Özgün araştırma / Original research

Artifisyel üriner sfinkter implantasyonunun başarı ve komplikasyonunu etkileyen faktörler ve uzun dönem sonuçlarımız (25 yıllık deneyim)

Factors affecting the success and complications of artificial urinary sphincter implantation and our long-term outcomes (25 years of experience)

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Özet

Amaç: Artifisyel Üriner Sfinkter (AUS) implantasyonu uyguladığımız olgularda yöntemin başarı ve komplikasyon oranlarını ve bunu etkileyen faktörler ile uzun dönem sonuçlarımızı sunmayı amaçladık.

Gereç ve Yöntemler:1990 ile 2015 yılları arasında Ankara Dışkapı Eğitim ve Araştırma Hastanesi Üroloji kliniğinde toplam 97AUS implantasyonu uyguladığımız 82 hastanın verileri retrospektif olarak incelendi. 11 hastaya 2 kez ve 2 hastaya 3 kez olmak üzere toplam 13 hastaya rekürren AUS implantasyonu uygulandı. Hastaların inkontinans derecesi International Consultation on Incontinence Questionnaire-Short form (ICIQ-UI SF)'a göre miktarı ise pad testi yapılarak, yaşam kaliteleri ise ICIQ-UI SF' daki 5. soru ile ayrıca değerlendirilip kaydedildi. Hastalarımızın yaş ortalaması 66.2 (15-79) yıl iken ortalama takip süresi 76 (6-300) ay idi. Bir kez ve rekürren AUS implantasyonu şeklinde 2 grup oluşturularak sonuçları karşılaştırıldı.

Bulgular: AUS uyguladığımız hastalarımızdan 57'sinde (%69.5) tam kuruluk, 15'inde (%18.2) sosyal kontinans ve 10 (%12.1) tanesinde ise inkontinans oranları saptanmıştır. Rekürren AUS uyguladığımız 13 hastamızın 5'inde (%38.4) tam kuruluk, 5'inde (%38.4) sosyal kontinans, 3'ünde (%23.07) ise kontinansa ulaşılamamıştır. Semptom skorları, inkontinans miktarları ve

Abstract

Objective: In this study we investigated the factors affecting both our success and complication rates in patients undergone artificial urinary sphincter (AUS) implantation and our long-term results.

Material and Methods: Data from 82 patients which were performed a total of 97 AUS implantation (including 13 recurrent patients; 2 were performed 3 times and 11 were performed 2 times) in Urology Clinic of Ankara Dıskapı Training and Research Hospital between the years 1990 and 2015 were analyzed retrospectively. Degree and amount of incontinence and quality of life were evaluated by International Consultation on Incontinence Questionnaire-Short Form (ICIQ-UI SF), pad test and the 5th question in ICIQ-UI SF, respectively. Mean age of our patients were 66.2 (15-79) years while mean follow-up period was 76 (6-300) months. Two groups were composed as AUS implantation one time and recurrent times and the results were compared.

Results: Of our AUS implantated patients, we noticed complete dryness in 57 (69.5%), social continence in 15(18.2%) and incontinence in 10 (12.1%). Of the 13 recurrent patients, we noticed complete dryness in 5 (38.4%), social continence in 5 (38.4%) an incontinence in 3 (23.07%). When compared;

yaşam kaliteleri karşılaştırıldığında 1 kez AUS uygulanan grupta rekürren uygulanan gruba göre sonuçlar daha iyi gözükse de istatistiksel olarak anlamlı bulunmamıştır. 12 hastada enfeksiyon ve/veya cuf erozyonu, 5 hastada ise mekanik arıza olmak üzere %20.7 oranında komplikasyon saptanmıştır.

Sonuç: AUS, inkontinans tedavisinde uygun hastalarda en etkin yöntemdir. Maliyet analizi, revizyon ve reimplantasyon imkanları göz önünde bulundurulduğunda güvenli ve ekonomik olması yönüyle de tercih sebebi olabileceğini düşünmekteyiz.

Anahtar Kelimeler: Üretra, prostatektomi, Artifisyel Üriner Sfinkter

symptom score, amount of incontinence and quality of life score results seemed to be better in the 1 time AUS performed group than the recurrent group, but it was not statistically significant. Complication rate was 20.7% including infection and/or cuff erosion in 12 patients and mechanical failure in 5 patients.

Conclusion: AUS is the most effective treatment method of incontinence in appropriate patients. We believe that it may be preferable by considering cost analysis and revision and re-implantation facilities in terms of being a safe and economical procedure.

Keywords: Urethra, Prostatectomy, Urinary Sphincter, Artificial

INTRODUCTION

Regardless of the cause, incontinence still remains to be a major health problem today in terms of raising both economical costs, nuisance and embarrassment. Previously, congenital and neurological diseases, trauma and prostate surgery were the most common causes for male incontinence while in recent years, it is not a surprise that the most common group is post-radical prostatectomy incontinence in parallel with the development in prostate cancer diagnosis and treatment. So that; in 2013, detection of 238,590 new cases of prostate cancer was estimated and about 40% of localized prostate cancer cases were expected to be performed radical prostatectomy (1, 2). Parallel to these developments, despite the surgical modalities such as synthetic tapes, urethral injections and sling, artificial urinary sphincter (AUS) took its place as the gold standard in treatment of post-radical prostatectomy incontinence (3). In this study, we aimed to present the factors affecting the success and complication rates and long-term outcomes of our 82 AUS-implantated patients.

MATERIAL AND METHODS

This study included the patients had at least one year total incontinence because of various ethiological reasons and applied AUS implantation. All the surgical procedures applied by same surgeon. Data from 82 patients which were performed a total of 97 AUS implantation (including 13 recurrent patients; 2 were performed 3 times and 11 were performed 2 times) in Urology Clinic of Ankara Diskapı Training and Research Hospital between the years 1990 and 2015 were analyzed retrospectively. All patients were signed approval form about the procedure and were performed preoperative blood tests, urine analysis, ultrasonography, cystoscopy and urodynamics. Before the surgery none of the patients had history of radiotherapy. All of the patients had a bladder capacity at least 150 cc or over. Urodynamic studies of the patients reported that none of the patients had detrusor over activity or instability. Urine analysis were sterile for all patients. 23 of patients had no comorbid diseases; 5 had all diabetes mellitus, hypertension and coronary artery disease; 33 had only one comorbid disease and 21 had two comorbid disease. Ten of the patients underwent urinary incontinence surgery because of nonurologic diseases (lumbar fracture, trauma or spinal tumor etc.) and epispadias or bladder surgery; 45 had urinary incontinence surgery because of radical prostatectomy (open, laparoscopic or robotic); 19 because of open prostatectomy; 8 because of transurethral resection of prostate. Eight of the patients underwent radical prostatectomy had applied two AUS procedures and 1 had applied 3 procedures. Also 3 of the patients underwent TUR-P applied 2 AUS procedures and one had applied 3 times. Degree and amount of incontinence and quality of life were evaluated by International Consultation on Incontinence Questionnaire-Short Form (ICIQ-UI SF), pad test and the 5th question in ICIQ-UI SF, respectively. If needed, intravenous urography and retrograde urethrographies were performed. Inclusion criteria for AUS implantation were adequate bladder function, absence of detrusor instability, at least 1 year of postprostatectomy incontinence, at least 6 months out of previous AUS removal, unfavorable effects of incontinence on daily life and quality of life and the absence of mental and physical conditions as the obstacles to the use of sphincter. Patients with resistant urethral stricture and/or bladder neck contracture were excluded from the study.

Appropriate prophylactic antibiotic treatment were started 24 hours before the procedure. Surgical procedure

Table-1: AUS etiology

Etiology	Patients 82	One Procedure	Two Procedures	Three Procedures
Radical Prostatectomy (Robotic)	4 (4.8%)	2	2	-
Radical Prostatectomy (Laparoscopic)	15 (18.2%)	11	3	1
Radical Prostatectomy (Open)	26 (31.7%)	23	3	-
Prostatectomy (Open)	19 (23.1%)	19	-	-
Prostatectomy (TUR)	8 (9.7%)	4	3	1
Epispadias	1 (1.2%)	1	-	-
Bladder extrophy	1 (1.2%)	1	-	-
Non-urological conditions (spinal tumor,myelomeningocele, lumbar fracture, trauma)	8 (9.7%)	8	-	-

was performed under general anesthesia. AUS implantation was performed in lithotomy positions and penoscrotal incision. The device AMS 800 sphincter (American Medical Systems, Inc., Minnetonka, MN, USA) was used for all patients. The appropriate size cuff of AUS was placed to the bulbar urethra after measuring the urethral circumference (3,5cm-4,5cm) the reservoir was placed to the space of Retzius with the pressure of 60-70 cmH20 and the pump of the device was placed to the scrotum to the side of the patient's dominant hand. Urethral catheters of all patients were withdrawn after 24 hours postoperatively and follow-up was perfomed by cold scrotal elevation. Patients were discharged at the average of 6th (4-8) day with deactivated AUS and pad use advice. All patients were recalled after 6 weeks for AUS activation and were checked at the first, third, sixth months and the first year after activation. Data such as degree of postoperative incontinence, pad requirement and quality of life scores were recorded. Full dryness or wetting less than 1 pad per day with valsalva was accepted as successful while wettingless than 1 pad per day was accepted as associal continence and wetting more than 1 pad per day was accepted as incontinence. Two groups were composed as AUS implantation one time and recurrent times and the results were compared.

Statistical Analysis

Data analysis was performed by "SPSS for Windows 16" package programme. Descriptive statistics were shown as mean ± standard deviation for variables with normal distribution, as median (min - max) for variables with abnormal distribution and nominal variables were shown as the number of cases and (%). The significance of the difference between the groups in terms of means and median values were determined by t-test and Mann Whitney test, respectively. P value of <0.05 was considered statistically significant.

RESULTS

Mean age of the patients was 66,2 (15-79). Eighty seven percent of the procedures underwent because of the prostate surgery. All of the patients were male. Mean follow-up period was 76 months (6-300 months). Among the etiologic factors of AUS implantation, the most common one was post-radical prostatectomy incontinence and the others are also shown in Table-1.

Efficiency

Of the once AUS-applied 69 patients, 52 (75.3%) achieved complete dryness and 10 (14.4%) achieved social continence. Of the remaining 7 patients (10.1%), cuff erosion was detected in 4 and extraction and elective reimplantation was performed. In the other 3 patients who declared that they had 2 pads of wetting per day and had no discomfort, incontinence was thought to be due to urethral atrophy. They did not accept to undergo revision procedure and were included into follow-up program .

In 5 of the 11 patients who had requirement of reimplantation and an average of 12 (7-23) years after the first implantation, we detected urethral cuff discharge, empty reservoir and insufficient tightening of the urethra and it

Table-2: Comparison of preoperative and postoperative parameters

Parameters	Preoperative	AUS (1 time)	AUS (2 times)	AUS (3 times)	P (between one and repeated AUS implantation performed groups)
Dryness		52 (%75,3)	5 (%45.4)		
Social continence		10 (%14.4)	4(%36.3)	1(%50)	
Incontinence		7 (%10.1)	2 (%18.8)	1(%50)	
Mean amount of pads (daily)	6.25 ± 1.2	1.5 ± 1.8	1.8 ± 1,6	3	0,0781
Mean Symptom Score (ICIQ-UI SF)	16.5 ± 1.18	5.06 ± 6.2	5.5 ± 5.4	4.5 ± 5.2	0,0673
Quality of life (ICIQ-UI SF 5thquestion)	6.38 ± 3.4	2.69 ± 2.9	3 ± 4.1	4.4 ± 3.1	0,0549

was considered that the device completed its life without another traumatic cause or irrevelant to comorbidities ; so the existing AUS devices were removed and revision or reimplantation was performed simultaneously. Finally, 3 had full dryness while 2 had social continence. Of the remaining 6 patients, requirement of AUS reimplantation was due to inserted urethral catheter for reasons such as non-urological surgery or angiography in 4 and primary cuff erosion and/or infection in 2, and reimplantation was administered to them after 6 months. Finally, 2 had continence, 2 had social continence but 2 had incontinence. As a conclusion, 5 patients (45.4%) in this group had complete dryness while 4 (36.3%) had social continence and 2 patients (18.18%) could not achieve continence.

Of the 2 patients who was performed third-time AUS implantation, the reasons for AUS reimplantation 6 months after AUS extraction were infection occured via the erosion of the scrotum by pump in one patient and elongated wetting in the incision site due to infection caused by cuff erosion in the other. Finally, one had social incontinence but the other one did not achieve continence.

As a result, we achieved complete dryness in 57 patients (69.5%), social continence in 15 patients (18.2%) and incontinence in 10 patients (12.1%). Dryness rates were 52 (75,3%), for AUS implantation patients and 5 (45,4%) for AUS reimplantation patients. Social continance rates for AUS implantation, AUS reimplantation and second time AUS reimplantation were 10 (14,4%) , 4 (36,3%), 1 (50%) and incontinance rates were 7 (10,1%), 2 (18,8%) and 1 (50%) respectively. Mean daily pad numbers for preoperatively, AUS implantation, AUS reimplantation and second time AUS reimplantation were 6.25 ± 1.2, 1.5 ± 1.8, 1.8 ± 1.6 and 3 respectively. Preoperative symptom score (ICIQ-UI SF) for preoperatively was 16.5 ± 1.18, 5.06 ± 6.2 for AUS implantation, 5.5 ± 5.4 for AUS reimplantation and 4.5 ± 5.2 for second time AUS reimplantation. Quality of life (ICIQ-UI SF 5th question for preoperatively, AUS implantation, AUS reimplantation and second time AUS reimplantation were 6.38 ± 3.4, 2.69 ± 2.9, 3 ± 4.1 and 4.4 ± 3.1 respectively. When compared; symptom score, amount of incontinence and quality of life score results seemed to be better in the 1 time AUS performed group than the recurrent group, but it was not statistically significant. Preoperative and postoperative quality of life scores, amount of incontinence and symptom scores of all patients are shown in Table-2.

Cuff Erosion and Infection

The most common reason for recurrent AUS implantation was detected to be cuff erosion. In our patient group, although cuff erosion due to urethral atrophy was more prevalent, cases of cuff erosion due urethral catheter insertion for various reasons in non-urology clinics were also present. Therefore, AUS-implantated patients should be alerted about further possible urethral interventions. Our patients who noticed that they had a problem related to device admitted to our clinic in the earlier period, therefore we were able to remove the device with a slight infection or without infection. On the other hand; in later periods, treatment has elongated because of scrotal abscess and/or prolonged discharge.

Mechanical Failure

One patient has admitted to our clinic 23 years after AUS reimplantation with the complaint of incontinence and the reservoir was detected empty. In our other cases, the reasons were reservoir discharge because of a hole, decreasing pressure of the cuff on urethra and leaks in the transfer pipes.

Table-3: AUS complication rates and etiology

Parameters	
Primary Cuff erosion	5 (% 6.09)
Cuff erosion via urethral intervention	4 (% 4.87)
Cuff erosion + infection	3 (% 3.6)
Mechanical Problems	5 (% 6.09)

We detected complications in 17 of 82 patients (20.7%), including infection and/or cuff erosion in 12 and mechanical failure in 5. (Table 3)

DISCUSSION

In several studies, the incidence of persistent incontinence after prostatectomy was determined at rates ranging from 1% to 40% (4-6). In NEJM study, 557 patients were followed after radical prostatectomy for 12 months. It was detected that 24% of the cases used pads and 8% defined the problem as moderate or severe (7). After 2 months of follow-up, prevalance of incontinence in another study was found to be 0.5% in 3885 patients who were performed transurethral resection of the prostate (8). Today, incontinence still remains to be a problem despite all the development in prostatic surgery. Given the efficacy and safety in appropriate cases and indication, AUS remains to be gold standard in incontinence (3, 9, 10).

Because there is no standard and objective criteria to assess the success and effectiveness of AUS, we may encounter a wide variety of rates in the literature. After a mean of 6.8 years of follow-up, S.P.Kim et al. reported complete dryness in 27% and social continence in 52% of 124 patients who were performed AUS implantation (11). In another study of 435 cases, G.V.Raj et al. reported success rates as 90% after the first implantation and 82% after recurrent implantation in 119 patients (12). In our study, we determined complete dryness in 52 patients (75.3%), social continence in 10 patients (14.4%) and incontinence in 7 patients (10.1%) after first implantation. On the other hand, we determined complete dryness in 5 (38.4%), social continence in 6 (46.1%) 5 (38.4%) patients and incontinence in 2 (15%) 3 (23.07%) of the 13 patients that we applied recurrent AUS implantations. As a result we achieved success rates similarly to the literature for first time AUS implantation and recurrent implantations 89% and 76% respectively.

The main critical process of AUS implantation starts after surgery because the reasons for AUS failure frequently seem to be as infection, paying poor attention to the perineal protection, excessive dissection of urethra and/or urethral atrophy, endoscopic procedures performed without AUS deactivation and cuff erosion caused by urethral catheterization for non-urological conditions. Besides, infections, patient adaptation to the equipment and mechanical failure are also important factors to achieve success.

AUS revision and reimplantation rates also show variations in the literature. Clemens et al. reported that 36% of 66 cases required revision after AUS during an average follow-up period of 41 months (13). In the study of Hajivassiliou, revision rate in the first 3 years was found as 30.5% and the reasons were determined as cuff erosion (12%), infections (4%) and mechanical problems (14%) (14). There are also some contradictious studies about the erosion and revision rates of AUS performed after radiotherapy. In the studies of Kim SP et al. and Gho ME et al., it was reported that radiotherapy was not associated with an increased risk of AUS complications while Walsh IK. et al. claimed an increase in AUS revision and complication rates (11, 15, 16). In our study, there was no post-radiotherapy case. A total of 13 patients (%15.8) required recurrent AUS implantation because of mechanical failure in 5 (6.09%) and infections and/or cuff erosion in 8 (9.7%) after an average of 76 months follow-up. Five patients with cuff erosion as a result of urethral instrumentation were performed reimplantation after an average follow-up of 47 months while the patients with cuff erosion due to urethral atrophy or infections were performed AUS extraction within the first 8 months. Therefore, we think that development time of cuff erosion may indicate the reason. In this regard, Mary HJ and Kurt PM pointed out that erosion occurring in the first weeks or months after AUS implantation may arise from unnoticed urethral injury occurred during the placement of the cuff while later erosions may arise from long-term catheterization secondary to non-uniform deactivation (17).

There is no standardization at the point of patient satisfaction. In a study of 50 cases with the average of 23.4 months follow-up, 90% of the patients were satisfied, 96% stated that he could recommend AUS implantation to his acquaintances and 92% may accept AUS reimplantation (18). In another study involving 113 patients with the average of 73 months follow-up, 28% declared that they were very satisfied while 45% were satisfied, 18% were neutral,

6% were not satisfied and 4% were very uncomfortable (19). In our study, 72 patients (87.8%) who achieved full dryness and social continence declared that they were satisfied while 8 were not very satisfied (but they felt better than the preoperative period) and 2 were not satisfied.

We also want to mention that daily diaper costs of a patient with total incontinence is $5-10, AUS with the cost of $4,270 is equivalent to the diaper cost of 1.1-2.3 years and when compared with our results of 76 months, cost of diaper use is $11,400-22,800 in the same time period.

CONCLUSION

AUS remains to be the gold standard in the treatment of incontinence. We believe that it can be performed safely in appropriate cases because of solvable complications, providing revision or reimplantation, costs and patient satisfaction rates.

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