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TREATMENT OF MODERATE TO SEVERE FEMALE STRESS URINARY INCONTINENCE WITH THE ADJUSTABLE CONTINENCE THERAPY DEVICE (ACT) AFTER FAILED SURGICAL REPAIR

Hypothesis / aims of study

Mid urethral slings are considered to be the treatment of choice for genuine stress urinary incontinence. Treatment of recurrent incontinence after failed surgical procedure is more complicated and repeat surgery has higher rates of complications and limited efficacy. We determined the technical feasibility, efficacy, adjustability, and safety of adjustable continence therapy device for treatment of moderate to severe recurrent urinary incontinence after failed surgical procedure.

Study design, materials and methods

Female patients with moderate to severe recurrent stress urinary incontinence who had at least one surgical procedure for incontinence were enrolled. Moderate and severe incontinence defined as 11-50 and >50 gram of urine loss in provocative pad test respectively. All patients underwent percutaneous placement of Adjustable Continence Therapy (ACT) device (Uromedica, Plymouth, Minnesota). Baseline and regular follow up tests to determine subjective and objective improvement were performed. Device adjustments were performed percutaneously in the clinic postoperatively. FDA protocol was followed to record all adverse effects and complications.

Results

A total of 89 patients have undergone implantation with 1-3 years of follow up. Data is available on 77 patients at one year. Of the patients 47% (34 of 72) were dry (less than 2 gm on provocative pad weight testing) at 1 year and 91% (66 of 72) improved (50% or more reduction in provocative pad weight testing) after 1 year follow up. Stamey score improved from 2.21 to 0.94 at one year ($p<0.001$). Incontinence Quality of Life questionnaire score improved from 33.9 to 71.6 in one year ($p<0.001$). Urogenital Distress Inventory reduced from 60.7 to 33.3 ($p<0.001$) in one year. Incontinence Impact questionnaire score reduced from 57.0 to 21.6 ($p<0.001$). Diary incontinence episodes per day improved from 8.1 to 3.9 ($P<0.001$). Diary wet pads number per day improved from 4.3 to 1.9 ($P<0.001$). The mean number of adjustment visits at 1 year was 2.03. Explantation was required in 21.7% of patients (18 of 83). Fifty percent of those patients (9) were re-implanted.

Interpretation of results

The ACT device is an effective, simple, safe and minimally invasive treatment for moderate and severe recurrent female stress urinary incontinence after failed surgical treatment. The device can be easily adjusted percutaneously to enhance efficacy. Complications are usually easily manageable. Explantation is an easy office procedure and does not preclude future repeat implantation.

Concluding message

The ACT device is an effective, simple, safe and minimally invasive treatment for moderate and severe recurrent female stress urinary incontinence after failed surgical treatment

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**www.clinicaltrials.gov Registration Number: NCT00113555**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Kaiser Permanente Southern California, Western, CHUS IRB committes**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**