UiT The Arctic University of Norway
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Surgical treatment of stress urinary incontinence in women

The shift from Burch colposuspension to the retropubic tension-free vaginal tape procedure

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A dissertation for the degree of Philosophiae Doctor

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Contents

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2 Abbreviations

EUS	External urethral sphincter
ISD	Intrinsic sphincter deficiency
LAM	Levator ani muscle
MUI	Mixed urinary incontinence
MUS	Midurethral sling
OAB	Overactive bladder
PFMT	Pelvic floor muscle training
SUI	Stress urinary incontinence
TVT	Tension-free vaginal tape
UI	Urinary incontinence
UR	Urinary retention
UUI	Urgency urinary incontinence
VD	Voiding dysfunction

3 List of papers

3.1 Paper I

Holdø B, Verelst M, Svenningsen R, Milsom I, Skjeldestad FE. Long-term clinical outcomes with the retropubic tension-free vaginal tape (TVT) procedure compared to Burch colposuspension for correcting stress urinary incontinence (SUI). Int Urogynecol J. 2017 Nov;28(11):1739-1746. doi: 10.1007/s00192-017-3345-0. Epub 2017 Apr 24.

3.2 Paper II

Holdø B, Verelst M, Svenningsen R, Milsom I, Skjeldestad FE. The retropubic tension-free vaginal tape procedure - Efficacy, risk factors for recurrence and long-term safety. Acta Obstet Gynecol Scand. 2019 Jun;98(6):722-728. doi: 10.1111/aogs.13535. Epub 2019 Feb 14.

3.3 Paper III

Holdø B, Møllersen K, Verelst M, Milsom I, Svenningsen R, Skjeldestad FE. Surgeon's experience and clinical outcome after retropubic tension-free vaginal tape – a case series. Acta Obstet Gynecol Scand. 2020 Feb 27. doi: 10.1111/aogs.13830. [Epub ahead of print].

4 Abstract

Until the late 1990s, the Burch colposuspension was considered the gold standard for the surgical treatment of stress urinary incontinence (SUI) and stress-dominated mixed urinary incontinence (MUI) in women. In 1996, Ulmsten introduced the minimally invasive retropubic tension-free vaginal tape (TVT) procedure, and the first case series reported high safety and effectiveness of this procedure at 2-year follow-up. Despite the lack of data showing the superiority of the new method, the TVT procedure replaced the Burch colposuspension as the preferred surgical method worldwide within a few years.

We at the Department of Gynaecology at Nordland Hospital, Bodø, Norway, introduced the TVT procedure in 1998, and from 2000 onwards we stopped carrying out Burch colposuspensions completely. In order to confirm or reject the superiority of the new method, we applied data from surgeries performed before, during, and after this overlapping time period to compare the long-term treatment effectiveness of both surgical methods. In addition, we wanted to present short- and long-term safety and effectiveness data and to assess the risk factors for recurrence of SUI symptoms after the TVT procedure. Furthermore, the safety of the TVT procedure has been questioned, due to reports of serious and debilitating problems among women who underwent the procedure to treat urinary incontinence (UI). After the introduction of the TVT procedure, the number of women undergoing UI surgery increased rapidly, and the quality of this surgical treatment came into focus. We were particularly interested in the role of surgeon's experience on clinical outcomes after TVT surgery.

The study population comprised 748 primary incontinence surgeries performed at our department in the period 1994-2012. In the assessment of clinical outcomes in Paper I, we compared the last 5 years of the Burch colposuspension (n = 127, 1994-1999) with the first 5 years of the retropubic TVT procedure (n = 180, 1998-2002). In Paper II, we assessed long-term clinical outcomes (n = 596, 1998-2012) of the primary TVT procedure and performed an analysis of demographic, clinical, and perioperative risk factors for treatment failure. Paper III was an assessment of associations between surgeon's experience with the primary retropubic TVT procedure and both perioperative complications and recurrence rates.

The 3 papers were designed as patient series, and the statistical analyses were done using the Statistical Package for the Social Sciences, with a 5% level of statistical significance. We applied the t-test, Chi Square test, survival analysis, Cox regression analysis, and binary regression analysis.

In Paper I, we found a significant, higher cumulative SUI symptom recurrence rate at 12-year follow-up in women who received the Burch colposuspension compared to those who received the TVT procedure, when pure SUI was used as the indication for surgery. However, we did not find any significant difference in treatment effectiveness among women who received this procedure for MUI. In Paper II, we found that the TVT procedure had a high long-term durability, and that long-term complications were rare. Furthermore, we demonstrated that the TVT procedure was much more effective in women with SUI than MUI; the recurrence rate was two-fold higher among women with MUI. In Paper III, we observed that patients of surgeons who have less experience with the primary TVT procedure showed higher risk of bladder perforation and urinary retention, with less impact on long-term recurrence rates. We found significant differences in recurrence rates between surgeons, and the differences in recurrence rates between women with MUI and SUI were similar for the two surgeons who had performed TVT procedures throughout the study period.

5 Summary in Norwegian (Sammendrag på norsk)

Burch kolposuspensjonen var fram til 1990-tallet den anbefalte operasjonsmetoden ved kirurgisk behandling av kvinner med stressinkontinens og blandingsinkontinens med dominerende stress-komponent. Den minimalt invasive operasjonsmetoden, tensjonsfri vaginal tape, ble introdusert av Ulmsten i 1996, og de første pasientseriene rapporterte god behandlingseffekt og høy sikkerhet ved to års oppfølgning. Innen få år hadde tensjonsfri vaginal tape erstattet Burch kolposuspensjonen som førstevalg i den kirurgiske behandlingen av stressinkontinens hos kvinner verden over, selv om ingen studier som sammenlignet de to metodene hadde vist noen klar forskjell i behandlingseffekt.

Kvinneklinikken ved Nordlandssykehuset i Bodø, Norge, introduserte tensjonsfri vaginal tape i 1998, og fra 2000 av ble det ikke lengre utført Burch kolposuspensjon ved vår avdeling. Vi ønsket å sammenligne behandlingseffekten for de to metodene ved å bruke oppfølgningsdata fra operasjoner utført i årene før, under og etter denne overgangsperioden. Videre ønsket vi å presentere kliniske oppfølgningsdata for komplikasjoner og behandlingseffekt samt å finne eventuelle risikofaktorer for tilbakefall av stressinkontinens etter tensjonsfri vaginal tape operasjon. Det er blitt satt spørsmåltegn ved sikkerheten ved tensjonsfri vaginal tape operasjoner de senere år, dette på bakgrunn av rapporter om alvorlige senskader hos kvinner som er blitt operert med denne metoden. Siden antall kvinner som ble operert for urinlekkasje økte sterkt i årene som fulgte etter at den nye operasjonsmetoden ble lansert, ble det også økt fokus på kvaliteten på det kirurgiske behandlingstilbudet. Derfor ønsket vi å se på hvilken rolle kirurgens erfaring hadde på resultatene etter tensjonsfri vaginal tape operasjon.

Studiepopulasjonen utgjorde 748 primæroperasjoner for urinlekkasje utført ved vår avdeling i perioden 1994-2012. I Artikkel 1 sammenlignet vi behandlingseffekt og komplikasjoner mellom de siste 5 årene med Burch kolposuspensjon (n= 127, 1994-1999) og de 5 første årene med tensjonsfri vaginal tape (n = 180, 1998-2002). I Artikkel 2 presenterte vi tidlige og sene komplikasjoner og behandlingseffekt etter 596 primære tensjonsfri vaginal tape operasjoner utført i perioden 1998-2012 samt en analyse av risikofaktorer for tilbakefall. Artikkel 3 er en analyse av mulig

sammenheng mellom kirurgens erfaring og risiko for komplikasjoner og tilbakefall etter tensjonsfri vaginal tape operasjon.

Alle 3 studiene ble utformet som retrospektive pasientserier. Statistiske analyser ble gjort med programmet Statistical Package for the Social Sciences med 5% signifikansnivå. Det ble anvendt t-test, Chi Square test, survival analyse, Cox regresjonsanalyse og binær regresjonsanalyse.

I Artikkel 1 fant vi blant kvinner som hadde ren stressinkontinens som indikasjon for operasjon signifikant høyere risiko for tilbakefall av symptomer på stressinkontinens hos de som var operert med Burch kolposuspensjon sammenlignet med tensjonsfri vaginal tape opererte kvinner ved oppfølgning inntil 12 år. Derimot var det ingen signifikant forskjell i behandlingseffekt mellom metodene blant kvinner som hadde blandingsinkontinens som indikasjon for operasjon. I Artikkel 2 fant vi god behandlingseffekt og lav risiko for senkomplikasjoner ved oppfølgning inntil 10 år hos kvinner operert med tensjonsfri vaginal tape. Videre fant vi at risiko for tilbakefall av symptomer på stressinkontinens var dobbelt så høy hos kvinner med blandingsinkontinens sammenlignet med kvinner med stressinkontinens som indikasjon for operasjon. I Artikkel 3 fant vi at det ved operasjoner der kirurgen hadde liten erfaring med tensjonsfri vaginal tape kirurgi var høyere risiko for blæreskade og blæretømningsproblemer i etterkant av operasjonen, mens effekten på behandlingseffekt ved inntil 10 års oppfølgning var liten eller usikker sammenlignet med operasjoner der kirurgen hadde større erfaring med metoden. Vi fant også at det var signifikante forskjeller i behandlingseffekt mellom enkeltkirurger, og at forskjellene i tilbakefallsfrekvens mellom kvinner med ren stressinkontinens og blandingsinkontinens som indikasjon for operasjon var gjennomgående for kirurgene.

6 Introduction

The thesis describes short- and long-term clinical outcomes among women who underwent urinary incontinence (UI) surgery at Nordland Hospital in 1994-2012.

UI is a significant health problem in women, with a prevalence of 25-29% among those aged >20 years (1). In addition to the economic costs incurred by patients and healthcare services, nearly 60% of affected women perceive their UI to be moderate or severe (1). After the introduction of the retropubic tension-free vaginal tape (TVT) procedure in 1996 (2), the number of women undergoing midurethral sling (MUS) surgery increased rapidly, probably due to both the increasing prevalence of UI (1) and the lower threshold for surgery.

In order to place this topic in perspective I present an unsystematic review of UI in women, including epidemiology, risk factors, pathophysiology, and non-surgical treatment followed by a review of the transition from the Marshall-Marchetti-Krantz operation, via the Burch colposuspension, to the modern MUS surgical procedures used to correct stress UI (SUI) in women.

6.1 Definitions - Urinary incontinence in women

It is generally accepted that there are three main types of UI in women; SUI, urgency UI (UUI), and mixed UI (MUI). The International Continence Society originally defined UI as *"…the involuntary loss of urine that is a social or hygienic problem"* (3). However, this definition only considers complaints related to quality of life. Newer definitions take into account symptoms, signs, and clinical and urodynamic observations. Furthermore, UI should be described according to relevant, specifying factors, such as type, severity, and precipitating factors. Therefore, the International Continence Society has presented a newer definition of UI: *"…the complaint of any involuntary loss of urine…"* (3). Newer definitions of the three main types of UI in women were presented in a report from the International Continence Society in 2002 and confirmed in 2010 (3) (4). SUI was defined as "…*the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing*." UUI was defined as "…*the complaint of involuntary leakage accompanied by or immediately preceded by*

urgency.", and urgency was defined as *"…the complaint of a sudden compelling desire to pass urine, which is difficult to defer.*" (4). Overactive bladder (OAB) is a syndrome which is defined by the presence of urgency, with or without UUI, usually accompanied by frequency and nocturia without any infection or other obvious pathology (4). MUI is *"…the complaint of involuntary leakage associated with urgency and also with exertion, effort, sneezing or coughing.*" (4).

6.2 Epidemiology and risk factors

The prevalence of UI among Norwegian women aged >20 years was estimated in the EPINCONT 1- and EPINCONT 2-studies (1), which showed an increase in crude prevalence from 25.0% in 1995-1997 to 29.0% in 2006-2008 in the same cohort of women. The significant change was mainly observed among women aged <50 years. In a review by Hunskaar et al. (5), which included 11 studies, SUI was the most frequent type of UI in the general female population, comprising 29-75% of cases (mean 48%), whereas MUI comprised 14-61% (mean 34%), and UUI 7-33% (mean 17%).

There is general agreement that the following risk factors or conditions determine incidence and severity of UI in women: age (1) (6), pregnancy (5) (7) (8), parity (9) (10) (11), mode of delivery (12) (13), menopause (5) (14) (15), heredity (16) (17), previous hysterectomy (10) (11), overweight (18) (19), smoking and other lifestyle factors (18) (20), and comorbidities like diabetes (21) (22), depression (10), neurological diseases (23) (24) (25), and cognitive dysfunction (26).

6.3 Urinary incontinence, pelvic floor anatomy, and pathophysiology

6.3.1 Pelvic floor anatomy and the urethral support system

The mechanisms of urethral continence are dependent on the urethral support system. The structures crucial for this support are the anterior vaginal wall, the endopelvic fascia and the levator ani muscle (LAM) (27).

The endopelvic fascia is a strong layer of connective tissue that surrounds the vagina and urethra. Laterally, this fascia condensates to the arcus tendineus fasciae pelvis (28), a fibrous band anteriorly connected to the posterior surface of the pubic bone near the midline, and posteriorly connected to the ischial spine. The arcus tendineus fasciae pelvis merges with the LAM and urethra, and thus resists caudal movement of the anterior vaginal wall and the urethra during increases in intraabdominal pressure (27) (28). The pubourethral ligament is a condensation of the endopelvic fascia with insertion on the posterior surface of the pubic bone, the urethra, the anterior vaginal wall and the bladder neck, and is hypothesized to play a role in the stabilization of the urethra (29) (30).

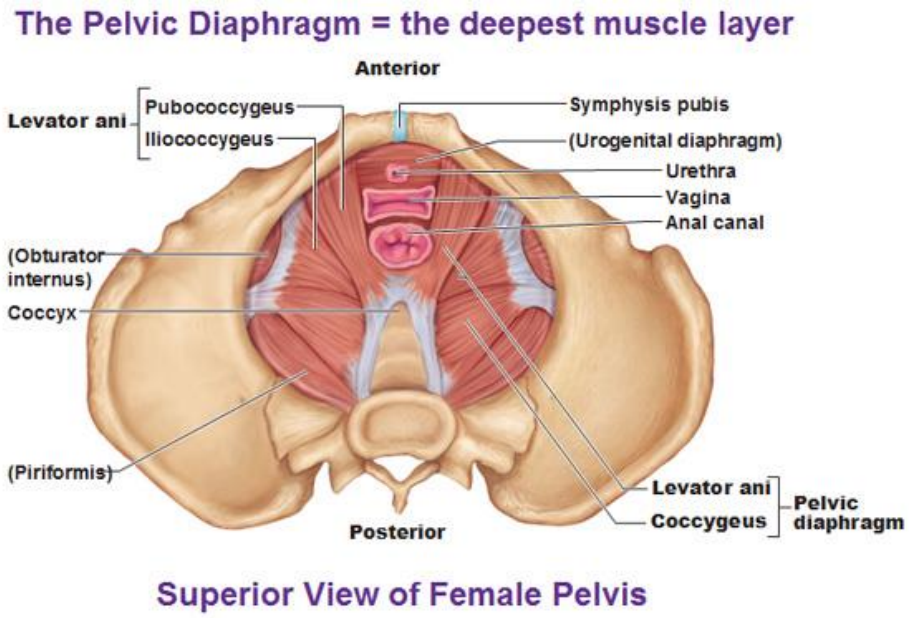


Fig. 1 Muscles in pelvic floor from above (https://antranik.org/)

The inner muscular layer of the pelvic floor (Fig. 1) comprises the left and right LAM anteriorly and the coccygeal muscles posteriorly (31). The LAM comprises medially the puborectal muscle, pubococcygeal muscle in the intermediate position, and the ileococcygeal muscle laterally. The puborectal and pubococcygeal muscles arise from the posterior aspect of the pubic bone, insert into the anal sphincter complex, and pass behind the rectum and fuses with contralateral counterpart to form a sling. The longitudinal muscle of the anus receives fibres from the puborectal muscle, traverses through the external anal sphincter, and is inserted in the perianal dermis. The

ileococcygeal muscle arises from the arcus tendineus fasciae pelvis. Posteriorly, the ileococcygeal and the pubococcygeal muscles insert into the coccygeal bone. The ileococcygeal muscle forms a horizontal sheet over the posterior region of the pelvis, providing a shelf on which the pelvic organs rest (27).

The inner border of the LAM forms the margin of the levator hiatus, through which the urethra, vagina, and rectum pass. The urogenital diaphragm is a musculofascial structure that bridges the gap between the inferior rami of the pubic bone below the pelvic diaphragm and closes the anterior part of the levator hiatus. The urethra and vagina pass through the urogenital diaphragm, thus they have a weak sphincter-like effect on the distal vagina; the external urethral sphincter (EUS) is also part of the urogenital diaphragm (31). The proximal one-third of the urethra is surrounded by striated muscle fibres from the EUS and has an intraabdominal location. In his study of the EUS, Wallner described its inferior section as a horseshoe-shaped structure that surrounds the lower urethra anteriorly and is inserted in the lateral vaginal wall posteriorly (32) (Fig. 2).

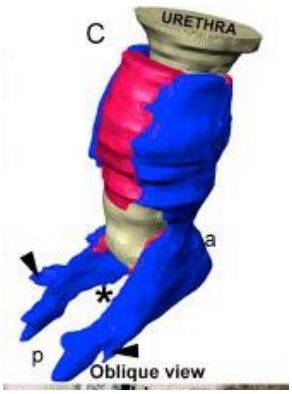


Fig. 2 External urethral sphincter (coloured blue) from (32)**, with kind permission from WH Lamers.**

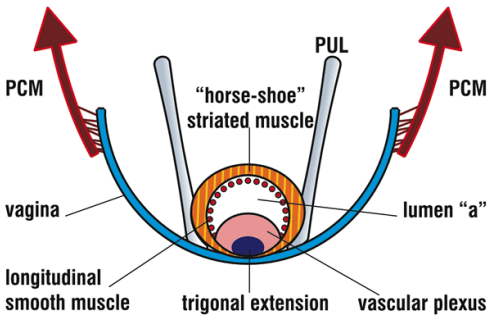


Fig. 3 Anterior vaginal wall as a "hammock" supporting the urethra (pubococcygeal muscle, PCM; pubourethral ligament, PUL) from (33)**, with kind permission from P Petros.**

6.3.2 The three mechanisms of continence

The mechanism of stress continence is provided by a complex interaction between striated and smooth muscles, nerves, connective tissue, and a well-vascularized urethral mucosa and submucosa. These structures act together to ensure a higher pressure in the urethra than in the bladder in situations with increased intraabdominal pressure. The original hypothesized mechanism of stress continence suggested that, by descending away from its intraabdominal position, the urethra loses compression during straining. This concept was gradually replaced by the **'hammock hypothesis'** (34) (35), which describes the structures that are crucial for the support of urethra and the mechanism of continence. The urethra is embedded in the endopelvic fascia; it is supported anteriorly by the pubourethral ligaments and posteriorly by the anterior vaginal wall. During straining, the urethra is compressed against this hammock-like supportive layer, which keeps the lumen closed. The muscles most important for the continence mechanism are the strong puborectal muscle and the weak EUS. The mechanical effect of the strong puborectal muscle is to pull the anterior urethral wall downwards in posterior direction during contraction and thereby stretch the anterior vaginal wall into a tympanitic membrane. The effect of the weaker EUS is to close the urethra by creating a waterproof seal for the bladder, supported by mucosa, a vascularized submucosa, smooth muscle fibres, and connective tissue (32) (36) (Fig. 3). Portions of the pubococcygeal muscle and the pubourethral ligaments attach to the endopelvic fascia in the "vaginal sulcus" between the lower and middle one-third of the anterior vaginal wall, and produce elevation anteriorly of the mid-urethra during contraction. A tendinous connection between the LAM and the EUS provides an anterior bending of the mid-urethra during simultaneous contraction of the LAM and the EUS, which is assumed to be critical to the mechanism of stress continence (37). The integral theory of Petros and Ulmsten describes this as **the first out of three closure mechanisms** (34).

The second closure mechanism is the closure of the bladder neck, which is performed through a complex interaction between the pubococcygeal muscle and the longitudinal muscle of the anus. This action closes the most proximal portion of urethra and is dependent on the elastic properties of the vaginal wall and its supporting

structures; most importantly the utero-sacral and the cardinal-ligaments, as well as the pubourethral and pubocervical ligaments.

During this action, contraction of the levator plate stretches the upper two-thirds of the vagina and the pubococcygeal muscle into a semirigid structure; by the contraction of the longitudinal muscle of the anus, the pubococcygeal muscle rotates downwards like a trapdoor against the urethra. During the same action, the bladder rotates downwards and backwards, stretching the bladder neck, which elongates and closes the proximal and most flexible portion of the urethra.

As the two first closure mechanisms are involuntarily actions dependent on the central nervous system (27). **The third mechanism** is a **voluntary action** not normally involved in bladder neck closure; therefore it requires training through pelvic floor exercises. In nulliparous women, the lower one-third of vagina is oriented more vertically and the upper two-thirds more horizontally when compared to multiparous women. This is due to the posterior attachments of the cervix provided by the cardinal and sacrouterine ligaments, and to the anterior position of the levator hiatus provided by the tension of the pubococcygeal muscle. During strain, the levator hiatus is shortened by the action of the LAM, and this compression of the pelvic organs in forward and upper direction provides support to the bladder neck and the “hammock” mechanism, thus comprising the **voluntary third closure mechanism** (32) (34) (37).

6.3.3 Mechanisms of stress urinary incontinence

The previous section outlines why the ability to stretch and stiffen the vaginal wall, i.e., “the hammock“, is crucial for the reflexive closure of the urethral lumen in the presence of increasing intraabdominal pressure. Both the Burch colposuspension and the TVT procedure aim to provide urethral support by creating a firm fulcrum for the forces applied by the pelvic floor muscles. Deterioration of urethral support by displacement of the vaginal wall following injury to its normal intrapelvic attachments is one postulated mechanism of SUI (37).

The structures responsible for stress continence may be damaged during pregnancy and delivery. The **pudendal nerv**e innervating the EUS can be damaged during vaginal delivery; the mechanism is assumed to be ischemia due to either stretch or compression (38). The **cardinal and sacrouterine ligaments** may be stretched or torn during pregnancy and delivery resulting in an anterior displacement of the uterus (37). Magnetic resonance imaging examination of women with SUI has shown damage to the pubourethral ligaments (39). Vaginal injuries can be detected by ultrasonographic examination (40). **Damage of the LAM** due to stretching, tearing, and avulsion results in a wider levator hiatus, which reduces the support of pelvic organs like the urethra and bladder. An **increase in the levator hiatus and loss of the posterior urethro-vesical angle** are strongly associated with urodynamic and clinical stress parameters (41) (42).

Changes in connective tissue have been proposed as an aetiological factor for SUI in several studies. Ulmsten et al. (43) reported a 40% lower collagen content in biopsies from the skin and ligamentum rotundum in women with SUI compared to continent women, which suggests an increased laxity in the pelvic connective tissue that could lead to reduced vaginal support of the urethra and the bladder base.

Falconer et al. (44) found different collagen properties in paraurethral tissue from women with SUI compared to matched continent controls, including a higher concentration of collagen and larger collagen fibrils in biopsies from women with SUI. These changes were hypothesised to result in a more rigid extracellular matrix, which was proposed to deteriorate the mechanical properties of connective tissue. Some studies have proposed that these metabolic changes in collagen may have a genetic origin (43) (44).

A review by Chen & Yeh (45) presents current knowledge from epidemiological data and studies of human tissue and animal models about connective tissue metabolism in the genitourinary organs. Data on collagen and elastin metabolism support the hypothesis of abnormal elastin metabolism and increased turnover of collagen with abnormal extracellular matrix remodelling. All these processes contribute to the alteration of normal tissue architecture, to the mechanical properties of pelvic connective tissue, and to SUI and pelvic organ prolapse. They can be explained by

genetic predisposition and are influenced by reproductive hormones, trauma, mechanical stress, and aging.

The second, generally accepted cause of SUI is either loss of support, resulting in a reduced urethro-vesical angle, or an intrinsic sphincter deficiency (ISD). It is assumed that ISD is due to factors independent of urethral support, i.e., deteriorated function of the pudendal nerve, EUS, urethral smooth muscle, mucosa, and submucosa. ISD has been equated with a "low pressure urethra" and is clinically defined as a subgroup of women with SUI at high risk of failure after surgical treatment (46). Age has been shown to be a risk factor for ISD, and age-dependent reduction in muscle mass in the EUS has been proposed as an aetiological factor (47) (48) (49).

Clinically, a reduced urethro-vesical angle results in a hypermobile urethra, and ISD is characterised urodynamically by low maximal urethral closure pressure (37). However, this dichotomy has gradually been replaced by a continuum, due to a growing clinical impression that both ISD and hypermobility may exist in patients with SUI (37) (46) (50).

6.3.4 Mixed urinary incontinence

The differences in the mechanisms of SUI and MUI are not fully understood. According to Brucker, two main theories are used to explain the pathophysiology of MUI. The "two pathway" theory defines the stress and urgency components as two distinct entities – with UUI being a neurogenic bladder dysfunction and SUI a bladder outlet dysfunction due to an insufficient pelvic floor – that require different treatment approaches. The alternative "common pathway" theory assumes that leakage of urine to the proximal urethra activates the detrusor reflex, providing an explanation for the improvement in UUI experienced by many patients with MUI after incontinence surgery (51). This indicates a more complex pathophysiology, as well as a more serious neuromuscular dysfunction in women with MUI.

6.3.5 Overactive bladder

Symptoms of OAB are suggestive of detrusor overactivity during the filling phase, but only about 50% of patients with detrusor overactivity have urgency, and about 50% of patients with urgency have demonstrable detrusor overactivity at cystometry (37). Cerebral, spinal, and peripheral nerve signalling is involved in the regulation of the detrusor function, as well as a complex system of cells, nerves, mediators, and receptors in the bladder. The aetiology of OAB is multifactorial and may involve any of these structures (52). However, the pathogenesis of UUI is poorly understood.

6.4 Non-surgical treatment of stress urinary incontinence – pelvic floor muscle training

Pelvic floor muscle training (PFMT) is a programme that trains the pelvic floor muscles by repeated contractions and relaxations under the supervision of a health professional, usually a physiotherapist. PFMT is recommended in both the prevention and treatment of SUI and MUI (53). Voluntary contractions of the LAM elevate the pelvic viscera upwards and forward giving support to the mechanisms that provide closure of the urethra, described in the third closure mechanism in the integral theory of Petros and Ulmsten (34). Ultrasonograpic and magnetic resonance imaging studies have confirmed this movement of the LAM during active contraction, as well as changes in the position of the urethra (54) (55). Studies that investigated magnetic resonance imaging before and after a PFMT programme revealed a reduction in the levator hiatus area, as well as improved urethra stability during rest and effort (56) (57).

There is good evidence for the short-term effectiveness of PFMT, but its long-term effectiveness has been questioned. A Cochrane systematic review, including 31 trials and 1817 women with SUI, MUI, or UUI, assessed PFMT versus no treatment, placebo, or sham (inactive) electrical stimulation (58). The results showed an association between PFMT and cure and improvement in women with SUI and any type of UI when compared to inactive control treatment, but follow-up data beyond 1 year was lacking. Few studies have assessed the long-term effectiveness of PFMT

without incentives for continued training. In the review by Bø et al., which included 19 trials and 1141 women, the heterogeneity across studies made a statistical meta-analysis impossible (59). Follow-up varied between 1 and 15 years, and in most of the studies, the outcome was assessed by self-administered questionnaires. Long-term success rates varied between 41% and 85%, and surgery rates between 4.9% and 58%. The effect of PFMT during pregnancy and the early postpartum period was assessed in a Cochrane review by Woodley et al. (60). The available data suggested that prenatal PFMT may be effective in the prevention of UI in continent women, but not in the treatment of incontinent women in late pregnancy or in the early postpartum period (up to 6 months postpartum). PFMT may have an effect on a mixed population of continent and incontinent women during pregnancy and up to 6 months postpartum. PFMT also seems to be effective in elderly women (61). The only study comparing PFMT and surgery found surgery to be superior (62).

6.5 Surgical treatment of stress urinary incontinence

Over the years, more than 120 surgical procedures have been applied in the treatment of SUI (34), reflecting that none of them is a perfect treatment modality. Urethral bulking agents in the treatment of SUI were described as early as 1904, when injection with paraffin was shown to cure UI (63). In 1907, Giordano proposed the use of the gracilis-muscle to form a hammock underneath the bladder neck and proximal urethra, thus introducing the first pubovaginal sling (64). Kelly and Dumm's publication from 1914 described performing a plication of the pubocervical fascia on either side of the bladder neck, combined with a colporhaphia anterior as treatment for SUI (65). The intention was to give support to the *"relaxed tissues at the bladder neck"*. In 1937, the method was modified by Kennedy (66), and named the Kelly-Kennedy plication (67).

6.5.1 Retropubic bladder neck suspension - the Marshall-Marchetti-Krantz procedure and the Burch colposuspension

The first Marshall-Marchetti-Krantz procedure on a female was performed on 8 June 1944 (68) and described in 1949 (69) (Fig. 4). The Marshall-Marchetti-Krantz procedure is an open **retropubic bladder neck suspension** involving fixation of the

bladder neck by suturation of periurethral tissue to the cartilage or periosteum of the pubic bone near the midline. A review of 56 articles assessing the clinical outcome of this procedure showed an overall success rate of 86.1%, varying between 92.1% for primary procedures and 84.5% for repeat procedures, and an overall rate of complications of 21.1% (70). However, long-term effectiveness was not reported in this review. A special complication of this procedure was infection in the pubic bone, with an estimated rate of 2.5% in this review.

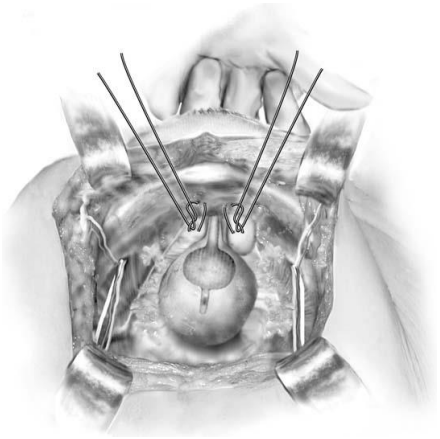


Fig. 4 Marshall-Marchetti-Krantz procedure (71)

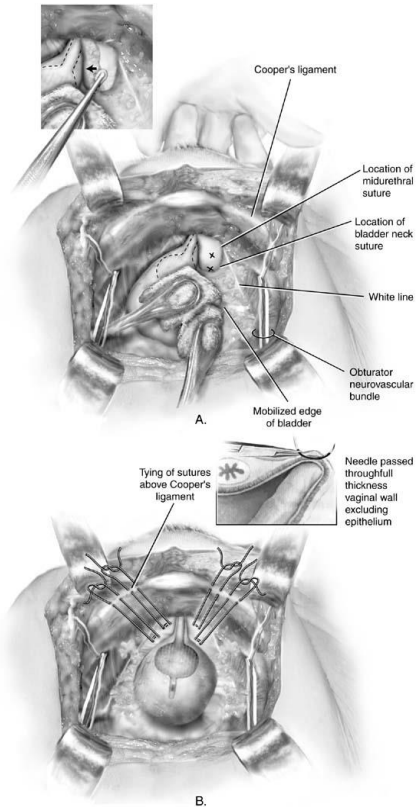


Fig. 5 Burch colposuspension procedure (71)

John C. Burch proposed a modification to the Marshall-Marchetti-Krantz procedure in 1961 (72), as he had identified some problems: "*the field is often deep and bloody, the edges of the urethra are difficult to define, and the periosteum on the posterior aspect of the symphysis is far from ideal as an anchoring structure*". He showed that the more laterally located Cooper's ligament was a more appropriate place for fixation of the sutures, thus resolving the problems with the pubic bone (Fig. 5). Burch published a patient series of 169 patients with a failure rate of only 7% and a rate of enterocele of 7.6%. Three trials comparing the effectiveness of the Burch colposuspension and the

Marshall-Marchetti-Krantz procedure at 6-12 months reported average cure rates of 87.9% and 80.3%, respectively.

A **modification of the Burch colposuspension** was introduced by Tanagho in 1976 (73): he placed his two sutures far laterally and emphasised the importance of not lifting of the vaginal wall too much in order to avoid problems with bladder emptying. Despite some studies reporting notable high total rates of complications after Burch colposuspension (74) (75), the procedure became the gold standard in the primary surgical treatment of female SUI until the TVT was introduced in the late 1990s. The subjective cure rates after the Burch colposuspension varied between 44% and 80%, and objective cure rates between 67% and 82% in studies with 5-10 years of follow-up. However, effectiveness appeared to decrease with time (76) (77) (78) (79) (80). Furthermore, as some studies reported a detrusor overactivity of rate up to 18% after bladder neck elevation surgery (81) (82), caution with this type of procedure in patients with urodynamically diagnosed detrusor overactivity was recommended (82) (83).

6.5.2 The modern midurethral sling

The development of the modern MUS was preceded by a better understanding of the mechanism of incontinence, which occurred simultaneously with an improvement in the diagnostic tools, i.e., better radiologic and ultrasonographic methods to explore pelvic anatomy, and more advanced urodynamic equipment to assess urinary tract physiology. There was a gradual change in focus from stabilisation and especially elevation of the bladder neck to support of the mid-urethra. The former way of thinking was founded on the hypothesis that the urethra, by descending from its intraabdominal position, loses transmission of intraabdominal pressure during straining (35) (37). The introduction of the ‘hammock hypothesis’, especially the integral theory of Petros and Ulmsten in 1990 (34), was preceded by research that revealed the role of the mechanisms of support of the mid-urethra (84) (85) (86). Although the integral theory has been questioned in recent years (87), mainly due to the absence of prospective clinical trials that support the theory, it represented a breakthrough in a process that eventually led to the introduction of the modern MUS.

Ulmsten and Petros introduced the intravaginal sling procedure in 1995 (81) (88). However, it was abandoned due to tissue reaction to Gore-tex and mersilene tapes in 8-10% of patients. Finally, Ulmsten introduced the retropubic TVT procedure in 1996, a minimally invasive surgical method performed on 75 women with genuine SUI (2). For this procedure, a polypropylene tape, covered by a plastic sheath which is removed after placement, was applied with a trocar. The trocar was obliquely guided through a small suburethral incision approximately 0.5 cm from the external urethral meatus, perforating the urogenital diaphragm on each side of the urethra, subsequently "shaving" the back of the pubic bone and eventually perforating the abdominal skin 2 cm bilateral of the midline above the symphysis. The plastic sheath assured that the sling did not become contaminated and enabled the sling to be pulled through the tissue without friction and trauma. Cystoscopy was performed to preclude bladder injury, and the tape was adjusted by means of a coughing test. In his first patient series, Ulmsten performed the procedure using local anaesthesia, and released the patients from the hospital the day of the procedure or the day after, granting a sick leave of 10 days. The mean operation time was 22 minutes, and no serious complications occurred, nor were there any tape rejections after a follow-up period of 2 years. 84% of women were cured, and another 8% improved significantly. Polypropylene had been used for years for abdominal hernia repair, and had shown inert qualities. Moreover, the Ulmsten team discovered a cut-off for pore size, which was crucial to prevent tape rejection.

7 Background for the study and aims of the thesis

7.1 Transition from the Burch colposuspension to the retropubic tension-free vaginal tape procedure

While the Burch colposuspension is an inpatient surgical procedure requiring general or regional anaesthesia, the TVT procedure is a minimally invasive outpatient procedure. Several studies showed high safety and effectiveness of the TVT procedure after 2 years of follow-up (2) (89) (90). Although no studies have proven the TVT procedure to be superior to the Burch colposuspension, within a few years, the retropubic TVT procedure replaced the Burch colposuspension as the gold standard in the primary surgical treatment of SUI and stress-dominated MUI in women. However, until 2005, neither randomised controlled trials nor meta-analyses had revealed any significant differences in effectiveness at 5-year follow-up in favour of the TVT procedure (91) (92).

7.2 Effectiveness of the retropubic tension-free vaginal tape procedure

To-date, numerous publications have shown a high long-term effectiveness of the TVT procedure. However, cure rates depend on patient selection; exclusion of women with MUI, and/or earlier or concomitant pelvic floor surgery. Subjective cure rates of 77-90% have been shown 10-11 years after primary TVT surgery among women with SUI (93) (94), whereas primary TVT surgery on populations comprising women with both SUI and MUI have subjective long-term cure rates of 75-80% (95) (96). Studies assessing the TVT procedure in patient populations that include women with earlier UI or prolapse surgery and concomitant prolapse surgery show subjective cure rates of 65-76% (97) (98); even lower cure rates (37-55%) are reported for women with MUI (99) (100).

MUI is the most consistently reported risk factor for recurrence after the TVT procedure (99) (100) (101). Furthermore, age, overweight, and diabetes mellitus have also been reported as risk factors in some studies (95) (99) (101) (102). Two studies

reported perioperative complications as a predictive factor for cure failure (101) (102). However, most long-term follow-up studies did not have sample sizes large enough for risk factor analyses (93) (95) (97).

7.3 Safety of the tension-free vaginal tape procedure

In recent years, the safety of TVT surgery has been questioned. A report from the UK Medicines and Healthcare Products Regulatory Agency concluded that *"Women have reported serious and debilitating problems following surgical treatment for SUI vaginal tape implants"* (103). A 2015 editorial from the Cochrane Library summarised 20 years of experience with surgical treatment of UI in women, and questioned the fact that only a few of the 35 trials that reported on long-term follow-up observed leakage and adverse effects 5 years or more after treatment (104). The authors also stated that more evidence was needed about the safety of new methods in comparison to older, abandoned methods (104).

The most frequent late complication of MUS surgery is de novo OAB in women with SUI, with a rate of de novo UUI of 15% (98) (100). Erosion is the most frequent late tape complication, with rates of 0-4.2% (98) (105) (106) (107) (108).

7.4 The importance of surgeon's experience in the clinical outcomes of the tension-free vaginal tape procedure

To date, numerous studies have assessed the demographic and clinical risk factors for adverse outcomes after TVT surgery. However, studies assessing the role of surgeon's experience in this context have mostly focused on perioperative complications (109) (110) (111). Existing evidence has shown an increased risk of bladder perforation when the surgeon is a 'beginner' (112) (113) (114) (115) (116). The decreasing rate of bladder perforation with increasing number of procedures performed has been defined as a possible measure of surgeon's experience (111). However, very different cut-off values have been applied to test this experience, from <16, <30, <50, or <100 surgeries (111) (112) (115). The literature is also inconclusive regarding the duration

of surgeon's learning phase when studying urinary retention (UR) (114) (117) and other perioperative complications (105) (109) (110) (118) (119). Moreover, few studies have looked at long-term effectiveness (102) (105) (120) (121), and most of these studies had low sample sizes (<500). At 2- and 4-year follow-up, two studies reported reduced cure rates in low- versus high-volume departments and when comparing low- versus high-volume TVT surgeons (120) (121).

Surgeon's experience is usually characterised by the number of TVT procedures performed and/or by the surgeon's position in the department (senior consultant/resident), while the institutions are described by their organisational level (university, central or local hospital, teaching/non-teaching hospital) and/or annual surgery volume.

7.5 Aims of the thesis

We at the Department of Gynaecology at Nordland Hospital in Bodø, Norway, introduced the TVT procedure in 1998, and from 2000 onwards we stopped carrying out Burch colposuspensions completely. In order to confirm or reject the superiority of the new method, we applied data from surgeries performed before, during, and after this overlapping time period to compare the long-term treatment effectiveness of both surgical methods. In case of confirmation of the TVT procedure as the "gold standard", we wanted to perform a further assessment of the TVT procedure with respect to clinical outcomes at long-term follow-up and a risk factor analysis. Other studies have identified groups of patients with lower expectations for cure following the TVT procedure, and we were particularly interested in identifying risk factors for treatment failure in our data. Furthermore, the safety of the TVT procedure has been questioned recent years due to reports of serious and debilitating problems among women who received the TVT procedure to treat UI. After the introduction of the TVT procedure, the number of women undergoing UI surgery increased rapidly, and the quality of this surgical treatment came into focus. We were particularly interested in identifying factors which may improve the quality of the treatment, and we performed an assessment of the role of surgeon's experience on clinical outcomes following the TVT procedure.

- The aims of Paper I were to compare short- and long-term clinical outcomes in women undergoing the Burch colposuspension and the retropubic TVT procedure.
- The aims of Paper II were to investigate clinical long-term outcomes and to assess demographic, clinical, and perioperative risk factors for recurrence within 10 years of a primary retropubic TVT procedure.
- The aims of Paper III were to assess the associations between surgeon's experience and 1) perioperative complications and 2) recurrence rates in women who underwent a primary TVT procedure.

8 Materials and methods

8.1 Study design

The studies were performed as consecutive, retrospective case-series.

8.2 Study population

The study population comprised women who received surgery for UI at The Department of Gynaecology, Nordland Hospital, Bodø, Norway in the period 1994-2012. In order to find all such cases (case ascertainment), we searched the hospital's patient administrative system for patients with a diagnosis of UI according to the International Classification of Diseases versions 9 and 10 (ICD 9 and 10), as well as those with registered UI-related surgical procedures (Table 1) according to the Norwegian system for classification of surgical procedures, 2nd and 3rd edition for the period 1994-1998, and to the Nordic Medico-Statistical Committee Classification of Surgical procedures for the period 1999-2012.

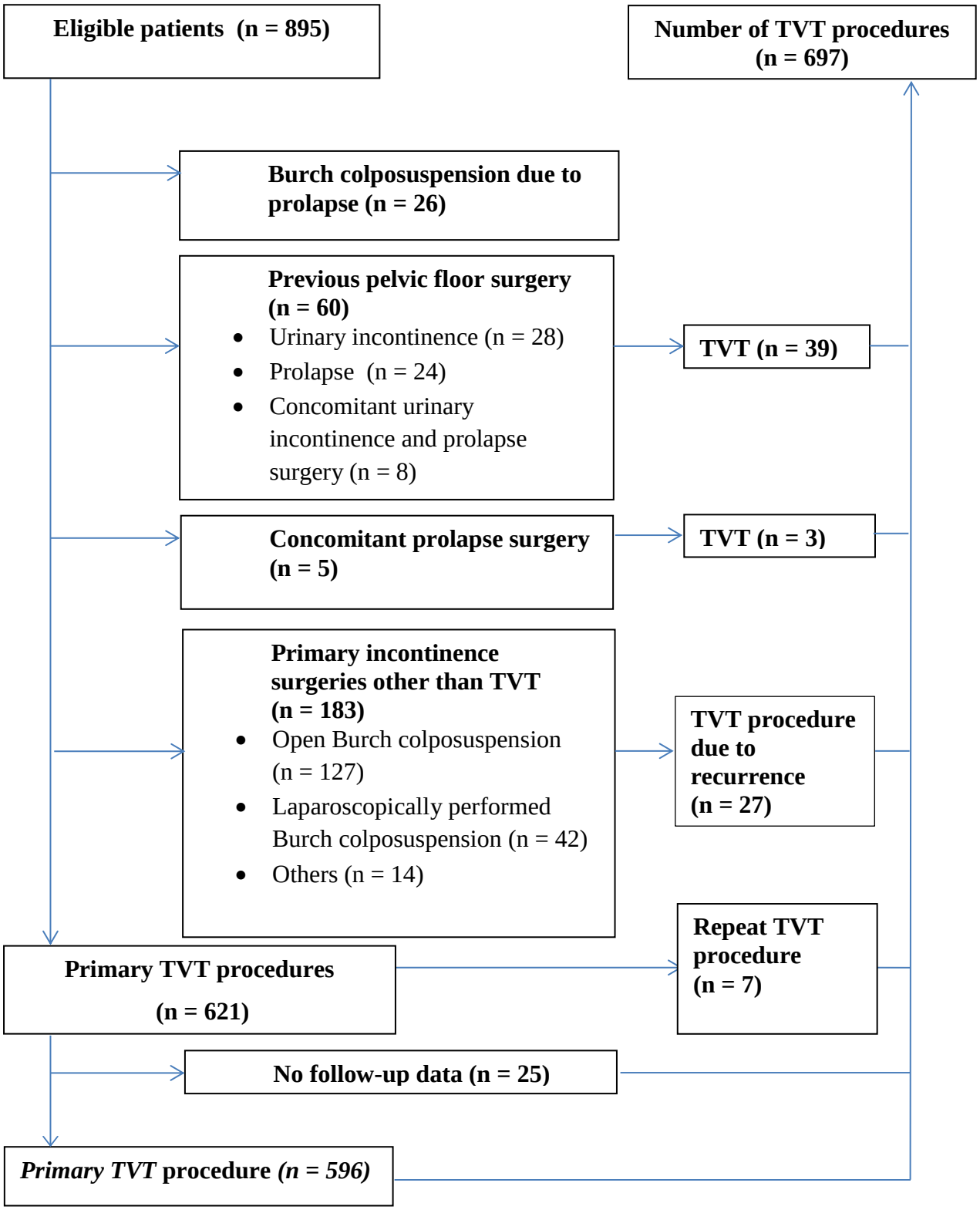
Table 1 Codes used to identify cases with a diagnosis of urinary incontinence or with registered urinary incontinence-related surgical procedures

Codes for diagnosis of urinary incontinence	**ICD-9**	**ICD-10**	**Denomination**
Urinary incontinence	625.6	N39.3	Stress incontinence
	788.3	N39.4	Other specified urinary incontinence
	788.4	N39.8	Other specified disorders of urinary system
Codes for urinary incontinence-related surgical procedures	Norwegian system for classification of surgical procedures, 2nd and 3rd edition	NSCP	
Urinary incontinence	747	LEG 00	Vaginal urethrocystorrhaphy *(Kelly-Kennedy, etc.)*
	7471	LEG 10	Vaginal urethrocystopexy with use of sling
		LEG13	Vaginal transobturatorial urethropexy
	7471	KDG 96	Other operation on urethra or bladder neck for incontinence
		KDV22	Transluminal endoscopic submucous urethral injection (Zuidex, Bulkamid)
	6356	KDG 00	Retropubic suspension of urethra *(Marshall-Marchetti-Krantz)*
	6356	KDG 20	Abdominal colposuspension (*Burch)*
	6355	KDG 30	Suprapubic sling urethrocystopexy
	7479	LEG 96	Other vaginal operation for incontinence
Period	**1994-1998**	**1999-2012**	

Abbreviations: ICD 9/10: International Classification of Diseases versions 9 and 10, NSCP: Nordic Medico-Statistical Committee Classification of Surgical procedures.

We identified 895 women who had undergone a UI-related surgical procedure during the study period (Fig.6). We excluded women operated with: Burch colposuspension on solely prolapse indication, past pelvic surgery of prolapse and/or incontinence, concomitant prolapse surgery, primary incontinence surgery other than open Burch colposuspension and TVT procedure.

Fig. 6 Flow chart of the study sample (Papers II and III)



Abbreviations: TVT, tension-free vaginal tape.

The final study sample comprised 127 women who received the Burch colposuspension and 621 women who received the TVT procedure as primary surgery for SUI or MUI. We performed the Burch colposuspension as originally described by Tanagho (73), and the TVT procedures were performed as described by Ulmsten (2). All women treated with the TVT procedure received prophylactic antibiotics, and we used surgical kits from Johnson & Johnson.

In Paper I, we restricted the study sample to women who underwent primary UI surgery during the last 5 years of the Burch colposuspension (n = 127, 1994-1999) and the first 5 years of the TVT procedure (n = 180, 1998-2002), in total 307 women.

In Paper II, we excluded 25 women with no follow-up data, thus the final study sample comprised 596 women who underwent a TVT procedure as primary surgery for SUI or stress-dominated MUI in 1998-2012.

In Paper III, we applied the same study population as in Paper II to assess perioperative complications by surgeon's experience. In the assessment of recurrence by surgeon's experience, we restricted the analyses to the three surgeons who had performed >50 primary TVTs; combined, they had performed 494 surgeries.

8.3 Data collection

We made the first draft of the study protocol in 2013 and updated it as necessary. Data collection took place in 2014-2015. The electronic medical records were screened retrospectively and the information transferred to a case report form that was especially designed for the study (Appendix 1). For patients referred for primary UI surgery from neighbouring hospitals (n = 166), the medical records were examined during follow-up at relevant local hospitals in our region (Nordland County) as well.

Data sources included referrals from general practitioners, private gynaecologists, and gynaecologist at local hospitals; discharge summaries from hospitalisations and visits at the outpatient clinic of the gynaecological department as well as other departments; validated questionnaires (from 2002 onwards); forms with data on frequency and

volume of urination that were completed by patients; clinical tests; operative reports; and anaesthesia records. All data was interpreted, systematised, and transferred to the case report form.

The preoperative evaluation comprised a stress test, assessment of bladder emptying, and cystometry. For stress tests in the early period, patients were asked to cough in a supine position with 300 ml of saline in the bladder (122). From 2004 onwards, we also performed a coughing test in an upright position with 300 ml saline in the bladder and a registration of pad weight before and after three forceful coughs and 20 sideway split jumps (123). Furthermore, we performed cystometry in patients with symptoms of OAB. Voiding function was assessed by measurement of residual urine (ml) and uroflowmetry analysis (including description of the shape of the curve and the estimate of maximum flow rate (<15 ml/s or ≥15 ml/s)) (124).

8.3.1 Demographic and pre-, peri-, and postoperative variables

The following preoperative data were included: type of UI (SUI/MUI), age at time of surgery (≤49, 50-59, ≥60 years), parity (0-1, 2, ≥3), menopausal status (premenopausal, perimenopausal, postmenopausal, Paper I only), body mass index, past hysterectomy (total and subtotal) and relevant comorbidities (cardiovascular disease/diabetes (0/1), pulmonary disease (0/1), and neurological disease (0/1)). The following information was collected during the preoperative examination: previous conservative treatment for UI (PFMT and electrical stimulation), uroflowmetry assessments (including the shape of the curve and the estimated maximum flow rate (<15 ml/s or ≥15 ml/s)). In addition, the results from two standardised stress tests (coughing with 300 ml saline in the urinary bladder in supine and/or upright position and/or pad weight before and after three forceful coughs and 20 sideway split jumps) and measurement of residual urine (ml) were included (122) (123). Date and type of UI surgery were also recorded, as were type of perioperative complications, date and type of surgery for perioperative complications, date of first visit for complication symptoms, type of late complication, and date and type of surgery for possible late complications. Finally, date of first visit for recurrence symptoms, date and type of

repeat UI surgery, date and type of urinary symptoms at last visit (including no symptoms), and date of possible prolapse surgery following UI surgery were recorded.

After the collection of the clinical data from 697 TVT procedures performed in 1998-2012, the names of the surgeons were coded in a separate file linked to the identity of the women on whom they operated. Data on surgeons were retrieved from the hospital's patient administrative system. Among the surgeons who performed the 596 primary TVT procedures included in the study sample, 18 had the status of lead surgeon (Table 2). Two surgeons operated continuously and performed more than two-thirds of the primary TVT procedures (surgeon A: n = 190, surgeon B: n = 237), while a third surgeon did 67 primary TVT procedures during the first 5 years of the study period (surgeon C). The remaining 15 surgeons performed 102 primary TVT procedures, varying from one to 32, mainly before 2007, and they comprised surgeon group D. While surgeons A, B, and C were specialists in gynaecology and obstetrics when they started to perform the TVT procedure in 1998, surgeon group D comprised experienced residents approaching their licensure as gynaecologists and experienced senior consultants who had performed the TVT procedure at other hospitals.

Table 2 Annual number of tension-free vaginal tape procedures by surgeon and calendar year

Surgeon	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	Total
A	5	8	8	4	1	7	10	19	11	13	12	26	32	26	8	190
B	1	10	13	14	4	8	13	4	19	20	28	28	30	25	20	237
C	6	19	19	17	6	0	0	0	0	0	0	0	0	0	0	67
E	0	0	0	1	8	8	8	5	2	0	0	0	0	0	0	32
F	0	0	0	2	3	6	0	6	2	0	0	0	0	0	0	19
G	0	0	0	0	1	3	6	1	0	0	0	0	0	0	0	11
H	0	0	0	0	0	0	0	0	0	0	0	0	0	0	8	8
I	4	4	0	0	0	0	0	0	0	0	0	0	0	0	0	8
J	0	5	0	0	0	0	0	0	0	0	0	0	0	0	0	5
K	0	0	4	1	0	0	0	0	0	0	0	0	0	0	0	5
L	0	1	0	2	1	0	0	0	0	0	0	0	0	0	0	4
M	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3
N	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	2
R	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1
Q	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1
S	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
T	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1
V	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1
Total	19	48	44	42	24	32	39	37	35	33	40	54	62	51	36	596

8.4 Definitions

8.4.1 Type of urinary incontinence

The classification of type of incontinence was based on a combination of symptoms documented in medical records, outcome of stress tests and/or urodynamic examinations, and a standardised, validated, short-form UI disease-specific questionnaire used from 2002 onwards (125). We defined SUI as bothersome symptoms of SUI described in the medical record and/or in the standardised questionnaire in combination with a positive stress test. MUI was defined as a combination of a dominant SUI component and UUI defined as a description of bothersome symptoms of involuntary urine leakage after sudden urgency to void in the medical record and/or in the standardised questionnaire. Positive cystometry was not mandatory for a diagnosis.

8.4.2 Recurrence of urinary incontinence

We defined recurrence of UI 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 questionnaire (125); or a positive standardised cough/jump pad stress test (123). Neither de novo UUI in women with pure SUI before UI surgery, nor recurrence of UUI in women with preoperative MUI was defined as recurrence. New evaluation with stress test and/or uroflowmetry analysis was performed according to individual clinical assessment of severity and type of complaints, especially if repeat surgery was an option. As most of the data were based on women's subjective description of symptoms, treatment effectiveness in this study largely reflected subjective cure.

8.4.3 Complications

Apart from voiding dysfunction (VD), different complications occurred in the perioperative period compared to weeks or months later. As most problems regarding

voiding function resolve spontaneously within a few days, we chose not to include need of catheterisation within 1 week of surgery as a complication. However, a few patients reported need of catheterisation several months after surgery. Due to a shorter hospital stay after the introduction of the TVT procedure and the use of antibiotic prophylaxis, it is possible that some urinary infections were diagnosed and treated by general practitioners after discharge, and therefore are not captured in our data. As we expected underreporting of urinary infections and lower incidence of urinary infections among women who received the TVT procedure, we decided not to include uncomplicated urinary infections among perioperative or late complications. Complications are listed and defined more in detail in Table 3.

Table 3 Definition of complications

Type	Paper I	Papers II and III
Perioperative complications		
Bladder injury	Perforation of trocar, tape, or sutures	Perforation by the trocar or by the tape
Early voiding dysfunction/urinary retention	Need of catheterisation for 1 week or more	Need for catheterisation more than 1 week after primary surgery and/or in need of traction and/or surgical correction necessitating cutting of the tape
Bleeding/hematoma	Surgeon's description of significant bleeding intraoperatively and/or clinical significant and/or ultrasonographically identified hematoma of any size	Clinically significant and/or ultrasonographically identified hematoma of any size
Other complications	Anaesthesiological complications, surgical site infections, removal of the tape in those who underwent the tension-free vaginal tape procedure, etc.	Anaesthesiological complications, surgical site infections, removal of the tape in those who underwent the tension-free vaginal tape procedure, etc.
Late complications		
Overactive bladder	De novo urgency or de novo urgency urinary incontinence in women with preoperative stress urinary incontinence	
Late voiding dysfunction	Permanent need of catheterisation	
Tape complications	Symptomatic or asymptomatic erosions, fistulas, and symptoms of dyspareunia and/or chronic pain/discomfort diagnosed three months or later after primary surgery	Symptomatic or asymptomatic erosions, fistulas, and symptoms of dyspareunia and/or chronic pain/discomfort diagnosed three months or later after primary surgery (Paper II only)

8.4.4 Follow-up

All patients who underwent surgery in 1994-2008 were invited to a follow-up visit after 6-12 months. Follow-up included an interview and clinical examination, followed by urodynamics if bothersome symptoms were present. In the interview, the women were asked about their satisfaction with the treatment, and from 2002 onwards the department used a standardised questionnaire including the categories “very satisfied”, “satisfied”, “neither satisfied nor dissatisfied”, “dissatisfied”, and “very dissatisfied”. For patients residing far from our hospital, we performed the interview by phone or by postal questionnaire. From 2009 onwards, the first follow-up was performed by means of a standardised questionnaire by post or phone, and the patients were offered a visit at the outpatient clinic if bothersome symptoms were present.

The department introduced a standardised 3-year follow-up using the validated short-form UI disease-specific questionnaire for women who underwent surgery from 2009 onwards (Appendix 2). All other follow-up data were retrieved from consultations at our outpatient clinic after referral from general practitioners or private gynaecologists. For patients not residing in our hospital’s local catchment area, we retrieved follow-up data from medical records at the local hospitals throughout our region.

Medical records were screened through 1 November 2015.

8.4.5 Main exposure and outcomes

The main exposure, and primary and secondary outcomes are presented in Table 4. Recurrence of SUI was a primary outcome, and due to a shorter average observation time in Papers II and III, we restricted the follow-up to 10 years in these papers.

Table 4 Main exposure, and primary and secondary outcomes

	Paper I	Paper II	Paper III
Main exposure	Surgical procedure (Burch colposuspension, retropubic tension-free vaginal tape)	Indication for surgery (stress urinary incontinence, mixed urinary incontinence)	Surgeon's experience
Primary outcome	Recurrence	Recurrence	Recurrence
Secondary outcomes	Perioperative complications	Urinary retention and other perioperative complications	Urinary retention and other perioperative complications
	Late complications	Late complications	

8.5 Statistical analysis

I performed all statistical analyses, save the analyses of recurrence rates by surgeon's experience in Paper III, and used the Statistical Package for the Social Sciences version 25 (IBM, Armonk, NY, USA).

Analyses of recurrence rates by surgeon's experience in Paper III were performed by a postdoctoral student, Kajsa Møllersen, with MatLab version 2019a.

Statistical significance was set to a 5% level.

The data were analysed with the t-test, Chi-squared test, survival analysis, Cox regression analysis, and binary logistic regression analysis.

The Chi-squared test was applied in the assessment of preoperative data (baseline characteristics, conservative treatment, and clinical examinations), perioperative data (complications, hospital stay), follow-up data, and rates of repeat surgery by study group (Burch group versus TVT group, women with SUI versus MUI, surgeon and surgeon experience group (1-19 ('beginner'), 20-49, and ≥50 primary TVT procedures performed)).

Survival analysis was applied in order to analyse duration of time from the exposure (surgery) to the event of interest (recurrence, late complication, repeat surgery due to recurrence or prolapse). Furthermore, survival analysis (life tables) was applied when estimating cumulative cure rates of TVT, and Cox regression analysis was applied in

the risk factor analysis of recurrence. In the survival and Cox regression analyses, only cases (recurrences, late complications, repeat surgeries due to recurrence or prolapse) occurring/performed within 12 years (Paper I)/10 years (Paper II) of primary surgery were included. In the survival and Cox regression analyses, recurrence of UI was recorded at the date of the first visit for bothersome symptoms following primary surgery (leading to/not leading to repeat UI surgery), or censored at the date of last visit with reported continence in the medical record or the date of repeat surgery due to complication or prolapse, when repeat surgery occurred prior to symptoms of incontinence. In the survival analysis of de novo OAB, the study participants became "cases" at the date of the first visit for bothersome symptoms, or they were censored at the date of the last visit without symptoms of OAB or the date of repeat surgery due to recurrence or prolapse if surgery took place prior to bothersome symptoms. In the survival analysis of prolapse surgery, study participants were recorded at the date of prolapse surgery, or censored at the date of the last visit without prolapse surgery or the date of repeat surgery due to recurrence if it was performed prior to prolapse surgery.

As the department introduced a standardised 3-year follow-up from 2009 onwards, we chose to assess changes in outcomes in three different time periods (1998-2003, 2004-2008, and 2009-2012) in Paper II. We also performed separate analyses of recurrence for the time periods 1998-2008 and 2009-2012 in Paper III.

In order to maintain power in Paper III, we restricted analyses of recurrence to surgeons A, B, and C, as they had all performed >50 surgeries. To investigate whether the recurrence rates decreased as the surgeons gained more experience, we performed a hypothesis test which stated that the recurrence rate is constant and equal to the mean recurrence rate over all surgeries (H_0) or the recurrence rate is a logit function of the number of surgeries performed (H_1). These hypotheses give the probability (p-value) of observing a change in recurrence rate, as the recurrence rate is unaffected by surgeon's experience.

The recurrence rate was estimated using logistic regression, assuming a binomial distribution. 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 five first surgeries in each time period were pooled to avoid the effect of highly variable recurrence rates for a small number of surgeries.

Each patient had a maximum of 12 years (Paper I)/10 years (Papers II and III) of follow-up; all analyses were stopped for any outcome thereafter due to few observations.

8.6 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, have reviewed and approved the study protocol (Appendix 3).

9 Main results

9.1 Primary outcome - recurrence

The 12-year cumulative recurrence rate of UI after primary surgery among women with preoperative SUI was significantly higher in the Burch group ($p = 0.03$) than in the TVT group, with no difference for women with MUI ($p = 0.74$) (Paper I).

Within 10 years of surgery, women with MUI had a significant, higher recurrence rate compared to those with SUI (25.2% versus 13.8%; $p = 0.001$). No other risk factors predicted recurrence (age, overweight, parity, previous hysterectomy, comorbidities, or UR at primary surgery) (Paper II).

Only three surgeons had enough surgeries for the assessment of performance on effectiveness. In 1998-2008, when surgeons were building competence, surgeons A (p

= 0.24) and C (p = 0.04) had a decreasing slope for recurrence, while surgeon B had a nearly flat slope (p = 0.71) (Paper III).

Due to better surveillance, the overall and individual recurrence rates nearly doubled from 1998-2008 to 2009-2012. In the latter period, the recurrence rate among patients of surgeon A was 19.6% (based on procedures 99 through 190) and 30.1% for surgeon B (based on procedures 135 through 237, p = 0.09) (Paper III).

In 2009-2012, recurrence occurred more often among patients with MUI in the TVT group (odds ratio 2.4, 95% confidence interval 1.2-4.9) compared to those who had SUI as indication for surgery (odds ratio 1.5, 95% confidence interval 0.7-2.9). We found the same differences in treatment effectiveness between surgeons in women with MUI and SUI (Paper III).

The recurrence curves by increasing number of surgeries indicated that each surgeon had an individual performance level, and we found no evidence of any statistically significant effect of better performance in surgeons who had performed a large number of TVT procedures (Paper III).

9.2 Secondary outcomes

9.2.1 Perioperative complications

We found similar overall rates of perioperative complications and no significant differences in the prevalence of bladder injury and bleeding/hematoma between women in the Burch and TVT groups (Paper I). We found stable rates of bleeding/hematoma, bladder perforation, and other complications by indication for surgery and across time periods. We explained the higher number of bladder perforations in 1998-2003 (n = 7) compared to 2009-2012 (n = 1) (p <0.04) by surgeon's experience (Paper II). There were no significant differences in the total rates of perioperative complications by category of surgeon's experience with the TVT procedure. However, the risk of bladder perforation decreased significantly when the

surgeon had performed ≥50 primary TVT procedures compared to fewer surgeries (p = 0.03) (Paper III).

9.2.2 Voiding dysfunction/urinary retention

In Paper I, we found similar rates of early VD in the Burch (7.9%) and TVT (6.1%) groups. Only two patients had late VD in the form of permanent need of catheterisation, both of whom were in the TVT group. There were similar rates of UR among women with SUI (5.6%) and MUI (4.4%) in Paper II. In Paper III, UR was more often diagnosed when the surgeon had performed 19 or fewer primary TVT procedures compared to a higher volume of surgeries (p = 0.06).

9.2.3 Late complications

In Paper I, the cumulative rates of de novo OAB in the Burch and TVT groups were similar (p = 0.86). Nine patients had tape or suture material complications: one (0.8%) in the Burch group and eight (4.4%) in the TVT group (p = 0.06). Only two patients had late VD in form of need of catheterisation, both of whom were in the TVT group.

In Paper II, 17 (2.9%) women had late tape complications within 10 years of primary surgery: 12 with erosion, three with pain, and two with fistula (one vesico- and one urethro-vaginal).

10 Discussion

10.1 Primary outcome - recurrence

Paper I revealed a significant, higher cure rate up to 12 years after primary surgery for the TVT procedure compared to the Burch colposuspension in women with preoperative SUI. Ogah's meta-analysis on randomised controlled trials reported no difference in effectiveness between the Burch colposuspension and the TVT procedure at 5-year follow-up (92). However, our overall 74.7% (95% confidence interval 66.5-82.9%) subjective cumulative cure rate at 12-year follow-up in the TVT group is in line with other reports (94) (95) (98) (126) (127) (128). Our study included only open Burch colposuspension, but even in newer publications comparing MUS surgery and laparoscopic Burch colposuspension, the superiority of the retropubic TVT procedure over the Burch colposuspension seemed to be confirmed (129).

Very few studies have assessed the long-term effectiveness of the Burch colposuspension and stratified data for SUI and MUI. Lose et al. found objective cure rates of SUI symptoms after the Burch colposuspension of 94% and 75% in women with SUI and MUI, respectively (130), whereas Eriksen found corresponding rates of 71% and 57% 5 years after Burch colposuspension (131). Regardless of the procedure, women with MUI have a lower chance for cure than women with SUI. We did not find any significant difference in effectiveness between the Burch colposuspension and the TVT procedure in women with MUI. Several factors may contribute to the explanation of this result. The TVT procedure may compensate for the laxity of the anterior vaginal wall and the pubourethral ligaments by providing support for the mid-urethra, but not for more serious neuromuscular impairments that could give rise to UUI symptoms in these women, according to Brucker's "common pathway" theory (51). Furthermore, subjective and objective cure after UI surgery are not the same, especially not in women with MUI, where both SUI and UUI symptoms, as well as other factors, contribute to the patient's satisfaction at follow-up.

Furthermore, MUI was the only factor that predicted recurrence within 10 years of primary TVT surgery. The covariates age, overweight, parity, comorbidities, and UR

had no impact on the effectiveness of TVT surgery. Women with MUI had a significantly lower satisfaction rate compared to those with SUI at the first follow-up visit.

The overall cumulative subjective cure rate at 10-year follow-up (69%) was somewhat lower than results from comparable studies (75-80%) (97) (101). When we stratified our results into pure SUI and MUI, the cumulative subjective cure rate at 10-year follow-up was 74% for women with pure SUI (95% confidence interval 66-82%) and 58% (95% confidence interval 48-68%) for those with pure MUI. Thus the long-term SUI cure rate was lower in our study than in other studies (77-90%) (93) (95), while the women with MUI had a higher cumulative subjective cure rate compared to other studies (37-55%) (94) (96).

In line with other reports, we found that the effect of surgery showed a higher decrease over time in women with MUI than in those with SUI (132). As we applied survival analyses in our study, we expected the estimates of cure rates to be lower, as recurrence was estimated only among those patients that remained in the study at the different time intervals. This differs significantly from most other studies, in which time and number of patients actually completing follow-up were not taken into account when estimating recurrence; instead the total number of patients who had surgery was used as the denominator (93) (95) (102) (133).

Only a few published studies have looked at perioperative complications as an independent risk factor for recurrence (101) (102). One explanation they offered for this association is that perioperative complications may lead to injury of the complex interplay between connective tissue, muscles, and innervation, all of which are essential for the support and functioning of the mid-urethra, which in turn ensures stress continence (34). However, as these complex mechanisms are already damaged, disturbed function of the tape itself may be a more plausible explanation. Hematoma, bleeding, and surgical site infection may deteriorate the optimal function of the tape. This is consistent with our findings that UR was not associated with a reduced cure rate, as we assumed that the mechanism of UR was too much tightening of the tape without traumatising the tissue. Intense or prolonged inflammation and immature collagen synthesis are also factors that have been hypothesised to disturb the optimal

biocompatibility and clinical performance of the mesh (134) (135). Our study showed a possible association between recurrence and non-UR perioperative complications. However, due to the low number of cases with such complications and inconsistency between women with SUI and MUI, this finding has to be interpreted with caution.

In studies that reported an association between overweight, advanced age, and lower cure rates, the results may have been influenced by the inclusion of women with past UI surgery and/or past or concomitant prolapse surgery (95) (101), which is not the case in our study.

In Paper III, we did not find any statistically significant association between surgeon's experience and risk of recurrence in two of the three surgeons during a maximum of 10 years of follow-up. However, for surgeon A, there was a tendency towards a declining rate of recurrence with increasing number of TVT procedures performed in the period 1998-2008. We found a statistically significant reduction in recurrence rate by number of TVT operations performed only for surgeon C, who was by far the most experienced gynaecologist in the department. During his early learning phase of about 30 primary TVT procedures, he performed a higher proportion of the procedures not 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. Thus, there may be a weak association between recurrence rate and surgeon's experience up to 67 primary TVTs performed, but this result has to be interpreted with caution due to the inconsistency between the three surgeons.

We found that recurrence rates by surgeon varied between 10.2% and 30.1%. However, this apparently wide range of variation is most likely due to both actual individual variations between surgeons and differences in follow-up across time periods. In our opinion, bias due to a different case-mix across surgeons is unlikely, as higher age, low parity, and previous hysterectomy are inconsistently reported, or not reported at all, as risk factors for recurrence (136). The recurrence curves by increasing number of surgeries indicate that each surgeon has an individual

performance level, but we have no evidence of any statistically significant effect of learning beyond 67 TVT procedures performed.

We found an increase in recurrence rates after the introduction of a systematic 3-year follow-up among women who received surgical treatment from 2009 onwards (Papers II and III). Before 2009, recurrences occurring after the first follow-up were diagnosed after referral from general practitioners or private gynaecologists. Systematic follow-up allowed us to also identify recurrences that were not so bothersome that the women sought medical advice. However, the increase in recurrence rates was significant only for women with MUI. There are some epidemiological differences between women with SUI and MUI, as those with MUI are older, more often overweight, and more often have comorbidities. However, after adjusting for these risk factors, the increase in recurrence rates from the early to the late time period remained, including in analyses stratified for the two doctors performing surgery in both time periods. This finding confirms that MUI is an important risk factor for recurrence.

10.2 Secondary outcomes

10.2.1 Comparison of the Burch colposuspension and the tension-free vaginal tape procedure

Ogah's meta-analysis comprised six randomised controlled trials that compared the Burch colposuspension and the TVT procedure and reported fewer perioperative complications, less early VD, shorter operative time, and shorter hospital stay. However, the meta-analysis identified significantly more bladder perforations in the TVT group than the Burch group (92). Our study did not find any significant difference in the number of perioperative complications, including bladder perforations and early VD (catheterisation >1 week). However, women with perioperative complications in the Burch group had a significantly longer hospital stay, probably due to a combination of more serious complications, a significantly higher rate of urinary infections ($p < 0.01$), and a gradual change in handling of early VD from prolonged hospital stay with permanent catheter to instruction in self-catheterisation before discharge from hospital. Furthermore, the traditional way of

handling surgical patients, with a gradual shift from inpatient to outpatient surgery, took place in parallel with the introduction of the TVT procedure.

Due to differences in definitions, selection of patients, and completeness and length of follow-up, rates of late complications differ between studies. Studies on long-term follow-up after TVT have found rates of de novo UUI to vary between 4% and 17%, and rates of VD between 23% and 32% (95) (98) (106) (120) (126) (137) (138). For the Burch group, reported rates of de novo UUI varied between 15% and 41%, and rates of VD between 2% and 36% at long-term follow-up (76) (77) (78) (79). So far, however, there are few studies with 12-year follow-up data. In our study, the cumulative rates of OAB symptoms at 12 years indicate that late complications may develop many years after surgery. We did not find any significant difference in the rate of OAB between the two surgical methods. This finding fits with the knowledge that the prevalence of urgency, UUI, and detrusor underactivity increase with age, and hence contribute to some long-term problems regardless of UI surgery (1) (139). However, and not surprisingly, the rate of complications related to tape and suture material was higher in the TVT group than the Burch group.

10.2.2 Safety of the tension-free vaginal tape procedure

Most studies assessing UR show that the need for catheterisation resolves spontaneously within 1 week of surgery, leading to large variations in published rates of women with postoperative UR (105) (117) (140). In our study, only nine patients (1.5%) reported serious problems with bladder emptying more than 3 months after surgery. Other studies that assessed UR after TVT have reported a rate of *"very disturbing UR"* of 1.2% more than 1 year after TVT (117) (140) (141).

Pain and discomfort in the pubic region have been reported in 7.5% of women after TVT surgery (142). This discomfort may resolve after some time (143). Sexual dysfunction following the TVT procedure is common. Both dyspareunia and leakage during intercourse have an impact on sexual function. According to Tunuguntla et al., a significant number of women report dyspareunia after sling surgery for UI, whereas some patients report improvement in overall sexual function due to relief of leakage

during intercourse (144). This is in line with Serati et al., who reported that 10-27% of women with UI report coital UI. They claim that coital UI during penetration is associated with SUI and has an 80% chance of being cured by surgery (145). Furthermore, Lindquist and Glavind reported an improvement in sexual function at follow-up nearly 5 years after TVT (143).

Only a small proportion of our TVT group reported a negative impact of the tape on sexual function. However, neither the rate of intercourse-related tape symptoms nor the relief of leakage during intercourse was systematically examined in our follow-up study, and thus may be underreported.

In our study, 2.9% of patients experienced long-term tape-related problems. Of these, less than 50% required repeat UI surgery. Only two patients needed major surgery: one due to fistula, and one with resection of the tape due to pain. This is in accordance with most other long-term studies that showed an incidence of tape complications ranging from 0% to 4.2% (98) (105) (106) (107) (108). The largest study to-date on late tape-related complications is the retrospective cohort study by Keltie et al. (146), which assessed 41,880 primary TVT surgeries in England between 2007 and 2015. In that study, the rate of surgery due to late tape complications was 2.7% in form of removal and 1.0% in the form of repair. However, data on removals was not stratified by major and minor surgeries, as removal may comprise both total removal and partial resection of the mesh. In our study, the number of major surgeries comprised only a small proportion of the surgeries needed due to complications.

10.2.3 Surgeon's experience and safety of the tension-free vaginal tape procedure

Several mechanisms can provide an explanation for complications that may arise in operations performed by less experienced surgeons. Inappropriate placement of the tape in the vaginal wall, too superficial or too deep, may increase the risk of erosion of the vaginal mucosa and perforation of the urethra, respectively. As the tape should provide support to the mid-urethra, placement of the tape too far distally or too far proximally may have an impact on treatment effectiveness. Inappropriate direction of the introducer device during placement of the tape into the retropubic space may

increase the risk of bladder perforation, and inappropriate tightening of the tape may increase the risk of either UR or reduced treatment effectiveness.

We did not find any statistically significant differences in the overall rate of perioperative complications by surgeon's experience. However, surgeons who had performed <50 TVT procedures had a significantly higher risk of bladder perforation compared to surgeons who had performed >50 procedures. However, we found a higher risk of bladder perforation in the middle category of surgeon's experience with TVT procedures (20-49; 5.8%) compared to the lowest category ('beginner', 1-19; 2.7%). This is probably an effect of the assistance from an experienced surgeon giving supervision in the 'beginner' phase. In Hilton's study (111), which assessed the learning phases of 16 surgeons who performed 1568 TVT procedures in total, the number of TVT procedures necessary to achieve a rate of bladder perforation ≤5% varied between 20 and 80. It is assumed that there is hardly any harmful effect of a bladder perforation, as these injuries are detected at the cystoscopy, which is always performed followed by withdrawal and re-introduction of the device on the same side as the perforation.

While Duckett et al. found no difference in UR rate between groups of surgeons with different levels of experience (117), Lebret et al. reported a significant, increased risk of UR during the first 50 TVT procedures compared to the subsequent 50 (114). We found a borderline significant increased risk of UR during the first 19 TVT procedures compared to the procedures thereafter, which may indicate that the learning phase comprises the first 20-50 TVTs for this particular outcome. These results emphasize both individual variations in the length of the learning phase (111), as well as disparities among surgeons across outcomes.

Three studies have reported evidence of an association between higher level of experience and lower risk of perioperative complications (109) (110) (119). However, we did not find any difference in the overall rate of perioperative complications by surgeon's experience ($p = 0.36$).

10.3 Strengths and limitations

When planning this study in 2012 and beyond, the only feasible study design was a retrospective case-series approach. As the Burch colposuspension is hardly performed anymore, a case-series design is the only viable method for comparison. We were able to conduct a comparison between the Burch colposuspension and the TVT procedure in an overlapping time period.

The strength of our study is the fact that all surgeries were performed in one department by its regular doctors. Thus we had consistent practices in the selection of patients, performance of surgery, and follow-up.

In order to avoid any confounding effect of earlier and concomitant pelvic floor surgery on effectiveness, we included only patients who underwent primary UI surgery without previous or concomitant prolapse surgery. In our analyses of recurrence, patients were censored at the date of surgery due to both prolapse and complications in order to avoid interpretation problems for outcomes occurring after these interventions.

Very few studies that have reported on effectiveness as a function of surgeon's experience have a sufficiently long follow-up time or a large enough sample size to find an effect (102) (105) (113) (118). Conversely, we had a large sample size, the proportion of patients with follow-up data was high, and the follow-up time was long enough for a valid comparison.

The most important weakness of this study is its retrospective design. Data were not collected systematically as in prospective studies. A prospective trial would have a protocol with a schedule for follow-up and systematic registration of data. In this retrospective study, our data relied upon stringent documentation in medical records. Grading of symptoms and complaints were based on the patient's subjective description, and how the doctor perceived these complaints and recorded them in the medical record. It is my impression that the quality of this type of documentation has improved over the years. Regarding data dependent on more complex clinical

judgement, for example classifying UI as either SUI or MUI, or diagnosing recurrence, the assessments of the doctors who offered women surgical treatment, the surgeon who performed the procedure, and the doctor who performed the follow-up were weighted most heavily. However, when I transferred these data to the case report form made for this particular study, I had to make the final decision based on the information in the medical record. When we planned this study in 2012-2013, we found it too time-consuming to involve two reviewers in the transfer for data from medical records to case report forms. We could have created a panel of two to three urogynaecologists to assist in cases where I found it difficult to settle on any outcome, for example recurrence or erosion, but we did not include such a back-up when we wrote the protocol.

We have systematic follow-up data from outpatient clinics 6-12 months after surgery for a high proportion of patients. From 2002 onwards, the documentation of symptoms was more systematic, as we applied a validated questionnaire introduced by the Norwegian Incontinence Registry both at preoperative counselling and at 6-12 month follow-up. For patients who underwent surgery from 2009 onwards, we introduced a systematic 3-year follow-up with a validated questionnaire. However, much of the data in our study are from referrals made by general practitioners and private gynaecologists of women who sought medical advice due to bothersome symptoms.

Thus, we have to take into account reporting bias across time periods due to changes in quality, methods, and frequency of follow-up. There is likely a relative underreporting of recurrence in the early compared to the late time periods. As we found a higher recurrence rate in the Burch group, who had their operation in the earliest time period (1994-1999), this bias will not change our main conclusions in Paper I. For the same reason, we performed separate analyses of recurrence for three and two time periods, respectively, in Papers II and III.

There are some other possible causes of reporting bias across time periods. A larger proportion of women were below 50 years of age in the period 2009-2012 (47.8%) compared to 1998-2008 (40.2%), and a younger population may have higher expectations of cure after surgery and a lower threshold for seeking medical advice. There was also an increase in the proportion of women who resided in our hospital's

local catchment area, from 69.2% in 1998-2008 to 85.7% in 2009-2012. A higher proportion of patients living the catchment area and a more standardised follow-up procedure in the last period may give more valid results which reflect a "true" quality of care regarding all outcomes in this period compared to the years before 2009.

There is a possible loss to follow-up among women who had repeat surgery at hospitals in other parts of Norway, as new legislation passed in 2001 gave people the right to choose their healthcare provider. However, a previous report stated that Norwegian patients have high loyalty to their local hospitals, especially in the rural areas in northern and western Norway. Thus the number of patients lost to hospitals outside of our catchment is likely very low (147).

11 Conclusions and implications

The aims of this study were to explore the shift from the Burch colposuspension to the retropubic TVT procedure with respect to long-term clinical outcomes. Furthermore, we wanted to explore the safety and effectiveness of the procedures, and try to identify any risk factors for recurrence after the TVT procedure. The last paper was an assessment of surgeon's experience and clinical outcomes. The same study population was applied for all three papers.

At follow-up 12 years after primary surgery, the effectiveness of the retropubic TVT procedure was superior to that of the Burch colposuspension in women with SUI. There were no significant differences in the rates of perioperative and late complications, but the Burch group had a 3-fold risk of later prolapse surgery 12 years after UI surgery, both for women with SUI and MUI.

Compared to the Burch colposuspension, the TVT procedure represented a significant improvement in the surgical treatment of women with pure SUI. We did not find any difference in recurrence rates or complications between women with MUI in the Burch and TVT groups. Despite no significant improvement in effectiveness for women with MUI, the TVT procedure is still a better option for this group, as this method is minimally invasive, and has a lower rate of later prolapse surgery and repeat UI

surgery compared to the Burch colposuspension. However, tape-related problems apply only to the TVT procedure.

Women with MUI comprised one-third of our study sample and were more often dissatisfied after surgery than women with SUI. At preoperative counselling it is important to give realistic information to this group about outcomes after the TVT procedure.

In some countries, reports of possible harmful effects of vaginal implants has caused public concern about the safety of the TVT procedure (103). However, in our study the rate of major repeat surgery due to late complications after primary TVT operation was very low (0.3%).

Our data suggest that there is a learning phase for TVT surgeons, and that experience is associated with bladder injury and UR, and to a lesser extent with effectiveness. Furthermore, we found individual variations in outcomes between surgeons, and the length of the learning phase may vary across surgeons on type of outcome. These factors have to be taken into account at teaching hospitals when educating residents and young surgeons in new techniques. Thus, in order to avoid complications and recurrences, it is important that surgical skills be carefully evaluated before 'beginners' are allowed to perform TVT procedures on their own.

Monitoring of long-term outcomes is time-consuming, but highly necessary, as it represents important feedback for surgeons, the hospital, and society. This emphasizes the importance of high-quality national registries like The Norwegian Female Incontinence Registry, where coverage is critical for validity of the performances across hospitals.

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13 Papers

14 Appendix

14.1 Appendix 1: Case Report Form

14.2 Appendix 2: Questionnaire from The Norwegian Female Incontinence Registry

14.3 Appendix 3: Ethical approval

Paper I

Int Urogynecol J
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ORIGINAL ARTICLE

Long-term clinical outcomes with the retropubic tension-free vaginal tape (TVT) procedure compared to Burch colposuspension for correcting stress urinary incontinence (SUI)

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Abstract
Introduction and hypothesis The retropubic tension-free vaginal tape (TVT) procedure replaced Burch colposuspension as the primary surgical method for stress urinary incontinence (SUI) and mixed urinary incontinence (MUI) in women in our department in 1998. In this study we compared the short-term and long-term clinical outcomes of these surgical procedures.
Methods Using a case series design, we compared the last 5 years of the Burch procedure (n = 127, 1994–1999) with the first 5 years of the retropubic TVT procedure (n = 180, 1998–2002). Information from the medical records was transferred to a case report form comprising data on perioperative and long-term complications as well as recurrence of UI, defined as bothersome UI or UI in need of repeat surgery. Other endpoints were rates of perioperative and late complications and the rates of prolapse surgery after primary surgery. The data were analyzed with the chi-squared and t tests and survival analysis using SPSS.
Results The cumulative recurrence rate of SUI in women with preoperative SUI was significantly higher after the Burch procedure, but no difference was observed in women with MUI. There were no significant differences in rates of perioperative and late complications. At 12 years there was a significant increase in rates of repeat surgery for incontinence and prolapse in women after the Burch procedure.
Conclusions The long-term efficacy of TVT surgery was superior to that of Burch colposuspension in women with SUI. In addition, the rate of late prolapse surgery was significantly higher after the Burch procedure.

Keywords Burch colposuspension · Complications · Long-term results · Midurethral slings · Mixed urinary incontinence · Stress urinary incontinence

The abstract of this work was presented as a poster presentation at the 40th Nordic Congress of Obstetrics and Gynecology, Helsinki, 12–15 June 2016, and at the Annual Assembly of the Norwegian Association of Gynecology and Obstetrics, Lillestrøm, 26–28 October 2016.

Key message TVT is superior to Burch colposuspension for treatment of SUI.

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Introduction

Until the late 1990s Burch colposuspension was considered the gold standard in the surgical treatment of stress urinary incontinence (SUI) and mixed urinary incontinence (MUI) in women [1]. The surgery is an open procedure requiring general or regional anesthesia, and involves a hospital stay of 7–10 days followed by sick leave of 3–4 weeks. In 1995 Ulmsten et al. described the retropubic tension-free vaginal tape (TVT) as a new surgical treatment for female urinary incontinence (UI) [2]. The TVT operation is an outpatient procedure performed under local anesthesia, requiring sick

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leave of 10–14 days. The first reported case series showed high safety and efficacy at 2 years [3–5]. Within a few years, the TVT procedure replaced Burch colposuspension as the preferred surgical method worldwide.

Five case series of Burch procedures with more than 5 years follow-up and two with more than 10 years follow-up have shown subjective cure rates between 44% and 80%, and objective cure rates between 67% and 82%. However, efficacy appears to decrease with time [6–10]. Until 2005, neither randomized controlled trials (RCTs) nor meta-analyses had revealed any significant differences in efficacy at 5 years in favor of the TVT procedure [11, 12]. The first study showing high efficacy of the TVT procedure with a long-term perspective (>10 years) was published in 2008 [13], and later several studies have shown similar results [14–18].

The safety of suburethral sling surgery has been questioned in recent years. An editorial from the Cochrane Library in June 2015 summarized 20 years of experience of surgical treatment of UI in women. The authors questioned the fact that only a few of the 35 trials including long-term follow-up showed leakage and adverse effects at 5 years or later. The editorial also referred to a report from the UK Medicines and Healthcare Products Regulatory Agency (MHRA) that concluded: "Women have reported serious and debilitating problems following surgical treatment for SUI vaginal tape implants." The authors thus questioned the safety of vaginal tape implants and requested more evidence about safety with new methods in comparison with older abandoned methods [19].

The aim of this study was to compare short-term and long-term clinical outcomes in women undergoing Burch colposuspension and the retropubic TVT procedure.

Materials and methods

The Department of Gynecology at Nordland Hospital, Bodø, Norway, introduced the TVT procedure in 1998. Within a year, TVT had replaced Burch colposuspension as the preferred method. We identified all patients undergoing UI surgery during the period 1994–2012. A total of 896 procedures had been performed. Patients who had undergone earlier or concomitant prolapse surgery (n = 35), earlier UI surgery (n = 52) and surgical procedures for UI other than open Burch colposuspension or retropubic TVT surgery (n = 58, including 45 laparoscopically performed Burch operations) were excluded from the study. For the present analysis the study population was restricted to the last 5 years of Burch colposuspension (n = 127, 1994–1999) and the first 5 years of TVT surgery (n = 180, 1998–2002). Thus the study included a total of 307 women who had undergone primary UI surgery.

Electronic medical records were screened in retrospect and the information was transferred to a case report form especially designed for the study. For patients referred from neighboring hospitals (n = 147), the medical records at all hospitals in Nordland County were examined. The following preoperative data were included: type of UI (SUI/MUI), age (≤49, 50–59, ≥60 years), parity (0, 1, 2, 3+), menopausal status, body mass index (BMI), earlier hysterectomy and relevant comorbidities. From the preoperative examination prior to primary and repeat surgery, the following information was collected: previous conservative treatment for UI including pelvic floor muscle training (PFMT) and electrostimulation, and urodynamic examinations such as cystometry and uroflowmetry assessments with description of the form of the curve and an estimate of maximum flow rate (less than or more than15 ml/s). In addition, the results of a standardized stress test (coughing during gynecological examination with 300 ml saline in the bladder) and measurement of residual urine were included [20].

The type of incontinence was classified on the basis of a combination of data on symptoms as documented in the medical record, and outcomes of stress tests and/or urodynamic examinations. Also recorded were the date and type of surgery, type of perioperative complications, date and type of surgery for perioperative complications, date of the first visit for symptoms of complications and type of late complications, date of the first visit for symptoms of recurrence and date and type of surgery for possible late complications, date and type of repeat UI surgery, date and type of urinary symptoms at the last visit (including no symptoms), and date of possible prolapse surgery following UI surgery.

Perioperative complications included bladder injury (defined as perforation of trocar, tape or sutures), early voiding dysfunction (VD, defined as the need for catheterization for 1 week or more), bleeding/hematoma (bleeding defined as surgeon's description of significant bleeding intraoperatively, and hematoma as clinically or ultrasonographically identified hematoma of any size), urinary infections and other complications. Recurrence of UI was defined as the presence of any bothersome symptoms of SUI documented in the medical record and/or identified by standardized stress tests and urodynamic examinations on follow-up. Late complications were divided into symptoms of overactive bladder (OAB), late VD, tape complications, and others. OAB was defined as de novo urgency or, in women with preoperative SUI, as de novo urgency UI. Late VD was defined as the permanent need for catheterization. Tape complications were defined as erosion with

Table 1 Characteristics of the study population according to the surgical procedure performed

Characteristic	No. (%) of patients		*p* value[a]
	Burch colposuspension (*N* = 127)	Tension-free vaginal tape (*N* = 180)	
Age (years)			
25–49	44 (34.6)	65 (36.1)	0.10
50–59	51 (40.2)	53 (29.4)	
60–93	32 (25.2)	62 (34.4)	
Body mass index (kg/m^2)			
Missing	7 (5.5)	7 (3.9)	0.36
17.21–24.99	45 (35.4)	57 (31.7)	
25.0–29.99	60 (47.2)	84 (46.7)	
30.00–37.80	15 (11.8)	32 (17.8)	
Parity			
0/1	10 (7.9)	26 (14.4)	0.12
2	38 (29.9)	60 (33.3)	
3+	79 (62.2)	94 (52.2)	
Menopausal status			
Premenopausal	52 (40.9)	64 (35.6)	0.49
Perimenopausal	13 (10.2)	25 (13.9)	
Postmenopausal	62 (48.8)	91 (50.6)	
Hysterectomy (yes)	12 (9.4)	20 (11.1)	0.64
Comorbidity			
Cardiovascular (yes)	28 (22.0)	35 (19.4)	0.58
Pulmonary (yes)	9 (7.1)	22 (12.2)	0.14
Neurological (yes)	11 (8.7)	21 (11.7)	0.40
Type of incontinence			
Mixed	32 (25.2)	55 (30.6)	0.31
Stress	95 (74.8)	125 (69.4)	

[a] Pearson chi-squared test

symptoms or erosion without symptoms diagnosed accidentally, fistulas, chronic pain/discomfort or dyspareunia without any other obvious explanation. Information about recurrent urinary infection without any other complaints was not considered a late complication.

Statistical analysis

The data were analyzed with the chi-squared and *t* tests and survival analysis. In all the analyses only recurrences, late complications, repeat incontinence surgery and prolapse surgery occurring/performed within 12 years of primary surgery were included. In the survival analysis, the recurrence of UI was recorded at the date of the first visit for bothersome symptoms following primary surgery (leading to/not leading to repeat surgery), or censored at the date of the last visit at which continence was documented in the medical record, or at the date of prolapse surgery, when prolapse surgery was performed prior to the occurrence of incontinence symptoms. In the survival analysis of de novo OAB, the study participants became "cases" at the date of the first visit for bothersome symptoms, or were censored at the date of the last visit at which they were free of symptoms of OAB, or at the date of repeat incontinence surgery/prolapse surgery, if surgery took place prior to the occurrence of bothersome symptoms. In the survival analysis of prolapse surgery, the study participants were recorded at the date of prolapse surgery, or censored at the date of the last visit without prolapse surgery, or at the date of repeat incontinence surgery, if repeat incontinence surgery was performed prior to prolapse surgery.

The Ethics Committee for Medical and Health Research, North Norway, Tromsø, and the Patient Ombudsman, Nordland Hospital, Bodø, reviewed the study protocol.

Results

There were no differences in baseline characteristics between the Burch group and the TVT group (Table 1). The mean ages of the women in the Burch group and the TVT group were 54.5 years (SD 11.5) and 55.2 years (SD 12.1; $p = 0.63$), respectively, and their mean parities were 3.0 (SD 1.2) and 2.6 (SD 1.2; $p < 0.01$), respectively. With regard to preoperative conservative treatment, 66.9% of the women (85/127) in the Burch group and 68.3% (123/180) of those in the TVT group ($p = 0.80$) had performed PFMT, electrostimulation or

Table 2 Immediate perioperative and postoperative major complications according to the surgical procedure performed

Complication	No. (%) of patients		*p* value[a]
	Burch colposuspension (*N* = 127)	Tension-free vaginal tape (*N* = 180)	
Voiding dysfunction	10 (7.9)	11 (6.1)	0.55
Bladder perf./injury	4 (3.1)	5 (2.8)	0.85
Bleeding/hematoma	3 (2.4)	2 (1.1)	0.39
Other[b]	4 (3.1)	1 (0.6)	0.08
Total[c]	20 (15.7)	19 (10.6)	0.18

[a] Pearson chi-squared test

[b] Uncomplicated urinary infection without any other complications not included. There were 23 urinary infections in the Burch group and one in the TVT group

[c] Number of patients with one or more perioperative complications

both prior to primary surgery. The medical records showed a positive standardized stress test in 78.0% (99/127) of women in the Burch group and in 94.4% (170/180) of women in the TVT group ($p < 0.001$). Urodynamic examinations including uroflowmetry and/or cystometry, in addition to clinical evaluation with stress tests and measurement of residual volumes, were performed in 120 women in the Burch group (94.5%) and in 178 women in the TVT group (98.9%; $p = 0.002$).

There were no significant differences in total rates of early complications (Table 2). The frequencies of early VD, bladder injury and bleeding/hematoma were similar, as well as the rates of reoperation due to early complications in the Burch group and the TVT group (3.1% and 2.2%, respectively; $p = 0.62$). Among the patients with bladder injury, two had the tape removed intraoperatively and later underwent repeat TVT surgery, and thus were included in the analysis of repeat incontinence surgery. Of patients with early VD, 11 reported a permanent problem with bladder emptying of any degree, 3.1% (4/127) in the Burch group and 3.9% (7/180) in the TVT group ($p = 0.73$), and of these seven patients in the TVT group, two needed permanent catheterization.

All surgical procedures were performed on an inpatient basis. The mean postoperative hospital stay was 6.3 days in the Burch group (range 3–22 days), and 2.2 days in the TVT group (range 0–15 days; $p < 0.01$). The postoperative hospital stay was protracted (>7 days) in 19.7% of patients in the Burch group and in 4.4% of patients in the TVT group ($p < 0.01$). No further follow-up was performed after the first visit in 20 patients (15.8%) in the Burch group and in 22 patients (12.2%) in the TVT group ($p < 0.40$). The mean follow-up time (within 12 years) in the Burch group ($n = 127$) was 85 months (range 1–144 months) and in the TVT-group ($n = 180$) was 84 months (range 1–144 months; $p = 0.86$). Within 12 years, 39 women in the Burch group and 32 women in the TVT group were diagnosed with recurrent UI. Table 3 shows the number of cumulative events. The overall cumulative recurrence rate of UI up to 12 years after primary surgery among women with preoperative SUI was significantly higher in the Burch group (Fig. 1; $p = 0.03$, Gehan test for survival), with no difference among women operated on for MUI ($p = 0.74$, Gehan test for survival).

Overall rates of repeat UI surgery (among women with recurrence within 12 years) were significantly different between the groups with 11.0% in the Burch group (14/127) and 1.7% in the TVT group (3/180; $p < 0.001$). Among women with recurrence, 33% (14/39) in the Burch group and 9% (3/32; $p = 0.02$) in the TVT group had repeat surgery. The time from recurrence to repeat surgery varied from 1 to 136 months, with more than half of the procedures performed within 6 months of recurrence (9/17). After TVT surgery was established as the preferred method, 11 of 12 repeat procedures were TVT procedures.

The cumulative numbers of women diagnosed with OAB up to 12 years after primary surgery are also shown in Table 3. There was no difference in cumulative rates of de novo OAB between the Burch and TVT groups ($p = 0.86$, Gehan test for survival). Only two patients had late VD in the form of the need for catheterization, both in the TVT group. Nine patients had tape or suture material complications, one (0.8%) in the Burch group and eight (4.4%) in the TVT group ($p = 0.06$). In total, 11 patients required surgery due to late complications, two (1.6%) in the Burch group due to a postoperative hernia, and nine (5.0%) in the TVT group ($p = 0.11$). Of these nine women in the TVT group requiring surgery, five had tape erosion and four had VD where cutting of the tape was necessary.

The cumulative numbers of patients undergoing prolapse surgery up to 12 years after primary surgery are also shown in Table 3. The cumulative rates of patients undergoing prolapse surgery up to 12 years after primary surgery were significantly higher in the Burch group ($p < 0.01$, Gehan test for survival; Fig. 2). However, there were no differences between the indications for primary surgery and subsequent prolapse surgery in either group. By 12 years after primary surgery, prolapse

Table 3 Numbers of recurrent urinary incontinence events, women with overactive bladder and women undergoing prolapse surgery, The numbers shown are cumulative numbers up to 12 years after the primary surgical procedure. The numbers of censored women and women without outcomes listed at 12 years are also shown

	Recurrent urinary incontinence		Overactive bladder		Prolapse surgery	
	Burch colposuspension ($N = 127$)	TVT ($N = 180$)	Burch colposuspension ($N = 95$)	TVT ($N = 125$)	Burch colposuspension ($N = 127$)	TVT ($N = 180$)
≤1 year	7	14	4	5	18	6
≤3 years	15	16	5	7	21	6
≤6 years	25	19	9	10	25	7
≤9 years	32	29	11	16	29	11
≤12 years	39	32	16	20	38	13
Censored	45	107	45	31	13	20
No outcome listed	43	41	34	74	76	147

surgery had been performed in 16.5% of patients in the Burch group (21/127) and in 5.6% of patients in the TVT group (10/180; $p = 0.01$).

Discussion

This study showed a significantly lower cumulative rate of recurrence up to 12 years after primary surgery in women with preoperative SUI after the TVT procedure than after Burch colposuspension. High cure rates for the retropubic TVT procedure persisting over time have been shown in several studies [13–18]. However, a meta-analysis of RCTs showed no difference in efficacy between Burch colposuspension and TVT surgery at 5 years [12]. Our overall 74.7% (95% CI 66.5–82.9) subjective cumulative cure rate at 12 years in the TVT group is similar to previously reported rates [13–18]. There was a significant difference in the rates of repeat surgery, with a lower rate in the TVT group, a difference higher than expected according to the difference in cumulative recurrence rates at 12 years. Our study showed a very low rate of

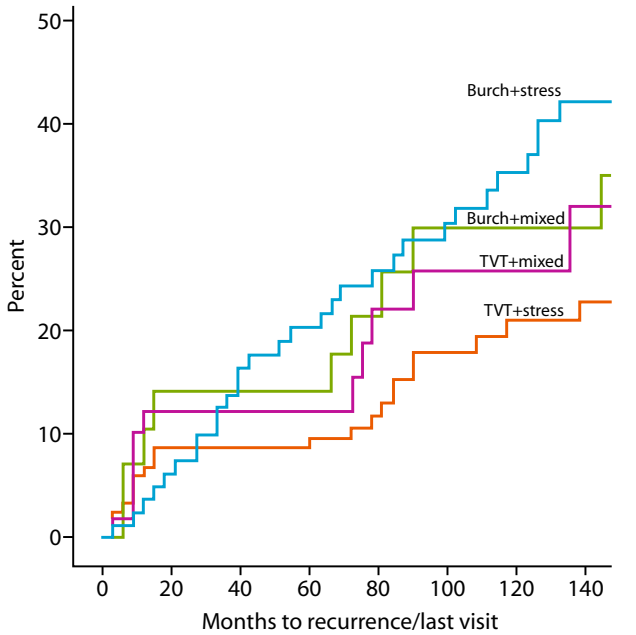

Fig. 1 Cumulative recurrence rates in women with preoperative stress and mixed urinary incontinence after primary incontinence surgery

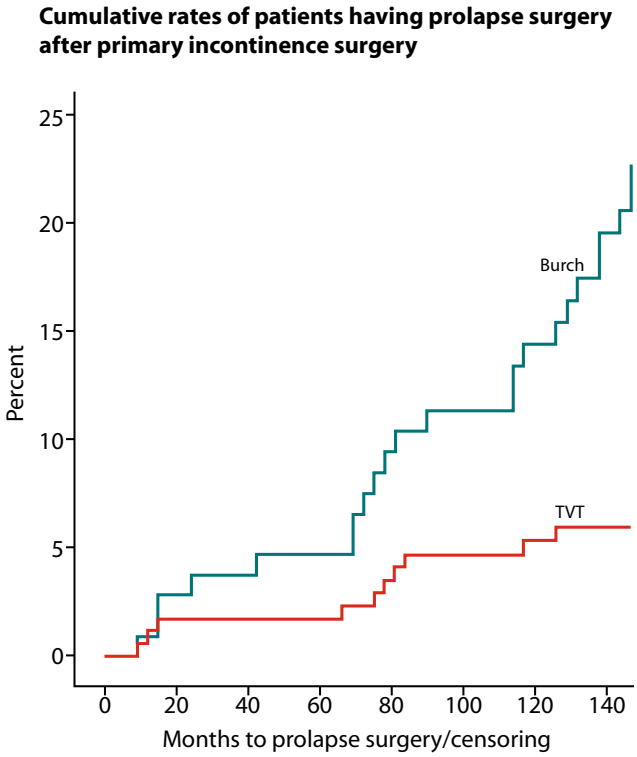

Fig. 2 Cumulative rates of patients undergoing prolapse surgery after primary incontinence surgery

repeat surgery after TVT, in line with the findings of other studies [14, 18].

Our diagnosis of recurrence was mainly based on description of typical symptoms by the patient. More thorough investigation with stress testing and urodynamics was reserved for patients with more serious symptoms in whom repeat surgery was an option. Thus, efficacy in this study largely reflects the subjective cure rate. Efficacy after UI surgery found in several studies has been lower in women with MUI than in those with SUI, due to persistent urgency UI and because the therapeutic effect is mainly related to the stress component. This may explain why we did not find any difference in efficacy between the methods of surgery among women with MUI.

One meta-analysis comparing Burch colposuspension and TVT surgery which included six RCTs showed lower rates of perioperative complications and early VD, and shorter operative times and hospital stay, but a significantly higher rate of bladder perforations after TVT surgery than after the Burch procedure [12]. Our study showed no difference in the rates of perioperative complications including bladder perforations and early VD (catheterization >1 week). However, patients undergoing the Burch procedure with perioperative complications had a significantly longer hospital stay, probably due to a combination of more serious complications, a significantly higher rate of urinary infection ($p < 0.01$) and a gradual change in handling of early VD from prolonged hospital stay with a permanent catheter to instruction in self-catheterization before discharge from hospital. Along with the introduction of TVT surgery, antibiotic prophylaxis was introduced in our department. As TVT surgery was found from the beginning to be associated with a shorter hospital stay, many urinary infections would have been diagnosed after discharge, and thus would have been under-reported among women undergoing TVT surgery. In view of this, we decided not to include urinary infection as a perioperative complication.

Rates of late complications differ among studies due to differences in definitions, selection of patients, completeness and length of follow-up. Studies involving long-term follow-up after TVT surgery have shown rates of de novo urgency UI ranging from 4% to 17% and rates of VD from 23% to 32% [14–16, 21–23], and after the Burch procedure have shown rates of de novo urgency UI ranging from 15% to 41% and rates of VD from 2% to 36% [6–9]. There are few studies with 12-year follow-up data. The cumulative rates of OAB symptoms in our study at 12 years indicate that late complications can develop many years after surgery, but we did not find any significant difference between the two surgical methods. In this respect, we have to take into account that rates of urgency, urgency UI and detrusor underactivity increase with age, and this may have contributed to some of the long-term problems reported regardless of UI surgery [24, 25].

Pain and discomfort in the pubic region have been reported by 7.5% of women after TVT surgery [26]. Sexual dysfunction after TVT surgery is well known. In a review of female sexual dysfunction after vaginal surgery, Tunuguntla and Gousse [27] found that a significant number of women reported dyspareunia after sling surgery for UI [27]. Some patients report improvement in overall sexual function due to relief of leakage during intercourse. This is in line with the findings of Serati et al. [28], who found that 10–27% of women with UI report coital UI, and coital UI during penetration is associated with SUI and has an 80% chance of being cured by surgery [28]. In our study eight patients (4.4%) in the TVT group had problems associated with the tape including discomfort, dyspareunia and symptoms from erosion. The tape appears to have had an impact on sexual function in only a small proportion of the TVT group, but, as tape symptoms were not systematically examined, they may have been under-reported in this study.

It is generally considered that there is a high risk of the need for prolapse surgery late after Burch colposuspension. The risk varies between 1% and 37% in the different studies [6–9, 29]. This applies primarily to rectocele and enterocele. A concomitant cystocele, on the other hand, has been reported to have an approximately 80% chance of being cured by Burch colposuspension alone [29]. The prolapse of the posterior vaginal wall is probably due to traction on the endopelvic fascia from the sutures in the Burch procedure. The TVT operation, on the other hand, is a tension-free procedure that ensures more precise support limited to the mid-urethra [2]. We found a significant difference in the rates of prolapse surgery, with a lower rate in the TVT group. In the TVT group, a patient with a cystocele needing surgery would often be offered surgery for the cystocele before TVT surgery in a two-step procedure. Borstad et al. found that 27% of women with concomitant prolapse and SUI were cured of their UI by prolapse surgery alone [30]. In our study, the process of selection was in principle the same in the Burch group as in the TVT group where we excluded patients with a concomitant cystocele and previous UI surgery. There were no differences in age, parity, BMI, previous hysterectomy and indications for surgery between the groups. Our results thus give support to the hypothesis that the high rate of prolapse surgery seen after Burch colposuspension may be a result of changes in the mechanical properties of the female pelvis that do not occur after TVT surgery. This explanation is strengthened by the finding that in both groups of patients the rate of prolapse surgery was not dependent on the indications for surgery.

The strengths and weaknesses of this study should be considered. In this retrospective study, data were not collected systematically as in prospective studies, and the recorded data were those documented in the medical records. Grading of symptoms and complaints was based on the patients'

subjective descriptions and the data need to be interpreted with caution as they may vary in quality and consistency.

The Burch operations were all performed by an experienced senior consultant, a less experienced senior consultant or a junior doctor under the supervision of an experienced senior consultant. As the Burch procedure is now seldom performed, there is no valid method for comparison other than by a case-series design. We were, however, able to conduct a comparison between these two techniques in an overlapping time period. The strengths of the study are the fact that all surgical procedures were performed in one department with the same surgeons with consistent practice regarding the selection of patients and performance of surgery. Furthermore, we included only primary operations without concomitant prolapse operations. The high proportion of patients with follow-up data and the long follow-up time ensured the validity of the comparison.

Conclusions

The efficacy of retropubic TVT surgery 12 years after primary surgery appears to be superior to that of Burch colposuspension in women with SUI. There were no significant differences in the rates of perioperative and late complications. The Burch group had a threefold risk of later prolapse surgery 12 years after incontinence surgery. The proportion of patients in the TVT group with problems due to tape was low, but we cannot rule out the possibility that these problems were under-reported. Our study provides detailed information about efficacy and late onset complications after TVT surgery, and this may be important information to discuss with women during preoperative counseling.

Compliance with ethical standards

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Conflicts of interest B. Holdø: none.
M. Verelst: none.
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Paper II

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ORIGINAL RESEARCH ARTICLE

The retropubic tension-free vaginal tape procedure—Efficacy, risk factors for recurrence and long-term safety

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Abstract

Introduction: The retropubic tension-free vaginal tape has been the preferred method for primary surgical treatment of stress urinary incontinence and stress-dominated mixed urinary incontinence in women for more than 20 years. This study presents long-term safety and efficacy data and assesses risk factors for long-term recurrence.

Material and methods: In a case-series design we assessed a historical cohort of primary surgeries performed with the tension-free vaginal tape procedure in 596 women from 1998 to 2012 with follow up through 2015. Information from the medical records was transferred to a case report form comprising data on early and late complications and recurrence of urinary incontinence defined as bothersome stress urinary incontinence symptoms. All analyses were performed with SPSS using Pearson chi-square, survival and Cox regression analyses.

Results: After a 10-year follow up, mixed urinary incontinent women (hazard ratio 2.1, 95% confidence interval [CI] 1.4-3.0) had a significantly increased risk of recurrence of stress urinary incontinence symptoms compared with women with pure stress urinary incontinence as the indication for surgery. Overall cumulative cure rates after 1, 5 and 10 years were 92% (95% CI; 90%-94%), 79% (95% CI; 75%-83%) and 69% (95% CI; 63%-75%), respectively. Recurrent surgery (0.3%) and serious tape complications needing major surgical treatment (0.3%) were rare. Six patients (1.0%) had the tape cut due to urinary retention, and nine patients (1.5%) reported urinary retention more than 3 months after surgery.

Conclusions: The tension-free vaginal tape procedure has a high long-term durability. Mixed urinary incontinence as an indication for surgery predicted long-term recurrence. Long-term complications were rare.

KEYWORDS

complications, long-term results, midurethral slings, mixed urinary incontinence, stress urinary incontinence, tension-free vaginal tape

Abbreviations: HR, hazard ratio; MUI, mixed urinary incontinence; SUI, stress urinary incontinence; TVT, tension-free vaginal tape; UI, urinary incontinence; UR, urinary retention.

1 | INTRODUCTION

Within a few years after the introduction of the retropubic tension-free vaginal tape (TVT) in 1996, several studies demonstrated excellent short-term clinical outcomes, making this minimally invasive method the gold standard in the surgical treatment of women with stress (SUI) and stress-dominated mixed (MUI) urinary incontinence.[1,2] From 2005 and onwards, the number of women undergoing midurethral sling surgery increased rapidly.[3] Probable explanations are an increased awareness of urinary incontinence (UI), a lower symptom threshold for surgery, as the surgical method being considered less invasive, and a possible increase in the prevalence of UI.[4]

To date, several studies assessing clinical outcomes and risk factors for failure have demonstrated excellent long-term clinical outcomes after midurethral sling surgery. However, patient selection varies according to indication for surgery, the inclusion of women with repeat UI surgery, and women with previous and/or concomitant prolapse surgery.[5-10] Most long-term follow-up studies do not have sample sizes large enough for risk factor analysis.[5-7] The highest long-term subjective cure rates of 77%-90% apply only to primary surgery on SUI women only,[5,11] whereas subjective cure rates of 75%-80% are reported for heterogeneous populations of women with both SUI and MUI.[6,12] Long-term studies including women with previous/concomitant pelvic surgery have reported lower subjective cure rates (65%-76%).[7,8] Subjective cure rates as low as 37%-55% have been reported for MUI women only.[13,14] Therefore, study population characteristics are crucial when comparing studies and may explain why clinical outcomes and risk factor patterns for recurrence vary.

Mixed urinary incontinence as an independent risk factor for recurrence is well established,[13-15] but across studies, age, body mass index and diabetes are inconsistently reported.[6,9,13,15] The possible impact of perioperative complications on long-term efficacy has only been evaluated in a few studies.[9,15]

The aims of this study were to investigate clinical long-term outcomes and to assess demographic, clinical and perioperative risk factors for recurrence within 10 years after primary retropubic TVT surgery.

2 | MATERIAL AND METHODS

The Department of Gynecology at Nordland Hospital, Bodø, Norway, introduced the retropubic TVT procedure in 1998. Within a year, TVT had replaced the Burch colposuspension as the preferred method. We identified all patients having undergone a possible UI-related surgical procedure during 1994-2012 either as primary or recurrent surgery, in a total of 895 women (Figure 1). After exclusion of women having had Burch procedures solely on a prolapse indication, past pelvic surgery, concomitant prolapse surgery, primary incontinence surgery other than TVT, and women with no follow up, the final study population comprised 596 women having had TVT as primary surgery for SUI or MUI. The TVT surgery was performed as originally described by Ulmsten.[1] All patients received prophylactic antibiotics, and we used the surgical kits from Johnson & Johnson (New Brunswick, NJ, USA).

We screened the electronic medical records retrospectively and transferred the information to a case report form designed especially for the study. The following preoperative data were included: type of UI (SUI/MUI), age at time of surgery (≤49, 50-59, ≥60 years), parity (0-1, 2, 3+), body mass index, past hysterectomy (total and subtotal) and relevant comorbidities (cardiovascular disease/diabetes [0/1], pulmonary disease [0/1] and neurological disease [0/1]). From the preoperative examination prior to primary surgery, we collected the following information: previous conservative treatment for UI (pelvic floor muscle training and electrical stimulation), uroflowmetry assessments (including the shape of the curve and the estimate of maximum flow rate [< or ≥15 mL/s]). In addition, the results from two standardized stress tests (coughing during gynecological

Key message

Tension-free vaginal tape is a surgical method with high safety and efficacy with low risk of serious long-term tape complications. However, mixed urinary incontinence predicts a shorter long-term cure.

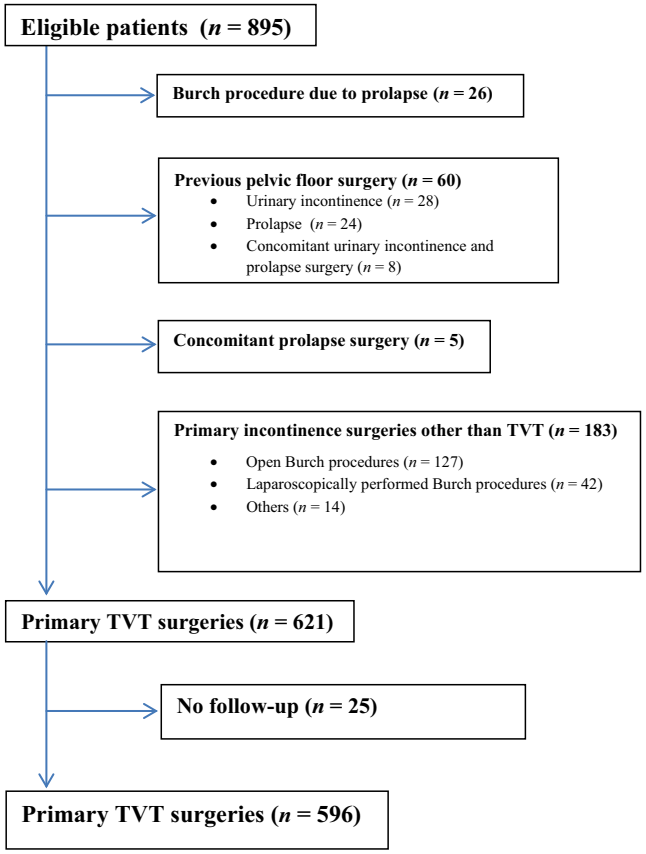

FIGURE 1 Flowchart of study participation. TVT, tension-free vaginal tape [Color figure can be viewed at wileyonlinelibrary.com]

examination with 300 mL saline in the bladder and/or pad weight before and after three forceful coughs and 20 jumping jacks [sideways splits]) and cystometry as well as measurement of residual urine (mL) were included.[16,17]

The classification of the type of incontinence was based on a combination of symptoms documented in the medical record, outcome of stress tests, and/or urodynamic examinations and a standardized validated short-form UI disease-specific questionnaire used since 2002.[18] We defined SUI as bothersome symptoms of SUI as described in the medical record and/or in the standardized questionnaire in combination with a positive stress test. MUI was defined as a combination of a dominant SUI component and urgency urinary incontinence defined as description of bothersome symptoms of involuntary leakage of urine after sudden urgency to void in the medical record and/or in the standardized questionnaire. A positive cystometry was not mandatory for a diagnosis.

Primary outcome was recurrence of UI defined as the presence of any bothersome symptoms of SUI reported by the patient and/or by a stress urinary incontinence index score >0 indicative of bothersome symptoms of SUI on the validated questionnaire and/or a positive standardized stress test at follow up. Neither de novo urgency urinary incontinence in women with pure SUI before surgery nor recurrence of urgency urinary incontinence in women with preoperative MUI was defined as recurrence.

Secondary outcomes were urinary retention (UR), other perioperative complications and late tape complications.

Urinary retention was defined as the need for catheterization more than 1 week after primary surgery and/or in need of traction and/or surgical correction necessitating cutting of the tape. Traction was performed non-invasively by stretching the urethra with a Hegar dilator in gel anesthesia.

Other perioperative complications comprised bladder injury defined as perforation by the trocar or by the tape, hematoma defined as clinical significant and/or ultrasonographically identified hematomas of any size and other complications. We chose not to include urinary infections as a complication as the prevalence will be underestimated most often when these infections are treated post discharge by general practitioners.

We defined late tape complications as symptomatic or asymptomatic erosions, fistulas, and symptoms of dyspareunia and/or chronic pain/discomfort diagnosed 3 months or later after primary surgery. Recurrent urinary infections without any other complaints were not considered to be a late complication, and de novo urgency urinary incontinence in SUI women was not included in the study.

All patients were offered a follow up after 6-12 months with an interview and a clinical examination, followed by urodynamics if there were bothersome symptoms. In the interview, the women were asked about their satisfaction with the treatment, and from 2002 and onwards the department used a standardized questionnaire including the categories “very satisfied”, “satisfied”, “neither satisfied nor dissatisfied”, “dissatisfied” and “very dissatisfied”. For patients residing far from our hospital, we performed the interview by post or phone.

Later follow-up data were based on consultations at our outpatient clinic after referral from general practitioners or private gynecologists. For patients not residing in the local catchment area of our hospital (n = 166), we retrieved follow-up data from the medical records at relevant local hospitals from in- and/or outpatient visits. As the department introduced a standardized 3-year follow-up using the validated short-form UI disease-specific questionnaire from 2009 and onwards, we assessed changes in outcomes in three different time periods (1998-2003, 2004-2008 and 2009-2012).

2.1 | Statistical analyses

In this case-series, the data were analyzed using SPSS version 25 (IBM, Armonk, NY, USA). Pearson chi-square test was used when comparing SUI and MUI, survival analysis (life tables) when estimating cumulative cure rates of TVT, and Cox regression analysis in the risk factor analysis of recurrence. In the survival analysis and the Cox regression analysis of recurrence, UI was recorded at the date of the first visit for bothersome symptoms of SUI following primary surgery, or censored at the date of last visit being continent as 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. All analyses were stopped for any outcome at 10 years of follow up due to the small number of observations thereafter. Medical records were screened through 1 November 2015.

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

Women with MUI as an indication for surgery were significantly older, had a higher body mass index and parity order, and more often had comorbidities compared with women with pure SUI as the indication for surgery (Table 1). Before surgery, women with MUI more often practiced electrostimulation alone or in combination with pelvic floor muscle training compared with women with SUI ($P < 0.001$), whereas women with SUI more frequently performed pelvic floor muscle training only (Table 2). The preoperative evaluations of the stress test, uroflowmetry, cystometry and measurement of residual urine were performed in almost all of the women (Table 2).

The surgeries were performed as day surgery procedures from 2005 and onwards. Mean postoperative hospital stay was 1.0 day (range 0-15). Ten patients (1.7%) had a protracted postoperative hospital stay of >7 days due to infection and UR.

Of the 596 patients, 499 (83.7%) had their first follow up within 12 months, 454 (76.2%) visited the outpatient clinic and 45 (7.6%)

TABLE 1 Preoperative baseline characteristics by indication for surgery (%)

	SUI (n = 390)	MUI (n = 206)	*P*-value
Age (y)			
28-49	51.3	26.7	<0.001
50-59	24.6	31.6	
60-93	24.1	41.7	
Body mass index (kg/m^2)			
Missing	1.3	1.0	<0.001
18.29-24.99	38.5	28.2	
25.00-29.99	45.4	43.7	
30.00-42.15	14.9	27.2	
Parity			
Para 0-1	11.8	12.6	0.01
Para 2	42.8	29.6	
Para ≥3	45.4	57.8	
Hysterectomy (yes)	12.8	14.1	0.67
Comorbidity			
Cardiovascular (yes)	18.5	33.0	<0.01
Pulmonal (yes)	9.7	16.5	<0.02
Neurological (yes)	7.9	11.2	0.19

MUI, mixed urinary incontinence; SUI, stress urinary incontinence.

responded to a standardized questionnaire either by post or phone. From interview and questionnaire data at the first postoperative follow up, 95.7% of SUI women and 82.1% of MUI women were "satisfied" or "very satisfied" ($P < 0.01$). UR and/or recurrence were significantly associated with not being satisfied.

Eighteen patients (3.0%), residing in Nordland County at the time of surgery, later moved to other regions of Norway, and 39 patients (6.5%) died during follow-up. These patients were censored at the last follow-up visit if there had been no prior outcome.

3.1 | Efficacy and risk factor analysis

Table 3 summarizes time to last observation for recurrence-free women, events leading to premature discontinuation (censoring) and recurrence rates by study group. In 54 (13.8%) SUI women and 52 (25.2%) MUI women, SUI symptoms recurred within 10 years of surgery ($P = 0.001$). There was no difference in the number of cases censored by study group (Table 3). Mean recurrence-free follow-up time in SUI and MUI women was 53.8 and 46.0 months ($P = 0.02$), respectively.

In the assessment of complications as a risk factor for recurrence, perioperative complications with the exception of UR applied only to women with SUI: none of the eight MUI women with other perioperative complications had a recurrence compared with 11 of 25 (44%) SUI women. Women with other perioperative complications had a hazard ratio (HR) for recurrence of 2.5 (95% CI 1.3-4.7) relative to women without such complications, and mixed incontinent women had an HR for recurrence of 2.1 (95% CI 1.4-3.0) compared with stress-incontinent women. Neither age, overweight, parity, previous hysterectomy or comorbidities listed in Table 1, nor UR were independent risk factors for recurrence and had only minor confounding effects (<4%) on the primary outcome. In the same model, the HR for recurrence was 4.0 (95% CI 2.4-6.7) in the third compared with the first time period. Cumulative cure rates after 1, 5 and 10 years by indication for surgery and in total are shown in Table 4. Figure 2 displays continuous cumulative recurrence rates by indication for surgery.

Two patients (0.3%) had recurrent surgery 17 and 68 months after primary surgery, respectively.

3.2 | Complications

In all, 5.2% of the patients had UR (Table 5); 22 of these 31 patients recovered within 3 months after surgery (10 recovered spontaneously after a period with self-catheterization, 10 after traction of the tape, and 2 after the tape was cut). Four of the remaining 9 patients reporting UR more than 3 months after surgery, had the tape cut. All patients with UR >3 months after surgery were, after

TABLE 2 Preoperative conservative treatment and clinical examinations performed by indication for surgery (%)

	SUI (n = 390)	MUI (n = 206)
Treatment		
Electrical stimulation	3.6	14.6
Pelvic floor muscle training	49.0	24.3
Both electrical stimulation and pelvic floor muscle training	5.9	16.0
Neither electrical stimulation nor pelvic floor muscle training/data missing	41.5	45.1
Clinical assessments performed		
Stress test	100.0	99.0
Measure of residual urine	99.2	98.1
Uroflowmetry	94.9	92.7
Cystometry	93.0	97.6

MUI, mixed urinary incontinence; SUI, stress urinary incontinence.

TABLE 3 Summary for recurrence and events leading to censoring by indication for surgery (%)

Outcomes	SUI (n = 390)	MUI (n = 206)	In total (n = 596)
Time to last observation among recurrence-free women			
Follow up <1 y	18.7	15.0	17.4
Follow up 1-5 y	28.5	28.6	28.5
Follow up ≥5 y	33.8	25.2	30.9
Events leading to censoring			
Removal of tape immediate perioperatively (n = 5)	0.8	1.0	0.8
Other surgery due to other perioperative complications (n = 1)	0.3	—	0.2
Urinary retention with cutting of tape (n = 5)	0.5	1.5	0.8
Late tape complications with resection of the tape (n = 3)	0.8	—	0.3
Prolapse surgery (n = 18)	2.8	3.4	3.0
Recurrence	13.8	25.2	17.8

MUI, mixed urinary incontinence; SUI, stress urinary incontinence.

TABLE 4 Cumulative cure rates after 1, 5 and 10 years by indication for surgery and in total

TVT surgery risk group	1 y (95% CI)	5 y (95% CI)	10 y (95% CI)
SUI	94% (92%-96%)	85% (81%-89%)	74% (66%-82%)
MUI	88% (84%-92%)	67% (59%-75%)	58% (48%-68%)
Overall cumulative cure rate	92% (90%-94%)	79% (75%-83%)	69% (63%-75%)

MUI, mixed urinary incontinence; SUI, stress urinary incontinence.

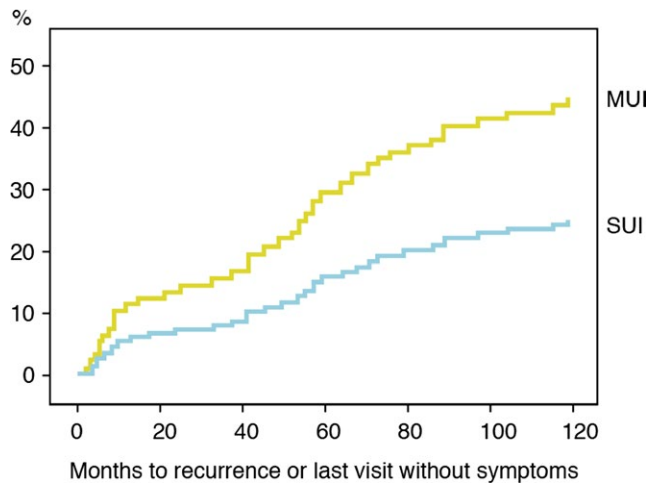

FIGURE 2 Cumulative rates of recurrence of stress incontinence after tension-free vaginal tape surgery by indication for surgery. SUI, stress urinary incontinence; MUI, mixed urinary incontinence [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 5 Complications by indication for surgery (%)

	SUI (n = 390)		MUI (n = 206)	
	n	%	n	%
Urinary retention	22	5.6	9	4.4
Other perioperative complications	25	6.4	8	3.9
Bleeding/hematoma	10	2.6	3	1.5
Bladder perforation/injury	10	2.6	2	1.0
Others[a]	5	1.3	3	1.5
Late tape complications within 10 y	13	3.3	4	1.9
Erosion	10	2.6	2	1.0
Pain	1	0.3	2	1.0
Fistula	2	0.5	0	0

MUI, mixed urinary incontinence; SUI, stress urinary incontinence.
[a]Five patients with superficial surgical site infection and 4 patients with other complications.

a clinical examination, offered cutting of the tape. However, as cutting the tape entails a risk of recurrent UI, these five patients preferred, after extensive counseling, to continue self-catheterization.

Other perioperative complications remained stable by study groups (Table 5) and over the time periods, apart from seven bladder perforations observed during the first time period vs one in the third period ($P < 0.04$). Among patients with other perioperative complications, one patient needed evacuation of an infected hematoma and two patients needed repeat surgery with total removal of the tape because of pain or graft-related problems. Three patients had the tape removed at primary surgery due to bladder perforation.

In all, 17 (2.9%) women had late tape complications within 10 years after primary surgery (Table 5). Two women developed a fistula, 1 vesico- and 1 urethro-vaginal. Seven of the 12 patients with erosions had neither symptoms nor recurrence at the time of diagnosis. The rate of surgery due to late complications was 1.3% (n = 8);

there was partial resection of the tape due to erosion (n = 6), fistula (n = 1) and pain (n = 1). The second patient with fistula (vesicovaginal) recovered with conservative treatment. Six patients with erosion were also treated conservatively with local estrogens without surgery. Mean time from primary surgery to surgery for late complication was 52 months (range 5-120 months).

4 | DISCUSSION

Mixed urinary incontinence predicted recurrence 10 years after primary TVT surgery. We did not find any association between age, overweight, parity, comorbidities, UR and recurrence of SUI.

Among patients not satisfied with the treatment, recurrence and UR within 1 year impacted on dissatisfaction. Already at the first follow-up visit we found a significantly lower satisfaction rate in MUI-operated women compared with SUI-operated women. As there were differences in follow-up time across the study period, with a shorter observation time in the third time period relative to the previous periods, we performed a Cox regression analysis of recurrence over 4 years of observation in order to avoid attrition bias. The overall HR for recurrence in the third compared with the first time period dropped from 4.0 to 2.2 (95% CI 1.2-4.0), indicating that attrition bias may account for 45% of the difference in HR for recurrence between the third period and the first. At the start of the third time period our department initiated a systematic 3-year follow up by a postal questionnaire. A larger proportion of women were below 50 years of age (47.8% vs 35.4%) in the third time period than in the first. We ascribe this to increasing awareness of TVT as an improved method for treatment of female incontinence. Furthermore, a higher expectation for cure after surgery may have led some women in the third period to seek medical advice for UI at a threshold that may have differed from that of women in the first period. These circumstances may have led to a reporting bias important for interpretation of the increased HR for recurrence in the third vs the first period.

The overall cumulative subjective cure rate after the 10-year follow up (69%) was somewhat lower than results from comparable studies (75%-80%).[7,8] When we stratified our results into pure SUI and MUI, the cumulative subjective cure rate after the 10-year follow up was 74% for the women with pure SUI (95% CI 66%-82%) and 58% for the MUI women. The long-term SUI cure rate was thus lower in our study compared with that reported by others (77%-90%),[5,6] whereas the MUI women had a higher cumulative subjective cure rate compared with that of other studies (37%-55%).[11,12] In line with other reports we found that the effect of surgery decreased more with time in MUI women than in SUI women (Figure 2).[19] As our study analyzed cure rates using survival analyses, we expected the estimates of cure rates to be lower, as recurrence was estimated only among patients remaining in the study at the different time intervals. This differs significantly from most other studies in which time most often is not taken into account when estimating recurrence using the total number of patients having surgery as the denominator.[5,6,9,10]

In studies showing an association between overweight, advanced age and lower cure rates, the results may be influenced by including in the study populations women with past UI surgery and/or past or concomitant prolapse surgery, which is not the case in our study.

The rates of repeat surgery due to recurrence vary in the literature from 0% to 4%.[5,6,9,10] Studies reporting "no" repeat surgery often comprise low-risk populations that included only primary surgeries on women with only SUI.[5,6]

Only a few studies have demonstrated perioperative complications as an independent risk factor for recurrence.[9,15] Our study finds a possible association between recurrence and non-UR perioperative complications. However, due to the low number of cases with such complications and the inconsistency between SUI and MUI women, this finding has to be interpreted with caution.

Most studies assessing UR include the need for catheterization resolving spontaneously within 1 week after surgery, leading to large variations in published rates of women with postoperative UR.[20-22] In our study, only nine patients (1.5%) reported serious problems with bladder emptying more than 3 months after surgery. Other studies assessing UR after TVT report a 1.2% rate of "very disturbing UR" more than 1 year after TVT.[21-23]

In 2015, an editorial from the Cochrane Library questioned the safety of sub-urethral slings.[24] In that editorial, the authors referred to a report from the UK Medicines and Healthcare Products Regulatory Agency (MHRA) claiming serious and debilitating problems reported by women operated for UI with vaginal tape implants.[25] However, in our study, only 2.9% of the patients had experienced long-term tape-related problems. Of these, less than 50% were in need of repeat surgery due to complications, and only two patients needed major surgery, one due to fistula and one with resection of the tape due to pain. This is in accordance with most other long-term studies stating an incidence of tape complications varying from <1% to 3.5%.[10,26]

Compared with most studies reporting outcome of incontinence surgery, our study has a large sample size, long follow-up time and a high follow-up rate (596/621), as we included information from neighboring hospitals in the follow up. To avoid any confounding effect of earlier pelvic floor surgery on efficacy, we have included only primary surgeries and, in our analysis of recurrence, patients were censored at the date of surgery due to prolapse or complications. Over the years, surgeries and postoperative follow up have been performed in our department in a standardized manner and by a limited number of surgeons.

The most important weaknesses of this study are the retrospective design, the possibility for bias due to changes in quality of reporting across the study periods, and the possible loss to follow up of women having repeat surgery at hospitals in other parts of Norway. However, a report from the Auditor General of Norway stated that Norwegian patients have high loyalty to their local hospitals, especially in the rural areas in northern and western Norway.[27] That report supports the escape of patients out of the catchment area of our hospital to be of limited magnitude.

5 | CONCLUSION

Retropubic TVT is a surgical method with high long-term safety and efficacy with low risk of long-term serious tape complications. MUI is a risk factor for long-term recurrence.

CONFLICT OF INTEREST

R. Svenningsen is part of the advisory board of Astellas and receives speaker fees from Astellas. B. Holdø, M. Verelst, I. Milsom and F. E. Skjeldestad declare no conflicts of interest.

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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 surgeon's 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. Surgeon's 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: Surgeon's 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.

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 surgeon's experience on clinical outcomes.

Surgeon's experience is usually characterized by the number of TVT procedures performed and/or by the surgeon's 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 surgeon's experience,[1-3] but few studies have looked at long-term effectiveness.[4-7] Furthermore, most of the studies that assessed effectiveness by surgeon's 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 surgeon's experience.[3] However, studies that have assessed surgeon's 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- versus high-volume departments and when comparing low- versus high-volume TVT surgeons.[4,6]

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

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.

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 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 surgeon's 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 questionnaire[17]; 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 surgeon's 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 surgeon's 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

TABLE 1 Baseline characteristics by surgeons

	Surgeon					
	A %	B %	C %	D %	In total %	*P* value[a]
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	

[a]Pearson Chi-square test.

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

	Surgeon's experience				
	1-19 TVT procedures %	20-49 TVT procedures %	≥50 TVT procedures %	In total %	*P* value[a]
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

[a]Pearson Chi-square test.

[b]Five 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 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	

[a]Maximum patient follow-up time: 10 years.

[b]Pearson Chi-square test.

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

	1998-2008	2009-2012
Months of follow-up	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)

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 surgeon's experience. However, 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 surgeon's 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 ≤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 phase[3] 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 surgeon's 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 surgeon's 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

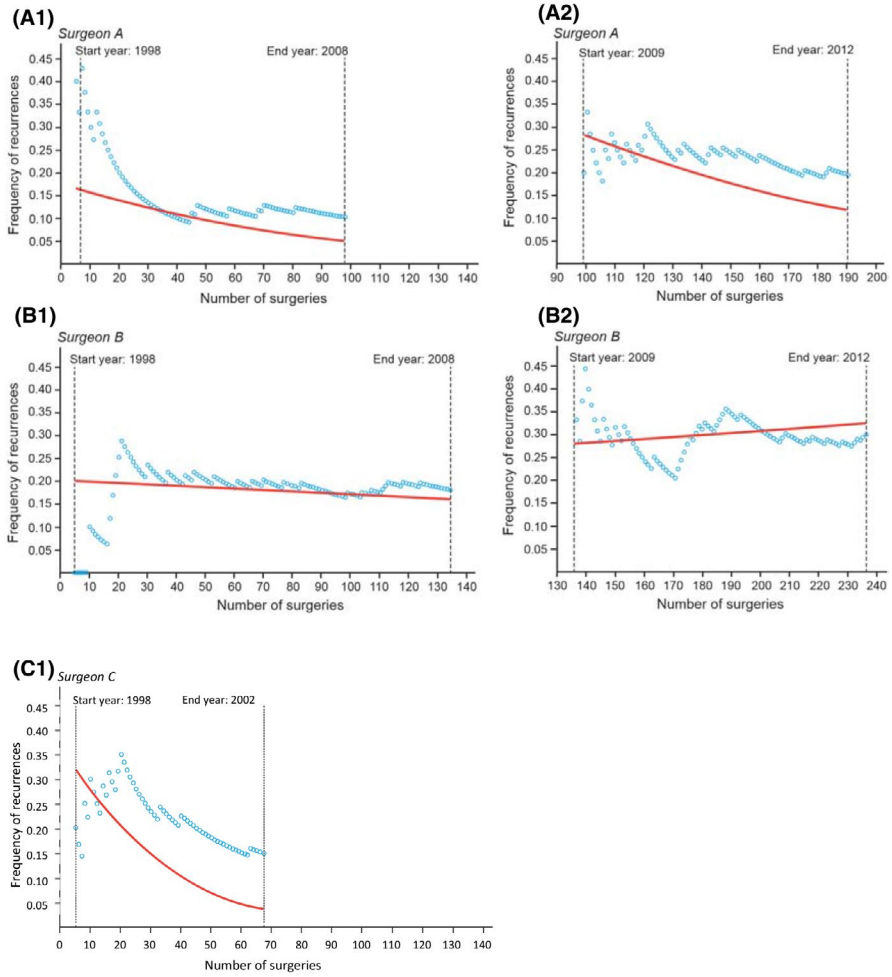

FIGURE 1 Frequency of recurrence by number of primary tension-free vaginal tape procedures performed by study period for surgeons A, B and C. The red line shows the fitted model [Color figure can be viewed at wileyonlinelibrary.com]

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 surgeon's 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 surgeon's 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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Appendix I

KURIPRO - CRF - Gynekologisk journal

Etternavn * | Fornavn * | Mellomnavn

Fødselesdato (dd.mm.åå) (skannes ikke)

5 siste siffer i fødselsnummeret (skannes ikke)

Dato registrering . . (Dag . Måned . År) Registert av

Sykehus *(Ett kryss)*

- ☐ Hammerfest
- ☐ Kirkenes
- ☐ Tromsø
- ☐ Harstad
- ☐ Narvik
- ☐ Stokmarknes
- ☐ Lofoten
- ☐ Bodø
- ☐ Sandnessjøen
- ☐ Mosjøen
- ☐ Mo i Rana

Type inngrep pr. operasjon: ☐ Inkontinens ☐ Fremfall ☐ Begge deler *(Ett kryss)*

Dato primær opr. . . (Dag . Måned . År)

Generelt (på tidspunktet for primær operasjon)

Høyde (cm):

Vekt (kg):

☐ Overvekt hvis ikke har data for høyde/vekt og det står overvekt/fedme i journalen (kryss av)

Anamnese på tidspunkt for primær operasjon

Paritet

Årstall menopause; (0) ikke nådd menop. alder; (1) i klimakteriet < 12 mnd siden siste s.m. (2) i klimakteriet - s.m. ikke angitt

Årstall hysterrekt.; (0) ingen

☐ Total ☐ Supravaginal *(Ett kryss)*

☐ Abdominal ☐ Vaginal ☐ LAVH u/LASH *(Ett kryss)*

Årstall ooforectomert; (0) ingen (bilateral)

Årstall tidl. Inkont. opr.; (0) ingen

- ☐ Retropubisk slynge
- ☐ Transobturator slynge
- ☐ Buch
- ☐ Bulking
- ☐ Mini-slynge
- ☐ Annet

(Flere kryss tillatt)

Årstall tidl. vag. F-fall opr.; (0) ingen

- ☐ Fremre kolporafi
- ☐ Bakre kolporafi
- ☐ Portio-amp
- ☐ Vag. hystereki
- ☐ Nett Prolift
- ☐ Nett Perigee
- ☐ Annet

(Flere kryss tillatt)

Årstall genit. ca. opr.; (0) ingen *(Ett kryss)*

☐ Vulva ☐ Vagina ☐ Cervix ☐ Corpus ☐ Ovarial

Stråleterapi: ☐ Nei ☐ Ja *(Flere kryss tillatt)*

☐ Ekstern ☐ Intracavitær/selektron ☐ Begge deler ☐ Uspes.

Årstall ano-rektal ca. opr.; (0) ingen

☐ Anus ☐ Rektum ☐ Perineum *(Ett kryss)*

Årstall tidl. analsfinkter-opr.; (0) ingen

☐ Primær op. ifbm fødsel ☐ Sekundær op. ☐ Annen *(Ett kryss)*

Årstall tidligere indre rektal-prolaps-opr.; (0) ingen

☐ Indre analspincterstomi ☐ Fistel ☐ Annen kir. *(Ett kryss)*

Tidligere sykdommer *(Flere kryss tillatt)*

☐ Diabetes mellitus ☐ Astma ☐ Hjertesvikt ☐ HRT

☐ Ikke gyn. kreft ☐ Kols ☐ Andre sykd.:

☐ Nattevæting som barn ☐ Nyresykdom

☐ Recidiverende UVI ☐ Hypertensjon ☐ Depresjon

☐ Intracranial - nevrologisk sykdom (slag, infeksjon etc.)

☐ Spinal - nevrologisk sykdom (lumbalprolaps , cauda equina, etc.) ☐ MS

☐ Perifer - nevrologisk sykdom (diabetisk polyneuropati, kollagensykd., etc.)

Kommentar:

Medikamenter som har innflytelse på inkontinens Navn på medikament

☐ Alfa adrenerg blokker (stressinkontinens hos kvinner)

☐ Antikolinergika (retensjon og obstipasjon)

☐ Antipsykotika (antikolinerg effekt)

☐ Tricykliske antidepressiva (antikolinerg)

☐ SSRI

☐ Beta-blokker (urge-inkontinens)

☐ Litium (polyuri)

☐ Ca-ion kanalblokk. (retensjon, deklive ødemer, polyuri)

☐ Østradiol (forverrer stress- og blandingsinkontinens)

☐ Østriol (forbedrer stressinkontinens)

☐ Loop diuretika (urgency, frequency)

☐ Annet

Tidligere behandling for urininkontinens

☐ Bekkenbunnstrening ☐ Elektrostimulering ☐ Annet *(Flere kryss tillatt)*

44959

Versjon 19.02.2014

(Ved samtidig urininkontinens hos kvinner med prolaps fylles også de nedenforstående urininkontinensrelaterte data inn)

Preoperative data

Urodynamiske undersøkelser

Finnes urodynamiske data: ☐ Nei ☐ Ja

Dato undersøkelse siste us.: ☐☐.☐☐.☐☐ (Dag . Måned . År) Preoperativt: ☐ Ikke utført

Cystometri - utført: ☐ Ja ☐ Nei

(Flere kryss tillatt)

☐ Detrusoraktivering spontan ☐ Detrusoraktivering ved host ☐ Negativt lukketrykk i urethra ved host

Maks. subjektiv kapasitet: ☐ < 199 ml ☐ > 700 ml *(Ett kryss)*

Flowmetri - utført: ☐ Ja ☐ Nei

☐ Klokkeformat kurve ☐ Intermitterende kurve *(Ett kryss)*

☐ maks. flow > 15 ml/sek ☐ maks. flow < 15 ml/sek *(Ett kryss)*

Ikke urodynamiske data

Resturin - utført: ☐ Ja ☐ Nei ☐☐☐☐ ml

Stresstest - utført: ☐ Ja ☐ Nei ☐☐☐☐ g

☐ Lekkasje synkront med hostestøt ☐ Ikke vurdert ☐ Oppl. mangler *(Ett kryss)*

☐ Lekkasje etter hostestøt ☐ Ikke vurdert ☐ Oppl. mangler *(Ett kryss)*

Vannlatingsskjema:

Dato vannlatningsskjema: ☐☐.☐☐.☐☐ (Dag . Måned . År)

Antall vannlatninger per døgn (helt tall): ☐☐

Antall vannlatninger per natt (helt tall): ☐☐

Lekkasjer per døgn (gram): ☐☐☐☐

Største vannlatningsvolum (ml): ☐☐☐☐

Væskeinntak per døgn (ml): ☐☐☐☐

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Årsak til lekkasje angitt på vannlatingsskjema

(Ett kryss)

Lekkasje ved tang ☐ Lekkasje ved fysisk aktivitet/hoste ☐ Lekkasje ved både tang, fysisk aktivitet og hoste ☐

☐ Lekkasje ved å reise seg fra en stol ☐ Urgency uten lekkasje *(Flere kryss tillatt)*

☐ Lekkasje når hører lyden av rennende vann ☐ Lekkasje ved samleie

☐ Opplysninger mangler

Diagnose ifølge anamnese (inkludert NUGG skjema), stresstest, vannlatingsskjema og urodynamisk u.s.

☐ Stressinkontinens ☐ Overflowinkontinens *(Flere kryss tillatt)*

☐ Urgeinkontinens ☐ Urinretensjon

☐ Blandingsinkontinens ☐ Ingen lekkasje

Diagnose ifølge anamnese (inkludert NUGG skjema), stresstest, vannlatingsskjema og uten urodynamisk u.s.

☐ Stressinkontinens ☐ Overflowinkontinens *(Flere kryss tillatt)*

☐ Urgeinkontinens ☐ Urinretensjon

☐ Blandingsinkontinens ☐ Ingen lekkasje

☐ NUGG skjema utfylt? ☐ NUGG skjema registrert i database?

Peroperative data

Type inngrep: ☐ Dagkirurgi ☐ Under innleggelse *(Ett kryss)*

	Dag	Måned	År		
Dato innskrevet:				Liggedager:	
Dato utskrevet:					
Dato operert:					

Operasjon

Type operasjon:	Nomesco- kode	90-talls- koder	
☐ Retropubisk slynge (TVT, etc.)	LEG 10	7471	
☐ Transoburator slynge (TOT, TVT-O, etc.)	LEG 13		
☐ Justerbar slynge	LEG 10		
☐ Mini-slynge	LEG 10		
☐ Vaginal urethrocystorafi (Kelly sut.)	LEG 00	7470	
☐ Annen vaginal inkontinensoperasjon	LEG 96	7479	
☐ Bulking (Bulkamid, Zuidex, etc.)	KDG 96 eller KDV 22		
☐ Retropubisk kolpopexi (ad modum Buch, Marshal.Marchetti, etc.)	KDG 20	6356	
☐ Retropubisk fascie-slynge (Stamey, etc.)	KDG 30	6355	

Umiddelbare komplikasjoner (under primær oppholdet): *(Flere kryss tillatt)*

☐ Blæreperforasjon ☐ Hematom
☐ Urinretensjon ☐ Smerter
☐ Infeksjon ☐ Annen organskade

Resturin før utreise operasjonsdagen (ml):

Resturin 1 ste postoperative dag (ml):

Antall postoperative dager med kateter:

Senere komplikasjoner

Dato reinnlagt for komplikasjoner: . . (Dag Måned År)

☐ Poliklinisk ☐ Reinnlagt *(Ett kryss)* Antall dager:

(Flere kryss tillatt)

Årsak: Hematom ☐ Stramt bånd ☐ Erosjon bånd i vagina ☐ i blæren ☐ i urethra ☐ Infeksjon rundt bånd ☐

Reoperert: ☐ Ja ☐ Nei

LEB 10 (Extirp. Lesjon/fremmedlegeme i vagina) : ☐ Ja ☐ Nei

1ste postoperative undersøkelse

Dato postoperativ undersøkelse: . . (Dag Måned År)

(Ett kryss)

Type konsultasjon: ☐ Poliklinisk konsultasjon ☐ Telefon (NUGG) ☐ Post (NUGG) ☐ Ikke fulgt opp

(Ett kryss)

Hvor fornøyd: ☐ Veldig fornøyd ☐ Ganske fornøyd ☐ Lite fornøyd ☐ Misfornøyd ☐ Indifferent

Urodynamiske undersøkelser

Finnes urodynamiske data: ☐ Nei ☐ Ja

Dato undersøkelse siste us.: . . (Dag Måned År) Preoperativt: ☐ Ikkeutført

Cystometri - utført: ☐ Ja ☐ Nei

(Flere kryss tillatt)

☐ Detrusoraktivering spontan ☐ Detrusoraktivering ved host ☐ Negativt lukketrykk i urethra ved host

Maks. subjektiv kapasitet: ☐ < 199 ml ☐ > 700 ml *(Ett kryss)*

Flowmetri - utført: ☐ Ja ☐ Nei

☐ Klokkeformat kurve ☐ Intermitterende kurve *(Ett kryss)*

☐ maks. flow > 15 ml/sek ☐ maks. flow < 15 ml/sek *(Ett kryss)*

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Ikke urodynamiske undersøkelser

Resturin - utført: ☐ Ja ☐ Nei ☐☐☐☐ ml

Stresstest - utført: ☐ Ja ☐ Nei ☐☐☐☐ g

☐ Lekkasje synkront med hostestøt ☐ Ikke vurdert ☐ Oppl. mangler *(Ett kryss)*

☐ Lekkasje etter hostestøt ☐ Ikke vurdert ☐ Oppl. mangler *(Ett kryss)*

Vannlatingsskjema:

Dato vannlatningsskjema: ☐☐ . ☐☐ . ☐☐
Dag Måned År

Antall vannlatninger per døgn (helt tall): ☐☐

Antall vannlatninger per natt (helt tall): ☐☐

Lekkasjer per døgn (gram): ☐☐☐☐

Største vannlatningsvolum (ml): ☐☐☐☐

Væskeinntak per døgn (ml): ☐☐☐☐

Årsak til lekkasje angitt på vannlatingsskjema

Lekkasje ved tang ☐ Lekkasje ved fysisk aktivitet/hoste ☐ Lekkasje ved både tang, fysisk aktivitet og hoste ☐ *(Ett kryss)*

☐ Lekkasje ved å reise seg fra en stol ☐ Urgency uten lekkasje *(Flere kryss tillatt)*

☐ Lekkasje når hører lyden av rennende vann ☐ Lekkasje ved samleie

Diagnose ifølge anamnese (inkludert NUGG skjema), stresstest, vannlatingsskjema og urodynamisk u.s.

☐ Stressinkontinens ☐ Overflowinkontinens *(Flere kryss tillatt)*

☐ Urgeinkontinens ☐ Urinretensjon

☐ Blandingsinkontinens ☐ Ingen lekkasje

☐ NUGG skjema utfylt? ☐ NUGG skjema registrert i database?

Langtidskomplikasjoner: *(Flere kryss tillatt)*

☐ Ingen ☐ Erosjon i vagina

☐ Residuer. UVI < 4x i året ☐ Residuer. UVI >= 4x i året

☐ Erosjon i blæren ☐ Stress sympt.

☐ Urinretensjon ☐ Erosjon i urethra

☐ Urge symptomer

Siste urodynamiske utredning før første residivoperasjon

Dato postoperativ undersøkelse: ☐☐ . ☐☐ . ☐☐
Dag Måned År

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Urodynamiske undersøkelser

Finnes urodynamiske data: ☐ Nei ☐ Ja

Dato undersøkelse siste us.: ☐☐ . ☐☐ . ☐☐ (Dag . Måned . År) Preoperativt: ☐ Ikke utført

Cystometri - utført: ☐ Ja ☐ Nei

(Flere kryss tillatt)

☐ Detrusoraktivering spontan ☐ Detrusoraktivering ved host ☐ Negativt lukketrykk i urethra ved host

Maks. subjektiv kapasitet: ☐ < 199 ml ☐ > 700 ml *(Ett kryss)*

Flowmetri - utført: ☐ Ja ☐ Nei

☐ Klokkeformat kurve ☐ Intermitterende kurve *(Ett kryss)*

☐ maks. flow > 15 ml/sek ☐ maks. flow < 15 ml/sek *(Ett kryss)*

Ikke urodynamiske undersøkelser

Resturin - utført: ☐ Ja ☐ Nei ☐☐☐☐ ml

Stresstest - utført: ☐ Ja ☐ Nei ☐☐☐☐ g

☐ Lekkasje synkront med hostestøt ☐ Ikke vurdert ☐ Oppl. mangler *(Ett kryss)*

☐ Lekkasje etter hostestøt ☐ Ikke vurdert ☐ Oppl. mangler *(Ett kryss)*

Vannlatingsskjema:

Dato vannlatningsskjema: ☐☐ . ☐☐ . ☐☐ (Dag . Måned . År)

Antall vannlatninger per døgn (helt tall): ☐☐

Antall vannlatninger per natt (helt tall): ☐☐

Lekkasjer per døgn (gram): ☐☐☐☐

Største vannlatningsvolum (ml): ☐☐☐☐

Væskeinntak per døgn (ml): ☐☐☐☐

Årsak til lekkasje angitt på vannlatingsskjema *(Ett kryss)*

Lekkasje ved tang ☐ Lekkasje ved fysisk aktivitet/hoste ☐ Lekkasje ved både tang, fysisk aktivitet og hoste ☐

☐ Lekkasje ved å reise seg fra en stol ☐ Urgency uten lekkasje *(Flere kryss tillatt)*

☐ Lekkasje når hører lyden av rennende vann ☐ Lekkasje ved samleie

Diagnose ifølge anamnese (inkludert NUGG skjema), stresstest, vannlatingsskjema og urodynamisk u.s.

☐ Stressinkontinens ☐ Overflowinkontinens *(Flere kryss tillatt)*

☐ Urgeinkontinens ☐ Urinretensjon

☐ Blandingsinkontinens ☐ Ingen lekkasje

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Residivoperasjon

Type inngrep: ☐ Dagkirurgi ☐ Under innleggelse *(Ett kryss)*

Dato innskrevet: Dag . Måned . År Liggedager:

Dato utskrevet: . . .

Dato operert: . . .

Operasjon

Type operasjon:	Nomesco- kode	90-talls- koder	
☐ Retropubisk slynge (TVT, etc.)	LEG 10	7471	
☐ Transoburator slynge (TOT, TVT-O, etc.)	LEG 13		
☐ Justerbar slynge	LEG 10		
☐ Mini-slynge	LEG 10		
☐ Vaginal urethrocystorafi (Kelly sut.)	LEG 00	7470	
☐ Annen vaginal inkontinensoperasjon	LEG 96	7479	
☐ Bulking (Bulkamid, Zuidex, etc.)	KDG 96 eller KDV 22		
☐ Retropubisk kolpopexi (ad modum Buch, Marshal.Marchetti, etc.)	KDG 20	6356	
☐ Retropubisk fascie-slynge (Stamey, etc.)	KDG 30	6355	
☐ Ekstirp. lesjon/fremmedleg. i vagina	LEB 10		

Umiddelbare komplikasjoner (under primær oppholdet): *(Flere kryss tillatt)*

☐ Blæreperforasjon ☐ Hematom

☐ Urinretensjon ☐ Smerter

☐ Infeksjon ☐ Annen organskade

Resturin før utreise operasjonsdagen (ml):

Resturin 1 ste postoperative dag (ml):

Antall postoperative dager med kateter:

Senere komplikasjoner

Dato reinnlagt for komplikasjoner: Dag . Måned . År

☐ Poliklinisk ☐ Reinnlagt *(Ett kryss)* Antall dager:

(Flere kryss tillatt)

Årsak: Hematom ☐ Stramt bånd ☐ Erosjon bånd i vagina ☐ i blæren ☐ i urethra ☐ Infeksjon rundt bånd ☐

Reoperert: ☐ Ja ☐ Nei

Antallet inkontinensoperasjoner totalt, primær operasjon inkludert:

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Appendix II

Norsk kvinnelig inkontinensregister. Spørreskjema for urinlekkasje

Registrering før og etter behandling

Dato for innfylling av skjemaet **pasientnummer**

☐☐.☐☐.☐☐ ☐☐☐☐☐☐

Vær vennlig besvar alle spørsmål. De opplysninger som avgis på dette spørreskjema vil bli rapportert til Norsk kvinnelig inkontinensregister. Navn og personnummer overføres ikke. Kun din behandlende lege kjenner din identitet

(Kryss av ja, nei, eller ikke aktuelt for alle alternativer i spørsmål 1)

1. Lekker du urin?

når du hoster	☐ ja	☐ nei	☐ ikke aktuelt
når du nyser	☐ ja	☐ nei	☐ ikke aktuelt
når du ler	☐ ja	☐ nei	☐ ikke aktuelt
når du går i trapper	☐ ja	☐ nei	☐ ikke aktuelt
når du står opp av sengen	☐ ja	☐ nei	☐ ikke aktuelt
når du løfter tungt (tunge bæreposer)	☐ ja	☐ nei	☐ ikke aktuelt
ved fysisk aktivitet(løper for å nå bussen)	☐ ja	☐ nei	☐ ikke aktuelt
ved sportsaktiviteter	☐ ja	☐ nei	☐ ikke aktuelt
ved samleie	☐ ja	☐ nei	☐ ikke aktuelt

(Kryss av et alternativ for hver av spørsmålene 2 - 6)

2. Hvor ofte lekker du urin i forbindelse med fysisk aktivitet, når du ler, hoster eller nyser?
   - ☐ aldri
   - ☐ 1 - 4 ganger per måned
   - ☐ 1 - 6 ganger per uke
   - ☐ en gang daglig
   - ☐ mer enn 1 gang daglig

3. Hvor stor mengde urin lekker du vanligvis ved fysisk aktivitet, når du ler, hoster eller nyser?
   - ☐ ingen
   - ☐ dråper/fuktig undertøy
   - ☐ drypper / vått undertøy
   - ☐ renner / går gjennom ytterklær
   - ☐ renner nedover bena eller ned på gulvet

4. Hvor ofte opplever du plutselig sterk trang til å late vannet og lekker før du når frem til toilettet?
   - ☐ aldri
   - ☐ 1 - 4 ganger per måned
   - ☐ 1 - 6 ganger per uke
   - ☐ en gang daglig
   - ☐ mer enn 1 gang daglig

5. Hvor stor mengde urin lekker du vanligvis når du har trang til å late vannet og lekker urin før du når frem til toilettet?
   - ☐ ingen
   - ☐ dråper/fuktig undertøy
   - ☐ drypper/vått undertøy
   - ☐ renner/ går gjennom ytterklær
   - ☐ renner nedover bena eller ned på gulvet

Norsk kvinnelig inkontinensregister. Spørreskjema for urinlekkasje

6. Dersom du har symptomer både som i spørsmål 2 og spørsmål 4, hva er du mest plaget av?

- ☐ lekkasje ved fysisk aktivitet mer enn lekkasje ved trang
- ☐ lekkasje ved trang mer enn lekkasje ved fysisk aktivitet
- ☐ like mye plaget av lekkasje ved trang som ved fysisk aktivitet
- ☐ Har ikke lekkasje hverken som ved spørsmål 2 eller 4

(Krvss av et alternativ for hver av spørsmålene 7 - 11)

7. Hvor mange inkontinensbind bruker du?

☐ ingen ☐ 1 - 3 per uke ☐ 4 - 6 per uke ☐ 1 - 4 daglig ☐ mer enn 4 daglig

8. Hvor mange ganger har du fått behandling for blære katarr de siste 6 måneder?

☐ ingen ☐ 1 gang ☐ 2 - 3 ganger ☐ 4 ganger ☐ mer enn 4

9. Hvor ofte unnlater du aktiviteter (f.eks. en hobby, fysisk trening, eller gå ut) fordi du er redd for å lekke urin?

☐ aldri ☐ sielden ☐ av oa til ☐ ofte ☐ alltid

10. Unngår du steder og situasjoner hvor du vet at toilett ikke er lett tilgjengelig?

☐ aldri ☐ sjelden ☐ av og til ☐ ofte ☐ alltid

11. Er ditt seksualliv blitt påvirket av ditt lekkasjeproblem? (skal besvares før behandling)

☐ ikke relevant ☐ uforandret ☐ blitt litt verre ☐ blitt mye verrre

(Kryss av ja, nei eller ikke aktuellt for alle spørsmål under punkt 12)

12. Påvirker din lekkasje

dine ferier?	☐ ja	☐ nei	☐ ikke aktuelt
ditt familieliv?	☐ ja	☐ nei	☐ ikke aktuelt
ditt sosiale liv (å gå ut, å treffe venner)?	☐ ja	☐ nei	☐ ikke aktuelt
din nattesøvn?	☐ ja	☐ nei	

(Kryss av kun et alternativ under spørsmålene 13 og 14)

13. Er ditt seksualliv blitt påvirket av ditt lekkasjeproblem? (skal besvares etter behandling)

☐ ikke relevant

☐ blitt mye bedre ☐ blitt litt bedre ☐ uforandret ☐ blitt litt verre ☐ blitt mye verrre

14. Er du fornøyd med resultatet av din behandling for hostelekkasje? (besvares etter behandling)

☐ veldig fornøyd ☐ litt fornøyd ☐ hverken fornøyd eller misfornøyd ☐ litt misfornøyd ☐ veldig misfornøyd

Pasienten samtykker i at data overføres til Norsk kvinnelig inkontinens register: ja ☐

nei ☐

Norsk kvinnelig inkontinensregister.

Fylles inn av helsepersonell etter undersøkelse og behandling

Dato for innfylling av skjemaet

☐☐ . ☐☐ . ☐☐

Fylles inn av medisinsk personell.

☐☐ utreder nummer

dato for inkontinens behandling

☐☐ ☐☐ ☐☐

☐☐ operatør nummer

☐☐ operasjonsnummer

☐ antall tidligere gjennomgåtte inkontinensoperasjoner

☐ ja ☐ nei operert for inkontinens ved vår avdeling tidligere

☐☐☐☐☐ pasientens pnr ved siste operasjon

☐ ja ☐ nei inkontinens og prolapsoperasjon samtidig

☐☐ antall vannlatinger per 24 timer

☐☐☐ gjennomsnitt vannlatings volum (ml)

☐☐☐ lekkasje ved 24 timers bleietest (ml)

maksimum lukketrykk (cm H2O) ☐☐

lekkasje ved stresstest (gr) ☐☐☐

resturin (ml) ☐☐☐

maksimum flow (ml/sec) ☐☐

pasientens høyde (cm) ☐☐☐

pasientens vekt (kg) ☐☐☐

dato for avbrutt og ikke fullført inkontinensoperasjon

☐☐ ☐☐ ☐☐

dato for å justere bånd operativt

☐☐ ☐☐ ☐☐

dato for å klippe bånd

☐☐ ☐☐ ☐☐

dato for operasjon for erosjon

☐☐ ☐☐ ☐☐

komplikasjon ☐ ja ☐ nei

blære perforasjon ☐ ja ☐ nei

hematom > 3 cm ☐ ja ☐ nei

overfladisk sårinfeksjon ☐ ja ☐ nei

dyp sårinfeksjon ☐ ja ☐ nei

kateter > 1 uke < 1 mnd. ☐ ja ☐ nei

kateter > 1 måned ☐ ja ☐ nei

justere bånd operativt ☐ ja ☐ nei

tarm perforasjon ☐ ja ☐ nei

kar skade ☐ ja ☐ nei

blødning > 500 ml. ☐ ja ☐ nei

urethra skade ☐ ja ☐ nei

cystitt 14 dg. e. op. ☐ ja ☐ nei

smerte styrke på skala fra 0 til 10 ☐

varighet av smerte
- ☐ ingen
- ☐ mindre enn 14 dager
- ☐ opp til 3 mnd
- ☐ mer enn 3 mnd

Andre komplikasjoner

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Appendix III

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK nord			08.04.2013	2012/1348/REK nord
			Deres dato:	Deres referanse:
			23.01.2013	

Vår referanse må oppgis ved alle henvendelser

Finn Egil Skjeldestad

2012/1348 Kirurgisk behandling av urininkontinens og vaginalt prolaps – epidemiologi og langtidsresultater – Helse-Nord 1994-2011

Forskningsansvarlig: Universitetssykehuset i Nord-Norge
Prosjektleder: Finn Egil Skjeldestad

Vi viser til søknad om prosjektendring datert 23.01.2013 for ovennevnte forskningsprosjekt.

Bakgrunn
Saken ble første gang behandlet i komitemøte den 20.09.12. Komiteen hadde merknader både til forespørsel og design og på det grunnlag det ble fattet et utsettelsesvedtak.

I tilbakemeldingen fra søker var det gjort flere vesentlige endringer utover det komiteen tidligere hadde merknader til. Nytt utsettelsesvedtak ble fattet 07.12.12, og prosjektleder ble bedt om å redegjøre for endringene.

Den 23.01.13 mottok REK melding om prosjektendring vedlagt revidert forskningsprotokoll.

Også denne gang var det uklarheter i protokoll som medførte at REK hadde merknader til den delen av protokollen som omhandlet "Materiale og metode". Det var også uklarheter knyttet til hvilke grupper de dødes data skulle hentes fra, og man savnet en bedre begrunnelse for at det skulle gjøres en frafallsanalyse. Videre var det beskrevet undersøkelser av deltagerne ved hjelp av ambulatoriske urodynamiske undersøkelser og ultralydundersøkelser av bekkenbunn. Dette var ikke beskrevet nærmere i protokollen og heller ikke nevnt i forespørslene.

I prosjektendring av 19.02.13, vedlagt revidert protokoll og informasjonsskriv, er det redegjort for de omtale merknadene og aktuelle dokumenter er revidert på en tilfredsstillende måte.

Vedtak
Med hjemmel i helseforskningsloven § 10 og forskningsetikkloven § 4 godkjennes prosjektet.

Klageadgang
Du kan klage på komiteens vedtak, jf. forvaltningslovens § 28 flg. Klagen sendes til REK nord. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK nord, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

Besøksadresse:
MH-bygget Universitetet i Tromsø 9037 Tromsø

Telefon: 77646140
E-post: rek-nord@asp.uit.no
Web: http://helseforskning.etikkom.no/

May Britt Rossvoll
sekretariatsleder

Kopi til: rek-svar@unn.no