Age at surgery is not a prognostic factor for the AdVance-XP male sling efficacy: A post-hoc analysis of a prospective 7-year multicentric study

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Abstract

Objective: To evaluate the factor age at the surgery on long-term post-operative outcomes in patients with postprostatectomy incontinence (PPI) after AdVance XP transobturator male sling implantation.

Methods: A total of 115 male patients with PPI, who had undergone AdVance XP sling implantation, were included. Patients had PPI with endoscopically confirmed good sphincteric contractility and a positive coaptive response. Kruskal–Wallis test with Dunn post-hoc tests were used to analyze the post-operative outcome differences between the patient groups aged less than 66, 66–75, and over greater than 75 years. Outcome measures were the 24 h pad test, the number of daily pads used, the International Consultation on Incontinence Questionnaire short form (ICIQ-SF), International Quality of Life Score (IQOL), Patient Global Impression of Improvement (PGI-I), International Prostate Symptom Score (IPSS), and Visual Analog Scale scores. Observation time points were 3, 6, 12, 24, 36, 48, 60, and 84 months after surgery.

Results: Between the age groups, there was no difference in the success rate of the procedure (defined as 0 pads/24 h and less than 5 g in the 24-h pad test) at any point in time. Subjective parameters measures using the ICIQ-SF, PGI-I, IQOL, and IPSS scores showed no differences between the two cohorts. Only erectile function (IIEF-5 score) was lower in older patients in comparison to the cohort aged less than 66 years ($p < 0.05$ at 3, 6, 12, 24, 36, and 48 months).

Abbreviations: EUS, external urethral sphincter; ICIQ-SF, International Consultation on Incontinence Questionnaire short form; IIEF-5, International Index of Erectile Function-5; IPSS, International Prostate Symptom Score; IQOL, International Quality of Life Score; PGI-I, Patient Global Impression of Improvement; PPI, postprostatectomy incontinence; PVR, postvoid residual urine volume; VAS, Visual Analog Scale; XRT, external radiation therapy.

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Conclusions: The present study complements the European multicentre AdVance XP follow-up study. Here, we show that age at surgery does not affect the objective success, subjective success, or the complication rate. Thus, we do not recommend factoring in chronological age into surgical selection criteria for the AdVance XP implantation.

KEYWORDS
AdVance XP, fixed male sling, inclusion criteria, male stress urinary incontinence, patients’ selection, postprostatectomy incontinence, predictive factors

1 INTRODUCTION

An estimated 1 400 000 men were diagnosed with prostate cancer in 2020 of which many would have undergone a prostatectomy. Although, prostatectomy is relatively safe with few complications, some notable complications do exist, mainly erectile dysfunction and postprostatectomy incontinence (PPI). PPI is defined as incontinence after 1 year following surgery and can severely affect the patient’s quality of life. Next to pelvic floor muscle training, there are some surgical options available: continence restoration by urethral compression (e.g., ARGUS, ATOMS, MRS) or by repositioning the urethral bulb (e.g., AdVance XP), with the AdVance XP being more widely used in Europe.

The AdVance XP (Boston Scientific) is the second generation fixed synthetic sling system for the treatment of nonneurogenic PPI. It functions to reposition the urethral bulb and support the distal urethral sphincter through its implantation behind the urethra and below the proximal urethral bulb. Both ends bilaterally pass through the obturator fossae. The second-generation AdVance XP is hallmarked by chevron anchors and cohesive tension fibers for better insertion, enhanced stability, and thus, better long-term results. The AdVance XP provides better fixation during the healing process and better outcomes in obese patients. There is, however, a higher risk of overtensioning that requires the delicate removal of the Tyvek liners.

Just like in its predecessor the AdVance system, the AdVance XP system showed a decrease in “dry” patients overtime, defined as less than 5 g in the 24-h pad test. The 5-year follow-up data showed a decrease of dry patients from 64.0% at 2 years, 61.2% after 4 years, and 57.6% after 5 years. This is less than the original AdVance system but still statistically significant. It must be noted though that the lesser decrease in dry AdVance XP system patients could also be a result of a better understanding of the sling system, which ultimately leads to a better patient selection for surgery.

Since the introduction of these systems, decisive predictors for sling efficacy have been intensely studied. Soljanik et al. first showed that a weak sphincter function and no elongation of the coaptive sphincter zone are important predictors of treatment failure following sling implantation. Furthermore, Serra et al. showed that each additional gram in the 24-h pad test decreased the success rate by 0.4%. Torrey et al. showed that external radiation therapy (XRT) statistically decreased success rate, increased postoperative pad usage, and lowered quality of life. These findings prompted Sturm et al. to define the “ideal” patients as one who has a visually intact external urethral sphincter (EUS), less than 300 g/day pad weight or uses less than 4 pads/day, voluntary detrusor contraction with voiding, a postvoid residual urine volume (PVR) less than 100 ml, no history of pelvic radio and cryotherapy and no previous surgical incontinence procedures.

Lately, the prospective multicentre study of Bauer et al., the longest follow-up for the AdVance XP system, showed that at midterm evaluation no significant differences in efficacy in patients who had a history of pelvic XRT. Furthermore, if using the Sturm et al. selection criteria, patients with mild and moderate incontinence benefited similarly from the system. Thus, selection criteria for optimal long-term results should primarily factor in good visual sphincter contractibility and a coaptive zone of at least 1 cm in the preoperative endoscopic evaluation.

The strict application of the Bauer et al. refined selection criteria showed excellent time-consistent continence results in AdVance XP treated patients at the 5-year follow-up. Furthermore, the 5-year follow-up showed low complication rates and an improved quality of life. The refined selection criteria likely contributed to the results. One criteria, which has not been looked at, is the age at surgery and its effect on the success of the implantation of the AdVance XP.

Today, people are chronologically living longer and with a higher quality of life into age. As a result of the
higher quality of life at age and the increase in the incidence of prostate cancer with age, an increase of older people are also undergoing prostatectomy. Hence, an increase of older people are also suffering from PPI, which can be debilitating and severely affect the quality of life. While these patients do often undergo AdVance XP surgery for their PPI, there is currently no published data that adequately compares the success of the surgery between younger and older patients. In this study, we aim to compare the efficacy of the AdVance XP system in patients with an age less than 66 years old (y.o.) versus ≥76 y.o. versus ≥76 y.o. at the time of surgery.

2 | MATERIALS AND METHODS

2.1 | Patient cohort

A total of 115 patients, across 6 European urology departments (in Germany, Austria, and Italy), who underwent AdVance XP sling implantation for PPI between January 2012 and March 2016, were included. Surgical selection criteria were a history of PPI, endoscopically confirmed good sphincter contractility, and long coaptive zone (greater than 1 cm). Exclusion criteria were stress urinary incontinence III° (“urine loss whilst lying”), preoperative endoscopic evaluation, prior XRT, prior incontinence surgery, or a history of urgency incontinence. All patients consented to the study. The study was approved by the local ethics committees (reference number: 522-11) and follows the ethical standards of the 1964 Helsinki declaration.

2.2 | Study design

This study is a retrospective analysis of prospectively collected data and statistical analyses have been specified after the data were collected.

The AdVance XP male sling was surgically applied as described in our previous studies. Patients were assessed by the operating surgeon at baseline, after 3, 6, 12, 24, 36, 48, 60, and 84 months. The baseline preoperative assessment included the following aspects: patient’s history, pad usage per day, urodynamics in patients having symptoms of urge incontinence, uroflowmetry, and ultrasound for PVR.

Multiple previously validated questionnaires were used to objectively assess the patients’ symptom at follow-up visits using the International Consultation on Incontinence Questionnaire short form (ICIQ-SF), International Index of Erectile Function-5 (IIEF-5), International Prostate Symptom Score (IPSS), International Quality of Life Score (IQOL), Patient Global Impression of Improvement (PGI-I), and Visual Analog Scale (VAS).

Additionally, postoperative urine leakage was quantified using a 24-h home pad test. All patients were educated and informed on how to perform the test. The results of the 24-h pad test along with their daily pad usage were assessed using a standardized questionnaire. In line with our previous studies, we defined cured patients as those who use zero pads in 24 h and a less than 5 g urine loss in the 24-h pad test (“cured” patients). Improved continence was defined as a ≥50% reduction in the 24-h pad test. All other patients not matching these parameters were classified as failed.

Patients were split according to their age at the time of surgery (“age”) and split into three groups: less than 66 y.o. versus 66–75 y.o. versus greater than 75 y.o. at the time of surgery. The effect of “age” on postoperative continence, quality of life, development of voiding, postmicturition symptoms, erectile function, and pain sensation was analyzed.

2.3 | Statistical analysis

The main goal of this study is to assess differences in outcome between patients aged less than 66 years versus 66–75 years versus greater than 75 years. For comparison of categorical data the \(\chi^2\) test was used. Comparison of pre- and postoperative scores was done using the Wilcoxon test. Comparison of ranked or continuous data between age groups was performed using Kruskal–Wallis test with Dunn post hoc tests (comparing the results of the 24-h pad test, IQOL, ICIQ, PGI-I, IIEF-5, IPSS, and VAS scores between the three age groups). A \(p < 0.05\) was chosen to indicate statistical significance. All statistical analyses were carried out using MedCalc 19.6 (MedCalc Software Ltd).

3 | RESULTS

3.1 | Patient population

The patient population consists of 115 PPI-patients, who had undergone surgical AdVance XP implantation between 2012 and 2016. The median age at surgery was 69 years (interquartile range: 66–73 years). We split our cohort into those aged under 66 years (less than 66 y.o.; \(n = 28\)), patients aged 66–75 years (66–75 y.o.; \(n = 74\)), and those aged greater than 75 years (greater than 75 y.o.; \(n = 13\)) at the time of surgery.

Our study population was followed up from 115 patients at 3 and 6 months to 114 patients at 12- and 24-month follow-up; 100 patients at 36 months; 85 patients at 48 months,
59 patients at 60 months, and 37 patients at 84 months. Lost to follow-up in total were 24 patients. Without any relation to sling implantation, two patients of this study deceased throughout the follow-up time frame. No further patients have been added. Other patients not included in this study have not yet met their follow-up period. There were no significant differences in the baseline characteristics (pad test, ICIQ score, uroflow, body mass index, IIEF-5 score) between the three age groups. Furthermore, there was no difference between the groups regarding the time interval between prostatectomy and AdVance XP implantation (Table 1).

### 3.2 Differences in success rate and degree of incontinence

All age groups had stable continence results over the 84 months. There was no significant difference in the success rate between the age groups of patients (Figure 1). This was also the case in the quantified 24 h pad test results where no significant difference between the three age groups was detectable during follow-up (Figure 2). Furthermore, age at surgery did not have any statistically significant impact on the functional outcome, assessed through the ICIQ-SF score (Figure 3A). The PGI-I assessment showed good, stable results across all age groups across the 5-year observation period ($p > 0.05$ for all follow-up time points from 3 to 84 months) (Figure 3B).

### TABLE 1  Patient baseline characteristics stratified by age group

| Characteristic          | ≤65 years (n = 28) | 66–75 years (n = 74) | >75 years (n = 13) | p Value |
|-------------------------|--------------------|----------------------|-------------------|---------|
| Pad test (ml)           |                    |                      |                   | 0.816   |
| Median                  | 274                | 270                  | 320               |         |
| IQR                     | 123–373            | 170–435              | 260–353           |         |
| ICIQ score              |                    |                      |                   | 0.197   |
| Median                  | 16                 | 16                   | 13                |         |
| IQR                     | 12–19              | 13–17                | 12–16             |         |
| Uroflow (ml/s)          |                    |                      |                   | 0.243   |
| Median                  | 35                 | 30                   | 25                |         |
| IQR                     | 20–51              | 19–42                | 21–41             |         |
| IIEF-5 score            |                    |                      |                   | 0.476   |
| Median                  | 4                  | 2                    | 4                 |         |
| IQR                     | 1–10               | 1–6                  | 1–5               |         |
| BMI                     |                    |                      |                   | 0.891   |
| Median                  | 26.0               | 25.4                 | 26.5              |         |
| IQR                     | 24.1–27.3          | 23.8–27.8            | 24.8–27.3         |         |
| Interval rPX–XP (months)|                    |                      |                   | 0.469   |
| Median                  | 29                 | 28                   | 33                |         |
| IQR                     | 24–43              | 18–64                | 23–121            |         |

Abbreviations: BMI, body mass index; ICIQ, International Consultation on Incontinence Questionnaire; IQR, interquartile range; IIEF-5, International Index of Erectile Function.
3.3 Differences in patient’s quality of life, development of voiding and postmicturition symptoms, erectile function, and pain sensation

Categorizing patients into age at surgery did not show any differences in the quality of life between the cohorts. All age groups saw a significant improvement from baseline to the 3-month follow-up and thereafter stable IQOL scores (Figure 3C). There was no time point along with the follow-up, at which significant differences between age groups occurred ($p = 0.146$ at the baseline, $p = 0.418$ after 3 months, $p = 0.414$ after 6 months, $p = 0.161$ after 12 months, $p = 0.482$ after 24 months, $p = 0.169$ after 36 months, $p = 0.327$ after 48 months, $p = 0.502$ after 60 months, $p = 0.161$ after 84 months).

There were no statistically significant findings with regard to alterations of erectile function (IIEF-5) and of IPSS score across the follow-up of the AdVance XP patients (Figure 4). However, the IIEF-5 score was significantly lower in older patients versus younger patients less than 66 years at 3, 6, 12, 24, 36, and 48 months (Figure 4A).

There were no significant differences between pre- and postoperative IIEF-5 scores in patients less than 66 years and in patients 66–75 years ($p = 0.360$ and $p = 0.198$, respectively). There was a significantly decreased IIEF-5 score in the patients greater than 75 years ($p = 0.012$) with a median preoperative score 3 and a median postoperative score 1. Our study showed that voiding and micturition symptoms, expressed by IPSS, were not influenced significantly by age ($p > 0.05$ at each follow-up time period; Figure 4B).

Preoperative and postoperative perineal and inguinal pain were compared between all patients, measured through the VAS score, and showed significant differences. In all age groups, less than 66, 66–75, and greater than 75 y.o., a significant reduction of perineal pain 3 months after the sling implantation was observed ($p = 0.004$, $p < 0.001$, and $p = 0.009$, respectively). There was also a reduction of inguinal pain, which was not significant in the oldest patient group ($p = 0.002$, $p < 0.001$, and $p = 0.062$, respectively).

Perineal and inguinal pain is a possible postoperative complication of the AdVance XP, which were both measured through the VAS score at all follow-up time frames. Perineal pain was low across all age groups after 3 months (median VAS = 0 in all groups) and after 84 months (median VAS = 0 in all groups) (Figure 5A). Inguinal pain can also be a potential postoperative complication and was at no stage significantly different.
between the age groups (Figure 5B). After 3 months median inguinal pain was VAS 0 in the less than 66 y.o., 0 in the 66–75 y.o. and 0 in the greater than 75 y.o. Similarly, at 84 months median inguinal pain was 0 in all age groups.

**FIGURE 4** Comparison of the IIEF-5 score (A) and IPSS score (B) between the age groups at each follow-up time. Lines above the box plots indicate a significant difference ($p < 0.05$). IIEF-5, International Index of Erectile Function-5; IPSS, International Prostate Symptom Score

**FIGURE 5** Comparison of postoperative perineal (A) and inguinal (B) pain between the age groups at each follow-up interval. There was no significant difference between age groups at any time regarding perineal pain and inguinal pain, respectively

PPI is a frequent complication after prostatectomy and can significantly decrease patient’s quality of life. The AdVance XP transobturator tape is one surgical option that can be offered to these patients and is the most widely used TOT system in Europe. Previously, Bauer et al. has extensively studied the efficacy and safety of the AdVance XP. The 5-year follow-up data showed time consistent results with 64.3% of patients cured at 3 months, which only decreased to 57.6% at 60 months. Furthermore, the mean quality of life score (assessed through the IQOL) increased from a 67.3 IQOL score before surgery to 97.0 at 24 months and 96.8 at 60 months. Thus, demonstrating long-term stable results for PPI patients. Our findings are in line with previous studies reporting that age at surgery was not a risk factor for failure in both AdVance and non-Advance trans-obturator retrourethral sling series.

**4 | DISCUSSION**


Very strict surgery selection criteria seem to be imperative for good postoperative continence. As mentioned earlier, predictive criteria have previously been studied by Soljanik et al. and Serra et al. Furthermore, Torrey et al. showed that previous XRT decreased success rate. Ultimately, Sturm et al. applied these findings to sort patients into “ideal” and “nonideal” TOT patients. The “ideal” patient of Sturm et al. had an intact appearing EUS, less than 300 g 24-h pad weight, less than 4 pad/day usage, volitional detrusor contraction with voiding, PVR urine volume less than 100 ml, and no history of XRT. “Ideal” patients have significantly lower postoperative pad usage than “nonideal” patients (0.6 vs. 2.4) and much higher satisfaction rates in “ideal” patients (92% vs. 30%). The prospective multicentre, mid-term follow-up by Kretschmer et al. applied these criteria but additionally showed no decrease in the efficacy of the AdVance XP system in previously irradiated patients, in contrast to the Torrey et al. findings. Furthermore, they also showed that mild and moderate incontinent patients benefited similarly. Thus, the authors recommended changing the selection criteria to exclude XRT from the Sturm et al. criteria.

There is currently no consensus on the patient’s age and its effect on the efficacy of the AdVance XP system, which we aim to address with this study. Our cohorts (less than 66, 66–75, and greater than 75 y.o. at surgery) showed no difference between them in respect to objective results, with both cohorts having similar post-operative 244-h pad weights and pad usage. Cure rates (less than 5 g in the 244-h pad test and 0 pad-usage per day) were also similar and not different between the age groups. Furthermore, these results were stable over the 84 months follow-up (Figure 2). In respect to the objective parameters, we would recommend not forcing age into the surgical selection criteria, since both cohorts fared evenly.

Additionally, to the objective parameters, it is also important to look at subjective outcomes. The findings of a reduced decrease in continence presented reflect the well-achieved patient selection for the study. Long-term postoperative inguinal or perineal pain can be complications of male sling systems and clearly affect the patient’s quality of life. Hence, we also subjectively assessed perineal and inguinal pain through the VAS score. For all age groups, the pain was not widespread. Thereby, no cohort has a higher prevalence of postoperative pain complication. Further subjective results were also very similar between the age groups. The median ICIQ score significantly decreased in all age groups from 16 (less than 66 y.o.), 16 (66–75 y.o.), and 13 (greater than 75 y.o.) before surgery down to 3.5 (less than 66 y.o.), 4 (66–75 y.o.), and 3.5 (greater than 75 y.o.) after 3 months (p < 0.001, p < 0.001, and p = 0.002, respectively) and remained stable thereafter. Similarly, the PGI score remained stable with a median of 1 after 3 months and 1 after 84 months in the age groups of less than 66 y.o. and 66–75 y.o. The very old patient cohort (greater than 75 y.o.) showed a median PGI score of 2. This is in line with the previously published 5-year follow-up data for the AdVance XP system, which also demonstrated little deterioration of the results past the 6-month time point. The IIEF-5 decrease after AdVance XP implantation was significant in the very old patient group, but there were only n = 12 cases in this group, and the difference is not clinically relevant. The only difference was seen in the erectile dysfunction (measured using the IIEF-5 score) in the two older patient groups compared to the patients less than 66 y.o. We do not attribute this to the Advance XP but rather to an increase of age. As known, older males have a higher prevalence of erectile dysfunction. Consequently, age should be seen as a confounder for the lower IIEF-5 score in older patients. Ultimately, all patient cohorts enjoyed similar good benefits from the AdVance XP implantation and if they meet the surgical selection criteria, can be offered this surgical procedure.

5 LIMITATIONS

This study is a complementation of a single-arm study and thus, lacks a suitable control group (e.g., AUS). Furthermore, there was also a significant loss of participants over the 7 years, with an initial 28 patients in the less than 66 y.o., 74 in the 66–75 y.o., and 13 in the greater than 75 y.o. group. After 84 months, this reduced to 8 patients in the less than 66 y.o., 23 in the 66–75 y.o., and 5 in the greater than 75 y.o. group. One question we, unfortunately, leave unanswered is whether very old patients (e.g., greater than 80 y.o.) benefit from this surgery. Unfortunately, comparisons between less than 80 y.o. patients versus ≥80 y.o. patients were not made, as only 2 of our patients (out of 115) were at the age of 80 plus. A further limitation of this study is that age can act as a confounding factor for other variables such as extended time after prostatectomy to receive PPI treatment, baseline severity of incontinence, and dissimilar proportion of irradiation. This study includes a highly selected patient selection at the start point of the study, this can be regarded as a limitation of the study, or in contrast the results highlight a well-selected patient cohort that attempts to answer the open question: “what is the ideal patient for Advance XP-implantation?”
6 | CONCLUSIONS

Our data show that age at surgery is not an important predictive factor for the postoperative outcome of AdVance XP implantation for PPI patients. Both objective (24-h pad weight and daily pad usage) and subjective parameters (IQLQ, PGI-I, ICIQ, perineal VAS, andinguinal VAS scores) showed no difference between the less than 66, 66–75.5, and greater than 75 y.o. Only, the erectile function was lower for some follow-up intervals in the 66–75 and greater than 75 y.o. group, which we attribute to age and not the procedure. Ultimately, the cure rate in all age groups was comparative and not significantly different. Thereby, we conclude that the implantation of the AdVance XP for PPI can be offered to patients all age groups, without ill effects on the efficacy of the intervention. The patient’s chronological age should not be a factor in the decision to offer the AdVance XP implantation to PPI patients.

ACKNOWLEDGMENT

Open Access funding enabled and organized by Projekt DEAL.

CONFLICT OF INTERESTS

Ricarda M. Bauer proclaims lectures, consultancy effort, and the contribution in clinical trials for AMS/Boston scientific. There is no conflict of interests stated by all other authors.

AUTHOR CONTRIBUTIONS

Jan-Niclas Mumm, Ricardo M. Bauer, and Alexander Buchner conceived and designed the project. Jan-Niclas Mumm, Alexander Buchner, and Benazir Abrarova wrote the paper. Jan-Niclas Mumm and Alexander Buchner carried out the statistical evaluation. Julius Schütz, Benedikt Klehr, Christian Gozzi, Florian May, Roland Homberg, and Peter Gebhartl, carried out the method. Christian G. Stief and Ricardo M. Bauer provided the concept, substantially contributed to the manuscript and supervised the research. Theresa Vilsmaier, Severin Rodler, Alexander Buchner, Benazir Abrarova, and Ricardo M. Bauer revised the manuscript for critical content and helped with statistical evaluation. All authors analyzed and interpreted the data and read and approved the final manuscript.

ETHICS STATEMENT

The authors received written informed consent from all patients included, formerly to this study (Reference number: 522-11). All local ethics boards contributing to this study permitted the prospective multicentre long-term follow-up analysis. The ethical principles set and its amendments in the 1964 declaration of Helsinki have all been met.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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**How to cite this article:** Mumm J, Abrarova B, Schütz J, et al. Age at surgery is not a prognostic factor for the AdVance-XP male sling efficacy: A post-hoc analysis of a prospective 7-year multicentric study *Neurourol Urodyn.* 2021;1-9. [https://doi.org/10.1002/nau.24727](https://doi.org/10.1002/nau.24727)