The Role of Artificial Urinary Sphincters in Modern Incontinence Management

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The first artificial urinary sphincter (AUS) was described in 1947. The AUS used now was first implanted in 1972. The initial device had valves that controlled flow direction and pressure. Later models included several modifications. The current three-part AUS incorporates high-quality aerospace components. After 20 years of use, this device has been implanted in more than 20,000 patients. The overall continence rate in female patients after insertion of an AUS is satisfactory. It should be considered first-line treatment in this group, although the risk of revision surgery is high. Pelvic irradiation is a contraindication to the AUS in female patients. The use of AUS in children has been extensively described mainly in those with neurogenic bladder dysfunction. This treatment has changed the quality of life of patients with this disease. Before AUS insertion, it is important to ensure that these patients have an adequate capacity and a stable bladder.

Introduction

The first artificial urinary sphincter (AUS) was described by Foley [1] in 1947. However, the AUS in current use (the AMS 721 [American Medical Systems; Minnetonka, MN]) was not implanted until 1972 [2] and was considered a milestone in the treatment of intrinsic sphincter deficiency. This device included valves to control the flow direction in the system and the pressure within it [3•]. Later models included several modifications such as the use of a pressure-regulating balloon (PRB) instead of valves to regulate pressure and the use of cuffs made entirely of silicone rather than of Dacron (Unifi, Inc.; Greensboro, NC) [3•].

Currently, the three-part AMS 800 (American Medical Systems) is used and incorporates high-quality aerospace components. After 20 years, these devices have been implanted in more than 20,000 patients worldwide [3•]. Improvements have been made to the patient selection process and to technical designs. Improved surgical techniques have decreased the rates of complications and revision, improving the long-term efficacy of this treatment.

The Devices

Since the AMS 721, the device has been redesigned four times. The fifth-generation model, the AMS 800, was introduced in 1983 [4].

The AMS 800 series

The AMS 800 consists of three components: a urethral cuff, a scrotal pump-control assembly, and a single PRB. These three parts are implanted individually and then connected by two tubes [5•]. The entire system is fluid-filled and functions hydraulically. The pressure in the system and the occlusive force of the cuff are determined by the PRB [3•]. The pressure produced depends on the elasticity in the balloon wall. The pressure-to-volume relationship is linear until it attains a plateau between 16 and 24 mL of fluid, where it remains predictable [6].

After the device is implanted, the pump is used to open the cuff, and the device is deactivated [5•]. The control pump incorporates a valve, a refill delay resistor, and a deactivation button. When this button is pressed, it stops fluid from being transferred among the three components, allowing the surgeon to maintain the sphincter cuff in a deflated state during the postoperative period [3•].

Deactivation is achieved by squeezing and releasing the pump. Each squeeze empties the contents of the pump into the balloon. The pump empties last and then starts to refill from the PRB [3•].

A new AUS

Recently Knight et al. [7•] described a new device as an alternative to the AMS 800. The principal design features include the following:

- A self-sealing port in the pump assembly for in situ pressure adjustment
- A stress relief mechanism, providing low-resting occlusion pressure and conditional occlusion of the urethra

- One-piece assembly to facilitate implantation and minimize mechanical failures
- Improved cuff design to reduce potential for creasing and fracture (decreasing the risk of urethral atrophy and erosion)
- Patient-activated rapid cuff re-inflation facility (effective protection against stress-induced incontinence) [7•]

The device includes a urethral cuff, a scrotal pump-control assembly, and two PRBs. The lack of tubing connections is proposed as an advantage; this may be true if it can be shown that tubing connections significantly lengthen implant time or are a source of mechanical failures [5•].

As the authors indicate, this new device needs to be implanted in greater number of patients, at different centers, and with longer follow-up periods. Montague [5•] affirmed that if this sphincter possesses all these new advantages, it will become an important tool in the management of urinary incontinence.

Long-term Outcomes

Recently, Lai et al. [8] published a large retrospective study from the Baylor College of Medicine. From 1992 to 2005, 218 patients that underwent AUS implantation were analyzed. Mean follow-up was 36.5 months. Of these patients, 60 underwent prostatectomy and pelvic radiation, 116 underwent prostatectomy without radiotherapy, 11 had neurogenic bladder, and 31 underwent secondary AUS implantation. The complication rate did not differ among the four treatment groups. Complication rates were infection in 5.5% of patients, erosion in 6.0%, urethral atrophy in 9.6%, mechanical failure in 6.0%, and surgical removal or revision in 27.1%. Median time-to-complication was 3.7 months for infection, 19.8 months for erosion, 29.6 months for atrophy, 68.1 months for failure, and 14.4 months for surgery. At 5 years, 75% of patients were free from revision or removal. A history of failed injection therapy or male sling or of Valsalva voiding did not adversely impact the outcome. The rate of bladder neck contracture was high in AUS candidates, especially in irradiated patients (36% and 57%, respectively). Patients with prior pelvic radiation continued to be at higher risk for contracture recurrence after AUS implantation (12%).

The authors concluded that AUS is a durable treatment for sphincter deficiency even in patients with a history of complications, neurogenic bladder, pelvic radiation, bladder neck contracture, Valsalva voiding, or failed injectables or slings [8].

Hajivassiliou [9] conducted a meta-analysis of the use of AUS in series of patients with sphincter incontinence of various etiologies. The published studies revealed that continence improved in 88% of patients, and total continence was achieved in 73%. The global revision rate was 32%. Urethral erosion occurred in approximately 12%, infection in 4.5%, and mechanical complications in 14% of patients. The complications relating to the AMS AUS were analyzed. Most patients (> 85%) required only one revision. Mechanical malfunction accounted for 22% of the complications. Infection comprised 12.9% of complications. The patterns of total revisions followed a double exponential decay curve: 50% of revisions were performed within 8 months and 90% within 3 years of implantation. Complications were still reported several years after implantation. These problems were related to the application of pressure and the presence of foreign material around the urethra. Therefore, long-term follow-up by a specialist is required for these patients.

Bosch [10] published a retrospective series of 86 patients using Kaplan-Meier analysis. Continence was satisfactory in 76% of patients and markedly improved in another 7%. The 5-year primary adequate function and additional procedure–assisted adequate function rates were 46% and 67%, respectively. The 5-year primary adequate function rates before and after the introduction of the narrow-backed cuff were 33% and 61%, respectively ($P = 0.03$). The AUS can give excellent results as far as urinary continence is concerned but only at the expense of a considerable reoperation rate.

Use of AUS After Radical Prostatectomy

Gousse et al. [11] studied 71 patients with AUS implantation after radical prostatectomy. This group included 29 patients (40.8%) who received an earlier version of the AMS 800 and 42 (59.2%) who received the newer narrow-back cuff device. Surgical revision was required because of mechanical failure in 18 patients (25%), device erosion in three patients (4%), and infection in one patient (1.4%). Of the patients, 41 (58%) were very satisfied, 14 (19%) were satisfied, and 16 (23%) were unsatisfied with the device. The degree of satisfaction correlated with the number of pads used ($P = 0.0005$) and sphincter design ($P = 0.028$). This was not related to the number of surgical revisions ($P = 0.521$) or patient age. The authors concluded that AUS is a viable treatment option for incontinence post-radical prostatectomy with a high rate of continence and satisfaction for a long period after the procedure. Patients should be informed that complications necessitating device revision may appear late in follow-up. A standard definition of treatment success and studies of homogenous groups of patients with an AUS would enable better understanding and patient education in the future [9].

Mottet et al. [12] reported their experience with 103 men. Surgical revision was necessary in 22 patients (21%). Infection and erosion accounted for 12 nonmechanical revisions leading to complete removal of six AUSs and to the eventual replacement of another six devices with new

ones. Mechanical malfunction accounted for revision in 10 patients (9.7%). Fifty-nine patients (61.45%) reported no leakage for the 96 working devices. Twenty-seven patients (28%) wore no pads, three patients used one pad, and four patients used two pads per day. All of these patients reported improvement, with only three patients (3%) using more than two pads per day. Currently, no non-prosthetic procedure reliably affords such good objective results. In conclusion, insertion of the AMS 800 AUS represents an attractive treatment modality available for male urinary incontinence following radical prostatectomy [12].

AUS in Women with Stress Incontinence

The use of AUS for primary treatment in women with severe, recurrent, type III stress incontinence is defended by some groups [3•]. Thomas et al. [13] published a study that included a total of 68 patients. Overall, 25 patients (37%) had the original AUS in situ and were dry at a median follow-up of 7 years. The AUS was replaced for loss of function in 12 patients, of whom 11 were dry with the replaced device. The device was removed for erosion or infection in 31 patients, of whom 19 underwent successful replacement or were continent after removal. Overall, 55 of 68 patients (81%) were continent. Those with neuropathic bladder dysfunction achieved a continence rate greater than 90%, although one half required sphincter removal initially. When the indication for insertion was stress incontinence, 70% of the patients had the original or a replaced AUS in situ, and 82% were continent. All patients with previous pelvic irradiation had the sphincter removed and urinary diversion was done. The authors concluded that the overall continence rate in female patients after insertion of an AUS is satisfactory. A satisfactory outcome was achieved in terms of stress incontinence. An AUS is recommended after adequate stress incontinence surgery fails. Continence in patients with neuropathic bladder dysfunction is excellent, and the AUS should be considered first-line treatment in this group, although the risk of revision surgery is high. Pelvic irradiation is a contraindication to the AUS in women.

Other series have reported 92% continence at 2.5 years when AUS is used as the primary method for treating stress incontinence [14].

Use of AUS in Children (Neurogenic Bladder)

The use of AUS in children has been extensively described mainly in those with neurogenic bladder dysfunction. This treatment has changed the quality of life of patients with this disease. It is important to ensure that these patients have a stable bladder with adequate capacity prior to sphincter insertion [3•].

Recently Lopez Pereira et al. [15] published their experience in 35 patients. Thirteen patients underwent enterocystoplasty combined with AUS placement, and 22 underwent AUS implantation alone. Mean follow-up was 5.5 years. Nine mechanical malfunctions occurred in seven patients (20%). Of the 22 patients who underwent AUS implantation alone, seven (31.2%) eventually required an enterocystoplasty because of unexpected bladder behavior changes, usually within 3 years of AUS implantation. In seven patients (20%), a continent catheterizable stoma was made (before or during the follow-up) because of problems with clean intermittent catheterization (CIC) through the urethra. Three AUSs (8.6%) were removed because of sphincter erosion at the bladder neck. All 32 patients (91.4%) with an AUS currently in place are dry, three void their bladders spontaneously, and 29 need CIC. In conclusion, AUS must be considered as an elective treatment in the surgical management of these patients because it produces better continence rates than other methods. However, these patients need long-term follow-up because their bladder behavior may undergo unexpected, clinically asymptomatic changes that could negatively affect their upper urinary tract and require bladder augmentation [15].

Ruiz et al. [16] studied the efficacy of the AUS to treat sphincter incontinence in pediatric patients with spina bifida. A total of 112 children and adolescents underwent implantation of the AMS 800 AUS. Of these patients, 19 males and four females (20.5%) between ages 4 and 17 years (mean 8.1) had no spina bifida. Instead, bladder exstrophy was present in 12 patients, anorectal malformation with a rectourethral or vesical fistula in seven, and epispadias in four. A bladder neck cuff between 5.5 and 7.5 cm and a 61 to 70 balloon were used in all patients. A total of 19 sphincters remained in place (86.3% survival rate) with five revisions (26.3%) because of the pump (2 patients), the cuff (2 patients), or balloon fluid leakage (1 patient). In this group, 13 patients (68.4%) voided spontaneously. Six (31.6%) performed CIC, although three patients in this group also voided spontaneously. Overall continence was good in 87% of patients; two were still incontinent at night. The authors concluded that AUS is a good long-term solution to urinary incontinence secondary to sphincter incompetence despite multiple previous surgeries of the bladder neck or proximal urethra. Patients with bladder exstrophy and many previous bladder procedures were more prone to complications such as erosion than patients with epispadias or anorectal malformation. The high percentage of patients maintaining spontaneous voiding and the good rate of continence are the most important benefits of this type of surgical option for sphincter incompetence [16].

Conclusions

AUS has been in use for more than 30 years. It went through various changes until the development of the AMS 800, which was introduced in 1982 and underwent

design modifications in 1987. Early complications following insertion are usually due to technical failure. Late complications are generally due to a leak in the system secondary to cuff perforation. The technical failure rate decreases as surgical experience increases. The risk of infection and erosion remains and it can only be decreased by ensuring that all precautions are taken.

AUS use for stress incontinence is controversial. It is not indicated except for intrinsic sphincteric deficiency because the revision risk is unacceptably high. Successful alternative treatments exist for most patients with stress incontinence and hypermobility rather than intrinsic sphincteric deficiency. Almost all patients with stress incontinence who are considered candidates for an AUS have undergone previous bladder neck surgery and, therefore, have a higher erosion risk. Furthermore, women with neurogenic bladder dysfunction who have not undergone previous surgery appear to be subject to erosion more often than men. This raises the question of whether the design of the current AUS is optimal for women.

The use of the AUS for post-prostatectomy incontinence is established with a social continence rate of around 90% (short- and long-term). Complications, particularly erosion and infection, are much rarer in this group due to the bulbar position of the sphincter cuff in the majority. No other treatment for this distressing problem is as successful. For neurogenic bladder dysfunction, AUS achieved high continence rates in the short and long term. The complication and revision rates in this group are much higher, but when no other effective treatment exists, patients are generally prepared to accept the need for revision to achieve continence.

Knight et al. [7•] described the preliminary clinical results of a new AUS with conditional occlusion in the treatment of urodynamically proven stress incontinence in a group of male patients. The results show that this device can provide significant improvements in continence with an 85% reduction in leakage volumes and up to 100% improvement in the Continence Index. Implantation was quick and technically less demanding, with no serious adverse events. This new AUS provides adjustability in regulating pressure in situ, which may reduce the need for surgical revision. This preliminary study has shown significant improvements in continence in this group of patients.

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