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Ureteroscopy in patients taking anticoagulant or antiplatelet therapy: practice patterns and outcomes in a surgical collaborative

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Abstract

Purpose: AUA guidelines recommend ureteroscopy (URS) as first-line therapy for patients on anticoagulant (AC) or antiplatelet (AP) therapy, and advocate using a ureteral access sheath (UAS). We examined practice patterns and unplanned healthcare utilization in these patients in Michigan.

Methods: Using the Michigan Urological Surgery Improvement Collaborative (MUSIC) clinical registry, we identified URS cases from 2016 to 2019. We assessed outcomes and adherence to guidelines based on therapy at time of URS: (1) AC: continuous warfarin or novel oral agent therapy, (2) AP: continuous clopidogrel or aspirin therapy, (3) Control: not on AC/AP therapy. We fit multivariate models to assess AC or AP therapy association with emergency department (ED) visits, hospitalization, and UAS use.

Results: In total, 9982 URS were performed across 31 practices, with 3.1% and 7.8% on AC and AP therapy, respectively. There was practice (0–21%) and surgeon (0–35%) variation in performing URS on AC/AP, regardless of volume. After adjusting for risk factors, AC or AP therapy was not associated with ED visits. Hospitalization rates in AC, AP, and control groups were 4.3%, 5.5%, and 3.2%, respectively, and significantly increased with AP therapy (OR 1.48, 95%CI: 1.02–2.14). Practice-level UAS use varied (23–100%), and was not associated with AC/AP therapy. Limitations include inability to risk stratify between type/dosage of AC/AP therapy.

Conclusions: We found practice and surgeon-level variation in performing URS while on AC/AP therapy. URS on AC is safe, however AP therapy increases the risk of hospitalization. Despite guideline recommendations, UAS use is not associated with AC/AP therapy.

Keywords

Ureteroscopy; antiplatelet agents; anticoagulant agents; laser lithotripsy; guideline adherence

Introduction

The use of anticoagulant (AC) and antiplatelet (AP) therapy is increasing worldwide.¹ Urologists are frequently presented with patients on AC or AP therapy and must balance these medications' thromboembolic protective effects with the potential increased risk of surgery-related bleeding. The practice of short-term periprocedural discontinuation AC and AP therapy appears safe,^{2, 3} however this is not appropriate for all patients.⁴ For these reasons, AUA guidelines for urinary stone disease recommend ureteroscopy (URS) as first-line therapy for a patient requiring intervention with an uncorrected bleeding diathesis or requiring continuous AC or AP therapy. The guidelines also state to "strongly consider" use of a ureteral access sheath (UAS) in order to minimize intrarenal pressure and reduce the risk of hemorrhage and hematuria.⁵

Data on outcomes for patients undergoing URS and lithotripsy on AC or AP therapy are limited. Initial studies suggested no difference in complications when compared to patients not on AC or AP therapy.⁶⁻⁸ More recently, single-institution data has emerged demonstrating that patients on AC therapy are at increased risk of bleeding-related complications,⁹ while those on AP therapy are not.¹⁰ Overall, questions remain regarding the safety of AC or AP therapy during URS. In particular, there is a paucity of multi-center data on patterns of care and objective outcome metrics such as unplanned healthcare utilization in these patients.

In this context we sought to understand practice patterns, outcomes, and AUA guideline adherence for URS while on AC or AP therapy among the diverse practices comprising the Michigan Urological Surgery Improvement Collaborative (MUSIC). By assessing unplanned healthcare utilization after URS, we aim to determine the safety of intervention in these patients, guide patient counseling, and inform guideline recommendations.

Methods

Data source

MUSIC was established in 2011 in partnership with Blue Cross Blue Shield of Michigan. The Reducing Operative Complications from Kidney Stones (ROCKS) initiative within MUSIC, started in 2016, now comprises 31 community and academic urology practices in the state of Michigan. ROCKS maintains a registry of URS cases performed by these practices in hospitals and ambulatory surgery centers, regardless of insurance type or status. Its goal is to reduce unplanned healthcare encounters following URS for patients with urinary stones. Trained abstractors prospectively record standardized data elements in a web-based registry by chart review. The data collection strategy has been described previously.^{11, 12} Stone size is determined by the diameter of the largest treated stone on

preoperative imaging. Each MUSIC practice has obtained an exemption or approval by the local institutional review board for participation in the collaborative.

Study population

All patients 18 years old undergoing a primary URS for urinary stones in the MUSIC ROCKS registry between June 2016 and July 2019 were included in this analysis. We excluded procedures that were bilateral, staged (ipsilateral surgery within 4 weeks), or second-look URS cases performed after percutaneous renal surgery. We also excluded patients taking both an AC and AP agent (n=90), because the small number of patients in this group prohibited multivariable statistics. On-site data abstractors perform a chart review to determine whether patients were taking oral AC therapy (warfarin or any novel agent (i.e. apixaban, rivaroxaban, etc.)) or AP therapy (aspirin 81mg or clopidogrel) at the time of URS. If the patient had interrupted therapy with any of these medications before URS, regardless of duration, they were recorded as not taking the drug and thus included in the control group. Cases were divided into three groups based on medication at time of URS: 1) continuous AC therapy, 2) continuous AP therapy, 3) Control: taking neither AC nor AP therapy.

Outcomes and statistical analysis

We assessed: 1) Practice-level and surgeon-level frequency of performing URS in patients on AC or AP therapy, 2) 30-day emergency department (ED) visit for any reason related to surgery and hospitalization rates after URS, 3) UAS use during URS for renal stones and associated outcomes. Hospitalization meant an admission to any hospital following URS. A bleeding-specific intraoperative complication meant the surgery was abandoned due to poor visualization from bleeding.

Clinical and demographic characteristics of cases were compared using Chi-squared testing for categorical variables and Wilcoxon rank-sum testing for continuous measures. Practice- and surgeon-level rates of AC or AP therapy use during URS were assessed in those with 10 cases and displayed on a bubble chart to incorporate surgical case volume. Because AUA guidelines recommend use of a UAS during URS in these patients, UAS use among cases for renal stones across practices with 5 cases were assessed using Chi-squared testing.

Mixed-effects logistic regression models were performed on all URS procedures, with outcomes being the presence of an ED visit or hospitalization. The model included two separate primary predictor variables, AC and AP therapy (with control group as the reference category). The model controlled for age, Charlson Comorbidity Index (CCI), urine culture, stone size, stone location, and postoperative ureteral stenting. The model also included random intercepts for each practice, each surgeon and patients to account for within-practice, within-surgeon and within-cluster correlation. Next, a separate mixed-effects logistic regression model was used to identify factors associated with use of UAS amongst patients with renal stones. The model included as predictors, the use of AC or AP therapy, as well as age, comorbidity, urine culture, stone size and preoperative ureteral stenting. The model also included random intercepts for each practice, each surgeon and

patients to account for within-practice, within-surgeon and within-cluster correlation. For this model, we combined the AC and AP groups due to the lower number of cases with renal stones. All the analyses were performed using SAS 9.4, and statistical significance was set at 0.05.

Results

A total of 9982 primary URS cases were included from 31 practices and 180 surgeons. Of these, 306 (3%) were on AC therapy, 776 (8%) were on AP therapy, and 8900 (89%) were in the control group. Table 1 compares demographic, preoperative and stone factors between AC, AP and control groups. The AC and AP groups were older and had greater comorbidity. Stones in these cases were larger, likely due to the recommendation against percutaneous nephrolithotomy in patients on AC or AP therapy. There was significant variation in frequency of performing URS in patients on AC or AP therapy across practices (0% to 21%, $p<0.001$; Figure 1) and surgeons (0% to 35%, $p<0.001$; Figure 2). For both practices and surgeons, the frequency varied regardless of case volume. Of the 144 surgeons who had more than 10 cases in the registry, 25 (17.4%) never performed URS in such patients (Figure 2).

Table 2 compares intraoperative and postoperative outcomes between AC, AP and control groups. Overall, there were no significant differences in the rates of intraoperative complications. Unadjusted rates of post-operative ED visit and hospitalization varied between AC, AP and control groups. ED and hospitalization rates were similar in cases for stones $>10\text{mm}$ in patients in AC, AP or control groups (ED: 7.7%, 12.2% and 8.9% respectively, $p=0.38$; hospitalization: 3.1%, 8.2%, 4.4% respectively, $p=0.98$). On multivariable analysis (Table 3), neither AC (OR 1.34, 95% CI 0.89–2.02, $p=0.16$) nor AP (OR 1.26, 95% CI 0.95–1.66, $p=0.12$) groups were significantly associated with an increase in 30-day ED visits. However, AP therapy (hospitalization rate 5.5%) was significantly associated with an increase in unplanned hospitalization (OR 1.48, 95% CI 1.02–2.14; $p=0.037$) while AC therapy (hospitalization rate 4.3%) was not (OR 1.12, 95% CI 0.60–2.09; $p=0.7$). Because patients that had interrupted AC or AP therapy were included in the control group, rates of ED visit and hospitalization in patients with CCI=0 in the control group were assessed. We found lower events in these control patients (ED visit 7.3%; Hospitalization 2.7%).

There were 2977 (30%) URS for renal stones, and of these, 359 were in patients taking AC or AP therapy. A UAS was used in 213 (59%) of these cases. Practice-level frequency of UAS use varied significantly ranging from 23% to 100% ($p<0.001$) (Figure 3). There were no differences in rates of ED visit (11.7% vs 12.3%, $p=0.9$) or hospitalization (7.5% vs 6.2%, $p=0.6$) with or without UAS. Table 4 provides multivariable analysis assessing odds of UAS use during URS for renal stones. After adjusting for surgeon and practice variation and clinical factors, AC/AP therapy was not associated with a significantly higher utilization of UAS (OR 1.16, 95% CI: 0.87–1.55).

Discussion

Our study has three principle findings. First, we found significant practice- and surgeon-level variation in the frequency of performing URS in patients taking AC or AP therapy. Second, after controlling for risk factors, AC and AP therapy did not significantly increase the odds of a postoperative ED visit. However, AP therapy was associated with an increased risk of hospitalization after URS. Finally, despite AUA guideline recommendations, we found the use of a UAS in these cases varied in clinical practice. Collectively, these findings suggest that while URS is safe in patients taking AC therapy, patients on AP therapy are at increased risk of post-operative hospitalization. The value and role of the UAS in these specific patients is not fully understood and needs further study.

Data on the safety of URS in patients taking AC or AP therapy is mixed. The AUA guidelines recommending URS as first-line therapy are based on two small retrospective studies, consisting of 12 and 37 patients with coagulopathies.^{7, 8} Two recent studies analyzed outcomes in patients from a single high-volume center.^{9, 10} Despite a large number of overall patients (n=4799), only 79 patients were taking AC therapy⁹, and only 80 were on AP therapy¹⁰, at the time of URS. Rates of bleeding-related complications, hospitalization and unplanned return to the operating room were significantly higher in patients that continued AC therapy compared to those bridged with enoxaparin and those withholding therapy.⁹ Patients continuing AP therapy were not at increased risk of complication but those on dual-AP therapy did have a higher rate of hospitalization.¹⁰ However, regression analysis was prohibited by the small number of patients in these studies.

We present outcomes on the largest number of patients actively taking AC or AP therapy during URS. Our registry includes a variety of practices across the state of Michigan which enables better representation of real-world practice patterns. Nevertheless, limitations of our study include the lack of granularity to determine the specific type of AC or AP therapy, confirmation of therapeutic levels of these agents, clinical indication for therapy, differences in institutional protocols as well as identify the cases in our control that interrupted AC or AP therapy preoperatively. There may be differences in risk between those taking different forms of AC therapy (warfarin vs novel oral agents) as well as AP therapy (aspirin 81mg vs aspirin 325mg vs clopidogrel vs dual-AP), and our study cannot address this. Our registry also does not contain data points such as operative time and size of UAS, and apart from stone size, this study cannot scale the complexity of URS. There are likely contributing factors, not addressed by this study but must be included in future research, that increase the risks associated with these medications, such as the increased risk of bleeding from an enlarged prostate. Lastly, we acknowledge that the increasing availability of reversal agents for the novel AC therapies has likely impacted temporal trends in practice patterns and their use cannot be accounted for by this study.

Limitations notwithstanding, our work has several implications. To our knowledge, no study has specifically looked at practice patterns of URS in patients taking AC or AP therapy. We found discordance between practice and AUA guideline recommendations regarding UAS use during URS for patients on AC/AP therapy. In the discussion of the AUA guideline statement #42, it is recommended that clinicians “strongly consider” use of a UAS in

patients on AC or AP therapy undergoing URS,⁵ however the studies cited do not evaluate the role of UAS in this specific context.^{7, 8} Given the lack of foundational evidence, it is not surprising that this recommendation does not accurately reflect practice patterns. Unfortunately, our analysis is underpowered to determine if UAS use improves outcomes highlighting the need for prospective studies.

Importantly, we found that patients taking AP therapy undergoing URS are at increased risk of hospitalization. A recent meta-analysis concluded that patients on AC or AP therapy were specifically at increased risk of a bleeding-related complication.¹³ In contrast to our study, they did not assess the risk of unplanned healthcare utilization. Our analysis is an important addition to the growing body of evidence that performing URS in patients taking AC or AP agents, while generally safe, does appear to be associated with increased risk. Our results are tempered by the inability to risk stratify by type and dosage of AP therapy. However, we feel that we have, if anything, underestimated the risk of hospitalization associated with AP therapy by including lower risk categories (e.g. low-dose aspirin), and including patients that had interrupted therapy in the control. These patients should be appropriately counseled and informed that URS may have increased risks, in order to guide treatment decision-making and informed consent. To determine the risks for individual patients, future research in this area should consider risk stratification for type of AC or AP therapy, dosages and indication for therapy.

Conclusions

In conclusion, we found significant practice and surgeon level variation in performing URS for urinary stones in patients actively taking AC or AP agents. While URS does not lead to an increase in postoperative ED visits in patients taking AC therapy, the risk of hospitalization is increased in those taking AP therapy. Despite AUA guideline recommendations, UAS use is not increased in these patients. Further studies are needed to better define the role of the UAS when treating these patients.

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Figure 1. Practice-level variation in frequency of performing URS in patients while on anticoagulant (AC) or antiplatelet (AP) therapy by MUSIC ROCKS practices with at least 10 URS in registry.

Total URS case volume indicated by bubble size.

Figure 2. Surgeon-level variation in frequency of performing URS in patients while on anticoagulant (AC) or antiplatelet (AP) therapy by MUSIC surgeons with at least 10 URS in registry.

Total URS case volume indicated by bubble size.

Figure 3. Practice-level variation in ureteral access sheath use during URS when treating renal stones in cases on anticoagulant (AC) or antiplatelet (AP) therapy in MUSIC ROCKS registry.

Table 1.

Demographic and stone characteristics of anticoagulant (AC), antiplatelet (AP), and control groups.

	AC	AP	Control	Total	P-Value
No. pts (%)	306 (3.1%)	776 (7.8%)	8900 (89.2%)	9982	
Mean age (standard deviation)	66.0 (13.8)	65.5 (11.5)	54.4 (16.0)		<0.001
Insurance					
No insurance	2 (0.7%)	10 (1.3%)	197 (2.2%)	209	<0.001
Private	119 (39.1%)	324 (41.9%)	5390 (60.9%)	5833	
Public	183 (60.2%)	440 (56.9%)	3270 (36.9%)	3893	
Charlson Comorbidity Index (CCI)					
0	144 (47.2%)	342 (44.1%)	6519 (73.3%)	7005	<0.001
1	66 (21.6%)	215 (27.7%)	1324 (14.9%)	1605	
2	95 (31.2%)	219 (28.2%)	1052 (11.8%)	1366	
Body mass index (BMI)					
30	125 (43.0%)	368 (49.7%)	4405 (53.6%)	4898	<0.001
>30	166 (57.0%)	373 (50.3%)	3819 (46.4%)	4358	
Gender					
Male	162 (52.9%)	454 (58.5%)	4254 (47.8%)	4870	<0.001
Female	144 (47.1%)	322 (41.5%)	4646 (52.2%)	5112	
Preoperative urine culture/urinalysis					
Positive	48 (15.7%)	128 (16.5%)	1035 (11.6%)	1211	<0.001
Negative	205 (67.0%)	504 (65.0%)	6136 (69.0%)	6845	
Not performed	53 (17.3%)	143 (18.5%)	1719 (19.3%)	1915	
Stone location					
Renal stone	109 (38.8%)	254 (35.2%)	2614 (32.2%)	2977	0.007
Ureteral stone	124 (44.1%)	382 (52.9%)	4366 (53.9%)	4872	
Both renal and ureteral stone	48 (17.1%)	86 (11.9%)	1126 (13.9%)	1260	
Mean stone size, mm (standard deviation)	8.36 (4.6)	8.16 (5.3)	7.46 (4.5)		<0.001
Stone size					
5 mm	75 (26.2%)	214 (28.7%)	2977 (34.9%)	3266	<0.001
>5mm – 10mm	146 (51.1%)	385 (51.6%)	4225 (49.5%)	4756	
>10mm	65 (22.7%)	147 (19.7%)	1326 (15.6%)	1538	
Pre-stented	128 (42.1%)	318 (41.3%)	3483 (39.4%)	3929	0.4

Table 2.

Intraoperative and postoperative outcomes of anticoagulant (AC), antiplatelet (AP) and control groups

Intraoperative					
	AC	AP	Control	Total	P-Value
UAS used during URS	139 (45.9%)	308 (40.4%)	3184 (36.4%)	3631	<0.001
Stent placed at URS	226 (73.9%)	584 (75.8%)	6481 (72.9%)	7291	0.2
Intraoperative complication	7 (2.3%)	12 (1.6%)	121 (1.4%)	140	0.4
Bleeding	0 (0%)	5 (0.7%)	50 (0.6%)	55	0.4
Postoperative					
	AC	AP	Control	Total	P-Value
ED visit	31 (10.1%)	76 (9.8%)	686 (7.7%)	793	0.043
Hospitalization	13 (4.3%)	43 (5.5%)	287 (3.2%)	343	0.002

Table 3.

Multivariable analysis assessing the odds of ED visit and hospitalization in cases performed while on continuous AC or AP therapy

	ED Visit				Hospitalization		
	Adjusted Odds Ratio	95% Confidence Interval	P-Value		Adjusted Odds Ratio	95% Confidence Interval	P-Value
AC (vs control)	1.34	0.89 – 2.02	0.16		1.12	0.60 – 2.09	0.7
AP (vs control)	1.26	0.95 – 1.66	0.11		1.48	1.02 – 2.14	0.037
Age (vs mean)	0.99	0.98 – 0.99	<0.001		0.99	0.98 – 1.00	0.026
CCI							
1	1.28	1.03 – 1.60	0.027		1.67	1.23 – 2.28	0.001
2	1.66	1.33 – 2.08	<0.001		2.23	1.64 – 3.04	<0.001
Preoperative UA/urine culture							
Positive (vs negative)	1.21	0.97 – 1.51	0.093		1.65	1.22 – 2.23	0.001
Not performed (vs negative)	0.79	0.62 – 1.00	0.053		0.87	0.61 – 1.23	0.4
Stone location							
Renal (vs ureter)	1.25	1.05 – 1.50	0.013		1.24	0.95 – 1.61	0.11
Both (vs ureter)	1.27	1.01 – 1.60	0.038		1.20	0.85 – 1.68	0.3
Stone size							
>5mm - 10mm (vs 5mm)	0.76	0.64 – 0.90	0.002		0.65	0.50 – 0.84	0.001
>10mm (vs 5mm)	0.90	0.70 – 1.14	0.4		0.96	0.68 – 1.34	0.8
Preoperative ureteral stent (vs no)	1.46	1.20 – 1.76	<0.001		1.40	1.06 – 1.86	0.019

Table 4.

Multivariable analysis assessing the odds of ureteral access sheath use during URS for renal stones in cases on anticoagulant (AC) or antiplatelet (AP) therapy relative to control group

	Adjusted Odds Ratio	95% Confidence Interval	P- Value
AC or AP (vs control)	1.16	0.87 – 1.55	0.3
Age (vs mean)	1.00	0.99 – 1.00	0.4
CCI			
1 (vs 0)	1.68	1.31 – 2.15	<0.001
2 (vs 0)	1.37	1.05 – 1.78	0.021
Urine culture			
Positive (vs negative)	1.31	0.99 – 1.73	0.063
Not performed (vs negative)	1.08	0.86 – 1.37	0.5
Stone Size			
>5mm – 10mm (vs 5mm)	2.41	1.93 – 3.01	<0.001
>10mm (vs 5mm)	4.65	3.58 – 6.03	<0.001
Preoperative ureteral stent (vs no stent)	1.43	1.18 – 1.74	<0.001