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THE ADJUSTABLE CONTINENCE THERAPY (ACT®) SYSTEM: 1-, 2- AND 3-YEAR RESULTS OF THE NORTH AMERICA CLINICAL STUDY GROUP

Hypothesis / aims of study

Management of stress urinary incontinence (SUI) associated with intrinsic sphincter deficiency (ISD) can be challenging after prior failed therapies. The Uromedica Adjustable Continence Therapy (ACT®) system is a novel device under FDA investigation that provides bulk at the bladder neck with adjustable silicone balloons for urethral coaptation and bladder neck support. Each balloon is attached to a titanium port buried in the labia majora allowing for post-operative titration of the balloons for maximal efficacy. We present 1-,2- and 3-year results about the efficacy, safety, adjustability, and technical feasibility of the ACT® system for treatment of recurrent female SUI.

Study design, materials and methods

The study population involves female patients with recurrent SUI with or without urethral hypermobility. Baseline and follow-up tests were performed at 6 weeks, 3 months, 6 months, 9 months, 12 months and annually thereafter including urinalysis, a 3-day voiding diary, provocative pad weight test, direct visual stress test, Stamey score and validated questionnaires to assess the degree of stress incontinence, voiding dysfunction, sexual function and quality of life. The surgical technique involves a small incision between the labia majora and minora at the level of the urethral meatus. A trocar is passed under fluoroscopic guidance to the urethrovesical junction. The device is delivered and the balloon filled with 1.5 cc dilute contrast. The injection port for balloon adjustment is placed into a subcutaneous pouch in the labia majora. Device adjustments were permissible when necessary beginning 6 weeks post-operatively.

Results

There have been 162 patients implanted to date, with 142, 81 and 52 patients completing at least 1, 2, and 3 years followup, respectively. The mean age is 67.4 years (31-94 years). 83% (N=135) had a previous anti-incontinence procedure, with 38.8%, 31.9%, 8.1% and 3.1% experiencing 1,2,3 and 4 prior failed procedures, respectively. Difficulty of ACT® surgery was rated as mild, moderate, or severe in 62%, 29%, and 9% of procedures respectively. Improvement in Stamey score $\geq$ 1 at 1 year in 75.4% (107/162), at 2 years in 76.5% (62/81) and at 3 years in 86.3% (44/51). Mean provocative pad weight decreased from 48.9, 40.2 and 43.0 grams at baseline to 11.1, 7.0 and 8.5 grams at 1, 2 and 3 years, respectively ($p<0.001$). Dry rate was 50.8%, 64.8% and 72.7%, and $\geq$ 50% improved rate was 79.7%, 88.4% and 83.7% at 1, 2 and 3 years, respectively. Patient's quality of life was assessed by the IQol, UDI-6 and IIQ-7 questionnaires and the results suggest improvement in quality of life at 1,2 and 3 years ($p<0.001$); for IQoL baseline scores were 37.1 (SD 23.4), 38.1 and 40.2 compared to 70.9 (SD 25.5), 71.9 and 76.5 at 1,2 and 3 years, respectively; for UDI-6 baseline scores were 59.8 (SD 16.4), 59.3 and 58.4 compared to 33.1 (SD 21.3), 34.6 and 27.7 at 1,2 and 3 years, respectively; and for IIQ-7 baseline scores were 53.9 (SD 27.1), 52.4 and 48.4 compared to 23.2 (SD 26.2), 22.1 and 19.7 at 1,2 and 3 years, respectively. The mean number of balloon volume adjustments through the study period to achieve maximum continence was 2.9 (0-15). Device or procedure related complications (bladder perforation, port or balloon erosion, balloon migration, port or balloon related pain/discomfort, intermittent urinary retention) were reported in 40.1% (65/162) of subjects. Of these, 54% were considered to be of mild severity.

Interpretation of results

Medium term, 3-year data suggest the Uromedica ACT® system is an effective, simple, safe and minimally invasive treatment for recurrent female SUI. The balloons are easily adjusted percutaneously to enhance efficacy. Complications are usually of mild and easily managed. Additional follow-up will determine the long-term durability of this device.

Concluding message

Medium term, 3-year data suggest the Uromedica ACT® system is an effective, simple, safe and minimally invasive treatment for recurrent female SUI.

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Specify Name of Public Registry, Registration Number	**Clinicaltrials.gov, NCT00113555**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Comite d ethique dl la recherche en sante chez l'human du Centre hosptilalier universitaire de Sherbrooke et de l'Universite**

	de Sherbrooke. There are also 7 IRB approvals for the United States, and one other EC approval for Canada by Western IRB/EC
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**