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SUB URETHRAL SLING FOR MALE URINARY INCONTINENCE: RANDOMIZED CLINIC TRIAL OF TWO SLINGS

Hypothesis / aims of study
Comparison of Argus® sling and AdVance® sling for male urinary incontinence in the mid-term (12 months) follow up.

Study design, materials and methods
From December 2010 to December 2011, 42 male patients with urinary incontinence were recruited and 22 were randomized through computer random table to sub urethral sling with Argus® (Promedon) or AdVance® (A.M.S.). All patients were evaluated, before surgery, with multichannel urodynamic study, 24 hour pad test, QoL questionnaires (ICIQ – SF), voiding diary and clinical examination including insertion of a 14 FR catheter to rule out urethral stenosis. All patients had minimum six months after surgery which caused incontinence. Patients with neurologic conditions, detrusor overactivity and urethral stenosis were excluded. Protocol was approved by institution's Ethical Committee and patients agreed to sign informed consent. Surgery was performed as recommended by manufacturers and follow up was planned in 7 days and 1, 6, 12 and 18 months post operatory. During follow up patients were submitted to pad tests, voiding diaries and QoL questionnaires. Patients with urinary leaks after Argus® were submitted to re-adjust of sling and followed as others. Success were defined as cured (no leaks in pad test or voiding diary and 80% reduction in QoL scores), improved (at least 50% reduction in leaks episodes or pad test weight and reduction of more than 50% in QoL scores) or failed (none of the previous conditions). Minimum 12 months follow up is presented. Results were analysed statistically with Fisher's exact test, Kolmogorov-Smirnov test, Friedman's non parametric test or Mann-Whitney test, according to the type of variable studied.

Results
Patients were comparable between age, time after surgery which cause incontinence, risk of cancer return according to Damico's criteria, intensity of incontinence, etc. Two patients (one in each group) did not complete 12 month follow up (both died for other cause not related to surgery, cancer or incontinence). The most important results are presented in the following table. Only one patient was cured in the Advance group and two patients were cured in the Argus group. In regard to improvement, both slings resulted in best QoL (see table). But in pad tests and pad changes, Argus group provided better results. When we looked up over incontinence episodes on voiding diaries both groups were statistically similar with a better result favouring Argus group, where two patients were submitted to readjustment. One patient were submitted to explantation of sling due to non-treatable perineal pain. There were no other complications.

Table: Results for several variables.

Variable	Surgery	Follow up	n	Medium	sd	min	max	p*
	Advance	Pré	10	19,10	1,97	16,00	21,00	
		6 m.	10	12,00	8,41	0,00	21,00	**0,004**
		12 m.	10	12,90	7,61	0,00	21,00	
QoL								
	Argus	Pré	10	17,80	3,39	11,00	21,00	
		6 m.	10	9,10	7,98	0,00	21,00	**0,015**
		12 m.	10	10,20	6,99	0,00	21,00	
	Advance	Pré	10	619,30	445,46	50,00	1334,00	
		6 m.	10	480,10	726,45	0,00	1913,00	0,110
		12 m.	10	284,40	331,04	0,00	880,00	
PAD test								
	Argus	Pré	10	686,20	721,06	100,00	2550,00	
		6 m.	10	173,00	297,36	0,00	893,00	**0,017**
		12 m.	10	70,00	110,64	0,00	343,00	
	Advance	Pré	10	3,25	3,04	0,00	7,30	
		6 m.	10	1,86	3,32	0,00	9,00	0,430
		12 m.	10	6,89	8,35	0,00	20,00	
Incontinent **Episodes**								
	Argus	Pré	10	4,10	3,70	0,00	10,00	

		6 m.	10	1,56	2,25	0,00	7,00	0,159
		12 m.	10	1,19	1,93	0,00	5,00	
	Advance	Pré	10	3,91	2,73	2,00	11,00	
		6 m.	10	3,13	4,05	0,00	12,00	0,349
		12 m.	10	2,55	3,51	0,00	11,60	
Pad changes								
	Argus	Pré	10	4,17	2,38	1,30	9,00	
		6 m.	10	1,90	2,81	0,00	8,00	**0,013**
		12 m.	10	1,69	2,30	0,00	7,30	

(*) Friedman's non parametric test

Interpretation of results

Our results show that both slings improve QoL in male patients with urinary incontinence. Argus were better than AdVance in reduction of pad tests weight and pad changes and tended to be better in reduction of incontinence episodes. This suggests that QoL does not necessarily reflect objective improvement and authors should look forward seeing closer the effects of this kind of surgery.

Concluding message

Argus tended to be better than Advance in male urinary incontinence in the mid-term follow up.

Disclosures

Funding: no sources or funding **Clinical Trial:** Yes **Public Registry:** No **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** Comitê de Ética em Pesquisa - Faculdade de Medicina do ABC -Santo André - Brasil Protocolo : CEP/FMABC, Registrado sob Numero: 199/2010 **Helsinki:** Yes **Informed Consent:** Yes