LONG-TERM RESULTS OF ARTIFICIAL URINARY SPHINCTER IMPLANTATION FOR THE TREATMENT OF URINARY INCONTINENCE

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SUMMARY
Aim: In this article, we aimed to report long-term results of the cases, which are treated with Artificial Urinary Sphincter.

Introduction: Many successful results have been obtained, following the utilization of AMS 800 Artificial Urinary Sphincter (AUS) implantation for the treatment of urinary incontinence due to pure sphincteric insufficiency.

Materials and Methods: We implanted AMS 800 (American Medical Systems, Minnetonka, MN, USA) to 20 male patients with pure sphincteric insufficiency. The device was placed to the bladder neck in one case and bulbar urethra in the others. The age range of our patients was between 15-74 (mean age 59) and average follow-up was 46 months (8-132 months).

Results: In 16 patients, incontinence was totally treated. Two patients required one pad daily or less, and two patients required more than one pad daily. Two patients were reoperated due to infection, two patients for erosion, another one for mechanical problems. Total success rate was 80%, reoperation rate was found to be 25%.

Conclusion: Implantation of AMS 800 Artificial Urinary Sphincter is the most effective treatment modality for the treatment of urinary incontinence due to pure sphincteric insufficiency. The success rate of the technique will increase with appropriate patient selection and surgical experience and the complication rate will decrease.

Key Words: Artificial Urinary Sphincter, Incontinence.

ÖZET
Uriner İnkontinansin Tedavisinde Artıfisyal Uriner Sfinkter Implantasyonu Uzun Dönem Sonuçları

Amaç: Bu makalede Artıfisyal Uriner Sfinkter implantasyonu ile tedavi edilen vakaların uzun dönem sonuçlarını bildiriyorum.

Giriş: Pür sfinkter yetmezliğine bağlı idrar inkontinansı tedavisi için kullanılan AMS 800 Artıfisyal uriner sfinkter (AUS) implantasyonu ile pek çok başarılı sonuçlar elde edilmişdir.


Bulgular: 16 hasta inkontinans tanımメディア tedavi edildi. 2 hastada günde 1 veya daha az ped ihtiyacı, 2 hastada ise günde 1'den fazla ped ihtiyacı vardı. 2 hasta enfeksiyon, 2 hasta erozyon, 1 hasta da mekanik problemler nedeniyle reopere edildiler. Total başarı %80, reoperasyon oranı %25 olarak bulundu.

Sonuç: AUS implantasyonu pür sfinkterik yetmezliğe bağlı idrar inkontinansı tedavisinde en etkili tedavi yöntemdir. Uygun hasta seçimi ve cerrahi deneyimin artması ile tekniğin başarı oranı artacaktır ve komplikasyon oranı azalacaktır.

Anahtar Kelimeler: Artıfisyal Uriner Sfinkter, Inkontinans
of artificial sphincters. It is well known that AUS treatment can be very successful for correct indications.

In this article we report the long term results of 20 patients, which were treated with AUS between 1993-2003 in our department.

Patients and Methods

Between 1993-2003, AMS 800, Artificial Urinary Sphincter was implanted to 20 incontinence cases with sphincteric insufficiency.

In the preoperative period, the patients were evaluated with routine blood tests, urinalysis, intravenous urography, retrograde urography, and cystoscopy and urodynamic tests. The criteria utilized for AUS implantation were the presence of sufficient bladder function, the absence of detrusor instability and the absence of previous surgical treatment for incontinence and urethral stricture.

Three patients had sphincteric urethral strictures; the stricture was treated with permanent urethral wall stent implantation in two cases and with internal urethrotomy in the other. The device was applied to the bladder neck in one patient with vesical extrophy and to bulbar urethra in all the others.

The patients did not have any intraurethral interventions during one week prior to surgery. Prophylactic antibiotics were initiated 24 hours before the surgery and were continued for one week. All the patients were catheterized during the first 24 hours; scrotal ice application was used for preventing edema in the early postoperative period. Pad utilization was recommended during the first six weeks following the operation until the activation of the device.

Following the activation of the implant, the patients were called for follow-up at one-month, three-months, six-months and one-year. During the follow-up; urinary continence and pad requirement were questioned in the patients. The number of pads that the patients needed to change at the end of the daily activities were calculated.

Results

The duration of follow-up was between 8-132 months (average 46 months). Average patient age was 59 (15-74) years. The etiology of the 20 cases treated with AUS is outlined in Table-1. In the follow-up period, the patients were questioned for incontinence and pad requirements. 16 patients out of 20 reported total dryness (%80) with only few drops of urinary incontinence due to stress and added that they were not disturbed by this event. Two patients told that they needed less than one pad per day (%10) and two patients needed more than one pad per day (%10). Pad use decrased from a mean of 3.5 to 0.5 units daily. (p<0.001) (Table 2).

AUS was retrieved from two patient due to infection and these patients were reoperated 6 months later and AUS was reimplanted. In one patient only the cuff was chanced because of erosion. In one patient the pump came out from the scrotum due to erosion; after the administration of proper antibiotics, the pump was replaced to the other scrotum and no further complications developed. In one patient, the device could not be activated, we believed that this was due to needle stick during surgery and changed the device. Causes of complication and revision types are outlined in Table 3.

<table>
<thead>
<tr>
<th>Table 1: The etiologies of incontinence.</th>
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<tr>
<td><strong>Etiology</strong></td>
</tr>
<tr>
<td>Open Prostatectomy</td>
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<tr>
<td>TUR Prostatectomy</td>
</tr>
<tr>
<td>Radical Prostatectomy</td>
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<tr>
<td>Epispadias</td>
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<td>Extrophia vesicale</td>
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<tr>
<th>Table 2: The success rate of AUS implantation</th>
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<tbody>
<tr>
<td><strong>Continence grades</strong></td>
</tr>
<tr>
<td>Totally dry</td>
</tr>
<tr>
<td>Minimally continance</td>
</tr>
<tr>
<td>Incontinence</td>
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</table>
Two patients out of three with urethral strictures had undergone wall stent implantation and during the follow-up, the strictures have disappeared and the AUS was placed to the distal part of the stent. Third patient had undergone AUS implantation after internal urethrotomy approach.

There was no relation between the etiologies of incontinence and success of AUS implantation (p>0.5).

**Discussion**

In incontinent patients with intact bladder and urethral functioning, many different surgical techniques have been developed to protect bladder capacity and compliance while providing continence. In cases of incontinence due to sphincteric insufficiency who are resistant to medical treatment, open surgical procedures described by Tanagho and Smith or Young-Dees Leedbetter are applied. The success rate for such interventions is around 50% and strictures develop at a very high rate at the anastomosis line (4,5).

In 1976, Rosen for the first time developed a prosthesis that was placed to bulbar urethra with a pump in the scrotum; on the other hand, Scott utilized AMS 800 model artificial sphincter in 1983 firstly (6).

In patients with AUS implants, the most important problems are infection around the prosthesis, cuff erosion and mechanical insufficiency of the device. In order to prevent infection and erosion, providing proper dissection, sufficient hemostasis, appropriate cuff selection and having the device inactive for 6 weeks are very crucial.

After conducting a metaanalysis, Hajivassiliou reported the revision rate as 30.5%; which was due to cuff erosion in 12%, infection in 4.5% and mechanical problems in 14% of the cases. Overall success rate was reported as 88% and continence rate was 73% (7). According to this study 50% of the reoperations were performed in the first 8 months and 90% in the first three years. After a follow-up of 10 years, Venn felt to retrieved the prosthesis in 37% of the cases, 56% of these were females and 23% males (8). The complication rates increased up to 25% and infection rates to 12% in cases who have received previous radiotherapy and who have been operated from the same region (9). The device has to be connected very carefully and special attention should be taken not to perforate it with the needle. Monteque et al reported a mechanical insufficiency rate of 8% in their own series (10). In our series, infection and erosion rate was 20% and mechanical complication rate was 5%. Most of the complications during the first years of our surgical experience, and we observed a decline in the complication rates during the following years. Thus, it’s suggested that this expensive procedure should be performed by experienced surgeons.

Device related foreign body reactions are one of the most frequently encountered problems and reasons for revision. An urethral erosion case that resulted in stone formation in the bladder 13 months after the implantation and cases who developed peritonitis due to peritoneal irritation have also been reported in the literature (11,12).

Urethral stricture accompanying incontinence is another problematic issue. For such a problem, priority should be given to the treatment of the stricture. This can either be achieved by internal urethrotomy or the stricture can be eliminated by the placement of a permanent wall stent and an artificial sphincter can be implanted consecutively. In three patients that we treated with the latter approach, both the problems

### Table 3: Cause of complications and revision

<table>
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<tr>
<th>Complications</th>
<th>Number</th>
<th>Revision</th>
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<tbody>
<tr>
<td>Infection</td>
<td>2</td>
<td>New AUS implantation</td>
</tr>
<tr>
<td>Mechanic problems</td>
<td>1</td>
<td>New AUS implantation</td>
</tr>
<tr>
<td>Cuff erosion</td>
<td>1</td>
<td>Only cuff revision</td>
</tr>
<tr>
<td>Erosion of scrotum</td>
<td>1</td>
<td>Proper antibiotics therapy and replaced of pump in the scrotume</td>
</tr>
</tbody>
</table>

infection and erosion, providing proper dissection, sufficient hemostasis, appropriate cuff selection and having the device inactive for 6 weeks are very crucial.
related to the stricture and to the incontinence have been disappeared. Although one of these cases complained of mild wetting, all patients stated that they were very satisfied with the implants.

Another dimension of the surgery is its difficulties when performed on children. We performed an implantation to the bladder neck in a 15 year old boy. Postoperative follow up was uneventful and there was no need to change the device. However, according to the report by Barrett, the reoperation rate is 56% in children and adolescents (13). On the other hand, Kyrger reoperated 13 cases out of 32 pediatric patients that he followed for 15.4 years (14).

The success of the operation is measured by the dryness of the patient and the number of pads that are wetted. Although the satisfaction decreases in the patients who wet more than 1 pad a day, the patients all feel themselves much better after the operation compared to their previous condition. The success rate was found as 80% in our series.

The need to reoperate due to erosion is declining in both the pediatric and the adult age group due to the technological advances in the field of AUS. The success rates are reported to be higher in cases in whom narrow back cuff has been utilized (15,16). Periurethral injections that were developed as an alternative approach in recent years do not provide comparable success rates. We are also aware of the migration risks and allergic features of such materials (17). Yet, we believe that this approach is still a good choice for cases of partial incontinence because of its ease of application, low rate of complications and high chance of repeatability.

As a result of 46 months mean follow-up of 20 patients implanted with artificial urinary sphincter, we suggest that this is an intervention, which increases the quality of life in this patient group with high success rates, especially for the cases with normal bladder function and complete sphincteric insufficiency, AUS should be considered as the first choice.
REFERENCES

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