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Original Article

Nine years follow-up after TVT-O; the mesh still available for women suffering from urinary incontinence

Aino Warro*, Johanna Ojala*, Seija Ala-Nissilä, Eija Laurikainen

Department of gynecology, Turku University Central hospital, Savitehtaankatu 5, 20520 Turku, Finland

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ABSTRACT

Objective: The efficacy of TVT-O is well established in patients with stress urinary incontinence (SUI). The objective of this study was to evaluate the efficacy, safety and patient satisfaction of TVT-O in patients suffering from primary or recurrent SUI or mixed urinary incontinence (MUI).
Methods: A single-center follow-up study was conducted. All consecutive women treated by TVT-O between August 2004 and October 2011 were included. Objective treatment success was a negative stress test. Patient satisfaction was assessed by questionnaires.
Results: The mean time from the surgery to the last follow-up visit was 9 years. One hundred and six patients were included in the final evaluation. Nineteen patients (18%) were previously operated on for urinary incontinence (UI). Ninety patients (85%) were objectively cured; 68 (89%) of the SUI and 22 (73%) of the MUI patients (p = 0.067). Fourteen (74%) of the previously operated patients and 76 (87%) of the patients who underwent first-time TVT-O were objectively cured (p = 0.158). Eighty-six patients (81%) achieved subjective success; 70 (92%) of the SUI and sixteen (53%) of the MUI patients (p<0.001). Eleven women (58%) who had repeat surgery and 75 women (86%) who had primary operation were subjectively cured (p = 0.008).
Conclusions: TVT-O is effective in women who suffer from SUI having 90% objective and subjective cure rate 9 years after surgery. There were no major complications, but 16% of the women suffered from groin pain and 37% had urgency symptoms. The results of TVT-O were still good, and it is a therapeutic alternative for different subgroups of UI including recurrent cases.

Introduction

Urinary incontinence (UI) is a common problem among women showing a prevalence of 19–26% [1]. Stress urinary incontinence (SUI) is the most frequent form of UI affecting approximately 50% of incontinent women [2]. Although of a benign origin, UI can severely impair the quality of life. SUI can be addressed with conservative management such as pelvic floor muscle training. However, operative procedures are often required.

The retropubic tension-free vaginal tape (TVT) procedure has become the gold standard for incontinence surgery because of its efficacy, safety and longevity [3]. However, complications such as vascular injury, bladder and bowel perforations have led to a search for alternative routes using transobturator insertion of the mesh. In the tension-free vaginal tape obturator (TVT-O) approach the sling is funneled from the vaginal incision through the obturator foramen to the thigh fold (inside-out) and in the outside-in transobturator technique (TOT) the mesh is inserted through the opposite direction [4,5].

At five years no significant differences were seen between TVT and TVT-O for female SUI in a randomized trial [6]. There are studies reporting long-term outcomes of at least 10 years' follow-up after TVT-O [7-10]. These studies reported subjective cure rates 64% to 95% and objective cure rates 69% to 92% in long-term (10 to 13 years) follow-up [7-9]. Similar results were submitted with elderly patients (>75 years) [10]. TVT-O seems to be safe, but Zhang et al. reported long-term complication rate 45.2% which was slightly high [8]. The randomized study reporting long-term outcomes of TVT-O and outside-in TOT in women with urodynamic mixed urinary incontinence (MUI) showed that transobturator tension-free vaginal tapes are associated with a good and sustained patient-reported success rate [11].

Abbreviations: DIS, Detrusor Instability Score; HRT, hormone replacement therapy; IIQ-7, Incontinence Impact Questionnaire-short form; MUI, mixed urinary incontinence; OAB, overactive bladder; PVR, post void residual urine volume; RUI, recurrent urinary incontinence; SUI, stress urinary incontinence; TOT, transobturator tape outside-in; TVT-O, tension-free vaginal tape inside-out; UI, urinary incontinence; UDI-6, Urogenital Distress Inventory-short form; UISS, Urinary Incontinence Severity Score

* Corresponding authors at: Savitehtaankatu 5, 20520 Turku Finland.
E-mail addresses: aino.warro@tyks.fi (A. Warro), johanna.ojala@tyks.fi (J. Ojala), seija.ala-nissila@tyks.fi (S. Ala-Nissilä), eija.laurikainen@tyks.fi (E. Laurikainen).

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Due to the potentially serious long-term complications of mid-urethral slings (MUS) such as erosion and pain England have published warnings about the use of MUS [12]. In our country the patients suffering from urinary incontinence undergo mainly mid-urethral tape surgery. An alternative option is a periurethral bulking agent (polyacrylamide hydrogel) which is also a minimally invasive treatment [13]. The aim of this study was to evaluate the efficacy, safety and overall patient satisfaction of the TVT-O technique in a long-term follow-up of patients suffering from primary or recurrent SUI or MUI.

Materials and methods

This is a cohort study of 136 consecutive patients who underwent the TVT-O operation between August 2004 and October 2011 in our hospital. Study inclusion criteria included patients, who suffered from urinary incontinence and did not response to conservative treatment, a positive cough stress test (CST) and the PVR volume less than 100 ml. All consecutive patients were included. Acceptance was obtained from the ethics committee hospital district of Southwest Finland and each patient completed a written informed consent. Our study has been registrated in ClinicalTrials.gov, identifier: NCT04240613. The pre- and perioperative data and the results of the three-month control visit were retrieved from medical records. Preoperative evaluation comprised patient medical history, urine analysis and physical examination including a standard cough stress test (CST) performed in a semilithotomy position with a comfortably filled bladder (200–300 ml). Post void residual urine volumes (PVR) were measured by ultrasonography. Patients with recurrent SUI and those with apparent MUI underwent complete urodynamics to find out if SUI was the predominant component of UI and whether incontinence surgery could be suggested. The Urinary Incontinence Severity Score (UISS) were used to find out the severity of incontinence [14]. The Detrusor Instability Score (DIS), which is a 10-item questionnaire, with a score of 0–20, were used to distinguish between stress and urgency incontinence [15]. A score of ≤ 7 is representative of SUI.

The TVT-O procedures were performed as originally described by de Leval under local anesthesia [4]. The TVT-O sling was brought from the vaginal incision (inside to outside) through the obturator membrane to support the middle part of the urethra. The intraoperative CST was performed with a bladder volume of 300 ml aiming on adjusting the tape to allow a drop of saline to escape from the outer meatus of the urethra on strong coughing. Cystoscopy using a 70-degree optic was performed to make sure of an intact bladder and urethra.

A mean of four years postoperatively, to evaluate the medium-term subjective cure, the patients were sent the validated UISS and the DIS questionnaires [14,15]. The Urogenital Distress Inventory-short form (6 items, UDI-6) and the Incontinence Impact Questionnaire-short form (7 items, IIQ-7) were used for a condition specific assessment [16]. In these questionnaires one point in each question indicates no bother at all. Six points in UDI-6 and seven points in IIQ-7 means that a patient has no urinary symptoms. Subjective success and patient satisfaction were assessed by asking if the patient was satisfied with the operation: very satisfied, satisfied, partly satisfied, partly unsatisfied, unsatisfied, very unsatisfied. The results of the 3-month control visit and of the medium-term subjective cure have previously been published in 2014 in the Journal of the Finnish Medical Association [17].

A mean of nine years postoperatively, the patients were invited to a follow-up visit which consisted of a clinical examination, a CST performed in the same manner as preoperatively and the PVR measurement by vaginal ultrasonography. The above-mentioned questionnaires were completed. Complications such as de novo incontinence or urgency symptoms, self-reported voiding difficulties or groin pain and tape extrusion or erosion were registered. Additionally, the hospital records of all patients were evaluated in April 2021 to find out later visits in the study hospital due to UI or other pelvic floor problems.

The primary outcome was an objective and a subjective treatment success. The objective cure was defined as a negative CST. The patient was subjectively cured if she answered to being very satisfied or satisfied with the operation.

Statistical analysis was performed using SAS® version 9.3 for Windows (SAS Institute Inc., Cary, NC, USA). Continuous variables were analyzed with the paired-sample *t*-test and the independent-sample *t*-test to calculate statistical differences between and within the study groups. The chi-square test or Fisher's exact test was applied for categorical values. A p-value of <0.05 was considered to indicate statistical significance.

Results

Of the 136 patients initially participating in the study, 106 (78%) patients were included in the evaluation at the mean of 9 years (range 5–12 years) after the operation (Fig. 1).

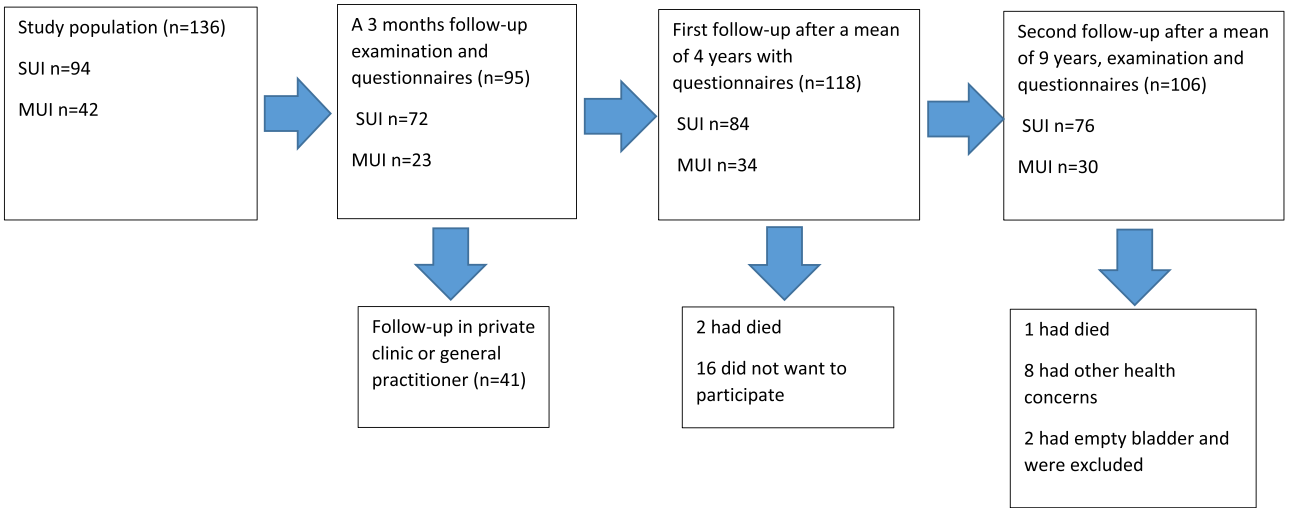

Fig. 1. The flowchart of the study.

The mean age at surgery was 57 years (range 31 to 80 years) and at the long-term follow-up visit 66 years (range 42 to 88 years), 23% of the patients being over 75 years**.** Before the TVT-O operation 76 women (72%) suffered from SUI and 30 (28%) from MUI. Forty patients (38%) underwent complete urodynamics. Nineteen patients (18%), including both SUI and MUI subgroups, were previously operated on due to urinary incontinence. Six of them had two or more incontinence operations. Twelve patients (13%) had concomitant surgery. The patient characteristics are presented in Table 1.

At a mean of 9-year follow-up (range 5 to 12 years), 90 patients (85%) were objectively cured; 68 (89%) of the SUI and 22 (73%) of the MUI patients (p = 0.067). Fourteen (74%) of the previously operated patients and 76 (87%) of the patients who underwent first-time TVT-O were objectively cured (p = 0.158). Objective cure rates in different subgroups are presented in Fig. 2.

Eighty-six patients (81%) achieved subjective success; 70 (92%) of the SUI and sixteen (53%) of the MUI patients (p< 0.001). Eleven women (58%) who had repeat surgery and 75 women (86%) who had no previous anti-incontinence operation were subjectively cured (p = 0.008). Subjective cure rates at the 9-year follow-up are presented in Fig. 3. Of the 106 women, 77 (73%) were subjectively and objectively cured, nine (8%) achieved a subjective but not an objective cure and two (2%) achieved an objective but not a subjective cure. One patient had undergone a TOT operation twice and one of the patients had both TVT and TOT operations before the TVT-O procedure. They were both subjectively satisfied and the patient who had two TOT operations also showed a negative CST. Four patients were unsatisfied or very unsatisfied with the operation. Sixteen patients could not define if they were satisfied or unsatisfied with the operation.

In the analysis of UDI-6 and IIQ-7 questionnaires were included also patients who had failed to respond to one item. In the MUI subgroup mean UDI-6 score was 14.2 (±4.2 SD, range 6–21) and in the SUI group mean UDI-6 score was 9.2 (±2.5, range 6–19). Mean IIQ-7 score in the MUI group was 13.4 (±5.1, range 6–24) and in the SUI group 8.5 (±2.6, range 7–24). DIS and UISS scores are presented in Table 2. Patients did not answer these questionnaires preoperatively.

At the final visit, seven women (7%) were using medication for an overactive bladder (OAB). Fourteen (14%) new prescriptions for OAB were written; seven (10%) prescriptions for patients in the SUI and seven (27%) for patients in the MUI group (p = 0.046). Nineteen patients (18%) had urgency symptoms defined by having both urgency and frequency of a moderate or severe degree in their UDI-6. Thirty-two patients (30%) had urgency symptoms before the TVT-O operation defined by having a score >7 in their DIS. At the 9-year follow-up visit 39 patients (37%) had urgency symptoms by the same definition. Sixteen patients were the same in both groups.

Three of the 106 patients (3%) were found to have vaginal tape erosions, which were asymptomatic. Surgical treatment was not required. One woman had retention problems postoperatively and the tape was cut three months after the surgery. Her CST was negative, but the patient was partly unsatisfied with the operation. There were no reoperations because of UI. One patient was treated twice with bulking agent after the surgery and was considered a failure. She had been treated with pelvic radiation therapy for endometrial cancer before the TVT-O procedure.

Three asymptomatic patients (3%) had PVR over 150 ml the largest PVR being 212 ml. The patient who had the largest PVR had a third degree anterior prolapse and surgery was offered. Twelve patients had an anterior and nine a posterior prolapse. Two patients had both anterior and posterior prolapse. The prolapses were no more than first to second degree and surgery was not required. Five patients had been operated on because of a urogenital prolapse during the follow-up time. Seventeen women (16%) reported groin pain, with thirteen having mild pain. Nobody had contacted the clinic because of groin pain. Sixteen (15%) patients had self-reported voiding difficulties. The operation related problems are presented in Table 3.

Eighty-six patients were satisfied with the operation, eleven (13%) of them suffered from groin pain and twenty-four (29%) of them had urgency symptoms. Four patients were unsatisfied with the operation and one (25%) of them suffered from groin pain and four (100%) of them had urgency symptoms.

We evaluated the hospital records of all patients in 2021. Five patients had started medication for OAB, and one patient was remitted to a urologic consultation due to urgency UI. Two patients had undergone urogenital prolapse surgery. Four patients had died.

Table 1
Characteristics of the 106 patients operated on using TVT-O and included in the final evaluation. FU Follow-up, BMI Body Mass Index; kg/m^2, HRT Hormone Replacement Therapy, TOT transobturator tape outside-in, TVT tension-free vaginal tape.

Patient Demographics (n = 106)	
Age at the surgery (mean ± SD; range)	57 ± 11; 31–80
Age at the 9-year FU (mean ± SD; range)	66 ± 11; 42–88
BMI ≥ 35 n (%)	5 (5)
HRT n (%)	23 (22)
Local estrogen n (%)	54 (51)
Vaginal deliveries n (%)	86 (81)
Cesarean sections n (%)	5 (5)
Previous incontinence surgery n (%)	19 (18)
Burch colposuspension	11
TOT	8
TVT	3
Bulking agents	2
Marshall-Marchetti-Kranz	2
Concomitant surgery n (%)	12 (13)
Vaginal hysterectomy	2
Posterior colporraphy	5
Anterior colporraphy	1
Cervical amputation	1
Salpingo-oophorectomy	1
Prolapse mesh, posterior compartment	2
Covering prolapse mesh erosion	1
TOT tape resection	1

Discussion

At the 9-year follow-up after TVT-O procedure 106 patients were evaluated clinically. Ninety (85%) were objectively and 86 (81%) subjectively cured. The cure rates are high considering that our study population included both SUI and MUI patients and also previously operated women. At a 13-year follow-up Serati et al. reported both subjective and objective cure rates over 90% [9] and Athanasiou et al. over 80% among elderly women [10]. Both studies included women with urodynamically proven pure SUI.

Subjective cure rate among MUI subgroup (53%) was worse compared to SUI subgroup (92%). At a randomized trial of 83 women comparing TVT-O and TOT tapes for patients with MUI patient-reported success rate was 64.6% at the 9-year follow-up, with no significant difference between the groups [11]. Patients suffering from MUI are twice as likely be bothered by their symptoms as compared to patients with SUI [18]. However, OAB symptoms prevalence is known to increase with age.

There were three (3%) asymptomatic tape erosions in our study. Erosion rates reported in the previous long-term follow-ups vary from 0% to 5.5%. Serati et al. did not find any tape erosions ten years after the TVT-O operation but found 4 (2.5%) at 13-year follow-up all these being symptomatic [9,19]. A systematic review and meta-analysis showed a low erosion rate with the retropubic TVT mesh and transobturator tapes [20]. In our study over half of the patients were using the local estrogen and the rest of the patients were advised to use it in the future to prevent tape erosions. Extrusion rates seems to be comparatively low with TVT-O, but further follow-up is needed.

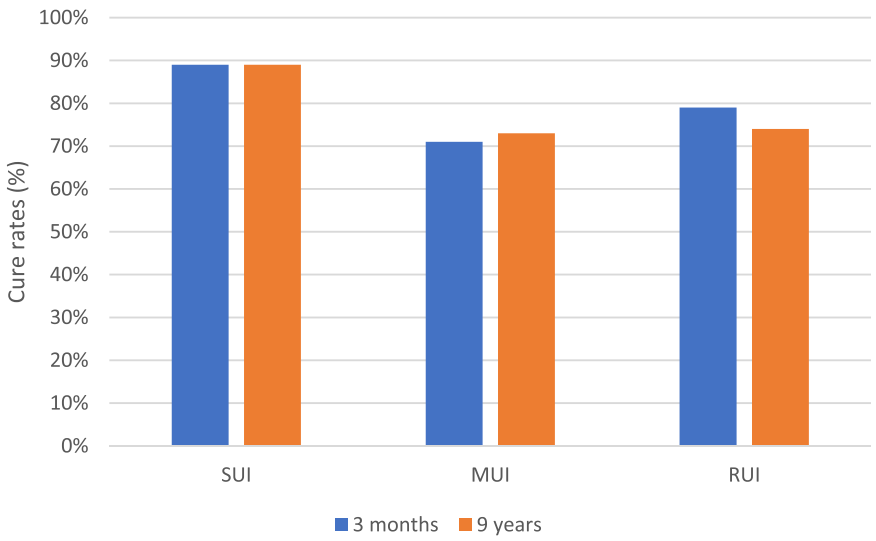

Fig. 2. The objective cure defined as a negative cough stress test after the TVT-O operation at the 3-month [17] and at the 9-year follow-up in different subgroups (stress, mixed and recurrent urinary incontinence).

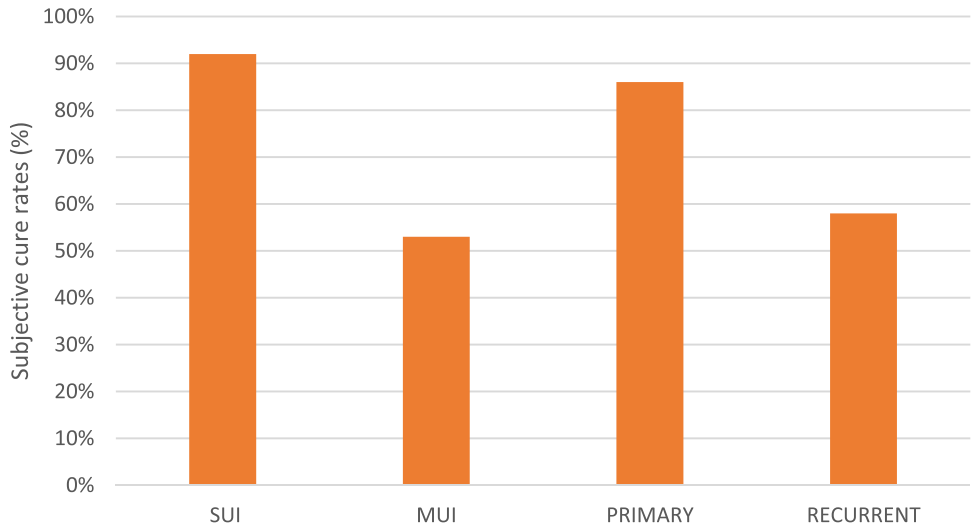

Fig. 3. The subjective cure rates after the TVT-O operation in different subgroups at the 9-year follow-up. The patient was subjectively cured if she answered to being very satisfied or satisfied with the operation.

In our study no major intra or postoperative complications, no bladder or urethra perforations occurred. In a review article including 5385 TVT-O patients, 0.04% risk of bladder perforation and 0.02% risk of urethra injury were reported [21]. Comparing retropubic and transobturator procedures in randomized trials bladder perforations have been shown to be more common using retropubic tapes [22] [23]. In our study one tape was cut because of retention problems and 15% had self-reported voiding difficulties. At the 12-year follow-up study 45.2% had long-term complications including 16 patients (21,9%) who had voiding changes compared with their preoperative condition, still there was no need to tape removal or catheterization [8]. In our study the patient who had the biggest PVR (212 ml) had a third degree anterior prolapse and underwent later on an anterior colporraphy. Although the exact incidence of voiding dysfunction

Table 2
DIS (Detrusor Instability Score) and UISS (Urinary Incontinence Severity Score) (mean ± standard deviation, range) in different subgroups (mixed, stress and recurrent urinary incontinence) at the 9-year follow-up. UISS defines the severity of incontinence [14] and DIS [15] the type of incontinence, both in scale 0–20. DIS score of ≤ 7 is representative of SUI.

	MUI (n = 30)	SUI (n = 76)	RUI (n = 19)
DIS	8 ± 4 (0–15)	5 ± 3 (0–13)	8 ± 4 (1–15)
UISS	7 ± 5 (0–14)	2 ± 3 (0–12)	6 ± 5 (0–13)

Table 3
TVT-O operation related problems at the 9-year follow-up (n = 106).

Tape later cut n (%)	1 (1)
Vaginal tape erosions with no surgical treatment n (%)	3 (3)
Groin pain	17 (16)*
Urgency symptoms n (%)	39 (37)**
Urgency symptoms preoperatively	32 (30)

* Mild pain reported by 13 patients.
** Urgency symptoms were defined by having a score >7 in the Detrusor Instability Score [15].

after anti-incontinence surgery is not known, but it has been estimated as being up to 20% of all cases [24].

In our study, 32 patients (30%) had urgency symptoms before the TVT-O operation defined by having a score of > 7 in their DIS. At the 9-year follow-up visit 39 patients (37%) had urgency symptoms by the same definition. In the study after 10 years of TVT-O a considerable reduction in the prevalence of de novo OAB after 5 years were recorded (24% to 14%) [19,25].

The number of patients suffering from post-operative groin pain has been reported to be higher after the transobturator compared to the retropubic technique [22]. The cause of the groin pain after TVT-O is unclear but may be related to injury to the posterior division of the obturator nerve [26]. In the randomized TVT versus TVT-O study there were postoperatively a greater number of groin pain complaints in the TVT-O group (16% vs 1.5%), a problem that was already resolved at the 2-month follow-up visit [27]. That trial did not mention groin pain at 5 years [6]. Zhang et al. reported that the TVT-O patients were more likely to experience groin/thigh pain after physical activities compared to the TVT patients (6.5% versus 1.7%) [28]. In long-term follow-ups 12 to13 years after the TVT-O 0% to 1.4% of the patients reported groin pain. In the present study, at the final visit, 17 (16%) women reported groin pain, with thirteen having mild pain. However, during these 9 years there were no contacts to the clinic because of groin pain and neither any tape was removed because of this complaint. We believe that groin pain incidence could be overestimated because of possible other medical comorbidities e.g., hip problems, nerve entrapment syndromes, hernia and lumbar disk pathology. Patients who reported groin pain at the follow-up visit were contacted by phone in 2021 to find out if they were still suffering from groin pain and if there was any other diagnosis for the pain. Fourteen patients were reached (2 had died), 4/14 reported groin pain and two of them had diagnosed musculoskeletal disorders.

In our study the subjective cure rate is lower than the objective cure rate which might be due to groin pain or urgency symptoms experienced by the patients. In long-term follow-up four patients were unsatisfied or very unsatisfied with the operation. One of them reported mild groin pain, three of them did not have any groin pain. All four unsatisfied patients had a score of > 7 in their DIS which could explain the patientśunsatisfaction.

There is no consensus of the management of recurrent SUI following primary insertion of a synthetic MUS. In a review by Nadeau and Herschorn, cure rates with different definitions varied from 45% to 100% among 642 patients followed up for a mean period of 23 months (6–57 mo) [29]. In our study 19 women (18%) were previously operated on due to urinary incontinence. At the final visit 74% of the patients were objectively and 58% subjectively cured. Similarly, after the second sling (TVT 49%, transobturator tape 48%) was placed, 68 (60.7%) were subjectively cured with a mean follow-up of 21 months in a report by Meyer et al. [30]. Abdel-Fattah et al. concluded that transobturator operations are associated with good patient-reported success rates (62%) in women (n = 29) with previous failed continence surgery with an up to 9-year follow-up [31]. In addition, it is noteworthy finding that our two patients who had undergone two other tape procedures before insertion of the TVT-O tape were satisfied without complications many years after the operation.

The strengths of our study are as follows: i) Turku University Hospital was one of the first clinics in Finland to adapt the TVT-O procedure shortly after its commercialization; ii) all the patients underwent clinical examination at the follow-up visit; iii) the patients completed validated questionnaires pre- and postoperatively; iv) follow-up time was 9 years which is quite long with patient material including SUI, MUI and RUI patients; v) we evaluated the hospital records of all patients in 2021, a mean of 14 years after the initial operation.

Additionally, we are aware of the limitations of the present study: i) the number of patients was moderate; we lost some women during the follow-up and the study material included patients only from one hospital; ii) thirty-eight percent of the patients suffering from recurrent SUI or apparent MUI underwent urodynamics; however, nowadays not all the patients undergo urodynamics before incontinence surgery.

In this study the TVT-O operation seems to be effective in the long term for women who suffer from SUI. There were no major complications but some women suffered from groin pain and urgency symptoms. The results of TVT-O are still good, and it can also be considered as a therapeutic alternative for different subgroups of UI including recurrent cases.

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