European Review for Medical and Pharmacological Sciences 2022; 26: 3185-3191

Retrospective study of visualized ultra-mini percutaneous nephrolithotripsy *vs.* flexible ureterorenoscopy for nephrolithiasis patients with 1.5-2.5 cm kidney stones and without hydronephrosis

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Abstract. – OBJECTIVE: To investigate the safety and efficacy of visualized ultra-mini percutaneous nephrolithotripsy (VUMP) and flexible ureterorenoscopy (FURS) in the treatment of nephrolithiasis patients with 1.5-2.5 cm kidney stones and without hydronephrosis.

PATIENTS AND METHODS: The clinical data of 143 nephrolithiasis patients without hydronephrosis (from April 2017 to March 2021) were collected and analyzed, including 65 cases in the VUMP group and 78 cases in the FURS group. The general clinical data, operation time, hospitalization time, recent stone-free rate (RSFR), long-term stone free rate (four weeks after operation, LSFR), Visual Analogue Scale (VAS), Bruggermann comfort score (BCS), and surgical complications of the two groups were collected and analyzed.

RESULTS: In the VUMP group, the operation time (49.14 ± 9.28 *vs.* 60.23 ± 9.45, $p < 0.001$), postoperative white blood cell count (11.05 ± 2.43 *vs.* 13.57 ± 2.71, $p < 0.05$) and BCS score (1.72 ± 0.80 *vs.* 2.81 ± 0.85, $p < 0.001$) were significantly lower than those of the FURS group, but the postoperative hemoglobin (8.25 ± 5.04 *vs.* 4.05 ± 3.07, $p < 0.05$), hospital stay (5.72 ± 1.75 *vs.* 3.12 ± 1.09, $p < 0.001$) and VAS score (3.18 ± 1.36 *vs.* 2.08 ± 1.28, $p < 0.001$) were significantly higher than those of the FURS group. Besides, the VUMP group was significantly higher than the FURS group in RSFR (90.32% *vs.* 72.22%, $p < 0.05$) and LSFR (95.38% *vs.* 85.89%, $p < 0.05$). The systemic inflammatory response syndrome rate (3.07% *vs.* 14.10%, $p = 0.037$) and total complications (9.23% *vs.* 20.51%, $p = 0.032$) were significantly lower in the VUMP group than in the FURS group.

CONCLUSIONS: Both VUMP and FURS are safe and effective in the treatment of nephrolithiasis patients with 1.5-2.5 cm kidney stones and without hydronephrosis, and the former is preferable for higher SFR, shorter operation time and lower complication rate.

Key Words:
Kidney stones, Nephrolithiasis patients without hydronephrosis, "All-seeing needle" optical puncture system, Ultra-mini percutaneous nephrolithotripsy, Flexible ureterorenoscopy, Safety, Efficacy.

Introduction

Nephrolithiasis is a common and frequent disease in the urinary system. The incidence rate is about 14.8%, and the recurrence rate is 50% in the first 5 years of the initial stone episode[1]. The etiology of nephrolithiasis is complex and probably related to heredity, metabolism, infection, environment, diet, anatomy, medicine, and other factors[1-3]. At present, the main operation methods of renal calculi are flexible ureteroscopy (FURS) and percutaneous nephrolithotomy (PCNL)[4,5]. In recent years, the treatment of renal calculi with FURS has rapidly developed. Current research suggests that FURS can be used to treat nephrolithiasis with kidney stones of 2-3 cm[6,7]. However, there are some disadvantages of FURS, such as infection, low SFR, high-pressure-caused renal injury, etc[6-8]. PCNL is the main surgical method for renal calculi larger than 2 cm and has a higher stone-removing rate but a lower invasion rate than open surgery[9,10]. However, PCNL is a kind

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of invasive surgery with high technical requirements, and has disadvantages, including bleeding and damage to the kidney and adjacent tissue and organs[9-11].

In 2011, Bader et al[12] adopted a visualized puncture technique in PCNL for the treatment of nephrolithiasis and proposed an "all-seeing needle" as the name of the technique. Compared with conventional PCNL, the visualized ultra-mini percutaneous nephrolithotripsy (VUMP) can significantly reduce the risk of bleeding and damage to the kidney and adjacent tissue and organs[12-14]. However, there have been few reports on the efficacy and safety of VUMP and FURS in the treatment of nephrolithiasis patients with 1.5-2.5 cm kidney stones and without hydronephrosis. In this paper, the authors collected the clinical data of 143 cases of VUMP and FURS in the hospital the authors worked at from April 2017 to March 2021 and compared the efficacy and safety between the two types of lithotripsy in the treatment of nephrolithiasis patients with 1.5-2.5 cm kidney stones and without hydronephrosis to provide reference for the clinical treatment of nephrolithiasis patients without hydronephrosis.

Patients and Methods

Case Collection

Between April 2017 to March 2021, the clinical data of 143 nephrolithiasis patients without hydronephrosis were collected and analyzed, including 65 cases in the VUMP group and 78 cases in the FURS group. The criteria for case collection were as follows: (1) nephrolithiasis patients without hydronephrosis diagnosed by urinary CT; (2) the stone size range was 1.5-2.5 cm; (3) patients underwent the renal stone surgery for the first time; (4) patients were above the age of 22 years. Meanwhile, the criteria for case exclusion were as follows: (1) patients with horseshoe or cavernous kidneys, or kidneys of other abnormal structures; (2) patients with a previous history of kidney stone surgery; (3) patients with missing clinical data or incomplete data. The study was performed in compliance with the ethical standards of the institutional and/or national research committee and the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. All patients included in this study signed informed consent, and this study was approved by the Ethics Committee of the Affiliated Southeast Hospital of Xiamen.

Surgical Methods and Instruments

The specific operation methods and standard procedures of visualized PCNL and RIRS are the same as those reported in previous literature[12-19]. A PolyDiagnost (Pfaffenhofen, Germany) was used as the visualized puncture system. When a puncture was made in a patient, a fascial dilator was used to expand it to 12 Fr, then a 12Fr disposable peeling sheath was indwelled, and an 8 Fr nephroscope was used in the sheath. A Lumenis medical laser device (America) with optical fibers was used as the holmium laser, an Olympus electronic ureteroscope (Olympus, Japan) as the soft ureteroscope, and the soft ureteral sheath used hereby was from COOK Medical. The FURS laser pulse energy was set at 1.0-1.2 J, with the frequency of 20-25 Hz, and 200 μm laser fibers were hereby used. In addition, the VUMP laser pulse energy was set as 1.0-1.2 J, with the frequency of 20-25 Hz, and 200 μm laser fibers were hereby used. After surgery, the double J ureteral tubes were retained for four weeks, and the abdominal plain film and CT were used to evaluate the recent stone-free rate (within two days after surgery, RSFR) and long-term stone free rate (four weeks after surgery, LSFR). The definition of stone-free is that no stone is shown in the image, or the residual stones in the urinary tract are less than 2 mm.

Clinical Data Collection

The general clinical data, operation time, hospitalization time, RSFR, LSFR and surgical complications of the two groups were collected and analyzed. The visual analogue scale (VAS) and Bruggrmann comfort scale (BCS) data of the two groups were collected for the analysis the next day. Blood routine, procalcitonin, and C-reactive protein were collected and analyzed before and 2 hours after surgery. The diagnostic criteria for urinary sepsis are the same as previously reported[20-22]. The diagnostic criteria for systemic inflammatory response syndrome (SIRS) were as follows: (1) body temperature < 38°C or > 38°C; (2) pulse > 90 beats/min; (3) Breathing > 20/min; (4) WBC > 12×10^9/L or WBC < 3×10^9/L. When any two of the four conditions here in above were met, SIRS could be diagnosed.

Statistical Analysis

SPSS 20.0 (IBM Corp., Armonk, NY, USA) was used for data analysis. The continuous or categorical data are presented as the mean ± standard deviation (SD), frequency, percentile,

Table I. Comparison of clinical baseline data between VUMP and FURS groups.

Parameter		VUMP group (N = 65)	FURS group (N = 78)	*p*-value
Gender (%)	Male	38 (58.46%)	40 (51.28%)	–
	Female	27 (41.54%)	38 (48.72%)	0.391
Age (year)		42.90 ±13.44	43.06 ± 12.32	0.942
BMI (kg/m^2)		26.02 ± 4.73	26.78 ± 5.31	0.141
Affected kidney	Left	35 (53.84%)	41 (52.56%)	
	Right	30 (46.16%)	37 (47.44%)	0.816
Stone location	Renal pelvis	47 (72.31%)	52 (66.67%)	
	Lower calyceal stones	18 (27.69%)	26 (33.33%)	0.467
Stone size (cm)		2.07 ± 0.27	1.98 ± 0.31	0.098
Diabetes		8 (9.67%)	10 (9.25%)	0.451
Hypertension		9 (13.85%)	12 (15.38%)	0.905
Coronary heart disease		4 (6.15%)	8 (10.25%)	0.378

and range, as appropriate. K-S single sample tests were used to calculate the normal distribution of continuous variables before further comparison. The Student's *t*-test and Wilcoxon test were used to compare the clinical characteristics of the VUMP and FURS groups. The variables in the contingency table were analyzed by χ^2 tests (or Fisher exact tests). When $p < 0.05$, the difference was significant.

Results

Comparison of General Clinical Data Between VUMP and FURS Groups

This study retrospectively analyzed 143 nephrolithiasis patients without hydronephrosis, including 65 in the VUMP group and 78 in the FURS group. The average age of the subjects was 42.99 ± 12.79, and the average size of the kidney stones was 2.02 ± 0.30. As shown in Table I, the patients in the VUMP and FURS groups were similar in gender, age, BMI, affected part of kidneys, location of stones, size of stones, and combined diseases, without significant difference ($p > 0.05$).

Comparison of Operation Indexes and Stone-Free Rate Between VUMP and FURS Groups

As shown in Table II, the VUMP group was significantly lower than the FURS group in terms of operation time (49.14 ± 9.28 *vs.* 60.23 ± 9.45, $p < 0.001$) and BCS score (1.72 ± 0.80 *vs.* 2.81 ± 0.85, $p < 0.001$), but had significantly more postoperative hemoglobin changes (14.62 ± 5.78 *vs.* 7.98 ± 3.27, $p < 0.001$), hospital stay (5.72 ± 1.75 *vs.* 3.12 ± 1.09, $p < 0.001$) and higher VAS scores (3.18 ± 1.36 *vs.* 2.08 ± 1.28, $p < 0.001$) than the FURS group. In terms of SFR, the VUMP group is significantly higher than the FURS group regarding RSFR (90.77% *vs.* 73.08%, $p = 0.007$) and LSFR (95.38% *vs.* 85.89%, $p = 0.036$). There is no significant dif-

Table II. Comparison of surgery and stone-free rate indicators between VUMP and FURS groups.

Parameter	VUMP group (N = 65)	FURS group (N = 78)	*p*-value
Operation time (min)	49.14 ± 9.28	60.23 ± 9.45	< 0.001
Hemoglobin changes (g/L)	14.62 ± 5.78	7.98 ± 3.27	< 0.001
hospital stay (d)	5.72 ± 1.75	3.12 ± 1.09	< 0.001
VAS score	3.18 ± 1.36	2.08 ± 1.28	< 0.001
BCS score	1.72 ± 0.80	2.81 ± 0.85	< 0.001
Procalcitonin (ng/ml)	0.10 ± 0.04	0.09 ± 0.05	0.658
C-reactive protein (mg/ml)	23.43 ± 19.09	27.81 ± 25.73	0.258
leukocyte count (10^9/L)	9.69 ± 2.68	10.53 ± 2.93	0.082
RSFR (%)	59 (90.77%)	57 (73.08%)	0.007
LSF (%)	62 (95.38%)	67 (85.89%)	0.036

VAS: Visual analogue scale; BCS: Bruggrmann comfort scale; RSFR: recent stone free rate (first day after operation); LSFR: long-term stone free rate (four weeks after operation).

ference in the procalcitonin, C-reactive protein or white blood cell counts between the VUMP and FURS groups ($p > 0.05$).

Comparison of Operative Complications Between VUMP and FURS Groups

As shown in Table III, there was no significant difference between the VUMP and FURS groups in the complications of postoperative bleeding, renal colic (1.53% *vs.* 2.56%, $p = 0.626$), urinary sepsis (0% *vs.* 1.28%, $p = 1.00$), perirenal hematoma, perirenal effusion (0% *vs.* 2.56%, $p = 0.501$) ureteral injury or death rate. However, the SIRS rate (3.07% *vs.* 14.10%, $p = 0.037$) and total complications (9.23% *vs.* 20.51%, $p = 0.032$) were significantly lower in the VUMP group than in the FURS group.

Discussion

Nephrolithiasis patients without hydronephrosis have kidney stones that are located in the kidney cavities or pelvis but have no obstruction of the urinary system. Besides, nephrolithiasis without hydronephrosis is a common type of urinary calculi, and some patients have obvious clinical symptoms. Since some of the stones are located in the lower calyces of the kidneys, extracorporeal shock wave lithotripsy is less effective[23,24]. At present, for 1.5-2.5 cm kidney stones, the main clinical treatment options are PCNL and FURS. As the retrograde treatment of nephrolithiasis is performed through natural cavities, FURS has the advantages of less bleeding and trauma, and fewer complications, thus is currently the main surgical method for the treatment of nephrolithiasis with kidney stones < 2 cm[25]. However, since the space of the renal pelvis is narrow and small and some stones are located in the lower calyces of the kidneys, in nephrolithiasis patients without hydronephrosis the space of FURS is limited, making the operation difficult to perform. Therefore, FURS has the disadvantages of low SFR, long operation time, high cost, and high incidence of SIRS after surgery[26-29]. Although conventional PCNL is better than FURS in SFR and operation time, it also has many disadvantages regarding the difficulty in puncturing, the incidence of postoperative bleeding and peripheral organ damage, the amount of hemoglobin loss, the duration of hospital stay, etc[6,7,26,27]. Therefore, it is of great clinical value to explore a surgical method to treat nephrolithiasis with 1.5-2.5 cm kidney stones.

With the development of technology and medical devices, the "all-seeing needle" system and ultra-mini PCNL are developing rapidly in the treatment of nephrolithiasis[12,17-19,30]. Compared to conventional PCNL, the "all-seeing needle" system and ultra-mini PCNL can significantly reduce the risk of bleeding and damage to the kidneys and adjacent organs[12,17-19,30]. Previous studies[12,17-19,26-30] have suggested that, compared with FURS, the "all-seeing needle" system and ultra-mini PCNL can significantly improve the SFR in the treatment of lower calyx calculi and renal pelvis calculi smaller than 3 cm, without increasing the incidence of surgical complications, indicating that they are safer and more effective. In this study, the authors combined the "all-seeing needle" system and ultra-mini PCNL for the treatment of nephrolithiasis with 1.5-2.5 cm kidney stones and without hydronephrosis and found that the VUMP group was significantly better than the FURS group in terms of surgical time, RSFR and LSFR. However, compared to FURS group, VUMP group showed a significant increase in hemoglobin change, hospital stay and

Table III. Comparison of surgical complications between the two groups of patients.

Parameter (%)	VUMP group (N=65)	FURS group (N=78)	*p*-value
Postoperative bleeding	0 (0)	0 (0)	–
SIRS rate	4 (3.07%)	11 (14.10%)	0.037
Renal colic	1 (1.53%)	3 (2.56%)	0.626
Urinary sepsis	0 (0)	1 (1.28%)	1.00
Perrenal hematoma	0 (0)	0 (0)	–
Perirenal effusion	0 (0)	2 (2.56%)	0.501
Peripheral organ damage	0 (0)	0 (0)	–
Ureteral injury	0 (0)	0 (0)	–
Death rate	0 (0)	0 (0)	-
Total complications	5 (9.23%)	16 (20.51%)	0.032

SIRS: systemic inflammatory response syndrome (SIRS).

VAS score and a significant decrease in BCS score. Therefore, the results suggest that VUMP has the advantages of short operation time and high SFR in the treatment of nephrolithiasis with 1.5-2.5 cm kidney stones, but provides poor patient comfort.

PCNL is an invasive operation with high technical requirements and can cause serious complications, such as infection, bleeding, and damage to the kidneys and adjacent organs[31,32]. Relevant literature[31,32] reports that the incidence of blood transfusion after PCNL is 5-8%, and the incidence of vascular interventional embolization is 0.3-1.4%. The postoperative complications of PCNL are often related to the location and size of the operation channel. In order to reduce bleeding and damage to adjacent organs after PCNL, the "all-seeing needle" system and micro channel have been gradually used for operation[12,17-19,26-30,31,32]. In this study, the authors found that there was no significant difference between the VUMP and FURS groups in the incidence of postoperative bleeding, peripheral organ injury, perirenal hematoma, perirenal effusion or ureteral injury. However, the incidence of total complications was significantly lower in the VUMP group than in the FURS group (9.23% *vs.* 20.51%, respectively; $p = 0.032$). The results suggest that VUMP had similar minimally invasive advantages to those of the FURS group but was superior to the latter in terms of the overall complication rate. The incidence of SIRS in patients with urinary calculi after endoluminal endoscopy was about 8.6-11.4%[31-33]. Failure to put the condition of a patient under control may lead to urinary sepsis or even death of the patient[31-33]. Previous studies[34,35] suggest that intrapelvic pressure > 30 mmHg and prolonged surgery are independent risk factors for SIRS and urogenic sepsis after endoscopy. In this study, the authors found that there was no significant difference between the VUMP and FURS groups in related postoperative inflammatory indicators (procalcitonin, C-reactive protein, leucocyte count). However, the authors also found that the incidence of SIRS (3.07% *vs.* 14.10%, $p = 0.037$) and urinary sepsis (0% *vs.* 1.28%, $p = 1.00$) in the VUMP group was lower than that in the FURS group. Although the difference in urinary sepsis is statistically insignificant, these results show a high incidence of SIRS and urinary tract sepsis after FURS in individual patients. This could have happened because the operation time of the VUMP group was shorter, and a negative pressure suction device was used to reduce the internal pressure of the renal pelvis during operation to reduce the incidence of urogenic sepsis and SIRS.

Although this study found that VUMP had the advantages of short operation time, high SFR, and low complication rate compared with FURS, there are still some limitations. First, this is a retrospective study, not a double-blind randomized controlled trial in design. Second, the sample size of the study was small, thus the conclusion needs to be verified by a large sample. Third, this study has all the limitations and risks of the inherent bias in the study design. Fourth, based on the surgical experience and skills of the surgical operator, the results of this study can only represent the conclusions of the hospital in which the authors worked.

Conclusions

According to this study, VUMP and FURS are both safe and effective in the treatment of nephrolithiasis with 1.5-2.5 cm kidney stones and without hydronephrosis, and the former has the advantages of high SFR, short operation time, and low complication rate.

Conflict of Interest

The Authors declare that they have no conflict of interests.

Funding

This study was supported by the project No. 18y007 of the youth nursery fund of the 909th Hospital of the people's Liberation Army.

Authors' Contribution

ZL and LMH: designing the study, analyzing the extracted data, writing the first manuscript draft. YZY and LH: searching the literature, extracting and analyzing the data. ZHR and GQH: analyzing the data, providing critical scientific input. ZYH and ZL, LMH and LJY: resolving discrepancies about the quality of the included studies, reviewing the manuscript, providing critical scientific input. All authors approved the final version of this manuscript.

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