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Self-expanding metal ureteral stent for ureteral stricture: Experience of a large-scale prospective study from a high-volume center - Cross-sectional study

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ABSTRACT

Background: The management of ureteral stricture is still a challenge for urologists. The aim of this prospective study was to assess the safety and effectiveness of self-expanding metal ureteral stents (URS) in ureteral strictures.

Methods: We performed URS placement procedures for ureteral stricture from Jan 2019 to July 2020, and prospectively collect various data before and after the operation. A paired T test was used to compare continuous variables before and after surgery, binary logistic regression analysis was used to identify the independent risk predictors of surgical failure.

Results: A total of 147 patients with 157 renal units received successful placement of URS. The mean operative time was 70.0 min. After a median follow-up time of 15 months, 73.2% (115/157) of stents were kept in situ. The most common complication was hematuria (13, 8.8%), followed by urinary tract infection (11, 7.5%) and pain (8, 5.4%). The volume of hydronephrosis (67.9 ± 34.9 VS 34.9 ± 51.1 cm^3, $P = 0.0001$), serum creatinine level (103.0 ± 54.5 VS 93.8 ± 45.1 μmol/L, $P = 0.034$) and blood urea nitrogen level (6.6 ± 6.7 VS 5.4 ± 2.4 mmol/L, $P = 0.032$) decreased significantly at last follow up when compared with baseline. Stricture of the distal ureter was an independent risk factor for stent failure (HR 1.77, 95% CI 1.15, 2.73, $P = 0.009$).

Conclusions: URS was found to be safe and effective for ureteral strictures with a limited complications and good long-term results. For those who are not suitable for surgical reconstruction, the URS is an alternative management.

1. Introduction

The treatment of ureteral stricture is still a challenge for urologists. For those unsuitable for reconstructive surgery, percutaneous nephrostomy tubes (PNTs) or double-J stents routinely applied to relieve the upper ureteral obstruction [1]. However, PNTs may cause skin erosion, urinary tract infection and tube obstruction, which negatively affects the quality of life [1,2]. Although the success rate of double-J stent insertion is high, the stent-changing is required every 3–6 months, which brings considerable inconvenience and costs to patients [3]. Thus, a novel procedure is needed to relieve the ureteral obstruction, and overcome the aforementioned shortcomings at the same time.

To answer the calls, the self-expanding, coated metal ureteral stent (URS) (Allium, Allium LTD, Israel) has been introduced in the treatment of urinary tract stricture [3]. This kind of stent has been proved safe and effective in small-scale studies [3,4]. However, no study had reported its use in a large population, especially in Chinese. Therefore, we conducted a single-center large-scale prospective study in a high-volume center to assess the safety and effectiveness of Allium stents in ureteral strictures caused by various etiologies.

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2. Method

2.1. Study population and data

This study was reported in line with the STROCSS criteria [5]. The inclusion criteria were patients with clinically diagnosed ureteral stricture and the patient's age was over 14 years old. Exclusion criteria include patients with severe urethral stricture, difficult to insert an endoscope, and unable to perform surgery; Uncontrolled acute and chronic inflammation of the genitourinary system; Severe hematuria, which may make it difficult to observe the visual field under endoscopy; Pregnant women or women with menstrual periods; Patients with severe systemic diseases who cannot tolerate anesthesia or surgery.

All patients were informed of the risks of surgery and signed consensus were obtained. From January 2019 to July 2020, 150 patients with ureteral stricture received Allium URS placement in our hospital. Three patients were lost to follow-up, and 147 patients were finally included in this study. Demographic characteristics, operative parameter, complications and outcomes were collected, including sex, age, body mass index, side, etiology, site and length of stricture, hydronephrosis volume, norm GFR (glomerular filtration rate) of the affected kidney, serum creatinine and urea nitrogen levels, operative time, complications, length of hospital stay, symptoms with stents, and hospital costs. The hydronephrosis volume was calculated based on computed tomography (CT): hydronephrosis volume = length * width * depth * 0.523 [6].

2.2. Surgical technique

All operations were performed by the same skilled urologist. URS insertion was performed in the lithotomy position under general anesthesia. A rigid cystoscope was inserted into the bladder, and the guide wire was retrogradely inserted into the obstructed ureter. The location and length of the ureteral stricture was determined by retrograde or anterograde radiography (if the patient had a nephrostomy tube) or both under fluoroscopic guidance. Then, a 6 cm ureteral balloon dilation catheter was inserted into the obstructed site, and the stricture was diluted up to 25 atm for 3 min.

If the stricture was longer than 6 cm, it was dilated from top to bottom several times. After confirming that the narrowed segment was dilated satisfactorily under fluorescence, an 8F/10F-coated metal ureteral stent delivery system was inserted along the guide wire. Then, the metal-coated URS was released in the narrowed ureter under fluoroscopy. When the stent was released satisfactorily, radiography was performed again to confirm the stent position and ureteral patency.

For patients with ureteral atresia, the scar tissue of the atresia segment is incised by holmium laser endotomy under the guidance of the ureteroscope, and then the guide wire is inserted retrogradely. Then the ureter dilation and stent were placed as described before.

2.3. Follow-up protocol

Routine follow-up items included blood test, urine test, CT of abdomen, serum creatinine and urea nitrogen at first month after surgery and every 3 months thereafter. Single-photon emission CT (SPECT) was only rechecked in first month to evaluated the renal function of the affected kidney. Symptoms related to stents were recorded during follow-up. Surgical failure is defined as increased hydronephrosis or deterioration of renal function because of stents migration, occlusion or encrustation.

2.4. Statistical analysis

Continuous variables were expressed as mean ± standard deviation, and categorical variables were described by frequency (proportions). Paired T test was used to compare continuous variables before and after surgery. Binary logistic regression analysis was used to find the risk factors of surgical failure. Multivariate analysis was performed when univariate analysis finds $p < 0.05$. All statistical analysis was performed on SPSS software version 22.0, and $p < 0.05$ indicated statistically differences.

3. Results

One hundred forty-seven patients with 157 renal units underwent URS insertion, 10 patients were bilateral ureteral stricture, and 26 renal units had two stents inserted in tandem because the ureteral stenosis was too long. The basic characteristics of the patients are detailed in Table 1. The mean patient age was 45.1 years, 94 (63.9%) procedures were performed on male patients, 59 (40.1%) patients had the procedure on left ureter. The stricture site was most common on the proximal ureter (n = 69, 43.9%) and the mean ureteral stricture length was 3.2 cm. Sixty-six (42.0%) ureteral strictures were caused by ureteral stones or stones after endoscopic treatment, 24 (15.2%) by open ureteroplasty, 13 (8.2%) followed surgery or radiation therapy for cancer, 11 (7.0%) resulted from urinary surgery trauma, 13 (8.2%) occurred after kidney transplantation, 7 (4.4%) strictures occurred after surgery for benign diseases of gynecology and obstetrics, 10 (6.3%) recurrent strictures were previously treated with internal incisions or balloon dilations, and 13 (8.2%) ureteral strictures no definite causal etiology. In 43 (27.39%) patients, there was atresia in strictures segment. Twenty-five (15.9%) patients underwent double-J tube insertion, and 67 (42.6%) patients underwent drainage via a PNTs before the operation.

All stents were placed successfully. The characteristics of the perioperative period are shown in Table 2. In 132 ureters (84.1%), balloon dilatation was required to successfully insert the mental stents. Twenty-six patients (16.56%) had two stents inserted in tandem because the ureteral stenosis was too long, and all the others had one stent. The mean operative time was 70.0 min, and the mean hospital cost was $ 11,119. Postoperative hematuria was the most common complication 13(8.8%), followed by urinary tract infection 11(7.5%) and pain 8(5.4%). After a median follow-up of 15 months (range 9–20 months), 115 (73.2%)

Table 1
General characteristics of the patients.

Variable	Overall
Number of patients, n	147
Number of renal units, n	157
Gender, male/female, n	94/53
Age, years	45.1 ± 14.1
BMI, kg/m^2	23.8 ± 3.2
Side, n (%)	
Left	59(40.1)
Right	65(44.2)
Bilateral	10(6.8)
Kidney transplantation	13(8.8)
Stricture location, n (%)	
Proximal	69(43.9)
Middle	25(15.9)
Distal	40(28.7)
Ureterovesical anastomosis	13(8.3)
Length of ureteral stricture, cm	3.2 ± 3.3
Etiology of ureteral stricture, n (%)	
Ureteral stones	66(42.0)
Following open ureteroplasty	24(15.2)
Following surgery/radiation therapy for cancer	13(8.2)
Following urinary surgery trauma	11(7.0)
Following kidney transplantation	13(8.2)
Following benign diseases of gynecology and obstetrics	7(4.4)
Following internal incision and balloon dilation	10(6.3)
No obvious cause	13(8.2)
Ureteral atresia, Yes/No, n	43/114
Obstruction drainage, n (%)	
Percutaneous nephrostomy tube	25(15.9%)
Double J tube	67(42.6%)

Continuous variables were expressed used mean ± standard deviation.

Table 2
Procedure related characteristics.

Successful stent insertion, n (%)	157(100.0)
Operative time, min	70.0 ± 34.4
Operative complications, n	
Pain	8(5.4)
Urinary tract infection	11(7.5)
Hematuria	13(8.8)
Stent number (one ureter), n (%)	
1	131(83.4)
2	26(16.6)
Stent type, n (%)	
8–100	10(5.8)
8–120	62(36.1)
10–100	41(23.8)
10–120	59(34.3)
Balloon dilation, Yes/No, n	132/25
Length of hospital stay, day	7.5 ± 3.7
Total cost, $	11119.0 ± 3839.8
Follow-up success rate, n (%)	115(73.2)
Follow-up, month, median (range)	15(9–20)
Reasons for failure of surgery, n (%)	
Stent migration	37(23.6)
Stent occlusion	2(1.3)
Stent encrustation	3(1.9)
Symptoms with stents, n (%)	
Persistent hematuria	6(4.1)
Recurrent urinary tract infection	8(5.4)
Persistent pain	10(6.8)
Lower urinary tract symptoms	8(5.4)

stents were kept in-situ. Stent-related complications were encountered in 10 (6.8%) patients with persistent pain, 6 (4.1%) patients who presented with persistent hematuria, 8 (5.4%) patients had lower urinary tract symptoms, and 8 (5.4%) with recurrent urinary tract infection.

The overall success rate of this procedure was 73.2% (115/157). There were 42 failed cases, including 37 (23.6%) stent migrations, 2 (1.3%) occlusions, and 3 (1.9%) stone encrustations. For migration cases, 30 stents were endoscopically adjusted to the normal position and 7 stents were exchanged. Stent exchange was performed in 2 patients with stent occlusions. For those with stent encrustations, retrograde flexible ureteral lithotripsy removed the stones successfully. After the second operation, all stents were kept in-situ with good patency at the last follow-up.

Follow up results are presented in Table 3. The follow-up results for 9 months after the operation are as follows. The volume of hydronephrosis decreased significantly from (67.9 ± 34.9) cm^3 preoperatively to (33.5 ± 49.8) cm^3 postoperatively. The blood creatinine level (103.0 ± 54.5 VS 92.8 ± 45.1 μmol/L, $P = 0.019$) and urea nitrogen level (6.6 ± 6.7 VS 5.2 ± 2.3 mmol/L, $P = 0.012$) also decreased significantly after surgery. The results of the last follow-up were consistent with the results at 9 months after the operation. The volume of hydronephrosis($P = 0.0001$), blood creatinine level ($P = 0.034$) and urea nitrogen level ($P = 0.032$)

Table 3
Long-term treatment outcomes of the Allium stents for ureteral stricture.

Variable	Preoperation	9 months after surgery	P	Last follow-up	P
Hydronephrosis volume/cm^3	67.9 ± 93.9	33.5 ± 49.8	0.0001	34.9 ± 51.1	0.0001
Norm GFR of affected kidney (ml/min/1.73 m^2)	25.0 ± 16.1	–	–	23.3 ± 13.1	0.051
Uptake of affected kidney (%)	31.7 ± 15.6	–	–	30.9 ± 16.4	0.400
Creatinine (μmol/L)	103.0 ± 54.5	92.8 ± 45.1	0.019	93.8 ± 45.1	0.034
Urea nitrogen (mmol/L)	6.6 ± 6.7	5.2 ± 2.3	0.012	5.4 ± 2.4	0.032

decreased significantly after surgery. Nevertheless, no significant change was found in the GFR of the affected kidney (25.0 ± 16.1 VS 23.3 ± 13.1 ml/min/1.73 m^2, $P = 0.051$) and uptake of the affected kidney (31.7 ± 15.6 VS 30.9 ± 16.4, $P = 0.400$) at last follow up when compared to baseline.

The predictor of procedure failure was analyzed and shown in Table 4, and found that obstruction in the distal ureter was an independent risk factor for stent failure (HR 1.77, 95% CI 1.15, 2.73, $P = 0.009$). No other independent factors affecting operation failure were found. The length, etiology and previous surgery of ureteral stricture affect the success rate of ureteroplasty, but these factors will not reduce the success rate of Allium URS surgery.

4. Discussion

To our knowledge, this is the largest prospective study of Allium stent for ureteral stricture. Our study has indicated that URS is effective in relieving the ureteral obstruction. The overall surgical success rate was 73.2% over a follow-up of 15 months. Even for those failed cases, after the remedial measures, all stents were in situ with good patency. In addition, the technique is safe and well tolerated, no patient requires stent removal because of complications.

Ureteral stricture is a common disease and remains a big challenge for urologists [7]. Currently, many treatment options exist for ureteral strictures, including open reconstruction surgery, endoureterotomy, balloon dilation, ureteral stent, and PNTs [8]. Treatment should be selected according to etiology, degree of ureteral stricture, complications, and prognosis [9]. PNTs is least favored because of the external drainage which restricts the patient's activities, and negatively affects the patient's quality of life [10]. In addition, the PNTs requires frequent replacement [3]. Insertion of a double J tube after balloon dilation has become a routine technique for the treatment of ureteral strictures [11]. Unfortunately, the failure rate of traditional double J tubes is 30–45% [12,13]. Stent related symptoms and frequent exchanges significantly decrease the quality of life as well [1]. Metal stent is developed to avoid frequent exchange of double J tube, but there is a high migration, tissue ingrowth, and stents encrustation [7,14].

The Allium URS is a fully covered and large caliber metal stent that offer an attractive solution for long-term ureteral drainage as it prevents drainage failure caused by tissue ingrowth [3]. While stent migration has been reported as a common complication [15]. Studies have reported that Allium URS has a good drainage in benign and malignant ureteral strictures [3,16–18]. Moskovitz and colleagues reported their 6-year experience with Allium URS in 49 ureteral stricture cases [3]. During a mean follow-up of 17 months, only 7 (14.2%) stents migrated and were removed [3]. The study also found that 20% of patients regained ureteral patency after stent removal and no intervention was required [3]. In addition, in 2015, a multi-center study reported 107 ureter strictures in 92 patients [18]. Stent migration occurred in 10.7% of patients within eight-indwelling months, and only 1 stent was obstructed during a mean follow-up of 27 months [18]. Guandalino et al. found that the incidence of stent migration was 18.9%, and over 60 years of age and female sex were risk factors for stent migration. Seven (18.9%) stents were removed because of infection and intolerance [4].

In our research cohort, all stents were retrogradely inserted. Balloon dilatation was required in 84.1% of patients to successfully indwelling of URS. During the follow-up, 9 stents were exchanged and 30 migrated stents were endoscopically adjusted to the normal position. Then, all stents kept patency until the last follow-up. We also identified distal ureteral stricture was an independent risk factors for stent failure. This was corroborated by Goldsmith's study, that distal obstruction increases the risk of stent failure [19]. Thus, for stricture in the distal segment of ureter, stent slippage into the bladder is a risk when inserting a metal stent. In addition, previous radiation therapy and urinary tract infection have also been reported as risk factors for stent failure [20,21].

Previous studies have reported few complications related to Allium

Table 4
Predictors of stent drainasge failure.

	Success	Failure	Univariate analysis			Multivariate analysis		
Predictor			HR	95% CI	P	HR	95% CI	P
Ureteral stents, n	115	42						
Gender, male/female, n	68/47	29/13	1.542	0.727–3.272	0.259			
Age, years	44.8–13.9	45.7–15.0	1.004	0.980–1.030	0.731			
BMI, kg/m^2	23.7–3.2	23.8–3.3	1.009	0.904–1.126	0.870			
Side								
Left	45	19	Ref.	Ref.	0.882			
Right	51	19	0.882	0.416–1.871	0.744			
Bilateral	10	1	0.237	0.028–1.982	0.184			
Kidney transplantation	9	3	0.789	0.192–3.241	0.743			
Obstructed location								
Proximal	60	15	Ref.	Ref.	0.057			
Middle	20	5	1.000	0.323–3.101	1.000			
Distal	26	19	2.923	1.289–6.627	0.010	1.774	1.151–2.733	0.009
Ureterovesical anastomosis	9	3	1.333	0.321–5.538	0.692			
Length of ureteral stricture, cm	3.2–3.4	3.3–3.0	1.014	0.913–1.125	0.799			
Etiology of ureteral obstruction, n (%)								
Ureteral stones	44	22	Ref.	Ref.	0.711			
Following open ureteroplasty	17	7	0.824	0.298–2.28	0.709			
Following surgery/radiation	12	1	0.167	0.020–1.365	0.095			
Following urinary surgery trauma	8	3	0.750	0.181–3.11	0.692			
Following kidney transplantation	10	3	0.600	0.150–2.404	0.471			
Following benign diseases	5	2	0.800	0.144–4.458	0.799			
Following internal incision and balloon dilation	8	2	0.500	0.098–2.557	0.405			
No obvious cause	11	2	0.364	0.074–1.785	0.213			
Ureteral atresia, Yes/No	34/79	9/32	0.653	0.282–1.516	0.322			
Obstruction drainage								
Percutaneous nephrostomy tube	20/95	5/37	1.558	0.545–4.456	0.408			
Double J tube	47/68	20/22	1.315	0.646–2.677	0.450			
Hydronephrosis volume/mm^3	72.9–100.8	54.1–71.0	0.998	0.993–1.002	0.271			
Norm GFR of affected kidney (ml/min/1.73 m^2)	25.0–15.5	26.2–17.8	1.005	0.984–1.026	0.660			
Uptake of affected kidney (%)	32.2–15.5	30.2–16.0	0.992	0.968–1.015	0.485			
Creatinine (μmol/L)	102.7–53.2	103.7–58.5	1.000	0.994–1.007	0.921			
Urea nitrogen (mmol/L)	6.9–7.7	5.8–2.4	0.948	0.839–1.072	0.396			

URS, including hematuria, urinary tract infections, irritation and encrustation [3,4,16–18]. These complications also occurred in our cohort. Studies have shown that proper stent size can reduce complications [22], so in our study we selected the appropriate stent model according to the situation of each patient. In our cohort, the overall perioperative complication rate was 21.7%, including hematuria, urinary tract infection and pain. Moreover, the total number of stent-related complications was only 15.0%, and all the complications were well-tolerated.

Compared with double J tubes, Allium URS has a higher incidence of migration, but lower incidence of encrustation or occlusion [23]. Regardless of the cause of ureteral stricture, timely alleviation of the obstruction can protect kidney function [8,24]. Ordinary polymer stents are effective but need to be changed regularly every 3–6 months, and hematuria, bladder irritation, or urinary tract infections is common [25]. Chen et al. compared the safety and effectiveness of ordinary and metal stents, they found that metal stents had a higher patency rates at 6 months (100% VS 83.8%) and 1 year (91.7% VS 40.0%) than that of ordinary ones [23]. Of note, the overall complication rate of metal stents was lower than that of ordinary ones (36.7% VS 63.6%), and the quality of life score was higher (30.9 ± 2.8 VS 23.6 ± 1.8) [23].

In our study, almost all patients were successfully drained within 15 months or were drained unobstructed after adjustment of stent position, and the average total cost was $ 11,119. He'ctor et al. reported that the cost of their Resonance metallic stent to manage ureteral stricture is similar to ours, with an annual cost of $ 13,633 [7]. In addition, the authors found that although metal stents are more expensive than polymer stents, the metal stents are associated with a 43% reduction in annual cost ($ 13,633 vs $ 23,999) [7]. This figure has not taken into accounts other savings compared to frequent stent replacement, such as time off from work due to hospital visits.

5. Conclusions

URS is safe and effective for ureteral strictures, with limited risk of complications and good long-term results. For patients who are not suitable for open surgical reconstruction, URS is a management option.

Provenance and peer review

Not commissioned, externally peer-reviewed.

Ethical approval

Ethical approval was approved by the Ethics Approval Committee of West China Hospital, and the registered number was 2019-009.

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Author contribution

Xiaoshuai Gao: Writing original draft. Turun Song: Conceptualization, Methodology. Liao Peng: Investigation. Chi Yuan: Software. Wei Wang: Reviewing. Jixiang Chen: Editing. Kaiwen Xiao: Data curation. Xin Wei: Supervision.

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Guarantor

Xin Wei.

CRediT authorship contribution statement

Xiaoshuai Gao: Writing – original draft. **Turun Song:** Conceptualization, Methodology. **Liao Peng:** Investigation. **Chi Yuan:** Software. **Wei Wang:** Writing – review & editing. **Jixiang Chen:** Writing – review & editing. **Kaiwen Xiao:** Data curation. **Xin Wei:** Supervision.

Declaration of competing interest

The authors declared that they had no competing interest related to this work.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijsu.2021.106161.

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Abbreviations

URS:: metal ureteral stents
PNTs: percutaneous nephrostomy tubes
CT: computed tomography
SPECT: Single-Photon Emission Computed Tomography
GFR: glomerular filtration rate