Tension-free Vaginal Tape (TVT)

S.E. Schraffordt Koops

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Cover design: Pascal Zrour, Johnson&Johnson, Medical bv
© Copyright: S.E. Schraffordt Koops
Production: F&N Eigen Beheer, Amsterdam
Lay-out: Fred Zurel, Amsterdam
Printing: Haveka bv, Alblasserdam

ISBN 10: 90 7383875 4
ISBN 13: 798907383875 8

Tension-free Vaginal Tape (TVT)

(met een samenvatting in het Nederlands)

Proefschrift

ter verkrijging van de graad van doctor aan de Universiteit Utrecht
op gezag van de rector magnificus, prof. dr. W.H.Gispen
ingevolge het besluit van het College van Promoties
in het openbaar te verdedigen op
14 juni 2006 des middags om 16.15 uur

Door Steven Evert Schraffordt Koops

Geboren op 3 mei 1966 te Groningen

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CONTENTS

Part 1 7

Chapter 1 9
Introduction and outline of the thesis

Part 2 37

Chapter 2 39
Prospective analysis of complications of Tension-free Vaginal Tape (TVT) from The Netherlands TVT Study

Chapter 3 57
What determines a successful TVT? A prospective multi centre cohort study, results from the Netherlands TVT database

Chapter 4 75
Quality of life before and after TVT, a prospective multi centre cohort study, results from the Netherlands TVT database

Chapter 5 87
The effectiveness of Tension-free Vaginal Tape (TVT) and quality of life measured in women with previous urogynecological surgery: Analysis from The Netherlands TVT database

Chapter 6 103
Urge incontinence and other forms of irritative bladder symptoms after TVT. A prospective multicenter, 3 year follow-up study with reference to quality of life

Chapter 7 121
Result of the Tension-free Vaginal Tape (TVT) in patients with concomitant pelvic surgery, a two year follow-up study, analysis from the Netherlands TVT database

Chapter 8 135
The prevalence of voiding difficulty after TVT, its impact on quality of life and related risk factors

Part 3 155

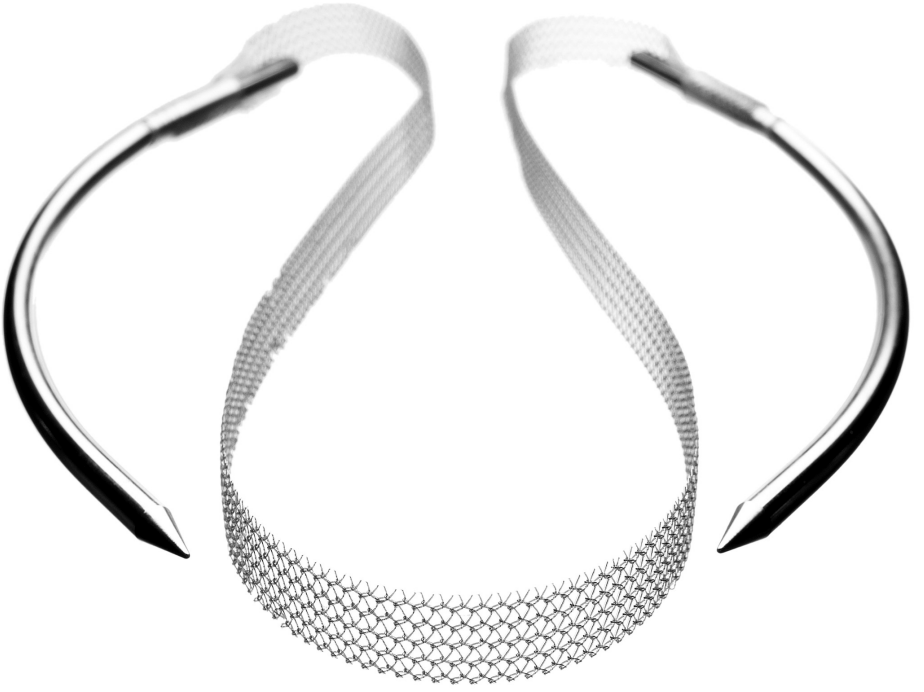
Chapter 9 157
Summary, conclusions, general discussion & recommendations for future research

Chapter 10 173
Nederlandse samenvatting

Part 4 179

Appendices 181
A. Abbreviations 183
B. Questionnaires 185
C. Acknowledgements - Dankwoord 187
D. List of co-authors 191
E. Curriculum vitae 193
F. List of publications 195
G. Grants 199

Part 1



Chapter 1

Introduction and outline of the thesis

The history and development of the TVT

The Tension–free Vaginal Tape (TVT) is a minimally invasive surgical procedure for the treatment of stress urinary incontinence. Since its development in 1996, over 900,000 procedures have been performed, making it one of the most commonly used interventions for Stress Urinary Incontinence (SUI).
The working mechanism is based on the mid-urethral support given by the tape and by the subsequent development of connective tissue. The theory behind this support mechanism originates from the Integral Theory, which was postulated in 1990 and 1993 by P.Petros and U.Ulmsten[1, 2]. Petros was inspired by Dr Zacharin's anatomical studies of the ligaments and muscles around the urethra and the importance of these for control of urinary continence[3]. Petros observed that implantation of foreign material created scar tissue and that this could reinforce tissue. This led to the hypothesis that implantation of artificial tape would lead to enforcement of the pubourethral ligament and anchoring of the muscles needed for urethral closure. In 1986, Petros described the insertion of a mersilene tape in the position of the pubourethral ligament. Animal studies and later human studies[4] followed, but unfortunately tape erosion remained a major problem. This problem was largely solved with the introduction of the polypropylene mesh of which the first results were published in 1996[5]. In this first study, seventy-five patients underwent a new surgical procedure, later called the TVT procedure. The operation took place under local anesthesia and sedation and was performed with the aid of two metal needles.
Since this first publication, an enormous amount of scientific papers on TVT or TVT-like procedures have been published. Just before the first publications of the TVT in 1996, Black and Downs analyzed the outcome of 11 randomised controlled trials (RCT), 20 non-randomized trials/prospective cohort studies and 45 retrospective trials of incontinence procedures. They concluded that the methodological quality of the studies that reported on the effectiveness of surgery for SUI was poor[6]. The considerable variation in inclusion criteria, surgical management and assessment of outcome precluded any statistical meta-analyses. Additionally, they concluded that the value of surgery and the effectiveness of different procedures was unclear. While the criticism of Black and Downs is still applicable to some of the studies published

on TVT, more studies on TVT have used Black and Downs' advice for appropriate methodological techniques.

Prevalence of urinary incontinence
Several epidemiologic studies of urinary incontinence (UI) exist. The methodologies of these studies vary. This was because no consensus on the definition of UI existed at that time. Another issue in studying UI is that UI is a condition with many varied types, occurring in different age groups and different populations. Also the severity of incontinence is of importance as 'daily' leakage shows a lower prevalence compared to 'any' leakage. The different types of UI and the most important definitions as made by the International Continence Society (ICS)[7] are:
Stress urinary incontinence: is the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing.
Urge urinary incontinence: is the complaint of involuntary leakage accompanied by or immediately preceded by urgency.
Mixed urinary incontinence: is the complaint of involuntary leakage associated with urgency and also with exertion, effort, sneezing or coughing.

Prevalence is the proportion of a population having a disease at a point in time.
The prevalence of UI described in European studies varies between 12-45% [8-19].
In the Netherlands, several studies have been performed to determine the prevalence of UI.
Rekers et al found an incontinence rate of 26.5% in 1299 women aged 35-79 years[20].
Kok et al found an incontinence rate of 23.5% in a sample of 1049 women aged over 60 years and living in a community. Van der Vaart found an overall urinary incontinence rate of 43.7% in a random population of 1393 women, aged 20-45 years[21].
Stress urinary incontinence has a prevalence of 50%, urge urinary incontinence of 10% and mixed incontinence of 40%[8, 22]. Overall, stress urinary incontinence is the most prevalent type of urinary incontinence among women[23, 24]. The prevalence of stress urinary incontinence decreases with increasing age, while urge incontinence increases with older age[25-27].

Impact of urinary incontinence
Urinary incontinence has a profoundly negative impact on the quality of life of women[28-31]. Psychological impact like shame, depression, anxiety, embarrassment and loss of self-esteem are described[32]. The impact of urinary incontinence can be measured by assessing the life-style adjustments in patients suffering from UI. Daily activities, social activities, relationships and emotions can be affected. Most studies report on adjustments on shopping, visiting friends, sporting, traveling long distances (patients report only visiting places with known location of toilet facilities)[20, 33-35]. Relationships may be affected due to incontinence during coitus[20, 35, 36]. Finally these adjustments can cause social isolation[37].
Many women think that their incontinence is a normal result of pregnancy and aging. Others do not seek help because of embarrassment. Hannestad et al, in study

among more than 34.000 women, found that only 25% of incontinent women seek help[38]. Reasons cited to seek help were a long history of incontinence and the impact of urine loss on the patient's life-style. More women with urge incontinence than women with stress incontinence, and more older women than younger women, seek help. There is a lack of knowledge by women and care-givers in general of all the opportunities to cure UI.

Assessing the outcome of incontinence surgery

Most studies addressing incontinence surgery use non-validated questionnaires, post-operative continence status on a visual analogue scale (VAS), micturition diary, pad weighing tests, interviewing women and urodynamic evaluation. Although some of these parameters are qualified as objective parameters, they have their limitations and are subject to bias.

In 2002 Soroka et al published a systematic review on pad tests, which showed a significant variability and repeatability of the pad test. The same is known from the VAS scoring system. Urodynamic testing also has it limitations. The test-retest reproducibility and validity in several urodynamic tests are not convincing[39] and because LUTS may fluctuate[40], the assessment may be done on an asymptomatic day. A normal urodynamic investigation cannot disprove the accuracy of a patient's history of urge incontinence[41]. *The bladder* is a notoriously bad witness, and the symptoms of frequency, nocturia and urgency may arise because of hypersensitivity of the bladder stretch but also may occur when the bladder contracts inappropriately due to detrusor over-activity. Conventional urodynamic investigation fails to detect detrusor over-activity in 62-74 % of the women with frequency and/or urgency symptoms and in 53-62 percent of the women with urge incontinence symptoms [42-47].

In recent years, assessment of efficacy of surgery has been measured by a more valid instrument: health-related quality of life (HRQoL) questionnaires. These questionnaires measure more than an objective cure rate, they can also measure the patient's perception of a surgical intervention. A general HRQoL questionnaire measures a general profile of perceived health such as social health, psychological health, emotional and physical health. These measurements are not specific for a particular disease on the quality of life. They therefore may lack sensitivity to specific aspects of incontinence and the effect on life-style of incontinent women.

Assessment of quality of life in women with lower urinary tract symptoms (LUTS) has been facilitated by the development of disease-specific questionnaire like the Urogenital Distress Inventory (UDI), Incontinence Impact Questionnaire (IIQ)[22, 48], the Bristol Female Lower Urinary Tract Symptoms questionnaire[49] the York Incontinence Perceptions Scale (YIPS)[50], I-QOL[51], the Norwegian stress and urge incontinence and quality of life questionaire[52] and the King's Health questionaire[53]. The application of quality of life instruments to assessing urogenital symptoms in women pre-operatively and postoperatively, enables an objective measurement of the impact of symptoms on lifestyle and can record the severity of the condition at a specific time.

Khan et al looked at whether the method of administration of questions, either by mail or by personal interview at the doctor's clinic, affected the outcome. The authors concluded that postal questionnaire responses had a better relationship with urodynamics, both for urodynamic stress incontinence and detrusor over-activity, than interview-assisted questionnaire responses[54].
Several studies recently published have used quality of life to asses the outcome of the TVT. These studies show an overall improvement of quality of life after TVT[28, 55-59].

Tension-free Vaginal Tape

Theories concerning the TVT
The Integral theory describes the complex interplay of the specific structures involved in female urinary continence. The theory and studies sustaining the theory have almost all been published by Petros and Ulmsten[1, 60].
According to the theory, stress and urge symptoms may both, for different reasons, derive from the same anatomical defect, namely a lax vagina. This laxity may be caused by defects within the vaginal wall itself, or its supporting structures for instance ligaments, muscles, and their connective tissue insertions. The vagina has a dual function. It mediates (transmits) the various muscle movements involved in bladder neck opening and closure through separate closure mechanisms. It also has a structural function, and prevents urgency by supporting the hypothesized stretch receptors at the proximal urethra and bladder neck. Altered collagen and elastin in the vaginal connective tissue or its ligamentous supports may cause laxity. This dissipates the muscle contraction, causing stress incontinence, and/or activation of an inappropriate micturition reflex ("bladder instability") by stimulation of bladder base stretch receptors. The latter is manifested by symptoms of frequency, urgency and nocturia, with or without urine loss.
An anatomical defect in the anterior vaginal wall results in a pubo-urethral ligament (PUL) and urethral or bladder neck closure dysfunction. This theory suggests that laxity in the suburethral vaginal wall (hammock) interferes with the function of the pubo-urethral ligament. The surgical intervention based on the integral theory to dissolve stress incontinence comprises the insertion of a tape around the urethra. The implantation of foreign material subsequently creates scar tissue that acts as an artificial peri-urethral ligament.
Secondly, the theory postulates that the suburethral hammock should be restored. Surgical intervention includes the excision of vaginal excess skin (vaginoplasty), anterior wall repair or a vaginal flap repair[4, 60-62]. This last part of the theory, the restoration of the hammock, is not commonly practiced by urologists and gynecologists.

The hammock theory was first postulated by DeLancy in 1994[63]. DeLancy divided the anatomical structures that provide urinary continence into two systems. The first system is the sphincteric system which consists of the striated urogenital sphincter, the smooth muscle in the vesical neck, the circular and longitudinal smooth muscle

of the urethra, the mucosal, the vascular tissues that surround the lumen and the connective tissue in the urethral wall.
The second system is the so-called hammock. This is the supportive anatomical structure against which the urethra is compressed when the abdominal pressure is increased. The hammock consists of the anterior vaginal wall and connective tissues that attaches it to the pelvic bones through the pubovaginal portion of the levator ani muscle and also the tendinous arch of the pelvic fascia. DeLancy used an analogy with a flow of water trough a garden hose[64]. If the hose was lying on a compliant trampoline, stepping on it would not result in stopping the water flow. If the hose was lying on a noncompliant trampoline, stepping on it would flatten the cross-sectional area, closing the lumen, resulting in cessation of water flow.

Surgical procedure of TVT
The TVT procedure was firstly described by Ulmsten[5]. The operation is mostly carried out under or local anesthesia, using 0.25% prilocaine with adrenalin together with sedation, spinal or general anesthesia. In general, 60 ml of the solution is injected abdominally in the skin above the symphysis and along the back of the pubic bone. Another 40 ml is injected intravaginally. Two minimal (1 cm) incisions, 5 cm apart, are made in the abdominal skin just above the superior rim of the pubic bone. A sagittal incision 1.5 cm long is made suburethrally in the vaginal wall starting 1 cm from the external urethral meatus. After minimal para-urethral dissection of the vaginal wall, a special prolene tape (Ethicon Inc, Sommerville, New Jersey, USA) covered by a plastic sheet is introduced using a two component needle instrument (MedScand Medical, Malmö, Sweden). The tip of this needle first perforates the urogenital diaphragm, and within the retropubic space immediately behind the pubic symphysis, the needle is brought up to the abdominal incision. The procedure is then repeated on the other side. After cystoscopy to ensure that there is no bladder perforation, the tape is adjusted without tension under the urethra. The patient is then asked to cough with the bladder filled to 300 ml of saline (0.9%) to confirm that she has become continent. If not, the tape may be further adjusted. The plastic sheets covering the mesh are then removed and due to the strong friction between the tape and the surrounding tissue, no other fixation is needed. The vaginal and abdominal incisions are closed after the ends of the abdominal tape are cut.

Anesthesia
Originally the TVT procedure was described under local analgesia (LA) and sedation[65]. This original paper used the cough-stress test to adjust the tape underneath the urethra. Most publications describe the outcome of the TVT using the originally-described procedure. General Anesthesia (GA) and regional analgesia (RA) do not offer the option of a cough test and therefore the outcome could be different. General anesthesia and local anesthesia also differ with regard to somatic, sympathetic and parasympathetic discharge. How nervous input to the bladder is altered between general and local anesthesia may be important to how a TVT is tensioned. When using GA or regional anesthesia, overcorrection and short-[66] and long-term

voiding problems could be a problem. Some suggest a simulated cough test, applying low abdominal pressure[67]. Regional anesthesia has been associated with short[66] term voiding problems and longer hospital stay[66, 68]. Other studies do not show a longer hospital stay with the use of regional analgesia[69-71]. In a retrospective study of 173 patients, Murphy et al[72] performed a univariate analysis of the TVT's performed by two surgeons. No difference in voiding dysfunction was found between the group with general anesthesia and without general anesthesia. However, no data on the final outcome for were mentioned. Kunde et al [73] observed a success rate of TVT under GA of 72%. Unfortunately, no comparison with a TVT under local anesthesia was performed. It is difficult to explain these contradictory findings. The cough-stress test is of limited value according to Barry et al[74] and Kuan-Hui Huang et al[75]. Three randomized trials assessed the differences between LA and RA. Wang et al[68] and Falconer et al[71] found earlier spontaneous voiding after LA but no other differences were found. Adamiak et al found no difference in both analgesia methods[70].
Overall the GA, RA or LA do not seem to have an influence on the outcome of the TVT procedure but more reliable data are necessary to strengthen this preliminary conclusion.

Clinical efficacy
The first publications on the TVT were published in 1998[65, 66, 76]. These studies were non-randomized, non-comparative studies with short follow-up. Ulmsten et al published their 3 year follow-up of 50 women in 1999[77]. The authors found a cure rate of 86% and concluded that the TVT operation was safe and effective. After this study more studies with a longer follow-up followed. The cure rates found in these studies varied between 66%-100%, subjective cure. Objective cure rates ranged from 67% to 100%[69, 76, 78-85]. The first large comparative studies started to emerge in 2001. Not all of these studies were randomized controlled trials, so heterogeneity of the groups may have influenced the results. Success rates between 86% and 96% were observed [86-95].
The UK and Ireland group presented the first results of their randomized controlled trial (RCT) in 2002. Ward et al found a cure rate of 66% when the non- attendees were counted as failures. The cure for the attendees was 76%[96]. The success rates after 2 years follow-up were 65% and 87% respectively[97]. The reason to publish both outcomes has also been described by Hilton[98]. The most important findings of the RCT were that the cure rates after TVT compared with the Burch colposuspension were comparable, and that the intra- and postoperative complications of the TVT were lower. The problem with the study was that the number of patients needed for the assessment, as calculated before with a power analysis, were not achieved.
More and more RCT's were published after 2003, often with a short follow-up and small numbers of women. Comparison of TVT with different sling procedures, Raz, laparoscopic suspensions and open colposuspension showed equal or better results and less complications[87-95, 99] for the TVT.
Few studies have a longer follow-up of more than 4 years[100-103]. Jooma et al and Nilsson et al describe a stable success rate until 7 years follow-up. Holmgren et al describe a stable success rate for stress incontinence, however for 112 women with a

mixed incontinence, the success rates did not persist after 4 years. The decline of cure rate for this group was from 60% to 30% between 4 to 8 years postoperative. This decline was not reported by Rezapour et al[104] in a follow-up period of 3-5 years.

Cost effectiveness

For the assessment of cost effectiveness of the TVT has been compared with open colposuspension and laparoscopic colposuspension (LC). When compared with the open colposuspension, the TVT was more cost effective. Shorter hospital stay and a shorter operating time were the main reasons for this conclusion[105-109]. Cody et al[109] and Manca et al[105] performed the most complete studies. Both used Quality-adjusted life years (QALYs). Both studies found a very high probability of the TVT being more cost effective than an open Burch colposuspension.

Cody et al also compared the TVT with laparoscopic colposuspension, traditional suburethral sling procedures and injectable agents (periurethral bulking agents). TVT was more likely to be considered cost-effective compared to the other surgical procedures. In one study the cost-effectiveness of the TVT compared to LC shows a better outcome for the LC. Persson et al conclude "In our hands, the laparoscopic colposuspension was less expensive to the country than the TVT procedure"[110].

In the Netherlands, Dubbelman performed a cost effectiveness study of treatment for SUI. The conclusions of his study were that no treatment at all was more expensive than most forms of treatment, TVT was found to be the most cost effective surgical method to cure USI, being cheaper than the five year use of incontinence pads, but slightly more expensive than physiotherapy.

Complications (per-, direct- and late postoperative complications)

The introduction of the 5 mm diameter TVT needles is relatively "blind" and no visual control is possible for the retropubic part of the introduction. This is a possible risk-factor for complications such as vascular, neurogenic, urethral, bladder or gastrointestinal injury. All different sorts of complications described in other retropubic operations have been described in the TVT procedure. The rates of these complications seems lower with the TVT.

Most complications are described in case reports, only two national prospective studies have been published recently[111, 112].

Bladder perforation is a one of the most common complications. It has often been described and when recognized and corrected, it does not cause much morbidity[96]. The perforation is comparable to the perforation made for the placement of a suprapubic catheter. An intraoperative cystoscopy is necessary to exclude this complication. Sometimes a bladder perforation is suspected when the bladder-filling fluid comes out of the plastic covering sheets at the vaginal or abdominal operative sites. Open as well as endoscopic procedures for removal of the tape from the bladder have been described[113, 114]. Late recognized bladder perforations have been reported[83, 115]. This can either be due to a missed perforation at cystoscopic check during surgery or may be due to migration of the tape?

Urethro-vaginal and cysto-vaginal fistulae have been described[112, 116, 117] but are

uncommon complications.
Few case reports describe bowel perforations[111, 118-121]. Most perforations were recognized immediately postoperatively, mainly in very thin women and in women with prior pelvic surgery. Bafghi et al and Fouri et al each presented a case of a bowel erosion with a late clinical manifestation occurring several months after surgery[122, 123].
Several case reports describe bleeding due to trauma to the perivesical venous plexus[124], iliac artery[125] and vein[126]. Retropubic and vulval hematomas have been described.
Urethral injury can be caused by direct trauma with the introduction of the TVT needle or due to late migration of the tape[115, 127]. Haferkamp et al[128] advocate reconstructive urethral surgery, while others [127, 129] suggest endoscopic resection of the urethral penetrations.
Persisting postoperative pain after a TVT procedure is a rare complication. It may be due to trauma of bladder[130], urethra[131], a hematoma, tape erosion or tape rejection. Barrington et al reported a case in which the postoperative pain after TVT was caused by a densely adhered tape to the ileopectineal ligaments[132]. The pain resolved immediately after dissection and division of the tape. Duckett et al reported five cases (1%) of groin pain after a TVT procedure (n=450)[133]. Vervest et al published a case report where the tape inadvertently ran through a nervous structure causing retropubic pain[134].
Tape erosion into the vagina has been described in publications as a late and very uncommon complication of the TVT[135-138]. Partial excision of the tape and the use of local estrogens is described as effective. Old age and post- menopausal status have been described as risk factors[135]. One comparative study compared the multifilament IVS procedure with the TVT. Glavind et al found more erosion in the multifilament group[139].
Obstructive voiding has been described, however the rate seems lower after TVT than in the Burch procedure[97]. Excessive tension on the tape has been thought to provoke these symptoms but several articles describe other risk factors for the development of voiding disorder, namely preoperative ISD [140], abnormal flow[141, 142], urgency[143], learning curve[138], repeat surgery[144-146], concomitant pelvic surgery[142, 147]. Obstructive voiding can also be a result of urinary tract infection[147]. Different options to resolve this complication have been described: tape excision[111, 148-150], tension readjustment by downward traction of the urethra[138, 151] via the vaginal incision[65, 111, 152], tape division[152-154] and interpositioning of another piece of tape[155].

Urge- and de novo urge incontinence, detrusor overactivity (DO) and mixed incontinence.
Long-term complications of the Burch colposuspension have been described before[156, 157]. *De novo* urge incontinence accounted for 15% of the long-term complications, and women with an unstable bladder before surgery had a detrimental outcome[157]. In both randomised controlled trials between Burch Colposuspension and TVT women with preoperative mixed incontinence, detrusor instability, prolapse, prior surgery for prolapse or incontinence surgery or voiding dysfunction were excluded[86, 96]. All these symptoms are very common in clinical practice in conjunc-

tion with SUI and the long-term results of the TVT on these symptoms should therefore be assessed.
Assessment of urge incontinence after TVT is difficult. Only a few large studies describe prospectively the long-term influence of the TVT on urge incontinence. The results of these published studies show a wide range in outcomes. Also a wide array of definitions were used to describe bladder function after the TVT procedure. This makes interpretation of these results difficult.
Two small (n=52 and n= 62 respectively) prospective studies showed de novo urge rates of 0-18%[82, 84]. A large cross-sectional, questionnaire based study of 743 woman showed de novo urge incontinence in 6.7%[102]. This complication even increased after several years. This finding suggests that slow ingrowth of tissue in the tape possibly changes the surroundings of the urethra. This 'sclerosis' may induce urge incontinence. But we must not forget that age is also a confounding factor for urge incontinence. It is thought that this phenomenon is a result of atrophy of the bladder epithelium.
The improvement or cure rates of the TVT are often lower in patients with preoperative mixed incontinence than in patients with only stress incontinence, that is 42%-100%[55, 69, 79, 81, 102, 158, 159]. For patients with preoperative detrusor overactivity, the cure or improvement rates described are 33%-100%[78, 79, 102, 159-161]. Holmgren et al described a steadily decline to 30% cure rate, after 4-8 years follow-up, due to increasing urgency symptoms[102]. The reverse, a reduction of the urge component, has been described (up to 57% by Segal 2004)[79, 82, 96, 97, 159, 161, 162]. It is thought that this occurs due to the stability the tapes provides underneath the urethra, which inhibits the urge incontinence[6, 60, 163].
Two large prospective comparative studies between the Burch colposuspension and the TVT showed de novo rates of detrusor overactivity (DO) of 7% and 17%after TVT and 9% and 14% after the Burch colposuspension[86, 96].

TVT and concomitant pelvic prolapse surgery.
Co-existing urinary incontinence and pelvic organ prolapse has been reported in 15-80%[164, 165]. Choe et al and Bai et al reported that 60-63% of patients with urinary stress incontinence also had pelvic organ prolapse[165, 166].
With the TVT as first choice for incontinence surgery, TVT in conjunction with other pelvic surgery is becoming more popular. This is especially so because the two procedures can be performed together without an abdominal incision. It is therefore remarkable that not many studies describe the success rate of this combination. Few studies have stratified for TVT versus TVT in conjunction with prolapse surgery. No significant difference in success was found in these studies[84, 151,167]. One study suggested a lower, however not significant, success rate for TVT with cystocele repair of 38% against 67% in patients without a cystocele repair[168]. Another study described a lower success rate for TVT with anterior colporrhaphy, but no statistical analysis was performed[83]. Partoll described 37 patients who underwent TVT and concomitant prolapse surgery[142]. After a follow-up of 11 months, the overall success rate for urinary incontinence was 94.6%. Success was defined as dry at a standing stress test with a

comfortably full bladder and no stress incontinence episodes having been reported verbally by the patient or noted in a voiding diary. Jomaa reported in 2001 on 32 women undergoing TVT and anterior and/or posterior colporrhaphy [169]
Success was defined as ≤ 10 g urine lost in a 24h pad test, no visible leakage at stress test, no anatomical defect and a patent satisfaction ? 90%. A 93% success rate was found. Lo et al found a success rate of 90.9% in 55 patients, part of the definition used to assess cure was a pad test[170]. In 2002 Soroka et al published a systematic review on pad tests which showed a significant variability and repeatability of the pad test[171]. Therefore studies using only the pad test as an outcome parameter should be treated with caution.
The results of all these studies are difficult to compare due to different definitions of success or cure.

TVT in patients with prior pelvic surgery
Burch colposuspension and sling procedures have been used in the past for women with recurrent stress incontinence. Success rates of 85-90% at 3-4 years follow-up are published but are associated with high complication rates such as significant urinary retentions and blood loss[172-174]. These complications are lower with the TVT procedure[111].
Only few articles describe the outcome of the TVT after prior incontinence surgery [58, 118, 146, 175-178] and prolapse surgery [78, 118]. Most studies do not report a difference in success rates between primary and secondary cases of incontinence surgery [80, 84, 179]. The success rate of the secondary cases reported is 84%-89%, but objective judgment of these studies is complicated. The groups are small, the outcome parameters are all different, the definition of repeat or secondary surgery is not uniform and sometimes the statistical significance is not reported [56, 58, 82].

TVT with intrinsic sphincter deficiency
Intrinsic sphincter deficiency (ISD) is defined as a urethra with a maximum closure pressure of less than 20 cm H_2O. There is some controversy whether immobility (so called "fixed urethra") should also be included in the definition and whether ISD is defined as a low pressure, fixed urethra. This makes comparison of data in studies addressing the outcome of TVT in cases with ISD difficult to interpret. Furthermore, confounding factors like prior pelvic surgery and age may be introduced , which may be independent etiological factors for the development of ISD.
Most studies comparing women with low urethral sphincter closure pressure with women with normal closure pressures, show better cure rates for women with normal closure pressures[180-182]. Several studies do report differences between the two groups but do not report on the statistical significance[56, 78, 82, 140]. A few studies did not compare the results of women with or without ISD and reported on the results of the group with ISD only[183-186]. The reported cure rates are between 56% and 90%.
Lower cure rates are reported in patients suffering from both ISD and an immobile urethra[183, 187]. One publication reports on a comparable high cure rate for both groups, ISD with immobility 83% and ISD without immobility 86%[188].

TVT and sexual function

There are few studies on sexual function after TVT. Yeni et al and Helstrom et al both suggested a negative influence[189, 190]. Yeni et al described a change in scores of sexual functions such as orgasm, pain and overall satisfaction. All except orgasmic function was found to be worsened. Desire and arousal was found not to change. Helstrom theorised that this negative influence might be due to disturbance of vaginal nerve and blood supply of the vaginal wall resulting in impaired sexual arousal and lubrication. Another study did not find the TVT to affect sexual life[191]. In a recent published study, Ghezzi et al reported on two patients (3.8%) with intercourse to be worse after surgery (one because of a vaginal erosion and the other cited de novo anorgasmia), while all other women reported better sexual function (34%) or no change (62%)[192].

TVT and pregnancy

Only three case reports exist on this subject. In two women with TVT, an elective caesarean section was performed and both remained continent[193, 194] postnatally. One case report describes a 37-year-old (para 2) woman who had a spontaneous vaginal delivery at 40 weeks gestation, after a TVT procedure performed 10 months prior to the delivery. At 5 months post-natal follow-up, the TVT was in situ on ultrasound examination and the patient remained continent[195].

TVT in different age groups

The morbidity of surgery in the elderly is higher than in the young. Concomitant diseases like diabetes or COPD play an important role. But also specific conditions of the lower urinary tract can cause increased risk factors. Postmenopausal urogenital atrophy, intrinsic sphincter deficiency, mixed incontinence, detrusor over activity and voiding disorders are considered risk factors with a higher prevalence in the older age groups. Due to these factors a higher risk for tape erosion, defect healing, bladder perforation, voiding dysfunction or urinary retention, overactive bladder, urge and urge incontinence may be expected. Another problem in comparing age groups is the difference between the operative history of the different age groups. Older women more commonly have a history of previous pelvic surgery. Furthermore, elderly patients with UI tend to be more depressed and have worse perceived health[31].

Pugsly et al compared the success rate and complications after colposuspension and TVT between women aged over 70 years and younger women. After colposuspension, urinary tract infections (UTI) and long-term self-catheterization were more common in women over 70. After TVT, recurrent UTI and tape division were more common in older women[196].

Stone et al compared women over 75 years to women younger than 75 years. The cure rates were comparable, but women over 75 years had worse outcomes on irritative symptoms and quality of life scores[197]. Another comparative study assessed the outcome of the TVT in women under and over 65 years[198]. The complication rates were comparable but the success rates of the elderly were lower (71% against 44%).

Prien-Larsen found comparable subjective and objective outcomes for women under and over 70 years[199]. In a comparative study of Gordon 157 women over 70 years and 303 younger women were assessed. The incidence of persistent postoperative SUI and persistent urge incontinence was similar in both age groups. However, de novo urge incontinence was significantly more common among elderly women (18% versus 4%, P <0.05)[200]. Walsh et al compared 2 groups, namely 21 patients who were 70 years and older, and a control group of 46 patients younger than 70 years and assessed quality of life changes following TVT. In both groups the quality of life improved significantly[59]
Alahdin et al looked at 3 age groups: 30-49 years, 50-69 years and 70-90 years. The cure rates were 84.9%, 81.3% and 85.3% respectively[135]. Abdel-Hady el et al found age over 70 years to be a risk factor[201]. In a non-comparative study in a patient group aged over 65 years, Lo et al found a success rate of 91% and de novo detrusor overactivity in 4%[67]. Sevestre et al, in a non comparative study in a group of 76 women over 70 years, found a 82% satisfaction rate but 21% rate of de novo urgency[202]. Liapis et al found in a group women aged between 65 and 86 years a satisfactory cure rate. However, in patients with significantly decreased bladder neck mobility (an angle <20 degrees on the Q-tip test), the success rates were lower[203].
A review article about risk factors influencing the complication rates of TVT found prior anti-incontinence surgery and old age to be possible risk factors for postoperative overactive bladder symptoms[204].
Wang et al found age not statistically significant in postoperative voiding dysfunction[147].

TVT in the obese patient
Many articles have described the consequences of obesity in curing urinary incontinence. Dwyer et al describe a higher rate of stress and urge incontinence with an increased body mass index[205]. Kjolhede performed a long-term follow-up of women undergoing a Burch colposuspension. In this study preoperative obesity seemed to be a long-term risk factors for an adverse outcome[206]. Although outcome of TVT for an increasingly obese population seems interesting, not many articles have assessed specifically the outcome for this group.
Kinn et al[78] and Hung et al found a lower cure rate for obese women (BMI>28 kg/m^2 and 27.3 kg/m^2 respectively). A few other studies found comparable cure rates for normal BMI and obese women [57, 207-209]. Rafii et al found a higher rate of UI after TVT but this group had a higher rate of preoperative urgency [208]. In a comparative study between TVT and laparoscopic Burch colposuspension in obese women, the authors concluded TVT to be safer, more effective, and easier to perform[207].

TVT after radiotherapy
Few studies report on the outcome of TVT after pelvic radiotherapy.
Ferrari et al found no specific complications or different success rate in women with a history of pelvic radiation[118]. Another study included 2 patients with pelvic beam radiation. One patient was found to be dry, the other patient is described as having

very slight leakage at stress[82]. Kinn et al also included 2 women with a history of pelvic radiation[78]. One patient was cured but showed a vaginal erosion of the tape. In the other patient the SUI was found to be worse after TVT. In a study of Al-Singary et al[210], 87 women were evaluated. In 16 of these women TVT was considered to have failed and 2 of these women had a history of radiotherapy
In the Austrian national TVT registry, 8 patients with a history of radiotherapy were included but no success rates or specific complications were described[111].

TVT in patients with neuropathic bladder
Patients with a neuropathic bladder have specific problems. In an upper motor neurone injury often a detrusor hyperreflexia exists combined with a weak external urethral sphincter. In lower motor neurone injury, an a non contractile bladder with a weak urethral sphincter exists. Stress incontinence in women with a neurogenic bladder is accompanied by either detrusor over- or under-activity. In women with hyperreflexia, suppressing the detrusor overactivitywith anticholinergics may be indicated prior to TVT. Acontractility may indicate a need for permanent postoperative bladder drainage.
Hamid et al published an article describing the outcome of TVT in 11 patients with a neuropathic bladder and SUI[211]. They found a success rate of 92%. The authors warned that an exacerbation of pre existing hyperreflexia could be caused by the insertion of a TVT.

Aims of the thesis

At the time of the initiation of this study, no large prospective cohort study had been performed. The aim of this study was to evaluate the outcome of TVT carried out by gynecologists and urologists in the Netherlands.
TVT was evaluated with a three year follow-up. At each follow-up a full urogynecological history, a physical examination and a cough-stress test was performed. Quality of life was separately assessed with disease specific health-related quality of life (HRQoL) questionnaire [48] [22].

The aims of the work presented in this thesis were:

1 To describe the anatomical complications, its frequency and the influence of risk factors such as the operative history, concomitant surgery, learning curve and type of anesthesia on the complication rate of the TVT.
2 To assess the pre- and intraoperative factors influencing the success of the TVT procedure for SUI.
3 To assess the long-term outcome of TVT in women in whom the TVT procedure was their first incontinence surgery and was not combined with prolapse or other urogynecological procedures.
4 To assess the outcome after a follow-up of three years of TVT in women with previous incontinence or prolapse surgery.
5 To assess the long-term outcome of TVT on urge incontinence and other forms of irritative bladder symptoms.
6 To assess the outcome with a follow-up of three years of the TVT procedure in women with concomitant pelvic surgery.
7 To determine the prevalence of immediate postoperative and long-term voiding difficulties after TVT.

Outline of the thesis

To address the research questions we conducted the following studies.

In chapter 2 we describe the anatomical complications, frequency and the influence of several risk factors such as the operative history, concomitant surgery, learning curve and type of anesthesia on the complication rate of the TVT. Furthermore a survey of complications of the TVT procedure as published in the English scientific literature is presented.

In chapter 3 we present the results of a multicenter study on the long-term outcome of TVT. The focus of this report is on the pre- and intraoperative factors influencing the success of the TVT procedure for SUI.

In chapter 4 we present the results of a multicentre study on the long-term outcome of TVT in women in whom the TVT procedure was their first incontinence surgery

and was not combined with prolapse or other urogynecological procedures. The focus of this paper is on the influence of TVT on the quality of life which was assessed with validated disease specific quality of life questionnaires.

In chapter 5 we present the outcome and follow-up of three years of a low tension mid-urethral sling (TVT) in women with previous incontinence or prolapse surgery by means of objective (patient self reported) results on their health status with the aid of disease specific HRQoL questionnaires (the Incontinence Impact Questionnaire (IIQ) and the Urogenital Distress Inventory (UDI)).

In chapter 6 we present the results of a multicentre study on the long-term outcome of TVT on urge incontinence and other forms of irritative bladder symptoms with well described outcome measures. Irritative symptoms and quality of life before and after the TVT were assessed with the aid of patients self reported disease specific validated health-related quality of life HRQoL.

In chapter 7 we present the outcome and follow-up of three years of the TVT procedure in women with concomitant surgery by means of objective (patient self reported) results on their health status with the aid of disease specific HRQoL questionnaires (the Incontinence Impact Questionnaire (IIQ) and the Urogenital Distress Inventory (UDI)).

In chapter 8 we report on the prevalence of voiding difficulties after TVT in the immediate postoperative period and on the long-term with the aid of reports of women, measurement of objective parameters, and with the use of validated quality of life questionnaires.

Chapter 9 of this thesis contains a general discussion, a summary in English and recommendations for future research.

Chapter 10 contains a summary in Dutch.

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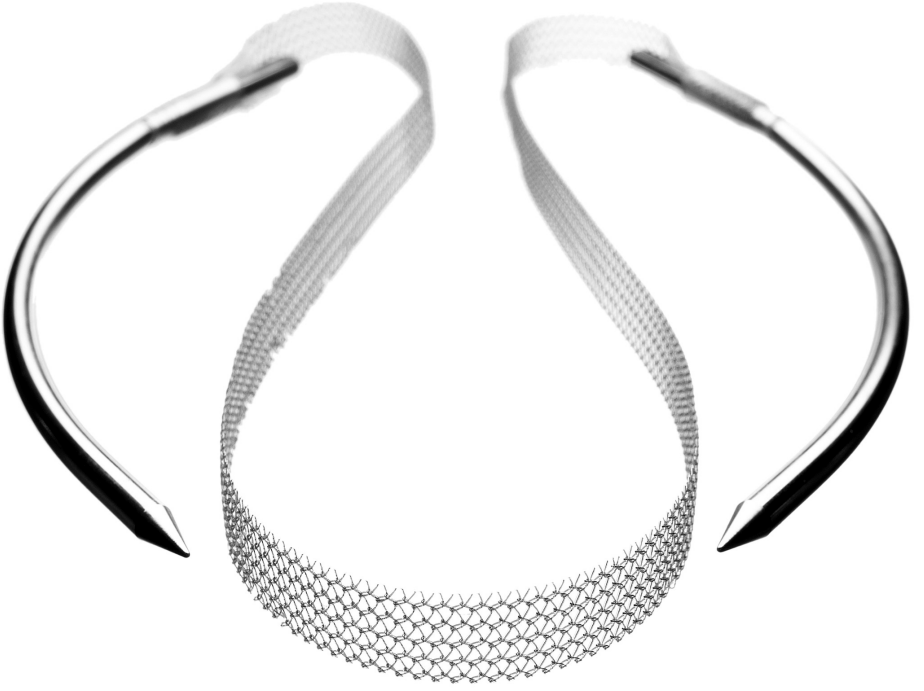
Part 2



Chapter 2

Prospective analysis of complications of Tension-free Vaginal Tape (TVT) from The Netherlands TVT Study

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American Journal of Obstetrics and Gynecology 2005, July 193: 45-52

Abstract

Objective: The intra- and postoperative anatomical complications, frequency, and influence of risk factors of the tension-free vaginal tape are described.

Study Design: This was a prospective cohort study of 809 patients.

Results: The total intraoperative complication rate was 6.2%. Previous prolapse surgery was a risk factor for complications (odds ratio, 2.86; 95% CI, 1.15 - 7.11). We found more intraoperative complications in patients with general anesthesia than with local analgesia with sedation (odds ratio, 4.14; 95% CI, 2.01- 8.53). In teaching hospitals the postoperative complication frequency was higher than in non-teaching hospitals (odds ratio, 0.55, CI 0.35- 0.85). The learning curve is short and more postoperative complications were found in the second ten patients operated by 1 surgeon (odds ratio, 1.94; 95% CI, 1.14 – 3.29). Spinal analgesia gives fewer postoperative complications than local analgesia with sedation (odds ratio, 0.35; CI, 0.13 – 0.92).

Conclusion: Tension-free vaginal tape is a relative safe procedure; concomitant pelvic surgery can be performed safely. Several risk factors for complications were identified: menopausal state, previous prolapse surgery, mode of anesthesia, teaching hospital, and the second ten procedures of each surgeon.

INTRODUCTION

Stress urinary incontinence (SUI) is a common health problem among women[1]. Besides physiotherapy, incontinence surgery is the cornerstone in the treatment of these women. Many different surgical techniques have been introduced for the treatment of SUI. The techniques not only differ with regard to success, but they also have different complication rates. These complications can be anatomic (eg, bladder perforation) or functional (eg, voiding dysfunction).

Currently, tension-free vaginal tape (TVT) is a well-established therapy for SUI in women. The procedure was introduced by Ulmsten et al[2,3] in 1995, and has replaced most other forms of anti-incontinence surgery, with > 500,000 devices sold worldwide. TVT is a minimally invasive procedure and is based on the concept of mid urethral support. The TVT has proved to be as successful as any other incontinence procedure[4]. Reasons for its popularity are the minimally invasive nature of the procedure and its high success rate. Nevertheless, minor and major complications have been reported[5]. Operative bladder or urethral perforation has been reported to be up to 15% of cases[6]. Several other severe intra- and postoperative complications like urethral erosion, injury to large vessels, hematoma, wound infection, and complete urinary retention have been described[5-9].

Several possible risk factors for complications have been described[5-9]. The operative history of the patient, the learning curve of the surgeon, concomitant surgery, and the different sorts of anesthesia, may all play a role in the occurrence of complications. To be able to prevent complications, knowledge of these possible risk factors is needed. No prospective study has ever been performed to establish insight into these risk factors. The study of Ward et al[4] was a trial that compared the TVT and the Burch procedures. The study reports the incidence of complications but does not report on the possible risk factors for complications. The results of the Austrian registry, as reported by Tamussino et al[8], described the complications of TVT in a large group (N=2795). Participating centers in that study were asked to complete a single-page questionnaire for every patient who underwent a TVT procedure. It is not clear from the article whether this was done prospectively for every patient. All other studies also have described the complications and its rate retrospectively, which gives a subjective insight in the real amount and severity of the complications.

The aim of this study was to describe the anatomic complications, their frequency, and the influence of several risk factors (such as the operative history, concomitant surgery, learning curve and type of anesthesia) on the complication rate of the TVT procedure. Furthermore, a survey of complications of the TVT procedure, as published in the English scientific literature, is presented.

MATERIALS AND METHODS

This study was approved by the Medical Ethical Committee of the St. Elisabeth Hospital Tilburg, as primary research center, and all other co-working hospitals, as required by Dutch law. Written informed consent for this study was obtained from all the women. Between March 2000 and September 2001, all patients with an indication for the TVT procedure were asked to participate in this study. The procedures took place in 41 different hospitals, in which 54 gynecologists and urologists performed the TVT procedure. Among the 41 hospitals, there were 3 university hospitals, 25 teaching hospitals, and 13 local hospitals. All participating gynecologists and urologists were qualified to perform vaginal surgery and had a short training in performing TVT procedure by an experienced surgeon.
Inclusion criteria were SUI that was proved at urodynamics or at history/physical examination with an indication for surgery. The urodynamic investigations were performed according to the standards recommended by the International Incontinence Society[10]. Exclusion criteria were recurrent and difficult-to-treat urinary tract infections, significant symptoms of urge urinary incontinence, a history of detrusor overactivity at cystometry, post voiding bladder retention (>150 ml), bladder capacity < 200ml or physical/mental impairment.
The TVT was performed as described by Ulmsten[2]. The operation was carried out with local anesthesia with 0.25% prilocaine with adrenalin and sedation, spinal analgesia, or general anesthesia.
A standardized history, physical examination, and urine culture was accomplished before the operation and at 2, 6, 12, and 24 months. The registration of intraoperative and direct postoperative complications was done by the surgeon.
The following complications were recorded: blood loss > 300 ml, bladder perforation, urethral lesion, major vessel lesion, and other intra operative complications. Post operative complications considered were the need for catheterization > 24 hours, the need for self-catheterization, postoperative bleeding, hematoma, wound infection, urinary tract infection, tape rejection, tape erosion, temperature rise > 38 °C. The number of TVT procedures that every surgeon performed and the complications per surgeon were counted. Groups were formed of the first 10 TVT procedures, 11-20 TVT procedures and over 20 TVT procedures that the surgeon performed.

Statistical analysis
All data were anonymous processed by a research physician (TMB) and the secretary of the research team. Statistical analysis was performed with SPSS 10.0 for Windows (SPSS Inc, Chigago, **I**11. The X^2 test was used to compare proportions that related to subjects in different groups. Categorical variables were compared with a 2-sided Fisher exact test. The Student t-test was used as a statistic to compare interval variables. Univariate odds ratios (ORs) and 95% confidence intervals (CI) and the probability values were calculated for risk factors.
Subsequently, multivariate logistic regression analysis was used to construct a prediction model to determine preoperative and postoperative factors that independently

influenced the complication rate. Logistic regression is a technique that can be used to evaluate the performance of multiple variables in a diagnostic model. The selection of variables usually is performed with a significance level of 5%. However, the incorrect exclusion of a factor would be more deleterious than including too many factors. Multivariate analysis included therefore all variables with a probability value $< .30$ in the univariate analysis.

RESULTS

In total 809 women participated in the study. Their mean age was 51.3 ±10.4 (range, 20-82) years and mean parity was 2.4 ±1.1. Of all patients, 46.6% were postmenopausal, and 34% of the postmenopausal women used hormone replacement therapy. The mean operating time for only the TVT procedure was 32.4 ± 11.2 minutes (range, 14 - 120 minutes). The incidence of intraoperative complications was 6.2% (n = 50 women; Table 1). Bladder perforation was the most common complication (n = 28 women; 3.5%). In all cases it was diagnosed during the procedure. In all but 1 case, the tape was reinserted, and an indwelling catheter was placed; at follow-up examination, none of these patients had any problems. There were no urethral lesions. Severe blood loss (>300ml) occurred in 10 cases. In 1 case, the internal iliac vein was lacerated, and a laparotomy performed. There was 2500-ml blood loss; the tape was left in place, and the patient recovered completely.

The total incidence for postoperative complications was 20.9% (n = 169 cases; Table 1). In this group there were 30 patients (3.7%) with a combination of > 1 complication. These complications were counted separately in the total incidence. Abdominal, vaginal, or retropubic hematoma was seen in 28 patients (3.4%). A temperature rise (> 38°C) was diagnosed in 1 case (0.1%). Tape erosion was found in 2 cases (0.2%) within the two-year follow-up examination. In 121 cases (14.9%), an indwelling bladder catheter was needed for > 24 hours. In 13 of these patients (1.6%), because of voiding difficulty, the TVT tape had to be cut. After reopening the midline incision, the tape was identified and cut laterally of the urethra. In one case, the tape was cut in the midline, a lesion arose in the urethra during surgery, which was closed. Afterwards a urethral-vaginal fistula developed which was closed vaginally. The patient recovered completely. Of the 13 patients in whom the TVT had to be cut, 5 patients were reported to be continent. All these 13 patients were able to void without residual volumes of > 150 ml at 12 months after the tape was cut. Three women required either self-catheterization or a suprapubic catheter.

There were 131 women with an operative history for incontinence or prolapse. In the group with previous incontinence surgery (n = 50 women), there was no significant difference in sort of complications. In this group, there were 9 patients who had undergone 2 previous incontinence procedures, and 1 patient who had undergone 3 previous incontinence procedures (Burch, re-Burch and hysterectomy with concomitant Raz sling procedure). In this group of 9, there were no intra- and postoperative complications; 1 patient had worsening of pre-existing urge incontinence.

A statistical difference was found in the intraoperative complication rate of the group who had a history of prolapse surgery (OR, 2.86, 95% CI, 1.15 - 7.11; Table 2). There were only 16 cases (2%) with a history of both prolapse and incontinence surgery. No significant difference in complication rate was found in this group. Women with a rectocele before surgery had statistically a lower chance at postoperative complications. General anesthesia was found to give more complications intra- operatively than local analgesia with sedation (OR, 4.14, 95% CI, 2.01- 8.53).

In 59 cases (7.3%) concomitant surgery was performed: vaginal hysterectomy for

uterine descent, 7 cases; anterior repair, 15 cases; posterior repair, 28 cases; and anterior and posterior repair, 9 cases. The intra- and postoperative complication rates in this group did not differ significantly (Table 2 and 3). The complication rate in the group with concomitant non-pelvic surgery was 9.5% (not significant).
The postoperative complication rate in the in the 25 teaching hospitals was 24% and 16% in the 13 local hospital. This indicates a significant difference in postoperative complication rate among the different types of hospitals (OR, 0.55, 95% CI, 0.35-0.85). In the group of premenopausal women, we found fewer postoperative complications (OR 0.67, 95% CI, 0.46 – 0.99). The multivariate regression analysis showed a significant difference for spinal anesthesia (OR 0.35, 95% CI, 0.13 – 0.92). The results of the learning curve are shown in tables 2 and 3. In the second ten procedures performed by the same surgeon, statistically most of the postoperative complications occur (OR 1.94, 95% CI, 1.14 – 3.29).

COMMENT

This study comprises 30% of all TVT procedures that were performed in the Netherlands during the inclusion period of our study. It analyzes the intra- and postoperative complications that are associated with the TVT procedure. We tried to get a clear view in the origin of these complications. Is there a learning curve? Does concomitant surgery complicates the procedure? Is a history of previous surgery the main factor in causing complications? Several studies report about the complication rates with different kinds of incontinence surgery (Table 1). However, to our knowledge, apart from the comparative study of Ward et al[4], a large prospective study of complications with the TVT procedure has never been published.

Different kinds of incontinence procedures result in different complications and different complication rates. The complications presented in this study do not differ much from, and in general occur less frequent than, the complications described with other incontinence procedures[11-14]. Table 1 shows the observations from several other studies on complications with the TVT procedure[4-9].

It appears that the rate of intra- and postoperative complications does not differ significantly among these studies. However, in a number of these studies, the data were collected retrospectively. Hence, under or over reporting and other sources of bias may have been introduced unwittingly.

The introduction of the TVT needles is relatively "blind", and no visual control is possible for the retropubic part of the introduction. Despite this, the number of complications (eg, hemorrhage, urinary, or visceral tract injuries) is low. Most common is a bladder perforation (2.7%-15%). In our study, all complications were reported by the surgeon. We found no obturator nerve and no urethral injury. Nevertheless, we did report 1 case of iliac vessel injury. Analysis of this case did not reveal any special circumstance for this complication to have happened. This is in concordance with literature, because case reports about these complications are limited[15-18]. One may conclude that serious complications are uncommon after TVT procedure.

In addition, complications that are seen often with the use of foreign body material (such as fever, erosion, or infection) are low with the TVT procedure. In our study, 2 tapes had to be removed because of infection or erosion within the 2-years follow-up examinations. Whether these cases could be attributed to real infection or to erosion or to a defective wound healing is unknown. Tape removal has been reported more often in the international literature[19, 20] and is especially seen in few cases in which the vaginal wall did not close completely over the tape. This might be due to extreme atrophy of the vaginal mucosa. In our study, this is reflected in the occurrence of more postoperative complications in postmenopausal women.

The learning curve is associated with complication rates in many medical procedures. Two studies in the English literature report about the learning curve of the TVT procedure [5, 21]. Kuuva et al[5] found a decline in the number of complications per surgeon after 15 procedures. Groutz et al[21] found 5 bladder injuries in the first 20 patients underwent operation by an experienced urogynecologist. These authors state: "We believe these injuries represent the learning curve because no further

injuries occurred subsequently". In our cohort, the complication rate was increased in the second 10 patients who underwent operation by 1 surgeon. We cannot explain the reason that the number of complications is higher in the second 10 procedures as compared to the first 10 procedures for each surgeon. We should emphasize that all gynecologists and urologists who participated in this study were trained in the procedure by experienced peers. Furthermore, they were able to carry out cystoscopy procedures to detect bladder injury, which is of paramount importance for a safe TVT procedure. Nevertheless, we conclude that, as compared to other incontinence procedures, the TVT procedure has a short learning curve. Related to the subject of experience, we observed significantly more postoperative complications in teaching hospitals. In these hospitals, procedures were carried out by residents and registrars who were supervised by experienced consultants. The increased number of complications in these hospitals may be the result of the fact that the retropubic part of the procedure is difficult to supervise. However, when this is true, one might expect more intra- than postoperative complications. Nevertheless, this observation strengthens the fact that, although short, there is a learning curve.

Simultaneous surgery may affect the complication rate. We found no differences in intra- or postoperative complication rates between isolated TVT procedures or TVT procedures in combination with prolapse surgery. To our surprise a pre-existing rectocele was associated with fewer postoperative complications. We do not have a clear explanation for this observation, and it may merely be a coincidence. Previous prolapse surgery was attributed to more intra-operative complications, predominantly bladder perforations. Others before have described this. Moss et al[22] found 3 bladder perforations in 154 primary TVT procedures. Ten bladder perforations occurred in a group of 163 patients with previous pelvic surgery. However, this was not significantly different. Moss et al did not make a difference between previous prolapse surgery and previous incontinence surgery because the last group was too small to analyze separately. In contrast, Daraï et al[23], who studied the outcome of 40 TVT procedure with and 41 procedures without simultaneous hysterectomy, found significant differences among women with previous incontinence surgery. They found no intra- and postoperative differences in complication rates between the 2 groups who were studied, except for de novo urge symptoms. Nevertheless, they did find a significant difference in complication rate among patients with previous incontinence surgery. Daraï et al claim that this occurred because of the scarification of Retzius space. Our data, however, did not associate incontinence surgery before the TVT procedure with an increase in intra- or postoperative complications.

Finally, the mode of anesthesia may influence the complication rate of the TVT procedure. Multivariate regression analysis for intraoperative complications and the type of anesthesia showed a significant difference for general anesthesia. This analysis corrects for confounding factors such as concomitant surgery and history of pelvic surgery. Spinal anesthesia was found to give fewer postoperative complications, especially no postoperative urinary obstruction. One might think that when the cough test that was described by Ulmsten et al[2] is not performed, more obstruction could have been encountered. Possibly the surgeons who performed the TVT with spinal anes-

thesia are aware of the possibility of this complication and left the tape lose under the urethra. In contrast, Bodelsson et al[6] found a higher incidence of bladder perforations in the spinal group.

In conclusion, this study shows that the TVT is a relatively safe procedure with a low complication rate. Several risk factors for complications were identified: menopausal state, previous prolapse surgery, general anesthesia, teaching hospital, and the second ten procedures performed by each surgeon. The TVT procedure has a short learning curve; however, good cystoscopic skills are essential for everyone performing the TVT procedure.

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Table 1. Complications of TVT's performed (N = 809) in comparison with other studies

Sort study	This study prospective	Ulmsten (7) retrospective	Kuuva (5) retrospective	Ward (4) prospective	Bodelsson (6) retrospective	Meschia (9) retrospective	Tamussino (8) retrospective
Only TVT	**no N=809**	**yes N=50**	**no N=1455**	**no N=170**	**no N=174**	**yes N=404**	**no N=2795**
intra-operative complications							
bladder perforation	3.5%	NA	3.8%	8.8%	13.8%	6%	2.7%
blood loss>300ml	1.2%	0%	1.9%⋆	0.6%#	4% ##	0.5%	2.3%‡
urethral lesion	0%	0%	0.1%	NA	1.2%	NA	NA
lesion of the iliac vessels	0.1%	0%	0.1%	0.6%	NA	NA	NA
other	1.4%		0.2%⋆⋆			0.2%¶	2.4%‡‡
post-operative complications							
hematoma	3.4 %	NA	2.4%	1.8%†††	0.6%	1.5%	NA
persisting complete retention	NA	0%	2.3%	2.9%	2.8%	NA	NA
need of catheter>24 hours	14.9 %	10%	NA	11.2%††	20%	4%	NA
tape rejection	0.2%	0%	0%	0.6%	1.7%	0.5%	NA
urinary infection	0.7%	0%	4.1%	22.3%†	7%	NA	17%
fever (>38 degrees Celsius)	0.1%	NA	0.8%	0.6%	NA	NA	NA
other				Vaginal perforation 2.9%			
remarks	1.6% adhaesiolysis of tape	No significant other complications were noted		This is a prospective study comparing TVT with Burch			

NA: not available
†: in 6 weeks postoperative
††: > 7 days
†††: retropubic hematoma
#: Obturator artery injured requiring laparotomy and bllod transfusion (4 units)
⋆: >200 ml.
⋆⋆: 1x obturator nerve lesion, 1x vaginal hematoma
##: amount of blood loss unknown, vaginal pack needed
¶: 1 obturator nerve lesion
‡: increased bleeding amount not stated
‡‡: needed reoperation

Table 2. Univariate and Multi variate Analysis of Riskfactors influencing Intra-operative Complications

		Univariate Analysis						Multivariate analysis			
	missing values	**no complications** (n = 759)		**complications** (n =50)		**OR[95% CI]**	***p***	**β**	**OR**	**[95% CI]**	***p***
General Data											
age (years ± sd)	6	51.31	± 10.3	50.7	± 11.6		0.690				
parity	75										
nulliparity		15	(88%)	2	(12 %)	0.5 [0.1 - 2.3]	0.378				
multiparity		671	(94 %)	46	(6 %)						
menopausal status	69										
premenopausal		370	(94 %)	25	(6 %)	1.0 [0.5 - 1.8]	0.979				
postmenopausal		323	(94 %)	22	(6 %)						
Urogynecological History	0										
no previous urogynecological surgery		641	(95 %)	37	(5 %)	+					
previous prolapse surgery		58	(89 %)	7	(11 %)	2.1 [0.9 - 4.9]	0.083	1.05	2.86	[1.15-7.11]	**0.02**
previous incontinence surgery		46	(92 %)	4	(8 %)	1.5 [0.5 - 4.4]	0.452	0.36	1.44	[0.46-4.51]	0.54
previous incontinence and prolapse surgery		14	(88 %)	2	(12 %)	2.5 [0.5 - 11.3]	0.227	1.31	3.72	0.77-17.94]	0.10
Pelvic Floor Status prior to TVT											
cystocele	121										
no cystocele		337	(93 %)	24	(7 %)	1.1 [0.6 - 2.0]	0.722				
cystocele		303	(93 %)	24	(7 %)						
rectocele	103										
no rectocele		501	(93 %)	39	(7 %)	0.6 [0.2 - 1.3]	0.17	-0.96	0.38	[0.15-0.96]	**0.04**
rectocele		159	(96 %)	7	(4 %)						
prolaps of uterine cerix of vaginal vault	94										
no prolapse of cervix of vaginal vault		522	(94 %)	32	(6 %)	1.4 [0.7 - 2.8]	0.29	0.29	1.34	[0.64-2.80]	0.44
prolapse of cervix of vaginal vault		148	(92 %)	13	(8 %)						
urethral hypermobility	192										
no hypermobility		98	(94 %)	6	(6 %)	0.8 [0.3 - 2.0]	0.694				
hypermobility		478	(93 %)	35	(7 %)						
type of hospital setting	0										
no. of TVT in teaching hospitals		439	(94 %)	30	(6 %)	0.9 [0.5 - 1.6]	0.764				
no. of TVT in non-teaching hospitals		320	(94 %)	20	(6 %)						

Simultaneous Procedures	0										
TVT only		643	(94 %)	44	(6 %)	+					
TVT with prolapse surgery		55	(94 %)	4	(6 %	1.1 [0.4 - 3.1]	0.91				
TVT with other surgical procedures		61	(97 %)	2	(3 %)	0.5 [0.1 - 2.0]	0.306				
Type of Anesthesia	64										
local anesthesia (with sedation)		564	(95 %)	32	(5 %)	+					
spinal analgesia		59	(95 %)	3	(5 %)	0.9 [0.3 - 3.0]	0.859	-1.09	0.34	[0.04-2.55]	0.29
general anesthesia		72	(83 %)	15	(17 %)	3.7 [1.9 - 7.1]	**0.001**	1.42	4.14	[2.01-8.53]	**0.01**
Surgeon's Experience	0										
learning curve effect											
first 10 procedures for each surgeon		265	(94.0%)	17	(6%)						
next 10 procedures for each surgeon		145	(92%)	13	(8%)	1.4[0.7-3.0]	0.432				
more than 20 procedures for each surgeon		349	(95%)	20	(5%)	0,9[0.5-1.7]	0.736				

Values are mean (SD). number (%) and Odds Ratio [95% CI]
A Fisher exact Tes was performed for catergorical variables
Student-t test was performed for interval variables
(+) Reference group
statistically significant differences are highlighted
p= p-value

Table 3.Univariate and Multivariate Analysis of Riskfactors influencing Postoperative Complications

		Univariate Analysis						Multivariate Analysis		
	missing values	no complicatior (n = 640)		complicatior (n = 169)		OR [95% CI]	*p*	β	OR [95% CI]	*p*
General Data										
age (years ± sd)	7	50.9	± 10.4	52.6	± 10.4		0.055			
parity	75									
nulliparity		13	(76 %)	4	(24 %)	0.9 [0.3 - 2.7	0.816			
multiparity		565	(79 %)	152	(21 %)					
menopausal status	69									
premenopausal		321	(81 %)	74	(19 %)	0.7 [0.5 - 0.9	**0.041**	-0.4	0.67[0.45-0.99	**0.044**
postmenopausal		259	(75 %)	86	(25 %)					
Urogynecological History	0									
no previous urogynecological surgery		543	(80 %)	135	(20 %)	+				
previous prolaps surgery		46	(71 %)	19	(29 %)	1.7 [0.9 - 2.9]	0.077			
previous incontinence surgery		38	(76 %)	12	(24 %)	1.2 [0.6 - 2.5]	0.487			
previous incontinence and prolaps surgery		13	(81 %)	3	(19 %)	0.9 [0.3 - 3.3]	0.908			
Simultaneous Procedures	0									
TVT only		532	(77 %)	155	(23 %)	+				
TVT with prolaps surgery		52	(88 %)	7	(12 %)	0.5 [0.2 - 1.04]	0.056	-0.64	0.53[0.21-1.33]	0.17
TVT with other surgical procedures		56	(89 %)	7	(11 %)	0.4 [0.2 - 0.96]	**0.035**	-0.25	0.78[0.33-1.87]	0.58
Pelvic Floor Status prior to TVT										
cystocele	121									
no cystocele		274	(76 %)	87	(24 %)	0.9 [0.6 - 1.2	0.401			
cystocele		257	(79 %)	70	(21 %)					
rectocele	103									
no rectocele		411	(76 %)	129	(24 %)	0.6 [0.4 - 0.9	**0.016**	-0.49	0.61[0.36-1.0]	0.07
rectocele		141	(85 %)	25	(15 %)					
prolaps of uterine cerix of vaginal vault	94									
no prolaps of cervix of vaginal vault		429	(77 %)	125	(23 %)	0.8 [0.5 - 1.2	0.287			
prolaps of cervix of vaginal vault		131	(81 %)	30	(19 %)					
urethral hypermobility	192									
no hypermobility		83	(80 %)	21	(20 %)	1.1 [0.7 - 1.9	0.679			
hypermobility		400	(78 %)	113	(22 %)					

type of hospital setting	0									
no. of TVT in teaching hospitals		355	(76 %)	114	(24 %)	0.6 [0.4 - 0.8(	**0.005**	-0.60	0.55[0.35--0.8!	**0.01**
no. of TVT in non-teaching hospitals		84	(84 %)	55	(16 %)					
Type of Anesthesia	64									
local anesthesia (with sedation)		462	(77 %)	134	(23 %)	+				
spinal analgesia		56	(90 %)	6	(10 %)	0.4 [0.2 - 0.9]	**0.019**	-1.1	0.35[0.13-0.92]	**0.03**
general anesthesia		65	(75 %)	22	(25 %)	1.2 [0.7 - 2.0]	0.561	0.27	1.31[0.71-2.42]	0.40
Surgeon's Experience	0									
learning curve effect										
first 10 procedures for each surgeon		233	(83%)	49	(17%)	+				
next 10 procedures for each surgeon		112	(71%)	46	(29%)	2.0 [1.2-3.1]	**0.005**	0.66	1.93[1.14-3.29]	**0.02**
more than 20 procedures for each surgeon		295	(80%)	74	(20%)	1.2 [0.8-1.8]	0.736	0.09	1.09[0.67-1.77]	0.73

Values are mean (SD). number (%) and Odds Ratio [95% CI]
A Fisher exact Tes was performed for catergorical variables
Student-t test was performed for interval variables
(+) Reference group
statistically significant differences are highlighted
p= p-value

Chapter 3

What determines a successful TVT? A prospective multicenter cohort study, results from the Netherlands TVT database

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American Journal of Obstetrics and Gynecology 2006, January 194:65-74.

Abstract

Ojective: The objective of this study was to report which preoperative and intraoperative factors influence the success of the tension-free vaginal tape procedure for stress urinary incontinence.

Study Design: This was a prospective cohort study of 809 patients. In 28 teaching hospitals and 13 local hospitals, 54 gynecologists and urologists performed the tension-free vaginal tape procedure.

Results: Before treatment and 2 years postoperatively, the following question from the Urogenital Distress Inventory for stress urinary incontinence was selected to define success or failure: "Do you experience urinary leakage during physical activity, coughing or sneezing?". Secondary outcome measurement was the outcome of the doctor's question, "Do you leak during physical activity, coughing or sneezing?" asked at two-year follow-up. Response rate was 78.7%. The success rate was significant higher in all analyses when the surgeons had performed more than 20 tension-free vaginal tape procedure (P= .003; beta 1.918 [95% confidence interval 1.24-2.97]). General anesthesia had a negative effect on the success of the TVT (P= .032; beta 2.21 [95% confidence interval 1.07-4.55]).

Conclusion: Inexperience of the surgeon with the tension-free vaginal tape procedure and general anesthesia had a negative effect on the result. We believe that the tension-free vaginal tape procedure should only be performed by experienced surgeons.

Introduction

Stress urinary incontinence (SUI) is a common condition in the female population[1]. During the last century, a variety of surgical procedures have been developed as treatment for this condition. Many of these procedures have disappeared because of poor long-term results. Until 1995 the golden standard of SUI surgery was the Burch colposuspension[2]. By now this procedure has been mostly replaced by the tension-free vaginal tape (TVT). The TVT has become the first choice as surgical treatment for stress urinary incontinence in women. The procedure was introduced by Ulmsten and collagues in 1995[3, 4]. TVT is a minimally invasive procedure based on one of the concepts of the integral theory for female incontinence: the midurethral support. TVT has proven to be as successful as the Burch colposuspension.

Assessing the efficacy of the surgery for incontinence represents a challenging issue. Black and Downs[5] analyzed the outcome of several incontinence procedures. They concluded that the methodological quality of the few prospective studies that have reported on the effectiveness of surgery for SUI is poor. Additionally, they conclude that the value of surgery and the effectiveness of different procedures are unclear. Since the introduction of TVT, many studies have described the results of TVT. However, the criticism of Black and Downs still stands for most of these reports. Ward and Hilton[6, 7] compared the Burch colposuspension and TVT in a prospective, well-conducted study. Besides this comparative study, there are only few studies that have determined prospectively the outcome of TVT. To our knowledge not one publication reports on the prognostic factors for success or failure of the TVT procedure.

In this article we present the results of a multicenter study on the long-term outcome of TVT. The focus of this report is on the pre- and intra operative factors influencing the success of the TVT procedure for SUI.

MATERIALS AND METHODS

Between March 2000 and September 2001, all patients with an indication for the TVT procedure were asked to participate in this study. Inclusion criteria were urodynamic proven stress incontinence or SUI at history/physical examination. The urodynamic investigations were performed according to the standards recommended by the International Incontinence Society[8]. Exclusion criteria were recurrent and difficult to treat urinary tract infections, predominant symptoms of urge urinary incontinence (defined as urge incontinence being more prevailing than the stress incontinence), detrusor overactivity at cystometry, postvoiding bladder retention (more than 150 ml), bladder capacity less than 200ml, or a physical/mental impairment. Intrinsic sphincter deficiency (ISD) was defined when the maximum urethral closing pressure (MUCP) was less than 20 cm H2O at preoperative urodynamics.
All participating gynecologists and urologists were qualified to perform vaginal surgery and had a short training in performing TVT by an experienced surgeon.
The TVT was performed as described by Ulmsten [3]. The operation was carried out under local anesthesia using 0.25% prilocaine with adrenalin and sedation, spinal analgesia, or general anesthesia.
Before and at 2, 6, 12, and 24 months after surgery a standardized history, physical examination, and urine culture was performed. At the same time intervals, all patients were asked to complete the short version of the urogenital distress inventory (UDI). The questionnaires, a postage-paid return envelope, and instructions were send to the patient by mail. The UDI is a disease specific, health-related quality of life (HRQOL) questionnaire. Uebersax et al[9] validated a short form for this questionnaire (UDI-6), which consists of 6 questions. These questionnaires were translated in the Dutch language and validated in the Netherlands by van der Vaart et al[10]. All items in the questionnaires consisted of a 4-step ordered category scale from "not at all" to "greatly". The answers were transformed to a scale from 0 (no complaints) to100 (very bothered). Registration of mode of anesthesia, intraoperative, and direct postoperative complications was performed by the surgeon.
The number of TVTs that every surgeon performed was counted. Groups were formed of the first 10 TVTs, 11-20 TVTs, and over 20 TVTs each surgeon performed.

Ethics
This study was approved by the Medical Ethical Committee of the St. Elisabeth Hospital Tilburg as primary research center and all other co-working hospitals as required by Dutch law. Written informed consent for this study was obtained from all women.

Outcome measures
According the recommendation of the International Continence Society, the question "Do you experience urinary leakage during physical activity, coughing, or sneezing?" was selected from the UDI, as primary outcome measure to define suc-

cess or failure for SUI[8]. Success was defined as the answer was "no". The questionnaires, a postage-paid return envelope, and instructions were send to the patient by mail. The questionnaires were anonymously processed in a database. Researchers as well as participating gynecologist and urologists were blinded to the individual results of these questionnaires.
The secondary outcome measure was the answer to the doctor's question "Do you leak during physical activity, coughing, or sneezing?" asked at 2-year follow-up. The answer "no" was defined as success. All other answers, as well as improved were considered as failure.
As tertiary outcome measure, both questions were combined. Women who had answered to be dry in the written questionnaire as well as to the oral question at χ^2-year follow up were defined to be a success.

Statistical analysis
All data were processed anonymously by a research physician (T.M.B.) and the secretary of the research team. Statistical analysis was performed with SPSS 11.5 for Windows. Proportions relating to subjects in different groups were compared by χ^2 test. Categorical variables were compared with a 2-sided Fisher exact test. Interval variables were compared by a Student t-test. Univariate odds ratios (OR) and 95% confidence intervals (CI), as well as P-values were calculated for risk factors.
Subsequently multivariate logistic regression analysis was used to construct a prediction model to determine pre- and intraoperative factors that independently influenced the incontinence rate. Logistic regression is a technique that can be used to evaluate the performance of multiple variables in a diagnostic model. Selection of variables is usually performed with a significance level of 5%. However, the incorrect exclusion of a factor would be more deleterious than including too many factors. Multivariate analysis included therefore all variables with a *P* value less than .10 in the univariate analysis.

RESULTS

The procedures took place in 41 different hospitals in which 54 gynecologists and urologists performed the TVT procedure. Among the 41 hospitals, there were 3 university hospitals, 25 teaching hospitals, and 13 local hospitals. Of all TVTs 58% were performed in teaching hospitals. In total 809 women participated in the study. Patient characteristics are shown in table 1.

One hundred and thirty-one women had previous incontinence or prolapse surgery. In the group that had undergone prior incontinence surgery, there were 9 patients who had undergone 2 prior incontinence procedures and 1 patient who had undergone three prior incontinence procedures (Burch, re-Burch and hysterectomy with concomitant Raz sling procedure). At preoperative evaluation 49.8% of all women said to have frequency (defined as >8 voids per day) and 62.6% had nocturia of more than once. Of all operated women, 94.1% had daily SUI. In 86.9% of all women, urodynamics were performed. In 5.8% intrinsic sphincter deficiency was diagnosed. In 6.3% detrusor overactivity was diagnosed. Despite the fact that this was an exclusion criteria for this study, surgeons performed a TVT on these patients. We believe it worthwhile to include these patients in this analysis.

The mean operating time for only the TVT procedure was 32.4 minutes (SD 11.2). Fifty-nine women had simultaneous prolapse surgery: vaginal hysterectomy for uterine descent (n = 7), anterior repair (n = 15), posterior repair (n = 28), and anterior and posterior repair (n = 9). TVT was combined with nonurogynecological procedures like , for example, sterilization in 7.8% of all women. These combined procedures were performed under general anesthesia. The incidence of intraoperative complications was 6.2% (n = 50) and have been described elsewhere [11]. Local anesthesia was used in 80%, spinal in 8.3% and general anesthesia in 11.7%.

The response rate for the primary outcome parameter was 78.7% at 2-year follow-up. Twenty-six patients were excluded for the study, for the reason: refused to take further part in the study (n = 22), diseased (n = 3), and did not fully complete the questionnaire (n = 1). Table 2 shows the univariate and multivariate analysis of the primary outcome. For this outcome measurement, the total success rate was 66%. The success rate was statistical significantly increased when the surgeon's experience was more than 20 TVTs performed.

Table 3 shows the univariate and multivariate analysis of the secondary outcome. The follow-up for the second measurement outcome was 78.5%. Excluded from the study were 26 patients: 22 women refused to take further part in the study, 3 patients had diseased, and 1 did not fully complete the questionnaire. Six hundred eleven patients came at the doctor's follow-up at 2-years. The success rate was 78%. The success rate was statistical significantly higher in the univariate and multivariate analysis when the surgeon's experience exceeded 20 TVTs. Success was negatively effected by general anesthesia.

The follow-up for the tertiary measurement outcome was 66.3%. The overall success rate was 64%. The outcome of this tertiary measurement was comparable with that of the secondary measurement.

COMMENT

Not many articles describe prospectively the influence of preoperative and intraoperative factors that influence the success for stress incontinence of the TVT.
In this study we observed that the experience of the surgeon significantly contributes to the success rate of the TVT procedure. The type of hospital setting did not make a difference for the outcome of the surgery. Twelve of the 51 surgeons performed more than 20 TVTs. In this group an effect of the learning curve was observed. An association between the learning curve for the TVT procedure and the complication rate has been described before[11-13]. However, only Grouz et al[12] suggest an effect of the learning curve on the final outcome of TVT. But with only 30 patients and only 1 surgeon, proper statistics cannot be performed.
A second observation in our study is a less successful outcome after general anesthesia (GA). In a retrospective study of 173 patients, Murphy et al [14] performed a univariate analysis of the TVT's performed by 2 surgeons. No difference voiding dysfunction was found between the group with GA and without GA. However, no data on the final outcome for were mentioned. Kunde and Varma [15] observed a success rate of TVT under GA of 72%. Unfortunately, no comparison with a TVT under local anesthesia was performed. It is difficult to explain these contradictory findings. The advantage of local analgesia is that the cough-stress test can be performed to adjust the tape. Although we are aware that a cough-stress test is of limited value (as shown by Barry [16] and Kuan-Hui Huang [17]), the advantage of the cough test is also not present when using spinal analgesia. In this group we did not observe a detrimental outcome. Furthermore, the negative influence of GA was not observed in outcome measurement 2. Nevertheless, general anesthesia and local anesthesia also differ with regard to somatic, sympathetic, and parasympathetic discharge.
How nervous input to the bladder is altered between general and local anesthesia may be important to how a TVT is tensioned. However, from this study and the other previously mentioned studies, the neural influence cannot be reliable determined. Rezapour et al [18] reported on another possible risk factor: ISD. ISD is believed to be more difficult to cure than other forms of SUI [19]. Rezapour found no improvement on stress incontinence in 7 of 49 patients. Five of these patients were older than 70 years and had an ISD. In our analysis preoperative ISD at urodynamic testing did not seem to influence the final success of the TVT. It should be noted, though, that this outcome was interpreted from the results of only 6% of the total group.
No difference was found in all outcome parameters for patients who had or had not undergone urodynamic testing, although this might suggest that urodynamic testing is not worthwhile. We think this is untrue. Those doctors who choose not to perform urodynamic testing before surgery could have been very certain about the diagnose SUI without detrusor overactivity because of the history and physical examination. So only for these cases, preoperative urodynamic testing does not change the outcome.
A number of studies have been published on concomitant prolapse surgery with the TVT [11, 17, 20-23]. Most state that TVT can be performed safely and effectively with con-

comitant surgery. Pang et al [24] published a retrospective study of 45 patients with a follow-up of 1 year using the stress test and urodynamics as an objective outcome measurement. The success rate in patients undergoing concomitant cystocele repair was 38%; in the noncystocele group, the success rate was 67% ($P = .19$). We could not confirm this finding. In our data 15 patients underwent an anterior repair with the TVT. No difference was found in the final outcome for SUI in comparison with the group (N = 421) undergoing TVT only.

In conclusion, this study reports on the prognostic factors determining success of the TVT procedure for SUI. General anesthesia seems to have a negative effect on the result; however, this observation was not constantly present in all outcome variables. Experience of the surgeon determines a successful outcome of the TVT. In fact, many traditional variables thought to be of importance in incontinence surgery appear not to be related to a successful outcome. Therefore, we believe that in the hands of an experienced surgeon the TVT is a clinically safe and effective method to cure stress urinary incontinence.

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Table 1. Baseline characteristics of all 809 women participating in the study

GENERAL DATA	number or mean	percentage	missing patient
age			
mean age in years	51.3 (20-82)		missing 6
categories			
20 - 30 years	8	1.0%	
31 - 40 years	807	13.3%	
41 - 50 years	284	35.4%	
51 - 60 years	254	31.6%	
61 - 70 years	117	14.6%	
71 - 80 years	28	3.5%	
older than 80 years	5	0.6%	
parity			missing 0
nulliparity	17	2.1%	
multiparity	792	97.9%	
menopausal status			missing 0
premenopausal	432	53.4%	
postmenopausal	377	46.6%	
HRT usage	128	33.9%	
previous urogynecological surgery			missing 2
no previous urogynecological surgery	678	84.0%	
previous prolapse surgery	65	8.0%	
previous incontinence surgery	50	6.1%	
previous incontinence and prolaps surgery	16	2.0%	
mean operating time in minutes	32.4		
DIAGNOSIS PRIOR TO TVT			
type of incontinence			missing 84
stress incontinence	577	79.6%	
mixed incontinence	148	20.4%	
day time frequency			missing 211
< 8 voids per day	300	50.2%	
> 8 voids per day	298	49.8%	
night time frequency			missing 167
no noctural micturition	237	37.4%	
once or more per night	396	62.6%	
severity of incontinence			missing 123
daily episodes	646	94.1%	
weekly episodes	39	5.7%	
monthly episodes	1	0.1%	
pelvic floor status			missing 107
cystocele	327	46.6%	
rectocele	166	23.6%	
prolapse of uterine cerix of vaginal vault	161	22.9%	
urethral hypermobility	513	73.1%	
loss at cough test			missing 183
yes	629	93.7%	
no	42	6.3%	

PREOPERATIVE URODYNAMIC STUDY			
urodynamic investagation performed			missing 0
yes	703	86.9 %	
no	106	13.1%	
urodynamic stress incontinence			missing 158
yes	529	81.3%	
no	122	18.7%	
detrusor overactivity at urodynamics			missing 187
yes	41	6.3%	
no	611	93.7%	
intrinsic sphincter deficiency			missing 106
yes	41	5.8%	
no	662	94.2%	
uroflowmetry			missing 287
peak flow (ml/s; value ± sd)	26.6 (21.3)		
flow pattern			
continuous flow	473	90.6%	
interrupted flow	49	9.4%	
SURGICAL DATA			
simultaneous procedures			missing 0
TVT only	687	84.9%	
TVT combined with prolaps surgery	59	7.3%	
TVT with non-urogynecological surgical procedures	63	7.8%	
type of anesthesia			missing 64
local anesthesia (with sedation)	596	80.0%	
spinal analgesia	62	8.3%	
general anesthesia	87	11.7%	
type of hospital setting			missing 0
no. of TVT in 28 teaching hospitals	469	58.0%	
no. of TVT in 13 non-teaching hospitals	340	42.0%	

Table 2. Univariate and Multivariate Analysis of determinants for the outcome of TVT. Sucess is difined as 'dry' at the postal question 2 years post operatively

	univariate analysis							multivariate analysis		
	succes (n = 408)		failure (n = 209)		OR [95% CI]	*p*-value	statistical method	β	OR [95% CI]	p-value
general data										
age (years ± sd)	51.19	9.50	51.17	0.58		0.937	t			
parity										
nulliparity	7	70.0 %	3	30.0 %	1.19 [0.31-4.68]	1.000	X^2			
multiparity	401	66.1 %	206	33.9%						
menopausal status										
premenopausal	203	65.7%	106	34.3%	1.04 [0.74-1.48]	0.859	X^2			
postmenopausal	172	66.7%	86	33.3%						
urogynecological history										
no previous urogynecological surgery	350	67.2%	171	32.8%						
previous prolapse surgery	31	70.5%	13	29.5%	0.86 [0.44-1.68]	0.739	X^2			
previous incontinence surgery	20	48.8%	12	51.2%	2.15 [1.13-4.07]	**0.025**		0.510	0.243-1.071	0.075
previous incontinence and prolapse surgery	7	63.6%	4	36.4%	1.17 [0.34-4.05]	0.757				
mixed incontinence										
stress	310	82.4%	148	17.6%						
mixed	66	80.0%	37	20.0%	1.17 [0.75-1.84]	0.488	X^2			
frequency										
< 8 voids per day	160	66.7%	80	33.3%	0,90 [0,61 - 1,33]	0.676	X^2			
> 8 voids per day	153	68.9%	69	31.1%						
incontinence episodes										
daily	333	66.7%	166	33.3%						
weekly	27	87.1%	4	12.9%	0.32 [0.11-0.93]	**0.027**	X^2	3.01	0.87-10.49	0.083
monthly	1	100.0%	0	0.0 %	n.a.					
urodynamic investagation performed										
yes	335	68.1%	157	31.9%						
no	46	63.0%	27	37.0%	1.25 [0.75-2.09]	0.744	X^2			
stress incontinence at urodynamics										
yes	251	68.4%	116	31.6%						
no	56	62.9%	33	37.1%	1.28 [0.79-2.07]	0.422	X^2			
detrusor overactivity at urodynamics										
yes	15	62.5%	9	37.5%						
no	296	68.0%	139	32.0%	0.78 [0.33-1.83]	0.654	X^2			
intrinsic sphincter deficincy										
yes	20	66.7%	10	33.3%						
no	361	67.5%	174	32.5%	1.04 [0.48-2.26]	1.000	X^2			

flow pattern preoperative										
continious flow	223	67.4%	108	32.6%						
non continious flow	24	70.6%	10	29.4%	0.86[0.34-1.86]	0.848	X^2			
simultaneous procedures										
TVT only	336	68.3%	156	31.7%						
TVT with prolaps surgery	21	60.0%	14	40.0%	1.44 [0.71-2.80]	0.350	X^2			
TVT with other surgical procedures	24	63.2%	14	36.8%	1.26 [0.63-2.49]	0.589				
pelvic floor status prior to TVT										
cystocele										
no cystocele	170	66.9%	84	33.1%	0.89 [0.61-1.31]	0.559	X^2			
cystocele	159	69.4%	70	30.6%						
rectocele										
no rectocele	275	70.2%	117	29.8%	1.44 [0.92-2.20]	0.128	X^2			
rectocele	67	62.0%	41	38.0%						
prolaps of uterine cerix of vaginal vault										
no prolaps of cervix of vaginal vault	272	68.0%	128	32.0%	1.09 [0.70-1.71]	0.730	X^2			
prolaps of cervix of vaginal vault	72	66.1%	37	33.9%						
urethral hypermobility										
no hypermobility	261	69.6%	114	30.4%	1.61 [0.93-2.78]	0.108	X^2			
hypermobility	37	58.7%	26	41.3%						
type of hospital setting										
no. of TVT in teaching hospitals	228	67.9%	108	32.1%	1.05 [0.73-1.50]	0.855	X^2			
no. of TVT in non-teaching hospitals	153	66.8%	76	33.2%						
type of anesthesia										
local anesthesia (with sedation)	287	68.2%	134	31.8%						
spinal analgesia	31	66.0%	16	34.0%	1.11 [0.59-2.09]	0.744	X^2			
general anesthesia	42	72.4%	16	27.6%	0.82 [0.44-1.50]	0.550				
surgeon's experience										
learning curve effect										
first 10 procedures for each surgeon	129	61.7%	80	38.3%			X^2			
next 10 procedures for each surgeon	79	67.5%	38	32.5%	0.78 [0.48-1.25]	0.337				
more than 20 procedures for each surgeon	173	72.4%	66	27.6%	0.615 [0.41-0.92	**0.020**		1.918 1.24-2.97		**0.003**
loss at cough test										
yes	230	71.0%	94	29.0%						
no	99	66.0%	51	34.0%	1.26 [0.83-1.91]	0.285	X^2			
no cough test performed	24	63.2%	14	36.8%	1.35[0.67-2.71]	0.460				

Values are mean (SD). number (%) and Odds Ratio [95% CI] X^2 = Fisher exact Test; statistically significant differences are highlighted t= s-Student-t test

Table 3. Univariate and Multivariate Analysis of determinants for the outcome of TVT. Sucess is defined as 'dry' at the doctors question two years postoperative

	UNIVARIATE ANALYSIS							MULTIVARIATE ANALYSIS		
	succes (n = 478)		failure (n = 133)		OR [95% CI]	*p*-value	statistical method	β	[95% CI]	*p*-value
general data										
age (years ± sd)	51.3	(0.45)	50.6	(0.89)		0.474	t			
categories										
20-40	64	75.3%	21	24.7%						
41-50	174	78.4%	48	21.6%	0.84 [0.47-1.51]	0.546				
51-60	157	80.9%	37	19.1%	0.72[0.39-1.32]	0.336	X^2			
61-70	66	73.3%	24	26.7%	1.11 [0.56-2.19]	0.863				
71-80	15	83.3%	3	16.7%	0.61 [0.16-2.31]	0.555				
>80	2	100.0%	0	0.0%	0.75 [0.67-1.01]	1.000				
parity										
nulliparity	11	91.7%	1	8.3%	3.11[0.39-24.30]	0.478	X^2			
multiparity	467	78.0%	132	22.0%						
menopausal status										
premenopausal	241	78.5%	66	21.5%	1.05[0.70-158]	0.836	X^2			
postmenopausal	204	79.4%	53	20.6%						
urogynecological history										
no previous urogynecological surgery	408	79.1%	108	20.9%			X^2			
previous prolapse surgery	33	75.0%	11	25.0%	1.26[0.62-2.57]	0.565				
previous incontinence surgery	28	70.0%	12	30.0%	1.62[0.80-3.29]	0.229	X^2			
previous incontinence and prolapse surgery	9	81.8%	2	18.2%	0.84[0.18-3.94]	1.000				
mixed incontinence										
stress	365	81.3%	84	18.7%	2.27[1.42-3.64]	**0.001**		1.84	0.96-3.54	0.066
mixed	67	65.7%	35	34.3%						
frequency										
< 8 voids per day	195	81.6%	44	18.4%	1.29[0.82-2.03]	0.301				
> 8 voids per day	175	77.4%	51	22.6%						
incontinence episodes										
daily	384	78.7%	104	21.3%						
weekly	30	88.2%	4	11.8%	0.49[0.17-1.43]	0.272				
monthly	1	100.0%	0	0.0%	0.78[0.75-0.82]	1.000				

urodynamic investigation performed										
yes	423	78.2%	118	21.8%	0.98[0.53-1.79]	1.000				
no	55	78.6%	15	21.4%						
stress incontinence at urodynamics										
yes	311	78.5%	85	21.5%	1.32[0.79-2.17]	0.289				
no	75	73.5%	27	26.5%						
detrusor overactivity at urodynamics										
yes	17	68.0%	8	32.0%	0.58[0.23-1.37]	0.218				
no	375	78.6%	102	21.4%						
intrinsic sphincter deficincy										
yes	29	85.3%	5	14.7%	0.61[0.23-1.59]	0.394				
no	449	77.8%	128	22.2%						
flow pattern preoperative										
continious flow	294	78.2%	82	21.8%	1.11[0.51-2.44]	0.837				
non continious flow	29	76.3%	9	23.7%						
simultaneous procedures										
TVT only	421	79.4%	109	20.6%						
TVT with prolaps surgery	29	65.9%	15	34.1%	1.99[0.99-3.86]	0.054				
colporaphia anterior										
TVT with other surgical procedures	28	75.7%	9	24.3%	1.24[0.57-2.71]	0.537				
pelvic floor status prior to TVT										
cystocele										
no cystocele	229	81.2%	53	18.8%	1.32[0.87-1.99]	0.206	X^2			
cystocele	200	76.6%	61	23.4%						
rectocele										
no rectocele	337	81.0%	79	19.0%	1.58[1.00-2.49]	0.051	X^2			
rectocele	97	72.9%	36	27.1%						
prolaps of uterine cerix of vaginal vault										
no prolaps of cervix of vaginal vault	343	80.7%	82	19.3%	1.64[1.05-2.58]	**0.038**	X^2	1.25	0.66-2.37	0.489
prolaps of cervix of vaginal vault	94	71.8%	37	28.2%						
urethral hypermobility										
no hypermobility	321	80.3%	79	19.8%	1.51[0.85-2.71]	0.201	X^2			
hypermobility	51	72.9%	19	27.1%						
type of hospital setting										
no. of TVT in teaching hospitals	291	80.2%	72	19.8%	1.32[0.89-1.94]	0.164	X^2			
no. of TVT in non-teaching hospitals	187	75.4%	61	24.6%						

type of anesthesia										
local anesthesia (with sedation)	365	81.1%	85	18.9%						
spinal analgesia	39	72.2%	15	27.8%	1.65[0.87-3.13]	0.147	X^2			
general anesthesia	47	68.1%	22	31.9%	2.01[1.15-3.51]	**0.017**		2.21	1.07-4.55	**0.032**
surgeon's experience										
learning curve effect										
first 10 procedures for each surgeon	162	74.3%	56	25.7%			X^2			
next 10 procedures for each surgeon	96	74.4%	33	25.6%	0.99[0.60-1.64]	1,000				
more than 20 procedures for each surgeon	220	83.3%	44	16.7%	0.58[0.37-0.90]	**0.018**		0.55	0.32-0.96	**0.035**
loss at cough test										
yes	299	82.4%	64	17.6%						
no	116	74.8%	39	25.2%	1.57[0.99-2.47]	0.055				
no cough test performed	28	71.8%	11	28.2%	1.84[0.87-3.88]	0.128				

Values are mean (SD). number (%) and Odds Ratio [95% CI]
statistically significant differences are highlighted
t= student-t test
X^2 = Fisher exact Test;

Chapter 4

Quality of life before and after TVT, a prospective multicentre cohort study, results from the Netherlands TVT database

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BJOG 2006;113:26-29

Abstract

Objective: To asses the long-term outcome of the tension-free vaginal tape procedure in women with isolated stress urinary incontinence (SUI).

Design: Prospective cohort study.

Setting: Twenty-eight teaching hospitals and 13 local hospitals with 54 gynaecologists and urologists performing the surgery.

Sample: Eight hundred and nine participants.

Main outcome measures: The Incontinence Impact Questionnaire (IIQ-7) and the Urogenital Distress Inventory (UDI-6) were used to measure the results of the TVT procedure (pre-operative at 2, 6, 12 and 24 months post-operative).
According the recommendation of the International Continence Society (ICS), the question "Do you experience urinary leakage during physical activity, coughing or sneezing?" was selected from the UDI to asses SUI.

Results: Both IIQ and UDI mean scores decreased significant after TVT, indicating an improvement in quality of life. Subjective improvement can improve for up tol two years post-operatively.

Conclusions: This is the largest study that used these validated disease-specific questionnaires to asses the long term outcome of the TVT procedure. This study shows a statistically significant and clinically relevant long term improvement of the quality of life after a TVT for women with SUI.

Introduction

The estimated prevalence of urinary incontinence in women aged 18 years and older varies between 23% and 57% [1, 2]. Around half of these women suffer from stress urinary incontinence (SUI). Until 1995 the "gold standard" for SUI surgery was the Burch colposuspension [3]. More recently, TVT[4, 5] has become the first choice as surgical treatment for SUI in many women because it has proven to be as successful as the Burch colposuspension [6, 7].

Assessing the efficacy of surgery for incontinence represents a challenging issue and Black and Downs examined the methodological quality of the few prospective studies that have reported on the effectiveness of surgery for stress incontinence, found it to be poor[8], and concluded that the value of surgery and the relative effectiveness of different procedures were therefore unclear. Ward and Hilton compared the Burch colposuspension and TVT in a well-designed prospective, randomised study but the criticism of Black and Downs still hold true for many published reports on TVT and other surgery. There are only few studies that have prospectively determined the outcome of TVT by assessing the influence of this procedure on quality of life with the aid of disease specific validated health-related quality of life (HRQoL) questionnaires[9, 10].

In this article we present the results of a multicentre study on the long term outcome of TVT in women as a primary treatment of urodynamic stress incontinence, assessed with validated disease specific questionnaires.

Methods

Between March 2000 and September 2001, women with an indication for a TVT procedure were asked to participate in this study. The study was approved by the Medical Ethical Committee of the St. Elisabeth Hospital Tilburg and all other co-working hospitals as required by Dutch law. Written informed consent for this study was obtained from all women.

Included were women who were willing to participate in the study and who had an indication for TVT. Excluded were women with concomitant urogynaecological surgery, a history of previous incontinence or prolapse surgery, recurrent urinary tract infections, significant symptoms of urge urinary incontinence, a history of or detrusor overactivity at cystometry, post-voiding bladder retention (>150 ml), a bladder capacity less than 200 ml or a physical/mental impairment which would make participation impossible. If more than two items on the IIQ or the UDI were not answered, the total score was not calculated and was not included in the results.

A standardised history was taken and physical examination was performed pre-operative and at 2, 6, 12 and 24 months post-operatively. Investigative pre-operative multi-channel urodynamics was not mandatory and left to the gynaecologist's or urologist's discretion. Urodynamical investigations were eventually carried out in 549 women (87%).

All women were asked to complete the short version of the Incontinence Impact Questionnaire (IIQ-7) and the Urogenital Distress Inventory (UDI-6). The questionnaires, a postage-paid return envelope and instructions, were sent to the patient by mail. The questionnaires were anonymously processed in a database. Researchers as well as participating gynaecologists and urologists were blinded to the individual results of these questionnaires. The long form IIQ (30 questions) and UDI (19 questions) are disease specific HRQoL questionnaires[11]. A short form for both questionnaires has been validated which consists of seven and six questions respectively (IIQ-7 & UDI-6 [12]). These questionnaires were translated into Dutch and validated for the Dutch female population[2]. All items in the questionnaires are on a four-step ordered category scale from "not at all" to "greatly" impaired. The UDI is subdivided in three domains: stress incontinence, irritative and obstructive/discomfort and the IIQ measures the implications of urinary incontinence for normal daily functioning. The total score of every domain is transformed to a scale from 0-100 (a higher score means more bothered).

The procedures took place in 41 different hospitals by 54 gynecologists and urologists. Of the 41 hospitals there were 3 university hospitals, 25 teaching and 13 non-teaching hospitals. TVT (Gynecare, Ethicon Inc, Sommerville, New Jersey, USA) was performed as described by Ulmsten[4]. The operation was carried out under local anaesthesia using 0.25% prilocaïne with adrenalin, spinal analgesia or general anaesthesia.

The primary outcome measures were the scores on the IIQ and UDI, with improvement defined as a lower score on follow up questionnaires. Secondary outcomes included the response to question three from the UDI: "do you experience urinary

leakage during physical activity, coughing or sneezing?" as a subjective record of success or failure for SUI as recommended by the International Continence Society (ICS)[13]. We also asked the patients directly "do you leak during physical activity, coughing or sneezing?" at each follow up visit. The answer "no" was defined as success. All other answers were considered as failure. The physical demonstration of urine loss coughing found during physical examination with a full bladder at follow up was used as an objective measure of cure.

Statistical analysis was performed with SPSS 11.5 for Windows. The ¯Ç test was used to compare proportions relating to subjects in different groups. Categorical variables were compared with a two-sided Fisher exact test. The Student *t* test was used as a statistic to compare interval variables. To analyse matched and paired data, the Wilcoxon's signed-rank test was used. The mean difference was chosen to be significant at the 0.05 level. Data are presented as mean [SE].

RESULTS

The original database comprised data from 809 women. One hundred and thirty-one women had previous incontinence or prolapse surgery and were excluded from the analysis reported here. Another 44 women had simultaneous prolapse surgery and were also excluded, leaving 634 women for analysis. Among these women, TVT was combined in 8.7% with non-urogynecological procedures like for example sterilisation. The mean age at the time of TVT was 50 years [10]. Only 15 women were nulliparous. The mean parity was 2.4 [1.1]. Forty-one percent of women were postmenopausal and 15% used hormone replacement therapy. The mean operating time was 32 [10] minutes. The follow up was at least two years for all women.

Twenty-six women were excluded from the study: 22 declined to take further part in the study, 3 had intercurrent illness, and 1 did not fully complete the questionnaire.

Both IIQ and UDI mean scores decreased significantly after TVT (Table 1). This improvement occurred up to six months after surgery and became stable after that. Mean IIQ and UDI scores at all follow up measurements showed no difference between women over or under 70 years of age. The secondary outcome measures are shown in Table 2.

Between 20% and 60% of the women who did not attend in person for follow up one or more times did return the questionnaires for the study. There was no consistent difference in reported outcomes between these women and the women who attended for full follow up.

Discussion

This study followed a large number of women for two years after TVT surgery, with the primary assessment performed with disease specific quality of life questionnaires. As might be expected, from the work of others, urinary incontinence has a profoundly negative impact on the quality of life of women[9, 14, 15]. The TVT procedure produced a lasting improvement in quality of life scores.

Our results show that women with residual SUI directly after surgery can improve for up to two years post-operatively, which is considered a 'long term' follow up by the WHO International Consultation on Incontinence[16]. At two years, 80% of patients reported cure of their stress incontinence. Another large study using the UDI and IIQ to asses the outcome of TVT confirmed a significant improvement in quality of life after a TVT[9]. In this study the follow up was done only once with a follow up of mean 22.1 months (range 6.1 - 49.8), although three quarters of the 114 patients underwent concomitant prolapse surgery, which may have contributed to the outcome, and contributed to the reported improvement in quality of life.

Mukuherjee and Constantine [17] used the validated Kings quality of life questionnaire to asses the medium term outcome of TVT, six months after surgery. Women with a normal BMI (<25) had a 85% cure rate, while obese women (BMI>25) had a cure rate of 90%. Our data showed a lower improvement on the quality of life after a TVT for all women participating in our study, but the longer follow up in our study and the differences between the questionnaires used could be the reason for the difference in outcome.

Inevitably, a longer follow-up means a greater drop out rate. In our study the drop out rate after two years for the follow up in clinic is about 34%. Normally, no information is gathered from those patients who fail to attend for follow up in research studies, and the (possibly incorrect) assumption is then made that these women performed the same as the attendees. Hilton even suggests to consider these non-attendees as failures[18]. In our study, however, we had some information via the UDI and IIQ. We found a small difference between the groups who did and did not show up in clinic but did fill in the questionnaires. The improvement rates in the "lost to follow-up" group were 5%-8% lower, but to consider this group a failure seems inappropriate.

Walsh et al.,[10] in a prospective study using quality of life questionnaires, found a difference in improvement of stress incontinence between women older than 70 years and women younger than 70 years. The improvement was greater in the younger group. The authors explained this by a higher incidence of intrinsic sphincter deficiency in the older group. We could not confirm this difference in improvement for different age categories.

This study reports the outcome of the tension-free vaginal tape procedure by means of the disease specific health related quality of life IIQ-7 and the UDI-6 questionnaires. A statistically significant and clinical relevant long term improvement of the quality of life after a TVT for women with SUI was found.

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Table 1. Mean IIQ & UDI scores

	Response rate (%)	Mean IIQ-scores (SE)	p*	Mean UDI-scores (SE)	p*
Preoperative	91.8	58 (0.8)		58 (0.8)	
2 months postoperative	67.4	15 (1.1)	0.000*	25 (0.9)	0.000*
6 months postoperative	69.7	12 (0.9)	0.022*	23 (0.9)	0.027*
12 months postoperative	73.1	11 (0.8)	0.760	21 (0.8)	0.300
24 months postoperative	77.3	12 (0.9)	0.180	23 (0.9)	0.060

Data are mean (standard error)
Wilcoxon's signed rank-test.
*analysis compared to the preceding value.

Table 2. Secondary outcome measures

	Response rate	**improved**	**no change**	**worsened**
Question 3⋆				
2 months	67.4%	91.6 %	7.4 %	1.0 %
6 months	69.7%	94.4 %	4.7 %	0.9 %
12 months	73.1%	95.7 %	3.6 %	0.7 %
24 months	77.3%	95.3 %	4.0 %	0.6 %
Direct question#		no leakage	leakage	
2 months	91.6%	88.5%	11.5%	
6 months	62.0%	88.5%	11.5%	
12 months	56.8%	84.1%	15.9%	
24 months	76.2%	80.1%	19.1%	
Observed leak§		no	yes	
2 months	91.6%	98.1%	1.9%	
6 months	62.0%	97.0%	3.0%	
12 months	56.8%	95.0%	5.0%	
24 months	76.2%	97.1%	2.9%	

⋆ Data are the percentage of patients responding to the question from the UDI: "do you experience urinary leakage during physical activity, coughing or sneezing?"
Data are percentages of the answer to the doctors question "do you leak during physical activity, coughing or sneezing?" asked at follow up.
§ Data are percentages of patients were loss of urine upon coughing was found during physical examination with a full bladder at follow up.

Chapter 5

The effectiveness of Tension-free Vaginal Tape (TVT) and quality of life measured in women with previous urogynecological surgery: Analysis from The Netherlands TVT database

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AJOG 2006, in press

Abstract

Objective: Long-term outcome of tension-free vaginal tape (TVT) in women with a history of surgery for urinary incontinence and/or prolapse.

Study design: Prospective cohort study of 809 women. Twenty-eight teaching and 13 local hospitals, 54 gynaecologists and urologists performed the TVT's.
The Incontinence Impact Questionnaire (IIQ-7) and Urogenital Distress Inventory (UDI-6) were used to measure the results of the TVT procedure (preoperative, at 2, 6, 12, 24, and 36 months postoperative). According the recommendation of the International Continence Society (ICS), the question "Do you experience urinary leakage during physical activity, coughing or sneezing?" was selected from the UDI to assess stress urinary incontinence.

Results: The decrease in IIQ/UDI mean scores was statistically significant. The UDI scores of women with a history of previous prolapse and/or incontinence surgery were not statistically different to the scores for primary cases after 3 years follow-up ($p = 0.193$).

Conclusions: TVT is effective for women with recurrent stress urinary incontinence and/or previous prolapse surgery.

INTRODUCTION

Urinary incontinence is a common condition in the female population. The estimated prevalence in women aged 18 years and older varies between 23% and 57%[1, 2]. Until 1995 the golden standard of stress urinary incontinence (SUI) surgery was the Burch colposuspension[3]. The Tension-free Vaginal Tape (TVT) has become the first choice for surgical treatment for SUI in women. The procedure was introduced by Ulmsten and Petros in 1995[4, 5]. This minimally invasive procedure is based on one of the concepts of the integral theory for female incontinence: improving mid urethral support. TVT has proven to be as successful as the Burch colposuspension [6, 7]. Many results have been reported on the outcome of the TVT. However, only few report on the effectiveness of the TVT in more complicated cases with prior surgery for prolapse and/or incontinence. In addition to this, most studies addressing incontinence surgery use nonvalidated questionnaires, postoperative continence status on a visual analogue scale (VAS), micturition diary, pad weighing tests, interviewing women and urodynamic evaluation. Most of these measurements are subject to bias.
In this study we present the outcome and follow-up of three years of a low-tension mid-urethral sling (TVT) in women with previous incontinence or prolapse surgery, by means of objective (patient self-reported) health-related quality of life (HRQoL) questionnaires (the Incontinence Impact Questionnaire [IIQ] and the Urogenital Distress Inventory [UD]).

METHODS

Between March 2000 and September 2001, women with an indication for a TVT procedure were asked to participate in this study. The study was approved by the Medical Ethical Committee of the St. Elisabeth Hospital Tilburg and all other coworking hospitals as required by Dutch law. Written informed consent for this study was obtained from all women.

Study design
A standardized history was taken and physical examination was performed preoperatively and again at 2, 6, 12, 24, and 36 months postoperatively. Investigative preoperative multi-channel urodynamics was not mandatory and left to the gynecologist's or urologist's discretion.
All women were asked to complete the short version of the IIQ-7 and the UDI-6 before and at 2, 6, 12, 24, and 36 months after the procedure. The questionnaires, a postage-paid return envelope, and instructions were sent to the patient by mail. The questionnaires were processed anonymously. Researchers, as well as participating gynecologists and urologists, were blinded to the individual results of these questionnaires. The long form IIQ and UDI are disease-specific HRQoL questionnaires[8]. These questionnaires consist of 19 questions (UDI) and 30 questions (IIQ). Uebersax et al[9] validated a short form for both questionnaires (IIQ-7 and UDI-6), which consists of 7 and 6 questions, respectively. These questionnaires were translated into Dutch and validated for the Dutch female population[2]. All items in the questionnaires are on a 4-step ordered category scale from "not at all" to "greatly" impaired. The total score is transformed to a scale from 0-100 (a higher score means more bothered). The IIQ measures the implications of urinary incontinence for normal daily functioning, whereas the UDI indicates the type of bother women experience.

Inclusion and exclusion criteria
Included were women who were willing to participate in the study, who had an indication for TVT, and had a history of previous incontinence or prolapse surgery. Excluded were women who had recurrent and difficult to treat urinary tract infections, predominant symptoms of urge urinary incontinence (defined as urge incontinence being more prevailing than the stress incontinence), detrusor over activity at cystometry, post voiding bladder retention (>150 ml), bladder capacity less than 200ml, or a physical/mental impairment that would make participation impossible. If more than two items on the IIQ or the UDI were not answered the total score was not calculated and was not included in the results.

Surgical procedure

The procedures took place in 41 different hospitals by 54 gynecologists and urologists. Of the 41 hospitals, 3 were university hospitals, 25 were teaching and 13 were non-teaching hospitals. TVT (Gynecare, Ethicon Inc, Sommerville, New Jersey, USA) was performed as described by Ulmsten[4, 5]. The operation was carried out under local anesthesia, spinal analgesia or general anesthesia.

Outcome measures

The primary outcome measurements were the IIQ and UDI scores.

According the recommendation of the ICS, the question "Do you experience urinary leakage during physical activity, coughing or sneezing?" was selected from the UDI, as secondary outcome measure to define success or failure for SUI[10]. Women who have a lower score on the UDI question score postoperatively were considered to be improved.

Statistical analysis

All the data were anonymously processed by a research physician (TMB) and the research team secretary. Statistical analysis was performed with SPSS 11.5 for Windows (SPSS Inc, Chicago, IL). The ÃÇ test was used to compare proportions relating to subjects in different groups. Categorical variables were compared with a 2-sided Fisher exact test. The Student *t* test was used as a statistic to compare interval variables. To analyze matched and paired data, the Wilcoxon's signed-rank test was used. The mean difference was chosen to be significant at the 0.05 level. To analyze statistical differences between groups, the one-way ANOVA test with a Post Hoc Bonferroni correction was used.

RESULTS

The original database comprised data for 809 women. Fifteen women were excluded for the study, for the following reasons: refused to take further part in the study (n=13), diseased (n=1), did not fully complete the questionnaire (n=1). There were 131 women who had previous incontinence and/or prolapse surgery and were the subject of this analysis. The operative history of these 131 women is shown in table 1. Fifty women had prior incontinence surgery. In this group there were 9 women who had undergone 2 prior incontinence procedures and 1 woman who had undergone 3 prior incontinence procedures (Burch, re-Burch and hysterectomy with concomitant Raz sling procedure). There were 16 cases with a history of both prolapse and incontinence surgery. In this group, 1 woman had undergone a Burch colposuspension twice; 1 woman had undergone a Stamey suspension followed by a Burch colposuspension. Sixty-five women had a history of prolapse surgery only. Two women had undergone prolapse surgery twice.
The TVT was combined in 6.1% of cases with non-urogynecological procedures, for example, sterilization; in 15 women (11.5%) it was combined with prolapse surgery. This concomitant prolapse surgery was performed in 6 women with previous prolapse surgery, in 7 women with previous incontinence surgery and in 2 women, who had both prior prolapse and incontinence surgery. General anesthesia was used in 14.1% of women, spinal in 7.8%, local analgesia in 78.1%. The mean age at the time of TVT was 55.5 years (SD 10.5; range 33 – 82yrs). One woman was nulliparous. The mean parity was 2.5 (SD 1.1; range 0 - 9). Of all women, 68.1% were postmenopausal and 23% of all women used hormone replacement therapy. The mean operating time of the TVT was 36 minutes (SD 15.5; range 20 -120 minutes).
The patient characteristics of the two groups are shown in table 2.
The results for outcome parameter 2 for both groups are listed in table 3. After 2 months the improved rate stated by women on the UDI question: "Do you experience urinary leakage during physical activity, coughing or sneezing?", compared to their pre-operative status is 86.1%. This increased to 92.9% after 36 months. The control group showed an improved rate of 92% after a follow-up of 3 years.
The UDI scores of women with recurrent SUI (n = 50) improved from preoperative mean score of 65 to 31 at 2 months, and to 28 at 36 months. In women with prior prolapse surgery (N=65), the UDI score improved from preoperative 59, to 26 at 2 months, and to 25 at 36 months. Women with a history of both prolapse and incontinence surgery (N=16) had improved UDI scores from preoperative 77, to 24 at 2 months, and to 33 at 36 months. No statistical differences were found in the outcome of the UDI among the 3 groups.
The mean preoperative and postoperative values of the IIQ-7 and UDI-6 QOL questionnaires of both groups are listed in table 4. The response rates for these outcome parameters was 79.3% at 3 year follow-up. The UDI scores of the previous-surgery group were significant higher pre-operatively. Both IIQ and UDI mean scores at the postoperative visit compared with the preoperative values decreased for both groups, which was statistically significant after TVT. The difference between the

UDI scores of the two groups at twelve months and at twenty-four months follow-up was statistically significant. For the IIQ score, no difference was found between preoperative values. A significant difference was found at 6 and 24 months follow-up. The results show that after a follow-up of 3 years, no statistical difference in UDI and IIQ scores between both groups could be identified.

COMMENT

Women with prior surgery for incontinence or prolapse represent a group of patients who are difficult to cure surgically. In this study group, 10 (7.6%) women had undergone more than 1 operation for incontinence before the TVT indicating the difficulty to cure these patients. Burch colposuspension and sling procedures have been used for women with recurrent stress incontinence. Success rates of 85 to 90% at 3 to 4 years follow-up are published, but this surgery is associated with high complication rates such as significant urinary retention and haemorrhage[11-13]. These complication rates are lower with the TVT procedure [14].

Only a few articles describe the outcome of the TVT after prior incontinence surgery[15-21] and prolapse surgery[17, 22]. Most studies do not report a difference in success rates between primary and secondary cases of incontinence surgery[23-25]. The success rate of the secondary cases reported is 84% to 89%, but objective judgment of these studies is complicated. The groups are small, the outcome parameters are all different, the definition of repeat or secondary surgery is not uniform and sometimes the level of statistical significance is not reported[19, 26, 27].

Liapis et al[15] described cure rates of 90% in women with recurrent stress urinary incontinence with a preoperatively mobile urethra. The success rate was only 33% in patients with a fixed urethra. Rezapour et al[28] found a complete cure in 74% and improvement in another 12% in women with stress incontinence and intrinsic sphincter deficiency (ISD).

In a previous publication[29] we showed no difference between women with or without ISD either. Data regarding the success rate in women with intrinsic sphincter deficiency (ISD) (either defined by a low pressure urethra or fixed urethra) are conflicting.

This study assessed a well-defined group of secondary incontinence and/or prolapse cases. A significant improvement was found for all outcome parameters, which shows that TVT is a successful treatment in secondary cases for recurrent incontinence and/or prolapse. No statistical difference was found in the UDI outcome parameter comparing 2 large groups with and without previous urogynecological surgery after a follow up of 3 years of all women. The groups compared at 12 and 24 months showed a significant difference in UDI. No statistical difference was found at 36 months this might be due to the number of patients included. The improvement of the group with prior surgery is encouraging because in this group, the preoperative UDI scores were significantly higher than for the other groups, indicating more preoperative bother.

The QOL scores are equally good for both groups after 3 years follow-up. A trend between both groups was found at all follow-up visits but was only significant different at 6 and 24 months. In conclusion, patients with prior pelvic surgery perform very well after a TVT but a slight difference in quality of life was noted.

Previous retropubic surgery is associated with more intraoperative complications[30, 31]. In a previous publication, we reported a higher intraoperative complication rate during the TVT procedure for women with prior prolapse surgery[14].

In conclusion, this study shows that the TVT is a valuable tool for women with recurrent stress urinary incontinence, prior prolapse surgery, or both. Therefore, we think the TVT should be recommended for the treatment of recurrent stress urinary incontinence in women with previous incontinence and/or prolapse surgery.

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Table 1. Operative history of women

Women with previous incontinence surgery (n = 50)	
Burch colposuspension	44
Abdominal hysterectomy	21
Vaginal hysterectomy	6
Raz procedure	4
Stamey procedure	6
MMK procedure	5
Women with previous prolapse surgery (n = 65)	
Vaginal hysterectomy, anterior and posterior colphoraphia	16
Vaginal hysterectomy & anterior colporrhaphy	13
Vaginal hysterectomy & posterior colporrhaphy	1
Anterior colporrhaphy	1
Anterior & posterior colporrhaphy	12
Posterior colporrhaphy	3
Sacrocolpopexy	4
Abdominal hysterectomy	12
Vaginal hysterectomy	3
Women with previous incontinence and prolapse surgery (n = 16)	
Burch colposuspension	13
Abdominal hysterectomy	4
Vaginal hysterectomy	2
Raz procedure	1
Stamey procedure	2
MMK procedure	2
Vaginal hysterectomy, anterior and posterior colporrhaphy	3
Vaginal hysterectomy & anterior colporrhaphy	2
Anterior colporrhaphy	5
Posterior colporrhaphy	3
Anterior & posterior colporrhaphy	3
Sacrocolpopexy	1

Table 2. Patient characteristics

	prior surgery	no prior surgery	p-value
age	55.5 (10.5)	50.5(10.2)	0.000
parity	2.5 (1.1)	2.4(1.1)	0.518
menopausal state			
premenopausal	31.90%	57.50%	0.000
postmenopausal	68.10%	42.50%	
HRT use			
yes	23.40%	16.00%	0.070
no	76.60%	84.00%	
simultaneous procedures			
TVT only	82.40%	85.40%	
TVT with prolapse surgery	11.50%	6.50%	0.112
TVT with other surgical procedures	6.10%	8.10%	
Type of Anesthesia			
local anesthesia (with sedation)	78.10%	80.30%	
spinal analgesia	7.80%	8.40%	0.685
general anesthesia	14.10%	11.20%	

Values are mean (SD) or %,Chi square test and Student-t test were used where appropriate.

Table 3. Continence status- women's reply to the UDI questionnaire, on the question: "Do you experience urinary leakage during physical activity, coughing or sneezing?", compared to their preoperative status

Prior surgery	**2 months**	**6 months**	**12 months**	**24 months**	**36 months**
improved	86.1%	90.5%	92.4%	90.1%	92.9%
no change	11.1%	6.0%	5.4%	8.8%	7.1%
worsened	2.8%	3.6%	2.2%	1.1%	0.0%
No prior surgery					
improved	91.2%	93.8%	95.5%	95.0%	92.6%
no change	7.9%	5.3%	3.9%	4.4%	6.3%
worsened	0.9%	0.9%	0.6%	0.6%	1.1%

Table 4. Differences in mean UDI and IIQ scores between women with no history of prolapse/incontinence surgery (N=678) and women with prior urogynecological surgery (N=131)

	UDI			IIQ		
	previous surgery	no previous surgery	p-value	previous surgery	no previous surgery	p-value
preoperative	63.4	58.3	0.007*	61.4	58.1	0.108
2 months postoperative	27.8	25.5	0.334	17.0	15.9	0.705
6 months postoperative	27.5	23.4	0.114	19.5	12.2	0.011*
12 months postoperative	26.0	21.5	0.011*	15.2	11.5	0.140
24 months postoperative	28.3	23.1	0.018*	20.2	12.2	0.003*
36 months postoperative	27.4	24.5	0.193	15.2	13.6	0.527

Student-T test. * Significant P-value<0.05

Chapter 6

Urge incontinence and other forms of irritative bladder symptoms after TVT. A prospective multicentre 3 year follow-up study with reference to quality of life

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Abstract

Objective: To asses the long-term bladder symptoms (3 yrs) after the TVT procedure.

Material and Methods: Prospective cohort study of 610 participants. In 28 teaching hospitals and 13 local hospitals, 54 gynaecologist's and urologist's performed the tension-free vaginal tape procedure. Urge incontinence (UI), wet over active bladder (OAB), nocturia, frequency, and the Urogenital Distress Inventory (UDI-6) was used to asses irritative bladder symptoms. The Incontinence Impact Questionnaire, IIQ-7, was used to measure quality of life. Definitions used are according the recommendations of the International Continence Society.

Results: Urge incontinence and OAB wet symptoms developed in 11% and 3% respectively and give less improvement on the quality of life scores. The presence of preoperative frequency (odds ratio 2.64; 95% CI, 1.16-6.03) and rectocele (odds ratio 2.39; 95% CI, 1.15-4.99) were independent factors for the development of irritative symptoms postoperative. Nevertheless, these women still had significant improvement in their quality of life compared to the preoperative situation. This is probably due to cure of their stress incontinence.

Conclusion: Over all, after TVT most symptoms resolved significantly more than they developed, resulting in a better quality of life.

INTRODUCTION

Until recently the "gold standard" for the treatment of stress urinary incontinence was the Burch colposuspension[1]. The TVT has become the first choice for surgical treatment of stress urinary incontinence (SUI), in women[2, 3]. TVT has proven to be as successful as the Burch colposuspension with less serious complications[4, 5]. Long term complications of the Burch colposuspension have been described before[6, 7]. *De novo* urge incontinence accounted for 15% of the long term complications and women with an unstable bladder preoperative, showed detrimental outcome[7]. In both randomised controlled trials between Burch colposuspension and TVT women with preoperative mixed incontinence, detrusor instability, prolapse, prior surgery for prolapse/incontinence surgery or voiding dysfunction were excluded. All these items are very common in clinical practice in conjunction with SUI. The long term results of the TVT on these symptoms should therefore be assessed.

Assessing the efficacy of surgery for incontinence represents a challenging issue and Black and Downs found a poor methodological quality of the few prospective studies that have reported on the effectiveness of surgery for stress incontinence[8]. They stated: "outcomes need to be clearly defined, valid and reliable, not confined to short-term assessment and include patients views".

In this article we present the results of a multicentre study on the long-term outcome of TVT on urge incontinence and other forms of irritative bladder symptoms with well described outcome measures. Irritative symptoms and quality of life before and after the TVT were assessed with the aid of patients self reported disease specific validated health-related quality of life (HRQoL) questionnaires[9, 10].

Material and Methods

Between March 2000 and September 2001, women with an indication for a TVT procedure were asked to participate in this study. The study was approved by the Medical Ethical Committee of the St. Elisabeth Hospital Tilburg and all other co-working hospitals as required by Dutch law. Written informed consent for this study was obtained from all women.

Inclusion and exclusion criteria
Included were women who were willing to participate in the study and who had an indication for TVT. Excluded were women: with recurrent and difficult to treat urinary tract infections, women in whom no urodynamic investigations prior to TVT were performed, women of whom the presence of detrusor over activity (DO) was not listed, women who had detrusor over activity on their preoperative urodynamic investigation, those who had a post voiding bladder retention (>150 ml), a bladder capacity less than 200 ml or a physical/mental impairment which would make participation impossible. If more than two items on the IIQ or the UDI were not answered the total score was not calculated and was not included in the results. Women who had detrusor over activity on their preoperative urodynamic investigation were assessed separately.

Study design
A standardised history was taken and physical examination was performed preoperatively and again at two, six, twelve, twenty-four and thirty-six months postoperatively. Investigative preoperative multi-channel urodynamics was not mandatory and left to the gynaecologist's or urologist's discretion. All women were asked to complete the short version of the Incontinence Impact Questionnaire (IIQ-7) and the Urogenital Distress Inventory (UDI-6). The questionnaires, a postage-paid return envelope and instructions were sent to the patient by mail. Researchers as well as participating gynaecologist's and urologist's were blinded to the individual results of these questionnaires. The long form IIQ (30 questions) & UDI (19 questions) are disease specific health-related quality of life (HRQoL) questionnaires[9]. A short form for both questionnaires has been validated which consists of seven and six questions respectively (IIQ-7 & UDI-6)[10]. These questionnaires were translated into Dutch and validated for the Dutch female population[11]. All items in the questionnaires are on a four step ordered category scale from "not at all" to "greatly" impaired. The UDI is subdivided in three domains: stress incontinence, irritative and obstructive/discomfort. The IIQ measures the implications of urinary incontinence for normal daily functioning. The total score of every domain is transformed to a scale from 0-100 (a higher score means more bothered).

Surgical procedure
The procedures took place in 41 different hospitals by 54 gynaecologists and urologists. All surgeons were qualified to perform vaginal surgery and received a brief

training in TVT. Of the 41 hospitals 3 were university hospitals, 25 were teaching and 13 were non-teaching hospitals. TVT (Gynecare, Ethicon Inc, Sommerville, New Jersey, USA) was performed as described by Ulmsten[12]. The operation was carried out under local anaesthesia using 0.25% prilocaïne with adrenalin, spinal analgesia or general anaesthesia.

Outcome measures

Definitions used are according the recommendations of the International Continence Society[12]. Specifically for this study the following definitions were used. Frequency is defined as a micturition frequency of more than 8 times per day. Nocturia is defined as a micturition frequency of more than once during sleep. Urge incontinence is the complaint of loss of urine after a sensation of urge and implies in this study the presence of mixed incontinence, but the dominant symptom (and indication for surgery) was stress urinary incontinence. Overactive bladder symptoms (OAB wet) is defined as the combination of a micturition frequency of more than 8 times per day combined with the presence of complaints of urge incontinence. Irritative symptoms score were measured on the UDI-6. The domain irritative consists of 2 questions: Do you experience, and if so, how much are you bothered by: 1. frequent urination, 2. leakage related to feeling of urgency. The IIQ-7 was used to measure the quality of life.

Statistical analysis

All data was anonymously processed by a research physician (TMB) and the research team secretary. Statistical analysis was performed with SPSS 11.5 for Windows. Because of possible multi-comparison the Chi-square test was used to compare proportions relating to subjects in different groups. If the chi-square test was significant the groups were compared pair wise with the Fisher exact test. Two by two cross tables were compared with use of a two sided Fisher exact test. The Student t-test was used as a statistic to compare interval variables. To analyse matched and paired data the Wilcoxon's signed-rank test was used for continuous data. To analyze paired data the Mc Nemar test was used, for categorical variables. The mean difference was chosen to be significant at the 0.05 level. Data are presented as mean (± standard deviation (SD)). Subsequently, multivariate logistic regression analysis was used to construct a prediction model to determine preoperative and postoperative factors that independently influenced the urge incontinence rate. Logistic regression is a technique that can be used to evaluate the performance of multiple variables in a diagnostic model. Selection of variables is usually performed with a significance level of 5%. However, the incorrect exclusion of a factor would be more deleterious than including too many factors. Multivariate analysis included therefore all variables with a P-value < 0.10 in the univariate analysis.

RESULTS

Excluded were patients: who did not have preoperative urodynamical investigations (N=106) and women of whom the presence of detrusor over activity was not listed (N=52). Patients who showed detrusor overactivity at preoperative urodynamical investigations (N=41) were separately analysed. In total 610 women were analysed. The mean age at the time of TVT was 51.3 years (± 9.8 yrs). Only 14 women were nulliparous. The mean parity was 2.4 (± 1.0), 53.7% of women were postmenopausal and 16.6% used hormone replacement therapy. Ninety-six women had previous incontinence and/or prolapse surgery. In the group that had undergone prior incontinence surgery there were nine patients who had undergone two prior incontinence procedures and one patient who had undergone three prior incontinence procedures (Burch, re-Burch and hysterectomy with concomitant Raz sling procedure). The mean operating time was 33 (±13) minutes. Thirty-seven women had simultaneous prolapse surgery. In this group, 7 vaginal hysterectomies, 1 sacrospinous fixation, 19 colporrhaphy anterior and 21 colporrhaphy posteriors were performed. TVT was combined in 5.4% with non-urogynaecological procedures like for example sterilization. These combined procedures were performed under general anaesthesia. Local anaesthesia was used in 79.6%, spinal in 9.2% and general anaesthesia in 11.2%.
The follow-up was at least 3 years for all women. The response rate for the postoperative visit at the doctor's office was 71% at 36 months. The response rate for the quality of life questionnaires was 77% at 36 months.
In table 1 the complaints of frequency, nocturia, urge incontinence, OAB wet and irritative symptoms scores prior to, 2 and 36 months post TVT are shown. Most symptoms decreased significantly until 3 years follow-up. Only nocturia decreased at 2 months follow-up and then returned to the same level at 3 years follow-up as preoperative. The OAB wet rates at 36 months did not statistically differ from preoperative rates.
In table 2 changes in complaints of frequency, nocturia, urge incontinence, OAB wet and irritative symptoms scores, preoperative and at 2 & 36 months post TVT are shown. This table shows that de novo symptoms may occur, but also that existing symptoms resolve. The degree of resolving of symptoms is for all symptoms significantly higher than the development of de novo symptoms both after 2 and 36 months. If symptoms resolve, this appears to be a lasting effect (no change between 2 and 36 months) except for nocturia. If symptoms develop, they all tend to increase slightly between 2 and 36 months and again only nocturia develops much more than the other symptoms.
Table 3 shows the outcome of the quality of life scores (IIQ-7) scores for patients with OAB wet, nocturia, frequency and urge incontinence. The presence of urge incontinence preoperative did not affect quality of life. All symptoms had a negative impact at 36 months, but all women were significantly less bothered than before surgery.
Table 4 shows the uni- and multi-variate analysis of determinants of irritative bladder symptoms. After uni- and multi-variate analysis associated factor for irritative

symptoms postoperative were; the presence of a rectocele grade 2 or more preoperative and the presence of pre-operative frequency.
The outcome for the group with pre-operative DO (N=41) was separately analysed. The scores on the IIQ pre-operatively, at 2 and 3 years follow-up were respectively; 65,33 and 34. The decline in IIQ postoperatively was statistically significant.

Discussion

This present study included a high number of women and the length of follow-up was 3 years for all women. We used several well described outcome measures, patient self reported results and findings of urologists and gynaecologists, to evaluate the results. The results of published studies show a wide range in outcomes. Also a wide array of definitions was used to describe bladder function after the TVT procedure, which makes it difficult to compare al studies. However, there are also some limitations in this study we need to address. Firstly, this is a prospective cohort study with a follow-up of 3 years. But if all non-responders would be counted as failures the results would be different. In an article published earlier by our group we showed that the improvement rates in the "lost to follow-up" group is a somewhat lower, but to consider this group a failure seems inappropriate[13]. Secondly we did not perform urodynamical investigation in enough patients postoperative to assess the results of postoperative urodynamical investigation properly.
This study showed a *de novo* rate for urge incontinence after 2 months and 3 years of 6.3% and 10.9% respectively and *de novo* OAB wet of 1.6% and 3.2%. Other small (N=52 & N= 62 respectively) prospective studies[14, 15] showed similar *de novo* rates of 0-18%.
A large cross-sectional, questionnaire based study of 743 woman showed *de novo* urge incontinence in 6.7% and even increased after several years[16]. The authors hypothesised that this finding suggests that slow in growth of tissue in the tape possibly changes the surroundings of the urethra. Holmgren et al also found that women with mixed incontinence were older, and theorised that this can be due to atrophy of the bladder epithelium[16].

In patients with pre-operative mixed incontinence the improvement/cure rates of the TVT described are often lower than in patients with only stress incontinence[16-19]. In our group of women with mixed incontinence, in 23% the complaints of urge incontinence remained but in 77% the complaints resolved. This reduction in symptoms of urge incontinence were reported before[4,14,20-22]. Possibly it is due to the urethral stability which the tapes provides underneath the urethra, inhibiting the urge incontinence[8, 23, 24]. Previous surgery is correlated with urge incontinence[16, 25]. This is thought to be a complication of the dissection of the bladder and traumatising neuromuscular innervation. In our results we found no correlation between previous surgery and urge incontinence. Although the percentage of urge incontinence was slightly higher in women with prior prolapse and incontinence surgery (8.6% & 10.3%) than those without prior surgery (5.9% & 6.4% respectively) this was not found to be statistically significant different.
The experience of the surgeon did not affect the development of irritative bladder symptoms. In prior publications of our group we found a higher success rate for experienced surgeons (more than 20 TVT's)[26] and we found a learning curve effect for the development of postoperative complications[27].
The presence of pre-operative frequency and rectocele were found to be independ-

ent factors for the development of irritative symptoms postoperative. The rectocele might have given a bladder outlet obstruction after which urge incontinence developed. Of the four symptoms that are currently considered to be part of the overactive bladder syndrome[12], frequency is described as one of the most objective parameters[28]. So in women, in whom frequency existed pre-operative, were more prone to develop urge incontinence symptoms at 36 months.

All symptoms resolved significantly more than they developed after TVT. Post-operatively women who have these symptoms are significantly more bothered than women without these symptoms, indicating that these symptoms influence the outcome of TVT significantly in a negative way. Nevertheless, these women still had significant improvement in their quality of life compared to the pre-operative situation. This is probably due to cure of their stress incontinence.

This study reports the long-term outcome of symptoms of frequency, nocturia, urge incontinence, OAB wet, irritative symptoms with reference to quality of life of the tension-free vaginal tape procedure. These symptoms are often prevalent prior to TVT and often resolve afterwards. Urge incontinence and OAB wet symptoms developed in 11% and 3% respectively and gave less improvement on the quality of life scores. Over all most symptoms resolved significantly more than they developed after TVT, resulting in a better quality of life after TVT.

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Tabel 1. Symptoms of frequency, nocturia, urge incontinence, OAB wet and irritative scores prior to and 2 & 36 months post TVT (N=610)

	prior to TVT	**after 2 months**		**after 36 months**	
		%	*p*		*p*
Frequency	32.6%	16.0%	0.000[a]	20.4%	0.000[a]
Nocturia	30.8%	16.6%	0.000[a]	32.9%	0.137[a]
Urge incontinence	19.6%	10.4%	0.000[a]	13.4%	0.012[a]
OAB wet	6.9%	2.3%	0.001[a]	4.8%	0.121[a]
Irritative symptoms score mean (± SD)	64.62 (± 26.45)	33.07 (± 25.71)	<0.0001[b]	32.64 (± 24.74)	<0.0001[b]

Statistical analysis: a.Comparison to preoperative value (Mc Nemar test)
b.Comparison to preoperative value (Wilcoxon's signed-rank test)

Tabel 2. Changes in symptoms of frequency, nocturia, urge incontinence and OAB wet, preoperative and at 2 & 36 months post TVT (N=610)

	after TVT	2 months		36 months	
Frequency			p		p
no frequency present prior to TVT	no frequency	93.1%	<0.0001[a]	85.5%	<0.0001[a]
	de novo frequency	6.9%		14.5%	
frequency present prior to TVT	frequency remains present	34.3%		35.1%	
	frequency resolved	65.7%		64.9%	
Nocturia					
no nocturia present prior to TVT	no nocturia	92.9%	<0.0001[a]	79.7%	<0.0001[a]
	de novo nocturia	7.1%		20.3%	
nocturia present prior to TVT	nocturia remains present	44%		65.4%	
	nocturia resolved	56%		34.6%	
Urge incontinence					
no urge incontinence present prior to TVT	no urge incontinence	93.8%	<0.0001[a]	89.1%	0.008[a]
	de novo urge incontinence	6.3%		10.9%	
urge incontinence present prior to TVT	urge incontinence remains present	24.5%		22.7%	
	urge incontinence resolved	75.5%		77.3%	
OAB wet					
no OAB wet present prior to TVT	no OAB wet	98.4%	0.001[a]	96.8%	0.015[a]
	de novo OAB wet	1.6%		3.2%	
OAB wet present prior to TVT	OAB wet remains present	15.6%		15.4%	
	OAB wet resolved	84.4%		84.6%	

Statistical analysis: a.Comparison of postoperative changes to preoperative groups of each symptom (Mc Nemar test).

Tabel 3. Changes on the impact score of incontinence (determined by the IIQ-7 scores) for the symptoms frequency, nocturia, urge incontinence and OAB wet after 2 and 36 months

	Incontinence Impact Score (IIQ-7) (mean ± SD)						
	prior to TVT		**after 2 months**		**after 36 months**		
		p★		p★		p★	p#
Frequency	mean (± SD)		mean (± SD)		mean (± SD)		
frequency absent	55.90 ± 20.33	<0.001[a]	14.68 ± 21.66	0.051[a]	10.42 ± 16.73	<0.001[a]	<0.001
frequency present	63.53 ± 20.55		21.78 ± 20.69		23.57 ± 24.78		<0.001
Nocturia							
nocturia absent	55.80 ± 20.00	<0.001[a]	14.39 ± 21.05	0.032[a]	10.10 ± 15.96	<0.001[a]	<0.001
nocturia present	64.72 ± 21.08		22.22 ± 23.49		18.84 ± 23.70		<0.001
Urge incontinence							
urge incontinence absent	57.77 ± 20.55	0.145[a]	14.37 ± 21.25	0.001[a]	9.47 ± 14.90	<0.001[a]	<0.001
urge incontinence present	61.12 ± 19.75		27.90 ± 22.11		41.40 ± 27.75		<0.001
OAB wet							
OAB wet absent	57.70 ± 20.49	0.002[a]	15.29 ± 21.78	0.01[a]	11.15 ± 16.64	<0.0001[a]	<0.001
OAB wet present	70.02 ± 19.29		32.13 ± 10.83		53.92 ± 25.01		<0.001

Statistical analysis: a. Comparison of values (Student T-test. independant samples).
P★= comparison between absence and precence of the symptoms. P# `comparison between p and postoperative.

Table 4. Univariate variate analysis of determinants of urge incontinence

	UNIVARIATE ANALYSIS						MULTIVARIATE ANALYSIS	
	urge incontinence (n =58)		no urge incontinence (n =374)		OR[95% CI]	*p*-value	statistical method	B[95% CI]	*p*-value
General Data									
age (years ± se)	51.9 (9.3)		51.1 (9.4)			0.565	*t*		
categories									
20-40	10	17.2%	46	12.3%					
41-50	15	25.9%	135	36.1%					
51-60	21	36.2%	133	35.6%		0.538	X2		
61-70	10	17.2%	50	13.4%					
>71	2	3.4%	10	2.7%					
Parity									
nulliparity	0	0.0%	7	2.0%	0.98[0.97-1.00]	0.600	F		
multiparity	56	100.0%	347	98.0%					
menopausal status									
premenopausal	24	45.3%	193	53.2%	0.73[041-1.30]	0.305	F		
postmenopausal	29	54.7%	170	46.8%					
Urogynecological History									
no previous urogynecological surgery	46	79.3%	321	85.8%					
previous prolapse surgery	5	8.6%	22	5.9%		0.578	X2		
previous incontinence surgery	6	10.3%	24	6.4%					
previous incontinence and prolapse surgery	1	1.7%	7	1.9%					
incontinence episodes									
daily	45	91.8%	315	92.9%	1.17[0.38-3.52]	0.768	F		
weekly	4	8.2%	24	7.1%					
intrinsic sphincter deficincy									
yes	2	7.1%	27	11.8%	0.57[0.13-256]	0.750	F		
no	26	92.9%	194	88.2%					
Pelvic Floor Status prior to TVT									
cystocele									
no cystocele	28	52.8%	189	56.9%	1.18[0.66-2.11]	0.655	F		
cystocele	25	47.2%	143	43.1%					
rectocele									
no rectocele	30	60.0%	271	79.0%	2.51 [1.35-4.67]	**0.006**	F	2.39[1.15-4.99]	**0.020**
rectocele	20	40.0%	72	21.0%					
prolaps of uterine cerix of vaginal vault									
no prolapse of cervix of vaginal vault	36	72.0%	285	81.4%	1.71 [0.87-3.34]	0.129	F		
prolapse of cervix of vaginal vault	14	28.0%	65	18.6%					
urethral hypermobility									
no hypermobility	7	15.9%	43	13.7%	1.18 [0.49-2.83]	0.647	F		
hypermobility	37	84.1%	270	86.3%					

	urge incontinence (n =58)		no urge incontinence (n =374)		OR[95% CI]	*p*-value	statistical method	B[95% CI]	*p*-value
Frequency									
frequency absent	24	50.0%	218	71.2%	2.48[1.33-4.59]	**0.004**	F	2.64[1.16-6.03]	**0.021**
frequency present	24	50.0%	88	28.8%					
Nocturia									
nocturia absent	31	66.0%	224	71.1%	1.27[0.66-2.43]	0.495	F		
nocturia present	16	34.0%	91	28.9%					
Urge incontinence									
- urge incontinence absent	36	67.9%	293	83.5%	2.39[1.25-4.53]	**0.012**	F	1.88[0.57-6.23]	0.299
- urge incontinence present	17	32.1%	58	16.5%					
OAB wet									
OAB wet absent	42	84.0%	323	94.7%	3.42[1.40-8.43]	**0.010**	F	1.12[0.23-5.59]	0.886
OAB wet present	8	16.0%	18	5.3%					
type of hospital setting									
no. of TVT in teaching hospitals	35	60.3%	239	63.9%	1.16 [0.66-2.05]	0.661	F		
no. of TVT in non-teaching hospitals	23	39.7%	135	36.1%					
Simultaneous Procedures									
TVT only	50	86.2%	338	90.4%					
TVT with prolapse surgery	6	10.3%	18	4.8%		0.216	X2		
TVT with other surgical procedures	2	3.4%	18	4.8%					
Type of Anesthesia									
local anesthesia (with sedation)	40	76.9%	287	80.6%					
spinal analgesia	3	5.8%	38	10.7%		0.101	X2		
general anesthesia	9	17.3%	31	8.7%					
Surgeon's Experience									
learning curve effect									
first 10 procedures for each surgeon	22	37.9%	117	31.3%					
next 10 procedures for each surgeon	11	19.0%	75	20.1%		0.594	X2		
more than 20 procedures for each surgeon	25	43.1%	182	48.7%					

X2: Chi-square test, *t* = student-t test, F = Fisher exact test; statistically significant differences are highlighted
Values are mean (SD). number (%) and Odds Ratio [95% CI]

Chapter 7

Result of the Tension-free Vaginal Tape (TVT) in patients with concomitant pelvic surgery, a two year follow-up study, analysis from the Netherlands TVT database

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International Urogynecology Journal 2006, accepted

Abstract

Objective: This study assessed the long-term outcome of TVT in women with concomitant pelvic surgery.

Material and Methods: A prospective cohort study of 809 746 patients in 51 hospitals was undertaken. The Incontinence Impact Questionnaire (IIQ-7) and Urogenital Distress Inventory (UDI-6) were used to measure the results of the TVT. Fifty-nine patients with concomitant prolapse surgery were compared with 687 women with TVT only.

Results: IIQ/UDI mean scores decrease statistically significant in both groups after the TVT. The success rates of 'no leakage at all' is comparable for both groups. But aHowever in a larger amount of women with concomitant surgery no change of the incontinence after TVT was found. After a follow-up of two years a statistical difference in UDI & IIQ scores could be identified.

Conclusion: TVT is effective for women without and with concomitant prolapse surgery, after 2 years a difference in UDI & IIQ scores could be identified.

INTRODUCTION

The estimated prevalence of urinary incontinence in women aged 18 years and older varies between 23% and 57%[1,2]. About half of these women suffer from stress urinary incontinence (SUI). Urinary incontinence in combination with pelvic prolapse is reported up to 80%[3,4]. Until 1995 the "gold standard" for stress urinary incontinence surgery was the Burch colposuspension[5]. More recently, TVT[6,7] has become the first choice as surgical treatment for stress urinary incontinence in many women because it has proven to be as successful as the Burch colposuspension[8,9]. A vaginal approach to both prolapse and incontinence is therefore nowadays possible.
Therefore it is surprising that the efficacy of the TVT in conjunction with other reconstructive pelvic floor surgery has not often been addressed. In this study we present the outcome and two years follow-up of the TVT procedure in women with concomitant surgery by means of objective (patient self reported) results on their health status with the aid of disease specific HRQOL questionnaires (the Incontinence Impact Questionnaire (IIQ) and the Urogenital Distress Inventory (UDI)).

Material and Methods

Between March 2000 and September 2001, women with an indication for a TVT procedure were asked to participate in this study. The study was approved by the Medical Ethical Committee of the St. Elisabeth Hospital Tilburg and all other co-working hospitals as required by Dutch law. Written informed consent for this study was obtained from all women.

Study design
A standardized history was taken and physical examination was performed preoperatively and again at two, six, twelve and twenty-four months postoperative. Investigative preoperatively multi-channel urodynamics was not mandatory and left to the gynecologist's or urologist's discretion.
All women were asked to complete the short version of the Incontinence Impact Questionnaire (IIQ-7) and the Urogenital Distress Inventory (UDI-6) before and at two, six, twelve and twenty-four months after the procedure. The questionnaires, a postage-paid return envelope and instructions were send to the patient by mail. The questionnaires were processed anonymously. Researchers, as well as participating gynecologist's and urologist's, were blinded to the individual results of these questionnaires. The long form IIQ & UDI are disease specific health-related quality of life (HRQOL) questionnaires[10]. These questionnaires consist of 19 questions (UDI) and 30 questions (IIQ). Uebersax et al[11] validated a short form for both questionnaires (IIQ-7 & UDI-6), which consists of seven and six questions respectively. These questionnaires were translated into Dutch and validated for the female population in the Netherlands[2]. All items in the questionnaires are on a four step ordered category scale from "not at all" to "greatly" impaired. The total score is transformed to a scale from 0-100 (a higher score means more bothered). The IIQ measures the implications of urinary incontinence for normal daily functioning, while the UDI indicates the type of bother women experience.

Inclusion and exclusion criteria
Included were women who were willing to participate in the study and who had an indication for TVT. Excluded were women: with a history off prolapse and/or incontinence surgery, with recurrent and difficult to treat urinary tract infections, those who had a post voiding bladder retention (>150 ml), a bladder capacity less than 200 ml or a physical/mental impairment which would make participation impossible. If more than two items on the IIQ or the UDI questionnaire were not answered, the total score was not calculated and was not included in the results.

Surgical procedure
The procedures took place in 41 different hospitals by 54 gynecologists and urologists. Of the 41 hospitals, 3 were university hospitals, 25 were teaching and 13 were non-teaching hospitals. TVT (Gynecare, Ethicon Inc, Sommerville, New Jersey, USA) was performed as described by Ulmsten[6,7]. All surgeons were qualified to per-

form vaginal surgery and received a brief training in TVT. The operation was carried out under local anesthesia, spinal analgesia or general anesthesia.

Outcome measures

The primary outcome measurement were the IIQ and UDI scores.

According the recommendation of the ICS, the question "Do you experience urinary leakage during physical activity, coughing or sneezing?" was selected from the UDI, as a secondary outcome measure to define success or failure for SUI[12]. Women who have a lower score on the UDI question score postoperative compared with preoperative were considered to be improved.

Statistical analysis

The data was anonymously processed by a research physician (TMB) and the research team secretary. Statistical analysis was performed with SPSS 11.5 for Windows. The Chi-square test was used to compare proportions relating to subjects in different groups. Categorical variables were compared with a two sided Fisher exact test. The Student t-test was used as a statistic to compare interval variables. To analyze matched and paired data the Wilcoxon's signed-rank test was used. The mean difference was chosen to be significant at the 0.05 level. To analyze statistical differences between groups, the one-way ANOVA test with a Post Hoc Bonferroni correction was used.

RESULTS

The original database comprised data of 809 women. Fifteen women were excluded, for the following reasons: refused to take further part in the study (n=13), diseased (n=1), did not fully complete the questionnaire (n=1). In 59 women (7.3%) concomitant surgery was performed and were the subject of this analysis. The surgical procedures performed concomitant to the TVT were: vaginal hysterectomy for uterine descent (n=7), anterior repair (n=15), posterior repair (n=28) and anterior with posterior repair (n=9). Of these 59 patients15 women underwent prior surgery, 6 women had prior prolapse repair: 3 women a vaginal hysterectomy, 5 underwent a colporrhaphy anterior, 3 women a colporrhaphy posterior. One Women underwent a sacrocolpopexy and rectopexy. Seven women underwent previous incontinence surgery, all underwent a Burch colposuspension. One Women underwent a re-Burch and 1 women a underwent a Marchall-Marchetti-Kranz (MMK) suspension after a Burch. Two women underwent both prior incontinence and prolapse surgery. One Burch colposuspension with a colporrhaphy anterior and colporrhaphy posterior and one women a MMK with abdominal hysterectomy with colporrhaphy anterior and posterior.
The mean age at the time of TVT was 56,2 years (SD 10.4; range 32 - 82). One woman was nulliparous. The mean parity was 2.7 (SD 1.1; range 0 - 6). Of all women 70.6% was postmenopausal and 28.3% of all women used hormone replacement therapy. The mean operating time of the TVT and concomitant surgery was 50 minutes (SD 27.4; range 20-150).
General anesthesia was used in 47.3%, spinal in 16.4%, local analgesia in 36.4%. In teaching hospitals 34 (58%) and in non teaching hospitals 25 (42%) of the surgery was performed.
The mean pre and postoperative values of the IIQ-7 and UDI-6 quality of life questionnaires are listed in table 1. The response rate for these outcome parameters was 72.9% at 2 years follow-up. Both IIQ and UDI mean scores decrease statistically significant after TVT at the two months. Thereafter, no statistical difference was found comparing the changes between two and six, six and twelve months and twenty-four months follow-up in the UDI scores. However, a statistical significant (but small) decline in the mean IIQ score at 12 months was observed, which at 24 months had disappeared.

The results for outcome parameter two are listed in table 2. The follow-up rates were the same as for outcome parameter 1 and are noted in table 3. After 2 months the continence rate stated by the women with concomitant surgery is 64.2%. This increased to 69.2% after 12 months to 7667.5% after 36 24 months. For women without concomitant prolapse surgery the success rate also increased in time. The difference lies in the larger amount of women with concomitant surgery in whom no change of the incontinence was found.

In table 3 the two groups were compared, the groups did not significantly differ in, parity and preoperative IIQ & UDI scores. The two groups did differ significantly in age (56.2 versus 51.2, p=0.000) and post menopausal state (70.6 versus 45.7, p=0.000).
The mean IIQ and UDI scores of women with concomitant pelvic surgery were compared with the mean IIQ and UDI scores of women without prior surgery (table 3). These two groups were the same as for outcome parameter two. The results show that after a follow-up of two years a statistical difference in UDI & IIQ scores could be identified.

Discussion

Co-existing urinary incontinence and pelvic organ prolapse has been reported in 15-80%[3, 4]. Choe et al and Bai et al reported that 60-63% of patients with urinary stress incontinence also had pelvic organ prolapse[4, 13].
With the TVT as first choice for incontinence surgery, TVT in conjunction with other pelvic surgery is becoming more popular. Especially because the two can be performed in one session without an abdominal incision. Therefore it is remarkable that not many studies describe the success rate of this combination. The intra and postoperative complication rates of this combined surgery have been described before[14]. The complication rate of our study group in comparison with women undergoing TVT without concomitant surgery was comparable[1]4. Tamussino et al and Partoll et al described a longer period of postoperative residual volumes for patients undergoing concomitant surgery[15, 16]. This was not demonstrated by Sokol et al[17]. Deval et al described a higher rate of bladder perforations when concomitant surgery was performed[18].
Few studies have stratified for TVT versus TVT in conjunction with prolapse surgery. No significant difference in success was found in these studies[18-20]. One study described a lower success rate for TVT with cystocele repair of 38% against 67% in patients without a cystocele repair. However this was not significant probably due the small amount of patients[21]. Another study described a lower success rate for TVT with colporrhaphy anterior but no statistical analysis was performed[22]. Tape migration has been described when performing a colporrhaphy anterior combined with TVT[23]. Migration from mid urethral to bladder neck can influence the outcome[24]. We could not find a statistical difference for those women who had undergone a colporrhaphy and TVT. This may be due to small numbers (n= 15) but also because several participating surgeons made separate incisions for the introduction of the TVT and the anterior colporrhaphy to prevent this migration. We could not compare these two approaches due to the small sample size.
Partoll et al described 37 patients who underwent TVT and concomitant prolapse surgery[16]. After a follow-up of 11 months the overall success rate for urinary incontinence was 94.6%. Success was defined as dry at a standing stress test with a comfortably full bladder and no stress incontinence episodes were reported verbally by the patient or noted in a voiding diary. Jomaa reported in 2001 on 32 women undergoing TVT and colporrhaphy anterior and/or posterior[25].

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Table 1. Mean UDI scores and mean IIQ scores (N=59)

	Mean UDI-scores (SD)	P-value	**Mean IIQ-scores (SD)**	P-value
Preoperative	63.3 (18.0)		58.4 (21.0)	
2 months postoperative	29.8 (21.9)	0.000	20.6 (23.5)	0.000
6 months postoperative	29.5 (20.7)	0.000	19.1 (24.2)	0.000
12 months postoperative	25.3 (18.6)	0.000	13.1 (18.8)	0.000
24 months postoperative	31.5 (22.6)	0.000	21.2 (22.6)	0.000

Wilcoxon's signed rank-test.
SE is standard deviation.
* Significant P-value < 0.05, compared to the preceding value.
The values presented are the mean scores on the UDI subscales.
A high score means more bother

Table 2. Continence status- women's reply to the UDI question: "do you experience urinary leakage during physical activity, coughing or sneezing?", compared to their preoperative status

Concomitant surgery(n=59)	**2 months**	**6 months**	**12 months**	**24 months**
no leakage	64.2%	63.8%	69.2%	67.5%
improved	17.9%	22.2%	23.1%	20.0%
no change	17.9%	11.7%	5.2%	12.5%
worsened	0%	2.8%	2.5%	0%
No concomitant surgery(=687)				
no leakage	68.3%	71.9%	71.9%	67.7%
improved	23.0%	22.8%	24.9%	28.3%
no change	7.6%	4.2%	2.6%	3.6%
worsened	1.1%	1.1%	0.6%	0.4%

Table 3. Differences in mean UDI and IIQ scores between women with concomitant surgery (N= 59),and women who had no concomitant surgery (N=687)

	UDI			IIQ			
	concomitant surgery	*no concomitant surgery*	*p-value*	*concomitant surgery*	*no concomitant surgery*	*p-value*	*follow-up*
pre-operative	63	59	0.274	58	58	1.000	
2 months postoperative	30	25	0.663	21	16	0.771	50.80%
6 months postoperative	30	23	0.172	19	13	0.185	64.40%
12 months postoperative	25	21	0.656	13	12	1.000	67.80%
24 months postoperative	32	23	0.019★	21	13	0.022★	72.90%

One–way Anova with post hoc Bonferroni correction, ★ Significant P-value < 0.05.

Chapter 8

The prevalence of voiding difficulty after TVT, its impact on quality of life and related risk factors

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International Urogynecology Journal 2006, in press

Abstract

Objective: To determine the prevalence of voiding difficulty (VD), quality of life and related risk factors after Tension-free Vaginal Tape (TVT).

Design: Prospective cohort study in 703 women undergoing a TVT procedure for stress urinary incontinence.

Main outcome measures: VD stated by women, Urogenital Distress Inventory (UDI-6) maximum flow rate, postvoid residual urine, necessity of postoperative catheterization, tape division, impact on quality of life (Incontinence Impact Questionnaire, IIQ-7).

Results: Postoperative catheterization (> 24 hours) was necessary in 11% and tape division in 1.3% of all patients. Twenty-six percent of women stated VD and 25% reported moderate to great impairment on the UDI-6 after 36 months. Women with abnormal voiding postoperative showed worse outcome on the quality of life. However, all women with and without voiding difficulties showed better scores in the IIQ postoperatively in comparison to preoperative. Preoperative existing voiding difficulty and concomitant prolapse surgery were found to be independent risk factors.

Conclusions: Symptoms of VD occured after TVT and caused less improvement on the quality of life.

INTRODUCTION

Until 1995 the "gold standard" for surgery for stress urinary incontinence (SUI) was the Burch colposuspension which resulted in good long term outcome[1, 2]. This procedure has mostly been replaced by the Tension-free Vaginal Tape (TVT) procedure. The TVT provides the same long term outcome, has lesser side effects and a much lower surgical impact on quality of life of women compared to the Burch colposuspension[3-7]. The TVT is based on the concepts of the Hammock Hypothesis and the Integral Theory[8-10], TVT provides reconstruction of the supporting tissue of the urethra using a polypropylene mesh without repositioning the bladder or securing the periurethral tissues to pelvic structures[5]. The TVT creates a dynamic kinking at the level of the mid-urethra without compressing the urethra at rest and hence, diminishing the obstructive nature of the sling procedure[11]. Nevertheless, voiding difficulty (VD) has been reported up to 60% after TVT and may impose a serious unfavorable outcome affecting quality of life in a negative way despite achieving urinary continence[7].

The aims of this study were to determine the prevalence, and risk factors for voiding difficulty after TVT with the use of objective parameters and validated quality of life questionnaires.

MATERIAL AND METHODS

Between March 2000 and September 2001 women with an indication for a TVT procedure were asked to participate in this study. This study was approved by the Medical Ethical Committee of the St. Elisabeth Hospital Tilburg (The Netherlands) as primary research center and all other co-working hospitals as required by Dutch law. Written informed consent for this study was obtained from all women.

Inclusion and exclusion criteria

Included were women with urodynamic proven SUI and who were willing to participate in the study. Excluded were women with predominant symptoms of urge urinary incontinence (defined as urge incontinence being more prevailing than stress incontinence), with recurrent and difficult to treat urinary tract infections, women who had a post void bladder retention (>150 ml), a bladder capacity less than 200 ml or a physical/mental impairment which would make participation impossible.

Study design

A standardized history was taken and physical examination was performed preoperatively, at 2, 6, 12, 24 and 36 months postoperatively. For this study the postoperative situation at 2 and 36 months was analyzed. Investigative preoperative multi-channel urodynamics was performed in all women. Flowmetry was carried out before and 2 months after TVT in respectively 552 and 182 women. Postvoid residual urine was determined preoperatively and at each visit postoperatively.

Women with a postvoid residual of more than 150 ml for more than 24 hours after surgery either stayed hospitalized until the postvoid residual was lower than 150 ml or left the hospital with a catheter (or learned self intermittent catheterization).

All women were asked to complete the short version of the Incontinence Impact Questionnaire (IIQ-7) and the Urogenital Distress Inventory (UDI-6) before surgery and at the at 2, 6, 12, 24 and 36 months postoperative. The questionnaires, a postage-paid return envelope and instructions were sent to the patient by mail. Researchers as well as participating gynecologists and urologists were blinded to the individual results of these questionnaires. The long form IIQ (30 questions) & UDI (19 questions) are disease specific health-related quality of life questionnaires[12]. A short form for both questionnaires has been validated and consists of seven and six questions respectively (IIQ-7 & UDI-6)[13]. These questionnaires were translated into Dutch language and validated for the Dutch female population[14]. All items in the questionnaires are on a four step ordered category scale from "not at all" to "greatly" impaired. The UDI is subdivided in three domains: stress incontinence, irritative and obstructive/discomfort. The IIQ measures the impact and implications of urinary incontinence for normal daily functioning. The total score of the IIQ-7 and UDI-6 and each domain is transformed to a scale from 0-100 (a higher score indicates more bother). If more than two items on the IIQ or the UDI were not answered the total score was not calculated and was not included in the results.

Surgical procedure

The procedures took place in 41 different hospitals by 54 gynecologists and urologists. Among the 41 hospitals were 3 university hospitals, 25 teaching and 13 non-teaching hospitals. All surgeons were qualified to perform vaginal surgery, received a brief training in TVT and performed TVT as described by Ulmsten[5]. The operation was carried out under local anesthesia using 0.25% prilocaïne with adrenalin (and general sedation), spinal analgesia or general anesthesia. At the end of the procedure a Hegar sound number 7 was introduced in the urethra in order to detect any obstruction of the urethra.

Outcome measures and definitions

VD was defined by several parameters, which were used as outcome measures. The first outcome measure was the need of postoperative catheterization. Secondly, women were asked whether voiding went easy or difficult. Third, question 5 of the short form of the Urogenital Distress Inventory (UDI-6) informing about difficulty in emptying the bladder, was used. This question has four options for an answer: not impaired (score 0), slightly impaired (score 1), moderately impaired (score 2) or greatly impaired (score 3). The fourth outcome measure was the maximum flow rate, prior to and 2 months after TVT. The fifth was the postvoid residual urine.

Definitions used are according the recommendations of the International Continence Society[15]. Postoperative urinary retention was defined as the need of catheterization for more than 24 hours. Abnormal maximum flow rate was defined as a flow rate of less than 15 ml/s. Abnormal postvoid residual urine was defined as higher than 100 ml, except for the direct postoperative period where the level was set at 150 ml. Pelvic organ prolapse was dichotomized according to Baden-Walker classification[16]. Grade 0 was defined as no pelvic organ prolapse and grade ? 1 as a pelvic organ prolapse.

Statistical analysis

All data were anonymously processed by a research physician (TMB) and the secretary of the research team. Statistical analysis was performed with SPSS 11.5 for Windows.

Chi-square test was used to compare proportions relating to subjects in different groups. The Student t-test was used as a statistic to compare interval variables. To analyze paired data the Mc Nemar test was used for categorical variables. Multivariate logistic regression analysis was used to construct a prediction model to determine pre- and postoperative factors that independently influenced the voiding difficulty rate. Logistic regression is a technique that can be used to evaluate the performance of multiple variables in a diagnostic model. Selection of variables is usually performed with a significance level of 5%. However, the incorrect exclusion of a factor would be more deleterious than including too many factors. Multivariate analysis included therefore all variables with a P-value < 0.10 in the univariate analysis.

The mean difference was chosen to be significant at the 0.05 level. Data are presented as mean ($\pm$ standard deviation) or numbers (%).

RESULTS

Data in this study are from the Dutch TVT database, which originally contained 809 women. For this study women in whom no urodynamic investigation prior to TVT was performed (n = 106) were left out of the analysis. This left 703 women for analysis.

The mean age at the time of surgery was 51.3 (± 10.1) years. The mean parity was 2.4 (± 1.0) and the median and range were 2.0 respectively 0 - 9, while only 16 women were nulliparous. 43.6% of women were postmenopausal and 13.9% used hormonal replacement therapy. Previous prolapse surgery was present in 61 (8.7%) women, previous incontinence surgery in 43 (6.1%) women, and prolapse and incontinence surgery in 15 (2.1%) women. The mean length of surgery was 34 (± 13.7) minutes. In 47 (6.7%) women TVT was combined with prolapse surgery and in 40 (5.7%) women non-urogynecological procedures, like for example sterilization, were carried out. Local anesthesia (with sedation) was used in 80.1%, spinal anesthesia in 8.2% and general anesthesia in 11.7%.

Postoperative catheterization due to urinary retention was necessary in 81 (11.5%) of women. Of these 81 women 66% voided normal within 2 days, 95% within 10 days, while in 4 women (5%) catheterization up to 90 days was needed. The mean length of catheterization was 5.07 (± 12.5, median 2) days. The mean number of voids before reaching a postvoid residual of less than 150 ml was 1.95 (± 1.04, median 2) in women after spontaneous voiding and 2.62 (± 0.9, median 3) in women who started voiding after catheterization ($p<0.001$). Tape division or adhaesiolysis of the tape due to permanent urinary retention was necessary 9 women (1.3%). Except for one woman, all voided normal afterwards and remained continent. Tape division was done in 5 women within 2 months after the TVT procedure, in 2 women between 2 and 6 months, and in another two women between 6 and 12 months. In one woman the removal of the tape resulted in an urethro-vaginal fistula.

In table 1 the prevalence of VD stratified by the various definitions and the response rates are presented. By omission women were not asked about VD prior to the surgical procedure. VD as assessed by the statement of the woman increased significantly between 2 and 36 months. The prevalence of women with an abnormal maximum flow rate and with abnormal postvoid residual urine increased significantly after 2 months.

In table 2 the changes in symptoms of voiding difficulty are listed. Significantly more women improved than developed voiding difficulty as assessed with the UDI after 36 months. The actual numbers of women having abnormal maximum flow rate or residual urine prior to TVT are low.

In table 3 the impact of the various parameters of voiding difficulty on quality of life is presented. All women improved significantly on the IIQ score 2 and 36 months postoperative. Women with difficulty emptying assessed with the UDI at 2 and 36 months scored lower at the IIQ then women without difficulty in emptying their bladder. Both groups though improved significantly compared to pre-operative scores on their quality of life. Women reporting voiding difficulty at 36 months

improved on their quality of life scores compared with pre-operative scores, but scored worse than women without voiding difficulty.
In table 4, a univariate and multivariate analysis are presented for possible risk factors in women reporting moderately to greatly impairment of voiding difficulty on the UDI at 36 months. After multivariate analysis two risk factors emerge for the development of voiding difficulty: preoperatively existing voiding difficulty and TVT with concomitant prolapse surgery.

Discussion

Voiding does not necessarily return to normal immediately after the TVT procedure. The need of postoperative catheterization ranges from 3% to 50% after TVT, while the length of catheterization may be up to 180 days postoperative as shown in table 5. Our data, being collected from a large multicenter study, are in accordance with other studies. It is apparent that in a small minority of women long-term postoperative catheterization, arbitrarily defined as more than 10 days, is necessary ranging between 0.6% in this study up to 11% in the study of Ward and Hilton[6].

The second way to determine VD is the number of voids before a normal postvoid residue is present. The median time to adequate spontaneous voiding was 2 days and is in agreement with other studies[17, 18]. In women needing postoperative catheterization the median time before reaching a postvoid residual of less than 150 ml was 3 days and statistically different from women with no need of postoperative catheterization. Despite this being a statistically significant difference, this has no clinical relevance. Longer periods have been observed in women undergoing TVT combined with prolapse surgery or when local or spinal analgesia is used[19-21].

A third method is the necessity of tape revision (either division or excision) or urethral dilatation due to permanent urinary retention, which ranges between 0.6 to 7.5% respectively 1.9 to 8% (table 5). The need of tape division in this study 1.3% and in accordance with findings in other studies[7, 21-25].

The fourth way to assess VD can be the reports of women (table 5). Difficult voiding as determined on the basis of what women report (either direct by oral history or by quality-of-life questionnaires) ranges between 4 to 78%. Often women do not directly state true VD, but more that voiding became less easy as in the study of Sander et al[26]. Difficult voiding may be present already prior to TVT: in this study in 30.9% and in Ward and Hilton's study in 79%, and after surgery this declines to 24.9 % respectively 60% [7].

The fifth way to asses VD can be with the aid of flowmetry. Reduced maximum flow rates are observed up to 43% after TVT. In this study, results indicate that the maximum flow rate diminished significantly after TVT. In women with a normal maximum flow rate prior to TVT, 37% developed an abnormal flow rate postoperative. However, we also found the opposite, abnormal flow rates returned to normal values after TVT in 50%. As far as postvoid residual urine values are concerned the same pattern was observed. Apparently VD may arise but can also resolve after a TVT procedure.

Several risk factors for the development of urinary retention and VD have been identified in literature. After multivariate analysis the following independent risk factors are described: increasing age[21], decreasing body mass index[21], previous incontinence surgery[21], low maximum flow rate[22, 25] and postoperative urinary tract infection[21, 22, 25]. In this study only preoperative existing VD, determined by the UDI-6, and simultaneously performed prolapse surgery could be identified as independent risk factors for developing VD after TVT. In a univariate analysis (but not after multivariate analysis) concomitant posterior repair was correlated to development of VD. This is

in agreement to Sokol et al. who found in a univariate analysis (but also not after multivariate analysis) that TVT with posterior repair was related to VD [21]. We feel that this may be due to low numbers. Voiding disorders might be attributed to surgical inexperience[27]. Wang et al. found more cases of urinary retention and obstructed voiding in their first 15 patients[25]. We found no differences between the first 10, second 10 or more than 20 procedures per surgeon, indicating no learning curve effect. Data about VD in literature are often difficult to interpret. This is due to the lack of proper definitions for VD, urinary retention and abnormal postvoid residue rates. Furthermore, the management of postoperative urinary retention is highly variable in the gynecologic community[28]. Finally the length of follow-up is quite different among all studies. These factors might in part explain the large differences in the need for postoperative catheterization and occurrence of VD after TVT as is shown in table 5.

VD may represent a major bothersome problem for women. For this reason we tried to determine the impact of difficult voiding on quality of life after TVT. Women reporting VD either during a visit to their physician or on the quality of life (IIQ-7) questionnaires have statistically significant higher IIQ-7 values after 36 months, indicating less improvement in quality of life than women without symptoms of voiding difficulty. Nevertheless, compared to their preoperative situation their IIQ-7 values are still significantly lower and hence, all women are still much better off after the TVT procedure. In more objective parameters like the maximum flow rate and postvoid residual urine this difference between normal and abnormal voiding was not found and women with or without these abnormal voiding parameters have an equal and statistically significant improvement in quality of life.

Several theories exist about the cause of urinary retention and VD after incontinence surgery. Peri-urethral edema, increased contractility or obstruction of the smooth urethral sphincter, inhibited relaxation of the striated urethral sphincter and suppressed contractility of the detrusor muscle have been suggested[29]. In all patients participating in this study, sounding of the urethra at the end of the TVT procedure was performed and never an anatomical obstruction was noted. Bladder neck position remains the same after TVT, this was demonstrated by the cotton swab straining angle (Q-tip test), perineal ultrasound and MRI studies[11, 30-32]. Urodynamic studies carried out before and after TVT showed increased stress maximum urethral closure pressure, decreased maximum flow rates and increased voiding detrusor pressure, mean detrusor pressure and mean urethral resistance postoperatively[31-35]. When no anatomical changes in the bladder neck support at rest occur, it is likely that the outflow resistance increases during voiding. No anatomical obstruction during surgery was observed in this study. We were unable to determine the cause of urinary retention and VD. However on the basis of above mentioned possible effects of TVT, increased outflow resistance seems a likely cause for the observed VD and reduced flow rates.

In conclusion, VD, irrespective how defined, may arise after a TVT procedure. In most women the clinical course of urinary retention after TVT is mild. Preoperative existing voiding difficulty and concomitant prolapse surgery were found to be independent risk factors. This study showed that quality of life after TVT was negatively

influenced by the existence of VD. However, all women with and without voiding difficulties showed better quality of life scores postoperatively in comparison to pre-operative.

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Table 1. Prevalence of voiding difficulty stratified by various definitions prior to and at 2 and 36 months after TVT

	prior to TVT		after 2 months				after 36 months				
	N	%	follow-up	N	%	p-value#	follow-up	N	%	p-value#	p-value⋆
As reported by the women	na		93%				73%				
no voiding difficulty				486	82.8%			365	74.0%		
reporting voiding difficulty				101	17.2%	na		128	26.0%	na	< 0.001
Difficulty in emptying the bladder (UDI-6)			68%				73%				
not at all or slightly impaired	436	69.1%		335	71.1%			374	75.1%		
moderately to greatly impaired	195	30.9%		136	28.9%	0.467		124	24.9%	0.026	0.163
Maximum flowrate								na			
≥ 15 ml/s	461	83.5%		108	59.3%						
< 15 ml/s	91	16.5%		74	40.7%	<0.001				na	na
Residual urine											
≤ 100 ml	594	99.0%		364	90.5%			75	96.2%		
> 100 ml	6	1.0%		38	9.5%	< 0.001		3	3.8%	0.039	0.105

X^2 test was performed
= p-value which compared postoperative values with preoperative values
⋆ = p-value which compared 2 months postoperative values with 36 months postoperative values
na = not assessed

Table 2. Changes in symptoms of voiding difficulty

		2 months postoperative		36 months postoperative	
		%	p-value	%	p-value
Difficulty in emptying the bladder (UDI-6)					
not at all or slightly impaired preoperative	*remained unchanged*	73.7%		82.5%	
	worsened	26.3%	0.090	17.5%	0.034
moderately to greatly impaired preoperative	*remained unchanged*	35.0%		41.1%	
	improved	65.0%		58.9%	
Maximum flowrate					
≥ 15 ml/s preoperative	*remained unchanged*	62.8%			
	became < 15 ml/s	37.2%	<0.001		
< 15 ml/s preoperative	*remained unchanged*	50.0%			
	became ≥ 15 ml/s	50.0%			
Residual urine					
≤ 100 ml preoperative	*remained unchanged*	91.2%		95.8%	
	became > 100 ml	8.8%	<0.001	4.2%	0.625
> 100 ml preoperative	*remained unchanged*	0.0		0.0%	
	became ≤ 100 ml	100.0%		100.0%	

McNemar test was performed

Table 3. Changes in mean IIQ-7 score stratified by various definitions for voiding difficulty

	preoperative		after 2 months postoperative			after 36 months postoperative		
	IIQ-7 value mean (SD)	p-value#	IIQ-7 value mean (SD)	p-value#	p-value⋆	IIQ-7 value mean (SD)	p-value#	p-value⋆
As reported by the women								
no voiding difficulty at 2 months	59.4 (29.2)		14.6 (20.8)		< 0.001			
reporting voiding difficulty at 2 months	51.7 (19.8)	0.001	17.2 (22.7)	0.340	< 0.001			
no voiding difficulty at 36 months	56.6 (19.4)					11.1(17.8)		< 0.001
reporting voiding difficulty at 36 months	60.0 (19.2)	0.101				21.1 (24.6)	< 0.001	< 0.001
Difficulty in emptying the bladder (UDI-6)								
not at all or slightly impaired at 2 months	57.1 (20.0)		12.7 (19.3)		< 0.001			
moderately to greatly impaired at 2 months	58.6 (20.0)	0.452	24.7 (25.1)	0.001	< 0.001			
not at all or slightly impaired at 36 months	56.0 (19.5)					9.77 (15.3)		< 0.001
moderately to greatly impaired at 36 months	62.0 (19.3)	0.004				26.9 (26.8)	< 0.001	< 0.001
Maximum flowrate								
≥ 15 ml/s at 2 months	56.5 (20.5)		14.1 (20.0)		< 0.001			
< 15 ml/s at 2 months	57.7 (20.5)	0.711	13.0 (18.0)	0.751	< 0.001			
Residual urine								
≤ 100 ml at 2 months	57.9 (20.2)		16.4 (22.2)		< 0.001	9.50 (16.4)		< 0.001
> 100 ml at 2 months	58.0 (22.1)	0.967	14.4 (21.3)	0.653	< 0.001	1.59 (2.7)	0.412	0.085
≤ 100 ml at 36 months	55.8 (20.0)					9.50 (16.4)		< 0.001
> 100 ml at 36 months	60.3 (29.0)					1.59 (2.7)	0.412	0.085

= p-value, Student t-test was performed
⋆ = p-value, Paired T-test was peformed
SD = Standard Deviation

Table 4. Uni- and multivariate analysis of determinants of voiding difficulty as determined by UDI question 5 at 36 months

	UNIVARIATE ANALYSIS				MULTIVARIATE ANALYSIS			
	moderately to greatly impaired (n =124)		not at all or slightly impaired (n =374)		OR [95% CI]	*p*-value	B [95% CI]	*p*-value
General Data								
age (years ± sd)	52.6 (10.6)		51.1 (9.2)			0.138		
parity (mean ± sd)	2.5 (1.1)		2.4 (0.9)			0.091	2.35 [0.26-5.86]	0.446
Parity								
nulliparity	1	0.8%	7	1.9%	2.34 [0.28-19.25]	0.686		
multiparity	123	99.2%	367	98.1%				
menopausal status								
premenopausal	51	43.2%	191	54.1%	0.64 [0.42-0.98]	0.044	0.75 [0.46-1.22]	0.255
postmenopausal	67	56.8%	162	45.9%				
Urogynecological History								
no previous urogynaecological surgery	98	79.0%	319	85.3%		0.105		
previous prolapse surgery	10	8.1%	26	7.0%				
previous incontinence surgery	10	8.1%	24	6.4%				
previous incontinence and prolapse surgery	6	4.8%	5	1.3%				
hysterectomy								
incontinence episodes								
daily	97	92.4%	309	92.8%	1.06 [0.46-2.44]	0.833		
weekly	6	7.6%	24	7.2%				
intrinsic sphincter deficincy								
yes	10	8.1%	18	4.8%	1.74 [0.78-3.86]	0.181		
no	114	91.9%	356	95.2%				
Pelvic Floor Status prior to TVT								
cystocele								
no cystocele	62	58.5%	183	54.8%	0.86 [0.55-1.34]	0.575		
cystocele	44	41.5%	151	45.2%				
rectocele								
no rectocele	78	72.2%	273	79.4%	1.48 [0.90-2.42]	0.147		
rectocele	30	27.8%	71	20.6%				
prolaps of uterine cerix of vaginal vault								
no prolapse of cervix of vaginal vault	86	78.2%	277	80.3%	1.13 [0.67-1.92]	0.683		
prolapse of cervix of vaginal vault	24	21.8%	71	19.7%				
urethral hypermobility								
no hypermobility	102	100.0%	303	100.0%	n.a.	1,000		
hypermobility	0	0.0%	0	0.0%				

type of hospital setting								
no. of TVT in teaching hospitals	77	62.1%	231	61.8%	0.98 [0.65-1.49]	1,000		
no. of TVT in non-teaching hospitals	47	37.9%	143	38.2%				
Simultaneous Procedures								
TVT only	101	81.5%	343	91.7%		r		
TVT with prolapse surgery	13	10.5%	18	4.8%	2.45 [1.16-5.18]	0.027	3.03 [1.16-7.88}	**0.023**
TVT with other surgical procedures	10	8.1%	13	3.5%	2.61 [1.12-6.14]	0.040	2.01 [0.69-5.86]	0.199
Type of simultaneous prolaps procedure								
TVT only	111	89.5%	356	95.2%		r		
TVT with vaginal hysterectomy	0	0.0%	3	0.8%	n.a.	1,000		
TVT with anterior vaginal wall repair	2	1.6%	5	1.3%	1.28 [0.24-6.70]	0.673		
TVT with posterior vaginal wall repair	9	7.3%	6	1.6%	4.81 [1.68-13.81]	0.004	3.40 [0.28-41.21]	0.336
TVT with anterior & posterior repair	2	1.6%	4	1.1%	1.60 [0.29-8.87]	0.632		
Type of Anesthesia								
local anesthesia (with sedation)	95	80.5%	286	80.6%		r		
spinal analgesia	5	4.2%	39	11.0%	0.38 [0.15-1.01]	0.059	0.31 [0.08-1.21]	0.091
general anesthesia	18	15.3%	30	8.5%	1.81 [0.96-3.38]	0.081	1.21 [0.38-3.85]	0.750
Surgeon's Experience								
learning curve effect								
first 10 procedures for each surgeon	50	40.3%	129	34.5%				
next 10 procedures for each surgeon	21	16.9%	79	21.1%		0.417		
more than 20 procedures for each surgeon	53	42.7%	166	44.1%				
Pre-operative Voiding Difficulty								
voiding difficulty								
no voiding difficulty (on UDI-6 Q5)	57	49.6%	269	76.4%	3.29 [2.12-5.12]	**0.000**	3.26 [2.01-5.29]	**0.000**
voiding difficulty (on UDI-6 Q5)	58	50.4%	83	23.6%				
maximum flow rate								
normal max flow rate (>= 15 ml/s)	77	78.6%	258	84.9%	1.53 [0.86-2.72]	0.161		
abnormal max flow rate (< 15 ml/s)	21	21.4%	46	15.1%				
postvoid residue								
normal postvoid residue (< 100 ml)	103	98.1%	323	98.8%	1.57 [0.28-8.68]	0.636		
abnormal postvoid residue (> 100 ml)	2	1.9%	4	1.2%				

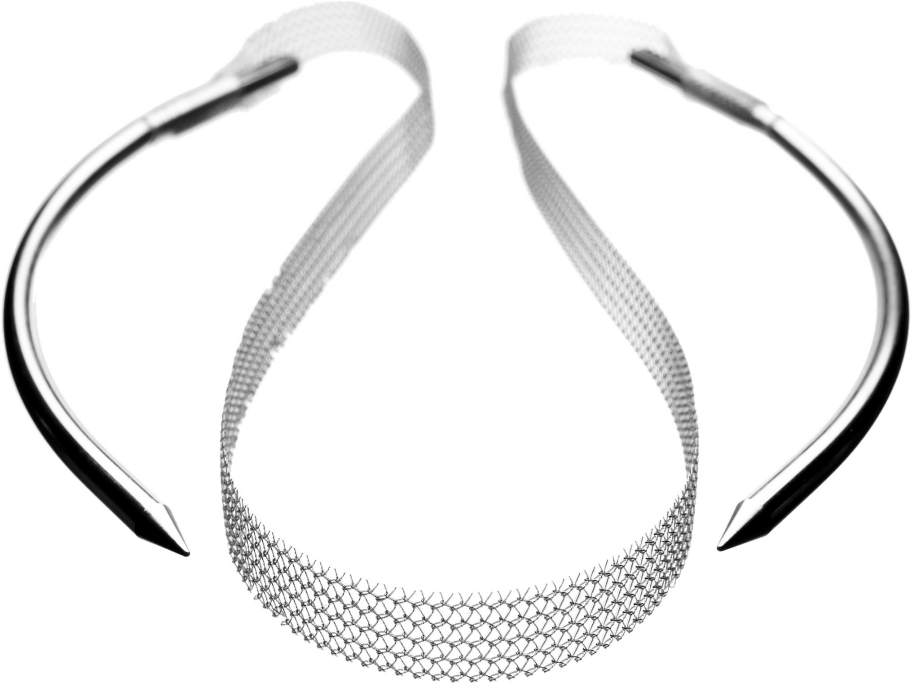
statistically significant differences are highlighted
Values are mean (SD). number (%) and Odds Ratio [95% CI]
r = reference group; n.a. = could not be determined

Table 5. Voiding difficulty after TVT in several studies

	this study		Ulmsten [36,37]		Ward [6,7]			Mishra [38]		Çetinel [39]		Minassian [40]	Lukacz [41]	Hong [22]			Kuuva [42]	Sokol [21]	Karram [23]	Klutke [24]	Wang [25]	Abd [43]
number of patients	703		131	50	175			52		75		63	103	375			1455	267	350	600	57	658
observation period (months)	2 -36				24					6-38			12						48		> 3	6
postoperative catheterization																						
needing catheterization (%)	10.9	0.6	3	10	38	5	6	19	4	9	3	50	37	5.9	1.6	1	2.3c	4.1				
length of catheterization																						
minimum (days)	1	11		1	1	11	29			1		9a	4b	1	15							
maximum (days)	10	90	3	14	10	28	180	90	> 90	30	> 30			14	31	> 34		> 42				
surgery for urinary retention																						
tape revision (%)	1.3				0.6									1.1				7.5d	1.7	2.8	1.7	
urethral dilatation (%)																		1.9	8			
report of voiding difficulty																						
oral history (%)	26																		4.9		26f	4.4
quality of life questionnaire (%)	24.9				60																	
flowmetry																						
decreased max flow rate (%)	40.7												43									
abnormal postvoid redisue (%)	3.8											50e						11.2				

a. mean 9 ± 2 days
b. is median value
c. complete urinary retention
d. tape revision in women with concomitant prolapse surgery was 3.7%
e. postvoid residue > 200 ml
f. combination of PVR > 100 ml, daytime and nighttime micturition frequency > 6 resp. > 2 and urinary stream considered abnormal by the woman

Part 3



Chapter 9

Summary, conclusions, general discussion & recommendations for future research

Summary

Chapter 1 consists of an introduction to the TVT procedure and a review of the literature. The history and development of Integral Theory and the TVT, prevalence and impact of urinary incontinence, the surgical procedure, different types of anesthesia for TVT, clinical efficacy and complications are described.
Further, this chapter comprehends the aims and outline of this thesis.

The aims of the studies presented in this thesis were:

1. To describe the anatomical complications, its frequency and the influence of risk factors such as the operative history, concomitant surgery, learning curve and type of anesthesia on the complication rate of the TVT.
2. To assess the pre- and intra-operative factors influencing the success of the TVT procedure for SUI.
3. To determine the long-term outcome of TVT in women in whom the TVT procedure was their first incontinence surgery and was not combined with prolapse or other urogynecological procedures.
4. To assess the outcome after a follow-up of three years of TVT in women with previous incontinence or prolapse surgery.
5. To assess the long-term outcome of TVT on urge incontinence and other forms of irritative bladder symptoms.
6. To assess the outcome with a follow-up of two years of the TVT procedure in women with concomitant pelvic surgery.
7. To determine the prevalence of voiding difficulties after TVT in the immediate and long-term postoperative period, its impact on quality of life and related risk factors

In **chapter 2** we described the anatomical complications, its frequency and the influence of several risk factors such as the operative history, concomitant surgery, learning curve and type of anesthesia on the complication rate of the TVT. Furthermore,

a survey of complications of the TVT procedure as published in the English scientific literature is presented.
In total 809 women participated in this study. Their mean age was 51.3 +/-10.4 (range 20-82) years and mean parity was 2.4 +/-1.1. The overall intra operative complication rate was 6.2%. Bladder perforation was the most common complication (n=28, 3.5%). In all cases it was diagnosed during the procedure. In all but one case the tape was reinserted and an indwelling catheter was placed, at follow-up none of these patients suffered any problems. There were no urethral lesions. Severe blood loss (>300ml) occurred in 10 cases. In one case the internal iliac vein was lacerated and a laparotomy followed.
The total incidence for postoperative complications was 20.9% (N=169). In this group there were 30 patients (3.7%) with a combination of more than one complication. A temperature rise (> 38°C) was diagnosed in 1 (0.1%) case. Tape erosion was found in 2 (0.2%) cases in two year follow-up. In 121 (14.9%) cases an indwelling bladder catheter was needed for more than 24 hours. In 13 (1.6%) of these patients the TVT tape had to be cut because of voiding difficulty, erosion, or infection.
Previous prolapse surgery was a risk factor for complications (OR 2.86, CI 1.15 - 7.11). We found more intra operative complications in patients with general anesthesia than local analgesia with sedation (OR 4.14, CI 2.01- 8.53). The postoperative complication rate in the 25 teaching hospitals was 24% and 16% in the 13 local hospital(OR 0.55, CI 0.35- 0.85). The learning curve is short and more postoperative complications were found in the second ten patients operated by one surgeon (OR 1.94, CI 1.14 – 3.29). Spinal analgesia gives less postoperative complications than local analgesia with sedation (OR 0.35, CI 0.13 – 0.92).

In **chapter 3** we presented the results of a multicenter study on the long-term outcome of TVT. The focus of this report is on the pre and intraoperative factors influencing the success of the TVT procedure for SUI. This is a prospective cohort study of 809 patients. In 28 teaching hospitals and 13 local hospitals, 54 gynecologists and urologists participated. Hundred and thirty-one women had previous incontinence or prolapse surgery. In this group there were nine patients who had undergone two prior incontinence procedures and one patient who had undergone three prior incontinence procedures (Burch, re-Burch and hysterectomy with concomitant Raz sling procedure).
Before treatment and two years postoperatively the following question from the Urogenital Distress Inventory (UDI) for stress urinary incontinence was selected to define success or failure: "do you experience urinary leakage during physical activity, coughing or sneezing?". Secondary outcome measurement was the outcome of the doctors question "do you leak during physical activity, coughing or sneezing?" asked at two year follow-up. As tertiary outcome measurement both questions were combined. Women who had answered to be dry in the written questionnaire as well as to the oral question at two year follow-up were defined to be a success.
The response rate was 78.7%. The success rate on outcome measurement 1 was 66%. The success rate was significant higher in all analyses when the surgeons had per-

formed more than 20 TVT's (p=0.003 b 1.918 [1.24-2.97]). Six hundred and eleven patients came at the doctor's follow-up at two years. The success rate of this second outcome measurement was 78%. General anesthesia had a negative effect on the secondary outcome measurement (p=0.032 b 2.21 [1.07-4.55]). The follow-up for the tertiary outcome measure was 66.3%. The over all success rate found was 64%.

In **chapter 4** we present the results of a multicentre study on the long-term outcome of TVT in women in whom the TVT procedure was their first incontinence surgery and was not combined with prolapse or other urogynecological procedures. The focus of this paper is on the influence of TVT on the quality of life which was assessed with validated disease specific quality of life questionnaires. The primary outcome measures were the scores on the IIQ and UDI, with improvement defined as a lower score on follow-up questionnaires. The original database comprised data from 809 women. 131 Women had previous incontinence or prolapse surgery and were excluded from the analysis reported here. Another 44 women had simultaneous prolapse surgery and were also excluded, leaving 634 women for analysis. The response rate was 77% at 2 year follow-up. We also analyzed the differences in UDI scores between women who did return for their postoperative visits and those who only returned their postal questionnaire. Our results show that women with stress urinary incontinence immediately following surgery can improve even up until 2 years postoperatively, which is considered a long-term follow-up by the WHO International Consultation on Incontinence[1]. With this follow-up time of two years the cure rate of patients when asked, was 80.1%. Only a low percentage (4.6% - 8.4%) of all women do not benefit from this form of surgery after 2 years follow-up. Both IIQ and UDI mean scores decreased significantly after TVT, indicating a significant increase in quality of life. Patients SUI can improve up until two years postoperatively. Mean IIQ and UDI scores at all follow-up measurements showed no difference between women over or under 70 years of age. Lost to follow-up patients show 5.4%-8.6% less improvement than patients who were followed-up in clinic. While some authors categorize women in the lost to follow-up group as failures, this 5.4% lower improvement rate indicates that still a considerable number of women in this lost to follow-up group have benefited from their surgery. Hence, considering lost to follow-up as complete failure is inappropriate.

In **chapter 5** we present the outcome and follow-up of three years of a low tension mid-urethral sling (TVT) in women with previous incontinence or prolapse surgery by means of objective (patient self reported) results on their health status with the aid of disease specific HRQOL questionnaires (the Incontinence Impact Questionnaire (IIQ) and the Urogenital Distress Inventory (UDI)). The original database comprised data for 809 women. Hundred and thirty-one women had previous incontinence and/or prolapse surgery and were the subject of this analysis. Fifty women had prior incontinence surgery. In this group there were nine women who had undergone two prior incontinence procedures and one woman who had undergone three prior incontinence procedures (Burch, re-Burch and hysterectomy with concomitant Raz

sling procedure). There were 16 cases with a history of both prolapse and incontinence surgery. In this group, one woman had undergone an Burch colposuspension twice; one woman had undergone a Stamey suspension followed by a Burch colposuspension. Sixty-five women had a history of prolapse surgery only. Two women had undergone prolapse surgery twice. The primary outcome measurement were the IIQ and UDI scores.
According the recommendation of the ICS, the question "Do you experience urinary leakage during physical activity, coughing or sneezing?" was selected from the UDI, as secondary outcome measure to define success or failure for SUI [2]. Women who have a lower score on the UDI question score post operatively were considered to be improved.
A significant improvement was found for all outcome measurements, which shows that TVT is a successful treatment in secondary cases for recurrent incontinence and/or prolapse. The research group (N=131) was compared with control group without previous urogynecological surgery (N=687). A difference between the UDI scores of the two groups was found at twelve months and at twenty-four months follow-up ($p=0.011$ & $p=0.018$ respectively). The improvement of the group with prior surgery was encouraging, because in this group the preoperative UDI scores were significantly higher than for the other groups, indicating more preoperative bother. The quality of life scores are equally good for both groups after 3 years follow-up.

In **chapter 6** we present the results of a multicentre study on the long-term outcome of TVT on urge incontinence and other forms of irritative bladder symptoms with well described outcome measures. Irritative symptoms and quality of life before and after the TVT were assessed with the aid of patients self reported disease specific validated health-related quality of life HRQOL.
This is a prospective cohort study of 610 participants. Excluded were women in whom no urodynamic investigations prior to TVT were performed, women of whom the presence of detrusor over activity (DO) was not listed and women who had detrusor over activity on their preoperative urodynamic investigation. Urge incontinence and OAB wet symptoms developed in 11% and 3% respectively and give less improvement on the quality of life scores. The presence of preoperative frequency (odds ratio 2.64; 95% CI, 1.16-6.03) and rectocele (odds ratio 2.39; 95% CI, 1.15-4.99) were independent factors for the development of irritative symptoms postoperative. Nevertheless, these women still had significant improvement in their quality of life compared to the preoperative situation. This is probably due to cure of their stress incontinence. This study showed a *de novo* rate for urge incontinence after 2 months and 3 years of 6.3% and 10.9% respectively and *de novo* OAB wet of 1.6% and 3.2%.

In **chapter 7** the long-term outcome of the TVT procedure in women with concomitant urogynecological surgery is described.
The Incontinence Impact Questionnaire (IIQ-7) and Urogenital Distress Inventory

(UDI-6) were used to measure the results of the TVT procedure (preoperative, at two, six, twelve and twenty-four months postoperative). Fifty-nine patients with concomitant prolapse surgery were compared with 687 women with TVT only. The surgical procedures performed concomitant to the TVT were: vaginal hysterectomy for uterine descent (n=7), anterior repair (n=15), posterior repair (n=28) and anterior with posterior repair (n=9). Of these 59 patients 15 women underwent prior surgery, 6 women had prior prolapse repair: 3 women a vaginal hysterectomy, 5 underwent a colporrhaphy anterior, 3 women a colporrhaphy posterior. One woman underwent a sacrocolpopexy and rectopexy. Seven women underwent previous incontinence surgery, all underwent a Burch colposuspension. One woman underwent a re-Burch and one women underwent a Marchall-Marchetti-Kranz (MMK) suspension after a Burch. Two women underwent both prior incontinence and prolapse surgery: one Burch colposuspension with a colporrhaphy anterior and colporrhaphy posterior and one women a MMK with abdominal hysterectomy with colporrhaphy anterior and posterior. The IIQ/UDI mean scores decrease statistically significant in both groups after the TVT, indicating a significant improvement in quality of life.
Both IIQ and UDI mean scores decreased statistically significant after TVT after two months. Thereafter, no statistical difference was found when comparing the changes between two and six, six and twelve months and twenty-four months follow-up in the UDI scores. The mean IIQ and UDI scores of women with concomitant pelvic surgery were compared with the mean IIQ and UDI scores of women without prior surgery. After a follow-up of two years a statistical significant difference in UDI & IIQ scores could be identified (p=0.019). Nevertheless, this study shows that the procedure in conjunction with prolapse surgery can safely be performed with good results .

In **chapter 8** we report on the prevalence of voiding difficulties after TVT in the immediate postoperative period and on the long-term with the aid of reports of women, measurement of objective measurements, and with the use of validated quality of life questionnaires. For this study women in whom no urodynamic investigation prior to TVT was performed (n = 106) were left out of the analysis. This left 703 women for this study. The follow-up period was 3 years.
The first outcome measure was the need of postoperative catheterization. Secondly, women were asked if voiding went easy or difficult. Thirdly, the following question of the short form of the Urogenital Distress Inventory (UDI-6) informing about difficulty in emptying the bladder, was used. A woman was considered to experience voiding difficulty if she replied positively to the question: "do you experience difficulty emptying your bladder?". The fourth outcome measurement was the maximum flowrate and the fifth was the amount of postvoid residual urine.
Postoperative catheterization due to urinary retention was necessary in 81 (11.5%) of women. Of these 81 women 66% voided normal within 2 days, 95% within 10 days, while in 4 women (5%) catheterization up to 90 days was needed. The mean length of catheterization was 5.07 (± 12.5, median 2) days. Tape revision or adhaesi-

olysis of the tape due to permanent urinary retention had to be performed in 9 women (1.3%). Voiding difficulty increased significantly between 2 and 36 months ($p=<0.001$). More women improved than developed voiding difficulty as assessed with the UDI after 36 months. The actual number of women having abnormal maximum flow rate or residual urine prior to TVT were low (3.8%). After multivariate analysis two risk factors emerged for the development of voiding difficulty: preoperatively existing voiding difficulty and TVT with concomitant prolapse surgery.

Conclusions

• TVT gives a statistically significant and clinical relevant long-term improvement of the quality of life after for women with stress urinary incontinence.

• The results of our study show that tension-free vaginal tape is a relative safe procedure and concomitant pelvic surgery can be safely performed. Previous prolapse surgery is a risk factor for complications. More intraoperative complications occur in patients with general anesthesia as compared to local analgesia with sedation. In teaching hospitals the postoperative complication frequency is higher than in non-teaching hospitals. The learning curve is short and more postoperative complications are found in the second ten patients operated by one surgeon.

• Of all prognostic factors determining success of the TVT procedure for SUI, general anesthesia seems to have a negative effect on the result. Experience of the surgeon determines a successful outcome of the TVT. In fact many traditional variables thought to be of importance in incontinence surgery, appear not to be related to a successful outcome.

• The TVT is a valuable tool for women with recurrent stress urinary incontinence, prior prolapse surgery or both. Therefore, TVT should be recommended as a first choice for the treatment of recurrent stress urinary incontinence in women with previous incontinence and/or prolapse surgery.

• Overall after TVT most urge incontinence and other forms of irritative bladder symptoms resolve significantly more than they develop, resulting in a better quality of life.

• TVT is effective for women with or without concomitant prolapse, however after 2 years a difference in favor of no concomitant surgery was found.

• Quality of life after TVT is not negatively influenced by the existence of voiding difficulty; women who develop voiding difficulty, are still significantly improved compared to their preoperative condition.

General discussion

Methodological considerations

Urogenital symptoms can be assessed objectively or subjectively. While both have different advantages, they also have some major drawbacks. Objective test available are urodynamic investigations, pad tests and bladder diary. In 2002 Soroka et al[3] published a systematic review on pad tests, which showed a significant variability and repeatability of the pad test. Using a bladder diary, patients may register time of voiding and voided volume for a few days. This provides valuable information in initially detecting frequency, urgency and urge incontinence because it offers a quantitative measure of the symptomatic degree of motor urgency[4]. However, the accuracy of the self-reported diary is point of discussion[5-7]. Urodynamic testing has been the "golden standard" to assess urogenital symptoms for a long period, but it also has its limitations. The test-retest reproducibility and validity in several urodynamic tests are not convincing[8] and because urogenital symptoms may fluctuate[9] the assessment may be done on an asymptomatic day. *The bladder* is a notoriously bad witness, and the symptoms of frequency, nocturia and urgency may arise because of hypersensitivity of the bladder stretch but also may occur when the bladder contracts inappropriately due to detrusor over activity. Conventional urodynamic investigation fails to detect detrusor over activity in 62-74 percent of the women with frequency and/or urgency symptoms and in 53-62 percent of the women with urge incontinence symptoms[10-15]. Therefore, a normal urodynamic investigation cannot disprove the accuracy of a patient's history of urge incontinence, urgency and urge incontinence[16].

Subjective symptoms can be measured with self-report questionnaires or in a personal interview. Khan et al looked whether the method of administration of questions changed the outcome[17]. They authors concluded that postal questionnaire responses had a better relationship with urodynamics, both for urodynamic stress incontinence and detrusor overactivity, than interview-assisted questionnaire responses. The International Continence Society (ICS) also uses definitions based on subjectively measured symptoms. But according to the ICS, using a questionnaire without objective assessment does not allow an accurate diagnosis of genuine stress incontinence or detrusor overactivity. The symptom of stress incontinence may be sensitive in predicting genuine stress incontinence, but there is a false-positive rate[18].

In this thesis the symptom-based ICS definitions for urogenital symptoms were used[2, 19, 20]. But we also employed a third method, assessment of quality of life, to determine the impact of urogenital symptoms. The Urogenital Distress Inventory (UDI) was used to assess urogenital symptoms. The UDI is a standardized, translated into Dutch language and validated for the Dutch female population questionnaire. This questionnaire consists of questions about urogenital symptoms, and the discomfort experienced by these symptoms. Each item measures if a urogenital symptom is present, and the amount of bother a woman experiences from that symptom. The amount of bother is measured on a 4-point Likert scale ranging from no bother at all to slight, moderate and great bother. These questions are grouped in three domains (irritative symptoms, stress incontinence and difficult voiding) and transformed to a score rang-

ing from 0 (no bother) to 100 (maximum bother).
Disease specific health related quality of life scores assessing the impact of pelvic floor symptoms were obtained from the Incontinence Impact Questionnaire (IIQ)[21, 22]. The impact of pelvic floor symptoms were measured on five domains; emotional functioning, physical functioning, social functioning, mobility and embarrassment. The scores on the domains range from 0 to 100. A high score indicated that a person's well-being on that particular domain is negatively affected.
The application of quality of life instruments to women preoperative and postoperative assessing urogenital symptoms enables a measurement of the impact of symptoms on lifestyle. Contrary to objective measurements which record a health status at just one specific moment, subjective parameters like symptoms and quality of life measurements can record the impression of a woman's health situation over a period of time. The main part of our results has to be viewed from this symptom-based point of view. Another reason to focus on symptom and quality of life based parameters is that it is merely impossible to perform objective measurements (like urodynamic investigations) in a large cohort of 809 women.

Design of the study
Randomized controlled trials are the best way to address differences between surgical procedures, when an effective randomization takes place. But to investigate the occurrence of for example complications with a very low prevalence a large cohort study is more appropriate. The same is true for prognostic factors.
At the start of our trial only few publications had appeared. A proper power analysis should be based on outcome differences generated by prior publications. At the time when this study was designed, such publications did not exist. In retrospect we believe that for all outcome measures the amount of 809 women included in this study was sufficient.
Another point of discussion is the length of follow-up. As Black and Downs have demonstrated the outcome of many incontinence procedures decline over time[23]. The WHO Consultation on Incontinence has defined that a follow-up of 2 years is considered long-term follow-up. We adhered to this definition and even more, we followed all women for three years.
However, a longer follow-up also leads to a greater drop out rate. In our study the drop out rate after 3 years for the follow-up in clinic is 20-30%, depending on which variable was used.
A fourth methodological problem is how to define the women who are lost to follow-up. Normally, no information at all is gathered from those patients who were failed to follow-up in clinic and the incorrect assumption is often made that these women perform the same as the attendees. Hilton suggests in his article; "Trials of surgery for stress incontinence-thoughts on the 'Humpty Dumpty principle'", to consider these non-attendees as failures[24]. In this study though we had information via the separately send postal questionnaires. We found a small difference between the groups who did and did not show up in clinic but did fill in the questionnaires. The improvement rates in the "lost to follow-up" group (chapter 4) is 5.4%-8.6% lower,

but to consider this group a failure seems inappropriate. The use of these questionnaires enabled us not only to minimize the number of women lost to follow-up, but also to gain information while these women did not attend the clinical check-up.

Outcome

Methods to describe the outcome of stress incontinence surgery (including TVT) vary enormous in the literature. Therefore we employed a systematical way to list the outcome of TVT in this thesis. First we looked at the clinical outcome (cure rates) and changes in quality of life. We consider quality of life as an important outcome parameter, because stress incontinence surgery is elective surgery and should lead to improvement in quality of life. Second we determined the adverse effects of TVT by describing anatomical and functional complications (bladder injuries for example respectively the development of urge incontinence and voiding difficulty). Third we examined how TVT performs in frequently encountered situations like women with previous incontinence or prolapse surgery and in women were incontinence surgery must be combined with prolapse surgery.

Quality of life

As might be expected urinary incontinence has a profoundly negative impact on the quality of life of women. This is in agreement with findings in other quality of life studies in patients with urinary incontinence[25-27]. Another large study using the UDI and IIQ to asses the outcome of TVT by Vassallo et al[25] confirmed an improvement on quality of life after a TVT.

Women with prior surgery for incontinence or prolapse, represent a group of patients who are difficult to cure surgically. In the study group in chapter 5, 10 (7.6%) women had undergone more than one operation for incontinence prior to the TVT, indicating the difficulty to cure these patients. Burch colposuspension and sling procedures have been used for women with recurrent stress incontinence. Success rates of 85-90% at 3-4 years follow-up are published but this surgery is associated with high complication rates such as significant urinary retention and haemorrhage[28-30]. These complication rates are lower with the TVT procedure as described in chapter 2.

The study described in chapter 6 showed a *de novo* rate for urge incontinence after 2 months and 3 years of 6.3% and 10.9% respectively and *de novo* OAB wet of 1.6% and 3.2%. Other small (N=52 & N= 62 respectively) prospective studies[31, 32] showed similar *de novo* rates of 0-18%. In patients with preoperative mixed incontinence the improvement/cure rates of the TVT described are often lower than in patients with only stress incontinence[33-36]. In our group of women with mixed incontinence, in 23% the complaints of urge incontinence remained but in 77% the complaints resolved. This reduction in symptoms of urge incontinence has been reported before[37,31,38-40].

Complication rates

It appears that the rate of intra and postoperative complications does not differ sig-

nificantly between our study and other studies addressing complications[39, 41-45]. However, in a number of these studies the data were collected retrospectively. Hence, under or over reporting and other sources of bias may have been introduced unwittingly. The study of Ward et al[39] was prospective randomized controlled trial (RCT) comparing the TVT and the Burch procedure. The study reports the incidence of complications but does not report on the possible risk factors for complications. From all published articles the data suggest a lower complication rate with the TVT procedure than in all other anti-incontinence procedures. An association between the learning curve for the TVT procedure and the complication rate has been described before[41, 46, 47]. However, only Grouz et al suggest an effect of the learning curve on the final outcome of TVT[12]. But with only 30 patients and only one surgeon proper statistics can not be performed. Kunde et al[48] observed a success rate of TVT under GA of 72%. Unfortunately, no comparison with a TVT under local anesthesia was performed. The advantage of local analgesia is that the cough-stress test can be performed in order to adjust the tape. We are aware that a cough-stress test is of limited value (as shown by Barry[49] and Kuan-Hui Huang[50]). The advantage of the cough test is also not present when using spinal analgesia. In chapter 3 we did not observe a detrimental outcome for patients with spinal analgesia. Nevertheless, general anesthesia and local anesthesia also differ with regard to somatic, sympathetic and parasympathetic discharge. How nervous input to the bladder is altered between general and local anesthesia may be important to how a TVT is tensioned. However, from this study and the other above-mentioned studies, the neural influence cannot be reliable determined. Rezapour et al[51] reports on another possible risk factor: intrinsic sphincter deficiency (ISD). ISD is believed to be more difficult to cure than other forms of SUI[52]. Rezapour found no improvement on stress incontinence in 7 of 49 patients. Five of these patients were older than 70 years and had an ISD. In our analysis in chapter 3 preoperative ISD at urodynamic testing did not seem to influence the final success of the TVT. It should be noted though that this outcome was interpreted from the results of only 6% of the total group.

Previous and combined incontinence or prolapse surgery

Co-existing urinary incontinence and pelvic organ prolapse has been reported in 15-80%[53, 54]. Choe et al and Bai et al reported that 60-63% of patients with urinary stress incontinence also had pelvic organ prolapse[54, 55]. With the TVT as first choice for incontinence surgery, TVT in conjunction with other pelvic surgery is becoming more popular. Especially because the two can be performed in one session without an abdominal incision. Therefore it is remarkable that not many studies describe the success rate of this combination. The intra- and postoperative complication rates of this combined surgery have been described by in chapter 2. Few studies have stratified for TVT versus TVT in conjunction with prolapse surgery. No significant difference in success was found in these studies[32, 56, 57]. One study suggested a lower success rate for TVT with cystocele repair of 38% against 67% in patients without a cystocele repair. However this was not significant probably due the small amount of patients[58].

Recommendations for future research

• In order to diminish operative complications and long-term adverse outcomes like urge incontinence and other bladder symptoms a randomized controlled trial with long-term follow-up of the new mid urethral trans obturator slings in comparison with the TVT is needed.

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Chapter 10

Nederlandse samenvatting

Incontinentie urinae, het ongewild verlies van urine, is een frequent voorkomend probleem bij vrouwen. De prevalentie (het vóórkomen) hiervan wordt geschat tussen de 25% – 57%, dagelijks optredend, ernstig urineverlies tussen de 4%-7%. Ongewild urineverlies is vooral een sociaal invaliderende aandoening die de kwaliteit van leven in behoorlijke mate nadelig kan beïnvloeden. Er wordt een onderscheid gemaakt tussen stress incontinentie (optredend bij hoesten, niezen, persen, bewegen en andere momenten van intra-abdominale (in de buik) drukverhoging, urge incontinentie (ongewild urine verlies optredend na een gevoel van aandrang) en gemengde incontinentie (een combinatie van beide vormen). Meer dan de helft van alle incontinente vrouwen heeft stress incontinentie.
Sinds het begin van de vorige eeuw zijn er meer dan 150 verschillende operatieve behandelingen voor stress incontinentie ontwikkeld. De gouden standaard voor operatieve behandeling van stress incontinentie tot de tweede helft van de jaren negentig was de Burch colposuspensie. Dit is een buik operatie waarbij de blaashals wordt opgehangen aan een deel van het bekken. In 1995 en 1996 publiceerden Ulmsten en Petros hun eerste resultaten van wat later de tension- free vaginal tape (TVT) zou worden. Bij deze operatie wordt via de vagina (schede) een kunststof (polypropyleen) bandje onder en naast de urethra geplaatst, zodat de plasbuis (urethra) op momenten van intra-abdominale drukverhoging tegen het bandje dicht gedrukt wordt. Op dit moment is de TVT een wereldwijd geaccepteerde behandeling voor stress incontinentie bij de vrouw. In Nederland heeft deze ingreep ook een grote vlucht genomen.
In dit proefschrift worden de resultaten weergegeven van een prospectief (onderzoek waarbij de onderzoeks groep vanaf een bepaalde start datum in de toekomst opgevolgd wordt) multicenter (hier: meerdere ziekenhuizen) onderzoek naar het succes, de invloed op de kwaliteit van leven en de complicaties van TVT als chirurgische behandeling van stress incontinentie.
Tussen maart 2000 en september 2001 werden 809 patiënten met een indicatie voor een operatieve behandeling van stress incontinentie geïncludeerd in 41 Nederlandse ziekenhuizen en geopereerd door 53 gynaecologen en urologen. De vrouwen die mee deden aan dit onderzoek werden voor de ingreep tot maximaal 3 jaar na de ingreep vervolgd door de eigen dokter en tevens met toegestuurde vragenlijsten om

te kijken hoe het ze verging. De vrouwen werden tenminste 2 jaar gevolgd, daar de World Health Organisation (WHO) dit als definitie hanteert voor lange termijn vervolg van patiënten na behandeling voor ongewild urine verlies.
Plasklachten werden gemeten met de Urogenitale Distress Inventory (UDI), De UDI meet hoe vaak een klacht voorkomt en hoeveel hinder vrouwen ondervinden van deze klacht. Het is mogelijk om te bepalen hoe hinderlijk een vrouw een afzonderlijke klacht vindt en er bestaan subschalen. Deze subschalen, urineverlies, overactieve blaas, obstructie gevoel tijdens plassen en verzakkingsgevoel, zijn opgebouwd door verschillende vragen van de UDI te combineren en hebben een score van 0 tot 100. Honderd betekent dat vrouwen alle klachten uit de subschaal ervaren en dat zij deze klachten zeer hinderlijk vinden. Deze vragenlijst bestaat uit 6 vragen. Het effect van de plas klachten op de kwaliteit van leven werd met de Incontinence Impact Questionnaire (IIQ) gemeten. Deze vragenlijst bestaat uit 7 vragen. De kwaliteit van leven wordt op verschillende niveaus gemeten; op mobiliteit, fysiek, sociaal en emotioneel functioneren en op schaamte. Al deze gegevens werden anoniem verzameld voor de Nederlandse TVT Database. Alle zeven artikelen gepubliceerd in dit proefschrift zijn met behulp van gegevens uit deze database geschreven.

In **hoofdstuk 1** wordt uitgebreid ingegaan op de achtergrond van dit proefschrift; de prevalentie van urine incontinentie, de invloed van urine incontinentie op het dagelijks leven van mensen, de historie en ontwikkeling van de TVT, de achterliggende (integral) theorie en de chirurgische procedure worden besproken. Verder wordt uitgebreid ingegaan op de tot op heden in de wetenschappelijke bladen gepubliceerde artikelen handelend over de TVT. In dit hoofdstuk worden ook de onderzoeksvragen van het proefschrift beschreven, het zijn de volgende:

1. Het beschrijven van de anatomische complicaties, de frequentie ervan en het beschrijven van de risico factoren zoals eerdere chirurgie, bijkomende operaties, leereffect en type anesthesie.
2. Het onderzoeken welke pre- en intra-operatieve factoren het succes van de TVT beïnvloeden.
3. Onderzoeken hoe het lange termijn effect is van de TVT alleen, dus zonder tegelijkertijd verrichte andere chirurgische ingrepen, bij nooit eerder geopereerde vrouwen.
4. Het onderzoeken hoe de TVT uitkomsten zijn tot 3 jaar na de ingreep bij vrouwen die eerder anti-incontinentie chirurgie ondergingen.
5. Onderzoeken hoe de lange termijn effecten zijn van de TVT op aandrangs incontinentie en irritatieve blaas symptomen.
6. Onderzoeken hoe de uitkomsten zijn na twee jaar voor vrouwen die naast de TVT andere bekkenbodem chirurgie ondergingen.
7. Onderzoeken hoe de prevalentie is van plas problemen ontstaan in de directe periode na de ingreep en op de lange termijn en de gevolgen hiervan op de kwaliteit van leven.

In **hoofdstuk 2** worden de anatomische complicaties beschreven die gevonden werden in ons onderzoek bij 809 vrouwen die een TVT ondergingen. De frequentie van het voorkomen van complicaties en de risicofactoren hierop zoals anesthesie type, operatieve voorgeschiedenis, leereffect en bijkomende chirurgische ingrepen werden onderzocht. Verder werden enkele eerdere publicaties over complicaties na de TVT systematisch besproken. De gemiddelde leeftijd van de vrouwen was 51.3 (range 20-82), het gemiddeld aantal kinderen van deze vrouwen was 2.4. Het totaal aan tijdens de operatie opgetreden complicaties was 6.2%. Blaas perforaties kwamen het meest voor, 28 keer, dit was 3.5%. In op één na alle gevallen werd deze complicatie tijdens de ingreep gediagnostiseerd en werd het bandje herplaatst en een blaas katheter ingebracht. Bij de controles na de operatie werden geen problemen hiervan waargenomen. Er werd in dit onderzoek geen enkele keer schade aan de uretheren (urineleiders) waargenomen. Meer dan 300 ml bloedverlies werd 10 keer gevonden. Eén keer betrof het schade aan een groot been bloedvat de Iliaca Interna, deze werd gerepareerd via een buikoperatie. De totale hoeveelheid complicaties die na de operatie optraden was 20.9% (169). Koorts werd 1 keer vastgesteld 0.1%, erosie van het bandje werd 2 (0.2%) keer gezien in de twee jaar dat deze patiënten groep vervolgd werd. Bij 121 (14.9%) van de vrouwen moest het blaas katheter langer inblijven dan 24 uur. Bij 13 van deze vrouwen moest daarna het bandje doorgenomen worden. Van de gehele groep ondergingen 30 (3.7%) vrouwen naast de TVT ook een andere chirurgische ingreep. Als risicofactor voor complicatie tijdens de ingreep werd algehele anesthesie gevonden (OR 2.86, CI 1.15 - 7.11). Na de TVT operatie optreden van complicaties kwam vaker voor in opleidings ziekenhuizen in vergelijking met regionale ziekenhuizen (OR 0.55, CI 0.35- 0.85). De leercurve is kort en de meeste complicaties werden gevonden in de tweede tien operaties die chirurgen verrichtte (OR 1.94, CI 1.14 – 3.29). Minder complicaties traden op na de ingreep bij patiënten die spinaal anesthesie (pijnstilling m.b.v. rugge prik) hadden gekregen.
De conclusie van de studie was dat de TVT een relatief veilige operatie is waarbij andere bijkomende chirurgische ingrepen goed verricht kunnen worden.

In **hoofdstuk 3** werden de resultaten van onderzoek beschreven welke factoren (voor en tijdens de operatie) het succes van de TVT, tot twee jaar na de ingreep, beïnvloeden. Van alle 809 vrouwen die in dit onderzoek mee deden hadden 131 vrouwen in het verleden een anti-incontinentie of verzakkings (prolaps) operatie ondergaan, 15.1% kreeg naast de TVT operatie een andere ingreep in het bekken gebied. Drie uitkomstmaten werden onderzocht; de resultaten op een vraag van de toegestuurde UDI vragenlijst; "heeft u wel eens urineverlies bij lichamelijke inspanning, hoesten of niezen?', de uitkomst op de vraag van de dokter;" heeft u wel eens urineverlies bij lichamelijke inspanning, hoesten of niezen?' en als derde uitkomstmaat een combinatie van beide voorgaande vragen. Succes werd gedefinieerd als vrouwen op de vragen 'nee' antwoorden. Voor de derde uitkomstmaat werd succes gedefinieerd als de vrouwen 'nee' op beide vragen had geantwoord. Van alle vrouwen beantwoordde 87.7% de vragenlijst na 2 jaar. Op de eerste vraag antwoordde 66% nee, op de tweede vraag 78% en op beide 64%. Als de dokter meer dan 20 operaties had uit-

gevoerd steeg het succes percentage. Algehele anesthesie had een negatieve invloed op de uitkomst van de tweede vraag (p=0.032 b 2.21 [1.07-4.55]). Wij concludeerden uit de onderzoeks gegevens dat algehele anesthesie en de leercurve van de dokter het uiteindelijke succes van de operatie voornamelijk bepalen.

In **hoofdstuk 4** worden de uitkomsten beschreven van de TVT bij vrouwen die niet eerder geopereerd waren. Vrouwen die eerdere chirurgie ondergingen werden dus uitgesloten van deelname, dit waren er 131. Ook vrouwen die andere bijkomende chirurgische ingrepen ondergingen in het kleine bekken werden uitgesloten, dit waren 44 vrouwen. Uiteindelijk resteerde 634 vrouwen van de originele groep. Van deze groep beantwoordde 77% de vragen en werden door hun dokter 2 jaar na de TVT onderzocht. Drie uitkomstmaten werden onderzocht; de resultaten op een vraag uit de toegestuurde UDI vragenlijst; "heeft u wel eens urineverlies bij lichamelijke inspanning, hoesten of niezen?', de uitkomst op de vraag van de dokter;" heeft u wel eens urineverlies bij lichamelijke inspanning, hoesten of niezen?' en als derde uitkomst maat werd gekeken of de vrouw urine verlies had tijdens hoesten met een volle blaas bij onderzoek door de eigen dokter. De onderzoeksresultaten lieten zien dat de klachten tot 2 jaar na de TVT nog kunnen verbeteren ook wanneer dit initieel niet tot succes leidde. Bij een klein percentage (4.6%-8.4%) vrouwen had de TVT geen succes twee jaar na de ingreep. Verder werd gekeken naar de uitkomsten bij vrouwen die niet meer bij hun dokter waren gekomen voor onderzoek na de ingreep. Sommige andere onderzoekers menen dat bij deze patiënten de ingreep niet tot succes leidde. Uit ons onderzoek bleek dat deze conclusie niet juist was, maar dat het succes percentage in deze groep 5.4%-8.6% lager lag.

In **hoofdstuk 5** worden de uitkomsten beschreven van de TVT bij 131 vrouwen die eerdere anti-incontinentie en/of prolaps chirurgie ondergingen. Dit werd gedaan met behulp van de UDI en IIQ vragenlijsten. Vrouwen die lager (beter) scoorde op deze vragenlijsten na de TVT, werden als verbeterd beschouwd. Wanneer het antwoord op de vraag ; "heeft u wel eens urineverlies bij lichamelijke inspanning, hoesten of niezen?', 'nee' was werd de vrouw als genezen beschouwd. Er werden 50 vrouwen geïdentificeerd die eerder een anti-incontinentie operatie hadden ondergaan. Van deze groep waren 9 vrouwen 2 keer eerder voor ongewild urine verlies geopereerd en 1 vrouw zelfs drie keer. Een eerder operatie voor verzakkings klachten hadden 65 vrouwen ondergaan, waarvan 2 vrouwen twee keer eerder werden geopereerd, 9 vrouwen werden voor beide, verzakking en incontinentie eerder geopereerd. Op alle uitkomst parameters werd een significante verbetering waargenomen. Dit betekent dat de TVT een succesvolle ingreep is voor patiënten die eerder werden geopereerd voor incontinentie of verzakking klachten.

In **hoofdstuk 6** worden de lange termijn uitkomsten beschreven na een TVT voor aandrangincontinentie en irritatieve blaas symptomen. De definities van de ICS werden hiervoor gehandhaafd. Als uitkomst maten werd gebruik gemaakt van de UDI en IIQ vragenlijsten. Voor dit onderzoek werden de gegevens van 610 vrouwen

gebruikt. Deze vrouwen werden allen minstens drie jaar gevolgd.
Aandrangincontinentie voor het eerst ontstaan na de operatie werd in 11% waargenomen. Symptomen van een over actieve blaas met urine verlies werd in 3% waargenomen. Deze symptomen hadden een negatiever effect op de kwaliteit van leven (gemeten met de IIQ) dan voor vrouwen zonder deze symptomen. De aanwezigheid van aandrangklachten en een vagina achterwandverzakking voor de operatie verhoogden het risico op aandrangincontinentie en irritatieve blaasklachten na de operatie. Deze vrouwen lieten ondanks deze klachten een verbetering zien op hun algehele kwaliteit van leven na de TVT. Dit komt waarschijnlijk door de verbetering van de inspanningsincontinentie.

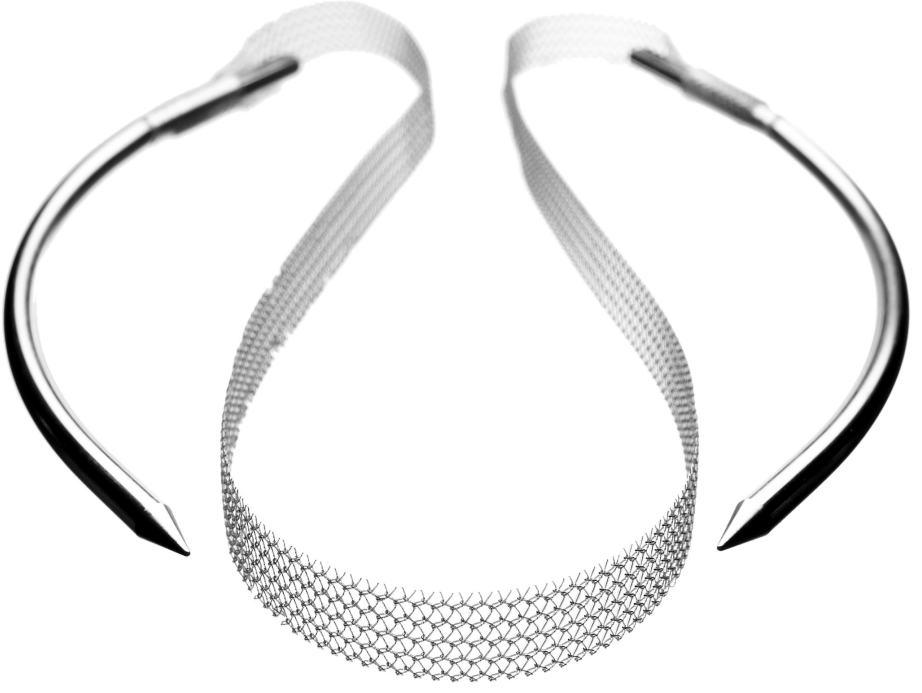
In **hoofdstuk 7** werden de lange termijn effecten van de TVT beschreven bij vrouwen die tevens tegelijkertijd een operatie voor verzakkings klachten ondergingen. Als uitkomstmaten werden gebruik gemaakt van de UDI en IIQ vragen lijsten. Zoals beschreven door de International Continence Society (ICS), werd gebruik gemaakt van de volgende vraag; "heeft u wel eens urineverlies bij lichamelijke inspanning, hoesten of niezen?', om hiermee ongewild urine verlies vast te stellen. De vrouwen met tegelijkertijd prolaps chirurgie (59) werden vergeleken met 687 vrouwen die alleen een TVT ondergingen. Van de 59 vrouwen ondergingen er: 7 een vaginale baarmoeder verwijdering, 15 een vagina voorwand plastiek, 28 een vagina achterwand plastiek en 9 een vagina voor- en achterwand plastiek. Van de 59 vrouwen hadden 6 eerdere prolaps chirurgie ondergaan, 3 een vaginale baarmoeder verwijdering, 5 een vaginavoorwand plastiek, 3 een vagina achterwandplastiek en 1 een sacrocolpopexy met rectopexy. Er waren 7 vrouwen met een anti-incontinentie ingreep in de voorgeschiedenis, allen ondergingen eerder een Burch kolposuspensie, één vrouw onderging deze ingreep twee keer en 1 vrouw onderging een Marchall-Marchetti-Kranz (MMK) suspensie na de Burch kolposuspensie. Twee vrouwen ondergingen beide, een anti-incontinentie en prolaps ingreep.
De gemiddelde IIQ en UDI score daalde voor beide groepen significant. Hieruit blijkt dat de TVT voor patiënten die tegelijkertijd een verzakkings operatie ondergaan een goed effect heeft op hun incontinentie urinae. Na twee jaar vervolgen van de vrouwen na de operatie werd een verschil waargenomen in de UDI/IIQ scores tussen beide groepen ten faveure van de groep zonder tegelijkertijd prolaps chirurgie.

In **hoofdstuk 8** wordt het onderzoek naar de prevalentie van plas (mictie) problemen op korte en lange termijn na de TVT beschreven. Hierbij werd gebruik gemaakt van objectieve parameters, gevalideerde kwaliteit van leven vragenlijsten en lichamelijk onderzoek bij de vrouwen tot 3 jaar na de ingreep. Mictie problemen (en met name obstructieve mictie) kunnen met diverse parameters gemeten worden. In dit onderzoek werden 5 uitkomstmaten onderzocht. Ten eerste de noodzaak van katheteriseren na de TVT. Ten tweede de vraag van de dokter hoe het plassen gaat, moeilijk of makkelijk. Ten derde werd gebruik gemaakt van de UDI vragenlijst. Eén van de vragen gaat over obstructieve mictie: ' heeft u moeite om uw blaas leeg te

plassen?'. Wanneer een vrouw 'ja' antwoordde op deze vraag werd zij beschouwd als een patiënte met obstructieve mictie. Vervolgens werd gevraagd hoeveel hinder deze vrouwen hiervan ondervinden (helemaal niet, een beetje, nogal, heel erg). Verder werden als uitkomst maten de zogenaamde 'flow rate' en het blaas residu na plassen genomen.
Katheterisatie meer dan 24 uur na de ingreep was nodig bij 11% en het doornemen van het bandje wegens plas problemen werd in 1.3% van alle vrouwen verricht. Obstructieve mictie bestond in 26% en 25% van deze vrouwen ondervond hiervan 'nogal, tot heel erge' hinder. Twee maanden na de TVT werd in 41% een abnormale flow rate gevonden en in 9% een residu van meer dan 100ml.
Ondanks dat de scores van de vrouwen met plas problemen na een TVT slechter waren op de kwaliteit van leven vragenlijsten dan vrouwen zonder deze plas klachten, hebben zij een veel betere kwaliteit van leven gemeten na de TVT dan ervoor.

Hoofdstuk 9, bevat de samenvatting, conclusies, worden de bevindingen van dit proefschrift bediscussieerd en aanbevelingenvoor klinische problemen en voor toekomstig onderzoek gedaan.

Part 4



Appendices

Appendix A

Abbreviations

BMI	Body Mass Index
CI	Confidence Interval
DO	Detrusor Over-activity
GA	General Anesthesia
HRQoL	Health related quality of life
ICS	International Continence Society
IIQ-7	Incontinence Impact Questionnaire (short form)
LC	Laparoscopic Colposuspension
LUTS	Lower Urinary Tract Symptoms
OAB	Overactive Bladder Symptoms
OR	Odds Ratio
PUL	Pubo-Urethral Ligament
QALYs	Quality-Adjusted Life Years
RA	Regional Analgesia
RCT	Randomized Controlled Trial
SD	Standard Deviation
SE	Standard Error
SUI	Stress Urinary Incontinence
TVT	Tension-free Vaginal Tape
UDI-6	Urogenital Distress Inventory (short form)
UI	Urinary Incontinence
UTI	Urinary Tract Infections
UUI	Urge Urinary Incontinence

Appendix B

Questionnaires

The Incontinence Impact Questionnaire short form (IIQ-7)

Has urine leakage and/or prolapse affected:
1 Household chores
2 Physical recreation
3 Entertainment activities
4 Travel > 30 minutes away from home
5 Social activities
6 Emotional health (nervousness, depression, etc.)
7 Feeling frustrated

Scoring for the IIQ-7: 0 for not at all, 1 for slightly, 2 moderately, 3 for greatly.
Domains of the IIQ-7: question 1+2= physical activity, question 3 +4= travel, question 5 = social activities, question 6+7 = emotional health.

The Urogenital Distress Inventory short form (UDI-6)

Do you experience, and if so, how much are you bothered by:
1 Frequent urination
2 Leakage related to feeling of urgency
3 Leakage related to activity, coughing, or sneezing
4 Small amounts of leakage (drops)
5 Difficulty emptying bladder
6 Pain or discomfort in lower abdominal or genital area

Scoring for the UDI-6: 0 for not at all, 1 for slightly, 2 moderately, 3 for greatly.
Domains of the UDI-6: question 1+2 = irritative symptoms, question 3 +4 = stress symptoms, question 5 + 6 = obstructive/discomfort symptoms.

Appendix C

Acknowledgements - Dankwoord

De studies die worden beschreven in dit proefschrift hadden niet kunnen worden uitgevoerd zonder de medewerking van ruim 800 patiënten, het is geweldig dat zo velen hebben meegewerkt aan dit onderzoek. Vooral deze deelnemers ben ik veel dank verschuldigd, omdat zij veel tijd hebben besteed aan het invullen van de vragenlijsten.

De volgende gynaecologen en urologen, L.W.A.R. Berger, M.G.M. Bergmans, S. de Blok, P.F. Boekkooi, S.D. Bos, R.S.G.M. Bots, G.M. Bouw, H.A.M. Brölmann, M. de Bruin, F.P.H.L.J. Dijkhuizen, C.A. Fiedeldey, S. Friese, J.M. van Geelen, D.A. Gietelink, J. de Graaff, J.F. ter Haar, E. Hallensleben, J.W. Hoekstra, C.J.A. Hogewoning, J. W.M. Hutten, W. IJzerman, M.M. IJand, P.H.N.M. Kampschoer, C. Kerckhoffs, M.H.H.M. Kerkhof, P.H. van Kessel, P.J.M. Kil, J.H. Kleinjan, H. Kragt, M.V.A.M. Kroeks, D. de Lange, I.L. Lie, A.H.P. Meier, W.F.A. Mensink, G.J. Montagne, A.F.P. Mulder, S.H. Oerlemans, R. Pal, A.A.F. Plancken, N.T.C.M. de Pree, F. Reijnders, R.J.C.I. Sassen, J. Scheepers, J.A. Schrickx, J.J.M. Schroeder, N.P.L. Venema, M. E. Vierhout, N.P.J. Vreuls, J.J. de Vries, P.H.S. Wassenberg, L.C.G. Wetzels, A.F.G.V.M. Ypma, A.F. Zürcher.
Allen dank ik voor hun geweldige inzet voor de Nederlandse TVT database. Zonder uw hulp had dit onderzoek nooit kunnen slagen.

Dr. H.A.M. Vervest, beste Harry, jij bent de grote initiator en geestelijk vader van hetgeen wat we met z'n allen hebben gepubliceerd. Behalve dat, heb je veel bijgedragen aan mijn vorming tot gynaecoloog. Verder heb ik je persoonlijke vriendschap, in goede en slechte tijden altijd erg gewaardeerd

Mevrouw G.E. Vervest-Nava , lieve Glenda, ik zal jou, maar ook je lasagne nooit vergeten. Zelfs toen je het me op een van de vele avonden die ik bij jullie doorgebracht, al werkend aan dit proefschrift, voor de zoveelste keer voorgeschotelde, smaakte het wederom prima.

Dr. H.M. Bisseling, lieve Tanya, jij hebt op de jouw karakteristieke, consciëntieuze wijze zeer veel bijgedragen aan het verzamelen van de patiënten gegevens. Veel dank voor al je werk.

Hooggeleerde A.P.M. Heintz, beste Peter, dank voor het vertrouwen dat je sinds mijn aanname als arts-assistent op jouw afdeling in mij hebt gehad. De vrijheid en de mogelijkheden die je me altijd hebt gegeven, ook om dit onderzoek uit te voeren zijn van groot belang geweest op het uiteindelijke resultaat.

Yvonne Farinazzo, dank voor het verzenden en verzamelen van alle pré- en postoperatieve controle formulieren en vragenlijsten.

Prof. de Graaf wil ik graag danken voor haar statistische adviezen betreffende het artikel over complicaties.

Hooggeleerden Prof. dr. J.L.H.R. Bosch, Prof. dr. B.C.J.M. Fauser, Prof. dr. M. Vierhout, Prof. dr. H.G. Gooszen en zeergeleerde dr. C.H. van der Vaart, ben ik erkentelijk voor het feit dat zij zitting hebben willen nemen in mijn beoordelingscommissie.

Collega's uit het Meander Medisch Centrum Amersfoort, Egbert Brinkhuis, Arien Bukman, Jitze Duk , Egbert Lenters, Paulien van der Salm, Willem Schöls, Jolande van der Stege, Christina Vermeulen-Meiners en Wim van Vliet, allen dank voor het doen van het extra werk tijdens mijn afwezigheid.

Dr. Susan Johnson-Alkema, lieve nicht Susan, vakgenote, ondanks de tegenwerking van de engelse postbodes heb je mijn Australische Engels altijd weer mooi weten om te buigen tot "proper" English, mijn dank.

Drs. E. Dietz, beste Eric, mooi dat je mijn paranimf wil zijn, met jouw humor overleef ik het hele gebeuren wel. Dank ook voor de steun die je altijd hebt gegeven in een verleden lang voordat dit proefschrift gestalte kreeg. Wel jammer dat jouw geliefde voetbalclub het volgend jaar niet zal redden tegen de 'godenzonen'.

Lieve familie; Pa, Moeke, Astrid, Inge en Jort, in voor- en tegenspoed altijd hebben jullie mij gesteund, ik ben jullie daar veel voor verschuldigd. Woorden hier op deze plaats zullen altijd tekort schieten en daarom houd ik dit deel van mijn dankwoord privé.

Lieve Pien, of mag ik al Dr. van Brummen zeggen? Een mooier congres dan in Florence 2003 kan ik me niet voorstellen. Alles is sindsdien in een heerlijke stroomversnelling gekomen. Ik hoop dat ons 'bootje', met bemanning, nog lang deze stroom mee mag hebben.

Appendix D

List of co-authors

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Appendix E:

Curriculum vitae

Steven Evert Schraffordt Koops werd op drie mei 1966 in Groningen als oudste zoon van vier kinderen geboren. Hij volgde het voorbereidend wetenschappelijk onderwijs aan de Rijks scholengemeenschap Noord Kennemerland te Alkmaar. Vervolgens studeerde hij geneeskunde aan de Rijksuniversiteit Groningen waarna de co-schappen en het Artsexamen (Cum Laude) werd gehaald aan de Erasmus Universiteit Rotterdam. In 1993 werd de auteur arts-assistent anaesthesiologie op de intensive care van het Catharina Ziekenhuis Eindhoven, waarna arts assistent gynaecologie in het Academisch Ziekenhuis Utrecht. In de periode 1994 tot 2000 specialiseerde hij zich tot gynaecoloog in het St. Elisabeth Ziekenhuis Tilburg (opleider Dr. P.J.H.M. Reuwer) en het Academisch Ziekenhuis Utrecht (opleiders Prof. A.P.M. Heintz en Prof G.H.A. Visser). Met name tijdens het perifere deel van de opleiding werd onder leiding van Dr. H.A.M. Vervest zijn interesse gewekt in de bekkenbodem chirurgie. Dit was reden voor hem om een fellowship in de urogynaecologie te volgen in Melbourne Australië (opleider Prof. P.L. Dwyer). Dit alles gaf aanleiding tot onder andere het wetenschappelijke onderzoek dat resulteerde in deze dissertatie. Sinds oktober 2000 is hij verbonden aan het Meander Medisch Centrum te Amersfoort als gynaecoloog met als speciaal aandachtsgebied de urogynaecologie. Vanaf het begin van zijn studie geneeskunde heeft hij verder diverse bestuurlijke functies bekleed.

Steven Evert Schraffordt Koops was born in Groningen, the Netherlands, on the third of May 1966. He is the eldest of four children. He studied Medicine at the University of Groningen and the Erasmus University Rotterdam, from where he graduated Cum Laude. In 1993 he became Resident in Anaesthetics in the Intensive Care Unit of the Catharina Hospital Eindhoven, and subsequently a Resident in Obstetrics and Gynaecology in the Academic Hospital Utrecht. From 1994 until 2000 he completed Specialist training in Obstetrics and Gynaecology at: the St. Elisabeth Hospital Tilburg (supervisor Dr P.J.H.M. Reuwer MD PhD) and the Academic Hospital Utrecht (supervisors Prof. A.P.M. Heintz MD PhD and Prof G.H.A. Visser MD PhD). During his training in Tilburg, whilst working with Dr H.A.M. Vervest MD PhD, he developed a special interest in Urogynaecology. A Fellow-ship in Urogynaecology in Melbourne (Australia) followed, supervised by Prof P.L. Dwyer. Since October 2000, the author has been working at the Meander Medical Centre in Amersfoort, where he works as a Consultant (Uro)gynaecologist. Furthermore he has, since the beginning of his studies, fulfilled several management roles.

Appendix F

List of publications

by March 2006

Anorectal symptoms after various modes of vaginal delivery
SE Schraffordt, HAM Vervest, HJM Oostvogel.
Int Urogynecol J 1997:8(1);S136.

Combined sacrocolpopexy and suture suture rectopexy
S.E. Schraffordt, M.P. Carey, J. Tjandra, C. Murray , C.F. Maher
Royal Women's Hospital & Royal Melbourne Hospital, Melbourne, Australia.
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Appendix G

Grants

Financial funding for this research project was provided by an unrestricted grant from the Foundation for Scientific Research of the Gynecology Associates Tilburg

The printing of this thesis was financially supported by Johnson & Johnson, women's health and urology, the Netherlands