

# ORIGINAL ARTICLES

## The Use of the Artificial Urinary Sphincter in the West of Scotland: a Single Centre 10-year Experience

AK Ramsay, P Granitsiotis, IG Conn

### Correspondence to:

Dr Alison Ramsay, Department of Urology, Southern General Hospital, 1345 Govan Road, Glasgow, G51 4TF  
Email: alisonramsay@doctors.org.uk

### ABSTRACT

#### Background

The artificial urinary sphincter (AUS) has been used successfully to treat sphincter weakness incontinence in males over the past 30 years. Postoperative complications are well-recognised, but patient satisfaction remains high.

#### Methods

We performed a retrospective single centre study of all patients who had an artificial urinary sphincter inserted over a 10-year period. We assessed patient satisfaction and continence post operatively as well as complication rate and need for revision or replacement surgery.

#### Results

Thirty-eight male patients (mean age 57 years) and 1 female patient had an AMS 800 (American Medical systems) AUS inserted between 1995 and 2005. Five (13%) patients have required replacement surgery to date. Male patients were divided into two groups according to the aetiology of their incontinence: neuropathic (n=11) and non-neuropathic (n=27). Social continence was achieved in all patients. Three (11%) non-neuropathic patients developed complications. Revision surgery was undertaken in 4 (15%) of non-neuropathic patients and in 1 (9%) neuropathic patient. The mean lifespan of the AUS in patients who required further surgery is 6.6 years.

#### Conclusion

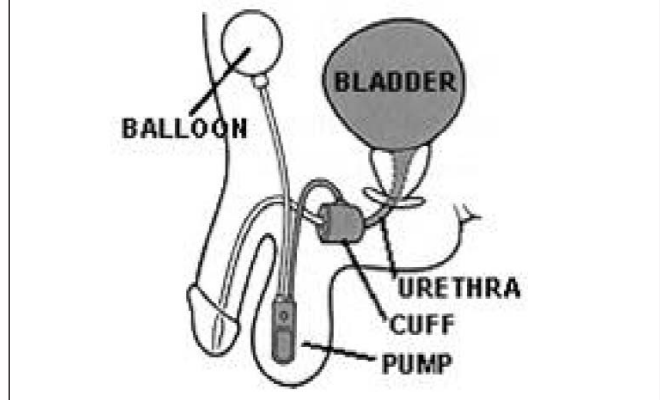
For patients with severe sphincter weakness incontinence the AMS 800 AUS is a safe and reliable solution. Our results are comparable with previous published studies of larger patient numbers from dedicated reconstructive units.

### Introduction

The artificial urinary sphincter (AUS) was developed in 1972 and has since been used to treat both men and women with urinary incontinence secondary to an incompetent urinary outlet.<sup>1</sup> The most common indication for insertion of the AUS is post-prostatectomy incontinence (PPI). It has also been used successfully in neurogenic bladder dysfunction and in lower urinary tract reconstruction.<sup>2</sup>

The AUS has developed in design over the years. The AMS 800 (American Medical Systems) prosthetic urinary sphincter is currently the only commercially available device in use.<sup>2</sup> It consists of 3 parts: a pressure regulating balloon which is placed extraperitoneally, an inflatable silicone cuff which is wrapped around the bulbar urethra or bladder neck and a control pump which is placed in the

Figure 1 AMS 800 AUS in a male



scrotum or labia majora (Figure 1). The entire system is fluid filled and it functions hydraulically. The patient is able to deflate the cuff by squeezing the control pump and thus enabling micturition.

It is essential that all patients are properly assessed pre sphincter insertion. Good manual dexterity is essential to manipulate the pump and perform intermittent self-catheterisation if required. All patients must be told about the possibility of malfunction, infection, erosion, or migration of the AUS. Postoperative pain can be both short and long term and therefore this potential complication must be explained prior to surgery. Counselling is also required for all patients regarding the possibility of future revision surgery or the need for AUS replacement. Success rates, long-term durability and patient satisfaction for the AUS are generally high.<sup>1</sup>

We present our experience of AUS implantation over a 10-year period at the Southern General Hospital.

### Materials and Methods

The Southern General Hospital is the tertiary referral centre for AUS surgery in the West of Scotland. Referrals are made from units within Greater Glasgow and Clyde, as well as Ayrshire, Forth Valley and Lanarkshire. The population in this catchment area is over 2 million people. All patients in this study were referred for AUS insertion having failed other treatment options.

Conventional filling and voiding urodynamics were performed in all patients to confirm sphincter weakness incontinence, assess for detrusor overactivity and voiding function. They all had maximum urethral closure pressure (MUCP) below 20cmH<sub>2</sub>O and leak point pressures (LPP) below 40cmH<sub>2</sub>O. Cystoscopy was performed in all non-neuropathic patients to exclude coexisting bladder outlet obstruction. Renal ultrasound was performed in all neuropathic patients to ensure no existing upper tract damage. Every patient had a pre operative urine culture in order to ensure sterility before AUS insertion.

This retrospective single centre audit was conducted using our departmental audit database. Our results include all patients who had an AUS implanted over a 10-year period by a single surgeon.

Clinical notes allowed us to extract relevant data for analysis regarding aetiology of incontinence, patient satisfaction and complications post operatively. Social continence is defined as the use of 1 pad or less per day.

## Results

Between 1995 and 2005 an AMS 800 AUS was implanted in 38 male and 1 female patients. Forty four procedures were performed in total as 5 (13%) patients required revision surgery. Patients had a mean age of 57 years (22-81) at the time of initial implantation. Between 2 and 7 procedures (mean=3.9) were performed each year.

Of the neuropathic patient group included 6 patients with spina bifida, 1 with thoraco-lumbar scoliosis, 1 post-meningitis, 2 spinal injury patients and 1 with sacral agenesis. The non-neuropathic patient group included 25 patients post-prostatectomy and 2 were incontinent secondary to trauma.

Fifteen of the non-neuropathic patients had previously had a radical prostatectomy (12 retropubic, 3 perineal). Seven patients were incontinent following transurethral resection of the prostate (TURP). Prostatic adenocarcinoma was an incidental finding in 1 TURP patient. Two patients were incontinent following laser ablation of the prostate and 1 post radical radiotherapy.

Eight of the patients post radical prostatectomy required a 3-point deep bladder neck incision to treat stricture at the vesicourethral anastomosis prior to AUS implantation. Twenty-four of the 25 patients in this group had bulbar cuff placement. One patient who was incontinent

secondary to laser ablation of the prostate, had the AUS cuff placed at the bladder neck as well as a free graft urethroplasty.

Three (11%) patients developed complications in the non-neuropathic group. One patient had a methicillin resistant staphylococcus aureus (MRSA) wound infection, 1 required control pump repositioning and 1 required cuff replacement due to erosion 3 years after insertion.

All patients were socially continent post operatively, with 8 describing minimal leak only. Four (15%) devices have required replacement to date in the non-neuropathic patient group.

In the neuropathic patient group additional procedures were performed in all 11 patients. Seven had ileocystoplasty and 2 had caecocystoplasty. One patient underwent a sphincterotomy and 1 had an urethrotomy. In the 9 patients who had augmentation cystoplasty the AUS cuff only was inserted at the time of initial surgery. Six of these patients had the remaining 2 parts of the AMS 800 AUS inserted at a later date where as the remaining 3 were continent with the cuff only. Seven neuropathic patients post operatively performed intermittent self-catheterisation.

All neuropathic patients are now socially continent. One patient developed cuff erosion and thus required cuff replacement 5 years after initial surgery. One patient was converted to an ileal loop diversion because of progression of his neurological condition.

An AMS 800 AUS was inserted in one female patient following two failed suburethral sling operations for sphincter weakness. She remains continent 4 years post operatively.

## Discussion

Over the past 30 years the AUS has been used to treat patients worldwide with stress urinary incontinence and intrinsic sphincter deficiency.<sup>1</sup>

Incontinence is the most important complication influencing patient morbidity post radical prostatectomy. Incidence may vary between 8% and 77%.<sup>4</sup> Early conservative management is implemented post operatively. However, if significant incontinence persists, patients can be offered implantation of an AUS.

The AUS has also revolutionised the quality of life for many patients with neurogenic bladder dysfunction.<sup>2</sup> In many cases augmentation cystoplasty is required in combination with AUS insertion in order to control neurogenic detrusor overactivity and poor bladder compliance.

Some surgeons perform these two operations at different times. Gonzalez et al found that simultaneous placement of the AUS and enterocystoplasty did not affect the outcome of sphincter implantation if good bowel preparation, intravenous antibiotics and sterility of urine were accomplished preoperatively.<sup>5</sup> Our results support this, as we show no increase in the risk of infection if the two procedures are performed at the same time.

Complications of AUS insertion are well recognised. Cuff leakage is the most common mechanical malfunction and is managed with component replacement or total device replacement. Other potential complications include device failure, infection, erosion and bladder stones.<sup>1</sup> In our experience only 5 devices have required replacement to date. The mean life expectancy in this study of patients who have required further surgery is 6.6 years.

Simon et al presented their series of 47 patients undergoing AUS implantation for PPI.<sup>6</sup> They reported that 23.4% of patients presented with at least 1 complication and that 21% required revision surgery. In our series of 25 patients post prostatectomy 2 (8%) presented with a complication post operatively and 4 patients (16%) have required revision surgery to date.

Previous studies have shown that complication and revision rates in neuropathic patients are much higher.<sup>2</sup> It is thought however that this can be reduced by careful patient selection, optimum preoperative bladder management and regular follow-up.<sup>7</sup> Although our numbers are small we report only 1 neuropathic patient requiring cuff replacement to date (9%).

Social continence was quantified in this retrospective study as the use of up to 1 pad per day. Review of clinical notes post operatively allowed us to assess success rates. We achieved continence in all patients with only 8 non-neuropathic patients describing minimal leak. This is comparable with previous studies, which have reported total or social continence in almost 90% undergoing AUS implantation.<sup>8</sup>

Insertion of sphincter cuff only during augmentation

cystoplasty may be sufficient to achieve continence in many incontinent patients who may not be cured by bladder augmentation alone. The procedure is not associated with increased risk of injury to the augmented bladder, neither with subsequent infectious complications.<sup>9</sup> Three patients in this study were continent with only the cuff in-situ however the remaining 6 required the entire device to be implanted to achieve continence.

AUS remains the gold standard for treating incontinence secondary to sphincter deficiency in male patients.<sup>4</sup> Other surgical options, which have been used for male stress incontinence, include the use of bulking agents, alternative sphincter devices and male sling operations. Success rates for bulking agents such as macropastique and collagen have been poor. Imamoglu et al suggested that if PPI is minimal that bulking agents are the first line treatment of choice rather than AUS insertion.<sup>10</sup> Their results demonstrated that AUS remains the best option if incontinence is severe.

Hubner et al reported results of an adjustable continence device ProACT<sup>TM</sup> in patients with PPI.<sup>11</sup> This device consists of two balloons placed by a perineal approach at the bladder neck attached via tubing to ports located in the scrotum. The ports allow for volume adjustments of the balloons at any time during and after surgery. The preliminary results did not achieve continence rates comparable to those reported with the AUS. Thirty-two of the 117 (27%) patients required reimplantation (mean follow up 13 (3-54) months).

Recently evidence has become available as to the possible use of slings in the management of male stress incontinence.<sup>12</sup> Various slings have been tried. However the most recent procedure involves using a bone anchoring technique with a synthetic mesh or autologous graft.<sup>13</sup> Results are comparable with the AUS but no randomised control trial has been done to date comparing these two techniques and therefore the AUS remains the best surgical option available.

Duloxetine (Yentreve<sup>R</sup>) has recently been licensed for the treatment of women with moderate to severe stress incontinence. It has not yet been fully evaluated for use in men with post surgical stress incontinence however preliminary results are promising.<sup>14</sup> Schlenker et al studied 20 patients with post surgical stress incontinence and found a significant reduction in pad use with

duloxetine. Side effects were problematic though and 30% of patients discontinued treatment.

In conclusion, the AMS 800 AUS is a safe and reliable solution for patients with severe sphincter weakness incontinence.<sup>15</sup> It produces good rates of continence and patient satisfaction. Replacement is a well-recognised risk and our results replicate that from previous published studies of larger patient numbers from dedicated reconstructive units. We have also shown that simultaneous cystoplasty and sphincter implantation appears to have good success rates with no evidence of the previous concerns regarding increased risk of AUS infection.

#### REFERENCES

1. Webster GD, Sherman ND. Management of male incontinence following artificial urinary sphincter failure. *Curr Opin Urol* 2005; 15: 386–390.
2. Gonzalez R, Merino GP, Vaughn M. Long-term results of the artificial sphincter in male patients with neurogenic bladder. *J Urol* 1995; 154: 769–70.
3. Rajkumar GN, Small DR, Conn IG. Computerised audit system in urology. *SMJ* 2005; 50: 61–63.
4. Klinger CH, Marberger M. Incontinence after radical prostatectomy: surgical treatment options. *Curr Opin Urol* 2006; 16: 60–64.
5. Gonzalez R, Nguyen DH, Koleilat N et al. Compatibility of enterocystoplasty and the artificial urinary sphincter. *J Urol* 1989 142(2 Pt 2):502–4.
6. Simon P, Zerbib N, Debre B et al. Resultats du sphincter artificiel AMS 800 chez l'homme: à propos d'une série de 47 patients. *Prog Urol* 2005; 15: 244–249.
7. Patki P, Hamid R, Shah PJ, Craggs M. Long-term efficacy of AMS 800 artificial urinary sphincter in male patients with urodynamic stress incontinence due to spinal cord lesion. *Spinal Cord* 2006; 44 (5):297–300.
8. Raj G, Peterson A, Toh KL et al. Outcomes following revisions and secondary implantation of the artificial urinary sphincter. *J Urol* 2005; 173: 1242–1245.
9. Mor Y, Leibovitch I, Colomb J et al. Reconstruction du bas appareil urinaire par enterocystoplastie d'agrandissement et mise en place isolée d'une manchette de sphincter artificiel. *Prog Urol*. 2004;14 :310–4.
10. Imamoglu MA, Tuygun C, Bakirtas H et al. The comparison of artificial urinary sphincter implantation and endourethral macroplastique injection for the treatment of postprostatectomy incontinence. *Eur Urol* 2005; 47: 209–213.
11. Hubner WA, Schlarp OM. Treatment of incontinence after prostatectomy using a new minimally invasive device: adjustable continence therapy. *BJU Int* 2005; 96 (4):587–94.
12. Nathan FE, Ullrich NFE, Comiter CV. The male sling for stress urinary incontinence: 24-month follow up with questionnaire based assessment. *J Urol* 2004; 172:207–9.
13. Rajpurkar AD, Onur R, Singla A. Patient satisfaction and clinical efficacy of the new perineal bone anchored male sling. *Eur Urol* 2005; 47:237–242.
14. Schlenker B, Gratzke C, Reich O et al. Preliminary results on the off-label use of duloxetine for the treatment of stress incontinence after radical prostatectomy or cystectomy. *Eur Urol* 2006; Feb 6 [Epub ahead of print].
15. Venn SN, Greenwell TJ, Mundy AR. The long-term outcome of artificial urinary sphincters. *J Urol* 2000; 164: 702–6.