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Original Research

Evaluating Predictive Factor of Systemic Inflammatory Response Syndrome and Postoperative Pain in Patients Without Ureteral Stent Placement After Ureteral Access Sheath Use in Flexible Ureteroscopy for Stone Management

Takaaki Inoue, MD, PhD,[1,2] Shuzo Hamamoto, MD, PhD,[3] Shinsuke Okada, MD,[4]
Fukashi Yamamichi, MD, PhD,[1] Masaichiro Fujita, MD,[1]
Koki Tominaga, MD,[1] and Masato Fujisawa, MD, PhD[2]

Abstract

Background and Objective: This retrospective cohort study aimed to evaluate the safety of stentless flexible ureteroscopy (fURS) using a ureteral access sheath (UAS) for stone management.

Patients and Methods: A total of 270 ureteral stentless postoperative patients were analyzed. Stentless indication was characterized by having no ureteral wall or mucosa injury with only slight erosion, <1 hour operative time, and no endoscopic stone fragments with or without stone dust. Postoperative complications and pain were analyzed for safety measurements. In addition, preoperative and intraoperative risk factors associated with the incidence of systemic inflammatory response syndrome (SIRS) and postoperative pain were evaluated.

Results: The most common UAS sizes were 10/12F (69.6%) and 9.5/11.5F (28.1%). The rate of patients who were stone free was 95.9%. The median operation time was 34 minutes. Only three grade 1 ureteral injuries occurred intraoperatively. Postoperative SIRS occurred in 8.8% of patients, and postoperative use of analgesics was 35.9%. Only four patients were required to undergo eventual ureteral stenting. Less than 10/12F UAS was the only factor positively associated with preventing postoperative SIRS (odds ratio [OR], 4.733; 95% confidence interval [CI], 1.085–20.644). Older age and preoperative ureteral stenting were positively associated with preventing postoperative pain (OR, 0.970; 95% CI, 0.951–0.990 and OR, 0.427; 95% CI, 0.232–0.786; respectively).

Conclusion: Stentless fURS with UAS in stone management was feasible for selected patients. UAS size of <10/12F, older age, and preoperative stenting are possible keystones to achieving stentless fURS with UAS postoperatively. IRB approval number; 20216101.

Keywords: ureteral stentless, flexible ureteroscopy, ureteral access sheath, postoperative pain, systemic inflammatory response syndrome

Introduction

With the development of endourological technologies and techniques such as the holmium laser, thulium laser, and single-use flexible ureteroscope (fURS), fURSs for upper urinary tract stones have become increasingly frequent worldwide.[1] In addition, the advent of the ureteral access sheath (UAS) facilitates access to the renal collecting system and prevents the increase of intrarenal pressure during fURS, decreasing postoperative urinary infection rates, maintaining a clear surgical field, and increasing the stone-free rate.[2–4] Therefore, fURS is expected to expand the indication of stone management as a minimally invasive surgery, instead of percutaneous nephrolithotomy. However, the frequency of postoperative stenting has been increasing, as with fURS and UAS use.

In general, routine ureteral stenting after ureteroscopy for stone removal is common. According to the Clinical Research

[1]Department of Urology and Stone Center, Hara Genitourinary Hospital, Kobe City, Japan.
[2]Division of Urology, Department of Surgery Related, Kobe University Graduate School of Medicine, Kobe City, Japan.
[3]Department of Urology, Medical School, Nagoya City University Graduate School of Medical Sciences, Nagoya, Japan.
[4]Department of Urology, Gyotoku General Hospital, Ichikawa, Japan.

Office of Endourology Society URS Global Study, stenting after renal stone removal was performed in 80% of patients because of longer operation time, older age, and use of UAS.[5] However, ureteral stenting negatively impacts quality of life because of stent-related pain, urgency, and hematuria, and can cause significant morbidities, such as stent encrustation, pyelonephritis, and sepsis. Therefore, the European Association of Urology (EAU) guidelines proposed that routine stenting after uncomplicated URS, such as complete stone removal, is unnecessary.[6] However, Traxer and Thomas[7] investigated the incidence of complications and possible ureteral damage after UAS use. Moreover, UAS insertion could harm the ureteral mucosa and induce ureteral ischemia.[2] Accordingly, ureteral stenting after fURS with UAS remains controversial. To the best of our knowledge, there are only a few reports regarding postoperative stentless fURS with UAS for removing upper urinary tract stones.

We aimed to evaluate the safety of stentless fURS using UAS for stone management.

Patients and Methods

Study design and patients

This retrospective cohort study was conducted between May 2019 and May 2021 at our institution after the approval of our institutional review board (approval number: 20216102). Among 932 patients who underwent fURS with UAS for upper urinary tract stones, 270 were stentless postoperatively, with the following indications: no intraoperative ureteral wall or mucosa injury with only slight erosion, <1 hour operative time, and no intraoperative endoscopic stone fragments with or without stone dust in the renal collecting system. However, those who underwent intraoperative ureteral stenting according to the surgeon's decision were excluded.

Data collection

Patient data, including age, body mass index, American Society of Anesthesiologists Physical Status, comorbidity, any preoperative pyuria, urine culture, colic pain, hydronephrosis, pyelonephritis, stent placement, or extracorporeal shockwave lithotripsy (SWL), and stone demographics, such as stone location, maximum stone size, and CT value, were collected from the patient's medical records. In addition, surgical and clinical outcomes, including UAS size, stone removal, stone-free rate (defined as no fragments with or without tiny dust on kidney, ureter, and bladder radiograph [KUB] ultrasonography [US] at the first postoperative day), operation time, total laser energy, intraoperative ureteral injury grade (classified by Traxer and Thomas as follows: 0, no ureteral lesions or only mucosal petechiae; 1, mucosal erosion or a mucosal flap without smooth muscle injury; 2, damage to the mucosa and smooth muscle but no adventitia, with no retroperitoneal tissue visible; 3, injury indicating ureteral perforation involving the full thickness of the ureteral wall, including the adventitia; and 4, total ureteral avulsion),[8] postoperative complications classified using the Clavien–Dindo grading system,[9] duration of postoperative pain, days in which pain persisted, and hospitalization time, were also noted.

Outcome measures

The primary outcome measure was the safety of stentless fURS with UAS. Therefore, we evaluated the rates of postoperative complications, including pain. The presence or absence of postoperative pain with or without analgesic use was evaluated after fURS. In addition, we evaluated preoperative and intraoperative risk factors associated with the incidence of systemic inflammatory response syndrome (SIRS), which was defined as the presence of at least two of the following criteria: fever (>38°C) or hypothermia, tachypnea (>20 breaths per minute) or PCO_2 <32 mm Hg, tachycardia (>90 beats per minute), leukocytosis (>12,000 cells/mm^3), and leukopenia (<4000 cells/mm^3) and postoperative pain.

Surgical steps

All procedures for the upper urinary tract were performed under general anesthesia by two expert endourological surgeons at our institution. Then, 1 gram of cefazolin sodium was administered to all patients 30 minutes before fURS. If prior urine culture was positive, antibiotics were administered orally for 3 days before fURS and injected intravenously right before fURS. The actual surgical steps of fURS with UAS are as follows: First, a 6F semi-rigid ureteroscope (Karl Storz, Germany) was inserted into the bladder through the urethra. We then checked the bladder and confirmed the ureteral orifice. Subsequently, a 6F semi-rigid ureteroscope under the guidewire (Sensor™; Boston Scientific) was routinely inserted into the ureter to observe the ureteral lumen size and the presence of ureteral stone before UAS insertion again. If a ureteral stone was present in the distal ureter, stone removal was carried out by using the ureteroscope. After routine ureteral observation, the surgeon decided on the appropriate UAS size and length. We preferred 10/12F (Proxis®; BD Ltd) or 9.5/11.5F (Flexor®; Cook Medical, Bloomington) to prevent UAS-associated ureteral injury as much as possible. The preferably selected UAS length was 45–46 cm in men and 35–36 cm in women. The UAS was placed just below the stone bed if the stone was located in the upper or middle ureter, or around the ureteropelvic junction if the stone was just located in the kidney. Subsequently, a flexible ureteroscope (URF-P7®; Olympus, Tokyo, Japan) was inserted through the UAS. A continuous irrigation system (UROMAT®; Karl Storz) was used to maintain a clear surgical field in all cases. A 120-W holmium–yttrium–aluminum garnet laser (VersaPulse PowerSuite, Lumenis, Yokneam, Israel) with a 200-μm end-firing laser fiber (Slim Line; Lumenis) was used to disintegrate the stone. A laser setting of 6–8 Hz and 0.6–1.0 J in fragmenting to remove the stone or 80 Hz and 0.3–0.5 J with MOSES™ technology (Lumenis) in dusting or pop dusting to be less-stone basketing was generally used depending on the stone hardness, size, and location. Quarried fragments were removed using a 1.5F nitinol basket (N-circle®; Cook Medical) as much as possible. After removing all stone fragments, the whole ureter was assessed, and it was decided whether a ureteral stent should be placed depending on the ureteral injury grade, operation time, and presence of stone fragments. Finally, surgeons decided whether a urethral catheter should be inserted depending on the history of urinary retention and the patient's performance. If there was no regulation, we simultaneously achieved a urethral catheterless and stentless procedure in patients. After undergoing fURS with UAS, the patients calmly stayed in bed for 2 hours. Then, they gradually walked around their room, and their first postoperative micturition was assessed. Then, they were discharged the next day after operation if there were no complications.

Statistical analysis

Data were analyzed using the IBM SPSS Statistics version 26. Continuous variables and nominal variables in retrospectively collected data were described as medians with interquartile ranges (IQRs) and numbers with percentages, respectively. In addition, a Mann–Whitney U-test and Pearson's chi-square test for univariate analysis and stepwise logistic regression analysis for multivariate analysis were used to evaluate the risk factors related to SIRS and postoperative pain. A two-sided value of $p<0.05$ was considered statistically significant.

Results

The median age of the stentless patients was 58.5 years, and the prevalence of diabetes as a comorbidity was 18.8%. The rates of preoperative pyuria, positive urine culture, and pyelonephritis were 63.3%, 42.2%, and 15.9%, respectively. In addition, the pre-stenting rate before operation was 78.8%. In stone demographics, the median stone size per stone was 8.0 mm, and the median CT stone value was 1051 HU (Table 1).

Although the most common UAS size was 10/12F (69.6%), a 9.5/11.5F UAS was used in 28.1% of the patients. Stone basketing (95.9%) was performed for stone removal, which showed that the rate of being stone free was 95.9% on KUB-US on the first postoperative day. The median operation time was 34 minutes. Only three grade 1 ureteral injuries with only slight mucosa erosion occurred intraoperatively. Regarding postoperative pain, 97 patients (35.9%) used analgesic medications. Furthermore, the median onset time of pain after the procedure was 2 hours (Table 2).

A total of 24 (8.8%) postoperative SIRS episodes, including 15 patients with fever >38°C, were recorded. Only four patients with Clavien–Dindo grade IIIa required ureteral stenting to mitigate febrile urinary infection with hydronephrosis because antibiotics therapy with intravenous injection did not have enough effect. However, there were no phone calls, emergency visits, or re-admissions after discharge (Table 3).

We analyzed preoperative and intraoperative risk factors in stentless patients who experienced postoperative SIRS or pain. In multivariate analysis, a <10/12F UAS size was the only risk factor positively associated with preventing postoperative SIRS (odds ratio [OR], 4.733; 95% confidence interval [CI], 1.085–20.644; $p=0.039$) (Table 4). In addition, older age and preoperative ureteral stenting were positively associated with postoperative pain (OR, 0.970; 95% CI, 0.951–0.990; $p=0.004$ and OR, 0.427; 95% CI, 0.232–0.786; $p=0.006$, respectively) (Table 5).

Table 1. Patients and Stone Demographic of Ureteral Stentless After Use of Ureteral Access Sheath in Flexible Ureteroscopic Lithotripsy ($N=270$)

Patient's demographic	
Age, year, median (IQR)	58.5 (50.0–67.0)
Gender, *n* (%)	Male: 179 (66.2), female: 91 (34.0)
BMI, kg/m^2, median (IQR)	24.2 (21.8–26.7)
ASA-PS, *n* (%)	
1	259 (95.9)
2	7 (2.5)
3	3 (1.1)
4	0 (0)
5	0 (0)
6	0 (0)
Diabetes, *n* (%)	51 (18.8)
Preoperative pyuria, *n* (%)	171 (63.3)
Preoperative positive urine culture, *n* (%)	114 (42.2)
Preoperative colic pain, *n* (%)	141 (52.2)
Preoperative hydronephrosis, *n* (%)	147 (54.4)
Grade 1	59 (21.8)
Grade 2	87 (32.2)
Grade 3	1 (0.3)
Preoperative pyelonephritis, *n* (%)	43 (15.9)
Preoperative stent placement, *n* (%)	213 (78.8)
Previous SWL treatment for the stone, *n* (%)	28 (10.3)
Stone demographic	
Stone location, *n* (%)	
Ureter	82 (30.3)
Kidney	117 (43.3)
Ureter and kidney	71 (26.2)
Max stone size per stone, mm, median (IQR)	8.0 (6–11)
CT value, HU, median (IQR)	1051 (751–1359.7)

ASA-PS = American Society of Anesthesiologists Physical Status; BMI = body mass index; IQR = interquartile range; SWL = extracorporeal shockwave lithotripsy.

Discussion

In this study, we found that stentless fURS with UAS for upper urinary tract stone removal was safe in selected patients who showed indications for the stentless procedure, such as no intraoperative ureteral wall or mucosa injury, <1 hour operative time, and no intraoperative endoscopic stone fragments with or without stone dust in the renal collecting system.

Postoperative stenting is useful in preventing complications, including ureteral obstruction owing to edema, hydronephrosis, ureteral stricture, and postoperative pain. However, the stent might cause symptoms such as pain, irritation, hematuria, and urinary infection.[10] The EAU guidelines on urolithiasis strongly recommended that routine stenting after uncomplicated URS, such as complete stone removal, is not mandatory.[6] However, the guidelines did not propose or recommend stentless fURS with UAS. In addition, the clinical criteria of ''uncomplicated URS'' were not clearly defined. Hollenbeck et al.[11] found that among 219 postoperatively stentless patients, one of the factors associated with postoperative morbidity was an operative time of ≥45 minutes, and thus reported that ureteral stenting was not necessary when undergoing ureteroscopy with a short operative time and

Table 2. Clinical Outcome Of Ureteral Stentless After Use of Ureteral Access Sheath in Flexible Ureteroscopic Lithotripsy ($N=270$)

Use of urethral catheter, *n* (%)	0 (0)
Size of UAS, *n* (%)	
9.5/11.5F	76 (28.1)
10/12F	188 (69.6)
10.7/12.7F	2 (0.7)
11/13F	4 (1.4
Stone removal, *n* (%)	
Basketing	259 (95.9)
Basketing with dusting	11 (4.1)
Stone-free rate, *n* (%)	259 (95.9)
Operation time, minute, median (IQR)	34 (26–52)
Total laser energy, J, median (IQR)	945 (335–2120)
Ureteral injury, *n* (%)	
Grade 0	267 (98.8)
Grade 1	3 (1.2)
Grade 2	0 (0)
Grade 3	0 (0)
Grade 4	0 (0)
Postoperative pain with analgesic, *n* (%)	97 (35.9)
Time of pain after operation, hours, median (IQR)	2.0 (1.0–3.0)
Pain persistence days, days, median (IQR)	1.0 (1.0–1.0)
Hospitalization days, days, median (IQR)	2.0 (2.0–2.0)

UAS = ureteral access sheath.

minimal ureteral trauma.[12] Although these findings were described in fURS without UAS, we prospectively defined the three indications for stentless fURS with UAS, according to a previous study.

Ureteral stenting after ureteroscopy in distal and middle ureteral stones <2 cm is not always necessary if the procedure is not complicated.[13–15] However, this remains a controversial issue after fURS. Denstedt et al.[16] compared nonureteral with ureteral stenting after ureteroscopic lithotripsy with holmium lasers, including fURS for ureteral stones at any ureteric level. They mentioned that although there was no difference in the nonstented and stented groups with respect to complications or stone-free status, the stented group had significantly greater irritative and painful symptoms. However, the UAS was not used in their study.[16] In general, UAS use has some risks of complications and possible ureteral damage because of direct ureteral injury or compressed ischemia of the ureteral mucosa.[7] Therefore, stenting after fURS with UAS is recommended by some authors. However, Astroza et al.[17] mentioned the necessity of postoperative ureteral stenting in patients with preoperative ureteral stenting. They concluded that postoperative stenting might not be needed if the ureteral stent was placed preoperatively because there was no difference in postoperative urinary tract infection between patients with and without postoperative stenting (7.8% *vs* 0%, $p=0.245$). In addition, they discussed that pre-stenting may have a greater advantage with respect to passive ureteral dilation.[17] Mi et al.[18] reported a 9.7% incidence of postoperative SIRS with stented fURS with UAS. In addition, Zhong et al.[19] reported an 8.1% incidence of postoperative SIRS after the same procedure. In our study, the incidence of postoperative SIRS even with stentless fURS with UAS was 8.8%, which was equivalent to that of previous reports.

As Astroza et al.[17] mentioned previously, the preoperative stenting before fURS with an 11/13F UAS was quite beneficial in achieving fewer complications and less pain with no stenting. Although preoperative stenting did not influence the incidence of postoperative SIRS in our study, the use of >10/12F UAS significantly affected the incidence of postoperative SIRS when practicing stentless fURS. We speculated that placing a larger UAS size results in severe postoperative edema of the ureteral mucosa, although it depends on the initial ureteral lumen diameter. Therefore, temporary postoperative ureteral obstruction can easily occur. SIRS may rarely occur owing to the degree of ureteral obstruction if coexisting bacteria are present in the urine. Therefore, in some cases in which the ureteral lumen size is initially much narrower, preoperative stenting can be quite useful for stentless fURS with UAS.

In general, the standard UAS size during fURS might be >11/13F. Lallas et al.[20] investigated the use of 10/12F, 12/14F, and 14/16F UAS during fURS, which showed a minimum ureteral blood flow decrease by 25%, 70%, and 80% below the baseline, respectively. A longer ischemic time in ureteral blood flow may lead to postoperative ureteral edema. In addition, upregulation of proinflammatory mediators cyclooxygenase-2 (COX-2) and tumor necrosis factor-alpha (TNF-α) was observed in the ureteral wall after UAS use, which might have also caused postoperative pain and complications.[21] Therefore, if stentless fURS with UAS is achieved, a smaller UAS size and shorter operation time are preferred to decrease postoperative complications and pain. In this study, the most frequently used UAS size was smaller, with <10/12F in 97.6% of cases. The median operation time was shorter at 34 minutes.

Regarding postoperative pain, patient age and preoperative stenting were significantly critical factors in our study. Gul et al.[22] reported that younger patients had higher chances of post-ureteroscopy pain. In addition, Hamamoto et al.[23] found that a younger age was an independent risk factor for distal ureteral tightness during ureteroscopy. If an even smaller

Table 3. Postoperative Complications of Ureteral Stentless After Use of Ureteral Access Sheath Flexible Ureteroscopic Lithotripsy ($N=270$)

Postoperative complication, *n* (%)	
SIRS	24 (8.8)
Fever (>38°C)	15 (5.5)
Urinary retention	0 (0)
Phone call	0 (0)
Emergency visit	0 (0)
Re-admission	0 (0)
Clavien–Dindo grade, *n* (%)	
Grade I	97 (35.9)
Grade II	20 (7.4)
Grade IIIa	4 (1.4)
Grade IIIb	0 (0)
Grade IV	0 (0)
Grade V	0 (0)

SIRS = systemic inflammatory response syndrome.

Table 4. Pre- and Intraoperative Risk Factors in Patients with Systemic Inflammatory Response Syndrome (N=270)

Variables related with SIRS	*SIRS (+)* n=*24*	*SIRS (−)* n=*246*	*Univariate analysis* (p-*value*)[a]	*Multivariate analysis (OR, 95% CI,* p-*value*)[b]
Age, year, median (IQR)	58.0 (51.0–65.1)	58.5 (50.2–67.3)	0.928	
Operation time, minute, median (IQR)	32 (25.5–46)	35 (26.2–49)	0.544	
Diabetes, *n* (%)			0.402	
Present	3 (12.5)	48 (19.5)		
Absent	21 (87.5)	198 (80.4)		
Preoperative pyuria, *n* (%)			0.214	
Positive	18 (75)	153 (62.1)		
Negative	6 (25)	93 (37.8)		
Preoperative positive urine culture, *n* (%)			0.342	
Positive	12 (50)	122 (49.5)		
Negative	12 (50)	124 (50.5)		
Preoperative pyelonephritis, *n* (%)			0.917	
Present	4 (16.6)	39 (15.8)		
Absent	20 (83.3)	207 (84.1)		
Preoperative stent placement, *n* (%)			0.108	
Present	22 (91.6)	191 (77.6)		
Absent	2 (8.4)	55 (22.3)		
Size of UAS, *n* (%)			0.024	4.733, 1.085–20.644. $p=0.039$
≥10/12F	22 (91.6)	172 (69.9)		
<10/12F	2 (8.4)	74 (30.0)		

[a]Pearson's chi-square test, Mann–Whitney *U* test.
[b]Logistic regression analysis, stepwise.
CI = confidence interval; OR = odds ratio.

Table 5. Pre- and Intraoperative Risk Factors in Patients with Postoperative Pain (n=97)

Variables related with pain	*Pain (+)* n=*97*	*Pain (−)* n=*173*	*Univariate analysis* (p-*value*)[a]	*Multivariate analysis (OR, 95% CI,* p-*value*)[b]
Age, years, median (IQR)	54.1 (47.0–63.1)	60.1 (52.0–69.1)	0.001	0.970, 0.951–0.990, $p=0.004$
Operating time, minute, median (IQR)	34 (28–53)	34 (24–46)	0.146	
Gender, *n* (%)			0.375	
Male	61 (62.8)	118 (68.2)		
Female	36 (37.1)	55 (31.7)		
Preoperative colic pain, *n* (%)			0.270	
Present	55 (56.7)	86 (49.7)		
Absent	42 (43.2)	87 (50.2)		
Preoperative hydronephrosis, *n* (%)			0.206	
Present	46 (47.4)	101 (58.3)		
Absent	51 (52.5)	72 (41.6)		
Preoperative ureteral stenting, *n* (%)			0.001	0.427, 0.232–0.786, $p=0.006$
Present	66 (68.0)	147 (84.9)		
Absent	31 (31.9)	26 (15.0)		
Size of UAS, *n* (%)			0.713	
≥10/12F	71 (73.1)	123 (71.0)		
<10/12F	26 (26.8)	50 (28.9)		

[a]Pearson's chi-square test, Mann–Whitney *U*-test.
[b]Logistic regression analysis, stepwise.

UAS was inserted into the narrow ureteral lumen of younger patients, the ureteral mucosa was swollen for only a limited time postoperatively. As in the study by Astroza et al., ureteral preoperative stenting was a significant risk factor for postoperative pain in our study.

There are some limitations to our study. First, this was a noncomparative retrospective cohort study. Therefore, future comparative studies such as randomized trials or matched retrospective trials between stentless and stented patients are recommended. Second, this study was conducted by endourological experts in a special institution. Stentless fURS with UAS is not a common procedure yet. Third, the use of <10/12F UAS was mainly used in this study. However, the preferred UAS size globally might be >11/13F. Therefore, there are still insufficient data, as our results cannot be adapted in cases with >11/13F UAS.

Nevertheless, this study includes important information on stentless fURS with UAS. Our definition of ureteral stentless seems to be feasible. If stentless fURS with UAS is achieved, a smaller UAS size and shorter operation time are preferred to decrease postoperative complications and pain. From this viewpoint, patient age, UAS size, and UAS application, including pre-stenting management, will be more important aspects in preventing postoperative SIRS and pain after stentless procedures.

Conclusions

Stentless fURS with UAS in stone management was feasible for selected patients. UAS size <10/12F, older age, and preoperative stenting can be keystones in achieving stentless fURS with UAS.

Authors' Contributions

T.I.: substantial contribution to conception and design of work, analysis, or interpretation of data for the work; S.H.: drafting the work and revising it; S.O.: drafting the work and revising it; F.Y., M.F., and K.T.: revising it critically; and M.F.: revising the article critically.

Author Disclosure Statement

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Address correspondence to:
Takaaki Inoue, MD, PhD
Department of Urology and Stone Center
Hara Genitourinary Hospital
5-7-17 Kitanagasadori, Chuo-ku
Kobe City 650-0012
Hyogo
Japan

E-mail: inouetak@harahospital.jp

Abbreviations Used

ASA-PS = American Society of Anesthesiologists Physical Status
BMI = body mass index
CI = confidence interval
COX-2 = cyclooxygenase-2
CT = computed tomography
EAU = European Association of Urology
fURS = flexible ureteroscopy
HU = Hounsfield units
IQR = interquartile range
KUB = kidney, ureter, and bladder radiograph
OR = odds ratio
SIRS = systemic inflammatory response syndrome
SWL = extracorporeal shockwave lithotripsy
TNF-α = tumor necrosis factor-alpha
UAS = ureteral access sheath
US = ultrasonography