

URODYNAMIC EFFECTS OF SUCCESSFUL PROSTATE ADJUSTABLE CONTINENCE THERAPY FOR STRESS URINARY INCONTINENCE AFTER RADICAL PROSTATECTOMY

Hypothesis / aims of study

Implantation of the Prostate Adjustable Continence Therapy (ProACT) is a minimally invasive procedure for the treatment of Stress Urinary Incontinence (SUI) after Radical Prostatectomy (RP). The system consists of two balloons placed bilaterally para-urethrally just beneath the bladder neck. Each balloon is attached via a conduit to a port placed subcutaneously in the scrotum. The ports allow postoperative balloon volume adjustment. Good clinical results have been published recently, but the exact mechanism of action remains unclear. We evaluated the urodynamic effects of ProACT placement and paid special attention to urethral resistance during voiding as it might be hypothesized that improvement of continence is accompanied by infravesical obstruction.

Study design, materials and methods

The ProACT device is used at our department since May 2007. All procedures are done by the same urologist. Postoperatively, patients are assessed at regular four-week intervals and the balloon volume is adjusted if required. A multichannel urodynamic examination is part of the evaluation after an optimal clinical result has been obtained.

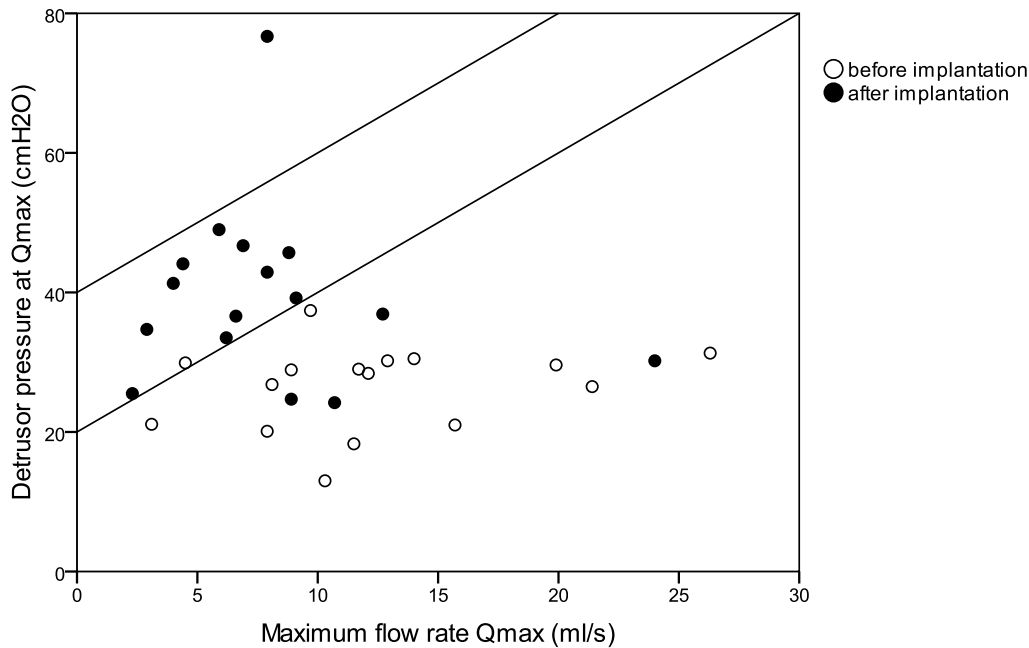
The results of the postoperative urodynamic studies were compared with those of the preoperative (diagnostic) studies. The studies included free uroflowmetry, two medium rate (50 ml/min) filling cystometries and two pressure-flow studies. A 7F double lumen transurethral catheter was used. The parameters considered are listed in the table. Results are shown as mean value and standard deviation. The paired t-test was used for statistical comparison.

Results

As of March 2010, 39 patients with SUI after RP received the ProACT system. The series of balloon adjustments to obtain continence were completed in 22 men. Of those patients, 17 had undergone the postoperative urodynamic study. One patient also underwent bladder neck incision between the preoperative urodynamic study and ProACT placement and was excluded from this study. The 16 evaluated patients had Stamey incontinence grade 2 (13 patients) or grade 3 (3 patients) at baseline. Mean age at implantation was 66 ± 7 years. Radical prostatectomy was performed 63 ± 43 months prior to implantation. Postoperative urodynamic study was done 34 ± 12 weeks after implantation. Mean balloon volume was 4.8 ± 1.9 ml, resulting from 4.3 ± 2.2 adjustments. The patients used one (six patients) or no pads (10) per day. The table summarises the results of the pre- and postoperative urodynamic studies.

Parameter	Pre-operative	Post-operative	p
Maximum cystometric capacity (ml)	486 ± 113	537 ± 167	0.129
Compliance < 20 ml/cm H ₂ O (# patients)	5	3	
Detrusor overactivity (# patients)	5	3	
Stress urinary incontinence (#patients)	8	0	
Voided volume (ml)	441 ± 154	340 ± 177	0.013
Residual volume (ml)	35 ± 86	173 ± 182	0.008
Bladder Voiding Efficiency (%)	92 ± 19	66 ± 30	0.003
Maximum flow rate Q _{max} (ml/s)	12.4 ± 6.1	8.1 ± 5.1	0.001
Detrusor pressure at Q _{max} (cm H ₂ O)	27.4 ± 6.1	39.5 ± 12.7	0.001
Bladder Outlet Obstruction Index (BOOI)	1.6 ± 12.3	23.4 ± 17.4	<0.001
Urethral Resistance Factor (URA)	15.0 ± 4.6	25.8 ± 8.2	<0.001
Bladder Contractility Index (BCI)	88 ± 32	80 ± 27	0.239
Residue after free uroflowmetry (ml)	9.4 ± 37.5	32.5 ± 71.6	0.148

As might be expected, urethral resistance (BOOI and URA) considerably increased. Voiding of most patients changed from the unobstructed area in the provisional ICS nomogram to the equivocal area (Figure). Although Bladder Voiding Efficiency decreased significantly in the pressure-flow studies, the post-void residual volume after free uroflowmetry did not considerably increase in most men; there were three patients with residues of 100, 175 and 230 ml, respectively. One of the five patients with detrusor overactivity preoperatively showed this condition after implantation as well. His threshold volume (bladder volume at first involuntary detrusor contraction) increased from 251 to 405 ml. Two additional patients developed de novo detrusor overactivity; the threshold volumes were 230 and 421 ml. Three of the five patients with a low preoperative bladder compliance (compliance <20 ml/cm H₂O) showed a normal compliance after successful ProACT placement. Compliance in these patients changed from 19, 15, 14, 14 and 18 ml/cm H₂O to 30, 10, 39, 23, and 17 ml/cm H₂O respectively. The compliance of one additional patient decreased from 24 ml/cm H₂O pre-operatively to 12 ml/cm H₂O post-operatively.



Interpretation of results

Effective treatment with ProACT on average resulted in an increased urethral resistance during voiding. The postoperative pressure-flow plot of most men projected on the equivocal area of the provisional ICS nomogram. Infravesical obstruction was found only in one case. Significant residual volumes after free uroflowmetry were found in three cases. The increased urethral resistance had no disadvantageous effects on the bladder storage function. In contrast, detrusor overactivity and bladder compliance seemed to improve, but the number of patients involved was too small for a useful comparison.

Concluding message

Successful treatment with ProACT on average resulted in an increase in urethral resistance without causing infravesical obstruction in most patients.

Specify source of funding or grant	None
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	The procedures involved were part of routine diagnostic and evaluation tools.
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	No