Original Article

Adjustable continence therapy (ProACT) and bone anchored male sling: Comparison of two new treatments of post prostatectomy incontinence

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Objectives: To compare the efficacy of two surgical treatments for male urinary stress incontinence: adjustable continence therapy (ProACT) and bone anchored male sling (BAMS).

Methods: Eighty-four consecutive post radical prostatectomy incontinent patients received ProACT ($n = 46$) or BAMS ($n = 38$) implantation by two different operators in two different centres. Eighty of them had a complete follow up. Both groups were prospectively assessed by number of pads per day and a validated questionnaire (UCLA/RAND). Complications rate and mean operating times were compared. All comparisons were analyzed using the t test, Fischer's exact test and χ^2 analysis (significance $P < 0.05$).

Results: At a mean follow up of 19 and 33 months respectively, 30/44 (68%) patients treated with ProACT were dry (0/1 safety pad) in comparison with 23/36 (64%) patients treated with BAMS ($P > 0.05$). Stratifying the results, ProACT had 33/39 (85%) dry patients in severe (more than three pads/day) preoperative incontinence, in comparison with 21/26 (81%) for BAMS ($P > 0.05$). The UCLA/RAND questionnaire showed an average increase of 11.7 points (from 10.2 to 21.9) for ProACT and of 10 points (from 11.9 to 21.9) for BAMS ($P > 0.05$). Complications included removal of ProACT and BAMS in 6/44 (14%) and 2/36 (6%), respectively. Mean operating time was 18 min and 45 min ($P < 0.05$) for ProACT and BAMS, respectively.

Conclusions: ProACT and BAMS are both associated with a satisfactory rate of success. ProACT results seem to be better for severe incontinence and BAMS for mild incontinence. The operation time of ProACT is shorter.

Key words: incontinence, ProACT, sling.

Introduction

The incidence of male stress urinary incontinence (SUI) following radical prostatectomy is reported as being wide-ranging, with some authors suggesting rates as high as 20–40%.[1] The consequences on quality of life for these patients are significant: most of them use continence pads or penile clamps and restrict fluids. Stress urinary incontinence remains a significant problem for both patients and urologists. The available pharmacotherapeutical treatment options are few: sympathomimetics[2] and lately, serotonin reuptake inhibitors.[3] Surgical treatment options include placement of an artificial sphincter (AUS),[4] bulking agent injection,[5] bulbourethral sling procedure and more recently, pro adjustable continence therapy (ProACT)[6] and bone-anchored male sling (BAMS).[7] AUS and bulking agent have already been assessed with comparison studies.[8] ProACT and BAMS have both been assessed individually but to our knowledge no comparison studies have been carried out yet between these two procedures. When comparing two different operations, it is necessary to use only objective evaluation tools. In particular for treatment of stress urinary incontinence, the most important results to assess are the effect on urinary leakage and the impact on quality of life. We used number of pads and the UCLA/Rand cancer prostate index quality of life questionnaire.[9]

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Methods

Preoperative study

Eighty consecutive, non-randomized men who had undergone either ProACT ($n = 44$) or BAMS ($n = 36$) for post prostatectomy incontinence between September 2001 and September 2004 comprised the study group and were prospectively assessed. The two procedures have been carried out in two different centres (ProACT in Italy, BAMS in USA) by two different surgeons. The learning curve of the operators was at the same level in the respective procedures at the beginning of the study. All men had significant stress urinary incontinence for at least 1 year after radical prostatectomy and the incontinence had persisted despite conservative measures (pharmacotherapy or kegel exercises). A complete history, physical examination, and urinalysis were obtained for all patients. All patients were required to fill out a preoperative UCLA/RAND questionnaire. The degree of incontinence was categorized as mild (one to two pads per day), moderate (three pads per day) and severe (more than three pads/day). All patients underwent a complete urodynamic exam. All patients with urge incontinence or pre-existing voiding dysfunction were excluded from the study.

Operative techniques

The BAMS is a polypropylene sling placed under the bulbar urethra by a perineal approach. The sling is eventually anchored to the pubic bone by three titanium screws (InVance-In bone drill, American Medical Systems, Minnetonka, MN, USA).

Patients undergoing BAMS surgery were placed in a lithotomy position after being given spinal anesthesia. A 16 F Foley's catheter was inserted. A 4 cm vertical midline perineal incision was made incising

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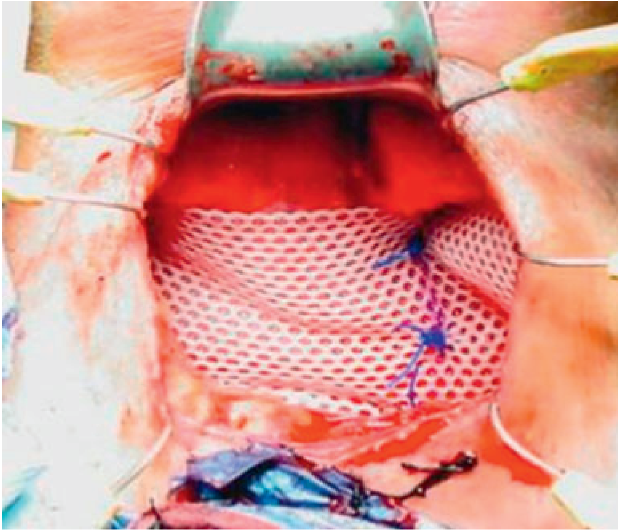

Fig. 1 Intraoperative picture after a bone anchored male sling (BAMS) placement.

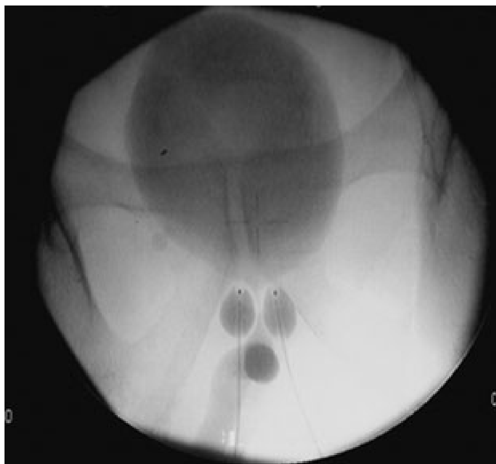

Fig. 2 Intraoperative Urethrogram after adjustable continence therapy (ProACT) placement.

skin and Colles' fascia. All subcutaneous fat and the bulbospongiosus muscle were left undisturbed. Further dissection was carried out laterally to expose the descending ramus of the pubic bone laterally. Three titanium bone screws with preloaded number 1 polypropilene sutures were placed into the inner aspect of the pubic rami bilaterally. A non-absorbable material (polypropylene) either alone or in combination with dermis, was used for the sling. One edge of the sling was anchored to the pubic bone by transferring the prolene sutures and tying over the bone. Cough test on the table was used to determine appropriate sling tension, pulling the sling towards the controlateral side with 2 Allis clamps to a point where no further leakage was observed. The controlateral prolene sutures were then transferred at that point onto the sling and tied over the bone (Fig. 1). The wound was closed in two layers.

The ProACT (Uromedica, Plymouth, MN, USA) implant is constructed from silicone elastomer. Each ProACT implant consists of a silicone balloon attached to a titanium port (re-injectable) via a short length of tubing. The re-injectable titanium ports are placed in the scrotum, under the dartos fascia, allowing for future percutaneous access to the implanted injection ports. This allows the surgeon or physician to adjust the volume of the balloon after implantation, thus making it possible to adjust the level of compression needed to keep the patient dry but still free from developing retention.

Patients undergoing ProACT were placed in a lithotomy position after being given spinal anaesthesia and prepared and draped in sterile fashion. A rigid cystoscope was inserted under direct vision, and 50 mL of contrast medium was instilled to visualize the bladder neck. Leaving the cystoscope sheath in place with the obturator, a 1-cm horizontal skin incision was made at the perineum, about 2 cm lateral to the median rafe on both sides. Using a specially-designed insertion instrument combining a trocar and a 'U-shaped' cannula to create a suitable tract under fluoroscopic guidance the pelvic floor was perforated next to the urethra in the cephalic and lateral direction. The two balloons were then positioned peri-urethrally above the pelvic floor, with the cystoscope sheath functioning as a parallel guide for correct placement. The balloons were then filled with 1.5 mL of contrast medium and sterile water mixed to an isotonic medium, and a urethrogram was taken to confirm the correct position of the devices (Fig. 2). Finally, the two ports were brought into a subcutaneous scrotal position. The incision was closed with a 4/0 reabsorbable suture and a 14 F Foley catheter inserted overnight. Beginning 1 month postoperatively, patients underwent monthly 'adjustments', a simple office procedure consisting of a percutaneous needle puncture to increase the volume of both devices.

Postoperative study

Postoperatively, the patient was discharged after a trial of voiding. Patients were evaluated at one week with an uroflow and post-void residual urine measurement. Eventually patients were evaluated during follow up visit at 1, 3, 6, 12 months and every 12 months thereafter. Efficacy of both procedures was assessed in all patients with the UCLA/RAND questionnaire, a validated questionnaire with five questions to assess urinary continence and the impact on quality of life. Specifically we used the overall score to assess the severity of the problem from urinary leakage and urinary function. For the statistic the preoperative and the last follow up visit score have been used. Additionally the postoperative number of pads used per day collected by recall assessed the efficacy on urinary leakage. In particular, patients were classified as 'dry' if they were using none or one safety pads a day, 'improved' if they use two or more pads a day with an improvement >50%, and failed if they use two or more pads a day with an improvement <50%.

Statistical analysis

All comparisons were analyzed using the t test, Fischer's exact test and χ^2 analysis (significance $P < 0.05$).

Results

We enrolled a total of 84 men, 80 of which had a complete follow up available.

The main characteristics of the two populations are summarized in Table 1.

The comparison of the outcomes is summarized in Tables 2–6.

The complications that required removal of the ProACT under local anesthesia include two erosions, one spontaneous deflation of the balloon, one infection and two migrations of the device. Four of six

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Table 1 Characteristics of the post radical prostatectomy incontinent patients that received adjustable continence therapy (ProACT) (*n* = 46) or bone anchored male sling (BAMS) (*n* = 38) implantation

	ProACT	BAMS	*P*
No. patients (total)	46	38	†
No. patients (complete f/up)	44	36	*
Mean age	67 years (range 45–82)	65 years (range 30–81)	*
Status post	Radical retropubic prostatectomy	Radical retropubic prostatectomy	†
Mean valsalva leak point press	40	50	*
Mild incontinence (1–2 pads/day)	5/44 (11%)	10/36 (28%)	*
Severe incontinence (≥3 pads/day)	39/44 (89%)	26/36 (72%)	*

**P* > 0.05; ***P* < 0.05; †not applicable.

Table 2 Operative details and complications of the post radical prostatectomy incontinent patients that received adjustable continence therapy (ProACT) or bone anchored male sling (BAMS)

	ProACT	BAMS	*P*
Follow up (months)	19 (range 12–48)	33 (range 18–44)	*
Mean operating time (min)	18	45	**
Day of catheterization (h)	12	12	*
Day of hospitalization (h)	24	24	*
Removal	6/44 (14%)	2/36 (6%)	*
Reason for removal	Infection, deflation, erosion, migration	Infection	†
Average number of adjustments	3 (1–7)	0	†

**P* > 0.05; ***P* < 0.05; †not applicable.

Table 3 Efficacy of adjustable continence therapy (ProACT) or bone anchored male sling (BAMS) at the last follow up visit

Dry (0–1 safety pads)	30/44 (68%)	23/36 (64%)	*
Improved (two pads, improved >50%)	7/44 (16%)	8/36 (22%)	*
Dry + improved mildly	4/5 (80%)	10/10 (100%)	*
Dry + improved significantly	33/39 (85%)	21/26 (81%)	*
Dry + improved mildly *vs* significantly	4/5 (80%) *vs* 33/39 (85%)	–	*
Dry + improved mildly *vs* significantly	–	10/10 (100%) *vs* 21/26 (81%)	*
Average number of pads	From 5 to 2	From 3 to 1	*
UCLA/RAND questionnaire difference pre-post	From 10.2 to 21.9	From 11.9 to 21.9	*

**P* > 0.05; ***P* < 0.05.

patients who had ProACT removed went for a successful reimplantation 60 days later, the other two went for an AUS with satisfactory result and no complication. The complications that required removal in spinal or general anaesthesia of the sling encountered two cases of infection in the BAMS group. The two patients who had to have the sling removed also underwent AUS. The mean number of adjustments was 3 (range 1–7) in the ProACT group; the BAMS does not have the possibility of postoperative adjustments.

Discussion

Persistent incontinence after radical prostatectomy is a psychologically and socially disabling problem.[10] Today, surgical options offer patients improvement and potentially a complete resolution of their incontinence. Some reports have evaluated either ProACT[6] or BAMS[7] therapy for post prostatectomy incontinence; however, a head-to-head comparison has not been reported yet. Our results show that the overall efficacy of both procedures is satisfactory and comparable (68% dry in ProACT *vs* 64% dry in BAMS, $P > 0.05$). Since the baseline is slightly different for the severity of incontinence in favor of the BAMS group, these data suggest that the ProACT has a good efficacy even in the most severe incontinence probably because of adjustability features. In fact after stratification of results between mild (one to two pads) and severe (more than three pads) preoperative incontinence, we noticed that ProACT results have the same efficacy in mild and severe incontinence (80% *vs* 84%, $P > 0.05$), whereas BAMS results seem to be poorer in

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Table 4 Average number of pads used visit by visit

Pads	Pre ProACT (n = 44) BAMS (n = 36)	1 year ProACT (n = 19) BAMS (n = 8)	2 years ProACT (n = 7) BAMS (n = 8)	3 years ProACT (n = 9) BAMS (n = 5)	4 years ProACT (n = 9) BAMS (n = 15)
ProACT	5.1	2.5	2.1	2.5	2.1
BAMS	3.2	1.4	1.3	1.4	1.1
P	*	*	*	*	*

*P > 0.05; **P < 0.05.

Table 5 UCLA/RAND questionnaire average scores visit by visit

QoL	Pre ProACT (n = 44) BAMS (n = 36)	1 year ProACT (n = 19) BAMS (n = 8)	2 years ProACT (n = 7) BAMS (n = 8)	3 years ProACT (n = 9) BAMS (n = 5)	4 years ProACT (n = 9) BAMS (n = 15)
ProACT	10.2	22.2	19.5	19.2	21.1
BAMS	11.9	20.3	20.2	20.1	21.7
P	*	*	*	*	*

*P > 0.05, **P < 0.05. QoL, quality of life.

Table 6 Patients that were dry and had improved visit by visit

	Pre ProACT (n = 44) BAMS (n = 36)	1 year ProACT (n = 19) BAMS (n = 8)	2 years ProACT (n = 7) BAMS (n = 8)	3 years ProACT (n = 9) BAMS (n = 5)	4 years ProACT (n = 9) BAMS (n = 15)
ProACT dry	0	14/19	4/7 (57%)	7/9 (78%)	5/9 (56%)
BAMS dry	0	(74%)	4/8 (50%)	4/5 (80%)	9/15 (60%)
ProACT improved	0	6/8 (75%)	2/7 (29%)	1/9 (11%)	2/9 (22%)
BAMS improved	0	2/19 (11%)	3/8 (37%)	1/5 (20%)	2/15 (13%)
		2/8 (25%)			
P	†	*	*	*	*

*P > 0.05; **P < 0.05; †not applicable.

severe than in mild incontinence (80% *vs* 100%, $P > 0.05$). These results confirm the published reports about BAMS.[11] Additionally, ProACT results seem to be better for severe incontinence (84% dry in ProACT *vs* 80% dry in BAMS, $P > 0.05$) and BAMS seems to be better for mild incontinence (80% dry in ProACT *vs* 100% dry in BAMS, $P > 0.05$). In the present study, the quality of life has been assessed by the UCLA/RAND questionnaire. The results confirmed the pad count assessment (see Table 2). The explanation for these results can be found in the theoretic and technical difference between the two procedures. The main difference is the adjustability that characterizes the ProACT, by which it is possible to cure even severe incontinence by filling the balloon afterwards to obtain as much volume as is required for that patient.

Comparison of operating time is broadly in favor of Pro ACT (18 *vs* 45 min, $P < 0.05$). The ProACT procedure is a percutaneous procedure, which does not require any dissection, whereas BAMS is a surgical procedure requiring dissection and implantation of screws. Finally the complication rate was higher for ProACT (13% *vs* 5%, $P > 0.05$), primarily reflecting the development and refinement of the new surgical technique and its instrumentation. Management of these complications was definitely easier for ProACT requiring the removal of the device in local anesthesia versus surgical removal in general or spinal anesthesia for BAMS.

Although we were able to demonstrate comparable overall continence outcome and quality of life in men who underwent placement of ProACT compared with those treated with BAMS, there are some limitations in our study, which may limit the broad applicability of our findings. The main one is that in this prospective non-randomized trial, the degree of pre-treatment incontinence was slightly different in the two groups although the difference wasn't statistically different. In general, the patients who received a ProACT had a greater degree of urinary leakage than the patients who received BAMS. This is due to a larger use of AUS in the department involved in the study that had the BAMS group treated. Since the degree of satisfaction after therapy may be influenced by the severity of incontinence before treatment, it may be difficult to directly compare quality of life changes in the two

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groups. Additionally, the shorter follow up could artificially improve the efficacy of ProACT, but we know from our and other ProACT series[6] that after 6 months the efficacy is durable to a follow up longer than 36 months. However, despite these limitations, we believe that the two treatment groups are representative of typical patients with post-radical prostatectomy incontinence. Finally, this study is prospective but not randomized, which is a limit for a comparative study. For this reason, after the first 84 patients we started a prospective randomized study which is ongoing.

Conclusions

Both the ProACT and the BAMS can effectively treat incontinence after radical prostatectomy. ProACT's operation time is lower. ProACT has the advantage of the postoperative adjustability that BAMS doesn't have. Although the complication rate seems to be much lower for BAMS as compared with ProACT, the removal of ProACT can be accomplished under local anesthesia. Our results indicate a significant improvement in urinary incontinence and quality of life improvement in patients undergoing these procedures based on pre-operative degree of incontinence. ProACT results seem to be better for moderate to severe incontinence and BAMS for mild incontinence.

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