

A Prospective Study Analyzing the Association Between High-grade Ureteral Access Sheath Injuries and the Formation of Ureteral Strictures



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OBJECTIVE	To assess the intermediate- and long-term effect of high-grade ureteral injuries from ureteral access sheaths.
METHODS	Patients undergoing ureteroscopy for upper tract calculi were prospectively enrolled at 2 sites from 2010 to 2015. A 12/14 French sheath was used and the ureter was inspected with a flexible ureteroscope during withdrawal of the sheath and recorded. The videos were then evaluated by 2 blinded endourologists, and any injuries were graded per the Traxer ureteral injury scale. Only high-grade injuries were included. The primary endpoint was defined as ongoing hydronephrosis without an obstructing stone on follow-up imaging indicating a ureteral stricture. Logistic regression analysis was used to assess the relationship between hydronephrosis, ureteral injury, and other patient variables.
RESULTS	Fifty-six patients were identified with high-grade ureteral injuries. Sixteen patients (28.6%) were female. Median age was 56.4 years (range 14-85). Median follow-up was 35.8 months (range 0-88). Three patients (5.5%) had hydronephrosis on follow-up imaging, only 1 of whom developed a de novo ureteral stricture. On univariate analysis, hydronephrosis was associated with a shorter stent duration ($P = .11$) and older age ($P = .17$).
CONCLUSION	Endoscopically identified high-grade ureteral lesions following ureteral access sheath placement do not lead to clinically significant sequelae on intermediate term follow-up, with a stricture rate comparable to those without visible injuries of 1.8%. UROLOGY 128: 38–41, 2019. © 2019 Elsevier Inc.

Ureteral access sheaths offer several advantages during ureteroscopy, including decreased intrarenal pressures, ease of multiple re-entries to the upper tract, and decreased damage to the ureteroscope¹. However, ureteral injury after ureteral access sheath use is not uncommon², and the theoretical risk of such an injury leading to long-term stricture formation is a deterrent to its use. There is limited literature regarding the long-term effects of ureteral injury secondary to ureteral access sheath use, but research indicates little to no risk when looking at all severity of injuries combined^{3,4}. This study is a comprehensive long-term follow-up of 2 main prospective studies looking at ureteral injury secondary to ureteral access sheath placement, specifically investigating

the median- to long-term risk of ureteral stricture formation after high-grade ureteral injuries^{2,5}.

METHODS

Patients were prospectively enrolled in the study at 2 centers from April 2010 to September 2015 after Institutional Review Board and all ethics committee approvals. Three attending surgeons at the 2 sites performed ureteroscopy for urinary stone disease using a Boston Scientific Navigator or Cook Flexor 12/14 French ureteral access sheath. A 0.035" hybrid guide wire was used as a safety wire next to the sheath. Two patients underwent balloon dilation of the ureter secondary to difficulty placing the 12/14 French sheath and were excluded from the study. Patients undergoing ureteroscopy with a smaller caliber sheath because of difficulty placing a 12/14 French sheath or sheathless were excluded from the study. Patients who were precluded were also excluded from the study. The ureter was inspected with a flexible ureteroscope during withdrawal of the ureteral access sheath and a video recording performed. No fluoroscopic evaluation of the injury was performed. The videos were evaluated by 2 blinded staff. The grading system was performed per the Traxer ureteral injury scale (Table 1). Only high-grade injuries, defined as a grade 2-4 injury, were included in the study. All patients with identified high-grade

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Table 1. Traxer ureteral injury scale

Grade	Ureteral Wall
0	No ureteral lesion or only mucosal petechiae
1	Mucosal erosion or mucosal flap without smooth muscle injury
2	Injury involves mucosa and smooth muscle, but not adventitia
3	Full thickness ureteral perforation
4	Ureteral avulsion with loss of ureteral continuity

injuries were treated with an indwelling ureteral stent with a median time of postoperative stent duration 16 days (range 1-48 days). All patients were recommended to have follow-up imaging (ultrasound or computed tomography [CT]) 6 weeks to 3 months after stent removal. The primary endpoint was defined as ongoing hydronephrosis without an obstructing stone on follow-up imaging indicating a ureteral stricture.

Data obtained included patient gender, age, BMI, and access sheath information including manufacturer, length, and if multiple attempts were made to pass the sheath. All patients were postoperatively managed with a ureteral stent and stent duration was recorded. Immediate perioperative data related to these patient cohorts have been previously reported^{2,5}. Planned long-term follow-up was conducted on the patients with high-grade injuries, representing 18.7% of the initial cohorts. Data was presented as median and range and percentages. Logistic regression analysis was used to assess relationship between hydronephrosis, ureteral injury, and other patient variables.

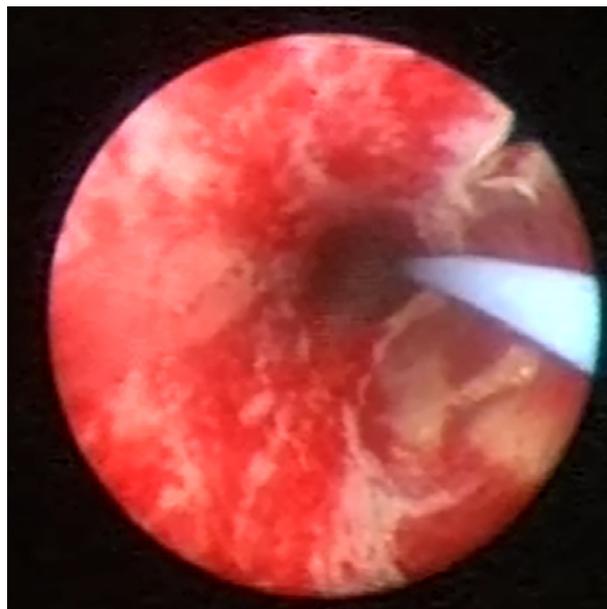
RESULTS

Four hundred and forty-six patients underwent ureteroscopy with the ureteral access sheath. Fifty-six patients (12.5%) were identified with a high-grade ureteral injury at the time of ureteroscopy for upper urinary tract calculi using a ureteral access sheath. Sixteen patients (28.6%) were female and 40 (71.4%) were male (Table 2). The median age was 56.4 years (range 14-85 years) and median BMI 29.5 kg/m² (range 18.4-46.6). Sheath placement in 2 patients required multiple passes. Thirty-eight patients (67.9%) had a grade 2 injury. Eighteen (32.1%) patients had a grade 3 injury (Fig. 1). None had a grade 4 injury. Median follow-up was 35.8 months (range 0-88 months). Median stent duration was 16 days (range 1-48 days).

Fifty-four patients had follow-up imaging—25 underwent ultrasound and 29 a CT scan. Median time from procedure to the most recent imaging was 30 months. Of the 54 patients with postoperative imaging, 3 (5.6%) had hydronephrosis noted. All 3 of those patients were male and all 3 had a grade 2 injury. One of those patients had a pre-existing ureteral stenosis and eventually underwent a nephroureterectomy for upper tract urothelial carcinoma on the affected side, another had spontaneous

Table 2. Patient demographics (N = 56)

Median age, years (range)	56.4 (14-85)
Median BMI, kg/m ² (range)	29.5 (18.4-46.6)
Gender, n (%)	
Male	40 (71.4%)
Female	16 (28.6%)

**Figure 1.** High-grade ureteral injury secondary to ureteral access sheath placement during ureteroscopy. (Color version available online.)

resolution of the hydronephrosis after 4 months, (Fig. 2) and 1 developed a noted de novo ureteral stricture, indicating an intermediate-term stricture rate after a high grade ureteral lesion secondary to ureteral access sheath of 1.8%. This number does not represent the total stricture rate after all ureteroscopies with sheaths or even all ureteral injuries from a ureteral access sheath, rather those specifically after grade 2 or higher injuries. On univariate analysis hydronephrosis was associated with a shorter stent duration ($P = .11$) and older age ($P = .17$), however the results were statistically insignificant given the small sample size.

DISCUSSION

The first ureteral access sheath was described by Takaysu and Aso in 1974, as a “guide tube” developed to aid in ureteroscope access to the proximal ureter⁶. Soon after, access sheaths were reported to be associated with a 19% ureteral perforation rate and fell out of favor⁷. With various improvements, including a hydrophilic coating, a locking mechanism to aid in passing the dilator and sheath

**Figure 2.** Hydronephrosis seen on postoperative ultrasound 6 weeks after ureteroscopy (left); hydronephrosis resolved on follow-up CT at 4 months postop (right). (Color version available online.)

together, and the introduction of multiple diameters and lengths, access sheaths again regained popularity^{1,7,8}. There are multiple reported advantages to using ureteral access sheaths including improved irrigation, decreased intrarenal pressures, ease of multiple passes to the proximal collecting system, and decreased damage to the ureteroscope¹. However, reported injuries associated with the use of sheaths continue to be a deterrent.

Traxer et al reported an overall injury rate of 46.5% with the use of an access sheath during ureteroscopy². He developed a scale to classify the injuries, determined by the depth of injury visualized with the ureteroscope after sheath removal (Table 1). Injuries were classified into 2 groups—low-grade and high-grade. Low-grade is defined as a grade 0 or 1 injury and high-grade is defined as grade 2-4. While the overall injury rate reported was significant, 86.6% of them were low-grade². There was no long-term follow-up on the patients to report the long-term clinical effects of such injuries. A more recent prospective study by Monga et al reported a 23.9% rate of high-grade ureteral injury with the use of 12/14 French ureteral access sheaths⁵. This rate was slightly higher than the high-grade injuries reported by Traxer, likely secondary to the exclusion of prestented patients in the latter⁵. The studies by both Traxer and Monga found that males had an increased risk of high-grade injury from sheath use. Although the rate of hydronephrosis in our study was small, all patients with hydronephrosis were male, potentially suggesting that not only is the risk of a high-grade injury from access sheath use greater in males, but the long-term risk of stricture from such injury may be greater as well.

In addition to visible injuries after use, there have been animal studies which indicate decreased blood flow to the ureter, and inflammatory changes on histopathology from ureteral access sheath use^{9,10}. The long-term effect of such changes remains unknown. Delvecchio et al noted a stricture rate after ureteroscopy with an access sheath to be around 1%-2%, however the patient in this study who developed a stricture actually developed it proximal to where the sheath was inserted, therefore essentially indicating a stricture rate of 0%³.

Ureteral stricture rate after ureteroscopy without a sheath remains a poorly reported on phenomenon. Historically it has been reported to be <1%, however recent data indicates the stricture rate after ureteroscopy may be as much as 3%¹¹. Silent obstruction, defined as persistent, asymptomatic, unilateral obstructive postoperative hydronephrosis, is estimated to occur at a rate of 1.9% after ureteroscopy¹². The mean interval from ureteroscopy to ureteral stricture is thought to be around 13 months¹³. This study has a mean follow-up of 33.5 months, indicating an adequate follow-up time to identify any postoperative stricture that may have developed after high-grade ureteral injuries secondary to the ureteral access sheath. Though one would hypothesize that selecting patients with high-grade injuries should lead to a higher rate of stricture formation, our data indicates that the stricture rate (1.8%) after such injuries is consistent with the

overall stricture rate after ureteroscopy and therefore, there is no significant increased risk in patients with endoscopically identified high-grade ureteral lesions following ureteral access sheath placement. Although the risk of ureteral stricture after ureteroscopy with an access sheath is not increased much beyond the risk of ureteroscopy alone, silent obstruction from a ureteral stricture can be devastating and result in long-term renal damage. Therefore, the authors recommend regular imaging follow-up with at least annual imaging after ureteroscopy to not only rule out silent obstruction but also aid in surveillance of urinary stone disease.

It should be noted that all patients with a high-grade ureteral injury were treated with a postoperative ureteral stent, with a median duration of 16 days and wide range of 1-48 days. Multiple factors contribute to stent duration including a patient's tolerability of the stent and the ability of the patient to be seen by a urologist for stent removal. Stent duration is surgeon-dependent, but the authors recommend a stent duration of 10-14 days after high-grade ureteral injury.

The limitations of this study include the small patient sample size (albeit a highly select group with high-grade injuries), and variation in follow-up imaging modality. As with other urolithiasis studies, it would be ideal to have a CT scan at follow-up. However, given that our endpoint was hydronephrosis and not stone-free rate, ultrasound should serve as an adequate substitute for CT imaging. In addition, all procedures were performed with a 12/14 French access sheath, and patients with "tight" ureters or ureters in which smaller sheaths needed to be used were not included in this study. This limits generalizability, since patients with ureters which cannot accommodate a 12/14 French sheath may be more prone to stricture formation. However, prior data has indicated an 87% success rate in placing a 12/14 French ureteral access sheath, therefore most patients would be considered to be in the cohort reviewed in this study⁵. In addition, the procedural times and incidence of infectious complications are not reported. Theoretically, an increased procedural time could lead to increased ischemia with a higher stricture rate or an infection could interfere with the healing of a ureteral injury.

CONCLUSION

The long-term risk of ureteral stricture formation after a high-grade injury secondary to ureteral access sheath use is similar to that of ureteroscopy without an access sheath. There is no significant association between a high-grade injury and stricture formation. Therefore, ureteral access sheaths can be used with little concern for a long-term effect on the ureter.

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