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Complications of Flexible Ureteroscopic Treatment for Renal and Ureteral Calculi during the Learning Curve

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Key Words

Flexible transureterolithotripsy · Learning curve · Complication · Urolithiasis

Abstract

Background: The flexible ureterorenoscope (URS) and associated devices have developed rapidly. However, despite its therapeutic benefits, URS may be associated with some complications. To the best of our knowledge, there are no studies discussing the complications of flexURS during the learning curve. ***Methods:*** A retrospective review of the records of patients who underwent flexURS from January 2005 to June 2013 was performed. To compare the complications after the introduction of flexURS, patients were divided into four groups based on the surgeon's training experience, that is, based on the number of cases performed by the surgeon. A total of 219 cases underwent flexURS. Groups 1, 2, 3, and 4 included 35, 50, 50, and 84 cases, respectively. The complications were classified using the Clavien system (I–IV). ***Results:*** The mean operation time and stone-free rate were significantly different (p < 0.001, p = 0.013, respectively). The total complication rates were 13.6, 10, 8.3, and 3.2%, respectively (p = 0.068). The more the surgeon's experience, the less was the complication rate. Despite our best efforts, the incidence of urosepsis was not reduced (p = 0.902). ***Conclusions:*** To reduce severe complications, it is necessary to have performed about 100 cases. Increased surgeon experience tended to decrease the risk of severe complications, but the incidence of urosepsis was not reduced.

Introduction

The flexible ureterorenoscope (URS) and associated devices have developed rapidly. Flexible ureterorenoscopy (flexURS) has shown superior results to SWL [1]. The major advantage of flexURS is that it can reach all parts of the urinary tract. However, despite its therapeutic benefits, use of flexURS for renal and ureteral calculi may be associated with some minor or major complications. Use of a URS is the most common cause of ureteral injury [2]. To the best of our knowledge, several studies have report-

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ed the complications of flexURS for renal and ureteral calculi. However, there have been no studies of the complications of flexURS for renal and ureteral calculi during the learning curve, and the complications that might occur when flexURS is introduced for renal and ureteral calculi. The complications of flexURS for renal and ureteral calculi during the learning curve and complications that one needs to be aware of when flexURS is introduced for renal and ureteral calculi are described.

Materials and Methods

The records of patients who underwent flexURS for renal and ureteral calculi from January 2005 to June 2013 were reviewed retrospectively to determine their age at the time of the procedure, stone location, stone greatest diameter, sex, number of procedures, intraoperative complications, stone-free rate, and postoperative complications. To compare the complications after the introduction of flexURS for renal and ureteral calculi, the patients were divided into four groups by surgeon training and the number of procedures performed by the surgeon. Group 1 included procedures performed by multiple surgeon experience before training at a high-volume center (n = 35). After Group 1, a single surgeon was responsible for almost all the procedures of fragmentation and extracting the stones. Group 2 included the first 50 cases following training at a high-volume center (cases 36–85, n = 50). Group 3 included the next 50 cases (cases 86–135, n = 50). Group 4 included cases performed by a surgeon familiar with flexURS (cases 136–219, n = 84). A total of 219 cases underwent flexURS for renal and ureteral calculi. The total number of procedures in each group was 44, 60, 60, and 123, respectively. The complications were classified using the Clavien system (I–IV) [3].

Techniques

A 0.035″ guide wire was placed into the renal pelvis through the cystoscope under fluoroscopic guidance. For continuous saline irrigation, SAPS (single action pumping system, Boston Scientific) was used. A semirigid ureteroscope (SemiURS, 6Fr–7.5Fr, Richard Wolf GmbH) was inserted through a guide wire under fluoroscopic guidance. A SemiURS was used to observe the upper urinary tract. Based on the results of SemiURS observation, the size of the ureteral access sheath was selected. This examination is useful for recognizing ureteral strictures and preventing severe ureteral wall injuries during ureteral access sheath placement. If the SemiURS reached the level of the stone, the stone was then fragmented using a holmium-yttrium-aluminum-garnet (Ho-YAG) laser with a 200-mm laser fiber (AMS, Minnetonka, Minn., USA) or a LithoClast (Electromedical Systems, Kaufering, Germany). The stone fragments were completely extracted using a nitinol basket catheter (1.5F, NCircle, Cook Medical or 1.9F, Zero Tip Basket, Boston Scientific). When the SemiURS could not be inserted, a double-J stent was left, and the operation was completed. After about 2–4 weeks, a re-operation was performed. A ureteral access sheath (11.5F-16F, Cook Medical) was placed over a guide wire under fluoroscopic guidance. A flexURS (7.5Fr, Karl Storz) was inserted over it. All ureteral or renal calculi were observed and localized. The stone was then fragmented using a Ho-YAG laser with a 200-mm laser fiber. Stone fragments were extracted using a nitinol basket catheter. At the end of each procedure, the ureteral access sheath was removed along with the URS, and a double-J ureter catheter was left for 2–4 weeks.

Statistical Analysis

SPSS 20 for Windows (SPSS, Inc., Chicago, Ill., USA) and R statistical software were used for statistical calculations. Statistical analysis was performed using the non-parametric Fisher's exact test and the Kruskal-Wallis test. A p value <0.05 was considered significant, and a multiple comparison testing (Ryan test, Steel-Dwass test) was done.

Results

Comparison of patients' preoperative characteristics and operative parameters of the flexURS for renal and ureteral calculi.

As shown in table 1, there were no significant differences in patients' age (p = 0.613) and sex (p = 0.496), number of procedures (p = 0.496), stone size (p = 0.054), and stone location (0.059). However, the stone size and rate of renal calculi tended to be lower in Group 1 than in the other groups. The number of stones was significantly different (p = 0.001) among the groups; the number increased significantly from Group 1, 2, and 3 to Group 4 (Group 4 vs. Group 1 p < 0.001, Group 4 vs. Group 2 p < 0.001, Group 4 vs. Group 3 p < 0.001). The mean operation time was significantly different (p < 0.001); the mean operation time decreased significantly from Group 1, 2, and 3 to Group 4 (Group 4 vs. Group 1 p < 0.05, Group 4 vs. Group 2 p < 0.05, Group 4 vs. Group 3 p < 0.05). The stone-free rate was also significantly different (p = 0.013); it increased significantly from Group 1 to Group 4. (Group 1 vs. Group 4 p = 0.0083).

Details of Medical Complications of FlexURS for Renal and Ureteral Calculi during the Learning Curve

As shown in table 2, the total rate of complications (Clavien grading scale II–IV) was 13.6, 10, 8.3, and 3.2%, respectively, for Groups 1–4 (p = 0.068). The rate of complications tended to decrease gradually with increasing surgeon experience.

There were 12 cases (4.2%) of intraoperative complications, including mucosal injury (2 cases, 0.7%), ureteral perforation and avulsion (9 cases, 3.1%), and significant bleeding (1 cases, 0.4%). Ureteral perforation and avulsion occurred during stone extraction in 5 cases, during SemiURS insertion in 3 cases, and during Ho-YAG laser use in 1 case. Five cases were managed with double-J ureteral stent

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Table 1. Comparison of patients' preoperative characteristics and operative parameters of flexURS for renal and ureteral calculi

Group, %	Group 1	Group 2	Group 3	Group 4	Overall	p
Intra-operative complications	4 (9.0)	3 (5.0)	3 (5.0)	2 (1.6)	12 (4.2)	0.129
Mucosal injury	0	0	0	2 (1.6)	2 (0.7)	–
Significant bleeding	0	1 (1.7)[a]	0	0	1 (0.4)	–
Ureteral perforation or avulsion	4 (9.0)	2 (3.3)[b, c]	3 (5.0)	0	9 (3.1)	–
Early complications	1 (2.3)	0	1 (1.7)	2 (1.6)	4 (1.4)	0.902
Urosepsis	1 (2.3)	0	1 (1.7)	2 (1.6)	4 (1.4)	–
Late complications	1 (2.3)	3 (5.0)	1 (1.7)	0	5 (1.7)	0.636
Ureteral stricture	1 (2.3)[b]	1 (1.7)[c]	1 (1.7)[c]	0	3 (1.0)	–
Retained ureteral stents	0	2 (3.3)	0	0	2 (0.7)	–
Total	6 (13.6)	6 (10.0)	5 (8.3)	4 (3.2)	21 (7.3)	0.068

[a] Endoscopic cauterization was done. [b] 1 patient had to have a polyp removed with a Ho-YAG laser. [c] Psoas hitch had to be performed after fluoroscopically-guided balloon dilatation.

Table 2. Medical complications of flexURS for renal and ureteral calculi observed during the learning curve

Group	Group 1	Group 2	Group 3	Group 4	Overall	p
Period	January 2005 to March 2010	April 2010 to July 2011	August 2011 to July 2012	August 2012 to June 2013	January 2005 to June 2013	–
Number of patients	35	50	50	84	219	–
Mean age (range)	59.4 (9–87)	58.4 (6–86)	59.6 (33–88)	61.7 (21–90)	60.1 (6–90)	0.613
Number of men, %	15 (42.9)	25 (50)	28 (56)	48 (57.1)	116 (53.0)	0.496
Number of women, %	20 (57.1)	25 (50)	22 (44)	36 (42.9)	103 (47.0)	
Total number of procedures	44	60	60	123	287	
Number of procedures						
1	29 (82.9)	42 (84)	40 (80)	61 (72.6)	172 (78.5)	
2 or greater	6 (17.1)	8 (16)	10 (20)	23 (27.4)	47 (21.5)	0.496
Maximum mean stone diameter ± SD, mm	10.7±3.7	15.17±13.5	11.1±5.7	13.4±8.4	12.8±8.9	0.054
Stone location, %	59.43					
Renal calculi	13 (37.1)	29 (58)	31 (62)	53 (63.1)	126 (57.5)	
R2	7 (20)	27 (54)	24 (48)	42 (50.0)	100 (45.7)	
R3	6 (17.1)	2 (4)	7 (14)	11 (13.1)	26 (11.9)	
Ureteral calculi	22 (62.9)	21 (42)	19 (38)	31 (36.9)	93 (42.5)	
U1	5 (14.3)	7 (14)	8 (16)	15 (17.9)	35 (16.0)	
U2	3 (8.6)	6 (12)	2 (4)	4 (4.8)	15 (6.8)	
U3	14 (40)	8 (16)	9 (18)	12 (14.3)	43 (19.6)	0.059
Number of stones, %						
Single	26 (74.3)	36 (72)	32 (64)	27 (32.1)	121 (55.3)	
Multiple (2 or greater)	9 (25.7)	14 (28)	18 (36)	57 (67.9)	98 (44.7)	<0.001
Mean operation time ± SD, min	135.2±70.5	149.8±69.1	114.4±44.7	88.6±47.7	113.9±61.1	<0.001
Stone-free rate, %	80	88	96	96.4	91.8	0.013

insertion and were well controlled (fig. 1). Four cases required additional treatments after the procedure. Ureteral strictures occurred in 3 cases, for which fluoroscopically-guided balloon dilatation was performed. A polyp was resected with the Ho-YAG laser in 1 case (fig. 2). Significant bleeding occurred when the Ho-YAG laser was used to irradiate a renal calyx penetrating stone (fig. 3). Endoscopic cauterization was done, and bleeding was controlled significantly. In 6 cases, the SemiURS and ureteral access sheath could not be inserted. The procedures were finished,

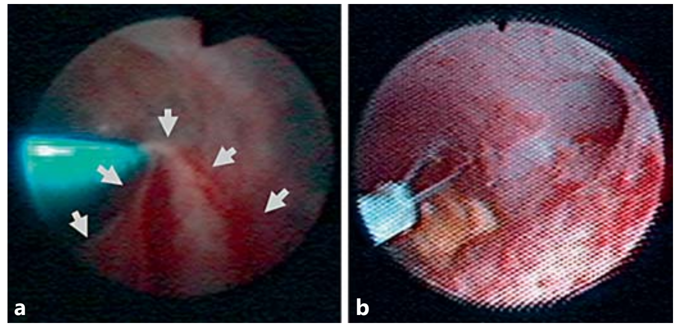

Fig. 1. Ureteral avulsion involving the full thickness of the ureteral wall, including the adventitia, is recognized during stone fragment extraction. The ureteral wall is indicated by the arrows. The periureteral fat or retroperitoneal tissue is seen outside of the ureteral wall (**a**). One month later, the stone was easily extracted without ureteral stricture (**b**).

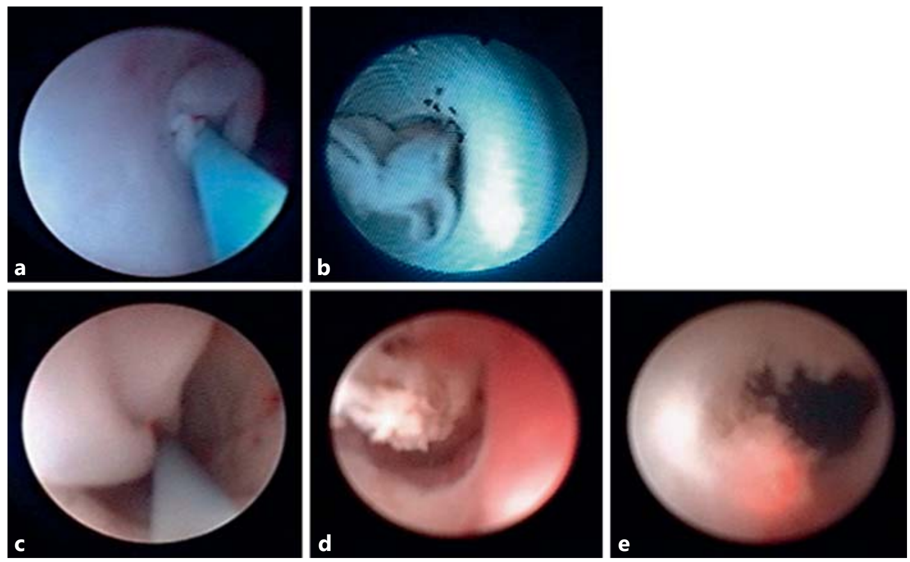

Fig. 2. The semiURS was inserted with excessive force, and the semiURS is trapped in the ureter and ureteral avulsion has occurred (see figure 4). A mucosal flap without smooth muscle injury is observed (**a**, **b**). A double-J ureteral catheter was placed, and 2 months later, URS shows a ureteral polyp. To remove the polyp, a flexible ureteroscope with a Ho-YAG laser was used. A guide wire was placed over the polyp (**c**). The base of the polyp was ablated with a 200-mm laser fiber at 6 W (power level 0.6 J, frequency 10 Hz) (**d**). The polyp has been removed from the ureter with a basket catheter (**e**).

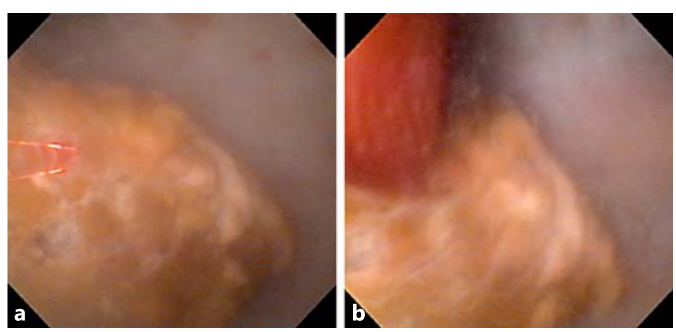

Fig. 3. The renal stone is irradiated by the Ho-YAG laser (**a**). A renal calyx penetrating stone is irradiated by the Ho-YAG laser. Significant bleeding can be seen (**b**).

and only a double-J stent was left. After 2–4 weeks, all patients underwent procedures without any problems.

There were 4 cases (1.4%) of early complications, which included urosepsis. These complications were all treated with conservative therapy. Despite our best efforts, the incidence of urosepsis was not reduced ($p = 0.902$). There were 5 cases (1.7%) of late complications, including ureteral stricture (3 cases, 1.0%) and retained ureteral stent (2 cases, 0.7%). The ureteral strictures were treated with fluoroscopically guided balloon dilatation in all cases. However, a psoas hitch had to be performed in 1 case, and 2 retained, encrusted ureteral stents were removed with the flexURS.

Discussion

The advantage of flexURS is that a flexible ureteroscope can reach all parts of the urinary tract, including the kidney, leading to the development of smaller-diameter scopes with increased flexibility, coupled with a greater angle of deflection of the scope and improved optics, which in turn has led to the ability to visualize and treat stones [1, 4–6]. Advances in laser technology led to the development of the Ho-YAG laser, which provides effective and efficient intracorporeal lithotripsy for hard stones. The treatment approach to ureteral and renal calculi has involved the use of retrograde URS as first-line treatment [7].

Furthermore, URS and a Ho-YAG laser can also be used to treat upper urinary tract tumors [6, 8]. The basket catheter should be flexible, durable, and have minimal impact on fluid inflow and tip deflection, such as the Cook N-Circle or Zero Tip nitinol basket catheter [9, 10]. We have performed flexURS for renal and ureteral calculi since January 2005, but flexible ureteroscopes and associated devices have improved rapidly, as described above. Most urologists would agree that ureteroscopes are safe when used in the right way [11, 12]. High volume center was not defined clearly in other literatures, but Hachinohe Heiwa Hospital has performed more than 300 cases per year. So according to our understanding, Hachinohe Heiwa Hospital is a high-volume center of flexible TUL. Thus, in March 2010, we participated in lectures and a hands-on medical training program to learn about the new medical equipment and to learn the proper, safe, and effective use. We then evaluated the introduction of flexURS for renal and ureteral calculi following a training program at a high-volume center during the learning curve.

According to our study, the stone-free rate was significantly increased and the mean operation time was significantly reduced with increasing surgeon experience. Much time was required for repeated insertion and withdrawal of the ureteroscope; however, the maximum time was needed only to reach the stone fragments. If one can shorten the time to reach the stone fragments, the operative time can be greatly reduced. To reach the stone fragments quickly, a surgeon requires knowledge of the ureteral structures and excellent operating technique and experience. These techniques, knowledge, and experience contribute to a high stone-free rate. However, the mean operative time increased from Group 1 to Group 2, likely because Group 2 had a higher rate of renal calculi than Group 1 (table 1).

The rate of complications tended to decrease gradually with increasing surgeon experience. This shows how important it is for the surgeon to gain experience and enhance his knowledge on the various complications that could arise. In the present study, severe complications tended to decrease in Group 4. Thus, in order to perform a safe operation, it is necessary for a surgeon to have performed about 100 cases after attending a hands-on medical training program at a high-volume center.

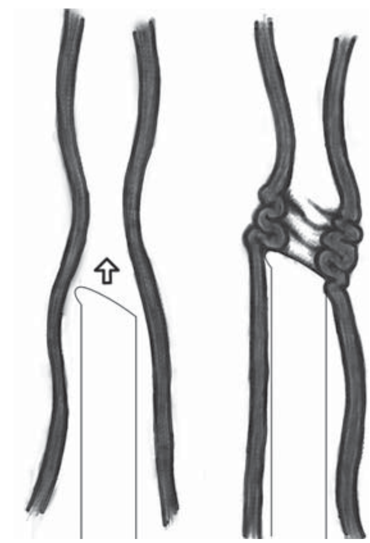

Fig. 4. Semirigid ureteroscope or a ureteral access sheath is trapped in the ureter. If inserted with excessive force, ureteral avulsion can occur.

The most severe complication of URS is ureteral avulsion. The diagnosis of ureteral perforation or avulsion is most often made immediately during the procedure. When a SemiURS or a ureteral access sheath is inserted, the ureteral mucosa and wall can be extended to a variable degree. The SemiURS or a ureteral access sheath can become trapped in the ureter, and if inserted with excessive force, ureteral perforation or avulsion will occur (fig. 4). According to our study, the SemiURS and ureteral access sheath could not be inserted in 6 cases. The procedures were completed but only a double-J stent was left. After 2–4 weeks, all patients underwent procedures without any problems. Cetti et al. reported that 8.4% were pre-stented because of failed access, without complication, and subsequently had successful interval treatment [13]. Passive dilation of the ureter for failed access is a beneficial technique with no associated complications. We believe that when we cannot insert a SemiURS and ureteral access sheath, the best approach is to leave a stent for passive dilation, and the procedure should be completed with that. Then, 2–4 weeks later, the procedure can be performed again.

It is also necessary to be careful when extracting the stone fragments. When the diameter of the stone is larger than that of the ureter, the stone can be trapped in the

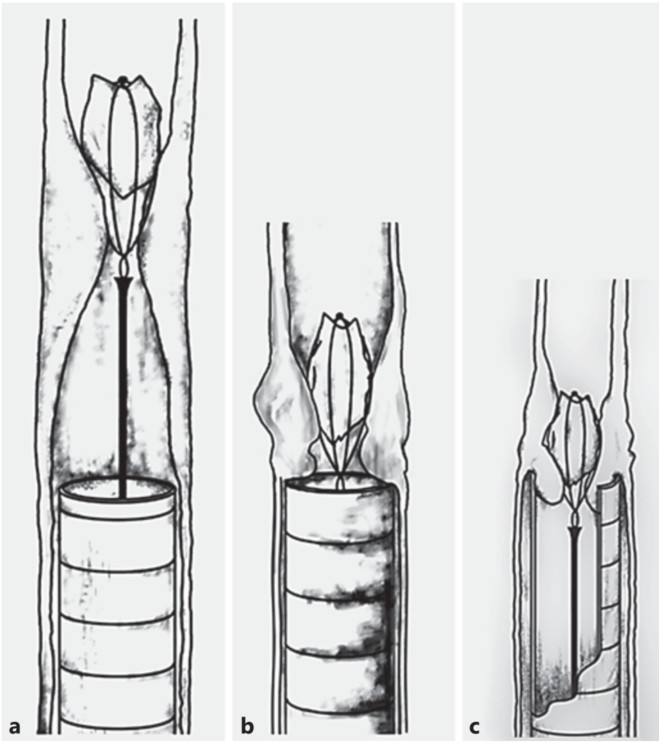

Fig. 5. a When the diameter of the stone is larger than the ureter, the stone is trapped in the ureter. **b** If the stone is trapped in the ureter, extracting the stone with excessive force can lead to iatrogenic injury to the ureter. **c** The ureter is more easily damaged by getting caught between the stone and the ureteral access sheath.

ureter. If the stone is trapped in the ureter, extracting the stone with excessive force can potentially lead to iatrogenic injury to the ureter. Furthermore, the ureter is more easily damaged by being caught between the stone and a ureteral access sheath (fig. 5). When the stone cannot be extracted, the stone is often trapped and caught in a ureter or a ureteral access sheath. Then, endoscopic evaluation should be performed to determine whether the stone can be extracted from the ureter. The size of the stone can be continually compared with the size of the ureteral lumen [14]. If the stone cannot be extracted, the stone has to be fragmented with the laser.

The treatment of ureteral perforation or avulsion is double-J ureteral stent insertion. If we cannot place the double-J catheter, the traditional treatment is a surgical approach. Subsequent ureteral reconstruction techniques depend on the location of the injury and the amount of viable ureter that remains. According to the amount of viable ureter, creation of an ileal ureter, renal autotransplantation, ureteroureterostomy, psoas hitch, Boari flap, or nephrectomy have to be performed [14]. To reduce these complications, the surgeon's experience and knowledge are paramount. Given the results of the present study, to reduce ureteral perforation or avulsion, it is necessary for the surgeon to have performed about 100 cases after participating in a hands-on medical training program at a high-volume center.

Early complications included urosepsis (1.4%). These complications were all treated with conservative therapy. Urine culture is mandatory for all patients before URS. Perioperative antibiotics can be appropriately tailored to culture-specific organisms. Ureteral access sheaths are useful adjuncts to URS that allow safe, repeated insertion and withdrawal of a ureteroscope [15, 16]. Access sheaths also allow for continuous irrigation of the renal pelvis and improved stone clearance, as well as lower renal pelvic pressures that may be protective against pyelovenous and pyelolymphatic backflow [17, 18]. Therefore, we have to be aware of irrigation solution discharge from the ureteral access sheath to prevent fever or urosepsis. Despite our best efforts, the incidence of urosepsis was not reduced with experience ($p = 0.902$); it occurred at a fixed frequency. According to the results of the present study, the rate of severe complications decreased from Group 1 to Group 4, with the exception of urosepsis. To avoid severe complications, with the exception of urosepsis, it is necessary to perform about 100 cases after a hands-on medical training program at a high-volume center.

Conclusions

In conclusion, surgeons have to be aware of the complications of flexURS. When performing flexURS for renal and ureteral calculi, we should always bear in mind the possibility of serious complications and their management strategies. FlexURS for renal and ureteral calculi was safely introduced after a training program in a high-volume center. According to the present study, to reduce severe complications such as ureteral perforation or avulsion, it is necessary for the surgeon to have performed about 100 cases after being part of a hands-on medical training program at a high-volume center. Increased surgeon experience tends to decrease the risk of complications, but the incidence of urosepsis was not reduced. In fact, urosepsis occurred at a fixed frequency.

Disclosure Statement

No competing financial interests exist.

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