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Bianchi A M[1], Jarmy-Di Bella Z[1], Castro R[1], Sartori M[1], Girão M[1]
1. *Federal University of São Paulo*

RANDOMISED TRIAL OF TVTO™ AND TVTS ™ FOR THE TREATMENT OF STRESS URINARY INCONTINENCE. PRELIMINARY STUDY

Hypothesis / aims of study

The objective of this study is to compare the efficacy and complications of TVT-O and TVT-S midurethral tapes as surgical treatment for stress urimary incontinence.

Study design, materials and methods

This is an ongoing prospective randomized study. Women with urinary stress incontinence, without detrusor overactivity and no concomitant prolapse stage ≥ 2 (POP-Q) were elligible. After signing an informed consent, 76 patients were randomized to have either TVTO™ (n=36) or TVT-Secur™ (n=40) procedure.

All patients underwent pre-operatory clinical evaluation with pad-test and urodynamic test. Quality of life was also evaluated through King's Health Questionnarie (KHQ).

The procedures were performed either under local anaesthesia and sedation (27 TVT-Secur™) or raquianesthesia (all TVTO™ and 13 TVT-Secur™) according to published techniques. Clinical evaluation, pad-test and the KHQ were again performed 30, 90, 180 days and 1 year after the procedure. Urodynamic test was again performed 6 months and 1 year after the procedure.

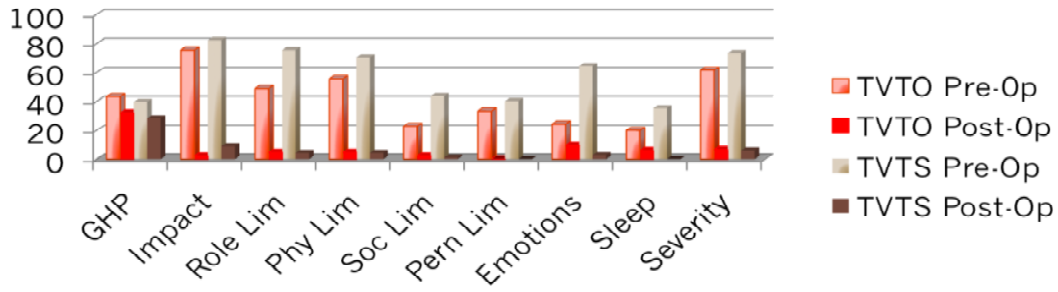
Results

Table 1. Pre-operatory data

	TVT-O	TVT-S	p
Number of patients	36	40	
Mean value pre-op pad-test (g)	16,3 (0-100)	20,3 (0-85)	0,40
Mean value pre-op VLPP (cm H2O)	81,4 (26-150)	83,7 (38-145)	0,61
			Mann-Whitney

Table 2. Post Operatory results

	TVT-O	TVT-S	p
Number of patients	36	40	
Mean Follow up (m)	18 (6-24)	18(6-24)	
Continent patient (subjective)	33 (91,6%)	37 (92,5%)	1,00
Negative post –op pad test (<1g)	33 (91,6%)	37(92,5%)	1,00
Negative VLPP post-op	33 (91,6%)	37(92,5%)	1,00
			Fisher



Graphic 1. King's Health Questionnarie Score

Table 3. Post-Operatoty complications

	TVT-O	TVT-S	p
Number of patients	36	40	
Mean Follow up (m)	12 (6-20)	12(6-20)	
Urinary retention	2 (5,5%)	2 (5,0%)	1,00
Urinary infection	4 (11,1%)	2(5,0%)	0,14
Tight pain	10 (27,7%)	0	0,0002
Tape exposure	1 (2,7%)	1(2,5%)	1,00
			Fisher

Interpretation of results

The two groups are similar regarding to demographic and clinical pre-operatory parameters. Up today, the two groups have had similar subjective and objective continence rates, without statistical difference (table 2). Only minor complications (table 3) have been observed: urinary retention up to five days, uncomplicated urinary infection, tight pain up to 10 days and 1 patient in each group have had assintomatic tape exposure. No patient had de novo urgency.

Concluding message

We have observed that both techniques have similar results in 18 months mean post operatory follow-up. This study is still underway in order to have a greater number of subjects and a longer following-up.

Specify source of funding or grant	**Federal University of São Paulo**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**NCT01095159**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Human Ethic's Commitee (Institutional Review Board - Comitê de ética e pesquisa do Hospital São Paulo - UNIFESP)**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**