

PREDICTIVE FACTORS FOR SUCCESSFUL OUTCOMES FOLLOWING IMPLANTATION OF VOLUME ADJUSTED BALLOONS.

Hypothesis / aims of study

The use of the Adjustable Continence Therapy (ACT) has been described for the treatment of intractable Urodynamic Stress Urinary Incontinence in females and for the treatment of post Prostatectomy incontinence in males. Given its further application for various aetiologies and anatomical differences, we determined to evaluate ideal balloon placement and establish an optimal patient selection.

Study design, materials and methods

The ACT device consists of two silicone balloons placed on either side of the bladder neck each attached via a conduit to a titanium port placed subcutaneously in the labia or the scrotum enabling post operative balloon adjustment. We reviewed the outcomes of our previously conducted male and female ACT efficacy studies. The results were reviewed noting post operative changes from baseline including urodynamics; quality of life assessment using IQOL questionnaire and daily pad count. Balloon volume and number of adjustments as well as adverse events were also noted. Correlation between each of the parameters was statistically analysed.

Furthermore, we evaluated our MRI study which had been conducted pre and post operatively on females implanted with ACT, to ascertain the importance of accurate balloon placement. In this imaging study, investigation included MRI (Magnetic Resonance Imaging); Ultra-sound evaluation and Retrograde Cystography at baseline and 12 months to compare the position of the bladder neck and the location of implanted ACT devices.

Results

In the 49 females, all patients had previously undergone pelvic or anti incontinence surgery. There was a significant improvement in Quality of life and pad usage from baseline. We performed a multivariate analysis considering dependent and independent variables.

We found a meaningful statistical correlation between % improvement and VLPP but determined no statistical relationship between any of the other dependent or independent variables. We noted that the higher the VLPP the better the response produced. A baseline VLPP of 10cm H₂O correlated with less than 50% improvement, whereas a baseline of 70cm H₂O facilitated an improvement of 90% (p=0.028). At 30cm H₂O a 70% improvement was still achievable. A strong correlation was shown in those patients stratified at baseline with a VLPP of between 30cm and 60cm H₂O with a significant improvement of 70% or greater (p=0.00176; CI 95%) based on both pad usage and reported change in I-QoL. We also noted that incidence of pre operative urge incontinence (p=0.8) and baseline Mean Urethral Closure pressure (p=0.77); initial and adjusted balloon volume (p=0.43) and the number of adjustments (0.84) bore no relation to immediate post operative continence.

In the male cohort implanted with ACT, there was an inverse linear correlation between baseline VLPP and the patient overall impression which was directly proportional to early post operative continence (within 24 hours) and the number of adjustments. Similarly, there was a linear correlation between IQOL and the mean balloon volume.

There was no correlation between baseline MUCP and any of the other outcome parameters.

Within this cohort, 11 patients had previously undergone external beam radiotherapy, which impacted on the rate of success in this group, with only 57% reported as being dry or improved (less than 1 pad per day) versus 77% in the non irradiated group. Additionally, erosion resulting in balloon explanation occurred exclusively in the irradiated group.

Of the 25 females who underwent MRI testing, 2 (84%) improved their continence after treatment, comprising of complete (16 patients - 64%) or partial response (5 – 20%). All of the 21 responsive patients demonstrated a reduction of bladder hypermobility and descent under maximum strain. However, those patients with greater bladder neck descent at baseline were less likely to respond as significantly.

Symmetrical positioning of the two balloons did not necessarily result in a guaranteed functional efficacy. Many patients with positional balloon asymmetry were continent following treatment.

There was a crucial relationship between balloon position with respect to the bladder neck and urethra. The two balloons provide a bulking effect on the proximal urethra. Additionally, as a result of the close relationship between the balloons and the cervico-urethral complex when ideally positioned, they also provide a stabilisation of the bladder neck during sudden increases in the intra abdominal pressure, preventing its descent.

In the images obtained at the 12-month follow-up, an encapsulation of the balloons by a 'pseudo-capsule' of fibrotic tissue was seen. This was not excessive and did not interfere with bladder emptying, but as seen in the case of one deflated balloon in a continent patient may serve to enhance stabilisation.

Interpretation of results

The Adjustable Continence Therapy can provide continence in women diagnosed with ISD and success of 70% or more can be reliably predicted in those patients with a baseline VLPP of 30cm H₂O with or without hypermobility. In males, an early improvement was a predictor of success, and can be further enhanced with balloon titration. Cautious management of post radiotherapy patients should be practiced to avoid the increased risk of possible complications. Symmetrical placement was not essential to good outcome.

Concluding message

Based on the improvement in continence in both the males and females assessed in our series, and given the ability to consistently place the balloons in an acceptable position, it is feasible to suggest the further evaluation of the ACT device for the treatment of urodynamic stress urinary incontinence arising from other aetiologies.

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HUMAN SUBJECTS: This study did not need ethical approval because This was a review of studies previously performed and approved by EC but followed the Declaration of Helsinki Informed consent was obtained from the patients.