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Transrectal Ultrasound–Guided Implantation of Adjustable Continence Therapy (ProACT): Surgical Technique and Clinical Results After a Mean Follow-Up of 2 Years

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Abstract

Background: Treatment for stress urinary incontinence (SUI) after radical prostatectomy (RP) with the male Adjustable Continence Therapy (ProACT) system, implanted using fluoroscopy for guidance, has been described with promising clinical results.
Objective: This retrospective study aims to describe the surgical technique in detail and to evaluate the continence recovery and complication rate of a cohort of male patients with SUI after RP. All patients were treated with a modified technique that uses transrectal ultrasound (TRUS) for guidance and that may be performed under local anaesthesia.
Design, setting, and participants: Between June 2005 and March 2009, we operated on 79 consecutive patients with post-RP urodynamic intrinsic sphincter deficiency.
Surgical procedure: ProACT system implantation was performed with TRUS guidance under general or local anaesthesia.
Measurements: Perioperative data and adverse events were recorded in all patients. Outcome data (24-h pad test, number of pads per day (PPD) used by patients, a validated incontinence quality of life questionnaire) were analysed in the 62 of 79 patients who completed the postoperative system adjustments. In this group of patients, the mean follow-up is 25 mo.
Results and limitations: According to the 24-h pad test and the mean number of PPD used, 41 patients were dry (66.1%), 16 patients improved (25.8%), and 5 patients failed treatment (8%). The dry rate in previously irradiated patients was 35.7%. Complications included intraoperative bladder perforations (2 of 79; 2.5%), transient urinary retention (1 of 79; 1.2%), migrations (3 of 79; 3.8%), and erosions (2 of 79; 2.5%). According to the degree of incontinence, the dry rate in patients with mild, moderate, and severe incontinence was, respectively, 85%, 63.6%, and 33.3%.
Conclusions: TRUS guidance for ProACT implantation results in success and complication rates that compare favourably with published data using fluoroscopy for guidance. Previous radiotherapy and severe incontinence seem to be a relative contraindication. Larger series and longer follow-up are progressing to establish long-term efficacy.

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1. Introduction

The male Adjustable Continence Therapy (ProACT) system (Uromedica, Plymouth, MN, USA) is a postoperatively adjustable, permanently implantable device for the treatment of stress urinary incontinence (SUI) after prostate surgery. Initially, as first described by Hübner and Schlarp, the system implantation was performed under two-dimensional fluoroscopic guidance [1–5]. More recently, the safety and feasibility of transrectal ultrasound (TRUS) guided ProACT system implantation has been described to achieve a more accurate placement by the use of multiplanar ultrasound imaging and to avoid radiation exposure [6].

This study aims to evaluate the continence recovery and complication rate of a cohort of male patients with SUI after radical prostatectomy (RP), all treated with the TRUS-guided ProACT system implantation. We describe the surgical technique in detail and retrospectively report our findings at a mean follow-up of 2 yr. To our knowledge this is the largest series with the longest follow-up on TRUS-guided ProACT system implantation.

2. Methods and patients

2.1. The ProACT system

The system is an adjustable permanent implant designed to achieve continence through increased outlet resistance in male patients with SUI. It is composed of an expandable silicone balloon attached with a 2-lumen conduit to a reinjectable titanium port. One lumen contains a 15-cm by 0.8-mm push wire, while the other acts as a channel for balloon inflation. The device is manufactured in two lengths: 12 cm and 14 cm. In general, the 12-cm device is employed for patients with residual prostate following benign surgery (ProACT balloons are placed more distally, on either side of the prostatic apex), and the 14-cm device is required for post-RP patients. Post-RP patients require two balloons, which are placed on either side of the vesicourethral anastomosis just above the pelvic diaphragm. A specially designed, sharp-tip, removable trocar contained in a 4.6-mm diameter U-shaped sheath is used to insert the balloons through a transperineal route. The two titanium ports are placed into a subcutaneous parascrotal position to allow easy percutaneous access for adjusting the balloons postoperatively (maximum: 8 ml) using a 23-gauge noncoring needle. This allows the device to be adjusted by modifying the level of coaptation needed to achieve continence.

2.2. System implantation: the original technique

As described by Hübner and Schlarp [1], system implantation is performed under fluoroscopic guidance with a cystoscope sheath inserted in the bladder functioning as a guide for correct placement. The balloons are then filled with contrast medium and sterile water mixed to an isotonic medium.

2.3. Patient population

After obtaining institutional review board approval, between June 2005 and March 2009 we operated on 79 consecutive patients (mean age: 67.9 yr; range: 51–82) with post-RP, urodynamic, intrinsic sphincter deficiency. Twelve patients had had a RP at our department while 67 patients were referred to our institution after a RP performed at different hospitals. All patients were free from distant metastasis. Flexible cystoscopy and TRUS were used to evaluate the bladder neck, anastomosis, and urethra in order to exclude local recurrences and strictures. At baseline, all patients underwent urodynamic examination according to the methodology and definitions of the International Continence Society guidelines [7]. Urodynamic investigations were performed to exclude detrusor overactivity or compliance abnormalities; Valsalva leak point pressure and maximal urethral closure pressure were measured.

Incontinence was evaluated as the number of pads per day (PPD) used by patients, and categorised as mild (one or two PPD), moderate (three to five PPD), and severe (more than five PPD or condom use). All patients were also assessed with a 24-h pad test and with the incontinence quality of life questionnaire (I-QoL) validated by Wagner et al [8]. Table 1 lists patient characteristics at baseline.

Table 1 – Patient characteristics

No. patients	79
Mean age, yr (range)	67.9 (51–82)
Mean interval between RP and ProACT implantation, mo (range)	35 (7–122)
No. patients with previous adjuvant radiotherapy	16
Degree of incontinence, No. patients	
Mild	25
Moderate	39
Severe	15
Mean 24-h pad test (range)	389.7 g (20–1300)
Mean VLPP (range)	58 cm H_2O (30–110)
Mean MUCP (range)	44.9 cm H_2O (9–100)
Mean PPD (range)	3.7 (1–10 or condom use)
Mean I-QoL score ± SD	49 ± 19.3

I-QoL = incontinence quality of life questionnaire; MUCP = maximal urethral closure pressure; PPD = pads per day; ProACT = male Adjustable Continence Therapy system; RP = radical prostatectomy; SD = standard deviation; VLPP = Valsalva leak point pressure.

2.4. Patient preparation

Patients are advised to take an antiseptic shower and a cleansing enema the night before surgery. A prophylactic antibiotic regime consisting of a single 2-g dose of ceftriaxone is administered intravenously prior to entering the operating room. Hair removal from the surgical field area is performed in the operating room just before surgery. Antibiotic solution is used to immerse the elements of the system prior to implantation and is used to liberally irrigate throughout the procedure.

2.5. Surgical technique

The patient is placed in the lithotomy position and the lower abdomen, genitalia, perineum, and the perianal area are disinfected. A 14- or 16-Ch Foley catheter is inserted in the bladder, which is filled with 40–50 ml of saline solution to clearly visualise the urethra and the bladder neck with TRUS. The scrotum is held above the perineum with tape. The anal ring is isolated from the perineum with a drape and TRUS is performed using a 7.5-MHz linear probe and a small convex probe.

When local anaesthesia only is used, 10 ml of ropivacaine 7.5 mg/ml is administered with a regular 20-gauge needle in skin and subcutaneous tissue at 1–2-cm intervals bilaterally around the intended perineal incisions.

Two horizontal 0.5–1-cm skin incisions are made in the perineum about 1 cm lateral to the median line and about 1.5 cm above the rectum (Fig. 1).