

The Utility and Safety of Ureteral Access Sheath During Retrograde Intrarenal Surgery in Children

Yiloren Tanidir, Cagri Akin Sekerci, Anna Bujons, Daniele Castellani, Stefania Ferretti, Claudia Gatti, Davide Campobasso, Yesica Quiroz, Jeremy Yuen-Chun Teoh, Amelia Pietropaolo, Deepak Ragoori, Tanuj Paul Bhatia, Chandra Mohan Vaddi, Anil Shrestha, Ee Jean Lim, Khi Yung Fong, Mriganka Mani Sinha, Stephen Griffin, Kemal Sarica, Bhaskar Kumar Somani, Olivier Traxer, and Vineet Gauhar

OBJECTIVE	To compare retrograde intrarenal surgery (RIRS) with and without ureteral access sheath (UAS) in different pediatric age groups.
METHODS	The data of RIRS for kidney stone in children were obtained from 9 institutions. Demographic characteristics of patients and stones, intraoperative and postoperative results were recorded. While analyzing the data, patients who underwent RIRS without UAS (group 1) (n = 195) and RIRS with UAS (group 2) (n = 194) were compared.
RESULTS	Group 1 was found to be young, thin, and short ($P < .001$, $P = .021$, $P < .001$), but there was no gender difference and similar symptoms were present except hematuria, which was predominant in group 2 (10.6% vs 17.3%, $P < .001$). Group 1 had smaller stone diameter (9.91 ± 4.46 vs 11.59 ± 4.85 mm, $P = .001$), shorter operation time ($P = .040$), less stenting (35.7% vs 72.7%, $P = .003$). Re-intervention rates and stone-free rates (SFR) were similar between groups ($P = .5$ and $P = .374$). However, group 1 had significantly high re-RIRS ($P = .009$). SFR had a positive correlation with smaller stone size and thulium fiber laser usage compared to holmium fiber laser (HFL) ($P < .001$ and $P = .020$), but multivariate analysis revealed only large stone size as a risk factor for residual fragments ($P = .001$).
CONCLUSION	RIRS can be performed safely in children with and without UAS. In children of smaller size or younger age (< 5 years), limited use of UAS was observed. UAS may be of greater utility in stones larger than 1 cm, regardless of the age, and using smaller diameter UAS and ureteroscopes can decrease the complications. UROLOGY xx: xxx-xxx, xxxx. © 2024 Elsevier Inc. All rights reserved.

Recent technological advancements have facilitated the treatment of urolithiasis in children with minimally invasive procedures. While percutaneous nephrolithotomy was initially the standard approach for kidney stones, in recent years, retrograde intrarenal surgery (RIRS) has emerged as a viable alternative, particularly for stones smaller than 20 mm². This

progress is significant in addressing the increasing incidence of urolithiasis in children, which negatively impacts their quality of life and contributes to higher morbidity rates.¹

The utility of ureteral access sheath (UAS) plays a crucial role in RIRS, and its effectiveness has been extensively assessed in numerous studies within the context

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From the Department of Urology, Marmara University School of Medicine, Istanbul, Turkey; the Division of Pediatric Urology, Department of Urology, Marmara University School of Medicine, Istanbul, Turkey; the Urology Department, Autonomous University of Barcelona, Fundació Puigvert, Barcelona, Spain; the Urology Division, Azienda Ospedaliero-Universitaria Ospedali Riuniti Di Ancona, Università Politecnica Delle Marche, Ancona, Italy; the Urology Unit, Azienda Ospedaliero-Universitaria di Parma, Parma, Italy; the Pediatric Surgery Unit, Azienda Ospedaliero-Universitaria di Parma, Parma, Italy; the Department of Surgery, S.H. Ho Urology Centre, The Chinese University of Hong Kong, Hong Kong, China; the University Hospital Southampton NHS Foundation Trust, Southampton, United Kingdom; the Department of Urology, Asian Institute of Nephrology and Urology, Banjara Hills, Hyderabad, Telangana, India; the Department of Urology, Sarvodaya Healthcare, Faridabad, Haryana, India; the Department of Urology, Preeti Urology and Kidney Hospital, Hyderabad, Telangana, India; the Department of Urology, National Academy of Medical Sciences, Bir Hospital, Kantii Path, Kathmandu, Nepal; the Department of Urology, Singapore General Hospital, Singapore, Singapore; the Yong Loo Lin School of Medicine, National University of Singapore, Singapore, Singapore; the School of Medicine, Faculty of Medicine and Health, University of Leeds, Leeds, United Kingdom; the Department of Urology, Biruni University, Istanbul, Turkey; the Department of Urology Hôpital Tenon, Sorbonne University, Paris, France; and the Department of Urology, Ng Teng Fong Hospital, Singapore, Singapore

Address correspondence to: Yiloren Tanidir, M.D., Marmara Üniversitesi Pendik Eğitim Araştırma Hastanesi, Department of Urology, Fevzi Çakmak Mahallesi, Mimar Sinan, Caddesi, No: 41, Ust Kaynarca, Pendik, Istanbul 34899, Turkey. E-mail: yiloren@yahoo.com

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of adult patients. One of its notable advantages is the reduction of postoperative sepsis and bleeding risk arising from the excessive distension within the pelvicalyceal system, achieved by decreasing the intrarenal pressure during the procedure.² Furthermore, it offers several other favorable outcomes, including enhanced visibility through continuous irrigation and the facilitation of multiple access points. In pursuit of the former benefit, increasing the irrigation output using a UAS becomes essential for improving visual clarity. However, it is crucial to note that elevating the hydrostatic column or irrigation pressure can potentially lead to an increase in intrapelvic pressure, considering the continuous irrigation.³ Nevertheless, it is worth highlighting that the most significant drawback of UAS lies in the potential for severe ureteral wall injury during insertion, including ureteral perforation or even avulsion, especially when inserted into a constricted ureter or inadvertently during the use of multiple baskets for fragment retrieval.⁴

The efficacy and safety of using UAS in children have been explored in few studies, albeit small with relatively small cohorts.⁵⁻¹¹ These studies collectively demonstrate that UAS usage in pediatric cases to be both safe and effective resulting in favorable outcomes, such as high stone-free rate (SFR) and minimal complications. However, it is noteworthy that, in contrast to the extensive body of research on adults, the evaluation of UAS's specific impact on surgical outcomes and complications in children with kidney stones has been limited to just 1 study.¹⁰

In a recent systematic review conducted by Ripa et al, a total of 22 studies involving 1317 patients were analyzed, among which 603 patients underwent UAS placement. The authors' findings indicated that there are currently no established recommendations regarding the use of UAS in pediatric ureteroscopy, and its effect on improving SFR remains uncertain. Nevertheless, they did observe that the use of UAS was associated with a low rate of ureteric injuries, highlighting the need for further exploration of its indications, safety, and utility in children undergoing RIRS across different age groups. Identifying which specific pediatric patient cohort would derive the most benefit from UAS utilization during RIRS is therefore a critical area of investigation.¹²

Our study's primary objective was to determine the most appropriate criteria for using UAS in pediatric patients undergoing RIRS and whether there is an optimal size for pediatric RIRS procedures. As a secondary aim, we aimed to investigate the impact of UAS usage on complications and SFR in children undergoing RIRS for renal stones, stratified by age, by comparing outcomes between those who underwent the procedure with UAS and those who did not.

MATERIALS AND METHODS

Retrospective evaluation of anonymized data obtained from 9 centers. The inclusion criteria comprised children/adolescent patients (aged under 18 years) who underwent RIRS for renal stones. The data encompassed the period between

January 2015 and December 2020. The exclusion included cases that involved both simultaneous lithotripsy for ureteral stones and bilateral procedures. Additionally, patients with incomplete or missing data were excluded from the analysis. Preoperative data were collected and included information such as gender, age, weight, height, symptoms at presentation, whether Tamsulosin was administered, the necessity for ureteral dilatation, the number of stones, their respective sizes, localization within the renal system, and stone density measured in Hounsfield units via computed tomography (CT). The stone size was measured based on the largest stone diameter. Data pertaining to intraoperative and postoperative outcomes were also meticulously recorded for the purposes of this study.

RIRS was performed uniformly across all centers, with slight variations in technique. The procedure began with cystoscopy, during which any existing J-stent was removed, and a guidewire was then inserted through the corresponding orifice. Retrograde pyelography was carried out using either a ureteric catheter or the smallest diameter ureteroscope available at the institution. Subsequently, a semirigid ureteroscopy was performed to evaluate the condition of the ureter and dilate the ureteric orifice. The decision to perform RIRS with or without a UAS was made based on the surgeon's preference and feasibility, and the procedure was initiated accordingly.

Surgical time was measured from the initiation of cystoscopy to catheter insertion. The placement of a ureteral stent was done before RIRS in cases of symptomatic obstruction or in accordance with the standard of care at each center, which might include passive ureteral dilatation before planned RIRS. The distal end of the scope ranged from 7-8 Fr. Stone-free status was defined as the presence of a single residual fragment (RF) measuring ≤ 2 mm or the complete absence of multiple fragments of any size. Postoperative follow-up was conducted within a timeframe of 4-6 weeks to assess complications, and RF were evaluated at the 3-month mark through kidney-ureter-bladder X-rays and ultrasound, or CT. RF was characterized as any fragment larger than 2 mm.

Each participating center obtained approval from their respective audit board or institutional ethics board committee. The data collected were anonymized before being subjected to pooled analysis. Patients were categorized into 2 groups based on UAS usage. Group 1 comprised children and adolescents who underwent RIRS without UAS, while patients in group 2 had RIRS with UAS.

Statistical Analysis

Data were checked for normality distribution with the Shapiro-Wilk test. Continuous variables were expressed as mean values along with their standard deviations. Categorical data were presented as absolute numbers and corresponding percentages. To compare the 2 groups with respect to continuous variables, the Student's *t* test

was employed, while categorical variables were assessed using the Chi-square test and Fisher's exact test. A *P* value less than .05 was considered statistically significant.

Univariable logistic regression analysis was conducted to predict the presence of RF. The results were presented in the form of odds ratios along with their corresponding 95% confidence intervals (CI) and *P* values. Variables that demonstrated a statistically significant *P* value in the univariate logistic regression analysis were subsequently included in a multivariable logistic regression model.

The statistical analysis was carried out using SPSS software version 25.0, developed by IBM Corp. in Armonk, NY.

RESULTS

Four hundred and five patients were identified who were eligible. Sixteen patients with incomplete data were excluded from the study. Table 1 shows patient baseline characteristics. Group 1 consisted of 195 patients and group 2 of 194 patients. The mean age of children in group 1 was 8.73 ± 4.75 years and 9.96 ± 4.67 years in group 2 ($P < .001$) (The youngest child is 16 months old in group 1 and 3 years old in group 2). Fifty-six point four percent in group 1 ($n = 110$) and 61.9% ($n = 120$) in group 2 were male ($P = .221$). Mean height and weight were significantly higher in group 2 (Table 1). Symptoms

at presentation were similar between 2 groups except hematuria that was more prevalent in group 2 ($P < .001$). Preoperative antibiotics use due to urinary tract infections was significantly higher in group 2 (80.9% in group 2, 53% in group 1, $P < .001$) (Table 1). The mean stone diameter was significantly larger in group 2 (11.59 ± 4.85 mm) compared to group 1 (9.91 ± 4.46 mm, $P = .001$) but there was no difference in stone localization and density between the 2 groups.

Table 2 shows intraoperative data. There was no difference in the need for meatal dilatation. Regarding lithotripsy mode, dusting was preferred in group 2 (46.7% vs 34.7%, $P = .023$). Surgical time was significantly shorter in group 1 (65.56 ± 29.17 minutes vs 73.38 ± 36.80 minutes, $P = .040$).

Perioperative and postoperative complications are shown in Supplementary Table 1. There was no difference in postoperative complication except for transient hematuria not needing transfusion that was significantly higher in group 2 (7.8% vs 1.2%, $P = .006$). There were 6 minor ureteral injury (ie, needing a ureteral stent) in group 2 and none in group 1 ($P = .504$). Fifty-six (29.9%) patients in group 1 had RF and 55 (35%) in group 2 ($P = .374$). Among them, there was no significant difference in reintervention.

At univariable analysis, stone size was significantly associated with RF, whereas thulium fiber laser (TFL)

Table 1. Baseline characteristics of included patients.

	Group 1 No UAS (N = 195)	Group 2 UAS (N = 194)	<i>P</i> Value
Age (y), mean (SD)	8.73 (4.75)	9.96 (4.67)	<.001
Patients per age group, n (%)			.008
< 5 y old	55 (28.2)	35 (18.0)	
5-10 y old	54 (27.7)	52 (26.8)	
10-15 y old	55 (28.2)	67 (34.5)	
> 15 y old	31 (15.9)	40 (20.6)	
Males, n (%)	110 (56.4)	120 (61.9)	.221
Height (cm), mean (SD)	119 (29.8)	130 (28.1)	.021
Weight (kg), mean (SD)	30.4 (18.9)	37.0 (19.2)	<.001
Symptomatic at presentation, n (%)	107 (74.8)	34 (72.3)	.709
Hematuria only	18 (10.6)	33 (17.3)	<.001
Loin pain only	77 (45.3)	84 (44.0)	.569
Hematuria and pain	14 (17.5)	40 (37.0)	>.99
Fever only	23 (13.5)	47 (24.6)	.569
Elevated creatinine at presentation, n (%)	6 (3.5)	4 (2.1)	.160
Urine culture positive, n (%)	32 (17.3)	38 (22.1)	.891
Recurrent stone former, n (%)	21 (12.3)	28 (14.6)	.321
Preoperative tamsulosin, n (%)	4 (2.2)	12 (6.2)	.463
Preoperative antibiotics, n (%)	96 (53.0)	157 (80.9)	<.001
Pre-stented, n (%)	97 (49.7)	100 (51.5)	.176
Cystinuria, n (%)	14 (7.6)	21 (12.2)	<.001
Largest stone diameter (mm), mean (SD)	9.91 (4.46)	11.59 (4.85)	.001
Single stone, n (%)	66 (34.4)	84 (43.5)	.006
Hounsfield units, mean (SD)	788 (351)	931 (338)	.827
Stone locations n (%) (includes those with multiple stones)			
Upper pole	31 (16.8)	44 (25.0)	.076
Middle pole	46 (25.0)	58 (33.0)	.122
Lower pole	68 (36.8)	81 (46.0)	.093
Renal pelvis	9 (47.4)	38 (47.5)	>.99

UAS, ureteral access sheath.

P value < .05 was considered statistically significant.

Table 2. Intraoperative characteristics.

	Group 1 No UAS (N = 195)	Group 2 UAS (N = 194)	P Value
Meatal dilation, n (%)	10 (5.2)	21 (10.9)	.059
Distal scope size, n (%)			< .001
7 Fr	0 (0.0)	39 (28.1)	
7.5 Fr	61 (81.3)	41 (29.5)	
8 Fr	14 (18.7)	59 (42.4)	
Reusable fURS, n (%)	193 (99.5)	183 (94.8)	.014
Type of laser, n (%)			.008
Holmium fiber	184 (95.3)	131 (86.8)	
Thulium fiber	9 (4.7)	20 (13.2)	
Dusting, n (%)	67 (34.7)	86 (46.7)	.023
Popcorning, n (%)	7 (3.6)	9 (4.9)	.724
Dusting + popcorning, n (%)	133 (68.6)	110 (57.0)	.025
Basket extraction, n (%)	2 (6.9)	24 (22.4)	.105
Intraoperative respiratory control, n (%)	23 (14.0)	21 (53.8)	< .001
Postoperative stenting, n (%)	35 (35.7)	16 (72.7)	.003
Fragmentation time (min), mean (SD)	24.82 (15.67)	63.39 (144.30)	.084
Total operation time (min), mean (SD)	65.56 (29.17)	73.38 (36.80)	.040

fURS, flexible ureteroscopy.

P value < .05 was considered statistically significant.

Table 3. Univariate analysis (SFR).

Predictors	Odds Ratio	95%CI	P
Male sex	0.73	0.46-1.15	.172
Compared to age < 5:			
Age 5-10	0.57	0.29-1.09	.093
Age 10-15	0.81	0.44-1.47	.481
Age > 15	0.80	0.40-1.59	.522
Stone size (mm)	1.12	1.06-1.18	< .001
TFL (as compared to HFL)	0.24	0.06-0.69	.020
Prestenting	0.77	0.49-1.22	.269
Usage of UAS	1.26	0.80-1.99	.315
Fragmentation time (min)	1.00	1.00-1.01	.377

CI, confidence intervals; HFL, holmium fiber laser; SFR, stone-free rates.

P value < .05 was considered statistically significant.

with a lower incidence (Table 3). At multivariable analysis (Table 4), only stone size was significantly associated with RF (odds ratios 1.20 95% CI 1.08-1.36, $P = .001$).

DISCUSSION

Guidelines still recommend similar treatment modalities for children with kidney stones as for adults, depending

on stone size and location. However, with the advancement of new technology, RIRS is becoming popular for the treatment of stones in children. For children with kidney stones smaller than 20 mm, both shock wave lithotripsy and RIRS may be offered as first-line therapy.¹³

Recently, Quiroz et al showed that RIRS in pediatrics has crossed many milestones, yet many areas need further research and larger data are required.¹⁴ One such area is

Table 4. Multivariate analysis (SFR).

Predictors	Odds Ratio	95%CI	P
Compared to age < 5:			
Age 5-10	0.35	0.04 - 2.30	.291
Age 10-15	0.86	0.18 - 4.36	.848
Age > 15	0.39	0.06 - 2.35	.300
Stone size (mm)	1.20	1.08 - 1.36	.001
TFL (as compared to HFL)	0.36	0.02 - 2.75	.392
Prestenting	0.91	0.30 - 2.95	.875
Usage of UAS	0.69	0.23 - 2.06	.503
Observations	106		
R ² Tjur	0.196		

P value < .05 was considered statistically significant.

the utility of UAS. UAS in adults has been shown to reduce intrarenal pressure and temperature. However, data on the impact of a UAS on SFR, postoperative pain, risk of infectious complication and ureteral stricture are still inconclusive.¹⁵ Since RIRS principles are adapted from adult practices, we did the following analysis to throw light on the utility of UAS and understand the Global practices and preferences by surgeons doing RIRS in children. To our knowledge, our series is the largest real-life global multicenter study in the literature.

In children with a low body mass index (BMI), and typically less than 5 years of age, insertion of UAS can be difficult, especially in patients who are not pre-stented, and a forced insertion may lead to ureteral injury. This is of utmost concern when used in younger children with a small body, namely light and short body shape, which can also be described as underweight (according to WHO underweight children/adult BMI is less than 15 kg/m²). However, Lim et al have shown that a UAS was used safely in 54.9% of their patients across all age groups without any significant complications, including those less than 5 years.¹⁶

This could explain why even in our study a significantly higher number of children aged < 5 years were operated using a UAS and more children in group 2 were older, taller, and had a higher mean body weight. In our study, a higher use of UAS was also seen in the children with previous history of urinary tract infection (UTI). As our study reflects a real-world practice, perhaps the intent was to reduce the risk of sepsis which is higher in patients with history of UTI¹⁷ worsened if intrarenal pressures are high causing retro renal reflux.¹⁸ Also, higher stone burden and cystine stone patients are complex stone patients and, in such cases UAS is preferred.^{13,14} Yuruk et al reported that 12 of their 14 cases aged 7-14 years who had RIRS for cystine stones needed a UAS, with a mild ureteral laceration noted in only 1 case.¹⁹ They concluded that treatment of patients with cystine stones is challenging but RIRS is a highly reproducible method that can be safely performed. A recent study demonstrated the use of UAS in children with cystinuria, but the authors failed to show a statistically significant difference in SFR.²⁰ We noted that in our study a higher number of patients known to have cystinuria had RIRS with a UAS (12.2% vs 7.6%, $P < .001$).

In our series, complications were mild and similar between the 2 groups. The reason for the higher percentage of transient hematuria is likely multifactorial. In adults, this phenomenon has been reported in studies analyzing high power lasers, such as TFL, longer fragmentation times, larger stone volumes, pre-stenting in patients, lower pole stones, harder stones but bleeding has mostly been transient, mild, not require any further intervention and did not add to significant morbidity of RIRS.^{21,22} All of these are seen in our study in group 2 patients and perhaps contributory. Safety of RIRS is well established and a low incidence of fever and sepsis have been reported in most series.^{23,24} In our series, only 3

patients had sepsis in group 2 vis a vis 1 in group 1. While simply managed with antibiotics, and it prolonged hospital stay. This might be related to the increased numbers of children with positive preop urine culture, larger stones, and increased numbers of pre-stenting cases in group 2. In adults, these factors contribute to post-operative sepsis.^{25,26}

In adults, Garcia et al have shown that utility of a smaller UAS and small diameter scopes was safer for anomalous kidneys and complex anatomy.²⁷ Similarly, a 7.5-Fr flexible ureterorenoscope with a small UAS was preferred by Chandramohan et al especially in children aged < 5 years. This was reiterated by Karunakaran et al who also advocated choosing age-based passive dilatation for RIRS access, especially if UAS is to be placed.^{23,24}

In our study, 8 or 10 Fr as the inner diameter was the maximum size UAS used, and scope tip diameters ranged from 7-8 Fr. UAS was used for all ages in our study, but group 2 had more older children and of bigger body weight and height. This could be a selective preference to avoid using a UAS in younger or children with a lower BMI. Multiple reasons can be hypothesized including (i) no pre-stenting in young children to avoid an additional anesthesia; (ii) avoid active ureteral dilation which may pose its own problem in younger or smaller children whose ureters may be narrow; (iii) avoid ureteral dilatation to lower the risk of ureteral ischemia, perforation, stricture formation, and vesicoureteral reflux due to forceful dilatation of small caliber ureteric orifice.^{25,26} In our series, stone locations were similar between the 2 groups but were significantly larger in group 2. Larger stones are generally managed by percutaneous nephrolithotomy, yet many series have reported good SFR and safety profiles after pediatric RIRS for large stones, but most authors recommended using a UAS.¹⁴ This may also explain why group 1 in our study had a shorter operation time. Interestingly, stone location and mean stone density did not affect the utility of UAS in RIRS. In the multivariate analysis, choice of using UAS seemed to be affected only by stone burden.

Our study is not without limitations and as any retrospective, multicenter study has inherent bias. However, this large multicenter study reflects real-life global practice of performing RIRS in children with and without UAS and as there are limited comparative studies, inferences here contribute to paucity of literature on this subject. We can safely extrapolate from our study that globally urologists prefer using a UAS only when it can be safely introduced in a favorable anatomy; however as this paper is retrospective, global representation of real-life practice having a uniform operation methodology was not possible and reflects the choices and preferences seen in 9 different institutions with different surgeons who used equipment and disposables available locally to their and influence the findings. This study has a retrospective design. Unfortunately, due to the retrospective nature of the study, we do not have an exact indication for the UAS placement, and each surgeon had his/her own preference. Also, while the indications of pre-stenting are similar in both groups namely relieving

obstruction or as part of staged RIRS, notably incidence of stenting is similar for both groups we could not collect information if the pre-stenting actually helped ease UAS placement. This database had only included patients in whom RIRS was successfully performed. Failed cases were not evaluated in this study. In children, not all patients have CT imaging for the evaluation of RF, and this may influence SFR. In addition, we lack longer follow-up time to see if there were any ureteric strictures. However, unlike adults, it has not been established that CT alone should be the gold standard for reporting postoperative outcomes for all ages. Another shortcoming of the study is that the exposure time to radiation was not evaluated.

By having 2 well-matched cohorts, a good comparison was possible and it is obvious that RIRS is safe with and without access sheath and can be used in all ages stone locations and for larger stones as well. This allows pediatric urologists to be bolder in making clinical decisions on intervention by RIRS.

CONCLUSION

RIRS is safe in children with and without the use of UAS using laser. In smaller or younger children (< 5 years), a limited use of UAS was noted in our study. We can recommend that its best utilized for bigger stones, cystine stones, and if used carefully can be safely deployed in all children especially older ones. Smaller scopes and smaller UAS diameters mitigate the risk of complications. However, merely using a UAS does not assure an improved SFR.

Ethical approval

The institutional review board and the local ethics committee at the Asian Institute of Nephrology and Urology, Hyderabad, Telangana, India, approved the retrospective study design and access to the patients' medical records (the ethical approval number is AINU06/2021). All methods were carried out in accordance with the Declaration of Helsinki. Written informed consent was obtained from individual participants in the study.

Ethical standards

All authors of this research paper have directly participated in the planning, execution or analysis of the study. All authors of this paper have read and approved the final version submitted. The contents of this manuscript have not been copyrighted or published previously. The contents of this manuscript are not under consideration for publication elsewhere.

Author contributions

T.P. Bhatia: Data collection or management. A. Bujons: Data collection or management, Manuscript writing/editing. D. Campobasso: Data collection or management.

D. Castellani: Data collection or management, Manuscript writing/editing. S. Ferretti: Data collection or management. K.Y. Fong: Data collection or management, Data analysis, C. Gatti: Data collection or management. V. Gauhar: Protocol/project development, Data collection or management, Manuscript writing/editing. S. Griffin: Data collection or management, Manuscript writing/editing. E.J. Lim: Data collection or management, Data analysis, A. Pietropaolo: Data collection or management. Y. Quiroz: Data collection or management. D. Ragoori: Data collection or management. K. Sarica: Manuscript writing/editing. C.A. Sekerci: Data collection or management, Manuscript writing/editing. A. Shrestha: Data collection or management. M.M. Sinha: Data collection or management. B.K. Somani: Protocol/project development, Data collection or management, Manuscript writing/editing. Y. Tanidir: Protocol/project development, Data collection or management, Data analysis, Manuscript writing/editing. J.Y. Teoh: Data collection or management, Manuscript writing/editing. O. Traxer: Protocol/project development, Data collection or management, Manuscript writing/editing. C.M. Vaddi: Data collection or management.

Declaration of Competing Interest

The authors declare that they have no conflict of interest.

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at [doi:10.1016/j.urology.2024.02.041](https://doi.org/10.1016/j.urology.2024.02.041).

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