

FOLLOW UP OF TVT OPERATIONS IN 1113 MIXED INCONTINENT WOMEN AT MEDIAN 7 AND 38 MONTHS

Hypothesis / aims of study

The aim of the study was to compare the outcome of Tension Free Vaginal Tape operations (TVT) in mixed incontinent women after 6 months and 3 years.

Study design, materials and methods

1113 mixed incontinent women recruited to a national database from 18 hospitals had a TVT operation performed between Sept. 1998 and Dec. 2002. 24 h pad test and standardised stress test were performed. A short form, validated, disease specific questionnaire was used to evaluate urge and stress incontinence and satisfaction. Urge incontinence (UII) and stress incontinence indices (SII) have been constructed for stress and urge incontinence from the questionnaire. Women were defined to have **mixed incontinence** when both stress and urge incontinence indices were larger than zero. The women were asked what bothered them most. The answers classified them into 3 groups: predominantly bothered by stress incontinence, predominantly bothered by urge incontinence or equally bothered by stress and urge incontinence. Postoperatively the women recorded their satisfaction with the operation. The choices were: very satisfied, some satisfaction, neither satisfied nor unsatisfied, slightly unsatisfied and very unsatisfied. The objective tests and the questionnaire were completed by the women pre- and postoperatively. A woman was defined as **objectively cured** when she had no leakage during stress test, less than 10 grams pad weight increase during the 24 h pad test and was very satisfied. The women were defined as **subjectively cured** when they were very satisfied and had both stress and urge indices of 2 or less. UII and SII 2 are found in women who have moist underwear or leak drops of urine 1 to 4 times a month. 96% of these women were very satisfied. The follow up was performed at median 7 and 38 months postoperatively (25 and 75 percentiles 6 and 9, and 36 and 41 months, respectively). The stress test and pad test were missing in 47 and 279, and 414 and 570 women, respectively. A **corrected objective cure** at median 7 and 38 months was calculated. Women were considered cured when they had a missing pad test, but were not urge incontinent (urge index 0) and when they had a missing stress test, but were not stress incontinent (stress incontinence index 0). The technique of **last observation carried forward (LOCF)** was used when a stress test or 24 h pad test was missing at 38 months but existed at 7 months. A corrected cure rate was calculated using the LOCF values. Statistics: Wilcoxon signed rank test, Mann-Whitney test

Results

Subjective and objective cure at median 7 and 38 months are shown in fig 1. Figure 2 shows subjective and objective cure at median 38 months in women according to their predominant bother. 88 and 85 % of the women did not leak during stress test and 78 and 76 % of the women had a stress incontinence index of 2 or less at median 7 and 38 months. All women were urge incontinent before the operation; postoperatively 41, 49 and 10% had respectively no, less and more urge incontinence than before the operation.

Fig 1 Overall cure rates at 7 and 38 months

	months follow up	total n	missing n	cure n	cure %	P
subjective cure	7 months	1062	51	623	58.7	*
	38 months	1050	63	547	52.1	
objective cure	7 months no correction	868	245	558	64.3	
	7 months corrected	993	120	744	74.9	* *** **
	38 months no correction	406	707	270	66.5	
	38 months LOCF	855	258	553	64.7	
	38 months corrected	485	628	339	69.9	

* P < 0,05, ** P < 0,01, *** P < 0,001

Fig. 2 Cure rates at 38 months according to predominant bother

	predominant bother	total n	missing n	cure n	cure %	P
subjective cure	stress incontinence	698	38	403	57.7	*** **
	urge incontinence	73	2	28	38.3	n.s.
	equal stress and urge incontinence	274	23	113	41.2	
	total	1 045	63	544	52.0	
objective cure	stress incontinence	720	167	384	53.3	*** ***
	urge incontinence	75	8	34	45.3	n.s.
	equal urge and stress incontinence	290	55	135	46.5	
	total	1 086	231	553	50.9	

P < 0,01, * P < 0,001

Interpretation of results

Stress incontinence is cured in approximately 80% and urge incontinence is cured or reduced in 90 % of mixed incontinent women after TVT operation. Subjective and objective outcome of TVT operations in mixed incontinent females is fair. Some reduction in outcome is seen after median 38 months. Women predominantly bothered by stress incontinence have a better subjective and objective cure rate than those predominantly bothered by urge incontinence and those equally bothered by urge and stress incontinence.

Concluding message

Mixed incontinent women obtain, both subjectively and objectively, good cure rates after TVT operation. Some reduction in outcome is seen with time. Mixed incontinent women should, before TVT operation, be informed about expected cure rates, depending on their predominant bother.

FUNDING: NONE

DISCLOSURES: NONE

CLINICAL TRIAL REGISTRATION: This clinical trial has not yet been registered in a public clinical trials registry.

HUMAN SUBJECTS: This study did not need ethical approval because part of ongoing quality insurance not needing ethics committee approval but followed the Declaration of Helsinki Informed consent was obtained from the patients.