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EXPERIENCE OF 4 YEARS WITH PRO-ACT™ AFTER INITIAL LEARNING CURVE

Hypothesis / aims of study

To evaluate the safety and efficacy of Pro-ACT™ as minimally invasive urologic implant for post-prostatectomy incontinence. We did an evaluation of this method after having finished the initial learning curve.

Study design, materials and methods

The adjustable continence therapy (Pro ACT™) consists of two balloons placed via a perineal approach bilaterally at the bladder neck in post-prostatectomy patients. Titanium ports, attached via discrete tubing to each balloon, are placed in the scrotum allowing for separate volume adjustments of the balloons at any time peri- and postoperatively. Baseline and follow up analysis at 1, 3, 6, 12 and 18 months examined various outcomes, including a Quality of life questionnaire (QoL), urodynamic response (particularly changes in Valsalva Leak point pressure (VLPP) and changes in pad usage of 89 consecutive men undergoing Pro-ACT™ implantation.

Results

28% of all patients were unsuccessfully treated with bulking agents before the surgery. We defined the first 20 cases as our initial experience and excluded them from analysis. Among the remaining 69 patients with a median follow up of 14 months (Range 2-28), the QoL score improved from median 51 (24-84), to 84 (29-104) after 6 months and to 89 (31-95) after one year. Daily pad count decreased from median of 5 (1-24) preoperatively to 1 (0-4) after one year. VLPP rose from a pre-treatment median of 13 cm H2O (2-130) to a median of 50 cm H20 (7-103).

Of 20 patients with 3rd degree incontinence, 10 (50%) were dry, 6 (30%) improved, 4 (20%) remained unchanged. Of the 40 patients, who were 2nd degree incontinent, 22 (55%) were dry after Pro-ACT, 9 (23%) improved, 9 (23%) remained unchanged. First degree incontinence (9 pat.) was cured in 8 (89%), 1 (11%) remained unchanged.

After median 3 (0-11) adjustments, 51 (74%) were dry with a maximum use of one "security" pad, 2 (3%) were improved and 11 (16%) patients showed no improvement. In 20 patients complications, intra- or postoperatively happened, including balloon leakage in 8 cases (12%), balloon migration in 5 (7%), and erosion in 11 (16%).

Interpretation of results

Pro Act™ compares favorably to preexisting treatment modalities for post prostatectomy incontinence. Its unique design allows for postoperative adjustment of the desired obstruction without surgical intervention thus allowing for an optimal balance between voiding pressures and continence. The promising results suggest that this may represent an appropriate and effective first line of treatment for males with stress urinary incontinence after prostatectomy.