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A prospective trial on ureteral stenting combined with secondary ureteroscopy after an initial failed procedure

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Abstract The aim of this study is to investigate the impact of the intentional ureteral stenting on the success rate of calculus extraction by second ureteroscopy, when the initial ureteroscopy failed. We prospectively enrolled 512 patients with ureteral calculi who underwent ureteroscopies from April 2005 to May 2011. The patients with failed initial ureteroscopies were classified into two groups depending on the stent type: the Double-J stent and the ureteral catheter group. The secondary ureteroscopies were performed in a short period (3-22 days). Data were abstracted on stone size, location, patient demographics, outcome and complications. A total of 453 patients had success after the initial ureteroscopy and the success rate was 88.5 %. Of the 59 failed patients, 40 were managed by reureteroscopy with Double-J stent placement and 19 with ureteral catheters. There were no statistically significant differences between patients in Double-J stent and ureteral catheter group in the aspects of age, primary stone size, gender, stone location and stone-free rate [39/40 (97.5 %) versus 19/19 (100 %), p > 0.05]. Moreover, the mean stents retaining period before the second ureteroscopy was significantly shorter in the ureteral catheter group, when compared with the Double-J stent group (3.9 versus 16.9 days, p < 0.01). The complications were moderate and not significantly different between the two groups (p > 0.05). Indwelling a ureteral stent leads to a high subsequent success rate for second ureteroscopy following

an initial failed procedure. In addition to Double-J stent, the ureteral catheter stent was an effective alternative with shorter retaining period, especially for impacted stones.

Keywords Ureter · Stent · Ureteroscopy · Urolithiasis

Introduction

Ureteral stone disease is one of the most prevalent and painful urologic disorders [1]. Since Hugh Hampton Young first passed a rigid ureteroscope (URS) into a dilated ureter in 1912, the field of URS has developed considerably. URS is becoming one of the most popular treatment options for patients with urolithiasis over the past 20 years [2]. Traditionally, stents were applied for drainage or splinting following ureteroscopy, ureteric injury, ureteric surgery, or extracorporeal shock wave lithotripsy (ESWL) [3]. It was also suggested that indwelling ureteral stents were a definitive therapy for distal ureteral calculus [4].

Statistical data showed that in about 10–15 % of the cases, the first URS was unsuccessful and URS was performed two or more times [5]. Flexible ureteroscopes were able to reach the entire urinary system and were more effective for proximal ureteral stones [6]. However, flexible URS equipment was relatively expensive and the flexible fiber optics required frequent repairs [7], and was not widely used in China. Shields et al. [5] and Rubenstein et al. [8] suggested that the preoperative ureteral stenting was associated with improved stone-free rates and had few complications. Chu et al. [9] presented that the pre-stenting is cost-effective for patients with stones >1 cm. But for those with stones <1 cm, pre-stenting increased the healthcare cost of URS.

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However, routine stent placement is not necessary before all ureteroscopic procedures. Jones et al. [10] proposed that the insertion of a double pigtail stent was associated with a higher subsequent success rate for stone removal by reureteroscopy following an initial failure. Actually, when an impacted stone prevented the passage of the guide wire, it was relatively difficult to indwell the double-J stent.

Based on our experience, we proposed that open-ended ureteral catheters might benefit in cases of impacted ureteral stones. Thus, we designed a study that included patients who underwent URS at our center. At the time of initial failure, a Double-J stent was indwelled or a 6-F ureteral catheter was indwelled for impacted stones. Then, secondary URSic procedure was attempted in a short period (3–22 days) after stent placement. We analyzed the profiles of patients who underwent URS in our center and compared the safety and efficacy of these two ways for stents

Materials and methods

Criteria

A prospective study was performed between April 2005 and May 2011. All patients were evaluated with an ultrasonography and a plain film of kidneys, ureter, and bladder (KUB). An intravenous pyelogram and noncontrast computed tomography (CT) were performed, if necessary. According to the Diagnosis and Management Guideline of Urolithiasis from the Chinese Urological Association (CUA), the protocol eligibility criteria for URS is: Midureteral and distal stones >10 mm or stones ≤10 mm without improvement in 2 weeks under conservative treatment; ESWL failed proximal stones and the ureteral steinstrasse after ESWL. Patients with renal calculi and those treated as a part of percutaneous procedures were not included in the analysis. Once the decisions to perform URS were made, patients were offered entry into the study after signing an institutional review board approved informed consent.

In the analysis, patient data were stratified by age, gender, stone size, stone location (proximal, mid, and distal ureter), retention period of their stents, number of procedures performed, stone-free rate, and complications of treatment. Economic effects were not examined. The "mid" was defined as the part of the ureter that overlies the bony pelvis, i.e., the position of the ureter that corresponds to the sacroiliac joint; the proximal ureter is above and the distal ureter is below. Stones were defined as impacted if they were surrounded by excessive mucosal edema that

caused high-grade ureteral obstruction and did not allow the ureteral catheter to pass.

Study protocol

All the patients received combined spinal-epidural anesthesia. A single surgeon (Weidong Gan) performed ureteroscope lithotripsy using an 8-9.5F rigid ureteroscope (Storz, Tuttinggen, Germany) and pneumatic lithotripter (Swiss Lithoclast® EMS, Switzerland). When it became difficult to extend the ureteroscope, an 18 Fr-4 cm balloon dilator (UromaxTM, Boston Scientific, USA) was applied for 3 min at the narrow point or the ureteral orifice to facilitate a passage of the ureteroscope. If the ureteroscope still could not be advanced, a 5-F Double-J ureteral stent (Urovision GmbH, Bad Aibling, Germany) placed over a 0.032 in. guide wire (Nitinol-black and white, OptiMed, Ettlingen, Germany) was inserted with fluoroscopic and ureteroscopic assistance. The secondary ureteroscopic procedure was attempted 2-3 weeks later. If an impacted stone prevented the passage of a guide wire, a 6-F openended ureteral catheter (Shagong Corp., Zhangjiagang, China) was inserted into the ureter about 1 cm below the stone and an 18-F Foley catheter was placed into the bladder. The ureteral catheter was bonded to the Foley catheter to prevent it from falling out. The ureteroscopic procedure was attempted again in 3-5 days.

Secondary ureteroscopy was performed after removal of the Double-J ureteral stent or catheter and the Foley catheter. The subsequent ureteroscopic lithotripsy was the same as a successful initial procedure. At the end of the procedure, a new Double-J stent was placed in all patients for a minimal period of 2 weeks.

Follow up

The patients were followed in our out-patient clinical center after ureteroscopy. All patients underwent KUB on the first day after URS treatment. "Stone free" was defined as having no residual fragments. At a follow-up visit 3 months later, intravenous urography (IVU) and CT were performed to assess any residual fragments or strictures.

Statistics

Statistical analyses were performed using SPSS V. 17.0 (SPSS, Chicago, IL). The two-sided Fisher's exact test and two-tailed Student's t test were used to compare clinical characteristics and treatment outcomes between patients with successful initial URS and those with a second URS, as well as between the Double-J ureteral stent group and the ureteral catheter group. A p value < 0.05 was considered statistically significant.



Results

A total of 512 patients with ureteric calculi underwent ureteroscopy in our center during the study period (Fig. 1). The majority of the initial procedures were successful (453 [88.5 %] patients). The other 59 (11.5 %) patients underwent a second ureteroscopy, when the initial treatment failed to produce the desired results. Reasons for the failure of the initial procedure included a narrow ureteral orifice (11 patients), difficulty in passing the vessels (43 patients), and poor visualization due to bleeding and narrow ureteral lumen (five patients).

The 59 patients with failed initial ureteroscopies were further enrolled into two groups according to two study protocols:

40 (67.8 %) cases were treated with Double-J stents with passage of a guide wire; and

19 (32.2 %) cases were treated with ureteral catheters because impacted stones prevented the passage of a guide wire.

Overall, patients with an initial failure with URS in this study had a mean age of 46.5 years (range 22–80 years), and 57.6 % were men (Table 1). For the Double-J stent group, the mean age was 46.9 years (range 22–80 years), and for the ureteral catheter group, it was 45.6 years (range 25–73 years). The average age and sex ratio were similar between the Double-J stent and ureteral catheter groups.

There were 31 (52.5 %) out of 59 cases with stones on the left side, 52.5 % for the Double-J stent group, and 52.6 % for the ureteral catheter group. The patients with an initial failure of URS had calculus stones with a mean size of 14.5 mm (range 8–24 mm), 14.1 mm in the Double-J stent group and 15.6 mm in the ureteral catheter group. The

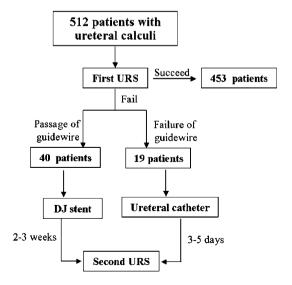


Fig. 1 Trial profile

Table 1 Patient characteristics and clinical data

	Double-J stent	Ureterl catheter	Total
Patients (n)	40	19	59
Mean age (year) ^a	46.9 (22–80)	45.6 (25–73)	46.5 (22–80)
Men/women	23/17	11/8	34/25
Stone side (n)			
Left	21	10	31 (52.5 %)
Right	19	9	28 (47.5 %)
Stone location (n)			
Proximal	19	7	26 (44.1 %)
Middle	12	10	22 (37.3 %)
Distal	9	2	11 (18.6 %)
Stone size (n)			
<10 mm	2	0	2 (3.4 %)
10–15 mm	27	6	33 (55.9 %)
>15 mm	11	13	24 (40.7 %)
Mean stone size (mm) ^a	14.1 (8–24)	15.6 (11–19)	14.5 (8–24)
Mean period for retaining stents (days) ^b	16.9 (14–22)	3.9 (3–5)	13.1 (3–22)
Stone-free rate ^c	39/40 (97.5%)	19/19 (100%)	58/59 (98.3%)
Complications $(n)^{c}$	2	1	3
	irritative urinary symptoms; stent- related flank pain	bladder spasms	(5.1 %)
Average time to follow-up imaging (days) ^a	94.5 (78–112)	91.6 (81–106)	93.6 (78–112)

 $^{^{\}mathrm{a}}$ p > 0.05 Double-J stents group versus ureteral catheter group (Student's t test)

mean stone sizes were similar in the two groups, as well as the stone side (p > 0.05). Nine (22.5 %) cases presented distal stones in the Double-J stent group, and 2 (10.5 %) cases presented distal stones in the ureteral catheter group. Because the placement of ureteral catheter and Foley catheter may cause inconvenience to the patient and have the potential to lead to infection, we tend to remove them without delay. In general, the ureteral catheters were kept for 3–5 days. The mean period for retaining stents in the



 $^{^{\}mathrm{b}}$ p < 0.01 Double-J stents group versus ureteral catheter group (Student's t test)

 $^{^{\}mathrm{c}}$ p>0.05 Double-J stents group versus ureteral catheter group (Fisher's exact test)

ureteral catheter group was significantly shorter than that in the Double-J stent group (3.9 \pm 0.7 versus 16.9 \pm 2.2 days; p < 0.01).

There was high rate of successful application for secondary ureteroscopy after the Double-J stent and ureteral catheter placement. All the patients (19/19, 100 %) in the ureteral catheter group, and 39 of 40 (97.5 %) patients in the Double-J stent group had access to secondary ureteroscopy. There was no significant difference in success rates of secondary ureteroscopy between the two groups (p > 0.05).

The patient suffering from a second failure of URS in the Double-J stent group was a 42-year-old woman, with a 16 mm mid ureteric stone. The success rate of the subgroup of mid ureteral stone was 91.7 % (11/12), compared to the 100 % success rate of the distal (19/19) and proximal (9/9) subgroups (p=0.302). The success rate of the subgroup with stone sizes >15 mm was 88.9 % (8/9), compared to the 100 % success rate of stone sizes <10 mm (2/2) and 10–15 mm (29/29) subgroup (p=0.171).In the case where both procedures were unsuccessful, the ureteroscopy failed to pass through the narrow ureter vessel to the level of the calculus. The patient refused a third ureteroscopy, and laparoscopic ureterolithotomy was performed 3 days after the procedure.

Three cases of complication were reported during the period for retaining stents (Table 1). According to the Clavien Classification of Surgical Complications, all 3 (5.1 %) complications were Grade I, which were tolerated and did not need anticholinergic or other further treatments. Two complications in the Double-J stent group were irritative urinary symptoms and stent-related flank pain, while the one in the ureteral catheter group was bladder spasm.

After a follow-up period of about 3 months, all 58 patients with successful secondary ureteroscopy underwent IVU and CT scans. The results showed that there were no residual fragments or strictures. The average time between the secondary ureteroscopy and the follow-up imaging was 94.5 days in the Double-J stent group, and 91.6 days in the ureteral catheter group.

Discussion

Ureterorenoscopy is effective for ureteral and renal calculi, and high success rates have been reported. A systematic review by Rubenstein et al. [8] showed that the ureteroscopic removal of ureteral stones achieves a higher stone-free rate (SFR) than ESWL. However, further studies showed that around 15 % of the cases had unsuccessful initial ureteroscopies. Shields et al. [5] reported that the rate of first failure was 14.6 %. In our study, 88.5 % patients underwent successful initial ureteroscopies, while

11.5 % were not successful. Several factors were associated with these outcomes of unsuccessful procedures, including symptomatology present for more than 3 months, a positive history of ureteral surgery, stones above the ischial spine, stones >5 mm in width, a dilated proximal ureter, and kidneys that failed to excrete contrast medium [11].

Considering the patients with unsuccessful initial ureteroscopies, some salvage procedures have been investigated to improve the therapeutic outcome for these patients. Aynehchi et al. [12] demonstrated that ESWL was an effective treatment, and 87 % of the patients had their stones dissolved after one ESWL session, when they failed initial ureteroscopy. ESWL is minimally invasive, can be done on an outpatient basis, and is suggested as a salvage procedure for patients with unsuccessful ureteroscopic treatments. However, its one time stone-free rate is not as high as ureteroscope lithotripsy and further sessions of ESWL are often needed [13]. Ureteroscopy was significantly better in terms of shorter operation time, fluoroscopy time, and time to achieve a stone-free status [14]. Thus, a second ureteroscopy combined with intracorporeal lithotripsy might be a better option for these patients [15].

In the past decade, improvements in the techniques and instruments have significantly enhanced the success rate of ureteroscopy. With some newer, smaller rigid or flexible endoscopic instruments, ureterolithotomy could be chosen for patients after unsuccessful endourological procedures [16]. However, the flexible URS equipment is relatively expensive and the flexible fiber optics require frequent repairs [7], and is not that widely used in China. The flexible ureteroscopy and laser lithotripter were not available in our center during the period of this study. A vast majority of the patient population (58/59 [98.3 %]) who would otherwise have ureterolithotomy after an unsuccessful uteroscopy, were rendered stone free with secondary ureteroscopy.

Insertion of a stent is known to cause ureteric dilatation, and was first proved in 1934 by Wiseman [17]. Shields and co-workers [5] analyzed 221 initial ureteroscopic procedures, and concluded that the success rate was positively related to a pre-existing ureteral stent, although not significantly so. They suggested routine stenting is not necessary before all ureteroscopic procedures for urinary stone disease. Rubenstein and colleagues [8] presented 90 patients who underwent ureteroscopic surgery on 115 renal units; the stone-free rate was 47 % in the 79 procedures without previous stents, compared with 67 % in the 36 procedures with stents (p < 0.05). They also concluded routine stent placement is not necessary, but prestenting is associated with good stone-free rates and few complications, especially in challenging cases. Jones et al. [10] reported that a pre-existing stent may improve the success



rate of a subsequent ureteroscopy. The mechanism by which the dilatation effect occurs has not been elucidated, and possible explanations include physiological relaxation and direct cytotoxic effects [18]. Singal et al. [15] presented their experience with performing salvage ureteroscopy following a previously unsuccessful attempt at endoscopic stone removal, and the stone-free rate of secondary ureteroscopy reached 95 %. They emphasized the importance of stent placement after a failed attempt at ureteroscopy and suggested that placing a ureteral stent following failed ureteroscopy might not only provide urinary drainage but also make subsequent ureteric instrumentation much easier.

The stent indwelling time used to range from 2 to 4 weeks [5, 10, 15, 19]. In our group, the mean time in the Double-J stent group was around 16.9 days, which was similar to the data published. As for the ureteral catheter group, it was difficult to maintain such a long retaining period, since patients tend to have more feelings of discomfort relative to ureteral and Foley catheters, and often required expedited treatment. We proposed to retain the stents 3-5 days; the average time was 3.9 days. The minimal indwelling time was only 3 days. Impressively, the success rate of the second ureteroscopy was similar between the two groups, as well as the low complication rate. The ureteral catheter group might benefit better when compared with the Double-J stent group, with shorter hospitalization time and lower cost. One of the limitations of this study relates to the morbidity of stent placement and ureteral catheter was not assessed in a more standardized fashion, i.e., with the Bristol Symptom Score [20], which should be applied in our future research and clinical practice.

Spontaneous passage of the stone was not noted in the current study, partly because of the relatively large sizes of the stones (minimum 8 mm). An unsuccessful initial ureteroscopy and the resulting ureteral edema might also portend an unsatisfactory outcome with spontaneous passage. In addition, the in situ stent is likely to cause mechanical obstruction to passage of the stone, reducing the antegrade pressure in the ureter and inhibiting ureteric peristalsis [3].

Conclusion

Our results show that indwelling ureteral stents after the unsuccessful first ureteroscopy facilitate the passage of the second ureteroscopy and subsequent extraction of the calculus. In addition to the Double-J stent, the ureteral catheter was firstly recommended as the effective alternative procedure, especially for those with impacted stones. Moreover, the success rate was similar between the ureteral

catheter group and the Double-J stent group, and the former was kept only around 3 days. Since it is a small sample report, further studies are needed to systemically evaluate ureteral stents as the salvage procedure, especially the ureteral catheter, which might be a new application in ureteral stone diseases.

Conflict of interest The authors declare that they have no conflict of interest.

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