

ADJUSTABLE CONTINENCE THERAPY (PROACT()) FOR THE TREATMENT OF MODERATE AND SEVERE STRESS INCONTINENCE AFTER RADICAL PROSTATECTOMY

Hypothesis / aims of study

This prospective study investigates the use of the Adjustable Continence Therapy (ProACT™) as a minimal invasive alternative for the treatment of moderate to severe stress urinary incontinence (SUI) after radical prostatectomy. Thusfar, ProACT™ is reserved primarily for the treatment of mild to moderate SUI.

Study design, materials and methods

The ProACT™ balloons were implanted in twenty five patients (51-79 years; mean 67 years) between May 2007 and March 2009. The procedures were done by the same urologist. All patients suffered from conservative treatment resistant SUI after radical prostatectomy (1 tot 14 years after initial operation). The grade of SUI was defined according to Stamey as mild (SUI only with severe stress, such as coughing or sneezing), moderate (incontinence with minimal stress, including walking), and severe (incontinence at bed rest). Twenty patients suffered from moderate continence (2 to 7 pads per day; mean 3.4 pads per day) and five from severe incontinence (using a condom catheter). None of the patients received irradiation at the prostate region.

Preoperatively and after implantation, patients were assessed at regular 4-week intervals, the balloon volume was adjusted if required, and patients filled in a QoL questionnaire with scaling from 6 (terrible) to 0 (delighted). Only patients who received a follow up (FU) of longer than 3 months were analyzed.

Results

The FU was longer than 3 months in 19 patients. Mean FU was 13 months (4 to 22 months). Fourteen of the 19 patients (73.6%; 12 moderate incontinence, 2 severe incontinence) were completely dry and did not wear pads. Another 3 patients (15.8%; 2 moderate, 1 severe) were significantly improved and used 1-2 pad per day, but their balloons will receive additional filling. The balloons were filled postoperatively on average 5.2 times (1 to 10x). The mean balloon volume was 5.6 ml (1.5 tot 10.5). Mean preoperative QoL score was 5.0 (3 to 6). Mean postoperative QoL score was improved to 1.1. One balloon was removed because of infection. In another patient the balloons were removed and replaced. The pad use of this patient went after the operation and first postoperative filling from 5 to 1 pad. Postoperative retention was observed in one patient. He received a catheter for one week, which was removed successfully after five days.

Successful treatment was not related to the time between radical prostatectomy and the implantation of the adjustable balloons.

Interpretation of results

The results show that implantation of adjustable balloons for male postoperative incontinence is a minimally invasive procedure, which can be used irrespective of the degree of incontinence. After 1 year follow up 89.4% of the patients are dry or significantly improved in both pad use and QoL scores.

Concluding message

The Adjustable Continence Therapy cured or improved significantly moderate and severe stress urinary incontinence after radical prostatectomy. The results suggest that ProACT™ might be the preferred initial method of treatment in SUI after radical prostatectomy, before other more invasive procedures are used.

<i>Specify source of funding or grant</i>	None
<i>Is this a clinical trial?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	No
<i>This study did not require ethics committee approval because</i>	evaluation of accepted treatment
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	No