Published in final edited form as:

Neurourol Urodyn. 2013 January ; 32(1): 63–65. doi:10.1002/nau.22263.

INDICATIONS FOR REVISION OF ARTIFICIAL URINARY SPHINCTER AND MODIFIABLE RISK FACTORS FOR DEVICE-RELATED MORBIDITY

Ifeanyichukwu I. Anusionwu, MD^a and E. James Wright, MD^a

^aJames Buchanan Brady Urological Institute, Johns Hopkins Medical Institution, Baltimore, MD

Abstract

Aims—The aim of the study is to evaluate the causes for artificial urinary sphincter (AUS) failure in a contemporary series, and to detect modifiable risk factors for device-related complications. The aim is to also report outcome after AUS revision.

Methods—We retrospectively reviewed the medical records of consecutive patients who underwent AUS revision at a tertiary care institution by a single surgeon from 2006 to 2011. There were 53 AUS revisions performed on 34 patients at a median age of 69 years.

Results—Urethral atrophy was the most common indication for revision. Fourteen patients (41%) underwent more than one revision. Seven patients had urethral catheterization in the setting of an active AUS while admitted to a non-urologic service; these patients all developed cuff erosion. Fifty four percent of urethral erosions were associated with such traumatic catheterizations. After revision, 80% of patients with an AUS in place were using one or no pad daily at mean follow up of 27 months.

Conclusion—Urethral atrophy remains the most common reason for AUS revision. More than half of all urethral erosions are secondary to urethral catheterization in the setting of an active sphincter, suggesting that some of the risk of device-related morbidity may be modifiable.

Keywords

Artificial urinary sphincter; incontinence; morbidity; outcome; revision

Introduction

Introduced in 1983, the American Medical System 800 artificial urinary sphincter (AUS) has become the established technique for management of moderate to severe male stress urinary incontinence. The 10 year continence rate for AUS approaches 90% (1, 2) but 37–50% will require revision in the first five to ten years after implantation (1, 3). There are several reasons for revision. Mechanical failure, urethral atrophy and device infection or erosion have historically been the most common reasons for reoperation. Raj and colleagues reported comparable 5-year durability and continence rates for primary implantations and secondary implantations of the AUS. (4)

The aim of our study is to evaluate the causes for failure of primary AUS in the contemporary era, to detect any modifiable risk factors for device-related morbidity, and to report the outcome of patients after revision.

Materials and Methods

Institutional review board approval was obtained for the study. We retrospectively reviewed the medical records of consecutive patients who underwent revision of artificial urinary sphincter at our institution between 2006 and 2011 by a single surgeon (EJW). Only adult males were included in the study. Data abstracted from the patients' electronic medical records include date of revision, type of revision, indication for revision, duration from initial sphincter placement to need for revision, pad usage prior to revision, subsequent revisions, demographic features including age and race, and prior treatment with radiotherapy or surgery of the prostate.

When patients presented with recurrent incontinence, the device was cycled to evaluate for mechanical failure. Cystoscopy was performed to detect erosion or poor coaptation at the cuff site consistent with subcuff atrophy. All pressure-regulating balloons were filled with 25cc of a mixture of hypaque diluted in sterile water according to proportions recommended by the manufacturer.(5) As previously described, if a plain radiograph showed increased filling of the cuff along with decreased diameter of the pressure-regulating balloon, this was considered suggestive of subcuff atrophy.(6) (7) In patients with subcuff atrophy, the appearance of the cuff on plain radiograph is more "pillow-like" than in patients without atrophy. Plain radiograph was also used to detect fluid loss from the system. In patients with urethral atrophy, the cuff was usually exchanged for a smaller sized cuff, or in a few instances, a transcorporal cuff or a tandem cuff was placed as previously reported (7). Erosions were managed with explantation and later replacement with or without a transcorporal approach. Mechanical failure was managed by replacement of the defective component. Cuff revisions were through a perineal incision, while pressure-regulating balloon and pump revisions were through a lower abdominal incision.

Results

There were 53 AUS revisions performed on 34 patients. Median age of the population was 69 years (range 54 to 86 years). There were 31 Caucasians and three African Americans. Thirteen patients (38%) had a history of pelvic radiotherapy, thirty (88%) had undergone radical prostatectomy, one (3%) had undergone radical cystoprostatectomy with neobladder construction, one (3%) had undergone transurethral resection of prostate, and one (3%) had undergone prostate cryoablation. Table 1 shows the indications for AUS revision. Urethral atrophy was the most common indication for AUS revision. For patients who underwent revision because of recurrent incontinence, median pad usage prior to revision was 2.5 pads per day (range 1–7 pads per day).

Seven patients had urethral catheterization in the setting of an activated artificial urinary sphincter while admitted to a hospital on a non-urologic service; all of these patients subsequently had cuff erosion with or without infection. Fifty four percent of urethral erosions were associated with such traumatic catheterizations. Mean duration between initial sphincter placement and revision was 34 months, (median 16 months, range 1–264 months). Fourteen patients (41%) underwent more than one revision. Table 2 shows the number of revisions undergone by patients. Forty-three percent of those requiring multiple revisions had a history of radiation therapy, as opposed to 25% of those who had one revision, but this difference was not statistically significant (chi square $P=0.45$). Twenty revisions were cuff exchanges, seven were change of reservoir, four were relocation of the pump, five were

transcortical cuff placement, eleven were replacement of multiple components, five were explants, and one was addition of tandem cuff. Mean follow up after revision was 27 months (median 20 months). Of the 30 patients who were followed up after revision and found to have all AUS components in place, 24 (80%) were using zero or one pad daily for stress incontinence. The remaining six patients were using a median of 2 pads per day (range 2–3 pads/day). Two patients experienced complications associated with AUS revision and both complications were urethral injuries, which were repaired primarily and revision was deferred.

Discussion

In our cohort, 80% of patients were using one or fewer pads daily for stress incontinence after AUS revision. Other authors have found similar continence rates (4). We found urethral atrophy to be the most common reason for device revision. In 2005, Raj and colleagues also found urethral atrophy to be the most common cause for device revision.(4)

We found mean duration between initial AUS and revision to be 34 months. Lai and colleagues(8) found a mean time to reoperation of 26 months, and Kim and colleagues(9) found that most AUS revisions or removals in their series occurred within the first 24 months after implantation. In our series, 41% of patients required more than one revision. In comparison, other investigators have reported repeat revision rates of 23.5% to 50% (3, 4).

Forty-three percent of those who underwent multiple revisions had a history of radiation, as opposed to 25% of those who underwent one revision. It has been suggested that radiation therapy is a risk factor for AUS complications and need for revision. However, there have been conflicting results reported in the literature. Kim et. al.(9) and Ghoma et. al.(10) reported that radiation therapy was not associated with increased risk of AUS complication. On the other hand, Walsh and colleagues(11) found higher rates of complication and surgical revision in patients who had a history of pelvic irradiation. Other investigators(12), have also found that prior radiation therapy, as well as prior AUS revision were statistically associated with risk of erosion. It is possible that we did not demonstrate a statistically significant association between radiotherapy and risk of repeat revision because of our limited sample size and the retrospective nature of the study.

Five patients (9%) underwent revision because of discomfort at the pump site or unsatisfactory accessibility of the scrotal pump. In most cases with discomfort, the pain was significant enough to preclude cycling of the device. None of these patients had induration or other signs of infection, and upon exploration, no abnormality was found in the device or tissue. In these instances, the pump was simply relocated to a different site, and the patients reported resolution of pain. It is possible that pain in these patients was due to a neuropraxic phenomenon or tethering of the pump.

There were two cases of urethral injury during AUS revision. Both patients had a history of prior pelvic radiation. One patient also had a history of prior AUS revision for erosion, while the other patient developed the urethral injury during a transurethral procedure performed in the same setting as the AUS revision. The latter patient had an AUS cuff replaced after urethral healing, and is continent. The former patient elected conservative management.

It is unfortunate that more than half of all erosions in our series were subsequent to urethral catheterization with an active urinary sphincter cuff. Patients with AUS are frequently encouraged to wear medical alert bracelets indicating the presence of the sphincter and need for caution with regard to urethral instrumentation. At our center, we educate patients about how to obtain these bracelets and to alert their healthcare providers about the need for caution with urethral instrumentation. We also provide an emergency contact number which

can be used 24 hours of the day for assistance, and encourage our patients to share this with their health care providers when needed. Despite these measures, many traumatic urethral catheterizations still occurred on non-urologic services in patients with AUS. Perhaps compliance with wearing the medical alert bracelet and education of non-urologic medical personnel need to be optimized to minimize these avoidable injuries and improve the quality of life of patients with artificial urinary sphincter.

Conclusion

Urethral atrophy remains the most common reason for AUS revision. Forty-one percent of patients undergoing AUS revision will have repeated revisions. A majority of urethral erosions are secondary to urethral catheterization in the setting of an activated sphincter; this is a modifiable risk of device-related morbidity, and education of patients and non-urologic staff is necessary to improve longevity of AUS devices and quality of life of patients.

Acknowledgments

None

Financial Support: The project was supported by Award Number T32DK007552 from the National Institute of Diabetes and Digestive and Kidney Diseases. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute of Diabetes and Digestive and Kidney Diseases or the National Institutes of Health.

References

1. Venn SN, Greenwell TJ, Mundy AR. The long-term outcome of artificial urinary sphincters. *J Urol.* 2000; 164:702–706. [PubMed: 10953129]
2. Hajivassiliou CA. A review of the complications and results of implantation of the AMS artificial urinary sphincter. *Eur Urol.* 1999; 35:36–44. [PubMed: 9933793]
3. Clemens JQ, Schuster TG, Konnak JW, McGuire EJ, Faerber GJ. Revision rate after artificial urinary sphincter implantation for incontinence after radical prostatectomy: actuarial analysis. *J Urol.* 2001; 166:1372–1375. [PubMed: 11547077]
4. Raj GV, Peterson AC, Toh KL, Webster GD. Outcomes following revisions and secondary implantation of the artificial urinary sphincter. *J Urol.* 2005; 173:1242–1245. [PubMed: 15758761]
5. AMS 800 Urinary Control System Operating Room Manual. http://www.amselabeling.com/DAM_IFU/5525
6. Webster GD, Sherman ND. Management of male incontinence following artificial urinary sphincter failure. *Curr Opin Urol.* 2005; 15:386–390. [PubMed: 16205488]
7. Peterson AC, Webster GD. Artificial urinary sphincter: lessons learned. *Urol Clin North Am.* 2011; 38:83–88. [PubMed: 21353083]
8. Lai HH, Hsu EI, Teh BS, Butler EB, Boone TB. 13 years of experience with artificial urinary sphincter implantation at Baylor College of Medicine. *J Urol.* 2007; 177:1021–1025. [PubMed: 17296403]
9. Kim SP, Sarmast Z, Daignault S, Faerber GJ, McGuire EJ, Latini JM. Long-term durability and functional outcomes among patients with artificial urinary sphincters: a 10-year retrospective review from the University of Michigan. *J Urol.* 2008; 179:1912–1916. [PubMed: 18353376]
10. Gomha MA, Boone TB. Artificial urinary sphincter for post-prostatectomy incontinence in men who had prior radiotherapy: a risk and outcome analysis. *J Urol.* 2002; 167:591–596. [PubMed: 11792924]
11. Walsh IK, Williams SG, Mahendra V, Nambirajan T, Stone AR. Artificial urinary sphincter implantation in the irradiated patient: safety, efficacy and satisfaction. *BJU Int.* 2002; 89:364–368. [PubMed: 11872025]

12. Raj GV, Peterson AC, Webster GD. Outcomes following erosions of the artificial urinary sphincter. *J Urol*. 2006; 175:2186–2190. [PubMed: 16697836]

\$watermark-text

\$watermark-text

\$watermark-text

Table 1

Indications for revision of artificial urinary sphincter

Indication for Revision	Number of revisions (%)
Urethral atrophy	31 (58%)
Erosion	13 (25%)
Infection	2 (4%)
Mechanical failure	1 (2%)
Patient discomfort	5 (9%)
Need for transurethral procedure	1 (2%)

Table 2

Number of artificial urinary sphincter revisions undergone by patients

Number of revisions	Number of patients (%)	Number of patients with history of pelvic radiotherapy (%)
1 revision	20 (59%)	5/20 (25%)
2 revisions	11 (32%)	6/11 (55%)
3 revisions	1 (3%)	0/1 (0%)
4 revisions	2 (6%)	0/2 (0%)