stage II surgery. A moderate response refers to basically disappeared stones according to the reexamination results 1-2 months after surgery and a need for drug therapy. No response refers to the remaining of stones or aggravated condition according to the reexamination results 1-2 months after surgery.

The overall response rate = (the number of marked response cases + moderate response cases)/total number of patients × 100%.

Detection rate = the number of patients with detected stones/total number of patients × 100%.

Misdiagnosis rate refers to the probability of errors in the diagnosis of patients, which was based on what was seen during the operation. The misdiagnosis rate = the number of misdiagnosed cases/total number of patients × 100%.

Rate of missed diagnosis refers to the probability of hidden stones that were not detected, which was based on what was seen during the operation. Rate of missed diagnosis = the number of missed diagnoses/total number of patients  $\times$  100%.

We recorded the surgery situation, including the operation time and the postoperative hospital stay.

Index	Control	Observation	
	group	group	
Male Female (case)	76/26	78/27	
Age (year)	48.8 ± 8.8	49.1 ± 9.1	
Course of disease (month)	8.0 ± 1.0	6.8 ± 1.1	
Site of disease			
Left	54	50	
Right	48	55	
Stone size (cm)	1.43 ± 0.67	1.39 ± 0.69	
Р	0.521	0.598	

Table 1. Comparison of general clinical	data
between patients in two groups	

Postoperative complications were also recorded, including hematuria, high fever, ureter stone street, and kidney damage. The total incidence of complications = the number of patients with complications/total number of patients × 100%.

#### Data processing and analysis

Statistical analysis was performed using the SPSS17.0. The measurement data were expressed as mean  $\pm$  standard deviation ( $\overline{x} \pm$  sd) and their intergroup comparison was analyzed by the independent sample t-test. Count data were expressed as n and their intergroup comparison was analyzed by the chi-square test. A univariate analysis based on a logistic regression model was performed to analyze whether age, sex, stone position, stone diameter, affected side, and the course of disease were independent risk factors affecting the treatment outcome. The chi-square test was used for single-factor screening, and the logistic regression analysis was followed if P < 0.05. Inclusion criteria: (1) patients aged 15-70 years; (2) patients with a stone diameter of less than 0.5 cm and greater than 0.2 cm. Exclusion criteria: (1) Patients with urinary tract obstruction below the stone; (2) patients during pregnancy; (3) patients with inflammation or acute infection; (4) patients with distal cavity obstruction or urinary tract malformation; (5) patients with malignant tumors. The difference was statistically significant when P < 0.05.

#### Results

#### Comparison of general clinical data

The two groups were comparable since they were not significantly different in sex, age, the

course of disease, site of the disease, and stone size (P > 0.05). More details are shown in **Table 1**.

#### Comparison of the stone detection rate

In the control group, 32 patients had upper ureteral stones, 21 had middle ureteral stones, and 22 had lower ureteral stones. In the observation group, 43 patients had upper ureteral stones, 32 had middle ureteral stones, and 30 had lower ureteral stones. The detection rate was markedly higher in the observation group than in the control group (100.00% vs. 73.53%, P = 0.000), and the difference between the two groups was statistically significant. More details are shown in **Table 2**.

## Comparison of the misdiagnosed rate and the rate of missed diagnosis

The rate of missed diagnosis was markedly higher in the control group than in the observation group (9.80% vs. 0.00%, P = 0.001), and the misdiagnosis rate was markedly higher in the control group than in the observation group (16.67% vs. 0.00%, P = 0.000). We then made a correct diagnosis for patients with a previous misdiagnosis. The differences in the rate of missed diagnosis and the misdiagnosis rate between the two groups were statistically significant. More details are shown in **Table 3**.

#### Comparison of treatment outcomes

In the control group, 45 patients had a marked response and 41 patients had a moderate response, with an overall response rate of 84.31%. In the observation group, 58 cases had a marked response and 41 patients had a moderate response. The overall response rate was markedly higher in the observation group than in the control group (94.29% vs. 84.31%, P = 0.020), and the difference was statistically significant. More details are shown in **Table 4**.

#### Comparison of the surgery situation

The operation time was  $73.1 \pm 8.1$  min in the control group and  $62.0 \pm 7.2$  min in the observation group, the intraoperative blood loss was  $67.09 \pm 7.09$  mL in the control group and  $66.99 \pm 7.02$  mL in the observation group, and the length of hospital stay was  $6.3 \pm 0.9$  d in the control group and  $6.5 \pm 0.7$  d in the observation group. The operation time was significantly

Group	Cases (n)	Upper ureteral stones	Middle ureteral stones	Lower ureteral stones	Detection rate (%)
Control group	102	32	21	22	75 (73.53)
Observation group	105	43	32	30	105 (100.00)
X <sup>2</sup>		39.026	28.930	26.321	31.963
Р		0.002	0.003	0.004	0.000

Table 2. Comparison of stone detection rate between patients in two groups

**Table 3.** Comparison of the misdiagnosed rateand the rate of missed diagnosis between pa-tients in two groups (n, %)

Group	The rate of	Misdiagnosed	
Gloup	missed diagnosis	rate	
Control group	10 (9.80)	17 (16.67)	
Observation group	0 (0.00)	0 (0.00)	
X <sup>2</sup>	10.817	19.066	
Р	0.001	0.000	

shorter in the observation group than in the control group (P = 0.000). There were no significant differences in the intraoperative blood loss and the length of hospital stay between the two groups (P = 0.065, P = 0.087). More details are shown in **Table 5**.

#### Comparison of the incidence of complications

In the control group, 7 patients had a hemorrhage, 5 had a hydropneumothorax, and 8 had organ damage. In the observation group, 3 patients had a hemorrhage, 2 had a hydropneumothorax, and 2 had organ damage. The total incidence of complications was markedly lower in the observation group than in the control group (6.67% vs. 19.61%, P = 0.006). More details are shown in **Table 6**.

# Univariate analysis of factors affecting the treatment effect of ultrasound-guided ESWL in patients with uncomplicated ureteral stones

We conducted a univariate analysis on the patient's age, sex, stone position, stone diameter, the affected side, and the course of disease and identified that the stone position, stone diameter, and the course of disease were the main factors affecting the treatment effect of the surgery (all P < 0.05). More details are shown in **Table 7**. The treatment outcomes of ultrasound-guided ESWL in patients with different stone positions are shown in **Figures 1-3**.

Logistic regression analysis of factors affecting the treatment effect of ultrasound-guided ESWL in patients with uncomplicated ureteral stones

We conducted a logistic regression analysis of the stone position, stone size, and the course of disease of patients. The results revealed that the middle-lower ureteral stones, a stone size of  $\geq$  10 mm, and a course of disease of  $\geq$ 60 d were independent risk factors affecting the treatment outcome (all P < 0.05). More details are shown in **Table 8**.

#### Discussion

As a prevalent urinary system emergency, ureteral stone has an incidence of 25% to 30%, more common in men than in women according to clinical statistics [11]. The pathogenesis of ureteral stones is the downward movement of kidney stones to the ureter, causing ureteral stenosis or blockage, ureteric spasm, and renal colic in severe cases [12, 13]. Most ureteral stones are in severe condition and have an acute onset. Ureteral stones not only have a significant impact on the patient's life and work, but also induce diseases such as renal failure and uremia if not diagnosed and treated in time [14]. Ultrasound-guided ESWL is currently widely used in the clinical treatment of stones, with simple operation procedures, significant effects, and few adverse reactions. It is a combination of ultrasound-based real-time position monitoring and ultrasonic lithotripsy technology to improve the rate of stone removal [15, 16]. In normal patients, the ureter is not easily seen. The ureter will dilate and the urine excretion will be blocked when stones are lodged in the ureter. Under conventional diagnostic techniques, the stones are mostly blurred and the acoustic shadowing is not obvious, making it difficult to check the state of illness. However, ultrasound-based diagnosis provides a clear view of the shape and size of the stones.

Table 4.	Comparison	of treatment	outcomes	between	patients in	n two
groups						

Group	Marked response	Moderate response	No response	Overall response rate (n, %)
Control group	45	41	16	86 (84.31)
Observation group	58	41	6	99 (94.29)
X <sup>2</sup>	6.235	4.269	5.263	5.417
Р	0.013	0.029	0.037	0.020

 Table 5. Comparison of the surgery situation between two groups

Index	Control group	Observation group	t	Р
Operation time (min)	73.1 ± 8.1	62.0 ± 7.2	10.428	0.000
Intraoperative blood loss (mL)	67.09 ± 7.09	66.99 ± 7.02	1.098	0.065
Length of hospital stay (d)	6.3 ± 0.9	6.5 ± 0.7	0.654	0.087

**Table 6.** Comparison of the incidence of complications between patients in two groups

Group	Hemorrhage	Hydroppoumothoray	Organ	Total
		пушорпешносногах	damage	incidence
Control group	7	5	8	20 (19.61)
Observation group	3	2	2	7 (6.67)
X <sup>2</sup>	3.065	4.069	6.980	7.640
Р	0.003	0.005	0.001	0.006

**Table 7.** The univariate analysis of factors affecting the treatmenteffect of ultrasound-guided ESWL in patients with uncomplicatedureteral stones (n)

Factors	Case	Success	Failure	χ²	Р
Age (year)				0.648	0.421
≥ 60	45	40	5		
< 60	60	50	10		
Gender				0.846	0.358
Male	78	69	9		
Female	27	22	5		
Stone position				5.237	0.037
Upper ureteral stones	45	28	17		
Middle ureteral stones	29	17	12		
Lower ureteral stones	31	15	16		
Stone diameter (mm)				5.092	0.021
≥ 10	30	12	18		
< 10	75	55	20		
Affected side				0.864	0.543
Left	50	24	26		
Right	55	27	28		
Course of disease (d)				6.095	0.019
≥60	78	24	54		
< 60	27	20	7		

Note: ESWL: extracorporeal shock wave lithotripsy.

In this study, the observation group had a markedly higher detection rate, a markedly lower incidence of complications, and markedly lower rates of missed diagnosis and misdiagnosis, indicating that ultrasound is more beneficial for the observation of ureteral stones. Conventional diagnosis is difficult to separate the ureter from surrounding tissues. However, ultrasound observation can clearly separate the ureter with a blood flow signal from the ureter without a blood flow signal, which is convenient for physicians to diagnose ureteral stones, leading to a higher detection rate of ureteral stones. The locating of stones by conventional diagnosis may be disturbed by obesity or intestinal gas, which results in indistinct images. During ultrasound localization, the physician performs a longitudinal scan of the patient's groin and umbilical midpoint and appropriately pressurizes the transducer to show the arteries, which is beneficial to find ureteral echoes [17, 18]. In the present study, the observation group had a higher treatment response rate and shorter operation time than the control group, indicating that ultrasound-guided ESWL can more quickly and accurately locate the stones and shorten the scanning time. Inaccurate positioning of the stone site can cause a series of complications such as bleeding [19, 20]. Ultrasound localization can enhance the accuracy of diagnosis and prevent complications.



Figure 1. Upper ureteral stones at the ureteropelvic junction. A: Ultrasound image before treatment. B: Ultrasound image after treatment.



Figure 2. Middle ureteral stones at where the ureter crosses the iliac vessel.



Figure 3. Lower ureteral stones at the ureterovesical junction.

Here the univariate analysis demonstrated that the stone position, stone size, and the course of disease can affect the treatment effect, and then the logistic regression analysis revealed that the middle-lower ureteral stones, a stone size of  $\geq$  10 mm, and a course of disease of  $\geq$ 

60 d were independent risk factors affecting the treatment outcome (all P < 0.05). Such results indicate that patients with middle or lower ureteral stones have a larger stone size and a longer course of disease, facing greater difficulty in the break and removal of stones. A larger stone will dwell in the ureter for a longer time and has a smaller chance to be discharged from the body on its own, which will easily lead to ureteral obstruction. What's more, a large stone is difficult to be smashed by the surgery, often requiring multiple attempts. Compared with the upper ureteral stones, the middle and lower ureteral stones show a smaller response to the treatment, because the smash of the middle and lower ureteral stones by the shock wave may be weakened by the lower abdominal and pelvic internal organs. A longer course of disease results in a worse effect of ultrasound-guided ESWL, because the long-time detention of stones in the ureter leads to an inflamed and thicker ureter wall, a narrowed lumen, a smaller liquid space, and a decreased cavitation capacity, attenuating the smashing power of the ESWL [21].

This study is deficient due to the small sample size. We will include more samples in the future to obtain more accurate and reliable data and analyze more influencing factors such as the patient's living habits.

In summary, ultrasound-guided ESWL can significantly improve the treatment effect, enhance the diagnostic accuracy, shorten the operation time, and reduce the harm to patients. Patients with a longer course of disease and larger stones close to the middle or lower

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Factors	Р	Wald value	β value	OR value	95% CI
Stone position					
Middle ureteral stones	0.012	7.097	0.769	1.764	1.098-2.326
Lower ureteral stones	0.023	12.087	0.543	1.901	1.012-3.098
Stone diameter $\ge$ 10 mm	0.009	6.775	0.909	2.321	1.436-4.092
Course of disease $\geq$ 60 d	0.032	5.097	0.408	1.539	1.012-3.013

**Table 8.** The logistic regression analysis of factors affecting the treatment effect of ultrasound-guidedESWL in patients with uncomplicated ureteral stones

Note: ESWL: extracorporeal shock wave lithotripsy.

parts of the ureter face a higher difficulty to remove stones successfully by the surgery.

#### Disclosure of conflict of interest

None.

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