original article

A comparison of the perineal and penoscrotal approaches in artificial urinary sphincter implantation for the control of male stress urinary incontinence

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BACKGROUND: The two most common surgical approaches to treat stress urinary incontinence in men are the traditional perineal and the new penoscrotal approach for artificial urinary sphincter (AUS) implantation. Each method carries its own advantages and disadvantages. The few reports that compare the approaches have disparate outcomes.

OBJECTIVE: Compare the outcome of first time AUS implantation by the perineal versus the penoscrotal approach.

DESIGN: Retrospective study.

SETTING: Tertiary referral center.

PATIENTS AND METHODS: We included all male patients who underwent primary perineal or penoscrotal AUS placement between June 2004 and October 2018 at our tertiary care hospital. Patients were followed at least one year postoperatively.

MAIN OUTCOME MEASURES: Rates of dry, infection, erosion, malfunction, atrophy, revision.

SAMPLE SIZE: 44 males who underwent 68 procedures.

RESULTS: Twenty-five (56.8%) patients underwent a perineal and 19 (43.2%) underwent a penoscrotal approach. The patients had 68 procedures: 36 (52.9%) perineal and 32 (47.1%) penoscrotal approaches. The median (25th-75th percentiles) age at the time of surgery was 61.0 (51.0-68.0) years (n=68 procedures). The median (25th-75th percentiles) operative time was significantly shorter for the penoscrotal approach, 87 (69-140), vs. 93 (72-210) minutes for the perineal approach (*P*=.016). The 44 patients were followed up for a mean (SD) of 52.5 (20.3) months for the 68 procedures. Postoperative complications occurred in 16 (36.36%) patients; 11 (44%) perineal approach patients and 5 (26.3%) penoscrotal. There were no significant differences in complications of infection, erosion, malfunction, or urethral atrophy between the two groups. Only removal/revision was significantly more common with the perineal approach (10 patients perineal and two patients penoscrotal, *P*=.042). At the last follow-up, dryness was comparable among groups.

CONCLUSION: The outcomes of AUS placement are comparable between perineal and penoscrotal approaches in terms of complications and one year dryness. The penoscrotal approach however has shorter operative time and less need for revision and removal.

LIMITATIONS: Small sample size, single-center.

CONFLICT OF INTEREST: None.

Stress urinary incontinence (SUI) can put males in psychological stress with a negative impact on quality of life.[1] SUI is defined as involuntary leakage of urine due to inadequate urinary sphincter function. Management of SUI ranges from conservative measures (pelvic floor exercises and injection of urethral bulking agents) to surgical intervention. The two most common surgical approaches are perineal and penoscrotal approaches for artificial urinary sphincter (AUS) implantation.

Perineal AUS implantation for treatment of urinary incontinence was first introduced in 1974 by Scott et al.[2] The traditional perineal approach required a second abdominal incision to place the reservoir. In 2003, Wilson et al introduced a single transcrotal approach through which both the cuff and reservoir can be placed. Another advantage is that concomitant penile prosthesis and AUS implantation can be done simultaneously, a scenario that is common for post-radical prostatectomy erectile dysfunction and urinary incontinence.[3] We utilized both approaches for the management of male SUI. The few reports in the literature have disparate outcomes.[4-6] In this study, we aimed to report the outcome of perineal versus penoscrotal AUS surgery and compare our institutional experience with the international literature.

PATIENTS AND METHODS

This was a retrospective study that included all male patients who underwent primary perineal or penoscrotal AUS placement between June 2004-October 2018 at our tertiary care hospital. The indication of AUS surgery in our institution was total urinary incontinence. No surgery was indicated for a milder form of incontinence including stress incontinence. One urologist with a subspecialty in reconstructive surgery performed all the procedures (WT). Patients were followed up at least a year after the procedure. Data were collected from the electronic medical records (Integrated Clinical Information System), and from the patient charts. The parameters that were collected included the type of surgery, age, cause of incontinence, follow-up period in months, cuff size, complications (infections, erosion, malfunction, and urethral atrophy), and complete dryness, defined as an absence of leak, at one year follow-up time.

Continuous data are summarized as median and 25th to 75th percentiles or mean and standard deviation (SD), whereas categorical data are summarized as numbers and percentages. Continuous variables were compared by the Mann-Whitney U tests or independent sample *t*-test, as appropriate; categorical variables were compared by the chi square and Fisher exact tests. The significance level is P<.05, and all values were two-sided. Data were analyzed using IBM SPSS version 25.

RESULTS

We had 44 patients who underwent a first-time AUS procedure;25 (56.8%) underwent the perineal approach and 19 (43.2%) underwent penoscrotal for a total of 68 procedures. The median (25th-75th percentiles) age was 61.0 (51.0-68.0) years at the time of surgery (n=68 procedures). There were 36 (52.9%) perineal and 32 (47.1%) penoscrotal procedures. The indication for the AUS procedure was incontinence secondary to prostatectomy in 82.4%, neurogenic bladder in 14.7%, and urethral injury in 2.9%. There were no significant differences between indications. All patients had total urinary incontinence and wore pads all the time. The pads were changed 4-5 times per day for complete soaking. No diaper count or weight was available. The selection of the method was not random. We took into consideration previous surgical scars, and we tried to avoid a second abdominal incision.

There was no difference in the age of patients at the time of surgery or hospital stay by approach to surgery (**Table 1**). However, the penoscrotal approach was

Table 1. Perineal vs the penoscrotal approaches for sphincter implantation (n=68 procedures).

	Perineal (n=36)	Penoscrotal (n=32)	Both approaches (n=68)	*P* value
Cuff size (cm)	4.3 (4-5.5)	4.0 (3.5-4.5)	4.0 (4.0-4.5)	<.001
Operative time (minutes)	93 (72-210)	87 (69-140)	90.0 (84.8-99.3)	.009
Follow up (months)	64.0 (17.8)	39.0 (13.8)	52.2 (20.3)	<.001
Hospital stay (days)	2 (2-4)	2 (2-5)	2.0 (2.0-3.0)	.295
Age (years)	59 (18-80)	64 (20-79)	61.0 (51.0-68.0)	.238 .188

Data are median (25th-75th percentile); mean (standard deviation) for follow-up time.

associated with a significantly shorter operative time, smaller cuff size, and shorter follow-up duration (**Table 1**). The rate of complete dryness following each procedure was higher for the perineal compared to the penoscrotal approach but the difference was not statistically significant (**Table 2**). Eventually, 65.9% of all patients achieved complete dryness at the end of follow-up, with no significant difference between approaches.

Postoperative complications occurred in 16 (36.4%) patients; 11 (44%) after the perineal approach and 5 (26.31%) after the penoscrotal approach (**Table 3**). There were no significant differences in complications between the approaches. Only removal/revision was significantly more common with the perineal approach. One patient from each group developed an early superficial skin infection which was managed conservatively. All patients who developed urethral erosion had an infection. We managed those cases by urethral repair followed by reinsertion of AUS after three months of recovery. Two patients had scarred urethra in which reinsertion of AUS was not possible. All revisions were done through the perineal approach with no tandem cuff placement. The revision was managed by removing the entire system and placing a new one. Revision in cases complicated with urethral atrophy was managed by removing the whole system and placing a new

Table 2. Postoperative dryness at last follow up for each procedure (n=68).

	Perineal (n=36)	Penoscrotal (n=32)	Both approaches (n=68)
Completely dry[a]	25 (56.8)	19 (43.2)	44 (64.7)
Urine leak	11 (45.8)	13 (54.2)	24 (35.3)
Total	44 (64.7)	24 (35.3)	24 (35.3)

Data are n (%). [a]*P*=.386

Table 3. Outcomes of the current study and reported studies that compared the two approaches for sphincter implantation.

Study	Patients	Dry	Infection/ erosion	Infection	Erosion	Malfunction	Atrophy	Removal/ revision
This study								
Total	44	29 (65.9)[a]	7 (15.9)	7 (15.9)[b]	5 (11.4)[c]	5 (11.4)[d]	4 (9.1)[e]	12 (27.3)[f]
Perineal	25 (56.8)	18 (72.0)	5 (20.0)	5 (20.0)	4 (16.0)	5 (20.0)	1 (4.0)	10 (40.0)
Penoscrotal	19 (43.2)	11 (57.9)	2 (10.5)	2 (10.5)	1 (5.3)	0	3 (15.8)	2 (10.5)
Shen et al, 2012[4]								
Total	27	16 (59.3)		7 (25.9)	1 (3.7)			
Perineal	12 (44.4)	6 (50.0)		4 (33.3)	0			
Penoscrotal	15 (55.6)	10 (66.7)		3 (20.0)	1 (6.7)			
Henry et al, 2009[5]								
Total	119	43 (36.1)	8 (6.7)			18 (15.1)	4 (3.4)	10 (8.4)
Perineal	70 (58.8)	30 (56.6)	6 (31.6)			9 (47.4)	4 (21.0)	8 (11.6)
Penoscrotal	49 (41.2)	13 (34.2)	2 (18.2)			9 (81.8)	0	2 (4.0)
Henry ER al, 2008[6]								
Total	64	24 (37.5)	8 (12.5)			17(26.6)	4 (6.3)	10 (15.6)
Perineal	33 (51.6)	17 (56.7)	6 (18.8)			8 (25)	4 (12.5)	8 (25.0)
Penoscrotal	31 (48.4)	7 (28.0)	2 (7.1)			9 (32.1)	0	2 (7.1)

Data are n (%). Fisher exact test: [a]*P*=.357, [b]*P*= .680, [c]*P*=.37, [d]*P*=.06, [e]*P*=.30, [f]*P*=.042 for comparison of approaches in this study (patients who underwent both approaches excluded).

cuff distal to the previously inserted one. We upsized the cuff by 0.5 cm in cases of urethral atrophy.

DISCUSSION

AUS has long been considered the gold standard procedure for the treatment of SUI in men regardless of the SUI severity, with a success rate >80%, cure of about 60% and 25% improvement rate, 90% satisfaction, and 92% of males are willing to undergo the procedure again if necessary.[7–10]

In this report the indication for AUS surgery in our institution was total urinary incontinence. No surgery was indicated for a milder form of incontinence including stress incontinence.

Our study showed a small but statistically significant reduction of operative time with the penoscrotal approach (**Table 1**). Shen et al reported a reduction in operative time of 29.4 minutes with the penoscrotal approach.[4] The contributing factor to this finding is that the penoscrotal approach used a single incision and may facilitate better exposure and mobilization of the bulbar urethra; in addition, if the patient needs concomitant penile prosthesis implantation, the penoscrotal approach provides for faster and easier placement of the prosthesis.[3] In our study, no patient had concomitant penile prosthesis insertion.

Although the penoscrotal method was introduced 9 years ago, there have been no prospective randomized trials comparing the outcome of the two techniques. Initially, Wilson et al reported no difference in the functional outcome and complication rate with the penoscrotal approach compared to the traditional perianal approach.[4,10,11] A few other studies have compared the perineal and penoscrotal approaches (**Table 3**).[5,6] The overall complication rate reported for AUS in a study on 1082 male patients was 338 (31.2%), which included device malfunctioning, pump, malpositioning, or tubing complications.[12]

The revision rate in our study was 27.3%, mostly in the perineal group. These results are comparable to another study that reported 31.2% revision surgery for perineal AUS placement.[12] Our results show a significantly higher revision rate with perineal (40%) compared to the penoscrotal approach (10.5%), (**Table 3**). These findings are in agreement with others. Two studies compared the revision rate in the two approaches. The revision rate was higher with the perineal approach 18.0% and 34.8%, while in the penoscrotal approach the rates were 14.5% and 28.6%.[5,13]

Infection is one of the most feared complications of AUS insertion. Studies that compared the two approaches reported a rate of 14.6% to 30.4% in perineal and 18.8% to 37.1% in the penoscrotal approach.[4-6] A systematic review that included 12 reports on the perineal approach showed a lower pooled risk of erosion or infection (8.5%); however, a comparison between the perineal and penoscrotal approaches was not done.[14] In a study on 1082 male patients with AUS placement through the perineal approach, 89 patients (8.2%) developed infection/erosion.[12] In our study, the infection erosion rates were not the same as reported in others, which indicates that the perineal approach has a lower infection complication rate than the penoscrotal approach.[4-6,12,14] On the contrary, our data showed a higher rate of infection and erosion in perineal vs penoscrotal approach (20.0% vs 10.5%, respectively). Discrepancies in patient characteristics, pathology and selection bias may account for the different results. The only cases where more infection was reported with the penoscrotal approach than the perineal approach in our study was superficial skin infection. Isolated superficial skin infection was seen in 1/25 (4.0%) and 1/19 (5.3%) of perineal and penoscrotal procedures, respectively, and were managed conservatively.

Erosion is another complication that can be seen after AUS placement. We found the overall urethral erosion rate to be 11.4%; 4 (16.0%) perineal and 1 (5.26%) penoscrotal. This is in contrast with other reports that favor the perineal approach in revision cases. A study that analyzed risk factors related to revision reported a significant increase in the risk of urethral erosion in patients who underwent the penoscrotal approach compared with perineal (21% vs 0%).[15] The difference was probably due to a different patient population as our cases included only first-time implantation.

In the present study, the overall atrophy rate was 9%, which is consistent with other reports. A systematic review on the perineal approach reported urethral atrophy in 1.9–28.6% of cases.[14] Perineal placement of AUS was done in 1082 males; 89 (12.1%) were complicated with urethral atrophy.[12] The rates of atrophy were not significantly different between perineal and penoscrotal methods in our study. However, the trend was toward more atrophy with the penoscrotal than perineal approach. We believe that the underlying factor is that in the perineal approach the AUS is inserted in the proximal bulbar urethra, where the wall is thicker making it less prone to atrophy. In contrast, the reported urethral atrophy rate in studies comparing the two methods demonstrated higher rates in the perineal approach (5.6% to 77.8%) compared with the penoscrotal (1.5% to 25.0%).[4-6] The discordance between atrophy and erosion rates in both approaches and the underlying

risk factors is unexplained and requires further investigation. It is difficult to compare these studies with ours as confounding factors may affect the interpretation of results of all these retrospective studies.

We report an overall malfunction rate of 11.4%. A systematic review of 12 studies on AUS insertion through the perineal approach showed the mechanical failure rate to be between 2.0% to 13.8%.[14] In our study, there was no statistical difference between the two approaches. Two studies from the same group published in 2007 and 2009 comparing the two approaches reported device malfunction of 32.1-81.8% with the penoscrotal and 25-47.4% with the perineal method.[5,6] More recent studies reported lower rates of malfunction, comparable to our results. Linder et al reported 131/1082 (12.1%) device malfunctioning in male patients with AUS placement through the perineal approach.[12] Improvement in device manufacture may have contributed to better durability.

We report an overall dry rate of 65.9% at follow up. There was no significant difference between perineal and penoscrotal approaches. Studies that compared the two methods showed a completely dry rate (no pad use for 1 year), between 28.0% and 66.7% with the penoscrotal approach and between 50.0% and 56.7% with the perineal approach.[4-6] The difference in dry rate between our study and others may result from differences in indication for AUS as our series did not include stress incontinence. Our results confirm the overall reported data showing a complete dry rate at one year of 72.0% for scrotal and 57.8% for perineal approaches. However, neither approach was better than the other. This might be related to the sample size and lack of randomization.

The current study is a report of a single urologist in the same center with a subspeciality of reconstructive surgery minimizing the variability of techniques and operative circumstances. A total number of 44 patients is comparable to single-center experiences reported elsewhere. In addition, this study had a long follow-up period of a mean of 52 months.

Our study has several limitations. It was retrospective, the sample size was small and there was no randomization in the selection of approach. These difficulties are also encountered in the reported experience of other investigators. Only after a randomized prospective study that includes a sample size powered enough to show a significant margin of difference will the true merits of either approach be shown with a high level of confidence. In the absence of such studies, the current work adds to the available literature to shed light on the possible advantages of both techniques. In conclusion, there appears to be a higher completely dry rate with the perineal approach compared to the penoscrotal approach; however, the complications rate is slightly better with the perineal approach.

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