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The Current Role of Memokath 051 Thermo-Expandable Metal Stent in Management of Benign and Malignant Ureteric Strictures

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Abstract

Stent technology has progressed dramatically over the past 100 years. JJ stents are essential tools for any urologist. They do have however have their own limitations with complications including stone formation, infection, reflux, stent pain, migration and importantly encrustation, which therefore requires stent changes every 3-6 months. Metal stents have been used to try to minimise these complications with mixed results.

In this paper we look specifically at the Memokath 051 thermo-expandable stent and the available evidence for its use in the treatment of benign and malignant ureteric strictures.

The Memokath 051 thermo-expandable stent is better tolerated than the conventional JJ stents and provides a statistically significant improvement in the patients' quality of life as well as low rates of bladder irritation, stent encrustation, reflux and flank pain. It also requires less frequent changes than conventional JJ stents which significantly reduces the episodes of hospital admissions and subsequently their possible associated morbidities, this also makes it a cost effective treatment option.

Keywords: Stent; Ureter; Stricture; Memokath

Introduction

Stent technology has dramatically progressed over the last century. Pigtail stents were designed by Finney in 1978 [1] and since then pioneers have tried to improve this design further to reduce the complications.

Metal stents were fist used in the vascular system in 1987 by Sigwart et al. [2] and are now commonly used in the cardiovascular and biliary system [3]. They were introduced to urology afterwards due to the reported problems with the use of the JJ stents. The first metal stent, the Wallstent, has been used in the urethra for urethral stricture, for bladder outlet obstruction, for detrusor-sphincter dyssynergia and also in the ureter for strictures and external compression [4]. The main complications were encrustation, infection, stent pain and stones.

In order to reduce these complications, other types of metal stents were developed from different alloys and with different coatings, to give them different properties which would minimize these complications [5]. The thermo-expandable alloys were invented so that stents could be inserted in a less traumatic fashion and to be more easily anchored into position. In this paper we review the Memokath 051 thermo-expandable stent and look into its applications and current role in management of benign and malignant ureteric disease.

Memokath 051 Stent

The Memokath 051 stent is a thermo-expandable, nickel-titanium alloy stent (PNN Medical A/S, Denmark). This was developed initially for insertion into the urethra for benign prostatic hypertrophy and urethral strictures. A ureteral stent was then developed further for use in benign and malignant strictures as well as external ureteral compression [6].

One key problem with the early metal stents was endothelial in-growth of the tumour or stricture into the stent [4]. This meant that the stent did not migrate but the lumen would get blocked eventually and made it very challenging if not almost impossible to remove and insert a new stent. The Memokath has a closed spiral shape which aids to prevent this particular complication from occurring.

The current Memokath 051 is 10.5 Fr in shaft diameter and has a fluted end which expands to 22 Fr. Different lengths are on the market at 30, 60, 100, 150 and 200 mm depending on stricture length. This is larger in diameter than the original stent when it was first launched which was 9.5 Fr in shaft diameter and had also a fluted end which expanded to 14 Fr. This was enlarged as the main complication of the stent was migration. The rationale behind the shape was that it would be more easily removed than previous metal stents as there would be less tumour in-growth as well as exerting less pressure on the endothelial wall and therefore enabling normal ureteric peristalsis to take place [7]. Being a small stent just placed in the region of the stricture, there are less bladder irritation symptoms which are common with the JJ stent [8].

The Memokath is thermo-expandable as it softens at less than 10°C and then retains its normal shape and conforms to the shape of the ureter at temperatures of 50-55°C [9]. It is more commonly inserted in a retrograde fashion, but it can still be inserted in either antegrade or retrograde manners.

The stricture length is first measured using retrograde or antegrade ureterography. An appropriately sized stent is then chosen, which is slightly longer than the original stricture. The guidewire is then passed across the stricture and then the stricture is dilated up to with either a balloon dilator or graduated Teflon dilator. The Memokath 051 is then inserted over the guidewire on an introducer and the guidewire

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is withdrawn. There is a port for insertion of preheated sterile water at 60°C at the end of the assembly. This allows the stent to take up the shape of the ureter as well as expand the flute at the end of the stent to anchor it in place. Stent position can be checked with either direct ureteroscopy or with an ureterogram. Previous JJ stenting is not essential as with other metallic ureteric stents [7].

Discussion

Benign ureteric obstruction can be treated with internal or external drainage. External drainage options involve either a nephrostomy or ureterostomy and both can have significant morbidity associated [9]. The internal drainage option of choice is the JJ stent which is the gold standard treatment. This however carries complications including stone formation, infection, reflux, stent pain, migration and importantly encrustation, which therefore requires stent changes every 3-6 months [10].

The role in malignant disease is mainly palliation as well as for post radiation strictures and for ureteric damage following surgery. Follow up for these patients in the studies are much shorter as people with pelvic cancers usually have a shorter life expectancy. The aim of the Memokath stent is to be inserted and left in situ for the expectant remaining life of the patient and thus improving their quality of life during that time and reducing their episodes of hospital admissions. If the patient were to live for 12 months, they would require 2-4 conventional JJ stents as they are changed every 3-6 months. Every stent change can carry with it an element of morbidity such as exposure to general anaesthesia in addition to the potential for life threatening complications such as urosepsis.

A study by Maan et al. [8] compared the stent related symptoms and quality of life with JJ stents to the Memokath 051 using a validated questionnaire. They posted out validated questionnaires to patients with either of the above stents. They had a response from 41 patients (58.5%). Within this group was a subgroup of 10 patients who had both stents. 70% patients with JJ stents experience urinary frequency of less than 2 hours compared with 47% of the Memokath group. 31.8% JJ stent patients were extremely bothered by their urinary symptoms compared with 5.6% of Memokath patients. The pain, urinary symptom index and general health were statistically better in the Memokath group. In patients who had experienced both stents, they would prefer the Memokath for future stent insertion.

Arya et al. [11] had only 13 stent placements inserted in 11 patients in their 3 year series. All 11 patients had benign ureteric strictures, 3 patients had radiation fibrosis, 2 had ischaemic uretero-ileal anastomosis, 2 had scarring post ureteroscopy and others had retroperitoneal fibrosis, diathermy damage, extra-luminal endometriosis and fibrosis following stone passage. The series reported very few side effects. 3 stents became encrusted and one migrated. These had to be removed but the range of time in situ was 4-33 months with a mean of 16 months. This is far longer than it is possible to leave in a conventional JJ stent. This study had much longer follow up than other studies as the patients had benign disease and so presumably lived longer. Their conclusion was that patients particularly at risk of encrustation needed regular follow up to check stent patency but it is a good treatment option as it can be left in situ for such a long time when compared to the JJ stent and gives fewer side effects.

Papatsoris and Buchholz [12] published their benign and malignant data in 2010, which is the largest reported series in literature, prior to an update on just their malignant data in 2011. Their series contained 73 patients with 86 strictures. 55 were benign and 31 were malignant. Patients were followed up with radiography, renal ultrasonography, and renography where required at 2 weeks, 3 months, and then every 6 months. They reported a quick operating time of a mean of 23 minutes and short hospital stay of mean 1.5days. Mean follow up was 17.1 months at which point, 68 stents were in situ. The main complications were stent encrustation, urinary tract infection and stent migration. In total there were 26 complications from a total of 102 Memokath stent insertions (25%). 15 stent migrations requiring manipulation, 5 stent removals due to encrustation and 6 urinary tract infections. There were 6 treatment failures. There were interestingly 12 cases of spontaneous ureteral stricture resolution after a mean indwelling time of 9 months. They also still reported an overall cost benefit compared to the JJ stent, as the average stent indwelling time was 11.2 months.

More cases were collected and combined to the series from Papatsoris et al. [12] and were published in a series by Zaman et al. [13] in 2011. This series was a purely malignant ureteric obstruction series treated with Memokath 051 stent. There were 37 patients and 42 stent insertions. 15 patients had gynaecological cancer, 8 had bowel cancer, 5 were post radiation treatment, 5 had prostate cancer and 4 had other malignancies. The complications were 5 stent migrations, 3 urinary tract infections and 2 cases of stent blockage secondary to progressive transitional cell carcinoma occluding the stent. The follow up range was 5-60 months with a mean of 22 months. They concluded that the use of Memokath 051 ureteric stents is safe, effective and durable in the long-term treatment of malignant strictures.

Klarskov et al. [14] reports a series of 34 patients, 22 had benign strictures, five had post-radiation strictures and seven had malignant strictures. They were followed up at 1 month and subsequently 3 monthly. 37 stents were inserted in total into 33 patients as pre-insertion dilatation was impossible in one patient. This patient had a radiation stricture. Median follow up was 14 months (range from 3-30 months). 15 stents were in place and functioning with no discomfort or complications at death or the end of follow-up. Complications included 10 stent migrations and 12 malfunctioning stents, 4 of which were due to underestimating the length of stricture and after a longer stent was inserted there were no further issues. 4 stents were occluded by stones but no tissue in-growth was seen. Stent removal was easy, with the exception of one patient with stent calcification.

Kulkarni et al. [14] have recently published their impressive long term 11 year follow up series [15] including 55 patients who were treated with 74 stents. 28 patients had malignancies, 10 of these were colorectal and the others were wide ranging from lymphoma to vulval cancers. 27 had recurrent benign disease. The mean hospital stay was 1.43 days (range 0-7 days). Post procedure imaging showed improved functional drainage in all but 3 cases which had urinary extravasation in one case, equipment failure in another case due to failure of the locking assembly and poor thermo-expansion in another case. Their most common complication was stent migration that occurred in 13 out of their 74 patients (17.5%). They did however report low rates of encrustation 3.7%, compared to other series which reported 12-27%. Overall, 29 patients died with the stents in-situ. The mean follow up was 16 months (Range=4-98 months).

A small series of just 16 patients with chronic ureteral strictures previously treated by JJ stents by Aziz et al. [16] yielded interesting results. 20 stents were inserted in total. They were unable to technically insert the stent in 2 patients and one stent had to be removed the day after insertion. The mean durability of the stent was 13months. The main complications were migration in 6 (30%) and 4 (20%)

obstructions. 13 of 14 patients experienced significant improvement of their previously reported JJ stent related symptoms.

Bonniol et al. [17] inserted 15 stents into 14 otherwise non-operable patients with benign recurrent strictures previously treated by JJ stents. The stent size ranged from 6-15 cm in length. Median follow up was 11 months, ranging from 6-24 months. There was recurrence of stenosis in 4 patients due to migration with 3 stents spontaneously expelled. Other complications were 3 urinary tract infections successfully treated with antibiotics. The stents were very well tolerated with a VAS pain score of 3/10.

Papadopoulos et al. [18] inserted 19 Memokath 051 stents over a 5 year period into 13 patients (10 benign strictures and 3 malignant strictures). All patients were previously treated with JJ stent or ureteric dilation. Average stricture length was 3.2 cm with median stent length of 60 mm. Mean follow up was 14.3 months. 6 patients had a satisfactory outcome after the first insertion, while 6 patients had stent migration of which 3 had successful insertion at second attempt. 10 of 13 (77%) had successful outcome eventually after the final stent insertion.

Another interesting publication was that by Boyvat et al. [19] who have published on a small cohort of patients who underwent antegrade Memokath 051 insertion. They treated 4 patients who developed anastomotic stricture following renal transplant. Memokath 051 was inserted via an antegrade approach in all 4 cases. Follow up was measured with creatinine levels as well as ultrasonography. There was one stent migration at 10 days. Another stent was removed at 14 months due to recurrent urinary tract infections. The replacement stent remained patent. The authors believe this is a promising alternative treatment to conventional JJ stents, balloon dilation and open intervention.

Cost is an important issue as the Memokath is expensive at around £1500 compared to the JJ stent at £80. Kulkarni et al. [9] worked out the cost, including hospital stay, in their centre of Memokath insertion at around £6295 compared to £3220 for the JJ stent. The advantage being that the JJ stent only lasts 3 months and so at 6 months providing there are no complications the more expensive Memokath becomes a cost effective option.

Conclusion

The Memokath 051 thermo-expandable stent is safe and effective for treatment of both benign and malignant ureteric strictures. Not only that it is better tolerated than the conventional JJ stents with a subsequent statistically significant improvement in the patients' quality of life, but it also has the advantages of bearing minimal risk for bladder irritation, stent encrustation, reflux and flank pain.

It requires less frequent changes when compared to the conventional JJ stents which significantly reduces the episodes of hospital admissions and subsequently their possible associated morbidities, this also makes it a cost effective treatment option.

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