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

Hypothesis / aims of study

Urinary incontinence following radical prostatectomy and subsequent salvage radiotherapy is a challenging situation. Aim of our study was the evaluation of safety and efficacy of Pro-ACT positioning in this cohort of patients.

Study design, materials and methods

Between 2006 and 2009, 27 consecutive patients with stress urinary incontinence following radical prostatectomy and adjuvant radiotherapy were treated in our centre with the implantation of ProACT device. Patients enrolled in this study underwent baseline urodynamic examination to confirm Intrinsic Sphincter Deficiency without detrusor overactivity. Efficacy was determined by daily pad count; Quality of Life questionnaires; overall patient impression was based on a global assessment score (PGI) questionnaire and Visual Analogical Scale. Additionally, operative details, adverse events, number of adjustments and balloon volumes were recorded at each of the post operative visits. Severity of the incontinence was based on Stamey score: mild incontinence 1-2 pads/day, moderate incontinence 2-4 pads/day and severe incontinence 5 or more pads/day

Results

The mean follow up was 16.2 months (range 12-38 months). 88% (24/27) of our patients had a moderate to severe incontinence. At the latest follow-up a reduction in at least one grade of Stamey score was observed in 85% (23/27). 2 out of 27 patients were completely dry and pad free. The mean volume in the devices was: right balloon 5.5 ml, left one 5.6 ml. Urethral erosion was the most common complication observed (6/27) 22%, device failure occurred in (5/27)18%, while infection in (2/27) 7%. Management of these complications was simply the removal of the device. The procedure was performed in an office setting under local anaesthesia. Erosions were also treated with an indwelling catheter for 5 days and subsequent uretrography that confirmed a complete healing. We observed that in patients with complications a higher balloon's volume was reached. (5.81 ml vs 5.2 in non complicated). Mean baloons volume was 6.9 ml (range 2-8.7 ml) in patients with erosion, 6.6 ml (6-7.5ml) in patients with device failure. Post-operative PGI questionnaire showed 11 pts (40%) extremely improved, 14 pts (51%) unmodified. IQoL increased from 30,2 at baseline to 62,4 at last follow-up.

Interpretation of results

Our results demonstrate a reduction in pad usage and improvement in Quality of Life in 85% of irradiated patients. Complications were related mainly to the final volume of the device. Radiation therapy after radical prostatectomy is a relative contraindication for Pro-ACT.

Concluding message

Patients unwilling to undergo an artificial sphincter implantation could be potential candidates for the implantation of ProACT.

References

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Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require ethics committee approval because	**Because this surgical technique doesn't cause any harm on patients.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**