An Adjustable Sling for the Treatment of All Degrees of Male Stress Urinary Incontinence: Retrospective Evaluation of Efficacy and Complications After a Minimal Followup of 14 Months

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**Purpose:** In this retrospective study we evaluated the efficacy and complications of the Argus® adjustable sling for the treatment of various degrees of male stress urinary incontinence.

**Materials and Methods:** Retrospectively we evaluated continence and complications in 100 men with stress urinary incontinence consecutively treated with the Argus between April 2005 and October 2008. Incontinence was defined as mild (1 to 2 pads per 24 hours), moderate (3 to 5 pads per 24 hours) and severe (more than 5 pads per 24 hours). Patient evaluation included medical history, pad count, a quality of life score, Patient Global Impression of Improvement and visual analog scale measurements to determine satisfaction with continence and with treatment. Results and complications were evaluated 6 weeks after surgery and in December 2009.

**Results:** After a median followup of 27 months (range 14 to 57) the Argus was successful in 72% of patients (68 of 95). Mild incontinence was treated in 13, moderate incontinence in 46 and severe incontinence in 41 patients. Success rates stratified to degree of incontinence were 92% (12 of 13), 67% (29 of 43) and 67% (26 of 39), respectively. Complications occurred in 55% of patients and most were Clavien grade I to II. Visual analog scale measurements on continence and quality of life showed significant improvement.

**Conclusions:** The Argus adjustable male sling is a valuable adjunct in the treatment of all degrees of stress urinary incontinence. Complications are not uncommon but are mostly Clavien grade I to II. Patients report significantly improved continence and quality of life after treatment.

**Key Words:** suburethral slings; urinary incontinence, stress; male

With the increasing number of radical prostatectomies performed, male SUI has become a common problem in current urological practice. The reported incidence of postprostatectomy SUI varies from 1% to 25% after 1 year. \(^1^{–}3\) The associated hygienic, psychological and social consequences of SUI are often underestimated, and have a significant impact on QoL. \(^4\)

Various male slings and devices are available for the treatment of SUI but the gold standard remains the artificial urinary sphincter. \(^5\) Although the success rates and the long-term results of the AUS are good, there are some disadvantages. The surgical procedure is somewhat intricate, revision procedures are not uncommon and the device is expensive. Furthermore, a recent investigation by Kumar et al showed that many patients would prefer a nonmechanical device such as a male sling to a mechanical device such as the AUS. \(^6\)

Therefore, the Argus adjustable male sling appears to be an attractive...

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**Abbreviations and Acronyms**

- AUS = artificial urinary sphincter
- FU = followup
- PGI-I = Patient Global Impression of Improvement
- QoL = quality of life
- SUI = stress urinary incontinence
- VAS = visual analog scale

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alternative. Literature on the Argus for the treatment of male SUI is still scarce. To our knowledge the only studies published are the initial results of Romano et al and their recently reported results after at least 3 years of FU in which they achieved a 79% rate of social continence after treatment with the Argus.7,8

There are few studies on other male slings, most describing short-term efficacy only. The value of male slings for various degrees of SUI and the impact on QoL are interesting subjects that deserve attention. Therefore, we retrospectively evaluated the efficacy and complication rate of the Argus male sling for the treatment of mild, moderate and severe SUI at our clinic. Furthermore, the subjective experience of patients regarding continence and QoL after treatment was assessed.

MATERIALS AND METHODS

Patients
All patients who were candidates for treatment with the Argus sling from April 2005 to October 2008 were consecutively included in this retrospective study. Eligible patients had SUI as a result of open or laparoscopic radical prostatectomy, transurethral resection of the prostate or external radiotherapy for prostate cancer. For patients to be eligible for inclusion in this study SUI had to persist after more than 6 months of pelvic floor muscle training. Incontinence was defined in 3 groups as (using 1 to 2 pads per 24 hours), moderate (3 to 5 pads per 24 hours) and severe (more than 5 pads daily).9 The only strict study exclusion criterion was urodynamically confirmed detrusor overactivity. Patients who underwent radiotherapy for local recurrence of prostate cancer after prostatectomy were not excluded from analysis. All patients were informed that the AUS is currently considered the gold standard for the treatment of SUI, and were offered the opportunity to be referred to another clinic for this procedure. However, no patients chose to be referred. Many patients in this cohort were referred by other clinics in The Netherlands with a special request for treatment of SUI with the Argus sling.

Preoperative Evaluation
Preoperative evaluation of male patients with SUI included medical history, pad count, VAS measurements on continence (scale of 1—severe incontinence to 10—dry) and a QoL score (scale of 1—poorest to 10—best). All patients were evaluated preoperatively with physical examination and cystoscopy. When cystoscopy demonstrated insufficient suppleness of the bulbar urethra to achieve adequate urethral compression, treatment with the Argus was dissuaded (2 patients). In cases of symptomatic urgency or urge incontinence, urodynamical evaluation was performed to exclude patients with detrusor overactivity. Patients with SUI and symptomatic urge but no detrusor overactivity were offered treatment with the male sling and anticholinergic therapy.

The Argus Device
The Argus system includes a silicone cushion, 2 silicone columns and silicone rings/washers (fig. 1). The rings are positioned on the columns, resting on the rectus fascia to regulate the tension of the silicone cushion on the bulbar urethra. The coned structure of the columns allows adjustment of sling tension by tightening or releasing the 2 silicone rings. Figure 2 shows the position of the Argus sling on a 3-dimensional computerized tomography reconstruction of the pelvis.

The Surgical Procedure
Implantation of the male sling. The operation was performed as described by Romano et al with some minor modifications.7,8 Preoperatively 1 gm cefazolin was injected intravenously. Patients were operated upon under spinal or general anesthesia. The patient was placed in the dorsal lithotomy position. The suprapubic and perineal areas were shaved preoperatively, disinfected and draped. A 16Fr Foley catheter was introduced and the bladder was emptied. A 7 cm perineal incision was made up to the bulbospongiosus muscle. The lateral borders were carefully dissected to reveal the perineal membrane on both sides. The urethra and the inferior border of the symphysis pubis were palpable. A transverse suprapubic incision of 7 cm was made and sufficient rectus fascia was exposed bilaterally to accommodate placement of the silicone rings. Guided by the operator’s index finger, a 90-degree crochet needle was carefully introduced, perforating the perineal membrane in the space between the bulbar urethra and the ischiopubic bone. The needle was then advanced just posterior to the pubic bone in the direction of the ipsilateral shoulder, toward the suprapubic incision. A second needle was similarly placed on the contralateral side. The needle handles were then relocated to the suprapubic ends of the needles. The columns of the Argus device were attached and pulled toward the suprapubic incision. The silicone cushion was positioned around the bulbar urethra. The Foley catheter was removed and cystoscopy was per-
formed to exclude bladder perforation. In case of perforation the column on the perforated side was retracted and repositioned correctly.

If the bladder was intact the 2 silicone rings were placed over the coned columns and positioned on the rectus fascia to regulate sling tension. The tension was adjusted to achieve a retrograde leak point pressure of 45 cm H2O. Sling tension was judged to be correct if cystoscopy showed coaptation of the bulbar urethra and a stop of water drip occurred with the water level at 45 cm from the pubic bone. The silicone columns were then positioned crosswise deep to the suprapubic subcutaneous fat and both wounds were closed in layers. The Foley catheter was reinserted at the end of the procedure. Normally the catheter was removed 24 hours postoperatively. In cases of bladder perforation or postoperative urinary retention the Foley catheter was left in situ for 1 week.

Revision procedures. A revision procedure was offered to all patients with persistent SUI after implantation of the device. This procedure was performed with the patient under spinal anesthesia. Preoperatively 1 gmcefazolin was injected intravenously. The suprapubic incision was opened and the sling tightened by pulling the coned columns through the washers over 1 or 2 cones bilaterally. Cystoscopy was performed as previously described. During revisions we aimed for a retrograde leak point pressure between 45 and 55 cm H2O, which may seem similar to the initial tension at sling implantation because the leak point pressure during revision procedures is maximally 10 cm H2O higher. However, the thickness of the bulbar silicone cushion decreased somewhat after placement, which may have slightly reduced the initially applied tension and leak point pressure. Furthermore, since the washers on the coned columns were always tightened over 1 or 2 cones bilaterally during revision procedures, the tension was always slightly increased.

Postoperative Evaluation
Outpatient clinical evaluation was performed 6 weeks postoperatively and late FU was achieved with telephone interviews in December 2009. Treatment was considered successful if patient reported pad use was 0 to 1 security pad per 24 hours (cured) or 1 to 2 pads per 24 hours, and greater than 50% reduction (improved). Patients were asked to fill out VAS measurements (1 to 10) on continence and QoL. Furthermore, overall patient satisfaction with the procedure and functional results were measured with a VAS score of 1 to 10 and with PGI-I score. Complications and revision procedures were registered.

Data Analysis
All data analyses were performed using SPSS® 16.0 for Windows. Preoperative and postoperative results were compared using the paired samples t test. Statistical significance was set at p <0.01.

RESULTS
Patient Characteristics
A total of 100 patients with SUI were treated with the Argus device between April 2005 and October 2008. Mean patient age was 66 years (range 50 to 89). There were 13 patients treated for mild incontinence (all using 2 pads per 24 hours at baseline), 46 for moderate incontinence (3 to 5 pads per 24 hours) and 41 for severe incontinence (6 to 10 pads per 24 hours, and 15 using a condom catheter).

Most men (96) were incontinent after radical prostatectomy (48 laparoscopic, 48 open). Of these men 13 were treated with radiotherapy for local recurrence of prostate cancer before Argus implantation. Three men were incontinent as a result of transurethral prostate resection, 1 was incontinent after external radiotherapy for prostate cancer and 9 had been diagnosed with urethral stricture or bladder neck stenosis at preoperative cystoscopy. Of these men 4 had been treated with radiotherapy for local recurrence of prostate cancer. These conditions were corrected surgically at least 6 weeks before Argus implantation. In December 2009 there were 5 patients lost to FU, including 3 who died of nonprostate cancer related causes and 2 in whom the cause could not be traced.

Operative Outcome and Revisions
The overall success rate (defined as patients who were cured and improved) was 92% at the first evaluation 6 weeks after surgery and 72% (68 of 95) after a median FU of 27 months (range 14 to 57). Figure 3 depicts cured and improved rates. The completely dry rate (0 pads) was 52% (52 of 100) initially and 40% (38 of 95) at late FU. The success rates for mild, moderate and severe incontinence are shown in figure 4. Completely dry rates were 62% (8 of 13), 59% (27 of 46) and 41% (17 of 41) at 6 weeks of FU, and 62% (8 of 13), 44% (19 of 43) and 28% (11 of 39) at late FU.
After the initial implantation procedure 68 patients were satisfied with achieved continence. The achieved success rates of these patients were 97% (66 of 68) at 6 weeks and 83% (55 of 66) at late FU. A revision procedure to tighten the sling via the suprapubic incision was desired in 24 patients once, in 7 twice and in 1 patient 3 times. The revision and complication rates for mild, moderate and severe incontinence are shown in figure 5.

The efficacy of the male sling appeared to be less in patients who had been treated with radiotherapy for local recurrence of prostate cancer before sling implantation compared to those without prior radiotherapy. The success rates at late FU were 15% (2 of 13) vs 79% (65 of 82), revision rates were 67% (10 of 15) vs 26% (22 of 85), sling explantation rates were 27% (4 of 15) vs 8% (7 of 85), complication rates were 60% (9 of 15) vs 54% (46 of 85) and urethral strictures occurred after sling implantation in 20% (3 of 15) vs 11% (9 of 85). The results of patients treated for urethral strictures or bladder neck stenosis before sling implantation also seem worse compared to those who did not have strictures or bladder neck stenosis in their medical history. Success rates at late FU were 55% (5 of 9) vs 72% (62 of 86), revision rates were 56% (5 of 9) vs 30% (27 of 91), sling explantation rates were 44% (4 of 9) vs 8% (7 of 91), complication rates were 56% (5 of 9) vs 55% (50 of 91) and prior radiotherapy had been applied in 44% (4 of 9) vs 12% (11 of 91).

The baseline and postoperative results of pad counts, VAS measurements on continence and QoL are demonstrated in figure 6. All cases improved significantly after Argus implantation (p < 0.01). PGI-I scores showed that 84% (80 of 95) of patients experienced this treatment as an improvement (fig. 7).
Complications

Complications occurred in 55 patients (see table). In 11 patients the sling had to be removed due to infection refractory to antibiotic treatment (6), erosion through the bladder/urethra (3), sling rupture (1) and hypersensitivity/pain (1). Of these patients 3 had been treated previously with radiotherapy for local recurrence of prostate cancer, and 2 had been diagnosed and treated with incision of urethral strictures or bladder neck stenosis before Argus implantation. At their request 5 patients were treated with implantation of a second Argus male sling 2 or 3 months after explantation of the old device, and of these patients 2 were dry.

Urethral strictures were diagnosed and treated in 12 patients after implantation of the male sling. After urethrotomy only 5 patients were still dry (1) or had improved continence (4) compared to the baseline situation. The male sling had to be removed for erosion in 2 patients and for infection in 1 eventually (included in the aforementioned explantation numbers).

DISCUSSION

The continence rate in our study indicates that the Argus adjustable sling may be a valuable adjunct in the treatment of all degrees of SUI after prostate surgery. The AUS remains the gold standard for moderate and especially severe SUI, with proven long-term durability (8 to 10 years). However, a recent investigation by Kumar et al. showed that many patients prefer treatment with a nonmechanical device. Therefore, we believe that Argus is a valuable solution to consider for all degrees of SUI if a patient wishes to be treated with a sling.

With this study we confirm earlier results of efficacy of the Argus as reported by Romano et al. These authors recently reported 79% social continence after a minimum followup of 3 years. However, the device still has to prove durability with long-term followup.

The most likely theory on the functional effect of the Argus is that it provides a passive minimum increase in intraurethral pressure, sufficient to achieve mucosal coaptation at 35 to 45 cm H₂O. This pressure can easily be regulated by releasing or tightening the sling. Compared to other male slings, such as the AdVance™ transobturator male sling and the bone anchored suburethral synthetic sling, the adjustable Argus achieved similar continence rates in this study. The reported continence rates of 2 other adjustable male slings (ProACT™ adjustable perineal male sling and Remex®) are also comparable to our results.

Complications are not uncommon. However, most complications were grade 1 or 2 and resolved within 2 weeks with minimal, conservative measures. There was a higher complication rate in patients treated for severe incontinence, which may be associated with the higher revision rate in this group.

Treatment failure, sling explantation and revisions seem to occur more often in patients treated with radiotherapy or for urethral strictures or bladder neck stenosis. We consider these factors relative contraindications of which patients should be informed preoperatively. A limitation of this retrospective study is the lack of preoperative and postoperative urodynamic investigation in all patients. We consider the Argus a promising therapeutic option in the field of male stress urinary incontinence. Although there is a considerable complication rate, the results of this study regarding improvement in QoL, overall patient satisfaction with the Argus implantation and patient impression of improvement speak for themselves.
CONCLUSIONS
This relatively new adjustable male sling is a valuable adjunct in the treatment of all degrees of iatrogenic male SUI. Long-term FU is warranted to assess durability. Prior radiotherapy and treatment for urethral strictures or bladder neck stenosis may be associated with an increased risk of treatment failure, wound infection or erosion and subsequent sling explantation. These factors are considered relative contraindications to the use of the device.

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REFERENCES