

Ureteral Access Sheath Use and Infection-Related Hospitalizations: Practice Patterns and Outcomes

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Study Need and Importance: Postureteroscopy infection can lead to substantial morbidity, emergency department visits, and unplanned hospitalizations. Elevated intrarenal pressure has been proposed as a mechanistic driver of infection and sepsis, and the use of a ureteral access sheath (UAS) is commonly assumed to reduce this risk by improving outflow and lowering intrarenal pressure. Despite this prevailing belief, evidence supporting a protective effect of UAS usage remains inconsistent, with previous studies limited by small sample sizes, heterogeneous definitions of infection, or inadequate adjustment for confounders. High-quality, real-world data are needed to understand whether UAS use meaningfully impacts infectious outcomes following ureteroscopy for renal stones.

What We Found: In this statewide collaborative of 6142 ureteroscopy cases performed by 233 urologists across 34 Michigan practices, UAS was used in 59% of procedures, with significant variation across practices (4.1%-99.5%) and surgeons (0%-100%). Overall, 2.5% of patients experienced an infection-related hospitalization within 30 days. Infection-related hospitalization rates were similar with (2.6%) vs without (2.3%) UAS use. After multivariable adjustment for clinical factors including comorbidity, recurrent UTI history, preoperative urine studies, stone size,

and perioperative stenting, UAS utilization was not associated with infection-related hospitalization (odds ratio 0.84, 95% CI: 0.57-1.24). Significant predictors of infection-related hospitalization included higher Charlson Comorbidity Index, history of recurrent UTI, positive preoperative urinalysis/culture, and larger stone size.

Limitations: As an observational cohort analysis, residual confounding is possible despite comprehensive covariate adjustment. Some postoperative events may be missed if patients present outside participating health systems. Operative details, such as irrigation pressure, operative time, UAS size, and unsuccessful UAS placement, were not captured. Findings reflect practice patterns in Michigan and may not generalize to other regions.

Interpretation for Patient Care: UAS use should not be expected to reduce postoperative infection or sepsis risk following ureteroscopy for renal stones. Instead, infection risk appears driven by patient-level factors such as comorbidity, recurrent UTI, urine culture positivity, and stone burden. Patient counseling, risk stratification, and perioperative planning should prioritize these factors. Future prospective studies, including randomized trials, are needed to better define strategies that meaningfully reduce infection after ureteroscopy.

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Introduction: Our goal was to compare rates and risk factors for infection-related hospitalizations with and without ureteral access sheath (UAS) use during ureteroscopy (URS) for renal stones.

Methods: Using the Michigan Urological Surgery Improvement Collaborative clinical registry, we identified patients who underwent single-stage unilateral URS for renal stones. We assessed variation in UAS usage across practices and surgeons. We compared demographics of cases with and without UAS. Multivariable logistic regression was used to evaluate UAS use and clinical factors on 30-day infection-related hospitalization.

Results: Six thousand one hundred forty-two patients underwent URS by 233 urologists across 34 practices, and 152 (2.5%) had an infection-related hospitalization within 30 days. UAS was used in 59% of cases, with significant variation between practices (4.1%-99.5%, $P < .001$). Infection-related hospitalization was similar with (2.6%) and without (2.3%) UAS use ($P = .5$). On multivariable analysis, infection-related hospitalizations did not differ by UAS (odds ratio [OR] 0.8 [95% CI: 0.6-1.2]), but were associated with higher Charlson Comorbidity Index (CCI; CCI 1 vs 0, OR 1.9 [95% CI: 1.2-2.9]; CCI 2+ vs 0, OR 2.3 [95% CI: 1.4-3.6]), history of recurrent UTI (OR 2.4

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Ethics Statement: This study received Institutional Review Board approval.

Author Contributions:

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Data analysis and interpretation: Fernandez Moncaleano, Konheim, Ross, Phelps, Jafri, Van Til, Kachroo, Daignault-Newton, Krishna, Higgins, Ghani, Becker.

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[95% CI: 1.4-4.0]), larger stones (OR per 5 mm 1.1 [95% CI: 1.0-1.3]), and positive preoperative urinalysis and/or culture (OR 1.8 [95% CI: 1.2-2.7]).

Conclusions: UAS use in URS for renal stones varies across Michigan and was not associated with lower infection-related hospitalization. Prospective studies on the implications of intrarenal pressure are needed.

Key Words: ureteral access sheath, ureteroscopy, UTI, infection, sepsis

Postoperative infection is a common complication after ureteroscopic (URS) stone treatment. Retrospective series and meta-analyses report up to 15% incidence of UTI and 5.5% sepsis after URS, depending on the methodology and definitions used.¹⁻⁴ Since many patients with post-URS infections get hospitalized, this event can be associated with significant morbidity and detriments to the patients' health-related quality of life, as well as increased health care costs.^{4,5} Although the etiologic mechanisms leading to sepsis remain incompletely understood, the prevailing dogma is that elevated intrarenal pressure during retrograde intrarenal surgery can lead to pyelovenous backflow, thereby facilitating seeding of bacteria from the urinary tract into the bloodstream.^{6,7} A ureteral access sheath (UAS), when positioned in the upper ureter or renal pelvis, lowers the outflow resistance and can lower intrarenal pressure.⁸⁻¹⁰ The use of the UAS has thus been suggested as a strategy to decrease the risk of infectious complications.

However, the evidence supporting a reduction in sepsis with the UAS remains inconclusive.¹¹ We identified at least 9 previous studies that assessed this, with 8 of 9 reporting no association for reducing the risk of sepsis when using a UAS.¹²⁻²⁰ Many of these studies are small or single-center cohort retrospective series, with varying definitions of sepsis and infection, and inadequate adjustment for clinical risk factors. In the 1 study noted to have a positive finding, which included 2239 patients undergoing URS for renal stones, the authors reported reduced incidence of postoperative fever, UTI, and sepsis when a UAS was used.¹² However, a discrepancy in the statistical calculations and their portrayal in the manuscript text suggests that this conclusion may not accurately reflect the data. In Michigan, through the Michigan Urological Surgery Improvement Collaborative (MUSIC), we have previously demonstrated UAS usage patterns for renal and ureteral stones among providers²¹ and characterized predictive factors of infection-related hospitalization following URS.¹⁸

Given the current state of evidence on UAS use and sepsis risk, we sought to characterize contemporary, real-world UAS utilization for renal stone treatment during URS among a diverse group of urologists in a statewide collaborative. Our primary objective was to evaluate whether UAS

use was associated with a reduction in infection-related hospitalization. We analyzed the MUSIC Reducing Operative Complications from Kidney Stones (ROCKS) clinical registry, consisting of prospectively collected data by independent abstractors that includes postoperative emergency department (ED) visits and unplanned hospitalizations from more than 36,000 kidney stone surgeries performed across 34 practices throughout Michigan. We hypothesized that UAS utilization would be associated with a decreased risk of infection-related hospitalization within 30 days following URS. The goal of our work is to inform patient counseling, surgical decision-making, and identify quality improvement (QI) interventions to improve care.

Methods

Data Source: MUSIC

MUSIC is a statewide QI initiative sponsored by Blue Cross Blue Shield of Michigan, with the goal to improve the outcomes, cost-efficiency, and value of health care for urologic patients in Michigan.²² MUSIC maintains a clinical registry that captures data from patients receiving urologic care across community and academic urology practices throughout Michigan. Within MUSIC, the ROCKS initiative was launched in 2016 and includes a prospective registry of patients undergoing ureteroscopy (URS) or shockwave lithotripsy for urolithiasis. Details of the MUSIC ROCKS QI initiative have been previously described.²³ In summary, the registry includes patients at participating sites regardless of insurance status, and a highly curated and standardized set of structured variables are systematically captured by independent trained abstractors 60 to 120 days after surgery. Data are subject to routine quality audits, and participating practices are provided with regular feedback and reports of key performance indicators.

Study Population

We identified all adult patients undergoing unilateral URS for primary treatment of renal stones from the MUSIC ROCKS registry from June 2016 through October 2022. This included

patients from 34 practices. Patients with ureteric stones were excluded, given the relatively uncommon utilization of UAS in ureteral stone treatment as well as the markedly different fluid dynamics within the ureter compared with the renal pelvis and collecting system. Staged procedures were excluded, as well as patients with abnormal anatomy (urinary diversion, horseshoe kidney, or solitary kidney). Cases with missing data on UAS usage (yes vs no) were excluded.

Characterization of Practice Patterns

For each participating practice with > 10 eligible URS cases and each urologist with > 5 eligible URS cases in the study population, we calculated the proportion of cases in which a UAS was used. Practice-level and surgeon-level rates of UAS use were displayed on bubble charts to indicate surgical case volume.

Outcome Definitions

Postoperative ED visits and unplanned hospitalizations within 60 days are captured in MUSIC. Abstractors indicate the reason(s) for the unplanned encounter, based on review of the electronic health record, by choosing 1 or multiple

selections from a list of 21 common postoperative issues, including options such as hematuria, urinary frequency/urgency, urinary retention, obstructing stone/fragment, abdominal pain, nausea/vomiting, and myocardial infarction. For this analysis, we identified patients with an unplanned hospitalization occurring within 30 days after their URS, with at least 1 of the following reasons indicated: fever, UTI, and/or sepsis. These patients were considered to have experienced an infection-related hospitalization. Patients in this group were compared with those without an infection-related complication, including those patients with 30-day unplanned hospitalization for other (not infection related) reasons.

Statistical Analysis

We generated descriptive summary statistics for the study population stratified by UAS use. Bivariable analysis was performed to examine differences in demographic, clinical, and perioperative variables with use of a UAS. χ^2 tests and Jockheere-Terpstra tests were performed for categorical and ordinal variables, respectively. A multivariable logistic regression model was used to estimate the odds of infection-related hospitalization, with UAS as the primary variable of

Table.

Clinical and Demographic Characteristics of Patients Undergoing Unilateral Ureteroscopy for Treatment of Renal Stones and 30-Day Emergency Department Visits and Hospitalizations Within the Michigan Urological Surgery Improvement Collaborative, Stratified by Use of Ureteral Access Sheath

Total study cohort N = 6142	Without UAS n = 2539 (41%)		With UAS n = 3603 (59%)		P value
Age, median (IQR), y	57 (44-67)		60 (49-70)		< .0001
Female, No. (%)	1471 (58)		2078 (58)		.8
Charlson Comorbidity Index, No. (%)					< .0001
0	1793 (71)		2259 (63)		
1	393 (15)		752 (21)		
2+	353 (14)		592 (16)		
History of recurrent UTI, No. (%)	112 (4)		203 (6)		.032
Largest stone diameter, No. (%)					< .0001
<5 mm	758 (30)		499 (14)		
5 mm-1 cm	1120 (44)		1476 (41)		
>1 cm	558 (22)		1372 (38)		
Pretested, No. (%)	655 (26)		1164 (33)		< .0001
Preoperative urine culture or urinalysis, No. (%)					< .0001
Positive	356 (14)		681 (19)		
Negative	1769 (70)		2190 (61)		
Not performed	414 (16)		731 (20)		
Postoperative stent, No. (%)	1543 (61)		3301 (92)		< .0001
Discharged with antibiotics, No. (%)	724 (29)		1509 (42)		< .0001
Postoperative alpha-blockers, No. (%)	1379 (54)		1945 (54)		.054
30-d ED visit, No. (%)					
All cause	225 (9.0)		329 (9.4)		.6
Infection related	75 (3.0)		110 (3.1)		.8
30-d hospitalization, No. (%)					
All cause	105 (4.2)		144 (4.1)		.8
Infection related	59 (2.3)		93 (2.6)		.5

Abbreviations: ED, emergency department; UAS, ureteral access sheath.

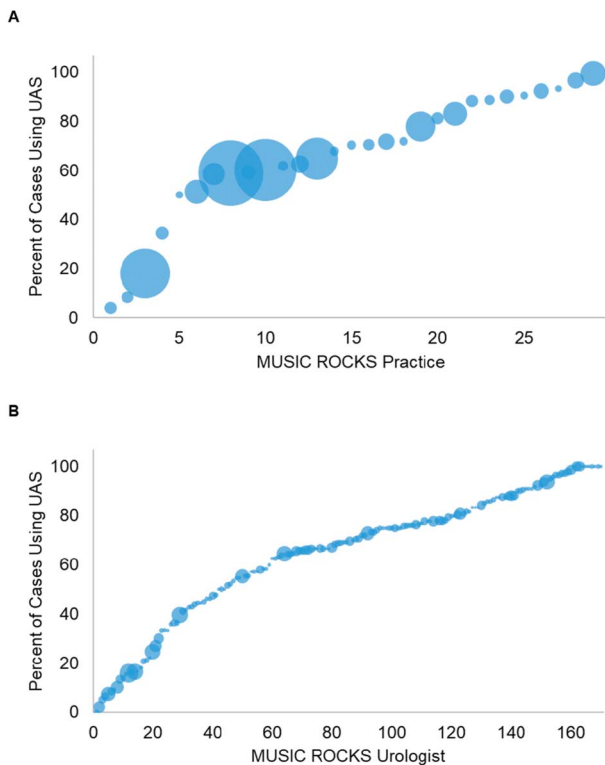


Figure 1. Variation in ureteral access sheath (UAS) use for ureteroscopic treatment of renal stones with ureteroscopy in the Michigan Urological Surgery Improvement Collaborative (MUSIC) among 29 urology practices with > 10 eligible cases in the study cohort (A), and among 170 individual urologists with > 5 eligible cases in the study cohort (B). Bubble size indicates operative case volume for each practice or surgeon. ROCKS indicates Reducing Operative Complications from Kidney Stones.

interest. The model also adjusted for patient's age, sex, Charlson Comorbidity Index (CCI), history of recurrent UTI, largest stone diameter, prior stent placed, positive urine

culture, and postoperative stent, as well as antibiotics and alpha-blockers prescribed at discharge. The statistical analyses were performed with SAS 9.4 (SAS Institute), and the statistical significance was set at .05.

Results

Study Population

Among 27,781 cases of unilateral URS captured in the MUSIC registry during the study period, 6330 were performed for renal stones without concomitant ureteric stones. Among these, 125 cases were excluded for abnormal anatomy and another 63 were missing data on UAS utilization, yielding a final study cohort of 6142 cases (Supplementary Figure 1, <https://www.urologypracticejournal.com>).

Variation in UAS Utilization

A UAS was used in 3603 cases (59%; Table). UAS was used preferentially for larger stones (38% of patients treated with UAS had stone size > 1 cm compared with 22% of those treated without UAS, $P < .0001$) and was associated with a higher rate of postoperative stent placement (92% of cases with UAS vs 61% of cases without UAS, $P < .0001$). Among participating practices with > 10 eligible URS cases ($n = 29$), rates of UAS utilization for renal stone cases ranged from 4.1% to 99.5% (χ^2 testing $P < .01$; Figure 1, A). Four of the 5 largest-volume practices clustered near the overall mean, with practice-level UAS usage rates (in order from highest volume) of 59%, 60%, 18%, 65%, and 78%. UAS use in surgeons with > 5 eligible URS cases ($n = 170$) ranged from

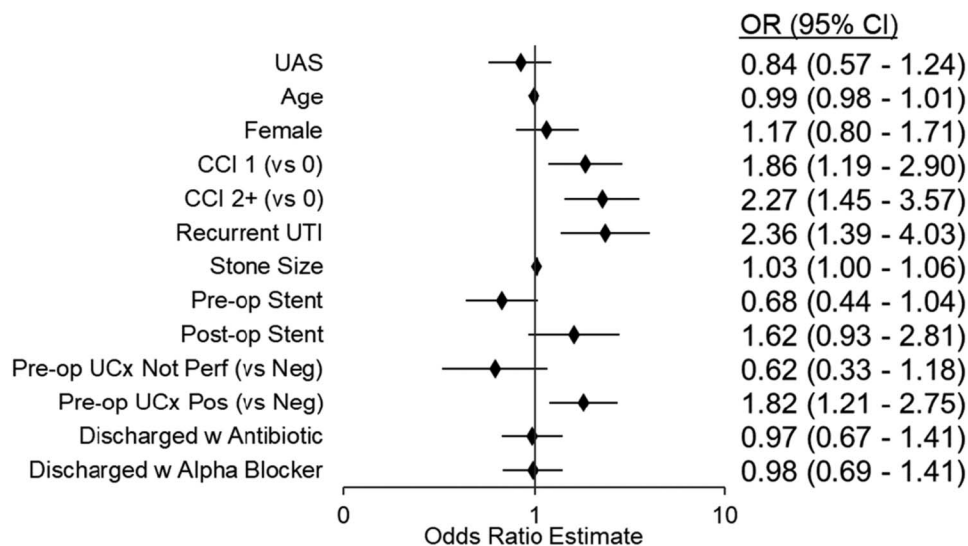


Figure 2. Forest plot showing estimated odds ratios (ORs) and 95% CIs for the multivariate logistic regression model of infection-related hospitalization within 30 days after ureteroscopy. CCI indicates Charlson Comorbidity Index; Neg, negative; Perf, performed; Pos, positive; UAS, ureteral access sheath; UCx, urine culture; w, with.

0% to 100% (Figure 1, B). Individual surgeons showed strong preference patterns with substantial variation, with some who used it all the time and others rarely. This variability did not reveal patterns in usage based on surgical case volume.

Unplanned Health Care Utilization

All-cause 30-day postoperative ED visit was reported in 554 cases (9.0%), which included 185 (3.0%) where the ED visit reasons included fever, UTI, and/or sepsis. Hospitalization within 30 days occurred in 249 cases (4.1%), including 152 (2.5%) where hospitalization reasons included fever, UTI, and/or sepsis. No significant differences were observed when comparing all-cause or infection-related postoperative ED visits or hospitalizations between cases without vs with a UAS (Table).

Infection-Related Hospitalization

A forest plot depicting the results of multivariable logistic regression modeling for infection-related hospitalization is shown in Figure 2. There was no evidence of an association with infection-related hospitalization based on UAS use after adjusting for other risk factors (odds ratio [OR] 0.84 [95% CI: 0.57-1.24]; $P = .4$). Factors found to be significantly associated with infection-related hospitalization were greater comorbidity (CCI 1 vs 0, OR 1.86 [95% CI: 1.19-2.90]; CCI ≥ 2 vs 0, OR 2.27 [95% CI: 1.45-3.57]; $P < .001$), history of recurrent UTI (OR 2.36 [95% CI: 1.39-4.03]; $P < .01$), large stone diameter (per 5 mm, OR 1.03 [95% CI: 1.00-1.06]; $P = .04$), and preoperative urinalysis or urine culture (not performed vs negative, OR 0.62 [95% CI: 0.33-1.18]; positive vs negative, OR 1.82 [95% CI: 1.21-2.75]; $P < .01$).

Discussion

In this study, the utilization of a UAS for treating renal stones was highly variable across practices and surgeons within Michigan. UAS use was not significantly associated with a reduction in infection-related hospitalization following URS. This finding held true after adjusting for clinical and surgical risk factors. UAS use was also not associated with any difference in all-cause hospitalizations or all-cause or infection-related ED visits within 30 days. Collectively, our results suggest that the UAS should not be viewed as a guaranteed protective measure against infectious complications following URS.

Several groups have previously attempted to characterize risk factors of postoperative infection following URS, with

consensus around common themes: increased medical comorbidity, history of recurrent UTI, positive preoperative urine culture, increased operative times, and female sex.^{1-3,17,18,24} We found that the risk factors most strongly associated with 30-day infection-related hospitalization on multivariable analysis were higher CCI, history of recurrent UTI, and positive preoperative urine testing. These findings closely match prior work in the field.^{2,3,17,25} Our postoperative infection-related ED visits and hospitalizations were somewhat lower than in previously published studies, which may reflect differences in methodology, or could relate to temporal and/or geographic differences in practice patterns such as universal preoperative screening.

In 2015, Traxer et al¹² published a comparison of 2239 renal stone patients treated with vs without the use of a UAS within the URS Global Study coordinated through the Clinical Research Office of the Endourological Society. This publication remains one of the most widely cited studies to date assessing the impact of UAS on clinical outcomes. One of their key messages is that postoperative infection-related complications were less frequent among those patients undergoing URS with a UAS. Indeed, the European Association of Urology Guidelines on Urolithiasis²⁶ indicates lower postoperative infectious complications with the use of a UAS, citing only this study as evidence. However, upon re-examination of the study findings, we discovered what seems to be a potential discrepancy in the calculated rates of postoperative fever, UTI, and sepsis and how these findings are conveyed in the manuscript text. These rates are reported in Table 3 of their manuscript.¹² The percentage rates quoted for each subtype of complication appear to report the prevalence of each type of complication among all complications, rather than the incidence among the group at risk, which would seem to be the more clinically relevant endpoint. For example, among all complications in the UAS group, 4.3% were sepsis. Similarly, 15.2% of all complications in the non-UAS group were sepsis. We recalculated the incidence rates of each type of complication among the total group at risk (Supplementary Table I, <https://www.urologypracticejournal.com>). This revealed that 0.5% of patients treated with UAS developed sepsis, compared with 0.9% of patients treated without UAS. This was not a statistically significant difference ($P = .2$). Similarly, there were no significant differences between groups in the rates of fever or UTI.

Our large-scale observational analysis from a broad spectrum of real-world practice settings across the state of Michigan did not find a statistically significant association of UAS utilization with postoperative infectious outcomes. Perhaps this should not be surprising. Numerous previous studies have failed to demonstrate a protective effect of UAS utilization in reducing postoperative infectious complications (see Supplementary

Table II, <https://www.urologypracticejournal.com> for a summary).¹³⁻²⁰ Our findings are consistent with these studies.

Our work must be interpreted in the context of certain limitations. As with any observational cohort study, there may be confounding variables that were not collected or corrected by statistical adjustments. While postoperative outcomes were abstracted using a systematic approach by independent trained data abstractors, nevertheless some clinical events may have been missed in the registry if patients moved between health systems over the course of their care. Owing to technical and methodological constraints, certain operative factors that may hypothetically affect infectious complication risk (such as operative time and irrigation fluid pressure) are not captured. Similarly, we do not collect data on unsuccessful UAS placement nor UAS type or size at this time. There are of course many factors that must be thoughtfully considered when determining whether to use a UAS in any particular patient or clinical scenario. The lack of association with postoperative infections in this study is one piece of evidence, among many others, for the urologist to take under consideration. Finally, our results are reflective of practice in Michigan and may not be representative of international practice patterns and outcomes.

Limitations notwithstanding, our findings represent the largest patient series to date evaluating the association of UAS and postoperative infection or sepsis. Our results demonstrate that UAS use should not be viewed as protective against sepsis. Future studies investigating the role of UAS and sepsis should make efforts to record factors such as sheath size and position, operative time, and irrigation pressure. The work reported herein has led to focused discussion within MUSIC to better capture these variables moving forward. Ultimately, our work shows the urgent need for a well-designed multicenter randomized clinical trial to assess this practice and whether there is any patient benefit. The use of a UAS is not without risk and necessitates a ureteral stent for many surgeons, especially if the patient is not pre-stented. Therefore, in any future study, it will be important to examine not only objective outcomes such as sepsis but also the patient experience and health-related quality of life. Novel technologies, such as flexible and navigable suction²⁷ and direct in-scope suction,²⁸ continue to reshape the landscape of retrograde intrarenal surgery, while advances to facilitate intraoperative monitoring of intrarenal pressure are expected to enhance our knowledge in this area.²⁹ These variables are currently under active discussion for future inclusion in the MUSIC prospective registry and analyses. Ultimately, while UAS as a proxy for lower intrarenal pressure was not associated with postoperative infection risk in our series, it remains possible that more precise understanding of intrarenal

pressure could lead to better strategies to prevent postoperative complications.

Conclusions

In summary, use of the UAS when treating renal stones varies widely across surgeons and practices within Michigan. UAS utilization was more common for larger stones and was associated with higher rates of postoperative stenting. UAS use was not associated with a reduction in infection-related hospitalization. Ultimately, we need further high-quality evidence and randomized clinical trials to better understand the role of intrarenal pressure, how this is modulated by UAS use, and how these factors impact key postoperative outcomes.

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