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Comparison of laparoscopic ureterolithotomy, retrograde flexible ureteroscopy, and mini-percutaneous antegrade flexible ureteroscopic lithotripsy for treating large (≥ 15 mm) impacted proximal ureteric stones: a prospective randomized trial

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Abstract

The purpose of this study is to compare the outcomes of transperitoneal laparoscopic ureterolithotomy (TPLU), retrograde flexible ureteroscopy (R-fURS), and mini-percutaneous antegrade flexible ureteroscopy (A-fURS) for treating large (≥ 15 mm) impacted proximal ureteral stones. A total of 105 adult patients were randomized into 3 equal groups: group A (35) patients underwent TPLU, group B (35) patients underwent R-fURS, and group C (35) patients underwent A-fURS. The initial stone-free rate was 100%, 68.6%, and 80% in groups A, B, and C, respectively. The mean operative time (OT) was (85.0 ± 7.57 min) in group A, (61.0 ± 8.21 min) in group B, and (89.57 ± 15.12 min) in group C. The three groups were comparable concerning the overall complications. R-fURS is a less invasive modality for treating such stones; however, it is associated with a lower SFR and a higher rate of auxiliary procedures. Both TPLU and miniperc A-fURS are effective and valuable alternatives for treating large impacted proximal ureteric stones.

Keywords Large proximal ureteric stone · Retrograde flexible URS · Antegrade flexible URS · Laparoscopic ureterlithotomy · Stone-free rate

Introduction

Treatment of large impacted proximal ureteral stones is still challenging and requires a full armamentarium. Many different treatment options, ranging from open ureterolithotomy to contemporary endourological approaches, are available for treating such stones [1, 2], each with a different rate of success and complications, including extra-corporeal shock wave lithotripsy (SWL), Ureteroscopy (URS) (either retrograde or antegrade), and laparoscopic ureterolithotomy (LU) [3].

Retrograde flexible URS (R-fURS) is now regarded as the first-line treatment for treating such stones, with an overall stone-free rate (SFR) of 81% [4]. The SFR is frequently hampered by retrograde stone retropulsion during fragmentation, which has a prevalence of 28–60% and raises the necessity for auxiliary procedures [5, 6]. Further, a stone impaction with nearby mucosal edema restricts the vision, raising the possibility of complications such as ureteral perforation and damage of endoscopes [7].

Antegrade flexible Ureteroscopy (A-fURS) is a valuable alternative in treating large proximal ureteric stones, particularly in the following circumstances: concurrent renal stones, failed retrograde URS or SWL, and the difficulty to gain retrograde access (due to ureteric strictures or urinary diversions). However, its invasiveness due to tract development should be put in consideration [8].

Laparoscopic ureterolithotomy (LU), either retroperitoneal (RPLU) or trans-peritoneal (TPLU), is another surgical modality for treating these stones. Despite being more intrusive, it has the highest SFR and less need for auxiliary

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procedures. This technique may be an option if URS or SWL failed or is unlikely to be effective, and there are technical limitations [4]. Herein, we aimed to compare the outcomes of three different treatment options; TPLU, R-fURS, and A-fURS in patients with large (≥ 15 mm) impacted proximal ureteric stones.

Patients and methods

Type of study and patients' recruitment

This is a prospective randomized study designed to compare the outcomes of (TPLU), (R-fURS), and mini-percutaneous (A-fURS) in treating patients with large (≥ 15 mm in the maximum dimension) impacted proximal ureteric stones. After the approval of ethical committee (approval code: 34,619/4/21), a total of 115 adult patients presented with a solitary stone and admitted at Tanta Urology hospital during the period from April 2021 to April 2023 were assessed for eligibility. Ten patients were excluded as shown in the flow chart (Fig. 1). The remaining 105 patients were equally randomized (1:1:1) using a computer random numbers into 3 groups as follows; group A (35 patients) who were treated by TPLU, group B (35 patients) who were treated by R-fURS, and group C (35 patients) who were treated by A-fURS. The participants were all asked to sign a detailed consent. Patients with stone size < 15 mm, uncorrected coagulopathies, untreated urinary tract infection (UTI), pregnancy, and cardiovascular and respiratory comorbidities were excluded. This trial was registered at clinicaltrials. gov (Registration number: NCT06199518).
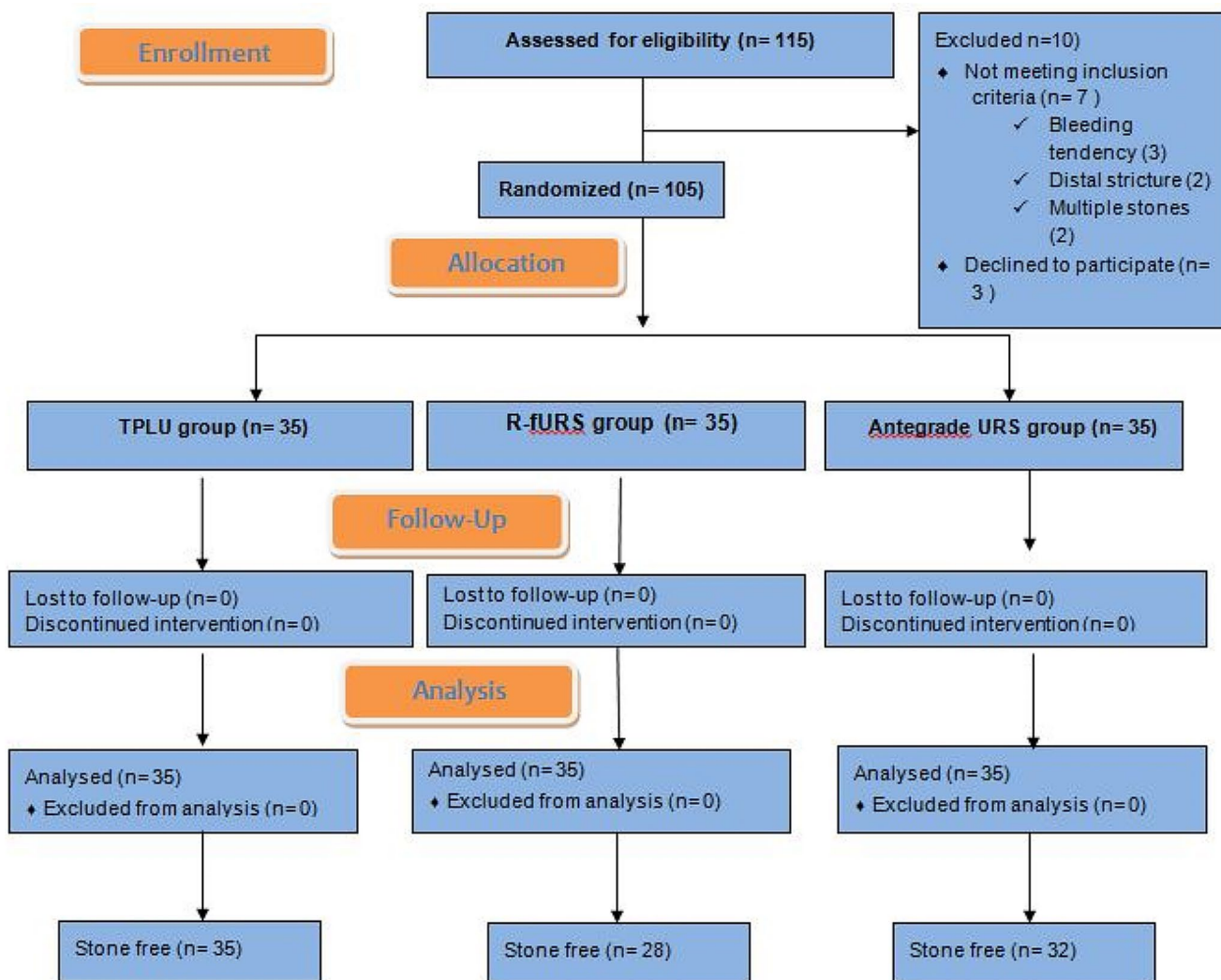

Fig. 1 The flow chart of the study

Patients' evaluation

All patients were preoperatively evaluated by detailed history taking, thorough examination, and laboratory investigations include; urine culture and sensitivity, renal function tests, complete blood film, and full coagulation profile. Radiological evaluation includes; plain X-ray or KUB film, pelvi-abdominal ultrasound and non-contrast spiral computed tomography (NCCT).

Proximal ureteral stones could be described as that located in between the pelvi-ureteric junction (PUJ) and the upper edge of sacrum. Stone impaction was defined as stones that have not moved in two months or that are not by passable with a guide wire or contrast agent. No remaining stone fragments or pieces ≤ 4 mm in follow up imaging was considered stone free.

Surgical technique

Group A (TPLU)

Under general anesthesia, the patients were located in a lateral decubitus position and fixed to the table by adhesive tape, with proper padding of all pressure points. A single dose of 3rd-generation IV cephalosporin was administered to all patients. Pneumoperitoneum (15 mm Hg) was achieved using the Veress needle. Then, a 10 mm camera port, and Two closed ports measuring 12 mm and 5 mm were introduced, one at the operator's right hand (12 mm) and the other at their left (5 mm). The procedure started with medial colon mobilization, followed by identification of the ureter anterior to the psoas muscle. Longitudinal ureterotomy over the stone was done using a cold knife or laparoscopic hook, followed by extraction of the stone by a non-traumatic grasper, and the stone was placed in a bag. Finally, antegrade JJ stent insertion was done and the ureterotomy was sutured with a 4/0 running Vicryl sutures. A drain was placed routinely in the peri-ureteral space in all patients.

Group B (R-fURS)

Under general anaesthesia, the patients were situated in a lithotomy position. Visualizing cystoscopy with the semi-rigid cystoscope (KARL STORZ, 22Fr. Germany) was performed to identify the ureteric orifice and the insertion of two guide wires (0.038 Fr, Sensor polytetrafluoroethylene (PTFE)-nitinol; Boston Scientific, Marlborough, MA, USA) under C-arm guidance into the collecting system; one wire is the safety and the other is the working one used for the insertion of the ureteral access sheath (UAS) (Navigator 11/13 Fr, Boston Scientific) under C-arm guidance. Then,

the flexible ureteroscope (WiScope Single-Use Digital, OTU Medical, USA) was introduced through the UAS. In some patients, the guide wire failed to pass easily beyond the stone due to marked impaction and edema; we insert the flexible or semi-rigid URS and start the fragmentation to create a space to help the passage of guide wire. If UAS failed to pass easily, we shifted to ureteric pre-stenting for 2 weeks. We used (Lumenis™ VersaPulse™ Holmium Laser 100 W) and 200 or 365-µm holmium laser fiber. Laser lithotripsy was done using dusting technique [low energy (0.8–1 J/pulse) and high frequency (10–15 HZ)]. Indwelling stent had been routinely inserted in all patients.

Group C (A-fURS)

Under general anesthesia, the patients were situated in a prone position. Ultrasonography (BK medical, Flex Focus 400) had been utilized to get a renal puncture using Chiba needle (18-G), and then dye had been injected to delineate the collecting system to obtain the proper lower or middle calyceal access (Fig. 2). Insertion of two guide wires (one is safety and the other is working) into the collecting system was done. Tract dilatation was done by Teflon dilators up to 14 Fr, followed by the insertion of a UAS (Navigator 11/13 Fr, Boston Scientific) over the guide wire. The disposable flexible URS had been inserted through the UAS and manipulated to reach the stone and fragment it using the holmium laser with similar settings as in group B (Fig. 2). An antegrade stent insertion had been routinely done in all patients, and then a tubeless procedure (no nephrostomy tube) was followed with removal of UAS.

Patients' follow up

The following data were compared in the 3 groups: operative and fluoroscopy time, intraoperative complications, hospitalization stay, SFR, and auxiliary procedures. The postoperative complications were categorized according to the Clavein Dindo grading system [9]. The patients were evaluated before discharge and after four weeks by NCCT to detect the stone-free status.

Statistical analysis

The data were interpreted using IBM SPSS software version 20.0. (Armonk, NY: IBM Corp). Numbers and percentages were applied to delineate the qualitative data. Quantitative data were represented using range, mean, and standard deviation (SD). Chi-square test was utilized for categorical variables, to compare between various groups. ANOVA test was utilized for normally distributed quantitative variables, to compare between > two groups, and Tukey Post Hoc
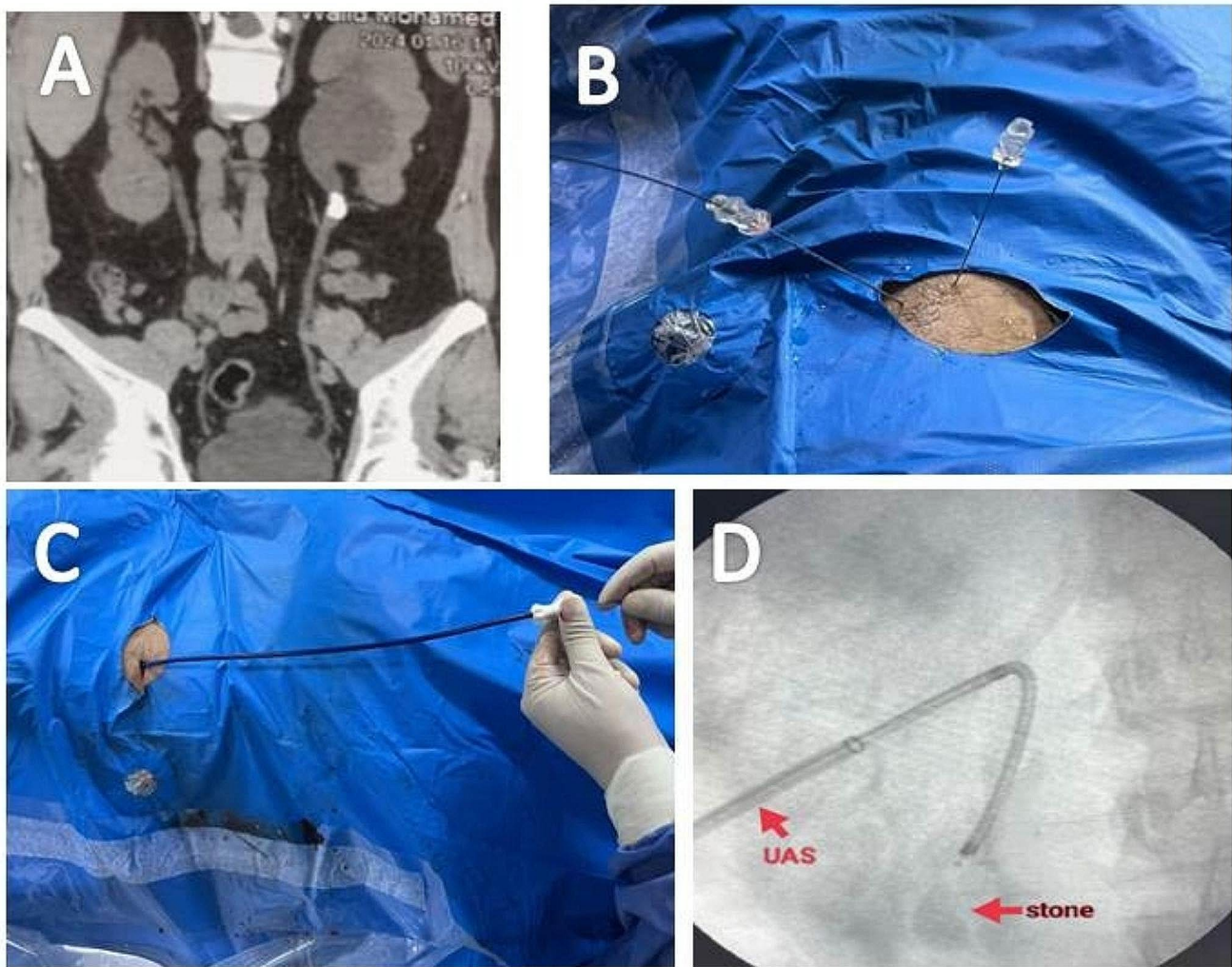
Fig. 2 Technique of antegrade flexible URS: **A** Non-contrast CT shows a large (1.8 cm) left-impacted proximal ureteric stone. **B** US-guided puncture using a Chiba needle (18-G), and then dye was injected to delineate the collecting system to obtain proper access. **C** The ure-teral access sheath passed percutaneously over the guide wire. **D** The flexible ureteroscope is inserted through UAS and manipulated until it reaches the stone

testing for pairwise comparisons. Kruskal Wallis test was used for abnormally distributed quantitative variables. A p-value < 0.05 was deemed significant.

Results

The mean age of our patients was 42.54 ± 10.09, 41.14 ± 10.06, and 42.11 ± 9.41 years in groups A, B, and C, respectively. Patients' and Stones' criteria are illustrated in (Table 1). The initial SFRs were 100% in group A, 68.6% in group B and 80% in group C. Auxiliary treatments were required in eleven patients (31.4%) in group B in the form of ESWL vs. six patients (17.1%) in group C (ESWL in 4 patients and RIRS in 2 patients). Final SFRs were 100%, 80%, and 91.4% in groups A, B and C, respectively. The peri-operative data are outlined in (Table 2).

Concerning the perioperative complications, mild mucosal injury (grade 1) occurred in four patients in group B and three patients in group C. Minor ureteral perforation (grade 2) developed in one case in each group B and C and was managed successfully by JJ stent insertion for 4 weeks. Failed retrograde access was encountered in 9 patients (25.7%) in group B and was treated by stenting followed by R-fURS after 2 weeks. Fever (grade 2) was reported in 3 cases in each group A and C and 4 cases in group B. All cases were managed by antipyretics and proper antibiotics. Hematuria (grade 1) was reported in 3 cases in each group B and C; it was mild and resolved spontaneously. Sepsis (grade 4a) developed in one case in each group B and C and was managed in the ICU with general supportive measures

Table 1 Patients' and stones' characteristics

	Group A (TPLU) (n=35)		Group B (R-fURS) (n=35)		Group C (A- fURS) (n=35)		Test of Sig.	p
	No.	%	No.	%	No.	%		
Gender							χ²= 0.560	0.756
Male	21	60	23	65.7	20	57.1		
Female	14	40	12	34.3	15	42.9		
Age, years, mean±SD	42.54±10.09		41.14±10.06		42.11±9.41		F= 0.185	0.831
BMI, (kg/m²), mean±SD	26.51±1.40		26.91±1.38		27.17±1.40		F= 1.973	0.144
Stone laterality							χ²= 0.238	0.888
Right	20	57.1	22	62.9	21	60.0		
Left	15	42.9	13	37.1	14	40.0		
Stone size, mm, mean±SD	17.37±1.77		18.20±2.37		17.23±1.70		F= 2.480	0.089
Stone HU, mean±SD	868.7±303.0		949.7±387.9		942.4±345.9		F= 0.583	0.560

SD: Standard deviation. F: for One way ANOVA test. χ²: Chi square test. P: P value for comparing between the three studied groups. HU: Hounsfield Unit. BMI: Body Mass Index

and broad-spectrum antibiotics. Paralytic ileus (grade 2) developed in 2 cases in group A and was managed conservatively. A univariate and multivariate analysis of the variables affecting SFR was executed and found that the size of stone, the technique of treatment, and hard stones > 1000 HU were the significant variables affecting the SFR (Table 3).

Discussion

Urologists still have a lot of controversy regarding the best technique to manage large impacted proximal ureteric stones, which makes choosing the best strategy for such stones a difficult decision. A variety of techniques have been documented for treating these stones, including ESWL, R-fURS, A-fURS, laparoscopy, and very rarely open surgery [10]. Additionally, the selection of the optimal treatment option relies on a number of variables, including the size, composition, and location of the stone, as well as clinical aspects, equipment accessibility, and surgical skills. Each procedure also has its own advantages and disadvantages [11].

The European Association of Urology (EAU) urolithiasis guidelines recommend URS (antegrade or retrograde) as the first option for treatment of large (> 1 cm) proximal ureter stones. In selected patients, antegrade URS and LU may be alternatives. Despite being the most effective therapy for large proximal ureter stones, RIRS has some fundamental drawbacks, including the need for several sessions and significant high intra-renal pressure. Regretfully, there are no particular recommendations for impacted ureteral stones in the current guidelines [4].

Percutaneous antegrade stone removal may be performed for impacted large ureteric stones after failure of retrograde access or as a primary treatment option because of its associated high success rate [12]. This procedure could be performed by using rigid or flexible endoscopes. Utilizing rigid endoscopes necessitates that the puncture be in direct access to the ureter, so upper calyceal puncture should be done in most cases to reduce the risk of endoscope and kidney damage from excessive torqueing [13]. However, in our study, we could finish most cases of antegrade approach through lower and sometimes middle calyceal puncture. Moreover, Mohey et al. [14] described their technique of A-fURS through lower calyceal puncture only in all cases to reduce the risk of bleeding and the need for blood transfusion that may occur with an upper or middle puncture. Therefore, based on the above findings, we preferred in our study to perform the antegrade approach using the flexible ureteroscope.

Concerning the operative time (OT) in the current study, the longest OT was in group C (89.57±15.12 min), while

Table 2 Peri-operative data in the three groups

	Group A (TPLU) (n=35)	Group B (R-URS) (n=35)	Group C (A-URS) (n=35)	Test	P value
Operative time, (minutes), mean ± SD	85.0 ± 7.57	61.0 ± 8.21	89.57 ± 15.12	F = 70.022*	**< 0.001***
Significance between groups. $p_1 < 0.001^*$, $p_2 = 0.187$, $p_3 < 0.001^*$					
Fluoroscopy time, (sec.), mean ± SD	NA	99.0 ± 21.41	248.57 ± 32.73	U = 0.0*	**< 0.001***
Hospital stay, (days), mean ± SD	4.03 ± 0.71	2.26 ± 0.61	3.11 ± 0.76	H = 57.985*	**< 0.001***
Significance between groups. $p_1 = <0.001^*$, $p_2 < 0.001^*$, $p_3 = <0.001^*$					
VAS for pain, mean ± SD	6.60 ± 0.95	5.06 ± 1.11	6.14 ± 1.44	H = 26.928*	**< 0.001***
Significance between groups. $p_1 < 0.001^*$, $p_2 = 0.088$, $p_3 = 0.001^*$					
HB deficit, mean ± SD	0.50 ± 0.24	0.33 ± 0.14	0.61 ± 0.23	H = 28.014*	**< 0.001***
Significance between groups. $P_1 = 0.001^*$, $P_2 = 0.075$, $p_3 < 0.001^*$					

SD: Standard deviation **NA**: Not available **VAS**: Visual Analogue Scale

F: F for One way ANOVA test, pairwise comparison between each 2 groups were done using Post Hoc Test (Tukey), **U**: Mann Whitney test, **H**: H for Kruskal Wallis test, pairwise comparison between each 2 groups were done using Post Hoc Test (Dunn's for multiple comparisons test)

p: p value for comparing between the three studied groups *: Statistically significant at $p \le 0.05$

Table 3 Univariate and multivariate logistic regression analysis for the variables affecting initial SFR

	Univariate		#Multivariate	
	p	OR (LL – UL 95%C.I)	**p**	OR (LL – UL 95%C.I)
Gender	**0.286**	1.835(0.601–5.603)		
Age (years)	**0.941**	1.002(0.951–1.056)		
BMI (kg/m2)	**0.941**	0.986(0.687–1.416)		
Comorbidities	**0.971**	0.978(0.288–3.319)		
Stone size	**0.032***	0.659(0.450–0.966)	0.068	0.596(0.342–1.040)
Technique				
TPLU	**0.998**	–		
R-fURS	**0.009***	0.242(0.084–0.698)	0.035*	0.235(0.061–0.901)
A-fURS	**0.584**	0.746(0.261–2.129)		
HU (> 1000)	**< 0.001***	0.060(0.016–0.227)	< 0.001*	0.068(0.016–0.289)

OR: Odd`s ratio **C.I**: Confidence interval **LL**: Lower limit **UL**: Upper Limit **HU**: Hounsfield Unit **BMI**: Body Mass Index

#: All variables with $p < 0.05$ was included in the multivariate

*: Statistically significant at $p \le 0.05$

the shortest OT was in group B (61.0 ± 8.21 min). In group A, the mean OT was 85.0 ± 7.57. Similarly, Elgebaly et al. [8] and Mohey et al. [14] reported that the mean OT was significantly longer in the antegrade group than the retrograde URS group. This significant difference between both groups could be explained by the time needed for percutaneous puncture, tract dilatation, and the time needed to manipulate the flexible ureteroscope to reach the impacted stones. Furthermore, Wang et al. [15] who enrolled 150 patients with proximal ureteric stones (> 15 mm); found that the mean OT was 55.7 ± 23.9, 125.6 ± 41.2, and 99.5 ± 34.6 in the R-fURS, M-PCNL, and RPLU groups, respectively. On the contrary, Güler Y and Erbin A [13] retrospectively analyzed 122 patients presented with impacted proximal ureteric stones (> 15 mm); reported that the mean OT was

60.1 ± 9.8 in R-fURS, 44.2 ± 6.1 min in the antegrade group, and 147 ± 67 in the TPLU group.

The accurate definition of SFR is variable and a debatable issue because of the lack of guidelines or consensus on the definition of SFR after ureteric or renal stone surgery. Some authors represented a new proposal to define levels of post-treatment SFR and described it according to the size of residual fragments as" no residual stone, residual stone ≤ 1 mm, ≤ 2 mm, ≤ 3 mm, or ≤ 4 mm'' [16]. We used ≤ 4 mm in the present study as the cut-off value. In the current study, the final SFR was 100%, 80%, and 91.4% in the TPLU, R-fURS, and antegrade groups, respectively. In accordance with our results, Güler Y and Erbin A [13], Wang et al [15], Basiri et al. [17] showed similar results. Furthermore, Lai et al in their meta-analysis conducted on

1416 adult patients with proximal ureteric stones > 10 mm; found that URS had a significantly lower SFR compared to PCNL and LU, while no differences were found between PCNL and LU concerning the SFR [18]. Interestingly, Liu et al [3] reported a 97.7% SFR in their antegrade group vs. 82.2% in their retrograde group. According to Elgebaly et al study [8], the SFR was 60% and 83.3% in R-fURS and A-fURS groups respectively. Furthermore, Mohey et al [14], in their study reported that SFR was significantly higher (90.3%) in antegrade group vs. (70%) in retrograde group ($p = 0.046$). Kallidonis et al [19] in their systematic review, included seven randomized controlled trials conducted on 778 patients demonstrated that minimally Invasive Surgical Ureterolithotomy (MISU) had a significantly higher SFR (initial and 3 months) in comparison with URS for proximal ureteric stones.

Another crucial factor that has considerable financial and psychological consequences is the necessity for auxiliary treatments for the residual stones. In our study, no cases needed auxiliary procedures in group A, versus eleven (31.4.7%) patients and six (17.1%) patients in both groups B and C, respectively ($p = 0.002$). Basiri et al. [16] reported that 22%, 14%, and 10% of cases needed auxiliary procedures in the R-fURS, A-fURS, and LU groups, respectively, which also consistent with our results except for the higher rate of auxiliary procedures in the laparoscopy group. Furthermore, Wang et al. [15] reported that 32.6% of the RURS group, 0% of the laparoscopy group, and 6% of the antegrade group required auxiliary procedures. Güler Y and Erbin A [13] reported that 7 patients (16.3%) in R-URS group needed auxiliary procedures. Mohey et al. [14] mentioned that nine patients (30%) in retrograde group required auxiliary procedure (ESWL) versus three patients (9.7%) in antegrade group (0.046). Sharma et al. [20], in their meta-analysis included 13 randomized studies conducted on 1871 patients with large proximal ureteric stones, reported that LU and PCNL were superior to URS and SWL for SFR and auxiliary procedures. Similarly, a network meta-analysis evaluating different approaches for proximal ureteral stones ≥ 10 mm was carried out by Wang et al. [21]. A total of 2.888 patients were recruited from 25 trials and evaluated. The authors revealed that LU and PCNL had a greater efficacy on SFR and auxiliary procedures. PCNL may result in more severe complications. As a result, LU may be the first option for treating such stones.

In the current study, the overall complications were comparable among the three groups. Despite the hemoglobin drop being significantly higher in the antegrade group, no patient in the three groups necessitated a blood transfusion. Similarly, Elgebaly et al. [8] stated that blood loss (< 150 mL) had developed in 4/30 (13.3%) patients in A-fURS, and no bleeding in R-fURS. However, blood transfusion wasn't

required in their patients. On the other hand, Güler A. and Erbin A. [13] showed that four patients in the antegrade group had a hemorrhage from the nephrostomy tube, requiring a transfusion after the operation. However, transfusion was not needed in the other two groups. In the current study, fever occurred in 3 patients (8.6%), 4 patients (11.4%), and 3 patients (8.6%) in groups A, B, and C, respectively. Urosepsis developed in 2 patients (one in each group B and C) and ileus occurred in 2 (5.8%) patients in the laparoscopy group. Additionally, one (2.3%) case in the laparoscopy group and two (5.3%) cases in the antegrade group showed prolonged urine leakage. According to Basiri et al. [16], urinary leakage > 3 days occurred in eight (16%) and nine (18%) patients in laparoscopy and antegrade groups, respectively. Güler and Erbin A [13] mentioned that 4 patients encountered urosepsis in RIRS group and no patient in the antegrade group.

As regards the radiation exposure in the current study, the mean fluoroscopy time was 99.0 ± 21.41 s in group B versus 248.57 ± 32.73 s in group C ($p < 0.001$). This was explained by using fluoroscopy during percutaneous puncture and dilatation of the tract, and this is one of the drawbacks of the antegrade route. Similarly, Güler Y and Erbin A [13] showed that the mean fluoroscopy time in the R-fURS group was 24 ± 12 s and 264 ± 60 s in the antegrade group ($p < 0.001$). Additionally, Elgebaly et al. [8] stated that the median fluoroscopy time in the R-URS group was 11 (8–16) sec and 200 (160–300) sec in the antegrade URS group ($p < 0.001$).

In the current study, the mean hospitalization stay was 4.03 ± 0.71, 2.26 ± 0.61, and 3.11 ± 0.76 days in groups A, B, and C, respectively ($p < 0.001$). Similarly, Güler Y and Erbin A [13] reported that the mean hospitalization stay was 2.0 ± 1.3, 4.1 ± 1.2, and 4.3 ± 0.8 in RIRS, A-URS, and LU groups, respectively ($p < 0.001$). Furthermore, Wang et al. [15] mentioned that the mean hospital stay was 2.5 ± 1.3, 6.8 ± 2.6, and 4.3 ± 2.2 days in URS, Mini-PCNL, and RPLU groups, respectively. Basiri et al. [16] in their study mentioned that the mean hospital stay was 0.53 ± 0.12, 5.8 ± 2.3, and 4.4 ± 1.4 in R-URS, TPLU, and PCNL groups, respectively.

To our knowledge, the current study is the first prospective randomized one in the literature designed to compare TPLU, R-fURS, and miniperc A-fURS for treating large (≥ 15 mm) impacted proximal ureteric stones. Despite, this study is not devoid of drawbacks, such as the small sample size and single center inclusion. Therefore, large-scale multi-center studies are warranted to confirm our findings. The lack of an assessment of the cost-effectiveness of the three techniques is another drawback in this study.

Conclusions

However, flexible ureteroscopy is a less invasive therapeutic option for treating large (≥ 15 mm) proximal ureteric stones; it is associated with a lower SFR and a higher rate of auxiliary procedures. The tubeless miniperc antegrade technique is a safe, feasible, and effective method, but it is associated with a longer operative and fluoroscopy time and more postoperative pain. TP-laparoscopic ureterolithotomy has the highest stone clearance rate and the lowest rate of auxiliary procedures; therefore, it is a valuable alternative technique, particularly if there is a lack of flexible endoscopes and also for hard stones (> 1000 HU).

Data availability No datasets were generated or analysed during the current study.

Declarations

Competing interests The authors declare no competing interests.

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