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ADJUSTABLE CONTINENCE THERAPY FOR THE TREATMENT OF MALE URODYNAMIC STRESS URINARY INCONTINENCE – SINGLE CENTRE STUDY.

Hypothesis / aims of study

Post Radical Prostatectomy is an under reported condition affecting quality of life in a group of patients who have already undergone extreme medical duress. As the degree of incontinence varies greatly between patients, the surgical treatment needs to be tailored to suit the individuals needs. The ProACT™ (Adjustable Continence Therapy) is a minimally invasive surgical technique for the treatment of male stress urinary incontinence which can be post operatively adjusted as required. We have used this as a treatment for post radical prostatectomy incontinence, and we aimed to evaluate the efficacy of this device and the merit of it's adjustability over time.

Study design, materials and methods

The ProACT device consists of two opposing silicone balloons implanted para urethrally at the bladder neck, each connected to a titanium port situated in the scrotum to enable post operative adjustments. Patients enrolled in this prospective single arm study underwent baseline urodynamic examination to confirm Intrinsic Sphincter Deficiency in the absence of detrusor overactivity. Efficacy was determined by daily pad count (0-1 "safety pad" -dry, 2 or more pads but decreased > 50% -improved, 2 or more pads but decreased < 50% - failure); Quality of Life questionnaires (I-QOL ,Wagner, Urology 1996); overall patient impression based on a global assessment score (PGI) questionnaire (1 to 7 from extremely better to extremely worst) and Visual Analogical Scale (VAS 0-100%) performed at baseline and 6, 12, 24, 36 and 48 months. Additionally, operative details, adverse events, number of adjustments and balloon volumes were recorded at each of the post operative visits. Mean Urethral Closure Pressures were measured at baseline and then post operatively following final adjustment.

Results

65 males with post radical prostatectomy incontinence have undergone ProACT implantation since April 2000. Operative time was 19 minutes (range10-35) with less than 20mls of blood loss. Analgesia was not required post operatively and all patients could be discharged following spontaneous voiding within 2.1 days. (1-4). Foley urethral catheters were retained for 4 days (range 3-5) where operative bladder perforation had occurred.

Mean follow up was 19.51 months (range 12-62) with all patients having longer than 12 months follow up. Post operatively, daily pad count showed 44 patients to be dry (68%), 10 pts improved (16%) and a further 14% unchanged. The post operative PGI questionnaire showed 42 pts (65%) extremely improved, 10 pts (16%) very improved, 6 pts (9%) slightly improved. Overall improvement was 80%.

	IQOL	Standard Deviation	P value	Pad Usage	Standard Deviation	P value
Baseline (n=65)	31.7			5.2		
1 month (n=65)	40.5	21.09	0.000063	3.55	3.29	0.000037
3 month (n=65)	51.3	23.8	0.00000	2.45	3.15	0.00000
6 months (n=65)	62.5	25.7	0.00000	2.01	2.83	0.00000
12 months (n=65)	71.1	23.89	0.00000	1.54	3.01	0.00000
24 months (n=22)	69.9	23.11	0.00000	1.14	2.85	0.000001
36 months (n=8)	74.8	10.9	0.00001	0.62	3.10	0.00612
48 months (n=7)	63.42	25.9	0.01	0.28	2.65	0.002452

Adjustments were required in 61 (95%) patients, with a median 3 (range 0-8) adjustments being required. Final balloon volume was 3.1mls (range 1-8).

Complications necessitating balloon explant occurred in eleven patients (17%) including 2 bilateral and 9 unilateral removals. Explant was required as a result of erosion (5/65), infection (2), migration (2) and balloon failure (2). Ten patients were subsequently reimplanted at least 6 weeks later. 2/10 became dry, 6 improved (one underwear liner) and 2 were unchanged. No patients were worse following reimplantation. Eleven patients had previously undergone external beam radiotherapy prior to balloon implantation. Four (33.3%) were dry following adjustment. Two (24%) were improved and 5/11 (42.7%) were unchanged at last follow up. Three of these patients required removal of single balloons due to erosion which occurred primarily within the first 6 months. Three patients had pre existent sensory urgency with 4 denovo cases reported. All 7 patients had resolution of symptoms following anticholinergic therapy within one month of surgery.

Interpretation of results

The implantation procedure is easy to perform and reverse if necessary. This feature was of particular significance in the radiotherapy group. The results demonstrate a reduction in pad usage and improvement in Quality of Life. The ability to post operatively titrate was of great benefit, and as shown by the numbers of adjustments performed was a well utilised feature.

ProACT is considered as a first line surgical therapy in our practise, and we will continue to further evaluate the long term outcomes of our already implanted males.

Concluding message

The Pro ACT is a minimally invasive surgical therapy for the treatment of male stress urinary incontinence, which is efficacious at 2 years with a low rate of complications.

Medium term continence can be successfully managed in this group of patients due to the ease of initial implantation and the ability to post operatively adjust as individually required.

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HUMAN SUBJECTS: This study was approved by the 3359 Novara Institutional Review Board and followed the Declaration of Helsinki Informed consent was obtained from the patients.