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ORIGINAL PAPER

Safety and efficacy of navigable suction- assisted ureteral access sheath for treatment of kidney stones

Ahmed Rabie [1, 2], Mahmoud Khalil [3], Zachary Dovey [4], Moustafa Elsawy [1], Ahmed Balah [1], Maida Bada [5], Mohamed Jabbo [6], Mohamed Elsaqa [1, 2], Maurizio Buscarini [4], Osama Zaytoun [1]

[1] Alexandria University, Egypt;
[2] Northwell Health, NY, USA;
[3] Department of Surgery, Division of Urology, University of Chicago, Chicago, Illinois;
[4] Mount Sinai, NY, USA;
[5] Uros Associates' Hospital Sagrada Familia, Barcellona, Spain;
[6] Hamah National Hospital, Syria.

Summary

Background: The recent innovation of ureteral access sheath (UAS) includes the use of flexible navigable UAS that allows pending into the collecting system and adding suction/evacuation that can improve the efficacy of fragment clearance. This study aimed to report on the experience of using navigable suction-assisted UAS (NS-UAS) for management of kidney stones through a large cohort.
Methods: A retrospective analysis was conducted for patients who underwent flexible ureteroscopy for kidney stones using navigable NS-UAS between 2022 and 2025 in a tertiary center. Perioperative outcome data regarding efficacy and safety were described. Univariate and multivariate analysis was conducted for risk factors associated with stone-free rate.
Results: The study included 2284 patients with mean (± SD) age of 48 (± 12.5) years. Half of the patients (49.7%) underwent prior ureteric stent placement. The mean (± SD) stone burden was 13.1 (± 3.7) mm. The mean (± SD) operative time was 95.91 (± 25.2) minutes. Stone basketing was required in 11% of patients. Approximately 70% of patients underwent intraoperative stent placement. Stone-free rate (SFR) at 1-month follow-up was 85.8%. A repeat procedure for stone clearance was required in 12% of the patients. The overall complication incidence was 9.6% with only 1.28% incidence of Clavien-Dindo grade III or IV complications. On multivariate analysis, older age (OR = 0.97 [0.96-0.98]), higher stone burden (OR = 0.45 [0.33-0.62]), and intraoperative stent placement (OR = 0.71 [0.54-0.95]) were associated with lower SFR, while the use of basketing (OR = 2.17 [1.33-3.53]) was associated with higher SFR.
Conclusions: NS-UAS can be used safely and effectively in patients with renal stone disease with low rates of complications and a favorable SFR. Stone basketing may still be necessary during NS-UAS to enhance overall SFR.

KEY WORDS: *Kidney calculi; Nephrolithiasis; Ureteroscopy; Holmium laser.*

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INTRODUCTION

Flexible ureteroscopy (FURS) is the surgical treatment of choice for patients with proximal ureteric stones and kidney stones ≤ 2 cm (1, 2). The continuous technological advances in FURS have improved procedural instrumentation, visualization, and stone free rates. These advances include high-power lasers, *ureteral access sheath* (UAS), single-use disposable scopes, digital high-resolution scopes, use of suction via the scope, and scopes monitoring the intrarenal pressure (3, 4).
The use of UAS with FURS has the advantages of lowering the intrarenal pressure which reduces the complications related to infection and fluid intravasation and of increasing the irrigation flow which improves the visualization during FURS. Also, UAS use facilitates multiple reinsertions and withdrawals of the FURS during surgery decreasing the operative time and potentially increasing the stone-free rate. On the other side of the coin, UAS may be associated with increased risk of ureteric injury especially with non-dilated ureters (5, 6).
The recent technological innovation of UAS includes the use of flexible/navigable UAS that allows pending the UAS into the renal pelvis and calyces and the use of the suction ureteral access sheath that adds suction to the sheath to improve the efficacy of fragment clearance during surgery. Continuous irrigation and suction through the UAS enable lowered intra-renal pressures and proper stone visualization, while simultaneously providing negative pressure to extract stone dust and fragments (4, 7-9).
In this study, we aimed to assess the efficacy and safety of a *navigable suction- assisted* UAS (NS-UAS) that provides both capabilities of intra-renal navigation and use of suction/evacuation through retrospective analysis of a large cohort.

METHODS

This is a retrospective study of patients who underwent FURS at a single institution (IRB # ITUCM66733451-89) between February 2022 and October 2025. All patients were older than 18 years and had kidney stone disease. All patients underwent standardized pre-operative assessments including *computerized tomography* (CT) without or with contrast. Preoperative stenting was performed in patients with signs of urinary tract obstruction or suspected infection.

Procedure details and postoperative assessments

All procedures were done under general anesthesia. The NS-UAS (*ClearPetra TM, Well Lead Medical Inc.*) of 10-12 Fr by 36, 46 or 55 cm was advanced over a guide wire within one centimeter of the stone. Following this, a flexible ureteroscope (*Olympus; URF P5, URF P6, URF-V, URF-V2R*) was inserted through the ClearPetra sheath to access the upper tract. Continuous pressurized irrigation was performed at a flow rate of 50-100 ml per minute to ensure proper visualization of the stone. Stone fragmentation was performed using Holmium-YAG Laser (utilizing 200-220-micron laser fiber, typically with standard settings starting at 0.8 Joules and 8 Hz, adjusted intraoperatively according to stone hardness and location). In cases where inadequate intraoperative stone clearance was noted, the surgeon used a basket to retrieve the remaining fragments. A double-J stent was placed at the end of the procedure when deemed necessary by the surgeon. One month following surgery, patients underwent a CT scan. The double-J stent, if placed and not removed earlier, was removed at this time if the patient was stone free. Patients with radiological evidence of residual disease underwent retreatment by repeat FURS.

Data variables

Preoperative patients' demographics, pre-operative creatinine and information on preoperative stent placement and stone characteristics were collected. Intraoperative details including operative time, ureteroscopy time, *estimated blood loss* (EBL), use of basketing, intra-operative stenting, and incidence of ureteral injury were analyzed. Post-operative outcome data collected included duration of hospitalization after surgery, post-operative creatinine, post-operative complication graded by Clavien-Dindo score (10), need for repeat procedures, and stone free rate at one month.

Study outcomes

The primary outcome measured was stone free rate (SFR) at one month. This was defined as either no residual stone fragments, or the presence of fragments ≤ 2 mm on postoperative CT (11, 12). Other key secondary outcomes included the operative and ureteroscopy time, number of repeat procedures, need for basketing, duration of hospital stay, the incidence of ureteral injury and incidence of any postoperative complications.

Statistical analysis

For continuous variables, means and standard deviation (or medians and *interquartile ranges* [IQR] where appropriate) were reported, while categorical variables were described as frequencies and percentages. Univariate logistic regression was performed using relevant perioperative variables, following which a multivariate model was created using those variables that demonstrated statistical significance. Odds ratios with 95% confidence intervals were generated for the relevant variables. All analysis was performed on R programming software version 4.3.3.

RESULTS

In total, 2284 patients were included in the study. Baseline patients' and stone characteristics are shown in Table 1. Almost half of all patients (49.7%) underwent preoperative stent placement prior to FURS. The mean ± SD stone burden was 13.1 ± 3.7 millimeters. Stones were lower pole stones in 20% of patients.

The mean ± SD operative time was 95.91 ± 25.2 minutes while the mean ureteroscopy time was 66.7 ± 11.4 minutes. Despite the use of the suction clearance, basketing was required in 11% of patients. Approximately 70% of patients underwent intraoperative stent placement. Median hospital stay was 1 day. Overall, 9.6% of patients experienced a complication during and after surgery. The incidence of intraoperative ureteral injury was 1.5% while only 1.28% of all patients experienced postoperative Clavien-Dindo grade III or IV complications within 90 days. At one-month follow up, 85.8% of all patients were stone-free, with either non-evidence of stones or fragments ≤ 2 mm on postoperative imaging. Overall, 12 % of all patients required a repeat procedure for stone clearance. Intraoperative and postoperative outcome data are detailed in Table 2.

Univariate logistic regression analysis of factors associated with *stone-free rate* (SFR) found statistical significance for age, stone burden, use of basket intraoperatively, and intraoperative stent placement. On multivariate analysis, age (OR 0.97 [0.96-0.98]), stone burden (OR 0.45 [0.33-0.62]), and intraoperative stent placement (OR 0.71 [0.54-0.95]) were inversely associated with SFR, while the use of basket intraoperatively (OR 2.17 [1.33-3.53]) was directly associated with SFR. The association for age, however, was small, with the odds ratio tending towards one (Table 3).

Table 1.
Baseline patients and stone characteristics.

Variable	Result (no = 2284)
Age, mean ± SD	48 ± 12.5
Sex, n (%):	
Male	1252 (54.8%)
Female	1032 (45.2%)
Body Mass Index, mean ± SD	29.8 ± 6.04
Pre-operative Creatinine (mg/dL), mean ± SD	1.15 ± 0.35
Preoperative Stent Placed, n (%)	1135 (49.7%)
Laterality, n (%):	
Right side	1213 (53.1%)
Left side	1071 (46.9%)
Stone Location, n (%):	
Upper Pole and Pelvis	1844 (80.7%)
Lower Pole	440 (19.3%)
Stone Burden (mm), mean ± SD	13.1 ± 3.7
Stone Density, Hounsfield Units (HU), n (%):	
< 600	968 (42.4%)
600-950	1123 (49.2%)
> 950	193 (8.4%)

Table 2.
Perioperative outcome data.

Parameter	Result
Operative time (minutes), mean ± SD	95.91 ± 25.2
Ureteroscopy time (minutes), mean ± SD	66.7 ± 11.4
Use of basket intraoperatively, n (%)	249 (10.9%)
Intraoperative stent placement, n (%)	1566 (68.6%)
Total Number of Post-operative Complications, n (%)	221 (9.6%)
Postoperative Fever, n (%)	105 (4.6%)
Postoperative Sepsis, n (%)	32 (1.4%)
Ureteral Injury, n (%):	34 (1.48%)
Need for post-operative transfusion, n (%)	13 (0.56%)
Hospital-stay, days, median (IQR)	1 (0-1)
Post-operative Complications within 90 days, n (%):	
Grade I	118 (5.2%)
Grade II	74 (3.1%)
Grade III	27 (1.2%)
Grade IV	2 (0.08%)
Stone Free Rate at one month, n (%)	1960 (85.81%)
Need for repeat procedures, n (%)	275 (12%)

Table 3.
Univariate and multivariate analysis of perioperative factors influencing stone-free rate at one month.

Parameter	Univariate analysis Stone- Free at 1 month	
	Yes	No
Age, mean ± SD	47.1 ± 14.6	53.3 ± 13.1
BMI, mean ± SD	29.9 ± 6.04	29.7 ± 6.05
Sex:		
Male	1069 (46.8%)	183 (8%)
Female	891 (39%)	141 (6.2%)
Preoperative Creatinine, mean ± SD	1.15 ± 0.36	1.16 ± 0.25
Preoperative Stent Placed, n (%)	969 (42.4%)	166 (7.3%)
Stone Burden, mean ± SD	11.06 ± 0.36	15.02 ± 0.39
Stone Density, (HU)		
< 600	830 (36.3%)	138 (6%)
600-950	956 (41.9%)	167 (7.3%)
> 950	174 (7.6%)	19 (0.8%)
Procedure Time, mean ± SD	66.8 ± 13.4	68 ± 11.5
Estimated Blood Loss, mean ± SD	49.9 ± 79	50.45 ± 84.6
Use of basket, n (%)	227 (9.9%)	22 (0.9%)
Intraoperative Stent Placed, n (%)	1320 (57.8%)	246 (10.8%)
Postoperative Creatinine, mean ± SD	1.23 ± 0.34	1.26 ± 0.38
Serum creatinine change, mean ± SD	0.1 ± 0.5	0.06 ± 0.45
Ureteral Injury, n (%)	30 (1.3%)	4 (0.2%)

Discussion

The goal of ureteroscopy is to maximize SFR with minimal complications. As surgeons embrace small diameters scopes, stone clearance became more challenging and ancillary devices have proved to be of great value (4, 5, 13). This study demonstrated that in 2284 patients, NS-UAS led to a one-month overall SFR of 85.8%. To our knowledge, this is the largest continuous series of patients in the literature to undergo NS-UAS. Though age was a statistically significant predictor on multivariate analysis, the odds ratio tended to one, thus we believe that this association may not be of clinical relevance. Our results regarding association of lower SFR with increased stone burden came intuitive and matched previous published data (2, 14, 15). In cases where the surgeon was not confident about complete stone clearance, a stent was placed to aid in collecting system drainage. This may explain the inverse association that was found between stent placement and a lower SFR.

Intraoperative basketing was significantly associated with a higher SFR. We hypothesized that clearance of relatively large particles is still beyond the capability of NS-UAS and still needs a mechanical removal of significant fragments to attain maximum stone clearance, as a key intraoperative decision.

Almost half of patients in our series were pre-stented. While previous studies have shown that pre-stenting facilitates access sheath placement and minimizes injury, we did not encounter any significant impact on pre-stenting on our final SFR (16, 17). We believe that pre-stenting plays a more crucial role in improving access success and ensure safe operation. Potentially, pre-stenting allows passive ureteral dilation which may facilitate pelvicalyceal manipulation, especially when addressing lower pole stones which constitute around 20% of our study population.

Our relatively high SFR comes in concordance with recent prospective studies using NS-UAS. In a multicenter study of 394 patients, Shrestha et al who used NS-UAS primarily for *lower pole stone* (LPS), reported a high single-stage SFR (Grade A+B, defined as 100% stone free and < 2 mm respectively) of 96.6% (for non-LPS) and 98.4% (for LPS). (18) Some dissimilarities with our study may have contributed to different outcomes. First, they prospectively recruited only patients with LPS. Our retrospective study encompassed around six times more patients with stones in different locations making our population more heterogenous. Second, type of laser technology, as many report an association between Thulium Fiber Laser use and higher SFR (19-21). In fact, Shrestha et al confirmed that thulium laser fiber was found to be a determining factor associated with higher odds of achieving Grade A SFR in their study. Our study, in contrast, utilized Holmium-YAG lasers in all patients (18). Notably, our basketing rate of 11% was still close to their reported basketing rate of 13% This again confirms that suction technology cannot entirely obviate the need for manual fragment extraction per surgeon's judgement. High IRP during FURS has been thought to be responsible for the translocation of bacteria into the bloodstream, increasing the risk of life-threatening urosepsis (22). The continuous suction evacuation of fluid and fragments by the NS-UAS decreases IRP, resulting in a lower incidence of infectious complications after URS (23). In the present study, infection complications were low and in concordance with previously reported data.12 Additionally, we noted an overall complication rate of 9.6%, with more than half of those being Clavien-Dindo 1. Only 1.28% of patients experienced a major complication (Clavien-Dindo ≥ 3). These rates are comparable to outcomes reported in other studies of vacuum-suction devices (24-26).

Gauhar et al. investigated the use of NS-UAS during same-session bilateral retrograde intrarenal surgery in 115 patients (27). They reported very low rates of significant complications, including no sepsis and only 1.7% low-grade ureteric injury, highlighting the safety of this approach even in complex bilateral procedures. Our findings of 1.4% sepsis and 1.48% ureteral injury in a much larger, heterogenous cohort emphasizes the general safety of the NS-UAS approach across different clinical contexts. However, we scored much less fever rate (4.6%) in 24 hours when compared to their study (16.5%). This difference may be intuitively attributed to factors like bilateral versus unilateral procedures, inclusion criteria, statistical methods utilized or operative duration.

The use of NS-UAS has been recently increasing due to shorter operating times, convenient instrumentation, and a lower incidence of postoperative infectious complications (14, 28). In a matched analysis of 330 patients undergoing flexible ureteroscopy, the authors depicted a significantly lower infectious complication rate in the NS-UAS group, along with shorter operative time, and higher early SFR (28). Another retrospective study examining the differences between traditional sheaths and NS-UAS found that patients with predictable risk factors for infections could benefit from the use of NS-UAS (29). Our findings support these earlier observations and stress the advantages of such ancillary devices for better outcomes. Further randomized control trials are required to truly ascertain the advantages of using NS-UAS over the conventional FURS.

This study is not without limitations. Firstly, the retrospective nature of our study which may have led to selection bias. Additionally, this was a single arm study that did not include a matched group for comparison. Finally, we did not measure IRP due to availability of specialized scopes and equipment back then. Nevertheless, we measured the rates of postoperative infectious complications (fever and sepsis) and postoperative renal damage (creatinine), which may be regarded as rough indicators for increased IRP.

Conclusions

The use of NS-UAS in patients with renal stone disease has proven safety and efficacy with low rates of postoperative complications and a favorable SFR. Manual extraction of fragments using baskets, per surgeon judgement, may still be necessary to enhance overall SFR.

Declarations

__Ethical approval and consent for participate:__ This retrospective study was reviewed and approved by the Institutional Review Board of Alexandria University (IRB # ITUCM66733451-89). The study included adult patients (> 18 years) who underwent flexible ureteroscopy (FURS) for kidney stone disease between February 2022 and October 2025 at a single institution. Given the retrospective design and use of existing de-identified clinical data, the requirement for informed consent was waived. All procedures were performed in accordance with institutional ethical standards and the principles of the Declaration of Helsinki.

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__Authors' contributions:__ Ahmed Rabie: Conceptualization, Data collection, Data analysis, Writing – original draft; Mahmoud Khalil: Critical revision, Supervision; Zachary Dovey: Data analysis, Data analysis; Moustafa Elsawy: Critical revision, Supervision; Ahmed Balah: Methodology, Critical revision, Supervision. Maida Bada: Supervision, Data analysis; Mohamed Jabbo: Critical revision, Supervision; Maurizio Buscarini: Methodology, Critical revision, Supervision; Mohamed Elsaqa: Critical revision, Supervision; Osama Zaytoun: Methodology, Critical revision, Supervision.

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Correspondence

Ahmed Rabie
dr.ahmed.hamdy.amin@gmail.com
Mohamed Elsaqa
mohamed.elsaqa@alexmed.edu.eg
Alexandria University, Egypt & Northwell Health, NY

Mahmoud Khalil
Mahmoud.khalil@bsd.uchicago.edu
Department of Surgery, Division of Urology, University of Chicago, Chicago, Illinois

Zachary Dovey
Zachary.dovey@mountsinai.org
Maurizio Buscarini
Sarchmb@yahoo.com
Mount Sinai, NY

Moustafa Elsawy
moustafa.elsawy@alexmed.edu.eg
Ahmed Balah
Dr.ahmedbalah@gmail.com
Osama Zaytoun (Corresponding Author)
OZaytoun@gmail.com
Alexandria University, Egypt

Maida Bada
Maida.bada@yahoo.com
Uros Associates' Hospital Sagrada Familia, Barcellona, Spain

Mohamed Jabbo
Abojabo91@gmail.com
Hamah National Hospital, Syria