

## LONG-TERM FOLLOW-UP OF TENSION-FREE VAGINAL TAPE (TVT): AN OBSERVATIONAL MULTI-CENTRE STUDY FROM A NATIONAL INCONTINENCE REGISTRY

### Hypothesis / aims of study

To evaluate long-term (10 years) subjective and objective outcomes and long-term complications after treatment of female stress and mixed urinary incontinence with retropubic midurethral tape (tension-free vaginal tape, TVT, Gynecare).

### Study design, materials and methods

We performed from 2009 to 2011 a prospective observational, 5 centre cohort study. All 5 centres had reported their female incontinence surgery to the national incontinence registry since its establishment in 1998. All patients who had been operated with a retropubic midurethral tape at these centres during the years 1998-2000 were asked to attend a clinical follow-up consultation. This unselected heterogeneous group of women consisted of patients having had TVT as primary or recurrent treatment for stress urinary incontinence (SUI) caused by hypermobility, low urethral pressure incontinence or mixed incontinence. Some patients also had concomitant pelvic organ prolapse surgery. The only exclusion criterion for the study was inability to give informed consent. Patients unable to attend a physical examination were asked to do a structured telephone interview for subjective data. Written consent was obtained from all patients. A questionnaire was used for the subjective data. The first part of the questionnaire was identical to the one used for the preoperative, 6 months and 3-year data and has been previously validated [1]. Primary objective outcome measures were overall cure rate (defined as negative stress test), failure rate (defined as stress test > 0 g or repeat SUI surgery) and reoperation rate. Primary subjective outcome measures were satisfaction rate, cure rate, improved rate and failure rate (defined from the questionnaire). All primary objective outcome measures and subjective satisfaction rate were compared to 6 months and 3 years follow-up data from the national registry. Secondary outcome measures were objective voiding difficulties (defined as low maximum flow rate  $Q_{max} < 15$  ml/s or post-void residuals > 100 ml), vaginal mesh extrusion, subjective voiding difficulties, increased voiding frequency, recurrent urinary tract infections (defined as > 3 UTI's in the last 6 months) and persistent painful voiding.

### Results

Of the 603 patients operated with TVT at the five departments, 14 (2.3%) could not be located, 56 (9.3 %) had died of unrelated causes during the 10 years and 50 (8.3 %) refused or were unable to participate in the 10-year study. Of the 483 patients who agreed to participate, 156 had a telephone interview only. The remaining 327 patients had a physical examination in addition to the interview. The median duration of follow-up was 129 months (range 114-160). The baseline characteristics are provided in table 1, the primary outcome measures in table 2 and the secondary outcome measures in table 3.

**Table 1. Baseline characteristics of study participants at 10-year follow-up (N = 483)**

Demographics	Median (Range)
Age	64 (36-97)
BMI	26 (17-51)
Follow-up time in months	129 (114-160)
	Percentage (numbers/total/missing info)
Concomitant pelvic organ prolapse surgery	7.8 % (37/477/6)
Complications during surgery	12.0 % (58/482/1)
Postoperative sling release	1.9 % (9/477/6)
Postoperative vaginal mesh extrusion	0.8 % (4/479/4)
Current use of antimuscarinic medication	7.9 % (38/481/2)
Repeat SUI surgery	2.3 % (11/476/7)

**Table 2. Primary outcome measures (%)**

Objective results (Patients with repeat SUI surgery are here classified as failures)	6 months (N = 327)	3 years (N = 327)	10 years (N = 327)
	Percentage (numbers/total/missing info)		
Objective cure rate (Stress test = 0 g)	90.7 % (262/289/38)	87.6 % (198/226/101)	89.9 % (285/317/10)
Objective failure rate (Stress test > 0 g or repeat SUI surgery)	9.3 % (27/289/38)	12.4 % (28/226/101)	10.1 % (32/317/10)
Reoperation rate (repeat SUI surgery):	0.6 % (3/476/7)	1.7 % (8/476/7)	2.3 % (11/476/7)
Subjective results (Patients with repeat SUI surgery are here excluded)	6 months (N = 480)	3 years (N = 475)	10 years (N = 472)
	Percentage (numbers/total/missing info)		
Subjective cure rate	*	*	76.1 % (359/472/0)
Subjective improved rate "cured" or better	*	*	94.1 %

Subjective failure rate "Not changed" or "failed"			(444/472/0)
Treatment satisfaction rated as "very satisfied"	88.8 (371/418/62)	% 86.4 % (331/383/92)	5.9 % (28/472/0) 82.6 % (389/471/1)

\* Subjective evaluation of result was not part of 6 months and 3 years questionnaire and hence subjective cure rate, improved rate and failure rate could not be calculated.

Table 3. Scondary outcome measures (%)	10 years	
For the evaluation of true 10-year secondary outcome measures the 11 reoperated patients were here excluded (6 with objective data and 11 with subjective data)	Percentage (numbers/total/missing info)	
Objective voiding difficulties (among N = 321)		
Q <sub>max</sub> < 15 ml/s	26.6 %	(79/297/24)
Post void residuals > 100 ml	3.5 %	(11/313/8)
Subjective voiding difficulties (among N = 472)	22.8 %	(107/469/3)
Patients stating subjective voiding difficulties among the 79 patients with Q <sub>max</sub> < 15ml/s	29.1 %	(23/79/0)
Increased subjective voiding frequency (among N = 472)	24.5 %	(114/465/7)
Asymptomatic vaginal mesh extrusion (among N = 321)	0.3 %	(1/317/4)
Recurrent urinary tract infections (> 3 UTI's in last 6 months) (among N = 472)	2.3 %	(11/471/1)
Persistent painful voiding (among N = 472)	1.1 %	(5/469/3)

#### Interpretation of results

The subjective and objective success rates 10 years after TVT surgery are remarkably high in this unselected, heterogeneous patient group. The slight decline in treatment satisfaction rate over the years may be partly due to an increasing incidence of urgency incontinence with older age. There was a surprisingly high rate of mild subjective voiding difficulties after 10 years that cannot be fully explained by increased post void residual volumes or diminished maximum flow rate.

#### Concluding message

Although there is a small decline in treatment satisfaction rates after 10 years, retropubic TVT shows excellent long-term objective results with few long-term complications. An exception is the surprisingly high number of patients who stated mild subjective voiding difficulties that cannot be fully explained by increased post void residual volumes or diminished maximum flow rate. Future investigations are needed to evaluate whether voiding difficulties will represent a significant clinical problem for these patients in the future.

#### References

1. BJOG (2003) 110(11); 983-988

#### Disclosures

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UDYDIG (Norwegian Urodynamic Discussion Forum) Grant 25 000 NOK **Clinical Trial:** Yes **Public Registry:** No **RCT:** No **Subjects:** HUMAN **Ethics not Req'd:** Approval for the study was sought from the Regional Committee for Medical and Health Research Ethics in Southern Norway. The Committee considered the application in May 2009 and assessed it in accordance with the Norwegian Research Ethics Act of 2006 and decided that the project represented a quality assurance measure for a treatment that was already established and that the project therefore did not need approval outside the Departments. Written consent was obtained from all patients. **Helsinki:** Yes **Informed Consent:** Yes