Submitted: 27 May, 2025 Accepted: 06 August, 2025 Published: 30 December, 2025 DOI:10.22514/j.androl.2025.046

ORIGINAL RESEARCH

REV INT ANDROL
Revista Internacional de Andrología

Male artificial urinary sphincter: long-term efficacy and patient satisfaction

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Abstract

Background: Artificial urinary sphincter (AUS) implantation is the standard of care for moderate-to-severe stress urinary incontinence (SUI), but long-term outcome data remain limited. We aimed to assess AUS' long-term efficacy, complications, explantation rate, and patient satisfaction. **Methods**: We retrospectively reviewed 70 male patients who underwent AUS (American Medical Systems (AMS) 800™) implantation for SUI at our tertiary center between 2008 and 2022. Neurogenic patients were excluded. Clinical and perioperative data were analyzed, including comorbidities (*e.g.*, diabetes, hypertension), history of pelvic radiotherapy, previous urethral stricture and/or surgical treatments (*e.g.*, suburethral sling, prior AUS). Patients completed the International Prostate Symptom Score (IPSS), International Consultation on Incontinence-Urinary incontinence Short Form (ICIQ-UI SF), Overactive Bladder Symptom Score (OABSS), and ICIQ-Satisfaction questionnaires during follow-up. Main outcomes were continence and explantation rates. **Results**: The mean age at surgery was 66.5 years, with a mean follow-up of 72 months. AUS explantation occurred in 21 cases (30%): 11 due to mechanical failure and 10 due to infection. Among the 36 patients alive and actively using their AUS, 33.3% reported no incontinence episodes, 30.6% one episode or less per day, and 36.1% multiple episodes per day. However, 38.5% of the latter reported losing small quantities of urine. The median ICIQ-UI SF score was 4, with 75% of patients using one or fewer pads daily. The median IPSS score was 3 and OABSS score was 1, indicating low lower urinary tract symptoms prevalence. Patient satisfaction was high, with 85.7% rating their surgical outcome as excellent and 94.7% stated they would recommend AUS or choose to undergo the procedure again. **Conclusions**: AUS is an effective long-term treatment for male SUI, achieving social or absolute continence in many cases. Patient satisfaction remains high despite the need for revisions or explantations.

Keywords

Artificial urinary sphincter; Urinary incontinence; Lower urinary tract symptoms

Esfínter urinario artificial masculino: eficacia a largo plazo y satisfacción del paciente

Resumen

Antecedentes: La implantación de un esfínter urinario artificial (EUA) es el tratamiento estándar para la incontinencia urinaria de esfuerzo (IUE) de moderada a grave, aunque los datos sobre sus resultados a largo plazo siguen siendo limitados. Nuestro objetivo fue evaluar la eficacia a largo plazo del EUA, sus complicaciones, la tasa de explantación y la satisfacción de los pacientes. **Métodos**: Se revisaron retrospectivamente 70 pacientes varones que se sometieron a la implantación de un EUA (American Medical Systems (AMS) 800™) para IUE en nuestro centro terciario entre 2008 y 2022. Se excluyeron los pacientes con patología neurogénica. Se analizaron datos clínicos y perioperatorios, incluidas comorbilidades (por ejemplo, diabetes, hipertensión), antecedentes de radioterapia pélvica, estenosis uretral previa y/o tratamientos quirúrgicos (por ejemplo, cabestrillo suburetral, EUA previo). Durante el seguimiento, los pacientes completaron los cuestionarios International Prostate Symptom Score (IPSS), International Consultation on Incontinence-Urinary incontinence Short Form (ICIQ-UI SF), Overactive Bladder Symptom Score (OABSS), e ICIQ-Satisfaction. Los principales resultados fueron las tasas de continencia y de explantación. **Resultados**: La edad media al momento de la cirugía fue de 66.5 años, con un seguimiento medio de 72 meses. Se realizó la explantación del EUA en 21 casos (30%): 11 por fallo mecánico y 10 por infección. Entre los 36 pacientes vivos que utilizaban activamente su EUA, el 33.3% no presentaban episodios de incontinencia, el 30.6% presentaban un episodio o menos al día y el 36.1% varios episodios diarios. Sin embargo, el 38.5% de este último grupo refería pérdidas de pequeñas cantidades de orina. La mediana del puntaje ICIQ-UI SF fue 4, con el 75% de los pacientes utilizando uno o menos absorbentes al día. La mediana del puntaje IPSS fue 3 y la del OABSS fue 1, lo que indica una baja prevalencia de síntomas del tracto urinario inferior. La satisfacción de los pacientes fue elevada, con un 85.7% calificando el resultado quirúrgico como excelente y un 94.7% afirmando que recomendarían el EUA o volverían a someterse al procedimiento. **Conclusiones**: El EUA es un tratamiento eficaz a largo plazo para la IUE masculina, logrando continencia social o absoluta en muchos casos. La satisfacción de los pacientes se mantiene alta a pesar de la necesidad de revisiones o explantaciones.

Palabras Clave

Esfínter urinario artificial; Incontinencia urinaria; Síntomas del tracto urinario inferior

1. Introduction

Urinary incontinence is a bothersome condition affecting males, although at a lower rate than their female counterparts [1]. In men, incontinence is most commonly associated with overactive bladder syndrome. Nevertheless, they can also experience stress urinary incontinence (SUI) [2]. SUI accounts for less than 10% of men with urine loss complaints [2]. While transient stress urinary incontinence is common following radical prostatectomy, persistent moderate-to-severe incontinence requiring surgical intervention affects approximately 2–6% of patients one year after surgery, particularly in the era of robot-assisted techniques. Additionally, the risk of SUI following transurethral treatment of benign prostatic obstruction has been estimated to be at least 1% [3, 4].

According to the European Association of Urology and American Urological Association/Society of Urodynamics, Female pelvic medicine, and Urogenital reconstruction guidelines, artificial urinary sphincter (AUS) implantation is the standard treatment for moderate-to-severe male SUI [5, 6].

Several observational studies on this therapy describe 55–77.2% continence rates and high patient satisfaction rates, with a few studies including follow-up periods of up to 15 years [7]. However, many of these studies define success as "social continence", typically understood as the use of one pad or fewer per day [8, 9]. Several authors have criticized this definition as even the use of one pad may negatively impact quality of life. Therefore, complete dryness has been proposed as a more meaningful, patient-centered outcome [10]. A recent trial by Abrams *et al*. [11] using a strict definition of incontinence—those who have indicated any frequency other than "never" or an amount greater than "none"—found that 84.2% of patients submitted to AUS implantation remained incontinent after 12 months.

Nevertheless, few studies report long-term outcomes of this therapy and even fewer use this strict continence definition. Some papers report poorer outcomes in patients with higher body mass index (BMI), previous pelvic radiotherapy, or detrusor hyperactivity [12]. However, predictors of treatment success are still uncertain.

Therefore, we aimed to evaluate the long-term functional outcomes of AUS implantation, and identify potential clinical predictors of continence

2. Methods

We reviewed all male patients who underwent AUS implantation at our tertiary center from 01 January 2008 to 31 March 2022. Patients with neurogenic lower urinary tract dysfunction were excluded, due to the small number of patients and the non-standard surgical technique in this population. Data on clinical characteristics, perioperative variables, and outcomes including complications and revision rates were collected from a dedicated database and analyzed.

All implanted AUS devices were AMS 800™ (Boston Scientific, Marlborough, MA, USA) systems with a single cuff. No tandem cuffs or transcorporal approaches were used in this

cohort. AUS implantation was performed via a perineal or penoscrotal approach according to surgeon's preference and individual patient characteristics using a standardized technique. Patients with an implanted AUS were approached at a follow up consultation and invited to complete several validated questionnaires—namely, the IPSS, ICIQ-UI SF, OABSS, and ICIQ-Satisfaction—after the study details were clearly explained and informed consent was obtained [13–16].

The main outcomes were continence rate (based on ICIQ-UI SF) and complications (explantations). Explantation was defined as any surgical procedure resulting in complete removal of the AUS apparatus or at least the removal of the cuff—whether due to infection, erosion, or revision for mechanical malfunction. Given the retrospective nature of the study and the clinical overlap between infection and erosion, all explantations due to signs suggestive of infection and/or suspected erosion were grouped under the same category of infection-related explantation. AUS follow-up time was considered from the date of implantation up to the last appointment/date of the interview or, in case of explantation, up to the date of AUS surgical removal.

Continuous variables are presented as mean and standard deviation (SD) or median and interquartile range (IQR) according to normality testing. Categorical variables are presented as absolute numbers and corresponding percentages. Differences in means between groups were analyzed using independent samples *t*-test; Mann-Whitney was preferred for non-parametric variables. Chi-square test or Fisher's exact test was applied when appropriate for comparisons of categorical variables.

Survival analysis was conducted using Log-rank test and Kaplan Meyer curves. A p value < 0.05 was considered statistically significant. All analyses were performed using SPSS, IBM (version 29, IBM Corp., Armonk, NY, USA). Data confidentiality was ensured, and this study was approved by Unidade Local de Saúde de São João ethics committee (CE 240-22).

3. Results

3.1 Population description

During the study period, 70 AUS were implanted in adult male patients at our tertiary center. The mean (±SD) patient age at the time of the surgery was 66.5 ± 10.2 years. Diabetes was present in 22 (31.5%) patients, hypertension in 41 (58.6%), arterial disease (including peripheral arterial disease, cerebrovascular, and acute coronary events) in 12 (17.1%), and 5 (7.1%) were smokers at the time of surgery. The cause of incontinence was radical prostatectomy in 63 patients (90%), cystectomy in three (4.3%), transurethral resection of the prostate in two (2.9%), simple prostatectomy in one (1.4%), and direct vision internal urethrotomy in one (1.4%). Twenty-five (35.7%) patients had previously undergone pelvic radiotherapy (RT). Mixed incontinence was present in six patients (8.6%), while the remaining complained of pure SUI. Direct vision internal urethrotomy had been previously performed in 36 patients (57% of those submitted to a radical prostatectomy) as a treatment for vesico-urethral anastomotic stenosis.

Patients used a median (IQR) of four (3) pads per day. A total of 21 (28%) patients had previously undergone other surgical treatments: 12 (17.1%) received a suburethral sling and nine (12.9%) had a prior AUS. AUS implantation was performed using a penoscrotal approach in 54 cases (77.1%) and a perineal approach in 16 cases (22.9%). A summary of the population characteristics is presented in Table 1.

TABLE 1. Population description (n = 70).

Characteristics	Mean± SD/n (%)/Median (IQR)
Age, yr (mean ± SD)	66.5 ± 10.19
BMI, kg/m^2 (mean ± SD)	27.66 ± 4.01
DM, n (%)	22 (31.5%)
Hypertension, n (%)	41 (58.6%)
Arterial disease, n (%)	12 (17.1%)
Smoker, n (%)	5 (7.1%)
Incontinence cause	
Radical Prostatectomy, n (%)	63 (90.0%)
Simple Prostatectomy, n (%)	1 (1.4%)
Cystectomy, n (%)	3 (4.3%)
TURP, n (%)	2 (2.9%)
DVIU, n (%)	1 (1.4%)
Incontinence type	
Stress, n (%)	64 (91.0%)
Mixed, n (%)	6 (8.6%)
Pads per day (median (IQR))	4 (3)
Pelvic Radiotherapy, n (%)	25 (35.7%)
VU anastomotic stenosis, n (%)	36 (51.4%)
Previous surgical treatment, n (%)	21 (30%)
Suburethral Sling, n (%)	12 (17.1%)
AUS, n (%)	9 (12.9%)
Surgical approach	
Perineal, n (%)	54 (77.1%)
Penoscrotal, n (%)	16 (22.9%)

AUS: artificial urinary sphincter; BMI: Body mass index; DVIU: Direct vision internal urethrotomy; DM: Diabetes mellitus; TURP: Transurethral resection of prostate; VU: vesico-urethral anastomotic stenosis; SD: Standard Deviation; IQR: interquartile range.

3.2 Surgical outcomes

Patients were followed for a mean (±SD) of 72 ± 47 months. AUS explantation occurred in 21 (30%) cases: 11 due to mechanical failure and 10 due to infection. The median (IQR) time to explantation was 48 (67) months. Devices removed due to suspected infection had a median (IQR) duration of 41.5 (79.5) months, while those removed for mechanical malfunction had a median (IQR) duration of 47.4 (57) months. During the first year, six AUS (four due to infection, two

due to mechanical failure) were explanted; between years one and five, seven devices were removed (five due to mechanical failure and two due to infection); and after five years, eight explantations occurred (four due to infection and four due to mechanical failure). Among patients who had their AUS implanted at least one year before the end of the study, 30% underwent explantation. In those with implants in place for at least five and ten years, the explantation rates were 37% and 39%, respectively.

The Kaplan-Meier survival curve for AUS is presented in Fig. 1. No statistically significant differences in device survival were observed when comparing patients who were smokers ($p = 0.311$), had arterial disease ($p = 0.162$), diabetes mellitus ($p = 0.266$), a history of pelvic radiotherapy ($p = 0.745$), obesity ($p = 0.946$), or had received at least one prior AUS ($p = 0.877$) with those without these respective comorbidities.

We performed a multivariable logistic regression analysis including age, history of pelvic radiotherapy, diabetes mellitus, arterial disease, prior AUS implantation, surgical approach, and history of direct vision internal urethrotomy (DVIU), and found no statistically significant predictors of AUS explantation. Similarly, there was no significant difference in survival between AUS implanted via the penoscrotal versus perineal approach (Log-rank $p = 0.091$).

3.3 Clinical outcomes

During the study period 21 AUS devices were explanted and eight patients died, leaving 41 patients eligible for interview. Of these, two had developed dementia and had their AUS deactivated, while three were lost to follow-up. The remaining 36 patients completed the questionnaires. Among them, 33.3% of patients reported no incontinence episodes, 30.6% reported one episode or less per day, and 36.1% experienced incontinence episodes occurring several times per day. Among the latter, 38.5% reported losing only small quantities of urine, 53.8% reported moderate quantities and only 7% (1 patient) reported losing large quantities of urine. Results from the whole cohort's responses to the ICIQ-UI SF question "How often do you leak urine?" are illustrated in Fig. 2, and responses to the question "How much urine do you think you leak?" are shown in Fig. 3. The median (IQR) ICIQ-UI SF score was 4 (9) and 75% of patients reported using one or less pads per day. Overall, patients reported a low incidence of lower urinary tract symptoms (LUTS) as the median (IQR) IPSS score was 3 (4) and OABSS score was 1 (3.5). Surgical approach (perineal *vs.* penoscrotal) had no impact on the median number of pads used per day or the amount of urine lost per day as reported by the patients (1 *vs.* 1 and 1 *vs.* 2.5; $p = 0.406$ and $p = 0.696$, respectively).

Patients with a history of pelvic radiotherapy had a significantly higher OABSS score ($p = 0.031$) when compared with those without such history. Similarly, patients with a history of a previous urethrotomy had a significantly higher IPSS score when compared with those without such history ($p = 0.001$).

3.4 Patient satisfaction

Regarding satisfaction, 85.7% of patients attributed maximum score to their surgical outcome, and 93.7% stated they would

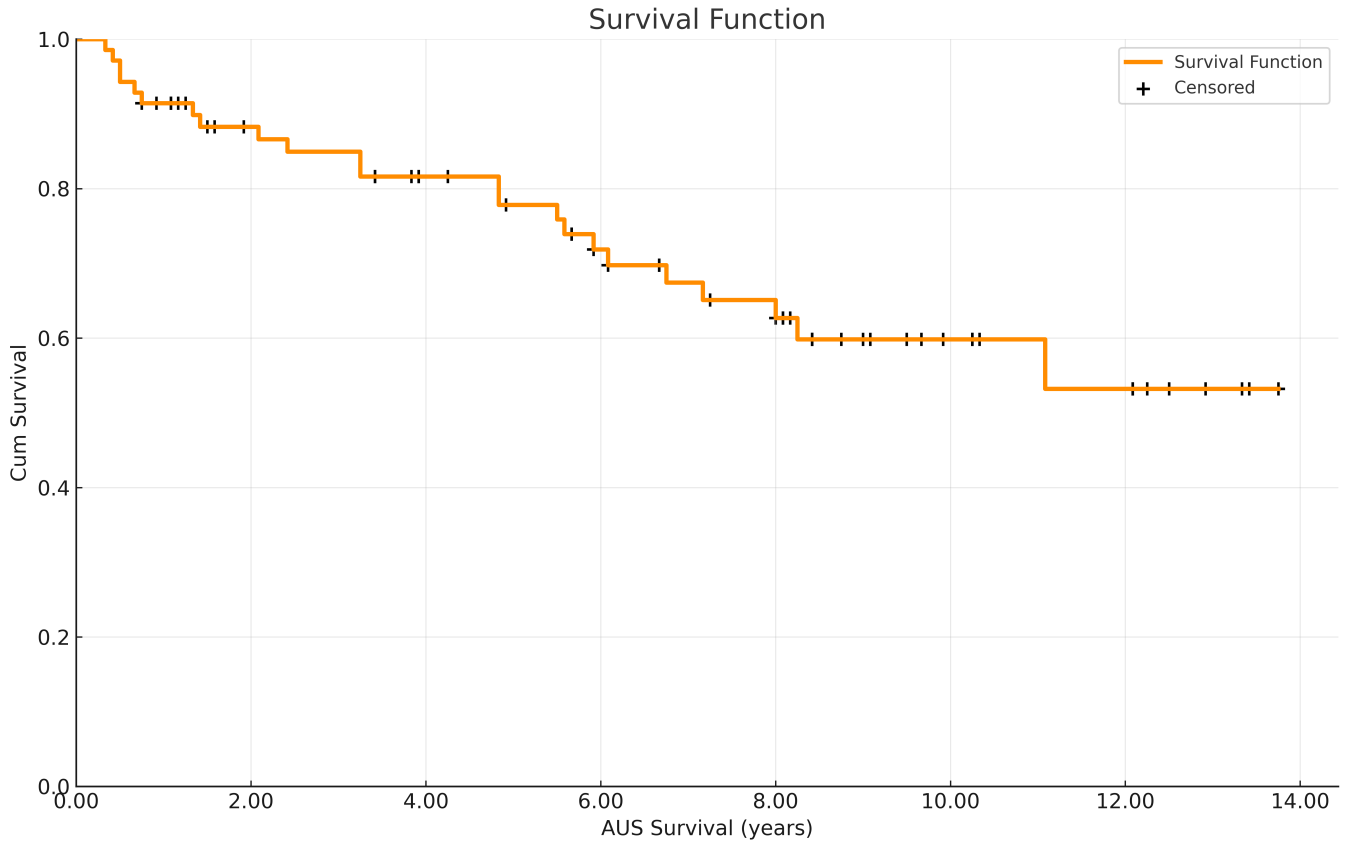

FIGURE 1. Kaplan-Meier survival curve for AUS survival. AUS: Artificial urinary sphincter.

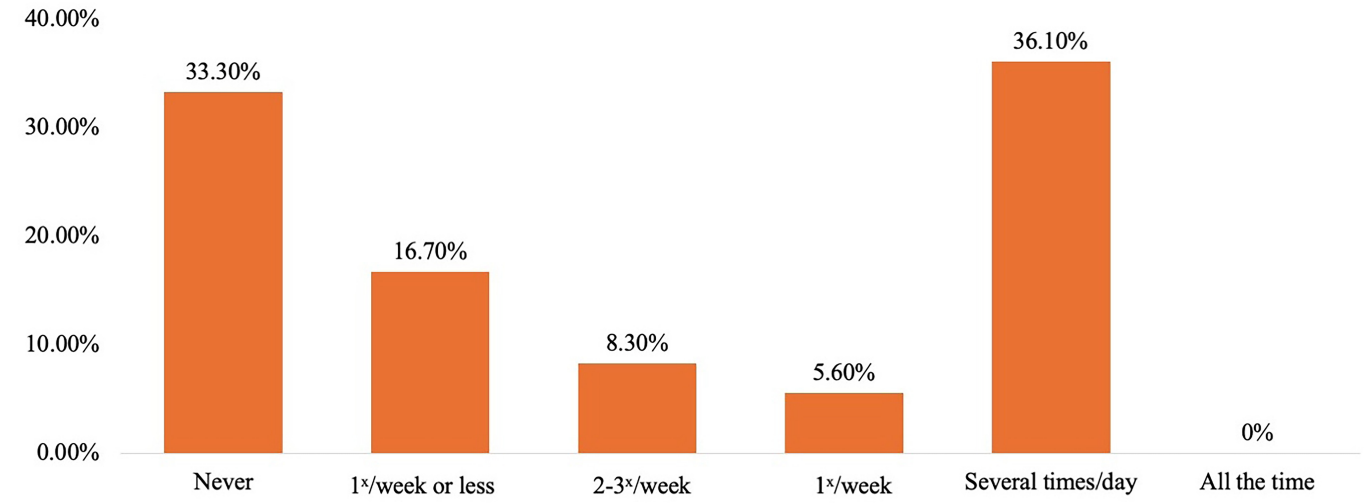

FIGURE 2. Response to the ICIQ-UI SF question "How often do you leak urine?".

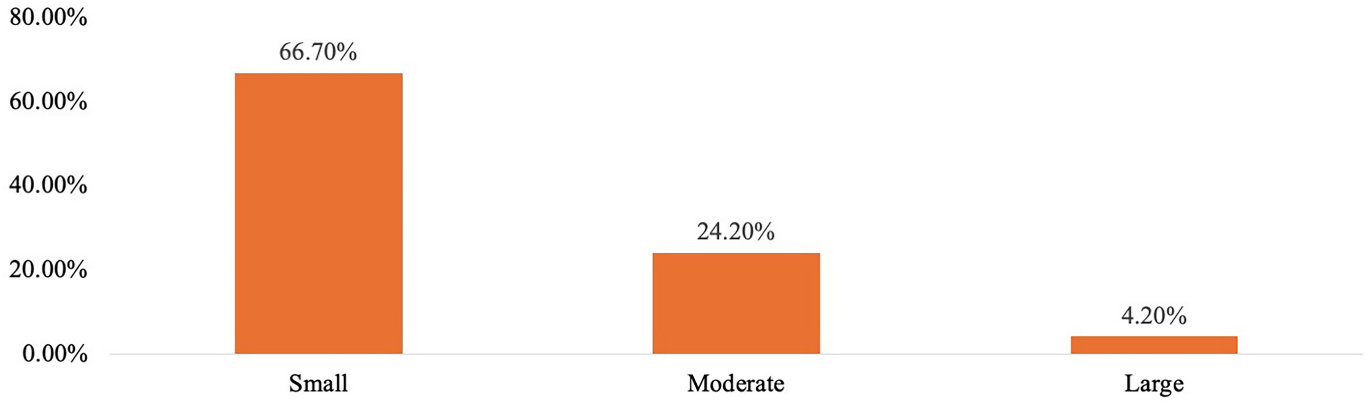

FIGURE 3. Response to the ICIQ-UISF question "How much urine do you think you leak?".

recommend AUS implantation to a friend and would choose the procedure again themselves. When asked to compare their condition to the preoperative state, 86% of patients reported feeling "much better", 11% "a bit better", and 3% "about the same". The results of these questions are summarized in Fig. 4. Patients with a history of pelvic radiotherapy had significantly lower ICIQ-Satisfaction scores (p = 0.009) compared with those without such history.

4. Discussion

This study describes a cohort of patients who underwent AUS implantation at a tertiary center, with a mean follow-up of 6 years (72 months) and a maximum follow-up of 13 years. All patients who underwent AUS implantation during the study period were included, resulting in a population with an age and comorbidity profiles similar to the those reported in the MASTER trial and in several other cohorts analyzing AUS outcomes [11, 17]. This similarity may be attributed to the fact that radical prostatectomy is a major driver of SUI and thus a common indication for AUS implantation. As a result, patient populations across studies likely reflect comparable epidemiological patterns and treatment strategies for prostate cancer.

In our cohort, 30% of the implanted AUS were explanted during the study period—a rate consistent with findings in the literature [18]. Brant *et al.* [19] reported an explantation rate of 8.03% in a multicenter study, but with a much shorter average follow up time of only two years. Nonetheless, in our study, the two-year explantation rate was similar at 8.6%. Papers reporting longer follow up duration found explantation rates similar to the present study. For example, Deruyver and colleagues described a five-year explantation rate of 25% in their cohort [20].

Data on timing of AUS explantation is not uniform across the literature. Some studies report a median AUS survival of one year for those explanted due to infection/erosion while others report survival times of up to four years in similar settings [21, 22]. Furthermore, regarding mechanical malfunction, median AUS survival has been reported to range from four to six years [21, 22]. The higher explantation rates at five and ten years in our cohort may reflect the inclusion of high-risk patients, such as those with prior radiotherapy or previous AUS, as well as cases from an earlier phase in the surgeons' learning curve. In addition to the above referred reasons, the relatively high infection-related explantation rate observed (14.3%) should also be interpreted in the context of the extended follow-up period and our study design, which

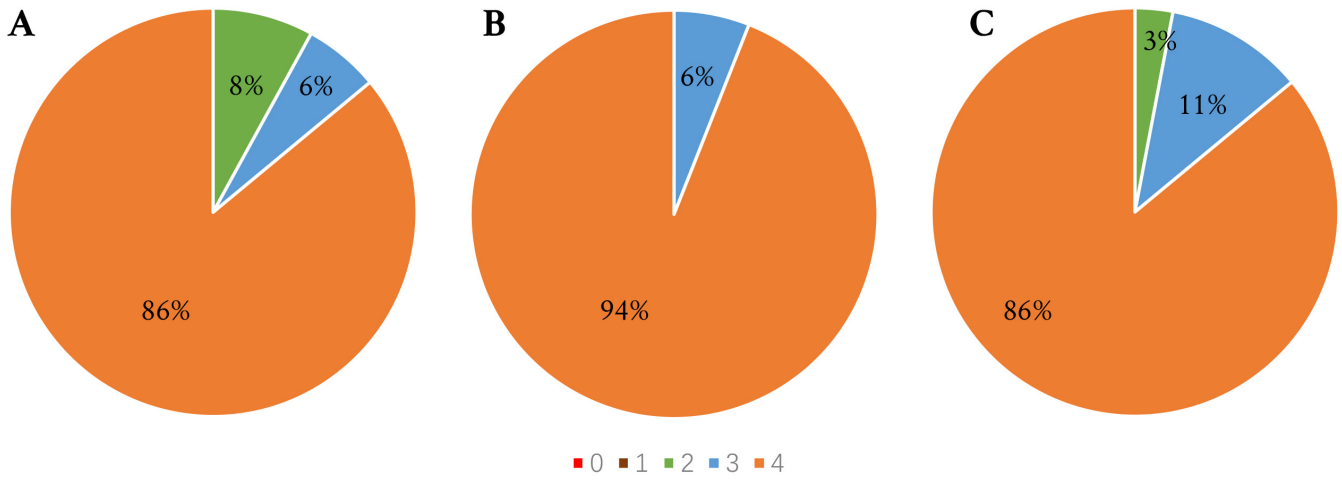

FIGURE 4. Answers to selected questions from ICIQ-Satisfaction. (A) "How would you rate the outcome of your surgery?" (4 = very successful, 3 = somewhat successful, 2 = neither successful nor unsuccessful, 1 = a little unsuccessful, 0 = very unsuccessful). (B) "Would you recommend this surgery to friends or relatives with similar problems?" (4 = yes, definitely, 3 = yes, probably, 2 = not sure, 1 = no, probably not, 0 = no, definitely not). (C) "Compared to how you felt before your surgery, how is your condition now?" (4 = much better, 3 = a bit better, 2 = about the same, 1 = a bit worse, 0 = much worse).

grouped all cases of suspected infection and cuff erosion under a single category. Published data on AUS surgery show infection rates between 0.46–7% and cuff erosion rates between 3.8–10%; when considered together, these rates help explain the seemingly elevated infection-related explantation rate in our study [23, 24].

Probably due to the relatively small sample size we could not find statistically significant differences in AUS survival regarding risk factors described in other cohorts such as smoking, arterial disease, diabetes mellitus, pelvic radiotherapy, obesity or having a second AUS implantation. Additionally, no significant difference in AUS survival was found between the perineal and penoscrotal approaches. Although this topic is not unanimously agreed upon in the literature, several studies have reported comparable explantation and complication rates between these two surgical techniques [25–27]. While the perineal approach has traditionally been considered standard, the penoscrotal technique—used in most of our cases—has been shown to be safe and effective. Current EAU guidelines do not clearly favor one approach over the other. Our findings support the penoscrotal approach as a valid alternative in appropriately selected patients [25].

The MASTER trial evaluated patient-reported SUI 12 months after randomization to either AUS or male sling using ICIQ-UI SF questionnaire [11]. Applying a strict definition of continence—patients reporting any leakage frequency other than "never" or any amount greater than "none"—the trial found an 84% incontinence rate in the AUS arm [11]. Our findings are comparable, with a reported incontinence rate of 77%, though our study features a much longer follow-up period. Furthermore, among the 77% of patients who reported some episodes of incontinence, 18% experienced urine loss only once per day or less, and 36% reported leakage several times per day. Nonetheless, among the latter, 38.5% reported losing only small quantities. When using a less stringent definition of continence—specifically, social continence defined as the use of one pad or less per day—we found that 75% of patients achieved this benchmark, which aligns with previously published data [8, 26]. Some papers describe a possible higher continence rate using a perineal approach for implantation [27]. Nevertheless, in our cohort surgical approach did not impact continence rate, which is consistent with other reports in the literature [25].

Analysis of IPSS and OABSS scores revealed a low prevalence of both storage and voiding LUTS. This is likely attributable to the underlying etiology of SUI in this population—as the majority had previously undergone radical prostatectomy—effectively eliminating benign prostatic hyperplasia (BPH) as a contributing factor. Additionally, pure SUI was the most common diagnosis, with only 8% of patients reporting mixed urinary incontinence (MUI), thereby limiting the proportion with preoperative storage LUTS. Although, as we have stated, this likely reflects a population with a low baseline burden of LUTS, our findings suggest that AUS implantation does not significantly exacerbate LUTS. Literature on post-AUS LUTS is heterogeneous, with some cohorts reporting a significant symptom burden. For example, the work by Son *et al.* [28] on a cohort of 129 AUS, found 78.4% had moderate to severe LUTS post-AUS (IPSS = 8–35 points).

We found that patients with a history of pelvic RT reported significantly more storage symptoms following AUS implantation compared to those without this comorbidity. Patients submitted to radiotherapy are known to display more LUTS, namely storage LUTS due to the effect of radiation on the bladder, which induces inflammation and scarring, limiting its compliance and capacity, and possibly enhancing neuronal pathways contributing to bladder overactivity [29]. This finding aligns with previous studies reporting a greater deterioration in OABSS scores over time in patients with a history of RT compared to those without [30]. Additionally, our results showed a higher prevalence of voiding LUTS among

patients who had undergone DVIU for vesicourethral anastomosis stenosis. This may be attributable to some recurrent degree of stenosis or even to a pre-existent degree of stenosis not completely treated with DVIU.

We report very high satisfaction rates following AUS implantation, which are consistent with findings in the published literature. Kahlon *et al.* [31] followed 39 patients for a median of two years and found that 91.2% would be willing to undergo the procedure again and 82.4% would recommend the procedure to a friend. Notably, even with longer follow-up, as in our study, satisfaction rates remain high [31]. Notably, in a previous study by Deruyver *et al.* [20], a satisfaction rate of 92% was observed after a median follow-up of 61 months. Importantly, our cohort includes patients who required revision surgery, device explantation or second AUS implantation, as well as patients maintaining some degree of urine leakage. These findings highlight that high patient satisfaction can be maintained even in the presence of suboptimal outcomes or postoperative complications.

Our study presents a long-term cohort of patients submitted to AUS implantation at a tertiary center. One of its strengths lies in the prospective evaluation of outcomes using validated questionnaires to assess incontinence, urinary symptoms, and satisfaction. Additionally, the extended follow-up period adds value to the findings. However, the relatively small sample size limited our statistical analysis to identify risk factors for AUS explantation, and the possibility to perform multivariable analysis for continence and satisfaction predictors. Furthermore, the retrospective nature of clinical and surgical variables hindered the results due to missing data. Moreover, another key limitation is the absence of preoperative ICIQ-UI SF and OABSS scores, as these questionnaires were only administered postoperatively. Consequently, we were unable to objectively quantify symptom improvement from baseline using validated instruments. Pad size and absorbency were not standardized, which limits the accuracy of pad count as a surrogate for pre-operative incontinence severity. Therefore, additional well-designed and larger prospective cohorts are needed to clearly understand the contribution of each variable to AUS explantation risk.

5. Conclusions

AUS implantation is a safe and reliable treatment for male SUI, offering long term social continence and, in some cases, absolute continence. These results are reflected in the exceptionally high patient satisfaction rates. Despite the relatively scarce complete continence rate, patients remain extremely satisfied and would recommend the technique. However, AUS has a finite lifespan and may require further surgical interventions due to complications or mechanical failure.

AVAILABILITY OF DATA AND MATERIALS

The data presented in this study are available on reasonable request from the corresponding author.

AUTHOR CONTRIBUTIONS

JO, MG, AM and CMS—designed the research study. JO and ACS—collected the data. TAL, JO and AM—analyzed the data. JO, AM and ACS—wrote the manuscript. CMS, TAL and MG—reviewed the manuscript. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study was approved by Unidade Local de Saúde de São João ethics committee (CE 240-22). Informed consent was obtained from all participants prior to inclusion in the study.

ACKNOWLEDGMENT

The authors would like to acknowledge the administrative support provided by the Department of Urology at Unidade Local de Saúde de São João.

FUNDING

This research received no external funding.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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How to cite this article: João Oliveira, Alberto Costa-Silva, Miguel Guimarães, Tiago Antunes-Lopes, Carlos Martins-Silva, Afonso Morgado. Male artificial urinary sphincter: long-term efficacy and patient satisfaction. Revista Internacional de Andrología. 2025; 23(4): 72-79. doi: 10.22514/j.androl.2025.046.