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INVASIVE VERSUS NON-INVASIVE EVALUATION OF SUCCESSFUL PRO-ACT TREATMENT IN POST RADICAL PROSTATECTOMY STRESS URINARY INCONTINENCE

Hypothesis / aims of study

Implantation of the ProACT™ (Adjustable Continence Therapy, Uromedica, Plymouth, MN, USA) device is a minimal invasive procedure for the treatment of stress urinary incontinence (SUI) in men. We hypothesized that improvement of continence after successful ProACT implantation is accompanied by an increased bladder outlet resistance. This, in turn, might result in bladder wall thickening with storage symptoms like de novo urgency. Long term follow-up data are not yet available so it is advisable to monitor ProACT patients urodynamically. Unfortunately, invasive urodynamics are unpleasant for the patient and not without possible complications, like urinary tract infection or damage to the ProACT device.
In this pilot study we measured (invasive) urodynamic changes due to implantation of the ProACT device and compared these to the results of the non-invasive external condom catheter method.

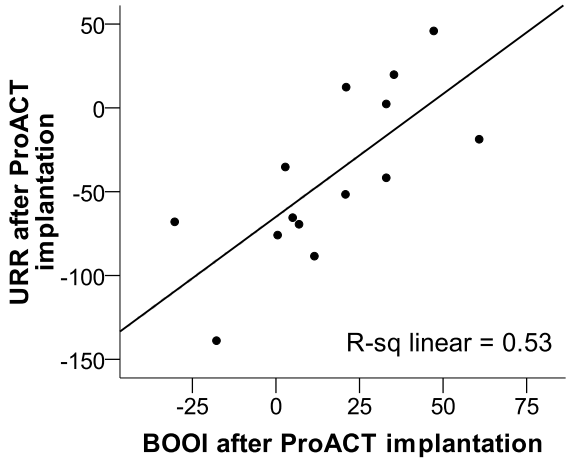
Study design, materials and methods

Since May 2007 the ProACT device has been implanted at our department to treat male SUI. All procedures were done by the same urologist. Postoperatively, patients were assessed at regular four-week intervals and the balloon volume was adjusted if required. Patients were invited to undergo conventional urodynamic studies and additional non-invasive condom catheter measurements. Inclusion criteria were: ≥18 years of age, subjectively dry or clinically significantly improved after ProACT implantation for post-prostatectomy SUI, maximum free flow rate ≥ 5 ml/sec, mentally and physically able to visit the outpatient clinic and signed informed consent. Exclusion criteria were: unable to urinate in standing position, previous lower urinary tract surgery between radical prostatectomy (RP) and ProACT implantation, congenital disease of the lower urinary tract and heart failure. Conventional urodynamic studies included free uroflowmetry to determine maximum free flow rate (Q_{max}) and two filling/voiding cystometries. The Bladder Outlet Obstruction Index (BOOI), urethral resistance factor URA, bladder contraction strength parameters W_{max}, W_{Qmax} and the detrusor pressure at maximum flow rate ($p_{det.Qmax}$) were automatically calculated by Andromeda Medical Systems® software [1]. Postvoid Residual (PVR) after free uroflowmetry was measured using an ultrasonic Bladderscan device. Bladder Contractility Index (BCI) was calculated using the formula $BCI = p_{det.Qmax} + 5 * Q_{max}$. The non-invasive investigation consisted of voiding through a condom catheter. During this voiding, the urine flow was repeatedly interrupted to measure the pressure in the condom, the maximum of which ($p_{cond.max}$) reflects the isovolumetric bladder pressure [2]. The urethral resistance (URR) was calculated as $p_{cond.max} - 5.8 * Q_{max} - 36.4$ [3]. The Wilcoxon signed Rank (WR) test was used for statistical comparison. Linear regression was used to test whether the non-invasively derived URR depended significantly on BOOI or URA and whether the non-invasively derived $p_{cond.max}$ depended significantly on W_{max} or W_{Qmax}. Data are presented as median (lowest quartile – highest quartile).

Results

As of March 2011, 60 patients with SUI after RP received the ProACT system. So far, the series of balloon adjustments to obtain continence were completed in 28 men. Seventeen of these men underwent a post treatment conventional urodynamic study and were invited to the non-invasive urodynamic investigation. Fifteen patients were included of which one was not able to void through the condom. One patient had a free flow rate Q_{max} below 5 ml/sec but was included as the voided volume during this free flow was too small (40 ml) to obtain a reliable Q_{max}. Furthermore, during the non-invasive investigation this patient had a Q_{max} above 10 ml/sec. Thus eventually a non-invasive urodynamic investigation was successfully done in 14 subjects. These 14 patients had Stamey incontinence grade 2 (n=11) or grade 3 (n=3) at baseline. Median age at ProACT implantation was 70 (62-74) years. RP was performed 60 (27-101) months prior to ProACT implantation. The postoperative conventional urodynamic study and non-invasive condom catheter measurement were done respectively 9 (6-11) months and 20 (11-32) months after implantation. Median balloon volume was 5.5 (3-8) ml, resulting from 5 (2-7) adjustments. The patients were subjectively dry or clinically significantly improved and used no pads (n=7) or 1 (n=5) per day. Two patients needed 2 and 3 pads per day. The table shows the pre- and postoperative study results.

Parameter (unit)	pre-operative	post-operative	p-value
Q_{max} (ml/sec)	13 (9 – 20)	9 (6 – 13)	< 0.01
PVR (ml)	0 (0 – 0)	0 (0 – 53)	0.08
BOOI	-8 (-20 – 12)	16 (2 – 34)	< 0.01
URA	12 (9 – 19)	20 (15 – 34)	< 0.01
BCI	94 (75 – 116)	84 (68 – 105)	0.16
W_{max} (W/m^2)	9 (6 – 12)	7 (5 – 12)	0.30
W_{Qmax} (W/m^2)	7 (6 – 8)	6 (5 – 9)	0.83



Slope = 1.47; 95% CI (0.61 – 2.33); p < 0.01

The figure shows the relationship between URR and BOOI. Linear regression confirmed a significant dependence of the non-invasively measured urethral resistance parameter URR on the invasively measured parameters BOOI and URA. Using URA instead of BOOI a very similar relation with URR was found, with a slope of 3.44; 95% CI (1.46 – 5.41); $p < 0.01$; $R^2 = 0.55$. There was no significant relation between the non-invasive contractility parameter $P_{cond.max}$ and the invasive contraction strength parameters W_{max} ($R^2 = 0.11$; slope = 2.76; $p = 0.25$) and W_{Qmax} ($R^2 = 0.16$; slope = 4.86; $p = 0.15$).

Interpretation of results

Even though there were relatively few patients in this study, our results show a clinically significant increased bladder outlet resistance (URA and BOOI) and decreased Q_{max} during voiding after effective treatment with ProACT. The bladder contraction strength (W_{max}, $W_{Qmax,}$ BCI) and PVR however did not significantly differ before and after implantation. Although urethral resistance increased, no ineffective voiding occurred since the PVR did not change significantly. Neither did it cause compensation or decompensation of the bladder wall (i.e. unchanged W_{max}, $W_{Qmax,}$ and BCI), although a long term effect cannot be excluded on the basis of our limited observation interval. Pressure-flow analysis is the gold standard for studying bladder outlet resistance. However, it is an invasive procedure that involves urethral catheterization. It may cause several complications and subjective complaints related to the procedure. In patients implanted with ProACT it is not inconceivable that during catheterization there may be an increased risk of damage to the device. Linear regression showed that URR is useful as a predictor of URA and BOOI. About 55% of the variance (R-squared) in URR can be explained by changes in BOOI or URA.. We therefore believe that the condom catheter measurement may be a useful tool for the evaluation of bladder outlet obstruction and the follow up of ProACT treated patients. Since we still do not exactly know the urodynamic consequences of the ProACT procedure, further follow up is needed.

Concluding message

Urethral resistance was significantly increased after successful ProACT implantation, but post void residual and urinary bladder contraction strength were not. This pilot study indicates that the non-invasively measured urethral resistance parameter URR is comparable to the invasively measured URA and BOOI and may be useful to follow up successfully treated ProACT patients.

References

1. Neurourol Urodyn 8:17-27 (1989)
2. Neurourol Urodyn. 18:455-475 (1999)
3. Neurourol Urodyn. 21:117-125 (2002)

Specify source of funding or grant	**None**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**Nederlands Trial Register, Registration number: NTR2346**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Medical Ethical Review Comittee Erasmus Medical Center**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**