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# Single institution experience with the transobturator sling suspension system AdVance® in the treatment of male urinary incontinence: mid-term results

**Andreas P. Berger, Alexander Strasak, Christian Seitz, Patrick Rein, Alfred Hobisch**

*Department of Urology (APB, PR, AH), Academic Teaching Hospital Feldkirch, Department of Statistics (AS), Medical University of Innsbruck, Austria and Department of Urology (CS), Barmherzige Brüder Vienna, Austria/General Hospital Bolzano, Italy*

**ABSTRACT**

*Purpose:* To evaluate the clinical outcome after placement of AdVance® sling in men with stress urinary incontinence after prostate surgery.
*Materials and Methods:* Incontinence was assessed on basis of number of pad usage. Patients´ satisfaction was evaluated using a non-validated patient questionnaire at 12 months post-operatively.
*Results:* Incontinence cure rate (no pad usage) was 61.5% (16/26) and improvement (1-2 pads per day) was seen in 26.9% (7/26). No improvement was observed in 11.5% (3/26) of patients. A total of 87.5% (21/24) of patients were very satisfied with the operation 22 months after surgery. Success rate in patients with prior radiation therapy (20% cure; 40% improvement) was significantly worse.
*Conclusions:* Placement of the AdVance® sling represents an effective and safe treatment option for patients with post prostate surgery incontinence. Patients that underwent radiotherapy after prostate surgery had lower success rate.

***Key words:*** *urinary incontinence; Prostatectomy; suburethral sling; prostate; radiotherapy*
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## INTRODUCTION

Stress Urinary Incontinence (SUI) is a major drawback of Radical Prostatectomy (RP). In the majority of men it occurs due to sphincter damage or bladder dysfunction. Progress in the surgical technique has led to a decrease in the risk of SUI and the reported one-year incidence of incontinence is less than 20% (1,2). The discrepancy in the Reported Postprostatectomy Incontinence (PPI) arises from differences in the definition of incontinence.

Male SUI may be managed by numerous approaches, such as pelvic floor exercises, pharmacotherapy and pad use. Second-line therapy involves the use of bulking agents or a sling that causes compression of the urethra or the placement of artificial urinary sphincters.

In 2006, a new transobturator polypropylene sling, The AdVance® male sling (American Medical Systems, Minnetonka, NM) for therapy mild to moderate urinary incontinence was launched in the market. The AdVance™ Male Sling System is supposed to place the proximal portion of the anterior urethra into the pelvic outlet (3). Force is applied parallel to the lumen, whereas compressive devices apply force into the lumen.

The present retrospective single institution study evaluates efficacy and safety of the AdVance®

sling in 26 men with stress urinary incontinence after prostate surgery with and without radiation therapy.

## MATERIALS AND METHODS

The retrospective analysis involved 26 male patients with SUI due to radical retropubic prostatectomy (21/26), radical perineal prostatectomy (3/26), or transurethral resection of the prostate (2/26; both with histologically proven prostate cancer). All patients were continent prior to surgery. Radiation therapy preceded AdVance® sling placement in 5 patients.

Incontinence was assessed on the basis of pad usage. All patients were evaluated with full history, physical examination and urinalysis. Urethroscopy was performed in each patient in neutral dorsal lithotomy under local anesthesia of the urethra (lidocain gel). Gentle pressure of the pointed index finger was performed to the midperineum dorsal to the level of the membranous urethra. The dorsal surface of the proximal bulb must be displaced proximally in patients facing surgery with the AdVance® sling. Because the AdVance® sling does not encompass the membranous urethra but pushes it away, tensioning the polypropylene sling positions the posterior bulbar surface parallel to the membranous urethral lumen. So a complete concentric occlusion of the urethral lumen should be observed, otherwise a compressive device (artificial sphincter) was recommended.

Patients with evidence of scarring, bladder-neck contracture, preceding bulking agents, urethral strictures and neurogenic causes of incontinence were excluded. Urodynamic studies were not performed. Uroflowmetry and residual urine measurement was performed all patients, and a 24-hour pad test was performed in 7/26 (26.9%) patients preoperatively and in all individuals postoperatively.

The time interval between primary surgery and the placement of the AdVance® sling had to exceed 6 months.

Surgery was performed as described earlier in the study by Rehder et al., who examinded the placement of the sling in detail in cadavers as well as men with stress urinary incontinence (3). Subcutaneous tunnelling of the distal ends of the sling was performed in all patients. Tensioning of the polypropylene sling was performed until there was a proximal relocation of the urethral bulb into the pelvic outlet by a distance of about 4 cm. No tensiometer was used intraoperatively. Due to anatomical studies in cadavers which have suggested a worse vascular safety margin with an inside-out approach than with outside-in the latter transobturator technique is applied. Catheter removal was performed at the 3rd postoperative day, followed by hospital discharge the next day. After catheter removal a micturition protocol was applied by exactly recording time and volume of each micturition over a time period of 24 hours with subsequent measurement of residual urine by ultrasound. In case of residual volume $\geq$ 200 mL or urinary retention, patients received a suprapubic tube until residual urine was below 100 mL.

Physical limitation was recommended for six weeks postoperatively to avoid sling loosening.

Cure was defined as no pad usage and improvement as usage of 1-2 pads per day. Patients are followed every 3 months after AdVance® sling implantation. Pad use is evaluated by personal interview, and in case of persisting incontinence by evaluation of pad weight (wet pad usage per 24 hours). All patients completed two single questions 12 months after surgery. They are asked whether they were very satisfied, satisfied, neutral, dissatisfied or very dissatisfied and if they would undergo surgery with the AdVance® sling again.

Informed consent was obtained from each patient, and the study was approved by the local Ethic review board (EK-Nr 2010-1/2).

Statistical analysis (one-sample Kolmogorov-Smkirnov test; nonparametric Wilcoxon Signed Ranks test; logistic regression model for analysis of predictors for worse outcome after surgery [age, perineal surgery, preceding radiation therapy]) was performed with the use of SPSS 17.00 software.

## RESULTS

The median patients age was 67 y.o. (range: 52-79), and median follow-up was 22 months (range: 10-27).

Six out of 24 patients with prior radical prostatectomy had non-organ confined disease (pT3), whereas 18/24 had pT2 disease on histological evaluation. 91.6% (22/24) of all men after radical prostatectomy had an actual PSA < 0.1 ng/mL, whereas 2 (one with pT3 and one with pT2 histology) presented with biochemical recurrence during follow-up. PSA relapse was not associated with clinical outcome after AdVance® sling surgery in patients with preceding radical prostatectomy. The two patients with prior palliative TUR-P presented with rising PSA.

Median time interval between primary surgery and placement of the AdVance® sling was 38.9 months (range: 6-121 months). All patients attempted pelvic floor exercises and received anticholinergics to improve continence status prior to AdVance® sling implantation. Further therapy prior to AdVance® sling placement included electrostimulation in 7 men.

The preoperative and 12- month postoperative patient-reported number of pad use was mean 5.58 (range: 2-12) and 1.06 (range: 0-7), respectively ($p < 0.001$). Mean pad use after 22 months was 1.13 pads per day (range: 0-7), which represents no statistical difference in comparison the 12 month results. The 24- hour pad test (wet pad usage per 24 hours) performed preoperatively (in 7 patients) and 12 months after surgery yielded a mean 24-h pad weight of 567 and 51 g, respectively ($p < 0.001$). Of the 26 patients, 23 (88.5%) were using 0-2 pad/d at a median follow-up of 12 months after insertion of the AdVance® sling. Those three patients using 1-2 pads per day preoperatively were all cured after sling implantation. Pad usage pre- and postoperatively after AdVance® sling implantation is shown in Table-1.

Prior to patients with previous radiotherapy were included, rate of men using 0 pad/d improved to 71.4% (15/21), and men with 1-2 pads/d improved to 23.8% (pre- and postoperative pad use: 4.83 and 0.48), resulting in 95.2% (20/21) men with 0-2 pads/d.

Five patients with preceding radiotherapy had less improvement of incontinence (mean pad usage per day decreased from 8.6 [range: 4-12] to 4.0 [range: 0-7]). Cure (defined as 0 pad/day) was observed in 1/5 patients, whereas 2/5 showed improvement (defined as 1-2 pads/day), resulting in an overall improvement in 3/5 (60%). Clinical conditions of two out of five patients did not improve after surgery, however, there was no worsening in contrast to the pad use before AdVance® sling implantation.

Preceding radiotherapy was associated with worse outcome ($p = 0.004$), in contrast to preceding perineal surgery ($p = 0.826$) and age ($p = 0.557$).

Transient urinary retention (> 200 mL) occurred in 9/26 (34.6%), which was treated with insertion of a suprapubic tube. This lead to resolution of the urinary retention in all 9 patients within a mean of 25.2 days (range: 10-56). In patients with

***Table 1 -*** *Pad usage pre- and postoperatively after AdVance® sling implantation in 26 men with stress urinary incontinence after prostate surgery after a follow-up time of 22 months.*

| number of pads | preoperatively n (%) | postoperatively n (%) |
|---|---|---|
| 0 | 0 (0%) | 16 (61.5%) |
| 1-2 | 3 (11.5%) | 7 (26.9%) |
| 3-4 | 12 (46.2%) | 2 (7.7%) |
| 5-6 | 5 (19.2%) | 0 (0%) |
| 7-8 | 2 (7.7%) | 1 (3.8%) |
| > 8 | 4 (15.4%) | 0 (0%) |

urinary retention and normal creatinine temporary medication with Diclofenac was administered.

Postoperative overall mean peak flow rates measured 12 months postoperatively showed a non-significant worsening in contrast to preoperative uroflowmetry (16.5 mL/sec vs. 15.0 mL/sec), while postoperative residual urine 12 months after surgery (24 mL; range 0-150 mL) was significantly increased (preoperative residual urine: 5 mL; range 0-40 mL); however, no further worsening was observed thereafter.

Five out of 26 (19.2%) patients felt permanent postoperative perineal pain (maximum Visual Analog Pain Scale rating of 3) which resolved spontaneously within 4 weeks. In all of these patients, infiltration with local anaesthetic (Bupivacaine 25 mg) was performed.

Clinical conditions were stable during follow-up time in 92.3% of patients (24/26). In 2 patients worsening occurred over time: one patient (no preceding radiotherapy) needed one pad only when drank of alcohol after being completely continent for 23 months. Another man with preceding radiotherapy and a preoperative use of pad 4/day observed a change for the worse (from 2 to 4 pads/day) after 12 months. No further worsening was observed in this patient. No improvement was observed over time after AdVance® sling placement.

No intraoperative complications occurred, no erosion of the urethra and no postoperative infection was observed.

Patient responses after a median time of 22 months were available for 24/26 patients. Patients were very satisfied (21/24; 87.5%), satisfied (0/26; 0%), neutral (1/24; 4.2%), dissatisfied (2/24; 8.3%) and very dissatisfied (0/24; 0%). 21/24 (87.5%) would undergo surgery with the AdVance® sling again if they had to decide while 3/24 (12.5%) would decline it.

## DISCUSSION

The Artificial Urinary Sphincter (AUS) is considered the gold standard in the treatment of postprostatectomy incontinence (PPI), however, there is a need for less invasive treatment options. On one hand, there is a significant re-operation rate > 35% after 10 years in patients with AUS implantations even in experienced hands (4). One may consider a less invasive treatment form. In addition, some men do not have sufficient fine-motor control or the motivation to operate the implanted pump used with an AUS. Male slings provide an alternative surgical treatment for patients with PPI who are not AUS candidates or who elect not to undergo AUS placement.

The AdVance® sling is a non-compressive retrourethral sling that is believed to support the dorsal structure of the sphincter. The sling that is placed at the proximal bulb moves from a vertical to a horizontal position underneath the membranous urethra. Therefore, force is applied parallel to the urethral lumen, which is in contrast to compressive devices. With the sling in correct position, which means the sling is not indenting the urethra but sliding against the back of the bulb and bringing the bulbar urethra up into the perineum, compression is unlikely to occur. Urodynamic studies after AdVance® sling implantation at baseline and 6 months postoperatively did not show any signs of obstruction (5). Urethroscopy performed immediately after surgery in the patients of the present series did not show obstruction but coaptation of the urethra that was easily “open” by simple irrigation of the urethra. Interestingly, the recently published data show varying success rates after AdVance® sling placement: While some authors report success rates between 60-80% (6,7), others observed no improvement in 36.5% and even worsening in 9% (8).

The mechanism of supporting the dorsal structure of the sphincter has extensively been described by Rocco et al., who showed that urinary leakage after radical prostatectomy might result from the shortening of anatomical and functional sphincter length due to caudal retraction of the urethral sphincteric complex and disruption of the median posterior fibrous raphe. Careful reconstruction of the posterior aspect of the rhabdosphincter during radical prostatectomy was shown to markedly shorten time to continence (9,10). The AdVance® sling mimicks this mechanism by shifting the bulbar urethra cranially and serves more as a suspension rather than a compression device, for which a sophisticated tensioning seems not to be necessary.

The technique was performed as described earlier (3), however, two points of technique are

highlighted due to its importance built on our experience: correct placement of the sling is of crucial importance, because a too distally placed sling might cause obstruction and even erode into urethra, as described in a recently case report of a patient undergoing surgery for an AdVance® sling after radical prostatectomy and external beam radiation (11). In a correctly placed sling the danger of erosion seems minimal because the mesh does not indent the urethra. Instead, it slides against the back of the bulbar urethra and draws it up into the perineum. To reach correct placement of the sling, the needle should come out in the uppermost corner of the triangle between inferior pubic ramus and bulb.

Moreover, subcutaneous tunnelling of the distal ends of the sling is performed in all patients. This might increase the holding capacity of the sling (3) and also reduce the likelihood of sling loosening.

Patient selection is of utmost importance when considering AdVance® sling placement. An important prerequisite for implantation of the AdVance® sling is preserved residual sphincter function without scar defects, which can be easily assessed by urethroscopy. Reasons for not seeing concentric occlusion of the urethral lumen during perineal compression on preoperative urethroscopy may be due to large sphincter defects. Urethral mobility is also of absolute importance. Postoperative urinoma due to dehiscence, preceding therapy with bulking agents, or extensive radiation make the urethra immobile and are, in our opinion, relative contraindications for AdVance® sling placement. For these patients, compressive or readjustable devices are recommended at our institution. The Argus® adjustable bulbourethral sling.has demonstrated good results even after external beam radiation treatment (12), whereas the Reemex system showed success in patients with intrinsic sphincter deficiency in the mid-term (13).

There is a question whether the indication for the implantation of the AdVance® sling can be extended to patients with preoperative radiotherapy or perineal surgery. Both therapies are known to potentially cause severe scarring. In the present series 3 patients underwent radical perineal prostatectomy and 5 patients had radiotherapy with a median of 64 Gy prior to AdVance® sling implantation. Pad-free rate and patient satisfaction was clearly lower in patients with prior radiotherapy, which makes the routine use of the AdVance® sling in these patients questionable. Extensive information is necessary when counselling patients with radiotherapy. This might be even more relevant nowadays due to the common usage of radiation doses beyond 70 Gy. Interestingly, perineal surgery was not associated with worse outcome; however, the low number of patients has to be considered.

A potential drawback of the AdVance® sling might be that it is not adjustable. Further investigations will be necessary to evaluate if there is a need for a readjustable sling in the long term.

It has been repeatedly shown that durability remains a primary concern with different surgical procedures for stress urinary incontinence (14,15). For this reason, one year results and results after a median f-up of 22 months are presented instead of short term results to demonstrate good durability of continence status in patients undergoing AdVance® sling placement. Stable clinical conditions have been observed in 92.3% of patients after a median follow-up of 22 months, whereas worsening of continence status was observed in 2/26 patients after placement of the AdVance® sling after 12 and 23 months. In one patient with previous radiation therapy worsening occurred after 12 months immediately after hard physical work. Loosening of the tape might have contributed to this condition. From this time, no further deterioration occurred in this patient. In accordance with the present data; Cornu, recently presented durable results after a mean follow-up of 21 months, confirming that the AdVance® sling is an efficient treatment option also in the mid-term. The mentioned study showed slightly lower success rates than the present study (no improvement in 22 vs. 11.5% of patients), but interestingly, Cornu also found a trend for an association with previous radiation therapy and treatment failure (16). Bauer and coworkers as well demonstrated a high success rate of the AdVance® sling of 51.6% cured and 23.8% improved patients after thelve months. Of great importance is the observation of no worsening at a mean follow-up of 27 months compared to the one year results in this study (17). Other studies have demonstrated that surgeons may even improve functional results with increasing experience (18).

Side effects after AdVance® sling implantation in the present study are mild. However, they oc-

cur frequently and consist of postoperative perineal pain and urinary retention. In contrast to recently published studies comprising 13 patients with PPI and AdVance® sling implantation and urinary retention rate of 15% (5) and a larger study evaluating complications after AdVance® sling implantation with a retention rate of 21.3% (19), the postoperative urinary retention rate in the present series (34.6 %) is substantially higher. Maybe surgical manipulation and consecutive swelling of the urethral mucosa might contribute to the temporary retention. After placement of a suprapubic tube, urinary retention resolved in all patients within a maximum of 8 weeks. The mechanism of urinary retention is unclear; recent urodynamic studies after AdVance® sling placement did not show obstruction (5) and also our experience is that urethroscopy performed immediately after surgery does not show signs of obstruction. The TOMS two arms bulbar sling, however, seems to have a decreased likelihood for urinary retention in patients with minor or moderate post-prostatectomy incontinence (20).

No case of de novo urgency following AdVance® sling placement was observed. This is a well-known complication after placement of midurethral slings and is attributed to obstructive or locally irritative causes (21). Due to decrease chance of urethral obstruction with AdVance® sling, de novo urgency should be rarely observed. No cases of infection or erosion were observed, however, urethroscopy was only performed immediately after surgery, but not thereafter on a routine basis. No surgical revision was necessary.

A limitation of the study is the low number of patients with preoperative evaluation of incontinence performed pad tests.

The present series demonstrates AdVance® sling placement to be safe and reproducible. The incontinence cure and improvement rate is significant; however, its use is questionable in patients with previous radiotherapy.

## CONCLUSIONS

AdVance® sling represents a safe and effective treatment for PPI and offers reproducible the mid-term results in terms of postoperative continence status. Patients with previous radiotherapy might not be optimal candidates for AdVance® sling placement.

## CONFLICT OF INTEREST

None declared.

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**Correspondence address:**
Dr. Andreas P. Berger
Department of Urology,
Academic Teaching Hospital Feldkirch
Carinagasse 47, A-6800 Feldkirch
Fax.: + 43 5522 303-7550
E-mail: andreas.p.berger@gmx.at