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## Article

# Clinical Efficacy of Digital Flexible Ureteroscopy for Renal Stone Management and Postoperative Quality of Life for the Treatment of Lower Pole Stones: A Single Center, Non-Randomised, Cohort Study

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**Abstract:** *Objectives:* This study aimed to evaluate the safety and efficacy of digital flexible ureteroscopy in the management of lower pole stones and to assess patients' postoperative quality of life. *Methods:* A longitudinal, single-center, nonrandomized cohort study was conducted on patients with renal calculi eligible for flexible ureteroscopy. The study population comprised 44 patients diagnosed with treatment of lower pole stones who underwent treatment at Bach Mai Hospital between January 2023 and October 2024. Surgical outcomes, including surgery duration, stone-free rate, duration of hospitalization, surgical complications, and quality of life, were evaluated and monitored during the follow-up period. *Results:* The mean age of the patients was 51.4 years, and the mean stone size was 13.7 mm. Immediately postoperative stone-free rates were 79.5 %, 77.3 % at 1-month and 68.2 % at 3-month. The mean operative time was 73.4 minutes, the lithotripsy duration was 55.7 minutes, and the average hospital stay was 5.7 days. Only 1 minor complication (2.3%) was recorded. The quality-of-life scores significantly improved over time ( $p < 0.001$ ), with most patients reporting no disruption to daily activities after 1 month. *Conclusions:* Single-use digital flexible ureteroscopy is a safe and effective modality for managing lower pole renal stones, offering high stone-free rates, low complication rates, and significant improvements in patient quality of life. Further large-scale, controlled studies are needed to confirm these findings and evaluate long-term outcomes.

**Keywords:** digital flexible ureteroscopy; renal stones; stone-free rate; lower pole stones; quality of life

## 1. Introduction

Urinary calculi represent one of the most prevalent urological conditions. The prevalence varies on the basis of geographical location, climate, ethnicity, dietary habits, and genetic predisposition. Globally, the prevalence is notably high, with reported rates ranging from 7–13% in North America, 5–9% in Europe, and approximately 1–5% in Asia [1]. The prevalence of renal calculi in Vietnam is recognized as 2–12%, of which approximately 40% are renal calculi [2]. This elevated incidence is potentially associated with dehydration due to high ambient temperatures during the summer months, resulting in reduced urine output [3]. With the ongoing rise in global temperatures attributable to climate change, projections suggest that the number of individuals affected by urinary stones could increase from 1.6 to 2.2 million by the year 2050 [4]. Urinary calculi are not appropriately

managed; these may lead to severe complications, including pyelonephritis, interstitial nephritis, hydronephrosis, pyonephrosis, anuria, oliguria, and both acute and chronic renal failure [5].

Currently, a variety of treatment modalities for upper urinary tract stones are being implemented both in Vietnam and globally. These include extracorporeal shock wave lithotripsy (ESWL), percutaneous nephrolithotomy (PCNL), and retrograde ureteroscopic lithotripsy, which utilize semirigid, reusable flexible, and increasingly single-use flexible ureteroscopes. The adoption of single-use flexible endoscopes has gained momentum because of their demonstrated efficacy and safety profiles [6]. In recent decades, there have been substantial advancements in both the technology and clinical application of minimally invasive procedures within the field of urology. Flexible ureteroscopy has evolved to become a widely used diagnostic and therapeutic tool for many upper urinary tract pathologies. The most common indication for ureteroscopy is the treatment of upper urinary tract stones with the aid of Holmium: Yttrium Aluminium Garnet (YAG) laser lithotripsy. This technique is recognized for its high efficacy and favourable safety profile, with relatively few complications. However, the effectiveness of lithotripsy for lower pole stones remains suboptimal due to anatomical constraints of the lower calyx. Several studies have indicated that the infundibulopelvic angle (IPA) plays a critical role in determining the success of flexible ureteroscopy (FURS) combined with holmium laser lithotripsy [7]. A systematic review of the literature reported that an acute IPA ( $<30^\circ$ ) is significantly associated with lower success rates, particularly when accompanied by prolonged operative time or larger stone size. In contrast, factors such as the use of a ureteral access sheath, infundibular width (IW), and infundibular length (IL) were not found to significantly impact treatment outcomes [8]. Ongoing innovations in flexible ureteroscopic technology have further expanded its clinical utility, positioning it as a first-line treatment option in the management of urolithiasis [9]. Conventional flexible endoscopy is associated with several limitations, including a high initial acquisition cost, substantial maintenance expenses, potential risk of cross-infection, and durability concerns [10]. In addition, the use of disposable flexible endoscopes may alleviate hand fatigue experienced by surgeons during prolonged procedures, as it eliminates the need for continuous manual deflection control, which is beneficial when managing calculi located in the lower pole calyx [11]. To address these limitations, disposable flexible endoscopes have been developed as an alternative to conventional reusable models. Numerous studies have demonstrated their high efficacy in the treatment of urolithiasis [10,12,13].

In Vietnam, several research efforts have explored the application of digital flexible ureteroscopy in the management of urinary calculi, yielding encouraging outcomes. However, to date, there has been no comprehensive and systematic investigation specifically addressing the use of digital flexible ureteroscopy for the treatment of urinary stones, particularly lower pole stones, and regarding post-treatment patient monitoring. Accordingly, the present study aims to evaluate the safety and efficacy of digital flexible ureteroscopy in the management of urinary calculi with lower pole stones, as well as to assess patients' postoperative quality of life.

## 2. Methods

### 2.1. Study Participants

This study was designed as a longitudinal, single-center, non-randomized observational investigation. The study population comprised 74 patients diagnosed with urinary calculi who underwent treatment at Bach Mai Hospital between January 2023 and October 2024.

Inclusion criteria included patients with renal calculi located in the collecting system, calyces, or pelvis, including recurrent or residual stones after previous open surgery, retrograde ureteroscopy with a semirigid scope, ESWL, or PCNL. Patients with stones accompanied by ureteral calculi were also eligible. Exclusion criteria were urinary tract obstructions (e.g., urethral or ureteral strictures, ureteropelvic junction obstruction, grade IV hydronephrosis), non-functioning kidneys, pregnancy, age under 16, congenital renal anomalies (e.g., duplex or horseshoe kidney), and significant spinal deformities.

## 2.2. Clinical Characteristics

The following clinical variables were recorded at the time of patient evaluation: age, sex, body mass index (BMI), prior history of treatment on the affected kidney, and reason for hospital admission. Comorbid conditions, including hypertension, diabetes mellitus, or other endocrine disorders, were also documented.

Paraclinical characteristics: relevant paraclinical data were collected, including laboratory investigations and imaging studies.

## 2.3. Laboratory Tests

Basic blood tests were performed for all patients, including complete blood count, blood glucose, total protein, serum urea, and creatinine levels. Urine cultures were selectively conducted in patients presenting with clinical signs of urinary tract infection or abnormalities in urine parameters (e.g., leukocyturia, nitrituria). In cases of positive cultures, targeted antibiotic therapy was administered until the infection was resolved or urine cultures became sterile before the procedure.

## 2.4. Ultrasound Assessment

All patients underwent renal ultrasonography to assess stone size, location, and the degree of hydronephrosis. Stone size was measured by maximum length, and the location was classified as upper, middle, or lower calyx.

Hydronephrosis was graded as follows: Grade 1: Mild dilation of the renal pelvis and calyceal base; normal parenchyma-to-pelvis index (PPI = 2:1). Grade 2: Dilated calyces and pelvis; parenchymal thickness < 15 mm (PPI = 1:1). Grade 3: Significant dilation with incomplete septa; enlarged kidney; PPI = 1:2. Grade 4: Severe dilation with indistinct anatomy and parenchymal thinning < 3 mm (PPI = 1:3). Grade 4 hydronephrosis cases were excluded from the study [14].

## 2.5. Technical Procedure

All procedures were performed under general anesthesia with the patient in the lithotomy position, consistent with conventional retrograde ureteroscopy. A C-arm fluoroscopy unit was positioned to allow continuous imaging from the bladder to the renal pelvis. A 6 Fr JJ stent (Marflow, Switzerland) was placed 7–14 days prior to facilitate passive ureteral dilation. In the absence of prior stenting, ureteral dilation was achieved intraoperatively using a semi-rigid ureteroscope followed by JJ stent placement. A cystoscope was introduced to retrieve the distal end of the JJ stent, and a guidewire was advanced through the stent into the renal pelvis under C-arm guidance. For cases involving ureteral, renal pelvic, or upper calyceal stones, a semi-rigid ureteroscope was advanced along the guidewire for initial lithotripsy, after which it was withdrawn, leaving the guidewire in place. A 12–14 Fr ureteral access sheath was then introduced over the guidewire into the renal pelvis under C-arm control, after which the guidewire and obturator were removed. A single-use flexible ureteroscope was inserted through the sheath to access the collecting system, guided by both direct vision and fluoroscopy, with continuous irrigation using normal saline. When the ureter was adequately dilated, the flexible ureteroscope could be introduced directly over the guidewire. Stones were identified, measured, and repositioned if necessary—particularly from the lower to the upper calyx or renal pelvis—to minimize scope deflection. Lithotripsy was performed using a 230  $\mu$ m Holmium: YAG laser fiber introduced through the ureteroscope's working channel via a protective sheath. Stone clearance was confirmed when fragments were  $\leq 4$  mm (assessed visually and under fluoroscopy) or when no residual stones were visible. A JJ stent was placed at the end of the procedure to ensure adequate drainage.



### 3. Treatment Outcomes

#### 3.1. Postoperative Assessment and Follow-Up

The procedure was considered successful when only fine gravel or stone fragments measuring  $\leq 4$  mm remained in situ, or when no residual stones were visualized on intraoperative C-arm fluoroscopy [15].

Stone-free status was assessed at 1 month and 3 months postoperatively using either plain abdominal radiography or renal ultrasonography. Patients were considered stone-free if no radiopaque shadows were detected at the site of the preoperative renal stone (in cases of radiopaque stones), or if any residual stone fragment or cluster had a maximal diameter of  $\leq 4$  mm.

#### 3.2. Complication Assessment

Complications were recorded throughout the perioperative and follow-up periods. Intraoperative complications include bleeding, ureteral laceration, ureteral perforation, ureteral avulsion (stripping), and ureteral dissection. Postoperative complications were categorized as early or late and included hematuria, febrile episodes, septic shock, ureteral stricture, and ureteral obstruction caused by residual stone fragments or stone chains. All were classified according to the Clavien-Dindo classification system, a standardized surgical complication grading system revised in 2004 by Dindo and Clavien, based on their earlier 1994 proposal. This system enables objective evaluation of complication severity based on the type of therapeutic intervention required [16].

#### 3.3. Quality of Life Assessment

The EQ-5D-5L was used to assess the quality of life at admission, immediately after surgery, and postoperatively (1-month and 3-month follow-up). The EQ-5D-5L instrument comprises a descriptive system and a visual analogue scale [17]. The descriptive system classifies health on five dimensions: mobility (MO), self-care (SC), usual activities (UA), pain/discomfort (PD), and anxiety/depression (AD). Within each dimension, respondents are asked to describe their current health using either five: 1) no problems, 2) slight problems, 3) moderate problems, 4) severe problems, and 5) unable to/extreme problems levels of severity. Disutility weights were used to calculate values for all health states in the Vietnamese EQ-5D-5L value set. For example, the value of the health state 12345 is calculated as  $1 - (MO1) - (SC2) - (UA3) - (PD4) - (AD5) = 1 - (0) - (0.0428) - (0.0587) - (0.2700) - (0.2388) = 0.3897$ .

#### 3.4. Statistical Analysis

The basic characteristics of the participants are shown according to gender and total number of patients. Continuous variables were reported as means  $\pm$  standard deviation (SD), and comparisons of mean values were made using Student's t-test. Categorical variables were expressed as numbers (percentages, %), and comparisons of proportions were made using the chi-square test. The paired t-test was used to compare the mean, and the McNemar test was used to compare proportions and calculate the p-values with variables that had 2 times follow-up. Repeated measurement was used to compare the mean and calculated p-value with variables from 3 times follow-ups. Statistical analyses were performed using SPSS (IBM Corporation, US) version 29.0 for Mac. All statistical tests were based on two-sided probabilities, and a p-value  $< 0.05$  is considered significant.

## 4. Results

#### 4.1. Patient Characteristics

The characteristics of the study population are presented in Table 1. The mean age of the participants was 51.4 years. The overall mean body mass index (BMI) was 22.4 kg/m<sup>2</sup>. The mean stone size was 13.7 mm. The number of stones detected did not differ significantly between the sexes.

Preoperative hematuria was reported in 4 patients (9.1%). Ultrasound findings revealed that 22 patients (50.1%) had grade 1 hydronephrosis, 5 patients (11.4%) had grade 2 hydronephrosis, and 1 patient (2.2%) had grade 3 hydronephrosis. A history of hypertension and diabetes was recorded in 7 and 5 patients, respectively. Notably, all patients (100%) had a prior history of intervention for kidney stones.

Table 1. Characteristic of participants.

	Total		
		(n=44)	
Age (year) <sup>†</sup>	51.4	±	13.1
Sex <sup>‡</sup>			
Men	23	(	52.3 )
Women	21	(	47.7 )
Mean BMI (kg/m2) <sup>†</sup>	22.6	±	2.9
Median size of largest stone (mm) <sup>†</sup>	13.7	±	4.9
Number of stone <sup>‡</sup>			
1	24	(	54.5 )
2	18	(	41.0 )
3	2	(	4.5 )
Hematuria <sup>‡</sup>			
Yes	4	(	9.1 )
No	40	(	90.9 )
BMI classification <sup>‡</sup>			
Normal	27	(	61.4 )
Overweight	17	(	38.6 )
The severity of hydronephrosis <sup>‡</sup>			
Grade 0	16	(	36.4 )
Grade 1	22	(	50.0 )
Grade 2	5	(	11.4 )
Grade 3	1	(	2.2 )
Disease history <sup>‡</sup>			
Hypertension	7	(	15.9 )
Type 2 diabetes	5	(	11.4 )
Treatment history <sup>‡</sup>	44	(	100.0 )
<sup>†</sup> Mean ± Standard deviation <sup>‡</sup> Number (%)			

4.2. Surgical and Follow-Up Outcomes

The surgical outcomes are presented in Table 2. The mean operative time was 73.4 minutes. The average lithotripsy time was 55.7 minutes. The mean postoperative hospital duration was 6.2 days. The overall stone-free rate immediately after surgery was 79.5%. There was one recorded intraoperative complication (2.3%).

Table 2. Surgical and follow-up outcomes.

	Total		
		(n=44)	
Surgery duration (min) <sup>†</sup>	73.4	±	26.7
Lithotripsy duration (min) <sup>†</sup>	55.7	±	27.4
Average hospital duration (day) <sup>†</sup>	6.2	±	4.7
Complication (Clavien-Dindo 1) <sup>‡</sup> ¶	1	(	2.3 )
Median size of largest stone (mm) <sup>†</sup> §	4.5	±	0.7
1 month	2.2	±	0.6

3 month	1.1	±	0.4
<b>p-value</b>		<b>&lt;0.001</b>	
Stone-free rate ‡ <sup>††</sup>	35	(	79.5 )
1 month	34	(	77.3 )
3 month	31	(	70.5 )
<b>p-value</b>		0.289	
QoL score † <sup>§</sup>			
Addmision	0.604	±	0.048
Postoperative	0.872	±	0.018
1 month	0.973	±	0.009
3 month	0.981	±	0.008
<b>p-value</b>		<b>&lt;0.001</b>	

† Mean ± Standard deviation ‡ Number (%)

§ Repeated measurement was used to compared mean and calculated p value

†† Mac-nemar test was used to compared proportions and calculated p value

The median size of the largest stone decreased over time, from 4.5 ± 0.7 mm immediately after surgery, 2.2 ± 0.6 mm at 1 month, to 1.1 ± 0.4 mm at 3 months postoperatively (p < 0.001). The stone-free rate improved from 77.3% at 1 month to 68.2 % at 3 months (p = 0.289). Additionally, the mean postoperative quality of life score increased significantly over the follow-up period (p < 0.001), with most patients reporting no disruption to daily activities after 1 month.

5. Discussion

The findings of this study demonstrate that single-use flexible ureteroscopy is a highly effective modality for the management of lower pole stones. This minimally invasive approach not only achieves a high rate of stone clearance but also contributes to significant improvements in patients’ postoperative quality of life. These results support the growing role of flexible ureteroscopy as a safe and efficient method in the treatment of lower pole stones.

The average lithotripsy time was 55.6 ± 27.4 minutes. The lithotripsy time in our study was similar some other studies [13]. The study by José A. Salvadó *et al.* (2018) reported that the average lithotripsy time was 56.6 ± 38.0 minutes [18]. Another study by Qiang Jing *et al.* (2024) reported the average lithotripsy time was 51.27 ± 13.8 minutes [19]. The study by Qinghua He *et al.* (2024) recorded a longer lithotripsy time, averaging about 72.4 ± 14.4 minutes [20]. This difference may be due to the complexity of the stones or the difficulty of performing the procedure in each study.

In our study, the average hospital stay was 5.7 days (Table 2). This is comparable to findings from other studies utilizing minimally invasive techniques. Huayu Gao *et al.* (2019) reported a mean hospital stay of 4.33 ± 1.55 days following digital endoscopic lithotripsy, while Qinghua He *et al.* (2024) observed a duration of approximately 3.9 ± 1.2 days. When comparing different minimally invasive approaches, both Gao and He noted that the hospital stay after digital endoscopic stone removal was shorter than that observed after percutaneous nephrolithotomy (PCNL) [20,21].

In the present study, the overall postoperative stone-free rate (SFR) was 79.2% (Table 2). These findings are consistent with those reported in international literature. El-Nahas et al. reported an SFR of 86.5% following flexible ureteroscopy (f-URS) for the treatment of 10–20 mm lower pole stones [22]. Similarly, Gao *et al.* (2019) reported a postoperative SFR of 78.2% at three days in a cohort of 100 patients treated with digital endoscopic lithotripsy [20]. The overall postoperative stone-free rate (SFR) was 70.5% after 3 months of follow-up. He *et al.* (2024) also recorded a 3-month stone-free rate of 71.5% [21].

Flexible ureteroscopy (f-URS) is currently considered the preferred technique for the management of renal stones due to its high stone clearance rate and favourable safety profile, with most complications being low-grade in severity [23]. In our study, only one minor complications (surgical fever) was recorded during the follow-up period, further supporting the minimally invasive

nature of the procedure. In comparison, other studies have reported slightly higher complication rates. For example, José A. Salva *et al.* (2018) noted two complications following f-URS: surgical fever and hematuria [18]. In a study by Huayu Gao *et al.* (2019), complications included fever in 23.6% of cases, abdominal pain in 7.3%, and urinary tract infection in 3.6% [21]. Additionally, Fankhauser *et al.* (2021) reported that Clavien-Dindo grade II complications occurred in approximately 5% of patients undergoing ureteroscopy [24]. These differences may reflect differences in patient populations, surgical techniques, or perioperative management protocols.

To our knowledge, there are relatively few studies that comprehensively assess patients' quality of life following laparoscopic lithotripsy. One such study reported significantly greater improvements in quality of life scores with digital flexible ureteroscopy compared to minimally invasive percutaneous nephrolithotomy [25]. In the present study, we assessed patient-reported quality of life at four time points: preoperatively, immediately postoperatively, and at 1- and 3-month follow-ups. The results demonstrate a steady improvement in quality of life scores over time, with most patients reporting minimal disruption to daily activities by the 1-month follow-up. These findings support the advantages of flexible ureteroscopic lithotripsy not only in terms of clinical efficacy but also in enhancing patient well-being and postoperative recovery.

However, several limitations should be acknowledged. The non-randomized, single-center study design limits the ability to establish causality or control for confounding factors. Additionally, the relatively small sample size may reduce the generalizability of the findings. Finally, the analysis did not fully address risk factors associated with postoperative complications, indicating the need for further investigation to improve clinical outcomes and guide patient selection. Future research should include larger, controlled studies with extended follow-up and a focus on identifying predictors of complications and long-term outcomes. It will be essential for optimizing the role of flexible ureteroscopy in the evolving landscape of minimally invasive urological surgery.

## 6. Conclusion

The findings of this study indicate that single-use flexible ureteroscopy is a promising and effective modality for the management of lower pole renal stones, demonstrating a high stone-free rate and notable improvements in patient-reported quality of life. However, to validate the long-term efficacy and potential clinical superiority of this approach, future research should include larger sample sizes, comparative evidence-based study designs, and extended follow-up periods to generate more robust and generalizable conclusions that could inform clinical practice.

**Author Contributions:** NHT designed the study, acquired the data, analyzed the data, drafted the manuscript, and critically revised the manuscript for important intellectual content. NHT, NMT, DAD, and DNM designed the study, drafted the manuscript, and critically revised the manuscript for important intellectual content. NXC, NTG, CMP, TQK and NTV analyzed the data, drafted the manuscript, and critically revised the manuscript for important intellectual content. All authors had full access to the data, contributed to the study, approved the final version for publication, and take responsibility for its accuracy and integrity.

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**Informed Consent Statement:** Not applicable.

**Data Availability Statement:** The datasets generated and/or analyzed during the current study are available from the corresponding author upon reasonable request.



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