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Difficulties in Manipulating the Female Artificial Urinary Sphincter Pump: Prevalence and Management

Alexandre Dubois[1], Valentine Lethuillier[1], Claire Richard[1], Camille Haudebert[1], Juan Penafiel[1], Caroline Voiry[2], Magali Jezequel[1], Emmanuelle Samson[2], Louis-Paul Berthelot[3], Lucas Freton[1], Juliette Hascoet[1], Andrea Manunta[1,4], Benoit Peyronnet[1]

[1]Department of Urology, University of Rennes, Rennes, France
[2]Department of Physical Medicine and Rehabilitation, University of Rennes, Rennes, France
[3]Department of Urology, Hôpital Privé des Côtes d'Armor, Plérin, France
[4]Department of Urology, Clinique Mutualiste La Sagesse, Rennes, France

Purpose: While pump manipulation is rarely problematic in male patients with artificial urinary sphincters (AUSs), the situation may differ in female patients due to anatomical or cultural factors. This study aimed to evaluate the prevalence of difficulties in pump manipulation among female AUS patients, identify associated risk factors, and explore management strategies for this challenging issue.

Methods: Data were collected from all female patients who underwent a robotic AUS implantation at a single academic center between 2014 and 2022. The primary endpoint was temporary difficulties, defined by at least one other short hospitalization to learn pump manipulation.

Results: Out of the 88 female AUS patients included in the study, 20 experienced initial difficulties manipulating the pump, accounting for 22.7% of the group. Temporary difficulties were reported by 16 patients (18.2%), while 4 patients (4.5%) had their devices permanently deactivated. Surgical reoperations to reposition the pump were necessary for 5 patients, representing 5.6% of the sample. The only variables significantly associated with temporary difficulties were longer operative time (183.4 minutes vs. 159.1 minutes, P = 0.04) and the overall experience of the center (32 vs. 50, P = 0.04). The sole variable significantly linked to serious difficulties was the overall experience of the center (11 vs. 47, P = 0.004). Although the median age and body mass index were higher in the group with temporary difficulties, these differences were not statistically significant.

Conclusions: Difficulties in manipulating the pump are relatively common among female AUS patients. Most of these difficulties can be resolved through repeated patient education and careful follow-up. However, some may lead to serious complications. Raising awareness of this issue, along with ongoing patient education and meticulous follow-up, may help to minimize these consequences.

Keywords: Artificial urinary sphincter; Urinary stress incontinence; Female

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- **Research Ethics:** This study was approved by the Institutional Review Board of CNIL (Comité National Informatique et Liberté) (CNIL number: 2234449v0). The study was conducted following the principles of the Helsinki declaration. On admission, patients are informed of the possibility of using their anonymized data for research purposes.
- **Conflict of Interest:** Benoit Peyronnet is a consultant for Boston scientific, Intuitive, Medtronic, Pierre Fabre, Ibsa, Coloplast, Schwa medico, Hollister, Ipsen, AbbVie. The other authors have nothing to disclose.

Corresponding author: Alexandre Dubois https://orcid.org/0009-0003-7374-7922
Department of Urology, University hospital of Rennes, 2 Rue Henri le Guilloux, Rennes, France
Email: alexandre.dubois@chu-rennes.fr, alexandreduboisint@gmail.com
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INTRODUCTION

An artificial urinary sphincter (AUS) is a therapeutic option for female patients with stress urinary incontinence (SUI) due to intrinsic sphincter deficiency (ISD) [1-3]. The popularity of the female AUS is increasing in various countries, facilitated by advancements in robotic implantation that significantly improve perioperative outcomes [4, 5]. The AMS-800 AUS consists of a silicone cuff placed around the bladder neck, a pressure-regulating balloon located in the Retzius space, and a pump situated in the labia majora. To void, the patient must squeeze the pump, deflating the AUS cuff and thereby opening the bladder neck to allow urine to pass with minimal urethral resistance. Although pump manipulation typically poses no issue for male AUS patients, it can be problematic for female patients due to anatomical or cultural factors. Despite this, only a handful of studies have addressed the issue of pump manipulation difficulties in female AUS patients, and none have specifically focused on this clinical challenge [6-9]. The aim of the present study was to evaluate the prevalence of difficulties in pump manipulation among female AUS patients, as well as to identify risk factors and explore management strategies for this complex issue.

MATERIALS AND METHODS

Study Design

After receiving approval from the institutional review board (CNIL number: 2234449v0), we prospectively collected data from all female patients who underwent robotic AUS implantation at a single academic center from January 2014 to December 2022. The database was subsequently analyzed retrospectively for this study.

For each female patient visiting our clinics with SUI due to ISD, we discussed the advantages and disadvantages of various treatment options. These included bulking agents, autologous pubovaginal slings, periurethral adjustable continence therapy balloons, and female AUSs. Taking into account the severity of their incontinence, along with their personal preferences, beliefs, and expectations, we selected the most suitable treatment option through a shared decision-making process [10].

The following baseline characteristics were recorded in a dedicated computerized dataset for all patients: age at the time of AUS implantation, body mass index (BMI), American Society of Anesthesiologists physical status classification grade, etiology of incontinence (neurogenic vs. nonneurogenic), history of radiotherapy, history of previous anticontinence surgery, number of pads used per day, type of pad, presence of urgency, maximum free urinary flow, postvoid residual volume (PVR), mean operative time, estimated blood loss, cuff size, and length of hospital stay. Postoperative complications were recorded and graded according to the Clavien-Dindo classification [11]. All patients underwent a urodynamic analysis before surgery. Each case was assigned a chronological number, which served as a surrogate marker for the center's overall experience with robotic female AUS implantation.

Preoperative Pump Manipulation Evaluation, AUS Implantation, and Activation

Preoperatively, the surgeon confirmed that the patient could reach and grasp her labia majora. In most cases, pumps were implanted in the left labia majora, except when preoperative evaluations indicated that implantation in the right labia majora would allow for better manipulation of the pump. The pump was only placed in the abdominal subcutaneous tissue adjacent to the umbilicus in patients who, due to obesity, had no access to the labia majora and for whom no other therapeutic options were considered suitable for their SUI.

All AUS were implanted using an anterior transperitoneal approach with robotic assistance, except for two that were implanted via a preperitoneal robotic-assisted approach, as previously described [12]. Briefly, the patient is positioned in a 23° Trendelenburg position, ensuring full access to the vagina. A 14-French urethral catheter is inserted, and 5 ports are strategically placed in a straight line at the level of the umbilicus, following the standard setup for robotic pelvic procedures.

The peritoneum is opened, and the bladder is detached from the anterior abdominal wall to access the Retzius space. Upon reaching the endopelvic fascia on both sides, all materials from previous anti-incontinence procedures, such as midurethral slings, Burch colposuspension stitches, and pubovaginal slings, are either removed or divided. Subsequently, the posterior aspect of the bladder neck is dissected. The assistant surgeon places a finger in each of the anterior vaginal fornices adjacent to the bladder neck. This allows the robotic surgeon to progressively access the intervesicovaginal plane, primarily using blunt dissection while sliding along the assistant's finger. Once the bladder neck is circumferentially dissected under continuous visualization, a measuring tape is used to determine its dimensions and select the appropriate cuff size. Following the placement of the cuff around the bladder neck, the balloon is insert-

ed through a 3-cm suprapubic incision. The surgeon then routes the cuff's tubing back through the same incision. A space is subsequently created in the labia majora via a subinguinal incision to insert the pump, and the tubing connections are made through this incision as well. The device is deactivated at the conclusion of the procedure. The urethral catheter is removed either in the operating room or on the first postoperative day, unless there is a bladder injury, in which case it is maintained for 10 to 14 days.

The AUS was activated at 6 weeks during a 6- to 10-hour hospitalization [13, 14]. Patients were instructed on how to operate the pump and were required to perform multiple voids under the close supervision of a specialized nurse. Typically, the first void was assisted by the nurse, the second was closely monitored, and the patient independently managed the third and any subsequent voids. PVR was measured after each micturition. Discharge with an activated AUS was contingent upon the final PVR being less than 100 mL and satisfactory demonstration of pump manipulation by the patient.

In cases where manipulating the pump proved difficult, the device was deactivated, and either a new outpatient visit or a new hospitalization was scheduled.

At the 3-month follow-up, both PVR and pump manipulation were systematically reevaluated. Subsequently, all female patients who had undergone AUS implantation were scheduled for annual follow-up visits at clinics where both PVR and pump manipulation were reassessed.

Outcomes of Interest

The primary endpoint of this study was defined as temporary difficulties, specifically the need for at least one additional short hospital stay or a physician consultation to learn pump manipulation. The secondary outcomes included: (1) initial difficulties in manipulating the pump, noted as any mention of challenges during the hospitalization for initial activation; (2) permanent difficulties, necessitating the permanent deactivation of the device due to unresolved challenges in pump manipulation despite multiple hospitalizations; (3) complications that arose directly from difficulties in manipulating the pump; (4) serious difficulties, characterized by permanent deactivation and/or surgical intervention to reposition the pump, and/or complications resulting from difficulties in manipulating the pump.

Statistical Analysis

Means and standard deviations were reported for continuous variables, while medians and ranges were used for categorical variables, and proportions were calculated for nominal variables. Group comparisons were conducted using the chi-square test or Fisher exact test for discrete variables, and the Mann-Whitney test for continuous variables, as appropriate. Statistical analyses were carried out using JMP v.12.0 software (SAS Institute Inc., Cary, NC, USA). All tests were 2-sided, with a significance threshold set at $P < 0.05$.

RESULTS

Patients' Characteristics

Out of the 88 female AUS patients included in the study, the median age was 66 (range, 65–73) years, and the mean BMI was 28.0 ± 5.5 kg/m^2. Eleven patients (12.5%) had neurogenic SUI. Two patients reported a history of pelvic radiotherapy. A significant majority, 78 patients (88.6%), had undergone previous anti-incontinence surgery; of these, 60 (69.0%) had previously received a midurethral sling. Seven patients (8.0%) underwent concomitant sacrocolpopexy. Two pumps were implanted abdominally. The median daily usage of pads was 3 (range, 2–5). The mean operative time was 163.5 ± 51.2 minutes. There were 24 postoperative complications within 30 days (27.3%).

Difficulties in Manipulating the Pump

Twenty patients initially experienced difficulties manipulating the pump, accounting for 22.7% of the study group. Sixteen of these patients faced temporary challenges that necessitated at least one rehospitalization, representing 18.2% of the total. Four patients encountered permanent difficulties, leading to the permanent deactivation of their devices (4.5%). The 2 patients who had abdominal pumps also experienced temporary difficulties but were ultimately able to successfully operate their pumps after an additional 1-day hospitalization.

We identified several factors that could explain the challenges encountered in operating the pump, with some patients exhibiting multiple issues. Half of the patients (8 individuals) experienced difficulties due to incomplete pump depression caused by manual dexterity problems. Three patients reported issues with the positioning of the pump. Two patients encountered persistent hematomas at the activation site 6-week postprocedure, which complicated their ability to use the pump even after the hematomas began to resolve. One patient struggled with pump manipulation due to a chronic skin condition known as

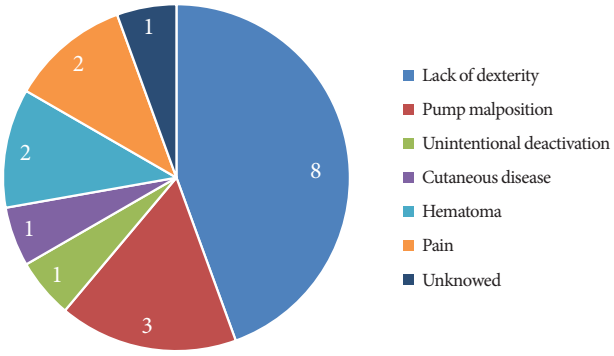

Fig. 1. Reasons for difficulty in manipulating the pump.

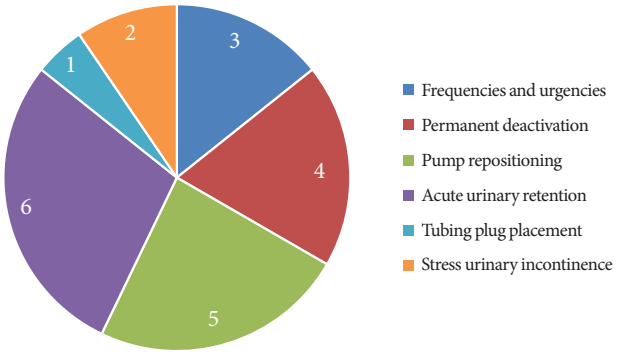

Fig. 2. Consequences of difficulty in manipulating the pump.

vestibular papillomatosis, which affected the labia majora. Another patient had accidentally deactivated the device. For 1 patient, the reason for the difficulty in manipulating the pump remained unclear (Fig. 1). In terms of consequences, dexterity issues can cause symptoms that vary from frequency and urgency to acute urinary retention (AUR). Six patients experienced AUR, with 1 case leading to a severe urinary tract infection and septic shock. One instance of AUR was attributed to the unintentional reactivation of a deactivated sphincter. Patients who reported discomfort with the pump's position noted pain during manipulation or sexual intercourse.

Surgical reoperations were necessary to reposition the pump in 5 patients, but successful manipulation of the pump was achieved in only 2 cases. Two pumps were transposed to the abdominal area, which led to an infection and subsequent removal of one pump.

In our analysis of patients who underwent device deactivation, we observed 2 cases of unintentional reactivation that resulted in AUR. Additionally, 1 patient requested the removal of her pump.

Two patients experienced persistent urinary incontinence (one because of incomplete depression of the pump with overflow incontinence, the other because of unintentional deactivation) (Fig. 2). Out of 16 patients, only 1 had a PVR >100 mL at last follow-up.

There were a total of 6 serious difficulties (6.8%). The median number of additional hospitalizations required to learn proper manipulation was 1 (range, 1–3). For patients experiencing temporary difficulties, the median time to achieve successful manipulation was 3 (range, 2–5) months.

Predictive Factors

The only 2 variables significantly associated with temporary difficulties were longer operative time (183 minutes vs. 159.1 minutes, P=0.04) (Table 1) and the center's overall experience (32 vs. 50, P=0.04). The median age was higher in the group experiencing temporary difficulties (70 years vs. 65 years), as was the BMI (29 kg/m^2 vs. 27.7 kg/m^2); however, these differences were not statistically significant (P=0.08 and P=0.19, respectively). The sole variable significantly associated with serious difficulties in manipulating the pump was the overall center's experience (11 vs. 47, P=0.004) (Table 2).

DISCUSSION

The present study is the first to assess the prevalence of difficulties in manipulating the pump and to describe its consequences and management. We discovered that these difficulties were more prevalent than anticipated: 18.2% of female AUS patients experienced temporary challenges. Given that 22.7% of female AUS implantations initially reported difficulties, we believe that evaluating device manipulation is crucial both at activation and during follow-up visits. Several factors have been identified as causes of these difficulties, including lack of dexterity, pain, and malposition of the pump. The consequences vary widely, ranging from minor issues such as urgency and frequency, to more severe problems like AUR, septic shocks, and permanent deactivation. While most issues could be resolved through rehospitalization and improved patient education, some required surgical revisions and led to permanent deactivation of the device. In light of these findings, we believe that the manipulation of the pump in female AUS patients warrants careful attention from both clinicians and researchers in the field. Further studies are necessary to elucidate the determinants of these difficulties.

Several mechanisms could be assumed to play a role. In our

Table 1. Patients' characteristics and perioperative outcomes

Characteristic	Full cohort (n = 88)	Temporary difficulties (n = 16)	No temporary difficulties (n = 72)	P-value
Age (yr)	66 (65–73)	70 (63–75.8)	65 (53–72)	0.08
BMI (kg/m^2)	28.0 ± 5.5	29.0 ± 5.6	27.7 ± 5.5	0.19
ASA PS classification grade				0.84
I	24 (27.3)	5 (31.2)	19 (26.4)	
II	55 (62.5)	9 (56.3)	46 (63.9)	
III	9 (10.2)	2 (12.5)	7 (9.7)	
Etiology of SUI				0.99
Neurogenic	11 (12.5)	2 (12.5)	9 (12.5)	
Nonneurogenic	77 (87.5)	14 (87.5)	63 (87.5)	
History of previous anti-incontinence surgery	78 (88.6)	15 (93.8)	63 (87.5)	0.36
Concomitant sacrocolpopexy	7 (8.0)	0 (0)	7 (9.7)	0.34
Operative time (min)	163.5 ± 5.5	183.4 ± 5.6	159.1 ± 50.9	0.04
30-Day postoperative complications	24 (27.3)	5 (31.3)	19 (26.4)	0.76
Overall center's experience	NA	32 (9–48)	50 (25–48)	0.04

Values are presented as median (interquartile range), mean ± standard deviation, or number (%).
BMI, body mass index; ASA PS, American Society of Anesthesiologists physical status; SUI, stress urinary incontinence.

Table 2. Comparison of patients with versus without serious difficulties in manipulating the pump

Variable	Serious difficulties (n = 6)	No serious difficulties (n = 82)	P-value
Age (yr)	68.5 (56–72)	66 (55–73)	0.82
BMI (kg/m^2)	28.0 ± 5.5	28.0 ± 5.6	0.73
ASA PS classification grade			0.84
I	1 (16.6)	23 (28.0)	
II	5 (83.3)	50 (61.0)	
III	3 (0)	9 (11.0)	
Etiology of SUI			0.99
Neurogenic	1 (16.7)	10 (12.2)	
Nonneurogenic	5 (83.3)	72 (87.8)	
History of previous anti-incontinence surgery	6 (100)	72 (87.8)	0.36
Concomitant sacrocolpopexy	0 (0)	7 (8.5)	0.99
Operative time (min)	167.5 ± 5.5	163.3 ± 5.6	0.42
30-Day postoperative complications	3 (50.0)	21 (25.6)	0.33
Overall center's experience	11 (5–24)	47 (26–68)	0.004

Values are presented as median (interquartile range), mean ± standard deviation, or number (%).
BMI, body mass index; ASA PS, American Society of Anesthesiologists physical status; SUI, stress urinary incontinence.

population, lack of dexterity and malposition of the pump were the 2 predominant causes. Although the literature has evaluated a link between cognitive function and dexterity, and tools for assessment have been proposed [15, 16], we had no available data on cognitive function and thus were unable to assess the potential relationship between cognitive dysfunction and diffi-

culties in manipulating the pump. However, most of our patients reported an incomplete depression of the pump. This issue may be attributed to a lack of digital strength or finger deformities in this relatively older population, where conditions like osteoarthritis and polyarthritis are common [17]. Regarding the malposition of the pump, most patients described an upward migration of the pump to the inguinal region during the postoperative period. One patient reported pain during sexual intercourse, which was linked to the pump being placed too low. We lack objective tools or specific information to more accurately evaluate these findings. Additionally, in our series, we did not consider the patient's dominant hand when deciding in which labia to implant the pump, but doing so might help reduce the prevalence of difficulties in manipulating the pump. We reported 6 cases of AUR that could lead to prolonged catheterization. Although there is no dedicated data for female patients, we can assume that prolonged catheterization may increase the risk of erosions [18]. In patients whose devices were deactivated due to difficulties in manipulating the pump, we observed 2 unintentional reactivations with AUR. To prevent this situation from recurring, we removed the pump in 1 patient.

The only 2 variables significantly associated with temporary difficulties were longer operative time and the overall experience of the center. Although the median age and BMI were higher in the group experiencing temporary difficulties, these differences were not statistically significant. This lack of significance can be attributed to the small size of our study population. Larger studies are necessary to more accurately assess the impact of these factors, as older age may contribute to cognitive dysfunction, and a higher BMI could complicate access to the labia majora and the pump, similar to difficulties reported with clean intermittent self-catheterization [19, 20]. Although we did not compare PVR volumes between the 2 groups, it is noteworthy that only 1 out of 16 patients in the difficulties group had a PVR greater than 100 mL. This suggests that PVR alone may not be adequate for assessing a patient's ability to manipulate the device, as some patients may completely empty their bladder while voiding with a closed cuff. Operative time could be indicative of case complexity but is more likely a reflection of the center's overall experience and the effects of the learning curve. Therefore, the primary factor influencing difficulties in manipulating the pump is likely the learning curve itself, which can impact patient selection, pump positioning, patient education, and follow-up necessary for proper pump manipulation.

To overcome the challenges of pump malposition and manipulation difficulties, various hypothetical solutions have been considered. We have experimented with relocating the pump from the labia majora to an abdominal site. Based on our limited experience, this approach is feasible, although it significantly increases the risk of pump infection. This adjustment might benefit patients who have trouble accessing the labia majora; however, it does not address issues related to the lack of dexterity or strength required for pump manipulation. Additionally, we could develop predictive tools to identify patients likely to face insurmountable difficulties, leading to permanent AUS deactivation, as has been observed in male patients [21, 22]. With ongoing technological advancements and the potential introduction of an electromechanical device, the frequency of difficulties experienced in pump manipulation is expected to decline [23].

The present study has several limitations that should be acknowledged. First, it is a retrospective analysis conducted at a single center, which introduces numerous inherent biases. Particularly, the information regarding pump manipulation issues was not always as detailed as expected. The sample size was relatively small, which precluded the ability to conduct a multivariate assessment of predictive factors. Additionally, there is no universally accepted definition of difficulties in manipulating the pump in the existing literature. We also lacked validated tools to assess manual dexterity, cognitive function, and access to the labia majora preoperatively. This may have led to misclassification and omission of some causes of difficulties in manipulating the pump. Finally, the study was unable to evaluate the number of female patients who were not offered an AUS implantation because they were deemed unfit to manipulate the pump, or the proportion of female patients who rejected the option of an AUS implantation due to concerns about the pump. These factors might have led to an underestimation of the impact of the pump and its manipulation on the use of AMS-800 AUS in female patients.

In conclusion, difficulties in manipulating the pump are relatively common among female AUS patients. Most of these issues can be resolved through repeated patient education and careful follow-up; however, they may lead to surgical revisions, multiple hospitalizations, and serious complications such as septic shock. Proper patient education, vigilant monitoring at the time of activation, and increased awareness within the medical community can help minimize the consequences of these difficulties. Developing and validating tools to preopera-

tively identify patients at risk of difficulties with pump manipulation could aid in treatment decisions, especially in the context of the forthcoming electromechanical AUS.

AUTHOR CONTRIBUTION STATEMENT

- Conceptualization: *AD, BP*
- Data curation: *AD, VL, CR, CH, JP, CV, MJ, ES, LPB, LF, JH, AM, BP*
- Formal analysis: *AD, BP*
- Methodology: *AD, BP*
- Visualization: *AD, AM, BP*
- Writing - original draft: *AD, BP*
- Writing - review & editing: *AD, AM, BP*

ORCID

Alexandre Dubois	0009-0003-7374-7922
Claire Richard	0000-0002-4374-5665
Camille Haudebert	0000-0001-9050-0030
Louis-Paul Berthelot	0000-0002-8927-3202
Lucas Freton	0000-0001-5624-1952
Juliette Hascoet	0000-0001-9615-4124

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