430

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USE OF THE ADJUSTABLE CONTINENCE THERAPY (ACT®) TREATMENT IN PEDIATRICS WITH NEUROGENIC DISORDERS.

Hypothesis / aims of study

Treatment of neurogenically derived stress urinary incontinence in pediatrics is often by major non reversible surgery, which is technically challenging and does not allow for the changing needs of a growing child. Whilst use of the Adjustable Continence Therapy (ACT) device has been well described for urodynamic stress urinary incontinence in male and female adults, we considered that the post operative adjustability may be benefficial in maturing children where long term titration and even reversibility might be of value.

Study design, materials and methods

The ACT device consists of two silicone balloons placed at either side of the bladder neck. Each balloon is attached via a conduit to a post operatively adjustable port buried in the scrotum or labia. We assessed a group of children with neurogenic bladders resulting from a number of causes for implantation of the ACT device. All patients underwent urodynamics at baseline to ascertain bladder function, and incontinence severity based on pad usage or leakage was recorded at baseline and at follow up visits.

<u>Results</u>

To date, 4 males and 2 females aged 10.8 (7-16) years have been implanted with ACT devices and evaluated for 18 months. Causes of incontinence included post myelomeningocele; post spinal cord haemorrhage; bladder extropy and epispadia. Baseline Mean Urethral Closure Pressure was <30 cm in all patients. Mean perioperative time was 66 (20-150) mins with an average length of ACT device being 8 (7-9cm). Mean number of adjustments was 1.8 (range 0-4) with a final balloon volume of 2.9 (1-4cc).

At baseline 3 patients were wearing an average of 7 pads (4-9) per day, with 2 patients completely incontinent. At last follow up, 3 patients were dry (no pads) with one girl requiring oral anticholinergics; one boy required one pad per day and one girl requiring injection of a bulking agent into her stoma. One of the totally incontinent patients was wearing only 3 pads a day with a 100ml capacity bladder and the other remained unchanged.

Interpretation of results

Despite the surgical challenges arising from the various anatomical abnormalities of paediatric neurogenic bladder disorders and the necessity to perform concomitant reconstruction, durable implantation of the ACT device is technically feasible. Bilateral placement of the device can be used either to completely occlude the urethra in the presence of a catheterising stoma or to increase the urethral resistance to avoid leakage where self catheterisation is performed. Implantation of the ACT creates a 'passive sphincter' where no manipulation is required for voiding or bladder emptying with a catheter .Importantly in this group is the ability to post operatively titrate to achieve optimum continence or prevention of urethral leakage. As device removal is easy and without sequale, implantation does not preclude alternative solutions should they be developed in the future.

Concluding message

Implantation of the ACT device in neurogenic paediatric patients is both feasible and effective in the short term. This offers a simple and encouraging solution for this group of patients. We will continue to evaluate these patients over the longer term.

FUNDING: No funding CLINICAL TRIAL REGISTRATION: This clinical trial has not yet been registered in a public clinical trials registry.

HUMAN SUBJECTS: This study was approved by the Udine District and followed the Declaration of Helsinki Informed consent was obtained from the patients.