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Reprint – Ureteral stent vs. no ureteral stent for ureteroscopy in the management of renal and ureteral calculi: A Cochrane review

Maria Ordonez, MD[1]; Eu Chang Hwang, MD[1,2,3]; Michael Borofsky, MD[1]; Caitlin J Bakker, MD[4]; Shreyas Gandhi, MD[5]; Philipp Dahm, MD[1,3]

[1]Department of Urology, University of Minnesota, Minneapolis, MN, United States; [2]Department of Urology, Chonnam National University Medical School, Hwasun, South Korea; [3]Urology Section, Minneapolis VA Health Care System, Minneapolis, MN, United States; [4]Health Sciences Libraries, University of Minnesota, Minneapolis, MN, United States; [5]Dalhousie University, Halifax, NS, Canada

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Abstract

Introduction: We aimed to assess the effects of postoperative ureteral stent placement after uncomplicated ureteroscopy.

Methods: We performed a comprehensive search with no restrictions on publication language or status up to February 1, 2019. We only included randomized trials. Two review authors independently examined full-text reports, identified relevant studies, assessed the eligibility of studies for inclusion, extracted data, and assessed risk of bias. We performed statistical analyses using a random-effects model and assessed the certainty of the evidence according to GRADE.

Results: We included 23 studies with 2656 randomized patients. Primary outcomes: It is uncertain whether stenting reduces the number of unplanned return visits (very low certainty of evidence [CoE]). Pain on the day of surgery is probably similar (mean difference [MD] 0.32; 95% confidence interval (CI) -0.13–0.78; moderate CoE). Pain on postoperative days 1–3 may show little to no difference (standardized mean difference [SMD] 0.25; 95% CI -0.32–0.82; low CoE). It is uncertain whether stented patients experience more pain on postoperative days 4–30 (very low CoE). Stenting may result in little to no difference in the need for secondary interventions (risk ratio [RR] 1.15; 95% CI 0.39–3.33; low CoE). Secondary outcomes: We are uncertain whether stenting reduces the need for narcotics and reduces ureteral stricture rates up to 90 days (very low CoE). Rates of hospital admission may be slightly reduced (RR 0.70; 95% CI 0.32–1.55; low CoE). This review was limited to patients in whom ureteroscopy was deemed 'uncomplicated.' In addition, time intervals for the grouping for the reported degree of pain were established post-hoc. The CoE for most outcomes was rated as low or very low for methodological reasons.

Conclusions: Findings of this review illustrate the tradeoffs of risks and benefits faced by urologists and their patients when it comes to decision-making about stent placement after uncomplicated ureteroscopy for stone disease.

Introduction

Ureteral stents are commonly placed after ureteroscopy (URS) and are usually indicated in the setting of ureteral injury, severe edema, and concerns over infection or renal failure. An international study found that stents are placed in 60% of patients after treatment for ureteral stones and in 80% of patients after treatment for renal stones.[1] Postoperative ureteral stenting is thought to decrease the risk of obstruction due to postoperative ureteral edema or small stone fragments. It is also thought to mitigate the effects of instrumentation and the sequelae of subsequent edema and to prevent ureteral stricture formation. Stents, however, also have downsides. Side effects from ureteral stent placement, including urinary frequency and urgency, hematuria, dysuria, flank pain, and pelvic pain, are the most common source of postoperative morbidity.[2] These side effects can lead to office and emergency department visits. Meanwhile, omitting a stent may lead to further interventions and additional visits as well.[3]

Several systematic reviews have summarized the body of evidence on benefits and harms of placing a ureteral stent.[4-11] However, none has adhered to the methodological standards of Cochrane, including application of GRADE and generation of a 'Summary of findings' table. In this review, we assessed the effects of postoperative ureteral stent placement after uncomplicated URS to help inform clinicians and guideline developers.

Methods

Search strategy and selection criteria

This systematic review and meta-analyses were based on a published protocol.[12] We performed a comprehensive

search using multiple databases of the Cochrane Central Register of Controlled Trials in the Cochrane Library, MEDLINE Ovid and EMBASE Ovid, and Western Pacific Region Index Medicus (Supplementary Table 1; available at *cuaj.ca*). We also searched the references of full articles retrieved for our review to identify any additional studies. To identify unpublished trials or trials in progress, we searched the following sources: ClinicalTrials.gov, the World Health Organization International Clinical Trials Registry Platform Search Portal (apps.who.int/trialsearch/). We hand-searched relevant conference proceedings from 2013–2018, for unpublished studies from annual meetings of the American Urological Association, European Association of Urology, Société Internationale d'Urologie, and World Congress of Endourology. Searches were initially performed on January 19, 2017 followed by an updated search on February 1, 2019. Three review authors (MO, MB, SG) independently screened all potentially relevant records and classified studies in accordance with the criteria for each provided in the Cochrane Handbook for Systematic Reviews of Interventions.[13] We search and reviewed randomized, controlled trials (RCTs) only as they are likely to provide the highest-quality evidence.

Types of participants

We included participants over the age of 18 who underwent URS for stone clearance. We excluded studies conducted in children, pregnant women, patients with systemic signs of infection, patients with a solitary kidney, patients undergoing bilateral stone procedures, patients with anatomical abnormalities, and transplant patients. We excluded studies in which URS was complicated by perforation of the ureter or gross bleeding.

Types of intervention

We compared URS with stent placement vs. URS with no stent placement.

Types of outcomes measured

The primary outcomes of the review were unplanned return visits to the emergency/urgent care department, postoperative discomfort and secondary interventions. Secondary outcomes were the requirement for narcotics, urinary tract infection (UTI), operating room time, ureteral stricture, quality of life, and postoperative hospital admission.

Assessment of risk of bias in included studies

Three review authors (MO, MB, SG) independently assessed the risk of bias of each included study on a per-outcome basis. We resolved all disagreements by discussion and consensus. We assessed risk of bias using the Cochrane "Risk of bias" assessment tool. We judged risk of bias domains as low-risk, high risk, or unclear risk, and evaluated individual bias items as described in the Cochrane Handbook for Systematic Reviews of Interventions.[13]

Data collection and data extraction

Data extraction was carried out independently by three review authors (MO, MB and SG) using data extraction forms created in Microsoft Excel and followed the domain-based risk of bias evaluation as described in the Cochrane Handbook for Systematic Reviews of Interventions.[13] We attempted to obtain numbers of events and totals for population for dichotomous outcomes and means with standard deviations (SDs) or data necessary to calculate this information for continuous outcomes. We summarized data using a random-effects model. We interpreted random-effects meta-analyses with due consideration of the whole distribution of effects. We planned to assess heterogeneity statistically with the I^2 statistic. I^2 values of 25%, 50%, and 75% were considered low, moderate, and high, respectively.[14] Tests for funnel plot asymmetry are generally only performed when at least 10 studies are included in the meta-analysis. We used Review Manager 5 software (The Cochrane Collaboration, Copenhagen, Denmark) to perform statistical analyses.

Subgroup and sensitivity analyses

We expected the following characteristics to introduce clinical heterogeneity, and we planned to carry out subgroup analyses with investigation of interactions.

- Patient age (40 or younger vs. over 40 years of age)
- Patient gender (male vs. female)
- Ureteroscope type (flexible vs. semi-rigid)
- Stone location (renal vs. proximal and mid vs. distal ureteral)
- Stone size (≤5 mm vs. 5–10 mm vs. >10 mm)
- Ureteral dilation including access sheath use or balloon dilation, or both (yes vs. no)

We performed sensitivity analyses to explore the influence of the following factors (when applicable) on effect sizes.

- Restricting the analysis by taking into account the risk of bias, by excluding studies at high risk or unclear risk
- Restricting the analysis to studies with a minimal stent duration of three days

Summary of findings table

We presented the overall certainty of the evidence for each outcome according to GRADE, which accounts for five cri-

teria not only related to internal validity (study limitations, inconsistency, imprecision, publication bias) but also to external validity, such as directness of results.[15]

Results

Search results

Our comprehensive literature search identified 5529 records. After removal of duplicates, we screened the titles and abstracts of 2631 records and excluded 2590. We screened 41 full-text articles and excluded 16 articles. In all, 14 studies did not meet the inclusion criteria or were not relevant to the question under examination.[1,11,16-27] We identified one ongoing trial.[28] In all, 23 studies with 24 relevant articles (abstracts or secondary publications: not listed in the references) ultimately met the inclusion criteria and were included in the qualitative synthesis of this review.[29-51] The flow of literature through this assessment process is shown in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flowchart (Fig. 1).

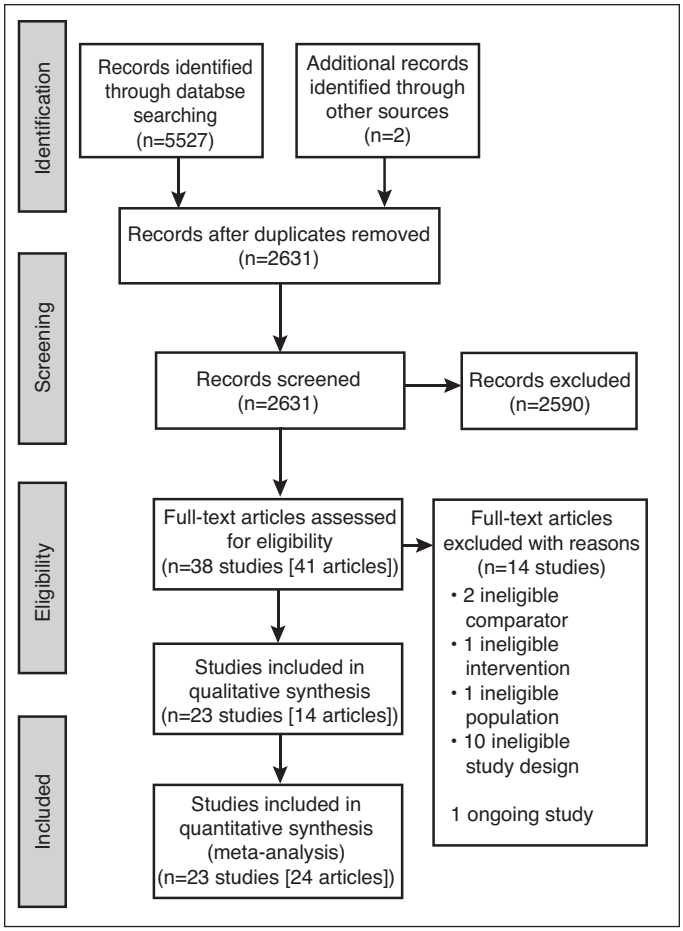

Fig. 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flowchart.

Included studies

Detailed characteristics of included studies are summarized in Supplementary Table 2 (available at *cuaj.ca*). We included 2656 randomized participants, of whom 2275 completed the trials. A total of 21 studies performed ureteral stenting after URS as an intervention and used no stent placement, with URS as a comparator. El Harrech et al[38] and Wang et al[48] compared three groups (i.e. , double-J stent placement vs. ureteral stent placement vs. no stent placement;[38] and double-J stent placement vs. no stent placement vs. sham [named "control"][48]); therefore, we selected one pair of interventions to create a single pair-wise comparison (i.e., double-J stent placement vs. no stent placement). Followup duration ranged two weeks to one year.

Two studies reported no funding source,[30,33] and one reported the funding source.[37] The remaining trials did not mention a funding source. Three studies reported no conflicts of interest,[30,33,38] and one reported a conflict of interest.[37] The remaining studies did not mention conflicts of interest.

Risk of bias in included studies

Further details on the assessment of Risk of Bias were stated in the review published in Cochrane Library. Assessments of risk of bias are summarized in Fig. 2.

Summary of findings tables

We summarized the results in summary of findings tables in accordance with GRADE methodology (Table 1).

Effect of the Intervention

1. Unplanned return visit to emergency/urgent care department

We included 16 studies with 1970 participants.[30,32-38,41,42,44-46,48,49,51] Stent placement may reduce the number of unplanned return visits slightly (risk ratio [RR] 0.69; 95% confidence interval [CI] 0.40–1.21; very low certainty of evidence [CoE]) but we are very uncertain of this finding. The funnel plot shows asymmetry, thereby suggesting publication bias (Fig. 3).

2. Postoperative discomfort

2.1 Postoperative day 0 (the day of surgery)

We included four studies with 346 participants.[31,34,46,47] There is probably no difference in postoperative discomfort on postoperative day 0 between stented and unstented participants (mean difference [MD] 0.32; 95% CI -0.13–0.78; moderate CoE).

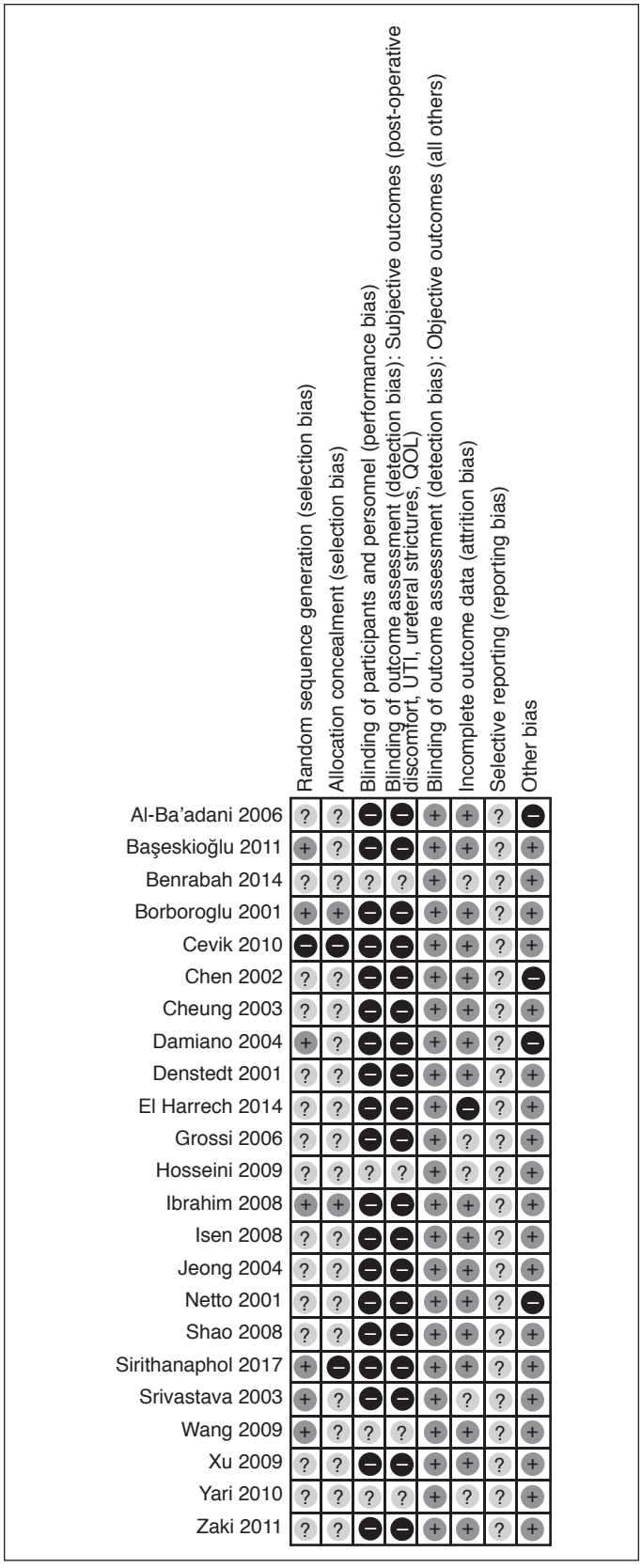

Fig. 2. Summary of risk of bias assessment. QOL: quality of life; UTI: urinary tract infection.

2.2 Postoperative days 1–3

We included eight studies with 683 participants.[32,35,36,38,46-49] There may be no difference in postoperative discomfort on postoperative days 1–3 between stented and unstented participants (standardized mean difference [SMD] 0.25; 95% CI -0.32–0.82; low CoE).

2.3 Postoperative days 4–30

We included eight studies with 903 participants.[30,32,36-38,42,45,49] Postoperative discomfort on postoperative days 4–30 may be greater in stented participants (SMD 0.62; 95% CI 0.08–1.16; very low CoE), but we are very uncertain of this finding.

3. Secondary interventions

We included 10 studies with 1435 participants.[30,35-38,41,45,46,48,49] There may be no difference in the number of secondary interventions between stented and unstented participants (RR 1.15; 95% CI 0.39–3.33; low CoE). The funnel plot shows symmetry, thereby giving no indication of publication bias (Supplementary Fig. 1; available at *cuaj.ca*).

4. Narcotic requirement

In contrast to our protocol,[12] we analyzed this outcome to assess the number of participants who required narcotics, rather than average narcotic requirements in morphine equivalents, which was not reported in any of the studies. We included seven studies with 830 participants.[29,33,36,44,46,48,49] Stent placement may reduce the need for narcotics (RR 0.80; 95% CI 0.48–1.36; very low CoE), but we are very uncertain of this finding.

5. UTIs

We included 10 studies with 1207 participants.[30,35-38,41,45,46,48,49] There is probably no difference in the number of UTIs between stented and unstented participants (RR 0.94; 95% CI 0.59–1.51; moderate CoE). The funnel plot shows symmetry, thereby giving no indication of publication bias (Supplementary Fig. 2; available at *cuaj.ca*).

6. Operating room time

We included 17 studies with 1981 participants.[29,30,33,35-38,41-49,51] Placement of a stent probably increases operating room time slightly (MD 3.72 minutes; 95% CI 2.30–5.14; moderate CoE). The funnel plot provided no indication of clinically relevant publication bias (Supplementary Fig. 3; available at *cuaj.ca*).

7. Ureteral stricture

We included 14 studies with 1625 participants.[30,32,33,35-38,41,42,45,47-49,51] Placement of a stent may slightly reduce the rate of ureteral stricture up to 90 days (RR 0.58; 95% CI 0.23–1.47; very low CoE), but we are very uncertain of this finding. The funnel plot thereby giving no indication of publication bias (Supplementary Fig. 4; available at *cuaj.ca*).

Table 1. Stent vs. no stent for ureteroscopy in the management of renal and ureteral calculi

Patient or population: Participants underwent ureteroscopy due to renal and ureteral calculi
Setting: Inpatient or outpatient
Intervention: Stent placement
Comparison: No stent placement

Outcomes	No. of participants (studies)	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects*	
				Risk with URS with no stent placement	Risk difference with URS with stent placement
Unplanned return visit to emergency/ urgent care department Followup: 2 weeks to 49 months	1970 (16 RCTs)	⊕◯◯◯ Very low[a,b,c]	RR 0.69 (0.40–1.21)	67 per 1000	21 fewer per 1000 (40 fewer to 14 more)
Postoperative pain day 0 Assessed with visual analogue scale (range 0–10): 4 studies	346 (4 RCTs)	⊕⊕⊕◯ Moderate[a]	-	The mean postoperative pain day 0 ranged from 2.3–4.82	MD 0.32 higher (0.13 lower to 0.78 higher)
Postoperative pain days 1–3 Assessed with visual analogue scale (range 0–10): 7 studies; pain questionnaire (range 0–100): 1 study	683 (8 RCTs)	⊕⊕◯◯ Low[a,d,e]	-	-	SMD 0.25 SD higher (0.32 lower to 0.82 higher)
Postoperative pain days 4–30 Assessed with visual analogue scale (range 0–10): 5 studies; pain questionnaire (range 0–100): 1 study; other: 2 studies	903 (8 RCTs)	⊕◯◯◯ Very low[a,b,d]	-	-	SMD 0.62 SD higher (0.08 higher to 1.16 higher)
Secondary interventions Followup: 1 month to 49 months	1435 (10 RCTs)	⊕⊕◯◯ Low[a,f]	RR 1.15 (0.39–3.33)	21 per 1000	3 more per 1000 (13 fewer to 48 more)
Narcotic requirement Follow up: 2 weeks to 6 months	830 (7 RCTs)	⊕◯◯◯ Very low[a,d,f]	RR 0.80 (0.48–1.36)	207 per 1000	41 fewer per 1000 (108 fewer to 75 more)
UTI (positive urine culture as well as symptoms) up to 90 days	1207 (10 RCTs)	⊕⊕⊕◯ Moderate[a]	RR 0.94 (0.59–1.51)	57 per 1000	3 fewer per 1000 (23 fewer to 29 more)
Ureteral stricture up to 90 days	1625 (14 RCTs)	⊕◯◯◯ Very low[a,b]	RR 0.58 (0.23–1.47)	15 per 1000	6 fewer per 1000 (11 fewer to 7 more)
Hospital admission Followup: 2 weeks to 49 months	1647 (13 RCTs)	⊕◯◯◯ Very low[a,b]	RR 0.70 (0.32–1.55)	49 per 1000	15 fewer per 1000 (33 fewer to 27 more)

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[a]Downgraded by one level for study limitations mainly due to concerns about performance bias across studies. [b]Downgraded by two levels for imprecision: wide confidence interval. [c]Downgraded by one level for publication bias: funnel plot asymmetry. [d]Downgraded by one level for inconsistency: clinically relevant heterogeneity. [e]We did not downgrade for imprecision, because it resulted from inconsistency. [f]Downgraded by one level for imprecision: confidence interval crosses the line of no difference and the assumed threshold of a clinically important difference. *The risk in the intervention group (and its 95% CI) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI). CI: confidence interval; MD: mean difference; RCTs: randomized controlled trials; RR: risk ratio; SMD: standardized mean difference.

8. Quality of life

We included only one study.[45] Quality of life may be reduced in stented participants (MD 2.9; 95% CI 2.52–3.28; low CoE).

9. Hospital admission

We included 13 studies with 1647 participants.[30-33,36-38,41,42,45,46,48,51] The risk of postoperative hospital readmission may be slightly lower in stented patients (RR 0.70; 95% CI 0.32–1.55; very low CoE), but we are very uncertain of this finding. The funnel plot shows symmetry, thereby giving no indication of publication bias (Supplementary Fig. 5; available at *cuaj.ca*).

Subgroup and sensitivity analyses

We were unable to conduct any preplanned subgroup or sensitivity analyses due to a lack of relevant data in the included studies.

Discussion

Findings of this systematic review indicate that we are very uncertain whether stenting may reduce the number of unplanned return visits to the hospital, the need for narcotics, ureteral stricture, and hospital readmission, given that these

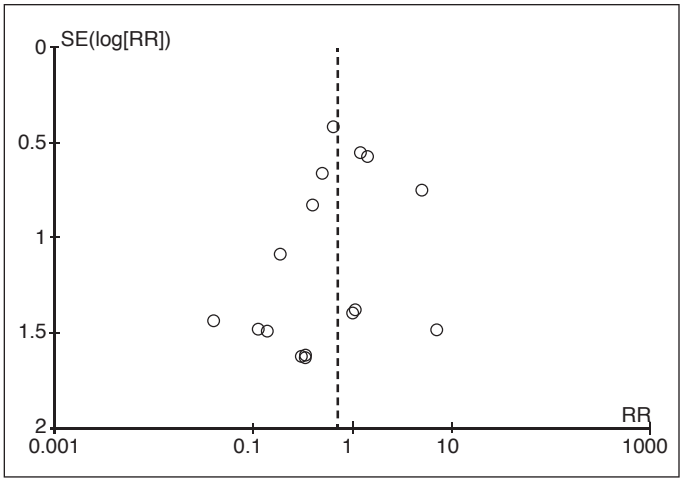

Fig. 3. Funnel plot of unplanned return visit to emergency/urgent care department. RR: risk ratio.

findings were based on very low CoE. Moderate to low CoE shows no difference in postoperative discomfort on the day of surgery (day 0) and in the early postoperative phase (days 1–3). Stented individuals may have more pain in the later postoperative phase (days 4–30), but we are once again very uncertain of this finding. There may also be no difference in the number of secondary interventions. With regard to other outcomes, rates of UTI are probably similar but quality of life may be better in unstented participants. Stenting probably increases operating room time slightly (by approximately four minutes), which appears of little clinical relevance.

Several other systematic reviews have been published on this topic. A systematic review by Tang et al that included 14 trials,[10] found an increase in dysuria, frequency, and hematuria in stented patients — outcomes that we did not deem of critical patient importance and that we did not investigate. However, effect estimates for the number of unplanned medical visits or hospital readmissions (RR 0.60; 95% CI 0.33–1.11) and for UTI (RR 1.20; 95% CI 0.62–2.32) showed similar results. Wang et al reported a systematic review of 22 RCTs but included among them three trials of shockwave lithotripsy (SWL),[11] which we perceived as sufficiently distinct as to not include in this review. This study also reported its findings as odds ratios (OR). One of the main findings highlighted in the abstract results and conclusion was a reduced risk of unplanned readmissions (OR 0.63; 95% CI 0.41–0.97) in the stented group. However, these numbers do not correlate with those in the results section (OR 0.54; 95% CI 0.34–0.87), suggesting an error in the analysis. Moreover, our findings mainly differ in the (routine) choice of a random-effects model, which provides the more conservative effect size estimate. A fixed-effect model analysis of this outcome based on our data yields an RR of 0.60 (95% CI 0.37–0.96), which comes close to the reported OR. In terms of the outcome of UTI, unlike our findings, they found that stenting increased UTI (OR 2.01; 95% CI 1.16–3.47), which may be attributable to the inclusion of two trials of SWL and one trial of patients with chronic, inflammatory, bilharzial ureters.[21] Another recent review by Pais et al reported that "unstented patients were significantly more likely to have an unplanned medical visit compared to those who received a post-ureteroscopy stent" (OR 1.63; 95% CI 1.15–2.30).[7] These findings were based on a pooled analysis of randomized and non-randomized studies. Included observational studies favored the unstented group, whereas RCTs favored the stented group; the test of interaction was significant (p=0.04), thereby questioning the appropriateness of pooling. This review, however, stands out for its thoughtful and detailed discussion of potential biases of its included studies that are equally relevant to the findings of our review despite its lack of a formal quality of evidence rating by outcome. None of the existing systematic reviews provided a certainty of evidence rating, which we consider critical to any systematic review.

Our review has limitations. First, all included studies excluded participants in whom URS was complicated in some manner, thereby compelling urologists to place a ureteral stent. The summarized body of evidence, therefore, applies only to uncomplicated URS; however, definitions of what that constitutes vary. Whereas post-ureteroscopic lesion scales have been developed,[52,53] they have not found widespread use. Second, included studies reported participants' degree of pain at different time points. To provide meaningful summary data that might be helpful for clinicians and patients, we grouped available data by three time periods of postoperative day 0, days 1–3, and days 4–30. These categories we established with input by expert clinicians after the protocol was written and the data were abstracted, but before any quantitative analysis was performed. Nevertheless, findings for these outcomes are potentially sensitive to the specific time ranges we chose, and this may be viewed as a potential source of bias.

Findings of the review raise questions over the gap between current best evidence as reflected by this review and contemporary clinical practice with most patients receiving a stent. Muslumanoglu et al reported the results of the Clinical Research Office of Endourological Society (CROES) Ureteroscopy Global Study Cohort and found stenting rates of approximately 80% for renal stones and 60% for ureteral stones, with overall variation from 29–96% across countries.[1] Reported stenting rates in the U.S. were 93%.[1] There appears to be an important research need to better understand this discrepancy. Moreover, given the low-quality evidence that characterizes most of the reported analyses and the complex tradeoffs involved in deciding whether or not to place a stent after uncomplicated URS, more research on shared decision-making in this setting appears important.

Competing interests: Dr. Borofsky has been a consultant in endourology and stone management for Boston Scientific, and a consultant in robotic surgery and endourology for Auris Health. The remaining authors report no competing personal or financial interests related to this work.

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Correspondence: Dr. Philipp Dahm, Minneapolis VA Health Care System, Minneapolis, MN, United States; pdahm@umn.edu