

Sutherland S E¹, Aboseif S², Nash S³, Slutsky J⁴, Baum N⁵, Tu L M⁶, Galloway N⁷, Pommerville P⁸, Bresette J⁹

1. Metro Urology, Centers for Continence Care and Female Urology, Mpls/St Paul, MN, 2. Kaiser Permanente, Los Angeles, CA, 3. Kansas City Urology Care, Leawood, KS, 4. Urological Surgeons, Kankakee, IL, 5. Neil Baum Urology, New Orleans, LA, 6. CHUS-Fleurimont, Quebec, CA, 7. Emory University School of Medicine, Atlanta, GA, 8. Can-Med Clinical Research, Victoria, BC, 9. Lahey Clinic,

IS AGE A PREDICTOR FOR SUCCESS WITH THE ADJUSTABLE CONTINENCE THERAPY (ACT®) SYSTEM FOR STRESS URINARY INCONTINENCE?

Hypothesis / aims of study

Although stress urinary incontinence (SUI) occurs in woman of all ages, the prevalence of severe SUI increases with age; 12% of women aged 25 to 44 years, 21% of women 45 to 59 years and 44% of women over 60 years. Previous studies have shown that the elderly population is under-represented in clinical trials for SUI. We present our 2-year results for the Adjustable Continence Therapy (ACT®) system comparing 3 groups of patients; less than 65 years of age, 65 – 74 and those 75 and over.

Study design, materials and methods

The study involved female patients ranging in age from 31 to 94 (mean 67.4 ± 11.6) years of age, with recurrent SUI diagnosed as urethral hypermobility and/or intrinsic sphincter deficiency (ISD). Baseline and follow-up tests included a 3-day voiding diary (one year only), provocative pad weight test (PPWT), direct visual stress test (DVST), Stamey score, the IQoL, UDI-6 and IIQ-7 questionnaires.

Results

A total of 162 patients were implanted with 140 (86%) and 68 (42%) of the patients, completing 1 and 2 years of follow-up, respectively. There were 60 (37%) patients < 65 years old, 61 (38%) patients 65 – 74 years old, and 41 (25%) patients 75 years or older. Age was associated with an increased frequency of HTN (p<0.001), CAD (p=0.012) as well as prior failed incontinence surgical procedures (p=0.021). Younger patients had more non-surgical treatments for SUI than older patients (p=0.024). Older patients had greater severity of SUI as indicated by the DVST severity and PPWT (p=0.025). Older patients were also less likely to be sexually active (p<0.001). At 1 year, all 3 groups demonstrated significant (p≤0.005) improvement on all efficacy endpoints compared to baseline including the Stamey score, PPWT, DVST severity, number of incontinence episodes per day, number of pads used per day, IQoL, UDI-6 and IIQ-7 scores. At 2 years, all 3 groups continued to show significant improvement (p≤0.021) on most tests conducted. There were no significant differences between the 3 age groups on any of the efficacy endpoints or complication rates.

Interpretation of results

The 1- and 2-year results demonstrate that the ACT® system can be effectively used for SUI in adult women, regardless of age.

Concluding message

Age is not a predictor for success with the adjustable continence therapy system. Women of all ages suffering from recurrent SUI due to ISD can benefit from this form of therapy.

Specify source of funding or grant	Uromedica
Is this a clinical trial?	Yes
Is this study registered in a public clinical trials registry?	Yes
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 hospitalier 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