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TREATMENT OF RECURRENT STRESS URINARY INCONTINENCE WITH ADJUSTABLE CONTIENCE THERAPY: A SERIES OF 57 PATIENTS

Hypothesis / aims of study

Recurrent stress urinary incontinence (SUI) after surgery presents a challenge to urologists. The Adjustable Continence Therapy (ACT) has been developed to treat recurrent SUI secondary to intrinsic sphincter deficience (ISD) by increasing urethral coaptation. The device consists of two balloons surrounding the proximal urethra each attached to an injectable port placed in the labia majora, which allows for postoperative adjustment of the balloon. We present our experience with the procedure and the prospective outcomes of 57 patients.

Study design, materials and methods

The ACT device consists of two opposing paraurethral silicone balloons connected to a subcutaneous port that enables postoperative adjustment. Between May 2001 and May 2006, 57 patients who had previously failed anti-incontinence surgery underwent implantation of the ACT device. Patients underwent baseline urodynamic examination to confirm intrinsic sphincter deficiency. Efficacy was determined by daily pad count, quality of life questionnaires (IQoL), overall impression based on a global assessment score (PGI), and a visual analog score. Additionally, operative details, adverse events, number of adjustments and balloon volumes were recorded at each postoperative visit.

Results

57 women with a mean age of 62.6 years (range 18-86) underwent implantation of the ACT device and were evaluated postoperatively for a median of 58 months (range 12-84). At latest follow-up, mean pad usage improved from 5.6 at baseline to 0.41 and IQOL score improved from 27.2 to 78.6 ($p < 0.001$). On visual analog score and overall impression, 68% of patients rated themselves as dry. Through the global assessment score, 64% of patients rated themselves as much better, 23% as better, and 13% as better or unchanged. Complications necessitating device removal included migration (14.1%), urethral erosion (3.5%), and device failure (8.8%). All patients underwent repeat reimplantation.

Interpretation of results

Recurrent stress incontinence can be challenging, particularly in patients who are unwilling or unable to undergo second sling procedure. In this series, we report a high success rate with long-term follow-up and high patient satisfaction in patients who underwent implantation of the adjustable ACT device. Though the complication rate was high and required device removal in approximately 25% of patients, all complications were easy to manage and the patients were amenable to device reimplantation. The ability to remove, replace, and revise the device under local anesthesia makes the ACT an attractive option to offer patients who are interested in minimally invasive therapy.

Concluding message

The relative ease of insertion, ability to tailor therapy to a patient's needs, and promising results in this series make the ACT an attractive option for the treatment of recurrent stress urinary incontinence due to intrinsic sphincter deficiency. In patients who are unwilling or unable to undergo repeat sling procedure or who desire a procedure under local anesthesia, the ACT is an ideal option.

Specify source of funding or grant	**Collaboration with Uromedica, Medtroni, Bard, Coloplast**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**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**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**