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Original Article

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An Observational Study on Success of Ureteral Access Sheath Placement during Primary Retrograde Intra-Renal Surgery for Renal Stones

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Abstract

Background: This study explores the effectiveness and challenges of ureteral access sheath (UAS) placement during retrograde intrarenal surgery (RIRS) for treating renal stones. This study aims to evaluate the success of ureteral access sheath (UAS) placement during primary retrograde intrarenal surgery (RIRS) for renal stones, with a focus on assessing both placement success and related complications and stone-free rates. ***Methods:*** This cross-sectional observational study was conducted over six months at M S Ramaiah Medical College, Bengaluru, India, focusing on patients aged 21 to 80 years with renal stones measuring 10 mm to 20 mm. The study evaluated UAS placement success, intraoperative stone-free rates. Data collection included demographics, stone characteristics, and surgical parameters. Statistical analysis employed descriptive and inferential methods. ***Results:*** Among 50 patients (52% female, 48% male), diabetes mellitus was present in 38%. Stones were primarily located in the upper calyx (42%). The UAS was utilized in 82% of cases, with 52% requiring dilatation. Intraoperative complete stone clearance occurred in 82% of procedures, and total intraoperative time was significantly prolonged in cases of complete stone clearance ($p < 0.001$). ***Conclusion:*** The study highlights the challenges of UAS placement in RIRS for renal stones in Indian patients, particularly concerning larger stone burdens and abnormal ureteral anatomy. Future approaches should focus on individualized strategies to optimize surgical outcomes and reduce complications.

Keywords: ***Retrograde intrarenal surgery, ureteral access sheath, renal stone.***

Introduction

Urinary stone disease is a significant concern in urology, with prevalence rates ranging from 1% to 15% worldwide [1]. The primary goal of kidney stone treatments is to achieve a stone-free status while minimizing tissue damage [2]. Minimally invasive techniques like percutaneous nephrolithotomy, Retrograde intrarenal surgery (has emerged as a preferred minimally invasive option, especially for stones smaller than 2 cm, alongside extracorporeal shockwave lithotripsy (ESWL), as recommended by the European Association of Urology (EAU) [3]. Recent advancements in endoscopic technology and surgical lasers have further established RIRS as a key treatment option for renal calculi [4]. The ureteral access sheath (UAS), introduced by Hisao Takayasu in 1974, is a crucial tool in RIRS, designed to facilitate the passage of endoscopic instruments, reduce intrarenal pressure, and enhance visibility and stone retrieval. However, its placement can be challenging, particularly in cases involving non-distensible ureters, which are frequently observed in the Indian population [5]. Even with the use of serial dilation techniques, successful UAS placement may not always be achievable, often requiring a staged procedure [6]. Despite advancements in UAS design such as variations in size and material its routine use remains controversial, with differing recommendations across guidelines [7]. Finding out what makes UAS implantation during primary RIRS in Indian patients with kidney stones successful is the goal of this observational study. Finding out how often UAS implantation is successful is the main goal, while evaluating post-procedure complications and stone-free rates is the secondary purpose.

Methods

Study Design: This study is a cross-sectional observational analysis conducted to evaluate the effectiveness of primary RIRS in 50 patients diagnosed with renal stones. The study assesses the success of ureteral access sheath placement and its associated techniques.

Study Duration: The study was carried out over a period of six months at M S Ramaiah Medical College, Bengaluru, India.

Inclusion Criteria: Patients were eligible to participate in the study if they were between the ages of 21 and 80 and had a confirmed diagnosis of renal stones measuring 10 mm to 20 mm using

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computerized tomography (CT KUB). The chosen treatment method was primary retrograde intrarenal surgery (RIRS).

Exclusion Criteria: The study excluded patients with renal stones smaller than 10 mm or larger than 20 mm, those who had undergone pre-stenting before RIRS, and patients with both ureteral and renal calculi in the same renal unit. Additional exclusion criteria included a history of renal stone passage in the past year, the presence of staghorn calculi, anatomical abnormalities in the kidneys, previous ureteral interventions such as ureteroscopy or other ureteral surgeries, and a history of genitourinary tuberculosis, malignancy, or radiation therapy affecting the ureters.

Patient Selection and Data Collection Parameters: Patients aged 21 to 80 years, diagnosed with renal stones measuring 10 mm to 20 mm via CT KUB, were recruited. Data collection included patient demographics, body mass index (BMI), co-morbidities, and renal stone characteristics such as size, number, hounsfield unit (HU), and stone location based on CT KUB imaging. Laboratory parameters relevant to renal function were also be collected.

Clinical Variables

- Patient Demographics: Age, sex (male/female), and body mass index (BMI).
- Comorbidities: Presence or absence of diabetes mellitus.
- Stone Characteristics:
  - Stone laterality (left/right)
  - Stone location (upper, middle, lower calyx)
  - Stone size (measured in millimeters)
  - Stone density (measured in Hounsfield units - HU)
- Ureteral Access Sheath (UAS):
  - Use of UAS (yes/no)
  - UAS caliber (9.5/11.5 French)
  - Presence or absence of UAS dilatation
- Intraoperative Complications: Presence of complications during surgery (yes/no).

Ureteral Access Sheath Placement Techniques: The techniques used during RIRS for successful ureteral access sheath placement were systematically recorded. If direct sheath placement is unsuccessful, serial dilation were attempted through the following steps:

Step 1: A guidewire was inserted into the ureter under cystoscopic guidance.
Step 2: Initial attempt at placing a 9.5/11.5 Fr ureteral access sheath.
Step 3: If unsuccessful, gradual dilation with 6 Fr and 8 Fr ureteroscopes were performed.
Step 4: Reattempt of the 9.5/11.5 Fr ureteral access sheath.
Step 5: In cases of failure, a 6/26 Fr DJ stent was placed for later intervention.

Informed Consent and Ethical Considerations: Informed consent was obtained from all participants or their legal representatives after clearly explaining the study's purpose, benefits, and risks. Written consent was secured before enrollment, adhering to the ethical standards set by the Institutional Ethical Committee (IEC) of M S Ramaiah Medical College. The study-maintained participants' rights and confidentiality, ensuring no additional risks or changes to clinical management, and fully complied with ethical regulations prioritizing informed consent and patient safety.

Data Analysis: In order to statistically assess the outcomes, statistical software was used for data analysis. Mean and standard deviation were used for descriptive statistics to describe the participants and important variables, while t-tests and analysis of variance were used for inferential statistics to evaluate differences between groups. The results of all analyses were interpreted in accordance to the study's aims, providing insights into the observed impacts, and a significance level of $p < 0.05$ was set to guarantee reliable results.

Results

In a sample of 50 patients, 52% were female and 48% were male. Diabetes mellitus was present in 38% of patients (**Figure 1**), while 62% did not have it. Stone laterality was evenly split, with 50% on the left and 50% on the right (**Figure 3**). Stones were most commonly located in the upper calyx (42%), followed by the middle calyx (38%) and lower calyx (20%) (**Figure 4**). Dilatation was observed in 52% of cases, with 30% showing no dilatation and 18% not using UAS (**Figure 5**). A 9.5/11.5 French caliber UAS was used in 82% of cases (**Figure 2**). Intraoperative complete stone clearance were reported in 82% of procedures (**Figure 6**).

Table 1 shows a crosstab analysis of variables by sex, with chi-square tests assessing associations. Diabetes mellitus was present in 19 participants (11 female, 8 male) and absent in 31 (p = 0.514), showing no significant sex difference. Stone laterality was evenly distributed between left and right sides (p = 0.517), and stone location (upper, middle, or lower calyx) also showed no sex-based difference (p = 0.435). UAS with or without dilatation (p = 0.882), UAS calibre (9.5/11.5 French) (p = 0.814), and intraoperative CSC (p = 0.814) showed no significant differences between sexes. Overall, all variables were similarly distributed between males and females.

Table 2 summarizes group statistics for age, BMI, stone size, stone density, and total intraoperative time among participants with and without intraoperative complete stone clearance (CSC). Participants with CSC had a mean age of 40 years (t-test: 0.286, p = 0.776) and a mean BMI of 24.26 (t-test: -0.578, p = 0.576), showing no significant differences compared to those without complications (mean age: 38.78 years; mean BMI: 25.24). The mean stone size was 12.80 mm in the CSC group versus 12.33 mm in the non-CSC group (t-test: 0.666, p = 0.517), and stone density was similar (869.83 HU vs. 882.11 HU; t-test: -0.323, p = 0.753). However, total intraoperative time was significantly longer in the CSC group (71.76 minutes) compared to the non-CSC group (20.00 minutes), with a t-test value of 43.094 and p < 0.001, indicating a highly significant difference. Thus, while age, BMI, stone size, and density showed no significant differences, intraoperative time was significantly prolonged for participants experiencing CSC.

Table 3 summarizes ANOVA results comparing age, BMI, stone size, stone density, and total intraoperative time among participants with stones in the upper, middle, and lower calyx. The F-test and p-values assess the significance of differences based on stone location. Participants with upper calyx stones had a mean age of 42.38 years, while those with middle and lower calyx stones had mean ages of 38.21 and 37.30 years, respectively; however, no significant age difference was found (F = 0.948, p = 0.395). BMI values were similar across groups: 24.54 (upper), 24.82 (middle), and 23.51 (lower), with no significant difference (F = 0.382, p = 0.685). For stone size, upper calyx stones averaged 13.14 mm, while middle and lower calyx stones averaged 12.32 mm and 12.60 mm, respectively, with no significant difference (F = 0.795, p = 0.458). Stone density also showed no significant variation (F = 1.143, p = 0.328). Total intraoperative time was longest for upper calyx stones (64.71 minutes), followed closely by middle (64.16 minutes) and lower calyx stones (54.40 minutes), but no significant difference was found (F = 0.894, p = 0.416). Overall, the ANOVA analysis indicates that age, BMI, stone size, stone density, and total intraoperative time are consistent across stone locations.

The table 4 displays ANOVA results comparing age, BMI, stone size, stone density, and total intraoperative time in participants with and without renal dilatation. The F-test and p-values indicate statistical significance. Participants with dilatation had a mean age of 39.65 years, while those without had a mean age of 40.60 years, with no significant difference (F = 0.71, p = 0.931). The mean BMI for those with dilatation was 23.80, compared to 25.07 for those without, also showing no significant difference (F = 0.751, p = 0.477). In terms of stone size, participants with dilatation had a mean size of 12.50 mm, while those without had a mean size of 13.33 mm, indicating no significant difference (F = 0.942, p = 0.397). Stone density was similar, with participants with dilatation averaging 850.23 HU versus 903.80 HU for those without, showing no significant difference (F = 1.545, p = 0.224). However, total intraoperative time was significantly shorter for participants with dilatation (71.12 minutes) compared to those without (72.87 minutes), with a highly significant F-test value of 199.133 and p < 0.001. Overall, while age, BMI, stone size, and stone density showed no significant differences, dilatation significantly impacts intraoperative time, suggesting it contributes to shorter surgical procedures.

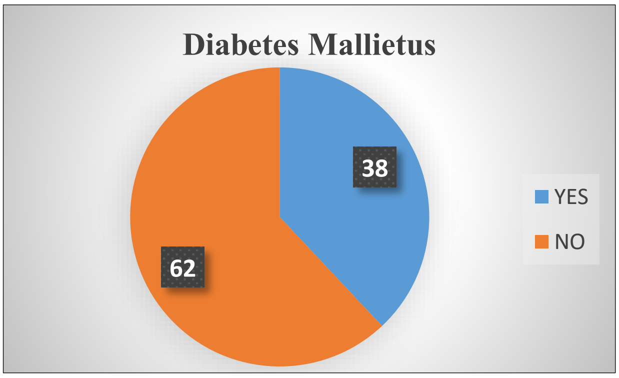
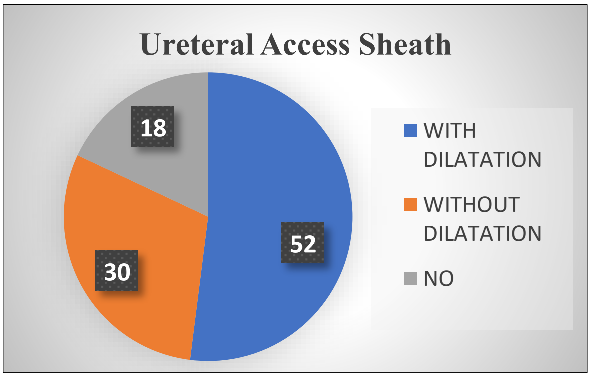


Figure 1



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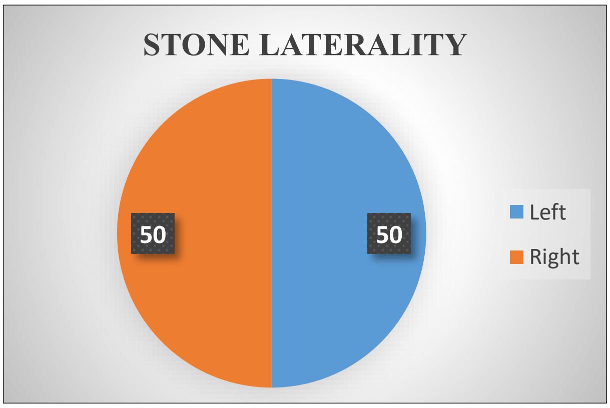

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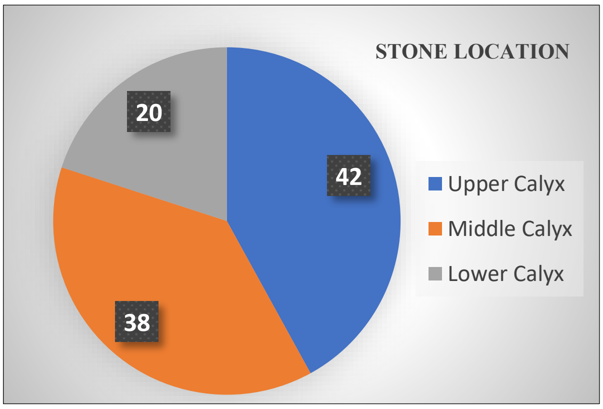

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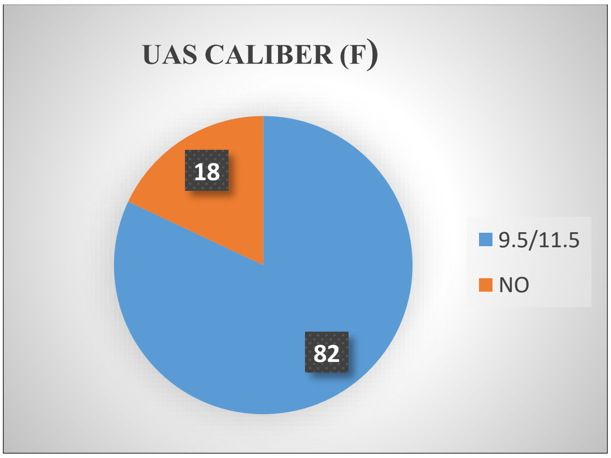

Figure 3

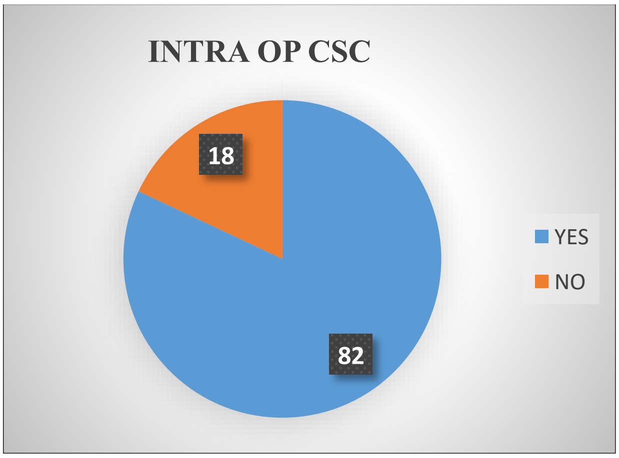

Figure 4

Figure 1-6: Figure 1 shows the distribution of Diabetes Mellitus among participants, Figure 2 illustrates stone laterality in patients undergoing RIRS, Figure 3 depicts the location of stones within the renal anatomy, Figure 4 highlights the use of Ureteral Access Sheath (UAS) during the procedure, Figure 5 details the UAS caliber measured in French units, and Figure 6 outlines intraoperative complete stone clearance (CSC) encountered during surgery.

Table 1: Crosstab analysis of various clinical variables

Count					
		SEX		Total	Chi-square
		F	M		
Diabetes Mallietus	YES	11	8	19	0.514
	NO	15	16	31	
Stone Laterality	Left	14	11	25	0.517
	Right	12	13	25	
Stone Location	Upper Calyx	9	12	21	0.435
	Middle Calyx	12	7	19	
	Lower Calyx	5	5	10	
UAS	With Dilatation	14	12	26	0.882
	Without Dilatation	7	8	15	
	No	5	4	9	
UAS Calibre (F)	9.5/11.5	21	20	41	0.814
	No	5	4	9	
Intra OP CSC	Yes	21	20	41	0.814
	No	5	4	9	

Table 2: Group statistics comparing age, BMI, stone size, stone density, and total intraoperative time between participants with and without intraoperative complete stone clearance (CSC)

Group Statistics						
Intra OP CSC		N	Mean	Std. Deviation	t-test Value	p-value
Age	Yes	41	40.0000	12.43382	0.286	0.776
	No	9	38.7778	5.73973		
BMI	Yes	41	24.2634	3.64381	-0.578	0.576
	No	9	25.2444	4.79456		
Stone Size (mm)	Yes	41	12.8049	2.14732	0.666	0.517
	No	9	12.3333	1.87083		
Stone Density (HU)	Yes	41	869.8293	96.38021	-0.323	0.753
	No	9	882.1111	104.71443		
Total Intra OP Time (min)	Yes	41	71.7561	7.69019	43.094	<0.001
	No	9	20.0000	0.00000		

Table 3: ANOVA Analysis of Age, BMI, Stone Size, Stone Density, and Total Intraoperative Time Based on Stone Location (Upper, Middle, Lower Calyx)

ANOVA						
		N	Mean	Std. Deviation	F-Test	p-value
Age	Upper Calyx	21	42.3810	11.86371	0.948	0.395
	Middle Calyx	19	38.2105	12.11784		
	Lower Calyx	10	37.3000	9.12932		
	Total	50	39.7800	11.48076		
BMI	Upper Calyx	21	24.5429	4.12414	0.382	0.685
	Middle Calyx	19	24.8158	3.53275		
	Lower Calyx	10	23.5100	4.02394		
	Total	50	24.4400	3.83885		
Stone Size (mm)	Upper Calyx	21	13.1429	2.08052	0.795	0.458
	Middle Calyx	19	12.3158	1.79668		
	Lower Calyx	10	12.6000	2.63312		
	Total	50	12.7200	2.09021		
Stone Density (Hu)	Upper Calyx	21	877.5238	107.74072	1.143	0.328
	Middle Calyx	19	848.8947	90.82027		
	Lower Calyx	10	904.5000	80.56916		
	Total	50	872.0400	96.93254		
Total Intra OP Time (min)	Upper Calyx	21	64.7143	19.67268	0.894	0.416
	Middle Calyx	19	64.1579	16.69419		
	Lower Calyx	10	54.4000	30.85162		
	Total	50	62.4400	21.25372		

Table 4: ANOVA Analysis of Age, BMI, Stone Size, Stone Density, and Total Intraoperative Time Based on Presence of Dilatation

Anova						
		N	Mean	Std. Deviation	F-Test	P-Value
Age	With Dilatation	26	39.6538	12.32540	0.71	0.931
	Without Dilatation	15	40.6000	13.03183		
	No	9	38.7778	5.73973		
	Total	50	39.7800	11.48076		
BMI	With Dilatation	26	23.8000	3.77349	0.751	0.477
	Without Dilatation	15	25.0667	3.37907		
	No	9	25.2444	4.79456		
	Total	50	24.4400	3.83885		
Stone Size (MM)	With Dilatation	26	12.5000	2.21359	0.942	0.397
	Without Dilatation	15	13.3333	1.98806		
	No	9	12.3333	1.87083		
	Total	50	12.7200	2.09021		
Stone Density (HU)	With Dilatation	26	850.2308	105.59860	1.545	0.224
	Without Dilatation	15	903.8000	68.39612		
	No	9	882.1111	104.71443		
	Total	50	872.0400	96.93254		
Total Intra OP Time (MIN)	With Dilatation	26	71.1154	8.07132	199.133	<0.001
	Without Dilatation	15	72.8667	7.11002		
	No	9	20.0000	0.00000		
	Total	50	62.4400	21.25372		

Discussion

The finding of this study provides valuable insights into the characteristics and surgical outcomes of patients undergoing procedures for urolithiasis. With a sample of 50 patients, the gender distribution was nearly equal, with 52% female and 48% male. The prevalence of diabetes mellitus was observed in 38% of patients, indicating a notable demographic characteristic, although no significant differences in sex distribution were found concerning diabetes status ($p = 0.514$). Stone laterality was evenly split between the left and right sides, while the location of stones predominantly involved the upper calyx (42%), followed by the middle (38%) and lower calyx (20%). This distribution aligns with existing literature that highlights the upper calyx as a common site for stone formation. Dilatation of the renal collecting system was present in 52% of cases, suggesting a substantial incidence of hydronephrosis associated with urolithiasis. Notably, intraoperative complications were reported in 82% of procedures, which raises concerns about surgical risk and patient management.

Crosstab analysis revealed no significant differences between male and female patients across various clinical variables, including stone location and UAS usage, suggesting that these factors may be independent of sex. However, a critical finding was that total intraoperative time was significantly longer in patients with intraoperative complete stone clearance (CSC), averaging 71.76 minutes compared to 20.00 minutes in those without CSC ($p < 0.001$). This indicates that intraoperative CSC are a significant factor influencing surgical duration [5].

ANOVA analysis also demonstrated no significant differences in age, BMI, stone size, and stone density based on stone location or the presence of dilatation. However, dilatation significantly impacted intraoperative time, highlighting its association with more complex surgical procedures. This suggests that patients with renal dilatation may require more extensive intervention, contributing to longer operative times.

Several studies support our findings Shrestha et al.,[8] found no strong correlation between stone laterality and patient sex or other demographics, mirroring our results. Damar et al.,[9] reported that upper and middle calyces are more frequently involved in stone formation, aligning with our observations on stone distribution. Additionally, Lima et al.,[10] echoed our findings regarding UAS usage and its intraoperative complications, underscoring the need for careful consideration in complex stone surgeries.

In another study Yuk et al.,[11] analysis of 344 patients (197 in Group 1 and 147 in Group 2), UAS were used more in Group 2 (56.8% vs. 39.5%, $p = 0.021$), resulting in significantly longer operation times ($p < 0.001$). The stone-free rate (SFR) was higher in Group 1 (84.7%) compared to Group 2 (63.7%). Overall complication rates were also significantly different, with Group 1 at 7.6% and Group 2 at 33.3%, where postoperative fever was the most common complication (4.4% vs. 14%, $p = 0.004$). Clavien I/II complications were 6% in Group 1 and 25.1% in Group 2 ($p < 0.05$), while Clavien ≥ III complications were 1.6% and 8.1%, respectively ($p < 0.05$).

Another study Kalpan et al.,[12] "included 12,993 patients and 13,293 procedures. There was no significant difference in SFR between UAS and non-UAS groups (OR = 0.90, 95% CI 0.63-1.30, $p = 0.59$), nor in intraoperative (OR = 1.13, 95% CI 0.75-1.69, $p = 0.5$) or postoperative complications (OR = 1.29, 95% CI 0.89-1.87, $p = 0.18$). However, UAS usage increased operation times (MD = 8.30, 95% CI 2.51-14.10, $p = 0.005$) and fluoroscopy times (MD = 5.73, 95% CI 4.55-6.90, $p < 0.001$), with no publication bias detected. In summary while UAS usage RIRS did not significantly improve SFR, complication rates, or hospitalization duration, it was associated with longer operation and fluoroscopy times". Thus, routine UAS use is not recommended, and decisions should be individualized. If we want to get the most out of UAS in RIRS, we need to do future studies with bigger samples and consistent methods.

Conclusion

In conclusion, this study underscores the complexities associated with the placement of ureteral access sheaths during retrograde intrarenal surgery for renal stones in the Indian patient population. Despite the advantages offered by UAS in enhancing surgical efficacy, significant challenges persist, especially in cases involving larger stone sizes and variations in ureteral anatomy. The high rate of intraoperative complications highlights the need for improved strategies and tailored approaches in managing urinary stone disease. Emphasizing individualized surgical planning and training may facilitate better outcomes and minimize risks associated with UAS placement.

Declarations

Ethics approval and consent to participate

Ethics approval was obtained from Institutional Ethics committee.

Approval number: MSRMC/EC/AP-01/04-2024

List of abbreviations

Ureteral access sheath (UAS)
Retrograde intrarenal surgery (RIRS)
Extracorporeal shockwave lithotripsy (ESWL)
Hounsfield unit (HU)
Body mass index (BMI)
Complete stone clearance (CSC)

Data Availability

The dataset used and/or analysed during the current study are available from the corresponding author on reasonable request.

Conflicts of Interest

The authors declare that there is no conflict of interest regarding the publication of this paper.

Funding Statement

None

Authors' contributions

Dron Sharma: Analysis of data, Manuscript drafting.
Shashwat singh: Data Acquisition
M A Vivek Kumar: Acquisition analysis
Rajat Agarwal: Data Acquisition
Rakesh Patil: Interpretation of Data
Mahesh Chalumuru: Data Analysis
D Ramesh: Conception, Draft revision
Tarun javali: Manuscript drafting, Draft revision
Puvvada Sandeep: Conception, Acquisition analysis

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