Ten-Year Followup after Tension-Free Vaginal Tape-Obturator Procedure for Stress Urinary Incontinence

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Purpose: Suburethral tapes are a standard surgical treatment for stress urinary incontinence. The aim of the study was to evaluate subjective and objective cure rates 10 years after a tension-free vaginal tape-obturator procedure.

Materials and Methods: All 124 patients who underwent the tension-free vaginal tape-obturator procedure at a total of 2 centers in 2004 and 2005 were invited for followup. Objective cure was defined as a negative cough stress test at 300 ml. Subjects completed KHQ (King's Health Questionnaire), IOQ (Incontinence Outcome Questionnaire), FSFI (Female Sexual Function Index Questionnaire) and PGI-I (Patient Global Impression of Improvement).

Results: Overall, 55 of 112 women (49%) who were alive were available for clinical examination and 71 (63%) completed the questionnaires. The objective cure rate in the 55 women examined clinically was 69%, 22% were not cured and 9% (5) had undergone reoperation for recurrent or persistent stress urinary incontinence. Treatment was counted as having failed in these 5 women for study purposes. Subjective cure was reported by 45 of 71 women (64%). Three patients (5%) had vaginal tape extrusion at the time of clinical examination. Extrusion in all of them was small and asymptomatic, and did not require treatment for a cumulative extrusion rate of 7%. Six women (9%) had undergone reoperation for tension-free vaginal tape-obturator associated complications and 18 (26%) experienced de novo overactive bladder.

Conclusions: Subjective and objective cure rates 10 years after the tension-free vaginal tape-obturator procedure were 69% and 64%, respectively. The vaginal extrusion rate in this study was slightly higher than in other series but major long-term complications appeared to be rare.

Key Words: urethra; urinary incontinence, stress; suburethral slings; patient outcome assessment; complications

Abbreviations and Acronyms

MUCP = maximum urethral closure pressure

OAB = overactive bladder

POP = pelvic organ prolapse

QoL = quality of life

SUI = stress urinary incontinence

TVT-O = tension-free vaginal tape-obturator

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PERMANENT suburethral tapes inserted through the vagina have become a mainstay of surgical treatment for SUI.[1] The first retropubic tape was described by Ulmsten et al in 1996 and it was soon available commercially as TVT™.[2] In 2003 Delorme[3] and de Leval[4] developed a transobturator version of the original TVT system. The purported rationale for the transobturator systems was a decreased potential for complications, such as bladder or visceral injuries and bleeding complications.[5,6] A number of retropubic and transobturator tapes became commercially available and TVT-O was introduced in Austria in 2004.

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Incontinence surgery is strictly elective to improve QoL but it has the potential for long-term problems. Thus, it is critical to assess long-term outcomes of these procedures.[7–10] The IUGA (International Urogynecologic Association) and ICS (International Continence Society) recommend using objective and subjective measures, ie QoL, as outcomes in clinical trials.[11]

The primary aim of the current study was to evaluate subjective and objective cure rates 10 years after the Gynecare TVT-O (Ethicon, Somerville, New Jersey) procedure. We also studied QoL, patient satisfaction, sexual health and long-term tape related complications.

MATERIALS AND METHODS

TVT-O was introduced in Austria in 2004. This is a retrospective cohort study of 124 consecutive patients who underwent the procedure in 2004 and 2005 at 2 Austrian centers that were early adopters of the procedure. No study exclusion criteria were applied. All patients were entered in the Austrian Transobturator Registry, which addressed perioperative complications.[12,13] None of the patients were included in the Austrian TVT vs TVT-O trial.[14]

Preoperative clinical and urodynamic assessment included a comprehensive history comprising demographic information, medical history, symptoms of lower urinary tract and pelvic floor dysfunction, clinical examination and urodynamics, including cystometry, MUCP and a cough stress test at 300 ml bladder filling. The TVT-O procedure was performed as originally described by de Leval[4] with or without concomitant surgery by consultants experienced with urogynecologic surgery. The TVT-O technique was performed according to surgeon preference.

Ten years after the procedure all patients were invited by mail for a followup examination. Evaluation included a comprehensive history and clinical examination, assessment of post-void residual urine, urodynamics using cystometry and MUCP, a standardized cough stress test, cystoscopy if necessary, and evaluation of QoL and sexual health by validated questionnaires.

Objective cure was defined as a negative cough stress test at 300 ml bladder filling. Subjective cure was defined when patients responded never to the question, "Does urine leak when you are physically active, exert yourself, cough, or sneeze?" All women were asked about postoperative voiding difficulties, ongoing groin pain and de novo or ongoing urgency symptoms. Electronic medical records of all 124 patients were reviewed to identify reoperations.

Patients not available for physical examination at the clinic underwent a telephone interview covering overall and disease specific history. Thus, reoperation rates were calculated from the total study population.

Questionnaires included the German KHQ,[15] IOQ,[16] FSFI[17] and PGI-I.[18] The German language KHQ is a 32-item questionnaire that assesses the impact of incontinence on QoL. KHQ contains 2 single item questions to address general health perceptions and incontinence impact as well as 7 multi-item domains, including role limitations, physical limitations, social limitations, personal relationships, emotions, sleep/energy and incontinence severity measures. The minimum score is 0—best health and the maximum score is 100—worst health.[19] IOQ is a 27-item questionnaire covering symptoms, complications, overall QoL, sexuality and treatment satisfaction with lower scores indicating worse treatment outcome, which is validated for postoperative assessment of QoL after surgical treatment of SUI.[16] FSFI is a 19-item questionnaire to assess female sexual health that contains the subscales desire, arousal, lubrication, orgasm, satisfaction and pain, and a summarizing total score with higher scores indicating better sexual function.[17] PGI-I is a validated tool to assess the response to an intervention.[18]

Statistical analysis was performed with SPSS®. Differences in cured vs not cured patients were analyzed by the chi-square test for categorical variables and the t-test for independent samples for numerical variables. In case of inhomogeneous variances a correction for heterogeneous variances was included. The Cohen κ was calculated to evaluate agreement between objective and subjective cure. The McNemar test was used to test for differences in overactive bladder between pre and post operation.

The study was approved by participating institutions and informed consent was obtained from all participants. There was no external funding for this study.

RESULTS

A total of 124 patients underwent the TVT-O procedure at the 2 hospitals in 2004 and 2005. Mean age at surgery was 60 years (range 40 to 80). At the 10-year followup 28 patients were lost to followup, 13 refused participation and 12 had died, leaving 7 (57%) available for followup assessment (see figure). Of 112 women who were alive 55 (49%) were available for clinical examination and questionnaires. An additional 16 women completed the questionnaires and the telephone interview only.

Table 1 lists demographic data, including previous surgery and concomitant procedures. Women who were lost to followup were significantly older than the study population ($p = 0.035$). No other significant differences were observed. Preoperative intrinsic sphincter deficiency, defined as MUCP less than 20 cm H_2O, was found in 4 patients.

Of the 55 women evaluated clinically at 10 years 38 (69%) were objectively cured, 12 (22%) were not cured and 5 (9%) had undergone reoperation for recurrent or persistent SUI with treatment counted as having failed for study purposes. In the total study population 46 of 71 patients (64%) achieved subjective cure (table 2). In 76% of the cases subjective cure was in accordance with objective cure (coefficient of agreement Cohen $\kappa = 0.52$, $p < 0.001$).