

# Evaluation of ureteral injuries caused by ureteral access sheath insertion during ureteroscopic lithotripsy

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## Research Article

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# Abstract

## Objective:

To evaluate ureteral injuries caused by insertion of a 13-Fr ureteral access sheath, and to identify factors (other than pre-stenting) that are predictive of ureteral injury.

## Methods:

We enrolled 201 patients who underwent ureteroscopic lithotripsy (URSL). We excluded 80 patients who underwent ureteral stent insertion before URSL, 10 patients who did not use a ureteral access sheath, and two patients in whom a ureteral access sheath could not be inserted. In total, 109 patients were analyzed; all underwent insertion of a 13-Fr ureteral access sheath. We investigated ureteral injuries using the Traxer ureteral injury scale.

## Results:

There were 21 (19.3%) cases of ureteral access sheath-related ureteral injury, including 11 (10.1%) grade 2 cases and 10 (9.2%) grade 3 cases. The ureteral injury location was the proximal ureter in 20 cases (18.3%), middle ureter in one case (0.9%), and distal ureter in 0 cases. Multiple logistic regression analysis showed that male sex was a significant predictive factor for ureteral injury ( $p = 0.045$ , odds ratio: 4.87, 95% confidence interval: 1.03–23.01). Postoperative ureteral stricture did not occur in any cases.

## Conclusion:

The rate of ureteral injury caused by a 13-Fr ureteral access sheath was considerable, and most ureteral injuries occurred in the proximal ureter. Male sex was a significant predictive factor for ureteral injury, according to multiple logistic regression analysis. The proximal ureter should be confirmed when using a 13-Fr ureteral access sheath, particularly in male patients.

## Introduction

Ureteroscopic lithotripsy (URSL) using a ureteral access sheath is becoming increasingly popular worldwide because of advantages that include reduced intrarenal pressure, multiple entry and reentry, scope protection, and avoidance of bulking.<sup>1–3</sup> However, the risk of ureteral injury after ureteral access sheath use should be considered; Loftus et al.<sup>4</sup> reported that ureteral access sheath-related ureteral injury may lead to ureteral stricture formation. Although the standard ureteral access sheath has an external diameter of 14 Fr, Zelenko et al.<sup>5</sup> reported that the mean diameter of the non-prestented ureter was 3 mm, according to imaging analysis. Concerning high-grade ureteral injury when using a 14-Fr ureteral access

sheath, Traxer et al.<sup>6</sup> reported a rate of 13.3% whereas Loftus et al.<sup>4</sup> reported a rate of 23.9%. Thus, there is a risk of ureteral injury when using a 14-Fr ureteral access sheath; we presumed that the risk of injury for non-prestented patients would be lower when using a < 14-Fr ureteral access sheath. Because Traxer et al.<sup>6</sup> reported that pre-stenting improved the risk of ureteral access sheath-related ureteral injury, we routinely use a 13-Fr ureteral access sheath for non-prestented patients and a 14-Fr ureteral access sheath for pre-stented patients in our institution. To our knowledge, there have been no reports concerning the incidence of ureteral injury caused by a 13-Fr ureteral access sheath. Here, we evaluated ureteral injuries caused by insertion of a 13-Fr ureteral access sheath and explored factors (other than pre-stenting) that were predictive of ureteral injury.

## Methods

The study protocol was approved by our institutional review board (approval number: R03-0201). This study adhered to the tenets of the Declaration of Helsinki (as revised in Fortaleza, Brazil, in October 2013).

We performed a retrospective review of prospectively collected data for 201 consecutive patients who underwent URSL from August 2018 to February 2021. We excluded 80 patients who underwent ureteral stent insertion before URSL, 10 patients who did not use a ureteral access sheath (because the stones were located in the distal ureter), and two patients in whom a ureteral access sheath could not be inserted. In total, 109 patients were analyzed; all underwent insertion of a 13-Fr ureteral access sheath.

Two endourologists performed URSL using the following procedure. Stones were approached using a guide wire and semi-rigid ureteroscope (6.5/8.5 Fr; Richard Wolf, Knittlingen, Germany). For proximal ureteral and renal stones, a ureteral access sheath was placed under fluoroscopic guidance and the stones were fragmented using a holmium YAG laser (5–10 Hz and 0.5–1.0 J; VersaPulse 30W; Lumenis, San Jose, CA, USA). All fragments larger than 2 mm were extracted using a tipless basket with a flexible ureteroscope (URF-P5 or P7; Olympus, Tokyo, Japan or LithoVue; Boston Scientific, Natick, MA, USA). The ureteral access sheath was a Flexor 12/14 Fr (Cook Medical, Bloomington, IN, USA) or Navigator 11/13 Fr (Boston Scientific). In accordance with our institution's criteria for sheath size selection, we used a 14-Fr ureteral access sheath for patients who underwent insertion of a ureteral stent before URSL and a 13-Fr ureteral access sheath for patients who did not undergo insertion of a ureteral stent before URSL. For mid- and distal ureteral stones, we performed the procedure as described above, but we omitted the ureteral access sheath. No patients required dilation of the ureteral orifice or ureter, and the ureteral stent was left in place after the procedure.

We investigated patient demographics and surgical outcomes, including ureteral access sheath-related ureteral injury; patients were divided into two groups (non-high-grade ureteral injury and high-grade ureteral injury) for comparison. The ureter was inspected with a flexible ureteroscope during withdrawal of the 13-Fr ureteral access sheath; the withdrawal procedure was recorded. All procedural videos were evaluated by a single endourologist. The Traxer ureteral injury scale (Table 1) was used to grade ureteral

injury caused by a 13-Fr ureteral access sheath. The primary endpoint of the study was high-grade (i.e., grade 2–4) ureteral injury caused by a 13-Fr ureteral access sheath. The secondary endpoints were the incidence of postoperative ureteral stricture; this respective endpoint was determined by computed tomography at 1 month postoperatively and by ultrasonography at 3 months postoperatively. Patients were considered stone-free if their residual stones were < 2 mm in diameter; postoperative ureteral stricture was defined as the onset or exacerbation of hydronephrosis after URSL. The chi-squared test was used to compare nominal variables, and Student's t-test was used to compare continuous variables between the two groups. Multivariate analysis was used to investigate factors (other than pre-stenting) that were predictive of ureteral injury. Logistic regression analysis was used to evaluate associations between ureteral injuries and predictive factors (age, sex, body mass index, preoperative urinary tract infection, and impacted stone presence). Statistical analyses were performed using BellCurve for Excel 3.20 (Social Survey Research Information Co., Ltd., Tokyo, Japan), and the significance level was set at  $p < 0.05$ .

## Results

Table 2 shows the overall and group-specific patient demographics. There was a significant difference in sex ratio between the two groups ( $p = 0.03$ ). No patients received  $\beta$ -agonists or  $\alpha$ -adrenergic antagonists.

Table 3 shows the overall and group-specific surgical outcomes. There were 21 (19.3%) cases of ureteral access sheath-related ureteral injury, including 11 (10.1%) grade 2 cases and 10 (9.2%) grade 3 cases. The ureteral injury location was the proximal ureter in 20 cases (18.3%), middle ureter in one case (0.9%), and distal ureter in 0 cases. Postoperative ureteral stricture did not occur in any cases.

Table 4 shows the factors predictive of ureteral access sheath-related ureteral injury. Multiple logistic regression analysis revealed that male sex was a significant predictive factor for ureteral injury ( $p = 0.045$ , odds ratio: 4.87, 95% confidence interval: 1.03–23.01).

## Discussion

To identify factors (other than pre-stenting) that were predictive of ureteral injury, we evaluated ureteral injuries caused by the insertion of a 13-Fr ureteral access sheath in non-prestented patients; we had three main findings. First, the rate of ureteral injury (grade  $\geq 2$ ) by a 13-Fr ureteral access sheath was 19.3%, which was considerable. Second, most ureteral injuries occurred in the proximal ureter. Third, male sex was a significant predictive factor for ureter injury, according to multiple logistic regression analysis. To our knowledge, there have been no reports concerning the incidence of ureteral injury caused by a 13-Fr ureteral access sheath. Although 13-Fr ureteral access sheaths are not very large in diameter, the risk of ureteral injury should be carefully considered. Furthermore, there have been no reports concerning the locations of ureteral access sheath-related ureteral injuries. Because most ureteral injuries occurred in the proximal ureter in our study, we recommend assessment of the ureteral wall with a flexible ureteroscope

at the end of URSL. Particular attention should be given to male patients, and it may be better to use a smaller diameter sheath during URSL in these patients.

Ureteral access sheaths have become popular because of their ability to access the upper lumen and evaluate any part of the kidney, repeatedly and rapidly enter the ureter and collecting system, improve drainage, improve visibility, reduce intrarenal pressure during pulse irrigation, protect the scope, and avoid ureteral lesions during stone fragment removal.<sup>7,8</sup> However, there have been some concerns about ureteral access sheath-related ureteral injuries.<sup>6</sup> Additionally, ureteral access sheath-related intraluminal compression of the ureter may compromise ureteral blood flow and cause secondary stricture.<sup>8-10</sup> Therefore, Breda et al.<sup>11</sup> considered the ureteral access sheath to be safe and useful, although its use is associated with some risks and limiting factors.

Traxer et al.<sup>6</sup> prospectively evaluated ureteral injuries by a 14-Fr ureteral access sheath using a new classification system; they found that the rate of high-grade (grade  $\geq 2$ ) injury was 13%. Furthermore, they reported that male, older, and non-prestented patients had greater risks of severe ureteral access sheath-related ureteral injuries. In a prospective randomized trial, Loftus et al.<sup>4</sup> found the rate of high-grade (grade  $\geq 2$ ) injury caused by a 14-Fr ureteral access sheath was 23.9%. Furthermore, they reported that male sex, high stone burden, longer sheath insertion time, and a more difficult subjective rating of sheath placement were associated with high-grade ureteral injuries. In the present study, the rate of high-grade injury was 19.3%. Because pre-stenting was not performed in our patients, whereas it was in the study by Traxer et al.,<sup>6</sup> our data was high than the data of Traxer et al. Furthermore, our data was low than the data of Loftus et al.<sup>4</sup> Because pre-stented patients were not included in the study by Loftus et al., we presumed that the difference in ureteral access sheath size led to the difference in results between studies (Loftus et al. used 14-Fr access sheaths, whereas we used 13-Fr access sheaths).

Some investigators have described ureteral access sheath-related ureteral injuries and the risk factors for such injuries. Traxer et al.<sup>6</sup> reported that the strongest predictor of severe ureteral injury was pre-stenting, whereas Tracy et al.<sup>12</sup> reported that use of a large-caliber (14/16-Fr) ureteral access sheath did not increase the risk of ureteral injury in a patient who was pre-stented. Thus, pre-stenting has been presumed to reduce the risk of ureteral access sheath-related ureteral injury.<sup>6,12,13</sup> However, several complications have been reported in relation to ureteral stenting, including incomplete emptying, bladder pain, frequency, hematuria, and migration. Additionally, ureteral stenting reportedly diminished urination-related quality of life in 80% of patients who underwent the procedure<sup>14</sup>. Accordingly, the American Urological Association and European Association of Urology guidelines recommend avoiding routine pre-stenting, although some methods to improve stent-related symptoms have been reported<sup>15-17</sup>. Thus, there is a need to investigate techniques that can reduce ureteral access sheath-related ureteral injury without pre-stenting. Loftus et al.<sup>4</sup> suggested that surgeons should have a low threshold for switching to a smaller sheath when resistance is encountered or if placement time is prolonged. In our multiple logistic regression analysis, we regarded sex, age, body mass index, impacted stone presence, and preoperative urinary infection as potential predictive factors for ureteral injury. Traxer et al. reported that sex and age might be

predictive factors for ureteral injury.<sup>6</sup> Therefore, we considered body mass index as a potential predictive factor; moreover, the presence of impacted stones and preoperative urinary infection may lead to ureteral wall weakening. Our results showed that male sex was a significant predictive factor for ureteral injury, according to multiple logistic regression analysis. Although this predictive factor has not been previously described, Traxer et al. suspected that ureteral injury is related to differences in sex hormones or to the higher tonic effect of the psoas muscle in male patients.<sup>6</sup> Thus, a smaller sheath may be preferable for URSL in male patients. However, the ureteral access sheath size should be carefully selected. The ureteral access sheath size was 14 Fr in the studies by Traxer et al.<sup>6</sup> and Loftus et al.,<sup>4</sup> whereas it was 13 Fr in our study. Therefore, a smaller sheath (e.g., 12 Fr or 11.5 Fr) may be more appropriate. Notably, Koo et al.<sup>18</sup> investigated the efficacy of preoperative  $\alpha$ -adrenergic antagonists to reduce the force of ureteral access sheath insertion. They concluded that preoperative  $\alpha$ -adrenergic antagonists and slow sheath placement may reduce the maximum force of ureteral access sheath insertion. The technique for ureteral access sheath insertion and the medication used during the procedure may also be important for reducing ureteral injuries during ureteral access sheath insertion.

This study had some limitations. First, it used a retrospective design. Second, long-term outcome data were not available for patients in this study. In future studies, we plan to investigate the relationship between ureteral injury and ureteral stricture. Third, this study used a non-randomized design and included only one comparison group. However, all patients were non-prestented patients who were presumed to require the use of a ureteral access sheath, and all patients underwent insertion of a 13-Fr ureteral access sheath. This approach may have reduced the potential for selection bias.

In conclusion, we evaluated ureteral injuries caused by the insertion of a 13-Fr ureteral access sheath. The rate of ureteral injury (grade  $\geq 2$ ) by a 13-Fr ureteral access sheath was 19.3%, and most ureteral injuries occurred in the proximal ureter. Furthermore, male sex was a significant predictive factor for ureteral injury, according to multiple logistic regression analysis. Although we recommend confirmation of a whole ureter, it is important to at least confirm the proximal ureter when using a 13-Fr ureteral access sheath, particularly in male patients.

## Declarations

**Funding:** Not applicable.

**Competing Interests:** None declared.

**Ethics Approval:** The study protocol was approved by our institutional review board (approval number: R03-0201). Informed consent was obtained from all participants included in the study. All methods were carried out in accordance with approved guidelines.

**Consent to Participate:** Informed consent was obtained from all participants included in the study.

**Consent to Publish:** Written informed consent for publication of their clinical data was obtained from each patient or their parent/guardian/relative, as applicable.

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## Tables

Tables 1 to 4 are available in the Supplementary Files section.

## Supplementary Files

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