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Ureteroscopy in Patients Taking Anticoagulant or Antiplatelet Therapy: Practice Patterns and Outcomes in a Surgical Collaborative

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Purpose: AUA guidelines recommend ureteroscopy as first line therapy for patients on anticoagulant or antiplatelet therapy and advocate using a ureteral access sheath. We examined practice patterns and unplanned health care use for these patients in Michigan.

Materials and Methods: Using the Michigan Urological Surgery Improvement Collaborative (MUSIC) clinical registry we identified ureteroscopy cases from 2016 to 2019. We assessed outcomes and adherence to guidelines based on therapy at time of ureteroscopy: 1) anticoagulant: continuous warfarin or novel oral agent therapy; 2) antiplatelet: continuous clopidogrel or aspirin therapy; 3) control: not on anticoagulant/antiplatelet therapy. We fit multivariate models to assess anticoagulant or antiplatelet therapy association with emergency department visits, hospitalization and ureteral access sheath use.

Results: In total, 9,982 ureteroscopies were performed across 31 practices with 3.1% and 7.8% on anticoagulant and antiplatelet therapy, respectively. There were practice (0% to 21%) and surgeon (0% to 35%) variations in performing ureteroscopy on patients on anticoagulant/antiplatelet therapy regardless of volume. After adjusting for risk factors, anticoagulant or antiplatelet therapy was not associated with emergency department visits. Hospitalization rates in anticoagulant, antiplatelet and control groups were 4.3%, 5.5% and 3.2%, respectively, and significantly increased with antiplatelet therapy (OR 1.48, 95% CI 1.02–2.14). Practice-level ureteral access sheath use varied (23% to 100%) and was not associated with anticoagulant/antiplatelet therapy. Limitations include inability to risk stratify between type/dosage of anticoagulant/antiplatelet therapy.

Abbreviations and Acronyms

AC = anticoagulant

AP = antiplatelet

AUA = American Urological Association

CCI = Charlson comorbidity index

ED = emergency department

MUSIC = Michigan Urological Surgery Improvement Collaborative

ROCKS = Reducing Operative Complications from Kidney Stones

UAS = ureteral access sheath

URS = ureteroscopy

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The MUSIC registry was issued a Notice of Determination of "Not Regulated" status by the University of Michigan Institutional Review Board (IRBMED), ID: HUM00054438. This registry did not fit the definition of human subjects research requiring IRB approval because the program is focused on quality improvement versus research on the human subjects themselves.

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Conclusions: We found practice-level and surgeon-level variation in performing ureteroscopy while on anticoagulant/antiplatelet therapy. Ureteroscopy on anticoagulant is safe. However, antiplatelet therapy increases the risk of hospitalization. Despite guideline recommendations, ureteral access sheath use is not associated with anticoagulant/antiplatelet therapy.

Key Words: ureteroscopy; platelet aggregation inhibitors; anticoagulants; lithotripsy, laser; guideline adherence

THE use of anticoagulant and antiplatelet 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, American Urological Association guidelines for urinary stone disease recommend ureteroscopy 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 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 have 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 multicenter data on patterns of care and objective outcome metrics such as unplanned health care use 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. By assessing unplanned health care use after URS we aimed 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 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 health care 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 (IRBMED ID: HUM00054438).

Study Population

All patients 18 years old or above 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 an AC and AP agent (90) because the small number of patients in this group prohibited multivariable statistics. Onsite data abstractors perform a chart review to determine whether patients were taking oral AC therapy (warfarin or any novel agent, ie apixaban, rivaroxaban etc) or AP therapy (aspirin 81 mg or greater 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 therefore included in the control group. Cases were divided into 3 groups based on medication at time of URS: 1) continuous AC therapy, 2) continuous AP therapy and 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 visit for any reason related to surgery and hospitalization rates after URS and 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-level and surgeon-level rates of AC or AP therapy use during URS were assessed in those with 10 or more 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 or more 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 2 separate primary predictor variables, AC and AP therapy (with control group as the reference category). The model controlled for age, Charlson comorbidity index, 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 9,982 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 8,900 (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; fig. 1) and surgeons (0% to 35%, p <0.001; fig. 2). For practices and surgeons the frequency varied regardless of case volume. Of the 144 surgeons who had 10 or more cases in the registry, 25 (17.4%) never performed URS in such patients (fig. 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 postoperative ED visit and hospitalization varied between AC, AP and control groups. ED and hospitalization rates were similar in cases for stones greater than 10 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

Table 1. *Demographic and stone characteristics of anticoagulant, antiplatelet and control groups*

	AC	AP	Control	Total	p Value
No. pts (%)	306 (3.1)	776 (7.8)	8,900 (89.2)	9,982	<0.001
Mean age (SD)	66.0 (13.8)	65.5 (11.5)	54.4 (16.0)		
No. insurance type (%):					<0.001
No insurance	2 (0.7)	10 (1.3)	197 (2.2)	209	
Private	119 (39.1)	324 (41.9)	5,390 (60.9)	5,833	
Public	183 (60.2)	440 (56.9)	3,270 (36.9)	3,893	
No. CCI (%):					<0.001
0	144 (47.2)	342 (44.1)	6,519 (73.3)	7,005	
1	66 (21.6)	215 (27.7)	1,324 (14.9)	1,605	
2 or greater	95 (31.2)	219 (28.2)	1,052 (11.8)	1,366	
No. body mass index (%):					<0.001
30 or less	125 (43.0)	368 (49.7)	4,405 (53.6)	4,898	
Greater than 30	166 (57.0)	373 (50.3)	3,819 (46.4)	4,358	
No. gender (%):					<0.001
Male	162 (52.9)	454 (58.5)	4,254 (47.8)	4,870	
Female	144 (47.1)	322 (41.5)	4,646 (52.2)	5,112	
No. preoperative urine culture/urinalysis (%):					<0.001
Pos	48 (15.7)	128 (16.5)	1,035 (11.6)	1,211	
Neg	205 (67.0)	504 (65.0)	6,136 (69.0)	6,845	
Not performed	53 (17.3)	143 (18.5)	1,719 (19.3)	1,915	
No. stone location (%):					0.007
Renal stone	109 (38.8)	254 (35.2)	2,614 (32.2)	2,977	
Ureteral stone	124 (44.1)	382 (52.9)	4,366 (53.9)	4,872	
Both renal and ureteral stone	48 (17.1)	86 (11.9)	1,126 (13.9)	1,260	
Mean mm stone size (SD)	8.36 (4.6)	8.16 (5.3)	7.46 (4.5)		<0.001
No. stone size (%):					<0.001
5 mm or less	75 (26.2)	214 (28.7)	2,977 (34.9)	3,266	
Greater than 5 mm to 10 mm	146 (51.1)	385 (51.6)	4,225 (49.5)	4,756	
Greater than 10 mm	65 (22.7)	147 (19.7)	1,326 (15.6)	1,538	
Pre-stented	128 (42.1)	318 (41.3)	3,483 (39.4)	3,929	0.4

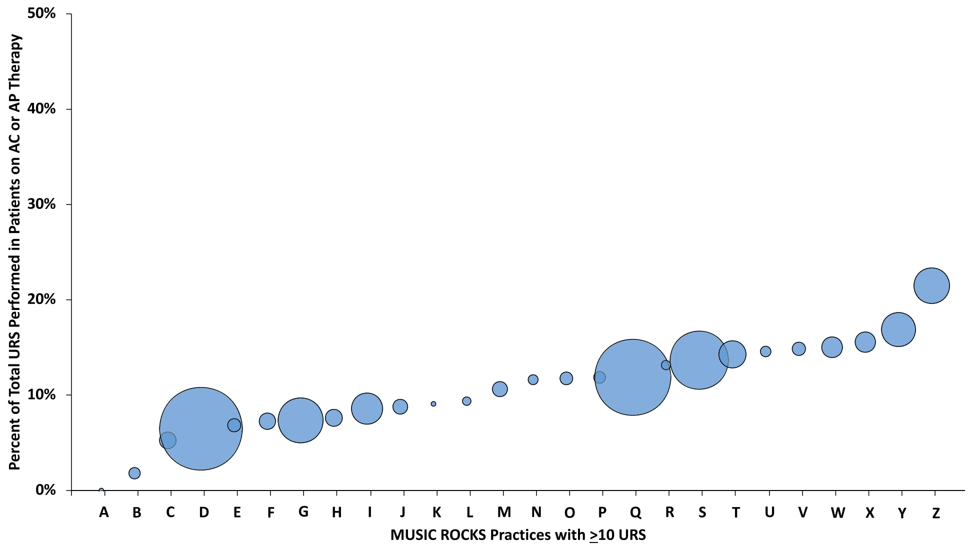

Figure 1. Practice-level variation in frequency of performing URS in patients while on anticoagulant or antiplatelet therapy by MUSIC ROCKS practices with at least 10 URSs in registry. Total URS case volume indicated by bubble size.

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 2,977 (30%) URSs 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; fig. 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 use of UAS (OR 1.16, 95% CI 0.87–1.55).

DISCUSSION

Our study has 3 principle findings. First, we found significant practice-level and surgeon-level variation in the frequency of performing URS in patients taking AC

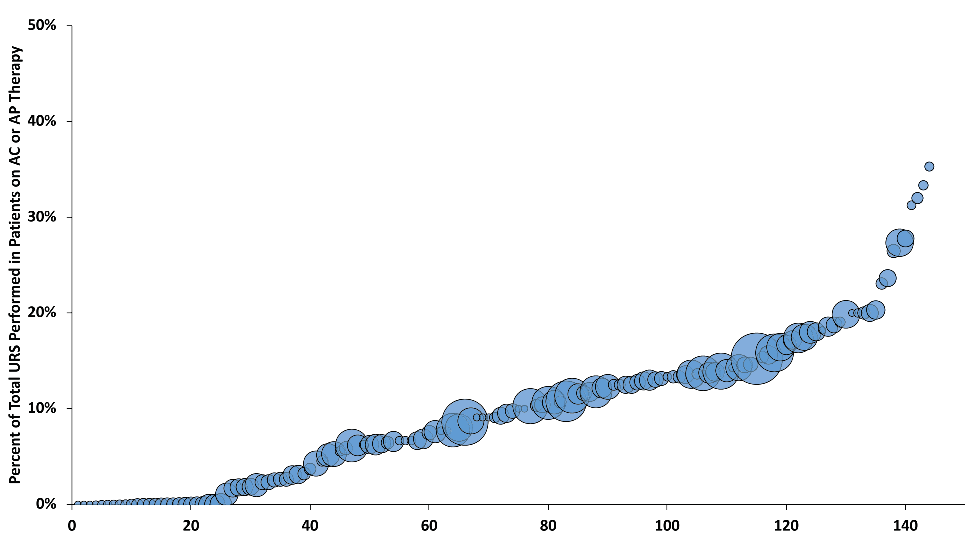

Figure 2. Surgeon-level variation in frequency of performing URS in patients while on anticoagulant or antiplatelet therapy by MUSIC surgeons with at least 10 URSs in registry. Total URS case volume indicated by bubble size.

Table 2. *Intraoperative and postoperative outcomes of anticoagulant, antiplatelet and control groups*

	No. (%)				
	AC	AP	Control	No. Total	p Value
Total pts	306	776	8,900		
Intraoperative					
UAS used during URS	139 (45.9)	308 (40.4)	3,184 (36.4)	3,631	<0.001
Stent placed at URS	226 (73.9)	584 (75.8)	6,481 (72.9)	7,291	0.2
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					
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

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 postoperative 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 2 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 (4,799) only 79 patients were taking AC therapy[9] and only 80 were on AP therapy[10] at the time of URS. Rates of bleeding-related complications, hospitalization and unplanned return to the operating room were significantly higher in patients who 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 identifying 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 81 mg vs aspirin 325 mg 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.

Table 3. *Multivariable analysis assessing odds of ED visit and hospitalization in cases performed while on continuous AC or AP therapy*

	ED Visit			Hospitalization		
	Adjusted OR	95% CI	p Value	Adjusted OR	95% CI	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 or greater	1.66	1.33—2.08	<0.001	2.23	1.64—3.04	<0.001
Preop UA/urine culture:						
Pos (vs neg)	1.21	0.97—1.51	0.093	1.65	1.22—2.23	0.001
Not performed (vs neg)	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:						
Greater than 5 mm to 10 mm (vs 5 mm or less)	0.76	0.64—0.90	0.002	0.65	0.50—0.84	0.001
Greater than 10 mm (vs 5 mm or less)	0.90	0.70—1.14	0.4	0.96	0.68—1.34	0.8
Preop ureteral stent (vs no)	1.46	1.20—1.76	<0.001	1.40	1.06—1.86	0.019

Bold text represents primary predictor variables of multivariable analysis.

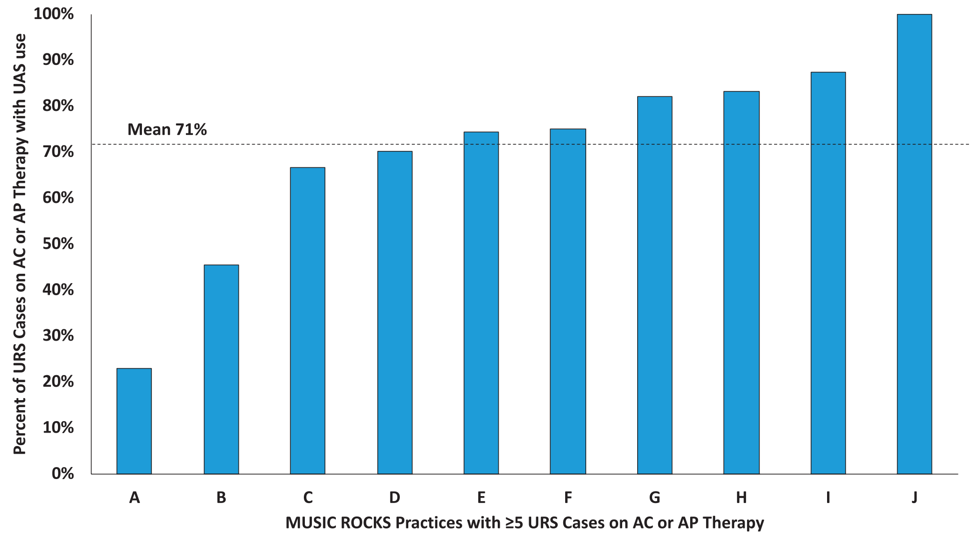

Figure 3. Practice-level variation in ureteral access sheath use during URS when treating renal stones in cases on anticoagulant or antiplatelet therapy in MUSIC ROCKS registry.

There are likely contributing factors not addressed by this study, that 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 health care use. 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

Table 4. *Multivariable analysis assessing the odds of ureteral access sheath use during URS for renal stones in cases on anticoagulant or antiplatelet therapy relative to control group*

	Adjusted OR	95% CI	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 or greater (vs 0)	1.37	1.05—1.78	0.021
Urine culture:			
Pos (vs neg)	1.31	0.99—1.73	0.063
Not performed (vs neg)	1.08	0.86—1.37	0.5
Stone Size:			
Greater than 5 mm to 10 mm (vs 5 mm or less)	2.41	1.93—3.01	<0.001
Greater than 10 mm (vs 5 mm or less)	4.65	3.58—6.03	<0.001
Preop ureteral stent (vs no stent)	1.43	1.18—1.74	<0.001

Bold text represents primary predictor of analysis.

categories (eg low dose aspirin) and including patients who 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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EDITORIAL COMMENT

Given the increasing prevalence of anticoagulation and urolithiasis, Hiller et al's pertinent inquiry into the safety and practice patterns of ureteroscopy in the setting of anticoagulant or antiplatelet use provides a unique insight into differences in the number of postoperative ED visits and unplanned healthcare use, with meaningful implications on patient quality of life and health care costs.

Current AUA guidance advocating ureteroscopy as first line treatment in those on AC/AP requiring intervention and strongly advising the use of a ureteral access sheath is based on small, retrospective studies (references 7 and 8 in article). Conflicting evidence has characterized anticoagulation as either a risk factor for increased postoperative bleeding or safe to continue perioperatively, highlighting the need for further study (references 6 and 9 in article).

In this analysis of a large clinical registry lacking specifics on exact medication type, the authors found neither AC nor AP to be associated with increased postoperative ED visits. A hospitalization rate of 5.5% for those taking AP was significantly higher (OR 1.48) than for the AC or control groups (4.3% and 3.2%, respectively). UAS use varied amongst practices (23% to 100%) and was not associated with AC or AP use.

These findings provide additional evidence highlighting the safety of URS on AC/AP. This will assist in counseling patients, although additional granularity, specifically medication type and combinations such as dual antiplatelet therapy, is needed in future studies to individualize risk stratification further. UAS deployment appears safe. However, considering the inconsistencies in its use at the present time, supplementary investigation is necessary to determine efficacy and need in this setting.

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