Temporary Prostatic Urethral Stenting as a Provocative Tool to Determine Surgical Eligibility in Complex Bladder Outlet Obstructed Patients: Our Initial Experience

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Abstract

**Background/Aims:** To evaluate the usefulness of a temporary prostatic urethral stent to determine which complex surgical patients would benefit from definitive surgical management of their benign prostatic hyperplasia. **Methods:** We retrospectively analyzed our benign prostatic hyperplasia database and identified all patients that received at least one temporary prostatic urethral stent between April 2008 and December 2010. **Results:** Forty Spanner™ stents were placed in 20 patients. Mean age was 78.1 years and prostate size was 62.1 cm$^3$. Urinary retention was present in 60% (12/20) of patients. No statistically significant changes in mean maximal flow rate, average flow rate, and post void residual was noted. Seven patients (35%) did well with the stent and progressed to definitive surgical management whereas 10% of the cohort (2/20) leaked urine with the stent in place and subsequently went back to catheter management. Another 30% (6/20) were unable to tolerate the stent while 1 patient passed away unrelated to the stent. **Conclusions:** The use of the temporary prostatic urethral stent provided a good provocative test that enabled patients to experience what their voiding status would be if they were to undergo definitive surgical management.

Introduction

The various treatments of bladder outlet obstruction (BOO) and lower urinary tract symptoms (LUTS) provide many potential options for patients and providers. Each treatment modality can have its own unique risks and benefits. For patients with moderate to severe LUTS who have failed medical therapy or who have developed benign prostatic hyperplasia (BPH)-related complications (i.e. urinary retention, renal insufficiency, etc), surgical modalities often provide the fastest and most robust treatment [1]. However, given the natural history of BPH, the older population of patients often present for surgical management in the context of profound medical complexity that increases the risk of surgery.

As such, many symptomatic patients are either unwilling to undertake the risks associated with surgery or are otherwise medically unfit to do so. One solution developed in recent years has been the intraprostatic urethral stent. The beneficial effects of the intraprostatic urethral stent on voiding function and quality of life among patients with severe LUTS secondary to BPH has previously been described. These stents have been shown to improve mean maximal flow rate (Qmax), average flow rate (Qavg), voided volumes and post void residuals (PVR) as well as improve IPSS scores and quality of life [2–6]. The first version of the prostatic urethral stent was the...
Urovolume™ (AMS, Minnetonka, MI, USA) which had significant morbidities. This has been replaced by the convenience of the temporary Spanner™ stent (Abbey Moore Medical, Parkers Prairie, MN) which is functionally and fundamentally different. This stent more closely resembles the proximal portion of a Foley catheter rather than the bare metal of the Urovolume.

In the current study, we propose an additional use of the temporary intraprostatic urethral stent. One of the greatest areas of concern for many patients considering transurethral surgical therapy is the possibility of incontinence or inability to void despite surgical intervention. Treatment failure, especially incontinence, can be devastating complication of the surgical treatment of BOO and despite advances in diagnostic evaluation, including video-urodynamics, it is extraordinarily difficult to reliably predict which patients will develop incontinence on any level. Most patients do not understand the interrupted results of urodynamics in the context of what their perceived and expected functional outcomes would be after surgery compared to the reality of their actual day to day outcomes. The purpose of this report is to detail our experience using the new temporary intraprostatic urethral stent (Spanner Prostatic Stent [Abbey Moore Medical, Parkers Prairie, MN]) as a provocative test to determine which patients are at higher risk for developing incontinence after their surgery and to allow the patient to simulate their expected outcomes following a surgical procedure.

Materials and Methods

Patients
Institutional review board approval was granted for a retrospective analysis of our institution’s BPH database and specifically our Spanner™ stent experience. Between April 2008 and December of 2010, 20 patients were identified with moderate to severe LUTS who were thought to be at high risk of complications from transurethral surgery. The patients agreed to a trial of prostatic urethral stenting with the Spanner™ stent prior to possible surgical management to observe and simulate their potential outcomes following surgical relief of their obstructive uropathy. All patients were continent at baseline.

Initial Evaluation and Stent Placement
At the initial visit, each patient received a questionnaire documenting the history of coexisting medical diseases, previous surgeries, and medication use. Routine lab tests were performed, including prostate specific antigen (PSA), urinalysis and bacterial urine culture. A general physical exam and digital rectal exam were performed in all patients. Recordings of Qmax, Qavg and voided volumes were made using an uroflow meter in those patients able to void. PVR and transrectal ultrasound were performed. The stents were placed in an outpatient setting using intraurethral lidocaine and standard equipment. Regular stent changes were offered if the patient was satisfied with their level of improvement in symptoms and generally occurred at intervals of 4–6 weeks.

Device Description
The Spanner™ stent is a steel-wire reinforced stent used for the temporary relief of prostatic urethral obstruction. It is designed to keep the prostatic urethra open without disrupting the external sphincter. The device consists of a proximal stent, a distal anchor, and connecting sutures. The proximal 20F stent contains a balloon, similar to a Foley, to keep the stent anchored at the bladder neck. The triangular soft plastic distal anchor is attached to sutures that traverse the membranous urethra and external sphincter, so that the anchor in the bulbular urethra prevents retrograde migration. The device is inserted using a standard introducer enclosed with the device, and can be inserted in an outpatient setting with only topical anesthesia. Stent placement was confirmed in all cases with flexible cystoscopy. A string attached to the device exits the urethra; pulling the string deflates the balloon and allows for removal of the device. The device comes in different lengths to accommodate different prostatic urethral lengths; a measuring device is included that assists with size determination. There are no conflicts of interests with any of the authors and the device manufacture and the research was supported wholly by institutional funding.

Statistical Methods
All statistical calculations were computed using Stata/SE® v 11.0 (College Station, TX) for Mac OS X. Univariate analysis using paired t-tests compared pre- and post-procedural characteristics. The normality of all continuous variables was examined using histograms and ladder-of-powers plots.

Results

Baseline
Table 1 demonstrates the cohort characteristics. The mean age of the cohort was 78.1 years and the mean prostate size was 62.1 cm³. The mean PSA was 3.3 ng/ml while the mean body mass index was 27.1 kg/m². The mean American Society of Anesthesia score was 3.0. In the 8 patients able to void, the mean Qmax was 10.8 ml/s while the mean Qavg was 5.0 ml/s. Mean IPSS score for all patients able to void was 22.3. The mean voided volume was 139 ml with a mean PVR of 208 ml. The Qmax, Qavg, volume voided and PVR after stent placement were measured for all patients regardless of their preprocedural voiding status. It is worth noting, however, that pre-stent uroflow data was no different from post-stent uroflow data on univariate comparisons. With respect to pre-stent management of obstruction, 25% of the cohort had chronic Foley catheterization, 35% performed self-intermittent catheterization, while 40% employed neither. Six patients were on one or more anticoagula-

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tion medications, and 80% of the patients had three or more associated medical co-morbidities. These included dementia, diabetes, Parkinson’s disease, cancer, coronary artery disease among other conditions making them high-risk surgical patients.

Test Period
Of the 20 patients in the cohort, only 2 patients leaked urine and were thus advised not to undergo surgical management due to the elevated risk of chronic incontinence. One patient died of non-stent related causes (Clavien grade V). Seven patients developed positive urine cultures after stent placement, though only 3 were symptomatic (Clavien grade II). Four patients developed urinary frequency while 3 developed discomfort associated with the stent (Clavien grade I). Of the 17 continent patients who remained alive during the study period, 7 progressed to definitive surgical management, which in the current series was HoLEP in 6 patients and HoLAP in one (the latter patient was on Plavix). Of the 2 patients who leaked following stent placement, one went back to chronic Foley catheterization and the other went back to self-intermittent catheterization.

Surgical Results
Of the 7 patients that progressed to definitive surgical management, 1 was lost to follow-up. The remaining 6 were all continent of urine at 1 to 3 months of follow-up. One patient with significant underlying neurological disease was initially wearing 1 to 2 pad/d at 1 month, but this completely resolved at the three-month follow-up. A second patient who had a history of brachytherapy for prostate cancer had symptoms of urgency but no frank incontinence. He is being treated with anticholinergic medication with excellent results. All of the patients noted successful results with major reduction in their symptoms. In a subset of surgical patients for whom postoperative IPSS data was available, the mean score was 5.25.

Discussion
The prevalence of bladder outlet obstruction increases with age and unfortunately, so does a decline in general health with additional co-morbidities complicating an already high-risk population when definitive surgical intervention is considered. The Spanner™ stent is a temporary self-contained device that bypasses the obstruction of the prostatic urethra while allowing the patient to maintain continence via their external urethral sphincter. This enables the patient to experience the functional results of a definitive surgical procedure without the need or risk of surgery and to evaluate the impact of a planned surgery on their quality of life.

Corica et al. [6] have already described the effect of the Spanner™ stent on voiding function and quality of life among patients with severe LUTS secondary to BPH. The mean Qmax increased from 8.2 ml/s at baseline to 11.6 ml/s after insertion, representing a 42% improvement. Furthermore, the PVR and IPSS demonstrated a 64 and 68% decrease, respectively. With these encouraging results, the Spanner™ stent has been recently applied to selected subgroups of patients with BPH, specifically patients with LUTS in the setting of prior brachytherapy and transurethral microwave therapy [7, 8]. It is worth noting that in the present study we did not observe any statistical differences in uroflow parameters. However, when one considers that over 60% of the patients were unable to void prior to stent placement and yet all were included in the post-stent analysis, this finding may be somewhat expected since only 40% of patients were able

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<tr>
<th>Table 1. Mean cohort characteristics</th>
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<td><strong>Value</strong></td>
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<td>Age, year</td>
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<tr>
<td>Body mass index, kg/m²</td>
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<td>Prostate size, cm³</td>
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<td>PSA, ng/ml</td>
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<td>Pre-procedural management of obstruction</td>
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<td>Self intermittent catheterization</td>
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<td>Pre-procedural urodynamics</td>
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<td>Post void residual, ml</td>
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<td>Post-procedural urodynamics</td>
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<td>Qavg, ml/s</td>
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<td>Number of stents</td>
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*p > 0.05 for all comparisons of pre- and post-procedural urodynamc data. *These patients represent only 40% of the cohort who were able to void prior to stenting and excludes those patients unable to void prior to stenting.
to perform a uroflow versus 100% before and after the stent was placed, respectively. It is notable in itself that all patients were able to void to some degree after alleviating their prostate obstruction with the temporary stent.

To our knowledge, this is the first study to evaluate the usefulness of the Spanner™ stent as a provocative tool to judge the risk of post-surgical incontinence while simulating effects voiding function for patients. We initially hypothesized that if patients tolerate the device with few side effects and no urinary leakage, this selected population of patients with high medical risks may be better candidates for definitive surgical management than patients with leakage following stent placement. In the present series, 2 patients who developed incontinence following placement of the device were subsequently advised to forego surgical management given the elevated risk of chronic incontinence. Since the Spanner™ stent is completely reversible, it was a useful adjunct to the evaluation of these high-risk patients at increased risk of post-surgical incontinence. As such, none of the seven patients that “passed” this provocative measure were incontinent 3 months following HoLEP/HoLAP.

Biodegradable stents have also been reported to likewise have utility in the diagnostic setting. In an effort to predict post-surgical outcomes in patients who exhibit a combination of BOO, severe detrusor overactivity and urge urinary incontinence, Knutson et al. [9] utilized a biodegradable intraprostatic stent to assess LUTS after relief from BOO. In their series, 37 patients underwent stent placement with a biodegradable stent, which lasts 3–4 weeks. Patients were examined 2 months after placement and if no leakage occurred during the stent period, they proceeded to TURP. The patients who experienced urge incontinence when the stent was in position were counseled not to undergo surgery. Twenty-five of the 37 patients did not experience incontinence during the stent period. Of these 25 patients, 18 patients underwent TURP and showed no episodes of post-TURP incontinence along with improvements in IPSS, PVR and Qmax. However, 1 patient with leakage after stent placement demanded surgical intervention despite counseling to the contrary and this patient developed incontinence for approximately 4 months postoperatively suggesting a good correlation between stent outcomes and surgical outcomes.

Often urodynamics or even video urodynamics are unable to predict exact functional and quality of life outcomes following BOO surgical intervention, especially in medically complex individuals. Even when patient’s specific information is gleaned, the description of these results by the physician to the patient is not always fully understood. Patients generally see themselves in their current state with impaired voiding or an inability to void in which any scenario would be preferred. Their current functional status can thus influence their decision making process as their expectations may not reflect the potential outcomes of an irreversible surgical procedure. The spanner stent allows a simulation of the expected results following surgical intervention to put that intervention into the context of actual outcomes and the impact on their quality of life. We believe that such a provocative test, while not necessary in every individual, can be used effectively with certain patients and especially in those who are medically complex.

However, intraprostatic urethral stents are not without risks. Many patients in our series developed various complications that must be weighed against the benefits of provocative testing. The incidence of bacteriuria after device placement, for example, in our series was 35%. Given this high incidence, we routinely culture the stents at 4 weeks when they are exchanged. Other factors that may limit the tolerability of intraprostatic urethral stents include hematuria, urinary frequency, stent discomfort, dysuria, and urinary retention. We even had one instance of an elderly patient in a nursing home who presented to the emergency department with urinary retention after an uninformed nurse saw “yarn in his urethra” and unknowingly deflated his device after pulling on the string thereby inadvertently obstructing his urethra with the device. In a separate instance, a patient presented to an outside emergency department for another reason and had a Foley catheter passed despite the stent and had to have a separate operation to retrieve it. As a result, our practice now routinely provides all patients with wallet size information card about the stent in case of medical emergency and provider unfamiliarity with the device.

Despite the potential utility of intraprostatic prostatic stenting as a preoperative provocative measure for the prediction of post-surgical incontinence, we interpret our results in the context of multiple methodological limitations. First and foremost, the study population is small and statistical powering is vastly limited in this respect. Second, this is a retrospective analysis and is inherently limited by its observational design. We cannot exclude the possibility that the seven patients who elected to undergo surgery would have had a good outcome even without provocative testing, or alternatively that the two patients who failed provocative testing would have necessarily become permanently incontinent with surgery. Randomized data would be helpful in this respect. Thirdly, the
database does not include individuals that received the stent for other purposes (not potential surgical candidates). The database likewise does not capture the patients who received stents prior to when the CPT code was provided by the Centers for Medicare and Medicaid Services, leaving no method for identification in the BPH database. Finally, close inspection of the pre- and post-stent uroflow data would imply minimal improvement in functional outcomes following stent placement. These measures, however, include all patients, even those in retention (60% of cohort) and many of these patients certainly have a component of detrusor dysfunction in addition to their BOO. Taken together, this may account for the lack of improvement observed between pre- and post-stent placement uroflow studies.

**Conclusion**

In our initial experience, the use of the temporary prostatic urethral stent provided a good provocative test that enabled patients to experience what their likely voiding status would be like if they were to undergo definitive surgical management. The fact that 41% of our content post-stent patients progressed to definitive surgical management ensures excellent patient outcomes and maximizes our ability to properly stratify patients with BOO with significant medical comorbidities.

**References**


