

## TENSION-FREE VAGINAL TAPE VERSUS TRANSOBTURATOR TAPE: TIGHTENING OF THE STRINGS?

### Hypothesis / aims of study

Stress urinary incontinence (SUI) is a common problem for women. SUI has proven to have a negative impact on the quality of life for women suffering from this condition. Treatment of the condition consists mainly of physiotherapy and/or operative treatment. Nowadays the midurethral sling is the operative procedure of first choice. This sling can be placed by two different techniques, either the tension-free vaginal tape (TVT) or the transobturator tape (TOT). In 2005 the TVT was gradually replaced by the TOT. This study was conducted to compare the short-term and long-term cure rates of the TVT and TOT and the rate of complications. It is expected that both techniques will have similar cure rates at both short-term and long-term follow-up. However the TVT group is expected to have higher complication rates and higher newly developed urge incontinence rates than the TOT group.

### Study design, materials and methods

In this study, the patients were selected retrospectively. The patients were all women who underwent a sling procedure for the treatment of urinary incontinence. Patients with concomitant surgery and pure urge incontinence were excluded from the samples. Definitions used were according to the *IUGA-ICS Joint terminology 2009*. Data were collected from the hospitals electronic patient database and a questionnaire sent to the patients. Short-term cure was defined as having no stress urinary incontinence at all, at 6 weeks follow-up. At long-term follow-up a patient was considered to be cured if she stated that she had no SUI or did have SUI but was not bothered by it. Improvement was defined as having a decrease in SUI symptoms at 6 weeks follow-up. All patients were sent a pelvic floor questionnaire, which contains the Dutch versions of the validated Urogenital Distress Inventory (UDI) and the Defecatory Distress Inventory (DDI). SPSS was used to analyze the short-term data. However no statistical analysis of the long-term data took place due to the sequential use of the TVT and the TOT, and therefore the large difference in follow-up. The Chi-square and the Fisher-exact tests were used for dichotomous variables and the independent-samples t-test was used for continuous variables.

### Results

The final analysis included a total of 440 patients, of which 230 patients received a TOT and 210 patients received a TVT. All but three of the baseline characteristics were not significantly different amongst the two groups. The body mass index at the time of surgery, urine residue complaints and physiotherapy before surgery were all significantly higher in the TOT group. Post-operative complications were significantly higher for the TVT group ( $p < 0,001$ ), specifically urine residue ( $p < 0,001$ ) and bladder perforations ( $p = 0,001$ ). At the follow-up visit (approximately 6 weeks after surgery) the 100% cure rate was obtained for 90.9% of the patients in the TVT-group and 80.8% of the patients in the TOT-group ( $p = 0.03$ ). The statistical power of this study is 85.2%, with a significance level of 0.05, as defined by a two-tailed test.

The TVT-group showed significantly more patients with (de novo) frequency complaints and urinary tract infections. The TOT-group, on the other hand, had significantly more patients with de novo vaginal discharge complaints.

In the TVT group the long-term follow-up took place at 6,3 years and in the TOT group at 2,9 years. The long-term cure rates in the TOT and TVT group were 58,9% and 71,7% respectively. Urge incontinence was present in 55% in the TVT group and in 50% in the TOT group. Frequency, a micturition frequency equal to or more than 8 times a day, was present in 45% of the patients in the TVT group and in 33% of the TOT group.

### Interpretation of results

The short-term 100% cure rate is higher for the TVT-group when compared to the TOT-group. However the post-operative complications and irritative micturition complaints also showed to be higher in the TVT-group. A higher average body mass index in the TOT-group might explain the lower 100% cure rates. The intra-operative tightening of the sling in the TVT-group might explain the higher cure rate, but it may also explain the higher incidence of de novo irritative micturition complaints.

The long-term follow-up shows that the cure rates have fallen for both treatment groups. It also shows that the difference between the two groups has increased. This is remarkable, especially since the TVT group has a longer follow-up time, 6,3 years in contrast to 2.9 years for the TOT group. This suggests that the TVT group has better long-term results. In contrast, other studies have shown that the two groups have quite similar results at a follow-up time of 48 months.[1] One study showed an 85% cure rate for the TVT at 7 years follow-up.[2] For the TOT 48 months is the longest follow-up time to be found, with a cure rate of 78%.[1] The long-term results also show that the TVT group has more irritative complaints, such as frequency. This might result from irritation of the urethra due to smaller angle of the tape or due to the tightening of the string during the operation.

The main limitation of this study is its retrospective character. Another limitation is the fact that urinary incontinence is mainly a subjective problem and that the cure rates at the long-term were based on a questionnaire instead of a cough test. However by using the questionnaire it was more clear whether people were bothered by their SUI. Future studies should examine whether intra-operative tightening can indeed improve the cure rates of the TOT.

### Concluding message

The TVT and TOT techniques are both effective in treating SUI in women in the short-term. The TVT group has a significantly higher cure rate than the TOT group. However it also had significantly more complications. This may be due to the tightening of the string during the operation. However at the long-term the cure rates clearly decrease. Future studies should examine whether tightening of the string during the TOT operation can increase its cure rates.

### References

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2. Song PH, Kim YD, Kim HT, Lim HS, Hyun CH, Seo JH, Yoo ES, Park CH, Jung HC, Gomelsky A. The 7-year outcome of the tension-free vaginal tape procedure for treating female stress urinary incontinence. *BJU Int*. 2009 Oct;104(8):1113-7.

<b><i>Specify source of funding or grant</i></b>	<b>No external funding.</b>
<b><i>Is this a clinical trial?</i></b>	<b>No</b>
<b><i>What were the subjects in the study?</i></b>	<b>HUMAN</b>
<b><i>Was this study approved by an ethics committee?</i></b>	<b>No</b>
<b><i>This study did not require ethics committee approval because</i></b>	<b>it is a retrospective analysis of an electronic patient database. The questionnaire also required no ethics committee approval. The welfare of the subjects was therefore not at stake. Patients already gave informed consent for the treatment at an earlier stage (that is to say, before the retrospective evaluation).</b>
<b><i>Was the Declaration of Helsinki followed?</i></b>	<b>Yes</b>
<b><i>Was informed consent obtained from the patients?</i></b>	<b>Yes</b>