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THE BONE-ANCHORED PERINEAL MALE SLING FOR POST-PROSTATECTOMY INCONTINENCE: RESULTS AT 3 YEARS.

Hypothesis / aims of study

For more than 30 years, the artificial urinary sphincter (AUS) has been considered the most reliable treatment for men with stress urinary incontinence (SUI) and has become the gold standard. The male perineal sling, however, has undergone significant modifications over the paste decade, and has been suggested as an efficacious, less invasive alternative to the AUS. We report the results of InVance bone-anchored perineal sling procedure for the treatment of pos-prostatectomy stress incontinence.

Study design, materials and methods

Between July 2003 and July 2006, fifty eight incontinent men underwent perineal bone anchored sling placement. Incontinence was caused by radical prostatectomy in 54 and by BPH prostatectomy in 4 cases. Three titanium screws loaded with polypropylene suture were placed in each descending pubic ramus through a 3-4 cm perineal incision at the level of the bulbar urethra. A polypropylene mesh was placed over the bulbospongiosus urethra and tied to the bone anchors. Maximum possible tension was used to adjust the sling. Incontinence was categorized as mild (1 to 2 pads per day) in 6 patients, moderate (3 to 5 pads per day) in 40 and severe (more than 5 pads per day) in 12. Sixteen patients received external bean radiation therapy and 22 had undergone prior treatments for stress urinary incontinence (periurethral injection of bulking material in 17, artificial urinary sphincter in 3, and adjustable vertical sling in 2). Patients were evaluated in a prospective manner (continence, side effects and satisfaction) before surgery, at the day the urethral catheter was removed, at 1-3-6-12 months and yearly. The patient was considered cured if stopped wearing any kind of continence pad, and improved if decrease of 50% or more in pads daily and stress incontinence small or small / moderate problem. Patient satisfaction with the treatment was assessed.

Results

Mean follow-up was 19 months (range 3 to 36). Overall, incontinence was cured in 40 (69%) patients, improved (stress incontinence small or small / moderate problem) in 12 (21%) and procedure failure (no improvement) in 6 (10%). Forty eight (83%) patients were satisfied with the results of the procedure. Failures had 2 out of 3 of the following risk factors: severe urinary incontinence, adjuvant radiotherapy and previous failed surgery for SUI. In the subgroup of patients with no risk factors (n = 25) incontinence was cured in 23 (92%) and improved in 2 (8%). In the subgroup of patients with previous surgery for SUI (n = 22) incontinence was cured in 9 (41%), improved in 9 (41%) and no improvement in 4 (18%). In the subgroup of patients with previous adjuvant radiotherapy (n = 16) incontinence was cured in 5 (31%), improved in 7 (44%) and no improvement in 4 (25%). In the subgroup of patients with severe urinary incontinence (n = 12) incontinence was cured in 3 (25%), improved in 5 (42%) and no improvement in 4 (33%). At 1 year follow-up (n = 42) 28 (67%) patients were cured and 10 (24%) were improved, at 2 years (n = 30) 20 (67%) patients were cured and 7 (23%) were improved, at 3 years (n = 12) 7 (58%) patients were cured and 3 (25%) were improved (table 1). Scrotal pain or perineal numbness affect 8 (13.8%) patients and resolve within 2 months. Perineal pain was reported in 3 (5.2%) patients. Prolonged post-void residual urine (> 100 cc) was observed in 5 (8.6%) patients and resolve within 15 days. One (1.7%) case of infection was reported and required explantation of the sling. The need for revision caused by bone-anchor dislodgement occurred in 1 (1.7%) patient.

Interpretation of results

The InVance bone-anchored perineal sling provide fixed urethral compression that offer some advantages over techniques that provide dynamic urethral compression: physiologic voiding, minimally invasive procedure, lower costs and immediate results. Our results with an overall cure rate of 69% could be explained by a careful selection of patients and the use of maximum tension to adjust the sling. Severe urinary incontinence, adjuvant radiotherapy and previous failed surgery for SUI, are, in our study, bad prognostic factors. The last two risk factors may be explained by increased periurethral fibrosis, urethral atrophy and diminished urethral compliance. The failures were observed on removal of the urinary catheter or within 1 month. Two patients changed the result from cured to improved, one at 6 months and the other at 1 year follow-up. The overall results at 1, 2 and 3 years suggested that the procedure remains an effective treatment at long-term follow-up. The acceptably low rate of morbidity without any significant complications seems to be an advantage of this friendly minimally invasive technique.

Table 1. Outcome of stress urinary incontinence after InVance procedure. Long term results.

InVance year	n	1 month (c/i/f)*	3 months (c/i/f) *	6 months (c/i/f) *	1 year (c/i/f) *	2 years (c/i/f) *	3 years (c/i/f) *
2003	12	8/2/2	8/2/2	8/2/2	7/3/2	7/3/2	7/3/2
2004	18	14/3/1	14/3/1	13/4/1	13/4/1	13/4/1	
2005	12	8/3/1	8/3/1	8/3/1	8/3/1		
2006	16	10/4/2	10/4/2	10/4/2			

*(c – cured; i – improved; f – failed)

Concluding message

InVance appears to be safe and effective first line treatment for stress urinary incontinence in male patients submitted to prostatic surgery. For the success of the surgery the mesh should be adjusted to a maximum tension. InVance is a simple technique that can be first option in: patients who have mild to moderate SUI, patients without previous radiotherapy or incontinence surgery and patients who have poor manual dexterity.

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HUMAN SUBJECTS: **This study did not need ethical approval because It is a treatment for stress urinary incontinence approved some years ago. but followed the Declaration of Helsinki Informed consent was obtained from the patients.**