

## OUTCOMES OF ARTIFICIAL URINARY SPHINCTER IMPLANTATION IN A POPULATION OF MEN WITH NEUROGENIC URINARY INCONTINENCE.

### Hypothesis / aims of study

The artificial urinary sphincter (AUS) is a treatment option in selected patients with urodynamic stress incontinence, widely-used in post-prostatectomy incontinence (PPI) and neurogenic bladder dysfunction (NBC). NBD represents a complex pathophysiology and may involve additional risk factors for complications. Accordingly, we undertook a retrospective medical record to study the safety and efficacy of AUS in a group of male neurogenic patients in comparison with men with PPI following radical prostatectomy.

### Study design, materials and methods

All men received an American Medical Systems AMS800 AUS, using a single narrow-backed cuff. Pre-operative preparation used a protocol of infection screening, prophylactic antibiotics and skin preparation. Placement was via a two-incision approach for bulbar cuff placement, or lower abdominal incision for bladder neck. Device activation was undertaken three weeks after placement or later. Notes of 158 patients were retrieved; follow up data was available in 116 patients. From the present study 22 patients were excluded due to previous radiation therapy, 12 due to post TURP incontinence and 1 due to post HIFU incontinence. Of the remaining 81 cases, 50 (61%) had a history of radical prostatectomy and 31 (39%) had neurogenic incontinence including spina bifida (20), pelvic fracture (4), spinal cord injury (2), and other causes of NBD (6). Mean age at the time of implantation was 66 years (56-77) for the post prostatectomy group and 37 years (13-70) for the NBD group. Mean follow up was 33 months (1-174) for the post prostatectomy group and 155 months (10-333) for the neurogenic group. The artificial sphincter was placed at the level of bulbar urethra for the post prostatectomy group. In the neurogenic group, the AUS was placed at the bladder neck in 20 patients and at the bulbar urethra in 11 patients. Four NBD patients underwent augmentation cystoplasty prior to the placement of the AUS, and 7 had simultaneous augmentation cystoplasty and cuff placement, with later staged placement of other AUS components according to individual circumstances. Patients were considered continent if they self-reported continence and did not use pads at the last follow up interview.

### Results

At the time of the last follow up 33 PPI patients (64%) and 21 NBD patients (68%) were continent. In the NBD group, four did not need activation or completion of the sphincter to be continent.

Revision was necessary in 4 (8%) prostatectomy patients for a total of 5 (mean 1.3) procedures (4 device failures, 1 infection). In the NBD group, 21 (68%) patients underwent a total of 40 (mean 1.29, range 0-5) revision procedures. 10 NBD patients used ISC to achieve bladder emptying; of these, one developed a false passage, one a mechanical AUS failure and three infection/erosion. Of the 11 patients with prior or concurrent augmentation cystoplasty, 3 used ISC. In the PPI group, three used ISC, one for bladder emptying and two because of outlet stenosis/ stricture.

Six NBD patients developed an AUS erosion or infection; three of these affected bulbar urethral cuffs, three bladder neck. Two of these had a prior or concurrent augmentation cystoplasty. 12 NBD patients had a mechanical failure or fluid loss from the AUS; five of these had bladder neck cuffs.

Two patients in the PPI group developed de novo urgency incontinence. This was not seen in NBD, although four out of 19 NBD patients had detrusor overactivity on pre-operative urodynamic work-up.

### Interpretation of results

The AUS is an established treatment in neurogenic urinary incontinence, which appears to have comparable efficacy rates when compared with its use in PPI. However, there were considerable differences in complication rates, with a high rate of revision surgery in men with NBD. There were not sufficient numbers of patients reviewed to comment on whether ISC or cystoplasty is a risk factor for erosion/ infection or device failure. On the other hand, the longer follow up of the NBD group, might have biased the revision rate. The complication rates appeared similar regardless of whether the AUS cuff was placed at the bladder neck or the bulbar urethra. The two populations differed in terms of mean age, duration of follow up and number of associated surgical procedures.

### Concluding message

The artificial urinary sphincter is as effective for continence control in men with sphincter deficiency due to NBD or PPI. However, the complication and revision rate is considerably higher in neurogenic patients, though the mean follow up duration was substantially longer in the NBD group. Site of AUS cuff placement did not obviously affect outcome in NBD, but a larger study is needed to confirm this conclusion.

### Disclosures

**Funding:** None **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** This is a retrospective review after a surgery included in our standard protocol of treatment of this condition, and considered as an established and a gold standard procedure. **Helsinki:** Yes **Informed Consent:** No