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ADJUSTABLE CONTINENCE THERAPY (PROACT®) FOR MEN STRESS URINARY INCONTINENCE: LONG TERM RESULTS

Hypothesis / aims of study

ProACT® (Adjustable continence therapy) is a mini-invasive therapy for the treatment of stress urinary incontinence following radical prostatectomy in men. Aim of this study is to evaluate the long-term efficacy of this treatment.

Study design, materials and methods

ProACT is a device made of two silicon balloons that are placed beside the bladder neck and that are connected through a tube to a titanium port placed in the scrotum to facilitate volume adjustments. All patients enrolled in our study underwent a urodynamic exam to confirm the presence of intrinsic sphincteric insufficiency in the absence of detrusor overactivity. Efficacy of the treatment has been evaluated with daily pads count and with Ideal Quality of Life questionnaires (IQoL). Moreover, patients' impression has been evaluated using Visual Analogue Scale (VAS) and Patient Global Impression Index (PGI). Surgical details and complications have been noted down and, at every post-surgical control visit, we measured balloons volume and the number of adjustments for each patient. Every subject also underwent a pre and post-operative measurement of mean urethral closure pressure.

Results

Since December 2005 a total of 98 subjects underwent ProACT implantation by fluoroscopy in our Centre. Mean surgery time was 18 minutes (range 10-35), with less than 20 cc of blood loss. Mean follow-up time was 20.2 months (range 12-67) and all patients have been followed for at least 12 months after surgery. Daily pads count highlighted that after surgery a total of 71 patients (70%) were completely dry. IQoL increased from 33,5% before ProACT implant, to 67% at last follow-up ($p<0,005$). Complications that required devices asportation happened in 22 patients (22%). Reasons were urethral erosion (8/98, 8%), infection (3/98, 3%), balloon displacement (4/98, 4%) and device rupture (8/98, 8%).

Interpretation of results

Our results demonstrate a decrease in daily pads use and an increase in quality of life. We consider this treatment a first line approach for this cohort of patients

Concluding message

ProACT is a long term effective mini-invasive therapy for the treatment of stress urinary incontinence following radical prostatectomy.

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 ethics committee approval because	**Because this surgical technique doesn't cause any harm to patients.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**