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Finazzi Agrò E[1], Farullo G[2], Vespasiani G[1], Giovannelli V[3], Carone R[4], Giammò A[4], Romanò A L[5], Martino P L[6], Volpe A[7], Favro M[7], Canepa G[8], Gregori A[9], Paoletti G[3], Ammirati E[4], Varca V[9], Saracino A[6], Pinto A[8]

1. *Department of Experimental Medicine and Surgery, University Tor Vergata, Roma, Italia,* ***2.*** *School of Specialization in Urology, University Tor Vergata, Roma, Italia,* ***3.*** *Urologia Azienda USL 8, Arezzo, Italia,* ***4.*** *Struttura Complessa di Neuro-Urologia, CTO Torino, Italia,* ***5.*** *Urologia ASST Fatebenefratelli-Sacco, Milano, Italia,* ***6.*** *Clinica Urologica Policlinico Bari, Italia,* ***7.*** *Clinica Urologica AOU Maggiore della Carità, Novara, Italia,* ***8.*** *Urologia Ospedale Galliera, Genova, Italia,* ***9.*** *Urologia ASST Rhodense, Garbagnate Milanese, Italia*

EFFICACY AND SAFETY OF ADJUSTABLE BALLOONS (PROACT™) TO TREAT MALE STRESS URINARY INCONTINENCE AFTER SURGERY: SHORT TERM FOLLOW-UP DATA OF A NATIONAL MULTICENTRIC RETROSPECTIVE STUDY

Hypothesis / aims of study

Male stress urinary incontinence (SUI) represents a possible complication after radical prostatectomy or BPO surgery. The artificial urinary sphincter (AUS) is considered the standard treatment for this condition but interest on other minimally invasive devices, as adjustable balloons or bulbourethral slings, has increased in the last few years. Unfortunately, evidence on efficacy of the adjustable balloons (ProACT™, Uromedica, Plymouth, MN, USA) is sparse and further data are needed to understand the real role of this therapy in male SUI. Aim of this national multicentric retrospective study is to evaluate the efficacy and safety of ProACT system in the short term follow up.

Study design, materials and methods

In this multicentric retrospective study, we report data from the databases of seven centers in Italy. Patients with SUI who underwent a ProACT device implantation for SUI after radical prostatectomy or BPO surgery between 2001 and 2016 were included. Efficacy was evaluated at the end of the balloons volume adjustment (6 months after the implant) and was assessed considering 24-h pad test. Patients were considered: “Dry” if presenting a urine leak count lower than 8g at 24-h pad test; “Improved” if presenting a reduction of urine leak higher than 50% compared to the pre-operatory assessment (but higher than 8g/24h); “Failure” if presenting a reduction in urine leak lower than 50% compared to the pre-operatory assessment. 24/h pad test and number of pads pre-op and at 6-month follow-up were collected. Evaluation included record of perioperative complications, pre-operative VLPP, medical history of radiotherapy, volume of balloons at the end of adjustment period, type of guidance and their impact on outcomes. T test was used to compare continuous and Chi square test to compare discrete variables. P value <0.05 was considered statistically significant. All statistical analyses were performed with STATA 14.2 program.

Results

A total of 515 consecutive patients were treated with ProACT implantation. The balloons adjustment period was 3-6 months. Data on outcomes were not available in 29 patients who were excluded from the analysis. Of the remaining 486 patients, 192 (39,5%), 181 (37,2%) and 113 (23,3%) were considered respectively dry, improved or failure, according to the previously reported definitions (Tab. 1). No correlation was found between age and treatment success (tab 1).

The mean number of daily pads per patient (1.52 vs 3.39 at baseline; p<0.001; data available in 478 patients) and the mean 24h pad test (113.9 vs 350 at the baseline; p<0.001; data available in 399 patients) significantly improved after ProACT implantation (tab. 2). Among the patients with a pre-operatory pad test <400ml, 262 patients were dry or improved (80%) whereas 67 patients were failed (20%); among the patients with a pre-operatory pad test >400ml, 76 patients were dry or improved (67%) whereas 37 patients were failed (33%) with a significant higher improvement in the first group (p <0.001). The pre-operative 24h pad-test was significantly lower in patients dry or improved (345ml vs 391ml p=0.001). No differences in outcomes were observed (p=0.464) as regards the pre-operatory VLPP (data available in 211 patients). Worse outcomes have been observed among the 77 patients who underwent previous radiotherapy: in this cluster 17 patients were dry (22%), 27 patients improved (35%) and 33 patients failed treatment (43%) (p<0.001). 301 patients underwent implantation under fluoroscopic guidance and 184 under TRUS guidance; no differences were found considering only Dry patients (40% vs 39%), but there is a slight evidence in favour of TRUS guidance considering patients Dry and Improved (73% of patients dry or improved under fluoroscopic guidance vs 83% under TRUS guidance, p=0.02). Mean volume of balloons at the end of adjustment was significantly lower in dry patients (4.83ml vs. 6.8ml in failure group, p<0.001). Perioperative complications were found in 42 patients (8.6%) and included bladder perforation (5.1%), urethral perforation (2.2%) and bleeding (1.2%). All complications were classified as grade I (8,3%) or II (0,2%) according to the Clavien-Dindo Classification of Surgical Complications (1) (Tab. 3).

Interpretation of results

To our knowledge, our database represents the larger series of patients treated by means of ProACT balloons. Despite the short follow up time, this treatment seem to represent a good option to treat patients with SUI after prostate surgery with a percentage of cured or significantly improved subjects of 76,7%. Patients with a lower pre-operative 24h pad test leakage (<400ml) seem to be better responder than those with more severe incontinence; on the other hand, radiation therapy seems to be a negative prognostic factor. Functional results were not affected by preoperatory VLPP and age but we found a slight better result in patient who underwent a TRUS guided procedure. Rate and severity of complications seem low.

Concluding message

ProACT implantation represents a safe and efficacious treatment option for male SUI after prostatic surgery. Studies with longer follow up are needed to evaluate results in the long-term.

Tab. 1

	N	%	Mean Age	sd
Dry	192	39.5	69.0	6.2
Improved	181	37.2	69.5	6.0
Failed	113	23.3	68.4	8.5

Tab. 2

	N	Pre-implantation Mean	sd	Post-implantation Mean	sd	P value
24h PAD test	399	350	142.2	113.9	151.2	<0.001
Daily PAD per patient	478	3.39	1.6	1.52	2.05	<0.001

Tab. 3

	N	%
Bladder perforation	25	5.1
Urethral perforation	11	2.2
Bleeding	6	1.2

References

1. Ann Surg 2009; 250: 187-196

Disclosures

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