

Research Article

Early Complications after Artificial Urinary Sphincter Insertion

Vladimir A Ruzhynsky^{1*}, Amanda Hird², Renu S Eapen³, Sidney B Radomski¹

¹Division of Urology, Toronto Western Hospital, University Health Network, University of Toronto, Toronto, ON, Canada

²Division of Urology, University of Toronto, Toronto, ON, Canada

³Department of Urology, Helen Diller Comprehensive Cancer Centre, University of California, San Francisco, California, USA

***Corresponding author:** Vladimir A Ruzhynsky, Division of Urology, Toronto Western Hospital, University Health Network, University of Toronto, Toronto, ON, Canada. Tel: +14166035713; Fax: +14166035391; E-mail: vruzhynsky@gmail.com.

Citation: Ruzhynsky VA, Hird A, Eapen RS, Radomski SB (2017) Early Complications after Artificial Urinary Sphincter Insertion. J Urol Ren Dis 2017: JURD-131. DOI: 10.29011/2575-7903.000031

Received Date: 22 April, 2017; **Accepted Date:** 03 May, 2017; **Published Date:** 10 May, 2017

Abstract

Objectives: To evaluate early postoperative complications following Artificial Urinary Sphincter (AUS) implantation within one year after the surgery in men.

Methods: Medical records of 158 patients who underwent AUS surgery between 2001 and 2016 at a single institution were retrospectively reviewed. Records were analyzed for patient's age at the time of AUS surgery, date of prostate surgery, history of radiation therapy, previous incontinence surgery, timing of AUS surgery, implanted cuff size, postoperative complications, and reported symptoms at follow-up visits. Postoperative in-office evaluations were performed at 6-8 weeks, 3, 6, and 12 months.

Results: Ninety six percent of the patients completed one-year follow-up. Scrotal swelling/hematoma and urinary retention occurred in 8% and 6% of the patients, respectively, and were the most common complication reported within 6-8 weeks after the surgery. Overactive bladder was a predominant complication at 3, 6, and 12 months postoperatively. Three patients required AUS explanation or cuff removal due to infection and/or cuff erosion and had subsequent cuff revision. Five patients underwent AUS revision due to mechanical issues. One patient had peritonitis due to an intraoperative bowel injury. The presence of postoperative bladder over activity symptoms was not associated with history of prior radiation therapy.

Conclusions: The results of this retrospective study shows that the most common initial adverse effects are minor local complications. The rates of urinary retention, infection, and erosion are low. A small number of patients require AUS revisions for both mechanical causes such as malfunctions and component leaks as well as non-mechanical causes such as erosions.

Keywords: Artificial Urinary Sphincter; Complications; Incontinence; Male

Introduction

Prostate cancer is a common diagnosis. According to the 2015 Canadian Cancer Society statistics, 24% of new cancer diagnoses in men are prostate cancer [1]. The prostate cancer treatments carry with them significant morbidity and may result in significant impairment in quality of life and patient satisfaction. One of the most troubling complications is Urinary Incontinence (UI). The reported rates of post-prostatectomy UI vary widely between

1 to 47% [2,3]. With improved survival of patients with prostate cancer, focus has shifted to managing UI effectively. The Artificial Urinary Sphincter (AUS) has been the gold standard of treatment for men with significant post-prostatectomy incontinence since early 1970s [4]. Early studies have demonstrated the efficacy and long term durability of the AUS [5-7]. Lai et al reviewed their 13-year experience of using AUS at Baylor College of Medicine, and concluded that the AUS is a safe and durable treatment for stress incontinence in men, even those with complicated histories such as neurogenic bladder, radiation, previous failed slings and bladder neck contractures [8]. AUS has been shown to have good

durability rates with 12% and 5% of patients requiring revision and removal of the sphincter, respectively, within 73 months of mean follow up [9]. The reported patients' satisfaction rates were also high in prior series [9]. Complication rates, especially in the first 48 months after implantation are also recognized [10]. We had previously studied the risk of AUS erosion in patients who had undergone radiation compared to those who had not and reaffirmed the notion that the risk of erosion, albeit low, is higher in patients who had undergone radiation treatment [11]. Linder et al evaluated the perioperative complications following AUS insertion and suggested that the most common complication of this procedure is urinary retention, seen in 32% of cases [12]. Our own experience did not support this finding. We hypothesized that the majority of early postoperative complications are minor. Here we evaluated the incidence and types of perioperative complications following AUS implantation at our institution within the first year after implantation of the sphincter.

Methods

We retrospectively reviewed 158 consecutive patients who underwent AUS placement at our institution between 2001 and 2016 by a single surgeon. Each patient underwent cystoscopy and Urodynamic (UD) studies before AUS insertion. It was ensured that the urethra and bladder neck would accommodate at least a 12 French (Fr) Foley catheter prior to surgery. All patients had the AMS 800TM device implanted (AMS Men's Health, Boston Scientific, USA). All patients underwent a 10-minute surgical scrub scrub and received Intravenous (IV) antibiotics prior to incision. The sphincter cuff was placed around the bulbar urethra via perineal approach. The cuff size was determined with the measuring device available in the AMS kit. Urethroscopy was performed at the end of the procedure. Patients were left with a 12 or 14 Fr catheter for 24 hours and a trial of void was performed on postoperative day one. Patients received IV antibiotics for 48 hours postoperatively followed by one week of oral antibiotics. Patients were reviewed at one week post operatively in the clinic, then at 6 to 8 weeks for activation of AUS depending on whether radiation treatment was given after RP. This was followed by a routine clinic visit at 3, 6 and 12 months after activation. All complications were determined by a retrospective review of hospital and office records. The primary outcome was postoperative complications, occurring at 6 to 8 weeks, 3 months, 6 months and 12 months following AUS implantation. Urinary retention was defined as a bladder scan volume of greater than 150ml after voiding. Other recorded information included age, time between insult (radical prostatectomy or other procedure) and AUS insertion, cuff size and history of radiation therapy. Data were analyzed using SPSS software.

Results

Medical records of 158 consecutive patients who had AUS surgery between 2001 and 2016 were analyzed (Table 1).

Total number	158
Median age, years (range)	67(49 - 82)
Etiology of incontinence, number of patients (%)	
Radical prostatectomy	155 (98)
Other	3 (2)
Radiation therapy, number of patients (%)	54 (34)
Previous anti-incontinence procedure, number of patients (%)	13 (8)
Length of time from insult to AUS surgery, number of patients (%)	
0-12 months	9 (6)
13-24 months	36 (23)
25-36 months	28 (18)
37-48 months	22 (14)
49-60 months	10 (6)
>60 months	53 (33)
Cuff size, number of patients (%)	
3.5 cm	4 (3)
4.0 cm	64 (40)
4.5 cm	82 (52)
5.0 cm	8 (5)

Table 1: Patients Demographics.

The median age was 67 years (range: 49-82). The majority of patients were in the 60-79-year age group (82%). One hundred and fifty-five of these patients were treated with radical prostatectomy. Three patients underwent other procedures, including simple prostatectomy for benign prostatic hypertrophy, radiation therapy for prostate cancer and microwave ablation therapy for lower urinary tract symptoms. In our cohort, 54 patients (34%) had radiation. This was completed in an adjuvant or salvage setting for the treatment of prostate cancer in all but one patient, who had primary radiotherapy. Ninety two percent of the procedures were primary AUS implantations. Thirteen patients (8%) had prior history of anti-incontinence surgery, including male slings, ProACTTM balloons (Uromedica, USA) and AUS insertions. The average length of time between the insult and AUS implantation was 57 months (range 7-256 months). Fifty-three patients (33%) had their AUS inserted more than five years after the treatment of prostate adenocarcinoma. Nine patients (6%) underwent AUS surgery between 7 to 12 months after prostatectomy or radiation treatment (two patients at 7 months, two at 10 months, two at 11 months, and three at 12 months). The majority of patients (52%) had 4.5cm sphincter cuff inserted. Four patients (3%) had a 3.5cm cuff inserted, and only one of these patients had prior radiation therapy.

Of the 158 patients, 151 (96%) completed their 12-month follow-up visit. Two (0.6%) patients died at 6 weeks and 12 months

after AUS implantation from unrelated causes. Five (3.2%) patients were lost to follow up due to various reasons such as location changes. One patient was lost to follow up at 3 months, three patients at 6 months and one patient at 12 months. There were 46, 30, 54 and 69 complications at 6-8 weeks, 3, 6, and 12 months, respectively (Table 2).

	Time after AUS surgery			
	6-8 weeks	3 months	6 months	12 months
Scrotal Swelling And/or Hematoma	12			
Inguinal Discomfort / Pain	3			
Wound Infection	5			
Urinary Retention	9			1
AUS Cuff Erosion	1 (also had device infected)	1	1	
Peritonitis/Bowel Perforation	1			
AUS Malfunction, Revised		1	1	3
Hematuria		2		4
Stress Leakage		3	10	12
Overactive Bladder		20	34	40
Pump Repositions			1	1
Scrotal Tenderness	1			
Perineal Pain	1			
Rash	3			
Low Grade Fever	2			
Scrotal / Wound Erythema	2			
Scrotal Fluid Collection	1			
Wound Dehiscence	1			
Penile Thrush	1			
Epididymitis	1			
Urinary Tract Infection	1	1	3	1
Decreased Stream		1	1	
Nocturia				1
Bladder Neck Contracture			1	4*
Pulmonary Embolism	1			
Atrial Fibrillation		1		
Inguinal Hernia			2	1
Ureteric Stone				1

TOTALS	46	30	54	69
*Bladder neck contracture: two managed conservatively, two managed with visual internal urethrotomy				

Table 2: Complications within the First Year After AUS Implantation.

The majority (70%) of complications, which occurred within 6-8 weeks after the surgery, were Clavien-Dindo Grade I (Table 3).

	Number of complications
Grade I	32
Grade II	12
Grade IIIb	2
* There were no Grades IIIa, IV, and V complications.	

Table 3: Clavien-Dindo grading of postoperative complications which occurred within 6-8 weeks after AUS implantation*.

[13]. There were only two Grade IIIb complications requiring removal of the entire AUS device. At 6-8 weeks, the most common complications were scrotal swelling/hematoma (8%) and urinary retention (6%). The majority of these patients had very short duration of early postoperative urinary retention, which resolved within less than a week. One patient had prolonged retention, which was managed with clean intermittent catheterizations for 6 weeks. One of the patients who experienced retention went on to developed cuff erosion at the 3 months. This patient had a 4cm cuff placed and had adjuvant radiation therapy after radical prostatectomy. One patient with a 4.5cm cuff went on to have early erosion at 6 weeks. This patient did not have prior radiation therapy. One patient suffered a pulmonary embolism at 6-8 weeks.

At 3, 6, and 12 months, the most common complication was Overactivity of The Bladder (OAB) (20, 34 and 40 patients, respectively), which was defined as a subjective report of urgency and frequency with or without urgency incontinence. Thirty five percent of patients who had radiation treatment preoperatively had postoperative OAB symptoms, though the association was not statistically significant ($p=0.96$, Chi-Square test). One patient with a prior history of radiation therapy had urinary retention associated with a urinary tract bacteriuria at 12 months. The patient was managed with clean intermittent catheterizations, which were stopped within one month. At 12 months, 12 patients (8%) had persistent stress urinary incontinence.

Three patients experienced device erosion (1.9%). One of these patients required removal of the whole device due to an infection at six weeks after the implantation. The other two patients underwent removal and delayed reimplantation of the cuff only. One patient with multiple prior abdominopelvic surgeries and neobladder developed peritonitis postoperatively secondary to intraoperative bowel perforation. He underwent AUS removal. Five patients experienced device malfunction requiring revision (3%). This included one patient who underwent two revisions, one at 6 months and again at 12 months. Two (1%) patients had a high riding

pump that required repositioning of the pump at 6 and 12 months.

Discussion

The types and the rates of postoperative complications which occurred within one year after AUS implantation at a single centre were examined in this study. Scrotal swelling and hematoma as well as the urinary retention were the most common complications reported within 6-8 weeks after the surgery. OAB was a predominant complication at 3, 6, and 12 months postoperatively. Three of 158 patients required AUS explantation or cuff removal and subsequent revision due to infection and/or cuff erosion. One patient developed bowel injury and had the whole device removed. Five patients underwent AUS revision due to mechanical issues. Two patients required repositioning of the high riding pump.

Urinary retention following AUS implantation may develop due to postoperative edema or inappropriate cuff sizing. It is usually observed in early postoperative period and resolves spontaneously with short-term intermittent catheterizations or rarely indwelling urethral or suprapubic catheters. Linder et al recently reported the rates of postoperative complications following AUS placement in a series of 100 primary AUS placements [12]. Their series had an overall rate of perioperative urinary retention of 32% within 6 weeks of surgery. Transcorporeal cuff placement was not associated with significant risk of retention in their series [12]. The rates of urinary retention were lower in other two large AUS implantation series [14,15]. In a study reported by Ravier et al only one patient had an acute urinary retention requiring Foley catheter placement [14]. Smith et al compared the risk of retention in patients who had undergone periurethral versus transcorporeal cuff placement [15]. The rate of retention was 8% in patients who had traditional bulbar urethral cuff placement [15]. Patients with transcorporeal cuff placement had a significantly higher rate of retention [15]. The overall retention rate was 6.3% (nine patients early postoperatively and one patient at 12 months) in the presented series and all patients had traditional placement of the cuff in the bulbar urethra. The majority of urinary retention episodes occurred during the early postoperative period and resolved within less than a week. Only one patient had retention at one year, which was associated with a urinary tract infection. He was managed with clean intermittent catheterizations, which were stopped within one month. One of the patients with early postoperative urinary retention had subsequent cuff erosion. The reported rates of retention vary due to the lack of commonly accepted definition of postoperative urinary retention. Retention was defined as a failure to empty 50% of bladder volume as measured by bladder scan ultrasound in the Linder et al series [12]. In the present series, urinary retention was defined as a bladder scan volume of greater than 150 ml after voiding. Other potential reasons for the variability include study population age difference, retrospective versus prospective data collection, surgical technique of periurethral dissection (extent of corpus spongiosus dissection, blunt versus sharp

dissection, use of diathermy), and transcorporeal cuff placement.

Linder et al showed that postoperative urinary retention was associated with an increased rate of device infection and erosion and decreased 6-month device survival [12]. Infection and erosion rates reported in the literature vary widely, occurring in as low as 3% to as high as 20% of patients [2,14,16,17]. Cuff erosion was seen in three out of 158 patients (1.9%) in our series, one of these being within the first 6 weeks, one at 3 months and one at 6 months after AUS placement. Two of these patients had received prior radiation treatments and one had perioperative urinary retention, as mentioned above. This rate is lower than the one reported by Linder et al where nine out of 100 patients had infection and erosion requiring device explanation during the 6-month mean follow-up [12]. Raj et al reported an erosion rate of 3.9% and 5% for primary AUS implantation and secondary revisions, respectively [17].

Several independent significant predictors for cuff explanation were identified in a large prospective series of 386 patients who underwent AUS implantation [16]. These included history of prior radiotherapy, history of urethral stent placement, and 3.5-cm cuff placement. Linder et al proposed that the possible reasons for early erosion are unrecognized urethral injury at the time of implantation, catheterization related trauma or the presence of any of the above-mentioned risk factors [12].

In cases of urethral erosion, current practice is to remove all components immediately, with the assumption that they are infected. Secondary AUS implantation is usually performed 6 months later [17]. In the absence of signs of infection or erosion Raj et al managed their patients with either complete replacement of all AUS components (53% of cases) or just with the cuff replacement alone (47% of cases) [17]. The reimplantations, either complete or cuff only, were performed at the time of presentation and had excellent outcomes [17]. Our approach differs from the one reported by Raj et al. Two of three patients with AUS erosions in our series had no evidence of infection. They were managed with removal of the eroded cuff only and delayed reimplantation of the new cuff in 7 months. The other patient had clinical signs of infection and underwent removal of all sphincter components. He subsequently underwent AUS reimplantation 7 months later. Overall, our results and other studies suggest that in the absence of infection, replacing the eroded cuff only is a reasonable approach.

It is not uncommon for patients after RP with UI to have detrusor over activity on UD studies. Lai et al studied the impact of OAB on surgical outcomes after AUS implantation after radical prostatectomy [18]. In their cohort, 26% of patients complained of OAB symptoms prior to AUS implantation with 35% of these patients having detrusor over activity confirmed on preoperative urodynamics. Of the patients who had OAB symptoms prior to surgery, 71% complained of symptoms after surgery and the majority required anticholinergics, despite improvement in their overall continence. De novo OAB in those with pure stress

incontinence developed in 23% of patients. The median time to development of OAB symptoms was 9 months. Lai et al found that the presence of OAB before AUS surgery was a significant predictor of the presence of OAB after surgery [18]. The finding of OAB symptoms before surgery in their cohort did not negatively affect continence results post implantation. Additionally, a low preoperative bladder capacity was associated with a higher risk of OAB after AUS implantation. In our series, 26% of patients suffered OAB symptoms at 12 months' post AUS implantation. Forty percent of patients who had OAB during early postoperative period reported resolution of their symptoms at 12 months. Lai et al found that there was no significant association between patient age at AUS implantation, history of prior radiotherapy and the development of de novo OAB after surgery [18]. Similarly, in our study, there was no significant relationship between post-operative OAB and prior treatment with radiotherapy.

There are limitations in our study. The presented data are from a single centre and a single surgeon. Data were retrospectively collected and reviewed. We relied on documentation of questions asked at follow-up visits as well as patients' reporting of their symptoms. Postoperative UDS was not routinely performed in all our patients. The majority of patients had postoperative urodynamic evaluations only if they had persistent voiding symptoms or incontinence that did not respond to medical therapy. Moreover, five patients were lost to follow-up, which may have had an impact on our results. In summary, the most common initial adverse effects in our series were minor local complications of scrotal swelling and hematoma. Contrary to recent reports, the rate of early postoperative urinary retention was low. The rates of infection and erosion were low and comparable with the literature. A small number of patients required AUS revisions for both mechanical causes as well as for non-mechanical causes. The presence of postoperative OAB symptoms was not associated with history of prior radiotherapy. In the great majority of men with post RP incontinence, AUS implantation is an effective option with a low complication rate in the first year after the surgery.

References

1. Prostate cancer statistics. Canadian Cancer Society.
2. Fowler FJJ, Barry MJ, Lu-Yao G, Roman A, Wasson J, et al. (1993) Patient-reported complications and follow-up treatment after radical prostatectomy. The National Medicare Experience: 1988-1990 (updated June 1993). *Urology* 42: 622-629.
3. Kielb S, Dunn RL, Rashid MG, Murray S, Sanda MG, et al. (2001) Assessment of early continence recovery after radical prostatectomy: Patient reported symptoms and impairment. *J Urol* 166: 958-961.
4. Scott FB, Bradley WE, Timm GW (1973) Treatment of urinary incontinence by implantable prosthetic sphincter. *Urology* 1: 252-259.
5. Elliott DS and Barrett DM (1998) Mayo clinic long-term analysis of the functional durability of the AMS 800 artificial urinary sphincter: A review of 323 cases. *J Urol* 159: 1206-1208.
6. Gousse AE, Madjar S, Lambert MM, Fishman IJ (2001) Artificial urinary sphincter for post-radical prostatectomy urinary incontinence: Long-term subjective results. *J Urol* 166: 1755-1758.
7. Venn SN, Greenwell TJ, Mundy AR (2000) The long-term outcome of artificial urinary sphincters. *J Urol* 164: 702-707.
8. Lai HH, Hsu EI, Teh BS, Butler EB, Boone TB (2007) 13 years of experience with artificial urinary sphincter implantation at Baylor College of Medicine. *J Urol* 177: 1021-1025.
9. Montague DK, Angermeier KW, Paolone DR (2001) Long-term continence and patient satisfaction after artificial sphincter implantation for urinary incontinence after prostatectomy. *J Urol* 166: 547-549.
10. Kim SP, Sarmast Z, Daignault S, Faerber GJ, McGurie EJ, et al. (2008) Long-term durability and functional outcomes among patients with artificial urinary sphincters: A 10-year retrospective review from the University of Michigan. *J Urol* 179: 1912-1916.
11. Hird AE and Radomski SB (2015) Artificial urinary sphincter erosion after radical prostatectomy in patients treated with and without radiation. *Can Urol Assoc J* 9: E354-358.
12. Linder BJ, Piotrowski JT, Ziegelmann MJ, Rivera ME, Rangel LJ, et al. (2015) Perioperative complications following artificial urinary sphincter placement. *J Urol* 194: 716-720.
13. Dindo D, Demartines N, Clavien PA (2004) Classification of surgical complications: A new proposal with evaluation in a cohort of 6336 patients and results of a survey. *Ann Surg* 240: 205-213.
14. Ravier E, Fassi-Fehri H, Crouzet S, Gelet A, Abid N, et al. (2015) Complications after artificial urinary sphincter implantation in patients with or without prior radiotherapy. *BJU Int* 115: 300-307.
15. Smith PJ, Hudak SJ, Scott JF, Zhao LC, Morey AF (2013) Transcervical artificial urinary sphincter cuff placement is associated with a higher risk of postoperative urinary retention. *Can J Urol* 20: 6773-6777.
16. Brant WO, Erickson BA, Elliott SP, Powell C, Alsikafi N, et al. (2014) Risk factors for erosion of artificial urinary sphincters: A multicenter prospective study. *Urology* 84: 934-938.
17. Raj GV, Peterson AC, Toh KL, Webster GD (2005) Outcomes following revisions and secondary implantation of the artificial urinary sphincter. *J Urol* 173: 1242-1245.
18. Lai HH and Boone TB (2011) Implantation of artificial urinary sphincter in patients with post-prostatectomy incontinence, and preoperative overactive bladder and mixed symptoms. *J Urol* 185: 2254-2259.