Clinical Study

Allium coated metal ureteral stent for the treatment of radiation induced ureteral stricture

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[**Abstract] Objective** To discuss the efficacy and safety of Allium coated metal ureteral stent in the treatment of radiation induced ureteral stricture (RIUS). **Methods** The data of 23 patients (34 sides) with RIUS treated with Allium coated metal ureteral stent from October 2018 to December 2019 in Peking University People's Hospital were retrospectively analyzed, including 1 male (1 side) and 22 female (33 sides). The mean age was (57.4 ± 11.5) years old. The preoperative median serum creatinine was 96.0(47.0 -421.0) μmol/L. Unilateral ureteral stricture was observed in 12 cases and bilateral stricture in 11 cases. The average width of the renal pelvis was (2.3 ±1.1) cm. The primary diseases included cervical cancer (17 cases), rectal cancer (3 cases), endometrial cancer (2 case) and ureteral cancer (1 case). There were 2 cases treated with radical radiotherapy and 21 cases with operation combined with chemoradiotherapy. Preoperative percutaneous nephrostomy tube was observed in 5 cases (7 sides). 18 patients (27 sides) had ureteral stents. Median indwelling time of D-J stent was 18.0 (2.0 - 84.0) months, replacement every 5.0 (1.0-12.0) months, and the total score of the ureteral stent symptom questionnaire (USSQ) 99.0 (59.0 - 126.0). The location and length of ureteral stricture were measured by retrograde urography. Then ureteral balloon dilatation [2 533.1 kPa (25ATM)], 3 min was performed. According to the length of ureteral stricture, 1-3 Allium stents were inserted under X-ray and released after in place, and finally urography was done again to confirm. The serum creatinine, ultrasonography and abdominal X-ray were reviewed in the first day, every 6 months after the operation to evaluate the renal function, location and patency of Allium stent, USSQ were recorded to evaluate quality of life. Postoperative complications were assessed by Clavien-Dindo system. **Results** All the 23 cases in this group were successfully operated, with an average operation time of (100.7 ±37.2) min. Retrograde urography revealed 8 full-length ureteral strictures, 20 cases in the middle and lower segments, 5 in the lower segments and 1 in the middle segments. The mean stenosis length was (15.9 ±5.9) cm. Three Allium stents unilaterally were placed on 6 sides, 2 stents on 18 sides and 1 stent on 10 sides. The success rate of indwelling is 100%. Compared with preoperative data, serum creatinine was 93.5 (54.0 -289.0) μmol/L in 6 months after surgery, significantly lower than that before surgery (P = 0.005), but there was no significant difference in renal pelvis width and USSQ total score. Serum creatinine 89.0 (45.0 -342.0) μmol/L, renal pelvis width (1.6 ±0.6) cm and USSQ total score of 66.0 (50.0 - 105.0) in the last follow-up after surgery were significantly reduced. Postoperative Clavien-Dindo I complications occurred in 3 patients (13.0%) , presenting stent related symptoms such as flank and abdominal pain, hematuria and lower urinary tract symptoms, which were all improved after conservative treatment. There were 4 patients (17.4%) with Clavien-Dindo III complications, including Allium ureteral stent displacement in 2 cases and stent encrustation in 2 cases. After endoscopic surgery, Allium ureteral stent was removed and D-J stents were inserted in 2 cases due to repeated encrustation. The median follow-up was 16.5 (11.0- 24.0) months. Allium ureteral stent was effective in 21 patients (32 sides, 94.1%). Conclusions Allium ureteral stent used for the treatment of RIUS could be safe and effective. Patient’s renal function and quality of life could be improved.

[Key words] Ureteral diseases; Coated metal ureteral stent; Radiation induced ureteral stricture; Efficacy; Safety

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Radiation induced ureteral stricture (RIUS) has always been a difficult problem in urology because ureter is long and the ureteral stricture under such conditions is refractory [1]. The incidence of ureteral stricture after pelvic radiotherapy against cervical cancer is 1.8% - 10.3%, mostly occurred 1-7 years after the radiotherapy [2-3]. Once occurred, RIUS is mostly progressive, and can result in serious damage to renal function. Currently, surgical restoration is the gold standard of the treatment of ureteral stenosis. However, RIUS patients have unfavorable factors such as long ureteral stenosis and retroperitoneal fibrosis, the operation is difficult, and in most cases the ureter is replaced by intestinal canal tissue. So surgical restoration is mostly used in patients with good basic conditions [4], not suitable for most RIUS patients. Now the most common clinical choice is long term indwelling of various double-J tubes, however complications related to double-J tube and frequent replacement often seriously affect the quality of life of patients [5]. In recent years, Allium coated metal ureteral stent (Allium, Israel) has been successfully used in the treatment of various refractory ureteral strictures abroad, and many studies have shown good long-term efficacy and less complications of this therapy [6-7]. This study retrospectively analyzed the medical records and follow-up data of 23 patients (34 sides) treated with RIUS in Peking University People's Hospital from October 2018 to December 2019, summarized the preliminary clinical experiences and discussed the efficacy and safety of this therapy.

Subjects and methods

I. General data

This study included 23 patients (34 sides), including 1 male (1 side) and 22 females (33 sides). The mean age of those patients was 57.4±11.5 years old. Eight patients were complicated with hypertension, 6 with diabetic mellitus, and 1 with solitary kidney. Among those patients, the mean body mass index was 23.3±2.9 kg/m^2, preoperative hemoglobin was 112.1±20.2 g/L, median serum creatinine was 96.0 (47.0~421.0) μmol/L. Twelve patients had unilateral ureteral stenosis while 11 patients had bilateral ureteral stenosis. Ultrasound or CT on kidney was carried out to assess hydronephrosis of the affected kidney after urination, suggesting a mean width of renal pelvis of 2.3±1.1 cm. The primary diseases included cervical cancer (17 cases), rectal cancer (3 cases), endometrial cancer (2 cases) and ureteral cancer (1 case), 2 cases of primary diseases were treated using radical radiotherapy and 21 using operation combined with chemoradiotherapy. The median onset time of hydronephrosis was 6.0 (1.0~84.0) months after radiotherapy.

To alleviate ureteral stricture and hydronephrosis, 5 patients had nephrostomy tubes (7 sides), 18 patients had ureteral stents (27 sides), including common double-J tubes on 21 sides and Resonance stents on 3 sides, and 2 ipsilateral double-J tubes on 3 sides. The median interval of retention is 18 (2.0~84.0) months, and median interval of replacement is 5.0 (1.0~12.0) months.. The ureteric stent symptoms questionnaire (USSQ) was surveyed in patients with preoperative double-J tubes, and the median total score was 99.0 (59.0~126.0), including urinary symptoms (U) of 29.0 (19.0~43.0), body pain (P) of 15.0 (2.0~24.0), general health (G) of 18.0 (6.0~24.0), work performance (W) of 16.0 (11.0~19.0), and additional problems (A) of 17.0 (8.0~21.0).

Figure 1 Allium coated metal ureteral stent and A. Appearance of ureteral stent; B. Delivery system of

the delivery system

II. Allium coated metal ureteral stent

Allium coated metal ureteral stent has a three-layer structure (figure 1). The middle layer is a spiral nickel titanium metal mesh, with 3 mark points containing tantalum on both ends which could be seen under X-ray, and inner and outer layers are copolymer films. The stent features large diameter, segment, self-expansion, anti-compression and tissue invasion prevention, could be uncoiled to be easily removed.

III Surgical method

Of 23 cases in this group, 17 cases were anesthetized by subarachnoid anesthesia, 3 cases by subarachnoid anesthesia combined with epidural anesthesia, and 3 cases by general anesthesia.

Surgical procedure: the patients were placed in lithotomic position. The ureteroscope was placed through urethra, and the bladder and ureteral orifice were observed under the ureteroscope. Ultra smooth guide wire (Cook Company, USA) was inserted into the affected ureter. Under X-ray, the guide wire was confirmed to enter the affected renal pelvis, and the ureteral catheter (Bard, USA) was pushed along the guide wire. Retrograde upper urography was carried out to observe the conditions of the affected renal calyces, renal pelvis and ureter, determine the stenosis site, and measure the length of the stenosis segment through the ureteral catheter. There were 8 sides with ureteral stricture in full length ureter, 20 in middle and lower segment of ureter, 1 in middle segment, and 5 in lower segment; the mean length of stenotic segment was 15.9±5.9 cm. Ureteral balloon dilatation catheter was pushed along the guide wire (Bard, USA), with F21 of balloon diameter and 6cm of balloon length. Under fluoroscopy, balloon part of the guide was placed into the stenotic segment, dilated using 2533.1 kPa (25 ATM) for 3 min. The stenotic segment was well dilated as observed under fluoroscopy. In this group, the length of urethral stricture was >6cm on 30 sides. The balloon was dilated from proximal end to distal end of the stenotic segment till the stenotic segment was completely dilated. Allium ureteral stent was sent along the guide wire, with the main body of the stent passing through the stenotic segment according to X-ray marks,

ureteral stent

both ends of the stent located in non-stenotic sites. For long length of stenosis, when more stents needed to be inserted, there would be more than 2cm overlay for 2 adjacent stents. In this group, ureteral stents were inserted into 34 sides, including 3 stents on 6 sides, 2 stents on 18 sides, and 1 stent on 10 sides. The stent was gradually released after reaching the predetermined position. After confirming that the stent position was not changed under fluoroscopy, the stent was inserted into the catheter again and retrograde angiography was carried out to confirm whether the stent position was ideal and the full length of ureter unobstructed. For patients with bilateral ureterostenosis, if the single side operation duration would be > 2h, the contralateral operation would be carried out 1 week later to reduce complications such as infection. The indwelling catheter was retained after the operation was completed.

For patients with bilateral ureterostenosis, 3 ureteral stents were placed on each side.

Figure 2 Plain abdominal radiograph after Allium coated ureteral stent implantation in ureterostenosis patients after radiotherapy

IV. Observation parameters

Operation duration and intraoperative complications were recorded. Antibiotics were administered for postoperative prevention. In the first day after operation, routine blood test was carried out, serum creatinine was examined, plain abdominal radiograph was performed to confirm the location and shape of Allium coated ureteral stent. Blood routine, serum creatinine, urine routine, plain abdominal radiograph and kidney ultrasound after urination were carried out for every 6 months after the operation, and USSQ was also recorded for patients. Clavien Dindo Classification was carried out to assess the postoperative complications.

V. Statistical method

SPSS22.0 statistical software was used for processing data. The enumeration data were expressed in case number (percentage), measurement data in normal distribution were expressed in Mean ± SD, or in medians (minimum ~ maximum). Paired sample t test or non-parametric test was performed to compare the difference of measurement data. P<0.05 was adopted as the statistical significance level.

Results

In this group of 23 patients, operations on 34 sides were completed successfully, including 13 cases with unilateral stents, 7 cases with bilateral stents inserted in the same period and 3 in different periods. All stents were successfully inserted. The mean duration of the operation was 100.7±37.2 min.

The mean hemoglobin was 102.8±17.9 g/L in the first day after operation, with statistical significance compared with the preoperative value (P<0.001), which might be caused by blood dilution due to postoperative rehydration. The median serum creatinine was 109.0 (37.0~384.0) μmol/L, not significantly different from the preoperative value (P=0.544). The second plain abdominal radiograph confirmed that all Allium ureteral stents had normal positions and shapes. The median postoperative hospital stay was 4.0 (1.0~14.0) d. Six months after the operation, the median serum creatinine was 93.5 (54.0~289.0) μmol/L, reduced significantly compared with the preoperative value (P=0.005), and the mean width of renal pelvis was 2.1±0.8 cm (P>0.05), not significantly different from the preoperative values. At the last follow-up, the median serum creatinine was 89.0 (45.0~342.0) μmol/L (P<0.001) and the mean width of renal pelvis was 1.6±0.6 cm (P<0.001), all significantly different from the preoperative values.

In 18 patients with ureteral stents retained before operation, the total score of USSQ 6 months after operation was 85.0 (76.0~100.0), which was obviously improved compared with the preoperative value (P=0.046), except that only total W score of 13.0 (9.0~17.0) was obviously reduced compared with the preoperative value (P=0.001). At the last follow-up, the total USSQ score was 66.0 (50.0~105.0), which was significantly different from the preoperative value (P=0.001), including the total U score of 21.0 (14.0~36.0), total P score of 11.0 (2.0~18.0), total G score of 10.0 (8.0~19.0), total W score of 13.0 (10.0~19.0), and total A score of 10.0 (7.0~20.0), all were significantly reduced compared with the corresponding preoperative values (P=0.002, P=0.016, P<0.001, P=0.007, P=0.001).

The median duration of follow-up was 16.5 (11.0~24.0) months, 21 cases (32 sides, 94.1%) with Allium ureteral stents maintained unblocked, 2 cases with Allium ureteral stents removed due to repeated encrustation, and double-J tubes were inserted instead.

During the follow-up, 2 cases (8.7%) had Allium ureteral stents shifted 6 months after the operation (Clavien Dindo III complication) (figure 3A, 3B), 1 case had the stents moved into renal pelvis, the other case within the ureter (to the connecting part of 2 stents). The moved stent catheters were removed, new Allium ureteral stents were replaced, the symptoms were relived and no shift occurred in the retest. Two cases (8.7%) had encrustation in the Allium ureteral stents 6 months after the operation (Clavien Dindo III complication), plain abdominal radiograph showed high density shadow on the stent (figure 3C), ureteroscopy showed soft crust attached bladder stent end or overlap site of two stents. After pneumatic lithotripsy, it showed that the crusts were all carbonate apatite, suggesting that the patient might have urinary tract infection. The symptoms were relived after pneumatic lithotripsy and anti-infective treatment, 2 cases all had 2 relapses by

intervals of about 6 months. Finally, Allium ureteral stents were removed for both 2 cases, double-J tubes were inserted instead. Three cases (13.0%) had stent related symptoms after the operation (Clavien Dindo I complications), mainly including urinary tract irritation, hematuria and lumbago, which were relieved after conservative drug treatment.

Figure 3 Abdominal X-ray film of patients with postoperative complications after insertion of Allium coated metal ureteral stents

A. Allium ureteral stent in superior segment of right ureter shifted and entered into renal pelvis (red circle);

B. Two Allium ureteral stents on the left were disassociated, with stenosis at the junction (red circle); C. encrustation at the intravesical end and within the Allium ureteral stent (red circle)

Discussion

RIUS adopts radiotherapy or the comprehensive therapy including radiotherapy to treat the serious and refractory urinary complications after abdominal and pelvic malignancies [8]. Studies have shown that the incidence of ureterostenosis is 1.8% ~10.3% after radiotherapy in pelvic cavity, mostly occurred 1~7 years after radiotherapy, from 2 months to even 10 years after the radiotherapy [2-3]. The middle and lower segments of ureter are located in the pelvic cavity, particularly adjacent to radiotherapy targeting areas such as uterus, so RUIS usually occurs in this region [9]. Radioactive rays can directly or indirectly damage the ureter by producing oxygen free radicals, resulting in ureteral fibrosis and scar formation, followed by secondary retroperitoneal fibrosis, and can also damage the ureteral and vascular epithelia, resulting in thrombosis and vascular occlusion [10]. Therefore, after ureter is exposed to radioactive rays, the stenosis usually occurs in long segment and is difficult to treat under the influence of impaired blood supply and progressive fibrosis. The mean length of ureterostenosis is 15.9±5.9 cm, including 8 sides with full length stenosis and 20 sides with middle and lower segment of ureterostenosis. Many patients have received repeated treatment, however, good long term efficacy has not obtained, indicating such ureterostenosis with serious fibrosis in long segment is refractory.

Once RIUS is confirmed, it should be treated to relieve the obstruction as soon as possible to salvage the renal functions. The current therapeutic methods include surgical restoration, endoscopic treatment of urinary tract, long-term indwelling ureteral stent, nephrostomy and ureterostomy, etc. [11] Of these therapies, 68.1% of surgical restoration succeeds, but only in patients with relatively good base conditions [4], moreover patients have relatively serious periureteral fibrosis and adhesion after pelvic radiotherapy, so the restoration is difficult and may induce major trauma, intestinal tract may even be needed to replace the ureter, so the surgical restoration has relatively many complications, and is rarely applied to treat RIUS. Intraluminal balloon dilatation or endotomy is optimal to treat short, benign, non-ischemic ureteral stenosis <2 cm [12-13], with uncertain long term efficacy, and it not applicable to long ischemic ureteral stenosis after radiotherapy. The biggest defect of nephrostomy and

ureterostomy is the severe influence on the quality of life [14], the removal and replacement of fistula tube and the daily nursing of ostomy bag bring great trouble to patients.

In clinical practice, many doctors choose to retain double-J tube to treat RIUS. This method is simple and has low risks. However, double-J tube has many complications, such as stent related urinary tract irritation, pain, hematuria, displacement, encrustation, obstruction, etc. [15]. In addition, double-J tube should be changed for every 3~6 months, which produces great burdens to the patients in terms of physiology, psychology and economy. Two double-J tubes or Resonance stents may alleviate symptoms of malignant ureterostenosis patients to certain extent [16-17], but the quality of life of the patient and long term patency rate are still not good. In this study, 18 patients (27 sides) have ureteral stents before operation, including common double-J tubes on 21 sides and Resonance stents on 3 sides, two double-J tubes on 3 sides. The median interval of retention is 18 months, and median interval of replacement is 5.0 months. As the disease progresses, some patients change the stents frequently, and usually have pyrexia and urinary tract infection at each replacement in future. Complications and frequent replacement of double-J tube bring great trouble to the patients, and the quality of life is severely reduced in the patients [18]. Moreover, double-J tube is relatively thin (about 2mm). In patients with severe stenosis in long segment after radiotherapy, double-J tube has no extraluminal drainage, the draining will further reduce, obstructive hydronephrosis will develop and gradually get worse, resulting in chronic renal dysfunction in patients.

Allium coated metal ureteral stent has the following features: (1) segmental metal support and larger caliber (8~10mm of diameter), with better support and drainage; (2) complete coated structure can effectively avoid tissue endogenesis and stent block; (3) the flexibility and segmental structure of the whole stent will provide patients with better comfort; (4) this stent can be retained in body for longer period, for more than 3 years as reported in literatures [6, 19]. Moskovitz, et al [6] reported 40 cases (49 sides) with Allium ureteral stents who were followed up for 17 (1~63) months, with stent patency rate of 81.6%, and shift rate of 14.2%. Eight cases had stents removed as scheduled, the ureters maintained unblocked for long term, achieving the effect of curing stenosis. Three studies assessed the efficacy of Allium ureteral stents in treatment of benign and malignant ureteral obstruction [7, 20-21], with 140 cases (158 sides) included, followed up of 7~27 months, long term patency rate of 52.8% ~100.0%, and stent shift rate of 10.3% ~18.9%. Our previous study assessed the clinical efficacy of Allium ureteral stent in treatment of ureteroileal anastomotic stricture, indicating that the stent maintained relatively long term patency rate, helped renal function protection, and improved the quality of life in patients [22]. Combining previous literatures and reports, Allium ureteral stent can achieve long term retention and maintain patency, and has lower incidence of complications. However, there is no definite result for maximal retention and long term patency rate. RIUS treated by using this method has not been reported in China or at abroad.

In this group of patients, Allium ureteral stents were inserted retrogradely. Postoperative retrograde urography showed all ureters on the affected sides were unobstructed, Allium ureteral stents had normal positions and shapes, and the operations had 100% successful rate. Compared with preoperative data, serum creatinine obviously decreased 6 months after operation, the width of renal pelvis and total USSQ score did not change significantly, however, the total score of work performance significantly decreased, suggesting that patients were improved in work performance. At the last follow-up, serum creatinine, the width of renal pelvis and total USSQ score all significantly decreased, scores in subgroups significantly decreased too, indicating that the general quality of life was obviously improved for all patients. In this group, the median duration of follow-up was 16.5 months, 21 cases (32 sides, 94.1%) with Allium ureteral stents maintained unblocked ureters. Therefore, Allium ureteral stent therapy against RIUS can produce good long term patency rate, alleviate hydronephrosis, and improve renal function. Compared with double-J tube, it has obviously improved the quality of life for patients, and makes it possible for patients to carry

stents without symptoms for long. In the aspect of economy, double-J tube should be changed for every 3~6 months, while Allium ureteral stent is used for 1 year at the least almost in all patients in this study. However, prospective control studies are still needed to further assess the benefits of health and economy.

When used to treat RIUS, Allium ureteral stent cannot only obtain good therapeutic efficacy, but also produce less complications. In this group, only 2 cases (8.7%) had stent displacement, 2 cases (8.7%) had stent encrustation, and 3 cases (13.0%) had stent related symptoms. For stent displacement, the stent shifted and entered into renal pelvis, or 2 stents were disassociated at the stent junction, the stenotic segments were exposed again, which could aggravate hydronephrosis, when the stent should be changed and stent position should be adjusted. In 2 cases with stent displacement, Allium ureteral stents were inserted again and no displacement was found again in subsequent follow-up. Stent encrustation mainly occurs at the stent end of the bladder, or at the overlay of 2 stents. When crust component is carbonated apatite, it suggests that the patients may be accompanied with urinary tract infection, when transurethral ballistic lithotripsy and anti-infective therapy can be chosen, the stent can be retained transiently, and if stent encrustation occurs repeatedly, the stents should be changed. In this group of patients, stent related symptoms were obviously reduced compared with double-J tube, but patients with longer protruding part in the bladder at the stent end (>1cm) had relatively severe lower urinary tract irritation, which could be prevented by controlling the protruding part of stent to be < 1cm. In addition, patients with stents to support the full length of ureter may be at the risk of urine reflux, and they should be reminded to avoid holding urine.

Limitations of this study: (1) this study is a retrospective study; (2) this study is a single center small sample size study, although the efficacy and safety of this method are investigated, the representativeness is not good; (3) this study has not assigned control study using other therapeutic method, without direct comparison between Allium ureteral stent long term retention and other method; (4) 5 cases in this group have nephrostomy tubes before operation, the quality of life cannot be assessed using USSQ, the effects of Allium ureteral stent and nephrostomy tube on quality of life for patients cannot be compared; (5) data are not available for health economics evaluation.

In general, long term retention of Allium coated metal ureteral stent against RIUS is safe and effective, can maintain higher patency rate of ureter for a long time and low incidence of complications, and obviously improve renal functions and quality of life in the patients.

Conflict of interests: all authors claim no conflict of interests.

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