A review of our experience in treating male urinary incontinence through the AMS-800™ artificial urinary sphincter


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**KEYWORDS**
Artificial sphincter; Urinary incontinence; Post-prostatectomy incontinence; Spain.

**Abstract**

Background: Since 1983, the AMS-800™ artificial urinary sphincter has been a therapeutic procedure in the management of urinary incontinence due to incompetent sphincter. We present herein treatment results and effectiveness according to our experience.

Methods: Within the time frame of 1997 to 2012, this prosthesis has been implanted in 50 patients presenting with incontinence due to sphincter incompetence that was secondary to prostate surgery in 90% of the cases. It was placed in the bulbar urethra in men and in the bladder neck in women, implanting a single cuff, between 4 and 5.5 cm, with reservoir pressures of 60 to 70 cm of water.

Results: The answers “very much better” and “much better” on the Patient Global Impression of Improvement (PGI-I) questionnaire and the need to use fewer than 2 compresses/day were regarded as the treatment outcome criteria. There was cure or improvement in 42 of the patients (84%). Eight patients (16%) presented with complications and a total of 8 patients (16%) were re-operated on for artificial sphincter removal and reimplantation, with good results in 3 patients.

Conclusions: Treatment with the AMS-800™ prosthesis for severe urinary incontinence in men due to sphincter incompetence is an effective therapeutic alternative. Nevertheless, the procedure is not without complications and other techniques with similar results are preferred for women.
PALABRAS CLAVE
Esfínter artificial; Incontinencia urinaria; Incontinencia posprostatectomía; España.

Revisión de nuestra experiencia en el tratamiento de la incontinencia urinaria en el varón mediante el esfínter urinario artificial AMS-800TM

Resumen

Introducción: El esfínter urinario artificial AMS-800TM es un procedimiento terapéutico, en el manejo de la incontinencia urinaria por incompetencia esfinteriana desde 1983. Presentamos los resultados y eficacia del tratamiento según nuestra experiencia.

Material y métodos: Se ha implantado esta prótesis a 50 pacientes, desde 1997 hasta 2012, con incompetencia debida a incompetencia esfinteriana secundaria a cirugía prostática en el 90% de los casos. En hombres se han colocado en uretra bulbar, y en mujeres en cuello vesical, implantado un solo manguito entre 4 y 5.5 cm, con presiones del reservorio de 60 a 70 cm de agua. Resultados: Se evaluó como criterio de curación las respuestas “muy mejor” o “mucho mejor” del cuestionario Patient Global Impression of Improvement (PGI-I) y la necesidad de menos de 2 compresas/día, siendo de curación o mejoría en 42 (84%) pacientes. Se observaron complicaciones en 8 pacientes (16%) y se reintervino a un total de 8 pacientes (16%) para la retirada del esfínter artificial, usándose el reimplante con buenos resultados en 3 pacientes.

Conclusiones: El tratamiento de la incontinencia urinaria severa en el varón por incompetencia esfinteriana mediante el uso de la prótesis AMS-800TM, es una alternativa terapéutica eficaz, sin olvidar sus posibles complicaciones, prefiriéndose en mujeres la utilización de otras técnicas de similares resultados.

Introduction

Urinary incontinence has an important psychological and social impact and affects the patient's quality of life. There are many therapeutic alternatives for the treatment of stress incontinence. Since 1983, AMS-800TM artificial urinary sphincter implantation1,2 (fig. 1) has been a good alternative in treating severe urinary incontinence in men due to sphincter incompetence, with much experience in its use.3,5 We present herein our experience using the AMS-800TM artificial urinary sphincter, evaluating both the effectiveness and complications in the treatment of severe urinary incontinence with the AMS-800TM artificial urinary sphincter, by means of a retrospective analysis of the etiology of incontinence, the functional results, and the surgical and postoperative complications.

Methods

We conducted a descriptive and retrospective study within the time frame of 1997 to 2012 during which this prosthesis was implanted in a total of 50 patients, 47 men and 3 women. Before implantation, all the patients underwent urothrocystoscopy to rule out stricture and foreign bodies and they also had a complete urodynamics study (cystometry and pressure-flow study).

The cause of incontinence has always been sphincter incompetence secondary to:

✓ Prostate surgery:
  • Radical prostatectomy: 36 cases.
  • TURP: 6 cases.
  • Adenomectomy: 3 cases.
✓ Neurologic origin:
  • Moyamoya disease: one case.
  • Intrinsic sphincter incompetence: one case.
✓ Ependymoma of the filum terminale: one case.
✓ Radical cystoprostatectomy and neobladder: one case.
✓ Failure of previous incontinence surgery: one case.

The procedure was performed with the technique habitually used with the AMS-800TM artificial urinary sphincter (fig. 2). A single cuff has always been implanted, varying between 4 and 5.5 cm, with reservoir water pressures of 60 to 70 cm; it was placed in the bulbar urethra in men and the bladder neck in women.

Mean postoperative hospital stay was 1.13 days, with a postoperative check-up at one month and activation of the artificial sphincter device. Patients answered the Patient Global Impression of Improvement (PGI-I) questionnaire6, which collects data on the current status of urinary symptoms in comparison with the situation prior to surgery. El PGI-I consists of a single question that asks the patient to classify the relief obtained from the treatment on a 7-point Likert scale as: “very much better”; “much better”; “a little better”; “no change”; “a little worse”; “much worse”; or “very much worse”. The established cure criteria were the answers “very much better” or “much better” (all the other answers were defined as treatment failure), together with the need for fewer than 2 compresses/day. Although the PGI-I has only been applied to women with stress urinary incontinence and urogenital prolapse, its use has not been established in men and women with other urinary tract symptoms or conditions. However, the PGI-I is an overall index that can be used to evaluate the response of a condition to a therapy (transition scale). It is a simple, direct, easy-to-use scale that is intuitively comprehensible for clinicians, which is why it was chosen for this study.
Results

The functional results showed that 24 patients (48%) achieved complete continence and 18 patients (36%) had minimum incontinence (defined as the use of 1-2 compresses/day). There was procedure failure in 8 cases (16%). These results were correlated with the Pgi-I questionnaire in which 42 patients (84%) referred to being “very much better”/“much better” and the remaining 8 patients (16%) did not.

A total of 8 patients (16%) were reoperated on, removing the artificial urinary sphincter and replacing it with a new implant. There were good results in 3 of those patients; 2 were reoperated on due to mechanical failure of the artificial urinary sphincter and the other because of infection of the prosthetic material. In these cases the AMS-800TM artificial urinary sphincter (inhibizone) covered with rifampicin and minocycline was implanted.

Of the women operated on, 2 had to have the sphincter removed due to vaginal and internal urethral erosion, with no new reimplantation. The other female patient had no clinical improvement and the sphincter was maintained, but inactive.

There were complications in 8 patients (16%) and the most frequent was internal urethral erosion (fig. 3) in 3 cases, as shown in table 1, resulting in the necessity for removal of the prosthesis. Only one patient presented with infection of the artificial urinary sphincter, ending in its consequent removal (fig. 4).

Discussion

There are currently many options for urinary incontinence treatment due to sphincter incompetence in men, such as pelvic floor rehabilitation exercises, drug treatments, transurethral injections of space-occupying substances like collagen and other polymers, or male slings, all with different results and complications. Since 1947 when Foley designed the first artificial catheter - a cuff that was inflated and deflated around the penis - many sphincters have been developed. The AMS-800TM artificial urinary sphincter (American Medical Systems) was first implanted in 1983, and has been progressively improved, with an average success rate of 82%.

The AMS-800TM artificial urinary sphincter is a device with a hydraulic mechanism that has 3 fundamental components connecting to one another: the occlusive cuff, reservoir, and control pump.

The cuff is made up of a silicon band with an inflatable balloon in its inner side that measure from 4 to 11 cm in length and 2 cm in width that can be placed around the bladder neck or the bulbar urethra. There is a reservoir covered with rifampicin and minocycline that is implanted intraperitoneally.

Table 1 Complications

<table>
<thead>
<tr>
<th>Complications</th>
<th>N of patients</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal urethral erosion</td>
<td>3</td>
<td>6%</td>
</tr>
<tr>
<td>Vaginal erosion</td>
<td>1</td>
<td>2%</td>
</tr>
<tr>
<td>Control pump failure</td>
<td>1</td>
<td>2%</td>
</tr>
<tr>
<td>Reservoir shift</td>
<td>1</td>
<td>2%</td>
</tr>
<tr>
<td>Scrotal hematoma</td>
<td>1</td>
<td>2%</td>
</tr>
<tr>
<td>Infection</td>
<td>1</td>
<td>2%</td>
</tr>
</tbody>
</table>

* Complications after AMS-800TM artificial urinary sphincter implantation.
ranges, but the most widely used are 51-60, 61-70, and 71-80 cm of water. The recommended pressure values are: in men 71-80 in the bladder neck and 61-70 in the urethra; in women 61-70 in the bladder neck; and in children 61-70 in the bladder neck and 51-60 in the urethra.5,10

The control pump is placed in the scrotum or labia majora. A system of valves in its interior directs the passage of the filling liquid in one direction or another, letting the cuff inflate or deflate, allowing for micturition during 3 to 5 minutes. Continence is re-established subsequent to sufficient time for micturition. The pump has a button that deactivates the prosthesis, emptying the occlusive cuff.5,11

The artificial urinary sphincter is indicated in all patients with genuine stress incontinence, men or women, and of any age, that have the ability to manipulate the control pump.10 There are a series of previous conditions such as bladder capacity > 200 mL, stable bladder, sterile urine, and absence of obstruction prior to implantation; therefore it is elective in the patient with irreversible sphincter insufficiency and normal bladder function.5,11

Indications for the prosthesis, in order of frequency, are incontinence after radical prostatectomy or transurethral resection of the prostate, congenital malformation, spinal trauma, neurogenic bladder, and stress incontinence in women when other surgical techniques have failed.4,10 The group of patients with sphincter deficiency after radical prostatectomy is the most important group that recurs most often to incontinence management with an artificial sphincter. In approximately 70% or more of the patients with implants, the cause of their incontinence is an aftereffect of radical prostate surgery. In our case series, this was also the main cause of incontinence in the patients with implantation, with a total of 36 patients (72%).

There are substantial variations in the literature in both the complication as well as the success rates. This can largely be explained by the heterogeneity of the studies and in the different definitions used to classify the results. In relation to incontinence improvement, our case series reported improvement of 84%, compared with other series that vary from 61.4% to 90.4%.3-5,12-16

There are different types of complications and they vary from 2.7% to 49.5%, depending on the series. In our case series the complication rate was 16%, and 16% of the patients were re-operated on; this is comparable to other series described in the literature (1.3% to 44%).3-5,12-16

When these devices were introduced, the mechanical failures of the equipment were an important cause of complications; there is a 7% to 53% incidence with an average of 13.8% reported on in the literature.3,4,17 Over time, this type of complication has been reduced, thanks to improvements in the devices themselves, and today’s prostheses are long-lasting and reliable systems. In general the problems arise from damage to the control pump or perforations resulting in the exit of the system’s liquid. The average prosthesis is calculated to have a useful life of approximately 10 years.10

The most devastating complication in the entire prosthetic procedure is infection; it is estimated that infection of the prosthesis makes up approximately 12.9% of the possible complications,4 and the seriousness of this is, that in order to resolve the infection, the artificial urinary sphincter almost always must be removed.10 Fundamental preventive measures are required to prevent this from happening; there must be scrupulous surgical asepsis and a meticulous surgical procedure. Additionally, in our case, we administered preoperative antibiotic prophylaxis to all our patients, with aminoglycosides and beta-lactam antibiotics in combination with the recommended antimicrobials as established by the chemoprophylaxis protocol of surgical procedures, with strength of evidence B, level III.18 We also carried out constant irrigations of the surgical site and all the components of the prosthesis with an antibiotic solution containing gentamycin.

In relation to prosthetic material erosion, the incidence in different case series varies from 12% to 14.9. It can present as an internal erosion, when the protrusion of the components (generally the cuff) is toward the bladder neck or the urethra; or external erosion, when the component (the control pump, reservoir and/or connecting tubes) protrude through the skin. The form most frequently reported in
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the literature is the internal erosion of the cuff toward the bulbar urethra, which can be caused by an excess of pressure in the system, infection, or progressive ischemia.\(^\text{10}\)

Conclusions

The treatment of urinary incontinence due to sphincteral incompetence through the use of the AMS-800™ prosthesis is an effective therapeutic alternative, keeping in mind its possible complications. In women, the use of other techniques is preferred. The most frequent indication is after prostate surgery and the most favorable results are obtained in these cases. In our experience, placement of the AMS-800™ prosthesis at the level of the bulbar urethra is the location of choice.

Conflict of interest

The authors declare that there is no conflict of interest.

Financial disclosure

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References