

RESULT FROM A NATIONAL INCONTINENCE REGISTRY: TVT IS A BETTER SURGICAL PROCEDURE FOR TREATING STRESS INCONTINENCE, COMPARED TO TVT-O AND TOT

Hypothesis / aims of study

To compare the outcome and the complication rate of the tension-free vaginal tape (TVT) compared with the transobturator vaginal tapes (TVT-O and TOT) in the treatment of urinary stress incontinence in women.

Study design, materials and methods

A multicenter prospective cohort study including 27 gynecological departments in Norway was undertaken. Patients that underwent stress incontinence surgery with TVT, TVT-O or TOT from January 2004 till January 2008 and completed a postoperative follow up were included. Patients that underwent concurrent vaginal prolapse surgery were excluded. All patients were subject to a preoperative evaluation including a validated Stress and Urge Incontinence Questionnaire, a 24-h pad test and a standardized stress test. A stress index and an urge incontinence index were estimated from the questionnaire. The stress incontinence index is derived from three questions regarding what kind of situations, how often and to what extent stress incontinence is experienced. In the same way, the urge incontinence index is derived from two questions regarding how often and to what extent urge incontinence is experienced. The indices are ranged from 0 to 12 and from 0 to 8 respectively. A high score is associated with severe leakage and bother. The choice of surgical approach was left to the performing surgeon. Postoperatively the women repeated the questionnaire, the 24-h pad test and the stress test. Perioperative complications were recorded by the surgeons.

Table 1: Preoperative urodynamic values

	TVT			TVT-O			P-values
	n	Median	IQR	n	Median	IQR	
Stress index	4052	9	7 – 10	667	9	8 – 10	n.s.
Urge index	4231	4	2 – 5	711	4	2 – 6	0,013
24-h pad test (g)	3779	50	20 – 104	558	49	19 – 106	n.s.
Stress test (g)	4175	38	15 – 75	727	38	15 – 75	n.s.

	TVT			TOT			P-values
	n	Median	IQR	n	Median	IQR	
Stress index	4052	9	7 – 10	308	9	7 – 10	n.s.
Urge index	4231	4	2 – 5	354	4	2 – 6	n.s.
24-h pad test (g)	3779	50	20 – 104	208	48	20 – 97	n.s.
Stress test (g)	4175	38	15 – 75	330	40	19 – 81	n.s.

n: Number of patients completing preoperative evaluation IQR: Inter quartile range 25% - 75%

Results

5942 patients were recruited. 4692 women had a TVT, 843 women had a TVT-O and 407 women a TOT performed. Respectively 91,3%, 86,8% and 90,0% of these women completed a postoperative follow-up at mean 9 months. No significant difference in mean age was found. Small significant differences were found in BMI and numbers of months to follow-up when comparing TVT with TVT-O and TOT, we estimated this to be of no clinical importance. The preoperative urodynamic variables between the three groups were similar, with exception of a significant higher urge incontinence score in the TVT-O group compared to the TVT group. At follow up, there were significant differences in all outcome values between the TVT and TVT-O groups. This was consistent after adjusting for preoperative difference in urge incontinence score. When comparing the TVT group with the TOT group, there were statistically differences in all outcome values except leakage during 24-h test and urge incontinence index. Perforation of the bladder occurred more often in TVT operation, than in TVT-O and TOT operations. Urinary retention was less often experienced after the TVT-O operations and hematoma occurred less often after TOT operations.

Table 2: Postoperative variables at mean 9 months follow up

	TVT		TVT-O		P-values
	n/N (%)	n/N (%)	n/N (%)	n/N (%)	
Low stress index (<5)	3701/4137 (89,5%)	581/695 (83,6%)			< 0,001
Low urge index (<5)	3724/4230 (88,0%)	599/713 (84,0%)			0,003
Very satisfied	3438/4120 (83,4%)	529/703 (75,2%)			< 0,001
Stress test negative	3203/3651 (87,7%)	470/587 (80,1%)			< 0,001
24-h pad test < 8 g	2052/2356 (87,1%)	356/424 (82,3%)			0,011

	TVT		TOT		P-values
	n/N (%)	n/N (%)	n/N (%)	n/N (%)	
Low stress index (<5)	3701/4137 (89,5%)	296/348 (85,1%)			0,015
Low urge index (<5)	3724/4230 (88,0%)	306/354 (86,4%)			n.s.
Very satisfied	3438/4120 (83,4%)	268/348 (77,0%)			0,003
Stress test negative	3203/3651 (87,7%)	228/278 (82,0%)			0,009
24-h pad test < 8 g	2052/2356 (87,1%)	103/113 (90,3%)			n.s.

n: number of women with index<5, very satisfied and no leakage. N: number of women performing tests

Table 3: Perioperative complications

	TVT n	TVT-O n	P-values
Perforation of the bladder	149 (3,5%)	6 (0,8%)	<0,001
Hematoma	50 (1,2%)	4 (0,5%)	n.s.
Urinary retention	69 (1,6%)	4 (0,5%)	0,028
Infection	28 (0,7%)	4 (0,5%)	n.s.

	TVT n	TOT n	P-values
Perforation of the bladder	149 (3,5%)	2 (0,5%)	0,001
Hematoma	50 (1,2%)	0	0,031
Urinary retention	69 (1,6%)	6 (1,6%)	n.s.
Infection	28 (0,7%)	3 (0,8%)	n.s.

Interpretation of results

In the hands of surgeons from 27 different hospitals, a significant better subjective and objective outcome is obtained with the TVT than with the TVT-O operation. Subjective stress incontinence, bother and leakage during stress test were larger and satisfaction with the operation was poorer in women who had a TOT than in women who had a TVT operation.

Patients who had TVT-O and TOT operations performed were less likely to suffer from perioperative complications.

Concluding message

Our national incontinence registry demonstrated better objective and subjective outcomes obtained after TVT operations for urinary stress incontinence than after the TVT-O and TOT operations. However, the TVT operation seems to be associated with a higher risk of perioperative complications. Departments who have poorer outcome with the TVT-O or TOT operations than with the TVT operations should consider improving their technique, or reintroducing the TVT operation.

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<i>Is this a clinical trial?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	No
<i>This study did not require ethics committee approval because</i>	It is an national quality database
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes