

Do the etiological factors in artificial urinary sphincter reimplantation cases affect success and complications?

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Background/aim: The artificial urinary sphincter (AUS) is still one of the best options for incontinence treatment. It may also have an advantage for revision or reimplantation in the management of complications. In this study we aimed to discuss the etiological factors for AUS reimplantation and effects of these etiological factors on success rates, patient satisfaction rates, time to reimplantation surgery, and complications.

Materials and methods: Data from 30 patients for whom AUS reimplantation was performed were analyzed retrospectively. Incontinence due to fluid loss from the cuff or reservoir balloon, inability of the cuff to adequately compress the urethra, and devices that were thought to have completed their lifespans were defined as mechanical reasons while incontinence caused by conditions such as cuff erosion and infection were defined as nonmechanical reasons. Patients who went through reimplantation due to mechanical and nonmechanical causes were included in Group 1 and Group 2, respectively. Success rates, patient satisfaction rates, time between the implantation of the first and second AUS, and complications were compared between the groups.

Results: The mean follow-up period was 79 (3–308) months for patients who went through primary AUS implantation due to postprostatectomy incontinence. Our success rates were found as 75% and 66% in Group 1 and Group 2, respectively. The differences between the groups in terms of success and patient satisfaction rates were not statistically significant, while the time to reimplantation was longer in Group 1 and statistically significant.

Conclusion: Reasons for AUS reimplantation may affect the success and patient satisfaction rates. Our success rates of AUS performed for nonmechanical reasons were slightly lower, but not statistically significantly so. AUS reimplantation may take a longer time if mechanical failure is detected.

Key words: Urethra, prostatectomy, urinary sphincter, artificial

1. Introduction

Urinary incontinence is a major health problem that affects the quality of life of affected individuals. Several epidemiological studies have shown that it arises due to lower urinary tract symptoms and has incidence rates of 10% and 21% in men under 65 years of age and over 65 years of age, respectively (1–3). Urinary incontinence often occurs as a complication after radical prostatectomy (RP) or various endoscopic procedures. It has incidence rates of 5%–48% after RP (1,4). In addition, detrusor overactivity and de novo bladder compliance impairment can occur in 77% and 50% of RP cases, respectively, particularly in the first-year follow-up visit after the procedure (5). Factors such as age, body mass index, urethral length, preoperative

bladder compliance, and sphincter preoperative status affect the occurrence of postprostatectomy incontinence (6,7). The experience and surgical skills of surgeons are other significant factors that can affect the occurrence of postprostatectomy incontinence (6,7).

Conservative treatment, medical treatment, and surgery are options for the management of postprostatectomy incontinence. Although urethral injections, slings, and synthetic tapes are options in surgical intervention for incontinence, an artificial urinary sphincter (AUS) still remains the gold standard in the treatment of postprostatectomy incontinence (8). In recent years, the development of novel diagnostic and treatment methods have made it possible to diagnose and treat patients with

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prostate cancer early (9,10). The main advantage of an AUS is that its use allows revision and reimplantation. The mechanical failure of an AUS, infections, cuff erosion, and iatrogenic factors are factors that can cause incontinence and repeat incontinence surgery.

Therefore, this study aimed to examine the effects of etiological factors on the success and satisfaction rates of AUS reimplantation cases, the time between the implantation of the first and second AUS (reimplantation), and complications of AUS in patients undergoing reimplantation.

2. Materials and methods

Data from 105 patients who had undergone AUS (AMS 800, Minnetonka, MN, USA) implantation between 1990 and 2017 were retrospectively analyzed. All patients had undergone AUS implantation by the same surgeon. Thirty of them required reimplantation. Prior to reimplantation, informed consent was obtained from all patients. All patients were then administered hemodynamic tests, urinalysis, ultrasonic examination, and cystoscopy preoperatively. When necessary, urodynamic testing, intravenous urography, and retrograde urethrography were performed. Cases of incontinence caused by the loss of the cuff or fluid from the reservoir balloon, inability of the cuff to adequately compress the urethra, and situations where the device seemed to have completed its lifespan were defined as mechanical causes. Cases of incontinence caused by conditions such as cuff erosion and infection were defined as nonmechanical causes. Patients who underwent reimplantation due to mechanical and nonmechanical causes were included in Group 1 and Group 2, respectively.

Criteria for AUS reimplantation included incontinence affecting the quality of life of a patient and the absence of new factors such as mental or physical disorders, conditions that would not constitute a pathology for the lower urinary tract with a high expectancy of life for AUS mapping or reimplantation, unexpected recurrence, and those who still maintained adequate bladder capacity.

2.1. Surgical technique

We waited for 6 months to reimplant a new device in the case of infection. In cases of mechanical failure or lack of active infection, simultaneous displacement and reimplantation or reoperation was performed. Prophylactic antibiotic treatment was initiated before the procedure. All of our patients in this study were approached with a perineal incision after placing the appropriate urethral catheter in lithotomy position. Bulbospongiosus and bulbocavernosus muscles were dissected from the bulbar urethra and attempts were made to determine the pathology necessitating reimplantation. First, we tried to change only the corrupted instrument of the device (urethral cuff, reservoir, pump, etc.). However,

if this was not possible and total replacement of the device was planned, urethral mobilization was attempted. It was passed under the bulbous urethra with the help of a right-angle clamp. The diameter of the urethra was determined for the appropriate urethral cuff. At this point, an attempt was made to avoid extreme dissection of the urethra and giving the cuff too much tension. We aimed to support the urethra with the adjacent connective tissues in order to avoid urethral atrophy. The air of the device was evacuated and the instruments were placed appropriately. An inguinal oblique incision was made for reservoir placement. The reservoir was placed in the retropubic area and the cuff and conducting tubes were connected. The reservoir was filled with 22 mL of saline. Subdartos space was then prepared for the pump. The cuff was properly assembled by passing the connector tubing under the scarpa fascia so as to provide the space between the reservoir and the pump. After all instruments were checked, the reservoir was filled and deactivated. A Penrose drain was placed into the scrotum. The layers were closed in accordance with the procedure. Urethral catheters of all patients were removed 24 h postoperatively. For preventing edema and hematoma we applied cold scrotal elevation for 6 h. Patients were discharged at an average of 6 (range: 4–8) days with pad use advice. We called all patients back 6 weeks after the surgery for device activation. All patients were examined 1, 3, 6, and 12 months after the activation. Data on postoperative incontinence level, daily pad usage, and quality of life parameters were recorded.

The degree and amount of incontinence and the quality of life of the patients were evaluated using the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF), a pad test, and the fifth question of the ICIQ-UI SF, respectively. Data such as postoperative incontinence level, pad requirements, and quality of life scores were recorded. Complete dryness or using less than one pad per day was regarded as social continence, while usage of more than one pad per day was regarded as incontinence.

2.2. Statistical analysis

Data were analyzed with IBM SPSS Statistics 21. Descriptive statistics are shown as mean \pm standard deviation for variables with normal distribution and as median (min–max) for variables with abnormal distribution. Nominal variables are shown as number of cases and (%). The t-test and Mann–Whitney U test were used in order to determine degree of significance for parametric and nonparametric variables, respectively. Success rates between the groups were evaluated by Fisher's exact test. $P < 0.05$ was considered statistically significant.

3. Results

The mean follow-up period was 79 months (range: 3–308 months) for patients who underwent primary AUS

implantation due to postprostatectomy incontinence. The mean age of the patients was 61.7 years (range: 15–70 years) and 67.6 years (range: 38–79 years) in Group 1 and Group 2, respectively. The overall rate of AUS reimplantation was 28.5%, and the causes for reimplantation were mechanical and nonmechanical in 40% and 60% of those patients, respectively (Table 1). Twelve patients in Group 1 were readmitted within a mean of 136 months (range: 14–276 months) after the first AUS implantation, while 18 patients in Group 2 were readmitted within a mean of 55 months (range: 3–192 months) after the first AUS implantation.

The causes of incontinence were reservoir discharge or urethral cuff in all patients in Group 1 (Table 1). In Group 2, four patients had infection due to scrotal erosion by the pump, six patients had cuff erosion due to attempts to place urethral catheters for urological or nonurological conditions, and the remaining eight patients had cuff erosions and secondary infections that were caused by factors such as age or comorbidities that had affected urethral blood flow (Table 1).

The success rates were 75% and 66% in Group 1 (9 patients became continent) and Group 2 (12 patients became continent), respectively. On the other hand, three and six patients remained incontinent in Group 1 and Group 2, respectively. In the six unsuccessful patients in Group 2, the reasons for AUS removal were scrotal erosion by the pump in one patient and infections due to cuff erosion in two patients. Intraoperatively, we noticed leakage from the transfer pipes of the device that failed after reimplantation in one of the three patients in Group 1. We performed another operation after 3 months and changed the device. As a result, in Group 1, transfer tubes was changed in one patient, a tandem cuff was placed in one patient, reservoir balloons were changed in two patients, and the rest had their devices completely replaced. Two patients stated that incontinence did not affect their quality of life and they did not want to undergo a third surgery. Follow-up of these patients is still ongoing. In Group 2, three of the six patients had cuff erosion, while the others had perineal or scrotal infections; therefore, we

removed the device. Three of these patients had undergone a third AUS implantation surgery 6 months after discharge and achieved continence. The other three patients did not consent to a third surgery.

The mean number of pads used daily was 1.04 ± 1.61 in Group 1 and 1.38 ± 1.72 in Group 2. The mean symptom score (ICIQ-UI SF) was 4.00 ± 3.07 in Group 1 and 5.61 ± 4.96 in Group 2. The quality of life score (ICIQ-UI SF, fifth question) was 3.33 ± 2.90 in Group 1 and 4.00 ± 2.76 in Group 2. Patient outcomes were better, but not statistically significantly so, in Group 1 in terms of success rates, postoperative symptom scores, average daily use of pads, and quality of life scores (Table 2). The time for reimplantation was longer and statistically significant in Group 1 (Table 2).

4. Discussion

Despite all technological advancements in the field of medicine, incontinence still remains a problem in the field of urology. Although developments in surgical techniques are expected to reduce the incidence rate of postprostatectomy incontinence (11), the increase in the number of prostatectomy cases has caused the incidence rate to remain stable (12). In spite of the high success rates of AUS implantations, reimplantation or revision is not rare. In the literature, it was recorded that the success rate of AUS implantation is over 80% (13–15), regardless of the severity of incontinence, and that 37%–50% of patients would need revision in the first 10 years (14,16). Urethral atrophy has been reported as the most common cause of revision surgery and recurrent incontinence in various studies (17,18). In another study, the total rate of revision was reported to be 30.5% in the first 3 years and the reasons were cuff erosion in 12%, infection in 4%, and mechanical failure in 14% of the cases (15). In the literature, research studies on the etiology and success rates of AUS are limited. The success rate of AUS revision was reported as 82% in a study of 119 cases, similar to the results of primary and secondary AUS implantation success rates (19). Tuygun et al. compared male bulbourethral slings and AUS reimplantation in patients with erosions after primary implantation. They reported that AUS resulted in better patient outcomes than bulbourethral slings (20). In another study (21), a success rate of 75% was documented in patients who had undergone AUS reimplantation due to infection. Studies mentioned in the literature did not take etiology into consideration in the assessment of success rates of AUS reimplantation. In our study, the success rate in Group 1 was similar to those found in the literature, while in Group 2 it was lower than those in the literature. It has been suggested that nonmechanical causes of continence lead to ischemia of the periurethral area and connective

Table 1. AUS reimplantation etiology.

Etiology	Patients
Mechanical	12 (40%)
Urethral cuff empty	8 (26.6%)
Reservoir discharge	4 (13.3%)
Nonmechanical	18 (60%)
Traumatic urethral catheterization	6 (20%)
Cuff erosion	6 (20%)
Infection	6 (20%)

Table 2. Comparison of parameters between groups.

Parameters	Group1 (n: 12)	Group2 (n: 18)	P
Dryness	9 (75%)	12 (66.6%)	0.704
Time to reimplantation (months)	136 (14–276)	55 (3–192)	0.0312
Mean amount of pads (daily)	1.04 ± 1.61	1.38 ± 1.72	0.408
Mean symptom score (ICIQ-UI SF)	4.00 ± 3.07	5.61 ± 4.96	0.639
Quality of life (ICIQ-UI SF) (5th question)	3.33 ± 2.90	4.00 ± 2.76	0.456

tissues that the cuff is placed in and, consequently, a higher potential for urethral trauma. Our reimplantation rate was slightly lower than the rates documented in the literature. We suggest that the lower rates were due to differences in etiological factors, follow-up duration, and other patient-based factors.

It is often not possible to predict the diagnosis of urethral atrophy in advance. In the literature there is still no consensus on this issue (22). In general, this may be noticed when the urethral cuff is placed during surgery, requiring a narrower cuff than before (22). Since AUS surgeries are mostly performed on elderly patients, these patients may have various chronic progressive systemic diseases that may increase with age, destroy the urethral blood flow, or cause atrophy. In addition, excessive squeezing of the urethral cuff placement during the first AUS implantation can cause urethral disruption and atrophy.

We observed that the most common causes of AUS reimplantation were urethral atrophy, cuff erosion due to urethral interventions, and nonmechanical causes such as infections. Therefore, AUS-implanted patients should be educated on the use of the device and possible urethral interventions. There are studies in the literature that have predicted AUS reimplantation rates and complications. In this sense, some studies in the literature have correlated AUS infection or erosion with the history of radiotherapy or comorbidities (21,23). Similarly, erosion has been reported to increase the risk of reimplantation up to four times (24). In reoperations performed due to erosion or infection, tissue structures may deteriorate because of scar tissue and fibrosis (23). Scar tissue may impair vascularization and create a vicious circle by causing reinfection or erosion.

In our study, there were no patients with a history of radiotherapy or any clinically significant comorbidity. Our rates of success, patient satisfaction, and incontinence were lower in patients with incontinence due to nonmechanical causes, and the AUS was removed in three patients due to developing infections. These results suggested that infection in the periurethral area or fibrosis due to urinary extravasation increases due to insufficiency of the cuff to squeeze the urethra or excessive urethral dissection.

It has been reported that mechanical failures of the AUS can lead to AUS reimplantation or revision less commonly than other known reasons (21). These mechanical failures are frequently associated with obesity (21). Furthermore, urethral atrophy and mechanical failure have been reported as factors that cause recurrent urinary incontinence (16,21). There were no morbidly obese patients in our study. Mechanical failures were commonly related to devices that had completed their lifespans. In addition, success and patient satisfaction rates were better, but not statistically significantly so, in Group 2. When compared with nonmechanical causes, mechanical causes of AUS reimplantation may lead to minimal urethral damage.

The time frame within which the need for AUS reimplantation or revision arises may give a clue to the etiology of incontinence. In this sense, incontinence that occurred in the first week or month after the first AUS implantation may reveal an unrecognized urethral injury that might have occurred during cuff insertion, while late-onset incontinence suggests improper device use, long-term catheterization, or urethral interventions without device deactivation (16). In our study, the time for reimplantation was longer and statistically significant in patients with incontinence due to mechanical causes. It is essential to manage the nonmechanical causes of incontinence to reduce the need for reimplantation and to extend the lifespan of the device. Therefore, patients should be taught to use the device properly and the device should be deactivated before urethral interventions.

As a result, it may not be possible to predict AUS complications. However, we think that it is important to warn patients and their relatives about possible urethral interventions to be applied and to teach the operating principles of the device to the patient in detail. In addition, we think that it is also important to avoid excessive dissection of the urethra and excessive cuff squeezing during surgery, and to give the necessary importance to sterility during and after surgery.

In conclusion, an AUS is a useful device that allows reimplantation and revision in incontinence surgery. However, several etiological factors may affect the

success and complication rates of an AUS. While it may not be possible to predict mechanical failures, it may be possible to predict and manage nonmechanical causes. Therefore, it is essential to explain the use of the device to patients, and both patients and physicians should be educated on urethral interventions. Although the success

and satisfaction rates of AUS reimplantation performed for nonmechanical causes were reported to be low, further clinical studies with a larger number of patients are required to obtain more data that can be more widely generalized.

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