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Artificial urinary sphincter implantation: what do patients and urologists face?

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Aim: To investigate the main problems faced by patients undergoing artificial urinary sphincter (AUS) implantation and the important factors that the surgeon should take into consideration in predicting these problems. Postprostatectomy incontinence continues to be a complication that most severely impairs the quality of life.

Materials and methods: Of 82 initial patients, 64 patients with complete data who responded positively to the invitation for examination were divided into 3 groups: patients with implant-tissue interaction, patients with no problems, and those with mechanical failure. Univariate analysis, Student's t-test, Pearson's chi-square test, logistic regression, and Kaplan-Meier analysis were used in this study.

Results: Of the 64 patients, 20 (31.2%) were reoperated on with a mean follow-up of 62 (range: 1-120) months. It was found that the risk of urethral erosion was higher in patients with obesity ($P = 0.04$), diabetes ($P < 0.0001$), radical prostatectomy ($P < 0.0001$), and adjuvant radiotherapy ($P < 0.0001$), and in those with the suspicion of urethral stricture who would undergo sphincter implantation within at least 3 months after the latest surgical treatment of urethral stricture, compared to other patients ($P < 0.0001$). Additionally, we found that surgical experience also had a strong effect on the risk of urethral erosion.

Conclusion: Given increasing medicolegal awareness, patients should be informed of the possible need for reoperation, and those in the specific patient groups mentioned above should particularly be notified of a higher risk before implantation of an AUS.

Key words: Urinary sphincter, artificial, erosion, incontinence, prostatectomy

Yapay üriner sfinkter uygulaması: Hastayı ve üroloğu neler bekliyor?

Amaç: Post-prostatektomik inkontinans yaşam kalitesini en ağır derecede bozan komplikasyon olmaya devam ederken, şiddetli inkontinansı olan olgularda artifisial üriner sfinkter implantasyonu halen altın standart tedavi yöntemidir. Bu çalışmada AUS implantasyonu uygulanan hastaları bekleyen belli başlı sorunlar ve cerrahın bu sorunları predikte edebilmesi için dikkat etmesi gerekenler araştırılmıştır.

Yöntem ve gereç: Verilerine tam olarak ulaşılabilen ve kontrol davetine olumlu yanıt veren 64 hasta; doku-cihaz etkileşimi gelişenler, sorun yaşamayanlar ve mekanik problem yaşayan hastalar olarak 3 gruba ayrılıp incelendiler. Univariete analiz, Student's t-test ve chi-square, logistic regresyon analizi ve Kaplan-Meier analizleri araştırmada kullanıldı.

Bulgular: 64 hastanın 20'si (% 31,2) reopere edildi ve ortalama takip süreleri 62 (1-120) ay idi. Obez ($P = 0,04$), diabetik ($P < 0,0001$), radikal prostatektomili ($P < 0,0001$), adjuvan radyoterapi almış ($P < 0,0001$), üretral striktür kuşkusu olan ve striktürün son cerrahi tedavisinden bu yana en az 3 ay geçmeden sfinkter implantasyonu uygulanacak ($P < 0,0001$) hastalarda üretral erozyon gelişme riskinin diğer hastalara kıyasla daha yüksek olduğu izlendi. Ayrıca cerrahi deneyimin de birebir üretral erozyon riskini etkilediği saptandı.

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Sonuç: Artan medikolegal uygulamalar nedeniyle artifisyal uriner sfinkter implantasyonu öncesinde hastalara reoperasyon gerekebileceğinden, şayet hasta yazıda bahsi geçen özellikli hasta gruplarından ise bu riskin daha da yüksek olabileceğinden bahsedilmelidir.

Anahtar sözcükler: Üriner sfinkter, yapay, erozyon, inkontinans, prostatektomi

Introduction

Urinary incontinence (UI) after prostatectomy is a complication that most severely impairs the quality of life and interferes with social life (1,2). The incidence of UI following surgery for benign prostatic hyperplasia (BPH) has been reported as 1%-5%, whereas the incidence of UI after radical prostatectomy (RP) has been reported to range between 8% and 77% (3). It is also known that 6%-7% of the patients undergoing RP need further surgical treatment for UI (4,5). Today, artificial urinary sphincter (AUS) implantation remains the gold standard surgical technique for the treatment of postprostatectomy incontinence (PPI) (6).

Even though AUS implantation is a successful and reliable procedure, approximately 25%-28% of the patients require reoperation (4-6). The most serious complication leading to the requirement for reoperation is urethral cuff erosion, which occurs in approximately 5% of cases.

In this study, the main problems faced by patients undergoing AUS implantation for PPI by 2 different surgeons at a single institution since 2001 were investigated. We also attempted to identify the important factors that the surgeon should take into consideration in predicting these problems and ways of dealing with them.

Materials and methods

Initially, 82 patients who underwent AUS (AMS 800^R, American Medical Systems, Minnetonka, MN, USA) implantation with 2 different surgeons at a single institution between January 2001 and January 2011 were enrolled in this study. Of these patients, 7 whose indications were not PPI were excluded from the study. First, we retrospectively reviewed the medical records of the patients. The data recorded included the patient's general characteristics at the time of AUS implantation, the type of prostatectomy procedure (transurethral resection (TUR), suprapubic transvesical prostatectomy (SPTVP), and RP), previously received adjuvant or neoadjuvant therapy for cancer treatment, urodynamic data, pad test results, history of urethral or bladder neck stricture and the number and type of operations undergone by patients thereof (endoscopic incision or resection), the time from the last operation to the implantation (stricture-free time), and postoperative early and late complications and the procedures performed for these complications. Subsequently, all of the patients reached by telephone were invited for an examination. Of those patients, 64 responded positively to the invitation and were enrolled in the study. Thereafter, problems experienced by the patients during the period from implantation to the day of the study and rates of dryness were determined by medical history, and the patients underwent a urogenital examination and uroflowmetry.

Operative technique: During preoperative preparation, all of the patients received 1 g of a first-generation cephalosporin intravenously 30 min before the procedure. With the patients in the lithotomy position, the surgical site was cleaned with povidone-iodine solution, and then the operation began. After 12 h, parenteral administration of antibiotics was repeated and a first-generation oral cephalosporin was administered to the patients with instructions to receive it for 7 days, beginning from the first postoperative day. The review of the medical records revealed that the procedure was performed through a perineal approach using the 2-incision technique in 24 of the 64 patients, whereas the procedure was performed through a single transverse penoscrotal incision in the remaining

patients, with the cuff placed around the bulbar urethra in each patient. All of the patients underwent a cystoscopy immediately before the procedure, and the implantation was performed at least 1 month after treatment in patients with urethral or bladder neck stricture. All of the patients had the urethral catheters removed at 24 h after the operation, and they were discharged after being instructed to begin operating the device 6 weeks later.

Statistical analysis: The data obtained were analyzed with the patients divided into 3 groups: Group 1, patients reoperated on for implant-tissue interaction (such as fistula or erosion); Group 2, patients who had no complaints and were not reoperated on; and Group 3, patients reoperated on for mechanical failure (Table 1). Statistical analyses were performed using univariate analysis, Student's t-test, Pearson's chi-square test, logistic regression, Kaplan-Meier analysis, and SPSS 15. $P < 0.05$ was considered statistically significant.

Results

We found that 20 (31.2 %) of the 64 patients undergoing AUS implantation for PPI, whose data were available and who responded positively to the examination invitation, were reoperated on. The mean follow-up period was 62 (range: 1-120) months, whereas the interval between implantation and reoperation was 10 (range: 0-25) months. The mean complication-free time was found to be approximately 62 months. Table 2 summarizes the characteristics of the patients.

Table 2. The characteristics of the patients.

Characteristics	No.
Number of patients	64
Mean age (years)	62 (53-74)
BMI 24.5 (21-30)	
Comorbid diseases	
DM	13
COLD*	10
Hypertension	13
Neurologic diseases	3
Types of prostate surgery	
TUR	3
SPTVP	5
RP	56
Number of patients receiving adjuvant therapy	
Radiotherapy	13
Hormonotherapy	2
Urodynamic findings before AUS implantation (mean)	
Q max (mL/m)	11 (5-19)
Max. capacity (cc)	274 (185-326)
Max. DP** (cmH_2O)	23 (11-42)
Compliance (mL/cmH_2O)	9.2 (3-17)
Pad test (g/24 h)	686 (420-1280)
Number of patients reoperated on	20 (31.2%)

*Chronic obstructive lung disease
**Detrusor pressure

Group 1: 11 patients reoperated on for implant-tissue interaction

All of the 11 patients in this group had urethral erosion, whereas 1 patient also had accompanying pump erosion through the skin. All of these patients had been admitted with complaints of scrotal swelling and inability to void. Erosion after implantation was found to occur frequently in

Table 1. Patient groups and study design.

Group 1: Patients reoperated on for implant-tissue interaction (urethral erosion, skin erosion, etc.) after AUS implantation.
Group 2: Patients who had no complaints or mechanical failures of the device and who were not reoperated on after AUS implantation.
Group 3: Patients reoperated on for mechanical failure of the device or a decrease in cuff pressure due to urethral atrophy after AUS implantation.

the early postoperative period, at an average of 2 months (range: 0-24). A univariate analysis revealed that, among the parameters that are likely to cause urethral cuff erosion, undergoing RP (P < 0.0001), a history of adjuvant radiotherapy (P < 0.0001), and accompanying diabetes mellitus (DM) (P = 0.02) caused erosion. The comparative analyses showed an inverse correlation between the increased number of patients and rates of erosion for the surgeon who performed 47 implantations and the surgeon who performed 17 implantations (P < 0.0001) (Table 3).

The comparison of patients with and without erosion revealed that RP (P = 0.05), a decrease in pad weight (P = 0.04), increased body mass index (BMI) (P = 0.04), DM, preoperative low urinary flow rates (P = 0.03), history of stricture (P = 0.04), and stricture-free time (P < 0.0001) also affected the risk of erosion (Table 4).

Similarly, for multivariate analysis, DM (P < 0.001), urethral stricture (P < 0.001), and a history of radiotherapy predicted urethral erosion. With Kaplan-Meier analysis, it was interesting to see that patients

Table 3. Comparison of the results of 2 different surgeons.

	Surgeon 1	P	Surgeon 2
Number of patients	47		17
Age (mean)	61.7	0.62	64.6
DM (%)	9 (19.2)	0.17	4 (23.5)
Pad test (g)*	827	0.04	580
History of urethral stricture (%)	27 (57.4)	0.91	10 (58.8)
Number of patients reoperated on* (%)	13 (27.7)	<0.0001	7 (41.1)
Urethral erosion* (%)	6 (12.8)	<0.0001	5 (29.4)
Urethral atrophy* (%)	5 (10.6)	<0.0001	1 (5.9)
Cuff replacement (%)	2 (4.25)	0.42	1 (5.88)

*Parameters showing statistical significance

Table 4. The association of study groups with the parameters investigated*.

	Group 1	P	Group 2	P	Group 3
Number (%)	11 (17.2)		44 (68.7)		9 (14.1)
Age (mean)	59.8	0.82	63.2	0.75	63.4
BMI	28.2	0.04**	23.7	0.45	24.3
DM (%)	8 (72.7)	<0.0001**	4 (9.1)	0.27	1 (11.1)
Prostatectomy indication					
BPH (%)	1 (9.1)	0.06	6 (13.6)	0.91	1 (11.1)
Carcinoma (%)	10 (90.9)	0.05**	38 (86.4)	0.07	8(88.9)
Adjuvant radiotherapy (%)	10 (90.9)	<0.0001**	2 (4.54)	0.09	1 (11.1)
Pad test (g/24 h)	650	0.04**	980	0.56	820
Urodynamic data (mean)					
Q max (mL/m)	6.8	0.03**	13.2	0.34	11.4
Max. capacity (cc)	284.6	0.68	270.5	0.74	292
Max. DP*** (cmH_2O)	18.3	0.19	17.2	0.38	17.9
Compliance (mL/cmH_2O)	6.4	0.07	10.5	0.85	19.2
History of stricture	6 (54.6)	0.04**	26 (59.1)	0.06	5 (55.7)
Stricture-free time (weeks)	6.3	<0.0001**	27.4	0.07	13.1

*Pearson's chi-square test and Student's t-test were used.
**Parameters showing statistical significance.
***Detrusor pressure

with a history of urethral stricture who underwent implantation, had the highest rate of erosion in the postoperative early period on approximately day 15, which decreased rapidly after 5 months. The risk of urethral erosion continued at a decreasing rate until 25 months in patients with a history of diabetes and radiotherapy (Figure). All of the implants of the 11 patients who had urethral erosion were removed. The patients with urethral catheters were followed up for 20 days and, subsequently, their catheters were removed after the absence of extravasation was confirmed by urethrography. Implantation was performed through a perineal approach using the 2-incision technique, enabling the surgeon to reach more posterior regions, in 3 patients (both had been operated on using a single penoscrotal incision) who accepted to undergo reoperation at least 1 year later; no complications were noted. The remaining 8 patients refused a reoperation. No significant results were found between the type of incision and urethral erosion.

Group 2: 44 patients who required no reoperation after implantation

Analysis of the 44 patients in this group revealed that 38 (86.4%) patients were completely dry, whereas 6 patients (13.6%) presented minimal stress urinary incontinence using 1 pad daily at most. We learned that 1 patient was unable to use his hand due to cerebrovascular problems after implantation and the pump was activated by his relative, whereas no other problems were noted or reported.

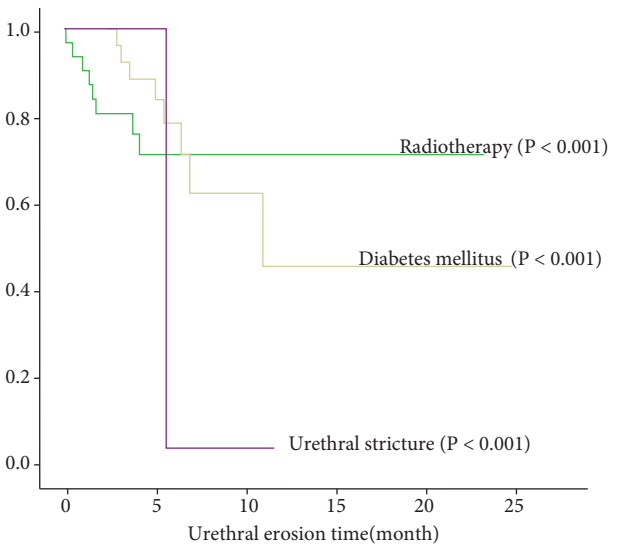

Figure. The relationship between predictive values and urethral erosion time by Kaplan-Meier analysis.

Group 3: 9 patients reoperated on for mechanical failure of the implant or decrease in cuff pressure after implantation

Of the 9 patients in this group, 3 had the cuff replaced due to mechanical problems. In 1 patient, a suprapubic catheter was placed because of the failure of the cuff to inflate 6 months after the procedure and, subsequently, the cuff was examined and replaced. The implant could not be activated after the procedure in the other 2 patients, and the 2 cuffs that failed to inflate were replaced. No further complications were noted in these 3 patients. At an average of 9 (range: 4-26) months after the operation, 6 patients had severe incontinence due to a pressure decrease in the cuff. Urethroscopy revealed that the cuff, though inflated, failed to obstruct the urethra completely, which was considered to be secondary to urethral atrophy, and saline was added to the reservoir, thus solving the problem. In the analyses performed, no findings predisposing to urethral atrophy were found (Table 4).

Discussion

AUS implantation remains the gold standard for the treatment of severe urinary incontinence after prostatectomy (6). This study has demonstrated that approximately one-third of the patients undergoing AUS implantation will require reoperation within 5 years. The most difficult complication to treat after implantation is undoubtedly urethral erosion (7). Patients in this study with increased BMI had significantly higher rates of urethral erosion. Given that obesity and microangiopathy are closely related, impaired urethral support is highly likely to cause a severe problem, such as erosion, in the postoperative period. Similarly, Raj et al. reported a significantly increased risk for urethral erosion due to microangiopathy in the whole body in patients with coronary artery disease (7). Additionally, given that wound healing is poor and the procedure is technically more difficult to perform in obese patients, higher rates of urethral erosion in patients with an increased BMI is not a coincidence. A similar

situation was found for DM. It is well known that DM is particularly associated with occlusion of small vessels and predisposes to infection due to neutrophil dysfunction (8,9). In this study, 73% of the patients with urethral erosion had DM, which is consistent with this finding.

Studies have reported a higher risk for incontinence after RP compared to surgeries performed for BPH, the cause of which is thought to be direct sphincter damage or parasympathetic or somatic nerve damage during RP (7,10). A higher rate of urethral erosion in these patients was considered to be caused by a problem in urethral support due to neurovascular bundle damage and dissection during RP.

The relationship between adjuvant radiotherapy and urethral cuff erosion has been addressed in different ways in the literature. Radiotherapy is known to induce small vessel occlusion, local tissue hypovascularity and fibrosis, poor wound healing, and impaired immunity against infection (11). A study by Walsh et al. reported that patients receiving adjuvant radiotherapy had a significantly higher risk of urethral erosion compared to other patients, which is consistent with our results (12). The studies by Lai et al., Elliot and Barrett, and Manunta et al. also yielded similar results (13-15). However, some authors, such as Martins and Boyd and Perez and Webster, advocate that implantation of an AUS should be attempted in patients with postprostatectomy incontinence who received adjuvant radiotherapy (16,17).

The other 3 parameters that were found to be significantly associated with the risk of urethral erosion were evaluated together since they were considered to be correlated with each other. These parameters were the pad test ($P = 0.04$), maximum flow rate ($P = 0.03$), and history of stricture ($P = 0.02$). Severe incontinence is defined as urinary leakage of greater than 400 g in the 24-h pad test. A significantly lower rate of urinary leakage (650 g vs. 980 g) per day and urinary flow rates (6.8 vs. 13.2) in the group with urethral erosion were considered to be caused by intravesical obstruction. Thus, the group with a history of stricture had a significantly higher rate of erosion. Based on the literature data, the AUS should be implanted after ensuring the absence of recurrence for at least 3 months after the latest surgical treatment of strictures of the urethra or bladder neck (endoscopic incision or resection) (7,12,18). It was also found that the stricture-free time was significantly shorter (an average of 6 weeks after the final treatment) in patients with urethral erosion.

Another issue that was investigated here but not found in the literature was the effect of surgical experience on the outcome of patients with AUS implantation. It is beyond doubt that surgical experience increases in parallel with the increasing number of patients operated on (19). There were no significant differences in patient profiles between the 2 surgeons, whereas the results obtained by the second surgeon, who operated on 3 times fewer patients than the other surgeon, were found to be significantly complicated, which suggests that AUS implantation is not as easy of an operation as it may appear and surgical experience is of great importance in performing this procedure, as in other surgeries.

In comparison with the current literature, the limitations of this study were: 1) the number of the patients was small, 2) the study was of a retrospective design, and 3) the number of patients operated on by one of the surgeons was much smaller than that by the other surgeon. It is believed, however, that this study will contribute to the literature by investigating patients from a different geographic location (different patient awareness and perceptions) and by encouraging urologists who consider performing this surgery.

Given increasing patient awareness and medicolegal claims around the world today, patients should be informed preoperatively about the possible outcomes of an operation. Of patients who will undergo AUS implantation, those with RP, obesity, diabetes, a history of adjuvant radiotherapy, and a history of recurrent strictures of the bladder neck and urethra should particularly be informed preoperatively and be reminded that, even in the absence of problems, mechanical failure of the device can occur, resulting in a need for further operation. In addition, the urologist should perform the procedure with the assistance of a surgical team until he gains enough experience and should determine the timing of implantation, taking into consideration the stricture-free time.

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