

Artificial Urinary Sphincter Outperforms Sling for Moderate Male Stress Urinary Incontinence



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OBJECTIVES	To determine the role of slings and artificial urinary sphincters (AUS) in the management of mild and moderate stress urinary incontinence (SUI).
METHODS	A retrospective review of our single-surgeon male SUI database was completed. Men having AUS or AdVance sling procedures between 2008 and 2019 were included in the analysis. Those with severe incontinence and/or incomplete pre- or postoperative data were excluded. All patients were evaluated by standing cough test and stratified according to the Male Stress Incontinence Grading Scale. Scores of 0-1 and 2-3 defined mild and moderate SUI, respectively. We performed 2 analyses: (a) sling outcomes were compared between mild vs moderate SUI patients, and (b) for men with moderate SUI, we compared outcomes between slings and AUS. Treatment failure was defined as >1 pad per day or need for subsequent incontinence procedure.
RESULTS	Among 202 sling cases, those with mild SUI had significantly higher success rate (69/88, 78%) than those with moderate SUI (72/114, 63%; $P = .02$). Among the 179 men with moderate SUI, those who underwent AUS had significantly higher success rate (52/65, 80%) than those who underwent sling (72/114, 63%; $P = .02$).
CONCLUSION	Male slings are more effective for men with mild SUI than for men with moderate SUI. Men with moderate SUI have a higher success rate with AUS than with sling. UROLOGY 141: 168–172, 2020. © 2020 Elsevier Inc.

The artificial urinary sphincter (AUS) has been the mainstay treatment for male stress urinary incontinence (SUI) since the 1970s.¹ Despite its well-established success rates,² many men with SUI are reluctant to pursue AUS due to concern for infection, erosion, device complexity, and/or mechanical failure. The male transobturator, retrourethral sling emerged as an alternative surgical option for men with mild-moderate SUI in 2006.³ Since then, the long-term safety and efficacy of the male sling has been established.⁴⁻⁹ While male slings have the advantage of decreased invasiveness, evidence comparing outcomes of slings to AUS is limited.¹⁰

According to the latest AUA and EAU guidelines,^{5,11} slings are best suited for men with persistent mild SUI, while those with severe SUI are best served by an AUS. Men with persistent moderate SUI, however, are often considered candidates for either sling or AUS.^{5,11} Counseling these patients is complicated by the absence

of an established universal definition of moderate SUI and by the paucity of comparisons of sling outcomes based on SUI severity.

We sought to determine the best treatment for the commonplace subset of men presenting with moderate SUI. We compared the outcomes of slings in men with moderate SUI versus those with mild SUI, and versus those with moderate SUI who underwent AUS. Our aim is to provide patients and urologists with more nuanced insight regarding expectations for treatment outcomes among men with more than minimal SUI.

MATERIALS AND METHODS

After institutional review board approval, we retrospectively reviewed our single-surgeon male SUI surgical database. All patients were evaluated in clinic by standing cough test (SCT) to physically demonstrate the degree of SUI and stratified according to the Male Stress Incontinence Grading Scale (MSIGS).¹² MSIGS scores of 0-1 and 2-3 defined mild and moderate SUI and were included in this study. Patients with MSIGS 4 (severe incontinence) and those with incomplete data were excluded from analysis.

AdVance and AdVanceXP slings (Boston Scientific, Minnetonka, MN) were all performed at our institution through a standardized midline perineal technique, which remained constant

Conflicts of interest: Dr. Allen Morey receives honoraria for being a guest lecturer/meeting participant for Boston Scientific and Coloplast Corp.

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during the study interval. Patients were evaluated postoperatively at 3 months, 1 year, and annually thereafter. Remote patients who followed up with their local urologists were contacted by telephone to assess degree of leakage. Treatment failure was defined as greater than 1 pad per day (PPD) usage or the need for subsequent incontinence procedure.

We performed 2 analyses: (1) among men who underwent slings, we compared those with mild SUI (Group A) to those with moderate SUI (Group B); and (2) among men with moderate SUI, we compared men who underwent slings (Group B) to those who underwent AUS (Group C). Preoperative and postoperative data were compared between groups with 2-tailed, unpaired *t* tests for continuous variables and chi-square tests for categorical variables. We considered $P < .05$ to be statistically significant.

RESULTS

We identified 978 total men who underwent anti-incontinence surgery (255 sling, 723 AUS) for SUI at our institution between 2008 and 2019 (Fig. 1). Early in our experience, we did not consistently obtain preoperative MSIGS data according to our current protocol. We excluded 669 patients with MSIGS 4 or incomplete preoperative data. We also excluded 13 AUS

patients with preoperative MSIGS 0-1. An additional 29 patients with incomplete postoperative data were excluded. A total of 267 patients (202 sling, 65 AUS) had complete postoperative data and were included in the analysis. Of the 202 sling cases analyzed, we identified 88 who had mild SUI (Group A) and 114 who had moderate SUI (Group B). Group B patients were also compared to the 65 men who underwent AUS for moderate SUI (Group C). Table 1 depicts the preoperative demographic and clinical data for each group.

Analysis 1: Sling Comparison—Mild (Group A) vs Moderate (Group B) SUI

Groups A and B had similar preoperative demographics, except Group B had a significantly higher rate of tobacco use history (63/114, 54%) than Group A (36/88, 41%; $P = .04$). As expected, Group B had a significantly higher baseline PPD (2.5 ± 1.4 vs 1.9 ± 1.2 , $P < .01$) and baseline MSIGS (2.2 ± 0.4 vs 0.5 ± 0.5 , $P < .001$) than Group A. At a median follow-up of 20.1 months (IQR 1.6-52.2 months), Group A had a significantly higher success rate compared to Group B (78% vs 63%, $P = .02$, Table 2). There were no significant difference in rates of complications or revisions between Group A (13/88, 15%) and Group B (26/114, 22%; $P > .05$).

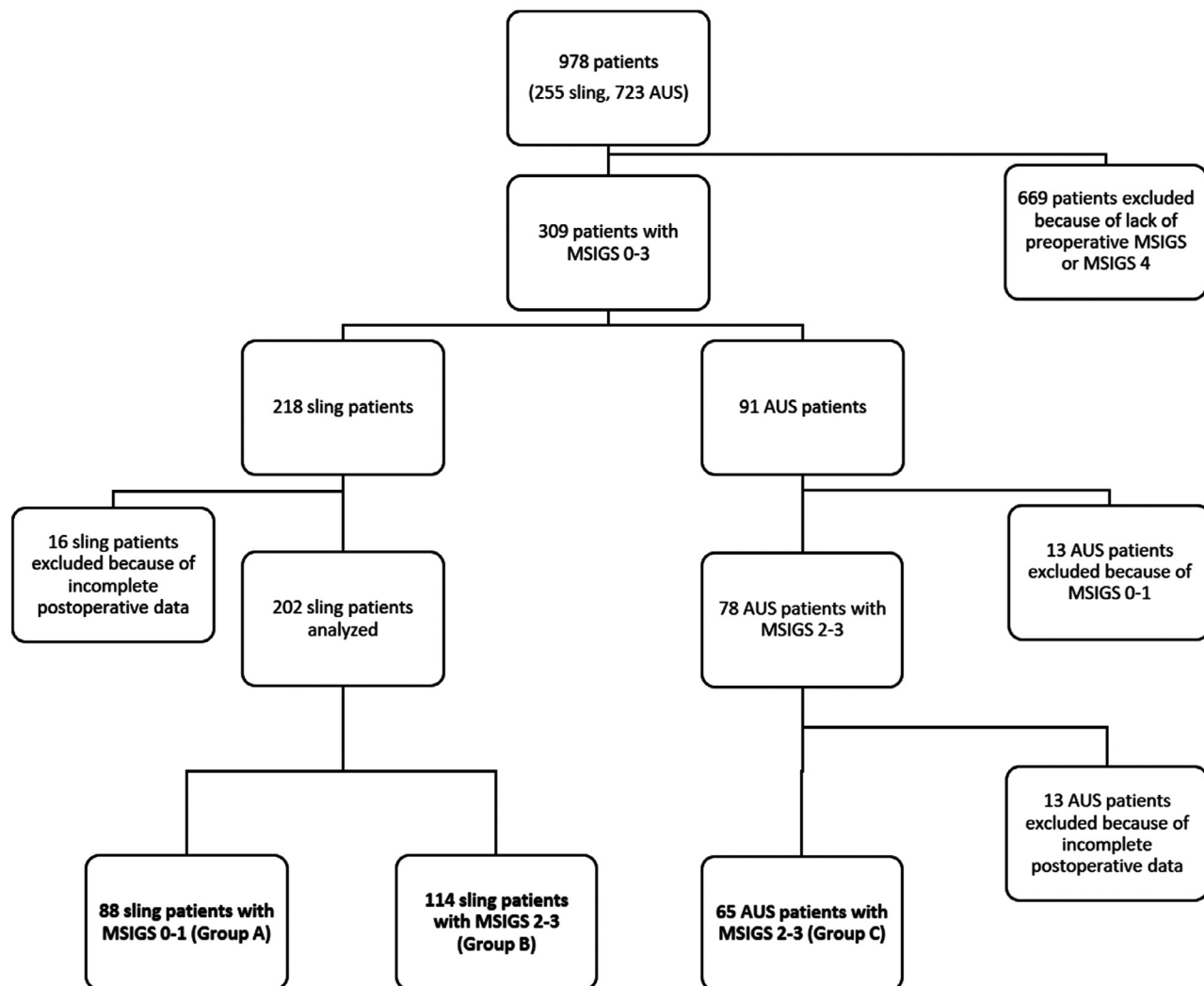


Figure 1. Group stratification flow chart.

Table 1. Baseline patient characteristics for each group. Group A includes all men with MSIGS 0-1 who underwent urethral sling placement. Group B includes all men with MSIGS 2-3 who underwent urethral sling placement. Group C includes all men with MSIGS 2-3 who underwent AUS placement (statistically significant values in bold)

	Sling for MSIGS 0-1 (Group A)	P Value (A vs B)	Sling for MSIGS 2-3 (Group B)	P Value (B vs C)	AUS for MSIGS 2-3 (Group C)
No. total patients	88		114		65
Mean Baseline PPD (SD)	1.9 (1.2)	<0.01	2.5 (1.4)	<0.001	4.2 (3.3)
Mean MSIGS (SD)	0.5 (0.5)	<0.001	2.2 (0.4)	<0.001	2.8 (0.4)
Mean age at SUI surgery (SD)	67.1 (7.9)	0.540	66.5 (7.7)	0.023	70.8 (7.1)
Mean BMI (SD)	27.9 (4.0)	0.710	27.7 (4.1)	0.021	29.3 (4.5)
No. comorbidities (%)					
-Hypertension	44 (50%)	0.536	62 (53%)	0.743	37 (57%)
-Diabetes mellitus	14 (16%)	0.885	19 (16%)	0.197	16 (25%)
-Tobacco history	36 (41%)	0.043	63 (54%)	0.703	34 (52%)
No. urological history (%)					
-Prostate surgery	86 (97%)	0.123	106 (91%)	0.824	61 (94%)
-Prostate radiation	8 (9.1%)	0.159	18 (16%)	0.003	23 (35%)
-Prior IPP	4 (4.5%)	0.620	7 (6.0%)	0.042	10 (15%)

Analysis 2: Moderate SUI Comparison—Sling (Group B) vs AUS (Group C)

Group C had significantly higher age (70.8 ± 7.1 years vs 66.5 ± 7.7 years, $P = .02$) and BMI (29.3 ± 4.5 vs 27.7 ± 4.1 , $P = .02$) than Group B. Group C also had significantly higher rates of prior prostate radiation (35% vs 16%, $P < .01$) and prior penile prosthetics (15% vs 6.0%, $P = .04$) than Group B. Group C had a significantly higher baseline PPD (4.2 ± 3.3 vs 2.5 ± 1.4 , $P < .001$) and baseline MSIGS (2.8 ± 0.4 vs 2.2 ± 0.4 , $P < .001$) than Group B. Group C had a significantly higher success rate (52/65, 80%) than Group B (72/114, 63%; $P = .02$). There were no significant differences in rates of complications or revisions between Group B (26/114, 22%) and Group C (13/65, 20%; $P > .05$).

COMMENT

To our knowledge, this is the first comparative study focusing on surgical management of moderate SUI — a common clinical scenario, comprising nearly half of our SUI patients. We found that men who underwent sling placement for moderate SUI (Group B) did significantly worse than those who underwent slings for mild SUI (Group A). Further, despite the fact that AUS patients had significantly worse preoperative PPD and MSIGS scores than those who underwent sling placement for moderate SUI, AUS outcomes were superior. Collectively, these findings suggest that slings should be reserved for men with mild SUI because men with moderate SUI will experience higher success with AUS.

Male Slings — Predicting Success

Patients may often be reluctant to undergo AUS placement, so predicting their chances of success with slings can help guide decision-making. For men with mild-to-moderate SUI who underwent urethral sling placement, our results are similar to the cure rates of 66%-73% at 2-4 year follow-up reported in the literature.^{6,13,14} Preoperative SUI severity has been shown to be the primary predictor of sling success.^{12,14-17} AdVance and AdVanceXP sling outcomes appear to be similar and correlated directly to 24-hour pad weight.⁸ Preoperative SUI severity (as determined by reported PPD) has been associated with continence outcomes 5 years following sling placement.⁴ Consistent and accurate preoperative grading of SUI severity appears to be a critical element of counseling men undergoing surgery for SUI.

Some urologists justify sling placement in men with moderate SUI because sling failure can be corrected with an AUS without adding significant risk or operative time to AUS placement surgery. However, placing a sling in a patient who is likely to ultimately need an AUS costs the patient an additional surgery with complication risk and financial burden. It also delays definitive treatment with AUS by months or years. Therefore, determining which procedure is most likely to succeed on the first attempt is essential. This is why we have created a nomogram that includes multiple variables in order to determine their probability of sling success.¹² The current study supports

Table 2. Clinical outcome measures for each group. Group A includes all men with MSIGS 0-1 who underwent urethral sling placement. Group B includes all men with MSIGS 2-3 who underwent urethral sling placement. Group C includes all men with MSIGS 2-3 who underwent AUS placement (statistically significant values in bold)

	Sling for MSIGS 0-1 (Group A)	P Value (A vs B)	Sling for MSIGS 2-3 (Group B)	P Value (B vs C)	AUS for MSIGS 2-3 (Group C)
No. total patients	88		114		65
No. complications/ revisions (%)	13 (15%)	0.151	26 (22%)	0.662	13 (20%)
No. success (%)	69 (78%)	0.019	72 (63%)	0.017	52 (80%)

the findings of our previous study and provides a more focused assessment of patients with moderate SUI in whom surgical decision making remains difficult.

Grading SUI Severity

Men with SUI often suffer for years before undergoing surgical intervention.¹⁸ We hypothesize that SUI treatment delay may be due to ongoing oncological interventions, erectile dysfunction concerns, hope for continence improvement over time, and possibly the concept that long-term prostatectomy follow-up may often be left to primary care or nonphysician providers. Counseling men with reported moderate SUI is an imperfect undertaking complicated by the absence of a universal SUI grading system. PPD measurements provide a quick estimate of SUI severity, but may be limited by recall bias, variations in pad types, activity variability, and variations in threshold for switching pads.

The 24-hour pad weight test is considered to be more accurate, but logistical hurdles limit its incorporation into our practice and many others worldwide.¹⁹ The SCT has the advantage of being rapid, efficient, practical, and it correlates closely with 24-hour pad weights.²⁰ These data underscore the concept that the SCT is a convenient and reliable indicator of SUI severity and sling success.

While urodynamic studies certainly provide more detailed information on the function of the lower urinary tract, several studies have demonstrated that they do not reliably predict sling success.²¹⁻²³ We find that urodynamics is helpful when the etiology of urinary incontinence is in question. However, in nearly all of our patients, the history and physical exam clearly point to SUI due to compromised sphincter function. Therefore, we do not include urodynamics as part of our routine workup for SUI.

Role for AUS

Many men are referred to our practice specifically for consideration of sling placement for what is presumed to be mild SUI. If we were to rely solely on the referral/reported severity of SUI, many of these patients would seem to be ideal sling candidates. However, standardized incorporation of the SCT into our routine office physical exam adds precision and enables us to counsel patients accordingly. We recommend that AUS placement be strongly considered for the majority of patients with MSIGS ≥ 2 , especially when their reported PPD usage is >1 ppd. Despite their initial aversion to a mechanical prosthetic, patients with moderate SUI generally choose AUS placement over slings after reviewing the risks and benefits of each.

A nomogram incorporating the SCT is available to help predict male sling success and facilitate patient counseling.¹² In addition to preoperative SUI severity, this nomogram incorporates radiation history into the calculation. Early in our experience, we offered slings to patients with radiation history and mild or moderate SUI at the patient's request. However, as the literature became clearer on this subject, we realized that patients with radiation history had significantly lower success rates with

sling. We now consider prior radiotherapy a contraindication to sling placement and offer only AUS to these patients.

Limitations

Our study is unique in that it directly compares treatment outcomes between slings and AUS for men in a highly selected group with well-documented preoperative SUI severity. The single-surgeon, single-institution, tertiary center study design might limit generalizability. The retrospective and nonrandomized nature of the study could allow for confounding variables. Groups B and C clearly had different preoperative demographics, urologic history, and SUI severity, and this must be considered when comparing these 2 groups. Although preoperative differences between the groups generally favored Group B, Group C still had a higher success rate. We therefore suspect that randomizing men with MSIGS 2-3 to AUS vs sling would show an even greater benefit of AUS.

Prospectively collected 24-hour pad weight data would add another objective measurement to our assessment of preoperative SUI severity and postoperative treatment success. Unfortunately, patients find the 24-hour urine collection tedious and cumbersome and many forget to collect all of their pads for a full 24-hour period or to bring the pads in for their clinic visits. The 24-hour pad weight test also varies depending on the patient's level of physical activity on that day. Furthermore, since the SCT correlates strongly with the 24-hour pad weight test and is much easier to perform for patients and providers,²⁰ we have not included 24-hour pad weight as a routine part of our assessment.

Our study is also limited by the lack of an assessment of continence at set time points throughout the study. However, long-term continence is likely the most meaningful outcome from a patient perspective. Postoperative SCT has not been assessed or validated as a metric of surgical success and thus is not a part of our routine post-operative visit.

CONCLUSION

Male sling procedures appear to be most appropriate for men with mild SUI. Those with moderate SUI have higher continence rates with AUS than with slings. These findings, when combined with precise preoperative grading of SUI severity, may help guide preoperative counseling and improve surgical outcomes among men with moderate SUI.

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