Original article

Anatomical basis for effective placement of adjustable continence therapy (ACT®) balloons for treatment of female stress urinary incontinence

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Abstract: A peri-urethrally implanted prosthetic, the adjustable continence therapy device (ACT®) has been developed for female Intrinsic Sphincter Deficiency (ISD). We aimed to reproduce in cadaveric dissections the recommended ACT placement and determine the exact relationship of this implant to the relevant internal pelvic anatomy and identify the anatomical location of the balloons in order to facilitate consistent clinical outcomes. Six hemi-pelves from post menopausal female cadavers were dissected after standardised insertion of 6 ACT balloons which were variously inflated to determine the best initial filling volume and to observe potential damage to the endopelvic fascia or the pelvic floor. Bilateral placement and expansion of the balloons at the posterolateral aspect of the vesico-urethral junction prevents downwards, lateral or posterior displacement. The endo-pelvic fascia forms the roof of the space with the vaginal wall acting as a barrier to movement. The floor is composed of the urogenital membrane which must be pierced by the trocar to permit successful placement. Rapid balloon expansion was associated with rupture of the overlying endopelvic fascia highlighting the importance of the slow expansion recommended by the manufacturer. Implantation of the ACT can be safely achieved through a thorough understanding of pelvic anatomy, and by maintaining full thickness between the surgeons' finger and the insertion instrument. Care should be exercised to correctly orientate the insertion instrument, to avoid any unintended trauma to normal structures.

Key words: Cadaveric dissection; Adjustable balloons; Incontinence.

INTRODUCTION

Treatment of stress urinary incontinence is an imperfect science often met with varying degrees of over-correction leading to the eventual development of urgency, frequency and urge-incontinence, or under-correction resulting in inadequate control of the stress-induced urinary leakage. The underlying tissues occur in a dynamic milieu, the changes associated with ageing and menopause also affecting urinary control and therefore the apparent outcome of a surgical intervention.

Although slings, both synthetic and autologous have become highly popular, and Burch colposuspension continues to enjoy favour as a "gold standard" many women remain incontinent despite a well executed operation. Whilst the cause in some cases is urethral obstruction leading to bladder overactivity, in a small proportion sphincteric incontinence remains. Sling procedures and less so the Burch colposuspension enjoy a reputation for very low morbidity. Despite that, efforts continue to develop procedures with even lower morbidity and mortality should be close to zero. The trans obturator approach is one strategy that avoids placement of trocars in the retropubic space or abdomen. It is relatively new and potentially associated with thigh related complications that have not occurred previously with slings.

Transurethral and periurethral injections continue to be a minimally morbid option, some clinicians offering this under local anaesthetic.[1] Regardless of the agent used all injection techniques to some extent are associated with a tendency for the need to reinject, some of the agent being absorbed or phagocytosed over time.

Because of the possibilities of having refractory intrinsic sphincter deficiency or developing recurrent stress incontinence, adjustable continence therapy (ACT) seems a logical approach. In this way an inert, minimally invasive approach is used which avoids access to the abdominal cavity or retropubic space. It is possible to add more fluid to the balloons to improve urethral closure further if ISD persists. Furthermore if urethral obstruction results, it is always possible to withdraw some of the fluid without significant morbidity or risk.

A number of prototypes were implanted into 4 female cadavers to establish the most efficient and reproducible placement with the aid of insertion trocars. Further to this, initial pilot studies in Brazil[2] and Germany[3] were performed to ascertain safety and efficacy of balloon placement at the bladder neck. Once mastered, the procedure is quick to perform, involves only a small peri-labial incision and can be done in high-risk patients.

Magnetic resonance studies conducted in 15 patients before and after implantation of ACT demonstrated that the lower the bladder neck mobility under maximum strain the better the clinical response. Statistical analysis showed that before treatment the mean pubococcygeal to bladder neck distance were significantly different in the patients who become dry after the surgery and those who did not respond. In the patients who failed the surgery the mean excursion of the bladder neck and the pubococcygeal line was 35.35 mm while in the patients who become dry after the surgery the mean distance was 14.92 mm ($p<0.01$). The best clinical outcomes therefore were obtained in patients with an open bladder neck without urethral hypermobility. Correlation between MRI studies and clinical outcome led to the development of our current technique. The technique recommended for ACT® balloon insertion involves cystoscopic and fluoroscopic guidance as well as intra-operative palpation. The exact structures traversed and the anatomical basis for what has proven clinically to be an optimal insertion strategy was unclear. Thus we aimed to study in a series of cadavers exactly what the trocar passes through and determine the anatomical correlates of the technique that has been associated with the best clinical performance.[4]

MATERIALS AND METHODS

From experience gained through clinical and radiographic studies, we determined the anatomical basis for the current recommendations for the surgical placement of the balloon prosthetic device for genuine stress urinary incontinence in females.[1] Detailed dissections were conducted in six hemipelves in three fresh post-menopausal cadavers after inserting the adjustable continent therapy (ACT®) balloon device in the way proposed. All cadavers had macroscopically

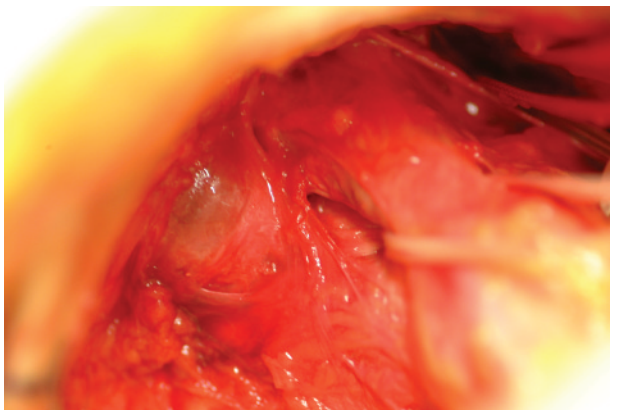

Fig. 1. – Image showing the balloons in relation to the deep perineal membrane, the deep transverse perineal muscle and the transverse perineal ligament, which originates from the medial fibres of the deep transverse perineal muscle where they attach to the lateral urethral wall.

normal gross anatomy. All hemi-pelves were dissected with the focus of the dissection being to determine the best orientation of inserting the instrument to obtain the preferred balloon location so as to achieve predictable support at the vesico-urethral junction. In the third cadaver (two hemi-pelves) the technique was repeated and further dissection was performed to establish whether the desired clinical placement was associated with unintended disruption of the clitoris and the related structures. Assessment of the positioning of the ACT® devices was made following the exposure of these critical structures. Measurements and photographic recordings were made at each dissection.

A standardised technique was used to place the ACT balloon device in each hemi-pelvis. This technique involves the following steps.

A Foley catheter is inserted into the bladder and the catheter's balloon inflated with 10 ml of water to allow us a better identification of the bladder neck. Placement of the ACT balloon is facilitated by the creation of a channel using a special trocar which consists of two parts: a U shaped channel and a stylet. A small (1 cm) incision is made at the level of labial sulcus below the urethral meatus. The trocar is inserted trough the incision and directed toward the bladder neck. Using digital vaginal palpation, the trocar is directed through the incision, perforating the pelvic floor towards the proximal urethra and the bladder neck. Once the tip of the trocar is at the bladder neck, the stylet is removed leaving the cannula in place.

The ACT balloon was inserted into the U shaped cannula using a pre loaded guide wire as a pusher. The balloon was filled with 1-3 cc of water to stabilise its position.

The adjustable continence therapy (ACT®) device consists of a silicone elastomer balloon connected via a two-lumen extrusion to a silicone encased titanium port, to facilitate postoperative fluid volume manipulation. On each side an ACT balloon was implanted at the level of the bladder neck. The injection ports were placed under the fat of the labia majora. Typically, such implantation is achieved using both tactile surgical skills and visualization provided by an image intensifier. However for the purposes of these studies, the implantations were conducted using tactile skills only without using the image intensifier. A definite "give" is experienced as the trocar pierces the urogenital diaphragm. This sensation is a necessary part of the operative technique.

Following the insertion of the ACT® balloon device, each retropubic space was exposed through a lower midline abdominal incision and the endopelvic fascia was cleared of all the fatty tissue to expose the location of the implanted balloon devices. The endopelvic fascia was then detached from the lateral pelvic side-wall and reflected medially. The vesicourethral junction and the balloons were exposed and their mutual relationship and the relationship to the surrounding structures were studied. The balloon devices were mobilised from above to visualise the levator ani exposing the urogenital diaphragm and pubourethral ligaments (Fig. 1).

RESULTS

In each hemi-pelvis, balloon deployment resulted in a definitive position of the balloons in the space wedged between the endopelvic fascia and the urogenital diaphragm, posterolateral to the bladder neck. This placement appears to trap the device in a confined space that then limits balloon movement in the event of movement of the trocar. When the balloon is in this location trocar movement is not associated with downward, lateral or posterior movement of the balloon. In each simulation, placement of the device was associated with full thickness preservation of the vaginal wall. Where the trocar punctures the urogenital diaphragm the vaginal wall abuts the clitoral bulb. The vaginal wall is fused to the urogenital diaphragm and in fact appears to be one and the same structure at the lateral edge of the clitoral bulb. A "safe" area exists laterally between the inferior edge of the crus of the clitoris and the lateral aspect of the vestibular bulb, forming a small 'indentation' just inferior to the ischial pubic rami. This area is on the labial side of the vaginal wall.[5]

In the third of the six hemi-pelves studied, where we intentionally inflated the balloons with 3 cc), the balloons were found to be projecting up into the retropubic space having partly ruptured the overlying endopelvic fascia. We believe rapid inflation (in this case 3.5 cc over a few seconds may have been too much for this space to immediately accomodate. This was found to have altered the critical spatial relationship between the balloon and the bladder neck (Fig. 2). In order to avoid such unintended balloon migration through the endopelvic fascia, only small volumes (1-2 ml) should be injected into the balloons both at the time of initial implantation and the subsequent incremental inflations if and when required.

Study in the final two hemi-pelves confirmed that introduction of the trocar paraurethrally, parallel to the urethra through the midpoint of the cleft between the labia majora and minora is relatively safe, sparing the bulb and crus of the

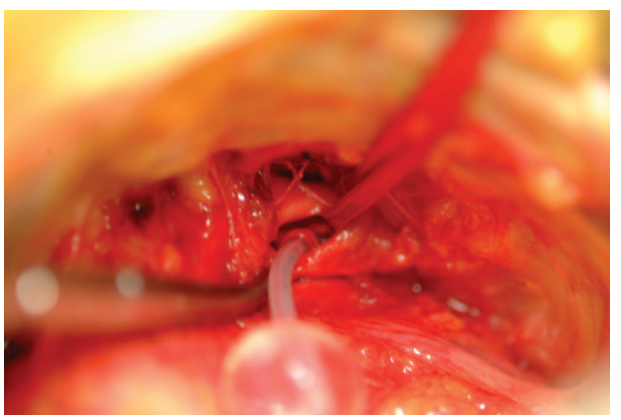

Fig. 2. – Image showing the balloons in relation to the endopelvic fascia, with one of the balloons having migrated ventrally so as to be now located in the fatty tissue above the endopelvic fascia, altering the critical spatial relationship between the balloon and the bladder neck.

clitoris and the major divisions of the pudendal neurovascular bundle from damage.

DISCUSSION

The introduction of a new modality of operative treatment requires careful anatomic examination and consideration of the potential effects upon local tissues. This newly proposed implant demands tactile surgical skills due to the dedicated instrumentation, which delivers this implant to the desired area of the pelvis via a low morbidity perineal approach. Although the progress of the metallic insertion instrument can be monitored by use of an image intensifier (C-Arm), several other skills must be simultaneously employed to ensure accurate placement of the prosthesis. The most important skill remains the surgeon's ability to conceptualize the internal anatomy structures. Additionally, an ability to assess the progress of the insertion instrument tactilely through the vaginal wall as it is moved towards the bladder neck and towards the desired area of implantation is paramount. Possible anatomical variants an individual patient may present with and any past surgical interventions may impede optimal placement.

This study demonstrates that the technique which has been associated with good results clinically makes anatomic sense. The balloons ultimately reach a location where their stability is enhanced by the limits of the space into which they will expand. Migration from the para-bladder neck position is detrimental to desired clinical outcome. Presumably with time, the position of the balloons is further stabilised by the development of pseudo-capsule formation around the prosthesis.

In order to fully appreciate the relevant anatomy, the potential pitfalls and the possible implications of utilizing deep insertion of instruments into the pelvis in a 'semi-blind' manner, it is important to thoroughly examine both internal and external anatomy, with the addition of this form of instrumentation. Cadaveric dissection provides an opportunity to examine and understand the immediate and potential long-term consequences of instrumentation and delivery of implantable materials to targeted anatomical areas. Ideally cadavers of varying age could be studied. A limitation of this study is that only elderly cadavers have been examined.

These cadaveric dissections have demonstrated consistent placement of adjustable periurethral balloons for the treatment of stress incontinence. Via small incisions at the sulcus of the labia majora and labia minora, at the level of the mid vaginal introital point it has been possible to position and expand the balloons within a relatively immobile location associated with favourable clinical outcomes. That location has been demonstrated in this study to be posteror-lateral to the bladder neck and proximal urethra between the endopelvic fascia and urogenital diaphragm whilst keeping the vaginal wall intact.

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