

Comparing Argus sling and artificial urinary sphincter in patients with moderate post-prostatectomy incontinence

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Post-prostatectomy incontinence (PPI) is a main complication of radical prostatectomy. The purpose of this study was to compare the efficacy and safety of the Argus male sling (Argus) with that of artificial urinary sphincters (AUS) in patients with moderate PPI. A total of 33 moderate PPI patients underwent AUS or Argus implantation from January 2009 to June 2013 (13 AUS, 20 Argus). We defined moderate PPI as the use of 2–4 pads per day. To compare efficacy, we assessed the success rate between the two groups. Success was defined as the daily need for no pads or one small safety pad that remained dry most of the day. The mean patient age was 73.5 ± 6.3 yr in the AUS group and 70.9 ± 5.1 yr in the Argus group, and the mean follow-up period was 29.8 ± 14.9 months in the AUS group and 24.7 ± 11.8 months in the Argus group. The success

rate was 72.7% in the AUS group and 85.0% in the Argus group ($P=0.557$). Abnormal postoperative pain persisted in more patients in the Argus group (6/20, 30%) than in the AUS group (1/13, 7.7%) ($P=0.126$). However, the rate of other complications was not different between the two groups (7.7% and 15.0% for AUS and Argus, respectively, $P=0.822$). Argus surgery showed similar success and complication rates to those of AUS in moderate PPI patients, indicating that it could be an alternative surgical option for the treatment of moderate PPI.

Keywords: Post-prostatectomy incontinence, Artificial urinary sphincter, Male sling

INTRODUCTION

Incontinence after prostatectomy is a significant problem for patients. Although most men recover from post-prostatectomy incontinence (PPI), if persistent, it can be incapacitating, leading to reduced health-related quality of life. Several articles have reported that up to 30–40% of patients who undergo prostatectomy complain of persistent PPI (Herschorn et al., 2010; Litwin et al., 2000). Some men continue to suffer from persistent urinary incontinence, and roughly half of these men seek treatment (Penson et al., 2008).

The initial management of persistent PPI usually consists of conservative measures such as pelvic floor muscle exercises and medication. Surgical treatments are usually not considered for men with urinary incontinence until conservative treatments have failed. Approximately 2–5% of patients with incontinence following radical prostatectomy exhibit persistent incontinence for at

least 1 yr postoperatively despite conservative therapy attempts. For these patients, surgical treatment is recommended (Bauer et al., 2009). The implantation of an artificial urinary sphincter (AUS) has been the gold standard for most cases of male stress urinary incontinence (SUI) over the last decades (Kumar et al., 2009). However, due to the cost of the device, patient reluctance, the inability to use a mechanical implant, and the fear of complications, it is not ideal for all patients (Herschorn et al., 2010).

Recently, several technically different, minimally invasive slings for male SUI were developed and successfully implanted. In fact, most patients with mild/moderate incontinence prefer something less invasive than the AUS. To address these needs, the male sling is suitable as it is less invasive, adjustable, and does not require manipulation before voiding as does the AUS. In addition, the efficacy of the male sling was recently reported to be similar to that of the AUS. The treatment success rate of the male sling ranges from 56% to 90% (Migliari et al., 2003; Romano et al., 2009).

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No study has compared the Argus male sling to the AUS. Here, we compared the efficacy and safety of the Argus male sling (Argus) to the AUS in moderate PPI patients.

MATERIALS AND METHODS

A total of 33 patients with moderate PPI underwent AUS or Argus implantation from January 2009 to June 2013 (13 in the AUS group, 20 in the Argus group) at our hospital. The choice of surgery was made by the patients after consultation with the surgeon who thoroughly explained the risks and benefits of both operations. We defined moderate PPI as the use of 2–4 pads per day. Clinical data were analyzed, including pre- and post-operative pad use and preoperative urodynamic study results in both groups. Follow-up visits of all patients were performed at 1, 3, 6, and 12 months postoperatively and annually thereafter. The primary endpoint was the success rates in the two groups. Cases were categorized as successes when no pads or 1 small safety pad, which remained dry most of the day, was used daily. Improvement was defined as the use of two or less pads daily or at least a 50% decrease in daily pad use. For evaluation of postoperative voiding function, we compared Qmax (Maximal peak pressure) and residual urine between the two groups.

All surgeries were performed by a single surgeon. All complications observed during follow up were graded according to the modified Clavien system (Dindo et al., 2004). Abnormal postoperative pain was defined as usage of analgesics for more than 1 month.

Statistical analyses were performed using the Statistical Package for Social Sciences, version 18.0 (SPSS, Chicago, IL, USA). Differences were analyzed by the Mann-Whitney U test and paired t test, and crosstabs were used to assess dependent samples. In this study, $P < 0.05$ was considered statistically significant.

Operative techniques

ARGUS (Argus T[®])

The Argus suburethral sling is composed of a silicone cushion attached to two silicone cone columns that are passed with needles through the obturator foramen from the perineum to both inguinal areas (Romano et al., 2006). With the needles in place, cystoscopy was routinely performed to confirm the integrity of the urethra and bladder. After suburethral sling implantation, the bladder was filled. The retrograde leak point pressure was adjusted to 35–40 cmH₂O intraoperatively using a simple standing column manometer and arterial line tubing. In all cases, the indwelling catheter was removed 24 to 48 h after surgery if perineal pain was

tolerable.

Patients were recommended to walk around the ward after catheter removal. If the patients voided well but incontinence persisted, tape adjustment was performed under local anesthesia through the bilateral incisions of both tape ends. In case of urinary retention, the tape was released using the same bilateral incisions.

AUS (AMS 800[®])

Surgical techniques consisted of a perineal incision for cuff placement around the bulbous urethra and a transverse abdominal incision for pressure regulating balloon and pump placement inside the abdomen and scrotum, respectively. Following placement of all three parts, the reservoir was then filled with 21–24 mL of normal saline. The parts were then connected using the quick-connect system supplied by the manufacturer (James et al., 2014; Trigo Rocha et al., 2008).

RESULTS

The preoperative characteristics of the study population are listed in Table 1. There were no differences in preoperative characteristics between the procedure groups. The mean age in the AUS and Argus groups was 73.5 ± 6.3 (range, 63–84) yr and 70.9 ± 5.1 (range, 63–81) yr, respectively ($p = 0.189$). The mean follow-up period was 29.8 ± 14.9 (range, 4.7–63.2) months in the AUS group and 24.7 ± 11.8 (range, 6.8–42.4) months in the Argus group ($P = 0.281$). Ten patients (76.9%) had PPI after retropubic radical prostatectomy and three patients (23.1%) after robot-assisted laparoscopic prostatectomy (RARP) in the Argus group, while these

Table 1. Comparison of preoperative characteristics and preoperative urinary function between patients who received the AUS and those who received the ARGUS

	AUS (n=13)	ARGUS (n=20)	Pvalue
Age	73.5±6.3	70.9±5.1	0.189
Follow up duration (months)	29.8±14.9	24.7±11.8	0.281
Previous surgery characteristics			
Retropubic RP	10 (76.9%)	18 (90%)	0.449
Robot assisted RP	3 (23.1%)	2 (10%)	
Radiation therapy	1 (7.7%)	2 (10%)	0.662
Preop pad/day	3.5±0.74	3.0±0.9	0.111
UDS			
DO	10 (76.9%)	17 (85%)	0.449
Q _{max} (mL/s)	14.4±12.7	18.3±11.1	0.766
PVR (mL)	5.0±10.8	13.2±18.8	0.215
Preop. MUCP (cmH ₂ O)	29.7±10.5	32.9±9.2	0.421
Preop. VLPP (cmH ₂ O)	63.0±17.1	70.0±11.2	0.259

Table 2. Comparison of postoperative and efficacy variables between the AUS and ARGUS groups

	AUS (n=13)	ARGUS (n=20)	Pvalue
Decreased pad use	2.9±1.0	2.2±0.8	0.241
Success	10 (76.9%)	17 (85.0%)	0.557
Improvement	2 (15.4%)	0	
Fail	1 (7.7%)	3 (15.0%)	
Postop Q _{max} (mL/s)	14.9±12.7	14.7±7.9	0.712
Decreased Q _{max} (mL/s)	-0.5±11.7	3.6±8.7	
Postop PVR (ml)	6.1±12.7	11.5±26.9	0.576
Operation time (min)	112.8±29.9	81.3±21.9	< 0.001*
Hospital stay (days)	4.6±0.8	7.0±1.9	< 0.001*
Adjustment		9 (45%)	
Postop. medication			
No	8 (61.5%)	12 (60.0%)	0.610
Anticholinergics	5 (29.5%)	8 (40.0%)	

numbers were 18 patients (90.0%) and two patients (10.0%), respectively, in the Argus group. One patient (7.7%) underwent radiation therapy in the Argus group, while two patients (10.0%) underwent radiation therapy in the Argus group.

The mean number of pads used preoperatively was 3.5±0.74 and 3.0±0.9 in the AUS and Argus groups, respectively ($P=0.111$). PreoperativeValsalva leak point pressure (VLPP) was 63.0±17.1 cmH₂O and 70.0±11.2 cmH₂O in the AUS and Argus groups, respectively ($P=0.259$). There were no differences in preoperative characteristics between procedure groups. Preoperative urinary function of the two groups is listed in Table 1.

The operation time was longer in the AUS group than in the Argus group (112.8±29.9 vs. 81.3±21.9 min, $P<0.001$). In addition, the admission period was longer in the Argus group compared to the AUS group (7.0±1.9 vs. 4.6±0.8 days, $P<0.001$). Nine patients (45%) required an adjustment operation in the Argus group (release: three patients, tightening: six patients). Pad use decreased by 2.9±1.0 pads in the AUS group and by 2.2±0.8 pads in the Argus group ($P=0.241$). The success rate was 72.7% in the AUS group and 85.0% in the Argus group, without statistically significant differences between the two groups ($P=0.557$). The Argus group showed a significantly larger decrease in Q_{max} compared to baseline than did the AUS group (3.6±8.7 vs. -0.5±11.7, $P=0.038$). After surgery, anticholinergics were used more frequently in the Argus group (40.0%) than in the AUS group (29.5%), but the difference was not significant ($P=0.610$) (Table 2). Cuff change (one patient) and removal of the sphincter (one patient) were performed because of malfunction and infection in the AUS group. The sling was removed in three patients due to

Table 3. Comparison of complications between the AUS and ARGUS groups

	AUS (n=13)	ARGUS (n=20)	Pvalue
Re-operation	1 (7.7%)		
Revision (cuff change)			
Abnormal postoperative pain	1 (7.7%)	6 (30%)	0.126
Other	1 (7.7%)	3 (15%)	0.822
Complications	Infection	Severe perineum pain: 1	
	Grade3	Infection: 2	
		Grade3	

infection (two patients) and severe persistent pain (one patient). Abnormal postoperative pain was more commonly seen in the Argus group (6/20, 30%) than in the AUS group (1/13, 7.7%) ($P=0.126$) (Table 3).

DISCUSSION

We found in our current study that the AUS and Argus devices showed similar efficacy and safety results. The success rate was 76.9% in the AUS group and 85.0% in the Argus group, but the difference between groups was not statistically significant. In addition, the complication rate was not statistically different between the two groups (7.7% vs. 15.0%).

PPI is a feared adverse effect following radical prostatectomy for prostate cancer. Noninvasive therapy is the first-line treatment for early incontinence that follows prostatectomy within the first 6 to 12 months. In particular, pelvic floor muscle training (PFMT) is the most widely recommended noninvasive treatment. However not only standardization of treatment is lacked, but also most trials are non randomized controlled study. Filocamo et al showed a significantly better early continence rate in patients attending a rehabilitation program with PFMT compared with patients who did not. But after 1 yr there was no statistical difference between the incontinence rates of the two groups.

The implantation of an AUS has been established for decades as the gold standard for most cases of male SUI. While the treatment of choice is AUS in severe cases of PPI, a convenient male sling could be an option for mild to moderate PPI. Generally, patients want a less invasive surgery (Herschorn, 2013).

There is extensive data on the efficacy of AUS insertion in the literature, with long-term follow-up available for many cohorts. The proportion of patients who continue to experience treatment success (as measured by requiring 0–1 pads per day) ranges from 59% to 90%, with follow-up of up to 11 yr (Herschorn et al., 2010). A meta-analysis published in 1999 reported that continence

improved in 88% of patients after AUS implantation and that 73% of patients achieved total continence (Hajivassiliou, 1999). In PPI, the reported success rate of AUS was 59-91.4% (Trost and Elliott, 2012). Although there is insufficient long-term efficacy data on the male sling, treatment success rates are reported to range from 56% to 90%. Ricarda et al. reported an AdVance success rate of 69.3% at a median follow up of 24.7 months, with the success rate increasing to 90.3% for AdVance XP at a median follow-up of 11.9 months (Bauer et al., 2014). The Argus device used in this paper, has also been evaluated in several clinical trials, and its initial success rate was in the range of 70% to 80% (Welk and Herschorn, 2012). While there is potential selection bias in previous studies, reported success rates were similar for the AUS and Argus. However, previous studies have not directly compared the AUS and Argus. In our current study, we demonstrate that the Argus has similar efficacy to AUS in moderate PPI patients.

The operation time was shorter in the Argus group than in the AUS group. Dissection of the bulbospongiosus muscle and circumferential dissection of the urethra was not needed during Argus implantation, and more AUS devices were placed than Argus. Argus is easier for the surgeon and less invasive than AUS. However the admission period was longer in the Argus group than in the AUS group. The causes of longer hospital stay in the Argus group were perineal pain and adjustment operation. In addition, 45% of patients underwent an additional adjustment operation, which is associated with a longer admission period, as well as an increased risk of infection. However, if needed, the Argus male sling can be adjusted, under local anesthesia, at any time after implantation.

The Argus group (3.6 ± 8.7) showed a bigger decrease in Qmax than did the AUS group (-0.5 ± 11.7). In patients with voiding difficulty with a low Qmax, AUS may be a more appropriate strategy than Argus. The complication rate was not statistically different between the two groups. However, the etiology of the complications differed, with infection cited in the AUS group and severe perineum pain and infection in the Argus group. In our present investigation, abnormal postoperative pain was more common in the Argus group than in the AUS group. Abnormal postoperative pain or paraesthesia is thought to stem from compression or intraoperative disruption of the superficial perineal nerves (Senechal et al., 2008). Transient perineal pain was reported in 9–15% of men with Argus, while persistent perineal pain was reported in 4–5% of patients (Bochove-Overgaauw et al., 2011; Hubner et al., 2011; Romano et al., 2009). In our current series, six patients complained of abnormal postoperative pain in

the Argus group, and eventually one patient underwent surgery to remove the device. All complications were categorized as Clavien system grade 3. The complication rate in this study is lower than that of a previous study by Gulpinar et al. in which an AUS complication rate of 41.1% was reported in long-term follow up (Gulpinar et al., 2013). Another article reported an AUS complication rate of 30% (Fulford et al., 1997; Haab et al., 1997). Dalpiaz et al. reported an Argus complication rate of 35.0% (Dalpiaz et al., 2011). We found no significant difference in the complication rate between the two groups.

The Argus operation had several disadvantages, such as a longer admission period resulting from the need of a readjustment operation, the possibility of a decrease in Qmax, and increased perineal pain compared to AUS. Nevertheless, Argus surgery is less invasive and has a similar success rate compared with AUS. If needed, the Argus male sling allows adjustments despite the risk of infection, and patients do not need to manipulate the device during voiding as is needed in AUS. Therefore, the Argus could be an alternative treatment for moderate PPI. However, in severe cases of PPI, AUS remains the treatment of choice.

The limitations in this study were the small number of patients analyzed, its retrospective design, and the lack of questionnaires on quality of life or satisfaction after surgery. However Argus has similar success and complication rates to AUS for the treatment of moderate PPI suggesting it as an alternative surgical option for this condition.

CONFLICT OF INTEREST

The authors have no conflicts of interest to declare.

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