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Complications and Short-Term Explantation Rate Following Artificial Urinary Sphincter Implantation: Results from a Large Middle European Multi-Institutional Case Series

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Key Words
Male stress urinary incontinence · Artificial urinary sphincter · Complications · Safety

Abstract
Background/Aims/Objectives: To analyze perioperative complication and short-term explantation rates after perineal or penoscrotal single-cuff and double-cuff artificial urinary sphincter (AUS) implantation in a large middle European multi-institutional patient cohort. ***Methods:*** 467 male patients with stress urinary incontinence underwent implantation of a perineal single-cuff (n = 152), penoscrotal single-cuff (n = 99), or perineal double-cuff (n = 216) AUS between 2010 and 2012. Postoperative complications and 6-month explantation rates were assessed. For statistical analysis, Fisher's exact test and Kruskal–Wallis rank sum test, and a multiple logistic regression model were used ($p < 0.05$). ***Results:*** Compared to perineal single-cuff AUS, penoscrotal single-cuff implantation led to significantly increased short-term explantation rates (8.6% (perineal) vs. 19.2% (penoscrotal), $p = 0.019$). The postoperative infection rate was significantly higher after double-cuff compared to single-cuff implantation (6.0% (single-cuff) vs. 13.9% (double-cuff),

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p = 0.019). The short-term explantation rate after primary double-cuff placement was 6.5% (p = 0.543 vs. perineal single-cuff). In multivariate analysis, the penoscrotal approach (p = 0.004), intraoperative complications (p = 0.005), postoperative bleeding (p = 0.011), and perioperative infection (p < 0.001) were independent risk factors for short-term explantation. ***Conclusions:*** Providing data from a large contemporary multi-institutional patient cohort from high-volume and low-volume institutions, our results reflect the current standard of care in middle Europe. We indicate that the penoscrotal approach is an independent risk factor for increased short-term explantation rates.

Introduction

Stress urinary incontinence (SUI) in men has a major impact on health-related quality of life and is becoming a more prevalent phenomenon with radical prostatectomy being the most important cause [1]. Pelvic floor muscle training is the first therapeutic option and may improve continence rates significantly [2]. However, in patients with persistent SUI, a surgical approach is recommended [3]. Due to its high success rates, the artificial urinary sphincter (AUS) is the standard treatment for persistent moderate-to-severe SUI [3, 4]. While there are alternatives available, the AMS 800 (Boston Scientific, USA) is the most commonly used AUS [3, 5–7]. However, the implanting surgeon can choose between the perineal and the penoscrotal approach and whether to implant a single-cuff or a primary double-cuff device. To date, there is conflicting evidence whether there is a superior approach, eventually leading to a more belief- than evidence-based daily practice. There is still limited comparative data addressing differences in complication as well as explantation rates and current evidence is based on retrospective single-center data and mostly small patient cohorts [8]. These trials usually include data from high-volume centers. However, in middle Europe, occasional implanters perform a majority of implantations. Since we are currently lacking prospective comparative trials investigating the outcome of the AUS, the 'Debates on Male Incontinence' working group aims to provide large comparative, externally validated multi-center studies that are therefore more able to represent the current standard of care in middle Europe.

In this comparative, retrospective, multi-center cohort study, we compare perioperative outcome and complication rates as well as short-term explantation rates after primary perineal single-cuff, penoscrotal single-cuff and perineal double-cuff AMS 800 implantation.

Materials and Methods

Patient Population

Data were collected from 1,047 male patients who received implantation of a device due to SUI between 2010 and 2012 in one of 18 participating centers, each of them being a regional incontinence surgery reference center. Patients had to fulfill the following criteria to be included in the study: clinically verified non-neurogenic SUI, primary AMS 800 implantation. A history of previous incontinence surgery, pelvic irradiation, or urethral stricture disease was no exclusion criteria. Patients receiving a second cuff after initial single-cuff implantation and patients receiving antibiotic-coated AMS 800 were excluded. A total number of 467 patients from 16 different centers were included in this study.

Study Design and Data Assessment

After approval by a local Ethics Committee, data collection was performed retrospectively by external independent physicians not being members of the implanting center. Analyzed postoperative complications included postoperative bleeding, wound healing disorders, acute urinary retention, infection, urethral erosion, device dislocation, and mechanical failure. Notably, infection was defined as any recorded infection due to clinical presentation (fever, local tenderness, erythema, skin fixation, abscess) and was not limited to device infections. Postoperative complications were classified using the Clavien–Dindo scale [9]. Pathological postoperative dislocations of the AUS pump, cuff or pressure-regulating balloon were summarizing classified as device dislocations. Furthermore, short-term explantation rates within 6 months were analyzed.

Statistical Analysis

Primary endpoint was the short-term explantation rate following AUS implantation. Secondary endpoints were complication rates and risk factors for short-term explantation. Continuous parameters were analyzed using Kruskal–Wallis rank sum test. Categorical parameters were analyzed using Fisher's exact test. Bonferroni correction was performed whenever indicated. Furthermore, a multivariate analysis using a multiple logistic regression model was performed. All statistical analyses as well as graphics were created using R statistics (version 3.1.0, R Foundation for Statistical Computing). A p value <0.05 was considered to be statistically significant.

Results

Pre- and Perioperative Patient Characteristics

Table 1 summarizes baseline characteristics of 467 consecutive patients (152× perineal single-cuff, 99× penoscrotal single-cuff, 216× perineal double-cuff) included in the study. Seven centers included 10 or less patients, 2 centers included more than 80 patients. The mean pre-

Table 1. Patient characteristics of 467 patients included in the current study

Study population, n (%)	467 (100)
Single-cuff	251 (53.7)
Double-cuff	216 (46.3)
Perineal implantation	368 (78.8)
Penoscrotal implantation	99 (21.2)
Age, years, mean ± SD	75.3±6.4
BMI, kg/m^2, mean ± SD	28.1±4.2
Diabetes mellitus, n (%)	76 (16.3)
Cardiovascular disease, n (%)	165 (35.3)
History of pelvic irradiation, n (%)	149 (33.8)
External irradiation	141 (32.1)
Brachytherapy	8 (1.7)
Previous incontinence surgery, n (%)	163 (34.9)
AUS	64 (13.7)
Male sling	65 (13.9)
Compressive balloon system	28 (6)
Bulking agents	33 (7.1)
Other	27 (5.8)
History of urethral stricture, n (%)	101 (21.6)
History of bladder neck stricture, n (%)	64 (13.7)
Etiology of SUI, n (%)	
Radical prostatectomy	387 (82.9)
Transurethral procedure	59 (12.6)
Adical cystectomy	10 (2.1)
Daily pad usage, mean ± SD	7.1±3.9

PPI = Post-prostatectomy incontinence.

Table 2. Perioperative complication rates stratified between perineal single-cuff vs. penoscrotal single-cuff AUS implantation

Complication	Perineal single-cuff	Penoscrotal single-cuff	p value
Intraoperative complications	6 (3.9)	3 (3.0)	1.000
Postoperative bleeding	9 (6.0)	7 (7.1)	0.793
Wound healing disorder	6 (4)	3 (3.1)	1.000
Acute urinary retention	15 (9.9)	9 (9.2)	1.000
Device dislocation	0 (0.0)	4 (4.0)	0.024
Mechanical failure	2 (1.3)	5 (5.1)	0.117
Urethral erosion	5 (3.3)	6 (6.1)	0.352
Postoperative infection	9 (6.0)	8 (8.2)	0.609
Explantation within 6 months	13 (8.6)	19 (19.2)	0.019

Values are n (%).

operative age, severity of incontinence based on daily pad usage, and body mass index (BMI) did not differ significantly between the respective patient cohorts. The decision to use single-cuff or double-cuff devices as well as the surgical approach was made upon the physician's preference. Notably, all primary double-cuff implantations included in the study have been performed via a perineal approach. Six-month follow-up was available for 70.6% of the patient collective.

Perineal vs. Penoscrotal Single-Cuff AUS Implantation

In a first step, we tested for potential differences in complication and device explantation rates between the gold-standard perineal single-cuff and the penoscrotal single-cuff approach. Intra- and postoperative complication rates and explantation rates within 6 months of the 2 groups are summarized in table 2. In detail, significantly increased device dislocation rates (0% (perineal) vs. 4% (penoscrotal), p = 0.024) as well as significantly increased

Table 3. Perioperative complication rates stratified between perineal single-cuff vs. perineal double-cuff AUS implantation

Complication	Perineal single-cuff	Perineal double-cuff	p value
Intraoperative complications	6 (3.9)	9 (4.2)	1.000
Postoperative bleeding	9 (6.0)	15 (6.9)	0.831
Wound healing disorder	6 (4)	3 (1.4)	0.172
Acute urinary retention	15 (9.9)	30 (13.9)	0.332
Device dislocation	0 (0.0)	6 (2.8)	0.045
Mechanical failure	2 (1.3)	5 (2.3)	0.705
Urethral erosion	5 (3.3)	5 (2.3)	0.746
Postoperative infection	9 (6.0)	30 (13.9)	0.016
Explantation within 6 months	13 (8.6)	14 (6.5)	0.543

Values are n (%).

Table 4. Summary of perioperative complications according to the Clavien–Dindo scale

Surgical group	Clavien I, % (n)	Clavien II, % (n)	Clavien IIIa, % (n)	Clavien IIIb, % (n)	Clavien IV, % (n)	Clavien V, % (n)	Total, % (n)
Perineal single-cuff	14.5 (22)	12.5 (19)	4.6 (7)	10.5 (16)	–	–	42.1 (64)
Penoscrotal single-cuff	16.2 (16)	10.1 (10)	6.1 (6)	31.3 (31)	–	–	63.6 (63)
Perineal double-cuff	11.6 (25)	21.3 (46)	3.7 (8)	13.0 (28)	–	–	49.8 (107)

short-term explantation rates (8.6% (perineal) vs. 19.2% (penoscrotal), p = 0.019) for penoscrotal implantation could be observed. Notably, most frequent reason for device explantation was device infection (n = 5, 38.5%) for the perineal approach, and urethral erosion (n = 6, 31.6%) for the penoscrotal approach.

Perineal Single-Cuff vs. Perineal Double-Cuff Implantation

Next, we compared complication and device explantation rates between perineal single-cuff and perineal double-cuff implantation. Intra- and postoperative complication rates and explantation rates within 6 months after perineal single-cuff or double-cuff implantation are summarized in table 3. Notably, 2 intestinal lesions (1× single-cuff implantation (low-volume center), 1× double-cuff implantation (high-volume center)) could be observed. Device dislocation rates were significantly increased after double-cuff implantation (0% (single-cuff) vs. 2.6% (double-cuff), p = 0.045). In addition, the postoperative infection rate was significantly higher after double-cuff implantation (6.0% (single-cuff) vs. 13.9% (double-cuff), p = 0.019). Most frequent postoperative infection after double-cuff implantation was urinary tract infection (n = 23, 76.7%). Short-term explantation rate was slightly higher after single-cuff implantation without reaching statistical significance (8.6% (single-cuff) vs. 6.5% (double-cuff), p = 0.543). Most frequent reason for device explantation after double-cuff implantation was urethral erosion (n = 5, 35.7%).

Table 4 summarizes all recorded complications within 6 months postoperatively for the analyzed surgical groups according to the Clavien–Dindo scale [9].

Prognostic Features for Explantation

In the next step, we evaluated the impact of multiple predefined prognostic features on short-term explantation rates of our patient collective focusing on potential patient-derived, intraoperative, and postoperative risk factors. Results of the univariate analysis of selected prognostic features including OR and 95% CI are summarized in table 5. In addition to the global previous incontinence surgery rate, we analyzed the impact of respective previous incontinence devices and found no differences after previous AUS (p = 0.821), male sling (p = 0.376), bulking agent (p = 1.000), and compressive balloon system (p = 1.000). Furthermore, there was no significant influence of preoperative age (p = 0.158), preoperative daily pad usage (p = 0.770), preoperative BMI (p = 0.265), and operation time (p = 0.148) on short-term explantation rate.

Table 5. Univariate analysis of predefined hypothesized predictive features of short-term device explantation rates

Prognostic feature	OR	95% CI	p value
Diabetes	1.719	0.748–3.684	0.143
Cardiovascular disease	1.780	0.917–3.442	0.074
Post-prostatectomy incontinence	0.547	0.260–1.220	0.100
Previous radical cystectomy	2.341	0.235–12.245	0.258
Pelvic radiation	0.680	0.300–1.434	0.313
Previous incontinence surgery	0.712	0.333–1.441	0.415
Urethral stricture	0.870	0.356–1.921	0.851
Single-cuff vs. double-cuff	1.348	0.564–3.199	0.543
Penoscrotal vs. perineal	2.991	1.492–5.902	0.001
Perioperative single-shot antibiotics	2.979	0.677–10.224	0.075
Intraoperative complications	5.082	1.483–15.607	0.005
Postoperative bleeding	3.609	1.304–9.099	0.007
Wound healing disorder	7.118	1.702–27.413	0.004
Acute urinary retention	1.705	0.647–4.012	0.222
Device dislocation	2.335	0.235–12.216	0.258
Postoperative infection	6.629	3.035–14.214	<0.001

Table 6. Multivariate analysis of selected features that showed significant results in univariate analysis

Predictive feature	SE	95% CI	p value
Intraoperative complications	0.068	0.081 to 0.304	0.005
Postoperative bleeding	0.052	0.047 to 0.218	0.011
Wound healing disorder	0.083	0.083 to 0.358	0.009
Postoperative infection	0.044	0.163 to 0.309	0.001
Single-cuff vs. double-cuff	0.030	–0.013 to 0.085	0.223
Penoscrotal vs. perineal	0.036	0.045 to 0.164	0.004

Finally, we performed a multivariate analysis using a multiple logistic regression model. Hereby, we included the prognostic features that showed significant results in the univariate analysis as well as the surgical groups (penoscrotal vs. perineal, single-cuff vs. double-cuff). Results of the multivariate analysis are displayed in table 6. In summary, the penoscrotal approach, intraoperative complications, postoperative bleeding, wound healing disorders, and postoperative infections could be identified as independent prognostic features for short-term device explantation after AUS implantation.

Discussion

In the current retrospective comparative international multi-institutional case series, we analyze perioperative safety as well as short-term explantation rates after AUS implantation, focusing on differences regarding the surgical approach (perineal vs. penoscrotal) as well as single-cuff and double-cuff devices.

In 2003, Wilson et al. [10] introduced the penoscrotal (or transscrotal) surgical approach to implant AUS. It has been argued that the penoscrotal approach allows better urethra manipulation and better posterior urethra dissection. However, critics of this technique claim that the more distal position of the cuff in more vulnerable areas of the urethra might lead to increased complication rates. In our contemporary Middle European patient cohort, 99 out of 467 procedures (22.0%) were performed via the penoscrotal approach, highlighting the clinical value that this procedure still has in many centers. To date, various publications focused on the outcome after penoscrotal device implantation. Henry et al. [11] analyzed complications after 28 initial penoscrotal implantations and found decreased overall complication rates and lower total revision rates after penoscrotal compared to initial perineal implantation. In a retrospective 4-center study by the same working group, postoperative complication rates of 49 patients were analyzed. The authors found slightly lower total complication rates after penoscrotal compared to initial perineal

AUS implantation [12]. However, in the above-mentioned studies, complications included only device malfunction, erosion/infection, and urethral atrophy rates. In the current study, we analyzed multiple postoperative complications and found significantly increased device dislocation rates as well as significantly increased short-term explantation rates after penoscrotal implantation. Likewise, overall postoperative complication rate was higher for the penoscrotal approach. In addition, multivariate analysis revealed the penoscrotal approach being an independent risk factor for short-term explantation.

Apart from the surgical approach, the implanting surgeon can choose whether to implant a single-cuff or double-cuff AUS system. It is noteworthy that, in our contemporary patient cohort, 215 out of 467 patients (46.0%) received primary double-cuff implantation. We found significantly increased postoperative device dislocation rates as well as postoperative infection rates after primary double-cuff placement. This is in line with previous findings, also indicating increased infection rates for double-cuff systems [13]. In contrast, O'Connor et al. [14] did not find any significant differences comparing postoperative infection rates between primary single-cuff and double-cuff implantations but, however, did observe an increased explantation rate after double-cuff placement. Short-term urethral erosion rates did not vary significantly between the single-cuff and double-cuff subgroups of our patient collective. This is in line with previous findings indicating that the increased periurethral pressure caused by the additional cuff does not result in increased urethral erosion rates [13, 14]. Notably, despite total intraoperative complication rates being low, we found 2 cases of intestinal lesions after perineal single-cuff or double-cuff placement. Since previous studies did not necessarily distinguish between intra- and postoperative complications, it is difficult to integrate our data into the current literature [8]. However, the intraoperative complication rate in our patient cohort, including data from low-volume institutions, is higher than previously described. Linder et al. [15], for instance, did not describe any urethral or intestinal lesions in their patient cohort. Therefore, our data might reflect what an average low-volume surgeon can expect.

To summarize, our data indicate that the penoscrotal single-cuff approach might be inferior in terms of short-term explantation rates compared to the gold standard perineal single-cuff AUS. In our contemporary multi-institutional patient cohort, no significant differences in terms of short-term explantation rates could be observed for primary single-cuff or double-cuff placement. With regard to the significantly increased postoperative infection and device dislocation rates, one can state that the double-cuff system might lead to comparable short-term safety results but, based on our results, there is no indication that it might challenge the perineal single-cuff AUS as current gold standard. Recently, Suarez and McCammon reviewed current literature regarding double-cuff placement and came to the same conclusion that double-cuff systems do not seem to be superior compared to the standard perineal single-cuff AUS [16].

Another important feature of this study is the exhaustive analysis of potential prognostic features for short-term device explantation investigating the impact of numerous potential predefined patient- and procedure-derived variables in the entire patient cohort. Here, we included previously investigated potential risk factors but also focused on novel variables that have, to our knowledge, not been analyzed before. Notably, we found no significant impact of previous pelvic radiation, urethral stricture disease and salvage operations on short-term device explantation rates. This is in line with recent risk factor analyses [13, 17]. However, there are also studies observing a worse outcome and increased complication rates for irradiated patients [18, 19]. Moreover, we observed a significant impact of any kind of intraoperative complications on the respective explantation rate in the univariate analysis and confirmed this finding in the multivariate analysis. We do also describe postoperative bleeding and postoperative infection as independent risk factors for short-term device explantation. Postoperative bleeding usually represents as scrotal hematoma and can be superinfected or cause urethral lesions leading to consecutive device explantation. Any kind of perioperative infection seems to be a strong predictor for impaired short-term device survival. It has to be kept in mind that our infection rate includes not only primary device infections but mainly tract infection and epididymitis.

Our findings have strong clinical implications since they highlight that the above-mentioned patients are at high risk for short-term device explantation and close monitoring should be mandatory. Furthermore, our results highlight the clinical importance of prevention of any kind of postoperative infection and the optimization of perioperative antibiotic prophylaxis strategies. This study is the first to show inferior results for the penoscrotal approach when it comes to short-term explantation rates and perioperative complications. These results have to be kept in mind when addressing a patient

who is suitable for the perineal as well as for the penoscrotal approach. Finally, our systematic risk factor analysis indicates that postoperative success defined by short-term device survival is not predominantly determined by patient-derived risk factors (patient selection), but rather by the (peri-)operative procedure itself, handing over the responsibility to the implanting surgeon and the clinical staff to facilitate a satisfying short-term outcome. In addition, we do include low-volume institutions in our analysis and therefore provide data that reflect what a low-volume surgeon may experience in daily practice.

There are several limitations to our study. First and foremost are the limitations inherent to retrospective analyses of heterogeneous patient cohorts. The follow-up in the current study was not standardized and due to its multi-institutional design with 16 participating centers, it is unclear if, and how, an individual learning curve may have affected our results [20]. However, in our opinion, this does not diminish the clinical relevance of the presented data, since, in daily practice, a relevant proportion of implants are performed by occasional implanters.

Conclusion

In this comparative, retrospective, multi-institutional case series, we compare perioperative complications and short-term explantation rates after perineal and penoscrotal as well as after single-cuff and double-cuff AMS 800 implantation and provide data from a large contemporary middle European patient cohort. Our results suggest that short-term explantation rates are significantly higher after penoscrotal implantation. Apart from the penoscrotal approach, intraoperative complications, postoperative bleeding, and postoperative infections are shown to be independent risk factors for decreased short-term device survival.

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