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Prostate stent is an option for selected patients who are unsuitable for transurethral resection of the prostate

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ABSTRACT

INTRODUCTION: Transurethral resection of the prostate (TUR-P) is the gold standard for treatment of severe lower urinary tract symptoms (LUTS) or urine retention. Some patients are unfit for surgery due to much co-morbidity and need alternative treatment. Intraprostatic stents are one example of minimally invasive treatment for LUTS. We present our results for 27 consecutive intraprostatic stents. **MATERIAL AND METHODS:** A retrospective chart review of all patients who had received an intraprostatic stent between January 2012 and December 2013 by the same surgeon at the Department of Urology, Roskilde Hospital, Denmark.

RESULTS: A total of 27 consecutive intraprostatic stents placed in 25 patients were reported. In all, 14 stents were still functioning at the end of follow-up after a mean 432.5 days. Four patients had died of reasons unrelated to the stent with a functioning stent in situ after an average of 102 days. A total of nine stents (33%) were removed in seven patients after a mean 165 days due to migration in two cases, infection in two cases, incontinence in two cases and retention in three cases. Residual urine was significantly reduced after placement of the stents. 72% of the patients avoided surgery or an indwelling catheter. **CONCLUSION:** An intraprostatic stent can be an important

option in highly selected patients with considerable co-morbidity who are unsuitable for TUR-P. **FUNDING:** not relevant.

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Lower urinary tract symptoms (LUTS) in men, mainly caused by benign prostatic hyperplasia (BPH), is a consequence of increasing age [1]. Transurethral resection of the prostate (TUR-P) is the gold standard treatment for severe LUTS caused by BPH [2]. However, a number of co-morbidities, especially cardiovascular diseases, are correlated with age, which results in an increased risk for complications to anaesthesia [3]. The complication rate of TUR-P (resulting directly from surgery) is also elevated in elderly patients [4]. Therefore, some patients are unfit for surgery and need to be treated with a permanent catheter.

Five-alpha reductase inhibitors are a well-docu-

mented treatment of LUTS, especially in combination with alpha-1 adrenoreceptor antagonists [5, 6]. A number of minimally invasive treatments exist [2], but their outcomes have currently not reached the same success rate as that of TUR-P. The kind of treatment offered to the patients differs according to the individual department with a large regional difference [7]. Two examples are transurethral microwave thermotherapy [8] and intraprostatic stents; the later have been available for three decades now [9].

We present our results from 27 consecutive intraprostatic stents.

MATERIAL AND METHODS

A retrospective chart review was performed including all patients who had received an intraprostatic stent between January 2012 and December 2013 by the same surgeon at the Department of Urology, Roskilde Hospital, Denmark. The medical records were analysed and the following information was recorded: Indication for the stent insertion; how long stents remained in situ; reason for discontinuation and previous treatments. The indication was divided into two groups: "LUTS" and "retention" depending on the condition prior to the insertion of the stent. The LUTS group covered patients with severe LUTS who were still able to void, whereas the retention-group covered patients with a permanent catheter due to chronic or acute retention, see **Table 1**.

In patients who were able to cooperate in further evaluation, the following were also noted: Danish Prostate Symptom Score (DAN-PSS); International Prostate Symptom Score (IPSS); flow measurement and residual urine. Patients in the LUTS group were evaluated both before and after insertion of the stent, whereas the evaluations were only done after insertion of the stent in patients with a permanent catheter.

The success criteria were defined as either a functioning stent that remained in situ until end of followup, or that the patient died with a functioning stent (due to reasons unrelated to the stent).

The intraprostatic stent

The surgeon had two brands of stents to choose from:

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TABLE 1

Demographic distribution of patients divided into the lower urinary tract symptoms group and the retention group.

	LUTS	Retention					
Age, mean, yrs	67	76					
Stents, patients, n	9, 7	18, 18					
Known prostate cancer ^a , n (%)	1 (14)	1 (5.6)					
Previous medical treatments ^a , n (%)	5 (71)	10 (56)					
Patients with no co-morbidity ^a , n (%)	5 (71)	10 (56)					
Dementiaª, n (%)	1 (14)	7 (39)					
Incontinence technique, n (%)	0	4 (22)					
Subsequent removal, n (%)	4 in 2 patients (44)	5 (28)					
Time to removal, mean/median (range), days	195.5/208.5 (6-359)	139.8/123 (7-335)					
Time the functioning stents had been in situ at end of follow-up, mean/median (range), days	298.3/215 (124-639)	486.2/559 (138-735)					
Success rate ^b , n (%)	5 (71)	13 (72)					
Died with stent in situ, n (%)	1 (11)	3 (17)					
UTS - lower uringery tract symptoms							

LUTS = lower urinary tract symptoms.

a) The same patients may appear more than once in the various groups.

b) Patients who had either a functioning stent at the end of follow-up or who died with a functioning stent in situ.

Memokath (Pnnmedical A/S) or Allium (Allium Medical). The stents used ranged in size from 30 mm to 80 mm.

The Memokath is composed of a nickel-titanium alloy with a thermal shape-memory effect. At the beginning of the procedure, the stent is a straight coil, mounted on a flexible cystoscope. The distal end of the stent expands into a cone shape when flushed with hot water (45 °C or above) to prevent migration. When flushed with cold water (10 °C or below), the stent becomes super-soft and can be easily retracted with a foreign body forceps.

The Allium stent is inserted by use of a delivery tool with a Thiemann tip. The stent is self-expanding and has a bulbar anchoring segment to prevent migration. It can be removed cystoscopically by grasping the distal end of the wire with a strong foreign body forceps.

The stents used in the study were as follows: Memokath 30 mm (n = 3), Memokath 40 mm (n = 4), Memokath 50 mm (n = 4), Memokath 60 mm (n = 6), Memokath 70 mm (n = 3), Allium 60 mm (n = 4), Allium 65 mm (n = 2) and Allium 80 mm (n = 1).

Placement procedures

The majority of the stents were placed as part of an outpatient treatment regimen. The patients were in a supine position, and local anaesthesia in the form of Instillagel (a gel containing chlorhexidine gluconate and lidocaine hydrochloride) was applied endourethrally. The procedures began by inspecting the urethra with a flexible cystoscope, and the length of the prostatic urethra was measured from the bladder neck to the veromontanum. To compensate for the straightening of the

🗹 🛛 FIGURE (

X-ray of the abdomen displaying the intraprostatic stent dislocated to the bladder. The patient has a transurethral catheter in situ.



urethra done by the cystoscope, a stent 5-10 mm longer than the length of the prostatic urethra was chosen and placed according to the description above. All patients had to void before they left the hospital. Prophylactic antibiotic in form of Penomax 400 mg, three times a day for three days was given.

When incontinence technique was used, a stent 15-20 mm longer than the length of the prostatic urethra was chosen to traverse the urethral sphincter, thereby making the patient incontinent.

Trial registration: not relevant.

RESULTS

A total of 27 intraprostatic stents were placed in 25 patients. The mean age was 73 years (range: 51-92 years). In all 40% (10 out of 25) had major cardiovascular comorbidities and 32% (8 out of 25) suffered from dementia or severe mental illness. The success rate is listed in Table 1. At follow-up, the stents had remained in situ for a mean 294 days (median 154 days, range 7-735 days). Nine (33%) of the stents were removed after a mean 165 days (median 123 days, range: 6-359). Fourteen stents were still functioning at the end of follow-up after a mean 432.5 days (median 474 days, range: 124-735 days). Four patients had died from reasons unrelated to the stent with a functioning stent in situ after an average of 102 days (median: 109 days, range: 37-154 days).

The indications for the intraprostatic stents are listed in Table 1.

A total of 15 patients (60%) had previously been treated medically with α -receptor blockers or

 $5-\alpha$ -reductase inhibitors or a combination without effect, and two patients (8%) had previously undergone TUR-P.

In four patients, who were all bed-bound and suffered from either dementia or severe mental illness and severe co-morbidity, the intraprostatic stent was inserted using the incontinence technique. Among these, one stent was removed after 140 days.

In total, nine stents were removed in seven patients; in three patients the stents were inserted due to their own interest (the patients feared complications to TUR-P, especially in form of erectile dysfunction), and these patients could have been candidates for TUR-P. The stents were removed after 94, 328 and 359 days. Two patients had a subsequent stent inserted. In one patient, the second stent was removed as well after 89 days. One patient with previous TUR-P had the stent removed after six days. One patient with the incontinence technique is mentioned above. The main reasons for removing stents were migration in two cases, infection not responsive to antibiotic in two cases, incontinence in two cases and retention in three cases. **Figure 1** shows migration of a stent after insertion of a bladder catheter.

There were no serious complications (clavian score \leq 2) [10] to either insertion or removal of the stents. Minor haematuria was common for a couple of days after the procedures, but resolved spontaneously in all cases.

The clinical evaluations regarding flow, residual urine, and the questionnaires IPSS and DAN-PSS were only used sporadically due to lack of compliance, mainly in patients with dementia; see **Table 2**. For the LUTS- group, residual urine on average declined by 282 ml, from 298 ml before the insertion of the stent to 16 ml after, p = 0.0342. The flow increased similarly by 4.7 ml/ sec from 6.3 ml/sec prior to insertion of the stent to 11 ml/sec after, p = 0.52. The symptom score declined by 15.5 points on the IPSS from 26.5 points before the stent to 11 points after, p = 0.11 and, similarly, the DAN-PSS declined 29 points from 43.3 before insertion to 14.3 points after p = 0.4.

DISCUSSION

Intraprostatic stents are a well-recognised alternative to a urethral catheter.

A wide inhomogeneous range of intraprostatic stents exists, and it is difficult to compare the results from the existing studies because different stents are used, different study designs and different success criteria. Some of the stents are no longer commercially available - in some cases due to a high migration rate, and in other cases due to patient discomfort and lack of significant effect [11]. The success rate for the different stents varies in international studies from 25% [12] to 86% [13]. However, the success criteria differ according to the different stents. The AbbeyMoorSpanner prostatic stent is designed to function for three months; and in the study of Grimsley et al [14], the success criteria was that the patients were able to tolerate stent removal and replacement every three months.

In some studies, including our study, the stents were used as a permanent alternative to both TUR-P and catheter, and the success criteria were either a functioning stent that remained in situ until end of fol-

TABLE 2

Evaluation of the patients in both the lower urinary tract symptoms group and the retention group. The patients in the retention group all had a catheter prior to insertion of the intraprostatic stent and were therefore only evaluated after insertion of the stent.

	Flow, ml/s		Residual urine, ml		IPSS		DAN-PSS	
	pre-operative	post-operative	pre-operative	post-operative	pre-operative	post-operative	pre-operative	post-operative
LUTS (N = 7)								
p-value ^a	0.52		0.034		0.11		0.4	
n	6	2	6	2	2	3	3	3
Mean	6.3	11	298	16	26.5	11	43.3	14.3
Median	5	11	239	16	26.5	12	56	16
Range	3-13	10-12	47-850	12-20	26-27	6-22	17-57	0-27
Retention (N = 14) ^b								
n	-	4	-	7	-	3	-	2
Mean	-	11.5	-	76.4	-	11.7	-	3.5
Median	-	10	-	23	-	6	-	3.5
Range	-	5-21	-	0-300	-	5-24	-	3-4
Median Range Retention (N = 14) ^b n Mean Median Range	5 3-13 - - - -	11 10-12 4 11.5 10 5-21	239 47-850 - - - - -	16 12-20 7 76.4 23 0-300	26.5 26-27 - - - -	12 6-22 3 11.7 6 5-24	56 17-57 - - - -	16 0-27 2 3.5 3.5 3.5 3-4

LUTS = lower urinary tract symptoms; DAN-PSS = Danish Prostate Symptom Score; IPSS = International Prostate Symptom Score.

a) p > 0.05 not significant.

b) The patients with incontinence technique were not followed after the insertion of the stent.

low-up or that the patient died with a functioning stent [15]. Other stents were meant to be a temporary solution, and the success criteria were modified to fit their usage. Temporary stents can, for example, be used diagnostically in evaluation of the patient's ability to void before making the decision concerning TUR-P or implantation of a permanent stent, or can be used as an alternative to a catheter until the patient becomes fit for surgery (i.e. after a cardiovascular disease) [9, 12].Because the intraprostatic stents were generally used in cases in which TUR-P was considered too risky, no randomised trial exists to evaluate the results and complications in these two treatments. Instead, some studies compare the results of the stents indirectly with the results of TUR-P, but this is done retrospectively and there are major differences between patient cohorts [15].Besides benign conditions, intraprostatic stents have also been used with considerable success in men with a prostate cancer occluding the urethra [16], or as a treatment for posterior urethral stricture after radical prostatectomy or radiation therapy for prostate cancer [17]. In our study, two patients were diagnosed with prostate cancer and treated with androgen deprivation therapy. The rest had infravesical obstruction due to benign conditions, predominantly due to BPH.

The long-term results of the first generations of Memokath showed a success rate of 66% in the first year [18]. The second generation of Memokath, first described in 1993, showed an even more promising result with a short-term success rate of 83% [19]. The largest study to date on Memokath was carried out by Perry et al [15]. In more than 200 men with up to eight years of follow-up, the study reported a success rate of 77% and estimated that in their patient population, the patients were more likely to die with the stent in situ than to outlive the usefulness of the stent [15]. Our study had a comparable outcome with a success rate of 72%.

Previous studies have shown that it is possible to elevate the success rate by repositioning the stent in some cases of migration [20]. In our cohort, repositioning of stents was not a standard procedure.

The amount of residual urine decreased significantly after insertion of the stent. Maximum flow of urine increased and symptom score decreased, but this was not statistically significant. This may be due to the small sample size and the fact that the response rate to the symptom score questionnaire was poor, mainly because many of the patients were either not physically or mentally able to perform the evaluations.

The weakness of this study is its retrospective design with a small number of patients and a poor questionnaire response rate, which can be explained by a high percentage of elderly patients in our cohort.

CONCLUSION

Insertion of prostatic stent is safe and can be performed as an outpatient procedure. In our study, 72% of patients avoided surgery or an indwelling catheter owing to the intraprostatic stent. An intraprostatic stent can be an important option in highly selected patients who are unsuitable for TUR-P.

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