Urodynamic effects of volume-adjustable balloons for treatment of post-prostatectomy urinary incontinence

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ABSTRACT

Aims

To evaluate the urodynamic changes in patients treated with Adjustable Continence Therapy for men (ProACT) for post-prostatectomy incontinence and to explore the clinical and urodynamic pre-implantation parameters as predictors of clinical outcome.

Methods

Patients underwent urodynamic studies before and after ProACT implantation. ProACT was considered successful if patients used none or 1 dry precautionary pad and non-successful if the patient reported ≥1 wet pad/day. The pre- and post-implantation assessments were retrospectively compared within and between the success and non-success groups. Multivariate logistic regression analysis was performed to investigate the association between the pre-implantation variables and the clinical outcomes of ProACT implantation.

Results

A total of 49 patients were included, 37 with successful and 12 with non-successful clinical outcome. Post-implantation urodynamic studies were performed a median of 9 months after ProACT implantation. In the successfully treated patients, maximum free flow rate, bladder contractility index, maximum of bladder contractility parameter w, and bladder voiding efficiency were significantly lower after implantation. The detrusor pressure at maximum flow rate, post void residual urine volume, and bladder outlet obstruction index were significantly higher. A longer duration of urinary incontinence, the use of >5 pads daily, and a smaller cystometric bladder capacity were all independently associated with non-successful clinical outcome after ProACT implantation.

Conclusion

ProACT implantation with successful clinical outcome resulted in greater urethral resistance during voiding and reduced bladder contraction strength. A longer duration of incontinence, the use of >5 pads daily, and a smaller cystometric bladder capacity were independent predictors of unsuccessful clinical outcomes, suggesting ProACT implantation should be considered sooner, rather than later, after conservative treatment of post-prostatectomy incontinence has failed.

INTRODUCTION

Men who have undergone radical prostatectomy (RP) for prostate cancer are at risk of stress urinary incontinence (SUI). The prevalence of post-prostatectomy incontinence (PPI) has ranged from 2% to nearly 60%.[1] PPI is a distressing disorder that affects men's quality of life[2] and often requires treatment. Surgical techniques can be considered if conservative treatment fails. Implantation of an artificial urinary sphincter (AUS) has been the reference standard surgical treatment of PPI; however, recently, less-invasive and less-expensive techniques have been introduced as potential alternatives.[3]

The Adjustable Continence Therapy system for men (ProACT, Uromedica, Minneapolis, MN) is a minimally invasive implant, consisting of 2 volume-adjustable balloons.[4] These balloons are placed paraurethrally just beneath the bladder neck. Each balloon is attached by a conduit to a port placed subcutaneously in the scrotum, allowing for separate volume adjustments after the initial implantation using an isotonic solution of contrast medium. The balloon volume is adjusted to create bilateral urethral compression. The balloons are adjusted until continence is achieved and the optimal balance between bladder emptying and continence has been obtained.

The clinical results of ProACT reported during the past few years have shown dry or improved rates ranging from 56% to 92%.[5-7] Nevertheless, the urodynamic working mechanism of ProACT implantation is not fully understood and needs additional elucidation. For instance, it is unknown whether the bilateral compression causes greater urethral resistance, and whether this resistance affects bladder contractility.

Various studies have shown acceptable to good reproducibility in diagnosing bladder outlet obstruction using urodynamic studies (UDS), varying from same session testing[8-10] to repeated testing within 6 months.[8,10] We, therefore, performed a study to evaluate the urodynamic changes in patients treated with ProACT for PPI and to explore which clinical and urodynamic pre-implantation parameters are associated with the non-successful clinical outcome of ProACT implantation.

METHODS

Since May 2007, ProACT balloons have been used at our department for the treatment of male SUI. The ProACT implantation procedure has been previously described.[4] In brief, using fluoroscopic guidance, 2 balloons were placed immediately adjacent to the urethra at the level of the bladder neck by way of 2 small incisions in the perineum. Each balloon was then filled with 1 mL of isotonic contrast medium solution. All implantation procedures were performed by the same surgeon. The patients were assessed after implantation at regular 3-4-week intervals. If required, we adjusted the balloon

volume with a maximum of 1 mL in each balloon per visit by way of the subcutaneous port sited in the scrotum.

The local ethical committee approved the retrospective analysis of the data from all patients who had undergone Pro-ACT implantation for PPI. All patients who had undergone ProACT implantation for PPI in our clinic until June 2012 with UDS available before and after ProACT implantation, were eligible for inclusion in the present analysis. The exclusion criteria for ProACT implantation included external radiotherapy for positive margins, salvage radiotherapy for increased prostate-specific antigen levels after RP,[4,11] and bladder neck sclerosis or urethral stenosis. The data collected from the patient medical charts included date of birth, date of RP, previous treatment of SUI, the use of anticholinergics, the reported number of incontinence pads used daily (PPD) before ProACT implantation, the date of ProACT implantation, the number of ProACT balloon adjustments and total ProACT balloon volume after implantation; the reported use of PPD after Pro-ACT balloon adjustments, and a non-validated Dutch translation of the bother question[12] of the International Prostate Symptom Score[13] (IPSS-BQ). The IPSS-BQ is a single disease-specific quality-of-life question that assesses the degree to which patients find their symptoms bothersome. The score of the IPSS-BQ ranges from 0 to 6, with a greater score indicating more bother from the patient's urinary condition. Patients were defined as having "mild" urinary incontinence if the PPD usage was 1 or 2, "moderate" if it was >2-5, and "severe" if >5 or if a condom catheter was needed.

After the volume adjustments, ProACT implantation was either "successful" or "non-successful." We defined "successful" if the patient was subjectively dry (i.e., if he used 0 PPD or 1 precautionary PPD). This precautionary pad is the smallest male incontinence pad available. "Non-successful" was defined as patients reporting the use of ≥1 wet PPD. Patients were excluded if a surgical intervention, other than ProACT implantation, had occurred between the pre-implantation and post-implantation UDS, such as internal urethrotomy, an AUS was in situ, or if the patient had a neurologic disease that could affect voiding function.

Before implantation of the ProACT balloons, the UDS was performed to determine the bladder and sphincter function. This was repeated after the balloon volume adjustments were completed. The latter, post-implantation UDS was a part of the standard evaluation protocol in our clinic either to detect bladder outlet obstruction in successful patients or to evaluate the persistence of incontinence in non-successful patients (e.g., urge incontinence).

Each UDS was performed according to the International Continence Society standards[14] and included free uroflowmetry, 2 filling cystometries, and subsequent pressure-flow studies (PFS). The maximum flow rate (Q_{max}) and average flow rate were measured using a rotating disk flow meter. A 7F double-lumen transurethral catheter was used for cystometry and PFS and were left in situ during voiding. The bladder was

filled to the maximum cystometric capacity at a medium rate (50 mL/min) using filling fluid at room temperature.[14] When filling the bladder was not possible because of total incontinence, the patient was asked to manually squeeze the urethra. The intravesical pressure transducers were placed at the level of the superior edge of the pubic symphysis. The pressure was zeroed to the atmospheric pressure.

The outcome variables derived from the cystometric studies were the parameters characterizing detrusor overactivity (DO) and compliance. DO was defined as the occurrence of involuntary detrusor contractions during the filling phase of the bladder, without a lower limit for the amplitude of an involuntary detrusor contraction.[15] Compliance was calculated at cystometric capacity[15] or at 500 mL if the capacity was >500 mL. The outcome variables derived from the PFS were Q_{max}, detrusor pressure at Q_{max} ($P_{detQmax}$), and parameters of urethral resistance and bladder contraction strength. The parameter for urethral resistance was the bladder outlet obstruction index ($BOOI=P_{det.Qmax}-2*Q_{max}$).[16] The parameters for bladder contraction strength were the bladder contractility index ($BCI=P_{detQmax}+5*Q_{max}$)[16] and parameter w[17] an approximation of the power generated by the detrusor muscle per unit of bladder wall area. The maximum of w (w_{max}) and the value of w at Q_{max} (w_{Qmax}) were used as contractility parameters.[17,18] Additionally, we determined the voided volume, postvoid residual urine (PVR) volume, cystometric bladder capacity (sum of the voided and PVR volume during PFS), and bladder voiding efficiency (BVE=(voided volume/bladder capacity)*100).[16] In the case of repeated PVR measurements, we used the lowest value measured.

The measurement with the largest cystometric capacity was used to assess the filling phase. The PFS with the greatest Q_{max} was used to assess the voiding phase. Artefacts were corrected manually. The urodynamic data were analysed using AUDACT software, version 4.50 (Andromeda Medizinische Systeme GmbH, Taufkirchen, Germany).

Statistical analysis was performed using SPSS Statistics, release 20.0.0.1 (IBM, Armonk, NY). Statistical significance was defined as $p < .05$. The median and interquartile range (lower quartile to upper quartile) are reported for continuous data. For discrete data, counts and percentages are reported.

To assess the change in outcome before and after ProACT implantation within the success and non-success group, the Wilcoxon signed rank test was used for continuous variables and McNemar's test for categorical variables. The Mann-Whitney U test was used to compare the pre-implantation urodynamic parameters between the success and non-success groups for continuous variables and the chi-square test for categorical variables.

Multivariate logistic regression analysis was conducted using the backward likelihood ratio method. All pre-implantation patient characteristics and pre-implantation urodynamic parameters with $p < .05$ on univariate analysis were considered in building the model to investigate the association between these variables and a non-successful outcome.

RESULTS

From May 2007 to June 2012, 81 patients with PPI received implantation of the ProACT balloons (Figure 1.1). At the last follow-up visit, 8 patients were still in the process of post-implantation balloon adjustments and had not yet undergone the post-implantation UDS. Another 8 patients had their ProACT devices removed because of infection (n=2), dislocation of the device (n=3), or tissue erosion (n=3). A final 8 patients met an exclusion criterion: 2 had undergone surgical intervention between the pre-implantation and post-implantation UDS, 3 had an AUS in situ, and 3 developed a neurologic disease (2 experienced a stroke and 1 developed Alzheimer's disease). Thus, 49 of the 57 patients (86%) completed the post-implantation UDS and were included in our study.

ProACT was the first surgical SUI therapy after failed pelvic floor muscle training in 38 of the 49 patients (78%). Of the 49 patients, 15 (31%) had mild, 18 (37%) had moderate, and 16 (33%) had severe SUI.

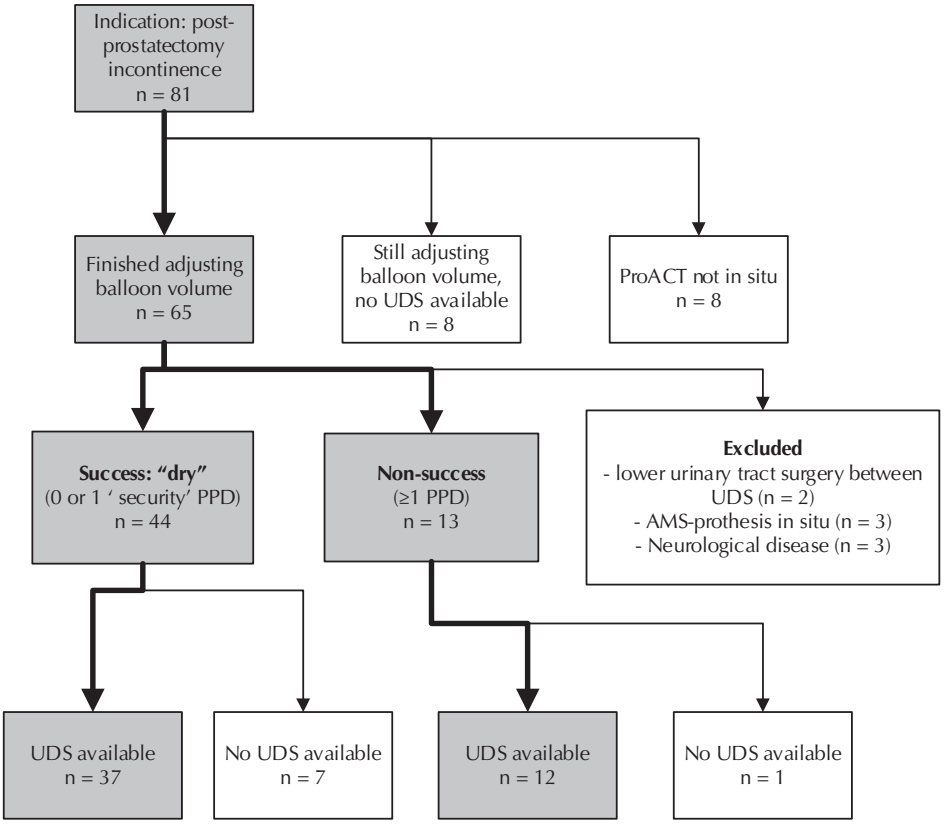

Figure 1.1 Flowchart of inclusion process of ProACT patients
Abbreviations: *UDS* urodynamic studies, *PPD* incontinence pads per day

After implantation, none of the 49 included patients had symptoms of persistent urinary retention or symptomatic urinary tract infection. ProACT implantation was successful in 37 patients and not successful in 12, although 4 of these 12 patients had a reduction in PPD of ≥50%. These 12 unsuccessfully treated patients had either received the maximal allowed filling volume (n=8) or had noted absolutely no improvement after several adjustments (n=4). The success rate was 93% (14 of 15) in patients with mild incontinence, 83% (15 of 18) in those with moderate incontinence, and 50% (8 of 16) in those with severe incontinence.

The patient characteristics were compared between the success and non-success groups (Table 1.1). In the non-success group, the median age was 7.5 years older (p=.001), the median duration of urinary incontinence was 7.5 years longer (p=.001), and the incontinence was more severe (p=.01). As expected, the patients in the non-success group had a greater balloon volume (p<.001) and a greater IPSS-BQ score (p<.001) than did the patients in the success group.

The urodynamic outcomes before and after implantation for the successful and unsuccessful groups are listed in Table 1.2. The pre-implantation cystometric bladder capacity and free flow Q_{max} were significantly lower in the non-success group than in the success group. The other parameters, including BCI (p=.06), were not significantly different between the 2 groups.

In the non-success group, only the average flow rate was significantly lower after implantation. We did not find any other significant differences between the urodynamic parameters before and after ProACT implantation. In the success group, 8 patients (22%) had DO during the pre-implantation UDS, of whom 3 continued to have DO during the post implantation UDS. Also, 7 patients showed de novo DO with threshold volumes of ≥250 mL. No statistically significant differences were found before and after implantation in the proportion of patients with DO, the cystometric bladder capacity, or bladder compliance (p=.77, p =.31, and p=.79, respectively). The urethral resistance during voiding, as described by BOOI, was significantly greater after implantation (p <.001). The BOOI increased in most patients after implantation (Figure 1.2). In 3 patients, the BOOI was lower after ProACT implantation. Four patients had a post-implantation BOOI >40 but had no clinical symptoms of symptomatic urinary retention or persistent urinary tract infection. The maximum free flow rate and average flow rate were significantly lower after implantation, and the PVR volume was significantly greater, with a median of 0 mL (interquartile range 0-25). Five patients (14%) had a PVR volume >100 mL. Consequently, the bladder voiding efficiency was significantly lower after implantation (p<.001). The proportion of patients who had to strain during the PFS (35%) was not significantly increased after implantation (32%). The bladder contraction strength, characterized by the BCI and w_{max}, was significantly lower after implantation (p<.001 and p=.004, respectively); however, w_{Qmax} was not (p=.09).

Table 1.1 Patient characteristics

Characteristic	Success (n=37)	Non-success (n=12)	*p*-value*
Before implantation			
Age, years	68.0 (63.5 – 72.5)	75.5 (69.5 – 79.8)	.001
Previous treatment of SUI			.22
Only PFMT	29 (78%)	9 (75%)	
Bulking agent	0 (0%)	1 (8%)	
AUS	2 (5%)	1 (8%)	
Unknown	6 (16%)	1 (8%)	
Urinary incontinence duration, years	3.0 (1.0 – 6.0)	10.5 (6.0 – 13.5)	.001
Incontinence severity			.01
Mild (1 or 2 PPD)	14 (38%)	1 (8%)	
Moderate (>2 to 5 PPD)	15 (41%)	3 (25%)	
Severe (>5 PPD)	8 (22%)	8 (67%)	
After implantation and balloon adjustments			
Interval between ProACT and UDS, months	7.0 (5.0 – 9.0)	13.5 (10.3 – 22.0)	<.001
Interval between last balloon adjustment and UDS, months	3.0 (2.0 – 3.0)	2.5 (1.0 – 4.0)	.87
Balloon volume, mL	4.0 (2.9 – 6.0)	7.5 (6.5 – 8.9)	<.001
Adjustments, number	3.0 (2.0 – 5.5)	6.0 (5.0 – 7.0)	.002
Incontinence severity			*NA*
No incontinence (0 or 1 security PPD)	37 (100%)	0	
Mild (1 or 2 PPD)	0	4 (33%)	
Moderate (>2 to 5 PPD)	0	2 (17%)	
Severe (>5 PPD)	0	6 (50%)	
IPSS-BQ "If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that?"			<.001
Delighted	13 (35%)	0 (0%)	
Pleased	13 (35%)	0 (0%)	
Mostly satisfied	5 (14%)	1 (8%)	
Mixed	2 (5%)	5 (42%)	
Mostly dissatisfied	1 (3%)	1 (8%)	
Unhappy	1 (3%)	4 (33%)	
Terrible	1 (3%)	1 (8%)	
Missing	1 (3%)	0 (0%)	

Abbreviations*: AUS* artificial urinary sphincter, *IPSS-BQ* International Prostate Symptom Score bother question, *NA* not applicable, *PFMT* pelvic floor muscle training, *PPD* incontinence pads per day, *RP* radical prostatectomy, *UDS* urodynamic studies

Data in median (lower quartile to upper quartile) or number (%)
*Mann-Whitney U test used for continuous variables and Chi-square test for categorical variables.

Table 1.2 Urodynamic data before and after ProACT implantation

Parameter	Success-group (n=37)			Non-success group (n=12)			
	Before implantation	After implantation	*p*- value*	Before implantation	After implantation	*p*-value*	*p*-value**
Storage							
Cystometric bladder capacity (mL)	514.0 (416.5 – 574.0)	504.0 (396.5 – 607.0)	.31	384.5 (257.0 – 425.5)	367.5 (278.8 – 528.8)	.27	.003
Compliance (mL/cmH_2O)	34.9 (18.6 – 94.0)	44.3 (22.1 – 70.8)	.79	26.5 (16.4 – 46.4)	17.1 (12.3 – 24.7)	.16	.33
DO (no.)	8 (22%)	10 (27%)	.77	5 (42%)	7 (58%)	.50	.17
Voiding							
Straining (no.)	13 (35%)	12 (32%)	.13	5 (42%)	7 (58%)	.22	.91
Free flow Q_{max} (mL/s)	18.2 (11.7 – 24.9)	9.9 (6.9 – 14.1)	<.001	9.6 (6.0 – 19.7)	5.5 (3.3 – 8.4)	.07	.01
Q_{ave} (mL/s)	10.5 (6.2 – 13.7)	5.1 (3.2 – 6.8)	<.001	5.7 (3.7 – 12.1)	2.9 (1.7 – 4.9)	.03	.12
P_{det} at Q_{max} (cm H_2O)	25.9 (19.1 – 31.5)	38.6 (31.4 – 46.2)	<.001	25.3 (13.8 – 42.9)	34.3 (11.4 – 44.4)[a]	.33	.85
PVR (mL)	0 (0 – 0)[a]	0 (0 – 25)	.005	0 (0 – 0)	0 (0 – 0)	.18	.56
Urethral resistance							
BOOI	-7.4 (-22.3 – 4.2)	23.1 (6.0 – 34.3)	<.001	-0.9 (-12.8 – 27.6)	16.2 (-23.7 – 34.5)[a]	.16	.19
Bladder contraction strength							
BCI	107.3 (81.9 – 135.8)	81.2 (68.3 – 102.8)	<.001	85.5 (63.5 – 104.1)	72.7 (68.3 – 100.4)[a]	.96	.06
w_{max} (W/m^2)	9.9 (7.1 – 14.9)	7.1 (6.0 – 11.1)	.004	8.4 (7.2 – 10.2)	8.3 (5.9 – 11.0)[a]	.53	.30
w_{Qmax} (W/m^2)	6.2 (5.0 – 8.9)	6.0 (5.0 – 6.9)	.09	7.0 (3.4 – 7.9)	5.1 (3.7 – 7.1)[a]	.72	.74
Bladder emptying function							
BVE (%)	100.0 (94.7 – 100.0)	80.0 (56.6 – 100.0)	<.001	97.3 (93.3 – 99.9)	95.4 (88.8 – 100.0)	.29	.14

Abbreviations: *BCI* Bladder Contractility Index, *BOOI* Bladder Outlet Obstruction Index, *BVE* Bladder Voiding Efficiency, *DO* detrusor overactivity, *PVR* post-void residual (urine volume), $P_{det}Q_{max}$ detrusor pressure at maximum flow-rate, Q_{ave} average flow-rate, Q_{max} maximum flow-rate, w_{max} maximum of bladder contraction strength parameter w , w_{Qmax} bladder contraction strength parameter w at Q_{max}

Data are presented as median (lower quartile – upper quartile) or number (%)

*Wilcoxon signed rank test used for continuous variables and McNemar's test for categorical variables to assess the changes in outcome before and after ProACT implantation.

**Statistical significances of pre-implantation variables between success and non-success groups explored using Mann-Whitney *U* test for continuous variables and Chi-square test for categorical variables.

[a] missing data for 1 patient

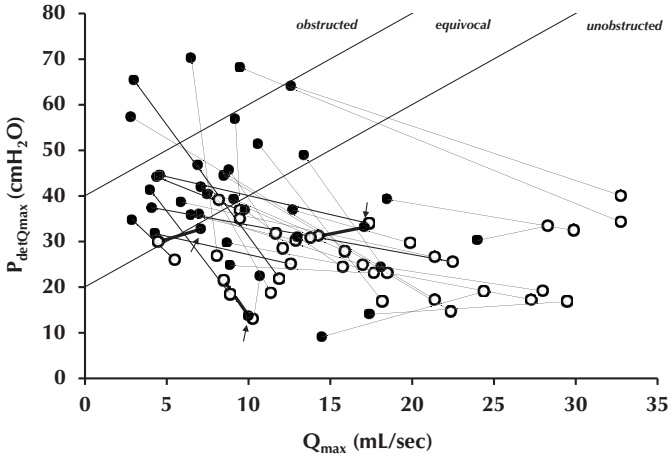

Figure 1.2 Graph showing detrusor pressure at maximum flow rate ($P_{det}Q_{max}$) and maximum flow rate (Q_{max}) before (open circles) and after (black circles) implantation of Adjustable Continence Therapy for men (ProACT). Bold lines and arrows indicate that bladder outlet obstruction index was lower after ProACT implantation.

Multivariate logistic regression analysis was performed to explore both the clinical and the urodynamic pre-implantation parameters as predictors of outcome. A longer duration of urinary incontinence (p=.007), severe incontinence (p=.02), and smaller cystometric bladder capacity (p=.05) were all independently associated with a non-successful outcome of ProACT implantation (Table 1.3). Patient age and free flow Q_{max} were not independently associated with the clinical outcome.

Table 1.3 Results of multivariate analysis for non-successful outcome

	Odds ratio	**95% CI**	***p*-value**
Duration of incontinence, *each year*	1.83	1.17 – 2.83	.007
Incontinence severity			
Mild (1 or 2 PPD)			Reference
Moderate (>2-5 PPD)	1.55	0.06 – 39.41	.79
Severe (>5 PPD)	136.42	2.10 – 9075.82	.02
Cystometric bladder capacity, *each 10 mL*	0.91	0.82 – 1.0	.05

Abbreviations: *CI* confidence interval, *PPD* incontinence pads per day, *RP* radical prostatectomy

Candidates for inclusion in the model: age, duration of urinary incontinence, severity of incontinence, maximum free flow-rate (Q_{max}), cystometric bladder capacity

DISCUSSION

The present study was designed to describe the urodynamic changes after implantation of ProACT for PPI. Our results have shown that successful treatment with ProACT increased urethral resistance and could affect the parameters of bladder contraction strength. In the successfully treated patients, a clear shift could be seen from the unobstructed area toward the equivocal and—to a lesser extent—to the obstructed area of the provisional International Continence Society nomogram (Figure 1.2). Nevertheless, no signs of clinical obstruction were found, because the proportion of patients who had to strain during voiding did not differ after ProACT implantation, and none of our patients had persistent urinary retention or symptomatic urinary tract infections during our follow-up period. Also, treatment success was demonstrated by patient-reported PPD use and IPSS-BQ, both important for quality of life. In 3 patients, the BOOI was lower after implantation, although the absolute differences were small and did not result in a clear change in the BOOI category assignments (Figure 1.2).

The BCI and w_{max}, representing bladder contractility, were significantly lower after ProACT implantation with a successful outcome. Several explanations are possible for this unexpected observation. First, the bladder can use its muscle contractility to generate a high pressure at low flow rate or a high flow rate at a low pressure.[19] Therefore, a contractility parameter should combine these 2 properties in an equation, such that when the muscle contractility does not change but the balance between the pressure and flow rate changes from external causes (e.g., a change in urethral resistance), the contractility parameter would remain constant. It might be that in the equations that define w_{max} and BCI, the decrease in Q_{max} caused by the balloon volume is not adequately compensated by the accompanying increase in $P_{detQmax}$. This would result in a decrease in contractility parameter value, which would not represent a true decrease in muscle contractility. Second, in patients with urethral obstruction from benign prostatic hyperplasia, the bladder contractions might slowly decline prematurely, leaving a PVR volume.[20] This decline could cause a lower w_{max}. It is likely that the decline does not affect the value of w at Q_{max} because the value of w at Q_{max} is usually attained earlier during the course of micturition than is w_{max}. This was also observed in our group. Parameter w_{Qmax} was not significantly lower after ProACT implantation. Third, it is physiologically plausible that our finding of lower bladder contraction strength could be caused by the decreased Q_{max} owing to the urethrovesical reflex. This reflex is responsible for the maintenance of the detrusor contraction in the normal bladder.[21] The reduced urine flow after ProACT implantation could thus lead to reduced stimulation of the bladder and, consequently, to a decreased bladder contraction strength. For these reasons, the lower bladder contraction strength we found could have resulted

from an inadequacy of the equation used to estimate the bladder contractility in urinary incontinence or might have a physiologic explanation.

Our second objective was to explore the clinical and urodynamic pre-implantation parameters as predictors of a non-successful outcome after ProACT implantation. A longer duration of urinary incontinence and severe incontinence (>5 PPD) were independent clinical predictors of a non-successful outcome. Possibly, scarred tissue around the neobladder neck from RP becomes less distensible as it ages. Consequently, inflation of the balloons might not result in sufficient urethral compression. Perhaps, ProACT treatment should be considered sooner, rather than later, after conservative treatment of PPI has failed. Patients with severe incontinence were more likely to have an unsuccessful outcome after Pro-ACT implantation than patients with either mild or moderate incontinence. Still, 50% of patients with severe PPI achieved continence with ProACT implantation. ProACT implantation has been suggested as a part of a "step-up" approach[22] before opting for AUS, which can be considered in the case of more severe incontinence. Of the urodynamic parameters, only a smaller pre-implantation cystometric bladder capacity was independently associated with non-success. This finding is in line with the results from Warner et al[23] on the urodynamic effects of transobturator male slings in the treatment of SUI. They also found that a small bladder capacity might be a predictor of an unsuccessful outcome.[23]

DO is a urodynamic diagnosis and is not necessarily symptomatic or clinically relevant. Therefore, only patients who experienced urgency in everyday life were treated with anticholinergic agents. Of the 3 patients who continued to have DO after implantation, 2 were treated with anticholinergic agents, the third patient had a threshold volume of 500 mL and no urge symptoms in daily life. Of the 7 patients had de novo DO, only 1 required treatment with anticholinergic agents; the remaining 6 patients were asymptomatic and did not need treatment. The "de novo" DO might have been already present but missed by the UDS before ProACT implantation.[24,25]

Various studies on the operative and clinical results of ProACT implantation have been published.[4,5,22,26,27] These studies were all cohort and/or feasibility studies, and our study focused on the urodynamic outcomes. Although some studies have evaluated leak point pressures and uroflowmetry,[5,26] important urodynamic outcomes of ProACT implantation such as urethral resistance and bladder contraction strength have never before been evaluated after implantation.

The limitations of our study included the use of a non-validated IPSS-BQ and the lack of a cough stress test as outcome measures. Although other ProACT studies used the same classification for incontinence severity,[27-30] it might be somewhat arbitrary, because it can vary by merely volume intake. The relatively short follow-up and small number of patients were other limitations of our study.

Still, to our knowledge, ours is the first study to review the urodynamic changes after ProACT implantation. Our results have provided a clear impression of the increased urethral resistance due to the paraurethrally placed balloons to achieve continence. Studies with longer follow-up are needed to determine the effects of chronically increased urethral resistance on bladder function from ProACT implantation. For now, individual follow-up is important to achieve the right balance between patient satisfaction and urethral resistance.

CONCLUSION

Our data have suggested that urethral resistance is increased to achieve continence with ProACT implantation without symptoms of clinical bladder outlet obstruction. We also found a decreased bladder contraction strength after continence was achieved with Pro-ACT, which could be either an artefact or part of a physiologic phenomenon. A longer incontinence duration, severe incontinence (defined by the use of >5 PPD), and a smaller cystometric bladder capacity were important predictors of a non-successful clinical outcome in patients undergoing ProACT implantation. Therefore, ProACT treatment should be considered sooner, rather than later, after conservative treatment of PPI has failed.

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