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IMPROVEMENT IN MEDIUM TERM OUTCOMES AFTER ARTIFICIAL URINARY SPHINCTER INSERTION

Hypothesis / aims of study

Artificial urinary sphincter (AUS) insertion has been the treatment of choice in male stress incontinence after improvements to devices in the 1980's.(1) Previous studies have shown high rates of complications and need for revision procedures in men undergoing AUS insertion for stress urinary incontinence or sphincter deficiency. Newer models have had modifications such as antibiotic impregnated coating aimed at reducing complications and therefore morbidity associated with revision surgery; however data on whether this has had an effect is scarce. Our hypothesis was therefore that current rates in the literature are overstated and outdated.

Study design, materials and methods

All patients who had an AUS inserted at our centre between December 2001 and September 2013 were identified by clinical codes. A retrospective review of case notes was performed, and patients additionally contacted by telephone for an up to date assessment. If patients were non-contactable then the duration of follow up was from the date of operation to date of last clinic appointment. All sphincters inserted were the AMS 800 (American Medical Systems). The inhibizone coating was introduced by AMS in 2007 – roughly halfway through our series. This has therefore allowed comparison of those with or without coating.

Results

69 patients underwent a complete AUS system insertion (5 by a 2 stage procedure) within the stated time period and had accessible case notes. 1 patient had undergone a complete second AUS insertion during this time period – this was included separately in the results and gave a total of 70 sphincter procedures to review. All patients were male with a mean age of 63 years at the time of insertion (24-80). 39 patients were contactable by telephone for further review. The mean follow up time was 1244 days (3.4 years, range 52-4436 days).

The most common indication for AUS insertion in our centre was previous radical prostatectomy (either open or laparoscopic). There were a variety of other indications which are demonstrated in table 1 below.

Indication	**Number**
Open Radical Prostatectomy (ORP)	22
Laparoscopic Radical Prostatectomy (LRP)	35
Post TURP incontinence	2
Neuropathic bladder	4
Urethral injury	
- post AP resection	1
- pelvic fracture	1
Epispadias	1
Post pelvic surgery incontinence	1
Cystectomy and orthotopic bladder	2
Post radiotherapy incontinence	1

Table 1: Indication for AUS

63 patients (90%) had proven urodynamic stress urinary incontinence (USI) pre-operatively, 3 patients had no USI and in 4 cases urodynamics results were not available. Concurrent detrusor overactivity was present in 12 patients with USI (19%).

Short term outcomes included 6 early complications within 28 days of surgery (8.6%). They included an enterococcus UTI (pre operative urine culture negative) which settled with antibiotics, a scrotal haematoma which did not require intervention, intermittent urethral pain, fluid leaking through perineal wound which settled after catheterisation and 2 patients who had difficulty voiding – 1 required catheterisation and had a successful TWOC with no need for ISC.

Documented pre-operative leakage showed nearly a quarter of the cohort (16 patients, 23%) had severe incontinence requiring sheath drainage, and 44.3% of patients were using 4 or more pads per day. Initial post operative continence rates were assessed by pad usage documented at clinic reviews pre and post operatively. Comparable data was available for 43 patients. The median number of pads used in 24 hours pre-operatively was 4, and post-operatively was 0. This was statistically significant using a paired T test with P value $<<0.05$. 26 patients were completely dry and using 0 pads. No patients were using more than 3 pads per day. Of the 16 patients requiring sheath drainage prior to surgery only 2 needed a sheath afterwards, and 43.8% used 0 pads.

20% of patients had their sphincters removed (8/70) or revised (6/70), with a further 3 patients (4.3%) awaiting revision. 56 patients (80%) had their original sphincter in situ at the time of follow up (mean 3.4 years).

As part of follow up the 39 patients (55.7%) contactable during telephone review completed an ICIQ-UI short form – a validated questionnaire designed to quantify the degree of urine leakage and the bother it causes. The total score of the questionnaire is

21 – the higher the score the more significant the leakage. Median total score was 7 out of 21. The median response to question 3 ('how often do you leak urine?') was 'about once per day'. 4 patients (10.3%) reported themselves as 'wet all the time'. 84.6% reported their leakage as a small amount or less. Question 5 which assesses interference in the patient's everyday life on a scale of 0 (not at all) to 10 (a great deal) had a median response of 2/10. 7 patients (17.9%) reported a score of $\geq$ 5/10.

Interpretation of results

In our series the early complication rate was 8.6%. There was an overall reoperation rate of 20%. Infection rate was 7.1% and erosion rate also 7.1% (5/70). Device failure occurred in 4 (5.7%) patients (2 holes in cuff, 2 needed higher pressure reservoirs). 80% of patients still had their original AUS in situ at time of last follow up, which was generally medium term with a mean of 3.4 years. A recent review of outcomes after AUS insertion [(2)] found a combined revision or removal rate of 12-64% in 12 contemporary series – our combined rate is comparable at 20% (24.3% if the 3 patients awaiting revision are included).

As previously stated we hypothesised that use of the more recent AMS 800 model with inhibizone coating has delivered a reduction in our complication rates. Splitting our series into pre-inhibizone and inhibizone groups shows a stark contrast. 6 of the 8 removals occurred before the introduction of inhibizone and 3 required revision, resulting in a reoperation rate of 60%. In the inhibizone group only 2 AUS systems were removed and 3 revised. The reoperation rate in this group was only 9.1% which is much lower than previously published rates. 26.7% of sphincters became infected pre-inhibizone, which dropped to 1.87% after its introduction. Whilst this is retrospective data it is demonstrating a clear reduction with no other changes in practice to explain the drop in rates. There has also not been as long a follow up period for the inhibizone group given this was only introduced in 2007, and therefore represents our more recent patients.

Concluding message

We have demonstrated improving medium term outcomes in our series of men undergoing placement of artificial urinary sphincters compared to contemporary literature. This improvement in complication rates is supplemented by satisfaction outcomes finding only a small proportion of patients who remain wet all the time following surgery, and on average most patients have minimal interference in their lifestyle from post-operative leakage. Modern sphincters are therefore producing good outcomes for our patients, and it is likely that the introduction of inhibizone is a significant factor in the observed improvements. Given our results we will continue to offer AUS insertion as a treatment for men suffering with USI.

References

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2. James, M.H. and McCammon, K.A. (2014). Artificial urinary sphincter for post-prostatectomy incontinence: Int J Urol (epub 16 Feb 2014).

Disclosures

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