

Urolume prostatic stents for urinary retention due to benign prostatic hyperplasia in patients with high medical risks

KH Yip, F Lee, PC Tam, KK Ho

A retrospective study was conducted to evaluate the efficacy of using urolume prostatic stents in patients who have developed urinary retention due to benign prostatic hyperplasia but who are medically unfit for conventional transurethral resection of the prostate. From April 1995 through May 1996, 12 patients were studied (mean age, 80 years; range, 72-92 years). Pre-operative assessment pointed to major risk due to an underlying medical condition. Flexible cystoscopy and video-urodynamics were performed to assess the detrusor function and to ascertain if prostatic obstruction was the cause of retention. After insertion of the prostatic stent, 11 patients managed to void on recovery from the anaesthesia and remained catheter-free during a mean follow up period of seven months (range, 2-18 months). There was no operative morbidity or mortality. Urolume prostatic stents represent a viable option for elderly patients with significant medical risks who have urinary retention. Pre-operative urodynamics are essential to identify appropriate candidates.

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Introduction

Surgical prostatectomy, mainly in the form of transurethral resection of the prostate (TURP), is the traditional treatment of choice for patients with symptomatic benign prostatic enlargement, especially those who develop urinary retention. Transurethral resection of the prostate remains the standard procedure against which alternative surgical therapies and medications need to be tested.¹ Unfortunately, despite constant improvements in anaesthesia techniques and the fact that TURP can be performed even under local anaesthesia, there is still a small but significant risk of morbidity and

mortality related to this procedure. There is increased interest, however, in the role of alternative non-invasive therapy, especially for the occasional patient with high medical risks.^{2,3}

Of the many innovative alternatives, only intraprostatic stents work in a mechanical manner to keep the urethra patent. The results produced are comparable to those obtained with transurethral resection, in terms of immediate relief of the obstruction.¹ The use of permanent prostatic stents has been well documented^{1,2,4-7} and we decided to conduct a retrospective study to evaluate its application since the stent became commercially available in Hong Kong in 1994.

Subjects and methods

The stent

The urolume prostatic stent is a woven tubular mesh of fine erosion-resistant wire that has been manufactured specially for use in the urethra. It was originally designed for endovascular use. Its

Department of Surgery, Tung Wah Hospital, 12 Po Yan Street, Western District, Hong Kong

KH Yip, FRCS (Edin)

F Lee, FRACS, FRCS (Edin)

PC Tam, FRACS, FRCS (Edin)

Department of Surgery, Queen Mary Hospital, Pokfulam, Hong Kong

KK Ho, FRCS (Glasg)

Correspondence to: Dr KH Yip

introduction to urology began when it was used to stent urethral strictures.⁸ Subsequently, it has been successfully used in patients with bladder outlet obstruction due to benign prostatic hyperplasia (BPH).^{1,2,6,7} There are also reports of its use in stenting malignant obstruction due to carcinoma of the prostate, but that is not the main use.⁹

During the study period, 12 patients (mean age, 80 years; range, 72-92 years) with acute urinary retention and major co-morbid medical conditions underwent the procedure. The underlying medical conditions included ischaemic heart disease or congestive heart failure (7), myelomatosis (1), and advanced malignancy (2). One patient had ischaemic heart disease and carcinoma of the lung. Another patient who was older than 90 years, despite there being no specific organ failure, was deemed to be too fragile to tolerate a TURP. All of these patients developed acute urinary retention and failed to be weaned off the indwelling urethral catheter. Assessment by physicians confirmed their being at major medical risk for conventional operation.

Treatment options including intermittent self-catheterisation, long-term indwelling catheter, and prostatic stenting were discussed and patients agreed to undertake this procedure. The stent had to be purchased by each patient as an individual item at HK\$10 000, which was separate from the hospital cost. Pre-operative assessment included formal video-urodynamic studies to evaluate the detrusor function, and flexible cystoscopy performed under local anaesthesia, to exclude the presence of concomitant urethral strictures, a grossly enlarged median lobe of the prostate, or other bladder pathologies. During the flexible cystoscopy, a rough estimate of the prostatic length was made so that the appropriate length of stent was brought to the theatre on the day of operation.

The operation

The patient was given local anaesthesia, intravenous sedation, and/or regional block, depending on the severity of their underlying medical condition and the pre-operative assessment made by the anaesthetist. With the patient placed in a lithotomy position, a rigid cystoscopy was performed. The bladder was distended and a temporary suprapubic catheter inserted. This enabled continuous drainage and enhanced the subsequent cystoscopic view. The actual prostatic length was measured using a calibrated balloon catheter with the balloon blown up and pulled onto the bladder neck. The distance from the bladder neck to the verumontanum was measured with the bladder distended. The

length of prosthesis to be used was calculated by subtracting 0.5 cm from the distance measured. The prostatic stent in its deploying device was mounted on the same telescope for placement.



Figure. X-ray showing good positioning of the urolume stent in the prostatic urethra (full radial expansion noted shortly after its insertion)

Proximally, the wires should just reach the 12 o'clock position of the bladder neck. In this position, the wires should be 1 mm to 2 mm below the bladder neck at the 6 o'clock position. This is because of the oblique angle that the prostatic urethra makes with the bladder. The device was partly deployed, the telescope was then withdrawn to assess the distal positioning, which should be just above the verumontanum (reference point for the external urinary sphincter). At this stage, the stent can still be manipulated to achieve satisfactory positioning. Then the safety lock was triggered and the device deployed at its desired position. Once deployed, the expansile force of the mesh holds it in position and should prevent its displacement. The epithelium will grow over the implanted stent until it becomes completely covered while the urethra is held open.¹⁰

Patients were left with a suprapubic drainage tube for one day, after which it was clamped and the patient was allowed to void on his own. Uroflow studies and X-rays were taken to document the stent's position (Figure). With satisfactory voiding, the suprapubic catheter was removed and the patient was discharged with a one-week course of oral antibiotics (ofloxacin, 200 mg twice daily). Patients were assessed and followed up (weeks 2, 4, 8, then two-monthly) regarding their ability to void and the presence of any irritative symptoms. Uroflow studies were repeated to document a sustained benefit.

Results

Pre-operative urodynamics confirmed a high pressure system that failed to void due to obstruction at the level of the bladder outlet. The maximal detrusor pressure averaged 85 cm water (range, 65-120 cm). The outcome of patients following insertion of urolume stents are as listed in the Table. Eleven patients managed to void on recovering from the anaesthesia and clamping of the suprapubic catheter. The only patient who failed to void had an unsustained detrusor pressure of less than 65 cm water, which could represent a rise of pressure due to poor bladder compliance, when normal saline was infused during the filling phase, rather than being a genuine detrusor contraction.

The remaining patients all managed to void during a mean follow up period of seven months (range, 2-18 months). The uroflow studies performed during the early follow up period showed a mean Qmax (maximal flow rate) of 10.8 mL/s (range, 8.3-12.5 mL/s). Most patients developed a certain degree of dysuria and irritation symptoms, which improved gradually with time. No patient had irritative symptoms severe enough to request removal of the implant. One patient had a documented urinary tract infection during the follow up period, which was treated with a one-week course of intravenous antibiotics (cefuroxime, 750 mg every 8 hrs).

One patient had a proximal migration of the stent after three months. Prior to this, he had been able to void but had developed increasing difficulty in voiding and had a progressive deterioration of uroflow until he presented with acute retention of urine; X-rays and flexible cystoscopy revealed a proximal migration of the stent. The stented portion of the prostatic urethra remained patent and satisfactorily epithelialised, but apical prostatic tissue just beyond the proximally migrated stent was causing outflow obstruction. In this patient, the removal of the stent required resection of the covering epithelium by diathermy (similar to doing a TURP) to expose the wires, before it could be dislodged, pushed back to the bladder, and retrieved. A limited TURP was performed as the patient remained haemodynamically stable throughout the operation. He made an uneventful recovery.

Discussion

A number of non-operative therapies have been devised for patients with prostatic symptoms and variable degrees of obstruction, including α -blockers, 5 α reductase inhibitors, microwave therapy, transurethral needle ablation, and various forms of laser therapy.^{1,3} These therapies improve symptom scores and uroflow to a certain extent, but generally will be of little help to patients who develop frank urinary retention. For patients who develop urinary retention, the immediate

Table. Outcome of patients following insertion of urolume prostatic stents for urinary retention

Patient	Age (y)	Medical problem	Anaesthesia given	Outcome
1.	90	Ca* kidney	SA	Voiding spontaneously
2.	72	Ca lung, IHD [†]	SA	Voiding spontaneously
3.	81	CHF [‡] , Parkinsonism	SA	Proximal migration at 3 months, TURP ^{**}
4.	92	Not specified	SA	Voiding spontaneously
5.	80	CHF	SA	Voiding spontaneously
6.	79	CHF	LA [¶]	Voiding spontaneously
7.	80	IHD, COAD [§]	SA	Voiding spontaneously
8.	77	IHD	Epidural	Voiding spontaneously
9.	72	Ca larynx	LA	Voiding spontaneously
10.	80	IHD	LA	Failure to void, long term catheter in place
11.	84	IHD	SA	Voiding spontaneously, urge incontinence
12.	78	Myeloma	IV ^{**} sedation	Voiding spontaneously, urge incontinence

*Ca carcinoma; †IHD ischaemic heart disease; ‡CHF congestive heart failure; §COAD chronic obstructive airways disease;

¶SA spinal (subarachnoid) anaesthesia; ¶LA local anaesthesia; **IV intravenous; **TURP transurethral resection of the prostate

concern is to relieve the mechanical obstruction by an effective treatment. Currently, the majority of TURPs performed by us are to relieve urinary retention, where in most instances an immediate response is expected. The urologist faces a dilemma, however, when a patient with severe co-existing pathology develops urinary retention, for whom a conventional TURP could prove to be a major risk. While there has been no mortality from the past 200 TURPs performed over the same period in our hospital, this could simply reflect a biased selection for the procedure. Undoubtedly, there were patients for whom this operation was not recommended.

Laser prostatectomy at one time offered some hope, especially for patients with bleeding disorders. Unfortunately, laser prostatectomy often works only in patients with a small- to moderate-sized prostate and many patients develop urinary retention after elective laser prostatectomy (including those patients who managed to void pre-operatively). As the coagulative necrosis takes a few weeks to work, the patient cannot benefit from an immediate relief of the obstruction, unless some form of laser-induced resection of tissue is performed at the same time, which is in general, not the principle of laser prostatectomy.¹¹

The radial expansion of a prostatic stent pushes aside the obstructing prostate gland and mechanically opens up a channel, thus enabling the patient to void. This works by the same principle behind TURP. Thus, provided the stent is maintained in the right position extending from the bladder neck to the verumontanum, a patient who has normal contractility of the bladder should be able to void spontaneously. There are several issues to consider. Firstly, whether stent placement should be done under local anaesthesia, intravenous sedation, or a brief regional block. Secondly, whether the relief of obstruction is long-lasting. Thirdly, the possible morbidity and complications that may arise from the presence of an indwelling stent. Lastly, the cost of the stent must be considered.⁷

The deploying device is very simple to master, and the procedure is straight-forward, as reflected by the short operative time. The procedure can be performed using local anaesthesia or intravenous sedation. The first few cases were operated on under spinal anaesthesia because we were learning to use the device and wanted to perform the procedure under better control. Once one has mastered the technique, spinal anaesthesia is not necessarily required. Previous reports on the urolume stent did not imply the necessity of pre-operative urodynamic studies, but some gave detailed pre-operative and post-operative uroflow rates to

document the improvement in a more objective manner.^{2,7} We believe that this is essential in the assessment of new treatment modalities, as well as in the confirmation of a functioning bladder prior to the stent placement.³ In the two patients who developed post-operative incontinence, repeat urodynamic studies revealed urge incontinence rather than stent misplacement beyond the sphincter causing incontinence; the pre-operative study results provided very useful baseline information. Their urge incontinence improved with the use of anti-cholinergic agents.

The most common morbidity experienced was dysuria, which in most patients subsided with time. As discussed in earlier papers, urinary tract infection was not a problem and prophylactic antibiotics were not usually required.⁷

Stent migration is a potential concern. Theoretically, the radial expansion of the stent holds it in position, and subsequent epithelialisation helps maintain the stent in position, decreasing its chance of dislodgement. The epithelialisation is completed over three to six months. Obviously, patients are alerted that no urethral instrumentation, including Foley's catheterisation is advisable in the first six to eight weeks.¹⁰ The patient who had proximal migration at three months had partial epithelialisation at the time of cystoscopy. The stent retrieval was relatively simple and involved minimal diathermy cutting of the epithelium over the wire, the prosthesis was then pushed back and retrieved (which could again be performed under local anaesthesia) using the supplier's kit. To minimise the possibility of proximal migration, it is important to check that the proximal wires are below the bladder neck prior to stent deployment. Otherwise, any intravesical protrusion will be prone to encrustation, which prevents complete epithelialisation and embedment.

We have only been able to document the early post-operative uroflow, due to the relatively short follow up period. Others report sustained and ongoing improvement of uroflow after more than one year's follow up.^{2,7}

We included four patients with advanced malignancy in this series. It is arguable whether a permanent or temporary stent should be used in such instances. There is no doubt that both have a role in the contemporary management of prostatic obstruction. Although considerably more expensive than the temporary stents, the urolume permanent stent does not have the many problems associated with temporary stents, which in addition, require regular changing.¹

It may be premature to recommend stent placement in an otherwise healthy patient, but the permanent stent is undoubtedly a viable option for the elderly unfit patient with urinary retention. The next consideration will be to extend its use to the elderly unfit patient with severe outflow obstruction symptoms before they develop frank retention of urine, if they are keen for an intervention to improve their quality of life.

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