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Chondros K[1], Ferreira C[2], Bryckaert P[1], Menard J[1], Mandron E[1]
1. *Department of Urology, Surgical Clinic Du Pre, Technopole Universite, Le Mans, France,* ***2.*** *Department of Urology, Unidade Local de Saúde de Matosinhos, Portugal*

LAPAROSCOPIC IMPLANTATION OF ARTIFICIAL URINARY SPHINCTER IN WOMEN. AN UPDATE ON A 12YEAR-LONG SINGLE CENTER'S EXPERIENCE

Hypothesis / aims of study
The artificial urinary sphincter (AUS) is an intracorporal external compression device that constitutes a treatment option for women with recurrent stress urinary incontinence (SUI) after a previous surgery failure, as well as for urodynamically-proven intrinsic urethral sphincter deficiency (ISD) [1]. Low evidence data for AUS implantation using an open surgical approach, report high cure rates up to 88%, but also common complications, including mechanic failure, infection and explantation [2]. The aim of this study is to examine the efficacy and safety of laparoscopic implantation of AUS in women, in a single center with 12 years of experience.

Study design, materials and methods
This study consists in an update of the data available in the largest prospective case-series trial of laparoscopic AUS implantation [3]. From 2005 up to date, 65 female patients with SUI have been submitted to laparoscopic implantation of the AMS 800 Urinary Control System (Boston Scientific, Marborough, MA, USA) after written inform consent. Patients' selection was carried out after clinical examination, urodynamic evaluation and individual motivation. Inclusion criteria were: women with primary or recurrent SUI with/without pelvic organ prolapse; urodynamic findings of low maximum urethral closure pressure (MUCL<20cm H_2O) and low Valsalva leak point pressure (VLPP<60cm H_2O), normal detrusor's function and bladder's compliance; no cervical-urethral hypermobility; a negative Ulmsten test (urine leakage on straining or coughing not corrected by urethral support); absence of cognitive and mobility dysfunction. Exclusion criteria included: monosymptomatic urge incontinence and previous pelvic radiotherapy. Patients' main characteristics are summarized in Table 1. All laparoscopic procedures were performed by two experienced urologists using the same technique. Patients were positioned on a 30-degree Trendelenburg dorsal lithotomy position. Using a transperitoneal approach, the urethra was dissected after the incision of the endopelvic fascia bilaterally and the assistance of an elongated dissector inserted through a "stab" incision made by one of the lateral ports. Then, after the measuring of the urethral circumference, the corresponding AUS cuff was positioned into place and the AUS reservoir was inserted into Retzius space, exteriorizing both connecting tubes. Subsequently, a space in the major labia was created, using blunt dilation, for the AUS control device and all tubing was connected. Laparoscopic sacrocolpopexy was performed in cases with concomitant pelvic organ prolapse, simultaneously. Patients were followed up in pre-scheduled time periods (3,6,9 months and then annually) after the first appointment at 6 weeks for the AUS activation and outcomes were defined as success, improvement or failure depending on the incontinence severity, while complications were documented. For statistical analysis, the IBM SPSS package v22.0 (Armonk, NY, USA) was used with $p<0.05$ indicating significance.

Results
The mean operation time was 122 ± 40.2 min. In 6 (9.2%) patients an anterior-posterior mesh was placed simultaneously for organ prolapse correction. No significant blood loss was documented and thus, there was no need for blood transfusion or procedure convention in any case. In all patients, a 61-70cmH_2O reservoir was used and several cuff lengths (5.5cm (9.2%), 6cm (15.4%), 6.5cm (30.7%), 7cm (20.0%), 7.5cm (13.8%) and 8cm (9.2%). Bladder catheter was removed at the first postoperative day in all cases, while the median hospital stay was 2 days. The mean follow-up was 31 months. The operation was successful in 49 (75.3%) patients, 10 (15.4%) patients had improvement and in 4 (6.1%) patients had failed. In terms of complications, there was only one intraoperative vaginal erosion that was repaired at the spot, 1 (1.5%) postoperative pelvic pain, 5 (7.7%) infections, 5 (7.7%) urinary retentions. De-novo late urgency presented in 8 (12.3%) patients which required anticholinergic medication 6 (9.2%), neuromodulation or intradetrusor onabotoliumtoxin-A injection 2 (3.1%). 12 (18.4%) patients required during follow-up surgical re-implantation mainly caused by mechanical dysfunction 6 (9.2%), erosion 5 (7.6%) and infection 1 (1.5%). In 8 (12.3%) patients the device was permanently removed.

Table 1. Basic patients' characteristics.

No of patients	65
Age (mean ± SD)	67.2 + 12.4
Body mass index (mean ± SD)	29.6 + 5.8
Diabetes, n (%)	13 (20)
Hypertension, n (%)	32 (49.2)
Obstetric history	
Nulliparous	9 (13.8)
<3 deliveries	46 (70.8)
≥3 deliveries	10 (15.4)
Dystocic deliveries	11 (16.9)
History of pelvic urogynecological surgery, n (%)	55 (84.6)
Hysterectomy	28 (43.0)
Vaginal	5 (7.7)
Suprapubic	23 (35.4)
Antincontinence surgery	53 (81.6)
TOT procedure	32 (49.2)
TVT procedure	7 (10.7)
Burch procedure	9 (13.8)
Marshall–Marchetti procedure	1 (1.5)
Artificial urinary sphincter (vaginal approach)	3 (4.6)
Surgical prolapse repair	17 (26.1)
Laparoscopic sacrocolpopexy	6 (9.2)
Abdominal sacrocolpopexy	3 (4.6)
Vaginal prolapse repair	6 (9.2)
Maximum urethral closure pressure, mean ± SD (cmH_2O)	15.9 + 5.9

Interpretation of results

In our series, it is demonstrated that Laparoscopic AUS implantation is comparable with standard AUS procedures in terms of efficacy and safety. 75.3% of patients were dry after the procedure. The main complication still was explantation which required revision and AUS removal. Laparoscopic approach, as a minimal-invasive procedure, has the advantage of safer urethral dissection, shorter patient's hospitalization, minimal post-operative pain, minor trauma and excellent cosmetic result. On the other hand, our study illustrates the 12-year-long experience in a retrospective series set and lacks comparison or randomization, creating a relevant bias.

Concluding message

According to our experience, laparoscopic AUS implantation is an option in selected patients with severe incontinence and ISD. This approach is feasible and safe, achieving comparable results against the standard treatment.

References

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Disclosures

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