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Aboseif S[1], Nash S[2], Slutsky J[3], Baum N[4], Galloway N[5], Tu L[6], Sutherland S[7], Bresette J[8], Pommerville P[9]
1. *Kaiser Permanente, Los Angeles, CA,* ***2.*** *Kansas City Urology, Leawood, KS,* ***3.*** *Riverside Medical Center, Kankakee, IL,* ***4.*** *Neil Baum Urology, New Orleans, LA,* ***5.*** *Emory University, Atlanta, GA,* ***6.*** *Chus- Fleurimont, Sherbrooke, Quebec,* ***7.*** *Metro Urology, Plymouth, MN,* ***8.*** *Lahey Clinic, Burlington , MA,* ***9.*** *Can-Med Clinical Research, Victoria, BC*

PRE-OPERATIVE PREDICTORS OF SUCCESS AND OF COMPLICATIONS WITH ACT® IMPLANTATION FOR STRESS URINARY INCONTINENCE

Hypothesis / aims of study
The Adjustable Continence Therapy (ACT) is a promising new therapy for the treatment of recurrent Stress Urinary Incontinence (SUI) after initial interventions have failed. Our objective was to assess whether there are pre-operative variables that could predict treatment success and the occurrence of complications following the implantation of the ACT system for the treatment of stress urinary incontinence (SUI).

Study design, materials and methods
This prospective study involved 162 female patients ranging from 31 to 94 years of age (mean 67.4 ± 11.6) with recurrent SUI diagnosed as urethral hypermobility or ISD. Baseline and follow-up tests included a 3-day voiding diary, provocative pad weight test, direct visual stress test, Stamey score, the IQoL, UDI and IIQ questionnaires.

Results
Pre-operative variables associated with successful outcome or complications at 12 months

Variable Pre-implant	Success at 12 months	p-value	≥1 Complications at 12 months	p-value
Previous anti-incontinence surgery		0.379[a]		0.134[a]
• Yes	68.1%		27.7%	
• No	59.3%		11.5%	
Concomitant feelings of urgency		0.478[a]		0.692[a]
• Yes	67.8%		24.7%	
• No	55.6%		33.3%	
Presence of prolapse (Grade1 or 2)		0.028[a]		0.352[a]
• Yes	56.7%		28.0%	
• No	73.7%		22.3%	
Patient sexually active		0.500[a]		0.038[a]
• Yes	69.1%		31.2%	
• No	63.2%		15.9%	
Incontinence Type		0.407[a]		0.579[a]
• ISD	70.1%		22.4%	
• Hypermobility	63.5%		27.5%	
Stamey Score pre-implant		<0.001[b]		0.864[b]
• Grade 1 (mild)	26.3%		29.4%	
• Grade 2 (moderate)	69.1%		25.3%	
• Grade 3 (severe)	77.6%		22.9%	
Explanted and re-implanted within 12 months		0.547[a]		<0.001[a]
• Yes	76.9%		100.0%	
• No	65.8%		17.6%	
Implants performed by physician		1.000[a]		0.625[a]
• First 3 patients	65.5%		29.6%	
• Subsequent patients	66.9%		24.0%	

[a] Fisher's Exact Test
[b] Pearson's chi-square

A total of 162 subjects have been implanted. The mean age is 67.4 years (31-94 years). Success, defined as improvement in Stamey score of at least 1 grade, was reported in 66.7% (108/162) of patients at 12 months using an intent to treat analysis. Improvement in quality of life as measured by the Incontinence Quality of Life Questionnaire score suggests improvement in quality of life at 12 months ($p<0.001$); mean baseline score of 36.8 to 66.1 at 12 months ($p<0.001$). Mean provocative pad weight decreased from 53.7 to 22.7 gm ($p<0.001$. Complications occurred in 24.1% of patients. Explantation was required in 17.3% of the patients and about half of these were re-implanted during the first year. In terms of complications 96% were considered to be mild or moderate.

Interpretation of results
An earlier analysis has shown that advanced age (75 and older) is not a risk factor for implantation of ACT. For mid-urethral slings, previous anti-incontinence surgery is often considered a risk factor; this variable does not appear to impact outcomes or

complications of ACT. Likelihood of success is not statistically different between patients with predominant ISD or predominant hypermobility. Patients who have had to be explanted and then are re-implanted have an equal chance of success compared to those patients that did not need to be explanted. There were only two variables that significantly predicted the outcome of the procedure. One was the pre-implant Stamey Score. Patients with moderate and severe incontinence (Stamey scores 2 and 3) have a significantly better likelihood of a successful outcome compared to patients with mild incontinence (Stamey Score 1). The other was the presence of Prolapse (Grade 1 or 2), these patients did on the whole have a lower likelihood of success than those who did not have a prolapse.
The only predictive factor for complications was the fact that Patients were sexually active prior to the surgery. As expected the explants appear as a significant predictor, however, this value is significant because all explants are complications, not because it is a good predictor.

Concluding messages

The ACT therapy will yield the best clinical outcomes when used in patients who have Moderate to Severe incontinence (Stamey Grades 2 and 3). Presence of prolapse appears to increase the likelihood of failure. Prolapse is best repaired prior to considering the ACT therapy.
Patients who were sexually active prior to implantation appear to have a higher likelihood of complications. Given the location of the balloons, these patients should be counselled to avoid sexual activity for at least the first 6 weeks following implantation.
On the whole ACT appears to be a safe and efficacious therapy for a difficult group of patients.

References

1. 1 The Adjustable Continence Therapy System for Recurrent Female Stress Urinary Incontinence: 1- Year results of the North-America Clinical Study Group. Aboseif S. et.al. Journal of Urology Vol. 181, (5), 2187-2191, May 2009

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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	**Clinicaltrials.gov NCT00113555**
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	**Kaiser Permanente IRB**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**