



# Patient goal achievement 2 years after a tension-free vaginal tape operation

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## Abstract

**Introduction and hypothesis** The primary aim of this study was to investigate long-term patient-reported goals after a tension-free vaginal tape (TVT) operation for stress urinary incontinence (SUI).

**Methods** In this prospective study involving 67 women, patients completed the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) preoperatively and stated three goals for the operation. Postoperatively, a visual analog scale (VAS) ranging from zero (none) to ten (worst) estimated the extent to which goals were achieved. Goals were divided into five groups: symptoms, quality of life (QoL) (physical), QoL (emotional), sexual function, avoidance, and others. Short-term achievement of goal was estimated after 3 months and long-term achievement of goals after a mean of 28.2 months.

**Results** A total of 201 goals were stated, most of which (38%) were in the group concerning QoL in physical domains. Mean VAS score for all goals was 9.1 after 3 months and 8.5 at long-term follow-up. ICIQ-UI SF preoperatively was mean 14.9; 3 months' postoperatively mean 1.4; and at long-term 3.8. The small rise in ICIQ-UI SF at long-term follow-up was statistically insignificant and due to urge urinary incontinence (UUI).

**Conclusions** Our study showed that patients achieved their goals to a high degree and maintained them at long-term follow-up. Most goals concerned QoL in physical domains. Although a proportion of women experienced episodes of UUI at the long-term follow-up, VAS score was not significantly changed.

**Keywords** Tension-free vaginal tape · Stress urinary incontinence · Patient goals

## Introduction

Originally, outcome after pelvic floor surgery has been measured objectively by using evaluation methods such as the Pelvic Organ Prolapse Quantification (POP-Q) system, pad-weighing tests, and urodynamics. It is now understood that patient-reported outcomes (PROs) are of utmost importance to the patient [1], and subjective assessment are recognized as being equally important as traditional objective measures of success following a midurethral sling (MUS) operation [2]. Questionnaires such as the International Consultation on Incontinence Urinary Incontinence Short Form (ICIQ-UI SF) have been developed to measure symptoms and quality

of life (QoL) [3, 4]. Patient-reported goals is another measure of PRO, and the extent to which patient-reported goals are achieved is an important measure of patient satisfaction. Previous studies have focused on the short-term achievement of goals after MUS operation for stress urinary incontinence (SUI) [5–7]. The primary aim of this study was to investigate patient-reported goals before surgery and determine to what extent these goals were met 3 months after surgery and at a long-term interview in a group of women operated with a tension-free vaginal tape procedure (TVT) for SUI. Secondly, we evaluated continence status at short- and long-term after the operation.

## Materials and methods

This was a prospective quality-control cohort study involving 70 women who underwent a TVT operation between September 2014 and October 2015 at a Danish university

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hospital and who consented to write down their preoperative goals for the operation. There were no exclusion criteria, all women agreed to participate, and the study was accepted by the regional ethics committee. Preoperative evaluation included medical history, physical examination including cough test, vaginal ultrasound (US) investigation, urine analysis, a 3-day voiding diary, urinary flow, and postvoid residual (PVR) urine volume measurement. Further urodynamic investigation with cystometry was not performed in patients with a history of SUI only and normal flow with no residual urine. Extracted data included age, parity, and previous cesarean section, prolapse, and urinary incontinence (UI) operations. All patients underwent the TVT procedure as described by Ulmsten et al. [8]. No concomitant procedures were performed in connection with the incontinence operation. All operations were performed under local anesthesia with sedation. A preoperative cough test with 300 ml in the bladder was performed. The catheter was removed before leaving the theater. Preoperatively, women completed the ICIQ-UI SF [3, 4] and were asked to write down in their own words three goals they wanted to achieve from the operation. The ICIQ-UI SF is used to evaluate the severity of urinary incontinence and its impact on health-related QoL. It contains three scored items and an unscored self-diagnostic item. A total score for the three subscores was calculated by adding them up. Maximum score for worst incontinence was 21. Total score was used to evaluate incontinence pre- and postoperatively. The unscored self-diagnostic item was used to classify incontinence type: SUI, urge (UUI), mixed (MUI), or undefined incontinence. The Danish version of the ICIQ-UI SF has been translated from English but has not been validated.

If the telephone follow-up had not been completed, a letter with the questionnaires was sent to the patient. Data on the early 3-month follow-up has previously been published [9]. A long-term telephone interview after mean 28 months (22–34) was performed. Once again, patients completed the ICIQ-UI SF and were asked to what extent preoperatively stated goals were now fulfilled. Patients' goals were divided into six categories: symptoms, QoL (physical), QoL (emotional), sexual function, avoidance, and others. The authors reviewed all goals and categorized each one. Category 2 included patients who wrote that they wanted to be able to play with their children, start to run, play badminton, dance, jump on the trampoline, etc. Category 3 included patients who wanted to get rid of the fear of wetting themselves, that someone would notice their wet pants, that someone might smell that they leaked, etc. Category 5 included patients who wanted to avoid using pads.

Results were reported as mean with a standard deviation (SD). The *t* test was used to compare ICIQ-UI SF before and goal scores after the operation. Statistical significance was considered to have been reached when the *p* value was <0.05. STATA version 14 (StataCorp LP, TX, USA, 2016) was used.

## Results

Seventy women completed the short-term follow-up and 67 patients the long-term follow-up. Three patients were lost the long-term follow-up. We analyzed data for women who completed both short- and long-term follow-up (per protocol). Demographic data are presented in Table 1.

A total of 201 goals were stated. The number of goals in each category is shown in Table 2. Most goals (38%) were in group 2 concerning QoL in physical domains; 20% of goals were in the avoidance group (not having to wear pads or avoid wearing special clothes). Most goals (81%) were in groups other than the mere resolution of incontinence symptoms.

Mean VAS score for all goals was 9.1 (SD 2.0) after 3 months and 8.5 (SD 3.2) at long-term follow-up. (*p* = 0.12). After 3 months, 37 women had a goal score of 10 on all goals, rising to 39 women at the long-term follow-up. ICIQ-UI SF preoperatively was mean 14.9 (SD 2.9), postoperatively (after 3 months) mean 1.4 (SD 4.0), and long-term 3.8 (SD 5.4). There was a statistically significant difference between ICIQ-UI SF preoperatively and at short-term (*p* < 0.05) and long-term (*p* < 0.05) follow-up but not between short- and long-term follow-up (*p* = 0.297). At short-term follow-up, 56 patients had an ICIQ-UI SF score of 0 and 11 >0 and six score >6. Five patients had UUI, three SUI, two undefined, and one MUI. At long-term follow-up, 37 patients had an ICIQ-UI SF score of 0, 29 a score >0, and 12 a score >6. At long-term follow-up, patients mainly had UUI symptoms (*n* = 15), seven had SUI, and seven MUI.

## Discussion

This study shows patients have realistic goals, which are met to a high degree after the TVT operation. Most patients have QoL goals within the physical domain. Even though some patients in the long-term experience episodes of UUI, the total achievement of goals remained unchanged.

**Table 1** Demographic data of the 67 participants

Patient variables	
Age, years, mean (SD)	53.9 (11.3)
BMI, kg/m <sup>2</sup> , mean (SD)	26.1 (4.3)
Parity, median (range)	2 (0–4)
Previous cesarean sectio, <i>N</i> (%)	5 (7.14)
Previous hysterectomy, <i>N</i> (%)	7 (10)
Previous prolapse operation, <i>N</i> (%)	4 (5.7)
Previous incontinence operation, <i>n</i> (%)	6 (8.6)

*BMI* body mass index, *SD* standard deviation

**Table 2** Goal groups and VAS scores

Group	Number (percentage)	VAS 10 short-term / long-term	VAS <10 short-term / long-term	Mean VAS (at < 10) short-term / long-term
1 Symptoms	38 (18.9%)	28 / 27	10 / 11	6.6 / 7.8
2 Quality of life (physical)	76 (37.8%)	62 / 60	11 / 16	7.3 / 4.7
3 Quality of life (emotional)	29 (14.4%)	22 / 26	6 / 3	7.0 / 7.7
4 Sexual function	13 (6.5%)	11 / 11	2 / 2	8.5 / 8.0
5 Avoidance	41 (20.4%)	25 / 23	16 / 18	5.4 / 2.7
6 Others	3 (1.5%)	1 / 1	2 / 2	3.0 / 0.0
0 Missing	1 (0.5%)	0 / 0	0 / 0	0.0 / 0.0
TOTAL	201 (100%)	149 / 148	47 / 52	5.4 / 4.4 ( $p = 0.6$ )

VAS visual analog scale

The strengths of the study are that we investigated a group of patients who were only treated for their SUI, that we used a validated questionnaire—the ICIQ-UI SF—to evaluate UI severity and its impact on HR-QoL, and that all goals were self-reported. Another strength is that we followed patients for a mean of 28 months. We used a very strict definition of cured incontinence, namely, an ICIQ-UI SF score of zero. In a newly published article by Karmakar et al. [10], it was estimated that a postoperative ICIQ-UI SF value of 6/21 is likely to be associated with a patient-reported successful outcome. This might be one of the reasons we still find a high VAS score regarding goals despite a somewhat higher ICIQ-UI SF score.

A limitation to this study is that although fulfillment of patient goals was unaltered in the long-term, we do not know whether some patients who developed UUI would have had other goals had they known of this possible complication. Lowenstein et al. [11] suggested that, apart from the three well-established dimensions for pelvic floor disorders—physical findings, symptoms, and QoL assessment—a new dimension of self-expressed urogynecologic goals should be integrated as the fourth dimension. Those authors found that, as expected, goals related to symptom relief were common, but nearly one third of women had goals not simply related to symptoms. We agree with the inclusion of a fourth dimension, and our study showed that 81% of goals were not directly related to pure symptom relief. Most previous studies on patients' goals involve patients with pelvic floor surgery for both prolapse and incontinence or prolapse alone [12–16].

The large Trial of Mid-Urethral Slings (TOMUS) multicenter study of 565 women randomized for either retropubic or transobturator MUS assessed patient satisfaction 12 months postsurgery using the Incontinence Surgery Satisfaction Questionnaire and found that satisfaction was associated with greater perceived improvement of SUI and fewer complications [6]. This study did not consider individual patient goals.

Maldonado et al., in a review of patient satisfaction following MUS surgeries, concluded that patient satisfaction is a complex outcome with a multidimensional influence

dependent on a variety of factors, which include resolution of SUI symptoms, severity of preoperative urinary symptoms, patient expectations, pre-existing comorbidities, and complications. Future studies should focus on elucidating long-term predictors of satisfaction and standardizing the tool for its assessment [7]. We believe our study adds to the possibilities of predicting patient satisfaction by using personalized patient goals.

Previous studies have shown that some patients experience de novo UUI after an MUS operation. In a long-term study by Holmgren et al. [17] concerning 463 women with a TVT operation and follow-up of mean 5.2 years, 15% developed de novo urgency symptoms. Lleberia-Juanos et al. [18] found de novo urgency in 22% of patients operated with an MUS after mean follow-up of 36 months. In a literature review by Marcelissen and Van Kerrebroeck, the incidence of de novo and persistent urgency and UUI was reported ~15 and 30%, respectively [19]. These data are in accordance with our findings. We find it important that patients are informed about these possible complications before the operation. Barber et al. in a study defining success after surgery for POP, stated that surgeons should describe success using a patient perspective to ensure a mutually agreeable definition of an acceptable outcome before the intervention. Perioperative goalsetting and achievement may augment this patient–surgeon communication [20]. In a recent study on patient goals after an anterior colporrhaphy operation on 100 patients, 63.4% of goals were fulfilled with a VAS score of 10. Goals concerning cure were only 31% fulfilled, with a VAS score of 10, showing the importance of patient–surgeon discussion before the operation concerning goals [21]. These studies confirm the importance of patient-reported goals and expectations in any patient treatment.

Our study showed that most patient goals were met in most cases and sustained for up to 2 years postoperatively. Some patients experience UUI after a TVT, and we do not know whether this would have altered goals reported preoperatively.

## Conflicts of interest

None.

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