


The tension-free vaginal tape operation: Is the inexperienced surgeon a risk factor? Learning curve and Swedish quality reference

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Abstract

Introduction: To reduce the risk of avoidable damage to the patient when training surgeons, one must predefine what standards to achieve, as well as supervise and monitor trainees' performance. The aim of this study is to establish a quality reference, to devise comprehensive tension-free vaginal tape (TVT) learning curves and to compare trainees' results to our quality reference.

Material and methods: Using the Swedish National Quality Register for Gynecologic Surgery, we devised TVT learning curves for all Swedish TVT trainees from 2009 to 2017, covering their first 50 operations. These outcomes were compared with the results of Sweden's most experienced TVT surgeons for 14 quality variables.

Results: In all, 163 trainees performed 2804 operations and 40 experienced surgeons performed 3482 operations. For our primary outcomes – *perioperative bladder perforations* and *urinary continence after 1 year* – as well as *re-admission*, *re-operation* and *days to all daily living activities*, there was no statistically significant difference between trainees and experienced surgeons at any time. For the first 10 trainee operations only, there were small differences in favor of the experienced surgeons: *patient-reported minor complications after discharge* (14% vs 18.4%, $P = .002$), *1-year patient-reported improvement* (95.9% vs 91.8%, $P < .000$), and *patient satisfaction* (90.9% vs 86.2%, $P = .002$). For both trainee operations 1-10 and 11-50, compared with experienced surgeons, *operation time* (33.8 vs 22.2 min, $P < .000$; 28.3 vs 22.2 min, $P < .000$) and *hospital stay time* (0.16 vs 0.06 days, $P < .001$; 0.1 vs 0.06 days, $P < .001$) were longer, *perioperative blood loss* was higher (27.7 vs 24.4 mL, $P = .001$; 26.5 vs 24.4 mL, $P = .004$), and *patient-reported catheterization within 8 weeks* was higher (3.9% vs 1.8%, $P < .000$; 2.5% vs 1.8%, $P = .001$). One-year voiding difficulties for trainee patients (operations 1-10:14.2%, $P = .260$; operations 11-50:14.5%, $P = .126$) were comparable to the experienced surgeons (12.4%).

Abbreviations: GynOp, The Swedish National Quality Register of Gynecological Surgery; TVT, tension-free vaginal tape operation.

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Conclusions: There is a learning curve for several secondary outcomes but the small effect size makes it improbable that the difference has clinical significance. Our national Swedish results show that it is possible to train new TVT surgeons without exposing patients to noteworthy extra risk and achieve results which are equivalent to the most experienced Swedish surgeons.

KEYWORDS

female urinary incontinence, learning curve, quality control, tension-free vaginal tape operation

1 | INTRODUCTION

Midurethral slings, originally introduced by Ulmsten and colleagues,¹ have become the most extensively researched surgical treatment for stress urinary incontinence and the new first-line treatment worldwide.²⁻⁶ The need for continuous training of a significant number of surgeons mastering this operation is obvious. When an inexperienced surgeon is learning a new procedure, results can initially be expected to be inferior.^{7,8} Simultaneously, patients must be informed about inherent risks of a planned procedure including the inexperienced surgeon as a risk factor.⁸

In the medical world the use of learning curves started late in contrast to industrial production units.⁹ A review and assessment of learning curves in health technologies by Ramsey et al in 2000¹⁰ found the reported studies and statistical methods weak and calls for methods that can estimate the rate and length of learning. There is no published systematic review for the learning curve of tension-free vaginal tape (TVT). A PubMed search in August 2020, search mesh: (["TVT" or "tension free vaginal tape"] and ["learning curve" or "learning curves"]), resulted in 28 papers, only five papers of which were deemed suitable for an analysis of a TVT learning curve (one database-derived, three institutional and one single-surgeon study).¹¹⁻¹⁵ The occurrence of intraoperative bladder perforations was significantly increased in all learning groups (as high as 40%) and the duration of the learning process was up to 80 cases. We were not able to find descriptions of what standards to achieve for the trainee before performing TVT operations independently and there is a scarcity of information about the possible adverse effects of the learning curve for TVT. The aim of this study was: (i) to establish a quality reference of results achieved by Sweden's most experienced TVT surgeons to serve as a guidance and goal for the learning surgeons and (ii) to devise comprehensive TVT learning curves for Swedish TVT trainees by comparing their results over time with our quality reference.

2 | MATERIAL AND METHODS

This is a population-based observational cohort study, describing and analyzing the volume and quality of the TVT learning process

Key message

Tension-free vaginal tape operation learning curves of 163 Swedish surgeons in training covering the first 50 operations show results which are equivalent to those of Sweden's most experienced surgeons. Swedish patients can safely accept being operated by a surgeon in training with little experience.

based on prospectively collected data from the Swedish National Quality Register for Gynecological Surgery (GynOp).

2.1 | The Swedish National Quality Register of Gynecological Surgery

The GynOp register includes all major gynecologic operations performed in Sweden.¹⁶ Inclusion and participation in national quality registers is regulated by Swedish law stipulating that all patients are to be included in the register; however, the patient has the opportunity to decline (opt out). GynOp has registered operations for incontinence since 2006 and contains information on more than 35 000 procedures. Yearly comparisons with the Swedish National Patient Register show that the completeness of Swedish incontinence operations in GynOp has been well above 90% during our observation period.¹⁷ The data collection process includes both surgeon- and patient-derived data preoperatively and up to 1 year postoperatively.

2.2 | Patient cohort

The basic data used in this study include all retropubic TVT¹ operations registered prospectively and consecutively in GynOp from 5 November 2009 to 31 October 2017 – in all, 15 980 operations. Since primary and recurrent operations represent different, non-comparable patient groups, only patients undergoing their first incontinence operation were included in the study. Patients with

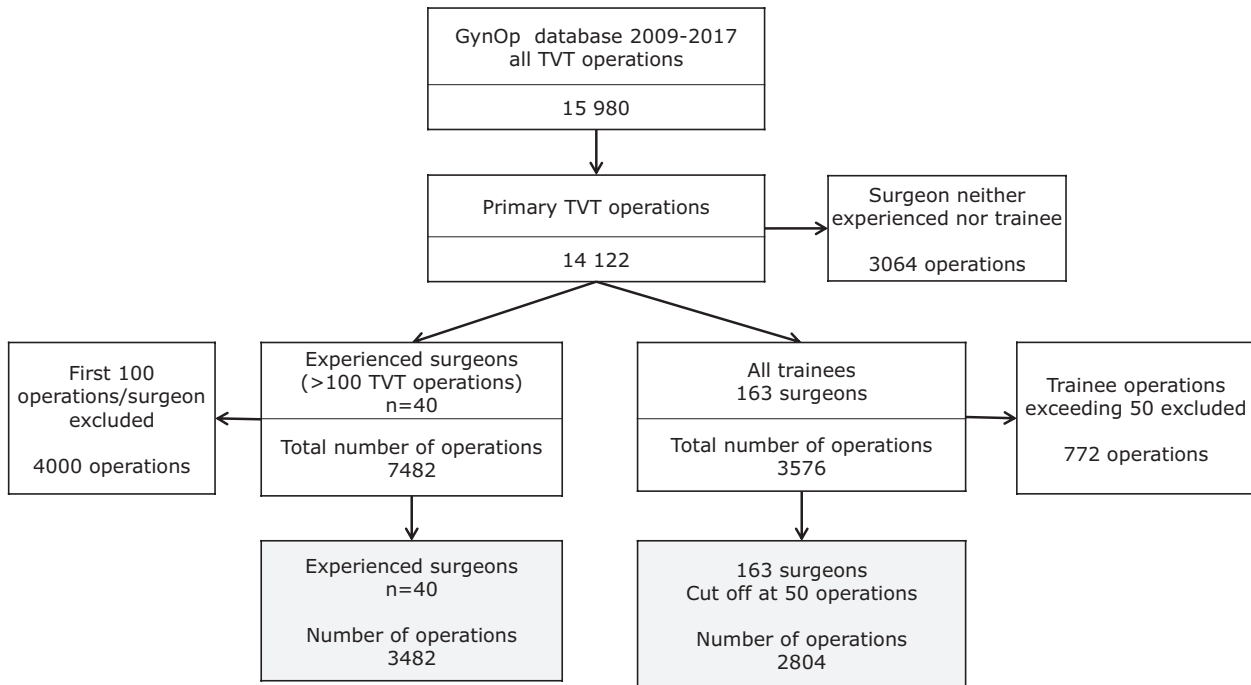


FIGURE 1 Flow chart: selection of patients and surgeons. GynOp, Swedish National Quality Register of Gynecological Surgery; TVT, tension-free vaginal tape

simultaneous operations for prolapse or other concomitant operations were excluded (Figure 1).

2.3 | Surgeon cohort

Surgeons who were registered as the main surgeon for the first time in a TVT operation after 1 January 2011 were labeled as “trainees” and their operations were arranged chronologically. All surgeons who were not trainees and had more than 100 TVT operations documented in GynOp were labeled as “experienced surgeons”. To avoid possible learning curves of these surgeons from being included, the first 100 documented operations of each surgeon were excluded. Only the results of operations beyond the first 100 were analyzed. This group contains all of the most experienced TVT surgeons in Sweden, representing the Swedish top level of skill in TVT surgery. Their averaged results were labeled as “quality reference” and regarded as a desirable goal for our TVT trainees.

2.4 | Definition of learning curve

At the individual level, learning curves are meant to show a single person’s progress towards competence including her/his rate of learning and the remaining distance to mastery. Learning curves for particular women can show wide intra- and interindividual scattering.¹⁸ To handle these individual differences and to avoid methodological uncertainties, trainee operations were categorized in “experience groups” where all trainees had the same level of experience: all first TVT operations labeled as “experience = 1,”

all second TVT operations labeled as “experience = 2”, and so on. The trainees gaining most experience during the observation period accumulated up to 186 TVT operations during our observation period, far beyond any reasonable learning volume. Based on the resulting learning curves we assessed that it was prudent to analyze trainees’ results only up to an experience of 50 TVT operations.

Outcomes of the trainees’ operations were compared with the outcomes of the experienced surgeons in two separate ways. First, outcomes for trainees from the first to the 50th operation were plotted, one by one, against the averaged outcomes of the operations of the most experienced Swedish TVT surgeons. The result is intended to visualize a learning curve, with 95% confidence intervals, illustrating the step by step difference (or lack thereof) for each outcome between trainees and experienced surgeons. Second, the trainees’ results were analyzed in two groups: the average results of operations 1-10 and 11-50, respectively, and compared, outcome by outcome, with the average total outcome of the experienced TVT surgeons.

2.5 | Outcome variables

Primary outcome variables: Surgeon-reported *perioperative bladder perforation* and patient-reported *urinary incontinence* 1 year after TVT operation (questionnaire rating scale for incontinence: never/hardly ever/every month/every week/every day. “Never” or “hardly ever” was classified as continent).

Three groups of secondary outcome variables: Complications (surgeon-reported *perioperative blood loss* and *re-operation within*

1 year, patient-reported complications after discharge from the hospital leading to medical control, re-admission within 8 weeks and urinary retention necessitating catheterization of the bladder within 8 weeks); resource consumption (operating time, hospital stay time, patient-reported postoperative pain expressed as number of days the patient took painkillers at home and patient-reported "days to normal activity of daily life") and 1-year outcome variables (patient-reported difficulty to empty the urinary bladder – never/hardly ever/ every month/every week/every day, "every week" or "every day" was classified as problem – and patient-reported improvement and patient-reported satisfaction). The proportion of reported incontinence after 1 year (influencing also the patient's improvement and satisfaction) is dependent on patients' type of incontinence,¹⁹ therefore these variables are analyzed for patients with "pure" stress incontinence only.

2.6 | Statistical analyses

Categorical data were analyzed by Pearson's Chi-square or Fisher's Exact test. Continuous variables were analyzed using the Student's *t* test. A *P* value <.05 was considered to be statistically significant. All statistical analyses were performed using SPSS version 26 (IBM Corp.).

2.7 | Ethical approval

The GynOp register is approved by the Ethics Committee of Umeå University, Umeå, Sweden (5 October 2004; Dnr 04-107), as are this study and the use of data from the register (9 September 2008; Dnr 08-076 M).

3 | RESULTS

Following our criteria, our cohort consists of 2804 TVT operations by 163 trainees and 3482 TVT operations by 40 experienced surgeons, performed 5 November 2009 until 31 October 2017 (Figure 1). There were no differences in basic patient characteristics except that experienced surgeons to a certain degree operate on urologically more complex patients than trainees do – more patients (21.9% vs 16.3%, *P* < .001) with mixed incontinence (Table 1). We established a quality reference using the average results of Sweden's most experienced TVT surgeons to serve as a goal for the learning surgeons (Table 2).

There were no statistically significant differences between experienced surgeons and trainees at any time for our primary outcomes: bladder perforations (3.8% vs 4.6%, *P* = .178) and urinary incontinence after 1 year (21.5% vs 21.0%, *P* = .784) (Table 2, Figure 2A,B). Likewise, the outcome for the variables re-admission, re-operation and days to normal activities of daily life were similar in trainees and experienced surgeons (Table 2, Figure 2C-E).

TABLE 1 Characteristics of women undergoing TVT surgery in Sweden in 2009-2017

	Experienced surgeons	Trainees	<i>P</i> value	Missing (%) ^a
	3482 operations	2804 operations		
Age (y)	51.4	51.1	.193	0/0
BMI	25.9	25.8	.468	18.7/24.6
Parity	2.4	2.4	.647	18.2/24.6
ASA classification	1.4	1.4	.494	0.3/3.4
Active smokers (%)	9.0	9.03	.918	24.6/27.4
Stress incontinence (%)	77.4	82.4	.000	0.2/3.7
Mixed incontinence (%)	21.9	16.3	.000	
Other types of incontinence (%)	0.2	0.1	.391	

Abbreviations: ASA, American Society of Anesthesiologists' Physical Status Classification System; BMI, body mass index; parity, number of births; TVT, tension-free vaginal tape.

^aMissing (experienced surgeons %/trainees %).

There was a difference in the secondary outcome *operation time*, demonstrating a learning process: an additional 11.6 minutes for trainees on average for the first 10 trainee operations (33.8 vs 22.2 min, *P* < .001), declining thereafter and approaching the experienced surgeons' benchmark after approximately 50 operations (Table 2, Figure 2F). Patient-reported urinary retention necessitating catheterization of the bladder within 8 weeks after the operation was 1.8% for the experienced surgeons and higher for trainees, both for operations 1-10 (3.9%, *P* < .000) and for operations 11-50 (2.5%, *P* = .001) (Table 2). After 1 year, patient-reported voiding difficulties for trainee patients (operations 1-10: 14.2%, *P* = .260; operations 11-50: 14.5%, *P* = .126) (Table 2) were not significantly different from patients of the experienced surgeons (12.4%).

For the first 10 trainee operations there were small differences in favor of the experienced surgeons for *patient-reported complications after discharge from the hospital leading to medical control* (14.0% vs 18.4%, *P* = .002), *patient-reported 1-year improvement* (95.9% vs 91.8%, *P* < .001) and *patient 1-year satisfaction* (90.9% vs 86.2%, *P* = .002). From operation 11 onwards, trainees' results matched the level of experienced surgeons (Table 2, Figure 2G,H,J).

Both for trainee operations 1-10 and 11-50, the experienced surgeons' *hospital stay time* was shorter (0.06 days vs 0.16 days, *P* < .000; 0.06 days vs 0.1 days, *P* < .000) and *perioperative blood loss* was less (24.4 vs 27.7 mL, *P* = .001; 24.4 vs 26.5 mL, *P* = .004) but the *number of days patients took painkillers at home* was higher (3.2 vs 2.8 days, *P* = .011; 3.2 vs 2.9 days, *P* = .041) (Table 2, Figure 2K-M).

TABLE 2 TVT surgery in Sweden from 2009 to 2017, outcomes arranged by surgical experience

	Experienced TVT surgeons (reference)		Trainee, operation 1-10			Trainee, operation 11-50		
	40 surgeons		163-77 surgeons ^b			69-24 surgeons ^b		
	n/N	% or mean (SD)	n/N	% or mean (SD)	P value	n/N	% or mean (SD)	P value
Primary outcome								
Bladder lesion (%)	3482/3482	3.8	1030/1030	4.0	.781	1774/1774	4.6	.178
Urinary incontinence (1 y, %) ^a	1682/2690	21.5	524/800	25.4	.060	796/1426	21.0	.784
Complications								
Perioperative blood loss (mL)	3384/3482	24.4 (25.2)	939/1030	27.7 (32.5)	.001	1700/1774	26.5 (25.9)	.004
Patient-reported complications (%)	2793/3482	14.0	809/1030	18.4	.002	1442/1774	14.4	.753
Patient-reported re- admission <8 wk (%)	2798/3482	1.4	806/1030	2.1	.125	1450/1774	1.5	.677
Patient-reported catheterization of the urinary bladder <8 wk (%)	2304/3482	1.8	643/1030	3.9	.000	1203/1774	2.5	.001
Surgeon-reported re-operation <1 y (%)	3482/3482	1.2	1030/1030	1.2	.858	1774/1774	1.1	.735
Resources								
Operating time (min)	3327/3482	22.2 (7.1)	928/1030	33.8 (11.8)	.000	1686/1774	28.3 (10.4)	.000
Hospital stay time (d)	3429/3482	0.06 (0.4)	982/1030	0.16 (0.6)	.000	1710/1774	0.1 (0.4)	.000
Painkiller at home (d)	2696/3482	3.2 (4.2)	720/1030	2.8 (4.2)	.011	1422/1774	2.9 (4.0)	.041
All daily living activities resumed (d)	2630/3482	3.1 (3.8)	751/1030	3.1 (3.9)	.730	1376/1774	2.8 (3.5)	.036
Outcome 1 y								
Improvement (1 y, %) ^a	1531/2690	95.9	450/800	91.8	.000	742/1426	95.8	.944
Satisfaction (1 y, %) ^a	1664/2690	90.9	521/800	86.2	.002	789/1426	90.9	.967
Patient-reported difficulty emptying the urinary bladder (1 y, %)	2669/3482	12.4	663/1030	14.2	.260	996/1774	14.5	.126

Abbreviations: n, number responding; N, total number of operations; TVT, tension-free vaginal tape.

^aPatients with stress incontinence only.

^bNumber of trainees decreasing successively from the 1st to the 10th and from the 11th to the 50th operation respectively due to continuous drop-out of trainees.

The number of trainees diminished over time as surgeons continuously drop out of their TVT training. Of the 163 surgeons doing their first operation, only 77 (47.2%) performed 10 operations and barely 24 (14.7%) reached 50 operations (Table 2). To investigate whether there is an increased number of complications for early dropout surgeons, we conducted a sensitivity analysis of our primary variables for surgeons who only completed one ($n = 31$), two ($n = 23$), three ($n = 8$), four ($n = 4$) or five ($n = 3$) operations as well as for trainee experience groups 11-15 and 16-20 operations. The results of these trainees were similar to those completing 50 operations and to our quality reference.

4 | DISCUSSION

The purpose of the TVT operation is to cure urinary incontinence. The prevailing complication is bladder perforation. For both outcomes we found no significant differences between trainees and experienced surgeons. For some of our secondary outcomes there are statistically significant differences but the absolute size makes it doubtful that they are of clinical importance (operating time 11 minutes, blood loss 3.3 mL, hospital stay time 0.1 days and patient-reported minor complications 4%). This is in stark contrast to the existing literature.

The results for urinary retention leading to catheterization include all types of catheter treatment, regardless of the duration. The clear difference of catheterizations in favor of the experienced surgeons suggests that the learning process for placing the sling is longer than 50 operations. After 1 year, however, there is no longer a discrepancy regarding problems emptying the urinary bladder.

In 2001, Leuret studied a cohort of 100 consecutive TVT patients operated by six surgeons.¹¹ In the first 50 patients, the proportion of bladder perforations was higher than in the last 50 patients (22% vs 8%). In 2002, Groutz reported a single-surgeon experience of his first 30 TVT operations that demonstrated a substantial decline

of bladder perforations with growing experience.¹² The outcome of 278 TVT operations by 23 residents divided into three experience groups was studied by McLennan in 2005.¹³ The proportion of bladder perforation decreased with growing experience: 40.9%, 30.7% and 25.9%. Contrary to our results, all three studies show a significantly higher rate of bladder perforations in the beginning of the learning curve. A retrospective database analysis of 1568 procedures undertaken by 16 surgeons with different experience levels in a single unit over a 16-year period was published in 2015.¹⁴ The rate for bladder perforations peaked at an average of 10.5% at between 10 and 30 procedures undertaken, and declined thereafter.

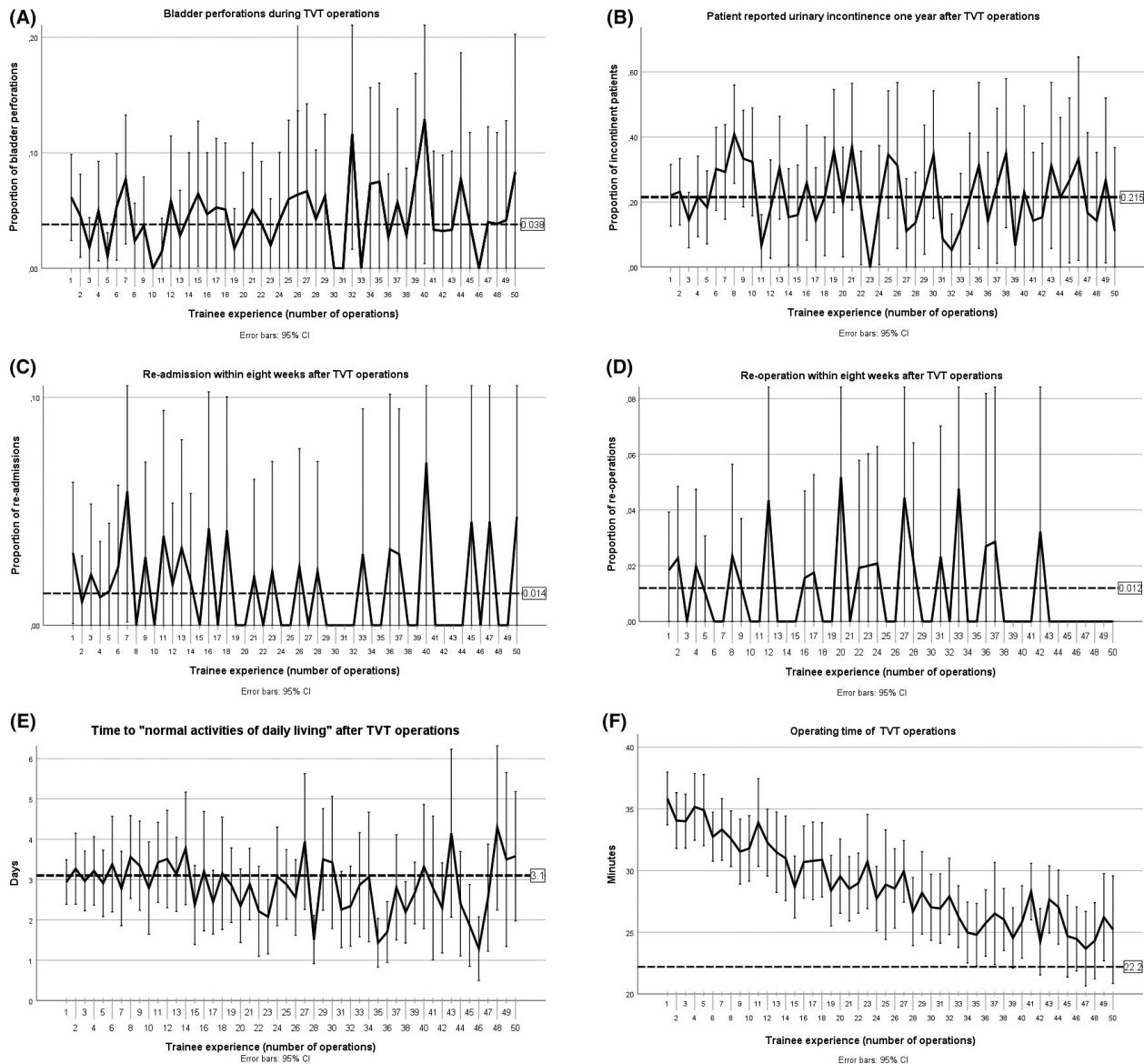


FIGURE 2 In all figures the horizontal dotted line represents the experienced surgeons' averaged results. (A) Intraoperative bladder perforations during tension-free vaginal tape (TVT) operations. (B) Patient-reported urinary incontinence 1 y after TVT operation. (C) Patient-reported re-admission to a hospital within 8 wk after TVT operation. (D) Surgeon-reported re-operation within 1 y after TVT operation. (E) Patient-reported number of days to "normal activities of daily life" after TVT operation. (F) Operating time of TVT operations. (G) Patient-reported complication after discharge from the hospital leading to any type of medical attention. (H) Patient-reported improvement 1 y after TVT operation. (J) Patient-reported satisfaction 1 y after TVT operation. (K) Hospital stay time after TVT operation. (L) Perioperative blood loss during TVT operation. (M) Duration of patient-reported use of painkillers at home after TVT operation

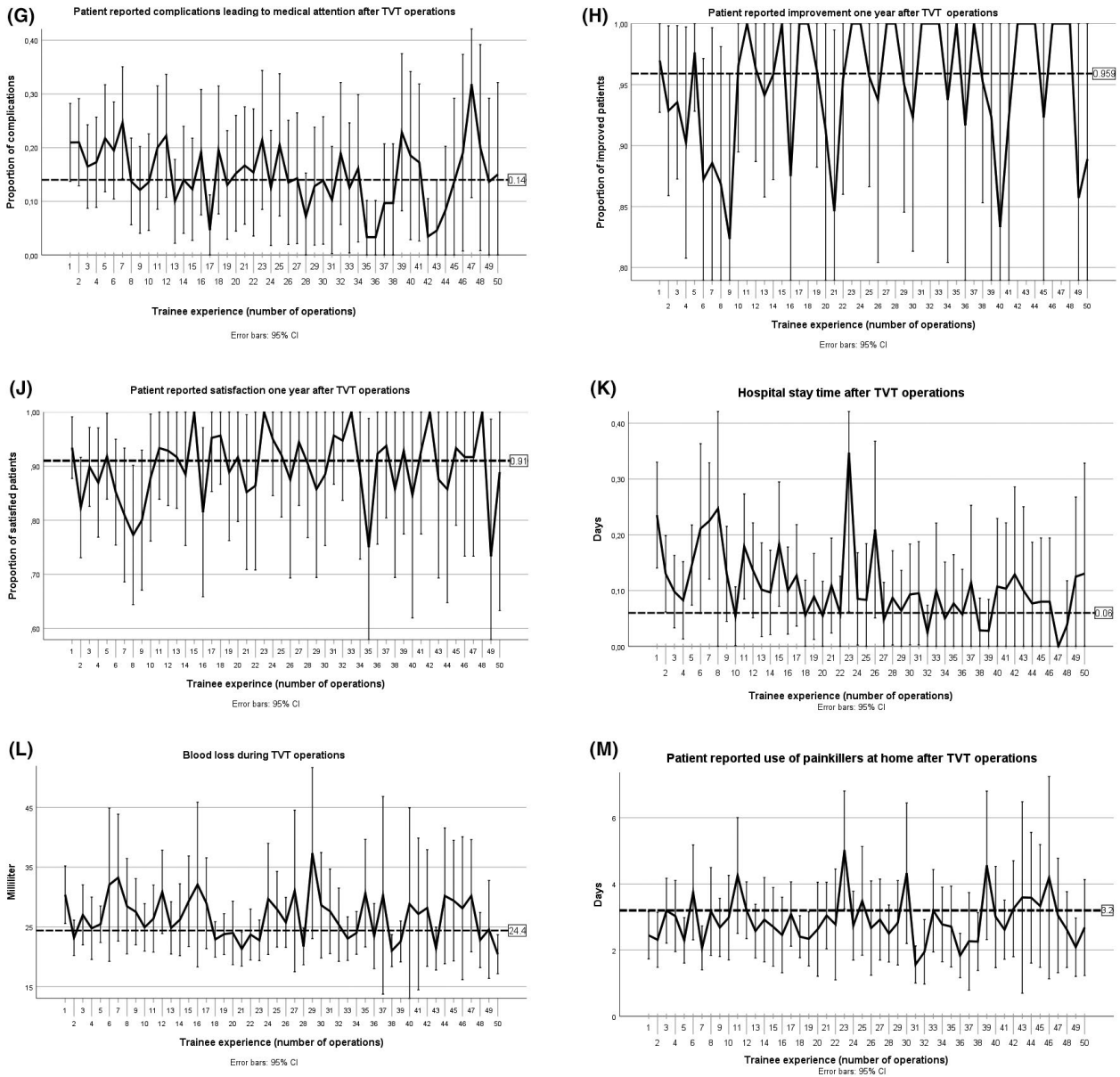


FIGURE 2 (Continued)

The target perforation rate of 5% was reached between 20 and 80 operations. In 2020, Holdø et al¹⁵ showed a lower rate of bladder perforations and urinary retentions among patients whose TVT procedures were performed by surgeons with experience of ≥ 50 primary TVT procedures.

Given these results, our outcomes seem very favorable. However, in 1998, Ulmsten published a prospective open multicenter study including six surgical centers, each operating on approximately 20 patients.²⁰ In the majority of the participating centers, surgeons without specific training in urogynecological surgery were involved and Ulmsten reported that “their results were as good as those in the more experienced centers”. That study was carried out in a setting similar to ours, Ulmsten in a subset of Swedish clinics in the 1990s and our study including nearly all Swedish TVT operations performed during our observation period.

The outcome of a trainee operation (and any avoidable complications) reflects a combination of the learning ability of the trainee, the quality of supervision and the robustness of the procedure.

Satisfactory supervision and guidance of Swedish trainees are likely, at least in part, to be a reasonable explanation for our trainees' good results. In addition, this study and the results published by Ulmsten et al²⁰ suggest that the TVT operation as such has a robust design methodology which achieves increased insensitivity to noise factors and sources of unwanted variations,^{21,22} in our case resistance towards possible variations of surgeons' characteristics or organizational conditions.

We devised TVT learning curves for all 163 Swedish TVT trainees covering their first 50 operations. The results of each variable are presented both as learning curves and as a comparison of the group average results. The different learning curves are intended

as a visual demonstration of the average progress of trainees over time. Our choice of trainee group size is arbitrary, the choice of cut-off might influence the result and is not necessarily optimal for all analyzed variables. After considering the learning curves and the drop-out pattern, we chose to regard the first 10 operations as "risk zone". A sensitivity analysis, using other cutoffs, did not substantially influence the results.

We established a Swedish quality reference for TVT operations to serve as "level to achieve," a guidance and goal for the learning surgeons. The results of all 163 surgeons in TVT training are compared with this reference. Experienced surgeons operated urologically more complex patients in the form of a moderate surplus of mixed incontinence (Table 2). The urodynamic characteristics of incontinence have no influence on the occurrence of surgical complications but do affect 1-year results such urinary continence and thereby patient satisfaction.¹⁹ To avoid any confounding by mixed indications we analyzed the 1-year variables "reported incontinence after 1 year", "improvement" and "satisfaction" for patients with "pure stress incontinence" only.

To cover all complications after discharge, we use two somewhat unusual patient-reported variables: "complications after discharge from the hospital, leading to medical control" and "urinary retention necessitating catheterization of the bladder". These variables are included in the patient's questionnaire 8 weeks after the operation and cover all types of medical contacts, even consultations with the family practitioner or other health institutions which might not be included in hospital records or GynOp.

A strength of our investigation is the fact that the data are not a sample but include all 163 TVT trainees who were active during our observation period of 8 years in all of Sweden. Likewise, all surgeons who meet the criteria of extraordinary experience in this time period are included.

There is a lack of completeness in our description of the learning process. We report only averaged results in spite of the fact that learning curves for particular persons can show wide disparities. An analysis of variations between individual learning processes over 50 operations for 163 surgeons and for 14 quality variables exceeds the scope of this study. The existing variations in learning speeds, both generally and for particular variables, and incomplete information in our database on the number of supervised operations per trainee limit our ability to formulate general recommendations about a "minimum number of operations" or how long a trainee generally should be supervised. Our analysis of the TVT learning process suggests that creation of a personal learning curve of key outcomes and a predefined "standard to achieve" (like our quality reference) might be useful for assessment of individual progress and professional level.

5 | CONCLUSION

For our primary outcomes, *perioperative bladder perforations* and *urinary continence after 1 year*, there was no statistically significant

difference between trainees and experienced surgeons at any time. There is a learning curve for several secondary outcomes, an increase regarding operating time, blood loss, hospital stay time, and patient-reported minor complications, but the small effect size makes clinical significance improbable. There is a slight increase in voiding problems leading to urinary catheterization for trainee patients but after 1 year there no longer was any difference in the ability to empty the bladder. Trainees achieve results that are in practical terms equivalent to the average results of Sweden's most experienced TVT surgeons. This indicates that guidance and supervision in the Swedish training system are satisfactory and emphasizes that the retropubic TVT operation is robust in the sense that it tolerates variations of surgeon characteristics or organizational conditions. Swedish patients can safely accept having a TVT operation by a surgeon in training with little experience.

CONFLICT OF INTEREST

The authors no conflict of interest.

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