ORIGINAL PAPER

Eighteen years of experience in laparoscopic implantation of artificial urinary sphincter in women with intrinsic sphincter deficiency

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Summary Introduction and objectives: Artificial urinary sphincter (AUS) is a treatment option for women with stress urinary incontinence (SUI) after failure of previous surgery or as a primary procedure in severe intrinsic sphincter deficiency (ISD). The aim of the study was to assess the long-term efficacy and risk factors for surgical revision and definitive explantation of AUS laparoscopic implantation in female patients.

Methods: A retrospective review of all women submitted to AUS implantation between April 2005 and March 2023 was conducted. The AUS was implanted via transperitoneal laparoscopic approach, by two experienced surgeons. The primary endpoint was postoperative continence. Continence was defined as no leakage and no pad usage or leakage and/or pad usage with no impact on social life and failure as leakage and/or pad usage impacting social life. As secondary outcomes, clinical predictive factors for AUS revision and definitive explantation were evaluated.

Results: In the last 18 years, females with a mean age of 68 ± 12 years-old were submitted to laparoscopic implantation of AUS. Early overall complication rate was 16%, but only one case was Clavien-Dindo ≥ 3 . After a median follow-up of 67 months, 22.2% of the patients needed a device revision, the majority due to mechanical device dysfunction. AUS definitive explantation was performed in 16%, mainly due to urethral/vaginal erosion (9.9%) and infection (6.2%). Patients with age \geq 70 years and follow-up ≥ 10 years significantly predisposed for device revision. At the time of the last follow-up, 72% of the patients were keeping the urinary continency.

Conclusions: Laparoscopic AUS implantation in females is an effective treatment for SUI due to ISD. Meanwhile, adequate patient selection, multidisciplinary evaluation and careful expectation management are essential to achieving good results, concerning their significant complication rate.

KEY WORDS: Artificial urinary sphincter; Female urinary incontinence; Intrinsic sphincter deficiency; Laparoscopy.

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INTRODUCTION

Stress urinary incontinence (SUI) in women is a prevalent and bothersome condition with significant impact on quality of life (1). It is mainly attributed to two pathophysiological mechanisms: urethral hypermobility and intrinsic sphincter deficiency (ISD) (2). While in the former case there is a more consensual treatment strategy, the latter has a less unanimous management approach. Artificial urinary sphincter (AUS) is a treatment option for women with severe SUI after failure of previous urinary incontinence surgeries and/or as a primary procedure in severe ISD (3, 4). However, since it is a challenging technique with high risk morbidity and due to the paucity of longterm follow-up, its current role in the surgical treatment of SUI is still lacking evidence. According to the European Association of Urology guidelines, AUS should be implanted only as a last resort procedure and only in expert centers. The panel recommends synthetic sling, colposuspension and autologous sling as first options in these patients. When proposing AUS, it is important to inform the patients of the high risk of complications, mechanical failure, or need for explantation (level of evidence 3, grade of recommendations: weak) (3). We report 18-year experience of AUS laparoscopic implantation in *Clinique* du Pré, assessing the long-term efficacy and risk factors for surgical revision and definitive explantation of AUS laparoscopic implantation in female patients.

MATERIALS AND METHODS

A retrospective and descriptive review of all female patients submitted to AUS implantation between April 2005 and March 2023 was conducted. Eighty-one females with SUI as a result of ISD were treated with laparoscopic implantation of the AMS 800 Urinary Control System (Boston Scientific, Marborough, MA, USA). All patients were diagnosed with ISD based on clinical history, physical examination and urodynamics, namely maximum urethral closure pressures (MUCP) and Valsalva leak point (VLPP). Manual dexterity was determined as no evidence of cognitive impairment, extremity weakening or tremor. Inclusion criteria included: motived women with type III incontinence, with proper dexterity and with no cervical urethral hypermobility; negative Marshall/Bonney or Ulmsten test (urine leakage on straining or coughing not corrected by urethral support); MUCP under 20 cmH₂O and a VLPP under 60 cmH₂O; and normal detrusor function and bladder compliance. Previous anti-incontinence procedures or the presence of genital prolapse were not a contraindication for AUS implantation. Patients with urge incontinence alone or previously submitted to pelvic radiotherapy were excluded. The AUS was implanted via transperitoneal laparoscopic approach, by two experienced surgeons, according to a previous described technique (5, 6). In cases of 132 concomitant genitourinary prolapse, laparoscopic anterior and posterior mesh sacrocolpopexy was carried out before inserting the AUS components, according to a previous described technique (7, 8). Informed consent was obtained from all patients. Patients were assessed at 6 weeks (sphincter activation), on periodical follow-up visits at 3-, 6- and 12-months post-operative and yearly subsequently. Data collected included demographic and baseline characteristics; surgical procedure details; post operative results and complications; revision for partial or total component replacement, deactivation and definitive explantation rates, as well as their causes; and current continence. The primary endpoint was postoperative continence. Continence was defined as no leakage and no pad usage or leakage and/or pad usage with no impact on social life and failure as leakage and/or pad usage impacting social life. The results were evaluated short term (1 year after implantation) and long term (at last follow-up), based on clinical interviews. As secondary outcomes, clinical predictive factors of AUS revision and definitive explantation were assessed.

Statistical analyses were performed using IBM SPSS Statistics software version 25. Categorical variables are presented as frequencies and percentages, and continuous variables as means and standard deviations, or medians and interquartile ranges for variables with skewed distributions. Pearson's chi-squared or Fisher's Exact test were used to test for associations in categorical variables. Simple and multiple logistic regression were performed to determine clinical predictive factors of need of revision and definitive explantation AUS surgery. A p-value ≤ 0.05 was considered statistically significant.

RESULTS

In the last 18 years, 81 females with a mean age of $68 \pm$ 12 years-old were submitted to laparoscopic implantation of AUS. All patients reported continual use of pads (> 3 pads/day). The median body index mass (BMI) was 29 kg/m² (IQR 25-35). The patients' medical history included hypertension (49.4%), anxiety/depression (17.3%), diabetes (17.3%), smoking (14.8%) and asthma or others pulmonary diseases (16.0%). In 4 patients (5.1%), ISD resulted from an underlying neurological condition (three myelomeningocele and one spinal cord injury). Most of the patients had previous pregnancies (64.5%) and the mean number of deliveries per patient was 2 ± 1. A total of 12 patients underwent to a primary AUS implantation without previous urogynecological surgeries as a result of severe ISD. Regarding previous surgeries, 38.3% underwent a hysterectomy, 84% incontinence surgery (mainly midurethral slings) and 27.1% prolapse surgery (mainly laparoscopic sacropromontofixation). A history of other abdominal or pelvic surgeries was present in 49.4% of patients, for example appendicectomy or cholecystecto-

Table 1.

Patient characteristics.

Variables	Value
No, patients included (n)	81
Age (years) [Mean ± SD]	68 ± 12
Body mass index (Kg/m ²) [Median (IQR)]	29 (25-35)
Diabetes, n (%)	14 (17.3)
Hypertension, n (%)	40 (49.4)
Smoking, n (%)	12 (14.8)
Anxiety or depression, n (%)	14 (17.3)
Asthma or others pulmonary diseases, n (%)	13 (16.0)
Previous birth number, [Mean ± SD]	2 ± 1
History of pelvic urogynecological surgery, n (%)	
Hysterectomy	31 (38.3)
Vaginal	7 (9.3)
Suprapubic	19 (25.3)
Laparoscopy	1 (1.3)
Missing data	4 (4.9)
Anti-incontinence surgery	69 (85.2)
TOT procedure	48 (59.3)
TVT procedure	7 (8.6)
Burch procedure	9 (11.1)
Marshall-Marchetti procedure	3 (3.7)
Artificial urinary sphincter (vaginal approach)	2 (2.5)
Surgical prolapse repair	14 (17.3)
Laparoscopic sacrocolpopexy	8 (9.9)
Abdominal sacrocolpopexy	2 (2.5)
Vaginal prolapse repair	3 (3.7)
Missing data	1 (1.2)
Others previous laparoscopic surgeries, n (%)	40 (49.4)
Maximum urethral closure pressure (cmH_O) [Median (IQR)]	16 (12-20)

my. On urodynamics, median MUCP was 16 cmH₂O (IQR 12-20). Patients' characteristics are summarized in Table 1. Mean operative time was 115 ± 40 minutes (range to 50-190 min). No case of laparotomy conversion was reported. In 6 cases, simultaneous laparoscopic anterior and posterior sacrocolpopexy was carried out. Intraoperative blood loss was negligible with no need of blood transfusion. The most frequently chosen cuff length was 7 cm (48.6%) and all patients had balloon pressure of 61-70 cmH₂O in the reservoir. The average length of hospital stay was 2 days (with a range of 1 to 8 days). There were no intraoperative complications, except for one small vaginal perforation (less than 1 cm). It was immediately repaired in two layers with resorbable sutures and without any comorbidity involved. Early overall complication rate was 16% (n = 13). Most were Clavien-Dindo as acute pelvic pain, urinary tract infections and acute urinary retention. Just one case of Clavien-Dindo \geq 3 was observed: a sepsis due to sphincter infection with necessity of AUS removal; the follow-up of this patient was lost. Considering the functional outcomes in the first 12 months, 77 patients were continent (96.3%) and 3(3.8%) had unchanged incontinence. After a median follow-up of 67 months (IOR 14-110), 48 of the patients were continent (72%). The follow-up was lost in 14 cases. Eighteen patients needed a device revision (22.2%). All revision surgeries were performed laparo-

	Device Revision				AUS definitive explantation			
Variables	Simple logistic regression	Multiple logistic regression			Simple logistic regression	Multiple logistic regression		
	P value	95% CI	OR	P value	P value	95% CI	OR	P value
Age \geq 70 years	0.03	0.08- 0.93	0.27	0.04	0.46			
Obesity	0.23				0.08			
Diabetes	0.50			0.04	0.36			
Hypertension	0.31				0.73			
Smoking	0.06				0.40			
Asthma or others pulmonary diseases	0.72				1.00			
Obstetric history	0.98				0.76			
History of previous hysterectomy	0.95				0.55			
History of previous anti-incontinence surgeries	1.00				1.00			
History of previous prolapse surgeries	0.37				0.04			0.13
History of other abdominal or pelvic surgeries	0.06			0.08	0.03			0.06
MUCP ≤ 16	0.71				1.00			
AUS surgery time > 10 years	0.01	1.67-18.1	5.5	0.01	0.28			
Surgery time ≥ 120 minutes	0.81				0.13			0.337
AUS: artificial urinary sphincter; MUCP: maximum urethr	al closure pressure.							

Table 2.

Simple and Multiple logistic regression analyses of clinical parameters in predicting device revision (n = 18) and AUS definitive explantation (n = 13).

scopically. Most of them were needed to mechanical device dysfunction (n = 12, 14.8%) such as perforation of the cuff/balloon/tubing or depressurization of the system. Failure in achieving continence, need for pump reposition and periurethral atrophy with cuff dislodgement (loss of weight in obese patients) were additional reasons for device revisions (n = 6, 7.4%). The mean time between implantation and device 197 exchange due to mechanical problems was 76 ± 49 months. Patients with age \geq 70 years and follow-up \geq 10 years significantly predisposed for device revision (OR = 0.27, 95% CI [0.08,0.93], p = 0.04 and OR = 5.5, 95% CI [1.67, 18.1], p = 0.01, respectively). Nine patients (11.1%) required AUS deactivation. The main reasons were decreased manual dexterity or cognitive ability due to diseases such as rheumatism, dementia and bedridden patients. These pathologies resulting in poor bladder emptying with high postvoiding residues, frequent urinary tract infections and incontinence were the main reasons to AUS deactivation. Two of these patients had permanent catheterization and the others used adsorbent pads. AUS definitive explantation was performed in thirteen patients (16%), mainly due to urethral/vaginal erosion (n = 8, 9.9%) and infection (n = 5, 6.2%). The median time between implantation and definite explantation was 38 months (IQR 2-75). Diabetes, history of previous prolapse surgery or history of other previous abdominal or pelvic surgeries are significantly associated with definitive explantation rate on univariate analyses but not in multivariate analyses.

DISCUSSION

AUS implantation in females is an effective long-term treatment for SUI due to ISD with a good postoperative success rate. With a median follow-up of 6-years, 72% of the patients were continent. The excellent functional outcomes of AUS in female patients with SIU due to ISD have been reported for decades (9). The definition of ISD is controversial, however, most authors advocate the use of a

combination of clinical and urodynamic criteria. The combined presence of a negative urodynamic evaluation and negative Marshall-Bonney and Ulmsten tests is the most favoured scenario to AUS implantation in women with non-neurogenic SUI (10). Peyronnet et al performed a systematic review and showed the complete continence rates and improved incontinence ranged from 61.1% to 100% and 81% to 100%, respectively, regardless of the surgical approach (11). Reus et al demonstrated that the outcome "zero to one pad" varied between 58% and 100% in the female AUS implantation (12). Comparing to other SIU surgeries, as transobturador tape outcomes, the cure rate was lower in females with ISD combined with fixed urethra (67%) (13). Women with low urethral closure pressure, isolated or combined with a lack of urethral mobility, have an increased risk of refractory SUI after midurethral slings, as high as 75% (14). The main theorical advantage of AUS over other surgical options for female SUI due to ISD is that it is the only anti-incontinence procedure that can mimic the physiological function of the sphincter with the ability to restore both normal storage and voiding function by increasing the outlet resistance at rest when the cuff is closed but maintaining low resistance during the voiding phase with the cuff being opened (11) Despite its efficacy there is a non-negligible associated morbidity. The revision rate (22.2%), including mechanical failure (14.8%) and explantation rate (16%), is comparable to those in the current literature. A recent systematic review reported revision rates ranging between 6 to 45%, with mechanical failure between 2% to 41%. The explantation rate due to infection and/or erosion varied between 2% to 31% (12). Peyronnet et al also reported explantation rates up to 45% (11). During the last decades, the retropubic open approach was the most popular, but the rise of minimally invasive surgical approaches reduced the inherent morbidity (9). The main advantage of laparoscopic and robotic-assisted approach is the easier access to the pelvis and better dissection of the bladder neck with better visualization, especially in obese patients (15). Mandron and colleagues were the first teams to publish their preliminary experience in laparoscopic AUS implantation in the late 2000s. Some of these patients were included in this cohort. They reported good results, as 82.6% of the patients were continent at a mean follow-up of 26.1 months (6). In the last years, several series with a roboticassisted approach were published, including "anterior" robotic technique and more recently a "posterior" technique (16-18). Considering the laparoscopic or robotic approaches, the continence rate reported as zero pads ranged from 63% to 83% in female patients, similar to what demonstrated in open technique (42 to 86%) (12). To our knowledge, there was only one study comparing robotic to open approach and reported a significantly decrease in intra- and postoperative complications rate with similar continence results (17). Robotic approach allows lower technical complexity, enhanced dexterity, better mobility of the instruments and physiological tremor filtering relatively to the laparoscopic route (9, 19). Given the limited information available in literature, it is still early to compare the performance and safety of the different surgical techniques and further prospective studies are required. We believe that the differences in complication and explantation rates between centers can be explained by distinct levels of experience. There was low level of evidence-based data, with significant clinical and methodological heterogeneity across studies. Most of the studies had a limited number of patients, had mainly short-term follow-up and were single-center retrospective in nature. The VENUS study is a prospective cohort study in recruitment with the purpose to evaluate the outcomes of female AUS surgery involving 25 European centers, including robotic assisted, laparoscopic and open patients. When compared to other works, our results are similar with the ones from larger series which may reflect that surgical experience and high volume could favour successful outcomes. As the AUS implantation is more demanding than sling procedures, specialized centers with a proper training are required to perform this surgery (10). Therefore, we believe that AUS implantation must be restrict to a limited number of hospitals/centers worldwide. It was advocated that the specialized centers are trained in making the correct diagnosis, had experience to perform other surgical interventions for SUI (not limiting the patients' choice) and, more importantly, had experience in managing the complications of AUS implantation (10). The optimal time to AUS implantation was unknown and AUS was rarely used as a first surgical intervention. Some authors support performing the procedure after failure of at least one and a maximum of two previous interventions. The number of previous anti-incontinence procedures decreases the success rate of AUS and increases the risk of erosion (10, 12, 16). In our study the number of previous surgeries did not correlate with the success rate. However, we demonstrate that advanced age and long-term AUS (more than 10 years) significantly predisposed for device change. The median time until mechanical failure was 76 months, which corresponds to approximately 6 years of device survival. Device failure was managed by either exchange of the damaged component or by total replacement, without the need of definitive explantation. Chung et al advised that all patients need to be informed that the risk for potential revision surgery increases with time; in his cohort the median time of AUS revision surgery was 88 months and he demonstrated that women with more than 35 years had more revision or removal surgery for cuff erosion and infection (20). Other study reported that a presence of higher BMI (more than 30 kg/m²) and multiple surgeries were associated with higher revision rates (21). In the literature, the major risk factors for explantation are pelvic irradiation, age > 70years, neurological pathology and history of pelvic surgery, including the Burch procedure and sacral colpopexy (16, 22, 23). In our cohort, history of diabetes, previous prolapse surgery or other previous abdomino-pelvic surgeries may predispose for definitive explanation, although these association were not statistically significant. Our study had several limitations. First, the single-center, retrospective design of the study and the fact that the procedures were performed by two surgeons with extensive experience in the implantation of AUS, limit the generalization of the results to centers with a low volume of procedures. Second, the absence of a validated incontinence questionnaire, since our surgeries started 18 years ago, to evaluate patient satisfaction. Thirdly, larger studies, prospective and randomized, are required to properly evaluate the value of laparoscopic female AUS implantation compared with the open or robotic approaches and other therapeutic options (eg, pubovaginal sling). Regarding the risk factors of surgical revision and definitive AUS explantation, more studies are needed.

CONCLUSIONS

Laparoscopic AUS implantation in females is an effective treatment for SUI due to ISD. Meanwhile, adequate patient selection, multidisciplinary evaluation and careful expectation management are essential to achieving good results, concerning their significant complication rate. The patients should be informed about the high risk of complications, need to surgical revision, mechanical failure or need for explantation. More studies are needed to identify the best approach and best candidates for the surgical intervention.

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