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ORIGINAL ARTICLE

Comparison of adjustable male slings and artificial urinary sphincter in the treatment of male urinary incontinence: a retrospective analysis of patient selection and postoperative continence status

M. Grabbert[1] · T. Hüsch[2] · A. Kretschmer[3] · R. Kirschner-Hermanns[4] · R. Anding[4] · A. Rose[5] · A. Friedl[6] · A. Obaje[7] · A. Heidenreich[1] · B. Brehmer[8] · C. M. Naumann[9] · F. Queissert[10] · H. Loertzer[11] · J. Pfitzenmaier[12] · J. Nyarangi-Dix[13] · M. Kurosch[2] · R. Olianas[14] · R. Homberg[15] · R. Abdunnur[16] · J. Schweiger[17] · T. Hofmann[8] · C. Wotzka[18] · T. Pottek[19] · W. Huebner[20] · A. Haferkamp[2] · R. M. Bauer[3]

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Abstract

Purpose To analyze and compare preoperative patient characteristics and postoperative results in men with stress urinary incontinence (SUI) selected for an adjustable male sling system or an artificial urinary sphincter (AUS) in a large, contemporary, multi-institutional patient cohort.

Methods 658 male patients who underwent implantation between 2010 and 2012 in 13 participating institutions were included in this study ($n=176$ adjustable male sling; $n=482$ AUS). Preoperative patient characteristics and postoperative outcomes were analyzed. For statistical analysis, the independent T test and Mann–Whitney U test were used.

Results Patients undergoing adjustable male sling implantation were less likely to have a neurological disease (4.5% vs. 8.9%, $p=0.021$), a history of urethral stricture (21.6% vs. 33.8%, $p=0.024$) or a radiation therapy (22.7% vs. 29.9%, $p=0.020$) compared to patients that underwent AUS implantation. Mean pad usage per day (6.87 vs. 5.82; $p<0.00$) and the ratio of patients with a prior incontinence surgery were higher in patients selected for an AUS implantation (36.7% vs. 22.7%; $p<0.001$). At maximum follow-up, patients that underwent an AUS implantation had a significantly lower mean pad usage during daytime ($p<0.001$) and nighttime ($p=0.018$). Furthermore, the patients' perception of their continence status was better with a subjective complete dry rate of 57.3% vs. 22.0% ($p<0.001$).

Conclusions Patients selected for an AUS implantation showed a more complex prior history and pathogenesis of urinary incontinence as well as a more severe grade of SUI. Postoperative results reflect a better continence status after AUS implantation, favoring the AUS despite the more complicated patient cohort.

Keywords Male urinary incontinence · Artificial urinary sphincter · Compressive adjustable slings

Introduction

Radical prostatectomy and transurethral resection of the prostate are major causes for stress urinary incontinence (SUI) in men [1]. If conservative treatment options like physio therapy fail, a surgical approach is recommended by current guidelines, whereas the artificial urinary sphincter (AUS) is standard of care.

The AMS 800 (Boston Scientific, USA; formerly American Medical Systems, USA) is the most commonly implanted device, whereas other systems like the Zephyr ZSU 375 sphincter (Zephyr Surgical Implants, Switzerland) are currently being evaluated [2]. Success rates of the AUS are high with a rate of approx. 80% of patients with a maximum of one pad per day after 2 years [3]. On the other hand, revision rates for complications like infection, erosion or urethral atrophy range from 5 to 20% [4–7].

Adjustable male slings are composed of soft and wide cushions positioned on the bulbospongiousus muscle resulting in a constant pressure on the urethra and therefore improving basic continence. A number of systems have been introduced in the last years. The Argus Classic (Promedon,

✉ M. Grabbert
markus.grabbert@uk-koeln.de

Extended author information available on the last page of the article

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Argentina) consists of a silicone foam cushion that puts pressure on the bulbar urethra and is implanted retropubically [8]. The Argus-T (Promedon, Argentina) was introduced in 2008 and is implanted via a transobturatoric approach [9]. Both systems can be readjusted via a small surgical intervention in which tension can be applied or released from the sling arms. Washers with a large diameter protect the underlying tissue. The ATOMS (A.M.I, Austria) was the third adjustable male sling system in our patient cohort and can be adjusted easily via injection of saline in the scrotal port system [10].

Current evidence indicates that efficacy of the different adjustable male slings is comparable with a success rate of approx. 65% of patients with a maximum of one pad per day after 2 years and the patients' demand for these systems is high. In addition, no cognitive or manual dexterity to actively use these systems is necessary [3].

The "Debates on Male Incontinence" (DOMINO) working group intends to provide evidence with the help of a robust "real-life" database with patients from various urological continence centers of very different patient volume from Central Europe. Due to the lack of prospective comparative trials investigating different surgical devices for the treatment of male urinary incontinence, most of the published data is based on the experience of a small number of high-volume surgical centers. However, a relevant number of devices in Germany and Central Europe are implanted by surgeons, performing the procedure only occasionally.

The purpose of our study was to analyze and compare preoperative patient characteristics and postoperative results in men with stress urinary incontinence (SUI) selected for an adjustable male sling system or an artificial urinary sphincter (AUS) in a large, contemporary, multi-institutional patient cohort. The primary goal of this work was to identify different indications for male incontinence surgery and not to focus on complications of the different surgical approaches since these have been widely described before.

Materials and methods

After ethical approval of the study, written informed consent was obtained from all the patients participating in the prospective evaluation of quality of life. Due to the retrospective nature of the study, patient selection was not standardized. The decision for the utilization of AUS or adjustable male sling was made by surgeons and patients' choice. All patients were assessed in an ambulatory clinical visit prior to surgery.

658 male patients who underwent implantation between 2010 and 2012 in 13 participating institutions were included. For statistical analysis, independent *T* test and Mann–Whitney *U* test were used to identify differences between both groups. All statistical analyses were performed with IBM SPSS Statistics 24.0 (IBM Co., Armonk, NY, USA). A p value ≤ 0.05 was considered statistically significant.

The primary outcome was the evaluation of postoperative pad usage, the secondary outcome was the subjective patients' perspective categorizing their continence status into one of the following four categories: worse, no change, improvement and completely dry.

Results

Table 1 summarizes the baseline characteristics of the included patients (artificial urinary sphincter—$n=482$ [AMS 800; $n=265$ single cuff and $n=217$ double cuff]; adjustable male slings—$n=176$ [$n=95$: Argus; $n=32$: Argus-T; $n=49$: ATOMS]). Briefly, patients undergoing adjustable male sling implantation were less likely to have a known neurological disease (4.5% vs. 8.9%, $p=0.021$), less likely to have a history of urethral stricture (21.6% vs. 33.8%, $p=0.024$) and less likely to have undergone a prior radiation therapy (22.7% vs. 29.9%, $p=0.020$) compared

Table 1 Preoperative patient characteristics

Parameter	Adjustable male sling	Artificial urinary sphincter	p value
Age (mean)	69.85 years	70.0 years	0.17
BMI (mean)	27.3	28.0	0.14
Neurological disease	$n=8$ (4.5%)	$n=43$ (8.9%)	0.021*
Urethral stricture	$n=38$ (21.6%)	$n=163$ (33.8%)	0.024*
Radiation therapy	$n=40$ (22.7%)	$n=144$ (29.9%)	0.020*
Cystoscopic evaluation	$n=119$ (67.6%)	$n=327$ (67.8%)	0.19
Urodynamic examination	$n=94$ (53.4%)	$n=218$ (45.2%)	0.12
Prior incontinence surgery	$n=40$ (22.7%)	$n=177$ (36.7%)	<0.001*
Pads per day (mean)	5.82 (SD 2.69) (min 1.0 to max 20.0)	6.87 (SD 3.98) (min 1.0 to max 30.0)	<0.001*
24 h pad test (mean-g)	472 g ($n=49$)	693 g ($n=31$)	<0.001*

*p value ≤ 0.05 was considered statistically significant

to patients that underwent AUS implantation. The incontinence degree was higher in patients selected for an AUS implantation with a mean pad usage per day of 6.87 vs. 5.82 ($p < 0.001$). The rate of prior incontinence surgery was higher in patients selected for an AUS implantation (36.7% vs. 22.7%; $p < 0.001$). Sufficient follow-up data was available for 411 patients and mean follow-up was 16.7 months (SD ± 14.81).

76.0% (366/482) of patients receiving an AUS underwent a perineal approach and 24.0% (116/482) underwent a penoscrotal approach. 55.0% (265/482) of patients receiving an AUS underwent a single cuff implantation and 45.0% (217/482) of patients underwent a double cuff implantation.

In the AUS group in total 9.1% (44/482) of the devices were explanted. The main reasons for explantation surgery were erosion of the urethra in 21 (47.7%) cases and infection in 13 (29.5%) cases. On the other hand, only 9 of 176 (0.05%) adjustable sling systems were explanted—mostly due to dysfunction or dislocation (6/9) and in addition to the postoperative adjustments, nine devices were explanted due to hyper continence with consecutive residual urine.

Time between the incontinence surgery and the previous incontinence causing surgery was comparable in both groups with a mean of 62.2 months (min. 3 to max. 241) in the AUS group and a mean of 52.3 months (min. 6 to max. 264) in the adjustable sling group ($p = 0.19$). The proportion of patients that started a course of radiation therapy within 1 year after the incontinence causing surgery was comparable with 43.1% (62/144) of patients in the AUS group and 50.0% (20/40) of patients in the adjustable sling group ($p = 0.17$).

Figure 1 summarizes the different prior urological surgeries leading to SUI. 89.2% of patients selected for an adjustable male sling implantation have had a radical prostatectomy as the primary cause of their stress urinary incontinence, whereas only 80.7% of patients selected for an artificial urinary sphincter have had a radical prostatectomy ($p < 0.001$).

Mean pad usage at maximum follow-up during daytime was 1.04 (AUS) vs. 1.95 (adj. male sling); $p < 0.001$. Mean pad usage during nighttime was 0.03 (AUS) vs. 0.17 (adj. male sling); $p = 0.018$. The subjective patients' perspective is summarized in Table 2 and shows a subjective complete dry rate of 57.3% (AUS) vs. 22.0% (adj. male sling); < 0.001. The postoperative adjustment rate in patients with adjustable male slings was 44.8% ($n = 79/176$) and the mean number of adjustments in these patients was 1.58 (SD ± 0.81; min. 1 to max. 4).

A logistic regression model was performed to analyze the potential influence of several pre- and postoperative factors, as listed in Table 1 on the subjective postoperative continence status as described in Table 2. Only the type of surgery ($p = 0.020$) favoring the AMS system and a lower number of needed pads per day ($p = 0.004$) could be identified as statistically independent factors for a better subjective continence status postoperatively. The other factors listed in Table 1 failed statistical significance or the logistic regression model was not applicable ($p > 0.005$, each).

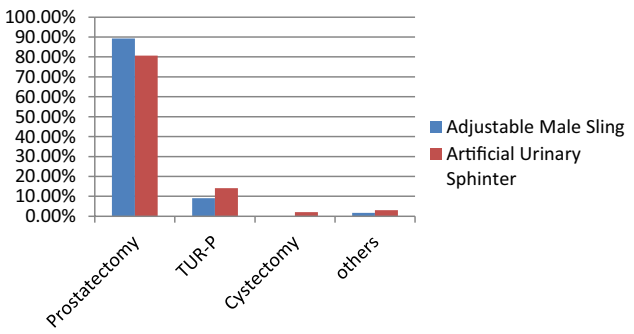

Fig. 1 Prior urological surgery leading to urinary incontinence

Discussion

Adjustable male slings are a minimally invasive treatment option in male patients with stress urinary incontinence without a high level of evidence regarding the optimal patient selection and postoperative results [11].

In our multi-institutional study, we compared the preoperative patient characteristics as well as the postoperative continence status in male patients that underwent surgery for stress urinary incontinence either with an adjustable male sling or an artificial urinary sphincter (AMS800). Although knowledge of different complication rates as well as complication profiles might be helpful for decision making, patient characteristics are essential for the selection of the optimal treatment option for each patient. In our study, we therefore focused on the preoperative patient characteristics and the postoperative continence status.

Radical prostatectomy was the primary cause of SUI in patients selected for an adjustable male sling, whereas approx. 20% of patients that underwent an AUS implantation had another prior surgery as the major cause of their SUI. Overall, patients that were selected for an AUS implantation seem to have a more complex prior history

Table 2 Subjective perception of changes in continence status

	Adjustable male sling ($n = 82$)	Artificial urinary sphincter ($n = 220$)	p value
No change	$n = 15$ (18.3%)	$n = 23$ (10.5%)	< 0.001*
Improvement	$n = 47$ (57.3%)	$n = 68$ (30.9%)	< 0.001*
Completely dry	$n = 18$ (22.0%)	$n = 126$ (57.3%)	< 0.001*
Worse	$n = 2$ (2.4%)	$n = 3$ (1.4%)	–

*p value ≤ 0.05 was considered statistically significant

and have a higher grade urinary incontinence. At the moment, there is no scientific data that is clearly indicating which preoperative features are crucial for the optimal treatment decision and which degree of urine loss should be a contraindication for an adjustable male sling [3]. A major problem seems to be a lack of a standardized assessment protocol that is currently only based on expert opinions as well as no established exclusion criteria or cut-off values for the different operative treatment options [3]. A current publication evaluating the Argus sling reported of the following preoperative assessment: 20-min pad test, different questionnaires, cystoscopy and uroflowmetry, if possible and also included approx. 30% of patients with a cause for their SUI other than a RP and approx. 20% of patients with a second-line course of irradiation.

A recent publication evaluating a large cohort of patients after RP in a long-term follow-up was able to identify older patients with an advanced tumor and adjuvant radiation therapy, who were at highest risk for an impaired functional outcome [12]. In the UK ProtecT trial, a good postoperative continence status without any urinary incontinence after a follow-up of 6 years after radical prostatectomy was 17%, with a baseline incontinence rate of 1% prior to surgery [13]. These results highlight the importance of the topic and the need of a standardized reporting system of functional results. The definition of postoperative incontinence varies widely and therefore a comparison with existing studies is complicated [3].

Our data suggest a better continence status after AUS implantation compared to patients that received an adjustable male sling. A current review of the available studies by Chen et al. concludes a decreased number of pads used per day by about three for both sling systems and artificial urinary sphincter in the treatment of male urinary incontinence after RP [14].

Published prospective data in very selected patients on adjustable male sling systems seem to show a better continence status after multiple adjustments than in our cohort. In the current study, we could show a reduction in pad usage from approx. 6 pads per day to 2 pads per day for the adjustable male sling systems and a reduction in pad usage from approx. 7–1 pad per day for the artificial urinary sphincter. The complete dry rate in patients' subjective perception was 22% for the adjustable mal slings resp. 57% for the artificial urinary sphincter. In the prospective evaluation of the adjustable transobturator Argus-T sling, Bauer et al. were able to show a dry rate of 61.9% and a rate of 26.2% of patients that improved after a mean follow-up of 28.8 months [9]. Friedl et al. reported a complete dry rate of 64% and a reduction in median pad usage from 4 pads to 1 pad/day for the adjustable transobturator ATOMS sling after a median follow-up of 31 months [10].

A recent review by van der Aa et al. summarizing several studies evaluating the results of the artificial urinary sphincter in the treatment of male urinary incontinence demonstrates results that are in line with our data and suggest a continence rate of 61–100% of cases (no pad or one pad per day). Dry rates (no pads) varied from 4% to 86% [15]. The conclusion of a recent meta-analysis by Chen et al. is in line with our results and shows a decreased number of pads used per day by about three for the artificial urinary sphincter [14].

There is a certain wish of patients for a less invasive alternative to the AUS that promises lower complication rates and does not require any manual handling [11]. The data of our study show a better continence status after AUS favoring the established gold standard in the treatment of male urinary incontinence but shows a higher complication and revision rate.

Decision making for male incontinence surgery remains a difficult topic and there clearly is a natural selection bias. International guidelines are mainly based upon incontinence grade—which is defined differently and excludes further important factors in decision making. There is a huge lack of comparative studies and we would like to contribute some insights of decision making in the included expert centers and compare the outcome of patients to further contribute to this topic.

Limitations

There are certain important limitations to this study. First, because of the retrospective character of this study, some data were missing. Furthermore, the multicenter character of this study and different levels of experience of the implanting surgeons are major limitations of this study. Nevertheless, we the current study represents clinical daily practice. Due to the lack of prospective comparative trials investigating different surgical devices for the treatment of male urinary incontinence, we believe that this study is able to give a realistic insight into patient selection and expected results. Clearly there is a need for a randomized controlled trial comparing adjustable male slings and the artificial urinary sphincter to identify the optimal patients for each surgical approach and being able to give patients a realistic idea of the possible postoperative results. Fortunately, several study protocols in Germany and the UK are currently being set up to further investigate this topic [16].

Conclusion

Patients selected for an AUS implantation showed a more complex prior history and pathogenesis of urinary incontinence as well as a more severe grade of urinary incontinence. Postoperative results reflect a better continence status

after AUS implantation, favoring the AUS despite the more complicated patient cohort.

Comparing both techniques in a retrospective fashion remains the major limitation of our study, since there is a huge selection bias and both systems might serve different patient populations. In addition, patients' subjective preference is also an important factor in the selection of the different surgical treatment options.

In future, a prospective trial comparing both systems in patients with a mid-grade urinary incontinence after radical prostatectomy seems to be necessary to answer the question if there are clear factors favoring one system in this distinct patient population.

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Compliance with ethical standards

Research ethics/informed consent The study was performed according to the Helsinki Declaration and approved by the local Ethics Committee of the Medical University Frankfurt (Johann-Wolfgang Goethe University, Frankfurt am Main, Germany; Number: 442/13). This was a retrospective study evaluating perioperative data. Different questionnaires were utilized prospectively. A signed informed consent from the patients participating in the prospective collection of the questionnaires was mandatory.

Conflict of interest M. Grabbert, T. Hüsch, A. Kretschmer, R. Kirschner-Hermanns, R. Anding, A. Rose, A. Friedl, A. Obaje, A. Heidenreich, B. Brehmer, F. Queissert, J. Pfitzenmaier, J. Nyarangi-Dix, M. Kurosch, R. Olianas, R. Homberg, J. Schweiger, T. Hofmann, C. Wotzka and A. Haferkamp declare no potential conflict of interest. C. M. Naumann declares lectures, consultancy work, and participation in clinical trials for Coloplast. H. Loertzer declares lectures, consultancy work, and participation in clinical trials for Coloplast. R. Abdunnur declares consultancy work, lectures, and participation in clinical trials for AMS/Boston Scientific (Minnetonka, MN, USA) and Promedon (Cordoba, Argentina). T. Pottek declares consultancy work, lectures for Boston Scientific/AMS, Promedon, Zephyr, and Teleflex. W. Hübner declares consultancy work, lectures, and participation in clinical trials for Uromedica (Plymouth, MN, USA) and Promedon (Cordoba, Argentina). R. M. Bauer declares consultancy work, lectures, and participation in clinical trials for AMS/Boston Scientific (Minnetonka, MN, USA) and Promedon (Cordoba, Argentina).

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Affiliations

M. Grabbert[1] · T. Hüsch[2] · A. Kretschmer[3] · R. Kirschner-Hermanns[4] · R. Anding[4] · A. Rose[5] · A. Friedl[6] · A. Obaje[7] · A. Heidenreich[1] · B. Brehmer[8] · C. M. Naumann[9] · F. Queissert[10] · H. Loertzer[11] · J. Pfitzenmaier[12] · J. Nyarangi-Dix[13] · M. Kurosch[2] · R. Olianas[14] · R. Homberg[15] · R. Abdunnur[16] · J. Schweiger[17] · T. Hofmann[8] · C. Wotzka[18] · T. Pottek[19] · W. Huebner[20] · A. Haferkamp[2] · R. M. Bauer[3]

1 Department of Urology, University Hospital Cologne, Cologne, Germany

2 Department of Urology, University Medical Center Mainz, Mainz, Germany

3 Department of Urology, University Hospital Munich Grosshadern (LMU), Munich, Germany

4 Department of Neurourology, University Bonn, Bonn, Germany

5 Department of Urology, Helios Klinikum Duisburg, Duisburg, Germany

6 Department of Urology, Krankenhaus Der Barmherzigen Schwestern Wien, Vienna, Austria

7 Department of Urology, St. Bernward Krankenhaus Hildesheim, Hildesheim, Germany

8 Department of Urology, Diankonie Klinikum Schwaebisch Hall, Schwaebisch Hall, Germany

9 Department of Urology, University Hospital SH, Kiel, Germany

10 Department of Urology, University Hospital Muenster, Muenster, Germany

11 Department of Urology, Westpfalzklinikum Kaiserslautern, Kaiserslautern, Germany

12 Department of Urology, Evangelische Klinikum Bethel Bielefeld, Bielefeld, Germany

13 Department of Urology, University Hospital Heidelberg, Heidelberg, Germany

14 Department of Urology, Klinikum Lueneburg, Lueneburg, Germany

15 Department of Urology, St. Barbara Hospital Hamm, Hamm, Germany

16 Department of Urology, Helios Klinikum Schwelm, Schwelm, Germany

17 Department of Urology, Catholic Hospital Erfurt, Erfurt, Germany

18 Department of Urology, Diakonie Klinikum Stuttgart, Stuttgart, Germany

19 Department of Urology, Vivantes Klinikum Am Urban, Berlin, Germany

20 Department of Urology, Landesklinikum Korneuburg, Korneuburg, Austria