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THE ADJUSTABLE CONTINENCE THERAPY FOR THE TREATMENT OF RECURRENT FEMALE URODYNAMIC STRESS URINARY INCONTINENCE- 4 YEAR RESULTS

Hypothesis / aims of study

Treatment of symptoms caused by Intrinsic Sphincter Deficiency (ISD) may be inadequately addressed when minimally invasive treatment options effective only in the management of urethral hypermobility are utilized. This component of Urodynamic Stress Urinary Incontinence is now more easily differentiated from it's counterpart, urethral hypermobility due to the increased adoption of the use of Valsalva leak point pressure (VLPP) as a diagnostic tool. It is therefore important to correctly diagnose specifically treat the ISD component. The Adjustable Continence Therapy (ACT®) was developed with the aim of increasing urethral coaptation in those patients with ISD. We evaluated the safety of the procedure and assessed its efficacy over time in our centre.

Study design, materials and methods

The ACT device consists of two silicone elastomer balloons placed para-urethrally in the vesico vaginal space at the level of bladder neck, each being attached to an injectable titanium port placed in the labia majora, enabling postoperative adjustment.
We evaluated this device in a prospective open study. Selection criteria included female adults with a diagnosis of Urodynamic Stress Incontinence and ISD (VLPP < 60cm H20 and MUCP <20cm H20). Patients were excluded if they presented with detrusor overactivity refractory to medication; reduced bladder compliance; residual volume ≥ 100 mL; (suspected) bladder anomalies; bleeding disorder, diabetes mellitus; active urinary tract infection; uncorrected grade II or more prolapse.
Patients were evaluated using daily pad count; Incontinence Quality of Life (IQOL) questionnaire and Visual Analogue Score (VAS) at baseline and in the early follow up period and then at 12, 24, 36 and 48 months. Furthermore complications were recorded at each time point.

Results

Fifty six patients, mean ages 62.59 (range15-86) years, were implanted with ACT and evaluated with a mean follow up of 42.1 months (range 11- 83). All patients had undergone at least one previous pelvic surgery. Operative time was 20.3 mins (range 10-30 mins) with minimal blood loss. No postoperative analgesia was required and all patients were able to void within 24 hours.

	Pre(n=56)	**12month (n=50)**	**24month (n=39)**	**36month (n=31)**	**48month (n=26)**
IQoL	46	83	84	89	91
Pads	5.5	1.1	1	0.6	0.4
VAS		78%	84%	86%	85%

There was a statistically significant increase in Quality of Life and pad usage with 29/50 (58%) patients completely dry, 12/50 (24%) significantly improved, and 9/50 (18%) remaining unchanged at last observed follow-up.
Eighteen patients (32.1%) did not require any post operative adjustments. The remainder required singular or multiple adjustments (range 1-11).
Complications were noted at each time point. Labial haematomas observed in 3 pre menopausal patients within 24 hours of implantation spontaneously reabsorbed without intervention. None of these patients reported any deterioration in sexual function post operatively.
Device removal resulted from migration seen in 6/56 (12%) patients and urethral erosion in 1/56 (1.7%) patient. Additionally, 3/112 (2.1%) balloons were explanted due to device failure. Of these, 1(0.6%) balloon deflated after one month with 5.5cc. The other two balloons failed at 3 years, one containing 6cc and the other with 2cc. In total, 12 balloons (10%) were removed in 10 (20%) patients with only 2 (4%) patients requiring bilateral removal. Five balloons in 5 patients were reimplanted 6 weeks after removal. 2 out 5 patients became dry (no pads), 2 were significantly improved (< 1 pad a day) and 1 was unchanged. Five patients did not undergo reimplantation of which 1 patient is continent with 1 balloon, One patient improved and another remained unchanged following prescription of anticholinergic medication. Two patients refused any further treatment.
Two (4%) patients had portal erosions due to poor positioning. The ports were successfully cleaned with antibiotic flush, repositioned and the incision was resutured without any further problem. Pre operative sensory urgency seen in 7 (.3%) patients was unresolved post operatively. Furthermore 6 (10.7%) patients reported denovo urgency post ACT implantation and appeared to be proportionally related to balloon volume. However, in all 6 patients this was transient and resolved within 3 months without the need for anticholinergic medication.

Interpretation of results

The minimal dissection required for insertion of the balloons makes this an ideal technique for the management of patients who have failed previous incontinence surgeries and present with existing autologous or heterologous material. The ability to post operatively adjust according to the individual patients needs seems to be beneficial in managing patients continence needs long term.

Concluding message

Implantation of the ACT balloons for the treatment of ISD is both safe and effective. We will continue to follow up our patients, and are further examining the benefits of this device in sub sets of patients to better determine optimal patient selection.

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Ospedale Maggiore della Carità Novara EC**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**