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GOOD INITIAL ACT® BALLOON PLACEMENT, REQUIRING FEWER ADJUSTMENTS, REDUCES LIKELIHOOD OF LATER COMPLICATIONS.

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 addition of volume to the balloons for maximal efficacy for each individual patient. One of the key features of this device is the ability to adjust it to the needs of the individual patient. Our objective was to assess if the number of adjustments affects complications.

Study design, materials and methods

This prospective, multicenter study involved 162 female patients ranging in age from 31 to 94 (mean 67.4 ± 11.6) with recurrent SUI (urethral hypermobility or Intrinsic Sphincter Deficiency). Baseline and follow-up tests included provocative pad weight testing, Stamey score and quality of life measures. Information on number of adjustments and number of complications was collected.

Results

A total of 162 subjects were implanted and 1 year data is available on 140. The mean provocative pad weight decreased from 49.6 (baseline) to 11.2 gm at 12 months (P<0.001), with more than 80% of patients having a 50% or greater reduction in pad weight. The mean Incontinence Quality of Life score improved from 36.5 (at baseline) to 70.7 at 12 months (p<0.001). Complications occurred in 24.4% of patients. Explantation was required in 18.3% of patients and about half of these were re-implanted during the first year. 96% of complications were considered to be mild or moderate. Mean number of balloon adjustments during the first 12 months was 2.3 (range 0-9). The majority of the adjustments occurred in the outpatient setting within 9 months from implantation. Mean volume per balloon at 1 year was 3.45 ml (range 1.0-10.0).

Most common complications related to number of adjustments during first year.

	Adjustments	n/N	%	P-value
Balloon Migration				0.045
	0	0/31	0.0	
	1	0/32	0.0	
	2 or more	8/86	9.3	
Worsened/no improvement incontinence				0.147
	0	0/31	0.0	
	1	0/32	0.0	
	2 or more	5/85	5.9	
Balloon Erosion				0.412
	0	1/32	3.1	
	1	1/32	3.1	
	2 or more	7/83	8.4	
Port Erosion				0.691
	0	4/33	12.1	
	1	2.32	6.3	
	2 or more	7/84	8.3	

Interpretation of results

Overall, patients with more adjustments do have a greater incidence of complications, although this does not reach the level of statistical significance. The one sub-category where this does reach the level of statistical significance is balloon migration. This is likely caused by the balloon migrating away from the original position (at the bladder neck) and this is compensated for by more filling to still achieve continence.

Concluding message

If a good initial placement can be achieved and no or only one additional adjustment (after the balloon filling during the implantation) is needed, than the chances of complications are much reduced. This is likely influenced by the learning curve of the individual surgeon.

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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	**Emory University IRB**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**