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ORIGINAL RESEARCH ARTICLE

Thermo-expandable intraprostatic nitinol stents in the treatment of bladder outlet obstruction: a consecutive case series

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ABSTRACT

Objective: In high-risk patients, prostatic stents may alleviate obstruction at the prostate level. Since 2020 we have used thermo-expandable intraprostatic nitinol stents. Here we document outcomes through the first years with the procedure.

Material and methods: We reviewed patients who had undergone stent treatment between May 2020 and October 2023. Patient and procedural data, urinary symptoms, complications and side effects were recorded. Descriptive statistics were used to summarize outcomes and we evaluated predictors of success and complications using robust multiple regression analyses.

Results: We included 52 consecutive patients with a median age of 82 years (range 71–96) and a median Charlson Comorbidity Index of 6 (3–11). Forty-seven men used indwelling catheters, two used clean intermittent catheterization, and three had severe lower urinary tract symptoms. Stents were placed under general anesthesia, sedation, and local anesthesia in 39, 4, and 9 men, respectively. The median treatment time was 14 min (range 8–40). One complication, in the form of an infection requiring IV antibiotics, occurred. Subsequently, 45 men (87%) were able to void spontaneously without bothersome symptoms. After a median of 11 (2–44) months, 8 men had their stents removed due to recurring symptoms. This gives an overall success rate of 37/52 patients (71%). No predictors of success or complications were identified.

Conclusions: Thermo-expandable intraprostatic nitinol stents demonstrate a high success rate with a low risk of complications and may serve as an alternative to permanent or intermittent catheterization for men who are unable or unwilling to undergo flow-improving surgery.

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Introduction

Lower urinary tract symptoms (LUTS) are common in the older segment of the population, and in men, these are often due to bladder outlet obstruction (BOO) caused by benign prostatic enlargement (BPE) [1]. When medication is insufficient to address the issue, the standard treatment for obstructive symptoms is surgery, most often by transurethral resection of the prostate (TURP) [2]. However, regardless of the chosen modality, this inherently carries risks of bleeding and infection. In some patients, surgery may either be impractical or considered too high-risk. This is particularly true for men of advanced age, those with significant comorbidity, and individuals with dementia. As a starting point, these patients might have to use a catheter to ensure bladder emptying, which can be greatly bothersome for some and infer risks including recurrent infections hence having a significant negative impact on quality of life [3]. An array of newer minimally invasive treatments (MISTS), including water vapor thermal therapy and prostatic urethral lift, has been introduced over recent years and may present options in the group [4]. However, these treatments are generally costly, require a large degree of patient cooperation, and may in some cases be associated with significant complications [5]. Meanwhile, simple stents may be offered to alleviate obstruction at the prostate level [6]. Such stents may be used in the treatment of ureteral and urethral strictures [7, 8] but its potential in BOO caused by BPE has been previously documented [9]. Therefore, the option is offered to selected patients deemed unsuitable for surgery at our department. Since 2020 we have used thermo-expandable intraprostatic nitinol stents (Memokath™, Pnn Medical A/S, Denmark). The aim of this study is to document outcomes and complications through the first years with the procedure.

Materials and methods

We performed a retrospective review of the electronic health records for all patients who had undergone treatment with thermo-expandable intraprostatic nitinol stents at our hospital between May 2020 and October 2023. Data were collected in January 2024 and included patients' age at the time of treatment, co-morbidities in the form of Charlson Comorbidity Index (CCI), prostate size, and previous surgical treatments for BPE. Urinary symptoms, including indwelling catheter use and

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use of clean intermittent catheterization, both prior to and following the intervention, were assessed based on both subjective and objective information available in the patients' charts and documented. Thermo-expandable intraprostatic nitinol stents (Memokath™, Pnn Medical A/S, Denmark) were inserted in the operating room in sterile conditions via a flexible cystoscope under local anesthesia, sedation, or full anesthesia depending on the patient. Subsequently, stents were flushed with hot water (45 degrees Celsius or higher), which causes the stent to expand, securing it in place. The type of anesthesia, and the duration of the procedure were also recorded. Furthermore, the occurrence of complications (graded according to Clavien-Dindo) and subsequent side effects arising from the treatment, as well as the need for any removal of the stents were noted. The information had been recorded during hospital stays. Surgical complications had been noted by the operating physician and/or the anesthesiologist, while postoperative complications had been noted by nursing staff or attending urologists. Patients were followed up via the outpatient clinic approximately 3 months after the procedure and subsequently on an individualized basis.

Descriptive statistics were used to summarize patients' characteristics, treatment outcomes and side effects with continuous variables presented as median and range and categorical variables presented as frequencies or percentages. We evaluated possible predictors of success and complications using robust multiple regression analyses and included the variables CCI, prostate volume, and the volume of urinary retention previously recorded in each patient. Age was omitted as an independent entity as it is factored into the CCI. We conducted a chi-squared post hoc analysis to determine if outcomes differed between men with dementia and those without. Statistical significance was defined as a *P*-value less than 0.05. Statistical analyses were conducted using SAS Enterprise Guide Version (Institute Inc., Cary, NC, USA). Stent treatment was deemed successful if patients were able to void spontaneously after its placement, with the primary outcome being success following the initial placement. Secondary outcomes included the degree of bladder emptying and success at follow-up.

The study was approved by the Regional Center for Register Research of the Capital Region of Denmark according to Danish law (journal number R-23065277). Patients would be excluded if they had stated that they did not consent to retrospective chart reviews on their mandatory patient form submitted at first hospital visit at our department. The manuscript was prepared according to the STROBE statement (www.strobe-statement.org).

Results

Fifty two consecutive patients were included. Demographics including CCI and prostate volume are listed in Table 1. Specifically, 19 men had dementia and 22 suffered from severe cardiac and/or pulmonary disease. In addition, 47 of the men had a pre-treatment indwelling catheter, while two used clean intermittent catheterization, and three men had severe LUTS. Retention/residual volumes are listed in Table 1. Eight men had undergone previous failed invasive BPE treatments in the form of TURP (n = 6), photoselective vaporization of the prostate (n = 1), and Transurethral microwave thermotherapy (TUMT) (n = 1). As a standard, BOO was confirmed by pressure flow urodynamic studies. However, these were not performed in men with dementia due to concerns with compliance. Before treatment, all patients underwent flexible cystoscopy in the outpatient clinic to rule out bladder pathology and to determine the size of the stent.

Table 1. Patients' demographics.

Demographic	Median	Range
Age (years)	82	71–96
CCI	6	3–11
Prostate Volume (mL)	71	20–300
Pretreatment catheterization (n = 49) with previous retention volume (mL)	1,000	200–2,500
Severe LUTS (n = 3) with residual volume (mL)	217	0–370

CCI, Charlson Comorbidity Index.

Stent placements were performed under general anesthesia in 39 men, under light sedation in four men and in local anesthesia in nine men. The median treatment time was 14 (range 8–40) min. No bleeding occurred in any of the patients, while one complication in the form of a post-treatment infection requiring IV antibiotics was observed (Clavien-Dindo grade II). No other complications occurred. In all other cases the patients were discharged on the day of treatment. After the placement of stents, 45 of the men (87%) were able to spontaneously void again. Twenty-seven men were able to empty their bladder completely with no measurable residual urine on bladder ultrasound, while the volume of residual urine was deemed acceptable in the remaining seven men with a median of 230 (range 17–300) mL.

After a median of 11 (2–44) months follow-up, 5 of the 45 men who had initially re-established spontaneous voiding experienced a new episode of urinary retention, and they had their stents removed and replaced by indwelling catheters. Another two patients had stents removed due to irritative symptoms and one had his stent removed due to urinary incontinence. This gives an overall success rate of 37/52 patients (71%). An additional two men reported to be bothered by urinary incontinence and one by urgency, but these patients preferred to keep the stents. An attempt at secondary stent placement were performed in two primary and two secondary cases of failure. This was successful in two of the cases. Neither CCI (P = 0.52), prostate volume (P = 0.70), or the previous volume of urinary retention experienced by individual patients (P = 0.42) were statistically significant predictors of a successful outcome. There was no difference in the prevalence of successful outcomes between men with dementia and those without (P = 0.71). Due to the low number of complications no analysis of potential predictors was conducted for this outcome. The key results are summarized in Table 2.

Discussion

The primary function of thermo-expandable intraprostatic nitinol stents is to relieve obstruction and they represent a simple

Table 2. A summary of results.

Type of anesthesia	
General anesthesia	39 men
Light sedation	4 men
Local anesthesia	9 men
Treatment time (min)	14 (8–40)
Spontaneous voiding after stent placement	45 men (87%)
Stent removals at follow-up	8 men
Overall success rate	37/52 patients (71%)

The median follow-up was 11 months (range 2–44 months).

form of treatment. In this study, we confirmed that the stents are a viable option for severe cases of obstructive LUTS. The stent placement is usually fast, with a high success rate and has a low incidence of complications. An additional advantage is that, in selected patients, the treatment can be administered under local anesthesia. Overall, our results underscore the potential of the stents to provide considerable relief from urinary obstruction symptoms, thereby enhancing quality of life for patients who otherwise have limited treatment options.

The findings from our study are important as they contribute to a limited body of evidence on thermo-expandable intraprostatic stents as an alternative to surgery for elderly patients with BOO and significant comorbidities. In this regard, a systematic review of studies conducted between 1992 and 2006 identified 14 individual case series reporting on a total of 839 men with BPE treated using thermo-expandable intraprostatic nitinol stents [9]. However, the quality of most studies was considered low with inadequate or unreported follow-up. Furthermore, failure rates varied widely, from 0% to 48%, only four studies reported on post-treatment residual urine volumes, and complications were reported inconsistently across the studies [9]. Therefore, it was difficult to draw definitive conclusions regarding the applicability of the stents.

Subsequent studies have added to these findings. In this regard, Lee et al. assessed the effectiveness of the stent in 12 men with acute urinary retention and co-morbidities severe enough to contraindicate TUR-P [10]. No peri-operative complications were recorded, and the treatment was deemed successful in 9 of the men remaining catheter free at a mean follow-up of 12 months. Reasons for failure included stent migration in two men and prostate overgrowth in one man. In addition, two major complications in the form of recurrent urinary tract infections and urge urinary incontinence were noticed. In a larger study, Sethi et al. used the same type of stent for symptomatic relief in 140 men unsuitable for surgery and followed them for a median of 7 years [11]. In this study, 62.5% of cases were considered successful, while the remaining patients experienced stent failures at a median of 6 months following the procedure due to issues such as urinary retention, return of obstructive voiding symptoms, stent migration and encrustation. Likewise, Kimata et al. found a 56.7% success rate with the stent in a group of 37 men who were deemed ineligible for surgery with no serious complications observed [12]. Notably, seven cases of stent migration were seen, all within 3 months, and the risk of failure was increased in men with poor performance status. Similar findings were reported by Schou-Jensen et al. who reported on a cohort of 25 consecutive patients receiving stents for urinary retention or bothersome obstructive voiding symptoms [13]. Here, 67% of the stents were still functioning at the end of follow-up after a mean of 432.5 days. Reasons for stent removal in seven patients included infection, incontinence, and urinary retention.

Taken together, the literature cited above and our study show, that thermo-expandable intraprostatic nitinol stents are effective in the medium term for approximately 60% – 70% of patients. In this regard, it is important to notice that the majority of complications seem to arise within the first few months after stent placement. Furthermore, one can argue that longer term follow-up is of less relevance, considering that the treatment is generally chosen for patients with severe comorbidities and a limited life expectancy. The literature generally shows a low rate of Clavien-Dindo >II complications, and none were seen in our series. This safety profile is particularly relevant given the high baseline vulnerability of the patient population, where the burden of comorbidities makes surgical options risky and potentially life-threatening. The approach to handling complications such as stent migration involves careful monitoring and, in some cases, stent replacement or removal. This management strategy is supported by the findings from Barber et al., in which ease of stent removal was highlighted as a crucial factor in the overall management of stent complications [14]. We agree with this conclusion. While stents are a viable option for treating LUTS, a significant drawback is their potential displacement during follow-up procedures such as catheterization and cystoscopy. This can be particularly problematic in cases involving hematuria, bladder tumor surveillance, or stone treatment. Moreover, it is important to observe that general anesthesia may be required for the extraction of the stents, as they may have been displaced to the bladder and be difficult to extract, or as they may become integrated into the urethral mucosa if they have been in place for several years [14]. Despite the successful outcomes in most patients, our results also highlight that stents are not ideally suited as first line treatment in men who are able and willing to undergo definitive surgery such as TURP. Thus, about 10% reported bothersome symptoms in the form of incontinence or urgency.

It would be relevant to compare the stent examined in this study with other types of stents as many different types exists, however, no comparative studies are available to date [15]. Of even more relevance, it is tempting to compare with newer MISTS, especially the temporary implantable nitinol device (iTIND) due to their similarities [16]. However, the newer devices are marketed toward younger men who wish to preserve sexual function and consequently examined in this patient group [17]. This means that there is a lack of published data on newer MISTS in comorbid men who are not fit for surgery, which constitutes a gap in our current knowledge. Further comparative studies should be conducted to elucidate this issue.

The main strength of our study is that we were able to analyze 52 consecutive patients and that both patient data and

treatment results were comprehensively documented in the patient charts. Due to the centralized patient chart system for hospitals in the Capital Region of Denmark, it is unlikely that we have missed any complications. Meanwhile, the study also has some limitations. Urodynamic studies were not conducted in patients with dementia prior to treatment. Consequently, it can be speculated that treatment failures in this subgroup may be attributed to weak detrusor contractions, but the limited number of patients hampers our ability to detect any potential group differences . Furthermore, we were not able to identify predictors for neither success nor complications with the treatment although our study is relatively large compared to previous publications on the topic. The single-center design of our study constitutes another limitation, as the results may not be generalizable to other settings. Nonetheless, the similarities between our findings and those of previous studies indicate that the results are likely reproducible, possibly due to the relative ease of stent insertion. Finally, we considered the treatment successful despite the presence of residual volume if patients could void spontaneously and did not report subjective discomfort. We believe this is reasonable, given that most men were dependent on catheters before treatment. However, we recognize that this approach may be open to critique, as there is no universally accepted cut-off value for residual volume.

Thermo-expandable intraprostatic nitinol stents demonstrate a high success rate in alleviating obstructive LUTS, offering rapid treatment with a low risk of complications. Therefore, they may serve as an alternative to permanent indwelling catheters or clean intermittent catheterization for men who are unable or unwilling to undergo flow-improving surgery and for whom newer MISTS are deemed inappropriate. This positions them as a crucial tool in managing LUTS in vulnerable BOO patients. Future research should aim to optimize patient selection criteria and develop comprehensive management strategies that address the specific needs of this high-risk patient population, thereby enhancing the therapeutic outcomes.

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