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A PROSPECTIVE CONTROLLED FOLLOW-UP STUDY FOR THE TREATMENT OF NEUROGENIC STRESS URINARY INCONTINENCE RELATED TO INTRINSIC SPHINCTER DEFICIENCY WITH ACT™ BALLOONS (ADJUSTABLE CONTINENCE THERAPY)

Hypothesis / aims of study

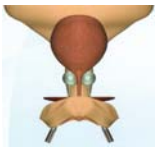
The treatment of neurogenic stress urinary incontinence related to Intrinsic Sphincter Deficiency (ISD) remains a therapeutic challenge. Conventional treatments (artificial urinary sphincter, bulking agents) may not be used because of the use of self clean intermittent catheterisation or lack of efficacy. ACT™ balloons have been able to treat SUI incontinence for non neurogenic challenging patients (1). This study has been designed to evaluate treatment of neurogenic ISD with ACT™ (Adjustable Continence Therapy) balloons.

Study design, materials and methods

The study was a monocentric prospective follow-up study that has been conducted in patients with stress urinary incontinence (SUI) related to neurogenic ISD. Study started November 2001 and patients have been included until July 2004 to obtain at least 1 year follow-up (study still running). The vast majority of the patients used Self Clean Intermittent Catheterization (SCIC). All patients suffered SUI and bladder management was done to ensure there was no urge incontinence associated. All patients were candidates for major surgery for SUI, depending on disease, handicap and local urethral feasibility of other treatments. All patients had to sign informed consent.

The ACT™ system is a minimally invasive periurethral prosthesis implanted via a percutaneous perineal approach. It consists of two silicone balloons (filled with sterile saline or isotonic contrast media) placed on either side of the urethra in female (Figure 1). For male patients balloons were placed at the prostatic apex, or vesico-urethral anastomosis level if patient has been previously operated on for radical prostatectomy. The balloon is filled with fluid via tubing connected by a conduit to a readily accessible titanium port implanted close to the surface of the labia majora or scrotum. Access to the port allows for post-operative adjustability with little discomfort for the patient and a quick convenient procedure for the doctor.

Figure 1



Analysis criteria were:

- technical feasibility
- tolerability
- efficiency (patient self assessment of urine leakage)

Results

Fifteen (12 female and 3 male) consecutive patients were included. The mean age at surgery was 51,9 years. Etiology of neurologic disease was spinal cord injury (6: 2 infra-sacral lesions, 3 medullaris conus and 1 cervical), congenital (2), spinal cord vascular disease (3), multiple sclerosis (1) and other (3). Mean duration time since neurogenic disease was 15 years (1 to 54 y.) All except 1 patient was using SCIC. Vesical status was controlled with anticholinergic therapy alone (6), Botox® injections (with or without anticholinergic therapy) (2), passed enterocystoplasty (4), none (3). All patients have been urodynamically checked and routinely controlled. No patient was anymore candidate for sling (female patients) because of pure ISD.

Eighteen implantations (including 3 revisions) rated ‘mild’ were performed in 15 patients under local anesthesia (72,2%), non (22,2%) or under general anesthesia (5,5 %). The average number of adjustments was 1,06 adjustment per patient (range 0 to 3). The mean initial balloon volume was 2.2 ml (1,8 – 3,5) and the mean final volume was 3.6 ml (2 – 9). No major complication has been described during the procedure which has been done as an ambulatory procedure depending on the patients request (75%).

Continence was evaluated through patient self report using voiding diary. Seven were totally dry not using any more pad (46%), 6 improved (not requesting any more treatment and/or filling)(40%), 2 were failure leading to artificial urinary sphincter (male patient) and cutaneous cystostomy with bladder neck closure (female patient suffering sequelae of passed indwelling catheter).

Eight implanted devices (/30) have been explanted in 5 patients because of erosion (6), device failure (1) and treatment failure (1). Three patients on five have been treated again with ACT balloons, 1 still waiting for re-implantation. Out of the three patients who were re-implanted, 2 are dry and significantly improved.

No patient complained about sub-cutaneous port.

Interpretation of results

The ACT balloons have been able to treat SUI neurogenic incontinence in 86% of our population. Mechanism of action of ACT™ balloons can be described as a compressive effect (male and female) on urethra associated to a bladder neck support in female. The pure and severe neurogenic ISD is such a way able to be treated provided that patients are able to perform SCIC (14/15 in our population). Opposite to artificial urinary sphincter, this device does not request any manipulation before SCIC. As no available bulking agent has been able to cure such neurogenic patients, this technique should be of great interest as an easy to perform urinary incontinence treatment to improve quality of life (not studied here) of such disabled patients. Erosion rate seems to be higher that for non neurogenic patients (1) but should decrease taking care of learning curve of implantation and standardized prophylactic antibiotics and local skin preparation that has to be defined for such patients.

Concluding message

ACT balloons could be part of armentarium of SUI neurogenic incontinence provided that patients are informed of a higher rate of erosions that do not contraindicate new implantation.

(1) Results (median 1 year) of a French, multicentric, prospective clinical investigation of ACT™ (adjustable continence therapy) balloons for treatment of stress urinary incontinence (SUI) due to intrinsic sphincter deficiency in female, Eur Urol Suppl 4 (2005) N°3(4):121