Herlev and Gentofte Hospital
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UNIVERSITY OF COPENHAGEN

#815
Thermo-expandable intraprostatic nitinol stents in the treatment of bladder outlet obstruction – a consecutive case series

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Hypothesis/aims

Lower Urinary Tract Symptoms (LUTS) are common in the older segment of the population, and in men, these are often due to benign enlargement of the prostate. When medication is insufficient to address the issue, the standard treatment for obstructive symptoms is surgery. 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 hence can have a significant negative impact on quality of life. For this group of patients, intraprostatic stents may be offered to alleviate obstruction at the prostate level. This treatment is offered to selected patients deemed unsuitable for surgery at our department. Since 2020 we have used thermo-expandable intraprostatic nitinol stents (Memokath^{TM}, 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 patient age at the time of treatment, co-morbidities in the form of Charlson comorbidity index (CCI), prostate size, and previous surgical treatments for benign prostatic enlargement. Urinary symptoms, including catheter use, both prior to and following the intervention were assessed based on both subjective and objective information available in the patient charts was documented. The type of anesthesia, and the duration of the procedure were also recorded. Further, the occurrence of complications and subsequent side effects arising from the treatment, as well as the need for any removal of the stents were noted.

Descriptive statistics were utilized to examine patient characteristics and treatment results. 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. Statistical significance was defined as a p-value less than 0.05.

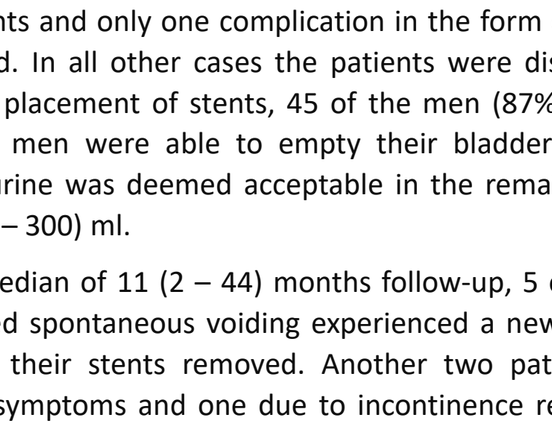
Results

52 consecutive patients were included. The median age was 82 years (range 71-96) and the median CCI was 6 (3-11). Notably, 12 men had dementia and 22 suffered from severe cardiac and/or pulmonary disease. The median prostate volume was 71 (range 20 – 300) ml. 47 of the men had a pre-treatment indwelling catheter, while 2 used clean intermittent catheterization. The median retention volume prior to catheterization in these patients was 1000 (range 200 – 2500) ml. The remaining 3 men had severe LUTS with a median residual volume of 217 ml (range 0 -370). 8 men had undergone previous failed invasive BPH treatments in the form of TURP (n=6), PVP (n=1), and TUMT (n=1).

The median treatment time was 14 (range 8 – 40) min. No bleeding occurred in any of the patients and only one complication in the form of urosepsis requiring IV antibiotics was noted. 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. 27 men were able to empty their bladder completely, while the volume of residual urine was deemed acceptable in the remaining 7 men with a median of 230 (range 17 – 300) ml.

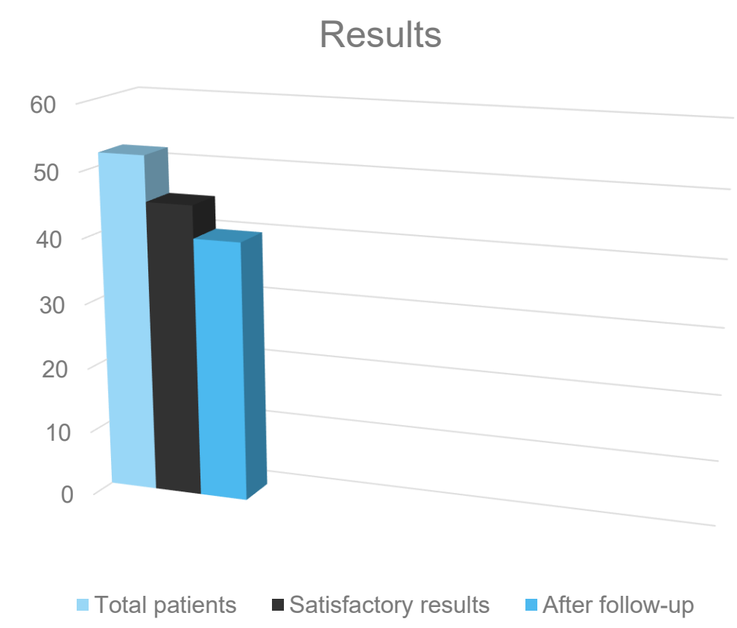
After a median of 11 (2 – 44) months follow-up, 5 of the 45 men who had initially re-established spontaneous voiding experienced a new episode of urinary retention, and they had their stents removed. Another two patients had stents removed due to irritative symptoms and one due to incontinence respectively. 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.

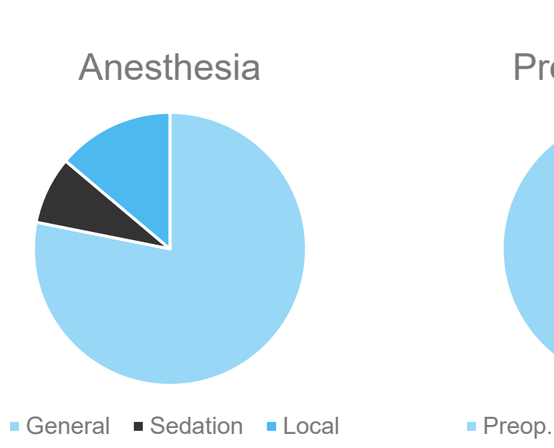
Neither CCI (p= 0.5173), prostate volume (p=0.7013), or the previous volume of urinary retention experienced by individual patients (p= 0.4207) were statistically significant predictors of a successful outcome. Due to the low number of complications no analysis of potential predictors was conducted for this outcome.

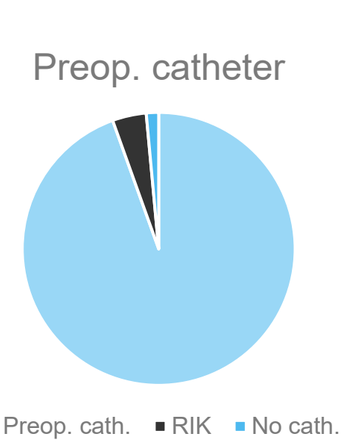


Interpretation of results

Thermo-expandable intraprostatic nitinol stents represent a viable option for severe cases of obstructive LUTS. The treatment duration is generally short, with a high success rate and low incidence of complications noted. An additional advantage is that, in selected patients, the treatment can be administered under local anesthesia. Perhaps due to the high success rate and minimal complications, no predictors for either outcome were identified. The primary function of these stents is to relieve obstruction at the prostatic level. Due to comorbidities and a relatively high proportion of patients with dementia, urodynamic studies were not systematically conducted prior to treatment. Consequently, it can be speculated that treatment failures may be attributed to weak detrusor contractions. One drawback of the stent is the potential for displacement during subsequent catheterization and cystoscopy procedures, for instance, in cases of hematuria, surveillance of bladder tumors, or stone treatment. Additionally, it is important to note that general anesthesia is usually required for the extraction of the stents, as they may become intimately integrated into the urethral mucosa. Finally, 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.







Concluding message

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 for men who are unable or unwilling to undergo flow-improving surgery. This positions them as a crucial tool in managing LUTS in men with significant comorbidities and/or dementia.