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Original Article

A new technique for the treatment of ureteric stricture after kidney transplantation

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Objective

To evaluate the safety and effectiveness of endoscopic treatments with Allium® metal ureteric stent (AMUS) for ureteric strictures after kidney transplantation (KT).

Patients and Methods

In a prospective manner, we gathered clinical data from 68 patients who underwent endoscopic treatments with AMUS for ureteric strictures after KT between January 2019 and March 2022. The definition of surgical success was the unobstructed drainage of the AMUS, or in cases where there was AMUS migration, occlusion or encrustation and subsequently removed, there is no worsening of renal hydronephrosis in the patient during the follow-up period.

Results

Based on the specific circumstances of the ureteric strictures, three distinct types of surgery were selected for treatment. The overall success rate of endoscopic treatments for ureteric strictures following KT was 90% (61/68) during a follow-up period of 1 year. Surgical complications included haematuria (18%), pain (10%), urinary tract infections (7.4%), and lower urinary tract symptoms (7.4%). The incidences of stent migration, occlusion, and encrustation were 10%, 2.9%, and 1.5%, respectively. Postoperatively, significant improvements were observed in various parameters. At 1 month after surgery, there was a notable decrease in blood creatinine levels (105.5 vs 90.4 mol/L), urea nitrogen levels (6.6 vs 5.4 mmol/L), and hydronephrosis volume (64.4 vs 43.9 mL). Additionally, the serum estimated glomerular filtration rate increased from 49.5 to 64.4 mL/min/1.73 m^2. The follow-up results of patients at 1 year after surgery were similar to those observed at 1 month after surgery.

Conclusions

Systemic endoscopic treatments with AMUS were found to be safe and effective for ureteric strictures after KT with short-term follow-ups. This technique offers a novel option for the treatment of post-KT strictures.

Keywords

endoscopic treatment, kidney transplantation, ureteric stricture, metal stent, ureteroplasty

Introduction

The incidence of ureteric stricture and ureteric leakage following kidney transplantation (KT) is estimated to be ~1.8% [1]. Despite remarkable progress in immune induction and maintenance protocols, as well as advancements in surgical techniques and instrumentation, the incidence of ureteric strictures following KT has shown little improvement over the past decades [2,3]. The development of ureteric strictures after KT can be influenced by various factors related to both the donor and recipient, as well as surgical techniques. These factors include: donor age, number of kidney arteries, cold ischaemic time, recipient age, delayed graft function, acute/chronic rejection, operation time, and the absence of stents [4–6]. Vesico-ureteric re-implantation is an effective treatment option for ureteric strictures following KT. However, it is essential to acknowledge that this type of surgery is intricate and carries a multitude of potential complications. In cases where vesico-ureteric re-implantation has proven unsuccessful; the long-term use of percutaneous nephrostomy tubes becomes necessary.

In recent times, endoscopic procedures have emerged as the preferred choice due to their minimally invasive nature and reduced burden on patients. However, alternative methods like JJ stents and percutaneous nephrostomy tubes require periodic replacement and long-term placement, which pose a significant risk of stent-related complications. These complications include stent intolerance, infection, encrustation, occlusion, and migration [7]. The Allium® metal ureteric stent (AMUS; Allium Ltd, Caesarea Industrial Park South, Caesarea, Israel) represents a notable advancement in the field, as it is a self-expanding stent composed of a nitinol skeleton with a polymer overlay. This unique design has demonstrated its efficacy as a reliable option for facilitating long-term drainage of the ureteric strictures in the native kidney [8,9]. However, the utilisation of the AMUS in ureteric strictures after KT has received limited attention in the literature. Therefore, the purpose of this study was to present our firsthand experience with AMUS in the endoscopic management of ureteric strictures after KT.

Patients and Methods

Patient Selection Process and Characteristics

This prospective clinical study was carried out with the approval of the Ethics Approval Committee of West China Hospital (number: 2019-009). Data collection was performed on patients who underwent endoscopic treatments for ureteric strictures after KT between January 2019 and March 2022. The inclusion criteria for this study were as follows: (i) patients who had received a renal transplant and had a confirmed ureteric stricture through antegrade or retrograde radiography; (ii) patients who had previously undergone JJ stent placement and/or balloon dilatation but were unable or declined to undergo re-operation; and (iii) patients who had previously undergone unsuccessful vesico-ureteric re-implantation. The exclusion criteria for this study were as follows: (i) ureteric strictures accompanied by severe UTIs; (ii) patients with ureteric strictures who had not yet undergone JJ stent replacement; (iii) patients who were unable to undergo anaesthesia or surgical procedures due to medical reasons. All patients included in the study provided their informed consent and signed an agreement for the publication of their clinical indicators. To ensure the preservation of kidney function, all patients underwent nephrostomy either due to ureteric obstruction or the inability to replace JJ stents at the local transplant centre.

The data collection encompassed various parameters including: sex, age, body mass index (BMI), time elapsed from KT to the occurrence of ureteric stricture, the length and location of strictures, prior treatments received, hydronephrosis volume before and after the operation, pre- and post-operative serum creatinine, urea nitrogen and estimated GFR (eGFR), characteristics of the surgical procedure, stent-related complications, and reasons for surgical failure. The calculation of hydronephrosis volume was carried out using abdominal CT: hydronephrosis volume = length × width × depth × 0.523 [10].

Surgical Procedure

The surgical procedure was conducted under general anaesthesia. Antegrade angiography with a nephrostomy tube was employed to ascertain the location and length of the ureteric stricture. Based on the specific location and severity of the stricture, three different types of endoscopic surgeries were available as options. The essential steps of the surgical procedure were as follows.

Type I: in cases of general ureteric strictures, under fluoroscopic guidance, a 0.089-cm (0.035-inch) Solo Hydro Hybrid Guidewire (Heraeus Medical Components, LLC, St. Paul, MN, USA) was inserted through the nephrostomy and carefully guided through the narrow segment of the ureter until it reached the bladder (Fig. 1A). A cystoscope was utilised to gently extract the guidewire through the urethra. Then, a retrograde ureteric balloon was inserted along the guidewire through the stricture (Fig. 1B), and the balloon dilator was inflated to a pressure of 1.72 MPa (20 atm) for a duration of 3 min (Fig. 1C). Subsequently, a 6-F flexible ureteroscope sheath and a second working wire were retrogradely inserted above the guidewire, reaching the upper renal calyx. Following that, the head end of the AMUS was placed in the proper position with the aid of the sheath. Finally, the sheath was withdrawn to implant the AMUS while ensuring the stent remained in the desired position (Fig. 1D).

Type II: in cases of ureteric strictures with a closed ureteric opening, the antegrade passage of the contrast agent and guidewire through the strictured segment was not feasible (Fig. 2A). Under fluoroscopic supervision, transurethral cystoscopic resection of the ureteric opening was performed, effectively eliminating the stricture. Once the stricture was resolved, the guidewire successfully entered the bladder (Fig. 2B). Subsequently, the guidewire was carefully withdrawn through the urethra using a cystoscope. Following this, balloon dilatation, as in Type I, was carried out (Fig. 2C). Finally, a retrograde AMUS insertion was performed under fluoroscopic guidance (Fig. 2D).

Type III: in individuals with an atretic ureteric segment (Fig. 3A), empirical transurethral resection of the ureteric opening was unable to restore the patency of the ureter (Fig. 3B). In such scenarios, simultaneous holmium laser resection guided by an anterograde flexible ureteroscope through the nephrostomy fistula was necessary (Fig. 3B). Then, balloon dilatation (Fig. 3C) and AMUS implantation (Fig. 3D) were performed as applied in the Type I group. Urography was performed at the end of the procedure to confirm the successful and unobstructed flow of urine through the AMUS.

Fig. 1 Surgical procedure of Type I. (**A**) Guidewire was introduced and passed through the ureteric stricture; (**B**) ureteric balloon was inserted retrogradely through stricture; (**C**) ureteric balloon dilatation; (**D**) a ureteric stent was implanted.

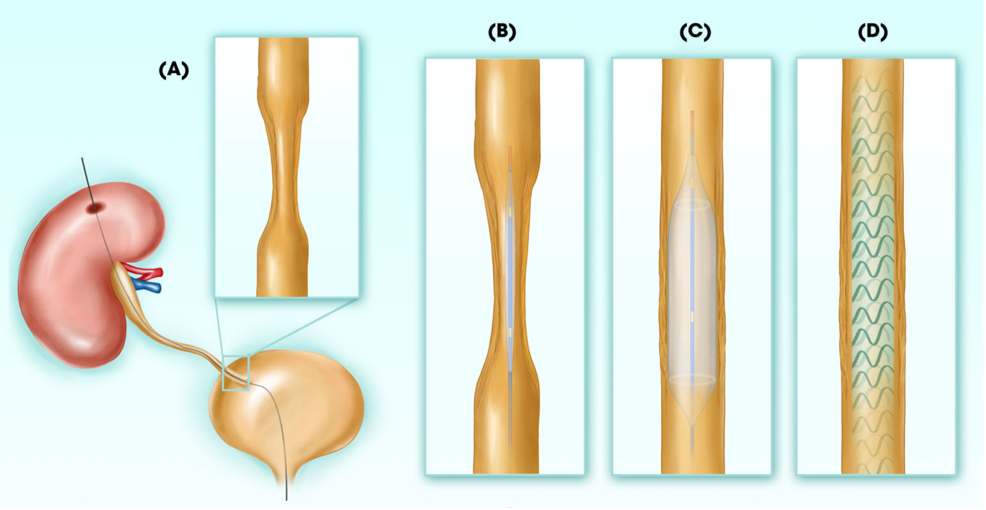
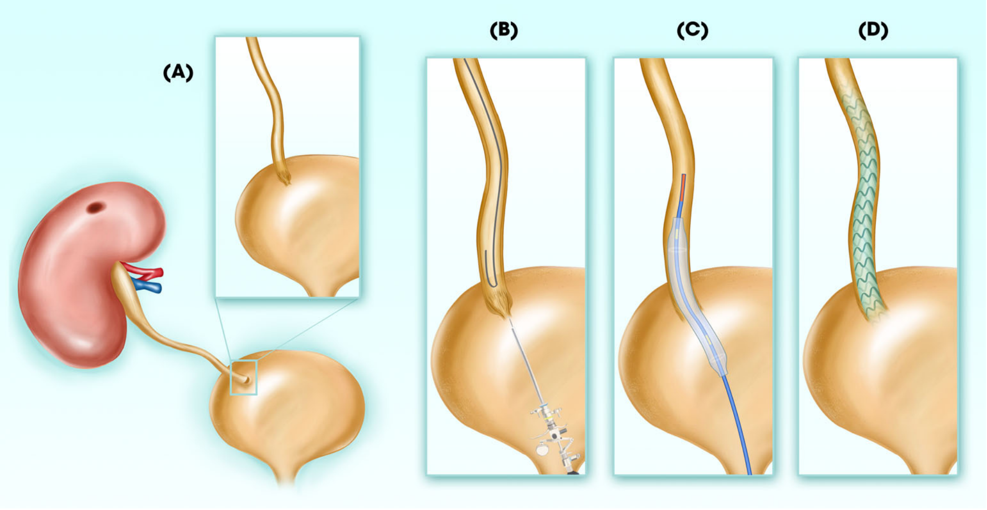


Fig. 2 Surgical procedure of Type II. (**A**) The stricture segment prevents the antegrade passage of the guidewire and contrast agent; (**B**) transurethral scar resection of the ureteric opening and the guidewire passed through the ureteric stricture; (**C**) ureteric balloon dilatation; (**D**) a ureteric stent was implanted.



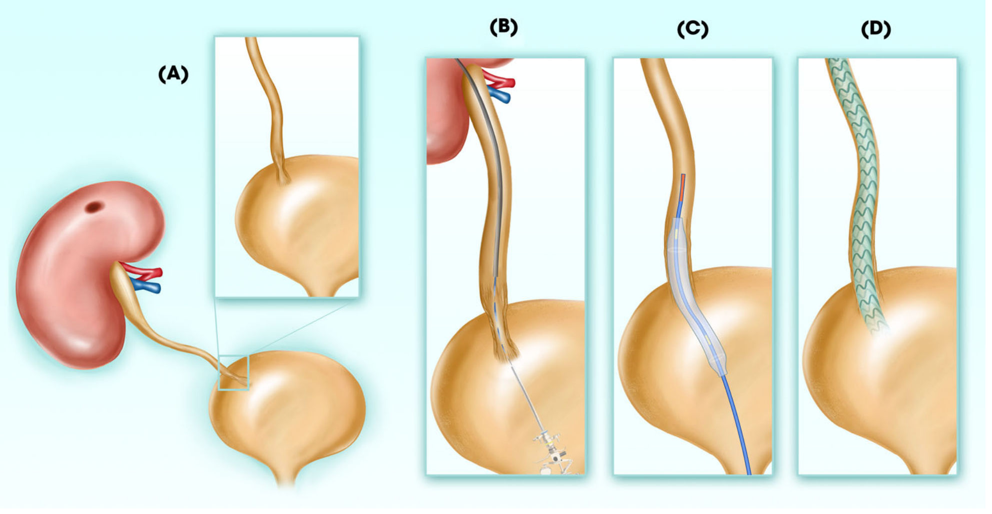
Follow-Up Protocol

At 1 month after the surgery, we performed tests to evaluate creatinine levels, eGFR, and blood urea nitrogen levels. The nephrostomy tube would be removed provided that the abdominal CT scan indicated a reduction in hydronephrosis and the correct placement of the AMUS. Subsequently, abdominal CT scans, urine routine tests, blood routine tests, and renal function evaluations were conducted every 3 months following the stent insertion. The follow-up cut-off time for our study was March 2023. During the follow-up period, the occurrence of stent migration, occlusion, and encrustation was carefully documented, including the time of their incidence and subsequent treatment. Stent-related complications were also recorded throughout the follow-up period. The definition of surgical success was the unobstructed drainage of the AMUS, or in cases where there was AMUS migration, occlusion or encrustation and subsequently removed, there was no worsening of renal hydronephrosis in the patient during the follow-up period.

Statistical Analysis

Normally distributed variables were presented as mean (± SD) or median (interquartile range [IQR]). Categorical

Fig. 3 Surgical procedure of Type III. (**A**) The stricture segment prevents the guidewire and contrast agent from passing antegradely through it; (**B**) transurethral scar resection of the vesico-ureteric junction and holmium laser resection guided by an anterograde ureteroscope; (**C**) ureteric balloon dilatation; (**D**) a ureteric stent was implanted.



variables were expressed as numbers and percentages. Paired *t*-tests were employed to compare continuous data before and after the surgical procedure, with a $P < 0.05$ considered statistically significant. The statistical analysis was conducted using the Statistical Product and Service Solutions (SPSS®), version 22.0 (IBM Corp., Armonk, NY, USA).

Results

Between January 2019 and March 2022, 68 patients were recruited for this study. The clinical characteristics of the patients who underwent AMUS insertion are presented in Table 1. Among the patients, there were 49 males and 19 females, with a median (IQR) age of 37.0 (30–44) years. Among the cohort of 68 patients included in our study, 53 underwent living-donor KT, one received an autologous KT, and 14 received donation after circulatory death. The median (IQR) duration from KT to the diagnosis of ureteric stricture was 2.5 (1–5) months. The median (IQR) length of the ureteric strictures was 2.0 (0.9–3) cm. Ureteric strictures were most commonly observed at the vesico-ureteric junction in 29 patients (43%), followed by 16 (24%) involving both the distal ureter and vesico-ureteric junction, 10 (15%) affecting the distal ureter alone, seven (10%) in the middle segment, and six (8.8%) in the proximal part. All patients underwent nephrostomy either due to ureteric obstruction or the inability to replace the JJ stent. Regarding the treatment history for ureteric strictures, 60 patients (88%) had received JJ stents on more than two occasions, 36 (53%) had undergone balloon dilatation, 23 (34%) had undergone endoscopic (endo)-incision, and 34 (50%) had previously undergone unsuccessful vesico-ureteric re-implantation.

Table 1 General characteristics of the patients.

Variable	Value
Number of patients	68
Age, years, median (IQR)	37 (30–44)
BMI, kg/m^2, median (IQR)	23.1 (21.4–25.0)
Male/female, *n*	49/19
Time to onset of ureteric stricture after KT, months, median (IQR)	2.5 (1–5)
Types of kidney transplantation, *n* (%)	
Living donor	53 (78)
Autologous kidney transplantation	1 (1.5)
Donation after circulatory death	14 (21)
Length of stricture, cm, median (IQR)	2.0 (0.9–3)
Location of stricture, *n* (%)	
Proximal	6 (8.8)
Middle	7 (10)
Distal	10 (15)
Vesico-ureteric junction	29 (43)
Distal ureter + vesico-ureteric junction	16 (24)
Nephrostomy, *n* (%)	68 (100)
Treatment history of ureteric stricture, *n* (%)	60 (88)
JJ stent	36 (53)
Balloon dilatation	23 (34)
Endo-incision	34 (50)
Vesico-ureteric re-implantation	60 (88)

Table 2 lists features related to procedures. The number of patients in Type I, Type II and Type III was 37, 18, and 13, respectively. Among them, one patient in Type II and one patient in Type III experienced a surgical failure due to the inability to implant the AMUS. Consequently, both patients underwent regular replacement of nephrostomy tubes. The mean (SD) operation times of the three types of surgery were 47.0 (12.0) min for Type I, 70.1 (5.0) min for Type II, and 121.2 (32.7) min for Type III. This indicates that Type III surgeries are the most challenging and necessitate the longest

Table 2 Procedure-related characteristics.

Variable	Type I	Type II	Type III	Total
Patients, *n*	37	18	13	68
Operative time, min, mean (SD)	47.0 (12.0)	70.1 (5.0)	121.2 (32.7)	67.3 (33.09)
Hospital stay, days, mean (SD)	7.0 (3.2)	7.1 (3.2)	10.0 (6.1)	7.6 (4.1)
Total cost, US $, mean (SD)	9740.8 (3507.6)	9617.3 (327.9)	11457.3 (4574.2)	10036.3 (3372.0)
Release of obstruction, *n* (%)	37 (100)	17 (94)	12 (92)	66 (97)
Follow-up success rate, *n* (%)	36 (97)	14 (78)	11 (85)	61 (90)
Stent migration	4 (11)	2 (11)	1 (15)	7 (10)
Stent occlusion	1 (2.7)	1 (0)	0 (0.0)	2 (2.9)
Stent encrustation	0 (0)	1 (5.6)	0 (0.0)	1 (1.5)
Operative complications, *n* (%)				
Pain	3 (8.1)	2 (11)	2 (15)	7 (10)
UTI	3 (8.1)	1 (5.6)	1 (7.7)	5 (7.4)
Haematuria	6 (16)	3 (17)	3 (23)	12 (18)
LUTS	3 (8.1)	1 (5.6)	1 (7.7)	5 (7.4)

Table 3 Follow-up outcomes of the surgery.

Variable	Preoperative	1 month after surgery	*P*	1 year after surgery	*P*
Hydronephrosis volume, mL, mean (SD)	64.4 (79.4)	43.9 (53.3)	0.023	40.4 (48.4)	0.006
eGFR, mL/min/1.73 m^2, mean (SD)	49.5 (16.6)	64.4 (17.5)	<0.001	65.2 (17.1)	<0.001
Creatinine, μmol/L, mean (SD)	105.5 (49.9)	90.4 (55.5)	0.021	81.9 (29.1)	0.019
Urea nitrogen, mmol/L, mean (SD)	6.6 (3.0)	5.4 (2.5)	<0.001	4.9 (1.7)	<0.001

operation time. The mean (SD) hospital stay duration for Type III surgeries was 10.0 (6.1) days, which exceeded that of Type I (mean [SD] stay 7.0 [3.2] days) and Type II (mean [SD] stay 7.1 [3.2] days). Additionally, Type III surgeries incurred the highest hospital costs, amounting to a mean (SD) of $11457.3 (4574.2) US dollars. Complications associated with the surgeries encompassed various issues including: haematuria (18%), pain (10%), UTIs (7.4%), and LUTS (7.4%). The overall success rate of endoscopic treatments for ureteric strictures following KT was 90% during a follow-up period of 1 year. The success rates varied among the different types of strictures, with Type I achieving a success rate of 97%, while Type II and Type III had success rates of 78% and 85%, respectively. In the case of Type I, the surgeries of four patients with AMUS migration were considered successful, as there was no recurrence of ureteric stricture after the removal of the AMUS. However, in Type II and Type III, three cases of AMUS migration required the exchange of the migrated AMUS with new ones, which resulted in surgical failure. Additionally, the endoscopic replacement of fresh AMUS in two patients with AMUS occlusion was unsuccessful. Retrograde flexible ureteric lithotripsy was performed to remove the stones associated with AMUS encrustations. Notably, the AMUS was successfully emptied during the second procedure and remained functional until the last follow-up.

The outcomes obtained during the follow-up are presented in Table 3. At 1 month after surgery, there was a significant decrease observed in the volume of hydronephrosis (mean [SD] 64.4 [79.4] vs 43.9 [53.3] mL, $P = 0.023$), as well as in the blood creatinine level (mean [SD] 105.5 [49.9] vs 90.4 [55.5] μmol/L, $P = 0.021$) and urea nitrogen level (mean [SD] 6.6 [3.0] vs 5.4 [2.5] mmol/L, $P < 0.001$). Furthermore, the eGFR showed a mean (SD) improvement from 49.5 (16.6) to 64.4 (17.5) mL/min/1.73 m^2 ($P < 0.001$). The follow-up results of patients at 1 year after surgery were similar to those observed at 1 month after surgery. These findings serve as robust evidence affirming the safety and efficacy of the endoscopic treatment administered for ureteric strictures following KT.

Discussion

Ureteric obstructions represent the most common non-vascular complications after KT [11,12]. Vesico-ureteric re-implantation is the prevailing procedure for KT strictures, with a success rate of 81.8% [13]. Nevertheless, reconstructive surgery poses significant challenges with high rates of complications, particularly in patients who have experienced a failed ureteric re-implantation. With the advancements in minimally invasive surgical techniques, endoscopic treatments for ureteric strictures have been successfully implemented, exhibiting notable efficacy in clinical practice. Moreover, our team possesses extensive experience in performing endo-incision and balloon dilatation for ureteric strictures [14]. At our centre, we recommend endoscopic treatment using AMUS for patients who have experienced unsuccessful traditional ureteroplasty and/or stent placement and/or balloon dilatation. Based on the present follow-up data, endoscopic treatment with AMUS has demonstrated both safety and efficacy, significantly enhancing the quality of life for patients.

In the present study, all cases underwent percutaneous nephrostomy tube or JJ stent implantation at the local transplantation centre upon diagnosis of ureteric strictures. In certain instances, endoscopic incision and balloon dilatation were carried out, albeit yielding unsatisfactory outcomes. Arpali et al. [15] proposed that the success rate of a minimally invasive approach as the primary treatment for ureteric strictures was merely 24.2%. However, a systematic review conducted by Kwong et al. [13] indicated that the endourological technique achieved a success rate of 64.3%. For the majority of patients who are unable or unwilling to undergo re-operation, regular replacement of nephrostomy tube or JJ stent becomes an inevitable requirement. Unfortunately, the replacement cycle is more frequent than anticipated due to tube displacement, blockage, UTIs, or bladder irritation. Consequently, the quality of life experiences a significant decline. Moreover, there is an increased risk of UTIs due to the prolonged retention of JJ stents or nephrostomy tubes. Recurrent UTIs may necessitate a reduction in immunosuppression, thereby augmenting the likelihood of chronic rejection and local inflammation [16,17]. In our cases, the JJ stents were not periodically replaced locally, leading to severe fluctuations in serum creatinine levels and impairment of renal function. Some cases even encountered acute renal failure or sepsis, requiring the re-insertion of a nephrostomy tube, ultimately compromising graft survival.

Metal ureteric stents have demonstrated notable efficacy and safety in the treatment of ureteric strictures following KT in recent years [11,18,19]. Current available products include three kinds of stents: Memokath, Uventa and AMUS. Bach et al. [18] reported an overall success rate of 84% after a 4-year follow-up in a series of eight patients treated with the Memokath stents. Salamanca-Bustos et al. [19] utilised the Uventa stents to resolve ureteric strictures in five cases following KT, maintaining ureteric patency in 100% of patients after a median follow-up of 18 months. In our initial experience with AMUS, we achieved a success rate of 87.5% in eight cases after KT, with a median follow-up of 13.5 months [11]. The AMUS offers several advantages over JJ stents. Firstly, it provides a higher patency rate and remains functional for an extended period, requiring fewer replacements. AMUS is a fully covered, self-expanding, large calibre metal stent specifically designed for the ureter. To prevent tissue ingrowth and early encrustation, the entire stent is coated with a novel biocompatible and biostable polymer, rendering it impermeable [20]. Additionally, ease of removal is another important consideration when selecting AMUS.

Large-scale prospective studies focusing on the endoscopic management of ureteric strictures after KT are currently lacking. However, our own study achieved an overall success rate of 90% for this procedure. The success rate for Type I strictures (97%) was notably higher than that for Type II (78%) or Type III (85%). This discrepancy in success rates may be attributed to variations in surgical techniques employed and the severity of the strictures encountered during the procedure [21]. Throughout the follow-up period, no severe postoperative complications were observed. In all, 12 patients experienced spontaneous resolution of haematuria within 3 days after the operation. UTIs or pain occurred in five or seven patients, respectively, postoperatively, but these symptoms were alleviated with appropriate symptomatic treatment. Only five patients reported urinary tract irritation symptoms. However, their overall quality of life demonstrated significant improvement compared to the previous traditional stent. Among the cases classified as Type I, there was no increase in hydronephrosis following the endoscopic removal of migrating AMUS. Three instances of AMUS migration in Type II and Type III were successfully addressed by exchanging them with new AMUS. In cases of simple strictures classified as Type I, the recurrence rate of strictures after endoluminal therapy remained relatively low. Two occluded AMUS were deemed unsuccessful and were replaced with new AMUS through endoscopic intervention. Additionally, retrograde flexible ureteric lithotripsy was performed to remove stones associated with one instance of AMUS encrustation. Following the second surgery, the AMUS achieved successful drainage until the last follow-up. One notable advantage of AMUS is its ability to substantially reduce the frequency of stent replacement. Patients enrolled in the study had previously endured the discomfort of having their JJ stents replaced every 3–6 months. In our follow-up, AMUS demonstrated fewer stent-related symptoms, less pain, and a lesser impact on patients' daily lives compared to JJ stents.

While the results of this study are indeed encouraging, it is essential to acknowledge the limitations that may have influenced the attainment of satisfactory outcomes. Initially, it is important to note that the patients included in our study, who experienced ureteric stricture after KT, were relatively young in age and had a relatively low BMI. Additionally, many of these patients had previously undergone unsuccessful reconstructive surgery. Therefore, it is crucial to recognise that our treatment experience may not be directly applicable or generalisable to other countries or patient populations. Furthermore, a notable limitation of this study is the absence of a control group for comparative analysis of outcomes. It is our hope that in the future, a long-term multicentre controlled trial can be conducted to definitively establish the superior reliability of AMUS in the treatment of ureteric strictures after KT. Such a study would provide more robust evidence and enhance our understanding of the efficacy of AMUS in this context.

Conclusions

Follow-up studies have demonstrated the safety and effectiveness of systemic endoscopic treatments with AMUS for ureteric strictures following KT. There are three types of endoscopic techniques available for eligible patients, offering a range of options for personalised treatment.

Author Contributions

Xiaoshuai Gao: Writing original draft. Xingpeng Di and Fei Li: Conceptualisation, Methodology. Liao Peng: Investigation. Wei Wang: Reviewing. Jixiang Chen: Editing. Xin Wei: Supervision.

Disclosure of Interests

All authors declared no competing interests.

Ethics Approval

This prospective clinical trial was approved by the Ethics Approval Committee of West China Hospital, and the registered number is 2019-009.

Clinical Trial Registration

Our clinical trial is registered in the Research Registry (https://www.researchregistry.com/browse-the-registry#home/), and registration identifier: researchregistry7266.

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Abbreviations: AMUS, Allium® metal ureteric stent; BMI, body mass index; eGFR, estimated GFR; IQR, interquartile range; KT, kidney transplantation.