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The Effect of Preoperative Tamsulosin on Pediatric Ureteroscopic Access: A Multi-institutional Experience

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Study Need and Importance: There has been a recent rise in ureteroscopy (URS) in children. However, the smaller diameter of the pediatric ureterovesical junction may limit the ability to pass a flexible ureteroscope into the pediatric ureter. While there is growing evidence to support the use of alpha-blockers to facilitate ureteral access in adults, pediatric-specific data are limited with only 2 single-center studies published on this topic. To our knowledge, this is the first multi-institutional study investigating the association of preoperative tamsulosin and successful primary pediatric ureteral access.

What We Found: This multi-institutional retrospective study reviewed 382 patients including 128 unique ureteroscopy attempts after receiving tamsulosin and 257 ureteroscopy attempts without tamsulosin exposure. There were no observed differences in sex, race, and stone characteristics between the groups; however, the tamsulosin group was significantly older and had a significantly larger BMI. At least 7 days of preoperative tamsulosin significantly increased the success of initial ureteral access with flexible ureteroscopy, with 87% success vs 76% success in the no-tamsulosin group ($P = .010$, Table).

Limitations: Our study was limited by the retrospective study design, including inability to confirm medication compliance and difficulty in assessing medication side effects. In addition, there were statistically significant differences in demographic data between groups, which may reflect biases in tamsulosin exposure.

Table.
Ureteroscopy Outcomes by Study Group

Characteristic	No Tamsulosin, N = 257[a]	Tamsulosin, N = 128[a]	*P* value[b]
Successful at gaining access with ureteroscope into the ureter during the case?	193 (76%)	109 (87%)	**.010**
Unknown	3	3	
Use of ureteral dilation during the procedure?	161 (64%)	82 (64%)	> .9
Unknown	6	0	
Stent placed after the case?	204 (80%)	95 (74%)	.2
Unknown	3	0	

[a]n (%).
[b]Fisher exact test.

Interpretation for Patient Care: In pediatric patients undergoing URS for urolithiasis, at least 1 week of preoperative tamsulosin was associated with a significantly increased success of accessing the ureter with a flexible ureteroscope compared with the no-tamsulosin group. These findings have the potential to spare children from multiple procedures and therefore anesthetic exposures. The results of this study provide an argument to incorporate prescribing tamsulosin, a low-risk medication, into preoperative surgical management of pediatric urolithiasis. In addition, our study highlights the need for further prospective trials to further investigate the role of alpha-blockade in pediatric ureteroscopy.

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The Effect of Preoperative Tamsulosin on Pediatric Ureteroscopic Access: A Multi-institutional Experience

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Introduction: The ability to perform flexible ureteroscopy in children may be limited because of a smaller pediatric ureterovesical junction and ureteral diameter. Tamsulosin has been shown to improve success rates of ureteral instrumentation in adults. To date, the efficacy of this medication to facilitate pediatric ureteral access remains unclear.

Methods: We conducted a multi-institutional retrospective review of patients aged 0 to 17 years who underwent ureteroscopy for the treatment of nephrolithiasis from 2013 to 2022. Patients were excluded if they had undergone ureteroscopy or ureteral stent placement within the prior year, underwent semirigid ureteroscopy, or had a known genitourinary abnormality. Study groups included patients prescribed 0.4 mg tamsulosin daily for at least 1 week preoperatively and patients who did not receive tamsulosin.

Results: There were 382 patients included, with 126 in the tamsulosin group and 256 in the no-tamsulosin group. Although there were no differences in sex, race, and stone characteristics between the 2 groups, the tamsulosin group was significantly older and had a larger BMI. One week

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Critical revision of the manuscript for scientific and factual content: Ostergar, Jadcherla, Storm, Traxel, Vetter, Kraft, Meyer, Asantey, McGee, Wendt, Ten Eyck, Kostman.
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of preoperative tamsulosin was associated with a significantly increased success of flexible ureteroscopic access on first attempt ureteroscopy, with a 24% failure in the no-tamsulosin group vs a 13% failure in the tamsulosin group ($P = .010$).

Conclusions: Our results expand on prior research and suggest that at least 1 week of preoperative tamsulosin facilitates flexible ureteroscopic access in the pediatric population. These results have significant clinical implications, with the potential to reduce multiple procedures and spare children from repeat anesthetic exposures.

Key Words: tamsulosin, ureteroscopy, urolithiasis, child, adolescent

There has been a rise in the incidence of pediatric urolithiasis over the past several decades, with estimated increases of 4 to 10% annually.[1-4] Medical expulsive therapy (MET) with adrenergic alpha-antagonists, particularly tamsulosin, is a well-established treatment of ureteral calculi in adults.[5] In children with ureteral calculi, tamsulosin utilization has also increased, with evidence suggesting it is both safe and efficacious for improving stone passage because of smooth muscle relaxation.[2,6-9] Tamsulosin's safety in children has been further verified with studies demonstrating its efficacy and safety profile in treating pediatric patients with bladder neck dysfunction.[10,11] In pediatric stone disease, however, anywhere from 37% to 68% of children will fail to pass ureteral stones spontaneously despite MET and ultimately will require surgical intervention.[12-14]

Technical advances in endoscopy have led to a rise in URS in children with evidence that it is a safe option for pediatric stone treatment.[5,11,14-17] One challenge of pediatric URS is the difficulty in passing a flexible ureteroscope into the child's ureter on the first attempt given the smaller diameter of the pediatric ureterovesical junction. This often necessitates abortion of the primary ureteroscopic attempt, placement of a stent for passive ureteral dilation, and a follow-up ureteroscopic procedure several weeks later. This adds cost, time, and possible morbidity. Tamsulosin, by its ability to dilate the ureter, has been shown to improve success rates of ureteroscopic access in the adult population.[18] In pediatric patients, single-center studies have similarly demonstrated that there is a trend toward a higher success rate of ureteral access in patients who receive preoperative tamsulosin.[19,20] However, these studies may have been underpowered to detect a statistically significant difference and were limited by single-center experiences. Therefore, the efficacy of this medication to facilitate ureteral access in children remains unclear.

The goal of this retrospective study was to expand on prior studies, using multi-institutional data to further elucidate the effect tamsulosin may have on the ability to access the pediatric ureter in children undergoing flexible URS. We hypothesize that pediatric patients prescribed tamsulosin for at least 1 week before flexible ureteroscopy will have a greater rate of success at gaining access to the ureter with a flexible ureteroscope.

Materials and Methods

Study Design and Population

This study is a multi-institutional retrospective review of patients aged 0 to 17 years who underwent attempted flexible ureteroscopy for the treatment of nephrolithiasis between January 2013 and March 2022. This study was approved by each study site's IRB. Data collected at each of the 4 participating institutions included demographic data as well as associated patient medical comorbidities, history of kidney stones, and history of ureteroscopy. Information about stone characteristics was also collected, including number of stones, stone location, and largest stone size. Other variables included operating surgeon, length of surgery, indication for surgery, use of intraoperative ureteral dilation, need for preoperative or postoperative stent placement, and length and size of stent placement.

All patients underwent surgery with a flexible ureteroscope, with the make of the ureteroscope determined by the surgeon and institution (P6 [Olympus] or Viper [Wolf] flexible ureteroscope). Patients were excluded from analysis if a semirigid ureteroscope was used during the procedure; if they had ureteroscopy or ureteral stent placement within the last year; if they received preoperative tamsulosin for < 7 days; or if they had a known genitourinary anomaly including prior renal, ureteral, or reconstructive surgery. Patients who met the inclusion criteria were divided into 2 groups: preoperative tamsulosin exposure and no exposure to preoperative tamsulosin. Study exposure was defined as 0.4 mg tamsulosin taken daily for at least 7 days before flexible ureteroscopy. The number of days of tamsulosin exposure was determined by the date tamsulosin was prescribed in the chart and included the day of surgery.

The primary outcome was the ability to pass a flexible ureteroscope during the initial surgery. A failed attempt was

defined as one in which the flexible ureteroscope could not be passed into the ureter at any point during the first surgery, requiring stent placement and staged management.

Statistical Analysis

Summary statistics stratified by treatment were presented using counts and percentages for categorical variables and using medians and IQRs for continuous variables. *P*-values were also provided to compare the treatment groups and were generated using Fisher exact test for categorical variables and using Wilcoxon rank sum tests for continuous variables. Outcome data were reported at the renal level, meaning that for patients who had bilateral stones with bilateral attempts at URS, both renal outcomes were considered to be their own case. Spearman correlation was used to evaluate the relationship between length of surgery and stone size. In addition, a multivariable logistic model was created assessing the association of demographic and clinical characteristics with the probability of successful ureteral access. Age and prior tamsulosin use were forced into the model, and then a forward stepwise selection approach aimed toward minimizing the Akaike information criterion was used to reach a final multivariable model. *P*-values $< .05$ were considered statistically significant throughout the article. R version 4.3.3 was used for all analyses.

Results

Study Cohort

Our study included 382 patients. The no-tamsulosin group included 256 patients while the tamsulosin group included 126 patients. There were no statistically significant differences between the groups with respect to sex ($P > .9$) or race ($P = .15$); however, the tamsulosin group was significantly older with a median age of 15 years vs a median age of 11 years in the no-tamulosin group ($P < .001$). In addition, the tamsulosin group had a significantly larger median BMI of 21 kg/m^2 compared with 19 kg/m^2 in the no-tamsulosin group ($P < .001$) (Table 1). There were no patients taking other alpha-blockers.

Surgery and Stone Characteristics

In terms of stone location, the only statistical difference between the treatment groups included a higher percentage of patients with right ureteral stones in the tamsulosin treatment cohort ($P < .01$). The median length of surgery for each cohort was 50 minutes (IQR 30-69) and 52 minutes (IQR 33-70) in the tamsulosin group and no-tamsulosin group, respectively ($P = .5$) (Table 1). The median size of the largest stone, as reported by imaging before surgery, was 6.0 mm

Table 1.
Patient Demographics and Stone Characteristics

Characteristic	No Tamsulosin, N = 256[a]	Tamsulosin, N = 126[a]	*P* value[b]
Height at the time of ureteroscopy (cm)	142 (119, 162)	160 (148, 165)	**< .001**
Missing	16	2	
Weight at the time of ureteroscopy (kg)	37 (23, 54)	54 (42, 67)	**< .001**
Missing	2	1	
BMI at the time of ureteroscopy	19 (16, 23)	21 (18, 25)	**< .001**
Missing	17	2	
Sex			> .9
Male	108 (42%)	53 (42%)	
Female	148 (58%)	73 (58%)	
Race			.15
Other	29 (11%)	21 (17%)	
White	227 (89%)	105 (83%)	
Age at the time of initial surgery (y)	11.0 (8.0, 15.0)	15.0 (12.0, 16.0)	**< .001**
Missing	54	17	
Laterality of surgery			.073
Right	129 (50%)	77 (61%)	
Left	108 (42%)	45 (36%)	
Bilateral	19 (7.4%)	4 (3.2%)	
Length of surgery (minutes)	52 (33, 70)	50 (30, 69)	.5
Missing	47	8	
Largest stone size (mm)	6.0 (4.0, 8.0)	5.0 (4.0, 8.0)	.2
Missing	35	5	
Stone location (choice = left renal collecting system)	90 (35%)	44 (35%)	> .9
Stone location (choice = right renal collecting system)	98 (38%)	52 (41%)	.6
Stone location (choice = left ureter)	56 (22%)	32 (25%)	.4
Stone location (choice = right ureter)	56 (22%)	50 (40%)	**< .001**

[a] Median (IQR); n (%).
[b] Wilcoxon rank sum test; Fisher exact test.

Table 2.
Ureteroscopy Outcomes by Study Group

Characteristic	No Tamsulosin, N = 257[a]	Tamsulosin, N = 128[a]	*P* value[b]
Successful at gaining access with ureteroscope into the ureter during the case?	193 (76%)	109 (87%)	**.010**
Unknown	3	3	
Use of ureteral dilation during the procedure?	161 (64%)	82 (64%)	> .9
Unknown	6	0	
Stent placed after the case?	204 (80%)	95 (74%)	.2
Unknown	3	0	

[a] n (%).
[b] Fisher exact test.

in the no-tamsulosin group and 5.0 mm in the tamsulosin group ($P = .2$).

URS Outcomes

There were 257 unique URS attempts in the no-tamsulosin group and 128 unique URS attempts in the tamsulosin group (Table 2). Among the patients receiving at least 7 days of preoperative tamsulosin, initial attempt at accessing the ureter in URS was successful in 109 cases (87%). This was significantly different from patients who did not receive preoperative tamsulosin, in which ureteral access on initial URS was successful in 193 patients (76%, $P = .010$). There was not a significant difference in the use of ureteral dilation during the case, with a rate of 64% in both groups ($P > .9$). Ureteral access sheaths were not used in either group. In addition, stent placement for ureteral edema at the conclusion of successful ureteroscopy passage was not significantly different between the 2 groups, with rates of 80% in the no tamsulosin group and 74% in the no tamsulosin group ($P = .2$) (Table 2).

On multivariate analysis, the odds of success at ureteral access were 1.87 times higher for patients with tamsulosin use before URS compared with those without tamsulosin use (CI = [0.97, 3.75], $P = .069$) (Table 3). Age and sex were not significantly associated with differences in ureteral access success, although location of the stone in the left renal collecting system was significantly associated with a lower likelihood of successful ureteral access (OR 0.39, CI = [0.22, 0.69], $P = .001$).

Table 3.
Multivariate Modeling of Success at Ureteral Access

Characteristic	OR[a]	95% CI[a]	*P* value
Tamsulosin used before surgery?	1.87	0.97, 3.75	.069
Age at the time of initial surgery (y)	1.01	0.95, 1.08	.7
Stone location (choice = left renal collecting system)	0.39	0.22, 0.69	**.001**
Female sex	1.19	0.66, 2.13	.6

Discussion

Our study provides evidence that tamsulosin is associated with successful ureteral access in pediatric patients undergoing URS for urolithiasis. This could have significant clinical implications, sparing children from repeat surgery following unsuccessful ureteral access.

For the purposes of this study, we focused on the use of MET with adrenergic alpha-antagonists, particularly tamsulosin. While MET can include other medications, the use of alpha-antagonists has particularly increased in popularity as adjunctive therapy in the pediatric population due to emerging evidence that it is safe and may have similar efficacy as seen in adults.[5,9,12,21] In fact, multiple recent meta-analyses consistently show an increased stone expulsion rate and a favorable safety profile when comparing the use of alpha-blockers for MET vs placebo.[6,7,9] In pediatric patients with ureteral stones that are unlikely to pass or who have failed observation with or without MET, URS is becoming an increasingly favored option for surgical stone treatment.[12,22,23] However, one risk of URS is the failure to pass the ureteroscope into the pediatric ureter given the smaller body habitus and ureteral diameter seen in children. Inability to access the ureter with a ureteroscope necessitates stent placement for passive ureteral dilation before repeat surgery. Alpha-blockade, in addition to MET, may facilitate endoscopic ureteral access. In adults, there has been substantial evidence supporting the hypothesis that preoperative alpha-blocker treatment facilitates ureteral access during URS, with a recent meta-analysis demonstrating a 61% risk reduction of need for intraoperative ureteral dilation and 16% increased ability to reach the stone ureteroscopically.[24]

While the data supporting the use of alpha-blockers to facilitate ureteral access in adults are promising, evidence is limited in the pediatric population. To date, there are 2 studies published on this topic. One preliminary study suggested that 1 week of preoperative tamsulosin decreased rates of failed URS compared with no alpha-blockade.[19] Similarly, another study demonstrated a statistically significant increase in successful ureteral orifice navigation in pediatric patients from 65.4% in the control group to 88% in those who received daily tamsulosin for at least 48 hours preoperatively.[20] These studies, however, were both conducted at single institutions with small sample sizes, among other limitations. Our current investigation aims to address some of these limitations with expansion to a multi-institutional collaboration to better clarify the role of preoperative tamsulosintamulosin for URS in children.

Our results are in concordance with prior adult and pediatric studies and suggest that at least 1 week of preoperative tamsulosin facilitates passage of a flexible ureteroscope

across the UVJ in the pediatric population. We found that patients who did not receive preoperative tamsulosin failed an initial ureteral access attempt 24% of the time, whereas patients receiving tamsulosin only failed their first URS attempt 13% of the time. On further analysis, we demonstrated that age and sex did not significantly affect the odds of successful ureteral access on URS. Tamsulosin use did increase the odds of success with an odds ratio of 1.87; however, this did not reach statistical significance. This may in part be confounded by the demographic discrepancies between the groups, with the tamsulosin group being significantly older and larger. The multivariate analysis did not account for the use of other medications used in combination with tamsulosin. However, we know that no patients were taking other alpha-blockers, and ketorolac was not routinely used at any participating institution. Tamsulosin exposure did not reduce the need for ureteral dilation or the rate of stent placement after URS. As the need to place a ureteral dilator and stent is determined by many factors, including stone location, total stone size, and number of passes with the ureteroscope, and the use of tamsulosin does not influence ureteral diameter, these additional findings are not surprising.

This is the first multi-institutional study investigating tamsulosin use in the preoperative period for urolithiasis surgical management and expands on prior research that similarly demonstrated a greater success rate at passage of a flexible ureteroscope in pediatric patients prescribed preoperative tamsulosin.[19] These results have significant clinical implications for pediatric surgical stone management. With an increase in success at initial-attempt ureteral access, this implies a decreased risk of surgical complications due to a reduction in multiple procedures and repeat anesthetic exposure. With each ureteroscopy attempt, there is a complication rate of approximately 12.6% with common complications including fever, UTI, hematuria, stent discomfort, and postoperative pain.[16] Furthermore, each anesthetic exposure poses its own risk. Specifically in the pediatric population, evidence has pointed to a detrimental impact of prolonged and/or repeated operative procedures on the developing brain.[25,26] While current clinical studies on the topic are inconsistent, basic studies have confirmed that anesthesia can cause neurotoxicity and possibly affect brain development.[27,28] Therefore, any means by which we may spare children from repeated anesthetic exposures is beneficial for their safety and possible long-term consequences.

We acknowledge the limitations of the study, especially those inherent to a retrospective study design. First, we are unable to confirm that the children prescribed tamsulosin preoperatively were compliant. Unless specifically documented, this study cannot account for the exact date tamsulosin was started or any missed doses or discontinuation of the medication, also limiting our ability to assess for any side effects of the medication. Second, there were no patients younger than 8 years in either cohort. This may be in part due to provider comfortability given that prescribing preoperative tamsulosin is not standard practice for children of all ages. The demographic differences between groups is also an important limitation and suggests there may have been biases in who received tamsulosin preoperatively. One possible explanation for the discrepancy could be that older and larger children are more likely to swallow a pill. This is less likely a significant driver for the difference, however, because tamsulosin capsules are able to be opened and sprinkled for easier consumption. Importantly, age was not shown to affect the odds ratio of the primary outcome. Finally, while the multi-institutional nature of this study increases the power, it introduces variability in surgeon comfort with ureteroscopic procedures and types of flexible ureteroscopes used. However, this variability also increases the generalizability of our study.

There remains a need for further prospective trials to more adequately evaluate the role of preoperative tamsulosin for ureteroscopy in children. In the study by Morley et al, the effects of tamsulosin were still promising after only being prescribed for at least 48 hours.[20] Therefore, further studies are needed to better understand the minimum required dosage necessary to see an effect on operative success, as well as monitoring more closely for adverse effects. Despite the limitations of our current study, we demonstrated significantly improved success rates at accessing the pediatric ureter after at least 1 week of preoperative tamsulosin across multiple institutions. Our study provides estimates of effect size and statistical error needed to design and adequately power larger prospective studies. In the interim, given the low risk of this medication, our study provides a compelling argument to adopt preoperative tamsulosin as an option for preoperative surgical management of urolithiasis in the pediatric population.

Conclusions

In this multi-institutional retrospective review, patients prescribed at least 1 week of tamsulosin preoperatively had a significantly higher success rate of accessing the ureter with a flexible ureteroscope compared with those who did not receive tamsulosin before surgery. These results expand on prior single-institution retrospective studies and highlight the need for prospective trials to further investigate this relationship. Prescribing preoperative tamsulosin has the potential to minimize ureteroscopy complications and the need for multiple surgeries, therefore sparing children from repeat anesthetic exposure.

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