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ORIGINAL ARTICLE

Thermo-expandable metallic urethral stents for managing recurrent bulbar urethral strictures: To use or not?

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KEYWORDS

Bulbar urethral stricture;
Stents;
Recurrent stricture

ABBREVIATIONS

DSD, detrusor sphincter dyssynergia; DVIU, direct visual internal urethrotomy; PVR, postvoid residual (urine)

Abstract ***Objectives:*** To assess the role of temporary thermally expandable urethral stents in maintaining urethral patency in patients with a recurrent bulbar urethral stricture.

Patients and methods: Twenty-three men with a recurrent bulbar urethral stricture after several attempts at direct visual internal urethrotomy (DVIU) and/or failed urethroplasty were managed with a thermally expandable, biocompatible nickel–titanium alloy urethral stent (Memokath® MK044, Pnn Medical, Kvistgaard, Denmark). The stents were applied by a special mounting device via a rigid urethroscope after DVIU. All patients were followed using plain radiography, uroflowmetry and urine analysis every 3 months for 1 year, and then every 6 months.

Results: The mean (SD) age of the patients was 55.4 (7.3) years and the mean (SD) stricture length was 3.6 (1.2) cm. All patients tolerated the stent, with minimal discomfort in some patients. Four patients (17%) had urinary tract infections, three (13%) had haematuria, three (13%) had obstructed stents due to encrustation, in five (22%) the stent migrated, and two patients had no delayed complications. The mean (SD) follow-up was 17.4 (6.1) months.

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Conclusion: Urethral stenting with nickel–titanium alloy thermally expandable stents can be an acceptable temporary procedure for patients with recurrent bulbar urethral strictures who are unfit for or who refuse urethroplasty. However, they have limitations; the search for an ideal urethral stent continues.

Introduction

A urethral stricture results from a scarring process that affects the anterior urethra, with subsequent spongiofibrosis that is gradually progressive and results in a decrease in the diameter of the urethral lumen. Patients usually start to complain of obstructive symptoms, according to the severity of the obliteration [1,2].

A definitive diagnosis can be made with an ascending urethrogram coupled with diagnostic cystoscopy [3]. The use of ultrasonography has been advocated as a reliable method to define the extent of spongiofibrosis and the absolute length of the urethral stricture [4].

The treatment plan for a urethral stricture includes variable options, e.g. dilatation, urethrotomy, stenting and reconstructive surgical techniques, and no one technique is appropriate for all stricture diseases [5].

Urethral dilatation alone or coupled with direct visual internal urethrotomy (DVIU) is not curative in all cases, but can be in selected patients [6]. DVIU is especially suitable for a short stricture in the bulbar urethra with no spongiofibrosis, has high failure rates when the stricture is long, and should not be used in the penile urethra. Also, several failed DVIU procedures compromise the chances of success in a future urethroplasty [5]. Urethroplasty remains the best option, with higher success rates and a satisfactory outcome, when indicated [6].

Urethral stents are another method used to oppose the forces of wound contraction after internal urethrotomy or dilatation. Removable urethral stents are designed to prevent the process of epithelialisation from incorporating the stent into the urethral wall, and are often left in place for up to 6–12 months before they are removed. Table 1 [7–18] shows the indications, complications and success rates of different types of stents, as given in previous reports.

A thermo-expandable stent with an 'inherited' shape memory, made of Nitinol, has been assessed in many studies in the USA, assessing its efficacy as a temporary treatment for urethral strictures [7]. In the present study we assessed the role of temporary thermo-expandable urethral stents in maintaining urethral patency in patients with a recurrent bulbar urethral stricture.

Patients and methods

This study was conducted in the Urology department of Menoufiya University Hospital, Menoufiya University, Egypt, from August 2008 to November 2011. The study was reviewed and approved by the hospital ethics committee. The study included a heterogeneous group of 23 men who presented with symptoms of BOO due to a recurrent urethral stricture. Most of the patients had undergone dilatation or DVIU and urethroplasty.

The study included patients who had a recurrent stricture of the bulbar urethra, referred to treatment, that was $\geq$50 mm long on urethrography and with $\geq$10 mm of healthy urethral tissue distal to the external sphincter. Patients were excluded if there was $<$10 mm of visibly healthy bulbar urethral tissue distal to the external sphincter, or any urological condition that would require additional urethral instrumentation, e.g. BPH requiring treatment, active prostate cancer, bladder malignancy, or recurrent urinary stone formation.

Patients were counselled about their condition and the possible management options. Patients who chose stent insertion were informed about possible complications and disadvantages. Written informed consent was obtained from all patients.

Preoperative preparation

All patients had a history taken, a general and local examination, preoperative laboratory tests and retrograde urethrography, uroflowmetry, an estimate of their postvoid residual (PVR) urine volume, and urethroscopy at the time of the stent insertion.

Instrumentation

The thermo-expandable stent (Memokath® MK044, Pnn Medical, Kvistgaard, Denmark) for bulbar urethral strictures was used; this is a temporary stent, made of a nickel–titanium alloy that has a 'shape memory' feature [8]. This alloy is present in two crystalline forms, the more rigid form holding the memorised shape of the Memokath at body temperature and higher. The other form is softer and pliable; transition to this form takes place when the alloy is cooled to $\leq$10 °C [19]. The stent is available in lengths from 30 to 70 mm in intervals of 10 mm. It expands from 24 to 44 F at its proximal end, forming a cone that fixes it to the urethra and prevents migration.

Operative procedure

The operating table for insertion should have available urethral dilators (up to 26 F), a guidewire (0.09 mm,

Table 1 Indications, complications and success rates of different types of stents in previous studies.

Study	No. of patients	Stent type	Indication	Complications, *n* or *n* (%)				Mean follow-up (months)	Success, *n* or *n* (%)
				UTI	Encrustation	Migration	Hyperplasia		
[9]	175	Urolume	BUS	15 (11)	NS	7 (4)	All had ES	24	163 (93)
[11]	29	Memokath	DSD	10 (35)	14 (48)	7 (24)	NS	21	NS
[12]	8	Medinvent wallstent	BUS	NS	NS	NS	All had ES	8	NS
[7]	18	Metallic coil self-expanding	BUS	7 (39)	No	NS	No	8	17 (94)
[13]	20	Expandable titanium	BPH & BUS	No	No	No	No	12	15 (75)
[14]	7	Medinvent wallstent	BUS	NS	NS	NS	4	23–31	3
[15]	49	Memotherm	25 BPH						
			21 BUS-otomy	NS	NS	NS	2 (4)	24	45 (91)
[16]	12	Medinvent wallstent	DSD	No	No	No	No	60	5
[10]	60	Urolume	BUS	NS	NS	NS	NS	45.6	52 (87)
[8]	211	Memokath	BPH	(6)	No	(13)	NS	96	(63)
[18]	13	Urolume	Posterior US	5	NS	2	NS	18	7
[17]	10	Memokath	BUS	2	2	3	2	12	5

(B)US, (bulbar) urethral stricture; NS, not specified; ES, encrustation of the stent.

0.038 inch) with a straight tip, a 50 mL plastic syringe, a thermometer, two markers and a ruler. An antibiotic was administered intravenously before the procedure. Most patients received spinal anaesthesia and some received local anaesthesia with intra-urethral 2% lidocaine gel 5–10 min before the procedure, and a mild sedative (midazolam) at a dose of $\leq$0.03 mg/kg given slowly over at least 2 min [20]. The patients were placed in the lithotomy position, prepared and draped appropriately; cysto-urethroscopy was used to assess the site of the urethral stricture and exclude the presence of stones or neoplasia.

The urethral strictures were treated by internal urethrotomy to a minimum diameter of 26 F, then the length of the stricture assessed to define the appropriate length of the Memokath stent, based on the estimated stricture length plus 2.0 cm to allow for a 10-mm overlap at either end of the stricture. The three retaining straps from the Memokath transport shell were removed using a scalpel, the transport shells removed from the stent delivery system, and the mandrel was pushed out of the delivery system, by inserting the cystoscope lens into the hub of the delivery system. The locking collar at the base of the insertion sheath was then rotated clockwise. A soft rubber ring inside the collar is compressed to create a watertight junction between the sheath and the cystoscope lens. Sterile water or saline is connected at $\leqslant$35 °C to the stopcock and the light source is mounted. The stent, on its introducing sheath, is mounted onto the cystoscope so that the tip of the cystoscope is clear of the stent by 2–3 mm, the cystoscope is advanced until the tip passes $\approx$1 cm proximal to the proximal end of the stricture, then 50 mL of hot water (50 °C) is flushed through the cystoscope. This expands the proximal 4–6 mm into a cone shape (44 F) which 'locks' the stent into position. The stent is released from the sheath when the cystoscope lens is withdrawn from the black connector at the tip of the stent. Under direct vision, while the outer sheath is steady, the joined inner sheath and the cystoscope lens are gently retracted from the outer sheath until the black connector at the tip of the introducer is outside the stent. The stent was then released [8]. The procedure was done as 'one-day' surgery.

Follow-up

An antibiotic was administered intravenously for 3 days after the procedure, and then oral antibiotics for 7 days; analgesics were given on demand [21]. Patients were discharged after taking a control plain film, uroflowmetry and an estimate of the PVR, to ensure the appropriate position and function of the stent. The patients were asked to take vitamin C to acidify their urine and thus decrease the incidence of encrustation. Patients were followed up by uroflowmetry, urine analysis and plain radiography at 2 weeks after the procedure and then every 3 months for the first year, and then every 6 months.

For stent removal the patients had local intra-urethral anaesthesia as noted above. Cold saline (5–10 °C) was used as the irrigant, and diagnostic cysto-urethroscopy was used to check the distal end of the Memokath stent. The tip of the stent was grasped by forceps and pulled distally, then released turn-by-turn linearly (Figs. 1 and 2) [19].

Results

The mean (SD) age of the 23 patients with a recurrent bulbar urethral stricture was 55.4 (7.3) years. All patients had a history of DVIU, dilatations and urethroplasties. The mean (SD, range) preoperative flow rate was 4.6 (1.2, 3–7) mL/s and the preoperative PVR volume was 165 (19, 130–190) mL. The mean (SD) stricture

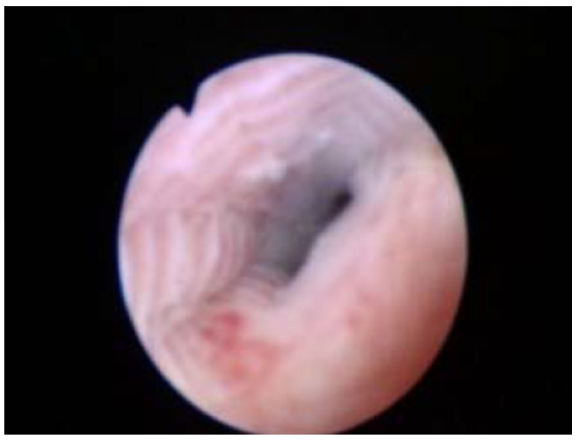

Figure 1 Impact of the stent rings on the urethra.

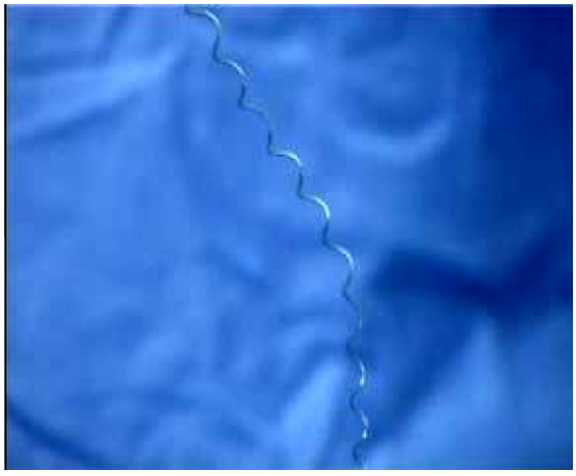

Figure 2 Stent removal.

length was 3.6 (1.2) cm. The procedure was done under spinal anaesthesia in 18 patients (78%) and with intra-urethral xylocaine gel and a mild sedative in five (22%). The mean (SD) operative duration was 34 (9) min.

All patients tolerated the stent, with minimal discomfort in some patients. Perineal pain occurred in six patients (26%) that was transient and disappeared within a few weeks of follow-up. The urinary flow rate improved after stent insertion, to a mean (SD, range) of 21 (2.5, 17–25) mL/s. The PVR volume decreased after stent insertion to 50 (14, 30–70) mL.

Four patients (17%) had UTIs twice or three times during the first 3 months of follow-up, and these were controlled by appropriate antibiotics, according to urine culture and antibiotic-sensitivity tests. Three patients (13%) had intermittent gross haematuria during the first 2 weeks after insertion. The haematuria was initially painful; one patient complained of the presence of a few drops of blood at the urethral meatus, and was managed conservatively, with no stent removal required. Urethral hyperplasia was noted in two patients (8%) who presented with lower urinary tract obstructive symptoms, and the diagnosis was confirmed by cystoscopy; they required removal of the stents. Three patients (13%) had obstructed stents due to encrustation during the first 6 months, and needed lithotripsy to clear the encrustation, which failed in one and the stent was exchanged (Fig. 2). In five patients (22%) the stent migrated, requiring exchange and correctly positioned new stents (Fig. 3). Two patients felt uncomfortable with the stent and had their stent removed at their request. Two patients were free of delayed complications. The mean (SD) follow-up was 17.4 (6.1) months. Thus overall, 10 patients (43%) developed complications (migration, urethral hyperplasia and encrustation) that required intervention.

Discussion

Urethral stents were first introduced in 1980 by Fabian [22] for treating infravesical obstruction due to BPH. Subsequently, the indications were expanded to include the treatment of detrusor sphincter dyssynergia (DSD) due to spinal cord injury and, in 1988, the treatment of urethral strictures [23]. Thermo-expandable urethral stents were first introduced by Soni et al. [24] to treat patients with DSD.

In the present series, 23 patients with recurrent bulbar urethral strictures were treated with the Memokath thermo-expandable urethral stent. The insertion of these stents was simple and minimally invasive, comparable with dilatation and DVIU. Unfortunately the stents failed to give good results during the long-term follow-up. This situation might differ in the near future, as there are further reports of urethroplasty and its acceptable results [25,26].

The main indications for their use are recurrent bulbar urethral strictures after failure of several previous urethroplasties and DVIUs, or in patients with medical comorbidities who are unfit for major surgery, or for those who refuse urethroplasty [27]. In the present study the original cause of the stricture had no effect on the decision to insert a stent or on the incidence of complications. This was similar to the results reported by Palminteri et al. [28] in their study of the management of patients with failed urethral stents. There was an appropriate stent position and function in all the present patients immediately after stent insertion, with an improvement in the flow rate and PVR. Also, Perry et al. [8] reported that most patients treated with the Memokath stent for BOO of the prostatic urethra voided immediately after the procedure, so that the outcome of stent placement was immediately apparent. Recurrent UTI was noted in 17% of the present 23 patients, which was lower than the rate observed by Badlani et al. [9],

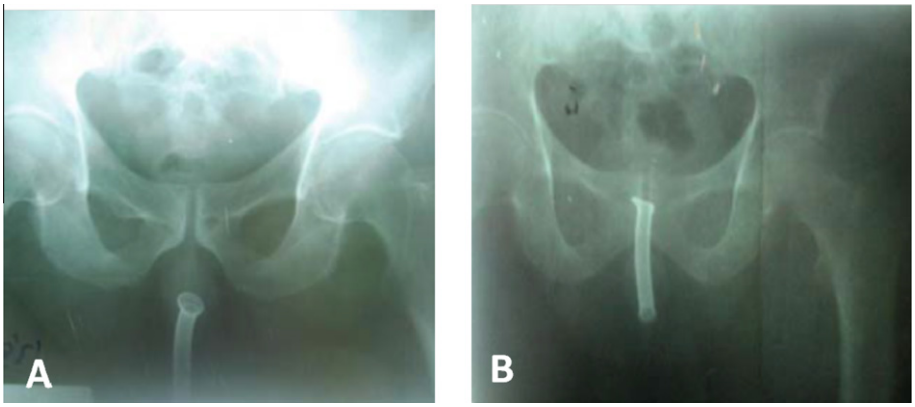

Figure 3 (A) A urethral stent normally placed; (B) Urethral stent migrated upwards into the prostatic urethra.

who reported UTI in 27% of the 60 patients in whom a Urolume stent was inserted and who were followed for 2 years. This difference might be due to the small sample size and the short follow-up in our study (the mean follow-up was 17.4 months). The incidence of UTI might be attributed to a previous history of UTI, together with a prolonged obstructed urinary flow and the presence of the stent as a foreign body. All these factors predispose to a high incidence of UTI that also might be resistant to treatment. Haematuria was present in 13% of the present patients, a higher rate than reported by Perry et al. [8] of 3% in their cases. This was explained by the previous DVIU done during stent insertion, and added vigorous perineal trauma (as during riding a bicycle). Although the Memokath stent has a funnel shape at one end to resist migration, the stent migrated in 22% of the present patients (five of 23). Migration was related to accidental perineal trauma, a faulty trial of catheterisation, and the presence of the stricture close to the sphincter. This was a higher rate than reported by Perry et al. [8], who had stent migration in 13% of their cases (29 patients of 211), and because the Urolume stents do not migrate due to their incorporation into the wall of the urethra [10].

Obstructive symptoms and a decreased flow rate were reported in eight of the present patients (35%). The symptoms became gradually more severe over 6–9 months. Encrustation was noted in five of these patients, that necessitated urethroscopy and lithotripsy to remove the encrusted material. Perry et al. [8] found encrustation in 2% of their cases (five of 211) and mentioned that the reason for the lack of encrustation on these stents was not known, but was attributed to the exceptional smoothness of the surface of the stent and the inert property of the alloy. Encrustation in the present patients was attributed to the higher incidence of UTI and the prolonged obstruction of urinary flow. Also, noncompliance of some patients with the prescribed medications for urine acidification predisposed them to encrustation. Urethral hyperplasia was noted at the ends of the stent in two patients (8%) who gradually developed obstructive symptoms after 9–11 months. This was managed by transurethral resection after stent removal. This rate was slightly lower than that reported by Badlani et al. [9] in their study of the Urolume stent (41.3%). The narrowing was the result of urethral epithelium overgrowth through the interstices of the stent. The low incidence of urethral hyperplasia with the Memokath stent was attributed to the tight coiling of the stent, the inert property of the nickel–titanium alloy from which it is made, and the short duration of indwelling. Yachia [29] reported that with the current urethral stents, other than the Memokath, occasional tissue ingrowth between the loops of the coils, and reactive tissue proliferation at the sphincter end, can cause partial or complete obliteration of the stent. The reason for such reactive tissue proliferation is that the radial stiffness of the sphincter end of the stent causes repeated friction to the urethral wall during opening and closing of the sphincter. Also, Eisenberg et al. [18] found that the most common surgical interventions required for failed urethral stent were transurethral resection of the hyperplasia (32%) and endoscopic litholapaxy for stent encrustation or stones (17%).

In the present study the occurrence of complications increased with time. The mean (SD) period for encrustation was 9.8 (2) months, while that of hyperplasia was 10 (1.4) months, and that for migration was 10 (3) months. With an increasing follow-up the stents tended to have a high failure rate that ultimately required removal of the stents in 35% of the patients after a mean (SD) period of 9 (3) months. This period was shorter than that reported by Chapple and Bhargava [27] in their study on managing the failure of a permanently implanted urethral stent, as the mean (range) duration for the stents to remain *in situ* before their removal due to failure was 26 (3–85) months. This suggested to us that the Memokath stent was best reserved for use as a temporary stent and not for permanent use.

The failure rate in our study was 52% (12 patients) and of these, eight stents were removed due to complications, for migration in five, in one for encrustation, in

two for urethral hyperplasia and in four as the patients were unwilling to continue with the stent. This rate was similar to that reported by Mehta and Tophill [11]. We had no difficulty in removing the Memokath stents, which might be attributed to the synthetic nature of the stents and the short period of insertion. This contrasts with the report by Elkassaby et al. [30], that failure of a permanently implanted urethral stent represents a significant therapeutic challenge, which often leads to a difficult substitution procedure, with consequent limitation of the success of the procedure. As permanent urethral stents tend to be incorporated into the wall of the urethra, this hinders their removal.

In conclusion, we recommend only the temporary use of thermo-expandable (Memokath) stents for patients with previously failed urethroplasties who refuse further surgical management, or those who are medically unfit for urethroplasty. The long-term results of the Memokath stent were not encouraging and the patients had complications related to the stent; they are also expensive. The use of these stents was associated with complications that sometimes required exchange or removal of the stent. The overall experience with Memokath stents was disappointing, and thus we use this stent only with highly selected patients, as noted, and do not use them when urethral reconstruction is feasible.

Conflict of interest

No conflict of interest.

Source of Funding

None.

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