EFFECTS AND EFFECTIVENESS OF THE TENSION-FREE VAGINAL TAPE PROCEDURE FOR TREATMENT OF FEMALE STRESS URINARY INCONTINENCE

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LIST OF ORIGINAL PUBLICATIONS

This thesis is based on the following original publications, which are referred to in the text by their Roman numerals:

I Nilsson CG, Kuuva N
The tension-free vaginal tape procedure is successful in the majority of women with indications for surgical treatment of urinary stress incontinence. Br J Obstet Gynaecol 108: 414-419, 2001.

II Nilsson CG*, Kuuva N*, Falconer C, Rezapour M, Ulmsten U
Long-term results of the tension-free vaginal tape (TVT) procedure for surgical treatment of female stress urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct 12 (suppl 2): 5-8, 2001.

III Kuuva N, Nilsson CG
A nationwide analysis of complications associated with the tension-free vaginal tape (TVT) procedure. Acta Obstet Gynecol Scand 81: 72-77, 2002.

IV Kuuva N, Nilsson, CG
Tension-free vaginal tape procedure: an effective minimally invasive operation for the treatment of recurrent stress urinary incontinence? Gynecol Obstet Invest 56: 93-98, 2003.

V Kuuva N, Nilsson CG
Long-term results of the tension-free vaginal tape operation in an unselected group of 129 stress incontinent women. Acta Obstet Gynecol Scand, accepted for publication March 4th, 2005 .

*These authors contributed equally to the study.

ABBREVIATIONS

BMI	body mass index
CS	cesarean section
GSUI	genuine stress urinary incontinence
HRQOL	health-related quality of life
ISD	intrinsic sphincter deficiency
IVS	intravaginal slingplasty
LPU	low-pressure urethra
LUT	lower urinary tract
MUCP	maximal urethral closure pressure
MUI	mixed urinary incontinence
NCSP-F	Nordic Classification of Surgical Procedures – Finland
NR	not reported
NS	not significant
STAKES	Sosiaali- ja terveysalan tutkimus ja kehittämiskeskus
SUI	stress urinary incontinence
TOT	transobturatoric tape
TVT	tension free vaginal tape
UI	urinary incontinence
UTI	urinary tract infection
VAS	visual analogue scale

ABSTRACT

The most usual type of female urinary incontinence (UI) is stress urinary incontinence (SUI). Conservative treatment options are helpful in mild cases, but treatment of moderate to severe SUI symptoms often requires operative means. Traditional operation alternatives, including open colposuspension and suprapubic slings, are invasive procedures associated with high risks and complications, whereas long-term results of less invasive operations, like needle suspension procedures, have been poor. Development of the tension-free vaginal tape (TVT) procedure evolved from the need to find an effective minimally invasive anti-incontinence procedure that could be performed on a day care basis under local anesthesia.

This study was undertaken to investigate the short- and long-term effectiveness as well as the intraoperative, immediate postoperative and long-term adverse events associated with the novel TVT procedure and to evaluate its applicability in general clinical practice.

We prospectively studied the effects and effectiveness of the TVT procedure in single center populations and in a multicenter population. The single center material included a heterogeneous group of 161 women comprising primary, recurrent, mixed urinary incontinence (MUI) and low-pressure urethra (LPU) cases and a homogeneous group of 54 women with recurrent SUI who were to undergo the TVT procedure. The multicenter material included a homogeneous group of 90 women with primary SUI who were to undergo the TVT procedure. Moreover, we retrospectively evaluated nationwide complications among 1455 women treated with TVT. All the involved surgeons were certified to perform the TVT procedure.

In the short term (< 5 years) the cure rate in the heterogeneous group was 87.0% and the cure rates in different incontinence categories were as follows: primary SUI 88.0%, recurrent SUI 84.4%, MUI 81.4% and LPU 66.7%. In the homogeneous group of recurrent SUI patients, the objective cure rate was 89.6% and the subjective rate 80.4%. The urge symptom improvement rate was 80% in the heterogeneous group and in the homogeneous group the urge symptom cure rate was 100%.

In the long term (≥ 5 years) the cure rate in the homogeneous group of primary SUI patients was 84.7%. In the heterogeneous group the rate of negative postoperative cough tests was 76.7% and it varied from 63.6% to 79.2% in different incontinence categories, whereas the rate of negative

postoperative pad tests was 85.3% and it varied from 81.8% to 93.9% in different incontinence categories. The urge symptom cure rate ranged from 56% to 89%.

Intraoperative and immediate postoperative (≤ 2 months) adverse events were recorded as follows: estimated bleeding of > 200 ml 0%–3.3%, bladder perforations 1.1%–5.9%, voiding difficulty 4.3%–7.6%, retropubic hematomas 0%–3.3%, urinary tract infection (UTI) 4.1%–7.8% and wound infections 0%–2.5%. In the nationwide material bladder perforation (3.8%) was the most common perioperative complication, whereas voiding difficulty (7.6%) was the most common postoperative complication.

Long-term (> 2 months) adverse events were recorded as follows: *de novo* urge 3.1%–5.9%, urogenital prolapses 1.6%–2.3%, recurrent UTI 1.2%–9.3%, lower urinary tract (LUT) symptoms 19.4% and tape exposure 3.1%.

Our results suggest that after a proper training period the TVT procedure is a safe and effective anti-incontinence operation, which can be successfully performed in the majority of patients generally thought to benefit from anti-incontinence surgery.

INTRODUCTION

Female urinary incontinence (UI) is a common problem and its prevalence increases with age (Minassian *et al.* 2003). The most usual type of UI is stress urinary incontinence (SUI) (Minassian *et al.* 2003). Conservative treatment options, including pelvic floor exercise, physiotherapy, lifestyle changes and medication, can be helpful in mild cases, but the treatment of moderate to severe SUI symptoms, however, often requires operative means. Traditional operation alternatives, including open colposuspension and suprapubic slings, are very invasive procedures associated with many complications (Nygaard and Kreder 1994), whereas the long-term results of less invasive operations, like needle suspension procedures, have been poor (Bodell and Leach 2002). Development of the tension-free vaginal tape (TVT) procedure evolved from the great need to find an effective minimally invasive anti-incontinence procedure that could be performed on a day care basis under local anesthesia (Ulmsten *et al.* 1996). The applicability of this new method, however, needed to be examined. Therefore, we studied, mainly prospectively, the short- and long-term effects and effectiveness of this novel procedure.

REVIEW OF THE LITERATURE

1. Urinary incontinence

1.1 Definitions of urinary incontinence

Urinary incontinence is the complaint of any involuntary leakage of urine, according to the International Continence Society. The three most commonly distinguished urinary incontinence types are stress urinary incontinence (SUI, the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing), urge urinary incontinence (the complaint of involuntary leakage accompanied by or immediately preceded by urgency) and mixed urinary incontinence (MUI, the complaint of involuntary leakage associated with urgency and also with exertion, effort, sneezing or coughing) (Abrams *et al.* 2002).

1.1.1 Additional terminology

Intrinsic urethral sphincteric deficiency (ISD)

McGuire observed that patients with prior failed incontinence surgery often had a low maximal urethral closure pressure (MUCP) of 20 cm H_2O or less and presumed that these patients presented a special subset of SUI cases (McGuire 1981), later labeled ISD. According to the Urodynamic Society, ISD signifies an "intrinsic malfunction of the urethral sphincter itself" (Blaivas *et al.* 1997). It has been described as a "condition in which the urethral sphincter is unable to coapt and generate enough resistance to retain urine in the bladder" (Lose and Brostrøm 2002; Betson *et al.* 2003). Etiological factors in women include previous pelvic surgery, hypoestrogenism, aging and pelvic radiation (Betson *et al.* 2003).

Low-pressure urethra (LPU)

In addition to a rigid urethra, as in ISD, urethral pressure can also be low in cases with hyperlaxity of the urethral closure apparatus (Lose and Brostrøm 2002). LPU is a general term that covers both of these conditions and it has also been defined by MUCP cut-off values other than 20 cm H_2O (Barranger *et al.* 2000). LPU has been associated with poor outcome of conventional bladder neck suspensions (Sand *et al.* 1987; Koonings *et al.* 1990;) and suburethral sling procedures have been recommended instead (Blaivas and Olsson 1988). However, the findings of some more recent

prospective comparative studies do not support this recommendation (Maher *et al.* 1999; Sand *et al.* 2000). Owing to problems emerging from the significant test-retest variability of urethral pressure measurements (Lose *et al.* 1998) and the arbitrary cut-off value of LPU, as well as the inability of MUCP to categorize urethral pathophysiology, the definition of LPU is unclear (Lose *et al.* 2002).

1.2 Prevalence of female urinary incontinence

Data on UI prevalence rates is affected by study material and methods as well as by the way UI is defined (Minassian *et al.* 2003). Urine loss at some time has been reported by 13–58% of women (Burgio *et al.* 1991; Brieger *et al.* 1997; Hannestad *et al.* 2002), while involuntary loss of urine that is a social or hygienic problem has been reported by 16–17% (Mäkinen *et al.* 1992; Milsom *et al.* 1993). Minassian and co-workers found in their study that the commonest type of UI was stress (50%), then mixed (32%) and finally urge (14%) (Minassian *et al.* 2003). The prevalence of UI increases with age. Simeonova and co-workers found that 3% of women aged 20–29 years and 32% of women aged 80 years or more suffer from UI. They further reported that SUI was most usual among women aged 30–39 years, whereas in older age groups the incidence of SUI decreased as the incidences of urge UI and MUI increased (Simeonova *et al.* 1999). Despite the fact that UI is a common symptom, only a relatively small proportion of women (6–26%) seek treatment (Burgio *et al.* 1991; Mäkinen *et al.* 1992; Simeonova *et al.* 1999; Hannestad *et al.* 2002), indicating that it is a concealed problem. Of women aged 30–49 years who had sought treatment for their UI, roughly one fourth had received operative therapy (Simeonova *et al.* 1999).

1.3 Effect on quality of life

Health-related quality of life (HRQOL) is a complex entity referring to a person's perceptions of the effect of a disease and its treatment. Primary domains of HRQOL include physical, psychological and social functioning and perceptions of health status. Secondary domains include somatic sensations (symptoms), sleep disturbance, intimacy and sexual functioning, and personal productivity (Lose *et al.* 1998). Even though UI is not a life-threatening condition it has a far-reaching impact on mental well-being (Norton 1982; Wyman *et al.* 1987; Stach-Lempinen *et al.* 2003), relationships with family and friends, as well as on activities of daily living, and hobbies (Norton 1982; Wyman *et al.* 1987). From this it follows that health care providers should be able to offer effective anti-incontinence treatments that are well tolerated. Urge UI and MUI have been found to have an even more negative impact on quality of life than SUI (Simeonova *et al.* 1999).

1.4 Continence mechanisms

According to a review article (Wall 2003), a type of incontinence where urine escapes in connection with exertion was described as early as 1814. Decreased tone of the bladder neck and the *meatus urinarius* in association with aging was presented as one reason for the symptom (Wall 2003). Subsequently, a decrease in the number of sphincteric muscle fibers (Cumston 1904) and torn or relaxed tissues at the bladder neck (Kelly 1913) were suggested as other reasons. It is now evident that the bladder neck lacks a local circular sphincter structure (Griffiths 1891; Griffiths 1895; Krantz 1951; Tanagho and Smith 1966). Factors that have been thought to contribute to incontinence include a changed urethrovesical relationship (Jeffcoate and Roberts 1952; Hodgkinson 1953), displacement of a smooth muscle "base plate" (Hutch 1967) and altered urethral length (Lapides *et al.* 1960; Bruschini *et al.* 1977).

The presumption that the urogenital diaphragm divides the urethra into intra- and extrapelvic portions laid the basis for Enhörning's pressure transmission theory, in which he concluded that passive transmission of intra-abdominal pressure to the proximal, intrapelvic, urethra was a central continence mechanism during exertion. He considered that the urethral portion closest to the bladder was of greatest significance, but he also considered the role of voluntary muscles with sphincteric action of importance in maintaining continence during stress (Enhörning 1961). With twin microtip transducer catheters it was demonstrated that intra-abdominal pressure transmission during stress may exceed 100% (Hilton and Stanton 1983). This, together with the finding that the intraurethral pressure increase preceded the abdominal one by a quarter of a second (Constantinou and Govan 1982) indicated the existence of an active closure mechanism which was mainly thought to be caused by mechanical factors (Hilton and Stanton 1983) rather than by enhanced pelvic floor reflex or improved muscle contraction (Heidler *et al.* 1979). It was further demonstrated that the urethral axis did not differ in continent and incontinent subjects, in a study involving use of a specially designed protractor (Fantl *et al.* 1986).

Combined urethrocystometry and urethrocystography studies revealed a urethral knee formation at the mid-urethra, distal to the area of maximal urethral pressure (Rud *et al.* 1979; Westby *et al.* 1982). The knee was thought to represent the site where the urethra enters the urogenital diaphragm (Westby *et al.* 1982; Huisman 1983), also known as the perineal membrane, and maximal urethral pressure was found to be located approximately 0.5 cm proximally to this point (Westby *et al.* 1982). It was apparent that several anatomical and physiological factors, of which some acted in the

urethra itself, intrinsically, and some through the periurethral supporting structures, extrinsically, were involved in the continence mechanism (Kessler and Constantinou 1986).

1.4.1 Periurethral supporting structures

The urethral portion above the urogenital diaphragm is mobile, whereas the portion below, approximately 20–60% of the total urethral length (DeLancey 1986), is firmly attached to the urogenital diaphragm (DeLancey 1990). The levator ani musculature, comprising the pubococcygeus, iliococcygeus and puborectalis muscles (Zacharin 1963), compose the muscles of the urogenital diaphragm (DeLancey 1988). The levator ani muscle is composed of a mixture of slow and fast twitch muscle fibers. The proportion of slow twitch fibers dominates and therefore it is functionally of slow twitch type. Additionally, however, it is also capable of producing rapid muscle contractions. The levator ani muscle exhibits features of a typical voluntary muscle and is suggested to play an active role in urethral closure, especially during sudden intravesical pressure rise (Gosling *et al.* 1981). Other structures involved in urethral support are the arcus tendineus fasciae pelvis and the endopelvic fascia, which hold the urethra and the anterior vaginal wall in close relationship with each other (DeLancey 1990; DeLancey 1994). Additionally, the role of pubourethral ligaments as a fulcrum that mediates forces directed to close the urethra have been emphasized (Krantz 1951). Zacharin further described this complex of ligaments, that consists of anterior, posterior and intermediate pubourethral ligaments, and termed it the urethral suspensory mechanism (Zacharin 1963). The elongated S-shape of the urethra and the close relationship of the proximal bend to the posterior pubic surface is proposed to be associated with this mechanism (Zacharin 1963), which covers the distal two-thirds of the urethra (Zacharin 1968). The posterior attachment sites of the ligamentous complex are of main importance for the suspensory mechanism (Zacharin 1968). The pubourethral ligaments are continuous with the perineal membrane (Milley and Nichols 1971).

The so-called integral theory states that stress as well as urge symptoms arise from the same anatomic defect, a lax vagina. The theory proposes that the vagina functions both as a mediator of muscle contractions involved in the urethral closure mechanism and that it also prevents urgency by supporting the hypothesized stretch receptors at the proximal urethra and trigone. Muscle dysfunction is held responsible for nearly all instances of urinary incontinence. The defect may exist in the muscle itself or in the perimuscular structures that attach the muscles to the vagina. The most important defect is a pubourethral ligament defect (Petros and Ulmsten 1990a).

1.4.2 Intrinsic continence mechanism

The striated muscle components of the urethral wall are situated along approximately 20–80% of the total urethral length (DeLancey 1986). They are composed of slow twitch fibers capable of producing a constant tone and they lack features of a typical voluntary muscle, indicating that the tonus might entirely be neurologically controlled (Gosling *et al.* 1981). There is evidence that the striated muscle fibers of the urethral wall extend at some points within the perineal membrane (Oelrich 1983). Smooth muscle is present in the proximal four-fifths of the urethra (DeLancey 1990). A multitude of venous sinuses exceeding the requirements for ordinary tissue vascularization have been found submucosally in female cadaveric specimens (Berkow 1953). Vascular pulsations have been noticed at the urethral high pressure zone (Asmussen and Ulmsten 1983), whereas in histological studies submucosal vascularity has been found to be especially concentrated at the internal and external urethral orifice (Huisman 1983). Altogether, the role of a vascular sealing component in the production of intraurethral pressure has been recognized. Additionally, the connective tissue (DeLancey 1990) and probably also the mechanical properties of the intraluminal urethral wall play a role in the intrinsic continence mechanism (Zinner *et al.* 1980). Incontinent women exhibit connective tissue deterioration (Ulmsten *et al.* 1987; Falconer *et al.* 1994).

Mechanisms within the bladder neck which may be involved in the closure of this region are the detrusor loop and the trigonal ring (Huisman 1983).

Many factors that contribute to the maintenance of continence are still unclear, but it is agreed that an efficient urinary continence mechanism relies on an intrinsically intact urethra as well as on proper anatomical urethral support. Results after female orthotopic bladder replacement, where the bladder neck was sacrificed, have shown the important role of the mid-urethra in preserving continence (Stein *et al.* 1994; Hautmann *et al.* 1996). Knee formation at the mid- urethra, and MUCP located approximately 0.5 cm proximally from this point, as well as the fact that vascular pulsations have been noticed at the urethral high pressure zone, highlight further the important role of the mid-urethra in preserving continence.

2. Surgical treatment of stress urinary incontinence

2.1. History of anti-incontinence surgery

2.1.1 Vaginal repairs

The history of anterior colporraphy begins in the 1880s, when several methods arose that employed the idea of narrowing the lumen of the urethra and vesical neck by dissection of the anterior vaginal wall and by suture placement into the suburethral tissue (Schultze 1888). The oldest anti-incontinence procedure, still utilized to some extent in modern medicine, is anterior colporraphy with Kelly–Kennedy plication. In 1913 Kelly introduced an operation that he had already successfully practiced for more than 10 years, which aimed to correct the torn and relaxed tissue at the bladder neck (Kelly 1913). He sutured together the damaged tissue with two or three mattress sutures after revealing the bladder neck through a sagittal medial line anterior vaginal wall incision, finished by resecting the redundant vaginal walls and closing the wound. In 1937 Kennedy further refined Kelly's plication by placing several approximating mattress sutures into the intact tissue beneath the bladder neck and urethra, after which he retracted the separated levator fibers with temporary silver wire sutures (Kennedy 1937).

Ingelman-Sundberg introduced his modification in 1947, in which he created extra support under the plastic repair by suturing together the pubocervical ligaments and anterior portions of the divided bulbocavernosus and levator muscles in the midline beneath the bladder and the urethra, whereas the posterior portions of the levator muscles he sewed together in front of the rectum (Ingelman-Sundberg 1947). Incidentally he found that the divided pubocoggygeus muscles preserved their ability to contract and later on he named the procedure the pubococcygeus muscle transplant (Ingelman-Sundberg 1982).

2.1.2 Suburethral slings

At the beginning of the 20th century ideas of substituting the damaged or destroyed urethral sphincter mechanism with a muscle transplant arose. The contractility of the transplant was thought to be retained by preserving the blood and nerve supply of the transplant.

In 1907 Giordano introduced the first suburethral sling (Giordano 1907). He dissected a gracilis muscle flap from the inner surface of the thigh and transplanted and sutured it around the urethra. In 1910 Goebell freed the pyramidalis muscles, except at the pubic crest, transplanted the freed ends and sutured them together beneath the urethrovesical junction (Goebell 1910). In 1914 Frangenheim modified Goebell's technique by leaving the pyramidalis muscles attached to strips of anterior rectus muscle fascia, making it possible to treat even patients with poorly developed pyramidalis muscles (Frangenheim 1914). In 1917 Stoeckel further refined the Goebell–Frangenheim procedure by additional plication of the periurethral fascia, followed by fixation of the sling body beneath the urethra with sutures (Stoeckel 1917).

Several modifications followed and other muscles were also used. However, complications were still common and it was also realized that the mode of action of the suburethral sling depended most likely on elevation of the urethrovesical junction rather than on the formation of a neosphincter. Fascia (both pedicled and free flaps), ligaments, dura and tendon structures now replaced muscle as sling material.

In 1933 Price used a strip of fascia lata, which he passed first beneath the urethra, then placed it retropubically and finally attached the free ends to the recti muscles (Price 1933). This principle was also employed by Aldridge, who in 1942 described his own variation: first anterior colporraphy was performed and thereafter aponeurotic fascial strips from the oblique abdominal muscles were passed through the recti muscles and drawn suburethrally where they were united in the midline (Aldridge 1942). In 1978 McGuire and Lytton described a sling procedure using rectus fascia supported by sutures extending through the space of Retzius and attached to the rectus fascia (McGuire and Lytton 1978). The two last mentioned autologous fascia sling procedures then became the prototypes of sling operations.

2.1.3 Retropubic open suspension procedures

In 1946, Marshall, Pollack and Miller reported their observations in male patients with urinary dysfunction after excision of the rectum (Marshall *et al.* 1946). Mobility and marked sagging of the vesical base and outlet in most of the patients suggested that lack of elevation and fixation might cause the problem. In some cases perineal support on voiding improved the flow. After an experimental suprapubic suspension of the vesical outlet by suturing it to the pubis was carried out successfully in a male patient, a procedure for female incontinence was developed by analogy. The

original urethrovesical suspension procedure was described in 1949 by Marshall, Marchetti and Krantz and it involved a suprapubic incision exposing the space of Retzius and elevation and immobilization of the vesical neck and urethra by suturing them to the pubis (periosteum or cartilage) and the rectus muscles (Marshall *et al.* 1949). Occasionally the pubic sutures pulled through, inspiring Burch to invent his colposuspension procedure, which he described in 1961 (Burch 1961). The principles were the same as in the procedure described by Marshall *et al.*, but the sutures were placed in the perivaginal fascia and attached to Cooper's ligament. In 1991 Vancaillie and Schuessler introduced a laparoscopic colposuspension technique (Vancaillie and Schuessler 1991).

2.1.4 Retropubic needle suspensions

In 1959 Pereyra described his simplified suspension procedure, which did not require retropubic dissection (Pereyra 1959). He had developed a special needle carrier that he introduced through a small abdominal suprapubic stab wound via the space of Retzius and para-urethral tissues into the vagina. Thereafter he threaded the needle with stainless steel wire and brought both wire ends through the suprapubic abdominal opening by retracting the needle carrier, repeating the procedure contralaterally and finally elevating the urethra and bladder by lifting and tying all four wire ends across the midline over the rectus fascia. In time the wires would cut through the tissues and fibrous tissue proliferation would stabilize the urethra.

Stamey developed his own needle system and suspension method, which he introduced in 1973 (Stamey 1973). It involved vaginal exposure of the bladder trigone, Stamey needle guidance through two separate suprapubic incisions alongside the internal vesical neck, intraoperative cystoscopy to ensure correct positioning of the needle, placement of monofilament heavy nylon loops with vaginal Dacron® buttresses to prevent tearing of the pubocervical fascia bilaterally to the urethra and internal vesical neck, and tying the two suspending nylon sutures individually on top of the anterior rectus fascia.

Pereyra collaborated with Lebherz and in 1978 they published a description of the revised Pereyra procedure known today as the modified Pereyra procedure (Pereyra and Lebherz 1978). The main innovations of the modified procedure were dissection of the anterior vaginal wall and preparation of the paraurethral tissues, bilateral vaginal blunt digital dissection of the retropubic space and helical Prolene® suture placement into the pubourethral ligaments and musculofascial tissues.

In 1981 Raz described his endoscopic modification, which differed from Stamey′s respective procedure mainly in the following steps: the retropubic space was entered from the vagina by means of sharp and blunt dissection, helical polypropylene or nylon sutures were used to anchor the vaginal wall and the deep endopelvic fascia, the needle was introduced from one abdominal suprapubic incision to the vaginal area and withdrawn under cystoscopic control, after which the suprapubic sutures were tied together (Raz 1981).

In 1987 Gittes and Loughlin described a modified, simplified needle suspension procedure without any incisions and using monofilament mattress sutures. The procedure could be performed as outpatient surgery and allowed the use of local anesthesia in selected patients (Gittes and Loughlin 1987).

It was common to all early needle suspension procedures that they involved use of the abdominal wall as a fixation point for the suspension sutures. This in turn could cause pain and a pulling sensation and sometimes the sutures cut through the tissues when the muscles contracted.

2.2 Modern minimally invasive continence operations

2.2.1 Periurethral bulking agents

The idea of periurethral injectable bulking agents is to reduce the caliber of the urethral lumen and to increase the resistance to urine flow. Notes on utilization of paraffin can be found from the beginning of the 20th century. In 1938 sclerosing agents that caused fibrosis of the periurethral tissues were employed (Murless 1938). Thereafter, several different compounds such as silicone, polytetrafluoroethylene (Teflon®), bovine collagen and autologous fat have been utilized. An optimal, safe and efficient agent, however, remains undiscovered and currently carbon beads (Durasphere®), calcium hydroxylapatite (Coaptite®) and detranomer/hyaluronic acid copolymer (Zuidex®/Deflux®) are being extensively studied (van Kerrebroeck *et al*. 2003). At present injections can be administered under endoscopic control by the periurethral route and also by the transurethral route. Insertion devices allowing transurethral injection without visualization of the injection site are also available (Bent 2004).

2.2.2 Bone anchoring procedures

In 1988 Leach reported a bone fixation technique for transvaginal needle suspension (Leach 1988). The procedure included vaginal wall incision, dissection beneath the vaginal epithelium laterally to the pubic bone, perforation of the deep endopelvic fascia, mobilization of the retropubic space, helical placement of polypropylene suspension sutures, incorporating the full thickness of the anterior vaginal wall (excluding the vaginal epithelium and deep endopelvic fascia), exposure of the pubic tubercle through one suprapubic incision, suspension suture placement deeply into the bone and individual tying of each suspension suture, with the pubic tubercle as the fixation point.

During the 1990s several commercial kits, Vesica® (Appell *et al*. 1996), Mitek® (Kane *et al*. 1999), InTac® (Madjar *et al*. 1998) and InFast® (Madjar *et al*. 2000), that employ bone anchoring devices for fixing a suture or sling to the posterior plane of the pubic bone (transvaginal approach) or superior aspect of the pubic bone (percutaneous suprapubic approach) were launched.

2.2.3 Mid-urethral tape procedures

2.2.3.1 Evolution from intravaginal slingplasty (IVS) to tension free vaginal tape (TVT)

The tuck procedure, one of the first procedures designed on the basis of the integral theory (Petros and Ulmsten 1990c), involved excision of bilateral, approximately 0.5 cm-wide, leaf-shaped pieces of vaginal mucosa (extending near, but not beyond, the bladder neck) and approximation of the cut edges using Dexon® sutures. The aim was to restore the closure mechanism by tightening the vaginal hammock. The success rate at 12 months was 47% (Petros and Ulmsten 1990c).

There was an interest to find a method by which damaged posterior pubourethral ligaments could be recreated. Therefore, a trial on dogs aimed at creating an autogenic neo-ligament was undertaken (Petros *et al.* 1990). After designing a specific tunneler that ensured minimal invasiveness and correct tape positioning, the investigators implanted a 5-mm Mersilene® tape retropubically as an inverted U on the rectus sheet, leaving the free ends in the vagina without fixation. The tapes were removed 8–19 weeks later. Four weeks after tape removal a fibrous tissue band in a position corresponding to the human posterior pubo-urethral ligament was observed. Later on this method was tested in humans (Petros and Ulmsten 1990b). Local anesthesia was used and a 1.5-cm incision was made in the mid-line just above the superior rim of the pubic bone. The bladder was drained

through a Foley catheter and a straight introducer was used in order to move the bladder away from the operating area. The tunneler was inserted immediately laterally to the urethra just behind the inferior surface of the pubic bone with the forefinger guiding it along the posterior surface of the pubic bone, whereafter it was brought out through the suprapubic skin incision. The tape was introduced to the needle eye, pulled down into the vagina, and the tunneler removed. After repeating the procedure contralaterally the vaginal ends of the tape were fixed to a silicone tube to allow postoperative adjustment. Bladder neck elevation was abandoned after the first six operations since it caused *de novo* urge and outflow obstruction. It was also noted in postoperative radiological examinations that almost all successful cases showed no bladder neck elevation. Tape removal was undertaken 4 to 8 weeks later as an outpatient procedure. The success rate at 12 months was 50% and it increased to 82% when failure cases were treated by means of an additional bilateral tuck operation under local anesthesia. The two-step, combined intravaginal sling and tuck operation was later referred to as IVS 1 (Petros and Ulmsten 1993).

A later procedure, IVS 2 (Petros and Ulmsten 1993), involved tape and bilateral tuck procedures simultaneously and cystoscopy always prior to removal of the tunneler. The tape ends were trimmed and left freely protruding into the vagina. Tape removal took place 6 to 8 weeks postoperatively. The success rate at a mean of 15 months was 64%. Two women out of 39 developed suprapubic abscesses after tape removal and 9 failed cases showed decreased elasticity in the bladder neck area due to scarring by the tuck incision. No preoperative antibiotic was used.

In IVS 3 (Petros and Ulmsten 1993) two parallel columns of tapes, and antibiotic prophylaxis (i.v. flucloxacillin and rectal metronidazole) were used in order to prevent abscess formation. In order to prevent scarring, only a single midline incision, not extending beyond the bladder neck, was made in the vaginal mucosa. Flaps were dissected off the urethra and the edges grasped with forceps while the patient was coughing (with a filled bladder) until continence was achieved. The vaginal tape ends left were 1.5 to 2 cm long and they were fixed to the vaginal wall. No postoperative catheterization was routinely performed. The success rate at 12 months was 70%. Subsequent loosening of vaginal tension was presented as an explanation for operative failure.

In IVS 4 (Petros and Ulmsten 1993) a 0.4 × 45 cm Teflon® tape was inserted as an inverted U, whereafter it was cut in the midline so that two parallel tape columns were created. The vaginal tape ends left were 1 to 2 cm long and they were fixed to the vaginal wall. “Double-breasted” vaginal flaps stopping approximately 1 cm below the bladder neck were created. The free ends of the flaps

were placed upon one another and sutured together. The primary cure rate was 72%. Failure of vaginal plasty was common in failure cases.

In IVS 5 (Petros and Ulmsten 1993) permanent Teflon®, Mersilene® or Goretex® tapes were used. The tapes were inserted in a U shape at the mid-point of the urethra without tension and an intraoperative cough test was performed to ensure continence. After finishing the vaginal part of the operation, which corresponded to that of IVS 4, the urethra was pressed downwards with a hegar dilator to ensure that no tension was present. Cystoscopy was performed intraoperatively. The cure rate at 12 months was 78%. In 1995 a report involving 50 women who had been operated upon by means of basically the same method as described in IVS 5 and who had been followed for a mean of 16 months was published. Tape materials included the same as in IVS 5, and Lyodura® was also used. The cure rate was 78% (Ulmsten and Petros 1995). Both of the above studies involved two patients with a Goretex® sling and they all experienced sinus formation which necessitated tape removal. Failure of the vaginal plasty was common among failure cases in both studies.

In 1996 an improved version of IVS was introduced in a study that involved 75 women who had been followed for two years. A commercial kit (Medscand AB, Johnson & Johnson, Sweden) comprising a 40-cm-long and 10-mm-wide Prolene® gauze sling covered by a plastic sheet, two disposable metal or plastic needles and a non-disposable metal handle, was used. In the last 25 operations two 1-cm-long transverse skin incisions 6 cm apart were made instead of the single incision initially used. A vertical incision maximally 1.5 cm long was made in the midline of the suburethral vaginal wall, starting approximately 0.5 cm from the outer urethral orifice. A blunt, bilateral, 0.5–1.0 cm, paraurethral dissection was made through this incision with scissors. The plastic sheet has two uses: it prevents contamination and enables non-traumatic insertion of the tape. The vaginal incision was closed and vaginal skin was excised only in cases of laxity. The cure rate was 84%, and no sling-related problems occurred (Ulmsten *et al.* 1996). This operation is at present called the tension-free vaginal tape or TVT procedure.

2.2.3.2 Modifications of the TVT procedure

Alternative placement methods of the mid-urethral tape comprise for the moment transobturatoric (Delorme 2001) and pre-pubic techniques (Daher *et al.* 2003).

2.3 Sling materials currently employed

2.3.1 Biological materials

Autologous sling materials currently employed are fascia lata, rectus fascia, and vaginal wall. Available allogenic cadaver graft products are fascia lata and dermis. Methods that are employed to sterilize cadaveric tissue include solvent-dehydration, freezing, freeze-drying and γ-irradiation. Xenografts currently employed are porcine dermis, bovine pericardium and porcine intestinal mucosa (Kobashi *et al.* 2005).

2.3.2 Synthetic materials – mesh classification

Synthetic meshes are divided into absorbable and non-absorbable types (Goldstein 1999). Absorbable meshes (produced from polyglycolic or polylactic acid) are unsuitable for procedures where prolonged tensile strength is required (Tyrell *et al.* 1989). Non-absorbable meshes are made of fibers comprising one (monofilament) or several filaments (double filament/multifilament). The structure of the fiber can be twisted, coated (single or double wrapped), braided or double braided. Mesh fabrics may be woven (plain, twill or satin weave), knitted (warp-knit, interlock and circular-knit) or nonwoven-nonknitted and the surfaces may be of the same or different materials (composite fabrics) (Cosson *et al.* 2003). Non-absorbable meshes are classified into four subtypes based on their pore size (Amid 1997). Type I meshes are totally macroporous (pores > 75 μ), type II meshes totally microporous (pores < 10 μ in at least one dimension), type III meshes macroporous with multifilamentous or microporous components and type IV meshes possess a submicronic structure (Amid 1997). The pore size of type I meshes allows admission of macrophages, fibroblasts, blood vessels and collagen fibers into the pores (Amid 1997), which is important in prevention of mesh-related adverse events and for good incorporation of the host tissue throughout the mesh.

Monofilamentous polypropylene mesh, which has proved to be superior to other available synthetic meshes, has all the qualities demanded of an ideal type I mesh: it is completely inert, infection-

resistant, rapidly fixed and entirely incorporated. Additionally, it does not promote sinus tract formation and tape removal is not required in cases of non-tape-related surgical infection (Amid 1997; Amid *et al.* 1995). At present polypropylene prostheses are widely used and they are available in various forms, including Prolene® (Ethicon, Summerville, NJ, USA), Marlex® (BARD, Cranston, RI, USA) and Atrium® (Atrium, Hudson, NH, USA) (Birch and Fynes 2002). Additional non-absorbable materials include polytetrafluoroethylene (PTFE, Teflon®), expanded PTFE (Gore-Tex®) and polyethylene terephthalate (Mersilene®) (Niknejad *et al*. 2002).

2.4 Clinical outcome of incontinence surgery

Cure rates associated with pubovaginal slings vary from 46% to 95% in studies with mean or median follow-up periods of under 5 years (Zaragoza 1996; Chaikin *et al*. 1998; Choe and Staskin 1999; Kuo 2001; Weinberger and Ostergard 1995; Young *et al*. 1995; Rutner *et al*. 2003) An overall success rate of 77.4% was reported in a study with a minimum follow-up period of 5 years (Morgan *et al.* 1985). These studies involved use of different sling materials as well as different study designs.

In a non-randomized study at a mean of 4.5 years after open colposuspension, 84% of patients were continent but only 44% were continent and complication-free (Galloway *et al.* 1987). In non-randomized studies with mean or median follow-up periods ranging from 5 to 13.8 years, cure rates ranged from 44% to 78% (Alcalay *et al.* 1995; Dietz and Wilson 2000; Drouin *et al.* 1999; Kinn 1995), whereas in a study with 5 to 10 years of follow up 81.6% were cured of SUI (Feyereisl *et al.* 1994).

In randomized controlled trials comparing open colposuspension with laparoscopic colposuspension, cure rates associated with the former procedure ranged from 79% to 96% and for the latter procedure from 62% to 80%, the follow-up periods varying from 1 year to 2.7 years (Su *et al.* 1997; El-Toukhy and Davies 2001; Ankardal *et al.* 2004;).

Cure rates after periurethral silicone injections have been reported to vary from 19% to 40% after 31 to 36 months (Harriss *et al.* 1996; Barranger *et al.* 2000). Cure rates after periurethral collagen injections varied from 28% to 30% after 8 to 55 months (Corcos and Fournier 1999; Winters *et al.* 2000). In a randomized trial no difference was found in cure rates between fat and placebo groups

three months after injection therapy (Lee *et al.* 2001). A cure rate of 31% at a mean of 78 months after dextranomer/hyaluronic acid copolymer injection has been reported (Stenberg *et al.* 2003).

The cure rate after bladder neck suspension was 90% at a mean follow-up time of 15 months (Raz *et al.* 1992), being 23% at 4.4 years (Elkabir and Mee 1998) and 20% at 9.8 years (Trockman *et al.* 1995).

Cure rates after TVT procedures are displayed in Table 1 and cure rates after pre-pubic tape and transobturator tape (TOT) procedures in Table 2.

Table 1. Cure rates after tension free vaginal tape (TVT) procedures

References	Patient number	Incontinence type	Follow up (months)	Study design	Mean age (y)	Anesthesia	Concomitant surgery	Subjective cure	Objective cure
Ulmsten *et al.* 1998	131	primary GSUI	≥ 12	prospective multicenter	53 (35–88)	local	-	91%	91%
Wang and Lo 1998	70	primary SUI	12 (3–18)	prospective muticenter	43 (22–74)	epidural	-	87%	83%
Olsson and Kroon 1999	51	GSUI/MUI, 6% recurrent	36	prospective	53 (34–80)	86% local 14% spinal	20%	90%	90%
Ulmsten *et al.* 1999	50	GSUI primary, MUI	36	prospective	57±11	98% local	-	86%	86%
Moran *et al.* 2000	40	primary GSUI	12 (6–24)	prospective two-center	51 (33–86)	local	-	80%	95%
Jeffry *et al.* 2001	112	6% recurrent 21% MUI	25 (18–34)	prospective	54 (33–102)	local/spinal	58%	66%	89%
Meschia *et al.* 2001	404	primary SUI, recurrent SUI, 43% MUI	21 (12–35)	prospective multicenter	57 (31–83)	50% epidural 44% local 6% general	21%	92%	90%
Laurikainen and Kiilholma 2003	191	21% recurrent SUI 34% MUI	17 (3–36)	retrospective	60 (32–84)	82% local 18% spinal	18%	88%	-
Levin *et al.* 2004	241	4% recurrent SUI	21 (12–55)	prospective	64±11	~50% local ~50% epid/spin	~50%	93%	86%
Lo *et al.* 2004	70	GSUI primary/recurrent MUI	36	prospective	57 (30–65)	local/spinal	-	-	89%
Nilsson *et al.* 2004	80	primary SUI, MUI, LPU	91 (78–100)	prospective multicenter	53 (35–87)	local	-	81%	81%
Price and Jackson 2004	89	42% recurrent	20 (6–40)	retrospective	59 (33–90)	80% spinal 14% general 7% local	36%	74%	-
Tsivian *et al.* 2004	52	GSUI, 18% recurrent	55 (48–65)	retrospective	63 (37–83)	67% spinal 33% general	81%	79%	-
Holmgren *et al.* 2005	692	84% SUI, 16% MUI	24–96	retrospective cross-sectional	62	local	-	6–8y SUI 85% (*n*=156) MUI 30% (*n*=13)	-
Tomoe *et al.* 2005	66	primary SUI/MUI	24	prospective	58 (40–80)	local	-	88%	82%

LPU = low-pressure urethra; MUI = mixed urinary incontinence; GSUI = genuine stress urinary incontinence; SUI = stress urinary incontinence

Table 2. Cure rates after transobturator tape (TOT) and pre-pubic tape procedures

References	Tape/passage	Patient number	Incontinence type	Follow up (months)	Study design	Mean age (y)	Anesthesia	Con-comitant surgery	Subjective cure	Objective cure	Combined subjective+ objective cure
Daher *et al.* 2003	TVT®/ pre-pubic inside–out	74	SUI	5 (2–10)	prospective	58 (34–79)	86% spinal 8% general 5% local	Yes, ratio ?	-	-	81%
Cindolo *et al.* 2004	UraTape®/ transobturator inside–out	80	SUI 20% recurrent 37% MUI	4 (1–8)	prospective	56 (39–79)	spinal	-	97%	92%	-
Costa *et al.* 2004	T.O.T®/ transobturator outside–in	130	14% recurrent 27% MUI 53% GSUI 5% LPU	6	prospective	56 (29–87)	31% spinal 69% general	14%	-	-	83%
Delorme *et al.* 2004	UraTape®/ transobturator outside–in	32	16% LPU 16% recurrent 56% MUI	17 (13–29)	prospective	64 (50–81)	spinal/ general	-	-	-	91%

LPU = low-pressure urethra; MUI = mixed urinary incontinence; GSUI = genuine stress urinary incontinence; SUI = stress urinary incontinence

2.5 Complications of incontinence surgery

Retropubic open suspensions and pubovaginal slings are regarded as the most effective anti-incontinence procedures in the long term (Leach *et al.* 1997). However, original articles with a focus on the complications associated with these procedures are difficult to find. Thus, the complication rates presented in this section are produced from articles concentrating mainly on results in general. Perioperative complications associated with Burch colposuspension are presented in Table 3.

Table 3. Perioperative complications associated with Burch colposuspension

Stanton and Cardozo 1979	Korda *et al.* 1989	Baker and Drutz 1991	Kiilholma *et al.* 1993	Kjølhede and Ryden 1994	Wang 1996
n=180	*n*=174	*n*=289	*n*=186	*n*=232	*n*=294
Hemorrhage 0.6% Bladder injury 1.1% Abscesses 0.6% Pulmonary embolism 0.6%	Ureteral injury 1.1% Catheterization > 10 days 24.7% UTI 45.4% Haematoma 4.0% Wound infection 2.9% Transfusion 1.7% Deep venous thrombosis 0.6%	Blood transfusion 33.2% Abscesses 2.4% Fever 6.2% Deep venous thrombosis 1.0% Pulmonary embolism 0.3%	Hematoma 2.7% Voiding difficulty < 1 month 14.0% UTI 14.0% Wound infection 4.3% Deep venous thrombosis 1.1% Pulmonary embolism 0.5%	Indwelling catheter > 2 weeks 9.1% UTI 27.6% Residual urine > 100ml > 7 d 16.4% Fever 5.2%	Hemorrhage 0.7% Bladder injury 2.4% Voiding difficulty 3 weeks after catheter removed 9.5% UTI 6.8% Wound infection 4.1%

UTI = urinary tract infection; d = days

Long-term complications after Burch colposuspension have been reported as follows: uterine/vault prolapse 7% (Dietz and Wilson 2000), rectocele/enterocele 30% (Feyereisl *et al*. 1994) to 57% (Dietz and Wilson 2000), cystocele 25% (Dietz and Wilson 2000), post-colposuspension syndrome 2.3% (Feyereisl *et al*. 1994), persistent voiding difficulty 2 % (Dietz and Wilson 2000) to 22% (Alcalay *et al.* 1995) and urge incontinence 23% (Alcalay *et al.* 1995) to 41% (Dietz and Wilson 2000).

Table 4 summarizes perioperative and long-term complications associated with pubovaginal slings. Table 5 shows respective results for the TVT procedure.

2.6 Nationwide hospitalization times associated with anti-incontinence surgery according to STAKES

The National Research and Development Centre for Welfare and Health (STAKES) maintains a register of all hospital discharges in Finland. The annual numbers of patients, as well as the respective hospitalization times of patients who were discharged from 2000 to 2004 with an NCSP-F (Nordic Classification of Surgical Procedures-Finland) code number referring to a tension-free vaginal tape procedure (LEG 10) and abdominal colposuspension (KDG 20) are summarized in Table 6**.** In the hospital discharge database, day care surgery is defined as an elective procedure performed under intravenous sedation or extensive regional anesthesia or general anesthesia in an operating theatre followed by a postoperative hospitalization period of less than 12 hours. Systematic problems related to the coding of the TVT procedure were usual before 2000. However, since 2000 the code number of the TVT procedure established its position and data can be considered reliable from this perspective. The number of abdominal colposuspensions has consistently decreased in Finland and in 2004 no procedure with the respective code number was reported. In contrast, TVT procedures have been extensively performed and the rate of TVT day care surgery has annually increased, being 54% in 2004.

Table 4. Perioperative and long-term complications associated with pubovaginal slings

Morgan *et al.* 1985	Weinberger and Ostergard 1995	Young *et al.* 1995	Choe and Staskin 1999	Chaikin *et al.* 1998	Rutner *et al.* 2003
n=274 Marlex®	*n*=98 polytetrafluoroethylene	*n*=110 Mersilene®	*n*= 141 Gore-Tex®	*n*=251 autologous rectus fascia	*n*=152 porcine small intestine
No rejections Sling pulling through urethra (tape cut transurethrally) 0.7% Severe chronic cystitis and end-stage contracted bladder requiring urinary diversion 0.7% Persistent outlet obstruction and urinary retention requiring anterior transurethral resection of the bladder neck 4.4% Self catheterization 0.7% Recurrent cystitis related to retention 3.6% Large hematomas requiring drainage 2.2% Catheter sinus tracts that were excised 1.1% Persisting urgency and frequency 5%	**Abdominal site** Abscess 6.1% Sinus tract 6.1% Seroma 3.1% Skin separation 3.1% Hematoma 2.0% **Vaginal site** Mucosal erosion 10.2% Granulation tissue 10.2% Sinus tract 5.1% Groin pain 1.0% **Voiding difficulties:** Self-catheterization all times or occasionally 8.2% **Complete or partial sling removal:** 22.4%	UTI during postoperative hospitalization 2.7% Superficial wound infections 2.7% Atelectasis 4.5% Ilioinguinal nerve entrapment necessitating suture release 0.9% Discharged using intermittent self-catheterization 37% Discharged with indwelling catheter 2.7% **At 6 weeks**: Voiding difficulties 7% Urgency 17% Urge incontinence resistant to medication 1.8% Urinary frequency and nocturia 4.5% UTIs between discharge and 6 weeks 13% **Long-term complications** Voiding difficulty 2.7% Sling erosion 1.8% Persistent unilateral groin sinus 0.9% Total rate of patients necessitating sling excision/removal 3.6%	Urethral obstruction (detrusor pressure >30 cmH_2O, max. urine flow <10 ml/s & post-void residual volume <100 ml) necessitating tape incision 1.4% Urinary retention (detrusor pressure >30 cmH_2O, max. urine flow <10 ml/s & post-void residual volume >100 ml) necessitating tape incision 2.8% Vaginal granulation tissue necessitating tape excision 3.5%	Permanent urinary retention 2% *De novo* urge incontinence 3% Bladder injury 0.6% Urethral injury 0% Prolonged pain 0.3% Death 0.3% (patient died of complications from an elective cardiac pacemaker implantation)	Intra- or postoperative dislodgement of bone screw 1.3% Gradual urethral obstruction during a 2-year postoperative period 0.7% *De novo* urge resolved with medication 5% No graft infections, erosions or extrusions occurred

UTI = urinary tract infection

Table 5. Complication rates (%) associated with tension free vaginal tape (TVT) procedures

	Meschia *et al.* 2001	Tamussino *et al.* 2001	Karram *et al.* 2003	Abouassaly *et al.* 2004	Levin *et al.* 2004	Paick *et al.* 2005	Schraffordt Koops *et al.* 2005
Study design	Prospective multicenter	Prospective multicenter questionnaire	Retrospective	Retrospective multi-institutional review	Prospective	Retrospective	Prospective
Patient number	404	2795	350	241	313	274	809
Concomitant surgery	38.5	41	55	9.1	40	nr	7.3
Bladder injury	6	2.7	4.9	5.8	5.1	4.7	3.5
Bleeding	0.5	2.3	1.1	2.5	nr	-	1.2
Special rare complications	0.2 #	0.03 ¶	0.9% ¥	-	1.3•	-	0.1 §
Voiding difficulty	4 (residual ≥ 100 ml)	nr	4.9 (intermittent self-catheterization >7 days)	19.5 (retension requiring catheterization)	2.5 (catheterization >7 days)	13.9 (residual ≥ 100 ml x 2 consecutively or failure to void)	14.9 (need of catheter >24h)
Hematoma	1.5	0.7 ‡	1.7	1.9	1.3	-	3.4
Wound infection	nr	nr	nr	0.4	nr	0.4	nr
UTI	nr	17	10.9	11.8	10	0.4	0.7
Defect healing	0.5	nr	0.9	0.4	nr	-	nr
De novo urge symptoms/incontinence	nr	nr	nr	5-15	8.3	1.7	nr
Tape transection/removal	0.5 ‖	0.6 ‖	1.7 ‖	1.0 ╪	0.3 ‖	1.4 ‖	1.6 ‖ 0.2*
Tape rejection	nr	nr	nr	nr	nr	-	0.2*

nr = not reported, po = postoperative, UTI = urinary tract infection, *etiology (infection, erosion, defective wound healing) unknown , # obturator nerve injury, § iliac vessel injury, ‡ rate of patients requiring reoperation for hematoma, ¶ small bowel injury, ¥ ilioinguinal, femoral and obturator nerve injury, strain or irritation, ‖ due to outflow obstruction, ╪ due to tape erosion, • vaginal erosion treated by local excision of the eroded tape

Table 6. Annual numbers of patients and their hospitalization times after TVT and after abdominal colposuspension, according to STAKES

STAKES – Tilastot: Päiväkirurgia	Annual number of discharged patients with different procedure codes					Annual mean/median hospitalization days					Annual percentage of operations performed on day care basis				
Year	-00	-01	-02	-03	-04	-00	-01	-02	-03	-04	-00	-01	-02	-03	-04
Tension-free vaginal tape procedure (TVT) (LEG 10)	1667	2169	2783	2508	1812	1.8 / 1	1.7 / 1	1.6 / 1	1.5 / 1	1.4 / 1	29	35	41	45	54
Abdominal colposuspension (KDG 20)	27	10	5	3	-	7.7 / 7	6 / 6	6.8 / 7	5 / 5	-	0	0	0	0	-

AIMS OF THE STUDY

The main goals of the present study were:

1. to study the short- and long-term effectiveness of the TVT procedure

2. to study the intraoperative, immediate postoperative and long-term adverse events associated with the TVT procedure

3. to evaluate the applicability of the TVT procedure in general clinical practice

SUBJECTS AND METHODS

Studies I, IV and V were carried out at the urogynecological unit of Helsinki University Central Hospital, whereas Study II was a multicenter trial involving the above mentioned unit and two additional Nordic centers (Danderyds Hospital, Karolinska Institute, Stockholm and Uppsala University Hospital, Uppsala in Sweden). All studies were approved by the Ethics Committees in respective centers and informed consent was obtained from all patients involved. Study III was a nationwide postal questionnaire study. The set-up was prospective in Studies I, II, IV and V, and retrospective in Study III.

1. Subjects (Studies I, II, IV and V)

Studies I and V: Out of 332 consecutive women who were referred to the urogynecological outpatient clinic because of UI the studies involved all 161 who met the inclusion criteria and who were scheduled to have a TVT procedure. Inclusion criteria were: urodynamically proven SUI with observed urinary leakage during the cough stress test, no need for additional concomitant surgery, no existing urogenital prolapse protruding beyond the vaginal introitus and no urge-dominated mixed incontinence. All women had failed to respond to pelvic floor exercises. Their age varied from 29 to 81 years and body mass index (BMI) from 19 to 35 kg/m^2. The numbers of women with

MUI, recurrent incontinence, and LPU were 59, 45 and 18, respectively. Recurrent SUI refers to patients who had undergone one or several unsuccessful anti-incontinence operations. Anterior repair with Kelly plication is considered as an anti-incontinence procedure, whereas anterior repair alone is not. No study subject had undergone previous periurethral bulking. The operations were performed between May 5, 1995 and March 17, 1999.

Study II: Ninety consecutive women who were to undergo TVT surgery because of primary SUI were enrolled into the study between 1 January 1995 and 15 October 1996. All women had urodynamically proven SUI, 25 women had symptoms of urgency, none had LPU. A cystocele that maximally extended to the mid-vagina but did not require operation was acceptable. Of 90 patients in this study, 17 were from the Finnish center and of these 17 women 16 also participated in Studies I and V.

Study III: In this nationwide study all women (1455) treated by means of TVT in 38 out of 40 Finnish hospitals by the end of 1999 participated. The women had been selected to undergo TVT surgery according to local operation criteria in each of the 38 hospitals involved. In 40 cases concomitant surgery was performed. The rest of the patients underwent the TVT procedure alone. Patient characteristics were not reported, since the main purpose was to evaluate the problems that emerge when a new anti-incontinence procedure is taken into practice.

Study IV: The study involved 54 successive women who were referred to the urogynecological outpatient clinic owing to recurrent SUI and who were scheduled to undergo a TVT procedure. The inclusion criteria were the same as in Study I and 45 of these patients had also participated in Study I. The women's age varied from 38 to 76 years, and BMI from 20 to 30 kg/m^2.

The TVT operations in Studies I, II, IV and V were performed by experienced urogynecologists. Gynecologists of varying operative skills performed all other operations (Study III). Patient characteristics are displayed in Table 7.

Table 7. Preoperative patient characteristics

Variable	Study I	Study II	Study IV	Study V
Age (y)	56 (29–81)	52 (35–86)	57 (38–76)	55 (35–81)
BMI (kg/m^2)	25 (19–35)	Nr	25 (20–30)	25 (19–32)
Parity	2 (0–9)	2 (0–4)	Nr	
Vaginal deliveries				2 (0–9)
CS				0 (0–3)
Hysterectomy	66 [41]	Nr	Nr	52 [40]
Recurrent UI	45 [28]	0	51 [100]	33 [26]
Duration of symptoms (y)	10 (1–50)	13 (2–25)	10 (1–37)	10 (1–50)
MUI	59 [37]	25 [29]	3 [6]	11-45 [8.5–35]
LPU	18 [11]	0	6 [12]	11 [8.5]

Values are given as median (range) or n [%].
Nr = not reported; BMI = body mass index; CS = cesarean section; UI = urinary incontinence; MUI = mixed urinary incontinence; LPU = low-pressure urethra

2. Study protocol (Studies I, II, IV and V)

Pre- and postoperative evaluation in Studies I, II, IV and V included gynecological examination, a cough stress test, a 24-h pad test, a voiding diary, residual urine measurement and a VAS estimation by the patient of the severity of urinary symptoms. Additionally, preoperative urodynamics were assessed in all subjects in Studies I, II, IV and V and postoperative urodynamics in Studies I and II, whereas 45 of 54 subjects in Study IV and 42 of 129 subjects in Study V underwent postoperative urodynamics. Bacteriuria was ruled out before urodynamic investigations, and all studies included an additional postoperative urine test. In Studies I and V the women were postoperatively asked to express their opinion about the operation outcome by choosing from various alternatives (worse, unchanged, improved and cured) the one that best suited their situation. Hospital records were retrospectively studied as regards previous anti-incontinence operations in Studies I, IV and V.

Intra-operatively registered parameters were: immediate complications (Studies I–IV), the amount of local anesthetic (Studies I and IV), total operation time including the time for administering the

local anesthetic (Studies I, II and IV), any amount of blood loss (Studies I and IV) and amount of blood loss > 200 ml (Study II). Postoperatively, at the ward, the amount of residual urine (Studies I, IV) and length of hospital stay (Studies I, II, IV) were recorded. During every post-operative research visit hospital records were retrospectively studied as regards possible TVT-related problems that had emerged after hospital release (Studies I, II, IV, V).

3. Questionnaire (Study III)

A questionnaire about TVT-associated morbidity was sent to 38 out of 40 Finnish hospitals where TVT operations had been independently performed by the end of 1999 after an obligatory and systematic training period. The two excluded hospitals were the primary TVT training center and a hospital that did not use the standard TVT equipment. Questions covered the number of TVT operations performed and the numbers of the following complications: blood loss over 200 ml, bladder perforation, major vessel injuries, other per-operative complications, complete postoperative urinary retention, minor voiding difficulties (residual urine volume > 100 ml on the second postoperative day), retropubic hematomas, wound infection, defective healing of the vaginal incision, urinary tract infection, tape rejection and other postoperative complications. The nature of the complications was requested and the associated management procedures listed.

4. Surgical technique (Studies I–V)

The TVT procedures were performed in a standard manner as described by its inventor (Ulmsten *et al.* 1996). All surgeons were experienced urogynecologists (Studies I, II, IV and V) or gynecologists specially trained and certified for TVT surgery (Study III). Diluted (0.25%) prilocaine with adrenaline was used for local infiltration anesthesia. Diazepam, 5 mg orally, was given as premedication half an hour before surgery. During surgery one to three doses of 0.05 mg of Fentanyl® (fentanyl citrate, Janssen Pharmaceutica, Beerse, Belgium) was given intravenously for analgesia. One intravenous dose of 500 mg of metronidazole was given during the operation as the only prophylactic antibiotic treatment. The standard TVT set was used (Ethicon Inc., Sommerville, New Jersey, USA and Medscand Medical, Malmö, Sweden). Cystoscopy was performed twice during the operation, after each retropubic penetration by the TVT needle. Adjustment of the Prolene® tape was performed with a bladder volume of 250–400 ml. During vigorous coughing a

drop of liquid was allowed to appear at the external orifice of the urethra in order to avoid postoperative retention.

5. Clinical evaluation methods

5.1 Cough stress test (Studies I, II, IV, V)

The cough stress test was performed with a comfortably filled bladder (bladder volume ~ 200–300 ml), first in a semilithotomy position, and if no urine escaped, additionally in a standing position. Leakage in one of the positions was always registered as a positive test result.

5.2 Description of urge symptoms (Studies I, II, IV, V)

In Study I the subjects were considered to have urge symptoms if they answered positively to the question "Do you experience a strong desire to urinate in relation to stressful situations?". In Study II, urge symptoms included frequency, urgency and nocturia. In Study IV, women were considered to have urge symptoms if they had eight or more daytime micturition episodes, more than one nighttime micturition episode and a strong desire to urinate in relation to stressful situations. In Study V the definition in Study I, as well as the definition in Study IV were included and the results were compared.

5.3 Urodynamic measurement (Studies I, II, IV, V)

All urodynamic measurements were performed by gynecologists and included urethrocystometry and urethral profilometry in the sitting and/or semilithotomy positions according to previously described techniques (Ulmsten *et al.* 1977). The bladder was filled to ~ 300 ml with body-temperature saline at a rate of 50 ml/min (Study II) or 70 ml/min (Studies I, IV and V). The following parameters were registered: first sensation, bladder capacity, urethral length, MUCP and detrusor contractions. LPU was defined as MUCP below 20 cm H_2O at rest.

5.4 Visual analogue scale estimation (Studies I, II, IV, V)

A 10-cm-long line was printed on paper. Zero at the left end represented no urinary problems and 100 at the right end represented unbearable urinary problems. Patients were asked to estimate the severity of their SUI symptoms by ticking off the corresponding point on the line.

5.5 Patients' subjective verbal estimation (Studies I and V)

The women were asked to express their subjective opinions verbally as regards the success of the surgery by choosing from four alternatives (worse, unchanged, improved and cured) that which best described their present SUI situation.

5.6 Residual urine measurement (Studies I, II, IV, V)

Residual urine was measured by ultrasonography (Bladderscan®) or by catheterization.

5.7 Voiding diary

Patients were asked to report the amount of voided urine and the time of each voiding episode during 24 hours (Study V) or 48 hours (Study I, II, IV).

5.8 Pad tests (Studies I, II, IV, V)

The women were requested to perform home pad weight tests over a 24-hour period on a day that resembled that of their general lifestyle, but not, however, while menstruating.

6. TVT training program (Study III)

The university clinic in Finland that had been involved in the development of the TVT procedure invited one experienced urogynecologist from each of the four other university clinics to be trained to perform TVT operations. The indications for performing the operation and the possible risks and complications were carefully explained to the trainees. The importance of registering in detail perioperative and immediate postoperative complications was emphasized. First the trainees performed four to five operations together with the main instructor, after which each trainee performed two operations alone, with guidance from the instructor. Later on the main instructor visited each of the four university clinics and observed how three to four operations were carried out by the local TVT team. A certificate to perform TVT operations was granted if these operations went well. Finally, each urogynecologist in each of the four university clinics had to perform 20 TVT operations and if the results were good after a follow-up period of six months, they were authorized to teach other gynecologists in smaller hospitals within their own districts. In the end, each central and local hospital in Finland had one certified TVT surgeon and the university clinics possibly had several.

7. Reporting of operation results (Studies I, II, IV and V)

Study I: Subjects were regarded as cured if they were continent during urodynamics (no leakage and no bladder contractions), had a negative stress test result, had leakage of < 8 g/24 h as measured by the pad test, scored <5 on the VAS, and if they regarded themselves as cured. Subjects were regarded as improved if they had a negative stress test result, an improvement of ≥ 75% on the VAS and if they regarded themselves as improved. The outcomes for all other patients were classified as failures.

Study II: Subjects were regarded as cured if they had a negative stress test result, had leakage of < 10 g/24 h as measured by the pad test and if their VAS scores had improved by ≥ 90%. Subjects were regarded as improved if they had leakage of < 15 g/24 h or > 50% reduction of leakage as measured by the pad test and if their VAS scores had improved by ≥ 75%. The outcomes for all other patients were classified as failures.

Study IV: Subjects were regarded as objectively cured if they had a negative stress test result and leakage of < 10 g/24 h as measured by the pad test. Subjects were regarded as subjectively cured if they scored ≤ 10 on the VAS. Subjects were regarded as objectively improved if they had a negative stress test result and > 80% reduction of leakage as measured by the pad test. Subjects were regarded as subjectively improved if they scored ≤ 25 on the VAS. The outcomes for all other patients were classified as failures.

Study V: The criterion for a negative pad test result was leakage of < 8 g/24 h. No other classifications were used.

8. Statistical analyses

In Study I binary and ordinal data from the preoperative and postoperative protocols were expressed as frequencies and paired *t*-tests were used to test changes in continuous variables. In Study II Wilcoxon's rank sum test was used to test changes in continuous variables. In Study III the likelihood ratio test in linear models was used to determine the significance of differences between hospitals. In Study IV pre- and postoperative data were processed as continuous variables and paired *t*-tests were used to find differences in mean values. Because of the small patient number in Study IV the robustness of the *t*-test made its use justified, although some of the variables were not strictly continuous. A probability value of < 0.05 was considered statistically significant in all studies. In Study V pre- and postoperative urodynamic, residual urine and voiding diary data were compared by using paired *t*-tests. Data on continuous variables in Study V were compared by using logistic regression analyses, whereas data on binary variables were compared by using Fisher's exact test. All statistical analyses were performed by using S-PLUS software (S-PLUS 2000 Guide to Statistics, Data Analysis Products Division, MathSoft, Seattle).

RESULTS

1. Short-term (< 5 years) effectiveness of the TVT procedure

The mean follow-up period in Study I was 1.3 years, with a range of 0.5–2 years. In Study I the cure rate in the total material was 87.0%, whereas the cure rates in different incontinence categories were as follows: primary SUI 88.0%, recurrent SUI 84.4%, MUI 81.4% and LPU 66.7%. The mean follow-up period in Study IV was 2.1 years, with a range of 2–5 years. Study IV involved only recurrent SUI patients, some of them had additional LPU or MUI; the objective cure rate was 89.6% and the subjective rate 80.4%.

In Study I the rate of negative postoperative cough tests was 93.8% in the total material (Table 8). In Study IV the rate of negative postoperative cough tests varied from 66.7% to 98.0% in different incontinence categories (Table 8). In Study I the rate of negative postoperative pad tests was 91.1% in the total material and it varied from 85.0% to 100% in different incontinence categories (Table 9). In Study IV the rate of negative postoperative pad tests varied from 66.7% to 84.3% in different incontinence categories (Table 9). The amount of urinary leakage measured in the pad test (Table 10) as well as the severity scores of subjective SUI symptoms measured by means of the VAS (Table 11), had decreased significantly in both of the above studies after the TVT procedure. In Study I the urge symptom improvement rate was 80% and in Study IV the urge symptom cure rate was 100%.

2. Long-term (≥ 5 years) effectiveness of the TVT procedure

The mean follow-up period in Study II was 4.7 years, with a range of 4–5.8 years. Study II involved only primary SUI patients, the cure rate being 84.7%, the rate of negative postoperative cough tests 92.9% (Table 8) and the rate of negative postoperative pad tests 80% (Table 9). The mean follow-up period in Study V was 6.0 years, with a range of 4.8–8.7 years. In Study V the rate of negative postoperative cough tests was 76.7% in the total material and it varied from 63.6% to 79.2% in different incontinence categories (Table 8). In Study V the rate of negative postoperative pad tests was 85.3% in the total material and it varied from 81.8% to 93.9% in different incontinence categories (Table 9). The amount of urinary leakage measured in the pad test (Table 10) as well as the severity scores of subjective SUI symptoms measured by means of the VAS (Table 11), had

decreased significantly in both of the above studies after the TVT procedure. In Study II the urge symptom cure rate was 56% and in Study V, 89%.

Table 8. Rate of negative postoperative cough tests in different incontinence categories

Study	Follow-up	Primary	Recurrent	MUI	LPU	Total
I	short term	#	#	#	#	93.8%
IV	short term	-	98.0%	66.7%	83.3%	98.0%
II	long term	92.9%	-	#	-	92.9%
V	long term	79.2%	69.7%	68.9%	63.6%	76.7%

MUI = mixed urinary incontinence; # = data not extractable from the total results

Table 9. Rate of negative (<10 g/24 h) postoperative pad tests in different incontinence categories

Study	Follow-up	Primary	Recurrent	MUI	LPU	Total
I	short term	91.7%	88.9%	85.0%	100%	91.1%
IV	short term	-	84.3%	66.7%	66.7%	84.3%
II	long term	80%	-	#	-	80%
V	long term	82.3%	93.9%	82.2%	81.8%	85.3%

MUI = mixed urinary incontinence; # = data not extractable from the total results

Table 10. Pad test results

Study	Follow-up	Preoperative amount of urinary leakage (g/24 h)	Postoperative amount of urinary leakage (g/24 h)	*p*
I	short term	59 (10–365)	0 (0–33)	<0.0001
IV	short term	62.5 (15–197)	0 (0–31)	<0.0001
II	long term	40.5 (11–315)	0 (0–35)	<0.0001
V	long term	57 (10–364)	0 (0–310)	<0.0001

Values are median (range).

Table 11. Visual analogue scale (VAS) results

Study	Follow-up	Preoperative VAS score	Postoperative VAS score	*p*
I	short term	75 (25–100)	2 (0–83)	<0.0001
IV	short term	80 (35–100)	3 (0–43)	<0.0001
II	long term	75 (35–100)	0 (0–90)	<0.0001
V	long term	75 (26–99)	4 (0–96)	<0.0001

Values are median (range).

3. Intraoperative and immediate postoperative (≤ 2 months) adverse events associated with the TVT procedure

The operating time, including the time to induce local anesthesia, varied from 10 to 55 minutes (Studies I, II and IV). The amount of local anesthetic ranged from 60 to 98 ml (Studies I and IV). The mean blood loss was 16.0 ml ± 52.7 in Study I and 16.7 ml ± 49.7 in Study IV. The proportion of patients who were discharged in the afternoon of the operation day was 80% in Study I and 75% in Study IV. In Study II the hospital stay varied from 1 to 5 days, the median duration being 1 day at two centers and 2.5 days at the third center. There were no clinically significant differences in postoperative versus preoperative urodynamic parameters. The occurrence of estimated bleeding of > 200 ml ranged from 0% to 3.3% and the rate of bladder perforations from 1.1% to 5.9%. The rate of voiding difficulty varied from 4.3% to 7.6%, the rate of retropubic hematomas from 0% to 3.3%, the rate of UTIs from 4.1% to 7.8% and the rate of wound infections from 0% to 2.5% (Table 12). No clinically significant differences were noted in the postoperative versus preoperative residual urine volumes (Table 13).

Table 12. Intraoperative and immediate postoperative adverse events associated with the TVT procedure

Adverse events	Study I	Study II	Study III	Study IV
Estimated bleeding > 200 ml	3/161 1.9%	3/90 3.3%	27/1455 1.9%	0/51 0%
Bladder perforation	6/161 3.7%	1/90 1.1%	56/1455 3.8%	3/51 5.9%
Voiding difficulty	7/161 4.3%	4/90 4.4%	111/1455 7.6%	3/51 5.9%
Retropubic hematoma	2/161 1.2%	3/90 3.3%	27/1455 1.9%	0/51 0%
UTI	10/161 6.2%	7/90 7.8%	59/1455 4.1%	3/51 5.9%
Wound infection	4/161 2.5%	1/90 1.1%	12/1455 0.8%	0/51 0%

Values are n (%).
UTI = urinary tract infection

Table 13. Residual urine volumes (ml)

Study	Follow-up	Preoperative	Postoperative	*p*
I	short term	5 (0–80)	0 (0–90)	<0.0001
IV	short term	7.5 (0–80)	10 (0–50)	NS
II	long term	2 (0–75)	6.5 (0–100)	0.0002
V	long term	5 (0–80)	0 (0–302)	NS

Values are median (range).

In the nationwide evaluation of 1455 TVT operations, bladder perforation (3.8%) was the most usual perioperative complication, whereas voiding difficulty (7.6%) was the most usual postoperative complication (Table 14).

Table 14. Nationwide number of complications associated with 1455 TVT operations performed in Finland by the end of 1999

	n	%	95% CI
Perioperative complications			
Blood loss over 200 ml	27	1.9	1.2–2.7
Bladder perforation	56	3.8	2.9–5.0
Injury of the epigastric vessel	1	0.1	0.0–0.4
Injury of the obturator nerve	1	0.1	0.0–0.4
Vaginal hematoma	1	0.1	0.0–0.4
Urethral lesion	1	0.1	0.0–0.4
Postoperative complications			
Complete postoperative urinary retention	34	2.3	1.6–3.3
Voiding difficulty	111	7.6	6.3–9.2
Retropubic hematoma	27	1.9	1.2–2.7
Hematoma outside the retropubic area	7	0.5	0.2–1.0
Wound infection of the abdominal incision	12	0.8	0.4–1.4
Defective healing of the vaginal incision	10	0.7	0.3–1.3
Urinary tract infection	59	4.1	3.1–5.2
Urge symptoms	11	0.8	0.4–1.4
Dysuria	2	0.1	0.0–0.5
Vesicovaginal fistula	1	0.1	0.0–0.4
Urinary retention related to urological anomaly	1	0.1	0.0–0.4
Pain in the region of the gluteal muscle and thigh	3	0.2	0.0–0.6
Venous thrombosis	1	0.1	0.0–0.4
Seroma formation	1	0.1	0.0–0.4
Total	367		

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4. Long-term (> 2 months) adverse events associated with the TVT procedure

In Studies I, II, IV and V the *de novo* urge rates varied from 3.1% to 5.9%. In Studies II and V the urogenital prolapse rate varied from 1.6% to 2.3% and the rate of recurrent UTI from 1.2% to 9.3%. In Study V LUT symptoms were reported by 19.4% of the women and the tape was visualized in 3.1% of the women. Table 15 displays the adverse events associated with the TVT procedure at a mean of 6 years postoperatively.

Table 15. Adverse events associated with the TVT procedure at a mean of 6 years postoperatively

Urge symptoms	6/129	4.7%
Tape visualized	4/129	3.1%
tape resection scheduled	2/129	1.6%
UTI during the last 2 years		
1–2 infections	37/129	28.7%
> 2 infections	12/129	9.3%
LUT symptoms	25/129	19.4%
did not feel cessation of the urine stream	2/129	1.6%
a stinging feeling in the urethra in connection with a strong desire to void	1/129	0.8%
weaker urine stream	11/129	8.5%
feeling of incomplete bladder emptying	5/129	3.9%
a need to urinate in a more upright position	4/129	3.1%
difficulties in starting the urine stream	1/129	0.8%
excessive straining in order to totally empty the bladder	1/129	0.8%
Urogenital prolapses	2/129	1.6%
Tape resection during the long term follow-up period	1/129	0.8%

Values are n (%).

DISCUSSION

Female SUI is a major burden for the woman herself as well as for the community (Hampel *et al.* 2004). The two traditional "gold standard" anti-incontinence procedures are abdominal colposuspensions and pubovaginal slings. However, Wiskind found in his review of 131 patients that 27% of the women required one or more operations to correct genital prolapse after they had undergone Burch colposuspension (Wiskind *et al.* 1992). Furthermore, morbidity associated with traditional slings of autologous origin is strongly related to fascial harvesting, whereas allografts include the potential risk of viral and prion infections (Blander and Zimmern 2000). In order to avoid these problems, synthetic sling materials were developed. Unfortunately, urogenital tract erosions, which are major complications, have been particularly associated with the non-biological materials (Clemens *et al.* 2000). Monofilament polypropylene, however, seems to be an exception, and at present it is regarded as the most ideal synthetic sling material (Boublil *et al.* 2002; Hammad *et al.* 2005). As our knowledge of continence mechanisms has increased, the role of the mid-urethra in maintaining continence has become evident and a notable shift in anti-incontinence operation practices towards mid-urethral prolene tape procedures has taken place.

The present study was undertaken to study the effects and effectiveness of the new TVT procedure. There is no consensus of opinion concerning how cure after anti-incontinence procedures should be defined and what kind of outcome measures should be used (Black and Downs 1996; Hilton 2002; Kobashi and Govier 2005). The situation regarding the reporting of complications is the same; no uniform requirements exist (Black and Downs 1996). In the present study a VAS (Stach-Lempinen *et al.* 2001) was used as a quantification method for subjective SUI symptoms, whereas pad and stress tests were employed for objective assessment of signs of SUI. Verbal estimation as regards the success of the operation was included in Studies I and V. Urodynamic methods were mainly used to rule out preoperative detrusor overactivity. At present, however, there is evidence that TVT operations can be successfully performed without urodynamic evaluation (Laurikainen and Kiilholma 2003). Initially we included "continence during urodynamics" in the success criteria. Later on this criterion was abandoned owing to limited research resources and also because of the fact that no clinically significant changes were noted in postoperative versus preoperative urodynamic parameters. In the present study voiding diaries were consistently utilized to assess preoperative and postoperative frequencies.

Our initial approach in this study was to set criteria for cure as strictly as possible by combining results from objective as well as subjective evaluation methods. This, however, was gradually rejected, since it became difficult to compare the present results with other investigators' results. In Study IV objective and subjective cure rates were reported separately, and in Study V the results were described according to the evaluation methods used. Some variation within the separate evaluation methods also exists in the way success was defined. In Study I, success as assessed by means of the VAS was defined as a VAS score of <5. This, however, turned out to be a far too rigid limit, since it was often difficult to interpret the exact point at which the patient had marked the VAS. Therefore, in Study IV success as assessed by means of the VAS was defined as a VAS score of ≤ 10. Leakage of <8 g/24 h was initially used as a criterion for a negative pad test result. However, while pad weight gains in asymptomatic women have been found to range from 0 g to 10 g (Lose *et al.* 1989), pad test values of < 10 g/24 h were later on also considered to be negative in some of the studies.

Although comparison of results from each separate study in this thesis may be difficult because of the above-mentioned reasons, the separate results are, however, reliable. Firstly, several widely accepted methods were employed for patient evaluation (Lose *et al.* 1998). Secondly, the clinical evaluation methods were carried out in a standard manner. Thirdly, the majority of the patients were evaluated by a clinician who did not participate in the operations.

The new TVT method had only recently been launched for clinical practice when this study was undertaken. Only some studies of a pilot nature, comprising small case series, had previously been published. Although these studies were small, they were, however, very detailed, with great focus on the operative method as well as on the tape material. Relatively strong evidence suggested that this new method was feasible in clinical practice. Since the initial clinical experiences were also very promising, the popularity of the TVT procedure rapidly increased. The situation as a whole was unfavorable as regards randomization. Furthermore, knowing that patients who primarily agree to participate in a randomized study might withdraw when placed in a more invasive treatment group, we rejected the idea of randomization and chose a study set-up that would provide us with the second best level of evidence.

In the present study the short-term cure rate after the TVT procedure was 87.0% in a heterogeneous patient population comprising primary SUI, recurrent SUI, MUI and LPU cases, whereas in a homogeneous population comprising only recurrent SUI cases the objective cure rate was 89.6%

and the subjective rate 80.4%. These results are in the same range as short-term results after pubovaginal slings (Zaragoza 1996; Chaikin *et al*. 1998; Choe and Staskin 1999; Kuo 2001; Weinberger and Ostergard 1995; Young *et al*. 1995; Rutner *et al*. 2003) and open colposuspension (Galloway *et al.* 1987). Of course a comparison like this is not watertight. However, neither Ward and co-workers nor Liapis and co-workers were able to demonstrate differences between cure rates in randomized trials when they compared the TVT procedure with abdominal colposuspension. The cure rate after the TVT procedure varied from 36% to 81% at six months depending on the assessment method (Ward *et al.* 2002) and it was 84% at 24 months (Liapis *et al.* 2002). Valpas and co-workers compared the TVT procedure with laparoscopic colposuspension 6 weeks postoperatively and demonstrated cure rates of 93% and 88% for the respective procedures (Valpas *et al.* 2003). However, at 12 months the cure rate after the TVT procedure was 86% and after laparoscopic colposuspension it was only 57% (Valpas *et al.* 2004). Like laparoscopic colposuspension, bladder neck needle suspensions were also formerly marketed as effective minimally invasive procedures. The short-term cure rate of 72% was promising, but the long-term rate of 43% disappointing (Bergman *et al.* 1989; Bergman and Elia 1995). The suggestion, that follow-up after surgical therapies should be ≥ 5 years is closely argued (Leach *et al.* 1997).

In the present study, in a homogeneous population comprising only primary SUI cases the cure rate after the TVT procedure in the long term was 84.7%, the rate of negative cough test results 92.9% and the rate of negative pad test results 80%, whereas in the long term in a heterogeneous population comprising cases of primary SUI, recurrent SUI, MUI and LPU the rate of negative cough test results was 76.7% and the rate of negative pad test results was 85.3%. We found that the volume of urinary leakage measured in the pad test as well as the severity scores of subjective SUI symptoms measured by means of the VAS had decreased significantly in the long term in the homogeneous as well as in the heterogeneous populations. Our results are in the same range as the long-term results of pubovaginal slings (Morgan *et al.* 1985) and open colposuspension (Feyereisl *et al.* 1994; Alcalay *et al.* 1995; Kinn 1995; Drouin *et al.* 1999; Dietz and Wilson 2000; Lapitan *et al.* 2005). Unfortunately, the results of randomized controlled trials comparing the TVT procedure with other anti-incontinence procedures in the long term are not available. Hence level I evidence of the effectiveness of the TVT procedure in the long term is still lacking, although level II evidence exists.

Complications associated with anti-incontinence surgery are common (Kinchen *et al.* 2004; Taub *et al.* 2005). In the present study intraoperative and immediate postoperative complications occurred at

low rates after the TVT procedure. We evaluated TVT operations performed at a single center and at three centers and registered the following complications and their incidence ranges: wound infection 0–2.5%, estimated bleeding > 200 ml 0–3.3%, retropubic hematoma 0–3.3%, bladder perforation 1.1–5.9%, voiding difficulty 4.3–5.9% and UTI 5.9–7.8%. No pneumonia or sepsis occurred.

Regardless of a successful operation outcome when measured by objective means, a patient's subjective perception can be poorer as a result of long-term adverse events. At a mean of 4.5 years after open colposuspension, Galloway found only 44% of the women to be both continent and complication-free (Galloway *et al.* 1987). Kobashi and Govier compared the outcome of four separate sling techniques (SPARC, bone anchors/polypropylene mesh, bone anchors/cadaveric fascia, autologous fascia) in a study that involved use of a mailed validated questionnaire at a minimum of six months postoperatively. Success was defined as completely dry or SUI ≤1 /week. Success varied from 74.9% to 85.7%, but the completely dry rate varied from 36.1% to 45.2%. Urinary urgency (urgency not defined in the text) with or without urge incontinence was reported at a rate ranging from 24.4% to 33.3% (Kobashi and Govier 2005). At a mean of 16.3 months after TVT surgery Manikandan and co-workers discovered (using a mailed questionnaire) that 56% of the patients regarded themselves as cured and 23% as improved. Urinary urgency occurred at a rate of 45.7%, and urgency was defined as a strong sudden desire to pass urine (Manikandan *et al.* 2004). In the present study the rate of *de novo* urge symptoms varied from 3.1% to 5.9% and at a mean of 6 years after TVT surgery 68.2% of the women considered themselves to be cured. Generally, the TVT procedure has been associated with low *de novo* urge symptom rates. Segal and co-workers evaluated the prevalence of *de novo* overactive bladder symptoms from 6 weeks to 1 year after the TVT procedure by means of a validated quality-of -life questionnaire. They found that 4.3% of the women suffered from *de novo* overactive bladder symptoms, while 9.1% suffered from *de novo* urge incontinence symptoms (Segal *et al.* 2004). It is a general assumption that a too tightly placed sling might be the cause of urge symptoms. All the patients in the study reported by Segal and co-workers, as well as the majority of the patients in our study, underwent the TVT procedure under local anesthesia while all the patients in the study reported by Manikandan and co-workers had spinal anesthesia. It is unclear what impact this might have on the conflicting urge symptom rates after the TVT procedure. Additional long-term adverse events registered in the present study after the TVT procedure, were: urogenital prolapses 1.6–2.3%, tape exposure 3.1%, recurrent UTI 1.2–9.3% and LUT symptoms 19.4%. We detected no cases of tape erosion. Seventeen percent of the women reported symptoms possibly indicating reduced flow, but the majority of these women

had post-void urine residual volumes ranging from 0 to 82 ml. The tape resection rate was 2.3%. No woman underwent tape resection due to outflow obstruction.

The complication rates in the present study are similar to those reported in randomized trials in which the TVT procedure has been compared with abdominal colposuspension at 6 months and at 2 years postoperatively (Ward *et al.* 2002; Ward *et al.* 2004). Moreover, Ward and Hilton demonstrated that TVT surgery was associated with more operative complications than colposuspension, but colposuspension was associated with more postoperative complications. Bladder injuries and vaginal perforations were particularly associated with the TVT procedure, whereas wound infection and fever were associated with colposuspension (Ward *et al.* 2002).

In the present study the recorded amount of bleeding was generally low and local anesthesia was utilized in all cases, except in the nationwide study where additional anesthesia methods were also employed, because 2.7% of the women underwent concomitant surgery. However, in the nationwide study also, the majority of the women underwent the TVT procedure under local anesthesia. Operation times were short. Most of the patients were discharged from hospital later during the day of the operation. Some differences in hospitalization periods were noted between the different centers in the Nordic three-center study. In randomized studies in which the TVT procedure has been compared with open colposuspension, the TVT procedure has been associated with shorter hospitalization times and faster recovery (Liapis *et al.* 2002; Ward *et al.* 2002). The discharge reports provided by STAKES also show shorter hospitalization times for the TVT procedure than for open colposuspension, and an increasing annual amount of TVT operations are carried out on a day care basis.

The systematic nationwide TVT training process was of a unique nature. All the trainees were advised to keep specific records of intraoperative as well as immediate postoperative complications. After exclusion of the primary TVT training center, a postal questionnaire was sent out to all 38 Finnish hospitals where TVT operations had been independently performed (using a standard TVT kit) up to the end of 1999. Postoperative follow-up varied from 2 weeks to 2 months, and therefore it is possible that urge symptoms in this nationwide analysis were under-reported. However, the fact that during the training process all trainees were advised to keep specific records of complications adds a strong prospective element to our nationwide evaluation and the results can in most aspects be regarded as very reliable. All 1455 TVT operations, even the very first independently performed ones, were included in the study. Hence the complication rates are associated with the learning

curves of respective surgeons. We observed that the complication rates clearly declined after 15 operations. Groutz and co-workers observed in their study a decreasing bladder injury rate after 20 operations (Groutz *et al.* 2002). We found no significant difference in the ratio of number of complications to performed TVT operations between different hospital types. In the total material of 1455 TVT operations, injury of the epigastric vessel, injury of the obturator nerve, urethral lesion, vesicovaginal fistula and venous thrombosis were each reported at a rate of 0.1%. Other complications and their rates were found to be similar to the ones in our single center and three-center studies.

In the present study biases due to patient selection were minimized by including patient groups that all represented the general operation practice. The TVT operations were not only performed in university hospitals by extremely skilled surgeons (who had participated in elaboration of the TVT method), but also in other types of hospitals by ordinary gynecologists certified to carry out the TVT procedure. Our results suggest that after a proper training period the TVT operation is a safe and effective anti-incontinence procedure, which can be successfully performed in the majority of patients generally thought to benefit from anti-incontinence surgery.

CONCLUSIONS

On the basis of the present work, the following conclusions can be drawn:

1. The TVT operation is an effective anti-incontinence procedure for treating female stress urinary incontinence.

2. It is a safe anti-incontinence procedure for treating female stress urinary incontinence.

3. The general applicability of the TVT procedure is good.

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