REVIEW PAPER

UROLITHIASIS

Outcomes of ureteroscopy and laser lithotripsy with and without ureteral access sheaths for the treatment of renal calculi: A systematic review and meta-analysis

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Citation: Connor J, Anderson S, Davis NF. Outcomes of ureteroscopy and laser lithotripsy with and without ureteral access sheaths for the treatment of renal calculi: A systematic review and meta-analysis. Cent European J Urol. 2025; 78: 228-236.

Article history
Submitted: Sep. 8, 2024
Accepted: Jan, 19, 2025
Published online: May 25, 2025

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Introduction The use of ureteral access sheaths (UASs) is an issue of contention among urologists, with their efficacy unclear in retrograde intrarenal surgery (RIRS). Therefore, we performed a systematic review and meta-analysis to assess RIRS with laser lithotripsy for the treatment of urolithiasis with and without the use of UASs.

Material and methods A systematic literature search was conducted in July 2023 using MEDLINE, EMBASE and the Cochrane library. The quality of the included studies was assessed using the Newcastle-Ottowa scale and Cochrane collaboration risk of bias tool. The primary outcome measures were stone-free rate (SFR), and post-operative complications. Secondary outcomes were operative time (OT), hospital length of stay (LOS) and ureteral injury rate. Effect sizes were calculated by pooled risk ratios (RRs) and mean differences (MDs) with confidence intervals (CIs).

Results In total, 16 studies met the inclusion criteria. There were 3,123 participants who had RIRS with a UAS and 1,478 without. Pooled analysis revealed no significant difference between groups in SFR (RR = 1.03, 95% CI: 0.99–1.07), complication rate (RR = 1.31, 95% CI: 1.00–1.73), ureteral injuries (RR = 1.13, 95% CI: 0.77–1.65) or LOS (MD = –0.01, 95% CI: from –0.08 to 0.11). OT was significantly longer in the UAS group (MD = 0.35, 95% CI: 0.01–0.7).

Conclusions The results of this meta-analysis demonstrate that the use of UASs during RIRS does not improve post-operative outcomes and is associated with a longer OT. While there are still times where the use of UASs may be beneficial, their routine use for patients undergoing RIRS is not currently indicated.

Key Words: urolithiasis ‹› endourology ‹› ureteral access sheath ‹› laser lithotripsy

INTRODUCTION

Urolithiasis is an increasingly prevalent and recurrent condition that poses a significant burden on both patients and healthcare systems worldwide, with a global incidence of approximately 10% [1]. The management of urolithiasis has evolved considerably over the years, encompassing a spectrum of interventions that range from conservative approaches to minimally invasive procedures [2]. One pivotal change in the field has been the introduction and widespread use of ureteral access sheaths (UASs) for patients undergoing retrograde intrarenal surgery (RIRS) [3].

RIRS with laser lithotripsy is a popular treatment modality for patients with symptomatic intrarenal calculi and is commonly performed with the ancillary aid of UASs [4]. The use of UASs gained popularity as they facilitate the repeated passage of flexible ureteroscopes to enable access to the proximal ureter and collecting system. This was particularly useful as the ureter was difficult to navigate with the first flexible ureteroscopes without the use of a guidewire. Although the ureter can often be easily navigated under direct vision with modern-day flexible ureteroscopes, the reported benefits of UASs extend beyond merely navigating the ureter and include reduced rates of ureteral injury and reduced intra-operative intra-renal pressures, which likely lead to reduced post-operative infections. However, some studies have reported that UASs are associated with longer operative times (OT), increased healthcare costs and post-operative complications [5–7]. The conflicting results reported in the literature to date have prevented a global consensus on the role of UASs, and as a result their routine use remains controversial.

A previous systematic review and meta-analysis examined the outcomes associated with laser lithotripsy with UASs for the treatment of urolithiasis up to 2017, however a low number of included studies limit the reliability of the results [7]. Therefore, an updated pooled analysis of the literature is timely. The aim of this systematic review and meta-analysis is to quantify and compare the benefits and risks of UAS and non-UAS laser lithotripsy for the treatment of urolithiasis.

MATERIAL AND METHODS

Study design

A systematic literature review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement [8]. The protocol was registered in the PROSPERO database (CRD42023448523). The MEDLINE, Embase and Cochrane controlled trial databases were searched in July 2023. A combination of key words and MESH terms were used in the search string to identify all relevant studies. The search strategy is detailed in the supplementary material. No language or year of publication restrictions were placed on the search. The search was supplemented by searching the reference lists of selected articles as well as the grey literature through a Google Scholar search.

Eligibility criteria

Two authors (JC and SA) independently examined the search results, and disagreements on study selection were resolved through open discussion with the senior author (ND). Study selection was limited to randomised control trials (RCTs) and non-randomised comparative studies in which two independent groups received laser lithotripsy for the treatment of urolithiasis, one group with UASs, and a control group without. Participants with primary or recurrent renal stones, and with stones of any size and composition were eligible for inclusion. Studies were excluded if either arm had less than 10 participants, the population included non-adults, those with congenital urological anatomical abnormalities or active malignancy. Letters, review articles, laboratory studies, case reports, animal studies and journal supplements were also excluded.

Intervention

The intervention was laser lithotripsy with and without the use of UASs. All sizes, models and types of sheaths were considered. All types of laser modalities, as well as all durations of laser time were included. Studies were also included whether a basketing technique was used or not.

Outcome measures

The primary outcome measures were stone free rate (SFR), as determined by the trial investigators at any time using any modality or parameters, and post-operative complications using the Clavien-Dindo system as reported by the investigators, at any point in the post operative period. If complications were not reported in the Clavien-Dindo system, they were converted to a numerical value by the authors [9].

Secondary outcome measures included hospital length of stay (LOS), OT, and the rate of ureteral injury using the Post-Ureteroscopy Lesion Scale (PULS) as reported by investigators [10]. Where data in relation to outcomes of interest were omitted from the included studies, the corresponding authors were contacted directly in attempt to obtain this.

Risk of bias assessment

Studies were assessed for risk of bias using the Newcastle Ottawa scale for non-randomised studies and were considered high quality if they achieved a score of seven or higher [11]. The Cochrane collaboration risk of bias tool was used to critically appraise the RCTs [12].

Statistical analysis

Statistical analyses were conducted using STATA Statistical Software (STATA v17, College Station, Tx: StataCorp LLC). Results are reported as pooled risk ratios (RRs) with 95% confidence intervals (CIs) and mean differences (MD) with 95% CI for dichotomous and continuous outcomes respectively. When calculating risk ratios for binary outcomes, if a situation arose where no cases were reported in one of the groups, it was not included in the meta-analysis as to not skew the results [13]. A fixed-effects model was used when heterogeneity using I^2 was <50% and a random-effects model was used when I^2 was >50%, or when heterogeneity based on study design or outcome definitions was suspected.

RESULTS

Search results

The literature search yielded 807 potentially eligible studies, with two further papers being identified through other means (website, n = 1; citation searching, n = 1). Following removal of duplicates, 662 articles were screened by title and abstract, of which 50 were selected for full-text review. In total, 36 of these were excluded, resulting in 16 final studies. The reasons for study exclusion are outlined in the PRISMA flow chart (Figure 1).

Study characteristics and risk of bias assessment

The baseline characteristics of the included studies are presented in Table 1 [4, 14–28]. The studies that met the inclusion criteria were published between 2001 and 2023, and conducted in France [14], Italy [15], Spain [15], Argentina [16], Turkey [17–19, 24, 25, 28], UK [4], USA [20, 21, 27], Denmark [22], Romania [23] and India [26]. Sample sizes ranged between 47 and 1,808 patients. In total there were 3,123 participants who had RIRS with a UAS and 1,478 without. There were three RCT's, five prospective non-randomised comparative studies, and eight retrospective non-randomised comparative studies. Follow-up time for the outcomes of interest ranged from three days to 18 months. Multiple sizes of UAS were used with 12/14 Fr being the most common (n = 7; Table 1). None of the included studies used vacuum-assisted UASs. The most common definition for SFR was a lack of residual stone fragments >3 mm on imaging [4, 14–28]. Stone burden in mm^3, when reported, was similar between groups. In all cases where the type of laser was reported (n = 11), holmium laser was used.

The methodological quality of the included studies was generally good. The RCTs were of moderate to high quality with low risk of bias [15, 18, 26]. All of the included non-randomised studies had low risk of bias, scoring at least 7/9 on the Newcastle-Ottawa scale [11].

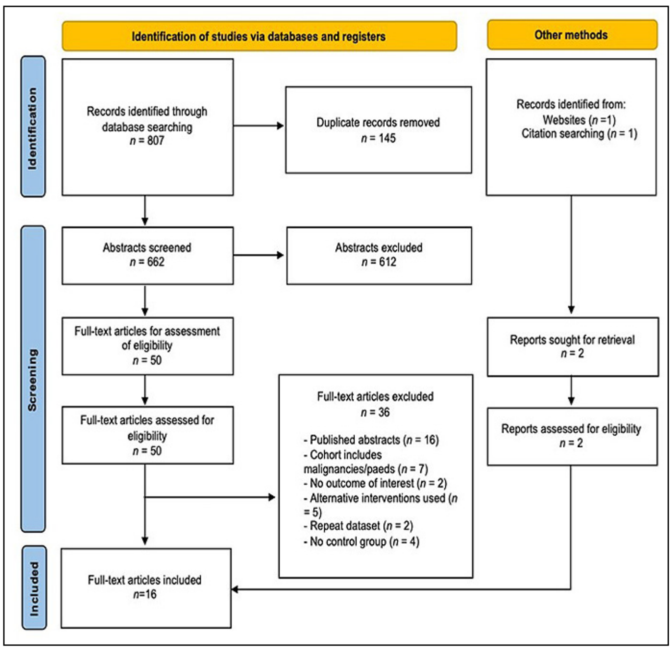

Figure 1. *Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram of studies identified, excluded, or included in the review. There were three randomised controlled trials, five prospective studies, and eight retrospective studies.*

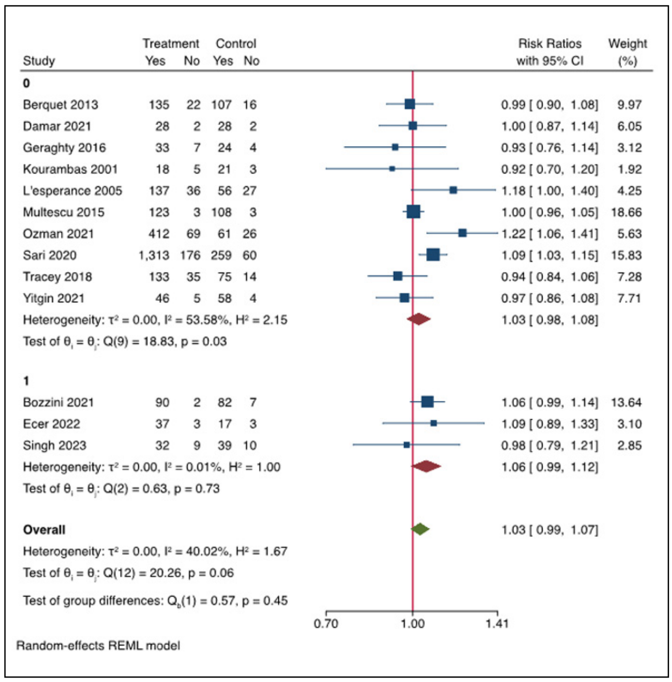

Figure 2. *Forest plots compare the stone-free rate for laser lithotripsy with and without ureteral access sheaths; (0) non-randomised control trials; (1) randomised control trials only. Procedures that used ureteral access sheaths were the reference approach, such that RR <1 indicated that procedures without a UAS have a lower SFR and RR >1 indicates that procedures without a have a higher SFR.*

CI – confidence interval; RR – risk ratio

Table 1. *Characteristics of studies comparing outcomes of laser lithotripsy with and without ureteral access sheaths*

Study and year	Study design	Country	SFR definition	Duration of follow-up	UAS Size	Sample size (n)	Patients per arm		Patient age (years)		Stone burden (mm)*	
							UAS	No UAS	UAS	No UAS	UAS	No UAS
Berquet et al. 2013 [14]	OBS	France	<3 mm	3 months	12/14 Fr	280	157	123	50	52	15.15 (9.8)	13.75 (8.0)
Bozzini et al. 2021 [15]	RCT	Italy, Spain	<3 mm	3 days	10/12 Fr	181	92	89	51.4	48.3	15.82 (4.12)	14.11 (4.89)
Cristallo et al. 2022 [16]	OBS	Argentina	NR	NR	12/14 Fr	241	43	198	54.1	53.2	11.5 (4.6)	9.2 (4.0)
Damar et al. 2021 [17]	OBS	Turkey	<3 mm	NR	9.5/11 Fr	60	30	30	49.6	48.4	NR	NR
Ecer et al. 2022 [18]	RCT	Turkey	<3 mm	14 days	9.5/13 Fr	60	40	20	47	50.5	13.65 (4.6)	14.95 (6.5)
Geraghty et al. 2016 [4]	OBS	UK	<2 mm	2–3 months	9.5/11 Fr 12/14 Fr	68	40	28	NR	NR	NR	NR
Karaaslan et al. 2019 [19]	OBS	Turkey	NR	NR	12/14 Fr	129	81	48	NR	NR	14.9 (5.7)	15.8 (6.0)
Kourambas et al. 2001 [20]	OBS	USA	NR	3 months	12/14 Fr	47	23	24	NR	NR	13.7	10.1
L'esperance et al. 2005 [21]	OBS	USA	NR	2 months	12/15 Fr	256	173	83	49	47	8.7	7.3
Lildal et al. 2018 [22]	OBS	Denmark	NR	NR	10/12 Fr	180	88	92	55	50	NR	NR
Mulţescu et al. 2015 [23]	OBS	Romania	NR	18 months	10/12 Fr	237	126	111	NR	NR	NR	NR
Özman et al. 2021 [24]	OBS	Turkey	<3 mm	1 month	10/12 Fr, 11/13 Fr	568	481	87	48.5	47.6	NR	NR
Sari et al. 2020 [25]	OBS	Turkey	<3 mm	2 months	11/13 Fr 9.5/11.5 Fr	1,808	1,489	319	46.2	44.9	15.6 (7.9)	12.53 (5.9)
Singh et al. 2023 [26]	RCT	India	<3 mm	1 month	9.5/11 Fr 12/14 Fr	90	41	40	39	39.1	14.7 (4.57)	15.3 (4.97)
Tracy et al. 2018 [27]	OBS	USA	TSB <100	3 months	12/14 Fr, 14/16 Fr	257	168	124	50.2	54	NR	NR
Yitgin et al. 2021 [28]	OBS	Turkey	<2 mm	3 months	10/12 Fr	113	51	62	45	46.1	NR	NR

*mm represents the mean diameter of stones noted on imaging of individual patients
NR – not reported; OBS – observational study; RCT – randomised control trial; SFR – stone free rate; UAS – ureteral access sheath

Outcome data

Stone-free rate

Thirteen studies reporting SFRs were included in the final meta-analysis. SFR as defined by the individual studies did not differ significantly between groups (Figure 2). A random effects model was used given the difference in definition of SFR and study designs, which generated a RR of 1.03, 95% CI: 0.99–1.07. There was moderate, but not significant heterogeneity among studies (Cochrane's Q = 20.26, p = 0.06, I^2 = 40.02).
Subgroup analysis of only RCTs is also presented in Figure 2. Again, no statistical difference was noted in the RR between UAS and non-UAS groups, with the pooled effect being 1.06, 95% CI: 0.99–1.12. There was no significant heterogeneity found in these studies (Cochrane Q = 0.63, p = 0.73, I^2 = 0.01). Further subgroup analysis of the difference in SFR based on UAS size (≤11/13 Fr compared to ≥12/14 Fr) showed no statistical difference (MD = 0.068 95% CI: from –0.10 to 0.24).

Operative time

Fourteen publications reported OT for both UAS and non-UAS groups (Figure 3). The mean OT was longer for the UAS group (60.7 ±18 minutes) compared to the non-UAS group (54.8 ±13.8 minutes), with a statistically significant mean difference (MD = 0.35, 95% CI: 0.01–0.7).
Subgroup analysis of RCTs only is also presented in Figure 3. The mean OT in the UAS group in RCTs was 48.98 ±11.42 minutes, and for non-UAS groups was 51.84 ±11.80 minutes. There was no significant difference between the groups (MD = –0.14, 95% CI: from –0.36 to 0.7).

Length of stay

Five studies reported LOS in both intervention and control groups as seen in Figure 3. The mean LOS for the UAS cohort was 1.45 ±0.41 days and was 1.48 ±0.38 days for the control group. The mean difference was not statistically significant (MD = –0.01, 95% CI: from –0.08 to 0.11).

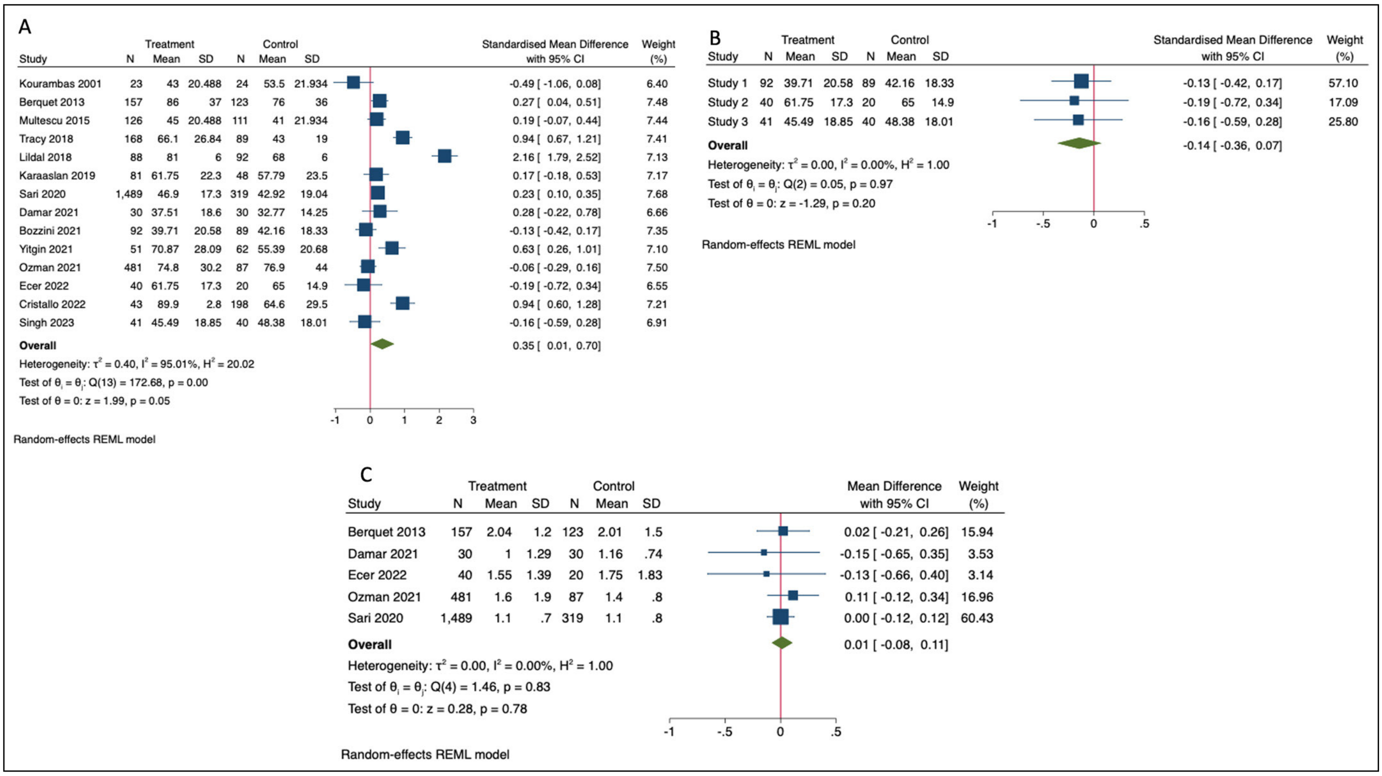

Figure 3. *Forest plots comparing standardised mean difference (SMD) in operations times for laser lithotripsy with and without ureteral access sheaths:* **A)** *all studies;* **B)** *randomised control trials; and mean difference in length of stay in hospital for patients undergoing laser lithotripsy with and without ureteral access sheaths.* **C)** *Procedures that did use ureteral access sheaths were the reference approach, such that a positive pooled value in SMD indicates the UAS cohort had a longer operation duration or LOS, and a negative result indicated the UAS group had a shorter operation duration or LOS.*

CI – confidence interval; N – number of participants per trial arm; SD – standard deviation

As only one RCT reported mean LOS a further subgroup analysis was not performed [18].

Clavien-Dindo complications

A total of twelve studies reported Clavien-Dindo complications. The meta-analysis of complication rates is presented in Figure 4. The overall incidence of post-operative complications was 13.4% in the UAS groups and 10.3% in the control groups. No statistically significant difference was seen between groups (RR = 1.10, 95% CI: 0.84–1.35).
A subgroup analysis was performed of RCTs only, and additionally found no significant difference in overall complications (RR = 1.97, 95% CI: 0.92–3.02). Further subgroup analysis of difference in complication rates based on UAS size (≤11/13 FR compared to ≥12/14 Fr) showed no statistical difference (MD = 0.37 95% CI: –1.40 to 1.48).

Post-Ureteroscopy Lesion Scale

Four publications reported PULS incidence. The overall incidence of ureteral lesions/injuries was 28.1% in the UAS group and 25.5% in the control group. A meta-analysis of the risk ratios of this data is presented in Figure 4. There was no significant difference in overall PULS incidence (RR = 1.13, 95% CI: 0.77–1.65).
A subgroup analysis of the two RCTs that reported PULS incidence also failed to demonstrate a significant difference between the two groups, as seen in Figure 4 (RR = 0.86, 95% CI: 0.62–1.19). Further subgroup analysis of difference in ureteral lesion rates based on UAS size (≤11/13 Fr compared to ≥12/14 Fr) showed a statistical difference in favour of smaller UASs (MD = 0.14, 95% CI: 0.09–0.19).

DISCUSSION

The incidence of urolithiasis is rising, and as such RIRS is being performed more commonly [2]. Although UASs have become routine ancillary endourological devices, there has been a paucity of robust evidence to support their use. This systematic review and meta-analysis provides a comprehensive review of post-operative outcomes such as SFR, OT, LOS, and post-operative complications, including all studies to date that compared laser lithotripsy with and without UASs in a well-matched cohort of urolithiasis patients.

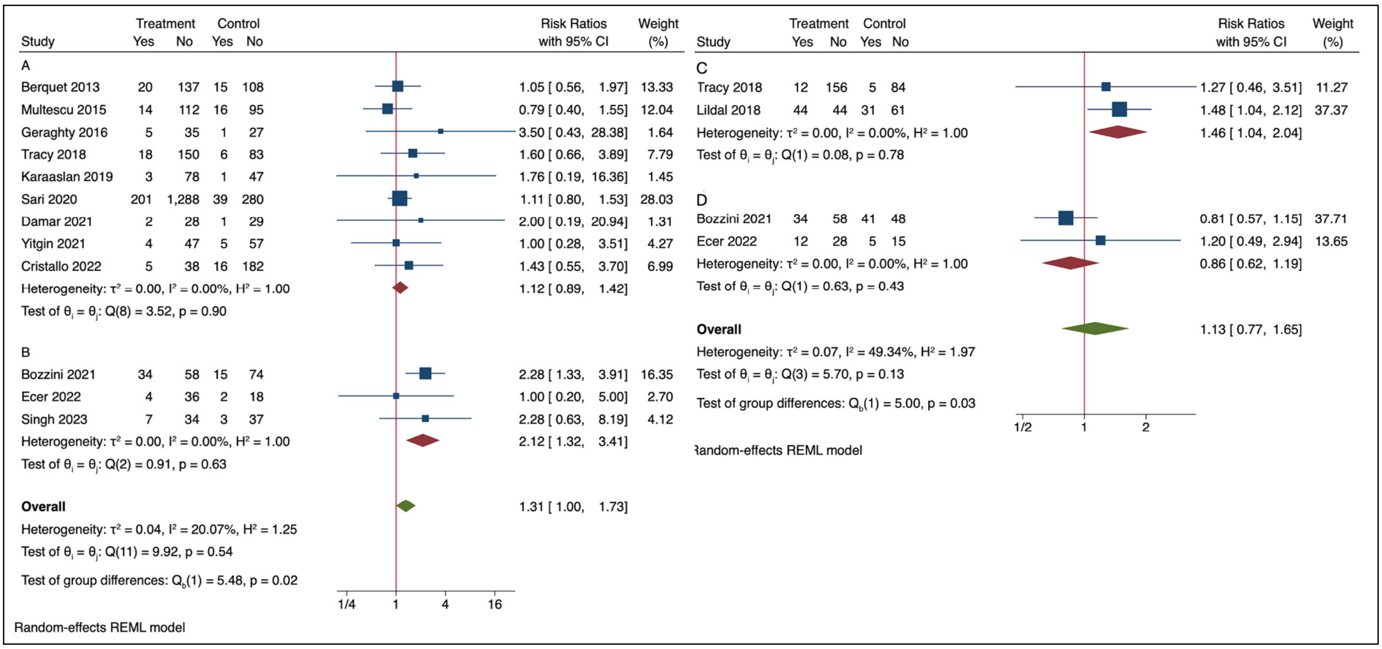

Figure 4. *Forest plots comparing Clavien-Dindo post-operative complication rates for patients undergoing laser lithotripsy with and without ureteral access sheath:* **A)** *all studies;* **B)** *randomised control trials only, and comparing ureteral injury rates for patients undergoing laser lithotripsy with and without ureteral access sheaths:* **C)** *for all studies;* **D)** *randomised control trials only. Procedures that used ureteral access sheaths were the reference approach, such that RR <1 indicated that procedures without a UAS have a lower post-op complication rate and RR >1 indicates that procedures with a UAS have a higher rate of post-op complications.*

CI – confidence interval; RR – risk ratio

The SFR was similar in both cohorts, with a pooled RR demonstrating no favourability towards one method over the other. A concordant literature review summarised that the use of UASs provides no clear benefit in terms of the success of RIRS for urolithiasis, attributing this to the advancement of laser therapy, as well as the downsizing of ureteroscopes [5]. A previous meta-analysis pooled the data until 2016 and reported comparable results; no significant difference in SFR, OT and LOS [7]. It has been hypothesised that the improved drainage associated with the use of a UAS can improve intra-operative visibility, however, the results of this meta-analysis have demonstrated that SFR are not significantly affected by the use of UASs, nor was the size of a given UAS used a determinant factor in the success of the procedure.

One limitation of our study is that we were not able to perform a subgroup analysis of SFR based on stone location. That said, an observational study by Berquet et al. 2014 found that stone location was not a significant factor in predicting SFR or post-operative complications in RIRS with the use of a UAS, but more research may be needed on this topic. There is no question that the use of UASs facilitates the repeated passage of ureteroscopes in cases where repeated basketing is required, and they also may provide some benefit in navigating anatomically challenging ureters. Interestingly, none of the included studies reported cases where the surgical technique was changed from not using a UAS to using one as a result of procedural difficulties. Some did report incidences where a UAS could not be safely placed and the procedure was therefore performed without one, suggesting that RIRS, when performed with modern-day flexible ureteroscopes, may be more easily performed without the use of a UAS compared to with one [4, 24]. However, access to the ureter was not a predefined outcome measure of any of the included studies, and so more studies are required to assess the impact of UASs on successful RIRS completion adequately.

While our study found an increased incidence of Clavien-Dindo complications in the UAS group, this difference did not reach statistical significance. Furthermore, we found that the size of the UAS used had no significant effect on the development of post-operative complications. These findings are in keeping with results from a previous meta-analysis, which concluded that post-operative complications were more prevalent in the UAS group [7]. There are however conflicting results reported in the literature, as many studies that report higher complication rates without the use of a UAS often find that UAS use reduces the risk of post-operative infection [15, 24, 29]. The likely explanation for this is the potential for reduced intra-operative pressures with the use of UASs. However, technological advances in ureteroscope diameter and laser technology allow modern RIRS for urolithiasis to be performed quicker and likely at lower intra-renal pressures. It is therefore unlikely that the routine use of UASs will reduce post-operative complications outside of specific cases, such as when repeated basketing is anticipated.

The rate of ureteral wall injury due to UAS placement has been reported to be as high as 46% [30]. Notably, the overall rate of ureteral wall injury was significantly lower in our systematic review, though this may be due to poor reporting of outcomes in the included studies. There was a higher rate of ureteral wall injury in the UAS group. However, this did not reach statistical significance. The lack of difference may be due to the experience level of the surgeons performing the procedure. The procedures were carried out by experienced urologists in the majority of the included studies, and perhaps a more significant difference would have been observed if the procedures were carried out by novice trainees. A subgroup analysis found a marginally higher incidence of ureteral lesions with smaller UASs, contrary to previous research, which demonstrated larger UAS size being associated with more ureteral lesions [31]. Though of note, only one study in this review reported ureteral lesions with the use of larger UASs (≥12/14 Fr), and therefore, this may be a limited representation of the actual distribution of ureteral lesions.

Our systematic review indicates that RIRS with laser lithotripsy can be performed safely and effectively without the use of a UAS. The main advantage of omitting routine UASs during RIRS is cost, as UASs can cost up to $300, and can contribute to nearly half the costs of a flexible ureteroscopy [32]. Furthermore, the shorter OT associated with omitting UASs may facilitate more procedures to be done in a similar timeframe. OTs are likely to be shorter in the non-UAS cohort because of the time needed at the beginning of the operation to insert the UAS. Our study found a difference of approximately 3 minutes in OT, favouring the non-UAS group, though it is unlikely that this would result in any clinical significance.

There are some important limitations to this meta-analysis to consider. Although the included studies were generally of high quality and low risk of bias, the majority of the included studies were non-randomised, with only three RCTs satisfying the eligibility criteria. The included studies came from ten different countries, and regional differences may have been a confounder and skewed the data collected. Another important limitation is the lack of a standardised definition of SFR. There was no consistent method used for detecting residual fragments, and the follow-up times were generally poorly reported in the studies. Sepsis, pain, and intrarenal pressure as independent outcomes were infrequently reported in studies, so we were unable to do subgroup analyses between groups for these outcomes. Confounding factors that influence the risk of ureteral wall injury, such as prior RIRS or stenting, were poorly reported across the studies. Finally, our study did not examine the use of novel vacuum or suction-assisted or UASs, which research has suggested may improve SFR and decrease intra-renal pressure when compared to standard devices [33].

CONCLUSIONS

This study is the largest and most comprehensive systematic review and meta-analysis that assesses the role of UASs in RIRS for urolithiasis. No statistically significant differences in SFR, LOS or post-operative complications were seen. While there are specific instances where the use of UASs may help facilitate RIRS, this study suggests that, at present, there is insufficient evidence to support their routine use in the treatment of all patients with urolithiasis.

CONFLICT OF INTERESTS

The authors declare no conflict of interest.

FUNDING

This research received no external funding.

ETHICS APPROVAL STATEMENT

The ethical approval was not required.

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