

The outcomes of flexible ureteroscopy for renal calculi of 2 cm or more with and without the use of ureteral access sheath: A retrospective study

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Summary

Introduction: The rate of success of retrograde intrarenal surgery (RIRS) for treating urinary tract stones is high, and the procedure is growing in popularity. The routine use of ureteral access sheath (UAS) remains somewhat controversial. The aim of this study was to assess the efficacy and safety of employing UAS during flexible ureteroscopy for treating renal stones ≥ 2 cm.

Methods: This retrospective study was accomplished from January 2021 to February 2023. From 495 consecutives flexible ureteroscopies, 112 patients had renal stones ≥ 2 cm (60 patients with the use of UAS and 52 patients without). The stone-free status was verified after 8 weeks of operation.

Results: The average diameter of the renal stones in non-UAS or UAS treated groups was 22.5 mm and 22.6, respectively. None of the groups differed significantly in terms of stone side, stone size, stone position, or Hounsfield unite but there was significant difference ($p < 0.001$) among two groups as regard pre-operative stenting (cases with UAS had 23.3% pre-operative stenting).

Conclusions: It is not always necessary to use UAS in conjunction with flexible ureteroscopy and laser lithotripsy to treat renal calculi bigger than or equal two cm. Without the assistance of UAS, the surgery may be carried out successfully and safely.

KEY WORDS: Retrograde intrarenal surgery; Laser lithotripsy; Ureteral access sheath; Kidney calculi.

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INTRODUCTION

The rate of success of retrograde intrarenal surgery (RIRS) for treating urinary tract calculi is high, and the procedure is growing in popularity (1, 2). The first reported introduction of a guide tube (with a polytetrafluoroethylene coating, a length of 38 cm and a diameter of 3 mm) through the ureteral orifice to pass a completely passive flexible ureteroscope was by Takayasu and Aso in 1974 (3). Its initial use was accompanied by a high rate of complications; 12 of 43 cases had ureter perforation (eight of them due to ureteral sheath and four cases to other causes) (4). In spite of those bad results, the use of ureteral access sheath (UAS) did not stop, and technological development made it more easy and safe to use UAS during the

routine practice of the endourologists, especially after the introduction of the hydrophilic coated UASs with the hub-locking mechanisms and in a study that compared the commonly used UASs they concluded that there were no differences between them as regard safety and efficacy. Also, less resistance during the insertion of UAS was noted in the pre-stented and dilated ureters (5, 6). UAS can allow repeated access to the renal pelvis without trauma to the ureter, improve visibility, protect the ureteroscope, improve drainage and allow rapid extraction of stone fragments (7, 8). Also, UAS will lower intra-renal pressures, which may reduce pyelovenous backflow, leading to a decrease in the risk of infectious complications (9). The routine use of UAS for standard URS remains somewhat controversial (10). UASs can directly damage the ureteral wall and compromise ureteral blood flow transiently (11, 12). The major aim of this study was to assess the efficacy, safety, and feasibility of employing UAS during flexible ureteroscopy for the removal of renal stones 2 cm in size or larger.

MATERIAL AND METHODS

This retrospective study compared the effectiveness of flexible ureteroscopy with and without UAS in the treatment of renal stones 2 cm or larger at “Al-Azhar” and “Benha University Hospitals”. 495 consecutives flexible ureteroscopies were accomplished from January 2021 to February 2023 for kidney and ureter calculi. From them, 112 patients had renal stones 2 cm or more (60 patients with the use of UAS and 52 patients without). Inclusion criteria included patients with renal stones ≥ 2 cm, while exclusion criteria were patients with ureteric stones or combined renal and ureteric stones, patients with kidney calculi < 2 cm, patients with related congenital renal abnormalities and cases with incomplete records of postoperative data (Figure 1). The “Faculty of Medicine for Girls at Al-Azhar University in Cairo (FMG-IRB)” in Nasr City, Cairo, Egypt, had accepted the study's protocol with “approval number: 1657”. All procedures were performed under the Helsinki Declaration. As this was a retrospective study, the necessity for obtaining informed permission was waived. We retrieved the following data for all patients of the study:

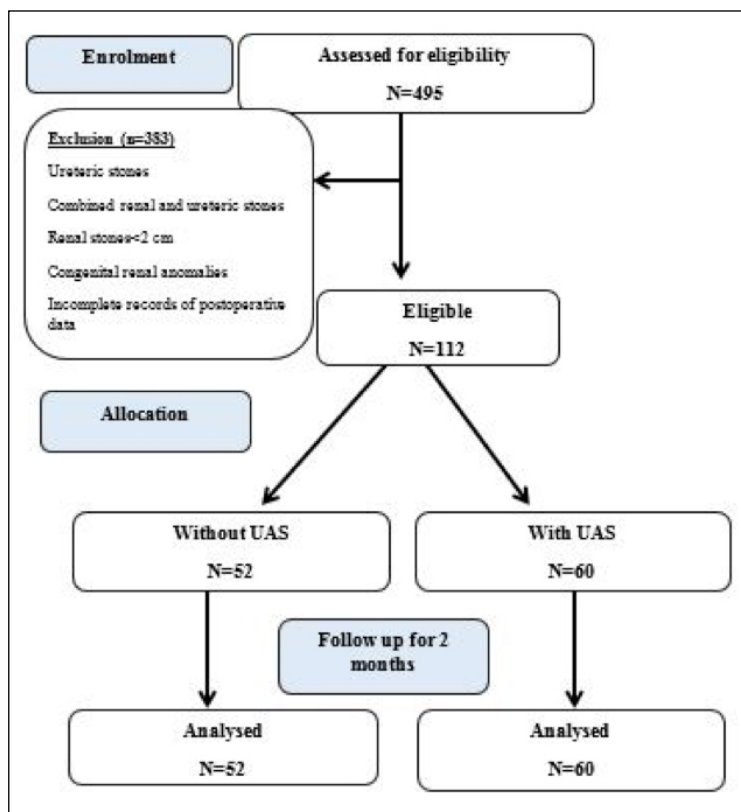


Figure 1.
A schematic representation of the study.

employed. All stones were fragmented to a very small sizes by means of holmium laser (30 W *Litho Quantasystem, Lumenis Pulse™ 120H Boston Scientific*) using a 365 -µm holmium laser fiber with power settings of 0.8-1.5 J at 10-15 Hz, except in lower calyceal stones where a 200-µm fiber was used. Two kinds of flexible ureteroscopes were used for all surgeries: “*OTU-100SR WiScope® Single-Use Digital Flexible Ureteroscope and LithoVue™ Single-Use Digital Flexible Ureteroscope Boston Scientific*”. After laser lithotripsy, stones were repositioned in the collecting system, and pieces were removed using a nitinol basket if needed. Patients underwent either plain abdominal X-rays with ultrasonography or a non-contrast-enhanced spiral *computed tomography* (CT) scan for radiolucent stones to verify stone-free status after 8 weeks from operation. Success was considered when there was no residual stone or if the residual stone was less than 5 mm.

age, sex, main presentation, previous surgeries, associated comorbidities, renal function, location and density of the stones, intra and after surgery details, surgery duration, stenting duration, *stone-free rates* (SFR) and any auxiliary procedures. A semi-rigid ureteroscope was used to check the ureter up to the level of the pelvis for any abnormalities and to widen the ureter while the patient was under general anaesthesia and in the lithotomy position. Another safety guide wire was utilized throughout. The decision for using UAS or not was strictly based on surgeon's preference and not on patient and stone characteristics. The UAS is inserted into the patient at the beginning of the surgery under fluoroscopic guidance, with the sheath's tip resting at the ureteropelvic junction. The *Flexor® UAS (Cook Medical)* was used; it is a hydrophilic, soft, two-piece device consisting of an inner tapered obturator that is detachable and an outside functioning sheath that may be any of three lengths (20, 28, or 35). It is offered in a choice of two sizes “*10/12F and 12/14F*”.

The dimension of the sheath is determined by the anatomy of the case and the endoscope being utilized. The flexible ureteroscope was positioned over a wire under fluoroscopic guidance on direct vision in circumstances where the UAS was not

Table 1.
Comparison of baseline parameters between studied groups.

			Without UAS N = 52		With UAS N = 60		P
Demographics							
Age (years)	Mean ± SD		42.1	11.6	40.7	10.5	0.505
	Range		23	73	20	67	
Sex	Males	N, %	30	57.7%	38	63.3%	0.542
	Females	N, %	22	42.3%	22	36.7%	
History							
Medical	Absent	N, %	46	88.5%	52	86.7%	0.987
	HTN	N, %	3	5.8%	4	6.7%	
	NIDDM	N, %	2	3.8%	3	5.0%	
	HTN&DM	N, %	1	1.9%	1	1.7%	
Surgical	Absent	N, %	32	61.5%	37	61.7%	1
	PNL	N, %	2	3.8%	2	3.3%	
	SWL	N, %	9	17.3%	11	18.3%	
	URS	N, %	6	11.5%	7	11.7%	
	Pyelolithotomy URS and SWL	N, %	2 1	3.8% 1.9%	2 1	3.3% 1.7%	
Main presentation							
Loin pain	Present	N, %	52	100.0%	60	100.0%	-
Hematuria	Absent	N, %	42	80.8%	48	80.0%	0.919
	Present	N, %	10	19.2%	12	20.0%	
Laboratory data							
Pus cell	Mean ± SD		9.3	17.9	10.3	17.6	0.755
	Range		0	100	0	100	
Urine culture	Absent	N, %	40	76.9%	48	80.0%	0.285
	E-coli	N, %	9	17.3%	8	13.3%	
	Klebsiella	N, %	3	5.8%	1	1.7%	
	Staphylococcus aureus	N, %	0	0.0%	3	5.0%	
Blood urea (mg/dL)	Mean ± SD		32.0	7.6	32.1	7.4	0.964
	Range		18	46	18	46	
Serum creatinine (mg/dL)	Mean ± SD		1.0	0.2	1.0	0.3	0.324
	Range		0.10	1.50	0.50	1.90	

Statistical analyses

Revisions, coding, tabulation, and introduction of the acquired data to a computer were made utilizing *Statistical Package for Social Science (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp)*. In order to assess the statistical significance difference between two study groups means, Student T test was used. When comparing two non-parametric groups, the Mann-Whitney test was utilized for analysis. χ^2 test was utilized to analyse the correlation among two categorial quantities. A probability (P) is regarded as statistically significant if less than 0.05 at CI (confidence interval) 95%.

RESULTS

The existing research was performed on 52 patients without UAS (first group) and 60 cases with UAS (second group). The indications of ureteroscopy were the failure of other therapies, comorbidities, skeleto-muscular deformity, body habitus and patient preference. No significant differences were found among both groups concerning demographic data, history (medical and surgical), presentation and laboratory data (Table 1). Additionally, there were no notable variations among the groups concerning the calculi side, dimension, position and Hounsfield unit, as shown in Table 2. The average dimension of the renal calculi in non-UAS or UAS treated groups was 22.5 mm and 22.6, respectively. The mean hardness was 953.6 HU in the first group and 953.1 HU in the second group. Another finding is that there was significant difference ($p < 0.001$) among both groups as regard pre-operative stenting (cases with UAS had 23.3% pre-operative stenting) (Figure 2). Additionally, as demonstrated in Table 3 and Figure 3, there were no discernible differences among the study groups in terms of intra- or post-intervention complications. Two cases were intra-operatively converted to standard *percutaneous nephrolithotomy* (PCNL) in each group based on the surgeon's decision. We also found that cases without UAS required another intervention in 17.3% (5 cases required a 2nd session of URS, and 4 cases required a session of SWL), while those with UAS required another intervention in 10% (4 cases required 2nd session of URS and 2 cases required a session of SWL), with no observable variations among the two groups. In addition, no obvious alterations were found between groups con-

Table 2.

Comparison of Stone characteristics between studied groups.

Stone characteristics			Without UAS N = 52		With UAS N = 60		P
Side	Left	N, %	25	48.1%	29	48.3%	0.978
	Right	N, %	27	51.9%	31	51.7%	
Stone size (mm)		Mean ± SD	22.5	2.0	22.6	2.5	0.839
		Range	15	26	14	27	
Stone location	Pelvis	N, %	29	55.8%	34	56.7%	0.987
	Upper calyx	N, %	7	13.5%	9	15.0%	
	Middle calyx and pelvis	N, %	8	15.4%	9	15.0%	
	Pelvis & lower calyx	N, %	8	15.4%	8	13.3%	
Hounsfield units		Mean ± SD	953.6	341.8	953.1	337.2	0.994
		Range		250	1700	250	

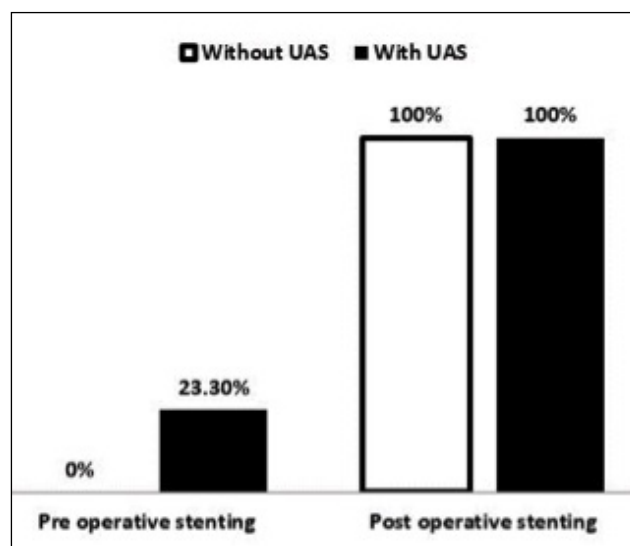


Figure 2. Pre and post-operative stenting among studied groups.

Table 3.

Comparison of complications between studied groups.

			Without UAS N = 52		With UAS N = 60		P
Intraoperative complication							
Mucosal injury	Absent	N, %	45	86.5%	52	86.7%	0.984
	Present	N, %	7	13.5%	8	13.3%	
Bleeding	Absent	N, %	43	82.7%	47	78.3%	0.563
	Present	N, %	9	17.3%	13	21.7%	
Failed	Absent	N, %	50	96.2%	56	93.3%	0.684
	Present	N, %	2	3.8%	4	6.7%	
Perforation	Absent	N, %	52	100%	59	98.3%	0.350
	Present	N, %	0	0.0%	1	1.7%	
False passage	Absent	N, %	50	96.2%	57	95.0%	0.768
	Present	N, %	2	3.8%	3	5.0%	
Converted to other procedure	Absent	N, %	50	96.2%	58	96.7%	0.884
	Present	N, %	2	3.8%	2	3.3%	
Post-operative complication							
Infection	Absent	N, %	47	90.4%	53	88.3%	0.726
	Present	N, %	5	9.6%	7	11.7%	
Fever	Absent	N, %	49	94.2%	56	93.3%	0.845
	Present	N, %	3	5.8%	4	6.7%	
Pain (loin or suprapubic)	Absent	N, %	32	61.5%	34	56.7%	0.601
	Present	N, %	20	38.5%	26	43.3%	
Hematuria	Absent	N, %	42	80.8%	45	75.0%	0.465
	Present	N, %	10	19.2%	15	25.0%	
Other complications	Absent	N, %	51	98.1%	58	96.7%	0.645
	Present	N, %	1	1.9%	2	3.3%	

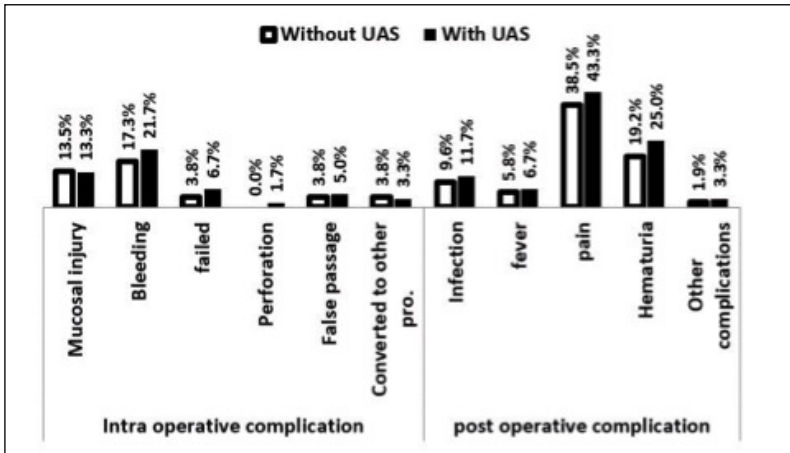


Figure 3. Complications among studied groups.

cerning operative time, stent duration and readmission (Table 4 and Figure 4). Hospital readmissions were due to fever and persistent pain.

DISCUSSION

Though PCNL was the first-line treatment of renal calculi greater than 2 cm, many studies demonstrated that RIRS can be a safer and effective alternative in managing renal stones 2 cm or more (13-15). According to a recent comprehensive study by *De Coninck et al.*, UAS installation is not something that should be done routinely during RIRS. It may be used only in cases when gaining access to the ureter is challenging, when treating patients with stones who have an elevated risk of infection complications, or in cases where visibility is poor owing to insufficient irrigation fluid outflow. The authors also draw the conclusion that, in the near future, the reasons for using a UAS might become less due to the advancement of smaller size single-use flexible digital ureteroscope (improved outflow by allowing more space between the ureteral wall and flexible ureteroscope), thulium fiber laser, and pressure-measuring instruments and integrated aspiration technology (16). In our study, we compared the utilization or not of UAS in treating renal stones 2 cm. Except for the fact that pre-stenting the ureter was much more common in the group that employed UAS, we found no statistically differences in the examined parameters between the two groups. *Aboumarzouk et al.* performed a meta-analysis and a comprehensive review of studies using flexible ureteroscopy and laser lithotripsy to treat renal calculi more than 2 cm. Nine studies involving 445 patients reported an average SFR of around 93.7 percent. The mean number of operations per patient was 1.6. The average time of operations was 82.5 minutes. SFR for stones between 2 and 3 cm was considerably higher than those for stones > 3 cm (95.7 % vs 84.6 %; p = 0.01). The researchers concluded that laser lithotripsy performed using a flexible ureteroscope could be an alternative to PCNL for individuals with calculi ≥ 2 cm

Table 4. Comparison of operative time and outcome between studied groups.

			Without UAS N = 52		With UAS N = 60		P
Operative time (min)							
Operative time (min)	Mean ± SD	81.4	4.5	82.8	13.6	0.469	
	Range	75	90	43	100		
Outcome							
Stone free rate	After the first procedure	N, %	43	82.7%	54	90.0%	0.257
	Another intervention		9	17.3%	6	10.0%	
	Free after 2 sessions of URS	N, %	5	55.6%	4	66.7%	0.667
	Free after one SWL session Post-URS	N, %	4	44.4%	2	33.3%	0.667
Stent duration (days)	Mean ± SD	24.6	7.1	24.0	6.0	0.650	
	Range	15	45	15	45		
Readmission	Absent	N, %	47	90.4%	56	93.3%	0.731
	Present	N, %	5	9.6%	4	6.7%	

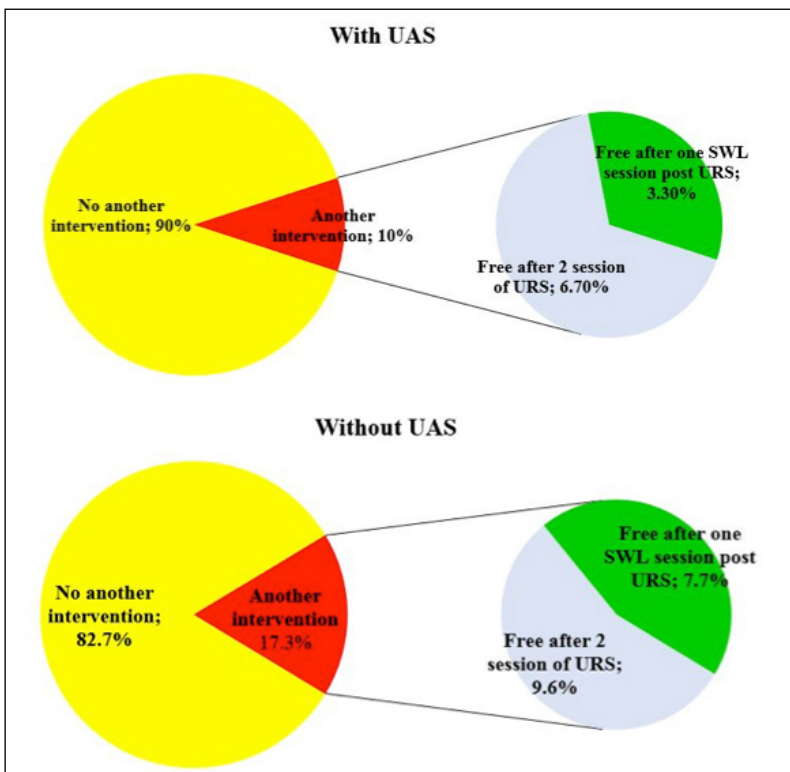


Figure 4. The stone-free rate among (A) with UAS and (B) without UAS.

(15). *Scotland et al.*, in their study for treating large renal calculi (average dimension 2.75 cm) in 167 patients achieved a SFR in the first session of 57.1%, 90.2% in the second session and 94.0% in the third session. In their study, significant complications occurred in patients who had received UASs, which were utilized in 47% of cases. It was determined that either one or many sessions of retrograde ureteroscopic lithotripsy could be used to successfully treat large kidney calculi (17). In the present study, we found that intra and post-operative complications were less in the group treated without UAS, although there was no significant difference. Also, the SFR after the first procedure was 82.7% in the group treated without UAS and 90.0% in the other group, although again the difference was not significant. Nine cases in the group treated without UAS (17.3%) and six cases in the other group (10.0%) required a second intervention. *Meier et al.*, in their study on 5316 patients who underwent primary flexible ureteroscopy used the UAS in 1969 patients (37.7%) and found that those in whom a UAS was used had increased visits to the emergency department and hospitalization ($p < 0.05$) compared to those without UAS use. They concluded that using UAS is not without risk and UAS should be judiciously employed (18). *Grasso et al.* did not use a UAS in their study on managing 2 cm or more stones in the upper urinary tract. The study included 51 patients with 66 large upper urinary tract stones. The rate of success was 76% next to the initial procedure, 91% after a second session of flexible ureteroscopy and laser lithotripsy, and 93% after a third endoscopic session. In conclusion, they found that large upper urinary tract stones could be treated appropriately and efficiently with flexible ureteroscopy and laser lithotripsy (19). *El-Anany et al.* performed a study that included thirty patients with a renal stone of more than 2 cm managed with either a semi-rigid ureteroscope or flexible ureteroscopy and laser lithotripsy without using the UAS. The success rate was 77% (23 of the 30 patients), with a negligible incidence of complications. Of the other seven patients, three of them converted to PCNL and four to *extracorporeal shock wave lithotripsy* (ESWL). If there was a lot of debris remaining after fragmentation, they employed two ureteric catheters with “a 5 F catheter in the most dependent calyx and a 6 F catheter in the upper calyx” for constant irrigation (100 mL/h of saline with 80 mg/L of gentamicin). They determined that a retrograde endoscopic approach employing laser lithotripsy was a secure and successful means of treating big renal calculi (20). *Palmero et al.* performed a retrospective review of 106 patients with renal calculi 2 cm or more who underwent RIRS with UAS in all cases. The average calculi size was 2.46 cm. The success rates was 73.6% (for a single procedure) and 93.4% for retreatment with a 6.7% postoperative minor complication rate. They concluded that for renal stones 2 cm or more, RIRS is a valid alternative to PCNL with few complications and a high success rate (21). Similarly, in a separate study by *Al-Qahtani et al.*, on 120 patients with renal stones more than 2 cm, they achieved stone-free status in 58.5% after the first session, 87% after the second session, and 96.7% after the third session. They concluded that flexible ureteroscopy using a holmium laser is a successful and

safe treatment with little morbidity. It could be an alternative to PCNL, especially for stone burdens from 2 to 3 cm (22). Another recent study was performed by *Huang et al.* to treat renal stones 2 cm or greater. In 279 patients with a mean stone diameter of 26.5 mm SFR was 61.9% at the first, 82.9% at the second, and 89.5% at the third procedure. Fever was the most common complication, with a 15.1% overall complication rate.

The conclusion was that RIRS could be utilized to treat large kidney stones (2 to 4 cm) with an acceptable complication rate and efficacy (23). This study has some limitations; the first is being retrospective in nature with selection bias. Second, the follow-up time is short, so long-term complications couldn't be assessed. The third, there were three surgeons and not only one who performed the operations in both groups. Last, stone-free rate was not assessed by the same modality in all cases, with plain abdominal radiography with ultrasonography being done in most of the cases. CT scan was only done in patients with radiolucent stones.

CONCLUSIONS

It is not always necessary to use UAS in conjunction with flexible ureteroscopy and laser lithotripsy to treat renal stones of 2 cm or more in diameter. Without the assistance of UAS, the surgery may be carried out successfully and safely. More studies are needed to corroborate this finding; ideally, they would be prospective and randomized and include long-term follow-up.

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