Maximum Urethral Closure Pressure Increases After Successful Adjustable Continence Therapy (ProACT) for Stress Urinary Incontinence After Radical Prostatectomy

Sarah H.M. Reuvers, Jan Groen, Jeroen R. Scheepe, and Bertil F.M. Blok

OBJECTIVE To evaluate changes of the urethral pressure profile (UPP) after implantation of adjustable continence therapy (ProACT), a minimally invasive procedure in which 2 volume-adjustable balloons are placed periurethrally for treatment of male stress urinary incontinence. The working mechanism of the ProACT to achieve continence has not been fully understood. We hypothesized that successful treatment with ProACT improves urinary continence by inducing a significant increase in static urethral pressure.

MATERIALS AND METHODS We included patients who underwent UPP before and after ProACT implantation. UPPs were initially performed with the Brown-Wickham water perfusion method and later with the T-DOC Air-Charged catheter method. Pre- and postoperative UPPs and International Prostate Symptom Scores were evaluated. UPP measurements of successfully (no or 1 precautionary pad per day) and unsuccessfully treated patients were compared.

RESULTS Twenty-seven patients were included in the study; 23 patients were successfully and 4 patients were unsuccessfully treated. Maximum urethral closure pressure (MUCP) increased significantly from median 58.0 to 79.0 cmH_2O in the successfully treated group ($P = .001$). Within the subgroup of unsuccessfully treated patients, MUCP did not change significantly ($P = .715$). The change in MUCP was statistically significantly different between the successful and unsuccessful group ($P = .034$). Total score of the International Prostate Symptom Scores did not change significantly after ProACT implantation ($P = .097$).

CONCLUSION Successful treatment with ProACT is associated with a significant increase of MUCP. This implies that increased static urethral pressure contributes to the working mechanism of the ProACT device to achieve continence. UROLOGY 94: 188–192, 2016. © 2016 Elsevier Inc.

Postprostatectomy incontinence (PPI) is a common complication after radical prostatectomy (RP) that can cause great distress.[1] One year after RP, the incidence of urinary incontinence is 9%-16% depending on the definition used and surgical technique.[2,3] Most of the PPI patients suffer primarily from stress urinary incontinence (SUI). The maximum urethral closure pressure (MUCP) and functional profile length (FPL) are decreased after RP, presumably caused by the loss of forces normally generated by the prostate and sphincter, and are associated with regaining continence.[4,5] Although implantation of an artificial urinary sphincter is still the gold standard treatment for moderate to severe SUI after RP, less invasive techniques have become more available.[6]

One such technique is the adjustable continence therapy (ProACT, Uromedica, Minneapolis, MN). This implies implantation of a device consisting of 2 periurethrally placed volume-adjustable balloons. ProACT implantation achieved continence (defined as the use of no or 1 precautionary pad) in 60%-80% of patients[7-11] and quality of life index scores for urinary incontinence improved by 31-48 points (score range 1-100).[8-10,12]

The working mechanism of the ProACT has not been fully understood. Other continence devices like the male

Financial Disclosure: *The authors declare that they have no relevant financial interests.*
Funding Support: *The submitted work is supported by a research grant from the Coolsingel Foundation. Outside of the submitted work, Uromedica financially supports the urology department at the Erasmus MC.*

From the Department of Urology, Erasmus MC, Rotterdam, The Netherlands
Address correspondence to: Sarah H.M. Reuvers, M.D., Department of Urology, Erasmus MC, Wijtemaweg 80, Room Na 1724, 3015 CN Rotterdam, The Netherlands. E-mail: s.reuvers@erasmusmc.nl, sarahreuvers@yahoo.com

Submitted: January 25, 2016, accepted (with revisions): April 15, 2016

http://dx.doi.org/10.1016/j.urology.2016.04.019
0090-4295

sling[13-15] elevate the MUCP after (successful) treatment. Utomo et al[16] demonstrated that the urethral resistance during voiding had increased in men who were successfully treated with ProACT for SUI after RP. We hypothesized that the ProACT induces changes of the static urethral pressure profilometry (UPP), especially an increase of MUCP, and that this mechanism contributes to regaining continence. The objective of this study was to evaluate the UPP and International Prostate Symptom Score (IPSS) measures before and after ProACT implantation in patients with SUI after RP.

MATERIALS AND METHODS

Subjects

We reviewed the medical charts of patients who had undergone ProACT implantation for SUI after RP at our institution. We included patients for whom a pre- and postoperative UPP was available. Patients who underwent urinary tract surgery between the pre- and postoperative measurements were excluded. This study was approved by the local ethics committee.

Intervention

The first ProACT implantation at our institution was performed on May 2007. Since then, all implantations were done by one surgeon (BFMB). The procedure was performed as firstly described by Hubner and Schlarp.[11] In the first cohort of patients, a rigid 19F cystoscope was used, and in the second cohort from April 2014, a flexible cystoscope was used. Patients initially visited the Department of Urology every 3-4 weeks after implantation. Balloon volume adjustments were made by percutaneous scrotal needle puncture with a maximum of 1 mL on each side if patients reported persistent SUI. Adjustments were made until continence was achieved, until the balloons were filled with a maximum of 8 mL or until there was any other reason to stop filling the balloons (eg, symptoms of obstructed voiding, infection, dislocation of the balloons).

Design

Relevant data were retrospectively retrieved from the patients' medical files, including the IPSS.[17] Urinary incontinence was classified as mild (1 or 2 pads per day), moderate (3 or 4 pads per day), or severe (5 or more pads per day or use of condom catheter). The treatment was defined as "successful" when patients used no or 1 precautionary pad per day after balloon adjustments.

Methods of Measurement

UPPs were performed by one physician (JG) pre- and postoperatively after the balloon volume adjustments were completed.

Two UPP techniques were used. In a first cohort of patients, we used the Brown-Wickham water perfusion method.[18,19] Two consecutive UPPs were performed. A side-hole 9F water perfusion catheter oriented at the 12 o'clock position was inserted into the bladder and withdrawn through the urethra (withdrawal rate 1 mm/s and perfusion rate 1 mL/min). Rectal pressure was monitored with an 8F tube. From 2011, the T-DOC Air-Charged 7F catheter (Laborie, Mississauga, Canada) method[20] was used. One UPP was performed in every patient pre- and postoperatively. After inserting the catheter into the bladder, the catheter balloons were inflated. The catheter was withdrawn at a speed of 1 mm/s. In each patient, the pre- and postoperative measurements were performed using the same technique. The measurements were done at a bladder volume of 100 mL. The FPL and MUCP were derived from the UPPs.

AUDACT software version 7.11 (Andromeda Medizinische Systeme GmbH, Taufkirchen, Germany) was used to measure and analyze UPP data.

Analysis

Statistical analyses were performed with the statistical package SPSS 21 version. A P value of <.05 was considered to reflect statistical significance. Descriptive results are presented as median and interquartile range for continuous data, and as counts and percentages for discrete data. We used the Wilcoxon signed-rank test for continuous variables to compare preoperative and postoperative data within groups. The Mann-Whitney U test for continuous variables and Pearson's chi-square test for discrete variables were used to compare variables between groups. Spearman rank correlation was used to test the association between 2 variables.

RESULTS

At our institution, 29 patients underwent UPP before and after ProACT implantation between December 2008 and March 2015. Two patients underwent urinary tract surgery between the preoperative and postoperative UPP and were excluded. Basic characteristics of the included men are displayed in Table 1. We compared the patient characteristics between the group with a successful clinical outcome (n = 23) and the group with an unsuccessful outcome (n = 4). The successful group had a significantly lower number of balloon volume adjustments than patients in the unsuccessful group (P = .001). We found no further statistically significant differences between the groups.

Changes of the UPP After ProACT Implantation

The MUCP and FPL increased significantly after successful treatment with ProACT (Table 2). In contrast, both parameters did not significantly change within the subgroup of unsuccessfully treated patients. The change in MUCP, from preoperative to postoperative, was median 13.0 cmH_2O in the successfully treated group and 4.5 cmH_2O in the unsuccessfully treated group. This increase was statistically significantly different between the groups (P = .034). The change in FPL was not significantly different between the groups (P = .576). A typical example of a UPP after successful treatment with ProACT is shown in Figure 1.

The UPP measurements were compared between the 2 measurement methods. MUCP increased significantly after ProACT in both groups (Table S1). No significant differences were found in baseline MUCP (P = .544), postoperative MUCP (P = .716), and change in MUCP (P = .610) between the 2 measurement methods. FPL increased significantly after ProACT in the Brown-Wickham group, whereas it did not change significantly in the T-DOC subgroup (Table S1). Although a significant difference was found in the postoperative FPL (P = .017), the preoperative FPL (P = .071) and the change in FPL (P = .645) were