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ORIGINAL ARTICLE

Functional follow-up after Advance® and Advance XP® male sling surgery: assessment of predictive factors

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Abstract

Purpose To evaluate the efficacy of the Advance® and AdvanceXP® slings in men with stress urinary incontinence (SUI) post-radical prostatectomy and to identify predictive factors for outcome.

Methods Included were male patients with SUI following radical prostatectomy who had a positive "repositioning test", 24 h-pad weight (PW) test < 400 g and who were continent at night and at rest. Urgency was defined as a sudden compelling desire to pass urine, which was difficult to defer. The cure rate was defined as no pad use.

Results From February 2008 to October 2014, 24 AdVance® and 70 AdVance XP® were implanted. The median (range) follow-up was 49 (12–102) months. The overall cure rate was 77%. The preoperative 24 h PW was significantly related to the continence outcome ($p = 0.044$). A total of 12 patients (13%) presented with postoperative AUR, which was significantly related to abnormal voiding detrusor activity ($p = 0.036$). Twenty-two patients (23%) had postoperative urgency (16% "de novo"), which was significantly related to preoperative urgency ($p = 0.003$). During follow-up, a degree of deterioration of continence was observed in five patients who were classed as cured initially. To date, no reports of urethral sling erosion have been made.

Conclusions The AdVance® and AdVanceXP® slings are safe and effective in relieving SUI following post-radical prostatectomy. There were no differences between the two slings in terms of efficacy, urgency or postoperative AUR. There was a moderate rate of "de novo "urgency and low rate of loss of continence during follow-up.

Keywords Incontinence · Radical prostatectomy · Advance® sling · Urgency · Acute urinary retention

Introduction

At present, artificial urinary sphincter remains the preferred therapeutic option for many authors to treat male stress urinary incontinence (SUI) after radical prostatectomy (RP), however, this technique is not free from complications. Sub-urethral slings are associated with less frequent and potentially less severe complications and it have been proposed to treat mild male SUI after radical RP [1].

In 1961, Berry described the increase of urethral resistance by compressing the bulbous urethra with an implantable prosthesis [2]. In 2007, the first realignment or anatomical sling was described. Redher and Gozzi postulate that the AdVance® (American Medical Systems, Minnetonka, MN, USA) implant corrects the weakness presented with using a posterior support [3]. In 2010, the second generation (AdVanceXP®) was introduced [4]. This sling included updated mesh weaves with integrated tensioning fibres to stabilize the sling configuration upon implantation, plus the addition of chevron anchors on the sling arms, which are intended to enhance acute tissue fixation of the sling arms and the helical needles have been redesigned to allow for easier tunnelling.

Male sub-urethral slings are implanted with tension over the bulbous urethra. Advance® is not an obstructive device [5]; however, approximately a 6–20% rate of acute urinary retention (AUR) in the postoperative period without a clear indication of the factors involved have been published. The increased resistance created in the urethra remains

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insufficient to trigger a permanent bladder outlet obstruction, and this is probably linked to the fact that the previously reported rates of de novo urgency were low (1.8–8%) [6, 7]. However, male sling reports are based on short- to moderate-term follow-up studies, and again, the factors involved have not been clearly described.

The objective of this study was to evaluate efficacy, the AUR rate and functional outcomes (urgency and loss of continence) following implantation of the Advance® and AdvanceXP® slings in men with SUI following radical prostatectomy and to identify predictive factors.

Materials and methods

Patients

Included in the analysis were 94 consecutive patients treated with AdVance® and AdVanceXP® between February 2008 and October 2014. Randomization was not possible as the AdVance® sling was already in use before the introduction of the Advance XP® in 2010. In addition, randomization could not subsequently be justified as the AdVance XP® represented an improved system over the original AdVance®. Patients were only considered as potential subjects 1 year after the radical prostatectomy was performed. This study is registered as: Fundación IVO registry for patients undergoing sling or artificial urinary sphincter after prostate cancer treatment, with clinicaltrials.gov identifier: NCT02901392.

Preoperative assessment

Continence was assessed by means of the 24-h pad weight test (24-h PW) (two measurements 2 weeks apart) and the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-UI SF). A preoperative urodynamic assessment and flexible cystoscopy were performed in all cases. The urodynamic study (MMS Solar®, The Netherlands) was performed according to the International Continence Society criteria [8]. Bladder compliance was calculated with poor bladder compliance defined as < 20 ml/cm^3 [9]. At the start of the study, abnormal voiding detrusor activity was defined using surrogate measures: absence of detrusor contraction during pressure-flow, presence of Valsalva voiding or low detrusor pressure at maximum flow (PdetQmax < 25 cmH_2O and Qmax < 15 ml/s or PdetQmax < 30 cmH_2O and Qmax < 12 ml/s [10]. Subsequently, isovolumetric detrusor pressure (Piso) was used to evaluate detrusor underactivity [11].

Patients who were at rest/continent at night, which resulted in a positive "repositioning test", and who had a 24-h PW < 400 g were considered for AdVance®. The pad weight test is correlated to the success of sub-urethral slings and above 400 g slings are not justified [6]. In the same way, patients with salvage radiotherapy with 24 h-PW < 400 g were also considered for AUS implantation(radiotherapy may produce stenosis, loss of elasticity and reduced mobility [6].The presence of urodynamic detrusor overactivity or previous anastomotic stricture surgery was not considered as a contraindication. Written informed consent was obtained from all patients.

Surgical procedure

All slings were placed by a single surgeon (ACS), as previously described [6]. Briefly, the bulbo-spongiosus muscle is incised in its longitudinal axis and the central tendon it is sectioned distally. A helical rounded tip needle is introduced along the lateral edge of the pubic ramus, pointing towards and coming out at the uppermost corner between the urethral bulb and inferior pubic ramus. The edge of the proximal flap of the sling should be located at the origin of the central tendon previously marked. Postoperatively, urinary catheter (16F) is leaved in place for 48 h and then the patient is discharged.

Follow-up

Outcome was assessed at 3 month intervals for the first year and every 6 months thereafter. The primary outcome was a pad count, with cure defined as no longer requiring pads; all other cases were defined as failures. The loss of continence was defined as the de novo need for pads in a patient who was initially cured. The secondary outcomes were an evaluation of urgency, AUR rates and 24-h PW. Acute Urinary Retention (AUR) was a condition characterized by the sudden inability to pass urine and completely empty the urinary bladder. The definition of urgency was that used by the International Continence Society, which is the sudden compelling desire to pass urine which is difficult to defer [12]. Severe urgency episodes (with or without incontinence) was measured using the Patient Perception of Intensity of Urgency Scale (PPIUS). Eligible patients had ≥ 3 severe urgency episodes (with or without incontinence) during the 3-day voiding diary period, defined as PPIUS grades 3 and 4, and ≥ 8 micturitions/24 h [13]. Surgical complications were evaluated according to Clavien classification [14]. Complications within 30 days after sling implantation were defined as early, and all other complications were defined as late.

Statistics

For continuous data, the median and range were reported. Frequency distributions were obtained for categorical and nominal variables; comparisons were made by a Chi-square test. Statistical analysis of quantitative variables was

assessed by a two-tailed student test to determine whether the difference between two groups was statistically significant. The logistic multivariate regression analysis was applied to find the potential predictors of successful, AUR and postoperative urgency. The set of predictor factors comprised quantitative and qualitative variables.

Results

Of the 94 patients treated, the first 24 patients were treated with AdVance®, and since September 2010, the next 70 patients were treated with AdVance XP®. Median (range) follow-up was 49 (12–102) months. Baseline patient characteristics are shown in Table 1. Included were three patients with 24 h-PW > 400 g who refused an artificial urinary sphincter. No incontinence surgery was previously performed in any patient.

At 3 months, 72 patients (77%) were considered to be cured, while the remaining 22 (23%) were still incontinent. In the cured patients, surgery resulted in a reduction of the median (range) ICIQ-SF score from 14.4 (5–21) to 2.1 (0–7) ($p < 0.01$) and in a reduction of the median (range) question 3 of ICIQ-SF score (quality of live) from 6.55 (0–10) to 1.03 (0–3) ($p < 0.0001$) In the 22 treatment failures, a reduction on the median (range) ICIQ-SF score from 14.8 (9–21) to 10.6 (4–18) was observed ($p < 0.01$) and in a reduction of the median (range) question 3 of ICIQ-SF score (quality of live) from 6.82 (3–10) to 4.32 (0–10) ($p < 0.0031$). The median 24 h-PW increased from 401 to 930 g in three of the failed patients, with a decrease from 162 to 96 g ($p = 0.235$) in the remaining 19 failed patients. Potential predictors of successful surgical outcomes are detailed in Table 2. Adverse urodynamics was significantly related with continence outcome ($p = 0.049$), while preoperative 24-h PW approached significance ($p = 0.070$).The success rate with 24-h PW > 200 g was 73% (19 of 26 patients cured); the success rate with 24 h-PW > 300 g was 45% (five of eleven patients cured); three patients with 24 h-PW > 400 g were not cured. There were no differences between the types of implant. This continence rate mainly remained stable during follow-up, so at the 12, 24 months and the end of the follow-up, 71(75%), 70 (74%) and 67 patients (71%), respectively, were considered to be cured. Fifty percent (11/22) of patients with initial failure accepted a second surgery treatment: five received an artificial urinary sphincter AMS-800® (Boston Scientific, USA) (with three cured), and six patients were treated with VIRTUE® (Coloplast, Humlebaek, Denmark) sling (with two cured). In all cases, it was unnecessary to remove the existing sling.

Twelve patients (13%) presented with AUR after sling surgery; 2/24 (8.3%) AdVance® and 10/70 (14.2%) AdVance XP®. Potential predictors of AUR are detailed in Table 3. Age($p = 0.006$), Charlson Comorbidity Index

Table 1 Preoperative status: quantitative and qualitative variables (n = 94)

Parameter	Median	Range
Preoperative status: quantitative variables		
Age	66 years	52–80
Body mass index	27.5	21–39
Time between prostatectomy and sling	24 months	12–156
Maximum cystometric capacity	311 ml	80–588
Questionnaire ICIQ-UI SF score	15	5–21
24-h pad weight test	93 g	12–507
VLPP	63 cmH_2O	14–157
Parameter	No (%)	Yes (%)
Preoperative status: qualitative variables		
Anastomotic stricture treated	80 (85%)	14 (15%)
Poor sphincter function[a]	81 (86%)	13 (13.8%)
Preoperative urgency[b]	83 (88.2%)	11 (11.8%)
Adverse urodynamics (cystometry)[c]	56 (59.6%)	38 (40.4%)
Abnormal voiding detrusor activity (pressure-flow)[d]	54 (57.4%)	40 (42.6%)

VLPP Valsalva Leak Point Pressure

[a]Patients with contraction present but inferior to 1 cm were indeed included labelled as poor sphincter function

[b]International Prostate Symptom Score question 4 (urgency) > 3

[c]Cystometry: low bladder compliance or detrusor overactivity

[d]Absence of detrusor contraction during pressure-flow, presence of Valsalva voiding or low detrusor pressure at maximum flow (PdetQmax < 25 cmH_2O and Qmax < 15 ml/s or PdetQmax < 30 cm H_2O and Qmax < 12 ml/s)

Table 2 Continence results: preoperative risk factors (logistic regression)

Risk factors associated with surgical outcome	Odds ratio	IC 95%	*p*
24-h pad weight test	1.005	1.000–1.010	0.070
Age	1.984	0.830–1.066	0.849
Body mass index	1.060	0.891–1.260	0.513
Charlson Comorbidity Index	0.551	0.155–1.960	0.357
Anastomotic stricture treated	0.391	0.087–1.760	0.221
Advance® vs AdVance XP®	0.200	0.033–1.231	0.083
Repositioning test[a]	0.300	0.061–14.83	0.140
Adverse urodynamics[b]	3.794	0.007–14.294	0.049
Maximum cystometric capacity	1.002	0.995–1.008	0.614
Time between prostatectomy–Sling	0.874	0.657–1.162	0.353
Valsalva leak point pressure	1.041	0.311–3.484	0.948
Preoperative urgency[c]	0.784	0.144–4.265	0.778
Open RP vx LapRP[d]	1.346	0.420–4.311	0.617

[a]Repositioning test: complete vs poor sphincter function (patients with contraction present but inferior to 1 cm)

[b]Cystometry: low bladder compliance or detrusor overactivity

[c]International Prostate Symptom Score question 4 (urgency) > 3

[d]Open radical prostatectomy (RP) vs laparoscopy radical prostatectomy (LapRP)

Table 3 Postoperative acute urinary retention: risk factors (logistic regression)

Parameter	Odds ratio	IC95%	*p*
Age	1.492	1.123–1.983	0.006
Charlson Comorbidity Index	0.108	0.016–0.741	0.024
Anastomotic stricture treated	15.749	0.819–302.696	0.068
Advance® vs AdVance XP®	0.402	0.048–3.359	0.400
Abnormal voiding detrusor activity[a]	7.069	1.267–39.436	0.026
Maximum cystometric capacity	1.001	0.994–1.009	0.795
Qmax preoperative	0.956	0.878–1.041	0.298

Qmax maximum flow-rate

[a]Absence of detrusor contraction during pressure–flow, presence of Valsalva voiding or low detrusor pressure at maximum flow (PdetQmax < 25 cmH_2O and Qmax < 15 ml/s or PdetQmax < 30 cmH_2O and Qmax < 12 ml/s)

($p = 0.024$) and abnormal voiding detrusor activity ($p = 0.026$).was significantly related. There were no differences regarding the type of sling. In preoperative urodynamic assessment, 9 patients had abnormal voiding detrusor activity and in 3 pressure–flow study was normal. All twelve patients declined clean intermittent catheterization. A urethral catheter was successfully removed in 1 week (four patients), 2 weeks (two patients) and 3 weeks (five patients). The sling was successfully transected (one arm) 3 months later in the remaining patient (AdVance XP®). In theses 12 patients, we observed a reduction in the median preoperative compared with the median postoperative maximum flow-rate, from 18.25 ml/s (range: 6–31) to 8.89 ml/s (range: 5–14) ($p = 0.0029$). We did not observe significant differences in the postoperative maximum flow-rate in the 9 patients with preoperative abnormal voiding detrusor activity (mean 8.33 ml/s, range 5–12) and the 3 patients with preoperative normal pressure–flow (mean 10 ml/s, range 6–14) ($p = 0.478$).A cystoscopy postoperative ruled out an anastomotic stricture recurrence. The PVR was less than 150 in all cases. Two patients (2/12) presented with postoperative urgency during the follow-up period, and they received anticholinergics. As the treatment was effective, they refused the urodynamic assessment. Finally, 11 out of 12 patients remained continent at the end of the follow-up (92% success rate in this group).

Twenty-two patients (23%) had postoperative urgency: 6/24 (25%) AdVance® and 16/70 (21.6%) AdVance XP®. Thirteen of 22 patients (59%) had urgency incontinence (two patients required pads). As 7/22 patients (31.8%) had preoperative urgency the rate of de novo urgency was 16% (15/94). Potential predictors of postoperative urgency are detailed in Table 4. Preoperative urgency was significantly related with postoperative urgency ($p = 0.003$). The postoperative acute retention of urine ($p = 0.196$) and type of sling were not related ($p = 0.655$).

Five (5.2%) patients cured by surgery had a degree of deterioration of continence: three patients with urgency (two AdVance® and one AdVance XP®) after 33, 60 or 19 months of follow-up, respectively, and two patients (AdVance XP®) with SUI after 12 and 36 months, respectively.

Table 4 Postoperative urgency: risk factors (logistic regression)

Parameter	Odds ratio	IC95%	*p*
Urgency preoperative[a]	0.090	0.018–0.445	0.003
Adverse urodynamics[b]	1.254	0.387–4.070	0.706
AUR after sling	0.230	0.024–2.169	0.199
Age	1.033	0.887–1.203	0.678
Body mass index	1.026	0.871–1.208	0.762
Advance® vs AdVance XP®	0.739	0.194–2.807	0.656
Maximum cystometric capacity	0.998	0.992–1.003	0.414
Charlson comorbidity Index	0.961	0.324–2.851	0.943

AUR acute urinary retention

[a]patients had ≥ 3 severe urgency episodes (with or without incontinence) during the 3-day voiding diary period, defined as PPIUS grades 3 and 4, and ≥ 8 micturitions/24 h

[b]Preoperative cystometry: low bladder compliance or detrusor overactivity

Complications

There were no intra-operative complications. A total of 22 early postoperative complications (23.4%) were reported. Twelve patients (13%) presented with AUR, five (5.3%) with perineal-scrotal pain (Clavien I) (two AdVance® and three AdVance XP®), of which only one AdVance® patient (Clavien II) required occasional analgesia. Five patients (5.3%) had a perineal haematoma (Clavien I) (three AdVance® and two AdVance XP®). To date, there are no reports of recurrent anastomotic stricture, urethral tape erosion or any other recognized late complication.

Discussion

Following implantation of the AdVance® post-radical prostatectomy Cornu et al. reported an incontinence cure rate of 62% and up to a 86% was published by Rapoport et al. [15, 16]. However, the 20–40% failure rate makes it necessary to inform all men that there is the possibility of having additional procedures if their incontinence is not cured [17].

The degree of incontinence was shown to be the most important preoperative outcome predictor [18]. Cornu et al. found that patients with 24 h-PW > 200 g were associated with sling failure [19]. The problem with pad usage over 24 h is that the measurement does not consider a patient's level of activity [20]. To avoid this problem, Barnard et al. proposes the use of Valsalva leak-point-pressure, as measured with video-urodynamics, as a preoperative predictor of success [20]. Similar to Kowalik et al., we found no differences in sling failure for patients with high BMI [17].

The most common postoperative complication after AdVance® surgery is AUR, which has a published range of 0–30% [17, 21]. Davies et al. and Soljanik et al. did not find any changes on maximum cystometric capacity, flow-rate or detrusor pressure at maximum flow-rate [5, 22] Bauer et al. has proposed that overtensioning of the sling, especially during the removal of the Tyvek liners resulting in persistent urinary retention, is more likely to occur with the Advance XP® [23]. However, there were no differences regarding the type of sling in our experience. When the study began, abnormal voiding detrusor activity was defined using surrogate measures. With this definition, abnormal voiding detrusor activity was significantly related with postoperative AUR ($p = 0.036$). However, currently, maximum isometric detrusor pressure is considered as the standard, direct measure of detrusor contractility and should be considered in the future as a predictor factor.

According to Kowalik et al. patients with urinary retention were less likely to be cured at 3 years [17]. However, Hall et al. reported that of the 16 patients in postoperative retention, 100% were completely continent compared with 26% (5/19) who passed the first trial of voiding [24]. In current series, the success rate was 92%.

Previous reported rates of de novo urgency have ranged from 0 to 8% [6, 17, 22, 23]. Currently, after a median follow-up of 49 months, a 16% "de novo" urgency rate was observed. With this rate, routine use of standardized questionnaires for urgency would be justified and useful in future studies.

Rehder et al. reported consisted cure rates up to 3 years: 53.8% at 12 months and 53% at 36 months [18]. However, Li et al. [21] noted a decreased success rate from 87.3 to 62.5%, and Zuckerman et al. [25] reported a decline in efficacy, which seems to plateau approximately 30–36 months postoperatively. One of the possible causes of the loss of continence could be secondary to sling slippage. Nevertheless, Bauer et al. reported that there was no improvement or worsening after 2 years of follow-up after AdVance XP® surgery [4]. Finally, related to a long-term follow-up and similar to other researchers, no patients had urethral erosion, and no slings were explanted [4, 17, 24]. In our knowledge, only an isolated case of Advance urethral erosion has been published

The study has several limitations, including lack of randomization between Advance® and AdvanceXP®, this is a single-centre project and the lack of standardized questionnaires for urgency. However, having a single surgeon and single-centre eliminates much of the bias in the assessment of prognostic factors.

Conclusions

The AdVance® and AdVanceXP® sling are safe and effective treatments for men with SUI after radical prostatectomy. There are no differences between the two slings in the early success rate. Patients with a preoperative 24 h-PW > 200 g

were more likely to have sling failure. There were no differences between either sling in a satisfactory long-term functional outcome, with a moderate rate of "de novo"urgency and low rate of loss of continence.

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Author contributions ACS and JR-B designed of the research study. ACS and JD-E acquisition of data. ACS and MR-B drafting the manuscript. JD-E and JR-B performed the research. IMOR and ACS analysis and interpretation of the data. CRT and IMOR statistical analysis

Compliance with ethical standards

Conflict of interest Argimiro Collado Serra: Surgical trainer for AMS-800 and AdVance (Boston Scientific) and Virtue (Coloplast). José Domínguez-Escrig, Isabel María Ortiz Rodríguez, Miguel Ramirez-Backhaus, Carmelo Rodríguez Torreblanca and José Rubio-Briones have declared that they have no conflict of interest

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. All applicable international, national and/or institutional guidelines for the care and use of animals were followed.

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