



The AdVance and AdVanceXP male sling in urinary incontinence: is there a difference?

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Abstract

Purpose To compare the efficacy and perioperative complications of the AdVanceXP with the original AdVance male sling.

Methods We retrospectively enrolled 109 patients with an AdVance and 185 patients with an AdVanceXP male sling. The baseline characteristics and complication rates were analyzed retrospectively. Functional outcome and quality of life were evaluated prospectively by standardized, validated questionnaires. The Chi²-test for categorical and Mann–Whitney *U* test for continuous variables were performed to identify heterogeneity between the groups.

Results Regarding operation time, there was no significant difference between the slings ($p=0.146$). The complication rates were comparable in both groups except for postoperative urinary retention. This occurred significantly more often in patients with the AdVanceXP ($p=0.042$). During follow-up, no differences could be identified regarding ICIQ-SF, PGI or I-QoL or number of pad usage.

Conclusions The AdVance and AdVanceXP are safe and effective treatment options for male stress urinary incontinence. However, the innovations of the AdVanceXP sling did not demonstrate a superiority over the original AdVance sling regarding functional outcome.

Keywords Male · Stress urinary incontinence · Male sling · AdVance · AdVanceXP

Abbreviations

ICIQ-SF	International Consultation on Incontinence Questionnaire-Short Form
IPSS	International Prostate Symptom Score
I-QoL	Incontinence-Quality of Life
PGI-I	Patient Global Impression-Improvement
SUI	Stress urinary incontinence
VRS	Verbal Rating Scale

Introduction

The AdVance[®] male sling (AMS Men's Health/Boston Scientific, Massachusetts, USA) has been the most frequently investigated fixed sling for the treatment of male stress

urinary incontinence (SUI) since its introduction by Rehder and Gozzi [1]. In comparison to compressive devices or slings, the AdVance[®] is hypothesized to function as a dynamic hammock during situations of increased abdominal pressure [2], thereby restoring continence. The efficacy and safety of the original AdVance[®] for the treatment of male SUI has been demonstrated in several trials [3–6]. In 2010, the second generation named AdVanceXP[®] was introduced to provide better stability by tensioning fibers, chevron anchors and Tyvek[®] liners and to facilitate the implantation by modifying the implantation needle [7]. Despite these minor modifications, the underlying mechanisms and surgical techniques have not changed substantially [8]; the insertion of the needles is somewhat easier, the removal of the tape sheaths slightly more difficult. To our knowledge, there is only one prospective [8] and one retrospective trial [9] of single tertiary reference centers comparing the AdVance[®] and the AdVanceXP[®]. The current study aims to investigate the safety and efficacy of both models in comparison

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to a large multi-institutional cohort study with a mid-term follow-up.

As there are limited prospective comparative trials investigating different surgical devices, the “Debates On Male Incontinence” (DOMINO) working group aims to provide large comparative multicenter studies that are independent of any commercial influence and therefore deliver robust data on daily routine at various reference centers for male incontinence surgery.

Materials and methods

After approval of the local ethics committee of Frankfurt University Hospital (Vote 442/13), a multi-institutional cohort study including 294 patients who received an AdVance or AdVanceXP male sling during 2010 and 2012 was initiated. Patient data (baseline characteristics, perioperative course, follow-up visits) were collected and analyzed retrospectively. All patients received standardized care at the respective reference centers. Furthermore, standardized and validated questionnaires were completed by the patients to evaluate quality of life and efficacy of the procedure in a prospective approach. A signed informed consent form was mandatory from all participating patients. The following questionnaires were used: “Incontinence-Quality of Life” [10] (I-QoL; scale: 0–100, higher score represents better QoL), “Patient Global Impression-Improvement” [11] (PGI-I; range 1–7, very much better to very much worse), “International Consultation on Incontinence Questionnaire-Short Form” [12, 13] (ICIQ-SF; range 0–21, 0: no incontinence, 1–5: slight, 6–12: moderate, 13–18: severe, 19–21: very severe), “International Prostate Symptom Score” [14] (IPSS, range 0–35, higher score presents more symptoms, 0–7: mild, 8–19: moderate, 20–35: severe), “Verbal Rating Scale of Pain” (VRS; range 0–10, minimal to maximum

pain) for perineum, genitals, inguinal groin and symphysis. Furthermore, the number of pads used per day and a 24-h pad test were evaluated.

Statistical analysis

Statistical analysis was performed by IBM® SPSS® (Armonk, New York, United States) Statistics Version 24 for Macintosh. Descriptive statistics were applied for presentation of population characteristics, complication rates and outcome. A Chi²-test for categorical and Mann–Whitney *U* test for continuous variables were performed to identify heterogeneity between the groups. A logistic regression analysis was conducted to predict the improvement of incontinence in both groups separately, as well as the variables history of pelvic irradiation, prior surgery for urethral stenosis and grade of urinary incontinence as predictor.

Results

109 (37.1%) patients received an AdVance and 185 (62.9%) patients an AdVanceXP male sling. There were no differences in baseline characteristics between the patients with AdVance or AdVanceXP beside a statistical significant higher age in the AdVance group (Table 1). The mean operation time was 70.1 ± 17.7 and 70.5 ± 24.0 (*p* = 0.146) minutes for the AdVance and AdVanceXP, respectively. No intraoperative complication occurred in either of the groups. There were no significant differences in the postoperative complication rates except for higher rates of urinary retention in patients with AdVanceXP (Table 2). No significant postoperative bleeding occurred. Furthermore, no significant difference in rehospitalization rate (*p* = 0.878) was observed. All patients with postoperative urinary retention were treated either by transient transurethral or suprapubic catheter.

Table 1 Patients’ baseline characteristics of the AdVance and AdVanceXP male sling

Variable	AdVance	AdVanceXP	<i>p</i> value
Mean age, years ± SD (range)	69.9 ± 6.3 (50–81)	69.1 ± 7.2 (49–100)	0.048*
Mean BMI, kg/m ² ± SD (range)	27.0 ± 4.0 (18.2–37.4)	27.7 ± 3.7 (20.1–38.4)	0.199
Mean number of pads preoperatively, <i>n</i> ± SD (range)	3.6 ± 2.0 (1–10)	3.8 ± 2.3 (1–15)	0.530
Mean grade of incontinence, grade ± SD (range)	1.9 ± 0.5 (1–3)	1.9 ± 0.4 (1–3)	0.222
Mean ASA-classification, <i>n</i> ± SD (range)	2.35 ± 0.520 (1–3)	2.26 ± 0.540 (1–3)	0.686
Origin of incontinence, <i>n</i> (%)			
Radical prostatectomy	103 (94.5)	176 (95.1)	0.810
TUR-prostate	6 (5.5)	9 (4.9)	
Diabetes mellitus, <i>n</i> (%)	14 (12.8)	23 (12.4)	0.918
History of pelvic irradiation, <i>n</i> (%)	9 (8.3)	25 (13.5)	0.173
Prior surgery for urethral stricture, <i>n</i> (%)	14 (12.8)	27 (14.6)	0.676

*Significance *p* < 0.05

Table 2 Postoperative complication rates of the AdVance and AdVanceXP

Variable	Clavien-Dindo	AdVance	AdVanceXP	<i>p</i> value
Impaired wound healing, <i>n</i> (%)	Grade I	1 (0.9)	1 (0.5)	0.704
Urinary retention, <i>n</i> (%)	Grade I and III [†]	4 (3.7)	19 (10.3)	0.042*
Pain, <i>n</i> (%)	Grade I	2 (1.8)	3 (1.6)	0.891
DeNovo urge, <i>n</i> (%)	Grade II	11 (10.1)	11 (5.9)	0.192
Infection, <i>n</i> (%)	Grad II	2 (1.8)	0	0.064
Symphysis/osteomyelitis	Grade II	1 (0.9)	1 (0.5)	0.704

*Significance $p < 0.05$ [†]Grade I: transurethral catheter, Grad III: suprapubic catheter

Nevertheless, unilateral transection of the sling was necessary due to persistent hypercontinence in 8 patients (4.3%) with AdVanceXP and 1 patient (0.9%) with an AdVance sling ($p = 0.101$). Due to recurrent or persistent incontinence, 10 patients (9.2%) with AdVance and 11 (5.9%) with AdVanceXP ($p = 0.299$) were retreated with a further continence procedure (including secondary fixed male sling, bulking agents, adjustable male sling or artificial urinary sphincter). One patient (0.5%) with AdVanceXP underwent cystectomy due to recurrent urethral strictures.

Follow-up

Less than half of the total patient number was available for long-term follow-up, 79 (42.7%) patients with AdVanceXP and 47 (43.1%) with AdVance, respectively. The mean follow-up time was 34.7 (SD 10.5, median: 31) and 52.6 (SD 10.1, median: 55) months, respectively. There were no significant differences in the quality of life or the impact of incontinence between the groups (Table 3). Detailed results of the ICIQ-SF are presented in Fig. 1. No correlation could be identified between the functional results according to the PGI-I and very obese patients (BMI > 25) ($p = 0.150$). Furthermore, 82.2 and 84.7% of the patients with Advance and 79.5 and 88.1% with AdVanceXP stated they would have had the operation again and recommend the operation to a friend respectively ($p = 0.723$, resp. $p = 0.617$). In a multivariate analysis, the only independent predictor for improvement of incontinence was the absence of prior urethral stricture ($p = 0.025$, CI 1.32–59.13, OR 8.84). No differences could be identified between AdVance and AdVanceXP ($p = 0.957$).

Discussion

The introduction of the AdVance[®] male sling has revolutionized the treatment options for mild to moderate male SUI [15, 16]. The second generation, the AdVanceXP[®], was introduced with the aim of improving long-term outcomes by adding anchors and to facilitate the implantation by modifying the implantation needle. Meanwhile,

Table 3 Results of the questionnaires of the AdVance and AdVanceXP

Variable	AdVance	AdVanceXP	<i>p</i> value
ICIQ-SF Score, mean (SD)	8.8 (5.8)	7.5 (5.4)	0.182
I-QoL Score, mean (SD)	81.4 (23.1)	86.2 (22.0)	0.267
Subscales, mean (SD)			
Avoidance and limiting behavior	29.1 (8.0)	30.6 (8.0)	0.269
Psychosocial impacts	34.7 (9.8)	36.7 (9.1)	0.368
Social embarrassment	17.4 (6.2)	19.1 (5.6)	0.204
PGI-I mean (SD)	2.3 (1.5)	2.2 (1.5)	0.508
Better (%)	82.6	80.8	
No change (%)	8.7	10.3	
Worse (%)	8.7	9.0	
IPSS, mean (SD)	11.3 (8.1)	11.6 (7.0)	0.649
VRS pain, mean (SD)			
Perineum	0.4 (1.2)	0.2 (0.6)	0.985
Genitals	0.4 (1.2)	0.2 (0.5)	0.461
Symphysis	0.2 (0.4)	0.2 (0.5)	0.600
Inguinal groin	0.3 (0.9)	0.2 (0.6)	0.684
Number of pads/day, mean (SD)	1.4 (1.3)	1.4 (1.3)	0.986
24 h pad test, g (SD)	45.8 (129.2)	59.3 (162.1)	0.521

ICIQ-SF International Consultation on Incontinence Questionnaire-Short Form; I-QoL Incontinence-Quality of Life, PGI-I Patient Global Impression of Improvement, IPSS International Prostate Symptom Score, VRS Verbal Rating Scale of Pain, SD standard deviation

Significance $p < 0.05$

the original AdVance[®] has been withdrawn from the European market. Nevertheless, considering the missing FDA approval for the AdVanceXP[®] in the USA, it is still of interest to know whether patients treated with the original AdVance[®] are at a disadvantage regarding complication rates and/or functional outcomes. The current study primarily aims at comparing the two sling generations in the largest patient cohort in a multicenter trial to date with a mid-term follow-up period, thus demonstrating the results of daily clinical routine.

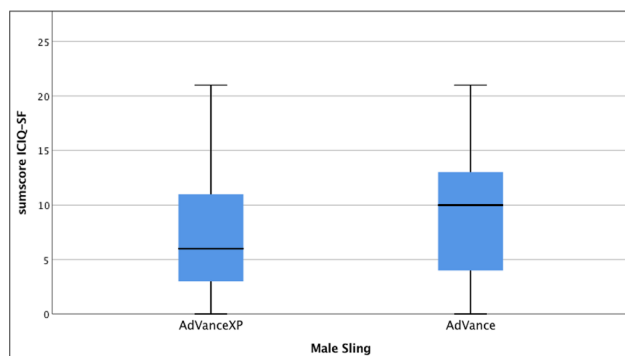


Fig. 1 Results of the postoperative ICIQ-SF sum score in comparison of AdVance and AdVanceXP. *ICIQ-SF* International Consultation on Incontinence Questionnaire-Short Form (range 0–21, 0: no incontinence, 1–5: slight, 6–12: moderate, 13–18: severe, 19–21: very severe)

With regard to the perioperative technique, the implantation needle was modified to facilitate the implantation process [7]. Consequently, shorter operation times and/or lower intraoperative complication rates should be expected if these changes were substantial. However, the mean operation time in both sling types only differed by merely 0.4 min; therefore, neither a statistical nor a clinical difference was observed. Although the new needle configuration seems to facilitate the implantation, most likely due to training and practice in reference centers, both procedures are performed equally fast. A substantial advantage of the novel needle configuration could not be identified.

Furthermore, as complication rates are generally low for the AdVance® [5, 15] and AdVanceXP [7], no significant difference could be expected. This was confirmed in the current study as no significant differences could be identified except for postoperative urinary retention. Urinary retention occurred significantly more often in patients with the AdVanceXP affecting 10.3% of the patients. These results are in contrast to recent studies of the AdVanceXP sling describing urinary retention rates as low as 2.1–4.9% [9, 17] in single tertiary reference centers. These studies underestimate the retention rate which in daily clinical practice is probably two-fold higher. The so far reported retention rates of the original AdVance comprise a wide span of 0–15.1% [4, 15, 18]. The discrepancy of these results may be explained by the lack of proper surgical training. As pointed out by Bauer et al. [17], overtensioning can easily occur if the sling arms are not adequately fixed (holding the sling firmly in place with forceps as a counterforce) while removal of the Tyvek liners is performed.

The necessity for unilateral transection of a sling arm in the AdVanceXP group in the current study was 4.3%. This is in line with other results reporting unilateral transection in 4.9% [9] and 2.1% [17]. Although statistical significance was

not reached in the current study, we could identify a trend for higher rates of unilateral transection in the AdVanceXP group. Therefore, patients with an AdVanceXP may be of higher risk for unilateral transection of the sling.

Regarding the functional outcomes, no differences between AdVance and AdVanceXP could be identified by validated and standardized questionnaires. This is in line with the results of Bauer et al. [9] and Cornu et al. [8] reporting comparable outcomes. The mean PGI, ICIQ-SF, and I-QoL for the AdVanceXP were recently reported at 1.0–1.6, 4.1–4.5 and 90.9–95.6 [7, 9] respectively. These results are slightly higher than in the current cohort. The same data for the AdVance are reported ranging between 1.0, 7.0–9.2, 82.5–93.0 [9, 15, 18], respectively, and revealing only slight differences. Furthermore, in contrast to the results of Bauer et al. [9], a correlation of the outcome with obesity cannot be confirmed in the current study.

A limitation of the current study is the in parts retrospective design with some pertinent data unavailable or incomplete. The heterogeneity of data depending on the type of prostate surgery (RPE, TURP), different inclusion criteria for the procedure according the reference centers and experience of the surgeon may influence treatment outcome and perioperative complication management. Furthermore, the total number of procedures varied between the reference centers. Thus, the current study included centers with different level of surgical experience of male slings. Moreover, follow-up assessment by urodynamics and flow studies were missing and may have yielded deeper insights into complication rates and efficacy. However, due to the withdrawal of the original AdVance from the European market, prospective trials comparing both slings are not likely to be performed in the near future.

In conclusion, both the AdVance and AdVanceXP have demonstrated comparable complication rates and functional outcomes. Despite of significantly higher rates of postoperative urinary retentions in patients treated with the AdVanceXP, both slings are safe and effective treatment options for male SUI. However, the utilization of the AdVanceXP may be correlated with a higher risk for unilateral transection of the sling due to hypercontinence.

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data analysis, manuscript editing. RMB, AH: design of study, protocol development, data management and contribution, manuscript editing.

Compliance with ethical standards


Informed consent This was a retrospective cohort study evaluating perioperative data. Validated questionnaires were utilized prospectively. A signed informed consent from the patients participating in prospective collection of the questionnaires was mandatory for this investigation.

Conflict of interest T. Hüsich, A. Kretschmer, F. Thomsen, D. Kronlachner, M. Kurosch, A. Obaje, A. Rose, R. Olianias, L. Lusuardi, A. Friedl, R. Anding, R. Kirschner-Hermanns, R. Homberg, J. Pfitzenmaier, U. Grein, F. Queissert, J. Schweiger, C. Wotzka, J. Nyarangi-Dix, B. Brehmer, K. Ulm, and A. Haferkamp have nothing to disclose. R. M. Bauer declares consultancy work, lectures, and participation in clinical trials for AMS/Boston Scientific (Minnetonka, MN, USA) and Promedon (Cordoba, Argentina). C. M. Naumann declares lectures, consultancy work, and participation in clinical trials for Coloplast. W. Hübner declares consultancy work, lectures, and participation in clinical trials for Uromedica (Plymouth, MN, USA) and Promedon (Cordoba, Argentina). T. Pottek declares consultancy work, lectures for Boston Scientific/AMS, Promedon, Zephyr, and Teleflex. R. Abdunnur declares consultancy work, lectures, and participation in clinical trials for AMS/Boston Scientific (Minnetonka, MN, USA) and Promedon (Cordoba, Argentina). Hagen Loertzer declares lectures, consultancy work, and participation in clinical trials for Coloplast.

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