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ORIGINAL PAPER

Adjustable bulbourethral male sling: Experience after 30 cases of moderate to severe male stress urinary incontinence

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Summary *Objective: To report our experience using the Argus perineal sling from July 2015 to April 2018 for male stress urinary incontinence (SUI) after prostatic surgery. To evaluate the safety, efficacy and health-related quality of life in patients undergoing this procedure.*
Patients and methods: The positioning of an adjustable bulbourethral male sling provides a perineal incision, exposure of the bulbospongiosus muscle and the application of the sling bearing on it with transobturator passage of the two extremities with out-in technique. To modulate the bearing tension on the urethra, with a rigid cystoscope the Retrogade Leak Point Pressure is measured, increasing it by 10-15 cm of H20 from baseline. We retrospectively evaluated the results of this implant performed by the same operator on 30 patients who presented post-operative SUI from medium to severe (> = 2 pads/day, pad test at one hour > = 11 g). Mean operative time and possible intra and postoperative complications were evaluated. Postoperatively each patient was reassessed according to the following parameters: number of pads consumed/die, pad tesy at one hour, ICQS-F, any related side effects.
Results: After the intervention, 21 of 30 patients (70% of the total) were totally continent (< 1 pad / day, pad test at 1 h < 1-2 g, ICQS-F < 11), out of them 4 required a single adjustment at 3 months in order to achieve this result. 9 of 30 patients (30 %) achieved a clinically significant improvement without obtaining total continence (mean reduction of the n° pads/day: -2.5 ± 1 DS; average reduction of the pad test at 1 h: -20 g ± 4 DS; ICQS-F average reduction: -6 points ± 2 DS), out of them 5 required a 3 month adjustment to obtain these improvements resulting, 4 needed 2 adjustments resulting because the first adjustment was not satisfactory and one who ameliorated from severe to moderate incontinence decided to live in this clinical condition.
Conclusions: The results of our study show that the positioning of this sling represents a valid treatment for the moderate and severe post-surgical male SUI. The possibility of adjusting the tension of the sleeve in a "second look" makes the intervention adaptable according to the results obtained. Only multicentric clinical trials on larger series would clarify and eventually confirm the clinical benefits of this sling in post-surgical male SUI.

KEY WORDS: *Male stress urinary incontinence; Sling; Prostatectomy.*

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INTRODUCTION

Stress urinary incontinence (SUI), defined according to *International Continence society* (ICS) as leakage from the urethra synchronously with exertion/effort or sneezing/coughing (1), can be listed within iatrogenic complications following different prostatic surgeries.
This condition represents a major issue since it has been proven that its occurrence negatively impacts patients' *quality of life* (QoL), leading to withdrawal from social activities (2-6) and affecting primary disease treatments outcomes (7, 8).
In these cases, according to different surgical technique implemented, the incidence of male SUI widely ranges, showing 0-2% rate following benign prostatic surgery and 5-35% after *radical prostatectomy* (RP) (9, 10). These high differences in SUI incidences can be due to a wide variation within different continence definitions, variable diagnostic evaluation, inclusion/exclusion criteria and type of surgical procedures performed among available literature evidence (11). It is important to remember that the incidence of this disorder will also depend on the general condition of the patient before surgery (26). This can change the risk that each individual patient will have to develop post-operative IUS.
According to the *European Association of Urology* (EAU) guidelines, surgical treatment is recommended when initial conservative treatments (i.e. floor muscle training, biofeedback and behavioral modifications) failed.
Artificial urinary sphincter (*AUS, AMS 800®, American Medical Systems, USA*) represents the gold standard to treat SUI, achieving continence rate of 59-90% with high patient satisfaction and best long-term outcomes (10, 12-14). Nevertheless, mechanical failure, infection or erosion have been documented within 25% at 10 years (15). Implantation of male sling either fixed (*Advance®, American Medical Systems, Minnetonka, MN, USA) or adjustable (ARGUS®, Promedon SA, Cordoba, Argentina; REEMEX®, Neomedic International, Barcelona, Spain; ATOMS®, Agency for Medical Innovations A.M.I., Feldkirch, Austria*) has been considered an option for surgical treatment of SUI following prostatic surgery (13). Even if the AUS demonstrated superior long-term outcomes, slings are attractive to patients since these devices showed sev-

eral advantages: absence of mechanical parts, no need for device training, immediate efficacy and no need to cycle device before micturition (16).

Argus® (*Promedon SA; Cordoba, Argentina*) adjustable male sling system is a minimally invasive device developed to treat male SUI and to achieve urinary continence. The possibility of intraoperative adjustments and postsurgical readjustments represent its main advantage allowing the necessary coaptation of the bulbar urethra, with low tension, reaching the needs of each patient and at the same time minimizing risks of erosion, ischemia and urine retention.

The aim of the present study was to report our preliminary results with the implementation of Argus male perineal sling for male SUI after prostatic surgery. To this purpose, we evaluated efficacy, safety and patients' health-related QoL outcomes in our retrospective cohort of patients suffering from SUI.

Materials and methods

The following analysis represents a single-center study in which 30 men who underwent male Argus sling implant as treatment for SUI following prostatic surgery were retrospectively reviewed from July 2015 to April 2018.

The study received formal Institutional Review Board. Written informed consent was obtained from all enrolled patients. Patients were informed about the opportunity for AUS implantation as well as risks and benefits of the Argus sling positioning, including the possible need of additional surgeries over the time.

All patients were suffering from moderate to severe SUI as result of prostatic surgery as follows: 23 (76.7%) post *Radical Prostatectomy* (RP), 5 (16.7%) post RP followed by adjuvant *Radiotherapy* (RT), 1 (3.3%) post *transurethral resection of the prostate* (TURP) and 1 (3.3%) post *Holmium laser enucleation of the prostate* (HoLEP) (Table 1). Three out of 30 patients (10%) had previously undergone an adjustable non-circumferential constrictor that was simultaneously explanted during the sling placement.

All patients presenting with persistent moderate to severe SUI (≥ 2 pads/day, pad Test at one hour ≥ 11 g) for > 1 year after surgery, despite conservative treatments, were enrolled in our study.

Patients previously diagnosed with urethral stricture, bladder neck sclerosis and/or bladder overactivity were excluded.

All procedures were performed by the same single surgeon. According to Romano et al, the technique was previously described (17).

Table 1.

Causes of SUI and previous surgery characteristics of the 30 men who underwent male Argus sling implant.

Parameter	Number (%)
RP	23 (76.7)
RP+RT	5 (16.7)
TURP	1 (3.3)
HoLEP	1 (3.3)

RP = Radical Prostatectomy; RT = Radiotherapy; TURP = transurethral resection of the prostate; HoLEP = Holmium laser enucleation of the prostate.

The positioning of the ARGUS sling (*Promedon SA, Cordoba, Argentina*) consisted in a perineal incision followed by exposure of the bulbospongiosus muscle and the application of the sling bearing on it with transobturator passage of the two extremities with out-in technique. Two vials of Gentamicin 80 mg were distributed at the level of the exposed tissues following the 3 incisions and always after positioning the sling. To modulate the bearing tension on the urethra, with a rigid cystoscope (Optic 0°) the Retrogade Leak Point Pressure was measured, increasing it by 10-15 cm of H20 from baseline without exceeding 40 cm of H20.

All patients were evaluated at baseline before surgery, and then every 3 months for 2 years.

Pre-operative assessment included: number of pads used/day; pad-test at one hour (mild SUI < 10 g, moderate between 11 and 50 g, severe > 50 g); administration of the *International Consultation on Incontinence Questionnaire - Short Form* (ICQS-F) (pathological value > 11, score 0-21); cystoscopy (to assess the presence and extent of the sphincter deficiency and to exclude post-surgical neck sclerosis or urethral stricture); urodynamic examination.

Mean operative time and possible intra and post-operative complications were collected.

Post-operatively each patient was evaluated according to the following parameters: number of pads used/day, pad-test at one hour, ICQS-F, any related side effects.

We defined patients as either totally continent if they were using no pads to 1 security pad/day or a urinary leakage of < 1-2 g at 1 h, or with a significant improvement if there was a reduction of > 50% in number of pads used/day or urinary leakage at 1 h.

Results

Overall, 30 men with median age of 73.5 years (range 51-79) undergone our male sling implant and were evaluated with a median follow-up of 13.5 months (range 3-24). Results reported are those obtained from the last follow-up visit of each patient. Surgical procedures were carried out within median operative time of 58 minutes (range 38-95) and no intraoperative complications were reported.

Postoperatively 21 out of 30 patients (70%) were totally continent (< 1 pad/day, pad-test at 1 h < 1-2 g, ICQS-F < 11); of these 4 (13.3%) required a single adjustment of the sling 3 months after the intervention in order to achieve continence. Nine out of 30 patients (30%) found a clinically significant improvement in their continence, with a mean reduction of the number of pads used/day of -2.5 ± 1, a mean reduction of the pad-test at 1 h of -20 ± 4 g and a mean reduction of ICQS-F of -6 ± 2 points. Out of these, 5 (16.7%) required single adjustment of the sling at 3 months to obtain this result, while 4 (13.3%) needed 2 revisions (at 3 and 6 months, respectively) since they were not satisfied after the first adjustment. All of these 9 patients presented with a severe pre-operative SUI (> 5 pads/die, pad-test at 1 h > 50 g, ICIQ-SF score 21), and 5 out of 9 were previously submitted to RT. The mean operative time for surgical revisions (increase of sleeve tension on the urethra) was 35 ± 8 min.

Early post-operative complications to report included: difficulties in emptying the bladder, which occurred in 3

patients (10%) and resolved spontaneously within 18 days (range 14-21); perineal and/or inguinal pain, which occurred in 17 patients (56.6%) and was conservatively managed with the use of NSAIDs (none required sling removal) within a maximum of 45 days (range 18-45).

Discussion

Male SUI almost exclusively recognizes prostatic surgery as a leading cause responsible for the majority of the cases. Injuries of the distal urethral sphincter are the basis of the pathophysiology of this form of incontinence. TURP, Holep and open adenomectomy give relatively low 1-year incontinence rates achieving 1% at 12 months after surgery (18). On the contrary RP has a higher percentage of risk, especially in elderly patients and associated with pelvic radiation or a previous TURP (14). Ficarra et al in their recent systematic review found that the mean continence rates at 12 months were 89-100% for patients treated with *Robotic-assisted laparoscopic prostatectomy* (RALP) and 80-97% for patients treated with *radical retropubic prostatectomy* (RRP) (19). A prospective controlled non-randomized trial of patients undergone RP in 14 centers using RALP or RRP showed an incontinence rate of 21.3% and 20.2% at 12 months for RALP and RRP respectively (OR 1.08, 95%CI: 0.87-1.34) (20).

Regardless of the considered studies it seems that increased surgical experience has lowered the complication rates of RP and improved cancer cure (21). The placement of an AUS represents today the first line treatment for male SUI. Despite it is the most established surgical procedure, with a high degree of patients' satisfaction and success (59-90%), it has shown a risk of revision due to mechanical failure, infection or erosion of 25% at 10 years (15). According to these considerations, over the last decade, a raising interest in male sling to treat SUI has been developed. In 2007, *Rehder and Gozzi* published their pilot study on the use of *AdVance®*, transobturator fixed sling which aimed to re-establish the anatomical position of the external sphincter (22, 23). In order to avoid overcorrection and to enable the sling to adapt to functional or anatomical changes in the patients, adjustable systems have been developed. The ARGUS system has become a valid option since it has countless advantages: minimally invasive approach, no exposure of the urethra, average learning curve and, above all, the possibility of adjusting the tension of the sleeve on the urethra, which allows us to "*customize the sling*" for each type of urinary incontinence.

In our series the percentage of patients with total post-operative continence was 70% with a median follow-up of 13.5 months. This percentage is similar to those reported by the current literature. *Hubner WA et al.* demonstrated a total continence rate of 79.2% in their 101 patient series after a 2.1 year mean follow-up (24). *Romano SV et al.* obtained 73% of continence rate in 48 patients after a mean follow-up of 7.5 months (17).

Regarding readjustments of the sling tension, the extreme ease and the reduced operating time reported in our series (mean operative time 35 ± 8 min), make this treatment extremely personalized and adaptable to each single case.

In the present study, post-operative sling adjustments (one or more) were necessary in 43.3% of patients, due to either persistence of incontinence or patient's dissatisfaction. This percentage is higher than those experienced by *Romano SV et al.* (4 cases, 8%) and *Hubner WA et al.* (39 cases, 38.6%) (17, 24).

The most frequent complication experienced in our patient series was inguinal and/or perineal pain (56.6% of patients), which has always been transient and never required explant of the device.

Interestingly, in our study, none of the cases experienced erosion and/or infection of the sling that required removal of the device. This data significantly differs from other available evidences in which infection and device removal rates of the sling are 5.4-8% and 10-15%, respectively (24, 25). This result could be explained by several factors: 1. the sling was opened only after the needle has passed through the obturator foramen; 2. the routinary use of 2 vials of Gentamicin 80 mg for each operation; 3. the positioning of the sling was always performed by the same operator who already had therefore a considerable experience.

In men who underwent adjuvant pelvic RT, the efficacy of the sling is unclear and results in the literature are still conflicting. Hubner et al in their series with 22 radiated men reported a good success rate of 90.9% (20 of 22 patients were dry) and a sling explantation rate of 9.1% (2 of 22 patients) (24); differently, Bochove-Overgaauw and Schrier in a series of 13 radiated men found a significantly worse success rate (15%, 2 of 13 patients) and sling explantation rate (27%, 4 of 15 patients) (25). In our study all 5 cases with a prior RT found a clinically significant improvement in their continence, thus demonstrating the feasibility of this surgery also in radiated patients.

Several limitations of our study should be acknowledged. Our sample size was limited to 30 cases, thus affecting clinical deducible implications from our analysis. The design of the present study is retrospective without a control arm for comparison. All surgical procedures were performed by a single experienced urologist and results may be a related to the surgical skills of the surgeon and may not be similar for naïve operators. Our follow-up does not allow an evaluation of efficacy and complications occurred 24 months after surgery, thus a longer follow-up should be necessary to report efficacy and safety data over the time.

Conclusions

Results from our study show that implantation of this type of sling represents a valid option to treat moderate and severe post-surgical male SUI. The technique by not providing exposure to the urethra minimizes the risk of iatrogenic damage, erosion and infection of the device and is feasible in radiated patients, especially if performed by experienced surgeons. On the other hand, the possibility to adjust postoperatively the tension of the sleeve makes the intervention adaptable according to the obtained results, thus achieving better patients' compliance and continence rate. Only multi-centric clinical trials with a larger cohort of patients could clarify and eventually confirm the clinical benefits of this sling in post-surgical male SUI.

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