Hypothesis / aims of study
To compare the long-term outcomes of the tension-free vaginal tape (TVT) with those of the tension-free vaginal tape obturator (TVT-O) midurethral sling procedures in the treatment of female stress urinary incontinence (SUI) within a multicenter randomized trial.

Study design, materials and methods
Power calculation required 130 patients in both groups to detect a 10% difference in either success rate or rates of complications, which was thought to be clinically important. Of the 273 randomized patients 136 were treated with TVT and 131 with TVT-O under local anesthesia (1). A cough test was used as an objective outcome measure. The following validated questionnaires were used for condition specific assessment: UISS (Urinary Incontinence Severity Score), DIS (Detrusor Instability Score), Visual Analog Scale (VAS 0-100), IIQ-7 (Incontinence Impact Questionnaire-short form) and UDI-6 (Urogenital Distress Inventory-short form). Quality-of-life (QoL) assessment was carried out with use of the EQ-5D VAS (EuroQol-5D Visual Analog Scale). A 24-hour pad test was included to be performed pre-operatively and at the two months, one, three and five years follow-up visits.

Results
At five years 95% of the patients were evaluated according to the protocol; 131 in the TVT and 122 in the TVT-O group. The objective cure rate defined as a negative stress test was 91.6% in the TVT and 91.8% in the TVT-O group, p=0.954. The corresponding percentages were 94.6% and 98.5% at the three years follow-up respectively, p=0.131 (2). There was a significant decrease in leakage measured by a 24 h pad test from 44±/-39g to 3±/-10g at three years follow-up to 4±/-12g 5 years postoperatively in the TVT group and from 44±/-48g to 3±/-10g at three years follow-up to 2±/-5g 5 years postoperatively in the TVT-O group with no difference between the groups, p=0.558 (3 years) and p=0.202 (5 years) respectively (2). The pad test was negative (<8g) in 89.2% in the TVT and 93.4% in the TVT-O group, p=0.237. Significant improvement from preoperative scores for both groups was seen in the condition specific parameters with no difference between the groups (Table). The EQ-5DVAS score increased from mean 80 preoperatively to mean 84 5 years postoperatively (p<0.001) in the TVT group and from mean 81 preoperatively to mean 83 5 years postoperatively (p=0.079) in the TVT-O group with no difference between the groups, p=0.335. Twenty seven patients (20%) in the TVT and 27 (21%) in the TVT-O group experienced at least one episode of urinary infection between three and five years follow-up visits, p=0.848. Antibiotic treatment for 5 or more urinary tract infections during the two years was needed in 0.8% of the patients in the TVT and 4.0% of the patients in the TVT-O group, p=0.113. The median post-void residual urine volumes were 6 (0-180) ml in the TVT and 10 (0-360) ml in the TVT-O group, p=0.167. A DIS score 7 or less was one of the exclusion criteria. Five patients (3.9%) in the TVT group and 7 patients (5.6%) in the TVT-O group had urgency symptoms, which was defined as having urgency or frequency of moderate or severe degree in the UDI-6 or a score >7 in the DIS, p=0.518. De novo urgency, defined as new symptoms of urgency or frequency of moderate or severe degree in the UDI-6 or a score >8 in the DIS, was found in 1 (3.6%) in the TVT and in 1 (4.6%) in the TVT-O group, p=0.099. Nine (7%) patients in the TVT and 3 (2%) in the TVT-O group used anticholinergic treatment, p=0.088. The number of patients complaining of lower abdomen or external genital pain of moderate or severe degree in the UDI-6 was 3 (2.3%) in the TVT and 6 (4.8%) in the TVT-O group, p=0.325. Two patients in the TVT and three in the TVT-O group were re-operated with a TVT procedure. One of these TVT-O patients had tape erosion tape resection was performed, which resulted in recurrence of incontinence. Eighty eight % of the TVT and 93 % of the TVT-O patients were completely satisfied with the operation, p=0371. In both groups 96% would definitely recommend the operation to a friend.

Interpretation of results
A majority of new surgical methods, mostly modifications of the TVT procedure, have been offered for routine clinical use without proper evaluation and with the clinical experience of only a small number of patients with inadequate follow-up. The present trial is one of the largest, in which the number of patients required by the power calculation could be operated on. We managed to bring back 95% of the women in our trial for the 5-year follow-up visit. We had seen a trend of lower cure rates by time for the TVT-O group during 3 years of follow-up (2). The 5 years results of this randomized trial, however, shows no significant differences in cure rates or complications rates between the “gold standard” TVT procedure and the TVT-O procedure.

Concluding message
The TVT and the TVT-O procedures result in high long-term cure rates and low rates of complication despite the fact that the mid-urethra support is different between the two studied procedures.

Table. Condition specific and General Health Quality-of-Life Parameters, Preoperatively and at 5-Year Follow-up
<table>
<thead>
<tr>
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<th>TVT (n=131)</th>
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<th>TVT-O (n=122)</th>
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<td>At 5-year follow-up</td>
<td>Preoperative</td>
<td>At 5-year follow-up</td>
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<td>11+/3</td>
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<td>84+/-10*</td>
<td>81+/-12</td>
<td>83+/-14**</td>
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</tbody>
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Data are expressed as mean+/− standard deviation.

*p<0.0003, significant difference compared with preoperative figures.

**p=0.079

References

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This study was instigated by the responsible researchers and funded by University-Administered funds.

Is this a clinical trial? Yes
Is this study registered in a public clinical trials registry? Yes
Specify Name of Public Registry, Registration Number ClinicalTrials.gov. www.clinicaltrials.gov, NCT00379314
Is this a Randomised Controlled Trial (RCT)? Yes
What were the subjects in the study? HUMAN
Was this study approved by an ethics committee? Yes
Specify Name of Ethics Committee Helsinki University Central Hospital Ethics Committee
Was the Declaration of Helsinki followed? Yes
Was informed consent obtained from the patients? Yes