

Initial Experience with the Resonance Metallic Stent for Antegrade Ureteric Stenting

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Abstract

Background and purpose We describe our initial experience with a new metallic ureteric stent which has been designed to provide long-term urinary drainage in patients with malignant ureteric strictures. The aim is to achieve longer primary patency rates than conventional polyurethane ureteric stents, where encrustation and compression by malignant masses limit primary patency. The Resonance metallic double-pigtail ureteric stent (Cook, Ireland) is constructed from coiled wire spirals of a corrosion-resistant alloy designed to minimize tissue in-growth and resist encrustation, and the manufacturer recommends interval stent change at 12 months.

Methods Seventeen Resonance stents were inserted via an antegrade approach into 15 patients between December 2004 and March 2006. The causes of ureteric obstruction were malignancies of the bladder ($n = 4$), colon ($n = 3$), gynecologic ($n = 5$), and others ($n = 3$).

Results One patient had the stent changed after 12 months, and 3 patients had their stents changed at 6 months. These stents were draining adequately with minimal encrustation. Four patients are still alive with functioning stents in situ for 2–10 months. Seven patients died with functioning stents in place (follow-up periods of 1 week to 8 months). Three stents failed from the outset due to bulky pelvic malignancy resulting in high intravesical pressure, as occurs with conventional plastic stents.

Conclusion Our initial experience with the Resonance metallic ureteric stent indicates that it may provide adequate long-term urinary drainage (up to 12 months) in patients with malignant ureteric obstruction but without significantly bulky pelvic disease. This obviates the need for regular stent changes and would offer significant benefit for these patients with limited life expectancy.

Keywords Antegrade · Metal · Percutaneous · Ureteric stents

Introduction

Long-term urinary drainage in patients with malignant ureteric strictures is often managed by internal ureteric stenting. A variety of ureteric stents, made from different plastic materials (polyurethane/polyethylene), are available, but the primary patency of plastic ureteric stents is often disappointing due to compression by the pelvic tumor [1, 2], and encrustation. Regular stent replacements are advised by the manufacturers (usually at 3-monthly intervals). Such stent replacements require either day-case admission for flexible cystoscopy under local anesthesia, or overnight admission to hospital for rigid cystoscopy under general anesthesia. Sometimes there are problems with stent changes and patients may then suffer a longer hospital stay and occasionally have to undergo reinsertion of stents via the antegrade route. Efforts have been made in developing metallic ureteric stents that aim to achieve more prolonged primary patency rate in malignant obstruction which might obviate the need for regular stent change. However, the most widely used self-expanding metallic stents (uncovered) have had problems with encrustation and tumor in-growth, and some patients require further

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insertion of an internally placed double-J plastic pigtail stent to achieve the desirable urinary drainage [3–5].

A recent development is the Resonance metallic double-pigtail ureteric stent that is formed by a tight spirally coiled metal wire of a special alloy (Cook, Ireland) (Fig. 1), which aims to prevent tumor in-growth and resist encrustation, thereby providing primary patency rates over longer periods of time. This device was initially designed for cystoscopic retrograde insertion by urologists, and we now describe our initial experience with percutaneous (antegrade) placement of this Resonance metallic ureteric stent for the management of patient with malignant ureteric obstruction. It is hoped that these stents can remain in situ for 12 months before stent change is necessary. This would obviate the need for regular stent changes and offer significant benefit for these patients with limited life expectancy.

Materials and Methods

The Resonance stent (Cook, Ireland) is a continuous, unfenestrated all-metal double-pigtail ureteric stent with no end or side holes and that has an internal safety wire welded to both closed ends (Fig. 1). It is therefore deployed through a long sheath rather than over a guidewire. It is made of MP35N alloy, which is a composite of non-magnetic nickel-cobalt-chromium-molybdenum. This metal alloy is corrosion-resistant, MRI-compatible, and has ultrahigh tensile strength.

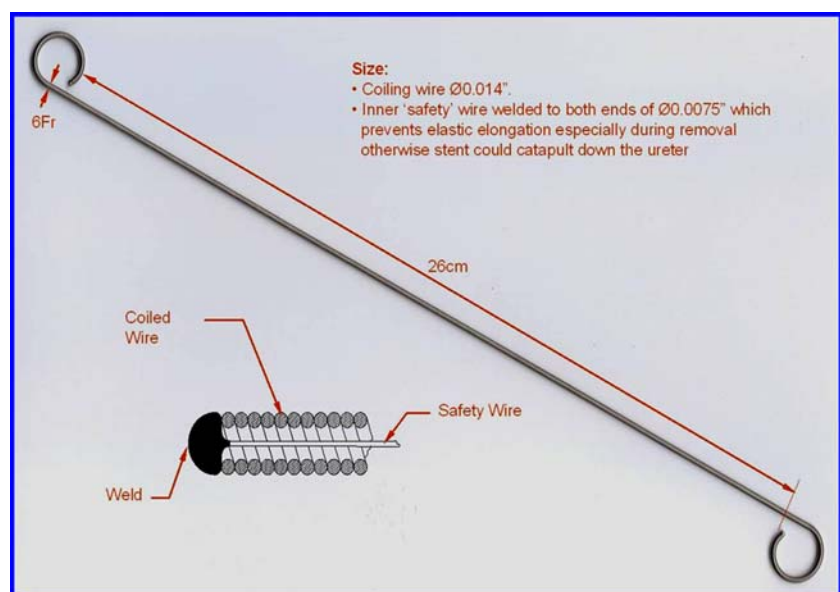
During the period from December 2004 to March 2006, a total of 17 Resonance stents were inserted via an antegrade approach into 15 patients (5 male, 10 female) with ages ranging from 37 to 78 years (mean 64 years). All

were selected for this type of stent on the basis of malignant disease and expected survival of greater than 6 months. The causes of ureteric obstruction were malignancies of the bladder ($n = 4$), colon ($n = 3$), gynecologic ($n = 5$), and others ($n = 3$).

All the cases were performed by a consultant uro-radiologist (T.M.W. and H.C.I) as either a one-stage procedure in patients without impaired renal function or a two-stage procedure in patients requiring percutaneous nephrostomy before antegrade ureteric stent insertion because of acute renal failure. Prophylactic antibiotics were routinely administered. Routine coagulation profiles were obtained prior to the procedure, and abnormal clotting was corrected with fresh frozen plasma, prothrombin complexes, or platelet infusions. A baseline renal function measurement was obtained. All procedures were performed under local anesthetic with intravenous sedation using a combination of midazolam and pethidine.

For the one-stage procedure, an antegrade approach is performed by puncturing a dilated interpolar calyx using a 19G sheathed needle under ultrasound guidance. A nephrostogram is performed to outline the collecting system. Fig. 2 shows a left tight distal ureteric stricture caused by recurrent cervical cancer. A J-tip guidewire (85 cm, Cook) is inserted into the collecting system, over which a 6 Fr manipulation catheter (Torcon Blue, 6 Fr, 55 cm, Cook) is used to cannulate the ureter. A hydrophilic-coated guidewire (Hiwire, 150 cm, Cook, Ireland) is used to negotiate the stricture so that the 6 Fr manipulation catheter can be passed over the wire into the bladder. The guidewire is exchanged for a superstiff Amplatz guidewire (Boston Scientific, MA, USA) and the catheter is removed. A coaxial system of catheter/sheath is then passed over the wire: an inner 5 Fr ureteric catheter and an outer 9 Fr

Fig. 1 A double-pigtail 6 Fr Resonance metallic ureteric stent (Cook, Ireland)



introducer sheath (Cook, Ireland) (Fig. 3). Both the guidewire and the inner ureteric catheter are then removed, leaving the tip of the outer sheath in the bladder, and a 6 Fr Resonance metallic ureteric stent (Cook, Ireland) is inserted through the introducer sheath into the bladder using a plastic pusher at the proximal end.

Once the distal pigtail has formed in the bladder, it is important to check the proximal end to avoid pushing the ureteric stent too far in, as there is no retrieval thread/mechanism with this deployment kit (Fig. 4a, b, c). Once the proximal end is placed within the calyx, the final step is to remove the introducer sheath over the pusher whilst holding the pusher in a constant position. When the introducer sheath reaches a marked site on the pusher, there is then only the proximal pigtail left inside the sheath at that point (Fig. 5). Further removal of the sheath over the pusher allows the formation of the final pigtail in the collecting system (Fig. 6).

All demographic variables, baseline renal function, radiological imaging, and immediate complications were prospectively documented. The stent patency was monitored with regular renal function tests to detect worsening of renal

function, and interval ultrasound performed (at 1 day, and 3, 6, and 12 months) to assess for the presence of hydronephrosis which may suggest stent blockage requiring earlier stent change. We have also performed nephrostograms in 6 patients (7 stents, as 1 patient had bilateral procedures) at 1 day following stent insertion. Three patients were the initial cohort within the series and the other 3 had bulky pelvic disease which was causing impaired drainage through the stents. All the patients were followed up for late complications until defined endpoints, which are either stent removal and change or patient death with the stent in situ.

Results

Between December 2004 and March 2006, 5 men and 10 women, with an age range from 37 to 78 years, underwent antegrade insertion of a Resonance metallic ureteric stent (Cook, Ireland). Two of these patients underwent bilateral insertion of Resonance metallic ureteric stents. Nine stents were on the right side and 8 were on the left. The insertion of 15 of the stents was performed as a single-stage procedure, whilst the insertion of 2 was performed as a two-stage procedure.

The causes of ureteric obstruction were malignancies of the bladder ($n = 4$), colon ($n = 3$), gynecologic ($n = 5$), and others ($n = 3$). All patients were selected on the basis of malignant pelvic disease causing ureteric obstruction in whom optimization of renal function was required prior to adjuvant chemotherapy and in whom there was an estimated life expectancy of greater than 6 months at the time of referral for stent insertion.

Renal function was monitored with serum creatinine. Before the stent insertion, 5 patients had normal renal function and 10 patients had abnormal renal function. All patients with normal renal function maintained this status following stent insertion. Amongst the patients with abnormal renal function, in 7 patients function showed improvement which ranged from 15% to 67%, 2 patients remained stable, and 1 patient had worsening of renal function associated with fulminant sepsis from pneumonia.



Fig. 2 A left nephrostogram shows a long tight distal left irregular ureteric stricture due to recurrent cervical cancer

Fig. 3 **a** The coaxial technique to anchor the tight stricture with superstiff guidewire, ureteric catheter, and introducer sheath as shown during the procedure. **b** The supplied kit

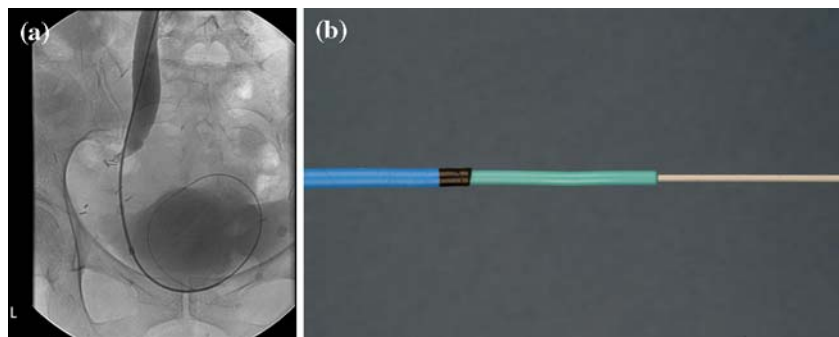


Fig. 4 **a, b** The distal pigtail of the metallic ureteric stent was beyond the introducer sheath and within the bladder. **c** The proximal pigtail of the metallic stent was within the collecting system



Fig. 5 The introducer sheath had been withdrawn to the marked site on the pusher and this meant that only the proximal pigtail end was left in the introducer sheath

During the follow-up period with radiology imaging, all patients had serial ultrasound scans and 6 patients with 7 stents (1 patient had bilateral stent insertions) also had a nephrostogram on the day following stent insertion. Four of 7 nephrostograms showed good drainage and their covering nephrostomies were removed. Three of the nephrostograms, all in patients with bulky pelvic disease, revealed sluggish flow via the stents due to significant increased intravesical pressure from the bulky pelvic malignant disease, and the patients' renal function deteriorated when the nephrostomies were spigoted off, thus confirming poor drainage via the stent. These 3 patients were maintained on long-term external urinary drainage via percutaneous nephrostomies.

All patients were subsequently followed up with both ultrasound scans at 3-monthly intervals to check for any hydronephrosis and with renal function monitoring until 1 year or death with the stent in situ. Apart from the 3 patients with failed stents from the outset, all other patients had no evidence to suggest stent blockage during their follow-up period until the time of stent change or death with the stent in situ.



Fig. 6 The final position of the double-pigtail Resonance metallic ureteric stent (Cook, Ireland) was satisfactory and as shown

The duration of ureteric stent drainage for these patients ranged from 1 week to 1 year. Amongst them, 1 patient had the stent changed after 12 months and 3 patients had their stents changed at 6 months by urologists in other hospitals according to the conventional stent change protocol. These stents were draining adequately with minimal encrustation. To date, 4 patients are still alive with functioning stents in situ for 2–10 months (1 patient each at 2, 6, 8, and 10 months follow-up to date) and 7 patients have died with functioning stents in place (follow-up periods of 1 week to 8 months). A total of 3 stents failed from the outset due to bulky pelvic malignancy resulting in high intravesical pressure, as occurs with conventional plastic stents.

Discussion

Percutaneous nephrostomy has traditionally been used to provide urinary drainage for patients with malignant

ureteric obstruction. It is now widely accepted clinical practice to provide internal ureteric stenting for long-term urinary drainage in these patients. This renders them “tubeless” and offers them a better quality of life.

Malignant ureteric strictures may be negotiated using the antegrade, retrograde or a combined (“rendezvous”) approach. Various ureteric stents of various materials are now available. However, the primary patency of plastic ureteric stents is often disappointing due to compression by the pelvic tumor [1, 2], and other disadvantages are: necessity of frequent ureteric stent change (most need to be changed every 3–6 months), insufficient relief of obstruction despite internal ureteric stenting, and premature ureteric stent blockage due to encrustation.

Efforts have therefore been directed at the development of metallic ureteric stents that aim to achieve a better primary patency rate in malignant obstruction, so as to minimize the need for ureteric stent change. However, the most widely used metallic (uncovered) stents have proved disappointing due to tumor in-growth and encrustation [3–5].

The new Resonance metallic double-pigtail ureteric stent consists of a tight spirally coiled metal wire (Cook, Ireland) and aims to prevent tumor in-growth. It functions as a conventional double-pigtail ureteric stent with better primary patency rate and a 1 year in-dwelling life span. It has no end hole, and the urine drains primarily around the outer aspect of the spiral coiled metal, although if pressure within the urinary system increases urine can enter the internal lumen of the coil and then drain outward once a low-pressure system is encountered (beyond the stricture). This device was initially designed for cystoscopic retrograde insertion by urologists using a ureteric catheter/guidewire and introducer sheath without a retrieval mechanism. We have described our initial experience with the antegrade percutaneous insertion of this stent and its feasibility. In our experience, the anchorage with the guidewire and inner ureteric catheter allows very tight malignant strictures to be negotiated by the wider bore introducer sheath. The introducer sheath allows insertion of the metallic double-pigtail ureteric stent with ease. Although there is no retrieval mechanism, this has proven not to be a problem with careful planning and placement. There are commercially available snares and other retrieval devices available if there is a need to retrieve a malpositioned ureteric stent.

To date, we have demonstrated that despite the fact that this stent has a different deployment mechanism to other antegrade stents we have used hitherto, it can be inserted with relative ease after an initial learning curve. All the stents at the time of exchange were changed via a cystoscopic approach with relative ease by the urologists. Some urologists prefer to pass a guidewire alongside the stent as this stent does not have an end hole for cannulation by the

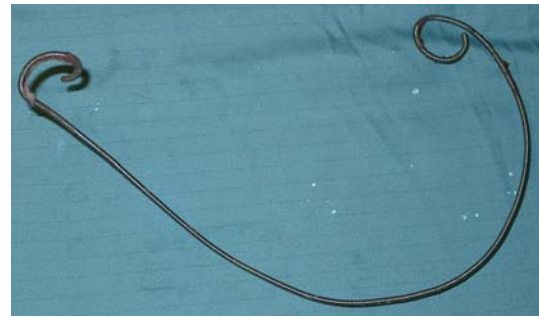


Fig. 7 This Resonance metallic ureteric stent which was removed at 12 months showed no significant stent encrustation

guidewire, whilst others prefer to remove the stent before reinsertion of the stent retrogradely. The one stent that was removed in our institution at 1 year had remained patent on imaging and was free of any significant stent encrustation at the time of removal (Fig. 7).

Our initial experience with the Resonance metallic ureteric stent indicates that it may provide adequate long-term urinary drainage (up to 12 months) in patients with malignant ureteric obstruction but without significantly bulky pelvic disease. This obviates the need for regular stent changes and would offer significant benefit for these patients with limited life expectancy.

In addition, for this selected group of patients, this stent not only improves their quality of life but also provides a cost-efficient service. The cost of this stent including the deployment kit is £600 (870 Euros). For most conventional plastic stents, at least two or three stent changes per year are required for each patient, the cost of each visit, including the theater time, anesthetic support, and overnight hospital stay, amounting on average to about £2000 (2900 Euros). Therefore, despite of the initial higher cost of the individual stent when compared with conventional plastic stents, we consider that the Resonance stent (Cook, Ireland) is a useful and valid alternative for patients with malignant disease who require long-term urinary drainage.

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