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Appropriateness Criteria for Ureteral Stent Omission following Ureteroscopy for Urinary Stone Disease

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Abstract

Introduction: To bridge the gap between evidence and clinical judgment, we defined scenarios appropriate for ureteral stent omission after uncomplicated ureteroscopy (URS) using the RAND/UCLA Appropriateness Method. We retrospectively assessed rates of appropriate stent omission, with the goal to implement these criteria in clinical practice.

Methods: A panel of 15 urologists from the MUSIC (Michigan Urological Surgery Improvement Collaborative) met to define uncomplicated URS and the variables that influence stent omission decision making. Over 2 rounds, they scored clinical scenarios for appropriateness criteria (AC) for stent omission based on a combination of variables. AC were defined by median scores of 1 to 3 (inappropriate), 4 to 6 (uncertain) and 7 to 9 (appropriate). Multivariable analysis determined the

Abbreviations and Acronyms

AC = appropriateness criteria

AUA = American Urological Association

EAU = European Association of Urology

MUSIC = Michigan Urological Surgery Improvement Collaborative

RAM = RAND/UCLA Appropriateness Method

UAS = ureteral access sheath

URS = ureteroscopy

Submitted December 6, 2022.

Support: The Michigan Urological Surgery Improvement Collaborative (MUSIC) is funded by Blue Cross and Blue Shield of Michigan (BCBSM) as part of the BCBSM Value Partnerships program. CPF is supported by the National Institutes of Health. RE is supported by the National Institutes of Health, Howard Hughes Medical Institute and the Wellcome Trust. JMH has grant support from the National Institute of Diabetes and Digestive and Kidney Diseases (R01 DK12170901).

Conflict of Interest: RS: Myovant Speakers Bureau, Genomic Health (past); RE: Johnson and Johnson; DL: Boston Scientific Corporation, Richard Wolf Medical; JSW: Ambu Corporation, Applaud Medical, Calyxo, *Urology Times*; CAD: Boston Scientific, AURIS Robotics; KRG: Boston Scientific, Coloplast, Storz, Olympus, Lumenis.

Ethics Statement: Each MUSIC practice obtained an approval (Henry Ford IRB #8045, Wayne State University IRB #032112MR2E) or an exemption by the local Institutional Review Board for participation in the Collaborative.

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https://doi.org/10.1097/UPJ.0000000000000302
Vol. 9, 253-263, May 2022
Published by Wolters Kluwer

association of each variable with AC scores. Uncomplicated URS cases in the MUSIC registry were assigned AC scores and stenting rates assessed.

Results: Seven variables affecting stent decision making were identified. Of the 144 scenarios, 26 (18%) were appropriate, 88 (61%) inappropriate and 30 (21%) uncertain for stent omission. Most scenarios appropriate for omission were pre-stented (81%). Scenarios with ureteral access sheath or stones >10 mm were only appropriate if pre-stented. Stenting rates of 5,181 URS cases correlated with AC scores. Stents were placed in 61% of cases appropriate for omission (practice range, 25% to 98%).

Conclusions: We defined objective variables and AC for stent omission following uncomplicated URS. AC scores correlated with stenting rates but there was substantial practice variation. Our findings demonstrate that the appropriate use of stent omission is underutilized.

Keywords: ureteroscopy, stents, quality improvement, urinary calculi

Guidelines from the European Association of Urology (EAU) and American Urological Association (AUA) state ureteral stents may be omitted following uncomplicated ureteroscopy (URS) in some situations.[1,2] However, stenting remains a common practice, occurring in over two-thirds URS for urinary stone disease.[3,4] Stents are associated with pain and urinary symptoms,[5] as well as increased risk of an emergency department visit after URS.[4,6,7] These unplanned encounters substantially increase the cost of URS.[8] Importantly, overuse of stenting can lead to unnecessary patient suffering and loss of income due to work incapacity.[9] Therefore, efforts to decrease stenting rates may improve health-related quality of life and reduce health care costs.

Idiosyncratic physician practice patterns are recognized as one of the strongest determinants of treatment variation.[10] In a recent publication, significant surgeon variation in stenting after URS was observed, ranging from 10% to 100%.[4] This variation may be an indication of uncertainty regarding the criteria outlined by the AUA and EAU guidelines. Specifically, the definition of uncomplicated URS or which scenarios are most suitable for stent omission.[1,2] One intervention that addresses variation and bridges the gap between evidence and clinical judgment is the RAND/UCLA Appropriateness Method (RAM) and creation of appropriateness criteria (AC).[11,12] This method has been used to reduce the inappropriate use of procedures, including percutaneous coronary interventions.[12,13] In urology, the RAM has been used to develop AC for active surveillance of prostate cancer.[14] Dissemination of AC helped decrease surgery for low-risk prostate cancer in the Michigan Urological Surgery Improvement Collaborative (MUSIC).[15,16]

In this context, we undertook a quality improvement project following the RAM with a diverse panel of urologists in MUSIC to 1) review the evidence supporting stent omission following URS for urinary stone disease and define uncomplicated URS, 2) develop a list of variables that determine eligibility for stent omission, 3) assign AC scores for all combinations of these variables and 4) retrospectively measure stenting rates within the MUSIC registry for each AC score. Our long-term goals are to reduce uncertainty regarding stent omission decision making, increase appropriate use of stent omission, improve patient outcomes and reduce avoidable health care utilization.

Materials and Methods

MUSIC

MUSIC was established in 2011, in partnership with Blue Cross Blue Shield of Michigan, and is a statewide quality improvement collaborative consisting of over 90% of urologists in the State of Michigan. Details on the ROCKS (Reducing Operative Complications from Kidney Stones) initiative and clinical registry have been previously described.[4,17,18] Each MUSIC practice has obtained an exemption or approval by the local Institutional Review Board for participation in the collaborative. This study was conducted by the MUSIC coordinating center and, thus, participants were limited to those within the state of Michigan.

RAM

RAM is a multistep process that requires a panel of experts in the field to score and, unlike the traditional Delphi method, discuss clinical scenarios for appropriateness a chosen intervention.[11] We began the process by inviting all MUSIC urologists to participate in the panel. In accordance with the RAM manual, we included only urologists on our panel because no other specialty is involved in the decision-making process for stent omission.[11] We ultimately selected 15 urologists from 25 respondents in order to include a diverse group of panelists from a variety of practice types and sizes across Michigan (supplementary fig. 1, https://www.urologypracticejournal.com). Since our findings were to be implemented in Michigan, we did not include outside urologists. At the first meeting (round 1), panelists were provided a synthesis of the available evidence, including a

Uncomplicated Ureteroscopy
Age ≥18 years
American Society of Anesthesiologists (ASA) score <3
Not immunocompromised or pregnant
No evidence of functional/anatomic solitary kidney
No anatomic abnormalities (i.e. stricture, ureteropelvic junction obstruction, horse shoe kidney)
No urinary tract reconstruction
No uncorrected bleeding diathesis, anticoagulant and/or antiplatelet therapy
No history of neurogenic bladder or incomplete bladder emptying
No signs or symptoms of sepsis
No history of sepsis associated with urinary tract infection
No untreated positive urine culture
No stones in multiple locations (i.e. both ureter and kidney)
Stone size ≤15mm
Operative time ≤60 minutes
No balloon dilation of the ureter
Unilateral procedure
No plan for second look procedure
Retrograde ureteroscopy only
No ureteral perforation or trauma

Figure 1. MUSIC AC panel consensus definition of uncomplicated URS.

literature review conducted by the MUSIC coordinating center (supplementary fig. 2, https://www.urologypracticejournal.com). Guideline statements from the AUA, EAU and UK National Institute for Health and Care Excellence were discussed by an expert in the field (JSW; supplementary fig. 3, https://www.urologypracticejournal.com).[1,2,19] At this meeting the panelists reached consensus on the definition of uncomplicated URS, for which ureteral stent omission was being considered (fig. 1). Following this, the panel had to decide on patient and surgical variables that determined stent omission decision making. At the conclusion of the meeting, consensus was reached on 7 variables: stone size ($\leq$5, $>5-\leq10$ or $>10-\leq15$ mm), stone location (kidney or ureter), pre-stent (yes or no), urinalysis or urine culture result (treated positive culture or negative), nonballoon ureteral dilation performed (yes or no), ureteral access sheath (UAS) use (yes or no) and presence of "basketable"-sized residual stone fragments (yes or no; fig. 2). Based on all combinations of variables, this resulted in 192 clinical scenarios to be scored for stent omission appropriateness (supplementary fig. 4, https://www.urologypracticejournal.com).

The panelists then individually scored these scenarios for stent omission using AC scoring of 1 (highly inappropriate) to 9 (highly appropriate) over a 3-month period. Scores were collated by the MUSIC coordinating center and presented to panelists at a second-round meeting, where they reviewed the distribution of all the panelists scores for each scenario (supplementary fig. 5, https://www.urologypracticejournal.com). Panelists were given the opportunity to discuss each scenario and to change the variables. At this meeting, there was unanimous consensus to remove the "ureteral dilation" variable from scenarios with pre-stenting, decreasing the total scenarios to 144. The panel decided any pre-stented scenario that still required ureteral dilation during URS should not be considered uncomplicated. A MUSIC patient advocate was present and contributed to the discussion. At the conclusion of the meeting, panelists again individually scored each clinical scenario. We created a color-coded heatmap based on the median round 2 scores for appropriateness of stent omission. We also categorized scenarios on agreement, determined by the quintile of standard deviation of the round 2 scores for a given scenario. Any scenario with $\geq$5 panelists assigning an AC score between 1 to 3 and 7 to 9 were reclassified as uncertain, regardless of the actual median, per the RAM manual definition of disagreement.[11]

Variable	Categories	Definition
Stone size	≤5mm	Maximum diameter of the single largest treated stone in millimeters
	>5mm - ≤10mm	
	>10mm - ≤15mm	
Stone location	Kidney	Treated stone or stones all located within the kidney - all calyces, renal pelvis and ureteropelvic junction
	Ureter	Treated stone or stones all located within the ureter - upper, mid, distal and ureterovesical junction
Pre-stent	Yes	Presence of a stent prior to therapeutic ureteroscopy
	No	Absence of a stent prior to therapeutic ureteroscopy
UA/Urine culture result	Treated positive culture	A positive preoperative urine culture that has been treated with an appropriate course of antibiotics
	Negative	Negative preoperative UA or urine culture
Ureteral dilation	Yes	Non-balloon mechanical ureteral dilation >10 French
	No	No dilation performed or use of a non-balloon ureteral dilator ≤10 French performed
Ureteral access sheath	Yes	Ureteral access sheath of any size placed during ureteroscopy
	No	No ureteral access sheath used
Fragments	Yes	Fragments of a size that could be easily basketed left within the upper urinary tract at the conclusion of ureteroscopy
	No	Complete absence of fragments or presence of very small fragments (too small to be easily basketed) left within the upper urinary tract at the conclusion of ureteroscopy

Figure 2. Panel consensus definitions of the 7 variables that determine appropriateness for ureteral stent omission following uncomplicated URS. *UA*, urinalysis.

			Pre Stented, Negative Culture					
			Size ≤5mm		Size >5mm - ≤10mm		Size >10mm - ≤15mm	
			Ureter	Kidney	Ureter	Kidney	Ureter	Kidney
No Dilation	UAS -	Frag -	9	9	9	9	7	7
	UAS +	Frag -	8	8	8	7	6	6
	UAS -	Frag +	7	7	7	6	5	4
	UAS +	Frag +	7	7	6	5	3	4

			Not Pre Stented, Negative Culture					
			Size ≤5mm		Size >5mm - ≤10mm		Size >10mm - ≤15mm	
			Ureter	Kidney	Ureter	Kidney	Ureter	Kidney
No Dilation	UAS -	Frag -	9	9	7	7	5	4
	UAS +	Frag -	3	3	3	2	2	2
	UAS -	Frag +	6	5	3	2	2	1
	UAS +	Frag +	3	2	2	2	1	1
Dilation	UAS -	Frag -	4	4	3	3	2	1
	UAS +	Frag -	3	2	2	2	1	1
	UAS -	Frag +	3	2	2	2	1	1
	UAS +	Frag +	2	1	1	1	1	1

			Pre Stented, Treated Positive Culture					
			Size ≤5mm		Size >5mm - ≤10mm		Size >10mm - ≤15mm	
			Ureter	Kidney	Ureter	Kidney	Ureter	Kidney
No Dilation	UAS -	Frag -	8	8	8	8	7	7
	UAS +	Frag -	7	7	7	7	5	5
	UAS -	Frag +	6	5	4	5	2	2
	UAS +	Frag +	5	5	2	2	2	2

			Not Pre Stented, Treated Positive Culture					
			Size ≤5mm		Size >5mm - ≤10mm		Size >10mm - ≤15mm	
			Ureter	Kidney	Ureter	Kidney	Ureter	Kidney
No Dilation	UAS -	Frag -	7	5	4	4	3	2
	UAS +	Frag -	3	3	2	2	1	1
	UAS -	Frag +	3	3	2	2	1	1
	UAS +	Frag +	2	2	1	1	1	1
Dilation	UAS -	Frag -	5	3	2	2	1	1
	UAS +	Frag -	2	2	1	1	1	1
	UAS -	Frag +	2	1	1	1	1	1
	UAS +	Frag +	1	1	1	1	1	1

Highly Inappropriate	Inappropriate	Uncertain	Appropriate	Highly Appropriate

Figure 3. Heatmap of AC for ureteral stent omission after URS: 1— highly inappropriate, to 9—highly appropriate. Displayed are median scores for all 144 clinical scenarios. *UAS+*, UAS used. *UAS−*, no UAS used. *Frag+*, yes, fragments left behind. *Frag−*, no fragments left behind.

Statistical Methods

To assess the strength of the association of the panel variables with AC score, a logistic regression model was used with stent omission AC as the dependent variable and the 7 decision-making parameters as independent variables. In only this model, median round 2 scores for each scenario were dichotomized into appropriate (scores 7 to 9) versus not appropriate (scores 1 to 6) for stent omission.

To provide context to the results, we identified all URS cases in the MUSIC registry between 2016 and 2019 that met criteria for uncomplicated URS (supplementary fig. 6, https://www.urologypracticejournal.com). These were assigned a corresponding AC score and the proportion with stent placement were determined. The association between AC scores and stenting rates was calculated with Spearman's correlation coefficient. Only practices with greater than or equal to 10 uncomplicated URS procedures appropriate or inappropriate for stent omission in the MUSIC registry were included. Scenarios with disagreement were excluded from the registry analysis. Statistical analysis was completed using SAS® 9.4 (SAS, Cary, North Carolina).

Results

Of the 144 clinical scenarios, 38 (26%) were scored highly inappropriate, 50 (36%) inappropriate, 30 (21%) uncertain, 20 (14%) appropriate and 6 (4%) as highly appropriate for ureteral stent omission. Figure 3 displays a heatmap of median appropriateness scores by each scenario. Most of the scenarios appropriate for stent omission can be found at the top of the heatmap, within the pre-stented scenarios. Of the 26 scenarios appropriate for stent omission, 21 (81%) were pre-stented. If a UAS was employed, only pre-stented

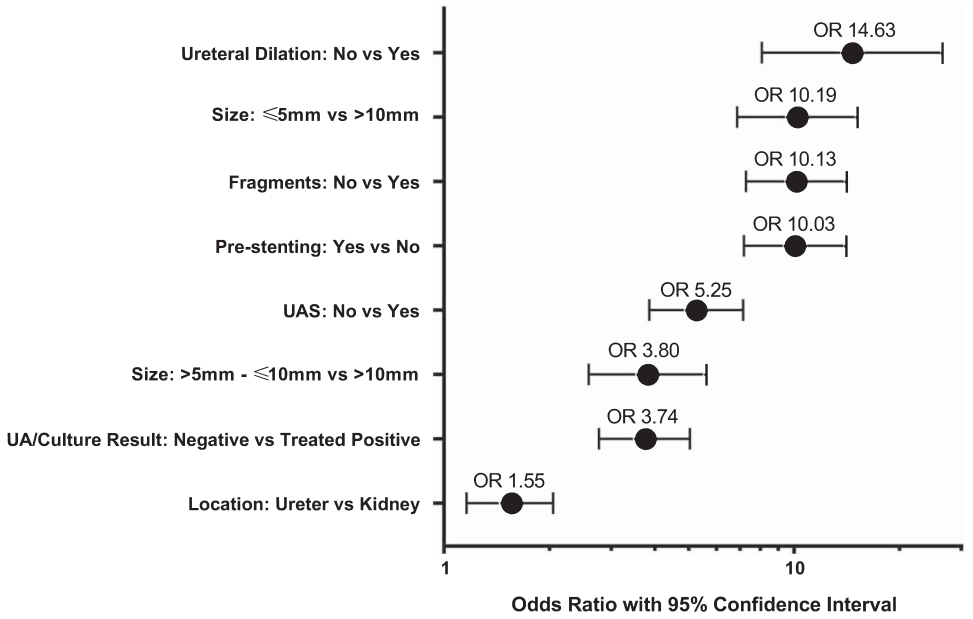

Figure 4. Forest plot of odds ratios of panelist scoring clinical scenario appropriate for stent omission by variable. *UA*, urinalysis.

scenarios were appropriate for stent omission. There were no scenarios with ureteral dilation performed that were appropriate for stent omission. Additionally, no scenarios with stones greater than 10 mm and without pre-stenting were appropriate for stent omission.

Each of the chosen variables significantly impacted stent omission decision making (fig. 4). The parameter with the greatest association was the absence of ureteral dilation (OR 14.6; 95% CI 8.08−26.49). Conversely, stone location had the least impact on decision making, evidenced by ureteral (vs renal) stones having the lowest odds of being scored appropriate for omission (OR 1.5; 95% CI 1.16−2.05).

We observed a wide distribution of agreement among panelists for individual scenarios (fig. 5). A total of 11 scenarios met RAM criteria for disagreement and are shaded in figure 5. In general, the least agreement (greatest standard deviation) was seen in scenarios with pre-stenting and a treated positive urine culture. The greatest agreement was seen in scenarios highly inappropriate for stent omission such as those without pre-stenting, stones greater than 10 mm, a treated positive urine culture and ureteral dilation performed.

We identified 5,181 cases that met AC for uncomplicated URS. A stent was placed in 3,654 (70.5%). AC scores correlated with stenting rates in these cases (rs=-0.967; fig. 6, *A*). Figure 6 also displays the variation in stenting rates between practices among cases appropriate (fig. 6, *B*) and inappropriate (fig. 6, *C*) for stent omission. Of the 2,735 cases appropriate for stent omission, a stent was placed in 1,659 (60.6%), and practice-level rates varied from 25.0% to 98.3%. Of the 1,881 cases inappropriate for omission, a stent was placed in 1,608 (85.5%), and practice-level rates varied from 35.7% to 100%.

Discussion

We sought to develop AC for stent omission following uncomplicated URS by using the RAM. Our study has several key findings. First, we created a consensus definition of uncomplicated URS to identify patients suitable for consideration of stent omission. Second, we identified 7 objective variables that affect decision making for stent omission. Third, we created AC for stent omission following URS. Lastly, we found that stenting rates correlated with our AC. However, there was variation in practice patterns and a high rate of stenting, even among cases highly appropriate for stent omission. Collectively, these findings demonstrate that appropriate use of stent omission after uncomplicated URS is currently underutilized.

Few studies have investigated decision making about stent placement or omission following URS. A recent Cochrane review assessing outcomes associated with stent placement following URS acknowledged the need for higher quality evidence.[20] AUA guidelines state clinicians may omit ureteral stenting if all the following criteria are met: normal contralateral kidney, normal renal function, no impediments to stone fragment clearance, no ureteric injury and no planned secondary URS.[1] EAU guidelines similarly advocate that routine stenting after uncomplicated URS is unnecessary; however, no criteria are provided.[2] In our study, the RAM panel created a consensus definition of uncomplicated URS based on clinical experience. Given the subjective nature of the topic, some considerations remain unclear. Although nonballoon ureteral dilation was chosen as a variable, none of the scenarios with dilation performed met AC for omission and its absence was the strongest predictor being scored

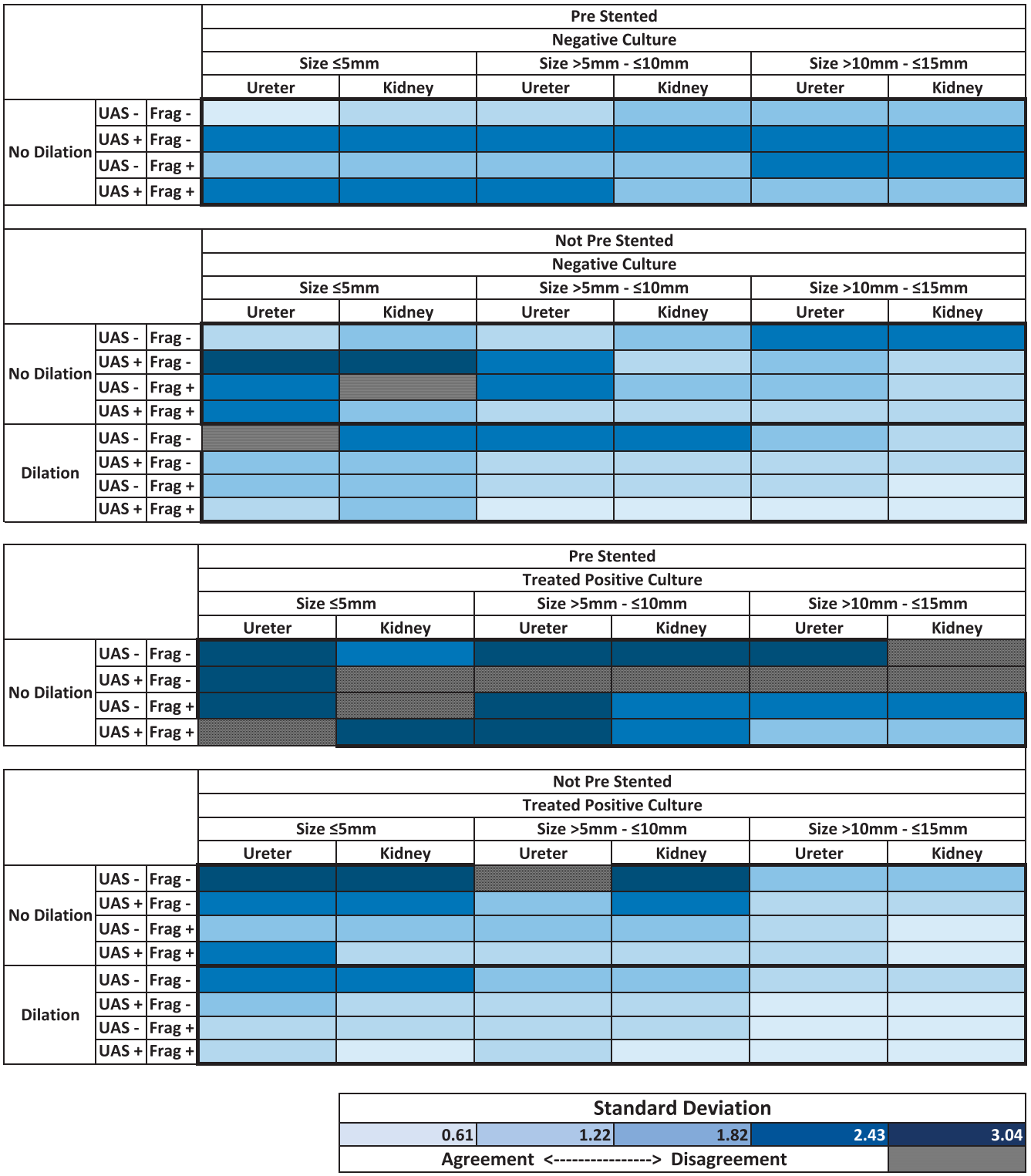

Figure 5. Heatmap of standard deviation of round 2 scores among panelists for all clinical scenarios. Darker blue represents less agreement (higher standard deviation). Shaded squares meet RAM manual criteria for disagreement. *UAS+*, UAS used. *UAS−*, no UAS used. *Frag+*, yes, fragments left behind. *Frag−*, no fragments left behind.

appropriate for omission. There is limited evidence regarding the safety of stent omission following ureteral dilation.[21,22] Future research should investigate the type and size of ureteral dilators used in order to provide additional clarity.

The majority of scenarios appropriate for stent omission occurred in pre-stented patients; however, many pre-stented scenarios were either inappropriate or uncertain. While some may advocate for stent omission in all pre-stented uncomplicated

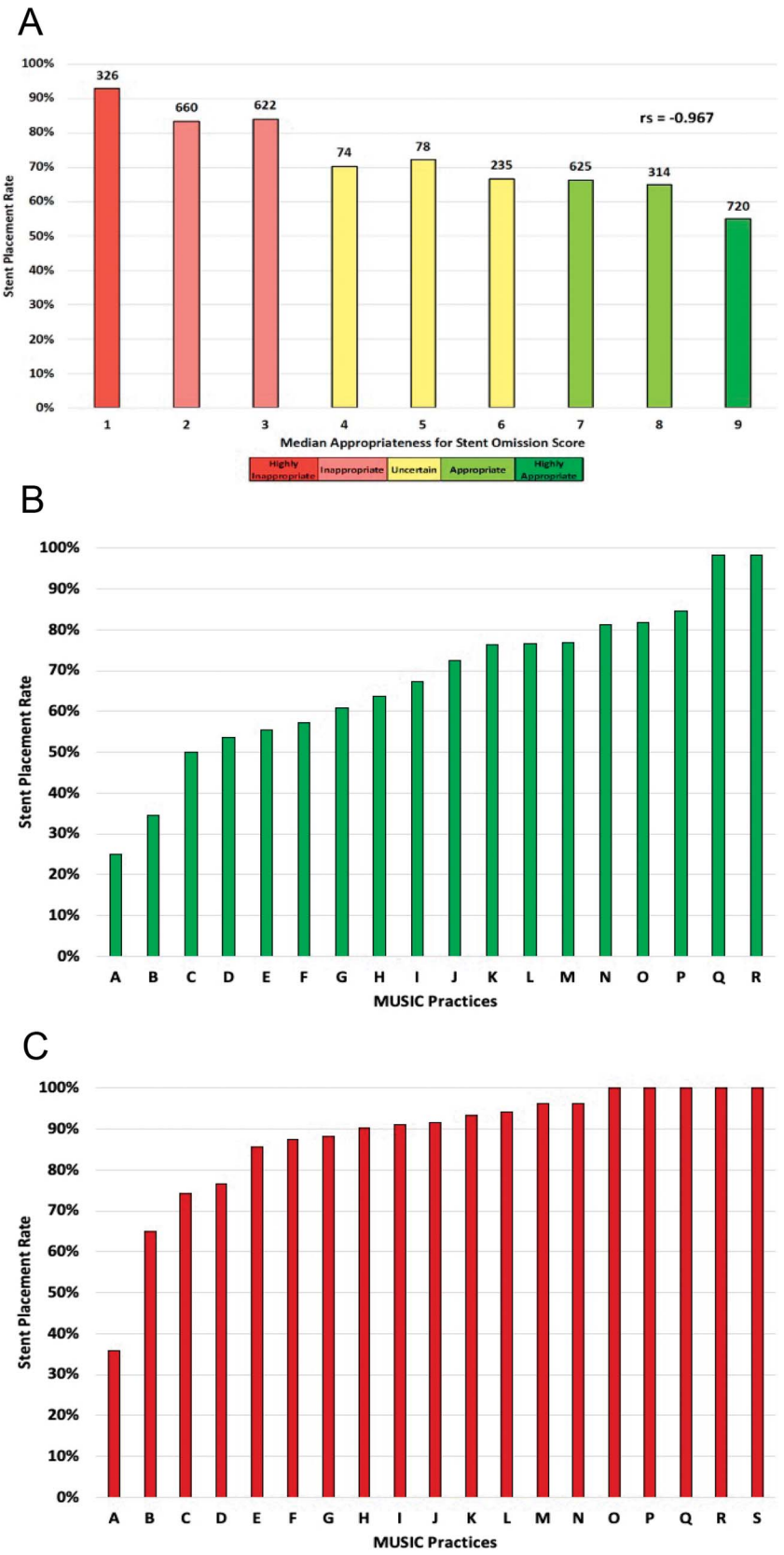

Figure 6. *A*, ureteral stent placement rates following uncomplicated URS in the MUSIC registry by assigned stent omission AC score. Number of stented cases for each score and Spearman's correlation coefficient (*rs*) are displayed. *B*, rates of ureteral stent placement among MUSIC practices for cases determined to be appropriate. *C*, rates of ureteral stent placement among MUSIC practices for cases determined to be inappropriate. Data shown for practices with 10 or more cases in each category.

URS,[23] this sentiment was not shared by the panel. Additionally, previous studies have demonstrated the safety of stent omission following UAS use in select pre-stented patients.[24,25] Our panel found that stent omission was appropriate in pre-stented scenarios with UAS use if the stone was less than or equal to 10 mm, across a variety of other parameters.

Surprisingly, stone location had little effect on stent omission decision making. The safety of stent omission following uncomplicated URS for ureteral stones is well established.[3,22,25–27] However, no randomized trial has assessed the safety of stent omission for patients with renal stones.[20,22,28,29] Despite having the least impact on decision making of our chosen variables, we found that scenarios with ureteral stones were significantly more likely to be appropriate for stent omission than scenarios with renal stones. Lastly, we found that stone size was associated with decision making, and contrary to AUA guidelines,[1] stones >10 mm were considered inappropriate for stent omission if not pre-stented.

Our study has several limitations. Our criteria for uncomplicated URS should be validated in future research. It was not possible to capture every variable under consideration during stent omission decision making. Several factors cannot be objectively quantified and were not included as variables. The panel spent considerable time discussing "tightness" of the ureter while passing the ureteroscope, degree of stone impaction, operative technique (dusting versus fragmentation/extraction) and size criteria for fragments; however, it was ultimately decided that variables such as these were too subjective for inclusion. The amount of time needed to score scenarios is a constraint of the RAM, and it was not feasible to include every proposed variable. Specifically, the panel discussed including preoperative hydronephrosis and stratification of the ureteral location but concluded these were not of sufficient importance. In the retrospective analysis, the MUSIC registry does not capture every factor included in the uncomplicated URS definition such as operative time, neurogenic bladder or incomplete bladder emptying. Practice patterns in Michigan may not be representative of international trends, where stenting rates may be much higher.[3] Lastly, the term "inappropriate" in the RAM is not meant to provide judgment from a patient safety or medicolegal perspective, but rather expert opinion in the absence of strong scientific evidence.[11] In future publications, it is possible to combine the 9 categories into 3 broad categories of stent omission such as "consider," "indeterminate" and "not consider," which may be easier for clinicians to implement.

Limitations notwithstanding, the implications of our work are substantial and we have laid the foundation for future efforts to address variation in stenting practices. In the section on future research in the AUA surgical management of stone guidelines, it is recommended that future efforts should better identify patients safe for stent omission.[1] Our study is the first instance of a standardized data-driven method being used to understand stenting after URS. As a result of this project, we have created a clinical decision aid for dissemination to all practices in Michigan (supplementary fig. 7, https://www.urologypracticejournal.com). All resources are freely available at www.musicurology.com/rocks. We also aim to develop target rates of stent omission for different scenarios, which can be tracked as a quality measure in the future. However, we expect widespread adoption will take time and, thus, a prospective analysis of our results did not occur in the current study.

Future research should focus on validation of the safety of stent omission in the aforementioned appropriate scenarios, as this should address the heterogeneity among panelists. The AC developed provide a framework for clinical trials, especially in scenarios found to be uncertain, such as the setting of an appropriately treated positive urine culture or non-pre-stented patients. Importantly, investigation into the linkage between patient-reported outcomes and stenting practices has not been previously done but we have begun to capture this. Finally, if appropriate stent omission reduces health care utilization and improves health-related quality of life, an increase in payment by payers for procedural services that includes stent omission may be an important lever for reducing utilization and changing physician behavior, thereby minimizing variation.[30]

Conclusions

We identified 7 objective variables that impact decision making for stent placement after uncomplicated URS. Through the development of AC, we defined scenarios that were appropriate and inappropriate for stent omission. Data from the MUSIC registry confirmed decreasing stenting rates with increasing AC for stent omission scores. However, there was significant practice variation. Implementation of these AC into practice could help address variation, reduce stenting rates and improve the quality of care.

Acknowledgments

The authors acknowledge the significant contributions of the clinical champions, urologists, administrators and data abstractors in each participating MUSIC practice (details can be found at www.musicurology.com), as well as members of the MUSIC Coordinating Center at the University of Michigan. We thank our patient advocates for their support, in particular Dennis Sitek, who provided valuable insight to our panelists. Lastly, we thank Michael Cher, MD, who forged the way

with the Appropriateness Criteria for Active Surveillance of Prostate Cancer panel, for his guidance and expertise through this process.

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Editorial Commentaries

Placing ureter stents after ureteroscopy (URS) is the generally accepted standard of care to maximize patient safety, just as treating prostate cancer was felt to be the generally accepted standard of care for all patients diagnosed. That being said, we have come to learn that prostate cancer is heterogeneous and based upon certain risk factors that active surveillance may be the preferred choice for certain patients. Similarly, URS is also heterogeneous, and despite studies from even decades ago showing the safety of stent omission after URS in appropriately selected patients, the adoption of such a practice has been slow. Why? If we compare the situation to that of active surveillance for prostate cancer, significant barriers needed to be addressed before widespread adoption, including having enough published literature proving the safety along with having published appropriateness guidelines. Were we to have similar appropriateness guidelines available for stent omission after URS in the appropriately selected patient, we may see a more widespread adoption. Studies like this serve as a springboard for further discussion to improve the care we take of our patients, which may end up improving patient outcomes. However, we do need to remember that we have yet to prove an improvement in health-related qualify of life and a reduction in health care costs with selective stent omission, the data for which would be helpful in our efforts to ensure we are providing the best and most appropriate care possible.

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AUA Guidelines are a major step forward in urological care, and their phrasing can make a significant difference. For example, the stone guidelines recommend against routine stents after shockwave lithotripsy or prior to ureteroscopy, but imply stenting should be the default by stating clinicians "may omit" stenting in specified circumstances after ureteroscopy.

These authors add to the dialogue, but there is room to push the question further in future studies.

Let's be honest—many patients are more miserable from a stent than from sequelae of the procedure. As such, future guidelines panels should consider whether justification for omitting stenting is the question, or do we have clear justification for stenting?

J. Stephen Jones
Editor