World J Urol (2016) 34:595–602
DOI 10.1007/s00345-015-1662-9

ORIGINAL ARTICLE

Risk factors for artificial urinary sphincter failure

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Received: 19 June 2015 / Accepted: 31 July 2015 / Published online: 8 August 2015

Abstract
Purpose To analyze revision rates and risk factors for artificial urinary sphincter failure.
Methods Eighty-four patients underwent implantation of an artificial urinary sphincter in one reference center. Continence rates were defined by daily pad usage. Influence of predefined risk factors for device explantation, revision, differences in preoperative pad usage, and device survival was analyzed using Chi-squared test, Wilcoxon signed-rank test, and Kaplan–Meier analysis. A multivariate analysis was performed using a logistic regression model. A p value below 0.05 was considered statistically significant.
Results After a mean follow-up of 39.7 months, the device was still in situ in 64 patients. In univariate analysis, perioperative need of anticoagulation led to a significant increase in urethral erosion (6 vs. 30 %; $p = 0.002$) and explantation rate (15 vs. 34 %; $p = 0.047$). Pelvic irradiation increased postoperative infection rates significantly (0 vs. 10 %; $p = 0.018$). Penoscrotal approach led to significant increase in urethral erosion rate (0 vs. 21 %; $p = 0.015$). Implantation of a double cuff led to a significant increase in explantation rate (58 vs. 24 %; $p = 0.014$), revision rate (75 vs. 38 %; $p = 0.017$), and infection rate (17 vs. 1 %; $p = 0.008$). When using cuff size of 3.5 cm, revision rate (20 vs. 50 %; $p = 0.026$) as well as incontinence rates (40 vs. 82 %; $p = 0.014$) was significantly lower. In multivariate analysis, only perioperative anticoagulation and double-cuff placement were independent predictors of artificial urinary sphincter failure.
Conclusions Our findings highlight the influence of perioperative anticoagulative therapy. In addition, the current study provides further evidence that double-cuff implantation should be performed only with caution during primary implantation.

Keywords Male urinary stress incontinence · Artificial urinary sphincter · Complications · Risk factors · Efficacy

Abbreviations

SUI	Stress urinary incontinence
AUS	Artificial urinary sphincter
EAU	European Association of Urology
ASA	Acetylsalicylic acid
SD	Standard deviation
PGI-1	Patient's global improvement score

Introduction

Offering high success rates in the treatment of male stress urinary incontinence (SUI), the artificial urinary sphincter (AUS) is still the standard treatment for persistent moderate-to-severe SUI [1, 2]. Excellent efficacy results, leading to a mean dry or improved rate of 79 % that is ranging from 61 to 100 % [3], and high patient satisfaction led to a widespread and worldwide use as well as to a grade B recommendation in the current EAU guidelines [1]. Nowadays, the AMS800 device (AMS, Minnetonka, MN, USA) is most commonly used, even though there are alternative devices now available [1, 4, 5]. Revision rates due to mechanical failure are reported to be 8–45 %, and those due to non-mechanical reasons such as erosion, urethral atrophy, and infections range from 7 to 17 %. [3, 6–8]. Despite the lack of well-designed confirmation studies with

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homogenous patient cohorts, high reintervention rates are generally accepted. However, a clear definition of potential risk factors for an increased complication rate after AUS implantation is still missing [3]. To address these flaws, we analyzed the complication and reintervention rates of one reference center and evaluated the impact of potential risk factors.

Materials and methods

Patient population

Implantation of an AUS (AMS800; AMS, Minnetonka, MN, USA) via perineal or penoscrotal approach with a 61- to 70-cm water pressure-regulating balloon was performed between 03/2002 and 05/2012 in 84 patients with persistent SUI after prostate surgery in one reference center. Eight well-experienced surgeons who had a minimum number of 25 previous AUS implantations performed the implantation. The implanting surgeon made decision regarding the surgical approach. It is general policy in our department to prefer the penoscrotal approach for irradiated patients and salvage operations, and the penoscrotal approach for non-irradiated patients without previous incontinence surgery. Variations are due to anatomical conditions, patients' preference or technical issues during the procedure.

Study design and data assessment

Data were collected retrospectively. Success rates were measured by daily pad usage. Patients were considered continent when using no pads.

AUS failure was defined by explantation due to urethral erosion, atrophy, and infection, as well as surgical revision without explantation.

The patients were evaluated regarding the following predefined risk factors: age, previous pelvic irradiation, history of urethral strictures, previous incontinence surgery, preoperative anticoagulation, surgical approach, operation time, cuff size, and double-cuff implantation. Secondly, the influence of the above-mentioned risk factors concerning AUS failure, as well as urethral injury (atrophy, erosion; diagnosed via urethroscopy), infection, and continence, was analyzed using uni- and multivariate models. Revision procedures were evaluated regarding time and cause of revision.

Surgical technique and perioperative standard procedures

Every patient received intravenous or oral perioperative antibiotic treatment. Standard perioperative antibiotics prophylaxis included intravenous cephalosporins followed by oral cephalosporins for at least 1 week.

During the whole time course, patients undergoing anticoagulation with acetylsalicylic acid (ASA) were instructed to continue anticoagulation and received additional antithrombotic prophylaxis as also depicted in current guidelines [9]. Patients undergoing preoperative anticoagulation with Vitamin K antagonists or antiplatelet therapy (clopidogrel) were firmly bridged with low-weight molecular heparins following expert opinions [10–12]. First 3.5-cm cuff was implanted in August 2010.

Statistical analysis

Primary endpoint was the explantation and revision rate of the sphincter device summarized by using the term "AUS failure." Secondary endpoints were specific complication rates (see above) and continence rates following AUS implantation. To analyze differences in pad usage, Wilcoxon signed-rank test was performed. Impact of the respective risk factors was measured using Chi-squared test for all possible combinations of risk factors and endpoints. To evaluate the impact on device survival and to analyze the actuarial survival rates of the sphincter device, a Kaplan–Meier analysis was performed. Additionally, a multivariate analysis was performed using a logistic regression model. All statistical analyses as well as graphics were created using STATISTICA 10 software (StatSoft, Tulsa, USA). A p value <0.05 was considered to be statistically significant.

Results

Pre- and perioperative patient characteristics

Table 1 shows baseline characteristics of 84 consecutive patients. Mean follow-up was 39.7 months, [standard deviation (SD) 32.6 months]. Mean follow-up for those patients who received a 3.5-cm cuff was 10.2 months (SD 7.4 months). Surgical approach was perineal in 24 of 84 cases (27 %) and penoscrotal in 60 cases (73 %). Mean operation time was 94 min (range 30–180, SD 29).

Deactivation phase

The sphincter device remained inactivated for at least 4 weeks. The implanting surgeon made decision for duration of deactivation. Mean time interval was 5.7 weeks (range 4–20, SD 2.2). Five devices (6 %) could not be activated.

Overall complication rate before activation was 11 % ($n = 9$). Urethral erosion could be observed in one case

Table 1 Summary of preoperative patient characteristics

Prostatic surgery
Open radical prostatectomy 82 % (69/84)
Laparascopic robot-assisted radical prostatectomy 5 % (4/84)
TUR-P (due to benign prostatic enlargement) 13 % (11/84)
History of radiation therapy
36 % (30/84)
Diabetes mellitus
20 % (17/84)
Anticoagulation therapy
None 63 % (53/84)
Aspirin 17 % (14/84)
Vitamin K antagonist 18 % (15/84)
Antiplatelet therapy (clopidogrel) 2 % (2/84)
Pre-AUS implant stricture disease
Missing data 43 % (36/84)
No stricture disease 56 % (27/48)
Stricture disease, with single treatment 33 % (16/48)
Stricture disease, with multiple treatment 10 % (5/48)
Previous surgical treatment for stress urinary incontinence
Missing data 1 % (1/84)
None 54 % (45/84)
Pro-ACT (solely) 2 % (2/84)
Periurethral injection (solely) 12 % (10/84)
Male sling (solely) 18 % (15/84)
Artificial urinary sphincter (solely) 5 % (4/84)
Combination of different therapies 8 % (7/84)
Preoperative pad usage (per day)
Median 9, range 4–20, SD 3.2
Double cuff
14 % (12/84)
Cuff size
3.5 cm 12 % (10/84)
4.0 cm 68 % (57/84)
4.5 cm 14 % (12/84)
≥5.0 cm 6 % (5/84)
Operation duration
≤60 min 13 % (11/84)
60–90 min 36 % (30/84)
91–120 min 29 % (24/84)
>120 min 14 % (12/84)
Unknown 8 % (7/84)

AUS artificial urinary sphincter

(1 %), urethral injury in four cases (5 %), and hematoma in two cases (3 %). Total rehospitalization rate before activation was 8 % ($n = 7$). Two patients (3 %) required surgical reintervention during the primary hospital stay due to postoperative hematoma with one of them undergoing surgery under ASA. All preactivation complications required surgical reintervention.

Efficacy after maximum follow-up

After maximum follow-up, the device was in situ in 76 %. These patients underwent further analysis concerning postoperative continence status. Mean postoperative daily pad usage was 1.6 (range 0–7; $p = 0.001$). Median patient's global impression of improvement (PGI-I) score was 1 (range 1–7, SD 1.3). Sixty-seven (81.7 %) of the patients would recommend the device to a friend. When using the strict definition of continence (no pads), 19 patients (29 %) were classified as continent.

Reinterventions and revisions

Reasons for reinterventions and respective time points are shown in Table 2. Within 3 months postoperatively, intervention was required in 12 patients (14 %). Leading reasons for revision were undetected intraoperative injury of the urethra and urethral erosion ($n = 3$, respectively). Between month 3 and 12, reintervention was necessary in 13 cases (15 %; leading cause: urethral erosion). Ten patients (12 %) required surgical intervention later than 12 months postoperatively (leading cause: urethral atrophy). In total, 47 cases (56 %) had no intervention during follow-up, 28 (33 %) had one surgical revision, seven (8 %) had two consecutive surgical revisions, and one patient required three surgical revisions (Table 2).

Risk factors for AUS failure

To analyze the impact of various risk factors on AUS failure, a Chi-squared test was performed. A summary of potential risk factors and combined endpoints including p values is given in Table 3. Summarizing, urethral erosion occurred in 6 % ($n = 3$) of 53 patients without anticoagulants and in 30 % ($n = 9$) of 31 patients undergoing anticoagulation therapy ($p = 0.002$). We found urethral erosion in 20 % ($n = 12$) of 60 patients who underwent penoscrotal implantation of the sphincter device and in none of the 24 patients after perineal implantation ($p = 0.018$). There were no significant inner-group inequalities regarding the number of irradiated and/or anticoagulated patients as well as patients who underwent double-cuff placement between the perineal and the penoscrotal device subgroup ($p = 0.44$, 0.22, 0.76, respectively). The device was explanted due to infection in 10 % ($n = 3$) of 30 patients with previous irradiation, whereas none of the patients without irradiation ($n = 64$) suffered from infection of their AUS device ($p = 0.018$). We found no statistically significant differences regarding explantation as well as infection rates in elderly patients ($p = 0.094$ and $p = 0.090$, respectively). Double-cuff implantation fostered surgical revision ($p = 0.017$) and device infection ($p = 0.008$) leading

Table 2 Need for reintervention in the time course after AUS implantation

Reinterventions	
During first 3 months	14 % (12/84)
Skin perforation of pump	1×
Dislocation of pump	2×
Undetected injury of urethra during implantation	3×
Cutaneous erosion	1×
Infection	2×
Urethral erosion	3×
Between month 3–12	15 % (13/84)
Skin perforation of pump	1×
Urethral atrophy	2×
Persistent SUI	4×
Infection	1×
Epididymitis	1×
Urethral erosion	4×
After 12 months	12 % (10/84)
Urethral atrophy	4×
Persistent SUI	1×
Impaired manual handling of pump	1×
Epididymitis	1×
Urethral erosion	2×
Iatrogenic urethral erosion	1×

SUI stress urinary incontinence

to a statistically significant increased explantation rate ($p = 0.014$).

We found significant higher continence rates in patients who received a 3.5-cm cuff ($n = 10$; $p = 0.014$). A significant increase in surgical revisions could be observed when comparing patients who received a 3.5-cm cuff to those receiving a 4.0- to 4.5-cm cuff ($n = 69$; $p = 0.026$). During the study period when the 3.5-cm cuff was available, 10 out of 12 patients (83 %) with penoscrotal device implantation actually received the 3.5-cm cuff. There was no statistical effect of patient's age, previous incontinence surgery, and a history of urethral strictures (Table 3).

In a second step, we performed a Kaplan–Meier analysis to evaluate the impact of the respective risk factors on the time course of AUS failure. Figure 1a shows the probability of a functional sphincter device in situ for patients undergoing preoperative anticoagulation therapy and those without ($p = 0.094$). There was no statistical difference between the respective subgroups regarding different types of anticoagulants ($p = 0.373$) (Fig. 1b). Thirdly, Kaplan–Meier curve was generated to display the impact of the respective surgical approach. We observed a statistical trend toward an increased AUS survival rate after perineal implantation without reaching significance ($p = 0.094$) (Fig. 1c).

In a last step, we performed a multivariate analysis of six predefined risk factors that showed striking results in the univariate analysis (Table 4). Multivariate analysis was performed for 72 patients of whom all analyzed data were available. We found perioperative anticoagulation as well as double-cuff placement acting as an independent predictor for AUS failure ($p = 0.041$, $p = 0.043$, respectively).

Discussion

In the current study we evaluated potential risk factors for AUS failure in order to create a certain risk profile when advising the respective patient before the final decision-making and therefore contributing to an individual surgical management of male SUI.

Table 3 Results of Chi-squared test of potential risk factors and various outcome parameters

	Explantation	Revision	Infection	Urethral erosion	Urethral atrophy	Persistent SUI
Age (<75a vs. >75a)	0.094	0.650	0.090	0.150	0.142	0.249
Previous irradiation (y/n)	0.829	0.231	0.018*	0.853	0.058	0.601
Urethral stricture (y/n)	0.983	0.353	0.765	0.937	0.458	0.926
Previous Incontinence surgery (y/n)	0.623	0.761	0.105	0.116	0.525	0.911
Anticoagulation (y/n)	0.094	0.191	0.918	0.002*	0.882	0.628
Approach (perineal vs. penoscrotal)	0.127	0.239	0.137	0.018*	0.503	0.718
OP duration (<90 vs. 91–120 vs. 121–150 vs. >150 min)	0.720	0.379	0.433	0.378	0.576	0.282
Double-cuff (y/n)	0.014*	0.017*	0.008*	0.252	0.863	0.277
Cuff size (3.5 vs. 4.0–4.5 vs. 5.0 cm)	0.108	0.026*	0.713	0.566	0.495	0.014*

SUI stress urinary incontinence, *OP* operation, *y* yes, *n* no

* $p < 0.05$

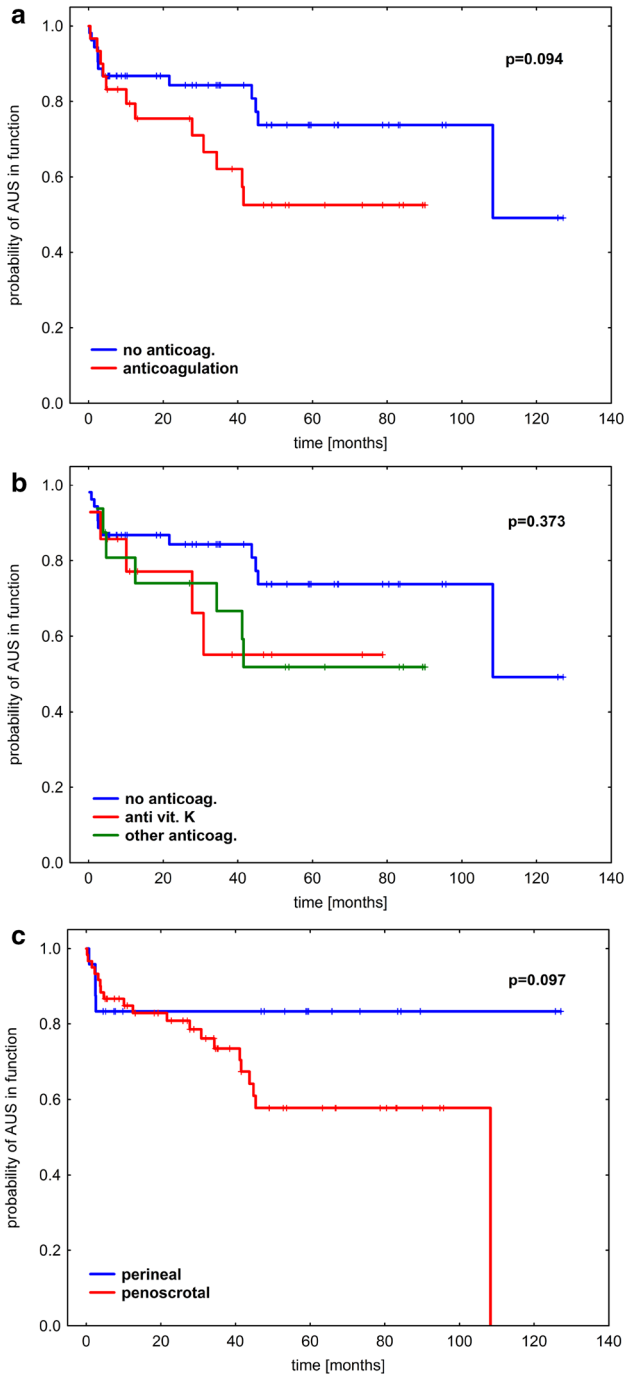

Fig. 1 Probability of artificial urinary sphincter (AUS) device in function based on existence of preoperative anticoagulation therapy (**a**) with respect to respective anticoagulants (**b**), and based on the respective surgical approach (**c**) (anticoag. = anticoagulation; vit. K = Vitamin K). A p value below 0.05 was considered statistically significant

Referring to efficacy rates, a significant reduction in median pad usage from 9.0 to 1.6 pads per day ($p = 0.001$) could be observed. Cure rate based on pad usage was 29 % after a mean follow-up of 39 months. This cure rate is at the lower end as previously reported by van der Aa et al. who found cure rates ranging from 4.3 to 85.7 % [3, 13, 14]. Nevertheless, patient satisfaction was high within our patient collective with 81.7 % of the patients recommending the AUS to a friend. Our relatively low success rates might be due to the long-term follow-up provided in the trial.

Table 4 Results of multivariate analysis using logistic regression model

	Odds ratio	95 % CI	p
Previous irradiation (y/n)	1.1	0.4–3.4	0.864
Previous incontinence surgery (y/n)	0.9	0.3–2.9	0.918
Anticoagulation (y/n)	3.3	1.1–10.4	0.041*
Approach (perineal vs. penoscrotal)	0.6	0.2–2.1	0.397
Double cuff (y/n)	4.6	1.0–20.4	0.043*
OP duration (<120 vs. ≥120 min)	0.3	0.1–1.2	0.085

OP operation, *y* yes, *n* no, *CI* confidence interval, $n = 72$

* $p < 0.05$

We observed a urethral erosion rate of 11.9 % ($n = 10$). This rate is in the predescribed range (3.3–27.8 %) [3]. It has to be stated that some of the reviewed papers did not differ between erosion and infection rates [3]. Relating our erosion/infection rates to a timeframe (Table 2), one can state that most of the reinterventions took place between the first 12 months. Nevertheless, there was one case of spontaneous urethral erosion after 41 months. This finding is congruent with previous findings also reporting late cases of spontaneous urethral erosion years after implantation [15]. This finding has clinical impact, as it demands a close follow-up during the first 12 months.

Urethral atrophy was defined by recurrent stress urinary incontinence during follow-up with a well-functioning AUS and urethroscopic exclusion of urethral erosion occurring in 7.1 %. Van der Aa et al. [3] found a median urethral atrophy rate of 7.9 % of cases. It has to be stated that comparison of the data is difficult due to incoherent and unclear definitions of urethral atrophy. Median time to urethral atrophy in our patient collective was 17.5 months (Table 2), whereas the predescribed range is currently between 3 and 23 months [3].

Our global reintervention rate of 44 % is at the upper end of the reported range of up to 44.8 % [3]. Our relatively high reintervention rate might be based on the fact that this retrospective analysis was particularly designed to detect risk factors for AUS failure, and it is therefore highly likeable that no complications and reinterventions were missed.

It has to be stated that neither age, nor previous incontinence surgery had a detectable impact on outcome after AUS implantation (Table 3). With previous incontinence surgery not being a risk factor for AUS failure, our results

underline the AUS as a salvage therapeutic option. Surprisingly, we could not detect a direct link between duration of implantation and an increased AUS infection rate (Table 3). It is also remarkable that we could not detect any impact of previous urethral strictures and consecutive transurethral stricture resections on AUS failure rates (Table 3). This is contrary to the findings of Brant et al. [16] who prospectively analyzed the outcome of 386 patients and classified patients with a history of urethral stricture as high risk of AUS failure.

According to previous studies, we found a history of pelvic irradiation being a statistically significant risk factor for AUS complications in the univariate analysis [17, 18]. However, contrary to previous studies, our results indicate a need for surgical revision due to increased infection rates ($p = 0.018$; Table 3) but not due to urethral atrophy ($p = 0.058$; Table 3), and urethral erosion ($p = 0.853$; Table 3). However, it has to be kept in mind that we have a relatively large cohort with a penoscrotal surgical approach within our study. This leads to a relatively high number of patients having their device implanted in an area being potentially less prone to irradiation-based complications. Accordingly, no significant impact on general AUS failure rate could be depicted in the multivariate analysis. These results are clinically important as they underline the significance of risk-adapted perioperative antibiotic prophylaxis. Unfortunately, most of the studies focusing on the outcome of AUS device implantation did not mention the use of perioperative antibiotics prophylaxis. Trigo Rocha et al. [19] used intravenous cephalosporins followed by 2 weeks of ciprofloxacin for perioperative antibiotics prophylaxis. Walsh et al. [17] used an intravenous perioperative antibiotics prophylaxis including ampicillin and gentamicin followed by oral cephalosporins for 1 week. In a recent review, van der Aa et al. [3] stated that data regarding perioperative antibiotics prophylaxis is insufficient, and applications are still based on institutional habits as well as expert opinions.

Concerning different surgical approaches, we found a significantly higher rate of urethral erosions in patients who underwent penoscrotal implantation ($p = 0.018$; Table 3). These results should be kept in mind by the implanting surgeon, for example when choosing the cuff size intraoperatively. However, the increased erosion rate did not lead to a significant difference in device survival and could not be confirmed in multivariate analysis. After maximum follow-up, 83 % (perineal) versus 67 % (penoscrotal) of the devices were still in situ ($p = 0.097$; Fig. 1c). Thus, it is not clear whether this particular finding is biased by a factor that could not be depicted by our statistical analyses. We looked for potential inner-group inequalities but did not find a significant difference regarding the number of irradiated and/or anticoagulated patients as well as patients that underwent double-cuff placement. We therefore cannot exclude that the experience of the respective surgeon might have biased the erosion rate of the penoscrotal devices. From a technical point of view, it seems unclear why a more proximal placement of the cuff would lead to an increased rate of urethral erosions. However, it has to be stated that one might suppose that a majority of patients might have been treated with a suboptimal cuff size in the pre-3.5-cm cuff era. A resulting increased mobility of the cuff might lead to micro-traumata and consecutively increase the erosion rate. Literature regarding complication rates in penoscrotal compared with perineal placed devices is still rare. There is one multi-center study by Henry et al. [20] that showed no statistically significant difference regarding urethral erosion rates between primary penoscrotal as well as perineal placed AUS. Recent analyzes (after the commercial launch of the 3.5-cm cuff) did not observe any differences concerning the functional outcome of the perineal compared to the penoscrotal approach [21]. Due to the above-mentioned shortcoming, our findings regarding the impact of the surgical approach have to be interpreted with caution.

Our results point out the importance of the 3.5-cm cuff for penoscrotal approach. Compared to the 4.0- and 4.5-cm cuffs, we found significantly better continence rates ($p = 0.014$; Table 3) leading to significantly lower revision rates ($p = 0.026$; Table 3). In line with Hudak et al. [22], the vast majority of our patients undergoing AUS implantation via penoscrotal approach actually received the 3.5-cm cuff since its commercial launch. To date, there are only few data about efficacy rates after 3.5-cm cuff implantation. Thus, our data give further ideas that the introduction of the 3.5-cm cuff might not only reduce revision rates but may also lead to an improved outcome. Within our study, placement of a double-cuff system was related to a significantly increased risk of device infection ($p = 0.008$; Table 3), surgical revision ($p = 0.017$; Table 3), and explantation of the device ($p = 0.014$; Table 3). These results were confirmed by multivariate analysis. This finding is in line with previous findings considering men receiving double-cuff implants being at higher risk of complications [23]. Our results indicate that a 3.5-cm cuff should be placed, and a double-cuff system should be spared whenever possible.

Most strikingly, there was a negative effect of the presence of any need for perioperative anticoagulation leading to a significantly increased urethral erosion rate ($p = 0.002$; Table 3). The respective patient subgroup consisted of patients undergoing antiplatelet therapy with ASA or clopidogrel as well as Vitamin K antagonists. To exclude any inner-group bias, a separate analysis for each compound was performed, leading to coherent results ($p = 0.094$; Fig. 1a, b). These findings could be confirmed by multivariate analysis indicating perioperative anticoagulative therapy

being an independent predictor for AUS failure. It has to be stated that all patients received a standardized perioperative bridging therapy based on general expert opinions [9, 10]. To our knowledge, there is no literature focusing on the impact on anticoagulative therapy on the outcome after AUS implantation. However, it is not hard to imagine that postoperative cuff-related micro-traumata can easily lead to urethral erosion in a patient who does not provide sufficient blood coagulation. Additionally, patients receiving anticoagulative therapy frequently have cardiovascular comorbidities leading to an impaired general microcirculation and consecutively to a less optimal blood supply to the surgical field and the urethra in particular. This is of high clinical impact as patients undergoing perioperative anticoagulative therapy should be considered high-risk, they should be counseled accordingly, and experienced surgeons should perform the implantation.

There are several limitations to our study. First and foremost are the limitations inherent to retrospective analyses. It has to be stated that our analysis includes a large number of patients who underwent surgery by eight well-experienced surgeons. Thus, it is unclear how the individual surgeon's learning curve may have affected the global reintervention rate in our patient collective [24]. However, this does not diminish the importance of the presented data, since actually a relevant proportion of devices are implanted by occasional implanters. This leads to the assumption that our data represent daily routine in many parts of the world, where most of the AUS devices are not implanted by single high-volume surgeons.

Despite the limitations of the study design, our findings may affect clinical routine. With an increased spectrum of technical opportunities to treat male stress urinary incontinence, patient management based on individual risk factors becomes more and more important [25]. Established risk profiles, usually classifying patients with secondary incontinence surgeries as high-risk, cannot be verified by our data [16, 22]. Moreover, increased use of AUS in elderly patients may consequently confront the surgeon with an increased population of patients in need of perioperative anticoagulation therapy that has been defined as a risk factor for AUS failure within our study [14]. In fact, our results affected daily routine in our hospital. Previously irradiated patients are regarded as more prone to device infections and therefore undergo extended antibiotic prophylaxis with at least two different agents. Due to higher erosion rates, penoscrotal approach is only chosen for those patients who underwent previous irradiation. In our opinion, these are the patients who profit the most by this approach because the previously irradiated tissue is spared as much as possible. Patients needing perioperative anticoagulative therapy are considered high-risk for postoperative erosion and are counseled accordingly. Double-cuff systems are no longer used in our department for primary implantation.

Author contributions Kretschmer: Protocol/project development, data collection or management, data analysis, manuscript writing/editing. Buchner: Protocol/project development, data analysis, manuscript writing/editing. Grabbert: Protocol/project development, manuscript writing/editing. Stief: Protocol/project development, manuscript writing/editing. Pavlicek: Protocol/project development, data collection or management, data analysis. Bauer: Protocol/project development, data collection or management, data analysis, manuscript writing/editing.

Compliance with ethical standards

Conflict of interest A. Kretschmer, A. Buchner, M. Grabbert, C.G. Stief, and M. Pavlicek have nothing to disclose. R. M. Bauer declares consultancy work, lectures, and participation in clinical trials for AMS (Minnetonka, MN, USA).

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