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USE OF ADJUSTABLE CONTINENCE THERAPY IN THE SPINAL CORD INJURED POPULATION: NEW APPLICATION FOR AN EVOLVING INCONTINENCE DEVICE

Hypothesis / aims of study

Quality bladder management within the spinal cord injury (SCI) population is imperative to ensure overall health both short and long term. Renal failure was the leading cause of death for these individuals prior to improved understanding of altered physiology post injury. Today bladder dysfunction continues to impact on both morbidity and quality of life.

Patients with low thoracic or lumbar injuries may experience stress urinary incontinence due to an incompetent sphincter mechanism and lack of pelvic floor muscle support. Existing management options include periurethral bulking agents, artificial urinary sphincter (AUS) or bladder neck closure. Periurethral bulking agents are not durable; AUS is associated with a high revision and explantation rate due to infection, erosion or mechanical failure (1). Bladder neck closure is an irreversible procedure and prevents later urethral access to the bladder. The aim of this study is to evaluate the efficacy of a durable, minimally invasive and adjustable continence therapy, the ProACT balloon device, for these patients.

The ProACT device consists of two silicone balloons attached via tubing to a titanium port (fig 1). These balloons are positioned via the perineum under radiological guidance to sit adjacent to the prostatic apex. The port is sited subcutaneously within the scrotum allowing percutaneous adjustment of balloon volume after surgery in an outpatient setting.

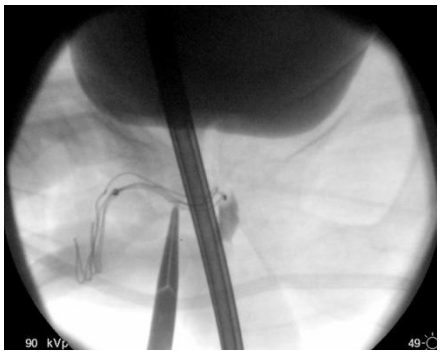
Figure 1: Serial inflation of the ProACT device

To date numerous studies have reported the ProACT balloon to be an acceptable alternative therapy for post prostatectomy incontinence (2, 3). This is the first study to our knowledge reporting outcomes of this device in the SCI population.

Study design, materials and methods

We report our initial prospective experience of the ProACT device in three SCI patients. All patients had urodynamic proven stress urinary incontinence and were wearing pads to manage their incontinence. No patient had previous anti-incontinence surgery, urethral stricture disease, active urinary tract infection, bladder pathology or bleeding disorder.

Preoperative procedures included a detailed bladder management assessment, medical history and physical examination. Video-urodynamic (VUD) was performed to assess bladder function and abdominal leak point pressure (ALPP).



All devices were implanted under a general anaesthetic. Rigid cystoscopy was performed initially and the cystoscopy sheath left in place. The bladder was then filled with 200mls of radiographic contrast medium. A transverse incision was made in the perineum and next a haemostat was used to puncture the pelvic floor and create a

Figure 2: Creation of paraurethral tract

A specifically designed trochar was then used to facilitate correct balloon placement under image intensifier guidance. Subsequently the balloons were filled with 0.5mls contrast (fig 3).

After bilateral placement a cystoscopy was again performed to ensure no bladder or urethral injury. An indwelling catheter was placed at the end of the procedure and removed the following morning.

Figure 3: Fluoroscopic image of balloons in place

Results

The patient demographics are demonstrated in the following table.

Characteristic	*Patient 1*	*Patient 2*	*Patient 3*
Age (years)	53	52	32
Level of Injury	L1	T10/11	T12
Interval since injury (months)	252	34	13
ASIA score	A	A	A
Present bladder management	CISC 4x/day with pads	CISC 5x/day with pads	CISC 4x/day with pads
Length of follow up (months)	17	17	5

Table 1: Patient Demographics

At time of urodynamics all patients had stable bladders with filling up to 600mls. End filling pressures were less than 15cm H_2O. ALPP were 65, 55 and 40 cm H_2O for patients 1, 2 and 3 as above respectively. Imaging in all patients revealed an open bladder neck and leakage past the external sphincter. No patient could void.

No adverse events occurred intra operatively. There have been no problems with infection, device failure, migration or denovo urgency during the follow up period.

All patients have improved continence post operatively. During the follow up period two patients have required two adjustments and one patient required only one adjustment. At each adjustment 0.5-1.5 ml extra volume was added bilaterally to each balloon.

One patient is completely dry and requires no pads. Two patients are now dry overnight and require one pad per day for leakage during transfers and activities. Subjectively these patients have all reported an improved quality of life.

Interpretation of results

We believe these early results are encouraging for the ongoing evaluation and use of this device in spinal cord injury patients.

Concluding message

These patients have been selected with the characteristics of a low pressure normal volume stable bladder with normal anatomy within the bladder neck and prostatic region and willingness to intermittently self catheterise. Further patient numbers and longer term follow up will be required to better evaluate the safety and efficacy of this implant.

References

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Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require eithics committee approval because	**.Ethics committee approval was not required as designated by regional guidelines**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**