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Allium stent for treatment of ureteral stenosis

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Aim. **The aim of our study is to value the efficacy of self-expanding Allium ureteral stent in the treatment of ureteral stenosis.**
Methods. **From 2010 to 2013, we treated 12 patients, aged from 23 to 64 years. Six patients were affected by congenital UPJ obstruction, four patients by iatrogenic unilateral ureteral stenosis and two patients by bilateral ureteral stenosis. All the patients showed hydronephrosis before the stenotic lesion and pain. In all the patients, we use a 30 Fr, 10 cm length self-expanding Allium ureteral stent. The medium follow-up is 10 months after Allium stent removal.**
Results. **All the patients were immediately free of pain after the procedure. We didn't experience intra, peri and postoperative complications. In all the patients, a complete correction of the stenotic lesion was obtained. No recurrence of stenosis occurred during follow-up.**
Conclusion. **Self-expanding allium ureteral stent represents an effective treatment of ureteral stenosis in patients not suitable for surgery.**

Key words: Allium - Stents - Ureteral diseases.

Ureteric stents are routinely used in the management of ureteric obstruction caused by benign and malignant disease. Although J-J stents have become the conventional way of managing ureteric obstructions, they are associated with several problems as encrustation (thus requiring 3-6 monthly changes), stone formation, pain, infection, reflux, decreased ureteric peristalsis and migration.[1, 2]

The ideal stent should be inert, cause no symptoms, be suitable for long-term use, and allow normal drainage with no increased susceptibility to encrustation. Many designs, coatings and materials have been tried. These include synthetic, biodegradable, autologous and pH-sensitive materials.

Several metallic stents have entered urological practice, with limited success. The main problems showed by metallic stents are tissue ingrowth through the mesh and difficult or impossibility of stent removal. The self-expanding Allium ureteral stent is thought to overcome many of their problems. The aim of our study is to value the efficacy of self-expanding Allium ureteral stent in the treatment of ureteral stenosis.

Materials and methods

Patient selection

From 2010 to January 2013, we used Allium stent in 12 patients. Six patients were

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affected by congenital UPJ obstruction, four patients by unilateral ureteral stenosis and two patients had bilateral ureteral stenosis.

The first patient was a 64 year old woman, affected by congenital UPJ obstruction. She had previous stroke and IMA (IV ASA score) and underwent an endopyelotomy and double-J positioning before.

The second patient was a 62-year-old man, affected by congenital UPJ obstruction. He underwent 3 attempts of open UPJ dismembering pyeloplasty and a balloon dilatation and double -J stent positioning before. The other four patients with UPJ obstruction were aged between 60 and a 62 years and were affected by severe chronic heart failure (Figure 1). They have been previously treated with endopyelotomy and double-J stent positioning. Four female patients had distal unilateral ureteral stenosis after hysterectomy. They were not suitable for ureteral reimplantation (IV ASA score) and had undergone J-J stent positioning.

Two patients had bilateral ureteral stenosis. One patient was a 23 year old man, affected by bilateral ureteral stenosis due to Schistosomiasis. The stenosis was 4 cm long bilaterally. He was treated with ballon dilatation before and open ureterolysis and uretero-uretero anastomosis after. Also in this case, we kept a double-J stent bilaterally (Figure 2). The other patient was a 64 year old man with bilateral ureteral stenosis due to retroperitoneal fibrosis. He underwent a J-J positioning to relieve high grade hydronephrosis.

Three months after the double J stent removal, IVP showed recurrent stenosis and hydronephrosis in all the patients. In the male patient with UPJ, IVP showed also secondary pelvic stones. All the patients complained flank pain.

Creatinine level was between 1.2 and 2 mg/dL.

Allium stent

The Allium stent is a self-expanding metal stent. It is made from an open-coiled metal skeleton in Nitinol (nichel + titanium alloy) with a copolymer cover. The co-polymer cover reduces stent clotting by encrustation. An independent anchoring segment prevents upwards stent migration and it's also used to remove the stent easily by unraveling. The gradual reduction of the radial force at the ends of the stent reduces the development of reactive tissue. The softer

Figure 1.—IVP showing recurrent left UPJ obstruction.

Figure 2.—IVP showing bilateral ureteral stenosis due to schistosomiasis.

stent end doesn't cause sphincteric function disturbance at the uretero-vesical junction by reducing vesico-ureteral reflux.

The Allium stent is available in a variety of lengths (10, 12 cm) and calibers (24 or 30Fr), in order to adapt the use of one stent to stenosis of different length and caliber.

The Allium stent is also available in two forms: for percutaneous and retrograde insertions. Both of them have an anchoring system in the bladder. The stent is provided by a 10 Fr insertion system. The indwelling time is up to one year. This could be the time to allow a rearrangement of ureteral wall, preventing restenosis.

Surgical technique

The Allium ureteral stent device (URS) is made by two components: the stent and a 10 Fr insertion system (Figure 3).

A retrograde approach was chosen in all cases. We used a 24 Fr cystoscope. After identification of the stenotic segment with retrograde pyelography, a 0.035”-in guidewire was introduced, passing through the stenotic segment. Under fluoroscopic control, the stenotic segment was dilated by a balloon catheter up to 8 mm. With the guidewire in situ, a 30 Fr, 10 cm length self-expanding Allium ureteral stent with its 10 Fr insertion system was inserted through the cystoscope and pushed until the anchoring system was visualized at the ureteral meatus in the bladder. The stent has an over-tube that keeps it in unexpanded form before insertion. To release the stent, the over-tube was retracted pulling gently the Y connector of the insertion system to the rear Lauer. Under fluoroscopic control, the stent self-expanded until the anchoring system was completely free of the over-tube and visualized into the bladder. Then the insertion system was carefully removed under endoscopic control.

At the end, the guidewire was removed too.

The procedures were done under ceftriaxone prophylaxis and the patient affected by schistosomiasis had also been treated with praziquantel.

In all the patients, we used a 30 Fr, 10 cm length self-expanding Allium ureteral stent.

Follow-up

Although the indwelling time is up to 1 year, we were more careful at our first experience with Allium stent. In the first two patients with congenital UPJ obstruction that we treated, we removed the stent after

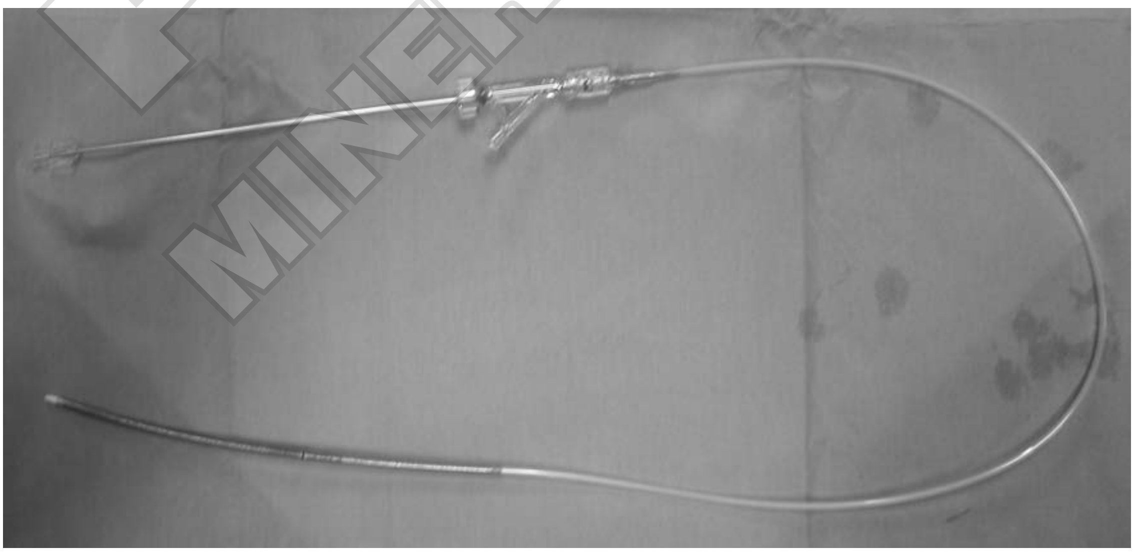

Figure 3.—Allium stent device.

6 months. The patient with secondary pelvic stones also received an ULT.

In the other patients, we removed the Allium stents after 9 or 10 months.

The medium follow-up after Allium stent removal is 10 months. Patients were scheduled for follow-up 1, 3, 6, 9 and 12 months after stent implantation and yearly thereafter. Urine culture, blood biochemistry tests, transabdominal ultrasound and IVP were performed at each follow-up examination to promptly detect any recurrent stricture. CT was done at 6 months in the patient with bilateral stenosis, because of the complexity of this case. All patients received specific instructions to present to our institution in case of symptoms such as flank pain, fever, dysuria, hematuria or vomiting.

Results

Allium stents were successfully placed in all patients (Figures 4, 5). The mean hospital stay was 2 days.

The patients who underwent the procedure were immediately free of pain. We didn't experience intra, peri and post-operative complications. In all the patients, a complete correction of the stenotic lesion was obtained, as proved by radiological imaging [Fig.6]. We didn't experience intraoperative complications such as urinary extravasation, poor stent expansion or equipment failure. Postoperative follow-up didn't show late complications including migration, encrustation, infection, hematuria or voiding symptoms caused by bladder irritation. No recurrence of stenosis occurred. A creatinine level reduction between 0.5 mg/dl and 1 mg/dl was gradually observed during the first 6 months.

Stent removal was easy in all cases. No calcification or incrustation were observed.

Discussion

The first use of a metallic ureteral stent was described by Gort *et al.* in 1990.[3] This was applied in a patient with ureteroileal stricture. Patency was maintained for 6 months. Pandian et al.[4] reported their early experience with anterograde placement of the Memotherm stent, which does not have the property of softening and cannot be removed. Wallstents were also used in the treatment of ureteral strictures, but they

Figure 4.—Allium stent positioned in a patient with UPJ obstruction.

Figure 5.—Bilateral Allium stent for bilateral ureteral stenosis due to schistosomiasis.

allow intraluminal ingrowth and stent incorporation into the ureteral wall in a short time.[5, 6]

In 2001, Kulkarni and Bellamy [7] published their results in the retrograde placement of Memokath stents in 28 patients, for a total of 37 stent insertions, including both benign and malignant ureteral strictures. They reported impressive results with only 4 migrations and no radiological evidence of calcification.

Arya et al. [8] published their own experience with 13 Memokath stents in 11 patients in 2001. All had a history of benign ureteral stricture. The main complication observed was encrustation in 3 stents and one migration. For this reason, the authors suggest a close monitoring of patients with metabolic predisposing factor to encrustation, when Memokath stent is inserted.

In 2010, Papadopoulos *et al.*[9] published their experience with Memokath stents in 13 patients (10 benign stricture and 3 malignant). Their main complication was migration (6 patients).

Liatsikos *et al.*[10] also evaluated the efficacy of the Resonance metallic stent in the setting of benign disease. In their series of 18 patients with obstruction from benign causes, only 44% of patients maintained patency after a mean of seven months.

Failure was defined as worsening dilation of the pelvicalyceal system on imaging studies, or in cases where bilateral metallic stents were placed as a rising serum creatinine level. When the Resonance stent failed, it tended to occur within a few weeks. Of note, seven of eight failures occurred in patients with ureteroenteric or severe iatrogenic strictures. The authors noted a hyperplastic reaction which actually grew through the coils of the stent in these cases. At the time of replacement, 12 of 54 stents displayed evidence of gross calcification, but this did not complicate removal in any case.

Figure 6.—IVP showing resolution of UPJ obstruction 6 months after Allium stent removal.

In an attempt to avoid the repeated cystoscopy during stent removal, several biodegradable-bioabsorbable materials have been introduced in stent composition.

Polyglycolide, Poly D, L lactide, Poly L lactide and Uriprene are biodegradable polymeric materials that when used for ureteral stent composition can induce total stent absorption over a varied period.[11, 12] Degradation time depends both on the material used and the amount of substance to be degraded. For example, second generation stents are degraded from the distal to the proximal end because the coating is thicker on the more proximal portion. Current data on biodegradable stent application in the human ureter is limited. Moreover, several problems with this novel idea has already been encountered. Phase II trials of a temporary ureteral drainage stent (Boston Scientific Microvasive, Natick, MA) revealed that in some cases stent fragments did not dissolve properly and required shock-wave lithotripsy and ureteroscopy for removal.[13] Another stent composed of poly-L-lactide-coglycolide (PLGA), evaluated for its use after retrograde endopyelotomy in a porcine model, was not pursued clinically due to incompatibility issues.[14] In addition, conditions such as ureteral strictures need a prolonged time of stenting in contrast to other procedures such as aftershock-wave lithotripsy when a short-term ureteral drainage is indicated. Consequently, a single biodegradable stent cannot fit all conditions and disease-specific stent development is required. New bioabsorbable stents are already under experimental evaluation demonstrating promising results and clinical trials are expected.[15]

Respect to Resonance and Memokath 051 stents, Allium stents are covered by a copolymer that reduces the probability of stent incrustation. While Memokath needs to be warmed to 50 °C to expand the anchoring segment only and Resonance doesn't expand at all, Allium stent is completely self-expanding. Its caliber is larger (24 or 30 Fr *vs.* 6 Fr of Resonance and 10.5 Fr of Memokath), in order to keep the best dimension of the ureter and prevent restenosis. Allium stent is 10-12 cm long, less than Resonance and Memokath. This could be a limitation in treating long stenosis.[16, 17]

The complete apposition of Allium stent to ureteral wall reproduces the physiological intraluminal urine flow, while Resonance apposition is only at the site of obstruction and Memokath is in contact with ureteral wall at the site of obstruction and at the intraureteral anchoring segment.

The softer ends of Allium stent and its intra-vescical anchor, prevent reflux reducing UVJ segment, while Memokath stent doesn't cause reflux only when positioned over the UVJ, because of its intra-ureteral anchoring segment.

In our patients, Allium stent was successful in treating the stenosis. No complications or restenosis were observed.

Our study represents a preliminary experience and some questions remain to answer: can it be successful also in the treatment of malignant strictures? Can it be used as primary approach for all ureteral strictures? What is the standard follow-up post-operatively?

Conclusions

Self-expanding Allium ureteral stent represents an effective treatment of ureteral stenosis in patients not suitable for surgery.

Cost is additional important issue. Allium stent is more expensive than a conventional J-J stent (1000 Euros).

Large studies with longer follow-up and cost-effective analysis, comparing Allium stent with other available devices are required before its role is firmly established in endourological practice.

Riassunto

Stent Allium stent nel trattamento delle stenosi ureterali

Obiettivo. Lo scopo del nostro studio è stato quello di valutare l'efficacia dello stent autoespandibile Allium nel trattamento delle stenosi ureterali.

Metodi. Dal 2010 al 2013, 12 pazienti di età compresa tra i 23 e 64 anni sono stai trattati; 6 pazienti erano affetti da ostruzione del giunto pieloureterale, 4 da stenosi iatrogena ureterale e 2 pazienti da stenosi bilaterale degli ureteri. I pazienti si presentavano con idronefrosi e dolore. In tutti i pazienti è stato posizionato stent autoespandibile (30Fr) Allium 10cm di lunghezza. Il follow-up medio dopo la rimozione dello stent è di 10 mesi.

Risultati. In tutti I pazienti si è avuta una risoluzione immediata del dolore. Nessuna complicanza è stata riportata e ad oggi si è avuta una risoluzione della stenosi in tutti i casi

Conclusioni. Lo stent autoespandibile Allium rappresenta un trattamento efficace nelle stenosi ureterali nei pazienti non candidabili a chirurgia.

PAROLE CHIAVE: Allium - Stents - Malattie ureterali.

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Conflicts of interest.—The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.