

EFFICACY AND SAFETY OF THE PROSTATE ADJUSTABLE CONTINENCE THERAPY PROACT™ FOR THE TREATMENT OF POST PROSTATECTOMY INCONTINENCE IN A LONG TERM FOLLOW-UP

Hypothesis / aims of study

Many devices have been proposed for the treatment of post radical prostatectomy urinary incontinence (PRPUI). Some of them have showed good results in a short term follow up and disappointing results in a longer follow-up. We investigated if the results obtained with ProACT™ are durable in patients with PRPUI in a follow-up longer than five years.

Study design, materials and methods

We evaluated in a prospective study 23 patients suffering from PRPUI and treated by ProACT™ and followed by a period longer than three years. Preoperative and postoperative evaluation included pads count, Incontinence Quality of Life Evaluation (IQoL) and evaluation of the impact of incontinence (IIQ). Preoperative and postoperative data were compared to determine if the variations were statistically significant.

Results

The follow up ranged from 60 to 83 months (m = 65 months). There was a significant reduction in pads count from a mean of $5,3 \pm 2,1$ to $1,4 \pm 1,1$ diapers/day ($p < 0,001$). There was also an important reduction on the impact of incontinence dropping from 34,42 to 19,53 ($p < 0,05$) and also an improvement in IQoL from 61,8 to 71,7. Overall from the 23 patients 15 (65,21%) are dry or wearing one pad a day in the last follow up. Revisions were necessary in four patients (17%) due to balloons leakage or migration. No major complications were observed

Interpretation of results

ProACT™ is a safe effective and long lasting procedure for the treatment of PRPUI. The procedure is associated to acceptable levels of complications and revisions.

Concluding message

In a long term follow up ProACT™ continues to be a good alternative for the treatment of patients suffering from PRPUI.

<i>Specify source of funding or grant</i>	Uromedica
<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>	Yes
<i>Specify Name of Ethics Committee</i>	Ethics Committee Hospital das Clinicas Sao Paulo University
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes