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EVALUATION OF THE PERIURETHRAL ADJUSTABLE CONTINENCE THERAPY (ACT() DEVICE FOR THE TREATMENT OF POST PROSTATECTOMY INCONTINENCE: PRELIMINARY RESULTS

Aims of Study

Post Prostatectomy stress urinary incontinence can be debilitating and is generally under-reported by both physicians and patients. The injection of bulking agents may not always provide sufficient coaptation of the urethra and placement of an artificial urinary sphincter requires surgical intervention and further requires the patient to have a level of manual dexterity. The Adjustable Continence Therapy (ProACT™) device has been designed to provide extrinsic compression of the membraneous urethra. It consists of two contralateral balloons each placed periurethrally, and attached via a conduit to a subcutaneous port placed in the scrotum. This enables postoperative balloon adjustment. We aimed to assess the efficacy of this device in the treatment of post-prostatectomy incontinence.

Methods

15 post radical prostatectomy (8 perineal and 7 retropubic) and 6 post transurethral prostatic resection or enucleation patients have been enrolled and treated to date. Subjective and Objective parameters including the Incontinence Quality of Life questionnaire (I-QoL) and pad usage were measured at baseline and followed up at 1, 3, 6 and 12 month intervals. Urodynamics studies were conducted at Baseline and repeated at 6 months. Perioperative data, number and volume of adjustments and adverse events were also recorded.

Results

There were no difficulties encountered with balloon placement and there were no perioperative complications. I–QoL scores increased from a mean of 52.67 (13.06- 94.03) at baseline (n=21) to 68.93 (32.95 - 94.3) at 1 month (n=21), 73.26 (18.2 - 98.9) at 3 months (n=16), 76.13 (29.5 - 96.6) at 6 months (n=15), and 89.17 (86.4 - 92) at 12 months (n=6), representing a significant improvement. Pad usage dropped from a mean of 2.8 (0 – 12) at baseline (n=21) to 1.8 (0 – 6) at 1 month (n=21), 1.5 (0 – 5) at 3 months (n=16), 0.54 (0 – 4) at 6 months (n=16) and 0.12 (0 - 0.5) at 12 months (n=6). At 3 months, 9 out of 16 patients required a one-time balloon adjustment and 4 out of 16 required a secondary or tertiary adjustment. By 6 months, only 3 patients required an additional adjustment. 1 patient did not require any post-operative adjustment. Two patients did not respond, and had their devices removed in the clinic. Baseline Visual Stress Testing showed 13 / 19 patients demonstrated moderate leakage and 6 / 19 severely leaked, whilst only 1 / 4 reported mild leakage and 3 / 4 reported no leakage at 6 months. Abdominal Leak Point Pressure at baseline averaged 89.73cm H20 (50 -120) with all patients leaking. At 6 months no leakage was observed in 2 / 9 patients, with 6 / 9 having an ALPP of >100. One patient had an improved ALPP of 70 at 6 months.

Conclusions

Early results with the ProACT™ are encouraging, particularly in patients with incontinence following transurethral surgery.