

CLINICAL AND URODYNAMIC RESULTS OF TRANS-OBTURATOR SLING FOR MALE STRESS URINARY INCONTINENCE TREATMENT: 6 MONTHS FOLLOW-UP.

Hypothesis / aims of study

Non-Neurogenic male stress urinary incontinence (SUI) has a major impact on Quality of Life. For more than 30 years, the artificial urinary sphincter (AUS) has been considered as a gold standard in incontinence treatment; however, male sling has become more popular in the last decade due to its potential efficacy, low cost and easier surgical procedure; being this less invasive than the sphincter. Several male slings have been developed in the last years. The aim of this study was to evaluate the clinical and urodynamic effect of trans-obturator adjustable sling on male SUI treatment.

Study design, materials and methods

We prospectively evaluate male patients suffering from SUI with at least 12 months post-operative of radical prostatectomy, using more than 3 pads a day, which were referred to the our institution between January and June 2009. It was excluded from the study those patients with non-treated narrowness of the urethra, active genitourinary infection, previous history of radiotherapy for Prostate Cancer and psychiatric illnesses. All patients were evaluated pre operatively, at 1, 3 and 6 months post operatively by means of 1 hour pad test, quality of life Questionnaire ICIQ –SF, International Prostatic Symptoms Score (IPSS), WHOQoL-Brief, Visual Analogue Scale (VAS) and urodynamic study (UDS).

All patients were treated by ARGUS T[®] implant. This device comprises of two columns with silicon cone-like sections and a silicon foam pad. A system of washers allows its tightening and strong fixation. It comprises a a) washer of 25mm in diameter and 1,5mm thick which is placed on the surface of the aponeurotic muscle, therefore, covering the obturator hole and b) gives support to an adjustment washer of 15mm in diameter and 3mm thick, being both of radiopaque silicon. Sling implant was done by using 2 helical needles of 3,5mm in diameter, which are specially designed to enhance the transobturator approach procedure. A general view of the Sling is here shown:



It was considered dry/cured those patients using no pad or a single daily pad, improvement up to 2 pads per day and failure 3 or more PADS per day

Results / Interpretation of results

It was completely evaluated 20 patients with mean age of 66.8 years old (range 51 to 76). There was a significant improvement on continence and general and specific urinary incontinence Quality of Life (Table 1). One of the major concerns regard male sling procedures is related to bladder outlet obstruction. The clinical and urodynamics parameters demonstrated that the sling did not create any significant obstruction, as shown in Table 2. Six months after treatment, we observed 90% of success, including 46.5 % of the patients that were completely dry and 43.5% patients that had an improvement > 50% on 1 hour pad test. The mean pad test in each time point is shown in table 3. We could not find any clinical or urodynamic parameter that could predict fail. Five days after surgery the mean VAS score (ranging from 0- 10) was 3.47. There were 5 (27%) patients with any complication.. In 2 patients with wound infection it was necessary to remove the Sling. Table 4 show all complications There was no major bleeding the mean estimated bleeding volume was 100 ml. The mean surgical time was 50 minutes. All patients were discharge from hospital in 24 hours after removing the urethral catheter.

Table 1 – Pre and post operative score from different questionnaire

	Pré	1º m	3º m	6º m	<i>p</i> (pré x 6º)
ICIQ SF	17.29	5.8	11.47	9	0.002
ICQ QoL	8.58	5.41	10.52	5.3	0.026
Who Qol	49.26	58.56	58.59	62.5	0.02

Table 2 - IPSS and Urodynamic parameters for bladder outlet obstruction, pre and post operatively.

	Pré	6º m	<i>p</i>
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Free Flow

volume	235.6	227.6	0.86
Qmax	13.5	12.5	0.17
PVR	8.4	12	0.63

Pressure/Flow

Qmax	14.55	11.66	0.26
PdetQmax	25.66	32.93	0.09
PVR	3.8	17.14	

Bladder Capacity

339.16	325.73	0.40
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IPSS

12	9.2	0.19
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(Qmax- flow maxim; PdetQmax – pressure detrusor in flow maxim; PVR – pos voiding residual)

Table 3 – Pre and post operative one hour pad test.

	Pré	1º m	3º m	6º m	P (pré x 6º)
1 hour pad test (g)	72.29	11.70	8.17	7.94	< 0.001

Table 4 – Complications after male Sling Procedure.

Complication	N (%)
Wound infection	3 (16%)
Sling removal	2 (10%)
Sling exposure	1 (5%)
Urinary Tract Infection	1 (5%)
Need reajustment	2 (10%)

Concluding message

The Trans obturator adjustable Male Sling (Argus T[®]) present a high chance of success (90%), with low rate of complication, significant improvement in Quality of life, without causing bladder outlet obstruction. Due to its low cost compared to artificial urinary sphincter and its high success rate, it should be considered as an safe alternative to male SU1 treatment.

References

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3. Comiter C.V. "The male sling for stress urinary incontinence: a prospective study." *J. Urol.* 2002 Feb; 167 (2 Pt 1):602

Specify source of funding or grant	No found.
Is this a clinical trial?	Yes
Is this study registered in a public clinical trials registry?	No
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	Committee of Federal University of São Paulo
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes
