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PATIENT EXPECTATIONS, SUBJECTIVE IMPROVEMENT AND OBJECTIVE CURE: IS THERE A DIFFERENCE BETWEEN THE TRANSOBTURATOR TAPE AND THE TENSION FREE VAGINAL TAPE PROCEDURE?

Hypothesis / aims of study
There is controversy in defining success in women presenting with stress urinary incontinence (SUI). The aim of the study was to see if there was any difference between subjective and objective outcomes in a randomized trial of transobturator tape procedure (TOT) and the tension free vaginal tape procedure (TFVT) at one year following surgery.

Study design, materials and methods
A randomized clinical trial of and TOT versus TFVT was carried out in one tertiary two community academic care centers.
Women electing for surgical management of stress urinary incontinence (SUI) were approached to participate in the trial. Boston Scientific devices were used for all procedures: the Advantage® transvaginal mid-urethral sling system was used for TFTV procedures, and the Obtryx® transobturator mid-urethral sling system for TOT procedures. All procedures were carried out according to the usual practice of participating surgeons, consistent with the recommendations of the device manufacturer.
Consenting patients were randomly allocated to receive either a TOT procedure or a TFVT procedure. Randomization was stratified by surgeon. Random allocation was centralized, and surgeons were blind to next allocation. Sample size calculation estimated that a sample of 100 patients per group would be required to detect a difference of the order of 15%, assuming 80% power and a significance level of 0.05. Measured outcomes at one year included: standard pad weight, UDI-6, IIQ-7 and subjective outcome in last seven days. Patients were asked if the outcome had met expectations, if they would have the same operation again under the same circumstances, and if they would recommend the same operation to someone else with the same problem.

Results
199 women were randomized in the study (94 in the TOT and 105 in the TFVT Group).

Outcome at 12 months	**TOT**	**TFVT**	**Statistical results**
PAD TEST	**n=84**	**n=87**	
<1g	68 (81%)	67 (77%)	
≥1g	16 (19%)	20 (23%)	p = 0.58
QUESTIONNAIRE	**n=86**	**n=95**	
Median UDI-6 score	3	11	
Mean Change in UDI-6 score	-34 (SD 20)	-30.1 (SD 22.8)	p = 0.24
Median IIQ-7 score	8	9	
Mean Change in IIQ-7 score	-30 (SD 24)	-30 (SD 27)	p = 0.90
Stress UI symptoms in past 7 days			
No, Yes but no problem, or small problem	85 (99%)	88 (93%)	p = 0.21
Operation met expectations			
Yes	78 (91%)	80 (84%)	p = 0.13
Would have same surgery again			
Yes	78 (91%)	79 (83%)	p = 0.28
Would recommend surgery			
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Interpretation of results
Subjective results showed a higher success rate than with objective pad weight testing, irrespective of procedure: 99% vs. 81% for TOT, 93% vs. 77% for TFVT. There were no statistical differences in all outcome measures between the TOT and TFVT procedures. Incontinence-specific quality of life improved significantly compared to baseline in both groups. Women were more likely to recommend their surgery to other women despite being less likely to choose it for themselves knowing what it entails: 95% vs. 91% for TOT, 93% vs. 83% for TFVT.

Concluding message
Although there was no difference in effectiveness between the two operative procedures, care must be taken in interpreting outcomes as differences between objective and subjective outcomes can occur. This reinforces the importance of measuring both objective and subjective outcomes in clinical trials.

Specify source of funding or grant	**Boston Scientific unrestricted research grant**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**Trials registration #NCT 00234754.**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**University of Calgary Conjoint Ethics Committee**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**