

Factors effecting the outcomes of artificial urinary sphincter placement: a single-center study

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ABSTRACT

Objectives: To evaluate the patients who underwent artificial urinary sphincter (AUS) placement and report outcomes of the procedure.

Methods: From March 2008 to February 2017, the data of patients who have undergone AUS placement were evaluated retrospectively. Age, body-mass index (BMI), comorbidities, education level, previous radiotherapy (RT) history of the patients were recorded. Cognitive status was examined using the Mini Mental Status Examination test (MMSE). International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF) was completed pre- and post-operatively. Quality of life and satisfaction of patients were evaluated using Patient Global Impression of Improvement (PGI-I) scale. To analyze factors effecting success and revision rates, patients were grouped according to age, BMI, comorbidities, smoking habit, previous RT history and etiology of incontinence. Treatment success was defined as requirement of ≤ 1 /day.

Results: A total of 61 patients were included in the study and each were cognitive intact (MMSE > 25). ICIQ-SF significantly improved in postoperative period ($p < 0.001$). PGI-I median score was 1 (1-4) in postoperative period. Success rate was 96.7% (n = 59) and 47 (77%) patients were complete dry. Revision requirement occurred in 10 (16.4%) patients. When patient groups were compared according to the success and revision rates; presence of BMI > 25 kg/m² was the only significant factor associated with revision requirement and there was no significant factor associated with success status.

Conclusion: AUS placement is a safe and effective method in the treatment of post-prostatectomy incontinence (PPI). Success and revision rates are similar regardless the etiology of PPI. Cognitive functions of patients may be crucial in the postoperative satisfaction status.

Keywords: Artificial urinary sphincter, post-prostatectomy incontinence, male incontinence

Stress urinary incontinence (SUI) may occur in men who underwent radical prostatectomy (RP) for the treatment of localized prostate cancer (Pca). In the literature, it was reported that 8% to 25% of the men were affected by persistent UI following RP [1-4]. Besides, as a more widespread procedure performed in urology practice, transurethral resection of the prostate (TUR-P) is associated with postoperative urinary in-

continence range 1.8 to 5%. [5-8]. Although it is not a lethal complication, SUI following prostate surgery (RP or TUR-P) may impact the quality of life adversely and cause financial problems. Internal urethral sphincter deficiency is the main reason associated with SUI in men. Nowadays artificial urethral sphincter (AUS) placement is the standard treatment of moderate and severe postprostatectomy incontinence [9-11]. However,

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success of this system can be affected by many factors such as previous radiation therapy (RT), bladder neck or urethral stenosis, comorbidities of the patient and surgeon's experience. Additionally complications such as infection, urethral erosion, urethral atrophy and device malfunction may occur following the procedure. Although it is an effective treatment, the patients may be disappointed because of high expectations from the device. Patients should be informed about the device, the possible complications and the definition of success.

AUS placement has been performed in our clinic since 2008. In this study, we aimed to evaluate the patients who underwent AUS placement and report our results.

METHODS

In this retrospective study, the data of the patients who have undergone AUS placement (AMS 800) in our clinic since 2008 were evaluated. The patients with more than one year follow-up were included. The age, body-mass index, comorbidities, education level, previous RT history and urethral or bladder neck stenosis history of the patients were recorded. Cognitive status was examined using the Mini Mental Status Examination test (MMSE). International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF) was completed in all patients before and 3 months after the treatment. The quality of life and satisfaction of the patients were evaluated using Patient Global Impression of Improvement (PGI-I) scale which is a transition scale that is a single question asking the patient to rate their urinary tract condition now, as compared with how it was prior to the treatment on a range from 1 (very much better) to 7 (very much worse). Filling these forms was a routine procedure as it was mandatory for preoperative decision-taking and postoperative follow-up. Number of pads used before and two months after the treatment were also recorded. Postoperative complications were assessed using Clavien-Dindo grading system [12]. Treatment success was defined as the requirement of maximum one pad per day. The patients who did not need any pad use were defined as complete dry. Additionally, to analyze the factors effecting success rate and revision rate, patients were grouped according

to the age (≥ 65 years and < 65 years), BMI (≥ 25 kg/m² and < 25 kg/m²), comorbidities, smoking habit, previous RT history, education level (lower than high school - high school and above) and etiology of incontinence.

Urine culture was sterile in all cases in the operation day. Ceftriaxone 1 gr intravenous was administered to all patients prior to the surgery in the operating room. The perineal area was shaved in the operating room and washed with povidone-iodine for 10 minutes.

Surgical Technique

A diagnostic cystoscopy was performed prior the treatment in all cases. If an urethral or bladder neck stenosis were seen, they were treated and the treatment was delayed for two months. All the procedures were performed using a modified perineoscrotal vertical single incision by the same surgeon. Following the placement of urethral cuff, fascia transversalis was opened and dilated with finger. Following finger dilation, reservoir balloon was forwarded through the Retzius space. The connector tubes and control pump was placed in the scrotum. A 12 F Foley catheter was inserted during the procedure and removed in the postoperative day morning. All the patients were discharged in the postoperative day 1 and 7 days of amoxicillin/clavulanic acid 875/125 mg peroral BID was administered for each. The device was left deactivated for 6 weeks.

Statistical Analysis

Descriptive statistics for normally distributed continuous variables are reported as the mean \pm standard deviation, with median (minimum–maximum) values calculated for non-normal distributions. Comparisons between groups were evaluated using the Fisher exact test for categorical variables and Wilcoxon test was used for continuous variables. The data was analyzed with IBM SPSS (version 20), and $p < 0.05$ was considered as significant.

RESULTS

From March 2008 to February 2017, a total of 66 patients who underwent AUS placement in our clinic

Table 1. Patient characteristics

| | |
|--------------------------------|---------------------|
| Age (years) | 69.69 ± 5.45 |
| BMI (kg/m ²) | 25.47 (22.28-31.53) |
| Diabetes Mellitus, n (%) | 12 (19.7) |
| Hypertension, n (%) | 23 (37.7) |
| Coronary Artery Disease, n (%) | 13 (21.3) |
| Smoking, n (%) | 20 (32.8) |
| Previous Radiotherapy, n (%) | 7 (11.5) |

were included in the study. Of the patients, 5 were lost to control and excluded. Patient demographics was shown in table 1.

All the patients completed MMSE and each were cognitive intact (MMSE > 25). The comparison of pre- and post-operative ICIQ-SF results of the patients was demonstrated in table 2. Questionnaire results significantly improved in the post-operative period ($p < 0.001$). Also, PGI-I median score was 1 (1-4) in the

antibiotic solution and povidone-iodine then scrotum skin was closed with suturation. Infection occurred in 2 patients and urethral erosion occurred in 1 patient in the postoperative period. The device was removed and the revision was performed 3-6 months later. Urethral atrophy occurred in 4 men and they were treated with tandem-cuff placement. Additionally, revision was performed due to the dysfunction of device in 2 men.

The comparisons of the patient groups according to the success rate and the revision rate were demonstrated in table 4. The presence of BMI \geq 25 kg/m² was the only significant factor associated with revision requirement. There was no significant factor associated with success status.

DISCUSSION

AUS, which was first described by Scott *et al.* [13] in 1973, is the standart tool for the treatment of post-

Table 2. The comparison of pre- and post-operative ICIQ-SF and median value of post-operative PGI-I

| | Preoperative | Postoperative | <i>p</i> value |
|------------------|--------------|---------------|----------------|
| ICIQ-SF (median) | 20 (17-21) | 1 (0-20) | < 0.001 |
| PGI-I (median) | | 1 (1-4) | |

ICIQ-SF: International Consultation on Incontinence Questionnaire Short Form ;PGI-I: Patient Global Impression of Improvement

post-operative period (Table 2).

The success rate of the procedure was 96.7% (n = 59) and 47 (77 %) patients were complete dry. Any complications did not occur peroperatively. Revision requirement occurred in 10 (16.4%) patients (Table 3). Skin extrusion of control pump and connector tubes occurred in one patient. The vehicle was washed with

Table 3. Revision requirements

| | |
|-----------------------------|----------|
| Urethral erosion (n%/CDc) | 1/1.6/3b |
| Skin extrusion (n%/CDc) | 1/1.6/3b |
| Urethral atrophy (n%/CDc) | 4/6.5/3b |
| Device dysfunction (n%/CDc) | 2/3.2/3b |
| Infection (n%/CDc) | 2/3.2/3b |

CDc = Clavien-Dindo classification

prostatectomy incontinence (PPI). Initially, neurogenic urinary incontinence was the main indication for AUS placement. In time, with the increase of RP cases by the widespread use of prostate specific antigen (PSA), PPI became the most frequent reason and the number of procedures increased dramatically. In the literature, there are various studies assessing the efficacy of the device, demonstrating success rates range from 61 to 100% [14]. In our study, compatibly with the literature, the success rate and complete dryness rate were 96.7% and 77.4%, respectively. To increase the success rate, the placement of 2 cuffs were described by Kowalczyk *et al.* [15]. However as most urologists, we preferred tandem-cuff only for the cases who needed revision surgery because of urethral atrophy.

Previous RT is a major concern about the success

Table 4. Comparison of the patient groups according to the success rate and revision rate

| | Success n (%) | <i>p value</i> | Revision n (%) | <i>p value</i> |
|-------------------------------|------------------|----------------|-------------------|----------------|
| | 59 (96.7) | | 10 (16.4) | |
| Age (year) | | | | |
| < 65 | 14 (100) | 0.433 | 2 (14.3) | 0.808 |
| ≥ 65 | 45 (95.7) | | 8 (17) | |
| BMI (kg/m²) | | | | |
| < 25 | 25 (100) | 0.231 | 1 (4) | 0.029 |
| ≥ 25 | 34 (94.4) | | 9 (25) | |
| DM | | | | |
| No | 48 (98) | 0.273 | 8 (16.3) | 0.977 |
| Yes | 11 (91.7) | | 2 (16.7) | |
| HT | | | | |
| No | 37 (97.4) | 0.715 | 7 (18.4) | 0.729 |
| Yes | 22 (95.7) | | 3 (13) | |
| CAD | | | | |
| No | 47 (97.7) | 0.314 | 8 (16.7) | 0.912 |
| Yes | 12 (92.3) | | 2 (15.4) | |
| Previous RT | | | | |
| No | 52 (96.3) | 0.605 | 10 (18.5) | 0.748 |
| Yes | 7 (100) | | 1 (14.3) | |
| Education level | | | | |
| Low | 24 (96) | 0.792 | 5 (20) | 0.526 |
| High | 35 (97.2) | | 5 (13.9) | |
| Smoking | | | | |
| No | 41 (100) | 0.104 | 2 (10) | 0.346 |
| Yes | 18 (90) | | 8 (19.5) | |
| Etiology of PPI | | | | |
| RP | 43 (97.7) | 0.483 | 9 (20.5) | 0.168 |
| TUR-P | 16 (94.1) | | 1 (5.9) | |

BMI = Body-mass index, DM = Diabetes mellitus, HT = Hypertension, CAD = Coronary artery disease, RT = Radiotherapy, PPI = Post-prostatectomy incontinence, RP = Radical prostatectomy, TUR-P = Transurethral resection of prostate

of device and complications. RT may decrease vascularity and increase fibrosis in bulbar urethra. Therefore it was speculated that, prior radiation therapy increases the risk of urethral atrophy and may increase the chance of cuff erosion [16]. Also in the consensus of the International Continence Society, RT was revealed as a factor which predisposes

complications [17]. There are controversial results in the literature. In the study performed by Ravier *et al.* [18], there was no statistically significant difference in continence status between irradiated and non-irradiated group. However, patients with prior RT were more prone to infection and explantation [18]. In another study, similar social continence rates and

complication rates were demonstrated in two groups [19]. In our cohort, 7 patients were irradiated prior to the surgery and success rate of this group was 100%. Also only one patient needed revision due to the mechanical dysfunction 5 years after the surgery. Regarding our limited data, previous RT should not be a concern for the treatment.

Infection following AUS placement is a devastating problem. As any prosthetic device, AUS is prone to infection. In the literature, infection rates range from 1 % to 8 % [20-23]. In the management, the device is removed and revision is performed after 3 months or more. It was revealed that a new device may be implanted with similar success rates [24]. In 2007, AMS presented InhibiZone-coated (rifampin and minocycline hydrochloride coating) AUS to reduce infection rate, however in the study performed by de Cogain *et al.* [20], it was revealed that antibiotic coating did not impact the infection rate and increased the cost of the device. Infection is commonly associated with urethral erosion. In our study, infection rate was 3.2 % (2 patients), however in our infected patients urethral erosion did not occur. In the study performed by Bryan *et al.* [25], immediate replacement for the infected patients without erosion was revealed as a valid option. We preferred the classic management as we think it is safer. Of the patients, 1 was completely dry and 1 was incontinent following the revision.

The periurethral tissue should be protected during dissection to avoid the erosion after the procedure. Erosion rates in contemporary series range from 2-15 % [14, 19, 26, 27]. Erosion in the early period is commonly associated with unrecognized injury, in the late period with iatrogenic reasons. In our study, erosion occurred in only 1 patient due to the urethral catheterization in emergency service 2 years after the surgery. Subsequent to the unsuccessful catheterization trial in emergency service, suprapubic catheterization was performed by us. Management of the urethral erosion is not clear. To remove only the cuff instead of the whole device in the non-infected cases is the primary suggestion. We removed the whole device and performed urethroplasty. Following the revision (4 months later), continence was not achieved. This was related with the urethral atrophy due to the damaged tissue vascularization.

A disadvantage of AUS is the periodic revision

requirement of the device. In the study performed by Linder *et al.* [10], of 1082 patients, 338 were undergone revision surgery due to the infection or erosion, device malfunction, urethral atrophy and pump malposition or tubing complications. They reported AUS survival rate of 90% at 1 year, 74% at 5 years, 57% at 10 years and 41% at 15 years [10]. Urethral atrophy is the most frequent indication of revision in long term follow-up. It is associated with continuous pressure on the tissue and damaged vascularization of the area and causes increased incontinence. Down-sizing the cuff and increasing fluid in the system are treatment choices, however we prefer to implant a tandem cuff. In our cohort, atrophy occurred in four patients and the revision procedure was successful in all cases. Additionally; as any prosthetic device, mechanical dysfunction can occur in AUS. Linder *et al.* [10], revealed that to replace the whole device instead of the dysfunctioning part achieved better results. In our clinical practice, we prefer to replace the whole device and continence was achieved in two patients who underwent revision surgery due to the device malfunction.

The AUS remains the most effective long-term surgical treatment for SUI in men. Despite to the high success rate, it is not suitable for some patients. To be able to use this mechanic device, a sufficient intelligence level and dexterity is an important requirement. Considering this; since AUS placement was first performed in our clinic, all the patients have completed MMSE test prior to the surgery. As far as we know, there is not any study assessing the preoperative cognitive status of the patients. In the current study, the patients completed MMSE prior to the surgery. We believe that to obey the directives and correctly use of this device may cause more satisfactory results and a longer device life. Perhaps as a result of all the patients' being cognitive intact (MMSE > 25), satisfaction rate was prominently high [PGI-I median= 1 (1-4)] in our study.

To our knowledge, there is not a study assessing the outcomes of the AUS placement according to the etiology of PPI. In this study, we divided the patients into two groups as those who had undergone TUR-P and those who had undergone RP. Any statistically significant difference was not observed between the success and revision rates when groups were compared. However, the number of patients was low

and further studies should be performed.

As known, the incidence of chronic diseases increases by the ageing [28]. In the literature, the number of the studies evaluating the outcomes of AUS placement in elderly males is lacking. Also controversial results were revealed. In the study performed by O'Connor *et al.* [29], age of the patient was not defined as a factor which adversely effects the outcomes of the procedure. However, Ziegelmann *et al.* [30] reported that older males were significantly more likely to experience device infection/erosion compared with younger patients. In the current study, presence of comorbidities and age ≥ 65 years were not associated with success of the operation or revision requirements. We think that AUS placement can be safely performed in elderly patients.

Limitations

There are some limitations of this study. First, it was a retrospective non-randomized design. The data such as detailed pathology results of the patients, length of incontinence period prior to the surgery, the medications used, could not be evaluated. Second, the number of patients was relatively low. Third, it was a single center and single surgeon study, which may limit generalizability.

CONCLUSION

The AUS placement is a safe and effective method in the treatment of SUI in men regardless the patient's age. Patient counseling about the definition of success and periodic revision requirement is important prior to the surgery. The success and revision rates are similar regardless the etiology of incontinence (TURP or RP). The patients who are cognitive intact and who have sufficient dexterity may be more satisfied from the device.

Conflict of interest

The authors disclosed no conflict of interest during the preparation or publication of this manuscript.

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