

Flexible and Navigable Suction Ureteral Access Sheath Combined With a Single-Use Flexible Ureteroscope Versus Percutaneous Nephrolithotomy for Impacted Proximal Ureteral Stones: A Single-Centre Retrospective Cohort Study

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Abstract

Background Percutaneous nephrolithotomy (PCNL) reaches impacted proximal ureteral stones (IPUS) antegradely but requires renal puncture and tract dilation, whereas a flexible and navigable suction ureteral access sheath (FANS) permits in situ lithotripsy with aspiration through the natural urinary tract. We compared the efficacy and safety of FANS combined with a single-use flexible ureteroscope with those of PCNL for IPUS.

Methods In this single-centre retrospective cohort study, 239 consecutive patients with IPUS treated between January 2024 and January 2026 were included. Both procedures were technically feasible in all patients after the exclusion criteria were applied, and the procedure was chosen by the patient, giving 169 patients in the flexible ureteroscopy (fURS) group and 70 in the PCNL group. Outcomes comprised immediate and 2-month stone-free rates; intraoperative and postoperative complications, the latter graded by the Clavien-Dindo classification; and operative time, haemoglobin drop, hospital stay, elective staging and salvage second-stage surgery. Follow-up was 6 months.

Results The groups did not differ in any of 25 baseline variables (minimum $P = 0.052$). Stone-free rates did not differ immediately after surgery (92.86% vs 90.00%, $P = 0.643$) or at 2 months (97.63% vs 95.71%, $P = 0.421$). The fURS group had a shorter operative time [34.00 (29.00–40.00) vs 73.00 (63.00–85.75) min], a smaller haemoglobin drop [(4.24 ± 5.50) vs (10.49 ± 9.71) g/L] and a shorter hospital stay [2.00 (2.00–3.00) vs 6.00 (5.00–7.00) days] (all $P < 0.001$). Intraoperative complications did not differ (4.14% vs 1.43%, $P = 0.443$). Early postoperative complications (8.88% vs 22.86%, $P = 0.007$), transfusion (0 vs 5.71%, $P = 0.007$), angioembolization (0 vs 4.29%, $P = 0.024$) and acute kidney injury (1.18% vs 11.43%, $P = 0.001$) were all less frequent after fURS, as were Clavien-Dindo complications of any grade (19.53% vs 35.71%, $P = 0.013$) and of grade II or above (6.51% vs 18.57%, $P = 0.010$). Elective staging was required in 8.88% of the fURS group only ($P = 0.007$).

Conclusions With balanced baseline characteristics, FANS combined with a single-use flexible ureteroscope achieved stone clearance comparable to that of PCNL with a shorter operative time, less blood loss, more rapid recovery and fewer postoperative complications, and may be the preferred minimally invasive option for these stones. Unmeasured confounding cannot be excluded in this non-randomized cohort.

Introduction

Urolithiasis is among the most prevalent urological disorders, and a nationwide ultrasonography-based survey estimated the prevalence of kidney stones in Chinese adults at 6.4%, with higher rates in the southern provinces^[1]. A stone that remains at the same site in the ureter for more than 2 months and cannot be bypassed by a guidewire or contrast medium is defined as an impacted proximal ureteral stone (IPUS)^[2]. Chronic impaction provokes mucosal inflammation, polyp formation, mural oedema and fibrosis, so that the ureter becomes tortuous and narrowed, obstruction worsens and renal function

deteriorates. Ureteral stricture has been reported in as many as 24% of patients after removal of stones impacted for more than 2 months^[3], and preoperative hydronephrosis and urinary tract infection are correspondingly more frequent^[4]. The management of IPUS has therefore remained a persistent clinical challenge.

Because the stone is typically embedded in polypoid tissue and adherent to the ureteral wall, shockwave lithotripsy performs poorly and is no longer recommended as first-line treatment for this indication^[5]. Percutaneous nephrolithotomy (PCNL) reaches the stone antegradely and is unconstrained by ureteral anatomy, with high stone-free rates^[6, 7]; however, creation of the percutaneous tract requires renal puncture and serial dilation of the parenchyma, and bleeding and infectious complications cannot be disregarded^[8, 9]. Conventional flexible ureteroscopy uses the natural urinary tract and represents the least invasive alternative; in impacted disease, however, it is limited by difficulty displacing the stone into the renal pelvis, poor visibility from impaired irrigation outflow and migration of fragments into dependent calyces^[2, 10].

The flexible and navigable suction ureteral access sheath (FANS) is a recently introduced device whose tip deflects passively with the scope and which is connected to continuous suction through a side port, allowing fragments to be aspirated during lithotripsy while intrarenal pressure is kept low^[11, 12]. Comparative studies have shown that, relative to conventional sheaths, FANS improves stone clearance, shortens operative time and reduces infectious complications^[13–16]. The evidence is not entirely consistent: a retrospective Chinese series that likewise found higher early stone clearance with a deflectable suction sheath reported a longer operative time and a greater haemoglobin drop than with a conventional sheath, and concluded that the technique carries a learning curve and is best undertaken by surgeons already experienced in flexible ureteroscopy^[17]. Pairing FANS with a single-use digital flexible ureteroscope allows the sheath tip to be positioned immediately below the stone so that lithotripsy is performed in situ, without any attempt to displace the stone proximally, and may in principle combine clearance efficiency with minimal invasiveness. Existing FANS studies have nevertheless been conducted almost exclusively in renal stones, evidence specific to IPUS is limited to small series^[18], and direct comparisons with PCNL remain insufficient.

We therefore retrospectively analysed consecutive patients treated with these two procedures for IPUS at our institution over the same period, comparing efficacy and safety between groups whose baseline characteristics were balanced, in order to inform the choice of procedure for this stone population.

Materials and Methods

1.1 Study design and participants

This was a single-centre retrospective cohort study conducted in the Department of Urology of Foshan Fosun Chancheng Hospital, a tertiary-level general hospital accredited by the Joint Commission

International in which minimally invasive management of upper urinary tract stones is an established area of institutional expertise. The department performs approximately 1500 upper tract stone procedures annually, of which roughly 1200 are flexible ureteroscopic lithotripsy and 300 are PCNL. All procedures were performed by the same treatment team; the surgeons were associate chief physicians with more than 5 years of experience in upper tract stone surgery, operating according to a standardized protocol, and instrumentation, laser settings and perioperative antibiotic and drainage management remained unchanged.

Two hundred and thirty-nine consecutive patients with an impacted proximal ureteral stone treated in our department were included. IPUS was defined as a stone located between the ureteropelvic junction and the lower border of the fourth lumbar vertebra that had remained at the same site for more than 2 months and that could not be bypassed by contrast medium on intravenous urography or computed tomography urography, with endoscopic evidence of mucosal oedema and granulation tissue adherent to the stone.

Patients aged 18 years or older with a stone 10–30 mm in maximum diameter who met the above definition and had complete clinical and follow-up records were eligible. Exclusion criteria were a stone in the mid or distal ureter; a concomitant ipsilateral renal stone requiring treatment at the same session; severe hydronephrosis with cortical thinning, in which the enlarged intrarenal space makes retrieval of fragments with a flexible ureteroscope difficult; retrorenal colon, which carries a risk of bowel injury during percutaneous puncture; anatomical anomalies including solitary kidney, horseshoe kidney and malrotation; coagulopathy; cardiopulmonary impairment precluding surgery; pregnancy; and severe spinal deformity.

Patients were grouped according to the procedure ultimately performed: 169 patients underwent flexible ureteroscopic lithotripsy with a flexible and navigable suction ureteral access sheath (fURS group) and 70 underwent PCNL (PCNL group). The flow of participants is shown in Fig. 1. The study was approved by the Ethics Committee of Foshan Fosun Chancheng Hospital (approval number CYEC-LCYJ-2025126-PJ-20251009).

1.2 Choice of procedure

After application of the exclusion criteria, all included stones were no larger than 30 mm and lay between the ureteropelvic junction and the lower border of the fourth lumbar vertebra, a region that can also be reached percutaneously, so that both procedures were technically feasible. Before surgery the attending urologist explained to each patient the principles of the two procedures, the degree of surgical trauma, the expected length of stay, the possible complications and the limitations of each; the patient then chose the procedure after full disclosure, and the surgeon did not make a directive recommendation. Although allocation was therefore not randomized, the choice of procedure did not depend on stone size, stone location, degree of hydronephrosis or other clinical and anatomical conditions, and the baseline characteristics of the two groups were comparable (Tables 1 and 5).

Patients presenting with fever underwent first-stage drainage to control infection, and the stone was treated electively once the infection had resolved; drainage was by percutaneous nephrostomy or ureteral stent placement, and the second-stage procedure was again chosen by the patient.

1.3 Surgical procedures

fURS group. Under general anaesthesia with tracheal intubation, patients were placed in the lithotomy position. An 8.0/9.8F semirigid ureteroscope was advanced into the bladder under direct vision, a nitinol guidewire was passed into the ipsilateral ureter and the ureter was inspected ureteroscopically. If ureteral tortuosity or stricture prevented the scope from reaching the stone, a 5F ureteral stent was placed for 2 weeks of passive dilation and the procedure was completed at a second session (elective staging). If ureteral conditions permitted, a 10F flexible and navigable suction sheath was advanced over the guidewire and connected to suction, and a 7.5F single-use digital flexible ureteroscope was introduced under direct vision. The sheath tip was positioned immediately below the stone, a 200 µm laser fibre was passed through the working channel, and holmium laser lithotripsy was performed at 1 J and 20 Hz aimed at the centre of the stone, with fragments aspirated continuously until clearance was achieved. A 5F ureteral stent and a urethral catheter were left in place.

PCNL group. Under general anaesthesia with tracheal intubation, a 6F ureteral catheter was placed into the ureter cystoscopically and a urethral catheter was left in situ. The patient was turned to the prone position, the target calyx was punctured under colour Doppler ultrasound guidance, the tract was dilated serially over a guidewire with fascial dilators and an 18F peel-away sheath was placed to create a single percutaneous tract. An 8/9.8F ureteroscope was advanced through the sheath into the proximal ureter, a 500 µm laser fibre was introduced, and the stone was fragmented with the holmium laser at 1 J and 30 Hz and evacuated by the irrigation pump, with larger fragments retrieved with forceps. A 5F ureteral stent and an 18F nephrostomy tube were left in place.

1.4 Outcome measures

The efficacy outcomes were the immediate and the 2-month stone-free rates. Immediate clearance was assessed by plain radiography or computed tomography early after surgery, on the first postoperative day in the fURS group and on the third postoperative day in the PCNL group; this difference in timing reflects the need for bed rest after PCNL, which renders early erect radiography impracticable, and not a difference in assessment criteria. A ureteral stent was routinely left in place for 2 months, and plain radiography or computed tomography was repeated before stent removal; a patient was considered stone-free in the absence of residual fragments or in the presence of an asymptomatic, non-obstructing residual fragment no larger than 4 mm. Patients who underwent elective staging because of unfavourable ureteral conditions received only a stent at the first session and were excluded from the denominator of the immediate stone-free rate.

Safety outcomes comprised three components: intraoperative complications, including ureteral injury, intraoperative bleeding that interfered with the procedure and conversion to another procedure; early postoperative complications, including postoperative fever, transfusion, urosepsis, angioembolization

and acute kidney injury; and late postoperative complications, defined as ureteral stricture. Only clinically significant injuries of the ureteral wall were recorded as ureteral injury, namely perforation, deep laceration or extensive mucosal avulsion requiring prolonged stenting, a change in the postoperative drainage plan, termination or modification of the planned procedure, or subsequent endoscopic or surgical intervention; simple mucosal abrasion or superficial erosion that did not involve the smooth muscle layer, did not result in perforation, did not interfere with completion of the procedure and required no additional treatment was not counted as a clinically significant ureteral injury, and whether such minor mucosal injury is associated with late ureteral stricture was assessed through long-term follow-up. Intraoperative bleeding that interfered with the procedure was defined as bleeding during surgery that markedly obscured the operative field so that the stone could not be located or fragmented and the procedure had to be discontinued; minor mucosal oozing that did not compromise the operative field was not counted.

Postoperative fever was defined as a temperature of 38.0°C or above and comprised transient fever and infection-related fever. Infection-related fever denoted a temperature of 38.0°C or above accompanied by clinical, laboratory or microbiological evidence of infection and requiring therapeutic antimicrobial treatment; transient fever denoted a temperature of 38.0°C or above that resolved with observation or symptomatic measures and did not meet the criteria for infection-related fever. Urosepsis was defined as sepsis arising from urinary tract infection, diagnosed according to the Sepsis-3 criteria, namely an acute increase in the total SOFA score of 2 points or more consequent to the infection, with the baseline SOFA score assumed to be zero in patients without known pre-existing organ dysfunction^[19]. Acute kidney injury was defined according to the KDIGO criteria as an increase in serum creatinine of at least 26.5 µmol/L above baseline within 48 h after surgery, or an increase to at least 1.5 times the baseline value within 7 days^[20]. Postoperative ureteral stricture was defined as a newly developed localized narrowing of the ureteral lumen, absent before surgery, causing ipsilateral upper urinary tract obstruction or obstructive hydronephrosis. Urinary ultrasonography was used for screening during follow-up, and patients with new or progressive ipsilateral hydronephrosis, ureteral dilation or clinical suspicion of obstruction underwent computed tomography urography or retrograde pyelography for confirmation; the first screening was performed 3 months after surgery, with further assessment at 6 months as clinically indicated. Postoperative complications were additionally graded with the Clavien-Dindo classification^[21, 22], and each patient contributed only the highest grade recorded; because the classification is intended for postoperative complications and does not cover intraoperative events, intraoperative complications were reported separately and were not graded.

Other outcomes included operative time, haemoglobin drop, postoperative hospital stay, the rate of elective staging, the rate of salvage second-stage surgery and stone recurrence during follow-up. Elective staging denoted intraoperative failure to advance the ureteroscope to the stone because of ureteral tortuosity or stricture, in which case only a ureteral stent was placed for passive dilation and lithotripsy was performed at a second session 2 weeks later; this constitutes part of the treatment pathway rather than a procedural failure. Salvage second-stage surgery denoted a second procedure

required because residual stone caused obstruction after the first operation, and also included cases in which the first procedure could not be completed because the operative field was compromised.

1.5 Statistical analysis

Analyses were performed with R version 4.5. Continuous variables were tested for normality with the Shapiro-Wilk test; variables normally distributed in both groups are presented as mean $\pm$ standard deviation and compared with the t test, and the remainder are presented as median (interquartile range) and compared with the Mann-Whitney U test. Categorical variables are presented as counts and percentages and compared with the chi-square test when all expected frequencies were at least 5 and with Fisher's exact test otherwise. Between-group differences and their 95% confidence intervals are reported for the principal outcomes. Outcomes that could be ascertained only at follow-up were analysed using the number of patients who completed follow-up as the denominator, with patients lost to follow-up excluded. Two-sided P values below 0.05 were considered statistically significant. The study is reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement^[23].

Figure 1 Flow of participants through the study

Elective staging denotes intraoperative failure to advance the ureteroscope to the stone because of ureteral tortuosity or stricture, in which case only a ureteral stent was placed for passive dilation and lithotripsy was performed at a second session 2 weeks later; this constitutes part of the treatment pathway rather than a procedural failure. These 15 patients were excluded from the denominator of the immediate stone-free rate, which was therefore 154 in the fURS group.

Results

2.1 Baseline characteristics

A total of 239 patients were included, 169 in the fURS group and 70 in the PCNL group. The groups did not differ significantly in any of 25 baseline variables, including sex, age, body mass index, ASA class, previous history, comorbidity, side, stone location, maximum stone diameter, stone density, duration of impaction, degree of hydronephrosis, perirenal stranding, ureteral tortuosity, preoperative markers of infection, complete blood count and renal function (all $P > 0.05$); the smallest P value was 0.052. The two groups were therefore balanced at baseline and comparable (Table 1).

Table 1
Baseline characteristics of the two groups

Variable	fURS (n = 169)	PCNL (n = 70)	Statistic	P
Male sex, n (%)	119 (70.41)	56 (80.00)	1.857	0.173
Age, years	53.01 ± 11.68	53.73 ± 11.57	-0.438	0.662
Body mass index, kg/m ²	25.00 (22.40–27.60)	25.35 (22.70–27.35)	-0.184	0.855
ASA class I/II/III, n	58 / 83 / 28	29 / 31 / 10	1.091	0.580
Previous ipsilateral surgery or stone passage, n (%)	46 (27.22)	16 (22.86)	0.289	0.591
Diabetes mellitus, n (%)	31 (18.34)	17 (24.29)	0.750	0.386
Hypertension, n (%)	49 (28.99)	19 (27.14)	0.017	0.896
Chronic kidney disease, n (%)	4 (2.37)	4 (5.71)	—	0.237
Left side, n (%)	101 (59.76)	37 (52.86)	0.705	0.401
Stone site above L3 / L3-L4 / below L4, n	66 / 60 / 43	30 / 25 / 15	0.508	0.776
Maximum stone diameter, mm	15.20 (13.20–18.00)	14.25 (12.70–16.50)	1.946	0.052
Maximum stone diameter > 20 mm, n (%)	18 (10.65)	7 (10.00)	0.000	1.000
Stone density, HU	1072.28 ± 269.38	1027.99 ± 273.06	1.146	0.254
Duration of impaction, months	2.60 (2.30-3.00)	2.80 (2.30–3.27)	-1.252	0.210
Hydronephrosis mild / moderate / severe, n	68 / 74 / 27	28 / 31 / 11	0.006	0.997
Perirenal stranding, n (%)	69 (40.83)	38 (54.29)	3.101	0.078
Ureteral tortuosity, n (%)	25 (14.79)	6 (8.57)	1.191	0.275
Preoperative urinary WBC, per HPF	43.00 (24.00–91.00)	48.50 (21.00–85.25)	0.733	0.464
Positive preoperative urine culture, n (%)	34 (20.12)	12 (17.14)	0.123	0.726
Preoperative fever with first-stage drainage, n (%)	23 (13.61)	15 (21.43)	1.716	0.190
Preoperative antibiotics, days	1.00 (0.00–4.00)	1.00 (0.00-4.75)	-0.328	0.732
Preoperative haemoglobin, g/L	139.57 ± 14.10	139.77 ± 17.31	-0.087	0.931

Variable	fURS (n = 169)	PCNL (n = 70)	Statistic	P
Preoperative platelets, $\times 10^9/\text{L}$	224.95 $\pm$ 53.51	222.63 $\pm$ 51.41	0.314	0.754
Preoperative creatinine, $\mu\text{mol/L}$	79.00 (65.00–91.00)	73.50 (64.00–92.00)	0.805	0.421
Preoperative eGFR, $\text{mL}/(\text{min}\cdot 1.73 \text{ m}^2)$	89.80 (75.40–102.10)	97.15 (76.50–105.10)	-1.263	0.207

Data are mean $\pm$ standard deviation, median (interquartile range) or n (%). The statistic is t, Z or χ^2 as appropriate; no statistic is given where Fisher's exact test was used. Preoperative antibiotic duration was bimodal: patients without infection received perioperative prophylaxis only, whereas those with fever undergoing first-stage drainage received a full therapeutic course. ASA, American Society of Anesthesiologists; eGFR, estimated glomerular filtration rate; HPF, high-power field; WBC, white blood cell.

2.2 Efficacy outcomes

The immediate stone-free rate was 92.86% in the fURS group and 90.00% in the PCNL group ($P = 0.643$), and the 2-month stone-free rate was 97.63% and 95.71%, respectively ($P = 0.421$). Given that stone size, stone location and stone density were balanced between the groups, these findings indicate that a flexible and navigable suction sheath combined with flexible ureteroscopy achieves a clearance efficiency comparable to that of PCNL for impacted proximal ureteral stones (Table 2).

Table 2
Efficacy outcomes of the two groups

Variable	fURS (n = 169)	PCNL (n = 70)	Statistic	P
Immediate stone-free rate, n (%) [‡]	143 (92.86)	63 (90.00)	0.215	0.643
Stone-free rate at 2 months, n (%)	165 (97.63)	67 (95.71)	—	0.421

[‡] The denominator excludes patients who underwent elective staging because of unfavourable ureteral conditions (15 in the fURS group), in whom only a stent was placed at the first session. Clearance at 2 months was assessed before stent removal; a residual fragment no larger than 4 mm that was asymptomatic and non-obstructing was regarded as stone-free.

2.3 Safety outcomes

Intraoperative complications occurred in 7 patients (4.14%) in the fURS group and 1 (1.43%) in the PCNL group, a difference that was not statistically significant ($P = 0.443$). In the fURS group these comprised ureteral perforation in 2 patients, intraoperative bleeding that interfered with the procedure in 3 and conversion to PCNL in 2; in the PCNL group there was 1 case of intraoperative bleeding that interfered with the procedure. Notably, bleeding that interfered with the procedure was slightly more frequent in the fURS group (1.78% vs 1.43%), the opposite direction to the haemoglobin drop. The two measures

capture different phenomena: the operative field in flexible ureteroscopy depends on irrigation, and because the impacted segment is covered by vascular granulation tissue, even minor mucosal oozing may obscure the endoscopic view and necessitate suspension of the procedure for irrigation, although the total volume of blood loss remains small; bleeding during PCNL arises from the percutaneous tract and renal parenchyma and is substantially greater in volume, whereas the percutaneous sheath permits continuous irrigation, so that the procedure is less frequently interrupted.

Early postoperative complications occurred in 15 patients (8.88%) in the fURS group, significantly fewer than the 16 patients (22.86%) in the PCNL group ($\chi^2=7.378$, $P = 0.007$). No patient in the fURS group required transfusion or angioembolization, compared with 4 (5.71%) and 3 (4.29%) in the PCNL group, both differences being statistically significant ($P = 0.007$ and $P = 0.024$). Acute kidney injury occurred in 2 patients (1.18%) in the fURS group and 8 (11.43%) in the PCNL group ($P = 0.001$). Postoperative fever and urosepsis did not differ significantly; one patient in each group developed urosepsis and recovered after intensive care and antimicrobial treatment.

Among late postoperative complications, ureteral stricture occurred in 2 patients (1.23%) in the fURS group, both of whom had sustained intraoperative ureteral perforation and both of whom recovered after ureteroplasty; no stricture occurred in the PCNL group, and the difference was not statistically significant.

Postoperative complications graded by the Clavien-Dindo classification occurred at any grade in 33 patients (19.53%) in the fURS group, significantly fewer than the 25 (35.71%) in the PCNL group ($\chi^2=6.204$, $P = 0.013$); grade II or above complications occurred in 11 patients (6.51%) versus 13 (18.57%) ($\chi^2=6.693$, $P = 0.010$). Grade III or above complications did not differ significantly, but their composition was entirely different: in the fURS group they comprised ureteroplasty for ureteral stricture in 2 patients and urosepsis in 1, whereas in the PCNL group they comprised angioembolization in 3 patients and urosepsis in 1, reflecting different sources of severe complications between the two approaches (Table 3).

Table 3
Safety outcomes of the two groups

Variable	fURS (n = 169)	PCNL (n = 70)	Statistic	P
Intraoperative complications				
Ureteral injury, n (%)	2 (1.18)	0 (0.00)	—	1.000
Bleeding interfering with procedure, n (%)	3 (1.78)	1 (1.43)	—	1.000
Conversion to another procedure, n (%)	2 (1.18)	0 (0.00)	—	1.000
Total intraoperative complications, n (%)	7 (4.14)	1 (1.43)	—	0.443
Early postoperative complications				
Postoperative fever, n (%)	14 (8.28)	10 (14.29)	1.365	0.243
Transfusion, n (%)	0 (0.00)	4 (5.71)	—	0.007
Urosepsis, n (%)	1 (0.59)	1 (1.43)	—	0.501
Angioembolization, n (%)	0 (0.00)	3 (4.29)	—	0.024
Acute kidney injury, n (%)	2 (1.18)	8 (11.43)	—	0.001
Total early postoperative complications, n (%)	15 (8.88)	16 (22.86)	7.378	0.007
Late postoperative complications				
Ureteral stricture, n (%)	2 (1.23)	0 (0.00)	—	1.000
Clavien-Dindo grade (postoperative)				
Any grade, n (%)	33 (19.53)	25 (35.71)	6.204	0.013
Grade II or above, n (%)	11 (6.51)	13 (18.57)	6.693	0.010
Grade III or above, n (%)	3 (1.78)	4 (5.71)	—	0.199

⊠ The Clavien-Dindo classification grades postoperative complications and does not cover intraoperative events; ureteral injury, bleeding interfering with the procedure and conversion are therefore reported separately under intraoperative complications and were not graded. Ureteroplasty for postoperative ureteral stricture is a further operation under general anaesthesia and was graded IIIb. ⊠ Only clinically significant ureteral injuries were recorded, namely perforation, deep laceration or extensive mucosal avulsion requiring prolonged stenting, a change in drainage plan, termination or modification of the planned procedure, or subsequent endoscopic or surgical intervention; simple mucosal abrasion or superficial erosion was not counted. ⊠ Bleeding that markedly obscured the operative field so that the procedure had to be interrupted; this measure differs from the haemoglobin drop (Table 4), the former reflecting interference with the procedure and the latter total blood loss. ⊠ Ascertainable only at follow-

up; the denominator is the number of patients who completed follow-up (fURS, n = 162; PCNL, n = 66). Each patient contributes only the highest Clavien-Dindo grade, so grade-specific counts sum to the total.

2.4 Other outcomes

Operative time was substantially shorter in the fURS group than in the PCNL group [34.00 (29.00–40.00) vs 73.00 (63.00–85.75) min, $P < 0.001$], a difference of 39.0 min between medians. The difference arose principally at the stage of establishing access: the flexible ureteroscope reaches the stone through the natural urinary tract and lithotripsy can begin as soon as the suction sheath is in place, whereas PCNL requires cystoscopic placement of a ureteral catheter, repositioning to the prone position, ultrasound-guided puncture of the target calyx and serial tract dilation, a sequence that usually takes 25 to 30 min from catheter placement to completion of the tract before lithotripsy can start.

The haemoglobin drop was substantially smaller in the fURS group [(4.24 ± 5.50) vs (10.49 ± 9.71) g/L, $P < 0.001$]. Postoperative inflammatory markers were also lower after fURS: white blood cell count [(9.21 ± 2.26) vs $(11.49 \pm 2.53) \times 10^9/L$, $P < 0.001$] and urinary white blood cell count [76.00 (47.00–135.00) vs 101.50 (64.00–189.75) per high-power field, $P = 0.013$]; postoperative procalcitonin did not differ. Postoperative serum creatinine and estimated glomerular filtration rate did not differ between the groups.

Postoperative hospital stay was markedly shorter in the fURS group [2.00 (2.00–3.00) vs 6.00 (5.00–7.00) days, $P < 0.001$]; 95.3% of patients in the fURS group were discharged 1 to 3 days after surgery, including 11 discharged on the day of surgery, whereas 81.4% of patients in the PCNL group were discharged 5 to 7 days after surgery. Patients who required transfusion or angioembolization stayed substantially longer, 11 to 17 days.

Fifteen patients (8.88%) in the fURS group could not have the suction sheath advanced because of intraoperative ureteral tortuosity or stricture and underwent stent placement for 2 weeks of passive dilation followed by a second session, whereas no such case occurred in the PCNL group ($P = 0.007$); this elective staging is part of the treatment pathway and was not counted as a complication. Salvage second-stage surgery for residual stone or postoperative ureteral stricture was required in 5 patients (3.09%) in the fURS group and 3 (4.55%) in the PCNL group, without a significant difference. Over 6 months of follow-up, 7 patients in the fURS group and 4 in the PCNL group were lost; stone recurrence occurred in 6 (3.70%) and 3 (4.55%), respectively, without a significant difference (Table 4).

Table 4
Other outcomes of the two groups

Variable	fURS (n = 169)	PCNL (n = 70)	Statistic	P
Operative time, min	34.00 (29.00–40.00)	73.00 (63.00–85.75)	-12.092	< 0.001
Haemoglobin drop, g/L	4.24 ± 5.50	10.49 ± 9.71	-5.056	< 0.001
Postoperative creatinine, µmol/L	73.00 (60.00–90.00)	73.50 (60.00–95.50)	-0.783	0.434
Postoperative eGFR, mL/(min·1.73 m ²)	95.70 (78.90–108.70)	96.90 (72.50–107.88)	0.333	0.740
Postoperative WBC, ×10 ⁹ /L	9.21 ± 2.26	11.49 ± 2.53	-6.553	< 0.001
Postoperative urinary WBC, per HPF	76.00 (47.00–135.00)	101.50 (64.00–189.75)	-2.495	0.013
Postoperative procalcitonin, ng/mL [‡]	0.80 (0.36–1.48)	1.02 (0.48–1.89)	-0.527	0.619
Postoperative hospital stay, days	2.00 (2.00–3.00)	6.00 (5.00–7.00)	-12.038	< 0.001
Elective staging for ureteral conditions, n (%)	15 (8.88)	0 (0.00)	—	0.007
Salvage second-stage surgery, n (%) [‡]	5 (3.09)	3 (4.55)	—	0.693
Stone recurrence within 6 months, n (%) [‡]	6 (3.70)	3 (4.55)	—	0.721
Lost to follow-up, n (%)	7 (4.14)	4 (5.71)	—	0.735

[‡] Ascertainable only at follow-up; the denominator is the number of patients who completed follow-up. [‡] Procalcitonin was measured only in patients with postoperative fever; the denominator is the number of patients in whom it was measured (fURS, n = 14; PCNL, n = 10). Elective staging denotes intraoperative failure to advance the sheath because of unfavourable ureteral conditions, with stent placement and lithotripsy at a second session; it constitutes part of the treatment pathway rather than a procedural failure and is reported separately from salvage second-stage surgery.

2.5 Distribution of factors related to the choice of procedure

To document comparability further, six factors that may influence the technical feasibility and difficulty of either procedure were compared separately. All were evenly distributed between the groups (Table 5).

Table 5
Distribution of factors potentially influencing the choice of procedure

Variable	fURS (n = 169)	PCNL (n = 70)	Statistic	P
Stone below L4, n (%)	43 (25.44)	15 (21.43)	0.243	0.622
Severe hydronephrosis, n (%)	27 (15.98)	11 (15.71)	0.000	1.000
Ureteral tortuosity, n (%)	25 (14.79)	6 (8.57)	1.191	0.275
Previous ipsilateral surgery or stone passage, n (%)	46 (27.22)	16 (22.86)	0.289	0.591
Maximum stone diameter > 20 mm, n (%)	18 (10.65)	7 (10.00)	0.000	1.000
Body mass index > 28 kg/m ² , n (%)	32 (18.93)	12 (17.14)	0.020	0.887

These factors may influence the technical feasibility and difficulty of either procedure. Severe hydronephrosis with cortical thinning and retrorenal colon were excluded from the study; in the remaining patients stones were no larger than 30 mm and lay between the ureteropelvic junction and the lower border of the fourth lumbar vertebra, a region also reachable percutaneously, so that both procedures were feasible. The even distribution of these factors supports the comparability of the two groups.

2.6 Effect estimates for the principal outcomes

Between-group differences were calculated as fURS minus PCNL. The confidence intervals for both stone-free rates, for intraoperative complications and for salvage second-stage surgery included zero, whereas those for operative time, haemoglobin drop, postoperative hospital stay, early postoperative complications and Clavien-Dindo grade II or above complications excluded zero, favouring the fURS group with respect to operative efficiency, blood loss, recovery and postoperative complications (Table 6).

Table 6
Between-group differences and 95% confidence intervals for the principal outcomes

Outcome	Difference (fURS – PCNL)	95% CI	P
Immediate stone-free rate	2.86%	(-5.26%, 10.98%)	0.643
Stone-free rate at 2 months	1.92%	(-3.35%, 7.19%)	0.421
Operative time, min	-40.48	(-44.52, -36.43)	< 0.001
Haemoglobin drop, g/L	-6.24	(-8.70, -3.79)	< 0.001
Postoperative hospital stay, days	-4.01	(-4.57, -3.44)	< 0.001
Intraoperative complication rate	2.71%	(-1.38%, 6.81%)	0.443
Early postoperative complication rate	-13.98%	(-24.71%, -3.25%)	0.007
Clavien-Dindo grade II or above rate	-12.06%	(-21.90%, -2.22%)	0.010
Salvage second-stage surgery rate	-1.46%	(-7.15%, 4.23%)	0.693

Differences and confidence intervals for continuous variables were derived from Welch's t test. Confidence intervals for risk differences were obtained by normal approximation, whereas the P values are those reported in Tables 2 to 4, that is, from the chi-square test when all expected frequencies were at least 5 and from Fisher's exact test otherwise; the methods used for the interval and for the P value may therefore differ. As a retrospective cohort, the between-group differences are unadjusted for confounding; the groups were balanced at baseline, but unmeasured factors cannot be excluded. CI, confidence interval.

Discussion

This study retrospectively compared consecutive patients treated over the same period with a flexible and navigable suction ureteral access sheath combined with a single-use flexible ureteroscope or with percutaneous nephrolithotomy for impacted proximal ureteral stones. After application of the exclusion criteria both procedures were technically feasible, the procedure was chosen by the patient after full disclosure, and the two groups did not differ significantly in any of 25 baseline variables, which provides an appropriate basis for comparison. Stone clearance was comparable between the procedures, whereas the fURS group was superior with respect to operative time, haemoglobin drop, postoperative hospital stay, early postoperative complications and postoperative complications graded by the Clavien-Dindo classification.

With regard to clearance, the immediate and 2-month stone-free rates were 92.86% and 97.63% in the fURS group and 90.00% and 95.71% in the PCNL group, neither difference reaching significance; the 95% confidence intervals for the risk differences were – 5.26% to 10.98% and – 3.35% to 7.19%, both including zero. Earlier reports have consistently found conventional flexible ureteroscopy inferior to PCNL in

impacted disease^[6, 7]. Two features account for the improvement observed here. First, the deflectable sheath can be advanced beneath the stone and follows the scope, so lithotripsy is performed in situ without any attempt to displace the stone into the renal pelvis, thereby avoiding both failed retropulsion and the scatter of fragments into dependent calyces^[10]. Second, continuous aspiration keeps the operative field clear and permits direct inspection of the ureter and renal pelvis for residual fragments at the end of the procedure. Tang and colleagues^[18] retrospectively compared FANS ureteroscopy with mini-PCNL for impacted proximal ureteral stones and reported stone-free rates of 90.7% and 83.8% ($P = 0.351$), concordant in direction with the present findings. It should be noted that clearance at 2 months was assessed before stent removal, by which time most residual fragments had passed spontaneously, so that the rates in both groups exceeded those measured immediately after surgery.

Operative time showed the largest between-group difference, with a median 39.0 min shorter in the fURS group and a mean difference of -40.48 min (95% CI -44.52 to -36.43). The difference is attributable chiefly to establishing access. The retrograde route uses the natural urinary tract, and lithotripsy begins as soon as the sheath has been advanced over the guidewire, whereas PCNL requires cystoscopic ureteral catheterization, repositioning to the prone position, ultrasound-guided calyceal puncture and serial tract dilation, a sequence that usually occupies 25 to 30 min from catheter placement to completion of the tract. Lithotripsy is also more efficient, since continuous aspiration maintains visibility and obviates repeated basket exchanges and scope withdrawals; a meta-analysis by Kayano and colleagues^[16] found that suction sheaths shortened operative time by approximately 8 min compared with non-suction sheaths (7.98 min, $P = 0.004$). A shorter procedure means less anaesthetic exposure, less absorption of irrigant and greater operating room throughput. Because stone size and stone density were balanced between the groups, the difference is difficult to explain by differences in stone burden.

Bleeding-related outcomes require interpretation at two distinct levels. In terms of total blood loss, the haemoglobin drop was (4.24 ± 5.50) g/L in the fURS group and (10.49 ± 9.71) g/L in the PCNL group, a difference of -6.24 g/L (95% CI -8.70 to -3.79); no patient in the fURS group required transfusion or angioembolization, compared with 4 (5.71%) and 3 (4.29%) in the PCNL group, both differences being significant. Bleeding after PCNL originates principally from injury to the renal parenchyma and interlobar vessels during puncture and dilation and is intrinsic to the approach^[8, 9]; flexible ureteroscopy operates entirely within the natural urinary tract, does not breach the renal parenchyma and is therefore not subject to tract-related bleeding. The haemoglobin drops reported by Tang and colleagues^[18] (3.65 vs 7.89 g/L) are concordant in direction with our findings. In terms of interference with the procedure, however, bleeding that interrupted the operation was slightly more frequent in the fURS group (1.78% vs 1.43%). The opposing directions of these two measures are not contradictory: the operative field in flexible ureteroscopy depends on irrigation, and because the impacted segment is covered by vascular granulation tissue, even minor mucosal oozing may obscure the endoscopic view and necessitate suspension of the procedure for irrigation, although the total volume of blood loss remains small; bleeding during PCNL arises from the tract and renal parenchyma and is substantially greater in volume, whereas the percutaneous sheath permits continuous irrigation, so that the procedure is less frequently

interrupted. Both total blood loss and interference with the procedure should therefore be reported when the bleeding risk of the two techniques is assessed, since either measure alone provides an incomplete assessment.

With regard to safety, intraoperative complications occurred in 7 patients (4.14%) in the fURS group and 1 (1.43%) in the PCNL group; the difference was not significant but was numerically higher after fURS, comprising ureteral perforation in 2 patients, bleeding that interrupted the procedure in 3 and conversion to PCNL in 2, all directly related to unfavourable ureteral conditions during retrograde instrumentation, whereas the single event in the PCNL group was bleeding that interrupted the procedure. This indicates that the intraoperative risk of the retrograde route lies chiefly in the ureter itself and differs in origin from that of the antegrade route. Early postoperative complications were significantly less frequent after fURS (8.88% vs 22.86%, $P = 0.007$), the largest difference being in acute kidney injury (1.18% vs 11.43%, $P = 0.001$). Because preoperative eGFR and the degree of hydronephrosis were balanced and postoperative creatinine and eGFR did not differ, this difference is more plausibly attributable to direct injury of the renal parenchyma by the percutaneous tract and to the transient fall in renal perfusion associated with perioperative bleeding than to differences in baseline renal function. Postoperative white blood cell and urinary white blood cell counts were also lower after fURS, which may reflect the lower intrarenal pressure maintained by continuous aspiration and the consequent reduction in pyelovenous and pyelolymphatic backflow of contaminated irrigant^[24–26]; postoperative procalcitonin did not differ, however, and one patient in each group developed urosepsis, suggesting that the two procedures do not differ appreciably in severe infectious complications.

Postoperative complications of any Clavien-Dindo grade occurred in 19.53% of the fURS group and 35.71% of the PCNL group ($P = 0.013$), and grade II or above in 6.51% versus 18.57% ($P = 0.010$). Grade III or above complications did not differ significantly, but their composition was entirely different: ureteroplasty for ureteral stricture in 2 patients and urosepsis in 1 after fURS, compared with angioembolization in 3 patients and urosepsis in 1 after PCNL. Severe complications after fURS therefore arise chiefly from the ureter and those after PCNL chiefly from bleeding; the two procedures therefore differ not merely in the magnitude of a shared risk but in the nature of the risk itself, and the choice of procedure should take account of the individual patient's risk profile. It should be noted that the Clavien-Dindo classification grades postoperative complications and does not cover intraoperative events, so intraoperative complications were reported separately and were not graded, in order to avoid conflation of the two categories.

Postoperative hospital stay was markedly shorter after fURS (median 2 vs 6 days), a difference of -4.01 days (95% CI -4.57 to -3.44); 95.3% of patients in the fURS group were discharged 1 to 3 days after surgery, including 11 discharged on the day of surgery, whereas 81.4% of patients in the PCNL group were discharged 5 to 7 days after surgery. Most patients after PCNL require a nephrostomy tube and observation for tract bleeding and urinary leakage before the tube can be removed and discharge considered, which is the principal reason for the longer stay; those who required transfusion or angioembolization stayed 11 to 17 days. In an era of diagnosis-related group reimbursement and

enhanced recovery after surgery, a reduction of approximately 4 hospital days is of clear health-economic significance; nevertheless, length of stay is also influenced by local postoperative practice and patient preference and therefore cannot be regarded as a fully objective measure in retrospective data.

Ureteral stricture is the outcome requiring the most careful interpretation. Over 6 months of follow-up, stricture developed in 2 patients (1.23%) in the fURS group, both of whom had sustained intraoperative perforation and both of whom recovered after ureteroplasty; no stricture occurred in the PCNL group. Impaction is itself a strong risk factor for stricture: Roberts and colleagues^[3] reported strictures in 24% of patients after removal of stones impacted for more than 2 months, and systematic reviews have identified intraoperative ureteral perforation and mucosal injury as the principal predictors^[27, 28]. Both strictures in the present series occurred in patients with documented intraoperative perforation, consistent with that pattern and indicating that intraoperative perforation should be regarded as a predictor of stricture and should prompt intensified surveillance. The observed rate of 1.23% is well below historical figures, plausibly because in situ lithotripsy avoids forceful retropulsion, aspiration limits abrasion of the ureteral wall by fragments, and the procedure is performed under continuous direct vision^[29]. Six months is, however, a relatively short observation period for an outcome that may manifest late, and the rate reported here is likely to underestimate the true incidence.

Fifteen patients (8.88%) in the fURS group could not have the sheath advanced because of intraoperative ureteral tortuosity or stricture and were managed by stent placement for 2 weeks of passive dilation followed by a second session, whereas no such case arose in the PCNL group. This is an intrinsic cost of the retrograde route, and current guidelines note that antegrade percutaneous removal remains an option when the upper tract is unsuitable for retrograde instrumentation^[5]. Elective staging and procedural failure are conceptually distinct: in these patients the inadequacy of the ureter was recognized at the first session and management was converted to a staged pathway according to protocol, and all second-stage procedures were completed without complication. Salvage second-stage surgery for residual stone or postoperative stricture was required at similar rates in the two groups (3.09% vs 4.55%), indicating that elective staging did not increase the overall burden of reoperation. Because ureteral conditions cannot be fully predicted preoperatively, patients scheduled for flexible ureteroscopy should be informed during the consent process that staging is required in approximately 9% of cases.

This single-centre retrospective cohort study, in which all patients were treated in one department by a single treatment team, has several limitations. First, allocation was not randomized but determined by the patient after disclosure. Although both procedures were technically feasible after application of the exclusion criteria, and baseline characteristics and the factors influencing procedural difficulty were evenly distributed, it remains possible that unmeasured factors such as economic circumstances, occupation and willingness to tolerate surgical trauma influenced both the choice of procedure and the outcome. Second, the groups were of unequal size and dominated by the fURS group, so that the power to detect differences in low-frequency events such as urosepsis, ureteral stricture and conversion was limited, and the absence of a significant difference in these comparisons should not be interpreted as

evidence of equivalence. Third, follow-up extended to 6 months, and some late complications, particularly ureteral stricture, may manifest beyond this period, so the observed stricture rate may be an underestimate. Fourth, procalcitonin was measured only in patients with fever, resulting in selective missingness by indication, and the between-group comparison of this variable applies only to those in whom it was measured. Fifth, patients with severe hydronephrosis and cortical thinning and those with a retrorenal colon were excluded, so the findings cannot be extrapolated to such patients. Sixth, immediate clearance was assessed at different time points in the two groups (the first postoperative day after fURS and the third after PCNL); although the criteria were identical, an effect of this difference on the assessment of clearance cannot be entirely excluded. Multicentre prospective randomized studies with longer follow-up are needed to confirm these findings.

Conclusions

For impacted proximal ureteral stones in which, after appropriate selection, both procedures are technically feasible, a flexible and navigable suction ureteral access sheath combined with a single-use flexible ureteroscope achieves stone clearance comparable to that of percutaneous nephrolithotomy; in this cohort it required less operative time, caused less blood loss, permitted more rapid recovery and was associated with fewer early postoperative complications and fewer Clavien-Dindo grade II or above complications, and may therefore be preferred as a minimally invasive option for these stones. The sources of severe complications differ between the procedures, being predominantly ureteral in origin after flexible ureteroscopy and predominantly haemorrhagic after percutaneous nephrolithotomy; in addition, approximately 9% of patients require elective staging because of unfavourable ureteral conditions, and the longer-term risk of ureteral stricture warrants continued attention. As this was a non-randomized retrospective cohort, these comparisons require confirmation in multicentre prospective randomized studies.

Abbreviations

AKI

acute kidney injury

ASA

American Society of Anesthesiologists

CI

confidence interval

eGFR

estimated glomerular filtration rate

FANS

flexible and navigable suction ureteral access sheath

fURS

flexible ureteroscopy

HPF

high-power field

IPUS

impacted proximal ureteral stone

IQR

interquartile range

KDIGO

Kidney Disease:Improving Global Outcomes

PCNL

percutaneous nephrolithotomy

SD

standard deviation

SOFA

Sequential Organ Failure Assessment

STROBE

Strengthening the Reporting of Observational Studies in Epidemiology

WBC

white blood cell

Declarations

Ethics approval and consent to participate

The study was approved by the Ethics Committee of Foshan Fosun Chancheng Hospital (approval number CYEC-LCYJ-2025126-PJ-20251009) and was conducted in accordance with the Declaration of Helsinki. As this was a retrospective analysis of anonymized clinical records, the requirement for written informed consent for study participation was waived by the ethics committee; all patients had provided written informed consent for their surgical procedure.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Author Contribution

Zhiwen Gu: Conceptualization, Methodology, Writing- Reviewing and Editing. Chun Wang: Investigation, Data curation, Software, Visualization, Writing- Original draft preparation. Bin Zheng: Supervision.

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Availability of data and materials

The datasets generated and analysed during the current study are available from the corresponding author on reasonable request.

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Figures

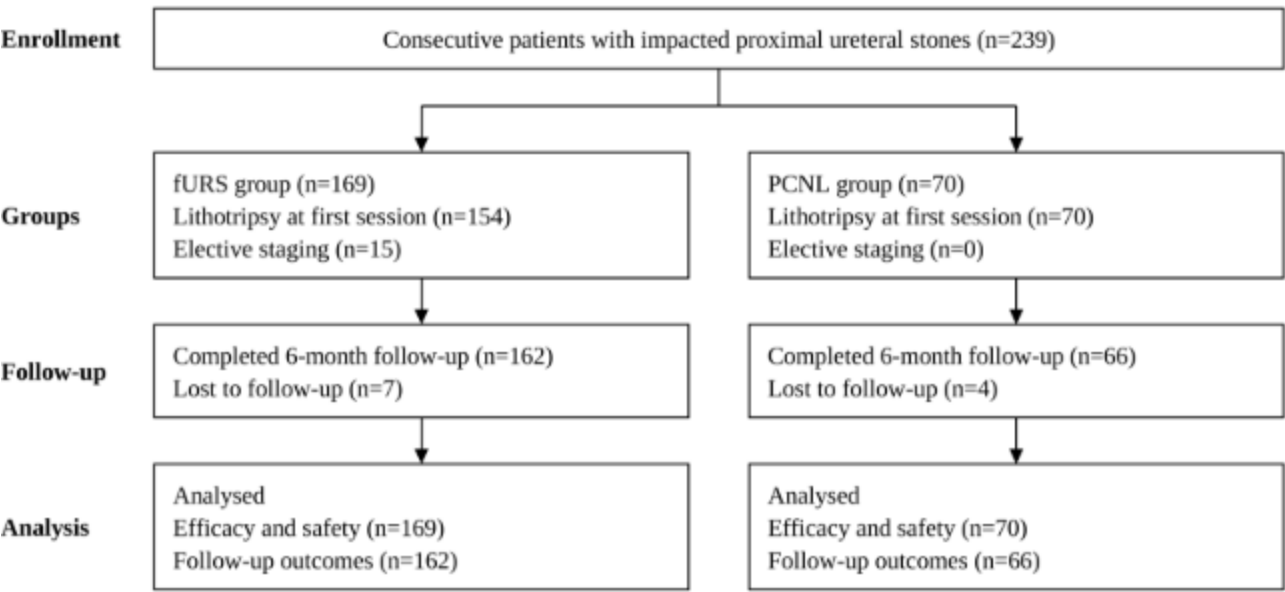


Figure 1

Flow of participants through the study