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PROSPECTIVE STUDY EVALUATING EFFICACY AND SAFETY OF ADJUSTABLE CONTINENCE THERAPY (ProACT) FOR POST RADICAL PROSTATECTOMY URINARY INCONTINENCE

FLAVIO TRIGO-ROCHA, CRISTIANO MENDES GOMES, ANTONIO CARLOS LIMA POMPEO, ANTONIO MARMO LUCON, AND SAMI ARAP

ABSTRACT

Objectives. To examine a new prosthesis, the Adjustable Continence Therapy (ProACT), to determine its ability to treat effectively post radical prostatectomy urinary incontinence. Urinary incontinence is one of the most significant complications of radical prostatectomy. Although the artificial urinary sphincter (AUS) is considered the standard treatment for this condition, many men seek a simpler and less expensive treatment option.

Methods. From November 2000 to March 2004, 25 patients with severe post radical prostatectomy urinary incontinence were treated using the ProACT device. The preoperative evaluation included pad count, Valsalva leak point pressure determination, and Incontinence Quality-of-Life scores. In the follow-up, the same parameters, as well as complications, were analyzed and compared with the baseline measurements to assess the efficacy.

Results. The follow-up period was 6 to 48 months (mean 22.4). Of the 25 patients, 23 had follow-up data available for analysis. The improvements in pad count, Incontinence Quality-of-Life score, and Valsalva leak point pressures from baseline to the last follow-up examination were all significant ($P < 0.05$). Overall, of the 23 patients followed up, 15 (65.2%) were continent using 0 to 1 pad daily and satisfied, 3 (13%) were improved but unsatisfied, and 5 (22%) did not have any improvement. Balloon adjustments were performed in all patents to achieve continence. Revision surgery was required in 4 (17%) of 23 patients.

Conclusions. The use of ProACT represents a safe and effective treatment for post radical prostatectomy incontinence with a good degree of patient satisfaction and a low complication rate. Postoperative adjustments were necessary in most patients and were undertaken as a simple outpatient visit. UROLOGY **67:** 965–969, 2006. © 2006 Elsevier Inc.

Post radical prostatectomy urinary incontinence (PRPUI) represents a serious complication of radical prostatectomy, significantly compromising a patient's quality of life.[1] In one of the most significant published series, 3% to 8% of all patients undergoing radical prostatectomy will have significant urinary incontinence, substantially affecting their quality of life. About 6% of patients who undergo radical prostatectomy will need surgical treatment for their incontinence.[2] In most of these patients, PRPUI is secondary to external sphincter deficiency that is isolated or associated with detrusor hyperactivity. Therefore, the treatment of PRPUI consists of increasing the urethral resistance for most patients with PRPUI.[3] Many methods have been used to achieve this aim, including operations for urethral compression using muscle and synthetic fascia,[4] slings,[5] and injectable agents,[6] with controversial results. The routine use of injectable agents as the first-line treatment seems to be an attractive option as a minimally invasive technique. However, the need to repeat the procedure significantly increases the costs of this treatment.[7] The World Health Organization has nominated the artificial urinary sphincter (AUS) as the reference standard treatment for postprostatectomy incontinence.[8]

Many reports have demonstrated the efficacy and safety of the AUS for the treatment of this condition; however, many patients seek simpler and cheaper treatment options. The Prostate Ad-

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From the Department of Urology, São Paulo University, São Paulo, Brazil

Reprint requests: Flavio Trigo-Rocha, M.D., Rua Barata Ribeiro, 237 cjs. 104-106, São Paulo, SP 01308-000, Brazil. E-mail: flaviotrigo@uol.com.br

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justable Continence Therapy (ProACT; Uromedica, Plymouth, Minn) involves the insertion of two balloons para-urethrally, one on either side of the urethra, just beneath the bladder neck to increase its resistance. What makes this device different from other implantable prosthesis or bulking agents is the presence of a titanium port connected to each balloon, allowing postoperative balloon adjustments by percutaneous injection. In this series, we evaluated the efficacy and safety of the ProACT implantable prosthesis in the treatment of PRPUI.

MATERIAL AND METHODS

From November 2000 to March 2004, after the university's ethics committee reviewed and approved the study, we conducted a prospective study to evaluate the efficacy and safety of the ProACT device in 25 patients with severe PRPUI. Patient age ranged from 61 to 72 years (mean 68.62). The interval between radical prostatectomy and ProACT implantation varied from 13 to 159 months (mean 40).

The preoperative evaluation included a daily pad count, urodynamic evaluation, and Incontinence Quality-of-Life (IQOL) questionnaire. During the urodynamic evaluation, the Valsalva leak point pressure (VLPP) was determined by measuring the bladder pressure using a 4F catheter. The patients were followed up and the data analyzed using the same parameters as used in the preoperative period. In addition, the postvoid residual urine volume was evaluated by ultrasonography using a bladder scanner (Diagnostic Ultrasound Corp., Bothell, Wash). Postvoid volumes less than 100 mL were defined as not significant. Early and late complications were recorded and managed appropriately. The postoperative parameters (number of pads used daily, IQOL score, and VLPP were compared with the baseline measurements using the Student *t* test. Statistical significance was defined by a *P* value less than 0.05.

All patients underwent implantation under general anesthesia or spinal blockage. Cephalothin 500 mg was administrated intravenously 30 minutes before surgery and was continued for 1 week postoperatively in an oral form. Patients were placed in the lithotomy position, and the procedure was started with a careful cystoscopic examination. The bladder was filled with 100 mL iodine contrast solution (Hypaque 15%), and the cystoscope sheath with its obturator was left in place inside the urethra and bladder, allowing fluoroscopic determination of the urethra and bladder neck position. A transverse skin incision approximately 4 cm in length was made at the perineum just below the scrotum. A combination of fluoroscopic imaging and cystoscopy was used to facilitate visualization of the Kelly clamp or dedicated inserter as it was moved parallel to the urethra and to assess the position of the inserter anteriorly/posteriorly to the urethral plane (not detectable by fluoroscopy alone). A Kelly clamp was introduced through the incision on each side in turn and directed to the point midway between the inferior pubic ramus and the urethra, as marked by the cystoscope. Under fluoroscopic guidance, the pelvic floor was perforated and the Kelly clamp directed toward the bladder neck. The Kelly clamp was maintained parallel and close to the cystoscopic sheath to avoid injury to the penile crura. Once the region lateral to the urethra and close to the bladder neck was reached, careful blunt dissection was conducted to create a space just beneath the bladder neck and lateral to the urethra. The Kelly clamp was then replaced by a special trocar in a U-channeled sheath to complete the development of a pocket or space, typically in the presence of dense scar tissue, to provide adequate room to position the first balloon. Possibly because of the heavy scarring often seen in men with PRPUI, very minimal bleeding was seen during the "coring"-type insertion of these delivery instruments. The trocar was then removed to facilitate ProACT balloon insertion by way of the U-channeled sheath (Fig. 1) to the area beneath the bladder neck and dorsolateral to the urethra. A radiopaque marker incorporated into the balloon tip allowed determination by fluoroscopy of the exact position of the balloon in relation to the urethra and bladder neck (Fig. 2). After checking its position, the balloon was filled with 1.5 to 2.0 mL of contrast mixed with sterile water to an isotonic solution. The procedure was repeated on the contralateral side to implant a second balloon, and a final cystoscopy was done to confirm the balloons' correct position. The correct position should be one balloon on each side, above the pelvic floor, causing bilateral urethral compression (Fig. 3). Cystoscopy was also used to exclude any perforation of the bladder or urethra. In 2 cases in which a bladder perforation occurred intraoperatively, the balloon on that side was not implanted.

After placing the balloons, blunt dissection was done from the perineal incision toward the scrotum, and the balloon ports were placed in the scrotum bilaterally just beneath the dartos fascia. This allowed easy percutaneous needle access for future filling or deflation of the balloons using these ports. A 14F Foley catheter was left overnight. In the 2 cases of accidental bladder perforation, the Foley catheter was kept in place for 3 days. All the patients were discharged on the first postoperative day. After 1 month, the patients who did not achieve appropriate continence (dry or one pad daily) underwent additional filling of the balloons through the scrotal ports with 0.5 mL of an isotonic mixture of contrast and water or isotonic sterile 0.9% saline using an insulin needle. These adjustments were very simple and were done by percutaneous port puncture using an insulin or noncoring needle. They did not require any anesthesia (Fig. 4) and were timed about 4 weeks apart to permit gradual dilation of the scarred tissue around the bladder neck. They were continued until complete or satisfactory continence was achieved or until the limit of 8 mL/balloon was reached.

RESULTS

Of the 25 patients, 1 was lost to follow-up and 1 died of a cause not related to the procedure (heart attack). We had no data about the continence status of these 2 patients. In the remaining 23 patients, the follow-up varied from 6 to 48 months (mean 22.4). Of the 23 patients available for follow-up, 16 completed at least 24 months of postoperative assessment. The operative time ranged from 22 to 58 minutes (mean 35.4). No significant bleeding or anesthetic complications were observed in any patient. Only 1 patient experienced urinary retention in the early postoperative period and was treated by removal of 0.5 mL from each balloon using an insulin needle through the titanium port. No patient presented with significant postvoid residual urine volumes during the follow-up period. The baseline daily pad count changed from a mean of 4.76 ± 1.71 to a mean of 1.83 ± 1.58 at the last follow-up visit ($n = 23$; $P < 0.05$). The IQOL score improved from a mean at baseline of 63.04 ± 20.42 to a mean of 82.59 ± 15.24 ($n = 23$; $P < 0.05$). The urodynamic evaluation revealed an improvement in VLPP from a

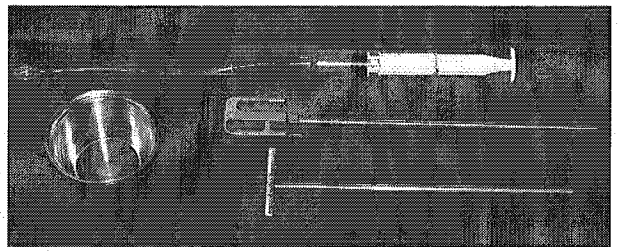

FIGURE 1. *ProACT balloon and trocar and U-shaped cannula used for insertion. Syringe shown injecting through port. Maximal permitted balloon volume 8 mL per balloon.*

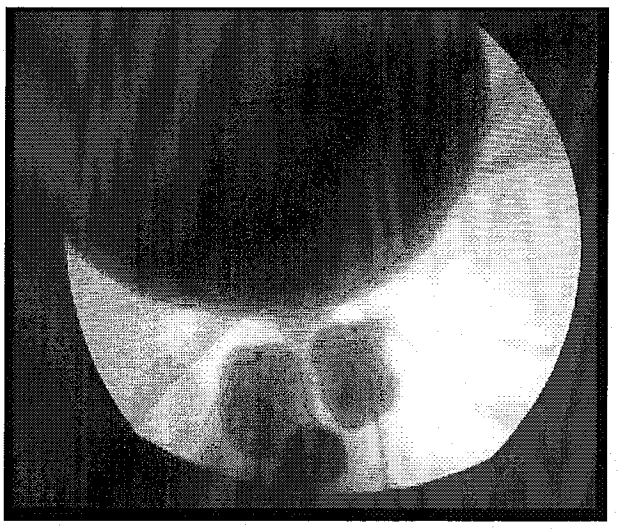

FIGURE 2. *Radioscopic view showing relation between balloon and bladder neck during implantation.*

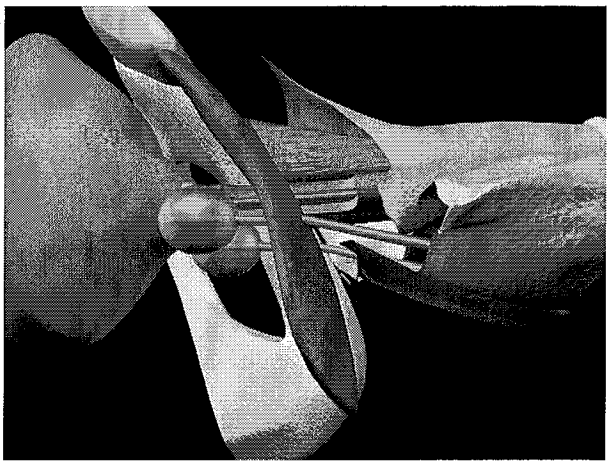

FIGURE 3. *Diagram showing relation among two balloons, urethra, and bladder neck. Ports are located under dartos fascia in scrotum. In situ cystoscope seen, as is normal during implantation.*

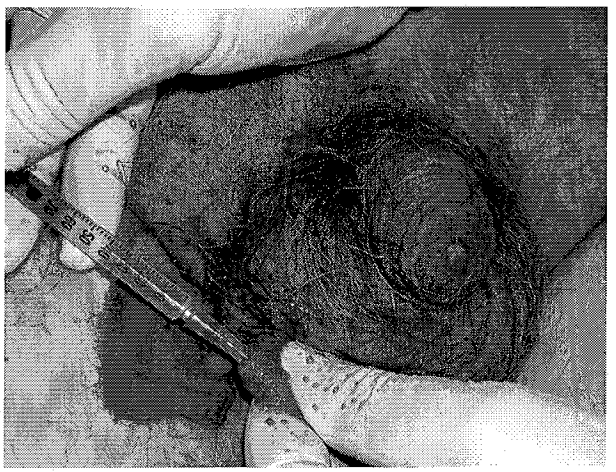

FIGURE 4. *Injection port located beneath scrotum skin allows easy filling or deflation of balloons.*

mean of 48.76 ± 25.37 cm H_2O before treatment to a mean of 84.1 ± 33.5 cm H_2O at the last evaluation ($n = 23$; $P < 0.05$).

Overall, of the 23 patients with follow-up data, 15 (65%) were continent using 0 to 1 pad/day and were satisfied, 3 (13%) had some improvement but remained unsatisfied, and 5 (22%) were unchanged. Of the 8 unsatisfied patients, 2 underwent AUS placement with simultaneous removal of the balloons without any difficulty. Three patients were waiting for surgical revision of the ProACT owing to balloon migration below the pelvic floor and, therefore, lacking urethral compression and three were considering alternative forms of treatment. Balloon adjustments were performed postoperatively as required to achieve and maintain continence in all patients. The average number of adjustments was 4.6 (range 1 to 7), all of which were done in an outpatient setting. The final balloon volume ranged from 2.0 to 7.0 mL (mean 3.5). All adjustments were made in the first 6 months after the procedure.

Revision procedures have been performed in 4 patients (17.3%). Two of the four revisions were to implant a single balloon after unintended unilateral bladder perforation during the initial implant surgery. One revision was necessary to replace a leaking balloon, and the last revision was to remove both devices after erosion of one injection port through the scrotal skin. No cases of urethral erosion or other major complications were observed in this series. Two patients (8%) presented with detrusor overactivity postoperatively, requiring temporary use of anticholinergic medication, with both patients able to discontinue this adjunctive therapy within 6 months.

COMMENT

PRPUI probably represents the complication of radical prostatectomy with the most significant impact on patients' quality of life. Conservative management should be the first choice during the first

12 months owing to the possibility of spontaneous recovery of continence.[9]

Patients with incontinence due to intrinsic sphincter deficiency, as well as those with intrinsic sphincter deficiency associated with bladder overactivity, represent the major population of patients with PRPUI. Both groups have a good response to procedures that increase bladder outlet resistance,[10] with dramatic improvement in quality of life.

Our study population was composed of patients with severe incontinence, as demonstrated by the pretreatment mean number of pads used daily (4.56 ± 1.71) and low pretreatment VLPPs (48.76 ± 25.37 cm H_2O) in the urodynamic evaluation. The preoperative IQOL score (mean 63.04 ± 20.42) demonstrated the significant effect caused by incontinence in this group.

According to the World Health Organization, only the AUS represents a viable alternative in the treatment of urinary incontinence after radical prostatectomy. Injectable agents were judged to be "of equivocal value" for the treatment of PRPUI because of the high failure rate (more than 50%) and thus the consequent need for repeat injection procedures to maintain efficacy of short-term duration.[8] For patients with VLPP greater than 70 cm H_2O, the use of injectable agents has been suggested by some investigators as a possible treatment alternative.[11] However, in the present cohort, most patients had a VLPP of less than 70 cm H_2O, casting doubt on these patients' ability to benefit greatly from the use of injectable agents.

We defined as continent those patients who require 0 to 1 pad daily. Regarding the quality-of-life assessment, a significant improvement was observed as evaluated by the questionnaires. Similar to other reports, we observed a strong association between the recovery of continence and improvement in the quality of life.[12,13] The degree of satisfaction was also similar in patients reporting complete dryness and those wearing one pad a day. Conversely, patients who required additional revision operations to recover continence also reported a high degree of satisfaction.[14]

The urodynamic evaluation revealed significant improvement in the VLPP, similar to other procedures that increase urethral resistance.[15] No patient had any clinical involvement in the upper urinary tract. The absence of urinary tract infections can be explained by the absence of significant postvoid residual urine volumes in all patients.

The results in this series, addressing men with severe incontinence, were superior to those obtained using bulking agents such as collagen.[6] Even though some investigators have showed results similar to ours using sling procedures with short-term follow-up,[5,16,17] the initial success rates were reduced after long-term observation.[18–20] Although one of our patients had a port erode at the scrotum, no patient experienced urethral erosion. The urethral preservation, as well as the easy removal of the ProACT, may represent an advantage over slings, especially for those patients with treatment failure who undergo AUS sphincter placement, such as occurred in two of our patients.

In terms of surgical technique, the ProACT procedure is relatively simple, requiring basic endoscopic equipment and fluoroscopy, both of which are present in the vast majority of hospitals. The absence of major complications and postoperative discomfort suggests that this procedure may be undertaken as day surgery or similar procedure.

The success rate of AUS for the treatment of urinary incontinence after prostate surgery ranges from 75% to 96.7%, according to several large series from centers of surgical excellence.[21–23] Although the success rate in this series with the ProACT system was lower than these reported numbers for the AUS, we were able to obtain success in two thirds of the treated patients with an average follow-up of just less than 2 years. This cohort of patients included those patients implanted as the surgical technique was being developed. The degree of satisfaction of the patients who obtained continence was very high, because they were able to urinate without manipulating any implanted prosthetic components. Additionally, the simpler mechanism of this device resulted in a significant reduction of costs, especially in the European market, where the ProACT device has been approved for clinical use. The need to make several adjustments to the balloon volumes did not disturb the patients once they understood that this was a normal adjunct to implanting this device.

In terms of adverse events, bladder perforation occurred unilaterally in 2 patients during primary implantation. In both cases, delaying implantation on the perforated side and keeping the indwelling catheter in place for 3 days easily managed this complication. Although immediate implantation after bladder perforation could have been possible with the ProACT device, a more conservative approach was taken and the new implantation was delayed in such cases for 60 days. One patient (4%) had a single port erode and another (4%) had a balloon deflate, which was replaced without incident. No other major complications were observed, demonstrating that the procedure is safe. Few reports have analyzed the complications of the AUS in a prospective way.[24] A review of published studies on the use of the AUS revealed reported rates of erosion and/or infection varying between 0% and 24.6%, with the greatest incidence reported with the longest follow-up (10 to 15 years).[1] Although our series of ProACT implants was small, the complication rate observed among the recipients of the

ProACT device compared favorably with those of most published series of the AUS, with a 17% rate of revision surgery for all reasons in our series to date. The mechanical failure rate and revision associated with the AUS has been 12.5% in some longer term studies.[25,26] This mechanical failure rate is unlikely with the passive ProACT prosthesis, which simply relies on creating sufficient passive urethral resistance to produce continence and is not manipulated by the patient during voiding.

CONCLUSIONS

In a long-term follow-up study, the use of the ProACT periurethral implant represents a safe and effective alternative treatment for PRPUI, as demonstrated by the reduction in pad count, improvement in IQOL scores, and increase in VLPPs. The procedure was accompanied by a high degree of patient satisfaction and low complication rates. Postoperative adjustments were necessary in most patients, but this consisted of a quick and simple outpatient procedure. Additional follow-up and larger series of patients are necessary to confirm whether ProACT, because of its simplicity, cost, safety, and efficacy, may be considered one of the first surgical choices for treatment of PRPUI.

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