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Complications and Risk Factors Associated with Explantation of Artificial Urinary Sphincter for Post-Prostatectomy Incontinence: A Nationwide French Study Using the PMSI Database

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Abstract

Background

The artificial urinary sphincter (AUS) is the reference surgical treatment for moderate-to-severe post-prostatectomy stress urinary incontinence. Despite durable functional outcomes, long-term device-related morbidity and explantation remain frequent. Nationwide real-world data jointly assessing postoperative complications and determinants of revision after AUS implantation remain limited. This study aimed to provide a comprehensive national overview of postoperative complications and identify risk factors for AUS revision or explantation.

Methods

We conducted a retrospective nationwide cohort study using the French Programme de Médicalisation des Systèmes d'Information (PMSI). All men undergoing primary AUS implantation after radical prostatectomy between 2017 and 2019 were included and followed until December 2023. Postoperative complications were identified using International Classification of Diseases, 10th (ICD-10) Revision codes and classified according to postoperative timing. Baseline comorbidities were analysed using univariate logistic regression, while post-implantation procedures were assessed using Poisson regression to estimate incidence rate ratios for revision or explantation.

Results

Among 1,790 patients, 268 (15.0%) underwent AUS explantation during follow-up. Most complication-coded rehospitalisations occurred during late follow-up. Urinary incontinence–related diagnoses were the most frequent events, whereas mechanical and infectious complications represented the most clinically relevant device-related outcomes. Urethral fragility conditions were the strongest predictors of explantation. Metabolic disorders, malnutrition, prior pelvic radiotherapy, anticoagulant therapy, tobacco use, and invasive procedures—including blood transfusion, indwelling catheterisation, and cystoscopy—were significantly associated with higher revision risk.

Conclusion

This nationwide PMSI-based study provides a comprehensive real-world assessment of postoperative morbidity and explantation risk after AUS implantation, highlighting the importance of optimised patient selection and cautious postoperative urethral instrumentation.

Introduction

Stress urinary incontinence (SUI) remains one of the most challenging complications after radical prostatectomy, with reported rates ranging from 5% to 60% depending on surgical technique, patient characteristics, and follow-up duration [1, 2]. When conservative management fails, surgery is recommended. Among available options, the artificial urinary sphincter (AUS) has been the reference

treatment for moderate-to-severe male SUI for more than four decades [3, 4]. Meta-analyses demonstrate higher dryness rates with the AUS compared with male slings [5].

Despite durable functional outcomes, device-related complications remain frequent over long-term follow-up. Large institutional series report 10-year revision-free survival rates of 40–60%, mainly related to mechanical failure, urethral atrophy, erosion, or infection [6]. At the national level, a French nationwide “Programme de Médicalisation des Systèmes d’Information“ (PMSI) based study of 8,475 implantations reported reintervention-free survival rates of 71% at 2 years and 40% at 10 years, with a cumulative reoperation risk of 29% [7].

Several patient-related factors influence outcomes. Diabetes, obesity, smoking, advanced age, and anticoagulant therapy are associated with increased risks of erosion, infection, and explantation [8, 9]. Prior pelvic radiotherapy remains one of the strongest predictors of early erosion and infection, doubling the likelihood of device removal [10]. Procedure-related factors also contribute: fragile urethral conditions, transcorporal cuff placement, and small cuff size increase erosion or atrophy risk [11–13], while institutional experience and revision strategy significantly affect long-term device survival [14, 15].

Using the French nationwide PMSI, this study provides a national overview of postoperative complications after AUS implantation and identifies comorbidity- and procedure-related risk factors for revision or explantation in real-world practice.

Methods

Study design and data source

We conducted a nationwide retrospective cohort study using the French PMSI database, which captures inpatient admissions in public and private hospitals for reimbursement. Diagnoses are coded using International “Classification of Diseases, 10th ” (ICD-10), while procedures and implanted devices are recorded using the “Classification Commune des Actes Médicaux” (CCAM) and the “Liste des Produits et Prestations” (LPP). The study received approval from the French data protection authority (CNIL, DE-2010-002), complied with the Declaration of Helsinki, and was registered with the Health Data Hub.

Study population

All men undergoing primary AUS implantation between January 1, 2017, and December 31, 2019, were identified using CCAM code JELA002. Inclusion was restricted to patients with a prior radical prostatectomy (laparoscopic, open retropubic, or perineal). Patients younger than 18 years and those with previous AUS implantation before 2017 were excluded. The implantation date defined the index hospitalization (T0). Follow-up extended until death or December 31, 2023.

Baseline comorbidities were retrieved using ICD-10 codes recorded during the index hospitalization. These diagnoses provided an overview of medical conditions present at the time of AUS implantation.

Outcomes

Postoperative complications were identified from ICD-10 codes recorded during rehospitalizations and categorized into three periods: index hospitalization (T0), early postoperative period (≤ 3 months), and late follow-up (> 3 months).

AUS revision or explantation was identified using CCAM codes for complete explantation, total replacement, or partial component exchange (cuff or pump/reservoir).

Statistical analysis

Patients were divided into two groups: those requiring AUS revision or explantation and those remaining revision-free. Baseline comorbidities were analyzed using univariate logistic regression, producing odds ratios (ORs) with 95% confidence intervals (CIs). Post-implantation procedures were analyzed using univariate Poisson regression, yielding incidence-rate ratios (IRRs), with group size used as an offset. Analyses were limited to exposures occurring at least 10 times per group, in accordance with French data-protection rules. All tests were two-sided, with $p < 0.05$ considered statistically significant.

Results

According to the national PMSI database, annual primary artificial urinary sphincter (AUS) implantations were stable from 2016 to 2023, except for a marked decline in 2020 related to the SARS-CoV-2 pandemic, with recovery by 2022 (Fig. 1A). Procedures were performed mainly in the private sector (46%), followed by public hospitals (41%) and ESPIC institutions (13%) (Fig. 1B).

Postoperative outcomes

Between January 1, 2017, and December 31, 2019, 1,790 men with prior radical prostatectomy underwent first-time artificial urinary sphincter (AUS) implantation for post-prostatectomy incontinence. All ICD-10 diagnoses recorded during index hospitalization (T0), early postoperative period (T1–T3, ≤ 3 months), and late follow-up (T4–T84, > 3 months) are summarized in Table 1. Overall, 3,525 diagnosis-coded rehospitalization events were identified after primary AUS implantation. Of these, 1,990 events (56.5%) occurred during index admission, 255 (7.2%) during the early postoperative period, and 1,280 (36.3%) during late follow-up. Eighteen distinct ICD-10 entities were considered AUS-related complications (full list in Supplementary Table S1).

Urinary incontinence was the most frequent complication. “Other specified urinary incontinence” (N39.4) accounted for 1,525 admissions, followed by stress urinary incontinence (N39.3; 646 admissions) and unspecified urinary incontinence (R32; 252 admissions). Mechanical complications of the urinary

prosthesis (T83.1) represented 210 admissions, predominantly during late follow-up, while urinary retention (R33) accounted for 154 admissions across periods.

Infectious complications included urinary tract infections, prosthesis-related infection or inflammation, sepsis, and systemic inflammatory response syndrome, mainly in the late phase. Hemorrhagic events comprised procedure-related hemorrhage or hematoma and hematuria. Less frequent complications included urethral stricture, pulmonary embolism, acute prostatitis, and dysuria.

Table 1
Complications coded during rehospitalisation stratified by postoperative interval

ICD-10	Diagnostic label	T0 (index)	T1-T3 (≤ 3 m)	T4-T84 (> 3 m)
N394	Other specified urinary incontinence	1104	93	328
N393	Stress incontinence	496	27	123
R32	Unspecified urinary incontinence	177	28	47
T831	Mechanical complication of other urinary prosthetic devices and implants	18	38	154
R33	Retention of urine	57	24	73
N390	Urinary tract infection, site not specified	50	14	80
R10	Abdominal and pelvic pain	22	0	114
T810	Haemorrhage and haematoma complicating a procedure, not elsewhere classified	42	13	55
T835	Mechanical complication of other internal prosthetic devices, implants and grafts	0	18	71
R31	Unspecified haematuria	0	0	55
R65	Systemic inflammatory response syndrome (SIRS)	0	0	50
A41	Other sepsis	0	0	50
N35	Urethral stricture	13	0	15
R57	Shock, not elsewhere classified	0	0	25
I26	Pulmonary embolism	0	0	14
N410	Acute prostatitis	0	0	13
N358	Other urethral stricture	0	0	13
R30	Pain on micturition	11	0	0

AUS revision or explantation

Of the 1,790 men who underwent AUS implantation, 268 (15%) required explantation, while 1,522 (85%) remained revision-free over the 84-month follow-up. No removals occurred within the first 6 months. Revisions peaked between 13 and 36 months, accounting for 124 cases (46.2%), and became rare beyond 5 years, with **Fig. 2 AUS revision by time intervals**

only 28 events (Fig. 2).

Overall, 284 baseline ICD-10 comorbidities were identified; for clarity, 16 clinically relevant codes are shown in Table 2 (full list in supplementary Table S2). Twelve were significantly associated with explantation. Metabolic and systemic factors included diabetes (OR 1.46), malnutrition (OR 1.96), obesity (OR 1.52), and hypertension (OR 1.47). Urological conditions showed the strongest associations, notably urethral stricture (OR 3.64), urethral fistula (OR 6.12), pelvic or urinary trauma (OR 12.11), and catheter-related complications (OR 3.39). Additional risk factors included beta-lactam resistance (OR 2.29), prior radiotherapy (OR 1.70), anticoagulant therapy (OR 1.70), and tobacco use (OR 1.74). Alcohol use disorder, atherosclerosis, COVID-19, and caregiver dependence were not significant.

Table 3 displays the 3 CCAM procedures we deemed most clinically relevant (full list in supplementary Table S3). Blood transfusion was strongly associated with subsequent AUS revision (IRR 2.47), as were indwelling urethro-vesical catheter placement (IRR 3.25) and flexible urethro-cystoscopy, which showed the highest relative increase in revision risk (IRR 3.24; all $p < 0.001$).

Discussion

To our knowledge, this is the first nationwide PMSI-based study to jointly assess postoperative complications and risk factors for revision after artificial urinary sphincter implantation within a single national cohort. Building on prior work focused on reintervention [7] and validated PMSI methodology [16, 17], our analysis integrates morbidity and comorbidity profiles, providing a comprehensive real-world assessment of AUS safety and outcomes.

Temporal trends

Device utilization trends confirm the AUS as the reference treatment for moderate-to-severe post-prostatectomy incontinence. Implantations declined sharply during the 2020 COVID-19 lockdown but rebounded within two years, consistent with national urological trends [7]. Meta-analyses demonstrating superior dryness and quality-of-life outcomes further support its leading role [18, 20].

Postoperative complications

Persistent or recurrent urinary incontinence was the leading cause of rehospitalization after AUS implantation. Incontinence-related ICD-10 codes (N39.4, N39.3, R32) accounted for 2,423 readmissions, representing 68.7% of complication-coded events. Most were recorded during the index hospitalization

(T0); however, coding likely reflects the preoperative indication rather than a true postoperative complication. By contrast, 21.8% of incontinence-related events occurred beyond 3 months, suggesting persistent or recurrent symptoms.

Early postoperative leakage does not necessarily indicate device failure. The AUS is routinely deactivated for 4–6 weeks after implantation, during which urinary leakage is expected and reflects the absence of active urethral occlusion during healing [3, 4]. Within the PMSI database, urgency and urge urinary incontinence were inferred from codes N39.4 and R32. Although these administrative codes cannot distinguish sphincteric from bladder-related mechanisms, they likely capture mixed incontinence or urgency-predominant symptoms, possibly reflecting de novo detrusor overactivity after AUS implantation [9].

These findings align with published series reporting persistent leakage or pad use in 10–30% of patients during long-term follow-up despite a functioning device [6, 18, 20]. Reported pad-free continence rates range from 60% to 80%, with some patients requiring a single “security” pad [3, 5].

Mechanical complications (T83.1/T83.5) and infections (N39.0, A41, R65) were the most clinically relevant device-related events, consistent with prior studies identifying erosion and infection as the main drivers of revision [7, 8, 11]. Hemorrhagic (3.1%) and thromboembolic complications were rare, in line with existing literature [6, 20].

ICD-10–based risk factors for AUS explantation

Urethral stricture (OR 3.64) and urethral fistula (OR 6.12) were the strongest predictors of explantation, confirming urethral fragility as the key risk factor for erosion [11]. Metabolic disorders, including diabetes (OR 1.46) and obesity (OR 1.52), significantly increased explantation risk, consistent with impaired healing and higher infection rates [8]. Malnutrition (OR 1.96) emerged as an independent determinant, in line with data linking hypoalbuminemia to adverse outcomes [21]. Prior pelvic radiotherapy increased removal risk by 70%, corroborating multicenter evidence [11]. Tobacco use and anticoagulant therapy were also significant [9]. Finally, beta-lactam resistance (OR 2.29) was associated with explantation, although robust data remain limited [22].

CCAM-linked risk factors for AUS explantation

Among procedural exposures, blood transfusion was associated with a more than twofold higher revision risk (IRR 2.47), likely reflecting perioperative complexity rather than causality. Indwelling urethral catheterization (IRR 3.25) and repeated cystoscopies (IRR 3.24) were also strongly associated, consistent with evidence that iatrogenic instrumentation contributes to up to half of erosions. These findings underscore the importance of strict adherence to guideline-recommended precautions during urethral manipulation in AUS patients [23, 24].

Strengths and limitations of a medico-administrative design

The PMSI captures nearly all inpatient stays in France, providing exceptional sample size and external validity, but is designed for reimbursement rather than research. Complications linked to higher Diagnosis-Related Group tariffs may be preferentially coded, whereas clinically relevant but non-billable events can be underreported [25]. Privacy regulations preclude analysis of cells with fewer than ten patients, limiting analyses to descriptive and bivariate approaches. Moreover, CCAM data report aggregate procedure counts only, allowing high-utilizer patients to disproportionately influence rates. Finally, key surgical variables such as cuff size, antibiotic strategy, and surgeon volume are unavailable, limiting risk adjustment.

Conclusions

This nationwide PMSI-based study provides a comprehensive overview of complications and explantation risk after AUS implantation in France. Urethral fragility, metabolic and infectious comorbidities, radiotherapy, and invasive procedures were key predictors. These findings support improved patient selection, risk-factor optimization, and postoperative management to enhance long-term AUS outcomes.

Declarations

Ethics approval and consent to participate :

This study was conducted using anonymized medico-administrative data from the French PMSI database. No direct patient involvement occurred. The study received approval from the French data protection authority (CNIL, DE-2010-002), complied with the Declaration of Helsinki, and was registered with the Health Data Hub.

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Author Contribution

C.Mo. and C.Ma. wrote the main manuscript text.JL.G. and H.B. contributed to the acquisition of the dataP.E. and C.Ma. supervised the manuscript preparation.C.Mo., A.B. , and A.P. contributed to data analysis and to the preparation of Tables 1 and 2.C.Mo. prepared figures 1-2.All authors reviewed the manuscript.

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Tables

Tables 2 and 3 are available in the Supplementary Files section.

Figures

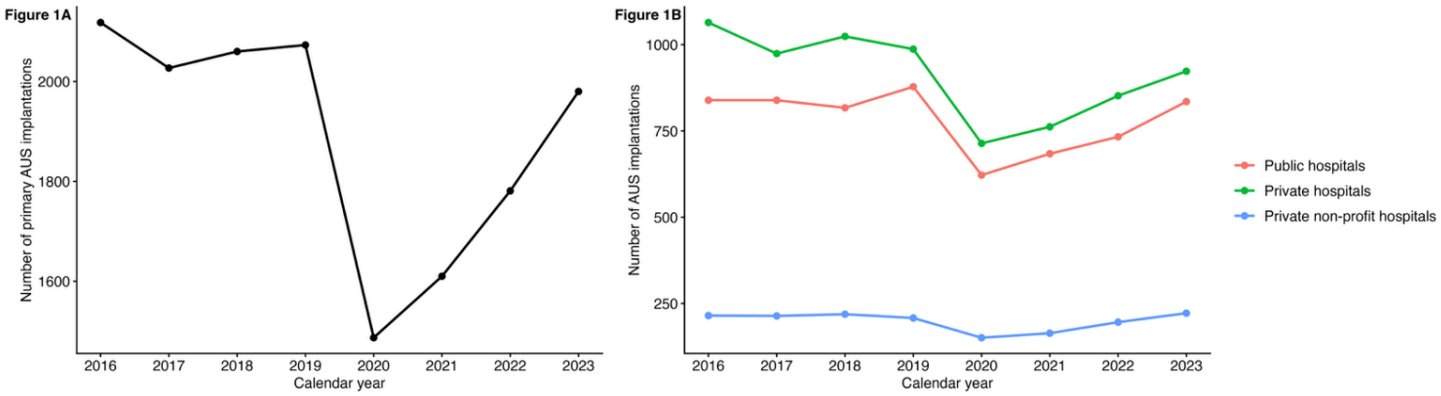
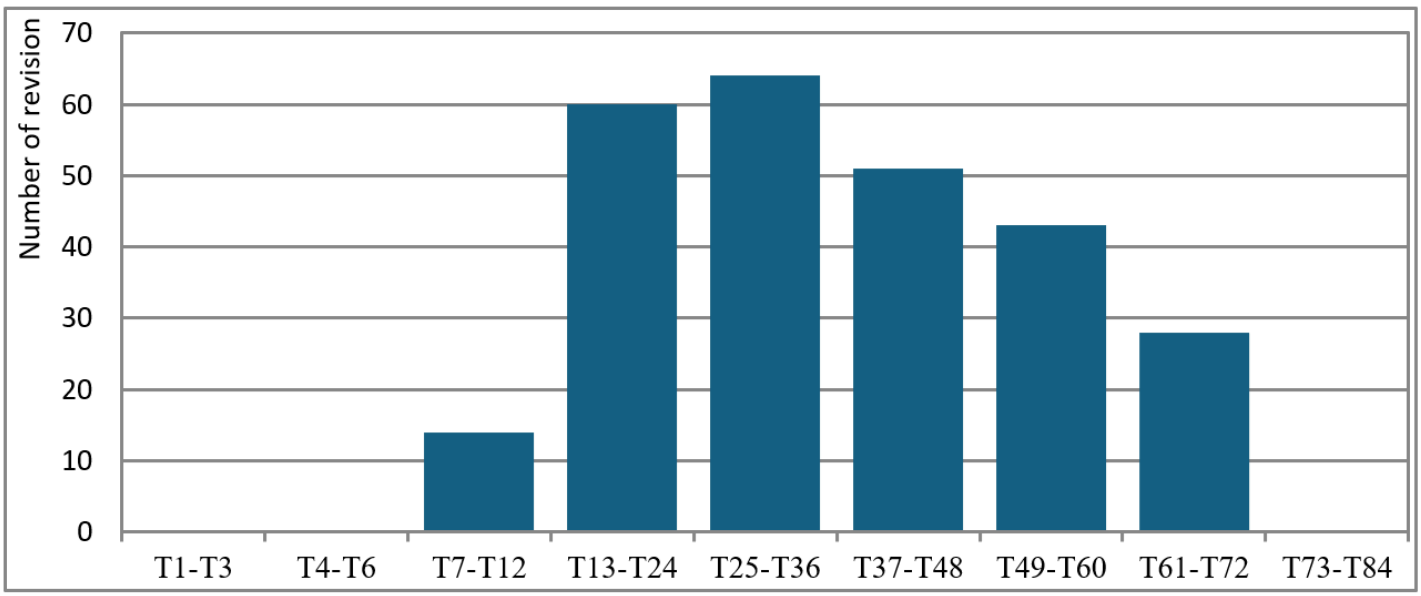


Figure 1

Characteristics of patients receiving AUS implantation in France

(A) Annual number of primary implantations, 2016-2023; (B) Distribution of procedures by hospital categories.



No devices were removed during the first 6 months.

Figure 2

AUS revision by time intervals

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Table2.ICD10riskfactorsforAUSrevision.png
- Table3.CCAMriskfactorsforAUSrevision.png
- Supplementaryappendix.docx