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ONE YEAR RESULTS OF THE ADJUSTABLE CONTINENCE THERAPY (ACT®) SYSTEM IN THE NORTH AMERICA ACT® CLINICAL STUDY GROUP

Hypothesis / aims of study

Stress urinary incontinence (SUI) with intrinsic sphincteric deficiency is a complex disorder that severely impairs patient's quality of life. The management can be challenging, particularly after failed therapies. The Uromedica Adjustable Continence Therapy system (ACT®) is a new minimally invasive delivery and a long term implantable system for the treatment of refractory SUI that provides bulk at the bladder neck to improve urethral coaptation and bladder neck support. We present our one year results about the clinical efficacy and safety of the ACT® system for treatment of female SUI.

Study design, materials and methods

This is a prospective study involving 9 different sites in North America. The study population involves female patients with SUI with or without urethral hypermobility who have failed at least 6 months of previous treatments for SUI. Baseline and follow-up tests were performed at 6 weeks, 3 months, 6 months, 9 months, 12 months and annually thereafter and they include urinalysis, a 3-day voiding diary, provocative pad weight test, direct visual stress test, Stamey score and questionnaires to assess the degree of stress incontinence, voiding dysfunction, sexual function and quality of life (IQoL, UDI and IIQ questionnaires).

Results

Of the 162 patients implanted, 125 subjects completed 12 months of follow-up and 48 patients completed 2 years of follow-up. The mean age is 66.7 years old (31-94 years old). 82.8% (N=111) had had a previous anti-incontinence surgical procedure which included bulking agents, sling, TVT, suspension procedures, Burch and AUS. The median number of adjustments needed up to one year to achieve maximum continence is 2 (0-14), the vast majority occurring in the first 6 months. Almost none of the patients needed adjustment after 12 months. Improvement in Stamey score of at least 1 grade was achieved in 97 patients (77.6%) at one year and 35 patients (72.9%) at 2 years. According to the provocative pad weight test, the average pad weight at twelve months was 11.2 grams (SD 25.8) and 7.3 grams (SD 21.4) after 2 years, compared to 50.8 grams (SD 59.8) at baseline. Patient's quality of life was significantly improved (see Table 1). Concerning complications, 11 patients (8.8%) suffered from balloon erosion that required removal, but 6 of them had the device re-implanted. Balloon migration interfering with continence and requiring explantation occurred in 12 patients (9.6%). However, 8 patients had been re-implanted. At one year, 3 subjects (2.4%) reported pain and discomfort and only one at 2 years, but it was of mild severity as it did not require the device removal. Only 1 patient still suffers from intermittent urinary retention.

Interpretation of results

The current therapeutic options for SUI include less invasive procedures such as injectable bulking agents and more invasive procedures, sling and abdominal suspension. Because of the systemic reabsorption of the bulking agents, it makes it a non-durable therapy, multiple injections are needed to achieve an maintain continence, which lead to multiple costs and the long term results are disappointing. The Adjustable Continence Therapy (ACT) is a new promising therapeutic option for women who failed previous treatment for SUI. Our preliminary results suggested that the ACT was an effective and simple procedure for refractory SUI. Most of the procedures were rated as mild difficulty by surgeons. The success rate was 75.6%, better than the actual bulking agents. However, longer follow-up was needed to assess the durability and reliability of these results.

The success rate of the 125 patients who have a complete one year of follow-up is excellent, with 77.6% of improvement in Stamey score of at least 1 grade after one year. Only a few adjustments is needed to reach maximum continence (median = 2) and the final adjustment is reached for most patients at 6 months. The results of the IQoL, UDI and IIQ questionnaires suggest an important improvement in quality of life ($p<0.001$). All those encouraging results are stable over time as they remain constant at 2 years after the surgery.

ACT is a safe procedure because the number of complication is small, they are of mild severity and most of patients who had their device removed could be reimplanted. The complications are easily managed. The device can be explanted under local anaesthesia and can be reimplanted few weeks later.

Concluding message

The one year results of the ACT® suggest that this is an effective and safe new minimally invasive procedure for the treatment of recurrent SUI and it is a good therapeutic option for patients who failed prior therapies. The patient's satisfaction and improvement of quality of life is excellent and remains after 2 years. The number of complications still present after 1 year is low, they are of mild severity and most of patients who had their device removed could be re-implanted.

Table 1
Questionnaires Results

	Baseline	1 year	2 years
IQoL	36.0 ± 23.2	71.0 ± 26.1	75.1 ± 25.9
UDI	60.2 ± 16.7	32.5 ± 21.7	32.3 ± 20.8
IIQ	54.2 ± 27.8	23.1 ± 26.9	17.2 ± 21.1

$p<0.001$

Specify source of funding or grant	**None**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**The registration number in the United States is : clinical trials.gov ID # NCT00113555**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**The Name of our ethics committee is Comite d'ethique de la recherche en sante chez l'humain du Centre hospitalier universitaire de Sherbrooke.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**