

CHANGES IN IRRITATIVE BLADDER SYMPTOMS AFTER TVT. A PROSPECTIVE MULTICENTRE 3 YEAR FOLLOW-UP STUDY WITH THE AID OF THE UROGENITAL DISTRESS INVENTORY (UDI-6) AND INCONTINENCE IMPACT QUESTIONNAIRE (IIQ-7)

Hypothesis / aims of study

All incontinence procedures have their own complications. Irritative bladder symptoms are the most unwanted complications because of their enormous negative effect on quality of life. Many studies were conducted to get insight in complication rates. Most of these studies are performed in a population in which concomitant surgery was performed. This made it impossible to exactly derive the rate of irritative bladder symptoms caused by the TVT only.

This study reports on the change of irritative bladder symptoms and quality of life (QoL) after TVT in a select group of healthy women with only stress urinary incontinence (SUI) pre-operative.

Study design, materials and methods

This was a multi centre prospective cohort study of 809 participants with a follow-up of 3 years for all patients. All patients were asked to complete the short version of the UDI-6 and IIQ-7 before and 36 months after the procedure¹. The questionnaires, a postage-paid return envelope and instructions were sent to the patient by mail. The questionnaires were validated and translated in the native language². The UDI is subdivided in three domains: stress incontinence, irritative and obstructive/discomfort. The IIQ measures the implications of urinary incontinence for normal daily functioning. The scales of the UDI & IIQ reach from 0-100 (a higher score means more bothered). Researchers as well as participating gynaecologists and urologists were blinded to the individual results of these questionnaires. Excluded were patients: who did not have pre-operative urodynamical investigations (n=71), who showed detrusor over-activity at pre-operative urodynamical investigations (n=32), who showed no stress urinary incontinence at pre-operative urodynamical investigations (n=3), who had a history of over active bladder syndrome (n=35), who used any medication which could influence bladder symptoms (1), who underwent urogynaecological surgery before (n=89), who had a general history which could influence bladder symptoms (n=1), who underwent concomitant surgery (n=122). To determine the change in irritative bladder symptoms the domain irritative of the UDI-6 was used. This domain consists of the questions: "Do you experience and if so, how much are you bothered by: frequent urination and leakage related to feeling of urgency ". The pre-operative and post operative scores were calculated and deducted. Improved was defined as no symptoms post operative or an improvement in score on the domain irritative. Both groups (irritative symptoms and no irritative symptoms) were compared on the quality of life scores on the IIQ-7 before surgery and 36 months after surgery.

Results

After exclusion the data of 455 women was evaluated. The procedures took place in 41 different hospitals by 52 gynecologists and urologists. Of the 41 hospitals there were 3 university hospitals, 25 teaching and 13 non-teaching hospitals. The follow-up after 3 years was 67.5% (307 women).

Table 1 shows the patient characteristics and a univariate analyses of the pre- and operative factors influencing bladder symptoms. Irritative symptoms were present in 19.2% 3 years post operative. No pre-operative or intra-operative factor could be identified. The mean IIQ score of the irritative symptom group was pre-operative 50.96 (SE 2.7) and 36 months post operative 23.7 (SE 3.7), this was a significant improvement (p=0.000). The non irritative group showed an improvement of 59.3 (SE 1.2) preoperative to 10.71 (SE 1.1) postoperative. When the IIQ's of both groups were compared at 36 months postoperative a significant difference was found (p=0.001).

Interpretation of results

This study shows the outcome of a very specific and well defined group of women with only SUI. All patients showed an improvement of quality of life after a TVT. The results of urodynamical investigation, history and questionnaires showed no specific pre- and or intra-operative factor for changes in irritative bladder symptoms after a TVT. This shows that it is impossible to predict pre-operative which patient is more at risk for developing irritative symptoms after a TVT. Both patient groups (irritative symptoms and no irritative symptoms) improve on quality of life scores after a TVT. The QoL of those who did not develop irritative symptoms is statistically better post operative.

Concluding message

Quality of life improves after a TVT in select group of healthy women with only stress urinary incontinence. The percentage of irritative symptoms developed after a TVT is about 19%. No specific pre- or operative factors could be identified for changes in irritative symptoms after a TVT. This study shows that irritative symptoms can give a negative impact on quality of life. Patients should therefore, pre-operatively be informed about the risk of developing these symptoms after a TVT procedure.

Table 1. Univariate analyses for the change in irritative bladder symptoms after a TVT

	Irritative symptoms (n=59, 19.2%)		no irritative symptoms (n = 248, 80.8%)		OR [95% CI]	p-value	Stat- istical method
general data		SD		SD			
age (years ± sd)	51	8.6	50.4	9.3		0.632	t
parity	2.4	0.7	2.33	0.97		0.892	
-nulliparity	0	0%	6	2.40%	1.24		
-multiparity	59	100%	2242	97.60%	[1.17-1.31]	0.6	X ²
menopausal status							
premenopausal	25	46.30%	140	57.90%	0.63		
postmenopausal	29	53.70%	102	42.10%	[0.35-1.14]	0.132	X ²
intrinsic sphincter deficiency							
yes	4	6.80%	13	5.20%	1.31		
no	55	93.20%	235	94.80%	[0.41-4.18]	0.75	
pelvic floor status prior to TVT							
-no cystocele	29	55.80%	130	58.30%	1.11		
-cystocele	23	44.20%	93	41.70%	[0.60-2.03]	0.757	X ²
-no rectocele	40	74.10%	190	82.60%	1.66		
-rectocele	14	25.90%	40	17.40%	[0.83-3.34]	0.177	X ²
-no prolaps of cervix	45	80.40%	196	84.50%	1.33		
-prolaps of cervix	11	19.60%	36	15.50%	[0.63-2.81]	0.428	X ²
type of hospital setting							
no. of TVT in teaching hospitals	42	71.20%	148	59.70%	0.59		
no. of TVT in non-teaching hospitals	17	28.80%	188	40.30%	[0.32-1.11]	0.135	X ²
type of anesthesia							
local anesthesia (with sedation)*	44	80.00%	199	85.00%	0.75		
spinal analgesia	3	5.50%	18	7.70%	[0.21-2.67]	1	
general anesthesia	8	14.50%	17	7.30%	2.12 [0.85-5.24]	0.111	X ²
learning curve effect							
-first 10 procedures for each surgeon*	24	40.70%	94	37.90%	0.94		
-next 10 procedures for each surgeon	12	20.30%	50	20.20%	[0.43-2.04]	1	X ²
-more than 20 procedures for each surgeon	23	39.0%	104	41.9%	0.87 [0.46-1.64]	0.746	

Values are mean (SD). number (%) and Odds Ratio [95% CI], t= student-t test

X2 = Fisher exact Test; statistically significant differences are highlighted, (+) Reference group

1. Neurourol Urodyn 1995;14(2):131-9.
2. Neurourol Urodyn 2003;22(2):97-104.