Compression or obstruction: Prospective analysis of the function of the Adjustable Transobturator Male System (ATOMS) based on pre- and postoperative urodynamic data

Fabian Queissert[1], Benedict Bruecher[1], Sonja Ruiz[2], Miguel Virseda-Chamorro[3], Andres J. Schrader[1], Javier C. Angulo[2]

[1]University Hospital of Muenster, Department of Urology and Pediatric Urology, Muenster, Germany; [2]Clinical Department, Universidad Europea de Madrid; Hospital Universitario de Getafe, Getafe, Spain

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Abstract

Introduction: This analysis, based on pre- and postoperative urodynamic data, is the first to elucidate the influence of the Adjustable Transobturator Male System (ATOMS, A.M.I. GmbH, Feldkirch, Austria) on the lower urinary tract and disclose possible obstructive properties.

Methods: A prospective study was performed in patients who had stress urinary incontinence and were scheduled for ATOMS implantation after radical prostatectomy. Apart from continence assessment (24-hour pad test, International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form [ICIQ-SF]), urodynamic testing was done with International Continence Society (ICS)-standardized pressure-flow analysis before and after ATOMS implantation/adjustment. The Wilcoxon signed-rank test was used for statistical analysis.

Results: The analysis included 12 consecutive patients from two centers (mean age 69 years) with a mean followup of 246 days. Median urine leakage dropped from 240 (72–1250) to 70 (0–700) g/24 hours postoperatively, with a pad reduction of 4 to 0.9 pads/day. Pressure-flow analysis revealed a significant change only in the bladder outlet obstruction index (BOOI). The bladder contractility index, intravesical pressure conditions, and uroflowmetry were not significantly affected. None of the patients showed de novo obstruction postoperatively in the ICS analysis.

Conclusions: The ATOMS significantly increases the BOOI in conjunction with good continence results. However, no case reached pathological level according to the BOOI and thus there is no potential danger to the lower urinary tract or urethral integrity.

Introduction

Various surgical options are available for treating male stress incontinence after radical prostatectomy. Apart from the artificial urinary sphincter (AUS) as the gold standard, fixed slings have become established, as well as adjustable urethral compression systems like the Argus, Reemex, ProACT, and more recently, the Adjustable Transobturator Male System (ATOMS). Although a short followup and comparatively low success rates are criticized in the guidelines for the ATOMS,[1] a current review examining a longer followup and including the new-generation ATOMS with a silicone-covered scrotal port (SSP) demonstrates higher success rates with continued low complication rates.[2] However, little is known as yet about the mechanism of action of the ATOMS, its safety, and its influence on lower urinary tract function. As a compression device, the ATOMS is implanted under the bulbar urethra, where obstruction is at least conceivable, depending on the filling level. This could exert a negative influence on bladder integrity and lead to urethral damage in the followup. After correct retrobulbar implantation of the fixed sling AdVance (Boston Scientific), urodynamic testing revealed no obstructive component and no relevant influence on voiding.[3] Similarly, this prospective non-interventional feasibility study in a small series of patients from two centers is the first to urodynamically evaluate ATOMS implantation for its effects on bladder function and to discard a possible obstructive implant property.

Methods

The opportunity to participate was offered to men who suffered from stress urinary incontinence >1.5 years after radical prostatectomy and were scheduled for ATOMS implantation during the investigation period, between November 2019 and December 2020. Approval by the Ethics Committee of Westphalia-Lippe was obtained before starting the study

(2019-248-f-S). Patients with previous incontinence surgery, active urethral/bladder-neck stenosis or former surgical treatment of any source of bladder outlet obstruction were excluded. Cystourethroscopy verified eligibility for ATOMS implantation by assessing residual sphincter function and excluding obstruction. Guideline-based urodynamic testing was done to check the indication and exclude relevant urinary stress incontinence.[4] Urodynamic testing was International Continence Society (ICS)-standardized and regularly took place in a standing position.[5] Apart from cystometric data acquisition (bladder volume at baseline, strong desire, detrusor overactivity, maximum detrusor pressure, and compliance), a pressure-flow study was performed to record maximum uroflow (Q_{max}), residual urine, bladder contractility index (BCI=Detrusor-pressure at maximum flow [$P_{Det}Q_{max}$] + 5 x Q_{max}), and bladder outlet obstruction index (BOOI= $P_{Det}Q_{max}$ - 2 x Q_{max}). The latter is regarded as a valid parameter for assessing infravesical obstruction and enables classification of micturition as unobstructed (BOOI <20), equivocal (BOOI 20–40), or obstructed (BOOI >40) according to ICS criteria.[6]

After screening and consent, preoperative continence data were recorded (pads/24 hours; 24-hour pad test; International Consultation on Incontinence Questionnaire-Short Form [ICIQ-SF]). All patients underwent perineal ATOMS SSP implantation using the method described by Seweryn et al.[7] The intervention was performed at both participating centers by a surgeon with appropriate expertise (>70 ATOMS). The system was initially filled with isotonic saline solution after venting by passive pressure equalization. Adjustment was done until either satisfactory continence was achieved or discomfort prevented further filling of the system. Urodynamic and continence parameters were again recorded after completing adjustment but three months after the intervention at the earliest and 12 months thereafter at the latest.

Statistical analysis was done with SPSS for Windows (Version 27.0). The Wilcoxon signed rank test was used to detect any differences in urodynamic parameters. P-values <0.05 were considered statistically significant.

Results

The study included a total of 15 patients who underwent urodynamic testing and subsequent ATOMS implantation in Münster or Getafe between November 2019 and December 2020. Patients had a mean age of 69 years (range 64–72) at the time of surgery and a mean body mass index (BMI) of 26.4 kg/m^2. During followup, two subjectively satisfied patients refused postoperative urodynamic testing, and in another case, catheter insertion proved difficult and was prematurely terminated at the patient's request. A median of 1.0 (range 0–3) adjustment was made in the 12 remaining patients, and the device had a median filling volume of 12.0 ml (range 6.5–19.0). Median urine leakage dropped from 240.0 g/24 hours (range 72–1250) preoperatively to 70 g/24 hours (range 0–700) postoperatively (Figure 1), with a pad reduction from a median of 4 pads/24 hours to 0.9 pads/24 hours. Nine patients (75%) achieved social continence (0–1 pad/24 hours), with mean urine leakage of 3 g/24 hours. The median ICIQ-SF sum score dropped from 16.0 preoperatively to 5.5 postoperatively (ICIQ-SF 1: 4.0→1.0; ICIQ-SF 2: 4.0→2.0; ICIQ-SF 3: 7.5→2.5). The median postoperative Patient Global Impression of Improvement (PGI-I) was 2.0 (1=very much better, 2=much better, 3=a little better, 4=no change, 5=a little worse, 6=much worse, 7=very much worse).

Urodynamics – Cystometry

Cystometric results are presented in Table 1. There were no significant differences between the following pre- and postoperative cystometric parameters: bladder volume at baseline and strong desire, maximum detrusor pressure, and compliance. Two patients had de novo detrusor overactivity (DO) postoperatively. In another case, DO was present initially and no longer detectable postoperatively. In both cases with DO, postoperative volume of first DO was higher than the maximum cystometric bladder volume in preoperative urodynamics.

Urodynamics – Pressure flow study

Maximum uroflow, residual urine, and BCI (Figure 2) did not change significantly in the Wilcoxon signed rank test. Median maximum detrusor pressure (25→32 cmH_2O, p=0.08) and maximum intravesical pressure (59→75 cmH_2O, p=0.09) tended to be higher postoperatively. The BOOI was the only

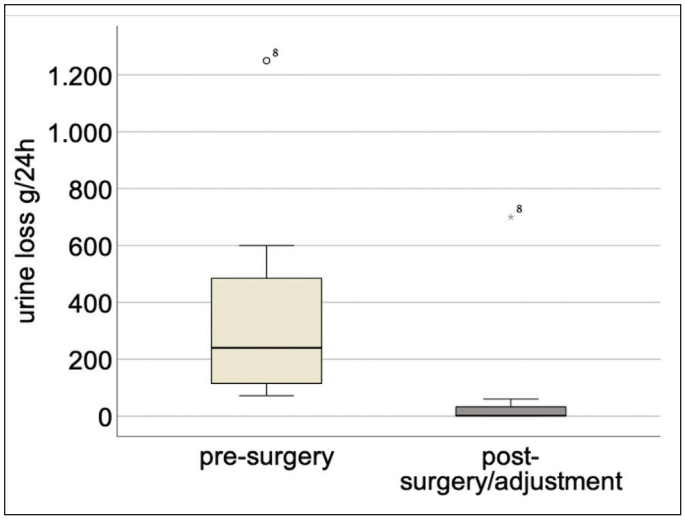

Figure 1. Continence results at time of postoperative urodynamics.

Table 1. Changes in urodynamic parameters after ATOMS implantation

Urodynamic parameter	Preoperative	Postoperative	p (Wilcoxon signed rank test)
Cystometry			
Median cystometric bladder capacity, ml (range)	309 (97–569)	359 (120–502)	0.88
Median volume first desire, ml (range)	181 (20–403)	205 (119–356)	0.43
Median volume strong desire, ml (range)	260 (97–491)	309 (120–480)	0.75
Detrusor overactivity (yes/no)	4/8	5/7	1.0
Median maximum detrusor pressure, cmH_2O (range)	10 (2–45)	19 (2–52)	0.24
Median detrusor compliance, cmH_2O/ml (range)	55 (8–223)	126 (15–224)	0.53
Pressure flow study			
Median maximum uroflow (Q_{max}), ml/s (range)	15.0 (2–37)	12.0 (3–32)	0.23
Median residual urine, ml	1.0 (0–185)	3.0 (0–372)	0.51
Median max detrusor pressure, cmH_2O (range)	25 (0–46)	32 (10–49)	0.08
Median max vesical pressure, cmH_2O (range)	59 (20–117)	75 (25–108)	0.09
Median BOOI (range)	-14 (-69–30)	5.5 (-32–29)	0.034*
Median BCI (range)	89 (10–213)	96 (40–199)	1.0

*Statistically significant. ATOMS: Adjustable Transobturator Male System; BCI: bladder contractility index; BOOI: bladder outlet obstruction index; Qmax: maximum flow rate.

parameter to show a significant increase, from -14 preoperatively to 5.5 postoperatively (p=0.034). One case (8.3%) was classed higher postoperatively according to ICS criteria (changed from unobstructed to equivocal) (Figure 3). After surgery and adjustments, none of the patients had obstructed micturition according to ICS criteria.

Discussion

Eight years after the device reached market maturity, our study undertook the first urodynamic analysis of bladder storage and emptying function before and after ATOMS implantation. Direct ventral compression of the bulbar urethra by the silicone cushion significantly increased the BOOI, but de novo obstruction did not reach a pathological level according to the BOOI in all examined cases. The absence of obstruction could be due to the urethra gaining many degrees of freedom through compression on only one side. Thus, the ATOMS appears to function not just by statically obstructing the urethra but rather by indirectly supporting the external sphincter muscle.

In their study on fixed sling function, Rehder et al already discussed the relevant function of the urethral bulb to maintain continence.[8] Physical activity causes physiological contraction of the bulbospongiosus muscle, which increases pressure in the bulb of corpus spongiosum and consecutively leads to additional narrowing of the urethral lumen in the distal part of the rhabdosphincter. This principle may be assumed for the ATOMS, especially since the implantation technique propagated by Seweryn et al leaves the bulbospongiosus muscle intact and does not require exposure of the urethra.[7] Therefore, in our opinion, the mechanism of action of the ATOMS involves not only direct compression of the proximal penile and bulbar urethra but also an indirect effect through increased pressure in the corpus spongiosum and consecutive narrowing of the membranous urethral lumen.

In line with our study, no obstructive effect or relevant voiding dysfunction was detected for the fixed transobturator retrobulbar sling (Boston Scientific).[3] For the adjustable ProAct system, on the other hand, Utomo et al demonstrated an obstructive component with a significant increase in the BOOI from -7.4 to 23.1 (i.e., equivocal, according to ICS criteria) in most of the patients treated.[9] This could be due to two-sided contralateral compression of the urethra. Despite long availability of these devices, thus far, there are no publications on urodynamic analyses before/after implantation of an AUS or any of the other adjustable continence systems.

To predict possible consequences of iatrogenic obstruc-

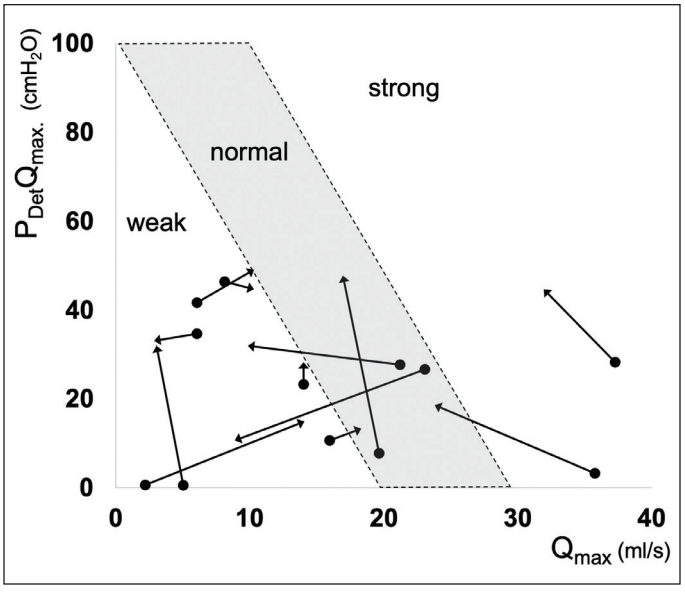

Figure 2. Changes in Bladder Contractility Index ($BCI=P_{Det}.Q_{max} + 5 \times Q_{max}$). P_{Det}: Detrusor pressure; Q_{max}: maximum flow rate.

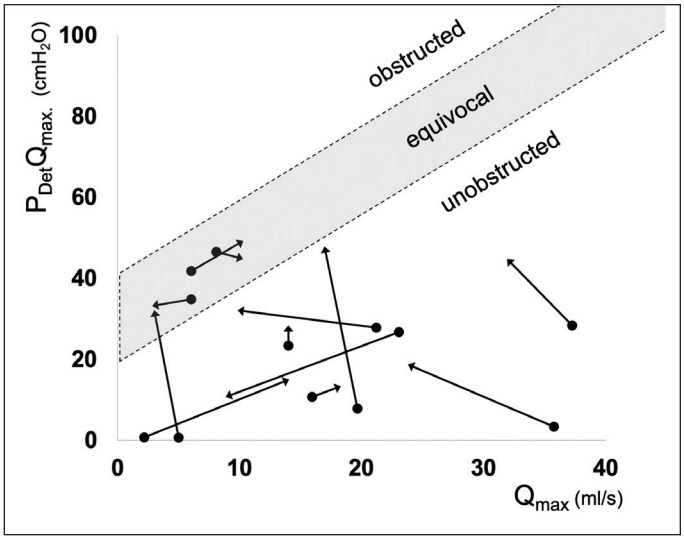

Figure 3. Changes in Bladder Outlet Obstruction Index (BOOI=$P_{Det}Q_{max}$ - 2 x Q_{max}). P_{Det}: Detrusor pressure; Q_{max}: maximum flow rate.

tion, it is helpful to consider the long-term consequences of obstruction assessed by Thomas et al.[10] No complete deterioration of urodynamic pressure-flow parameters was seen in the 10-year followup of patients with bladder outlet obstruction. Detailed analysis, however, revealed significantly more prevalent DO, reduced detrusor contractility, and increased residual urine in the group that did not undergo deobstruction during the entire observation period.[10]

Another possible and more direct consequence of long-term obstruction is atrophy of the compressed tissue with the risk of urethral erosion. In the first publication on ATOMS, Seweryn et al already noted that absence of the circular compression, as that created by the AUS, is associated with a markedly lower urethral erosion rate.[7] Even larger long-term followup studies revealed no relevant prevalence of urethral erosion after ATOMS implantation.[11] In contrast, Utomo et al detected unspecified tissue damage requiring revision during a short followup in 3.7% of patients who received the adjustable balloon device ProAct.[9] Urethral erosion after AUS implantation is also attributed to urethral atrophy caused by circular compression and impaired perfusion.[12,13] Apart from the risk of urethral erosion, urethral atrophy in the cuff area also harbors the risk of recurrent incontinence through inadequate urethral closure. Our analysis, therefore, supports the view that, unlike the AUS, the ATOMS carries no risk of relevant urethral atrophy and consecutive erosion. The possibility of adjustment via the scrotal port during followup additionally reduces the risk of recurrent incontinence as a reason for revision/reimplantation.

Cystometry showed no significant changes in our cohort. Low compliance was not observed during our short followup. Two patients in the group we examined had de novo DO, although this did not influence the subjective outcome or continence results. The fact that preoperative maximum cystometric volume in both cases were lower than volume at first DO in postoperative surgery let us assume that preoperative DO could be underestimated due to early urine leakage. Schoenburg et al found no de novo DO in their prospective study in 361 patients with an ATOMS.[14] Open to debate is the fact that urodynamic testing was not done regularly in the preoperative phase and that the postoperative symptoms of an overactive bladder were initially recorded only via questionnaires. Only 18 of 361 patients underwent urodynamic testing, which revealed no DO and only one case of low compliance. Thus, DO could have remained undetected in asymptomatic/satisfied patients.

Limitations

The BOOI was originally developed to estimate the degree of obstruction in men with an enlarged prostate. It has to be noted that it has not been validated for use after radical prostatectomy. Due to its widespread use, the well-investigated connection between higher BOOI and bladder deterioration, and the fact that other working groups also applied the BOOI,[3,9] we decided to use it in our analysis.

The short followup harbors the risk of underestimating effects of the ATOMS, since any subsequent adjustments could cause more severe obstruction. Moreover, influences on bladder function often become apparent only in the long-term.[10] However, comparison of the ATOMS filling volume in our study (median 12 ml), along with the results of the long-term followup in the Iberian study,[11] discloses only a marginal difference in the adjusted volume (mean 13.2 ml). Furthermore, our patient with the highest filling volume (19 ml) still had a BOOI of only -3. It, therefore, seems to us that our results have sufficient informative value.

Conclusions

The ATOMS is a safe and successful treatment method. Despite a slight increase in the BOOI, none of the patients treated show any indication of relevant obstruction according to BOOI or deterioration of bladder function. Long-term urethral integrity and bladder function may be assumed but require a longer followup in a larger number of patients.

Competing interests: Dr. Queissert and Dr. Angulo have lectured and been consultants for AMI GmbH. The remaining authors do not report any competing personal or financial interests related to this work.

This paper has been peer-reviewed.

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Correspondence: Dr. Fabian Queissert, University Hospital of Muenster, Department of Urology and Pediatric Urology, Muenster, Germany; Fabian.Queissert@ukmuenster.de