

## PATIENT-REPORTED OUTCOMES AND CONTINENCE FIVE YEARS AFTER THE TENSION-FREE VAGINAL TAPE OPERATION

### Hypothesis / aims of study

The tension-free vaginal tape (TVT, Ethicon/Women's Health and Urology) procedure has been shown to be comparable to other stress incontinence procedures in terms of success rates, both short-term and after up to 11 years follow up.<sup>1</sup> Only a few studies have addressed long-term patient-reported outcomes after this operation.

We assessed patient-reported outcome data and objective continence rate 5 years after TVT operation with the Incontinence Outcome Questionnaire (IOQ) to evaluate quality of life, satisfaction and symptoms after TVT operation.

### Study design, materials and methods

A total of 101 patients underwent clinical and urodynamic assessment and completed the Incontinence Outcome Questionnaire (IOQ) 5 years after the TVT operation for stress urinary incontinence (SUI). Patients were considered objectively continent by a negative clinical cough stress test. Both patients and physicians rated continence status as cured, improved, unchanged or worse. These assessments were compared with the results of the IOQ. The IOQ is an instrument for a one-point assessment after treatment; therefore we compared the 5-year IOQ results with the reference population in the validation study of IOQ.<sup>2</sup> The reference population consists of 171 women who underwent the TVT or TVT-O operation for SUI and completed the IOQ 3 months after surgery.

### Results

The overall objective continence rate at 5 years was 86% and 89% of patients had stable cystometry to 300 ml. No patient had residual urine exceeding 100 ml. 25% of patients reported overactive bladder symptoms, but objectively these symptoms were found in 11%. 60% of patients reported subjective cure, 32% improvement, 5% no change and 3% worsening of incontinence symptoms. According to physician assessment 81% patients were cured, improvement was found in 11%, no changes in 4% and worsening in 5% of patients. Patient-reported outcomes assessed with the IOQ showed statistically significant differences in the questions about complications, urinary tract infection and other infection with the better score at 3 months than 5 years after operation. The patients reported significantly more pain at 3 months than 5 years after operation.

There were no statistically significant differences in the overall score of the subscale Quality of life/Satisfaction (questions about tiredness, irritability, depression, global evaluation of health, limitations in daily activities, change in sex life and feeling about body, time of recovery, satisfaction with information, improvement in well being, recommending operation) However, questions about depression, symptom changes pre- and postoperatively, residual urine and OAB symptoms pre- and postoperatively show statistical significant differences with worse results in our population compared with the reference population

The results of the IOQ correlated with patient-reported grade of continence, as well as with subscale IOQ/Satisfaction. This correlation is low with physician assessment of degree of incontinence.

A total of 6 patients required reoperation tape-related reasons after 30 days or more. Two tapes were cut because of OAB symptoms at 2 and 4 years after TVT; OAB symptoms resolved in one of these patients. Two patients underwent a repeat TVT operation (2 and 5 years after the first operation), both without success. One patient underwent Burch colposuspension 6 months after TVT; she is continent but has OAB symptoms 2 years later. One patient underwent periurethral injection for recurrent stress incontinence but remains incontinent. One asymptomatic mesh erosion in a sexually inactive patient was diagnosed at the 5 year follow-up visit and trimmed in the clinic.

### Interpretation of results

The objective continence rate of 86% reported in our study 5 years after the TVT operation is similar to the cure rates reported previously.<sup>3</sup> Compared to the short and long-term objective results in other studies, our results suggest that there is no significant decline in efficacy over an extended period. Patient-reported outcome data suggest that there is no significant decline in these results after the TVT operation over an extended period.

### Concluding message

The results of this 5-year follow-up of patients after TVT operation show that improvements seen in quality of life 3 months after TVT placement are maintained at 5 years.

The grade of continence assessed by the patients showed a better correlation with the results of patient-reported outcomes assessed by IOQ than did the physician's assessment. This underlines the importance of patient-reported outcomes as opposed to physician assessment only.

### References

1. Nilsson CG, Palva K, Rezapour M, Falconer C. Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence. *Int Urogynecol J* 2008 ;19 :1043-7
2. 16. Bjelic-Radisic V, Dorfer M, Tamussino K, et al. Incontinence Outcome Questionnaire: an instrument for assessing patient-reported outcomes after surgery for stress urinary incontinence. *Int Urogynecol J* 2007; 18: 1139-1149.

3. 14. Olsson I, Abrahamsson A-K, Kroon U-B. Long-term efficacy of the tension-free vaginal tape procedure for the treatment of urinary incontinence. Int Urogynecol J 2010 (Eupub ahead of print)

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<i>Is this a clinical trial?</i>	Yes
<i>Is this study registered in a public clinical trials registry?</i>	No
<i>Is this a Randomised Controlled Trial (RCT)?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	The Ethics Committee of the Medical University of Graz, Austria
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	No