Review Article on Surgical Management of Stress Urinary Incontinence in Men

Changes and debates in male stress urinary incontinence surgery practice patterns: a contemporary review

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Abstract: Surgery plays a crucial role in the definitive management of male stress urinary incontinence (SUI). The most utilized and well-studied surgical options include the artificial urinary sphincter (AUS) and the male sling (MS). The AUS has long been considered the "gold standard" and more versatile option in this space, showing effectiveness in mild, moderate, and severe SUI cases, whereas the MS is preferred in cases of mild to moderate SUI. Not surprisingly, and importantly, much of the published literature on male stress incontinence has focused on determining the "ideal" candidate for each procedure and identifying which clinical, device-specific, and patient factors play an important role in the objective and subjective success rates. There are, however, more granular, and sometimes debatable, topics to assess regarding the real-life practice patterns of male SUI surgery. The aim of this clinical practice review is to examine current trends of several of these topics including: AUS *vs.* MS utilization, the prevalence of outpatient procedures, 3.5 cm AUS cuff use, preoperative urine studies utilization, and intraoperative and postoperative antibiotics. As with many things in surgery, dogma rather than evidence-based medicine can significantly influence everyday clinical decision making. We seek to highlight which practice patterns in male SUI surgery are changing and/or being challenged and debated.

Keywords: Stress urinary incontinence (SUI); artificial urinary sphincter (AUS); male sling (MS)

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Introduction

Male stress urinary incontinence (SUI) results from the failure to effectively store urine secondary to a poorly competent urinary sphincter complex (1). Urologists classically encounter this diagnosis in patients who have undergone radical prostatectomy surgery. However, other etiologies include, but are not limited to, pelvic fracture urethral injury, benign prostatic hyperplasia surgery, pelvic radiation, and neurologic disorders (1). SUI can lead to a financial burden, physical and mental health issues, and overall poor quality of life causing men to seek treatment. Conservative management includes the wearing of pads or diapers, pelvic floor muscle exercises or formalized pelvic floor physical therapy, penile clamps, or various catheterization regimens. Alternatively, surgical management mainly consists of the artificial urinary sphincter (AUS) and the male sling (MS). Adjustable balloon devices and urethral bulking agents are less commonly utilized treatment options in this space.

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In terms of surgical management, the AUS is considered the "gold standard" for male SUI, as it is an effective option for the complete spectrum of incontinence severity (1). In comparison, the MS is best utilized in the setting of mild to moderate SUI (2). Much of the available published literature is focused on the efficacy of these surgical options based on incontinence severity and other pertinent patient factors and device-related factors, as corroborated by the American Urological Association (AUA) Guideline on Incontinence after Prostate Treatment [2019].

In contrast, there are more specific everyday clinical practice patterns in male SUI surgery that are not as clearly agreed upon in the literature. We seek to summarize the contemporary literature regarding such topics in male SUI surgery over the past decade. This includes AUS *vs.* MS volumes, the prevalence of outpatient surgery, 3.5 cm AUS cuff use, preoperative urine studies utilization, and intraoperative and postoperative antibiotics. In doing so, we seek to shed light on these everyday clinical practice patterns that are changing and/or being challenged and debated in this field.

Methods

A thorough literature review was conducted using the PubMed database. With a focus on contemporary practices and trends, the database search was limited to studies within the previous 10-year period, 2012–2022. Specific search terms included, but were not limited to, "male urinary incontinence", "male stress urinary incontinence", "artificial urinary sphincter", "AUS", "male urethral sling", "male sling", "outpatient", "3.5 cm", "catheter", "urinalysis", "urine culture", and "antibiotic". The search was limited to studies in the English language. Given that our target population was SUI in adult males, we excluded studies on the pediatric or adult female populations. Our search also included review of AUA and European Association of Urology (EAU) Guidelines and pertinent urologic reconstruction and prosthetics academic texts (1-7).

Discussion

AUS vs. MS utilization

There have been multiple comparative studies in recent years between the AUS and MS for male SUI. Many indicate the superiority of the AUS in cases of moderate to severe SUI (8-10), while one recent randomized controlled trial (RCT) by Abrams *et al.* showed noninferiority of the MS compared to the AUS (11). This study is the only published RCT to date that compares MS versus AUS in the setting of bothersome urodynamic SUI after prostate surgery. The authors' primary outcome was patient-reported SUI 12 months after randomization and the noninferiority margin was 15%. Noninferiority was confirmed in this study and both devices were effective in significantly reducing urinary incontinence, however, complete dryness (i.e., the absence of any leakage) was rare in both groups. Despite showing noninferiority at 12 months, the MS group had larger leakage quantities, higher pad use, and less improvement in quality of life/satisfaction than the AUS group. The authors conclude that these better results of the AUS must be balanced with the fact that the AUS requires manual operation and the higher incidence of device problems. The AUA Guideline on Incontinence after Prostate Treatment [2019] specifically states that "male slings should not be routinely performed in patients with severe stress incontinence" (2). Contemporary published literature on trends in male SUI practice patterns was reviewed to assess if this mirrored what comparative studies have concluded and what urologic guidelines recommend.

In a retrospective study using data from the National Inpatient Survey (NIS) database between 2000–2012, MacDonald *et al.* reviewed the rates of AUS and sling use (12). This data included 32,416 anti-incontinence procedures. The authors found no significant change in the incidence of radical prostatectomies performed over the study period. However, there was a significant decline in the overall number of incontinence procedures performed; and when stratifying by procedure type, there was a significant decline in AUS cases, but a concomitant significant increase in MS cases. The hypothesized reasons for the decline in overall incontinence procedures were improved post-prostatectomy continence rates and a shift from inpatient to outpatient SUI management that may not be captured well in the NIS data. Patient preference, surgeon preference, and patient factors/co-morbidities may have also influenced the decision to pursue treatment at all and/or deciding between AUS and MS. The authors point out that the observed shifting trend is likely multifactorial and that despite the decrease in AUS cases, it was still the more utilized option for surgical SUI correction by a factor of four.

Del Giudice *et al.* assessed contemporary trends in post-prostatectomy surgical SUI management in the United States by querying Optum's deidentified Clinformatics® Data Mart Database between 2003–2017 (13). A total of

844 unique incontinence procedures were performed over the study period. In contrast to the MacDonald *et al.* study, MS was the most common procedure performed (47.5%), whereas AUS was utilized in 35.3%. The authors concluded that the likely reasons for this were the less invasive nature of sling operation, the fact that subsequent AUS placement remains a viable option after sling failure, the fact that short-term MS success rates approach those of the AUS, and the AUS being the more expensive treatment option. After 2010, there was a decreasing trend in all incontinence procedures. However, when stratifying by procedure type, MS rates initially increased and then subsequently decreased, while AUS rates remained fairly stable.

Pusateri *et al.* addressed a similar question by reviewing AUA section data to examine device utilization trends between the AdVance™ sling (American Medical Systems, Minnetonka, MN, USA) and the AUS (14). Relative to the AUS, the proportion of AdVance™ sling usage increased after its introduction in 2007 (36%) through 2008 (48%), remained stable from 2008–2011, decreased in 2012 (29%), and remained stable from 2012–2015, indicating an overall decreasing trend over the study period.

Dosanjh *et al.* studied post-prostatectomy AUS and MS implantation in England utilizing the Hospital Episode Statistics (HES) dataset between January 2010 and March 2018 (15). The AUS cohort included 1,414 patients, while the MS cohort contained 816 patients. The number of AUS implantations increased every year while the number of slings performed peaked in 2014/2015 and subsequently decreased.

Liu *et al.* examined 6-month American Board of Urology case log data of 1,615 certifying urologists between 2003–2013, specifically analyzing those cases involving the AUS or MS (16). The authors showed an increase in overall SUI surgeries between 2003–2013. AUS placement was slightly more common overall (52%), however, the rate of sling use increased from 28.6% in 2003 to 45.5% in 2013 with a peak in 2011 (62.2%). Between 2008–2011, MS placement was more common than AUS placement. The authors comment on the fact the "initial sling enthusiasm" may have caused this increase in sling utilization and that the more recent decline in sling use could be explained by this enthusiasm being tempered secondary to observed sling failures. The authors also showed that academic urologists were 1.5 times more likely to perform AUS than MS and that most SUI cases were performed by a small number of high-volume surgeons.

In summary, the increasing utilization of MS after it initially came to market may have been due to the interest in adopting a new technology, its arguably less invasive nature, and the lack of a need for manual operation; while its subsequent decline in use may be related to its decreased efficacy in more severe incontinence cases as well as the need for further surgery with an AUS secondary to post-MS recurrent or persistent incontinence. It is worth noting though that the MS was found to be noninferior to the AUS in the recent Abrams *et al.* RCT and it will be interesting to see if this has an impact on practice patterns moving forward. Additionally, as technological advances in SUI surgical devices continue to develop (different sling types and modifications, adjustable balloon devices, AUS modifications, among others), this will certainly have an impact on future device practice patterns.

Outpatient surgery

Historically, male SUI surgeries involved an overnight post-operative admission for continued intravenous antibiotic therapy and a void trial on postoperative day #1 prior to discharge. In more recent years though, there has been a shift toward performing these operations as outpatient procedures to improve patient experience and medical costs, while maintaining patient safety and minimizing postoperative complications and surgical failures.

Shelton *et al.* assessed 1,176 AUS male patients in the NSQIP database between 2007–2016, with 232 being categorized as early discharge (24 hours or less) and 944 being categorized as late discharge (>24 hours) (17). Operative time was shorter in the early discharge group (mean of 83 *vs.* 95 minutes) and early discharge cases became statistically significantly more common beginning in 2012. Importantly, the 30-day complication rate showed no significant difference between the 2 cohorts.

In a retrospective single institution study, Nasri *et al.* reviewed 81 men who underwent outpatient AUS surgery between May 2016–March 2020 (18). The authors' primary goal was to assess surgical success, which they defined in 2 ways. The first, more narrow definition was a one-day hospitalization without any unscheduled consultation or re-hospitalization within 3 days following surgery. The second, more broad definition was a one-day hospitalization without any unscheduled re-hospitalization within 3 days following surgery. Success occurred in 71.6% using the narrow definition and 93.8% using the broad definition. Anticoagulant use and low socio-economic status were found as significant risk factors for failure on multivariate analysis.

In another retrospective single institution study at a high-volume tertiary care academic medical center, Dropkin *et al.* analyzed 525 AUS cases between August 2013 and January 2020, with 318 cases in the same day surgery (SDS) group and 207 cases in the overnight observation (OBS) group (19). The SDS group showed a slightly lower American Society of Anesthesia (ASA) score, but were more likely to have hypertension. The OBS group was more likely to have had a previous MS surgery and more likely to have a history of bladder neck contracture. All other compared patient demographics did not show statistically significant differences. When reviewing intraoperative and postoperative results, the SDS group had more virgin AUS placements, while the OBS group showed increased transcorporal cuff placement, percutaneous drain placement, complication prior to discharge, subsequent suprapubic tube placement, and readmission within 90 days of discharge. There was no difference in non-routine clinic visits or outpatient phone calls within 7 days of discharge between the 2 groups. The same held true for the need for device explant or revision within 90 days or discharge. As expected, the OBS group showed higher room and bed charges than the SDS group ($745 *vs.* none). The authors comment on how their practice has significantly shifted over the study period to a primarily SDS approach given that it is safe, cost-effective, and successful.

Another single institution retrospective study by Dropkin *et al.* reviewed 163 AUS patients between June 2013 and September 2017 (20). All but 1 patient in the cohort were discharged on postoperative day #1. The authors showed that these patients required minimal intravenous and total narcotic requirements postoperatively and that immediate postoperative complications rates were ~1%. The authors concluded that, given this information, outpatient AUS surgery is likely to be safe, effective, cost saving, and optimize patient experience.

Given the retrospective nature of the available literature on this topic, it is difficult to make definitive conclusions on the outpatient volume trend and outcomes; however, one can expect this approach to continue to become more prevalent, especially if more robust future data confirms the safety and cost-effectiveness of this approach, while also maintaining successful patient outcomes.

3.5 cm cuff utilization

The 3.5 cm AUS cuff was introduced in an attempt to accommodate patients with a small urethral circumference to improve postoperative continence rates in this population (1,21). The routine use of this specific cuff size, however, is highly controversial in the AUS literature with many authors warning of the increased potential risks and complications associated with its use, while others have advocated that these risks may be overstated and that optimizing urethral coaptation and continence outcomes should be the primary focus.

A large, multi-institutional, prospective study by Brant *et al.* showed that men who underwent 3.5 cm AUS cuff placement had significantly higher device explant rates than those patients who received larger cuffs (22). Additionally, a large, retrospective, multicenter cohort study in Central Europe by Queissert *et al.* showed that smaller cuff size was a risk factor for urethral erosion on multivariate analysis (21). Simhan *et al.* reviewed an initial 100-case single surgeon experience with the 3.5 cm cuff (23). The authors showed that there was a 21% urethral erosion risk in irradiated patients who received this cuff size compared to only 4% risk in patients who no history of radiation. History of radiation was the only significant risk factor in this study associated with 3.5 cm cuff erosion. Mechanical failure rates were also found to be higher with the 3.5 cm cuff than with larger cuff sizes in a large retrospective review by Loh-Doyle *et al.* (24).

In contrast to the studies mentioned above, others have seen more positive results. McKibben *et al.* showed in series of 410 AUS cases that erosion rates in the 3.5 cm cuff group (10.8%) were nearly identical to the 4+ cm cuff group (10.7%). Both groups showed similar continence rates (82% *vs.* 90%). More important clinical factors for device erosion included history of pelvic radiation, prior device erosion, urethroplasty, and IPP surgery (25). The same center published two other pertinent studies. Bergeson *et al.* showed that urethral atrophy was a rare cause for AUS revision surgery in the 3.5 cm cuff population (2%) *vs.* the 4+ cm cuff population (11.6%) and Davenport *et al.* showed that TC cuff placement was a higher risk factor for urethral erosion than 3.5 cm cuff placement (47% *vs.* 15%) (26,27). In a single center European study including 84 patients, multivariate analysis showed that only perioperative anticoagulation and double-cuff placement for independent predictors of device failure. The 3.5 cm cuff size resulted in significantly lower revision rates and incontinence rates (28).

The available data is mixed and conflicting on what role the 3.5 cm cuff plays in the SUI surgical space. It is a delicate balance for the surgeon to strive to optimize continence, while at the same time minimizing

postoperative complications. This is clearly an area where additional, more conclusive data is needed to assist with perioperative decision making and identification of the ideal surgical candidates for this particular cuff size.

Postoperative catheter utilization

The use of an intraoperative 12–14 French urethral catheter is standard during AUS and MS surgery. Typically, this catheter is left in place overnight with a postoperative day #1 void trial performed either prior to hospital discharge or during a scheduled outpatient clinic visit if the patient was discharged home on postoperative day #0 (1,5-7). We are aware that some urologists are now choosing to remove the urethral catheter at the conclusion of the surgery and perform a void trial in the post anesthesia care unit (PACU), however the published literature is sparse on this approach. The primary concern with such an approach is that urinary retention in the PACU would result in the need to immediately re-instrument the urethra and risk damage to the newly placed device. When this approach is successful, the patient's immediate postoperative experience may be slightly enhanced, but one can argue that a small indwelling catheter for less than 24 hours is a minimal burden for the patient, especially if it potentially prevents the risk of immediate re-catheterization.

Preoperative urine studies

Classic teaching and expert opinion have advocated for a preoperative urinalysis and/or urine culture for urologic prosthetic cases in order to effectively sterilize the urine, if necessary, and minimize the risk of subsequent device infection (1,5-7). However, real-life practice is not as uniform. In an anonymous web-based survey of sexual medicine physicians, up to 50% of surgeons did not routinely obtain preoperative urine cultures for penile implant cases (29). Unfortunately, we have no RCTs to date evaluating the utility of preoperative urine studies for urologic prosthetic surgery, which is ultimately what is needed to formally address this issue.

Kavoussi *et al.* published a retrospective review of 713 urologic prosthetic cases (337 AUSs and 376 penile implants) from 2007–2015 at a large tertiary referral center (30). There were 259 cases in which the patient did not obtain a preoperative urine culture. In this subgroup, device infection occurred in 1.5% (2% of AUS cases, 1% of penile implant cases). The authors comment that this is a comparable infection rate to other published literature on urologic prosthetics infection rates. They also discuss some of the potential downsides of a routine urine culture approach including the added financial costs, possible future antibiotic resistance and pharmacologic adverse effects, and difficulty in obtaining such tests for patients that do not live locally. This same center published a related study showing a 93% discordance between preoperative urine culture results and the bacteria found at the time of device explant for infection (31). Another pertinent finding was that despite their AUS cases having a 4.5-fold greater risk of positive urine cultures compared to those in their penile implant cases, device infection rates were comparable between these 2 groups at 3%, again questioning the utility of the preoperative urine culture.

A preoperative urinalysis and/or culture is standard of care practice in most settings for operations that involve urinary tract manipulation. Certain contemporary studies question the utility of this practice in genitourinary prosthetics surgery, however as with other topics represented above, stronger multi-center prospective data is needed to definitively and confidently change these practice patterns on a widespread scale.

Perioperative antibiotics

Perioperative antibiotic choice for most urologic procedures is based on best practice statements and guidelines such as the AUA Best Practice Statement on Urologic Procedures and Antimicrobial Prophylaxis [2019] (32). For urologic prosthetic surgery, the statement advocates for administering an aminoglycoside or aztreonam along with a first or second-generation cephalosporin or vancomycin for up 24 hours or less. The penile prosthesis literature has demonstrated some critique of this particular AUA recommendation due to the variability in described antibiotic regimens and having not incorporated the most current data of device infection etiology (33). For male SUI cases, in particular, there is no such published critique to date.

Regarding postoperative oral antibiotic regimens for male SUI surgery, there is significant variability among surgeons, with some providing no additional coverage while others providing up to a week of additional therapy. Adamsky *et al.* queried the MarketScan database for AUS and IPP cases between 2003–2014. Device explant rates were similar whether or not postoperative oral antibiotics were given and no individual antibiotic class was found

to be superior in preventing device explant (34). Dropkin *et al.* performed a retrospective review of 155 AUS patients between 2013–2017 at a single institution. Postoperative antibiotic use did not seem to affect rates of device explant due to infection or cuff erosion (35). Despite this data, many urologists continue to prescribe postoperative antibiotics routinely. In editorial response to the Adamsky *et al.* paper, the author discusses that given the steep consequences of device infection, the "burden of proof" should actually be on "those who claim antibiotic administration does not provide a net positive effect" before sweeping practice changes are made (36).

Conclusions

In male SUI surgery, as with many other surgical fields, specific clinical practice patterns can vary significantly among surgeons. Overarching principles may be reflected well in published clinical guidelines, best practice statements, and academic texts. However, for many of the debated topics that are covered in this review, RCTs are ultimately needed to definitively address these questions, rather than single-institution retrospective studies or retrospective reviews of large public databases, which have clear limitations. In addition, current and future advances in surgical device technology will certainly have an effect on device utilization patterns moving forward, which may not be captured in the published literature until several years later.

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Footnote

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