

ProACT™ for Stress Urinary Incontinence after Radical Prostatectomy

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Key Words

Operative therapy · Adjustable continence therapy ·
Radical prostatectomy · Stress urinary incontinence

Abstract

Introduction: Stress urinary incontinence is a bothersome complication of radical prostatectomy. Surgical treatment consists of the artificial urinary sphincter (AUS), the male sling and bulk injections. This study presents the results of the first series of implantations of ProACT™ in the Netherlands. **Materials and Methods:** A non-validated questionnaire was sent to 29 male patients implanted with ProACT to determine Stamey score, pad count and questions about quality of life and satisfaction. Complications, revisions and explantations were registered. **Results:** Mean follow-up was 41 months. Based on Stamey score four patients are continent at the end and nine patients according to the pad count. The average pad count decreased significantly. Remarkable was the high rate of dislocations and revisions and patients' satisfaction. **Conclusions:** ProACT is a less invasive treatment compared to the AUS. However, the procedure is associated with a substantial revision and explantation rate. ProACT can be part of a so-called step-up approach before opting for a more invasive treatment.

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Introduction

Prostate cancer is predominantly a disease of older men. Radical prostatectomy (RP) is one of the treatment options. Stress urinary incontinence (SUI) is a well-known complication of RP, mainly caused by dysfunction of the sphincter [1]. A considerable variation consists of the published incontinence rates. Postoperatively, some degree of incontinence is reported in 1–87% of the cases [2–4]. The reported percentages partly depend on the definition used for incontinence and the time lapsed since the prostatectomy. The majority of patients recover spontaneously following conservative treatment. Physiotherapy could contribute to the recovery [5]. Eventually, approximately 3% of RP patients will permanently suffer serious incontinence [4, 6]. This embarrassing condition has a considerable negative influence on the patient's quality of life. In addition, 5–30% experience minimal to light loss of urine during exertion [4, 6].

Implantation of an artificial urinary sphincter (AUS), the gold standard at this moment, is one of the possibilities for surgical intervention when incontinence persists. The patient must have some degree of manual dexterity and mental capacity to be able to control the AUS. The AUS requires an invasive operation and cannot be adjusted after implantation without operating again. A high

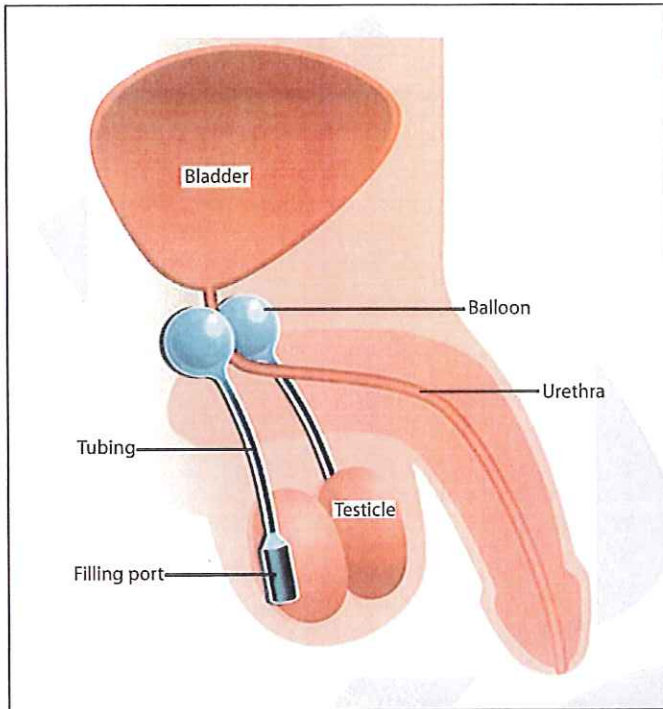


Fig. 1. Positioning of ProACT.

revision rate (16–36%) is reported, which decreased after introduction of the narrow-backed cuff in 1987 [7–9]. The male sling and bulking agents are other treatment modalities, trying to fill the void between conservative treatment and invasive AUS. The sling is increasingly being applied. The known effects are primarily short term: 40–90% need one or fewer pads per day and 16–76% require no incontinence material after an average of 12–18 months [10–12]. Bulking agents have shown reasonable short-term results. The long-term results, however, are disappointing due to a decrease of the achieved results over time [6, 13, 14].

ProACT™ (Adjustable Continence Therapy, Uromedica, Plymouth, Minn., USA) has been applied since 2003 at the Urology Department of the Radboud University Nijmegen Medical Center, The Netherlands. The system consists of two para-urethral balloons filled with contrast fluid, each one implanted at the level of the bladder neck (fig. 1). After RP, the balloons provide external compression at the urethra at the level of the vesicourethral anastomosis. The balloon volume can be adjusted postoperatively by means of a filling port in the scrotum.

This article will give an overview of our experiences regarding ProACT as a treatment for SUI after RP.

Patients and Methods

Patients

The study group consists of 29 men implanted with ProACT because of SUI after RP. All men were treated by one urologist at the Radboud University Nijmegen Medical Center in the period February 2003 through February 2007.

Procedure

The patient is positioned in a modified lithotomy position with general or spinal anesthesia. The scrotum and the perineal area are disinfected and prepared for surgery. Mainly AP fluoroscopy is used to identify relevant anatomy and instruments. A rigid cystoscope is inserted under direct vision and contrast fluid is used to visualize the bladder neck fluoroscopically. The cystoscope remains inserted for use as a landmark with respect to the positioning of the instruments and ProACT balloons. Two incisions are made in the perineum, on either side approximately 1 cm off the midline. A U-shaped cannula with a trocar is inserted up to the bladder neck. If the balloons are positioned underneath the pelvic floor muscle layer, compression is not possible. Once the cannula and trocar are in the correct position, the trocar is removed while the cannula is left behind. If necessary, a tissue-expanding device (TED) can be inserted via the cannula to create space for the balloon. The balloon can be inserted via the cannula, using a guidewire. Correct positioning of the balloon is determined by fluoroscopy. Subsequently, following the same procedure, the second balloon is implanted on the other side via the second perineal incision. A tube connects each balloon with a filling port. After filling the balloons during surgery with isotonic contrast fluid, the positioning is checked again by fluoroscopy. The filling ports are buried subcutaneously in the posterior scrotum.

Data Collection and Analysis

The data were analyzed retrospectively. At the end of the follow-up period, all 29 men were sent a nonvalidated questionnaire with questions regarding functioning and patient-satisfaction. Urodynamic investigations were conducted preoperatively. In order to determine the Schäfer graduation, urodynamics were repeated postoperatively for the first 22 participants. In addition, the preoperative and postoperative complications, revisions and explantations were registered.

Continence was defined as a Stamey score degree zero or a pad count of one or less pads per day, the latter also known as social continence.

Schäfer graduation, Stamey score, pad count and the questions regarding quality of life, bother in social life and the overall inconvenience of incontinence are analyzed using the Wilcoxon rank test. Results are considered significant if $p < 0.05$.

Results

After an average duration of 41 months of SUI following a RP, ProACT balloons were implanted in 29 male patients. The average age was 65 years. Before the implantation, 24 men were treated with physiotherapy and 2

men with bulk injections for their SUI. However, the results of these preceding treatments were insufficient. The duration of the surgery varied from 13 to 99 min ($n = 26$), skin-to-skin. For two men, a Sachse urethrotomy was included in this time. The positioning of the fluoroscopic equipment, the sterile covering and the sterile connection of the cystoscope to the endoscopic tower are also included in the duration of the surgery. Most subjects could go home 1 or 2 days postoperatively. Two men were admitted for 4 and 5 days, respectively. During follow-up, the volume of the balloons was adjusted 3.7 times on average. The volume was not adjusted if the result was satisfactory, if there was no further progress in the continence, or if a dislocation was noticed. The average balloon volume was 3.7 ml at the end of follow-up.

Effectiveness

The Schäfer graduation showed a significant increase of on average 1.0–1.5 ($p = 0.047$) in the group of the first 22 patients, of whom 21 patients underwent urodynamics prior and after implantation. The increase in Schäfer graduation implies a modest obstruction induced by implantation of the balloons, which is the expected mechanism of action of ProACT. However, no long-term effects of the Schäfer graduation are known from this study.

Questionnaires were sent to 29 patients, 28 of whom returned their questionnaires, of which 26 were completed. Using the questionnaire, the degree of incontinence was specified bases on the Stamey score and the pad count shortly before implantation and at the end of follow-up ($n = 25$). The Stamey score decreased significantly from an average degree of 2.5 to 1.7 ($p = 0.001$). Four patients were continent (Stamey score degree zero). At the end of follow-up, the average pad count was 3.1 pads per day. This is a significant decrease in relation to 4.8 pads per day before implantation ($p = 0.001$). Based on the pad count, 9 patients are continent at the end of follow-up, of which 5 patients are completely dry and do no longer need any pads.

On a scale of zero to ten (zero being 'not inconvenient/no bother' and ten being 'very inconvenient/much bother') the 'general inconvenience' and 'social bother' experienced before implantation were on average 7.9 and 6.9, respectively. At the end of follow-up, the scores decreased to 5.4 ($p = 0.004$) and 5.5 ($p = 0.079$), respectively. On a scale of zero to ten (zero being 'very bad' and ten being 'very good') quality of life scored a 4.7 before implantation. This score improved to 5.9 ($p = 0.087$) at the end of the follow-up period.

Table 1. Complications, revisions and explantations

<i>Peroperative complications (n = 10)</i>	
Bladder perforation	
Minimal (implantation of balloons is possible)	4
Significant (new surgery necessary)	2
Balloon defect (with reposition)	
Unilateral	1
On both sides with separate operations	1
Hematoma scrotum	1
Urinary retention	1
Allergic reaction (iodine)	1
Atrium fibrillation	1
<i>Postoperative complications (n = 20)</i>	
Dislocation	
Once	10
Twice	3
Six times	1
Urinary retention	3
Erosion	2
Scrotum pain	2
Irritation/pain tubing	2
Balloon inflammation/contamination	2
Perineal pain	1
Bladder perforation	1
Pain due to balloon adjustment	1
Filling port penetrating through the skin	1
Empty balloon/leakage	1
Obstruction of lumen	1
<i>Revisions (n = 12)</i>	
Reposition balloon(s)	
Once	8
Twice	2
Six times	1
Reposition tubing/filling port	2

Ten patients indicated improvement in performing physical labor or sports, only one person indicated a worsening. Sexual functioning improved for one person and worsened for one person ($n = 25$). The remaining patients did not indicate an alteration or were not sexually active. At the end of follow-up, 11 patients were not satisfied as apposed to 14 patients that were ($n = 25$). Nevertheless, 17 patients would choose ProACT when having to make the same decision over again and 18 patients would recommend it to someone else ($n = 24$). Only 8 patients would not choose ProACT again and 6 patients would not recommend it to others.

Complications

The complications are shown in table 1. In 6 patients the bladder was perforated peroperatively. Only 2 of these

patients needed a second operation, because the balloons could not be placed or could not be placed correctly at the first operation. Urinary retention could be corrected simply by decreasing the volume of the balloons. In a number of cases, the dislocation had consequences for the effectiveness and needed revision. Revisions were also done for other indications.

The ProACT device was removed in 13 patients on one (4) or both sides (9) because of bladder perforation, dislocation, balloon infection, erosion, failing of repositioning or insufficient result. After one-sided removal of a ProACT device because of erosion, 1 patient became completely continent. One patient will have the ProACT removed in the future because of unsatisfactory results. In 1 patient, a balloon was removed at the end of the follow-up period because of erosion. The implantation of a new balloon has been scheduled.

Discussion

At this time, the AUS is considered the gold standard for the treatment of SUI after RP. The effectiveness of ProACT has already been investigated and some results have been published [15–18]. The exact position within the arsenal of treatment options of SUI in patients after RP is not known. The current study group consists of 29 male patients with SUI after RP without prior radiotherapy. This seems to be an ideal group; there are no prostatic tissue remnants and no compromised tissue quality due to radiation. The results of ProACT used for SUI after TURP or RP with adjuvant radiotherapy or radiotherapy alone are unclear.

In 2005, Hübner et al. [15] published the results of a prospective study evaluating the effectiveness of ProACT in 117 men with SUI, of whom 110 men after RP. The pad count decreased from an average of 5.6 pads per day at the beginning to 1.4 after 1 year and 1.2 pads per day after 2 years ($p < 0.001$). The I-QoL, with a maximum score of 100 points, showed a significant improvement from 34.7 before ProACT to 64.9 and 66.3 after, respectively, 1 and 2 years ($p < 0.001$). The Stamey score showed a significant improvement as well. In 54 of 117 patients, 79 revisions were needed.

Hübner et al. [16] compared the results of the first 50 and the last 50 operations performed. The results showed a greater increase in the I-QoL score without a significant difference in pad count in patients belonging to the last group. The number of complications in the last group was lower compared to the first group.

Kocjancic et al. [17] showed good results in 64 patients with 67% of the patients considered to be dry in terms of pad count. Pad count decreased from 5.2 to 1.5 at 12 months with an increase in I-QoL score.

Trigo-Rocha et al. [18] prospectively analyzed the results of 23 men. The pad count decreased from 4.76 on average to 1.83 with 15 men being continent after an average follow-up of 22.4 months. The I-QoL score improved. In addition to four already performed revisions, 3 patients were scheduled for a revision.

In the literature, ProACT is often indicated as a 'minimally invasive' therapy. The term 'less invasive' therapy seems to be more appropriate in comparison to the AUS considering the necessary surgery and the (large) number of complications, dislocations and necessary revisions in our study group and the aforementioned studies of Hübner and Trigo-Rocha. Contrary to the AUS, it takes much longer to reach continence. ProACT appears to be a procedure with a considerable complication rate. Part of these complications are temporary and/or can be managed easily. Regular evaluation is needed to determine whether the treatment with ProACT should be continued, possibly including a revision, or if another treatment option, like the AUS, should be considered. Since ProACT can easily be removed and does not exclude another treatment, ProACT can play a role as step-up therapy.

The costs for one pair of ProACT balloons are about one third of the costs for the AUS device. A revision does not always require the use of new balloons, as the same balloons will be re-used when possible. The mentioned complications are the total number of complications of both the first implantation and revisions. Cost-effectiveness and the burden for the patient should be analyzed in more detail for ProACT used as a step-up therapy.

This study shows that patients were mostly satisfied, despite the fact that the objective results were not always optimal. Providing appropriate information about different therapies is important for a well-informed decision taken by the patient, together with his surgeon. The degree of incontinence and the specific characteristics of the possible treatments should be taken into account. ProACT can also be considered if there are contraindications for the AUS.

From the current published studies and our own study no factors emerged to help us predict the effectiveness of ProACT. The possibility of determining in advance which patients will benefit could improve the results and decrease the complications and necessary revisions. Stecco et al. [19] studied the possibility of MRI to predict the ef-

fectiveness of ACT™ (adjustable continence therapy for the treatment of SUI in women) and to determine the correct localization of the ACT balloons.

There have been technical enhancements in the past in order to improve the procedure. The ProACT device and procedure are still under development. Gregori et al. [20] researched the possibility of implanting ProACT using transrectal ultrasound (TRUS). It is possible to implant ProACT using local anesthetics, although no results have been published.

Similar studies concerning predictive characteristics and improvements of the device and procedure could contribute to improvement of the results.

Conclusions

ProACT is a less invasive treatment for SUI after RP than the AUS with reasonably good results. However, the procedure is associated with a substantial revision and explantation rate. Adjustments of the procedure and studies to identify prognostic factors may help improve the results. The application of ProACT does not preclude other treatment modalities and the device can easily be removed if the results are unsatisfactory. ProACT can be part of a so-called step-up approach before opting for a more invasive treatment, such as the AUS. It is advisable to do a cost/benefit analysis for such an approach. Both the burden for the patient (various admissions for different procedures, greater chance of complications, etc.) as well as the financial consequences should be analyzed.

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