ORIGINAL RESEARCH

A Retrospective Study on Retrograde Intra-renal Surgery With versus Without the Use of Ureteral Access Sheaths in Patients with Nephrolithiasis

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Introduction: Placement of ureteral access sheath (UAS) prior to retrograde intra-renal surgery (RIRS) is done to provide easier re- entries, shorter operation time and better vision. However, some studies have associated the placement of UAS to increased morbidity and complications.
Objective : The study aimed to compare outcomes of patients with nephrolithiasis who underwent RIRS with versus without placement of UAS
Methods: This is a retrospective cohort study among patients with nephrolithiasis who underwent RIRS with or without placement of UAS. The authors analyzed a total of 52 patients who underwent RIRS, 22 without, and 30 with UAS. Comparison of patients' clinical profile, duration of post-operative hospital stay and the difference of their frequency were determined using Independent Sample T-test, Mann-Whitney U test and Fisher's Exact test, respectively. STATA 15.0 was used for data analysis.
Results: The two groups were similar in terms of clinical profile and operative outcomes. In terms of complications, there was one patient who had a failed surgery in the UAS group. Bleeding was reported in both groups. One-fourth of the patients had abdominal/bladder cramps and 13% had fever. Stone-free rate was 94% at 1 month and 92% at 3 months post-op. Readmission within 3 months was seen in four patients (8%) and retreatment was done on three patients (6%).
Conclusion: There is no significant difference in placing UAS or not prior to RIRS in terms of clinical profile and operative outcomes. Safety measures should be observed to prevent any bleeding and ureteral injuries during placement of UAS intra-operatively.

Key words: Retrograde intrarenal surgery (RIRS), uretral access sheath (UAS)

Introduction

Ureteral access sheath is one of the accessories/ tools that can be used during retrograde intrarenal surgery (RIRS). Its use is popular and diffused among endourologists. Placing UAS prior to RIRS is preferred by most urologists since it allows easy access to the upper tract cavities and evaluation of any portion of the kidney, allows rapid repeat entrance into the ureter and collecting system, lowers the intrarenal pressure during pulse irrigation, improves visibility, avoiding ureteral lesion when extracting stone fragments, improves the drainage, and protects the scope.

The use and safety of ureteral access sheath during retrograde intrarenal surgery remains controversial despite the advantages of using UAS such as allowing fast, safe, and rapid repeated entrance into the collecting system, lowers the intrarenal pressure, improves visibility,

and increases the ureteroscope lifespan[1,2] there are concerns related to UAS use about damage to the ureter by over distension which compromises ureteral blood flow, resulting in ureteral ischemia or direct damage to the ureter during the insertion of the UAS.[2]

In the Philippines, there hasn't been much literature/ study done about retrograde intra-renal surgery and no study yet on the outcomes of RIRS with or without using UAS. Thus, this study will be a pioneer to the local setting and an adjunct to the limited data available. Hence, we aim to investigate the necessity of using routine access sheath for RIRS versus sheathless RIRS.

Objectives

The study aims to investigate if placement of UAS is necessary prior to RIRS by comparing outcomes of patients with nephrolithiasis who underwent RIRS with UAS placement from those without UAS placement. Specifically, it aimed to present the clinical profile and demographics of all patients who underwent retrograde intrarenal surgery (with and without the use of UAS) and to evaluate their operative outcomes including intraoperative complications and stone free rate. Lastly, it also intends to describe and assess the safety and efficacy of placing UAS during retrograde intrarenal surgery compared with a sheathless RIRS.

Methods

After obtaining Institutional Review Board approval, a retrospective review of all patients who underwent RIRS from July, 2018 to September 2021 were included in the study. Patients who had incomplete follow-up (no follow up nor imaging done within 3 months post- operatively) were excluded in the study. Basic demographics including presence of comorbidities, previous stone surgeries were documented. Pre-operative locations of the stone, presence of kidney abnormalities were also checked. The intraoperative course of the patients were reviewed, specifically, the authors determined which among the patients underwent RIRS with or without UAS. They then took note of the operative time (starts at the time the flexible scope was first inserted upto the time the procedure ended), intra-operative findings, the fragmentation device used and any complications during the procedure such as acute ureteral injuries, bacteremia/ sepsis. They also documented which among them placed ureteral stent after the procedure. Furthermore, they reviewed the post- operative outcomes of the patients who underwent RIRS, including stone free rate (absence of stone fragments or with residual fragments $\leq$5mm on imaging) and post-operative complications such as bleeding, fever, sepsis, urinary tract infection (UTI), pneumonia and abdominal/bladder cramps which were all recorded.

They analyzed a total of 52 patients who underwent retrograde intrarenal surgery, 22 without, and 30 with ureteral access sheaths. Descriptive statistics was used to summarize the general and clinical characteristics of the participants. Frequency and proportion were used for categorical variables such as sex, body mass index (BMI) category, presence of comorbidities, and presence of outcomes. Shapiro-Wilk test was used to test normality of interval/ratio variables. Age, BMI, and operating time were noted to be normally distributed so mean and standard deviations were used to present them. The duration of post-op hospital stay was noted to be non-normally distributed, thus median and range was used to describe it.

Independent Sample T-test was used to compare age, BMI, and operating time of those operated with vs without ureteral access sheaths. Mann-Whitney U test was used to compare the duration of post-op hospital stay of those operated with vs without ureteral access sheaths. Fisher's Exact test was used to determine the difference of frequency of those operated with vs without ureteral access sheaths.

Accounting for possible confounder or effect modifiers from the differences in the baseline characteristics, subgroup analyses were done removing those with 1) solitary kidney and 2) those with ASA I.

All valid data were included in the analysis. Initial missing data were rechecked from the medical charts. The study noted no missing data after rechecking. Null hypothesis was rejected at 0.05α-level of significance. STATA 15.0 was used for data analysis.

Results

The two groups were similar in terms of age, sex, BMI, co-morbidities, and previous stone operations. In both groups, half of the patients had a pre-operative stent. None of the patients had a renal congenital abnormality. Among the 22 patients without UAS, there were four patients who had a solitary kidney ($p = 0.027$), and all patients were ASA II ($p < 0.001$).

Table 1. Demographic and clinical profile of patients who underwent retrograde intrarenal surgery (n=52)

	Total (n=52)	**Without UAS (n=22)**	**With UAS (n=30)**	**p-value**
	Median (Range); Frequency (%)			
Age, years	49.37 ± 13.73	48.18 ± 16.14	50.23 ± 11.87	0.599*
Sex				>0.999†
Male	25 (48.08)	11 (50)	14 (46.67)	
Female	27 (51.92)	11 (50)	16 (53.33)	
BMI, kg/m^2	23.53 ± 3.65	22.95 ± 4.01	23.95 ± 3.38	0.599*
Underweight (<18.5)	5 (9.62)	4 (18.18)	1 (3.33)	
Normal (18.5 to <23)	14 (26.92)	5 (22.73)	9 (30)	
Overweight (23 to 27.5)	26 (50)	10 (45.45)	16 (53.33)	
Obese (>27.5)	7 (13.46)	3 (13.64)	4 (13.33)	
Comorbidities				
Hypertension	8 (15.38)	1 (4.55)	7 (23.33)	0.118†
Diabetes Mellitus	9 (17.31)	4 (18.18)	5 (16.67)	>0.999†
Cardiovascular disease	26 (50)	12 (54.55)	14 (46.67)	0.779†
Asthma	1 (1.92)	1 (4.55)	0	0.423†
Chronic kidney disease	4 (7.69)	3 (13.64)	1 (3.33)	0.299†
Other	5 (9.62)	3 (13.64)	2 (6.67)	0.639†
Previous stone operation				
PCNL	10 (19.23)	5 (22.73)	5 (16.67)	0.725†
ESWL	11 (21.15)	5 (22.73)	6 (20)	>0.999†
URS	16 (30.77)	9 (40.91)	7 (23.33)	0.229†
RIRS	1 (1.92)	1 (4.55)	0	0.423†
Other	11 (21.15)	6 (27.27)	5 (16.67)	0.495†
Renal congenital abnormality	0	0	0	-
Solitary kidney	4 (7.69)	4 (18.18)	0	**0.027†**
Pre-operative stent	27 (51.92)	11 (50)	16 (53.33)	>0.999†
ASA score				**0.001†**
I	11 (21.15)	0	11 (36.67)	
II	40 (76.92)	22 (100)	18 (60)	
III	1 (1.92)	0	1 (3.33)	

UAS, Ureteral access sheath

The two groups were similar in terms of stone location, stone size, fragmentation device, and use of post-op stent. The group without the UAS had a substantially longer operative time at an average of 101.23 ± 31.28 versus 71.30 ± 36.43 minutes (p = 0.003); and all patients had a Clavien-Dindo classification I versus the with-UAS group which had 23.33% with Clavien Dindo II (p = 0.016).

In terms of complications, there was one patient who had a failed surgery in the UAS group. Bleeding was reported in one patient in the without UAS group and in two patients in the UAS group.

Stone-free rate was 94% at 1 month and 92% at 3 months post-op. One-fourth of the patients had abdominal/bladder cramps as post-op complications and 13% of the patients had fever. Readmission within 3 months was seen in four patients (8%) and retreatment was done on three patients (6%). The patients without UAS had a longer post-operative hospital stay at a median of 4 days (versus 2 days, p < 0.001).

Accounting only those without solitary kidney (n=48), the presence of residual stone at 1 month and retreatment were significantly higher among those operated without UAS compared to those operated with UAS (Table 3.1).

Accounting only those with ASA 2 or 3 (n=41), only the post-op hospital stay was significantly different (longer among those without UAS compared to those UAS). The outcomes in this subgroup did not differ from the outcomes of overall patients which could mean that the ASA grouping may not be an effect modifier nor confounder but may be treated as a bias in selecting treatment (Table 3.2).

Table 2. Operative profile of patients who underwent retrograde intrarenal surgery (n=52)

	Total (n=52)	**Without UAS (n=22)**	**With UAS (n=30)**	**p-value**
	Frequency (%);Median (Range)			
Type of URS				**<0.001†**
Flexible	12 (23.08)	12 (54.55)	0	
Flexible + Semigrid	40 (76.92)	10 (45.45)	30 (100)	
Stone location				
Superior	12 (23.08)	6 (27.27)	6 (20)	0.740†
Middle	22 (42.31)	11 (50)	11 (36.67)	0.401†
Inferior	37 (71.15)	15 (68.18)	22 (73.33)	0.762†
Stone size, cm				0.262†
<1 cm	25 (48.08)	13 (59.09)	12 (40)	
≥1 cm	27 (51.92)	9 (40.91)	18 (60)	
Fragmentation device				-
LASER	52 (100)	22 (100)	30 (100)	
Other	0	0	0	
Operating time, minutes	83.96 ± 37.15	101.23 ± 31.28	71.30 ± 36.43	**0.003***
Complication				
Failed	1 (1.92)	0	1 (3.33)	>0.999†
Bleeding	3 (5.77)	1 (4.55)	2 (6.67)	>0.999†
Ureteral injury	0	0	0	-
Converted	0	0	0	-
Others	0	0	0	-
Clavien-Dindo classification				**0.016†**
I	45 (86.54)	22 (100)	23 (76.67)	
II	7 (13.46)	0	7 (23.33)	
Post-op stent	39 (75)	18 (81.82)	21 (70)	0.518†

UAS, Ureteral access sheath
Statistical test used: * - Independent sample T-test; † - Fisher's Exact test

Table 3. Outcomes of patients who underwent retrograde intrarenal surgery (n=52)

	Total (n=52)	**Without UAS (n=22)**	**With UAS (n=30)**	**p-value**
	Median (Range); Frequency (%)			
Post-op hospital stay, days	3 (0–19)	4 (0–19)	2 (1–5)	**<0.001‡**
Presence of residual stone at 1 month	3 (5.77)	3 (13.64)	0	0.070†
Presence of residual stone at 3 months	4 (7.69)	3 (13.64)	1 (3.33)	0.299†
Post-op complication				
Abdominal/bladder cramps	13 (25)	5 (22.73)	8 (26.67)	>0.999†
Fever	7 (13.46)	5 (22.73)	2 (6.67)	0.119†
Sepsis	1 (1.92)	0	1 (3.33)	>0.999†
UTI	1 (1.92)	0	1 (3.33)	>0.999†
Pneumonia	1 (1.92)	1 (4.55)	0	0.423†
Bleeding	0	0	0	-
CVA	0	0	0	-
Readmission within 3 months	4 (7.69)	3 (13.64)	1 (3.33)	0.299†
Retreatment	3 (5.77)	3 (13.64)	0	0.070†

UAS, Ureteral access sheath
Statistical test used: ‡ - Mann-Whitney U-test; † - Fisher's Exact test

Table 3.1. Outcomes of patients without solitary kidney who underwent retrograde intrarenal surgery (n=48)

	Total (n=48)	**Without UAS (n=18)**	**With UAS (n=30)**	**p-value**
	Median (Range); Frequency (%)			
Post-op hospital stay, days	3 (0–19)	4 (0–19)	2 (1–5)	**<0.001‡**
Presence of residual stone at 1 month	3 (6.25)	3 (16.67)	0	**0.047†**
Presence of residual stone at 3 months	3 (6.25)	2 (11.11)	1 (3.33)	0.547†
Post-op complication				
Abdominal/bladder cramps	12 (25)	4 (22.22)	8 (26.67)	>0.999†
Bleeding	0	0	0	-
Fever	6 (12.5)	4 (22.22)	2 (6.67)	0.179†
Sepsis	1 (2.08)	0	1 (3.33)	>0.999†
UTI	1 (2.08)	0	1 (3.33)	>0.999†
Pneumonia	1 (2.08)	1 (5.56)	0	0.375†
CVA	0	0	0	-
Readmission within 3 months	3 (6.25)	2 (11.11)	1 (3.33)	0.547†
Retreatment	3 (6.25)	3 (16.67)	0	**0.047†**

UAS, Ureteral access sheath
Statistical test used: ‡ - Mann-Whitney U-test; † - Fisher's Exact test

Table 3.2. Outcomes of patients with ASA II or III who underwent retrograde intrarenal surgery (n=41)

	Total (n=41)	**Without UAS (n=22)**	**With UAS (n=19)**	**p-value**
	Median (Range); Frequency (%)			
Post-op hospital stay, days	3 (0–19)	4 (0–19)	2 (1–4)	**0.001‡**
Presence of residual stone at 1 month	3 (7.32)	3 (13.64)	0	0.235†
Presence of residual stone at 3 months	4 (9.76)	3 (13.64)	1 (5.26)	0.610†
Post-op complication				
Abdominal/bladder cramps	10 (24.39)	5 (22.73)	5 (26.32)	>0.999†
Bleeding	0	0	0	-
Fever	7 (17.07)	5 (22.73)	2 (10.53)	0.419†
Sepsis	1 (2.44)	0	1 (5.26)	0.463†
UTI	1 (2.44)	0	1 (5.26)	0.463†
Pneumonia	1 (2.44)	1 (4.55)	0	>0.999†
CVA	0	0	0	-
Readmission within 3 months	4 (9.76)	3 (13.64)	1 (5.26)	0.610†
Retreatment	3 (7.32)	3 (13.64)	0	0.235†

UAS, Ureteral access sheath
Statistical test used: ‡ - Mann-Whitney U-test; † - Fisher's Exact test

Discussion

Among the 52 patients who underwent RIRS there is no significant difference in placing ureteral access sheath or not prior to RIRS in terms of clinical profile and operative outcomes. However, one of the significant findings noted was that those who underwent sheathless RIRS have longer operative time as well as longer hospital stay compared with those who underwent RIRS with UAS placement. This may be attributed to difficulty in accessing the ureters especially those who are not pre-stented or no previous ureteroscopy done. Although not statistically significant, another finding was that patients with UAS placement has more incidence of bleeding intraoperatively and a higher Clavien-Dindo class of ureteral injury probably because of improper or forced placement of the UAS. Similar to the study of Traxer et al. wherein they evaluated the incidence and severity of ureteral injury due to use of UAS during RIRS in a series of 359 patients treated in two different centers. They found a rate of 46.5% for ureteral wall injury. Risk factors for severe injuries were identified as age, male sex

and absence of preoperative stent[3] Hence, the authors still advise on taking safety precautions when placing UAS to avoid any ureteral injuries.

Among the post operative complications, it was noted that abdominal/ bladder cramps and fever are common presentations and should be anticipated and explained by any urologists to patients who would want to undergo RIRS.

Retrograde intra-renal surgery is one of the latest minimally invasive/ endoscopic procedure for the active removal of renal stones. It is specifically beneficial in patients with lower pole calculus where the efficacy of ESWL is limited and also serves as an alternative option of treatment of renal stones in patients where PCNL is not an option. With the results of the current study, the authors could still recommend doing RIRS even without UAS, since they offer the same stone free rate and not significant intraoperative and post-operative complications. Also, some would prefer non- UAS placement because of cost- effectiveness. However, patient selection is still important especially if Urologists opt to not use a UAS. Among the findings the pre- stented patients or those who have had previous ureteroscopy can undergo RIRS safely without UAS, however compared to those who do not have previous ureteroscopy, stent placement and those with UAS placement, they may have a longer operation time.

Limitations

Since this study included patients treated from 2018 to 2021, the pandemic may not have had played that large of a role in limiting the number of patients that were included. The main limitation of this study is that it has a retrospective design. Therefore, no randomization was done and the sample sizes of the groups being compared are not equal. These may have affected the results despite there being similarities in the demographic characteristics of both groups. It was also not mentioned the criteria used by urologists in selecting when or when not to use a UAS.

Conclusion

There is no significant difference in placing ureteral access sheath or not prior to RIRS in terms of clinical profile and operative outcomes. Although, UAS placement still shows advantage of having shorter operative time compared to a sheathless RIRS, safety measures should be observed to prevent any bleeding and ureteral injuries during placement of UAS intra-operatively. Post operative abdominal/ bladder cramps and fever is a common complication on patients who underwent RIRS regardless of placement of UAS and should be anticipated and explained by any urologists to patients who will underwent RIRS.

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