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RESEARCH ARTICLE

Rates of subjective and objective cure, satisfaction, and pain 10–20 years after tension-free vaginal tape (TVT) surgery: A retrospective cohort study

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Abstract

Objective: To evaluate rates of subjective and objective cure, treatment satisfaction, pain, and the correlation between cure and body mass index (BMI), at 10 and 20 years after tension-free vaginal tape (TVT) surgery.

Design: Retrospective cohort study.

Setting: Multicentre study including 19 units in Norway.

Population: Women undergoing TVT surgery for stress urinary incontinence (SUI) during 2001–2006 (20-year cohort) and 2011–2012 (10-year cohort).

Methods: The Norwegian Female Incontinence Registry was used to identify women eligible for the study, who answered validated questionnaires about urinary incontinence, pain and satisfaction.

Main outcome measures: Subjective cure of SUI (with stress index of <3, range 0–12), objective cure (<3 g on stress test) and persisting pain and satisfaction after TVT (scored on a five-point Likert scale).

Results: In total, 1210 of 1903 (64%) patients responded. The subjective cure rate was 68% after 10 years, versus 59% after 20 years, and did not significantly differ after adjusting for age, BMI, parity and preoperative stress index (adjusted OR 1.27, 95% CI 0.82–1.94). The objective cure rate was 100% versus 93% ($P < 0.001$), with 89% versus 76% reporting subjective satisfaction ($P < 0.001$), and with 4.7% versus 2.7% reporting persisting pain ($P < 0.001$), after 10 versus 20 years, respectively. Women in obesity classes I and II, compared with women of normal weight, had an increased risk of not being subjectively cured (crude OR 2.02, 95% CI 1.42–2.90; OR 2.95, 95% CI 1.60–5.46, respectively).

Conclusions: Tension-free vaginal tape (TVT) provided high rates of subjective and objective cure at 10 and 20 years after surgery, with no significant difference between the two cohorts. Although 3%–5% of women experienced persisting pain, most women were satisfied with TVT surgery. Obesity was associated with a lower cure rate.

KEYWORDS
long-term patient-reported outcome, pain, stress urinary incontinence, tension-free vaginal tape

1 | INTRODUCTION

Stress urinary incontinence (SUI) is a common condition that exerts a great economic burden on society and on the quality of life for the women affected.[1,2] The prevalence of female urinary incontinence varies from 25% to 45% in epidemiological studies, with a peak for SUI around menopause.[3,4] Retropubic tension-free vaginal tape (TVT) has been the preferred surgical treatment for SUI for the last 20 years, providing mid-urethral support to restore continence.[5,6]

An abundance of studies has shown good results for rates of subjective and objective cure after TVT and high satisfaction among patients up to 5 years after surgery.[7–9] However, the number of studies documenting long-term results is limited and there are few studies with a follow-up of longer than 15 years.[10–12] There is also still an uncertainty whether the effect of TVT might wear off over time, and what the true prevalence of long-term complications are. A high body mass index (BMI) is an established risk factor for SUI, but whether BMI has an impact on long-term results after TVT has not yet been studied.[13]

In recent years the use of synthetic polypropylene mesh in vaginal surgery has been brought into disrepute after reports of serious long-term complications, such as chronic pelvic pain. This has also affected the use of mesh in incontinence surgery in parts of Europe and the USA.[14–16] A national review, commissioned by the English Department of Health and Social Care and published in 2020, reported several cases of women suffering from adverse events after synthetic vaginal implants as treatment for pelvic organ prolapse or SUI.[17] Complications such as voiding difficulties, erosions and pain in the vagina or lower pelvis have been reported after TVT.[18,19] Long-term complications are therefore a major concern in international reports and reviews,[7,14] and long-term studies are recommended by the International Continence Society.[20]

The aim of this study was therefore to investigate the long-term subjective and objective cure rate, satisfaction rate and persistent pain 10 and 20 years after TVT surgery, with a comparison between the 10- and 20-year cohorts. A secondary aim was to evaluate the associations between subjective cure and satisfaction in women with high BMIs, compared with lower BMIs.

2 | METHODS

This was a retrospective cohort study among women who underwent TVT surgery in Norway over two periods of time: 2001–2002 and 2011–2012. To reach the statistical power estimate, the inclusion for the first period was extended at two hospitals: Oslo University Hospital (2001–2003) and Trondheim University Hospital (2001–2006). The national Norwegian Female Incontinence Registry (NFIR) was used to identify patients from all hospitals in Norway that had undergone previous TVT surgery.[21] Exclusion criteria were not being able to consent, not being able to communicate in Norwegian or English, or being deceased. For the 2011–2012 cohort, women older than 42 years at the time of surgery were also excluded, as we aimed to include a substantial number of premenopausal women in the total study cohort. The reason for this is that previous studies have shown that age has a large impact on the prevalence of incontinence, and by including a relatively large proportion of younger women, the impact of age could be studied.[4] Women older than 42 years were not invited in this cohort, to avoid overshooting the power estimate. Women included from three of the hospitals reporting to the NFIR were also invited to a physical follow-up (at Oslo University Hospital, Trondheim University Hospital or Ålesund Hospital). All women undergoing surgery between 2001 and 2006 were considered for the 20-year follow-up cohort, and women who had surgery in 2011 and 2012 were considered for the 10-year follow-up cohort.

All women signed an informed consent. The study was approved by the Regional Committee for Medical and Health Research Ethics (REK) in Mid-Norway (REK Midt 2020/141799), and the study was registered with Clinical Trials (NCT04912830).

Electronic questionnaires were sent to potential participants in September 2021, with a total of two reminders and with at least one postal mailing cycle to non-responders. Questionnaires included height and weight at time of follow-up (study inclusion), level of education, smoking habits, parity, hormone treatment and pelvic floor muscle training. There were also questions concerning previous medical history, including previous abdominal or pelvic floor surgery. A validated questionnaire was used to assess the degree of bothersome symptoms for stress and urge urinary incontinence, generating a stress urinary incontinence index score with a range of 0–12 and an urgency urinary incontinence index score with a range of 0–8. Higher scores indicate more bothersome symptoms. In the NFIR registry, a stress index of <3 is defined as subjectively cured.[21] In this study we performed analyses for both a stress index of <3 and a stress index of ≤3. Women also answered a question at the time of follow-up about persisting pain that had occurred in relation to TVT surgery. They graded treatment satisfaction using a five-point Likert scale, ranging from 'very satisfied' to 'very unsatisfied'. The categories 'very satisfied' and 'satisfied' were merged as the 'satisfied category'. There were also questions about repeat incontinence procedures, removal of parts or all of the TVT sling, voiding problems or lower urinary tract infections. In addition, we included previously registered data from the NFIR registry on preoperative stress index, urgency index and BMI, as well as subjective cure rate and satisfaction rate at the 1-year follow-up, again from the NFIR registry.

Women invited to the physical long-term follow-up were asked to complete a 24-h pad-weighing test if they still experienced urinary leakage, where they summed

the weight difference before and after the use of all pads during a period of 24 h. They underwent a gynaecological examination by a trained gynaecologist (BRS/RA) with the woman in the lithotomy position. Here, inspection and palpation for any tape exposure and evaluation of pain along the course of the TVT tape at palpation was conducted. Furthermore, uroflowmetry using FLOWMASTER (LABORIE, Portsmouth, NH, USA), a wireless flowmeter and a computer-based Bluetooth-enabled flowmeter, was used to evaluate voiding function, and a pad-weighing cough/jump stress test with at least 200 mL of urine volume in the bladder was performed.[22] The stress test is a standardized test in which women are asked to cough three times followed by 20 star jumps (jumping jacks) and their pads are weighed before and after the test for the calculation of leakage, using the same digital scale throughout the study period.[22] Objective cure was defined as <3 g of leakage on the stress test. Voiding difficulties were assessed by flow rates and post-void residual volumes. Post-void residual volume was measured by catheterisation.

2.1 | Power calculation

A significance level of 0.05 with an 80% power estimate was chosen. We assumed BMI to be an important marker for general health and divided the women into two groups using the 75th percentile as the cut-off point. We assumed, based on best guess, that the subjective cure rate for the women with BMIs above the 75th percentile would be 60%, compared with 70% for women with BMIs below the 75th percentile. The null hypothesis was that there was no difference between women below and above the 75th percentile. To find a significant difference in subjective cure rates, 988 women were needed. There was an assumption that approximately 50% of the invited women would answer the questionnaire after 10 and 20 years, and thus 2000 women were needed to be invited.

2.2 | Statistical methods

Statistical methods were performed using SPSS 28.0 (IBM. Armonk, NY, USA). Normality was tested using quantile–quantile (QQ) plots. To identify any differences between groups in demographic and clinical background data, we used independent-sample and paired-sample Student's *t*-tests for normally distributed continuous variables and the chi-square and Fischer's exact tests for categorical variables. The Mann–Whitney *U*-test was used for the non-normal distributed continuous variables. When comparing subjective cure (with stress index of <3) between the two cohorts we used multivariate logistic regression analyses adjusting for age, BMI, parity, 10- or 20-year cohort and preoperative stress index. Subanalyses were performed for the variables subjective cure, satisfaction and pain, after excluding women with transobturator tapes. The level of statistical significance was set at 5%.

3 | RESULTS

A total of 1210 (64%) out of 1903 invited women agreed to inclusion: 427 women for the 10-year cohort and 783 women for the 20-year cohort (Figure 1). In the 10-year cohort 12.7% (54/426) had transobturator tapes, versus 5.5% (53/783) in the 20-year cohort. The remaining had retropubic tapes. No mini slings were used. Demographic features and clinical background data of all women answering the questionnaires are presented in Tables 1 and S1. A total of 268 women were examined in the physical follow-up, 93 of whom were from the 10-year cohort and 175 of whom were from the 20-year cohort (Figure 1), with an attendance rate of 75% (268/356). The mean age for all women attending the physical follow-up was 62 years (range 37–91 years), the mean BMI was 26.5 kg/m^2 (SD 11.9 kg/m^2) and the mean time since surgery was 16.5 years (SD 4.5 years).

Preoperatively, the stress and urgency indices were 8.3 (SD 2.1) and 2.8 (SD 2.3) for the total study population (Table 2). These indices were significantly reduced for the total cohort at the long-term follow-up, with a stress index of 2.3 (SD 3.0) ($P < 0.001$) and an urgency index of 2.5 (SD 2.1)

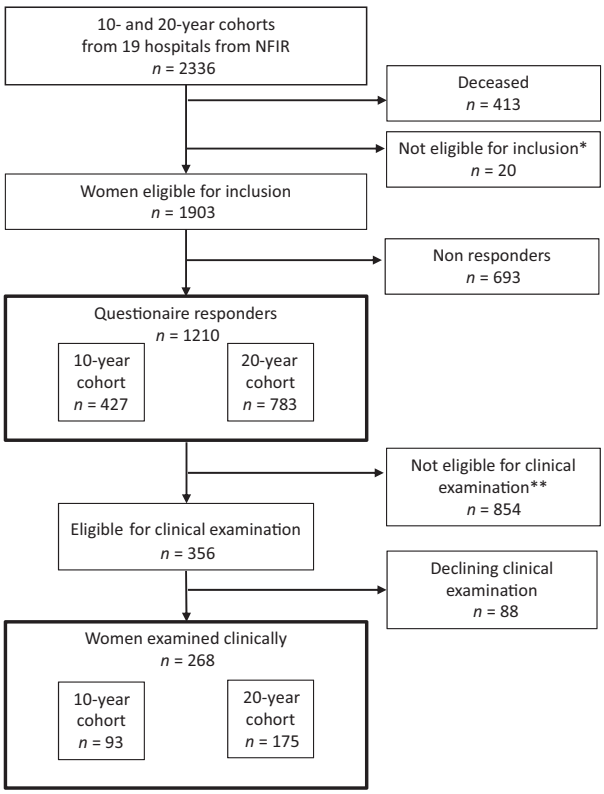

FIGURE 1 Flow chart of study participation. Reasons for exclusion from the study: *living abroad, change of social security number or no contact info in the National Female Incontinence Registry (NFIR); **not living in the area around Trondheim, Oslo or Ålesund.

TABLE 1 Demographics and clinical background data for the total cohort and for the 10- and 20-year cohorts after tension-free vaginal tape (TVT) surgery, with comparison between the cohorts.

	Total cohort *n* = 1210	10-year cohort *n* = 427	20-year cohort *n* = 783	*P**
Continuous variables mean (SD)				
Age at surgery, years	46.4 (9.2)	39.5 (5.5)	50.2 (8.6)	<0.001
Age at inclusion, years	62.7 (12.2)	49.9 (5.5)	69.7 (8.7)	<0.001
BMI at surgery, kg/m^2	25.6 (4.3)[a]	25.4 (4.2)	28.3 (5.1)	<0.001
BMI at inclusion, kg/m^2	26.7 (4.5)	26.3 (4.3)	26.9 (4.7)	0.039
Time since surgery, years	16.9 (9.6)	10.9 (0.7)	20.2 (1.6)	<0.001
Parity	2.5 (0.9)	2.5 (0.9)	2.5 (0.9)	0.110
Categorical variables, *n* (%)				
Any delivery (vaginal or caesarean)	1175/1204 (97.1)	414/425 (97.4)	761/779 (97.7)	0.764
Only caesarean section	13/1198 (1.1)	3/422 (0.7)	10/776 (1.3)	0.357
Any delivery after TVT	42/1018 (3.3)	24/374 (5.6)	18/644 (2.3)	0.005
Smoking	142/1202 (11.8)	47/424 (11.0)	95/778 (12.1)	0.640
Concomitant disorders				
Diabetes	102/1209 (8.4)	15/426 (3.5)	87/783 (11.1)	<0.001
Pulmonary disease	158/1209 (13.1)	27/426 (6.3)	131/652 (16.7)	<0.001
High blood pressure	311/1209 (25.7)	53/426 (12.4)	258/783 (33.0)	<0.001
Hypothyroidism	154/1209 (12.7)	46/426 (10.8)	108/783 (13.8)	0.079
Rheumatological disorder	160/1209 (13.2)	27/426 (6.3)	133/783 (17.0)	<0.001
Other	245/1209 (20.3)	56/426 (13.1)	189/783 (24.1)	<0.001
Previous abdominal/pelvic surgery	477/1206 (39.4)	137/426 (32.2)	340/780 (43.6)	<0.001
Hysterectomy	156/1206 (12.9)	34/426 (8.0)	122/780 (15.6)	<0.001

Note: Number of women in each category = 435.

Abbreviations: BMI, body mass index; SD, standard deviation.*Student's *t*-test/chi-square test.

($P < 0.001$). At the study long-term follow-up, the subjective cure rate (stress index of <3) was 62.1%, but this increased to 73.7% if the cut-off value was set to a stress index of ≤3 (Table 2).

Using the 75th percentile as the cut-off point for BMI yielded a value of 29.4 kg/m^2, and women with BMIs over the 75th percentile had a significantly lower subjective cure rate of 50.6% (135/267), compared with 66.9% (528/789) for women with a BMI below the 75th percentile ($P < 0.001$). When comparing women in BMI obesity classes I and II with women of normal weight, a two- to three-times increased risk of not being subjectively cured was found, with odds ratios of OR 2.02 (95% CI 1.42–2.90) and OR 2.95 (95% CI 1.60–5.46) for the two cohorts (Table S2). Similar results were seen for satisfaction (Table S2).

Women in the 10-year cohort reported a higher subjective cure rate compared with women in the 20-year cohort (68% vs 59%, $P < 0.001$), but after adjusting for age, parity, BMI at follow-up and preoperative stress index, we found no significant difference between the cohorts (adjusted odds ratio, aOR 1.27, 95% CI 0.82–1.94, $P = 0.282$).

Women in the 10-year cohort were more satisfied compared with women in the 20-year cohort (Table 2). There was no significant difference between the cohorts in the reporting of persisting pain after TVT surgery, but the 20-year cohort reported more repeat SUI surgery for tape exposure or tape removal (Table 2). In the 10-year cohort, 100% were objectively cured on testing, compared with 93% in the 20-year cohort ($P < 0.001$) (Table 3). One woman in the 10-year cohort and four women in the 20-year cohort had tape exposure on examination, of whom only one woman was symptomatic.

The rates of subjective cure, satisfaction and pain did not change when excluding women with transobturator tapes.

4 | DISCUSSION

4.1 | Main findings

This long-term follow-up study of women after TVT surgery shows rates of 68% subjective and 100% objective cure after 10 years, and 59% subjective and 93% objective cure after 20 years. Rates of repeat surgery for persistent or recurrent SUI were 0.9% and 4.4% after 10 and 20 years, and the treatment satisfaction rates were 89% and 76%, respectively. The prevalence rates for persisting pain were 4.7% and 2.7% after 10 and 20 years, respectively, and 1.4% and 4.1% reported partial or total tape removal, respectively.

The subjective cure rate of 68% at 10 years is comparable with that of other studies, reporting rates of cure between

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TABLE 2 Preoperative data, subjective outcomes and complications for the total, 10- and 20-year cohorts after tension-free vaginal tape (TVT) surgery, with comparison between the cohorts.

	Total cohort *n* = 1210	10-year cohort *n* = 427	20-year cohort *n* = 783	*P*
Continuous variables, mean (SD), with *P* calculated by Student's *t*-test				
Stress index (range 0–12)				
Preoperatively	8.3 (2.1)[a]	7.8 (2.0)[b]	8.6 (2.2)[c]	<0.001
1 year postoperatively	0.9 (1.9)[d]	0.8 (1.8)[e]	1.0 (1.9)[f]	0.220
Long-term follow-up	2.3 (3.0)[g]	1.8 (2.6)[h]	2.6 (3.2)[i]	<0.001
Urgency index (range 0–8)				
Preoperatively	2.8 (2.8)[a]	2.3 (2.1)[b]	3.2 (2.3)[c]	<0.001
1 year postoperatively	1.2 (1.6)[d]	0.9 (1.5)[e]	1.3 (1.7)[f]	<0.001
Long-term follow-up	2.5 (2.1)[j]	2.0 (1.8)[k]	2.8 (2.2)[l]	<0.001
Categorical variables, *n* (%), with *P* calculated by chi-square test				
Satisfied with TVT surgery				
1 year postoperatively	1076/1120 (96.1)	367/382 (96.1)	709/738 (96.1)	1.00
Long-term follow-up	919/1142 (80.5)	374/422 (88.6)	545/720 (75.7)	<0.001
Stress index of <3				
Preoperatively	16/1209 (1.3)	5/426 (1.2)	11/783 (1.4)	0.482
1 year postoperatively	968/1172 (82.6)	340/405 (84.0)	628/767 (81.9)	0.418
Long-term follow-up	668/1075 (62.1)	273/401 (68.1)	395/674 (58.6)	<0.001
Stress index of ≤3 at long-term follow-up	792/1075 (73.7)	317/401 (79.0)	475/674 (70.5)	0.002
Voiding difficulties at long-term follow-up	487/1195 (40.8)	186/424 (43.6)	301/771 (39.0)	0.104
>1 urinary tract infection last year	127/1199 (10.6)	38/424 (9.0)	89/775 (11.5)	0.175
Persistent pain associated with surgery	41/1189 (3.4)	20/422 (4.7)	21/767 (2.7)	0.070
Reoperation for stress urinary incontinence	30/1196 (2.5)	4/424 (0.9)	26/772 (3.4)	0.010
Removal of part or all of TVT, indication:	37/1174 (3.1)	6/421 (1.4)	31/753 (4.1)	0.011
Pain	7/1174 (0.6)	1/421 (0.2)	6/753 (0.8)	
Infection	6/1174 (0.5)	0/421 (0)	6/753 (0.9)	
Other	21/1174 (1.8)	5/421 (1.2)	16/753 (2.1)	

Note: Number of women in each category: [a]1209, [b]426, [c]783, [d]1172, [e]405, [f]767, [g]1075, [h]401, [i]674, [j]1182, [k]419 and [l]763.

Abbreviations: *n*, number of women; SD, standard deviation; TVT, tension-free vaginal tape.

65% and 76%.[23–26] The few studies including data up to 20 years after TVT surgery show higher subjective cure rates (72%–94%) than the 59% found in the present study.[10–12,27] This could in part be explained by different definitions of subjective cure and differences in the questionnaires used. The present study used the validated NFIR questionnaire to determine symptoms, and the cut-off for cure was defined as a stress index score of <3.[28] When changing the definition to a stress index score of ≤3, the subjective cure rate in the 20-year cohort increased from 59% to 71%, more similar to that of other long-term follow-up studies. This is also more in line with the subjective satisfaction of 81% found in the present study and implicates that the NFIR definition for subjective cure may be too strict. Furthermore, Braga et al. and Nilsson et al. had smaller cohorts, possibly explaining their higher rates of subjective cure. However, our study arguably has higher external validity as it includes women operated upon in departments of different sizes and by doctors with different levels of training.

The objective cure rate in the present study was 100% after 10 years, which is higher than is reported in other studies, ranging from 77% to 90%.[23–25,29] The objective cure rate was 93% for the 20-year cohort, which is in line with other studies reporting cure rates from 84% to 92%.[10,11,30]

The present study showed a lower cure rate after 20 years than after 10 years, possibly indicating that efficacy wears off over time. However, when adjusting for confounding factors, there was no significant difference in subjective cure between the 10- and 20-year cohorts, indicating that the effect of TVT persists, even after 20 years. This is somewhat in contrast to the study by O'Leary et al., where they found a decrease of 54% in subjective cure between the initial postoperative follow-up and the 20-year follow-up.[12] In that study they did not adjust for confounding factors, which might explain the difference compared with our study.

Satisfaction was high after 10 and 20 years (89% and 76%), and similar to other studies, with 89%–90% satisfaction reported after 10 years and 76%–98% reported after

TABLE 3 Objective outcomes and complications for the total, 10- and 20 year cohorts after tension-free vaginal tape (TVT) surgery, with comparison between the cohorts.

	Total cohort *n* = 268	10-year cohort *n* = 93	20-year cohort *n* = 175	*P*
Continuous variables, mean (SD), with *P* calculated by Student's *t*-test				
Stress test (g)				
Preoperatively	44.5 (41.6)[a]	36.3 (34.1)[b]	48.9 (44.6)[c]	0.018
1 year postoperatively	1.4 (18.8)[a]	3.0 (31.7)[b]	0.5 (4.0)[c]	0.318
Long-term follow-up	1.8 (12.6)[a]	0.06 (0.2)[a]	2.60 (15.2)[c]	0.007
24 h pad weighing test (g)				
Preoperatively	67.1 (84.7)	55.7 (85.0)	73.1 (84.2)	0.113
1 year postoperatively	3.2 (22.2)	1.9 (13.5)	3.9 (25.6)	0.484
Long-term follow-up	25.2 (128.3)	4.6 (36.1)	36.1 (155.7)	<0.001
At inclusion:				
Urinary maximum flow (mL/s)	17.8 (10.0)[a]	22.6 (10.7)[b]	15.7 (9.0)[c]	0.060
Urinary mean flow (mL/s)	8.4 (5.1)[a]	10.8 (5.2)[b]	7.3 (4.6)[c]	0.133
Residual volume (mL)	86.4 (105.8)[a]	70.0 (84.1[b]	90.1 (104.5)[c]	0.768
Categorical variables, *n* (%), with *P* calculated by chi-square test				
Negative stress test (<3 g)				
1 year postoperatively	181/189 (95.8)	48/50 (96.0)	133/139 (95.7)	1.0
Long-term follow-up	210/221 (95.0)	69/69 (100)	141/152 (92.8)	<0.001
Tape exposure	5 (1.9)	1 (1.1)	4 (2.3)	0.482
Urine test strip				
Leucocytosis	8/268 (3.0)	5/93 (5.4)	3/175 (1.7)	0.094
Erythrocytosis	5/268 (1.9)	2/93 (2.2)	3/175 (1.7)	0.802
Nitrites	10/268 (3.7)	1/93 (1.1)	9/175 (5.7)	0.007
Pain at palpation along TVT	36 (13.5)	9/94 (9.7)	27/174 (15.5)	0.183

Note: Number of women in each category: [a]221, [b]69, and [c]152.
Abbreviations: *n*, number of women; SD, standard deviation.

20 years.[11,12,25] In our study satisfaction was higher than the subjective cure rate. Robinson et al. suggested that a milder degree of SUI might not be bothersome, and that the rate for satisfaction could therefore be higher than the rate of cure.[31]

Tape exposure was found in 2% of the women, in line with other studies (0.8%–2.7%).[10,23,26,27] Repeated SUI surgery for persistent or recurrent SUI was reported by 2.3%, which was also similar to other studies, where 2.2%–3.8% needed new SUI surgery within 10 years.[10,25,27] In contrast, a large cohort study showed a higher prevalence of repeat SUI surgery at 10 years (14.4%) and 15 years (17.9%) after surgery.[32] This can be explained by other indications for SUI surgery in the USA. Persisting pain after TVT was reported by 2.7%–4.7% of women, in line with previous long-term studies showing a prevalence of 4%–7%.[12,27]

Keltie et al. reported that 9.8% of women had experienced a complication within 5 years of surgery.[14] This result is, however, not directly comparable with our study as they combined resolved and unresolved complications from 1 month to 5 years postoperatively.

The urgency index was 2.0 after 10 years and 2.8 after 20 years. The urgency index was higher among older women, which is in line with other studies.[12,23,27] Therefore, the influence of TVT surgery on urgency symptoms is difficult to separate from the known increase in urgency symptoms caused by advancing age.

This study also shows that higher BMI is associated with lower rates of cure over time. Hunskaar reported a strong association between stress incontinence and high BMI.[13] It has been proposed that as high BMI is a strong risk factor for urinary incontinence, weight loss should be the first-line treatment for women who are obese.[33,34] However, our study cannot answer whether weight loss would have improved the result after TVT in women who are obese.

4.2 | Strengths and limitations

This is the largest study to date investigating long-term subjective and objective cure rates, satisfaction and persisting pain following TVT surgery, including self-reported and objectively measured data. It is a multicentre study with 19 participating hospitals consisting of both small and large units as well as doctors with differing levels of training, which strengthens its external validity. The women included represent a heterogenous group, which

may therefore better reveal the "true" long-term results for continence, pain, tape exposure and tape removal. Another strength is the use of register-based data, which minimizes selection bias.[35] The NFIR has been proven to have high coverage and accuracy, making it an excellent tool for research.[36] The cough-jump pad-weighing stress test is validated and has high reproducibility.[22] A validated questionnaire used in many previous studies was used, adding further strength.[28]

A possible weakness is the recruitment rate of only 64% for the questionnaire and 75% for the clinical examination, but these rates are comparable with those of other long-term studies.[10,12,27] Women with bothersome symptoms may be more motivated to participate in studies, introducing a selection bias that might indicate that the 'true' long-term results are even better than reported in this study.[23,37] Questionnaires are based on self-reported information, with the risk of introducing bias through misinterpretations of the questions. Another weakness is that we have no reliable information about the different TVT kits used in the 10-year cohort. GYNECARE TVT™ (Johnson & Johnson, New Brunswick, NJ, USA) was the only option for the 20-year cohort. In 2011–2012 this was still used in most hospitals, but also other tapes, such as GYNECARE TVT EXACT® (Johnson & Johnson) or Advantage Fit™ (Boston Scientific, Marlborough, MA, USA) were available. As the subanalysis excluding women with transobturator tapes showed no differences in the results, we believe that slight differences in design between different retropubic kits would have no substantial impact on the results of the study.

4.3 | Interpretation

This study provides highly demanded long-term efficacy and safety data after TVT surgery and, as such, can be used to balance the negative focus on vaginal synthetic implants. The study shows high rates of subjective and objective cure, high satisfaction, and low rates of long-term persisting pain, repeat SUI surgery and surgery for tape removal up to 20 years after surgery. This is important information for doctors and women needing SUI surgery. The results of the study have the potential to empower patients to make an informed decision regarding treatment choice for SUI.

5 | CONCLUSION

Rate of satisfaction and cure were high up to 20 years after TVT surgery, and did not differ between the 10- and 20-year cohorts when adjusting for confounding factors. High BMI was associated with a lower cure rate. The risk for repeat SUI surgery, tape removal or persisting pain after TVT surgery was low. Our study adds to the growing evidence that TVT surgery is effective and safe in the long term, and the procedure should still be considered as a treatment option for women with SUI.

AUTHOR CONTRIBUTIONS

BRS collected and analysed the data and wrote the article. MN and IV conceived the project/study and contributed with data analyses and editing the article. RS contributed with the planning of the project/study and editing the article. This article has been read and approved by all authors.

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CONFLICT OF INTEREST STATEMENT

IV has acted as a speaker for Normedi in 2022, but has not received a speaker's fee. RS has received speaker's fees from Astellas. The other authors have no conflicts of interest to declare.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available upon request from the Norwegian Female Incontinence Registry in Norway and by contacting the corresponding author.

ETHICS APPROVAL

The study was approved by the Regional Committee for Medical and Health Research Ethics (REK) in Mid-Norway (REK Midt 2020/141 799) and the study was registered in Clinical Trials (NCT04912830).

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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