

THE ATOMS DEVICE FOR MALE STRESS URINARY INCONTINENCE: 5 YEAR RESULTS OF A PROSPECTIVE-MULTICENTER STUDY

Hypothesis / aims of study

The effectiveness and safety of the Adjustable Transobturator Male System (ATOMS) with inguinal or scrotal port (IP, SP) for treatment of male stress urinary incontinence (SUI) has been described multiple times in short and medium term studies. This prospective multicenter study is the first to report functional long term results in 5 year follow-up (FU).

Study design, materials and methods

A prospective multicenter study was carried out from 11/2009 to 2/2015 including 222 male patients with mild (<150ml/24h) to severe (>500ml/24h) SUI after radical prostatectomy (RPE), transurethral resection (TURP) and single or adjuvant radiotherapy (RT). Patient performance status was determined using the Charlson Comorbidity Index (CCI) and the ASA-classification. Baseline (BL) and FU measurements included 24h pad-usage and pad-weight test, uroflowmetry (Qmax), post void residual urine (PVR), VAS/LANSS for pain analysis and quality of life scores (ICIQ-SF, PGI-I). Complications of surgery were assessed using the Clavien-Dindo classification. Failure rate and reasons of explantation were shown and postoperative device adjustments were recorded. Cure was defined as zero to one pad-use in 24h or urine loss of 0-5 g in the 24h pad-weight test.

Results

All patients (mean age 64.4 [39-94] yr) underwent urodynamic investigation before implantation. At BL 75.7% of patients were older than 65 yr. Reasons for SUI were RPE (86.9%), TURP (10.8%), TURP+RPE (2.3%) and single/adjuvant RT (26.2%). 26.6% had previous implants or bulking agents (ProAct, AMS800, AdVance, Deflux, Argus, InVance, Zephyr). Previous implant count of 1/2/3 was seen in n=44/9/3 patients respectively. Mean BMI was 27.4 [20.1-40.0] and average CCI/ASA was 7 [4-12]/2 [1-3]. 7.6% of patients had urgency pre implantation. Mean time from primary prostate treatment to ATOMS implantation was 4.7 years. At implantation 67.1% (n=149) got the IP and 32.9% (n=73) the SP.

At FU (median 39.1 [4.4-63.9] months), after a mean number of 3.1 adjustments, 24h pad-usage/pad-weight test decreased significantly from 4.5 [2-11]/539g to 1.5 [0-8]/106g (p<0.05). Mean Qmax showed a reduction from 20.3ml/s (169ml filling) to 15.1ml/s (177ml filling). The mean VAS/LANSS increased from 0.1/0.1 to 0.9/1.4 and the ICIQ-SF/PGI-I improved significantly from 16.5/3.9 to 5.9/1.7 (p<0.05). Zero to one 24h pad-rate was 62.6% (=cured); 90.1% of patients had an overall benefit (=24h reduction of pad-use).

There was marginal PVR at BL/FU, however 19.4% (n=43) required an urethrotomy for catheterization during implantation. No intraoperative complications occurred. Average operation time was 47.1 minutes (IP/SP = 51.3/36.6; p<0.05). Postoperative infection rate was 21.5%/16.4% (IP/SP). Explantation rate was 17.1% (n=38, [13 leak/defect, 24 infection, 1 persistent pain]) with a mean implantation to explantation time of 14.1 (0.1 – 56.8) months. Of these, 9 received an implant change immediately and 20 patients received a re-implantation after >3 months; 4 patients had a re-explantation again. A solitary port-system change was carried out in 4.9% (n=11) due to port infection or malrotation. The majority of complications were Dindo grade I, two patients died during FU due to tumor progression.

Interpretation of results

Similar to initial experiences (1) and early results (2), the ATOMS device shows good effectiveness in long term FU of up to 5 years, high patient satisfaction and low complication rates (table 1). Operating time is short and secondary implantation is possible after failure. Infection prevention is the key to long implant endurance and to best functional outcomes.

Table 1. Short and long term results of the ATOMS device

Authors	n	Age	FU (mth)	Prev. Impl. (%)	IP/SP (n)	Mean OP time (min)	Mean 24h...		Dry rate (%)	Overall success rate (%)	Infect. Rate (%)	Expl. Rate (%)
							pad-use (BL/FU)	pad-weight (g) (BL/FU)				
Seweryn et al., 2012	38	70.0	16.9	28.9	38/0	52.0	6.8/1.4	747/115	60.5	84.2	10.5	7.0
Hoda et al., 2012	99	70.4	17.8	34.3	99/0	47.4	7.1/1.3	681/80	63.0	92.0	4.0	4.0
Friedl et al., 2015	222	64.4	39.1	26.6	149/73	47.1	4.5/1.5	539/106	62.2	90.1	21.5	17.1

Concluding message

The ATOMS is a safe, effective and well tolerated device for the treatment of persistent male SUI in FU of up to 5 years.

References

1. Hoda MR, Primus G, Fischereeder K, Von Heyden B, Mohammed N, Schmid N, Moll V, Hamza A, Karsch JJ, Brössner C, Fornara P, Bauer W. Early results of a European multicentre experience with a new self-anchoring adjustable transobturator system for treatment of stress urinary incontinence in men. BJU Int. 2013 Feb;111(2):296-303.
2. Seweryn J, Bauer W, Ponholzer A, Schramek P. Initial experience and results with a new adjustable transobturator male system for the treatment of stress urinary incontinence. J Urol. 2012 Mar;187(3):956-61.

Disclosures

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