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Application of resonance metallic stents for ureteral obstruction

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OBJECTIVE

- To determine the effectiveness of the Resonance ureteral stent and clarify the risk factors that lead to stent failure. In the present study, we review our clinical experiences using Resonance stent in treating malignant and benign ureteral obstruction.

PATIENTS AND METHODS

- Nineteen patients with extrinsic malignant ureteral obstruction ($n = 15$) and benign stricture ($n = 4$) were retrospectively evaluated.
- All patients had received Resonance stent insertion through antegrade or cystoscopic retrograde approaches. The pre-insertion and follow-up interventions included image studies and biochemical tests. The insertion success rate, obstruction patency rate and complications were reviewed.
- For categorical variables, the chi-square test and Fisher's exact test were carried out to determine associations between variables.

RESULTS

- The technical success rate of stent insertion was 84.6%. The mean follow-up was 5 months (range 1–10.5 months).
- Five stents failed to alleviate the obstruction, and the patency rate was 77.3% (17/22).
- Patients who had had previous radiation therapy had a lower ureter patency rate in comparison with non-radiation patients (50% vs 92.3% respectively, $P = 0.039$).
- The 6- and 9-month patency rates were 81.0% with 11 stents and 27.0% with 3 stents, respectively.

CONCLUSIONS

- The results of the present study demonstrated that malignant or benign ureteral obstruction could be treated safely and sufficiently with the Resonance metallic stent.
- Careful patient selection is critical to achieve successful results.
- For malignant ureteral obstruction, previous radiation therapy is a risk factor for stent failure.

KEYWORDS

ureteric stent, ureteral obstruction, metal stent

INTRODUCTION

Upper urinary tract obstruction occurred in a variety of benign or malignant diseases. Long-term urinary diversion is mandatory in certain conditions, such as advanced malignant disease or benign retroperitoneal fibrosis and ureteral stricture [1,2]. Malignant unilateral or bilateral ureteral obstructions are caused by extrinsic compression of a primary tumour, metastatic disease and retroperitoneal lymphadenopathy. Although such obstructions establish themselves gradually and usually present with few clinical symptoms, these patients require immediate urinary drainage to preserve the renal function, which is important for further treatment or chemotherapy.

For decompression of an obstructive collecting system in benign or cancer patients, antegrade or retrograde indwelling of ureter stents or percutaneous nephrostomy (PCN) have been the most favourable options in the past decades [3]. PCN placement for relieving obstructions has a high technical success rate, however, it can easily become dislodged and the external tube with drainage bag compromises the health-related quality of life (HRQL) [3,4]. As the HRQL is an important issue in patients with malignant ureteral obstruction (MUO), whose mean survival is generally less than 7 months [5], ureter stenting is an alternative choice to treat extrinsic or intrinsic ureter obstructions. Polymeric ureteral stents can be an initial approach to relieve the obstruction. However, long-term failure of indwelling stents in the setting of extrinsic compression occurs in nearly half of treated patients [6].

The Resonance metallic double pigtail ureteral stent (Cook Medical, Bloomington, IN, USA) has been introduced as a potential solution to this difficult problem of extrinsic ureteral obstruction for up to 12 months. Clinical experience with the use of Resonance stents has been reported in a limited amount of literature with promising results [7–10]. In the present study, we present our experience in using this novel stent for the management of ureteral obstruction as a result of malignant and benign aetiologies, and identify the risk factors that lead to stent failure.

TABLE 1
Malignant and benign disease causing ureteral obstruction

Primary disease (case numbers)	No. of obstructed ureters
Malignant	
Prostate cancer (7)	10
Colon cancer (2)	2
Cervix cancer (2)	2
Ureter cancer (2)	2
Leiomyosarcoma (1)	2
Breast cancer (1)	1
Benign	
Ureter intrinsic stricture (3)	4
Benign lymphadenopathy (1)	1

PATIENTS AND METHODS

Data were retrospectively obtained from the medical records of patients who presented with upper urinary traction obstruction and who received Resonance stent insertion. This retrospective study was approved by the institutional review board in our hospital. From May 2009 to February 2010, a total of 26 Resonance stents were inserted via retrograde or antegrade approaches in 19 patients (12 males, 7 females) with ages ranging from 31 to 80 years (mean 61.8 ± 12.6 years). The underlying diseases causing ureteral obstruction were benign stricture ($n = 4$) and malignancies of the prostate ($n = 7$), colon ($n = 2$), gynaecological ($n = 2$) and others ($n = 4$). In these benign cases, one had benign retroperitoneal lymphadenopathy with multiple enlarged lymph nodes cause extrinsic ureter obstruction. The other three patients had retroperitoneal fibrosis and extended ureter stricture which could not be treated with ureterolysis or other surgical interventions. Table 1 lists the primary aetiologies of obstruction. Patients with ureteral obstruction and hydronephrosis were detected with ultrasonography (US), CT or i.v. urography pre- and post-stenting. Serum creatinine levels were also checked and recorded before and within 2 weeks after stent insertion. Most of the patients were followed up on a 1-month basis. Stent failure, considered as insufficient drainage, was defined as re-dilation of the pelvicaliceal system based on comparative image assessment during the follow-up. In cases of re-obstruction, the patients underwent PCN placement to relieve the obstruction. Clinical courses including complications after stent insertion were collected for analysis.

The Resonance stents were inserted using antegrade or retrograde techniques based on the condition of each patient. For retrograde stent insertion, we followed the procedures recommended by the manufacture (Cook Medical, Bloomington, IN, USA). In short, with local or light anaesthesia, the patient was placed in a lithotomy position. During the cystoscopic procedure, a 0.035-inch floppy guide wire was inserted into the collecting system. Then a coaxial system, which included an outer 9-F introducer sheath and an inner 5-F ureteral catheter, was passed over the guide wire to the renal pelvis. The outer sheath was kept in place, then the guide wire and inner catheter were removed. The Resonance stent was pushed through the introducer sheath using the inner catheter as pusher at the proximal end. After the distal curl was formed in the renal pelvis, we retrieved the introducer sheath with the pusher catheter held in place until the distal pigtail curl was deployed in the bladder.

For the antegrade approach, a standard PCN tract was created, and the Resonance stent was inserted 2 weeks later. In patients with previous PCN drainage, the stent insertion was performed through the existing tract. An antegrade nephrostomogram was performed to identify the renal pelvicaliceal and ureteral anatomy. Then a similar technique was used to that as described for the retrograde approach. Care was taken not to push the proximal end of the stent into the ureter. The stent length was 28 cm, and the stent diameter was 6 F in all cases.

Statistical comparisons of continuous data were performed using the Student's *t*-test. For categorical variables, the chi-square test and Fisher's exact test were used to compare the differences. A Kaplan–Meier curve was constructed to illustrate the patency rate for restoring ureteral patency with time. Statistical analyses were performed using a commercial available program, Prism, version 5.0c (GraphPad Software Inc., La Jolla, CA, USA).

RESULTS

Of all the obstructed ureters, 11 were located in the right side and 15 in the left side. A total of 26 stents were intended to be inserted in 19 patients. Retrograde insertion was performed in 10 ureters, and antegrade insertion in 16 ureters. Bilateral obstructions were treated in five patients. A total of 22 Resonance stents were successfully placed. Four stents failed to be inserted. Two of these 4 patients had bilateral obstruction and achieved successful contralateral Resonance stent insertion. Therefore, we had successful stent insertion in 17 patients. In these four failed placements, two guide wires were not able to pass the stricture locations and the other two guide wires were able to pass the stricture location but failed to follow the coaxial catheter in obstructive ureters. However, in one case stent insertion was attempted again 1 week after the first attempt, this time with success. In the successful stent placement group, one stent was removed 1 week after insertion as a result of the stent becoming dislocated into the bladder. Three months later, another stent was inserted into the same renal unit with success. Therefore, two obstructive renal units were inserted twice. The total technical success rate of stent insertion was 84.6%. The failure of stent placement was not related to the antegrade or retrograde technique ($P > 0.05$), sex ($P = 0.28$) or underlying disease (malignant or benign, $P > 0.05$) (Table 2). No major complications were encountered during the insertion procedures.

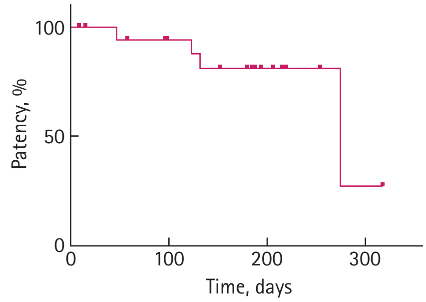
The mean follow-up was 5 months (range 1 week to 10.5 months). Two patients died of metastatic disease with the stents functioning well, and two patients were lost to follow-up as a result moving to another city and seeking other treatment options for malignant disease. No stents were exchanged during the follow-up. The pre- and poststenting serum creatinine levels were 1.4 ± 0.78 and 1.29 ± 0.60 mg/dL, respectively ($P = 0.65$). Stent-related complications were noted in six patients. Four patients had mild haematuria for more than 1 week which resolved spontaneously after conservative treatment. Two patients had slight urgency and bladder irritation symptoms. No UTIs occurred in our patients during follow-up.

Variable	Patency	Re-occlusion	*P* value
Total stents	17	5	
Mean age (years)	61 ± 3.6	65 ± 3.8	0.648*
Insertion methods			0.360†
Antegrade	9	4	
Retrograde	8	1	
Radiation therapy			0.039†
Yes	4	4	
No	13	1	
Primary disease			0.535†
Malignant	13	5	
Benign	4	0	

TABLE 2 Comparison of clinical factors regarding stent failure

**Student's t-test. †Chi-square test.*

FIG. 1. Kaplan-Meier survival curves show stent patency with time.



No mechanical injury or other serious complications were encountered.

During the follow-up, five stents failed to alleviate the obstruction, and the patency rate was 77.3% (17/22). Mean time to failure was 5.7 months (range 1.6 to 7.2 months). The overall success rate was 65.4% (four failed placements and five failed stents during follow-up). The results are summarized in Table 2. Neither primary disease nor insertion technique had an influence on stent failure, however, patients who had had previous radiation therapy had a lower ureter patency rate in comparison with non-radiation patients (50% vs 92.3%, respectively; $P = 0.039$). The 6- and 9-month patency rates were 81.0% with 11 stents and 27.0% with 3 stents, respectively (Fig. 1). As demonstrated by the Kaplan–Meier curve, the patency rate decreased with time.

DISCUSSION

Extrinsic ureteral compression and intrinsic stricture often create a dilemma when sufficient urinary diversion and uncompromised HRQL have to be achieved simultaneously. Several endoscopic and percutaneous approaches have recently evolved for restoring ureteral patency [3,11,12]. PCN has proved to be effective in relieving upper-tract obstruction [13], however, the influence of nephrostomy in HRQL is significant [4]. Since the introduction of double pigtail stents to relieve ureteral obstructions in 1978 [14], various ureteric stents made from different materials have become available. The ideal stent should be easy to insert, biocompatible without causing inflammation, durable, resistant to incrustation and with a long exchange interval [10,11]. However, in dealing with malignant ureteral obstruction, the result of using regular polymeric stents is often disappointing as a result of tumour compression [6]. Docimo [15] reported a 44% stent failure rate in the first 30 days of stent insertion in patients with extrinsic obstruction. While the simultaneous multiple double pigtail ureteral stent was introduced to provide better flow under the condition of extrinsic compression, other disadvantages such as frequent stent change and premature stent blockage as a result of encrustation into the lumen still persisted [16,17]. Encouraged by the successful implantation of metal stents in the cardiovascular and gastrointestinal systems, metal stents have been used in the treatment of extrinsic compression with the aim of achieving better resistance to external compression, and to extend the stent exchange interval. Liatsikos *et al.* [12] reported long-term results of using metal stents with malignant ureteral obstruction treatment. Although the stents provide long-term decompression in select cases, certain problems limit the application including hyperplastic reaction and tumour in-growth, insufficient stenting length, stent migration and encrustation [12,18].

The new Resonance metallic double pigtail stent was introduced for the management of malignant ureteral strictures. This 6-F Resonance metal stent is a continuous unfenestrated metal coil with an inner safety wire welded to both closed, tapered ends. An inner safety wire prevents elastic elongation especially during removal otherwise the stent could catapult down the ureter. The shape of Resonance stent is identical to conventional plastic stent. However, the stent is made from MP35N alloy, a composite of non-magnetic nickel-cobalt-chromium-molybdenum that possesses a high tensile strength and resistance to corrosion [19,20]. It is compatible with a 1.5T MRI scan (MRI safe), which is useful in cancer follow-up [20]. As the Resonance stent has no side ports or end holes, it can prevent tumour in-growth, which is commonly encountered in plastic stents or short metal stents [12,15]. The urine drainage depends on the situation. When the space between the outer aspect of the stent and ureter wall is not obstructed, urine will drain through this space. However, when the aforementioned space is occluded and resistance is encountered, urine will soak in and out of its coils and drainage will be achieved through the lumen of the stent [21]. The Resonance stent provides a lower overall flow rate than a standard stent. However, when extrinsic ureteral compression is sufficient to occlude a standard stent, the metal Resonance stent still provides satisfactory drainage [21].

Borin *et al.* [9] first reported the use of Resonance stents to relieve malignant ureteral obstructions. They inserted the stents into bilateral collecting systems in the conventional way as for standard double pigtail stents. Both stents provided unobstructed flow of urine at up to 4 months of follow-up. Wah *et al.* [22]presented their experience of 17 Resonance stents in 15 patients, where only 3 of the 17 stents failed during follow-up. Nagele *et al.* [10] relieved ureteral obstructions in 18 collecting systems, with benign disease in five and malignant disease in 13 for a mean stent duration of 8.6 months. Two stents were removed because of encrustation, and another six stents were removed as a result of persistent haematuria, flank pain and insufficient drainage. Liatsikos *et al.* [8] reported a 50-patient cohort study where all of the patients were treated using Resonance stent insertion. Their cohort

TABLE 3 Comparison of clinical results from different series of Resonance and conventional double pigtail stent insertion for ureteral obstruction

Series	Stent inserted	No. of patient	No. of obstructive renal unit	Aetiology of ureteral obstruction	Technical success rate	Mean follow-up (months)	Patency rate	Mean time to failure (months)	Overall success rate*
Chung SY *et al.* (2004) [6]	Plastic double pigtail	101	138	Malignancy Benign	95%	11	58%	NA	52.9%
Liatsikos E *et al.* (2010) [8]	Resonance	25	25	Malignancy	100%	11	100%	NA	100%
		18	18	Benign	100%	6.8	44%	NA	44%
Wah TM *et al.* (2007) [22]	Resonance	15	17	Malignancy	NA	Range 2–10	82%	NA	NA
Nagele U *et al.* (2008) [10]	Resonance	10	13	Malignancy	NA	7.3	69.2%	NA	NA
		4	5	Benign	NA	11.8	100%	NA	NA
Current series	Resonance	19	22	Malignancy Benign	84.6%	5	77.3%	5.7	65.4%

**Including failed placements and failed stents during follow-up. NA, data not available.*

consisted of 25 patients with malignant disease ureteral obstruction, 18 patients with benign disease obstruction and 7 patients with a previously obstructed metal mesh stent. They had a 100% patency rate in the malignant disease group with a mean follow-up of 8.5 months, while patency was only achieved in 44% of the benign disease group after 6.8 months of follow-up. Failure of the Resonance stent was observed in all cases of obstructive metal mesh stent shortly after the insertion (2 to 12 days) [8].

In the present study, the overall stricture patency rate was 77.3% after a mean follow-up time of 5 months. Unlike the results reported by Liatsikos *et al.* [8], all of our stent failures occurred in malignant patients, and the patency rate in the benign patients was 100%. In their cohort, they included cases of ureteroenteric anastomotic strictures and cases of stone disease, which are difficult cases to manage and more likely to form encrustation and stones, respectively. The difference could also result from the bias of an insufficient case number. Therefore, a larger series of studies with medium- and long-term follow-up is needed to clarify the results. Table 3 compares clinical results from different series of Resonance and conventional double pigtail stent insertion for ureteral obstruction.

There was a significant difference in stent patency for our patients if they had had radiation therapy. Fifty percent of the patients who had had previous radiation therapy failed to achieve sustained patency. However, Nagele *et al.* [10] showed no difference in stent duration between their patients whether or not they had received radiation therapy ($P = 0.97$). In a previous animal study [23], radiation was shown to induce ureter fibrosis, and the ureter lumen was significantly decreased after radiation. As a sign of functional loss, the pleating of the mucosa was reduced, and a loss of muscle was also observed. From these histopathological findings, it is possible to infer that after radiation therapy the peristalsis of the ureter decreases and the pressure in the ureter increases. Urine will therefore be drained insufficiently and encrustation is more likely to be formed. This could be the reason why the radiation patients had a higher stent failure.

We encountered 15% technical failure in inserting the Resonance stent. In two of the failed procedures, the guide wire was able to pass the stricture site but failed to follow the outer sheath. We did not perform any balloon dilation in any patient. Liatsikos *et al.* [8] reported their experience using Resonance stents for the management of malignant and benign obstructions. They performed balloon dilation in 35% of their patients to ease stent passage, and they achieved a technical success rate of 100%. This means dilation is mandatory in certain cases to facilitate overall success. Compared with other metal stents, dilation is only needed with a ureter diameter of 10 F. This reduces ureter trauma caused by overstretching, which will result in further tissue hyperplasia and stent occlusion.

Although the Resonance stent was initially designed for cystoscopic retrograde insertion, Wah *et al.* [22] first described their promising experience with Resonance stents for antegrade ureteric stenting. In our series, we inserted the stent using either antegrade or retrograde approaches. According to our results, there was no correlation between the approach technique and success rate of transversal and stenting of the strictures. Choosing the proper approach method will facilitate stent placement. In the cases of pelvic tumour invasion or distal ureter stricture, we chose the antegrade route through the PCN tract as it was easier to dilate and push the stents. If the stricture is located in the upper ureter and is not extensive, the retrograde approach will be sufficient to complete the insertion.

The Resonance stent was intended to be indwelled up to 12 months. From our stent survival curve, more than 80% of stent patency can be achieved for 8.5 months with a dramatic drop in patency rate to 27% at 9 months. In a previous study [10], the mean stent duration was 8.6 months, whereas the mean stent durations for benign and malignant disease were 11.8 and 7.3 months, respectively. In another series, stent exchange was necessary in 12 patients with malignant obstruction after a mean indwelling period of 11 months (range 8–14 months) [8]. Encrustation was present on all exchanged stents, even in the macroscopically normal stents. Therefore, attempts to extend the stent indwelling time could be problematic. Stent exchange may be considered 9–12 months after insertion.

From the results of the present study, patients with malignant or benign ureteral obstructions can be treated safely and sufficiently with Resonance metallic stents. The stent may provide adequate drainage for nearly 9 months, obviating the need for frequent stent exchange. However, careful patient selection is critical to achieve better results. For malignant ureteral obstructions, previous radiation therapy is a predictor for stent failure. As results in different series have been conflicting, further clinical studies are mandatory to clarify the indications for the use of this novel stent.

CONFLICT OF INTEREST

None declared.

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Abbreviations: **PCN**, percutaneous nephrostomy; **HRQL**, health-related quality of life; **MUO**, malignant ureteral obstruction; **US**, ultrasonography; **RMS**, resonance metallic stent.