**Early results of a our experience with a new self-anchoring adjustable transobturator system for treatment of stress urinary incontinence in men**

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Abstract

Surgical treatment options for male stress urinary incontinence (SUI) include collagen injection, artificial urinary sphincter, or male sling placement. In recent years, various minimally invasive sling systems have been investigated as treatment options for post-prostatectomy SUI. One of the drawbacks of using male slings is the lack of ability to make postoperative adjustments. To overcome the challenges associated with peri- and postoperative adjustment of male sling systems, the adjustable transobturator male system (ATOMS®) was introduced.

Our experience with this device treatment shows a significant improvement in the severity of incontinence and mean pad use as well as quality-of-life scores. Our data suggest that the ability at any time to make

adjustments in male sling systems should be considered as a prerequisite when managing men with SUI.

Objective

 To report our experience with a new self-anchoring adjustable transobturator male system (ATOMS®; AMI,

Vienna, Austria) for the treatment of stress urinary incontinence (SUI) in men.

Patients and Methods

From September 2013 to November2015, 12 men with SUI were treated with the ATOMS® device. The exclusion criteria were detrusor overactivity, urethral or anastomoticstricture, and rising PSA levels for the previous 1 year.

Primary outcome variables were changes in usage of pad/24 h und differences in pad test/24 h before and after the operation. Secondary outcome variables were related to the safety of the procedure such as urinary retention,bladder or urethral injuries, pain and infections.

Preoperative Diagnostic Evaluation

The preoperative evaluation consisted of a complete history and physical examination, 24-h pad testing, 24-h pad count, retrograde cysto-urethrography, urodynamics, and cysto-urethroscopy. Patients using 1 or 2 pads/day were considered as having mild SUI,patients with 3–5 pads/day were considered as having

moderate SUI and those using 5 pads/day as having severe SUI. The multichannel urodynamics consisted of uroflowmetry and measurement of post-void residual urine volume, cystomanometry and a pressure-flow

study according to the recommendations of the ICS.

Urodynamics were performed in patients with signs of detrusor instability with frequency or in patients with

significant residual volume. As a consequence, patients with these types of voiding dysfunction were excluded from the operation. In addition, preoperatively and at 6-month

follow-up, patients completed a validated translated quality-of-life (QoL) questionnaire, the multipurpose

36-item short-form health survey (SF-36).

The Device

The ATOMS® device has two components: the mesh implant with integrated adjustable cushion, and the implantable titanium port for adjusting the volume of the cushion (The silicone cushion is located in the middle of the mesh tape and filled via the low-profile port and catheter both intra- and postoperatively The mesh (sling) is built of macroporous, monofilament polypropylene.

Surgical Technique

The surgical procedure was performed under general anaesthesia, and a 16-F transurethral catheter was inserted.The patients were placed in the lithotomy position and a 5-cm median vertical perineal incision below the inferior border of the pubic symphysis was made in order to expose the bulbospongiosus muscle, then to expose the perineal aponeurosis at the top of the triangular space delimited laterally by each ischiocavernous muscle and medial to the bulbospongiosus. A short 2-mm incision through the pelvic fascia allowed access to the obturator muscle just under the ischiopubic ramus bone. The implant was inserted in all patients using an outside-in technique by passing the obturator foramen The mesh arms were moved back to the central part and sutured. The port was placed deeply s.c. on the left scrotum region and anchored with two sutures. Using 6 mL of a saline–contrast medium mixture (1:1), the system was filled intraoperatively.Thereafter, the perineal incision was closed without drainage and the urethral catheter left indwelling for 24 h.

Before hospital discharge, uroflowmetry, a post-void residual volume measurement by ultrasonography, and a pelvic pain evaluation on Visual Analogue Scale (VAS) were obtained. Postoperative adjustments required no surgical intervention and were performed using 2 mL of saline solution starting 6 weeks after the device was implanted. If further adjustments were needed, they were performed every 6 weeks until the desired result (dryness,improvement and/or patient satisfaction) was reached.

Regardless of the need for further adjustments,postoperative follow-up examinations were conducted every 3 months including a physical examination and anevaluation of incontinence severity, as determined by 24-h pad test and 24-h pad count. Patients were considered ‘cured’ when they used 0 pads after the procedure (dry = 0 pad, 10 mL 24-h pad test), ‘improved’ when daily pad use was reduced by 50% or patients needed 1–2 pads/24 h,(10–40 mL 24-h pad test), and failed when \_3 pads/24 h(40 mL 24-h pad test).

Results

A total of 12 patients with an mean (SD; range) age of 70.4

(6.2; 55–86) years underwent placement of the ATOMS® device. The most common indication for placement of the adjustable male system was incontinence after radical laparoscopic, perineal or retropubic prostatectomy (9/12patients), and ¾ patients had experienced failure of previous surgeries or devices (including Pro-Act®, InVance® bulking agents,and previous radiotheraphy.The mean (SD; range) preoperative use of pads/day was 7.1 and ¾ hadsevere SUI. Peri- and postoperative clinical data are shown in Table 2.Mean (SD; range) surgery time was 47 (13.8; 29–112) min.

After removal of the transurethral catheter, 24 h after surgery no temporary urinary retention occurred Transient perineal/scrotal numbness or pain was reported by 4/12 patients (30%) and resolved spontaneously after using non-opioid analgesics for 3–4 weeks. There were one case of infection at the site of mesh implantation with the complete explantation of the device. No urethral or bladder injuries related to the device occurred. Mean (SD; range) follow-up time was 17.8 (1.6; 12–33) months with 100% of patients completing at least 6 months follow-up .

After the initial intraoperative filling of the device with 6 mL saline-contrast solution mixture (1:1), 6/12 patients

(50%) were dry (0 pads/24 h, 10 mL in 24-h pad test). In the remaining patients (50%) further adjustments were necessary, starting with the second adjustment 6 weeks after surgery. For every adjustment, 2 mL saline solution was added to the system via the port. The mean (SD; range)number of adjustments to reach the desired result (dryness,improvement and/or patient satisfaction) was 3.5

Conclusion

Many cases must be treated and we need a longer follow up but the treatment of male SUI with this self-anchored adjustable system is safe and effective.

Keywords

incontinence, prostatectomy, transobturator mesh,

adjustable, quality of life

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Abbreviations: SUI, stress urinary incontinence; AUS,

artificial urinary sphincter; QoL, quality of life; SF-36,

36-item short-form health survey.