

Surgeon's experience and clinical outcome after retropubic tension-free vaginal tape—A case series

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Abstract

Introduction: The retropubic tension-free vaginal tape procedure has been the preferred method for primary surgical treatment of stress and stress-dominant mixed urinary incontinence in women for more than 20 years. In this study, we assessed associations between surgeons' experience with the primary tension-free vaginal tape procedure and both perioperative complications and recurrence rates.

Material and methods: Using a consecutive case-series design, we assessed 596 patients treated with primary retropubic tension-free vaginal tape surgery performed by 18 surgeons from 1998 through 2012, with follow up through 2015 (maximum follow-up time: 10 years per patient). Data on perioperative complications and recurrence of stress urinary incontinence from medical records was transferred to a case report form. Surgeons' experience with the tension-free vaginal tape procedure was defined as number of such procedures performed as lead surgeon (1-19 ["beginners"], 20-49 and ≥ 50 procedures). All analyses were done with a 5% level of statistical significance. We applied the Chi-square test in the assessment of perioperative complications. The regression analyses of recurrence rate by number of tension-free vaginal tape procedures performed were restricted to the three surgeons who performed ≥ 50 procedures.

Results: We found a significantly higher rate of bladder perforations ($P = .03$) and a higher rate of urinary retentions among patients whose tension-free vaginal tape procedures were performed by "beginners" ($P = .06$). We observed a significant reduction in recurrence rates with increasing number of tension-free vaginal tape procedures for one surgeon ($P = .03$).

Conclusions: Surgeons' experience with the tension-free vaginal tape procedure is associated with the risk of bladder perforation and urinary retention, and may be associated with the long-term effectiveness of the procedure.

Abbreviations: SUI, stress urinary incontinence; TVT, tension-free vaginal tape; UR, urinary retention.

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KEYWORDS

complications, long-term results, mixed urinary incontinence, surgeon's experience, tension-free vaginal tape, stress urinary incontinence

1 | INTRODUCTION

For more than 20 years, the retropubic tension-free vaginal tape (TVT) procedure has been the gold standard in primary surgical treatment of stress urinary incontinence (SUI) and stress-dominated mixed urinary incontinence in women. Numerous publications have assessed demographic, clinical and urodynamic risk factors for adverse outcomes after mid-urethral sling surgery. However, there are few studies assessing surgeons' experience on clinical outcomes.

Surgeons' experience is usually characterized by the number of TVT procedures performed and/or by the surgeons' position in the department (senior consultant/resident). Measures such as organizational level (university, central or local hospital, teaching/non-teaching hospital) and/or annual volume of surgery are used to describe institutions. The majority of publications have assessed perioperative complications by surgeons' experience,¹⁻³ but few studies have looked at long-term effectiveness.⁴⁻⁷ Furthermore, most of the studies that assessed effectiveness by surgeons' experience had low sample sizes (<500) and looked at only a few outcomes.^{4,5,8} Existing evidence has shown an increased risk of bladder perforation when the surgeon is a "beginner".⁹⁻¹³

In the TVT procedure, the decreasing rate of bladder perforation as a function of the increasing number of procedures performed has been defined as a possible measure of surgeons' experience.³ However, studies that have assessed surgeons' experience used very different cut-off values to test that experience, <16, <30, <50 or <100 surgeries.^{3,10,12} The literature is also inconclusive regarding the surgeon's learning phase when studying urinary retention (UR)^{11,14} and other perioperative complications.^{1,2,5,8,15} At a 2- and 4-year follow up, two studies reported reduced cure rates in low-vs high-volume departments and when comparing low-vs high-volume TVT surgeons.^{4,6}

The aims of this study were to assess associations between surgeons' experience with the primary retropubic TVT procedure and both perioperative complications and recurrence rates.

2 | MATERIAL AND METHODS

The Department of Gynecology at Nordland Hospital, Bodø, Norway, introduced the retropubic TVT procedure in 1998. At that time, none of the doctors in the department's permanent staff had any previous experience with the procedure; therefore, the first TVT procedures in the department were performed by the most experienced senior consultants, under the supervision of an experienced urogynecologist from a university hospital. Less experienced surgeons continued to be trained in the procedure by the most experienced surgeons

Key message

Patients of surgeons who have less experience with the tension-free vaginal tape procedure show higher risks of bladder perforations and urinary retention, with less impact on long-term recurrence rates.

until they were judged to be qualified to perform it alone, usually after having performed 10-20 TVT procedures.

We recently published a study on clinical outcomes and risk factors for recurrence in patients receiving the TVT procedure from 1998 through 2012.¹⁶ During this period, the Department of Gynecology at Nordland Hospital performed 697 TVT procedures, 621 of which were primary procedures in women with no previous incontinence or prolapse surgeries. The present analysis includes the 596 patients for whom we had follow-up data, which was collected through 2015.

The main exposure was surgeons' experience, measured as total number of primary TVT procedures performed. Main clinical outcomes were rate of perioperative complications and recurrence rate.

During the study period, 18 surgeons had the status of lead surgeon. Two surgeons operated continuously and performed more than two-thirds of the primary TVT procedures (surgeon A, n = 190, surgeon B, n = 237) and a third surgeon did 67 primary TVT procedures during the first 5 years of the study period (surgeon C). The remaining 15 surgeons (surgeon group D) performed 102 primary TVT procedures, varying from 1 to 32 each, mainly before 2007. While surgeons A, B and C were specialists in gynecology and obstetrics when the TVT procedure was initiated in 1998, surgeon group D comprised experienced residents approaching their licensure as gynecologists and experienced senior consultants who had performed the TVT procedure at other hospitals.

Perioperative complications included UR, bladder injury, hematoma and other perioperative complications. UR was defined as the need for catheterization more than 1 week after surgery and/or need for traction and/or surgical correction necessitating cutting of the tape. Bladder injury was defined as perforation by the trocar or the tape, and hematoma as clinically significant and/or diagnosed by ultrasound. Traction was performed non-invasively by stretching the urethra with a Hegar dilator under gel anesthesia. We chose not to include urinary infections as complications, as the prevalence would have been underestimated because such infections are most often treated after discharge by general practitioners.

Recurrence of urinary incontinence was defined as the presence of any bothersome, patient-reported symptoms of SUI; a SUI

index score >0 indicative of bothersome symptoms of SUI on a validated questionnaire¹⁷; or a positive standardized cough/jump pad stress test.¹⁸ Neither de novo urgency urinary incontinence in women with pure SUI before the TVT procedure nor recurrence of urgency urinary incontinence in women with preoperative mixed urinary incontinence was defined as recurrence. All patients were followed up either at the outpatient clinic or by post or phone, 6-12 months after their primary TVT procedure. Between 1998 and 2008, further follow up occurred only after referral from a general practitioner or private gynecologist due to lower urinary tract symptoms or other gynecological problems. Patients who received the TVT procedure from 2009 onwards had a systematic 3-year follow up, comprising a validated short-form urinary incontinence disease-specific questionnaire from The Norwegian Female Incontinence Registry.¹⁷

2.1 | Statistical analyses

Analyses were performed in the Statistical Package for the Social Sciences (SPSS) version 25 (IBM) and MATLAB version 2019a. Statistical significance was set to a 5% level. In the analysis of perioperative complications, we applied the Chi-Square test, categorizing the number of primary TVT procedures that surgeons performed as 1-19 ("beginner"), 20-49, and ≥ 50 .

Recurrence of urinary incontinence was recorded as the date of the first visit for bothersome symptoms of SUI following the primary TVT procedure, or censored at the date of the last visit at which continence was documented in the medical record or at the date of repeat surgery due to complications or prolapse, when repeat surgery occurred prior to debut of SUI symptoms. Each patient was followed up for a maximum of 10 years; analyses were stopped for any outcome thereafter due to few observations.

To maintain power, we restricted analyses of recurrence to surgeons A, B and C, as they had performed >50 surgeries. To investigate whether the recurrence rates decreased as the surgeons gained more experience, we performed a hypothesis test which stated: the recurrence rate is constant and equal to the mean recurrence rate over all surgeries (H0) or the recurrence rate is a logit function of the number of surgeries performed (H1). These hypotheses give the probability (*P* value) of observing a change in recurrence rate, given that the recurrence rate is unaffected by surgeons' experience.

The recurrence rate was estimated using logistic regression, assuming a binomial distribution.

The binomial distribution describes a situation in which each observation (in this case each TVT procedure) has only two possible outcomes (in this case recurrence or no recurrence). For each surgeon, the first five surgeries in each time period were pooled to avoid the effect of highly variable recurrence rates for small number of surgeries.

As the department introduced a standardized 3-year follow up from 2009 onwards, we performed separate analyses of recurrence for 1998-2008 and 2009-2012.

2.2 | Ethical approval

The Regional Committee for Medical and Health Research Ethics (REC-North ref. number 2012/1238/REK Nord; date of approval: 8 April 2013), and the Patient Ombudsman, Nordland Hospital, Bodø, reviewed and approved the study protocol.

3 | RESULTS

There were no differences between surgeons regarding indications for surgery (SUI/mixed urinary incontinence) or comorbidity (cardiovascular, pulmonary, or neurological diseases). However, surgeon C operated on more women who had undergone a hysterectomy (Table 1).

Over the study period, the average annual number of TVT procedures performed in the department was 46 (range 27-64). Among the 596 primary TVT procedures included in this analysis, 146 (24.5%) were performed by surgeons with an experience of ≤ 19 primary TVT procedures, 103 (17.3%) were performed by surgeons with an experience of 20-49 primary TVT procedures, and 347 (58.2%) were performed by surgeons with an experience of ≥ 50 primary TVT procedures.

3.1 | Surgeon's experience and complications

Despite decreasing trends, there were no significant differences in the total rate of perioperative complications by category of surgeons' experience with the TVT procedure. UR was more often diagnosed when surgeons had an experience of ≤ 19 primary TVT procedures ($P = .06$), whereas the risk of bladder perforation decreased significantly when the surgeon had performed ≥ 50 TVT procedures compared with fewer surgeries ($P = .03$) (Table 2).

3.2 | Surgeon's experience and effectiveness

There were no statistically significant differences in recurrence rates by age, body mass index, parity, earlier hysterectomy or comorbidity during follow up (Table 3). Compared with 1998-2008, there was a lower proportion of recurrences diagnosed the first year after surgery and a higher proportion of recurrences diagnosed 3-5 years after surgery in 2009-2012 ($P = .00$) (Table 4). During 1998-2008, mean recurrence rates varied from 10.2% for surgeon A (based on this surgeon's TVT procedures 1-98, Figure 1, panel A1) to 17.9% for surgeon B (based on this surgeon's TVT procedures 1-134, Figure 1, panel B1) ($P = .10$). These rates nearly doubled in 2009-2012, with a mean recurrence rate of 19.6% for surgeon A (based on this surgeon's TVT procedures 99-190, Figure 1, panel A2) and 30.1% for surgeon B (based on this surgeon's TVT procedures 135-237, Figure 1, panel B2) ($P = .09$). During the latter period, recurrence occurred more often among

	Surgeon				In total %	P value ^a
	A %	B %	C %	D %		
Age at time of surgery						
25-49 years	42.6	49.8	34.3	32.4	42.8	.051
50-59 years	28.4	21.9	34.3	31.4	27.0	
60-93 years	28.9	28.3	31.3	36.3	30.2	
Body mass index (kg/m ²)						
Missing	0.5	0.4	1.5	3.9	1.2	.119
18.29-24.99	41.1	33.8	28.4	30.4	34.9	
25.00-29.99	40.0	45.6	50.7	48.0	44.8	
30.00-42.15	18.4	20.3	19.4	17.6	19.1	
Parity						
0-1	7.9	13.5	16.4	13.7	12.1	.059
2	41.6	41.8	25.4	32.4	38.3	
3+	50.5	44.7	58.2	53.9	49.7	
Hysterectomy (yes)	15.8	11.8	19.4	7.8	13.3	.098
Comorbidity						
Cardiovascular (yes)	25.3	21.5	23.9	24.5	23.5	.823
Pulmonary (yes)	15.3	8.9	9.0	15.7	12.1	.112
Neurological (yes)	6.8	9.3	13.4	9.8	9.1	.428
Type of incontinence						
Stress urinary incontinence	63.2	65.8	68.7	66.7	65.4	.843
Mixed urinary incontinence	36.8	34.2	31.3	33.3	34.6	

^aPearson Chi-square test.

TABLE 2 Perioperative complications by surgeon's experience with primary tension-free vaginal tape (TVT) procedure

	Surgeon's experience			In total %	P value ^a
	1-19 TVT procedures %	20-49 TVT procedures %	≥50 TVT procedures %		
Urinary retention	8.2	1.9	4.3	4.9	.059
Other perioperative complications	4.8	9.7	4.6	5.5	.126
Bleeding/hematoma	0.0	2.9	2.9	2.2	.116
Bladder perforation/injury	2.7	5.8	0.6	2.0	.03
Others ^b	2.1	1.0	1.2	1.3	.683
Total perioperative complications	13.0	11.7	8.9	10.4	.360

^aPearson Chi-square test.

^bFive patients with surgical site infection and four with other complications.

patients who received the TVT procedure for mixed urinary incontinence (odds ratio 2.4, 95% CI 1.2-4.9) than among those who received it for SUI (odds ratio 1.5, 95% CI 0.7-2.9).

In 1998-2008, when surgeons were building competence, surgeons A and C had a decreasing slope for the recurrence rate, whereas surgeon B had a nearly flat slope (Figure 1, panels A1, B1, C1). For surgeon B, this resulted in neither a clinically significant nor

a statistically significant change in recurrence rate by increasing number of surgeries (based on this surgeon's TVT procedures 1-134) ($P = .71$). For surgeon A, the decreasing slope may suggest a clinically significant effect on performance by increasing number of surgeries (based on this surgeon's TVT procedures 1-98), but it was not statistically significant ($P = .24$). For surgeon C, the recurrence rate decreased ($P = .04$), which indicates both a clinically and statistically

TABLE 1 Baseline characteristics by surgeons

TABLE 3 Recurrence rates by study population characteristics

	Recurrence rate ^a %	P value ^b
In total	17.8	
Study population characteristics		
Age		
25-49 years	16.5	.507
50-59 years	16.8	
60-93 years	20.6	
Body mass index (kg/m ²)		
Data missing	28.6	.158
18.29-24.99	16.3	
25.00-29.99	15.7	
30.00-42.15	24.6	
Parity		
0-1	19.4	.473
2	15.4	
3+	19.3	
Hysterectomy		
Yes	21.5	.351
No	17.2	
Comorbidity		
Cardiovascular		
Yes	17.1	.82
No	18.0	
Pulmonary		
Yes	18.1	.949
No	17.7	
Neurological		
Yes	14.8	.549
No	18.1	

^aMaximum patient follow-up time: 10 years.

^bPearson Chi-square test.

significant effect, with fewer recurrences by increasing number of surgeries (based on this surgeon's TVT procedures 1-67).

At the start of the 2009-2012 period, surgeons A and B had experience with 98 and 134 primary TVT procedures, respectively. In this period, the slope of the recurrence curve for surgeon A decreased slightly for surgeries 99-190 (Figure 1, panel A2) ($P = .22$), which may indicate a clinically significant, but not a statistically significant effect of learning, whereas for surgeon B we observed nearly no change in the slope for the recurrences for surgeries 135-237 (panel B2) ($P = .77$).

4 | DISCUSSION

We did not find any statistically significant differences in the overall rate of perioperative complications by surgeons' experience. However,

TABLE 4 Number and proportion of recurrences by months of follow up and study period

Months of follow-up	1998-2008	2009-2012
	n (%)	n (%)
0-11	27 (47.4)	13 (26.5)
12-35	6 (10.5)	8 (16.3)
36-59	4 (7.0)	27 (55.1)
60-120	20 (35.1)	1 (2.0)
In total	57 (100)	49 (100)

surgeons who had performed ≥ 50 TVT procedures had a significantly lower risk of bladder injury compared with surgeons who had performed fewer such procedures. We found a significant reduction in recurrence rate by increasing number of TVT procedures performed for one of three surgeons, with indifferent results for the other two.

As reported by others,^{3,10,13} we found a significant, lower risk of bladder injury with increasing number of TVT procedures performed above 50. However, we found a higher risk of bladder perforation in the middle category of surgeons' experience with TVT procedures (20-49; 5.8%) compared with the lowest category ("beginner", 1-19; 2.7%). This may be an effect of the assistance from an experienced surgeon supervising in the "beginner" phase. In Hilton's study,³ which assessed learning phases for 16 surgeons performing 1568 TVT procedures, the number of TVT procedures necessary to achieve a rate of bladder perforation $\leq 5\%$ varied between 20 and 80 surgeries. Whereas Duckett et al found no difference in UR rate between groups of surgeons with different levels of experience,¹⁴ Lebret et al reported a significant, increased risk of UR during the first 50 TVT procedures compared with the subsequent 50.¹¹ We found a borderline significant increased risk of UR during the first 19 TVT procedures compared with the procedures thereafter (Table 2), which may indicate that the learning phase covers the first 20-50 TVTs for this particular outcome. These results emphasize both individual variations in the length of the learning phase³ as well as disparities across outcomes.

Three studies with sample sizes of 187, 809 and 1455 TVT procedures, respectively, all reported evidence of an association between a higher level of experience and a lower risk of perioperative complications.^{1,2,15} However, we did not find any difference in the overall rate of perioperative complications by surgeons' experience, though we did find a slight declining trend by increasing number of TVT procedures ($P = .36$).

We did not find any statistically significant association between surgeons' experience and risk of recurrence in two of three surgeons during a maximum of 10 years of patient follow up. However, for surgeon A, there was a tendency towards a declining rate of recurrence by increasing number of TVT procedures performed in the period 1998-2008. A statistically significant reduction in recurrence rate by number of TVT procedures performed was shown only for surgeon C, who was by far the most experienced gynecologist in the department. During his early learning phase of about 30 primary TVT procedures, he performed a higher proportion of the procedures not

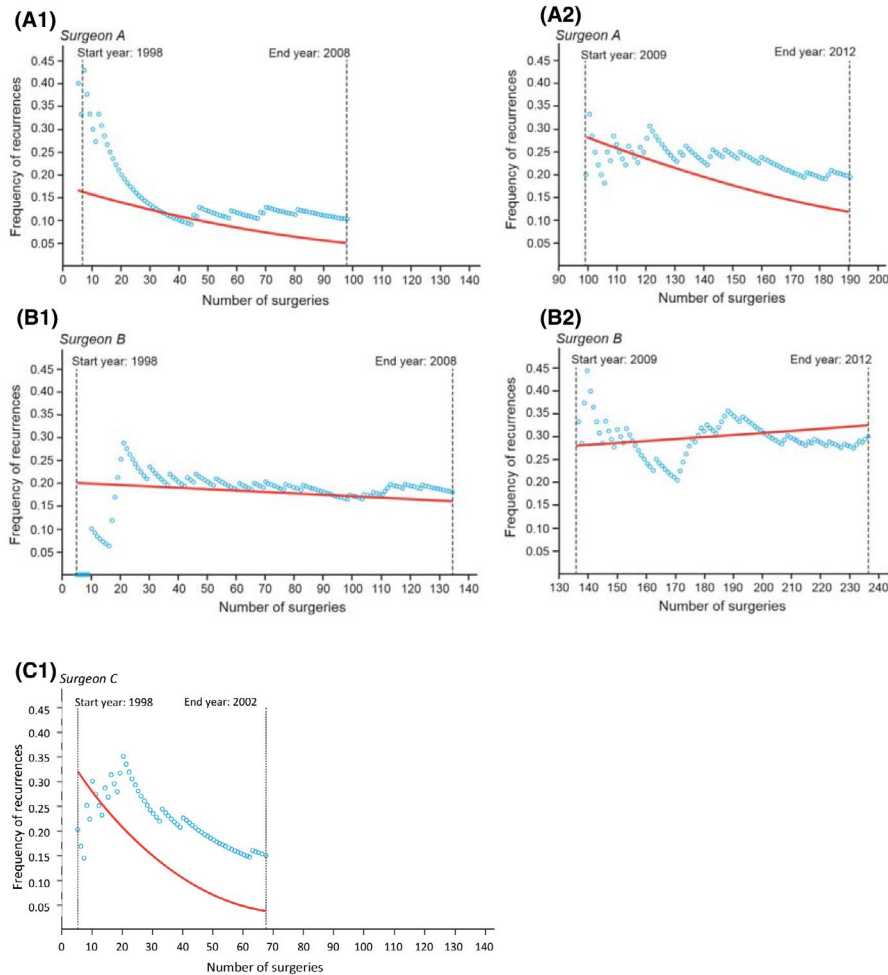


FIGURE 1 Frequency of recurrence by number of primary tension-free vaginal tape procedures performed by study period for surgeons A, B and C. The red line shows the fitted model [Color figure can be viewed at wileyonlinelibrary.com]

included in the study and participated in the training of less experienced surgeons to a greater extent than did surgeons A or B. In the period 2009-2012, surgeons A and B had already achieved a significant level of experience, and inconsistent changes in recurrence rates were observed with increasing number of TVT procedures.

In our assessment of clinical outcomes and experience, we assessed individual learning phases for each surgeon with SUI recurrence rates during a maximum of 10 years of patient follow up. Most studies in the literature assessing surgeons' experience compare institutions and groups of surgeons.⁴⁻⁸ However, in our opinion, any effect of learning by experience needs to be transparent on an individual level, as there were individual variations in recurrence rates among the surgeons in our study. Furthermore, reporting on effectiveness as a function of surgeons' experience is inconsistent, and very few studies have a sufficiently long follow-up time or a large enough sample size to find an effect. Of four studies without any statistically significant findings when comparing effectiveness between high- and low-volume departments or surgeons,^{5,7-9} three had a sample size of <200 women, with a follow-up time of less than 2 years. Thus, compared with most studies reporting outcomes of incontinence surgery, our study has a larger sample size, longer follow-up time (10 years) and fewer patients lost to follow up (596/621).¹⁶

To avoid any confounding effect of earlier pelvic floor surgery, we included only patients undergoing primary TVT procedures, and in our analysis of recurrence, patients were censored at the date of surgery for both prolapse and complications. The overall SUI recurrence rate in our study was 17.8% (Table 3), which is lower than that reported in the literature, where long-term subjective treatment effectiveness after TVT surgery in populations of women with stress and mixed urinary incontinence has been reported to be 57%-80%.¹⁹⁻²²

The most important weaknesses of this study are the retrospective design and the possibility of reporting bias due to the observed doubling of the recurrence rate from 1998-2008 to 2009-2012. Our results showed that between these periods there was a reduction in the proportion of recurrences diagnosed within 1 year of surgery (from 47.4% to 26.5%) and an increase in the proportion of recurrences diagnosed 3-5 years after surgery (from 7.0% to 55.1%) ($P = .00$). We think it is unlikely that this represents an actual increase in the recurrence rate, but rather illustrates the effect of systematic follow up, in this case the introduction of a systematic 3-year follow-up questionnaire that was implemented from 2009 onwards, providing a clustering of recurrences 3-5 years after surgery.

We found that recurrence rates by surgeon varied between 10.2% and 30.1%. However, this apparently high range of variation is most likely due both to actual individual variations between surgeons

and to differences in follow up across time periods. We find bias due to different case-mix by surgeons unlikely, as higher age, low parity order and previous hysterectomy are inconsistently or not reported as risk factors for recurrence.¹⁶ The recurrence curves by increasing number of surgeries indicate that each surgeon has an individual performance level, but our data provide no evidence of any statistically significant effect of better performance in surgeons having performed >100 TVT procedures.

5 | CONCLUSIONS

Our data suggest that there is a learning phase for TVT surgeons, and that experience is associated with complications as well as long-term effectiveness. Furthermore, we found individual variations, and the length of the learning phase may vary as well by type of outcome. These factors have to be taken into account at teaching hospitals when educating residents and young surgeons in new techniques. Surgical skills need to be carefully evaluated before “beginners” are allowed to perform TVT procedures on their own. Monitoring of long-term outcomes is time-demanding, but extremely necessary, as it provides important feedback for surgeons. This emphasizes the importance of high-quality national registries such as The Norwegian Female Incontinence Registry.

CONFLICT OF INTEREST

RS: Advisory board Astellas and speaker fees from Astellas. The rest of the authors have no conflicts of interest to declare.

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