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EFFICACY AND SAFETY OF ADJUSTABLE BALLOONS (PROACT™) TO TREAT MALE STRESS URINARY INCONTINENCE AFTER SURGERY: MEDIUM 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 multicentric national retrospective study is to evaluate the efficacy and safety of ProACT system in the medium term follow up.

Study design, materials and methods

In this multicentric retrospective study, we report data from the databases of nine centers in Italy. Patients with SUI who underwent a ProACT device implantation for SUI after radical prostatectomy or BPO surgery between 2001 and 2015 and had a minimum follow-up of 24 months were included. Efficacy was evaluated at the maximum available follow-up 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. Evaluation included record of complications. 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

On a total of 515 consecutive patients treated with ProACT implantation, 247 had a follow-up time ≥24 months. The mean 24h pad test significantly improved after ProACT implantation (125,52 (0-900) ml vs 364,77 (40-1000) ml); p<0.001; data available in 227 patients).

Seventeen patients had incomplete data and were excluded from the study; on the remaining 230 patients, 89 (38,7%), 91 (39,6%) and 50 (21,8%) were considered respectively dry, improved or failure, according to the previously reported definitions. Mean follow-up was 77,5 (SD 37, range 24-174)) months.

Forty-six complications were recorded in 44 patients (19%) and included: ProACT device ropture (22, 9,5%); recurrent urinary tract infection (1, 0,4%); acute urinary retention (2, 0,8%); ProACT infection (7, 2,8%); ProACT migration (9, 3,6%); urethral erosion (5, 2%). Thirty-one complications (67,4%) were considered grade I, 3 complications (1,2%) grade II and 12 grade IIIa according to the Clavien-Dindo Classification of Surgical Complications (1). No grade 4 or higher complications were found. Fifteen patients (6%) underwent monolateral (12, 4,8%) or bilateral (3, 1,2%) reimplant of ProACT balloons. Three (1,2%), 9 (3,6%) and 3 (1,2%) of these patients were respectively dry, improved or failure at maximum follow-up.

Interpretation of results

To our knowledge, our database represents the larger series of patients treated by means of ProACT balloons with a follow-up time ≥24 months. At a mean follow-up of 77,5 months, 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 78,3%, even if only 38,7% of patients were cured. Rate complications is 19% at this follow-up time; on the other hand, severity of complications seem low with the majority being grade I or II according to the Clavien-Dindo Classification of Surgical Complications. Grade IIIa complications are managed usually in an office setting, not requiring major surgical procedures. Patients after a ProACT reimplantation may be dry (20%) or improved (60%) in the majority of cases.

The limitations of this study are: retrospective design, incomplete evaluation of patients with no patient reported outcome data, no cross-sectional evaluation at different follow-up times. Strengths of this study are: multicentric nationwide database; mean follow-up of 77,5 months.

Concluding message

ProACT implantation represents a safe and efficacious treatment option for male SUI after prostatic surgery at a mean follow-up of more than 6 years. Cured or improved patients are 78,3%. Complications rate is 19% but the majority of complications is low grade, with no life threatening complications.

References

1. Ann Surg 2009; 250: 187-196

Disclosures
Funding: None. Study conducted on behalf of "Italian Society of Urodynamics (SIUD) working group on adjustable balloons evaluation" **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Tor Vergata University Hospital Ethics Committee **Helsinki:** Yes **Informed Consent:** No