

## DOES CONCOMITANT TRANSOBTURATOR TAPE (TOT) FOR STRESS URINARY INCONTINENCE WITH VAGINAL PROLAPSE SURGERY PERFORM AS WELL AS TOT WITHOUT PROLAPSE REPAIR?

### Hypothesis / aims of study

To investigate the outcome of TransObturator Tape (TOT) for Stress Urinary Incontinence (SUI) combined with simultaneous vaginal prolapse surgery by comparison to TOT procedures without vaginal prolapse surgery.

### Study design, materials and methods

Prospective, observational study. The study group consisted of 34 women with either a Monarc or TVT-O procedure combined with vaginal prolapse surgery and was compared to the control group (190 women with the same TOT procedures but without prolapse surgery). Women with mixed urinary incontinence were included when their urge incontinence was not the major symptom.

The simultaneous prolapse procedures were all for grade 2 or more vaginal prolapse (Baden & Walker classification) and consisted of vaginal hysterectomy (n=3), vaginal hysterectomy with anterior repair (n=4), vaginal hysterectomy with anterior and posterior repair (n=4), anterior repair (n=5), posterior repair (n=8), anterior and posterior repair (n=6) and Prolift (n=4). All procedures were under either general anaesthesia or spinal analgesia. All women received antibiotics starting during surgery and continued to 1 week postoperatively.

Before surgery history, physical examination and urodynamic investigation was performed in all women according to ICS standards. All women in both the study and control group had complaints of SUI and demonstrated either loss of urine on physical exertion and/or urodynamic SUI. Women were evaluated after 2 and 12 months by assessment of symptoms, physical examination and Quality of Life assessment (short forms of the Incontinence Impact Questionnaire IIQ-7 and Urodynamic Distress Inventory UDI-6 [1]).

The number of women between 2 to 12 months and beyond 12 months postoperative is in the study group 16 and 18, in the control group 33 and 157. The overall response rate for postoperative visits was 90% in the study group and 91% in the control group, for the QoL questionnaires 78% respectively 83%.

### Results

See table. Not surprisingly women in the study group are significantly older and postmenopausal. Women in the study group were not randomized to either type of TOT procedure contrary to the control group (women from a different study specifically addressing differences between these 2 TOT procedures) and explains why the number of type of TOT in the study group are not equal.

There is significant improvement in SUI and Quality of Life in both groups after 2 and 12 months, but no difference between the groups. Women with vaginal prolapse have significantly more symptoms of urge urinary incontinence (UUI) prior to surgery. Two months after surgery significantly less women have UUI, but after 12 months this reduction is not statistically significant different. Nevertheless, a considerable number of women in the study group are still improved.

There was no major intra- or postoperative complication. In the control group 4 vaginal erosions occurred, but none in the study group. In the control group on 2 occasions the tape was released (once for pain with a superficial located tape and once for voiding difficulty). No other major postoperative complications were observed.

### Interpretation of results

The results indicate that SUI is equally cured with a TOT procedure with or without concomitant prolapse surgery. There is a significant short-term resolution of UUI. However, most likely due to the small numbers this resolution of UUI is not statistically significant after 12 months, but still there is considerable improvement in UUI on medium-term follow-up.

### Concluding message

Monarc and TVT-O combined with a simultaneous vaginal prolapse repair provide the same favourable outcome on SUI as without concomitant vaginal prolapse surgery.

### References

1. Neurourol Urodyn (1995) 14:131-139.

	Study Group		Control Group		p-value
<b>PRE-OPERATIVE CHARACTERISTICS</b>					
Number of women	34		190		
<u>Type of TOT procedure (N, %)</u>					
TVT-O	26 (76%)		93 (49%)		0.003 [1]
Monarc	8 (24%)		98 (51%)		
Age (years; mean ± SD)	57.71 ± 11.29		49.37 ± 9.64		<0.001 [2]
Parity (N, mean ± SD)	2.31 ± 1.07		2.25 ± 0.92		0.766 [2]
Postmenopausal status (N, %)	22 (65%)		74 (39%)		0.001 [1]
<u>Urodynamic investigation</u>					
max. bladder capacity (ml, mean ± SD)	400 ± 129		437 ± 126		0.146 [2]
urodynamic SUI (N, %)	18 (53%)		125 (65%)		0.415 [1]
detrusor overactivity (N, %)	3 (8%)		13 (7%)		0.355 [1]
MUCP (cm H <sub>2</sub> O, mean ± SD)	73.04 ± 57.45		64.33 ± 39.96		0.354 [2]
<b>OUTCOME</b>					
<u>Stress Urinary Incontinence (SUI), N (%)</u>					
2 months after surgery					
- no SUI	24 (80%)	[3]	152 (84%)	[3]	
- improved	6 (20%)		20 (11%)		0.183 [1]
- unchanged	0		10 (5%)		
12 months after surgery					
- no SUI	10 (72%)	[3]	106 (77%)	[3]	
- improved	3 (21%)		24 (18%)		0.875 [1]
- unchanged	1 (7%)		7 (5%)		
<u>Quality of life analysis (mean ± SD)</u>					
Incontinence Impact Questionnaire (IIQ-7)					
- prior to surgery	50.38 ± 25.80		52.47 ± 22.10		0.682 [2]
- 2 months after surgery	10.17 ± 18.77	[4]	12.79 ± 20.49	[4]	0.571 [2]
- 12 months after surgery	15.47 ± 22.16	[4]	13.95 ± 20.85	[4]	0.785 [2]
Urodynamic Distress Inventory (UDI-6)					
- prior to surgery	47.02 ± 21.04		43.78 ± 17.42		0.422 [2]
- 2 months after surgery	18.36 ± 14.55	[4]	16.71 ± 17.74	[4]	0.678 [2]
- 12 months after surgery	26.19 ± 18.56	[4]	16.89 ± 17.65	[4]	0.073 [2]
<u>Urge Urinary Incontinence (UUI)</u>					
Prior to surgery					
- no UUI	15 (52%)		144 (77%)		0.003 [1]
- UUI present	14 (48%)		42 (23%)		
2 months after surgery					
- no UUI	24 (80%)	[5]	162 (89%)	[5]	
- improved	3 (10%)		4 (3%)		0.080 [1]
- unchanged	3 (10%)		15 (8%)		
12 months after surgery					
- no UUI	10 (72%)	[5]	102 (74%)	[5]	
- improved	2 (14%)		20 (15%)		0.931 [1]
- unchanged	2 (14%)		15 (11%)		

[1] X2-test or Fisher Exact Test; [2] Student-T Test (independent samples, two-sided)

[3] Postoperative value is significantly different from pre-operative value, indicating improvement (p<0.05, X2-test)

[4] Postoperative value is statistically significant lower compared to pre-operative value, indicating a significant improvement in Quality of Life (p<0.05, Wilcoxon Signed Rank Test)

[5] After 2 months significantly fewer women have UUI (p<0.05, X2-test), but after 12 months this difference is not statistically significantly different

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**CLINICAL TRIAL REGISTRATION:**

**This clinical trial has not yet been registered in a public clinical trials registry.**

**HUMAN SUBJECTS: This study was approved by the METC, St. Elisabeth Hospital Tilburg (The Netherlands) and followed the Declaration of Helsinki Informed consent was obtained from the patients.**