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IMPLANT OF ATOMS® SYSTEM FOR THE TREATMENT OF POSTOPERATIVE MALE STRESS URINARY INCONTINENCE. MEDIUM TERM RESULTS OF A SINGLE CENTRE EXPERIENCE.

Hypothesis / aims of study

Male stress urinary incontinence (SUI) after radical prostatectomy ranges from 4% to 40% according to surgical technique and surgeon expertise. After failure of conservative measures, different surgical treatments can be considered: bulking agents, slings, compression devices (i.e. pro-ACT) and artificial urinary sphincter (1). The aim of this study is to evaluate the medium-term results of ATOMS® system implant (2) in a single center.

Study design, materials and methods

We enrolled male patients suffering of postoperative stress urinary incontinence. Each patient underwent anamnestic data collection, pad test, physical examination, urodynamic evaluation, ICIQ-UI SF and PGI questionnaire. We excluded patients with low bladder compliance, uncontrolled detrusor overactivity (DO) and low cystometric capacity. All patients were implanted with ATOMS® system. It is an extra urethral bulking system in form of a sling, made of three parts: two polypropylene mesh arms, a cushion and a titanium port. Compression can be modulated with outoffice filling procedures.
For the statistical analysis we used T-test and Chi-square test.

Results

From January 2015 to February 2017 we treated 43 male patients with ATOMS® system. The average age was 72.28 years (median 73.95, range 57.51-81.8 years). In this population, 38 (88.3%) patients had undergone open radical open prostatectomy, one (2.3%) laparoscopic radical prostatectomy, 2 (4.7%) patients transvesical prostatic adenomectomy and 2 (4.7%) transurethral resection of the prostate (TURP). The average interval between the intervention and ATOMS® implant was 8.4 years. Among the patients who underwent radical prostatectomy, 6 had undergone urethrotomy for an urethral stricture, 5 had undergone vesico-uretheral anastomosis resection. Six patients had undergone adjuvant radiotherapy (RT), four were on hormone therapy with LHRH analogue / LHRH antagonist. All patients were in complete remission from cancer disease, in cases of radical prostatectomy, with undetectable PSA. Among the patients' comorbidities, we report that 6 (14%) had diabetes with good glycemic control.
Urinary incontinence severity was assessed by the number of pads used daily. The average number of pads used was 4.2 (median 4, range 2-8). 3 patients (7%) were suffering from mild incontinence (1-2 pads/day), 33 patients (76.7%) moderate incontinence (3-5 pads/day), 7 patients (16.3%) severe incontinence (>5 pads/day). 23 patients (53.5%) had already undergone surgical treatment for urinary incontinence: in 20 cases ProACT device, in one case artificial sphincter (FlowSecure), in two cases both a ProACT device that an artificial sphincter (AMS800). 18 patients had undergone pelvic floor rehabilitation. The average surgical time was 50.0 minutes (median 48 minutes, range 40-84 minutes).
The mean follow-up was 1.2 years (median 0.98 years, range 0.2-2.55 years). All patients were observed at regular intervals. The first filling of the device, in case of persistence of incontinence, was performed at one month after surgery. Subsequent fillings were not established on a regular basis, but according to the persistence of urinary leakage. The average number of fillings was 1.67 (median 1, range 0-7) with an average filling volume of 10.89 ml (median 10, range 0-31ml). In one case it was necessary a complete deflate of the cushion for voiding difficulties. In the early postoperative time, there were any severe complication (Clavien-Dindo ≥2), only 3 cases of symptomatic scrotal edema, treated with oral anti-inflammatory therapy and suspension of the scrotal sac, and a case of transient dysuria, treated with temporary deflate of the cushion.
In the postoperative follow-up complications were detected in 8 patients (19%): 5 cases of displacement of the scrotal port, in 2 cases catheterization difficulties and difficulty to deflate the device, one case of epididimitis and concomitant superficial wound infection, treated with prolonged antibiotic therapy. There has been any prosthesis infection.
At last follow-up, 15 patients (34.9%) were completely dry and did not use any pad, 23 (53.5%) improved more than 50%, 4 (9.3%) improved less than 50% and 1 (2.3%) did not change; In any case there was worsening of urinary incontinence. In total 31 patients (72.1%) reached social continence (use of 0 or 1 security pad/day) and 38 (88,4%) had substantial benefit. Taking into account the degree of preoperative incontinence, all patients (n = 3) with mild incontinence were dry. In patients with moderate incontinence (n = 33), 11 (33.3%) were dry, 18 (54.5%) improved more than 50%, 3 (9.1%) improved less than 50% and only 1 (3.1%) unchanged ($p < 0.01$); a total of 25 patients (75.8%) reached social continence and 29 (87,8%) had substantial benefit. In patients with severe incontinence (n = 7), one (14.3%) was dry, 5 (71.4%) improved more than 50%, and one (14.3%) improved less than 50% ($p < 0.01$); three patients (42.9%) achieved social continence and 6 (85,7%) had substantial benefit.
In the subpopulation of radio-treated patients, 3 (50%) were dry, 2 (33.3%) were improved more than 50% and one (16.7%) had improved less than 50% ($p < 0.01$). A total of 4 patients (66.7%) reached social continence and 5 (83,3%) had substantial benefit.
In the subpopulation of patients who have previously undergone surgical treatment for incontinence, 4 (17.4%) were dry, 16 (69.6%) improved more than 50%, 2 (8.7%) improved less than 50%, and one (4.3 %) was unchanged ($p < 0.01$). In total 14 patients (60.9%) reached social continence and 20 (87%) had substantial benefit.
The comparison between the two populations has shown that there is no statistically significant difference between patients treated with RT and those not treated with RT, with regard to complete dryness (p 0.40) and social continence ($p = 0.75$). The comparison of patients who have undergone previous surgery for incontinence has evidenced that there is a statistically significant difference with regard to completely dryness ($p = 0.0099$), but not to social continence ($p = 0.078$).
The average result of the quality of life questionnaire ICIQ-UI SF before treatment was 16.05 (median 16, range 12-20), at last follow-up it was 7.7 (median 8, range 0-15), with a statistically significant variation ($p < 0.01$). The questionnaire on the subjective

satisfaction the result of continence (PGI-I) showed that 20 (47.6%) patients reported being much improved, 14 (33.3%) improved, 8 (19.1%) only moderately improved; it is noteworthy that no patient expressed a negative subjective judgment towards treatment.

Interpretation of results

ATOMS® system should be defined as an “extraurethral bulking device” instead of a simple sling. Patients are satisfied with this technique and 72,1% reached social continence ad 88,4% has substantial benefit. Its strengths are: the possibility of regulation in outpatient office, the mininimally invasive surgical technique and its possibility to be offered to all degrees of incontinence. Previous radiation therapy, urethral strictures and previous surgery, indicators of a worse urethral quality, do not represent contraindication having good results in terms of social continence. Absence of device explantation, both for migration or infection, make it a safe and valuable device. Perineal pain, when present, is easily treatable by common painkillers and tends to disappear over 1-3 months. Finally the device doesn’t require patient’s manipulation, and can be proposed after failure of other surgical treatments.

Concluding message

ATOMS® system represents a significant innovation for male urinary incontinence: Our mid-term results support the very good efficacy and safety of this device, even in complex cases of SUI.

References

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