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MINIMALLY INVASIVE TREATMENT FOR STRESS URODYNAMIC INCONTINENCE AFTER RADICAL PROSTATECTOMY AND SALVAGE RADIOTHERAPY

Hypothesis / aims of study
Urinary incontinence following radical prostatectomy and subsequent salvage radiotherapy is a challenging procedure. Traditionally bulking agents are providing poor results and slings are generally not recommended for the treatment of severe urinary incontinence that can occur after the procedures. The aim of our study was the evaluation the safety and efficacy of a novel minimally invasive anti-incontinence procedure named pro-ACT in this demanding cohort of patients.
Study design, materials and methods
Between year 2006 and year 2008, 25 consecutive patients with stress urodynamic urinary incontinence followed after a radical prostatectomy and adjuvant radiotherapy were treated in our centre with the implantation of the ProACT device. The ProACT device consists of two opposing silicone balloons implanted para urethrally at the bladder neck, each connected to a titanium port situated in the scrotum to enable post operative adjustments. Patients enrolled in this study underwent baseline urodynamic examination to confirm Intrinsic Sphincter Deficiency in the absence of detrusor overactivity. Efficacy was determined by daily pad count; Quality of Life questionnaires; overall patient impression based on a global assessment score (PGI) questionnaire and Visual Analogical Scale performed. Additionally, operative details, adverse events, number of adjustments and balloon volumes were recorded at each of the post operative visits. The severity of the incontinence was based on the Stamey score: Mild incontinence 1-2 pads/day, moderate incontinence 2-4 pads/day and severe incontinence 5 or more pads a day.
Results
The mean follow up was 15.8 months (range 12-36 months). 92% (24/25) of our patients had a moderate to severe incontinence according to the Stamey score. At latest follow-up a reduction in at least one grade of Stamey score was observed in 88% (23/26). 2 out of 26 patients were completely dry and pad free. There were no differences in outcome in the different severity groups of incontinence. The mean volume in the devices was the following: (right balloon 5.38 ml, left balloon 5.24 ml). Urethral erosion was the most common complication observed (6/25) 24%, device failure occurred in (4/25)16%, while an infection was present in (2/25) 8%. The management of this complications was relatively easy by the removal of the device. The procedure was performed in an office setting with a local anaesthesia. The erosion were also treated with an indwelling catheter for 5 days and subsequent uretrography that confirmed a complete healing. We observed that in patients with complication a higher balloon's volume was used. (5.71 ml vs 5.24 in non complicated). Mean baloons' volume was 6.7 ml (range 2-8.5 ml) in patients with an uretral erosion, 6.6 ml (6-7.5ml) in patients with device failure. 4 out of 25 patients received an artificial urinary sphincter after the explantation of the ProACTs, while 29,6% requested the repositioning of another ProACT balloon. The post operative PGI questionnaire showed 11 pts (44%) extremely improved, 14 pts (56%) invarieted. The IQoL increased from 31,7 at baseline to 63,4 at last follow-up
Interpretation of results
Incontinence after a radical prostatectomy and subsequent radiation therapy is challenging procedure. All the available therapies in this group of patients reports a lower success rate and a higher number of complications. The Pro ACT is well known minimally invasive surgical therapy for the treatment of male stress urinary incontinence. The results demonstrate a reduction in pad usage and improvement in Quality of Life in 85% of irradiated patients. Only a limited percentage gain a complete drynaes. The complication rate is high aldo easy to manage. Complications where related to the final volume of the de
Concluding message
Pro- ACT is a relative contraindication for irradiated patients after radical prostatectomy. A subsequent positioning of an artificial urinary sphincter is feasible and the results are not compromised by the previous procedures. Patients who refused the artificial sphincter, after a detailed explanation of the results and complications could be potential candidates for the implantation of ProACT.

Specify source of funding or grant	**Collaboration with Uromedica, Bard, Coloplast, Medtronic**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Ethical Commitee of Novara University general Hospital**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**