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KIRSI RINNE

Comparison of Two Mid-Urethral Sling Operations and Their Effect on Urethral Mobility Assessed by Dynamic Magnetic Resonance Imaging

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and

their effect on urethral mobility assessed by

dynamic Magnetic Resonance Imaging

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ABSTRACT

Female urinary incontinence (UI) is a common condition, with a prevalence in the Finnish population ranging between 20% in women of the age of 25-60 years and 59% in women over 70 years of age. Female urinary incontinence has a high negative impact on quality of life, particularly on social, physical, psychological, occupational, and sexual aspects of life. Moreover, urinary incontinence has a major cost effect on the health care system.

Permanent cure of the most common form of urinary incontinence, i.e. stress urinary incontinence, is usually achieved by anti-incontinence surgery. New minimally invasive anti-incontinence surgical procedures aimed at supporting the middle portion of the urethra in order to achieve continence have resulted in higher cure rates and lower rates of morbidity than those found as a result of more invasive traditional anti-incontinence operations, which are aimed at correcting hypermobility of the bladder neck.

Two different approaches to support the mid-urethra have been presented, the retropubic and the obturator routes. By means of a multicenter randomized clinical trial carried out at seven centers in Finland we wanted to compare two different mid-urethral sling operations, TVT and TVT-O, for the treatment of female stress urinary incontinence in terms of cure rates and complication rates. In order to evaluate the validity of support of the mid-urethra as an important element of maintaining urinary continence in healthy volunteers and in stress urinary incontinent women before and after mid-urethral sling surgery, we carried out an investigation by means of dynamic magnetic resonance imaging (MRI).

Our randomized clinical trial, being one of the largest (n=273) and with the longest follow-up period, confirms the results of other follow-up studies. The cough stress test was negative as many as 95.5% in the TVT group after one year follow-up and 93.1% after three year follow-up. In the TVT-O group the cough stress was negative 94.6% and 89.5%, respectively. The medium-term cure rates were similar in both groups. Complication rates were low, with no difference between the groups.

The MRI studies were carried out at Kuopio University Hospital. By dynamic MR imaging the behavior of the mid-urethra of 15 healthy volunteers and 40 stress urinary incontinent women was assessed during different maneuvers. The results revealed a significant difference in the behavior of the mid-urethra between healthy continent women and urinary stress incontinent women. The mobility of mid-urethra of incontinent women was significantly restricted after both mid-urethral sling operations. The finding suggests that support of the mid-urethra is important in maintaining urinary continence.

National Library of Medicine Classification: WJ 146, WJ 168, WN 185
Medical Subject Headings: Female; Finland; Follow-up Studies; Magnetic Resonance Imaging; Multicenter Study; Quality of Life; Randomized Controlled Trial; Suburethral Slings; Treatment Outcome; Urethra; Urinary Incontinence, Stress/surgery

Rinne, Kirsi. Kahden vähänkajoavan virtsankarkailuleikkauksen tulosten ja haittavaikutusten vertailu. Keskivirtsaputken liikkeen kuvantaminen dynaamisella magneettitutkimuksella. Itä-Suomen yliopiston julkaisu. Terveystieteiden tiedekunnan väitöskirjat 33. 2010. 77 s.

TIIVISTELMÄ

Naisten virtsankarkailu on yleinen ongelma. Suomessa 20%:lla 25-60-vuotiaista naisista esiintyy virtsankarkailua ja yli 70-vuotiailla sitä esiintyy 59%:lla. Naisten virtsankarkailu huonontaa merkitsevästi naisen elämänlaatua vaikuttaen sosiaaliseen, fyysiseen, psykologiseen, ammatilliseen sekä seksuaaliseen elämään. Lisäksi virtsankarkailulla on suuri taloudellinen merkitys terveydenhuollon menoihin.

Pysyvään paranemiseen naisen ponnistusvirtsankarkailussa päästään usein vasta leikkauksella. Uudet vähänkajoavat virtsankarkailuleikkaukset pyrkivät tukemaan virtsaputken keskiosaa. Vähänkajoavilla leikkauksilla paranemisprosentit ovat yli 90% kuten perinteisellä Burchin mukaisella rakonkaulan kohotusleikkauksellakin. Kuitenkin vähänkajoavissa leikkauksissa haitat ovat pienempiä kuin rakonkaulan ylilliikkuvuutta korjaavilla leikkauksilla.

Käytössä on kaksi eri leikkaustapaa tukea virtsaputkea: häpyluun takaa kulkeva reitti ja obturator-aukkojen kautta kulkeva reitti. Vertasimme satunnaistetussa monikeskustutkimuksessa kahta keskivirtsaputkea tukevaa nauhaleikkausta keskenään: häpyluun takaa kulkevaa reittiä (TVT) ja obturator- aukkojen kautta kulkevaa reittiä (TVT-O). Tutkimus tehtiin seitsemässä eri sairaalassa Suomessa. Selvittääksemme keskivirtsaputken tukemisen tärkeyttä tutkimme dynaamisella MRI:llä keskivirtsaputken liikettä terveillä vapaaehtoisilla sekä virtsankarkailupotilailla ennen ja jälkeen vähänkajoavaa slinga-leikkausta.

Satunnaistettu kliininen tutkimuksemme on yksi suurimmista (n=273) ja pisimmän (36 kk) seurannan omaavista tutkimuksista. Paranemisprosentit olivat TVT ryhmässä 1 vuoden seurannan jälkeen 95.5% ja 3 vuoden jälkeen 93.1%. TVT-O ryhmässä parantuneitten osuus oli 94.6 % 1 vuoden jälkeen ja 89.5% 3 vuoden jälkeen. Tuloksemme tukevat muita keski-pitkän seurannan tutkimustuloksia, joissa paranemistulokset ovat korkeita ja eikä ryhmien välillä ei ole todettu merkittävää eroa. Haittavaikutukset olivat 1 ja 3 vuoden seurannoissa pieniä eikä leikkaustapojen välillä todettu eroja.

Dynaamiset magneettitutkimukset suoritettiin Kuopion yliopistollisessa keskussairaalassa. Keskivirtsaputken liikettä kuvannettiin 15 terveellä vapaaehtoisella ja 40 virtsankarkailupotilaalla. Magneettitutkimukset tehtiin erilaisissa toiminnallisissa testeissä. Dynaamisella magneettitutkimuksella voitiin kuvata merkittävä ero terveiden naisten ja virtsankarkailupotilaiden keskivirtsaputken liikkeessä. Keskivirtsaputken liike rajoittui merkittävästi molempien leikkaustapojen jälkeen. Tämä löydös tukee ajatusta, että virtsanputken keskikohdan tukeminen on erityisen tärkeää virtsanpidätyskyvyn kannalta.

National Library of Medicine Classification: WJ 146, WJ 168, WN 185
Yleinen suomalainen asiasanasto: elämänlaatu – naiset; magneettitutkimus;
virtsanpidätyskyvyttömyys – leikkaushoito – menetelmät, virtsaputki – tukeminen

To Jaakko, Roosa and Roope

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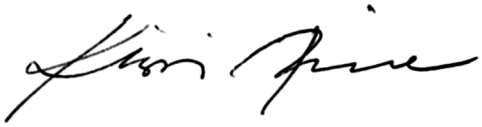


Kirsi Rinne

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 Rinne K, Laurikainen E, Kivelä A, Aukee P, Takala T, Valpas A, Nilsson CG. A randomized trial comparing TVT with TVT-O: 12-month results. Int Urogynecol J 2008; 19: 1049-1054.

II Palva K, Rinne K, Laurikainen E, Kivelä A, Aukee P, Takala T, Valpas A, Nilsson CG. A randomized trial comparing tension-free vaginal tape with tension-free vaginal tape-obturator: 36-month results. Int Urogynecol J 2010; 21: 1049-1055.

III Rinne K, Kainulainen S, Aukee S, Heinonen S, Nilsson CG. Dynamic magnetic resonance imaging of the behavior of the mid-urethra in healthy and stress urinary incontinent women. Acta Obstet Gynecol Scand 2010; 89: 373-379.

IV Rinne K, Kainulainen S, Aukee S, Heinonen S, Nilsson CG. Dynamic MRI confirms support of the mid-urethra by TVT and TVT-O surgery. Acta Obstet Gynecol Scand (submitted).

CONTENTS

TABLES

FIGURES

ABBREVIATIONS

BF	Biofeedback
BMI	Body mass index (kg/m^2)
DIS	Detrusor Instability Score
EMG	Electromyoraphy
EQ-5D	Euro quality of life five-dimensions
FDA	Food and Drug Administration (United States)
HERS	the Heart and Estrogen/Progestin Replacement Study
HRQoL	Health-related quality of life
HRT	Hormone Replacement Therapy
IIQ-7	Incontinence Impact Questionnaire
ICS	the International Continence Society
ISD	Intrinsic sphincter deficiency
MRI	Magnetic resonance imaging
MUCP	Maximal urethral closure pressure
MUI	Mixed urinary incontinence
OAB	Overactive bladder syndrome
PFMT	Pelvic floor muscle training
POP	Pelvic floor prolapse
POPQ	Pelvic floor prolapse quatification system
QoL	Quality of life
RCT	Randomized control trial
SERM	Selective estrogen receptor modulator
SUI	Stress urinary incontinence
SPSS	Statistical Package for Social Sciences
TVT	Tension-free vaginal tape
TVT-O	Tension-free vaginal tape obturator, transobturator tape inside-out technique
TOT	Transobturator tape, transobturator tape outside-in technique
UDI-6	Urogenital Distress Inventory
UISS	Urinary Incontinence Severity Score
UI	Urinary incontinence
UPP	Urethral Pressure Profile
UTI	Urinary tract infection
UUI	Urgency urinary incontinence
VAS	Visual analog scale
WHI	Women´s Health Initiative

APPENDICES

ORIGINAL PUBLICATIONS I- IV

1 INTRODUCTION

1.1 Definitions of modes of urinary incontinence (UI)

Urinary incontinence is defined by the International Continence Society (ICS) as the complaint of any involuntary leakage of urine (Abrams et al. 2002). Incontinence is classified into three common types: 1) stress urinary incontinence (SUI), 2) urgency urinary incontinence (UUI) and 3) mixed urinary incontinence (MUI). SUI is defined as involuntary leakage on effort or exertion, or on sneezing or coughing and UUI is involuntary leakage accompanied by or immediately preceded by urgency, whereas MUI is involuntary leakage associated with urgency and with exertion, effort, sneezing or coughing. Urodynamic SUI is defined as the involuntary leakage of urine during increased abdominal pressure, in absence of detrusor contraction (Abrams et al. 2002). The commonest type of female UI is stress (50%), followed by mixed (32%) and urgency (14%) (Minassian et al. 2003).

Subjectively, urgency, with or without urgency incontinence, and usually with frequent urination and nocturia, can be described as overactive bladder syndrome (OAB), urgency syndrome or urgency-frequency syndrome. This group is subdivided on the basis of urinary leakage into OAB wet and OAB dry (Toozs-Hobson et al. 2006).

2.1 Epidemiology

2.2 Prevalence

Urinary incontinence in women is a common condition. The reported prevalence of female UI ranges considerably from study to study. A possible explanation could be different definitions of urinary incontinence and different populations of women studied. Considerable evidence indicates that the prevalence increases with age. Pooled data from 17 different epidemiological studies, in which incontinence was judged to occur at least once per week, showed a linear increase with age (Milsom et al. 2000). The prevalence ranged from 3 to 58 percent, while the median was 28% (Thomas et al. 1980, Simeonova et al. 1999, Minassian et al. 2003).

The prevalence of incontinence in a Finnish female population has been found to be 20 % in the age group 25 to 60 years and 59% in women over 70 years of age (Mäkinen et al. 1992a, Nuotio et al. 2003). In a large study in the United States moderate or severe urinary incontinence was reported to affect 7% of women aged 20 to 39 years, 17% of women aged 40 to 59 years, 23% of women aged 60 to 79

years and 32% of women aged ≥80 years (Nygaard et al. 2008). The rates in men are approximately one third of those in women until the age of 80, when rates converge (DuBeau et al. 2009).

The proportion of women suffering from stress urinary incontinence decreased ($p<0.001$) with increasing age while the portion of women with urgency and mixed urinary incontinence increase ($p<0.01$) with increasing age (Simeonova et al. 1999).

Female urinary incontinence is not a static condition. Remission rates vary from 6% to 13% (Samuelsson et al. 2000). Although urinary incontinence is a common symptom among women, only 5 to 56% of incontinent women seek help (median 18%). Even with severe UI, only 42.5% of patients consulted health care professionals. Thus, UI remains an underreported and embarrassing condition across all countries and nations (Minassian et al. 2003).

2.3 Risk factors

2.3.1 Pregnancy

Urinary incontinence is a common condition during pregnancy, affecting 30 to 60 percent of pregnant women (Burgio et al. 2003). The prevalence of urinary incontinence is greater in parous women than in nulliparous women and it increases with increasing parity (Milsom et al. 1993). In the postpartum period 6 to 38% of women report mild leakage at 6 to 8 weeks postpartum (Burgio et al. 2003, Mørkved et al. 1999). Postpartum incontinence is significantly associated with several factors: smoking, incontinence during pregnancy, vaginal delivery, use of forceps, length of breast feeding, frequency of incontinence and body mass index. After the first delivery, women who deliver vaginally have a two-fold greater rate of incontinence than those delivering by cesarean section. Cesarean section reduces the risk of postpartum incontinence from 16 to 9.8 percent. However, to prevent one case of UI 15 cesarean sections would be needed (Press et al. 2007). The presence of SUI in early pregnancy increases the risk of SUI one year after delivery both vaginal delivery and cesarean section (van Brummen et al. 2006). The prevalence of postpartum SUI has been reported to be similar after spontaneous vaginal delivery (10.3%) and cesarean section performed because of obstructed labor (12%) (Groutz et al. 2007). This finding implies that the pathophysiologic process of SUI begins during pregnancy, prior to active labor or delivery. Moreover, a first vaginal delivery at

an older age (37 years or more) carries an increased risk for postpartum SUI (Groutz et al. 2007).

2.3.2 Lifestyle factors

Several cross-sectional studies have revealed a significant association between body mass index and incontinence (Brown et al. 1999, Hannestad et al 2003, Fornell et al. 2004). These studies have demonstrated that body mass index is a risk factor for all types of incontinence, being strongest for the mixed type. The EPICONT (The Norwegian Epidemiology of Incontinence in the County of Nord-Trodelag) study showed that a body mass index of ≥40 kg/m^2 increased the risk of severe mixed incontinence six-fold compared with women of normal weight (Hannestad et al 2003). Moreover, weight loss in obese women has been shown to improve incontinence symptoms (Bump et al. 1992, Subak et al. 2002). Lifestyle factors such as current heavy smoking (more than 20 cigarettes per day) or former smoking are associated with an elevated risk of incontinence. However, former smokers have been reported a higher rate of incontinence than current smokers (or those who had never smoked). In addition, tea drinkers are at a higher risk of all types of incontinence. No important correlation has been found between high intensity activity, intake of alcohol or coffee and urinary incontinence (Hannestad et al. 2003).

2.3.3 Age

Numerous epidemiologic studies have shown that the incidence of UI increases with age (Simeonova et al.1999, Peyrat et al 2002, Minassian et al. 2003). Along with age various co-morbid conditions including heart disease, asthma and depression increase the odds of urinary incontinence (Tennstedt et al. 2007). In addition to age functional impairment (mobility limitations) and cognitive impairment (e.g. dementia and stroke) are associated with UI (Hunskaar et al. 2000). Women with urinary incontinence are also likely to suffer from fecal incontinence and genital prolapse and vice versa (Fornell et al. 2004). In a meta-analysis of 12 studies the risk of urinary incontinence was found to be increased after hysterectomy among women of 60 years of age or older but not in women younger than 60 years (Brown et al. 2000).

2.3.4 Ethnicity

The prevalence of urinary incontinence according to race or ethnicity in women has been variably reported. In a large US survey the prevalence of weekly leakage in non-Hispanic white women (11.7%) was higher than in African American women (9.4%) (Tennstedt et al. 2007). In the Nurses Health Cohort study including 76.724 participants, the incidence of incontinence was higher in white women (7.3/100 person-years) compared with Asian (5.7/100 person-years) and black women (4.8/100 person-years) (Thom et al. 2005). Other studies however, have not shown differences between racial or ethnic groups. (Nygaard et al. 2008, Goode et al. 2008).

2.3.5 Menopause and HRT

The Cochrane review from (2003) supports the opinion that exogenous estrogen administration improves lower urinary tract symptoms (Moehrer et al 2003). Higher doses of estrogens have a greater benefit and the benefits are not dependent on the route of administration. However, in two large RCT studies: the Heart and Estrogen/progestin Replacement Study (HERS) and the Women´s Health Initiative (WHI), the hormone therapy was associated with worsening of urinary incontinence in older postmenopausal women (Simon et al. 2001, Wassertheil-Smoller et al. 2003). Both estrogens alone and in combination with progestins increased the prevalence of incontinence compared with placebo in the elderly population in these studies. The conflicting results may be explained by the fact that the trials included in the Cochrane review were expicitily designed to evaluate the effect of HRT on urinary incontinence, while the HERS and WHI trials were primarily designed to evaluate the effects on cardiovascular events. Estrogen dose, route of delivery, duration of use, user´s age and/or individual variations in collagen metabolism may also play a part (Erickson 2009).

2.4 Economic consequences of UI

2.4.1 Impact on society

The impact of UI on health care costs is substantial and increasing. Total urinary incontinence-related costs in the US were nearly $20 billion in 2000 (Hu et al. 2004). The distribution of the costs was: 56 percent consequence costs (e.g. nursing home costs), 32 percent treatment costs, 9 percent routine care costs, and 3 percent

diagnostic costs. These estimates do not include the cost of the effect on quality of life. Costs in the US have nearly doubled for older men and women during the past decade (Wagner et al.1998, Hu et al. 2004). In Sweden, the estimated annual cost related to UI was approximately 2% of the national Health Care budget (Milsom et al. 1992).

The majority of the direct costs of incontinence are attributed routine care, including absorbent pads, protection, and laundry. Women with severe urinary incontinence pay $900 annually for routine care (Subak et al. 2006). The costs were 65% higher for individuals suffering from urgency incontinence compared with those having stress incontinence. There are also costs arising from adverse consequences as dermatological problems, urinary tract infections and falls or broken bones caused by rushing to the bathroom (Hu et al. 2004).

2.5 Impact on the individual

The effect of incontinence on the individual can be measured by health-related quality of life (HRQoL) questionnaires. The questionnaires can be divided into three categories: generic instruments that provide a global value for HRQoL, condition-specific instruments that focus on single disease states such as incontinence, and instruments measuring single aspects of quality of life, such as pain or anxiety (Patrick et al. 1989).

The EuroQoL-5D and 15D (Sintonen et al. 1994) are examples of generic questionnaires. The 5D has 5 dimensions (3 levels in each dimension) and 15D questionnaire consists of 15 questions with 5 levels. These produce a single index score to be used for evaluation of the number of quality-adjusted years of life. EuroQoL questionnaires have also been used in a cost utility analysis of tension-free vaginal tape (Manca et al. 2003).

The first questionnaire used to measure the effect of being incontinent was developed by Norton(1982). This questionnaire consist of ten questions about the effects of incontinence upon physical health, mental well-being, domestic chores, social life, relationships with family, husband or boyfriend, work, dress and whether fear or odor or embarrassment restricted activities. Four possible responses were available. This instrument served as the basis of the Incontinence Impact Questionnaire (IIQ) developed by the Continence Program for Women Research Group (Wyman et al 1993).

The IIQ was designed to assess the impact of all forms of incontinence on quality of life. The original IIQ consisted of 30 questions. Later it was updated and this led to two additional questionnaires: 1) The Urogenital Distress Inventory (UDI) measuring prevalence and the bother it causes and 2) The Incontinence Impact Questionnaire assessing impact on quality of life. Short versions of these are widely used (Uebersax et al. 1995).

The Detrusor Instability Score (DIS) was designed to detect urgency incontinence based on a patient´s history. The instrument consists of 10 items each scored 0-2. The items include frequency, urgency, urgency incontinence, nocturia and inability to interrupt voiding. A sum of scores >7 indicates a high risk of urodynamically proven urgency incontinence.

A Visual Analog Scale (VAS) has been commonly used to detect pain.A 10 cm line is usedand the ends indicate either no pain or worst bearable pain. It has also been used to assess the degree of bother caused by urinary incontinence (Dowell 1999).

The Finnish Gynecological Society´s urogynecological working group designed the Urinary Incontinence Severity Score questionnaire (UISS) (Mäkinen et al. 1992b). The UISS questionnaire consists of 10 items scored 0-2 (0= not at all, 1=sometimes, 2=often). The score is expressed as a percentage of the possible maximum possible score. The VAS and the UISS questionnaire have proven to be valid, reproducible and responsive to treatment of UI women (Stach-Lempinen et al. 2004). Urodynamic parameters correlate poorly with incontinence-specific QoL measures (Stach-Lempinen et al. 2004). Among the clinical objective measures of the severity of urinary incontinence, the amount of leakage in the pad test has been found to be the best predictor of QoL impairment. Change in urine leakage best predicted change in QoL scores and VAS scores one year after initiating treatment (Stach-Lempinen et al. 2004).

A study by Schultz-Lampel revealed that urinary incontinence, Alzheimer´s disease and stroke are the three chronic health conditions that most adversely affect an individual´s health –related quality of life (Schultz-Lampel 2003). The advantage of determining health-related quality of life is that it allows comparison between different health conditions and can be used for cost-utility analysis. Willingness to pay for incontinence improvement is another measure of the physical and psychological burden of incontinence. According to Subak et al. (2006), women are ready to pay $70 per month for a 100% improvement. African-American women were willing to pay

4- to 6-fold more than white women for similar improvement in incontinence. Willingness to pay increased with household income to over 2.3-fold more in the highest compared with the lowest income categories (Subak et al. 2006).

2.6 Theories on the cause of stress urinary incontinence

More than 200 surgical procedures for treatment of female stress urinary incontinence have been described, a fact that indicates that understanding of the causes of stress urinary incontinence has remained obscure. Several theories on the pathophysiology of SUI have been proposed.

2.6.1 The bladder neck concept

Early theories about SUI were focused on a lack of sphincteric compression of the urethra at the bladder neck during straining. The first sling procedure was described in 1907 by Giordano, who utilized the gracilis muscle as a sphincteric sling around the urethra (Giordano 1907, Schulz et al 2006). Later, Goebell, Frangenheim and Stoeckel used the pyramidalis muscles elongated by a strip of the rectus muscle fascia as a pubovaginal sling for the purpose of supporting the bladder neck (Schulz et al 2006). In 1913, Howard Kelly described a vaginal technique to suture together the torn or relaxed tissues at the neck of the bladder (Kelly 1913). Later studies revealed that the long-term success of using Kelly´s sutures was only 60% (Bergman 1995). Victor Bonney (1923) suggested that incontinence is caused by a sudden and abnormal displacement of the urethra during straining with concomitant alteration of the angle at the urethrovesical junction immediately dorsal to the symphysis. In order to avoid this hypermobility of the position of the bladder neck surgical fixation techniques were developed (Schulz et al. 2006). Marshall, Marchetti and Krantz (1949) described a fixation technique, in which the bladder neck was sutured to the periosteum of the dorsal surface of the symphysis pubis (Schulz et al 2006). The technical problems of retaining sutures in the periosteum and the risk of osteitis complications led to the development of the colposuspension procedure, in which the vaginal wall at the level of the bladder neck was sutured to Cooper´s ligament in order to correct hypermobility of the bladder neck (Burch 1961).

Enhörning launched the pressure transmission theory, according to which the proximal urethra and the bladder neck must be located intra-abdominally above the pelvic floor, so that intra-abdominal pressure affecting the bladder is equally

transmitted to the urethra, thus compressing the urethra and avoiding urinary leakage (Enhörning 1961). This theory has been criticized for several reasons. Firstly, DeLancey showed in cadaveric studies that the female urethra is not located above the pelvic floor (DeLancey 1994). Secondly, there is little correlation between the position of the urethra and SUI (Fantl 1986, Shafik 1992). Thirdly, during coughing, urethral pressure rise precedes bladder pressure rise among continent women (Constantinou 1982). Moreover, urethral pressure is partly actively created, disproving the idea of passive pressure transmission (Lose 1991).

2.6.2 The mid-urethra concept

A number of separate findings on the anatomy and function of the urethra directed attention towards the mid-urethra as an important element in maintaining continence. The pubourethral ligaments as a support for the middle portion of the urethra were first described by Zaccharin (1968). These ligaments were elegantly shown by DeLancey to connect the mid-urethra and the posterior surface of symphysis pubis (DeLancey 1994). Histological studies by Huisman revealed an area of rich vascularization located specifically at the mid-urethra (Huisman 1983). Pronounced urethral pulsatility was found at the mid-urethra in fertile women indicating a rich supply of arterial blood vessels (Asmussen and Ulmsten 1983). By radiological urethrocystography Westby et al demonstrated how urine flow was interrupted at the mid-urethra in continent women voiding and asked to hold their urine (Westby et al. 1982).

The Integral Theory, later called the mid-urethral theory, was formulated on the basis of the above-described functional and anatomical aspects of the urethra and presented in 1993 (Petros and Ulmsten 1993). According to this theory the mid-urethra is supported by the pubourethral ligaments and the anterior vaginal wall, while part of the pubo-coccygeal muscle inserts at the level of the mid-urethra. Forward forces of these elements on the urethra together with dorso-caudal forces of the levator plate on the bladder and the bladder neck cause closure of the urethra at its middle part by kinking. Weakness or damage to any part of this system would result in defective closure of the urethra and urinary incontinence.

A minimally invasive surgical procedure for treatment of stress incontinence was subsequently developed on the basis of the mid-urethra theory. This procedure, the Tension-free Vaginal Tape (TVT) operation put the theory into practice and has been

proven to be an effective and safe surgical intervention for treatment of stress incontinence and has gained the status of “Gold Standard” of incontinence surgery.

2.7 Diagnostic investigation of SUI

2.7.1 Urodynamic tests

2.7.1.1 Non-invasive urodynamics

2.7.1.1.1 Stress tests

A stress test is generally used to objectively demonstrate urinary leakage objectively. Stress is brought about either by coughing (cough stress test) or by a Valsalva maneuver (Valsalva stress test). During the test the bladder volume should be 200-300ml, either filled by saline through clean catheterization or spontaneously filled to a comfortable volume, preferable tested by ultrasonography. The stress test is regarded as being positive, if involuntary leakage can be demonstrated during coughing. The test should be performed both in a lithotomy position and standing up. The positive predictive value of a positive stress test is around 88% (Hsu 1999). Reliability is more consistent in women with pure SUI than in other forms of UI (Swift and Yoon 1999). However, a negative stress test cannot rule out SUI.

2.7.1.1.2 Pad-weighing tests

By calculating the weight increase of pre-weighed protective pads used during a fixed time period or during specific physical activity the occurrence and amount of urinary leakage can objectively be measured. These pad tests are either short-term 1-hour tests performed in the clinic or home-administered tests of longer duration, mostly 24-48 hours. Ryhammer et al. compared short- and long-term pad tests, and found the short-term tests to be easy and quick to perform providing information immediately. Patient compliance can be monitored and activities can be standardized enabling comparison between the groups (Ryhammer et al.1999). Many studies have shown that the positive predictive value of the 1–h test is high (90%), but the negative predictive value is relatively low. It fails to detect urinary leakage in 15-45% of patients (Versi et al. 1986a and 1996, Klarskov et al. 1984, Lose et al.1986). Standardization only exists only for the ICS 1-hour test.

The predictive value of a negative 24-h home test (<8g/24h, Victor et al. 1987) has been demonstrated to be superior to that of the 1-h test, while the positive predictive value is comparable in patients with stress and mixed incontinence (Lose 1989). The

24-hour home-based pad test is reliable and reflects the severity of incontinence in everyday life. It seems to be superior to the stress test and voiding cystourethrography in detecting urinary leakage (Mouritsen 1989). Obviously a pad test cannot be used to diagnose the type of urinary incontinence, but a positive test result strongly indicates urinary incontinence. Reproducibility is good for both 24-h and 48-h test (Karantanis et al 2005, Versi et al. 1996).

2.7.1.1.3 Voiding diary

A voiding diary includes the time at which each void takes place, the voided volume, the intake of fluid and episodes of leakage and urgency. Recording of micturition and symptoms for a minimum of 2 days, preferably 3-5 days, is recommended. From the recordings, the average voided volume, voiding frequency, nocturia, incontinence episode frequency as well as pad usage per day can be determined. Recording of micturitions provides invaluable informations for the assessment of voiding disorders and for follow-up of treatment.

2.7.1.1.4 Measurement of residual urine volume

Measurement of the volume of urine remaining in the bladder after spontaneous micturation is of importance, because it has some relationship to the risk of adverse events such as urinary infection. Measurement of residual volume (<100 ml) can be performed by invasive catheterization or by non-invasive ultrasonographic imaging. Residual volumes observed at the end of invasive diagnostic tests must be interpreted with caution. The result can be inaccurate because of difficulty in voiding after instrumentation of the urinary tract.

2.7.1.2 Invasive urodynamic tests

Complete urodynamic evaluation includes filling and voiding cystometry. During artificial filling of the bladder (filling rate 50 ml/min) intravesical pressure is measured by a thin pressure catheter in the bladder. In current practice, abdominal pressure is also estimated by a pressure catheter placed either in the vagina or the rectum. Detrusor pressure is obtained by subtracting abdominal pressure from intravesical pressure. Pressure-flow measurements during voiding can be performed with a thin pressure catheter in the bladder during voiding.

The parameters recorded during cystometry are the patient´s first sensation of voiding, normal and strong sensation of voiding, urgency, bladder capacity, bladder compliance and detrusor pressure. Cystometry helps to detect an overactive detrusor. In patients suffering from stress urinary incontinence, cystometry confirms the diagnosis when leakage occurs during an increase in intra-abdominal pressure during straining in the absence of detrusor contractions. Because there is an overlap of urodynamic findings between incontinent and continent women, the diagnosis of incontinence should not be based on a single parameter. A positive cough stress test together with a negative cystometric recording concerning detrusor activity is the most reliable technique for detecting urodynamic SUI (Kauppila 1982, Swift 1995).

Urethral pressure can be measured using a microtransducer mounted on a catheter placed in the urethra. By slowly withdrawing the catheter, urethral and bladder pressures can be recorded simultaneously giving the Urethral Pressure Profile (UPP). A static profile can be obtained at rest and a stress profile by having the patient cough repeatedly during catheter withdrawal. Maximal urethral closure pressure (MUCP) is defined as the maximum difference between urethral pressure and intravesical pressure. An MUCP <20 cmH_20 is suggestive of an intrinsic sphincter deficiency (ISD) (Abrams et al. 2005).

Negative correlations between MUCP and age and parity have been observed. There is also a trend towards lower MUCP with previous incontinence surgery (Dietz et al. 2002, Hilton and Stanton 1983). Dietz et al also observed a positive correlation between urethral diameter measured by perineal ultrasonography and MUCP, which agrees with a recent report showing reduced urethral sphincter thickness in women suffering from urinary incontinence. Moreover, urethral thickness has been shown to decrease with advancing age, as does MUCP (Yang 1991). Hypermobility and levator muscle contraction registered during ultrasound imaging did, however, not correlate with any UPP measurements (Dietz and Clarke 2001).

The results of urethral pressure profile measurements are dependent on many technical and patient–related factors. Reproducibility of the measurements is not always consistent. Invasive urodynamic measurement must be considered as a complementary investigation and must always be interpreted with clinical data and the results of the other morphological and radiological investigations.

2.7.2 Electomyography

Electromyography (EMG) is concerned with study of the electrical potentials generated by depolarization occuring in striated muscle fibers. Needle EMG is an accurate method to investigate small muscle areas and to detect suspected peripheral nervous system lesions (Podnar and Vodusek 2001).

Needle EMG is uncomfortable and therefore unsuitable for repeated measurements. Surface EMG has been used as a well tolerated method to study muscular function within occupational health and sports medicine (Sihvonen 1991, Kankaanpää 1998). Surface electrodes pick up the electrical activity of superficial muscles. The amplitude reflects the number and size of action potentials and the complex signal is analyzed by computer.

Surface EMG, however, has been criticized because of two limitations. Firstly, it does not measure direct muscle force and secondly, a change of the electrode position can cause a significant change in derived electrical muscle activity (Ferdjallah 1998).

2.7.3 Imaging methods

2.7.3.1 Radiologic imaging of the lower urinary tract

The original technique of lateral cystourethrography was described by Hodkinson, one of the first to emphasize the importance of accurate study of urethrovesical relationships (Hodgkinson 1953). Although this technique has been known for over 50 years and has been widely used as a diagnostic tool of female urinary incontinence, the indications for cystourethrography are currently limited. Cystourethrography has been used to observe the relationship between the bladder base, the urethra and the pubic bones both at rest and during provocative maneuvers such as straining, coughing, sneezing and during micturition (Tubaro et al 2006).

Imaging studies have involved comparison of cystourethrography with dynamic MRI and with perineal ultrasonographic imaging. Gufler et al showed good correlations between MRI and lateral urethrocystography measurement data as regards the bladder neck position and the extension of cystocele (Gufler et al. 2000).

2.7.3.2 Ultrasonography

Ultrasonography is a supplementary investigational tool also used in urogynecology. It allows documentation of functional and morphologic findings. Two basic ultrasonographic techniques, based on the mode of probe used, can be

distinguished: the endosonographic and external techniques. Two endosonographic techniques, the endoanal and transvaginal technique are associated with probe–induced changes in bladder anatomy (Koelbl et al. 1995). The transabdominal technique has been replaced by other external techniques, except in the case of determination of residual urine volumes. The reason why mainly the perineal and introital external techniques are in use is that these examinations can be performed with the same probes as used in obstetric and gynecological ultrasonographic examinations. The frequencies used in these probes are 3.5-5.0 MHZ in perineal ultrasonography and 5.0-7.5 MHZ in introital ultrasonography (Tunn et al. 2005).

Although the diagnostic value of ultrasonography in assessing the urethra and bladder in women with stress urinary incontinence was described as early as 1980, recommendations for standardized perineal and introital ultrasonographic examination were not published until 1995 (Tunn et al. 2003). The newest recommendations were updated in 2005 (Tunn et al. 2005). Perineal and introital techniques are equally good in depicting the internal urethral orifice and the lower edge of symphysis. The pubic bone has been used as a stable pelvic landmark.

2.7.3.2.1 Bladder neck localization

The bladder neck can be determinated by a coordinate system based on the longitudinal axis of the pubic bone (Schaer et al. 1995). Another way to determine the bladder neck is to measure a distance and an angle (Creighton et al. 1992, Pregazzi et al. 2002). The length of a line between the bladder neck and the inferior border of the symphysis pubis and the angle between this line and the midline of the symphysis can be determined. This alpha angle measurement is performed according to the technique first described by Mouritsen and Rasmussen (1993). The height of the bladder neck is determined as the distance between the bladder neck and a horizontal line drawn at the lower border of the symphysis. Measurement of the height of the bladder neck has been used to assess its position. The retrovesical angle has been used as a quantitative finding. One side of this angle lies along the proximal urethra and the other side along the tangent of the bladder base.

2.7.3.2.2 Funneling

Funneling of the proximal urethra is a common finding in women suffering from stress urinary incontinence, but may also be observed in continent women. In a study by

Schaer funneling could not be demonstrated in continent nulliparous women but was frequently found in incontinent parous women (Schaer et al. 1999). Versi et al. however showed that funneling of the bladder neck may be a common variant and not a sign of incontinence (Versi et al. 1986b). There is a wide variation in the incidence of urethral funneling in women with stress urinary incontinence during straining. Reported rates range from 18.6-97.4%. In a study by Harms et al. (2007) funneling of the bladder neck was decreased from 37.2% preoperatively to 17.3% postoperatively ($p<0.0001$). The continence rate was 57.5% in persistent postoperative funneling versus 96.2% in the group without postoperative funneling ($p<0.0001$).The TVT procedure clearly reduces funneling of the bladder neck region and correction of a funnel is associated with higher success rates. The majority of patients who are cured despite a persistent funnel after mid-urethral sling have delayed cure (Harms et al. 2007).

In a perineal ultrasonographic study carried out by Sarlos et al. (2003) funneling of the bladder neck was seen in 57.5% of SUI patients preoperatively. After TVT operation all patients had negative cough stress test. Postoperatively 39.1% of the cases had persistent funneling. There was no significant difference in pre- and postoperative bladder neck mobility during Valsalva (Sarlos et al. 2003).

The pathogenesis of urethral funneling is still unclear. Tunn et al. (2005), using MRI, did not find any morphological defects of the urethra, levator ani muscle or endopelvic fascia in cases of funneling. Using transrectal ultrasonography, the internal smooth sphincter and outer striated sphincter of the urethra have been described as being thinner in women with SUI (Kuo 1998). Urethral funneling is also correlated with a low MUCP (Dietz et al. 2001).

2.7.3.2.3 Mobility of the urethra and bladder neck

Perineal ultrasonography can also be used during provocation test. The Valsalva and cough stress tests affect the mobility of the bladder and the urethra and can be visualized by ultrasonography. The bladder neck has been shown to move in a ventro-cephalad direction during pelvic floor muscle contraction in healthy women (Miller et al. 2001) thus increasing closure pressure within the urethra as it is displaced towards the symphysis pubis (Bump et al. 1991). In contrast, the bladder neck moves in a dorsal-caudad direction during maximal straining, as intra-abdominal pressure increases (Howard et al. 2000). Dietz et al have presented

normal values for urethral, bladder, cervical and rectal mobility in 118 young continent nulliparous women. They found wide ranges of values for all parameters, such as the retrovesical angle, urethral rotation and bladder neck mobility. The average bladder neck movement during the Valsalva maneuver was 17.3 mm (range 1.2-40.2mm) (Dietz et al. 2004). Peschers et al. showed a mean bladder neck movement of 14 mm. In this study bladder neck mobility was significantly less during coughing (8± 4mm) than during Valsalva (15±10 mm) (Peschers et al. 2001).

The etiology of SUI is likely to be multifactorial (Wilson and Herbison 1996).Urethral hypermobility is one of the potential etiological factors explaining stress urinary incontinence. Bai et al performed a study involving 38 continent and 90 stress urinary incontinent patients to evaluate the effects and predictive value of urethral hypermobility in terms of bladder neck movement in the diagnosis of stress urinary incontinence in both the supine and the sitting position. They could not detect any significant difference between the two groups (Bai et al. 2004). Shek and Dietz measured urethral mobility before and after first delivery. They found in 3D/4D ultrasonography that proximal urethral mobility was significantly increased after childbirth (Shek and Dietz 2008). The distal urethra was consistently less mobile than the proximal part ($p<0.001$). This hypermobility is already seen before vaginal delivery (King 1998). Wijma documented this observation as early as at 12 to 16 gestational weeks in nulliparas (Wijma et al. 2001). Howard and DeLancey (2000) demonstrated racial differences in bladder neck mobility: white women had greater bladder neck mobility than black nulliparous continent women. Age (Dietz et al. 2007) and menopause (Wakavaiachi et al. 2001) do not appear to be associated with significant changes in the ultrasonographic parameters of bladder neck mobility.

Viereck et al defined urethral hypermobility as a linear dorsocaudal movement over 15 mm during straining in perineal ultrasonography. All postoperative measurements showed a significant reduction of funneling and hypermobility 6 months after colposuspension. They found that bladder neck hypermobility after colposuspension surgery was associated with higher recurrence rate of SUI and postoperative complications than in patinents without this hypermobility (Viereck et al 2006).

Schaer et al. have shown that perineal ultrasonography is superior to urethrocystography in assessing bladder neck mobility during maximal Valsalva (Schaer et al 1995). In a study by Dietz et al. a good correlation between ultrasonographic findings and the clinical pelvic floor prolapse quantification system

(POPQ) was found looking at the anterior and central compartments (Dietz et al. 2001).

2.7.3.2.4 Urethral kinking

A parameter which can be investigated by dynamic ultrasonography is the urethral knee or urethral kinking. Lo et al. detected urethral knee angles ultrasonographically in all surgically cured and improved patients during maximal straining (Lo et al. 2001). Virtanen et al, however did not find any urethral knee or kinking by perineal ultrasonography after TVT operation (Virtanen et al. 2002).

2.7.3.2.5 Localization of the mid-urethral sling

Recently, Masata et al. reported reduced mobility of all parts of the urethra during Valsalva after a successful TVT operation. The operation also decreased funneling during maximal Valsalva (Masata et al. 2006).There are a few ultrasonographic studies in which TVT and TVT-O tape localizations have been compared. Long et al. showed that the TVT-O tape is located more distally under the urethra than the TVT tape, resulting in less urethral compression and lower rate of dynamic kinking of the urethra (Long et al. 2008). Dietz and de Tayrac reported no association between tape placement and subjective cure rate following TVT surgery (Dietz et al. 2004, deTayrac et al. 2006). This may imply a high margin of safety and high success rate. Over a median of 1.6 years of observation TVT tape seems to migrate caudally together with the tissue in which it is implanted. No contraction or shortening was detected by Dietz et al. (2003). Similarly, Lo et al. showed a 1.7 mm downward descent of TVT tape at 3 years of follow-up (Lo et al. 2001).

2.7.3.2.6 Role of ultrasonography

Ultrasonography is a cheap and easily available tool for clinical assessment of morphological and functional changes in the female pelvic floor before and after surgery. It has replaced radiological techniques. There is, however, a need to find standard approaches and more objective parameters using ultrasonography for the diagnosis of urinary incontinence in the near future.

Patients with postoperative voiding disturbances following mid-urethral sling insertion should undergo ultrasonography to assess the position and configuration of the tape. The examination should be performed at rest and during a Valsalva maneuver.

Moreover, perineal ultrasonography could be used as a visual feedback tool when teaching how to contract pelvic floor muscles. Perineal ultrasonographic assessment has been reported to allow quantification of levator activity and visual feedback was easily understood and readily accepted by women (Dietz et al. 2001). Bernstein et al. were able to show hypertrophy of the pelvic floor muscles in urinary incontinent women after pelvic floor training (Bernstein et al. 1997). Khullar et al. have found correlation between bladder wall thickness and urgency incontinence (Khullar et al. 1994). While there is an association between increased detrusor wall thickness and detrusor overactivity in urodynamic testing, ultrasonic measurement of detrusor wall thickness cannot replace urodynamic testing (Lekskulchai and Dietz 2008).

Measurements of bladder neck behavior and different angles associated with the pelvic floor structures give us additional information of urethral motion in continent and incontinent women. Wide overlapping of findings between continent and incontinent women, however, exits. Sufficient evidence of ultrasonographic investigations being able to predict SUI do not presently exist.

2.7.3.3 MR Imaging

In the past, cadaveric dissections have been used to aid understanding of the female pelvic anatomy but these have been limited by artifacts of fixation and other changes which occur when living tissue become non-viable (Hoyte et al. 2006). Strohbehn et al. compared MRI findings among 13 cadavers and demonstrated that those of the female urethra and surrounding tissues reflected actual anatomy (Strohbehn et al 1996). MRI has been used to assess normal pelvic anatomy as well as pelvic floor dysfunction in conditions such as pelvic floor laxity or urinary incontinence.

At the beginning of the 1990s pelvic floor dysfunctions were imaged by static MR: later dynamic MR imaging became more popular (Yang et al. 1991) and now MR based 3D constructions of female pelvic floor structures are available (Fielding et al. 2000). There is no standardized protocol for MRI of patients with pelvic floor disorders. However, the main elements of dynamic MR imaging are to image the patient at rest and during maximal straining or rectal evacuation. The rectum and vagina can be opacified by ultrasonographic gel or gel with gadolinium. Imaging is then performed with the patient supine in a closed-magnet unit or with the patient sitting in an open-magnetic unit. A pelvic phased-array coil is used on the lower abdomen to ensure complete coverage of the pelvic organs. However, intracavitary

MR coils, endovaginal (Kim et al. 2003, Tan et al. 1998), endorectal (Nurenberg et al. 1997) and endourethral (Macura et al. 2006) coils have subsequently allowed high-resolution of the female urethral MR imaging.

The spectrum of abnormalities detected by MR imaging in women with stress urinary incontinence is classified as (a) findings related to urethral sphincter deficiency and (b) defects of the urethral support ligaments and urethral hypermobility. These abnormalities include a small urethral sphincter, funneling at the bladder neck, distortion of the urethral support ligaments, cystocele, asymmetric pubococcygeus muscles, abnormal shape of the vagina, enlargement of the retropubic space, and an increased vesicourethral angle (Macura et al. 2006). The results of some MRI studies suggest that general laxity of the pelvic floor is associated with stress urinary incontinence (Unterweger et al. 2001, Fielding et al. 1998). The pubococcygeus muscle can be evaluated well with MR imaging. Loss of the symmetric appearance of the pubococcygeus muscle, lateral deviation and thinning or complete attenuation of the muscle have been found in patients with urinary incontinence (Stoker et al. 2003, Macura et al. 2006). Kirscher-Hermanns et al reported increased T1 signal intensity (lighter in the picture) as evidence of muscle atrophy in 66% of their subjects with stress urinary incontinence suggesting a relationship between levator weakness and SUI (Kirscher-Hermanns et al. 1993).

These results could however be a reflection of the wide normal range of levator variation. Tunn et al for example found a two- to three-fold difference in distance, area, and volume of pelvic floor structures among a group of 20 asymptomatic nulliparous women (Tunn et al. 2003).

2.7.3.3.1 MR Imaging of the female urethra

The urethral muscle volume depends on both the thickness of the muscle (smooth and striated layers included), and the length of the sphincter. The mean normal thickness of the urethral sphincter has been shown to be 4.3mm±0.9 (SD) mm at the mid-urethral level, and the anatomical length of the urethra to be 38mm±3 as imaged by MRI. The striated muscle is thicker on the ventral and lateral sides of the urethra, and thinner on the dorsal side (Macura et al. 2004). Ageing causes an increase of the volume of connective tissue and decrease of the volume of striated muscle and the volume of vascular tissue. Thinning of the striated sphincter muscle has been shown in patients with stress incontinence (Athanasiou et al. 1999). Patients with significant

loss of sphincteric muscle volume and patients with a short urethra may suffer from intrinsic sphincter deficiency (Macura et al. 2004).

According to the findings by Macura on MRI studies three groups of ligaments support the female urethra: periurethral ligaments arising from the puborectalis muscle coursing ventral to the urethra, the paraurethral ligaments arising from the lateral wall of the urethra to the periurethral ligaments, and the pubourethral ligaments. Distortion or failure of the urethral ligaments to hold the urethra behind the pubic bone may cause stress incontinence (Kim et al. 2003).

2.7.3.3.2 MR imaging of pelvic floor descent

The pubococcygeal line extending from the inferior part of the symphysis pubis to the last coccygeal joint, is the most commonly reported reference line used in dynamic MRI (Figure 2.7.3). Gousse et al. showed that pelvic organ prolapse was accurately staged by dynamic MR imaging for the anterior and the central compartment, but not for the posterior compartment (Gousse et al. 2000).The pubococcygeal line approximates the plane of the levator muscle plate. Yang et al. have suggested that a normal vertical distance of the bladder neck from the pubococcygeal line at strain should be less than 1 cm from the pubococcygeal line (Yang et al. 1991). Another reference line used is the mid-pubic line for evaluating pelvic floor descent (Woodfield et al. 2010). This line was expected to correspond with the hymenal level. Agreement between clinical and MR staging was however only moderate. In a study by Fauconnier et al. clinical measurement points were compared with POP-Q points on dynamic MR images. Good correlation has been found between clinical and MRI staging for anterior and central compartment (Fauconnier et al. 2008).

2.7.3.3.3 Levator muscle MR imaging

Fielding et al. demonstrated the feasibility of using an MR-based 3D technique and estimated the normal range of levator volume in 10 asymptomatic women aged 22-33 years (Fielding et al. 2000). Hoyte et al. showed that the levator symphysis gap (anterior puborectalis attachment disruption) is bigger in SUI and POP patients than in healthy controls (Hoyte et al. 2001).

MR-based segmentation has also been used to generate color maps of the levator ani muscle, with the color varying according to the muscle thickness at each point.

This color-mapping technique was first used by Fielding et al. to detect bladder tumors (Fielding et al. 2002).

2.7.3.3.4 MRI after incontinence surgery

Schuettoff et al. compared introital ultrasonography and MRI to locate the polypropylene tape after mid-urethral sling operations. Depiction by MRI was limited and was poorer in comparison with ultrasonography, especially at a sub- or paraurethral location. Retropubically, however, MRI was more suitable for evaluating the TVT tape (Schuettoff et al. 2006).

Perk et al found that the bladder base was significantly lower and the posterior urethro-vesical angle was significantly increased after a colposuspension operation compared with findings preoperatively (Perk et al 2002). MR imaging has been used before and after tension-free vaginal tape procedure. Using MRI, no excess scar formation after TVT insertion has been identified (Tunn et al 2007).

To clarify the spatial relationship of female pelvic structures and mid-urethral slings MRI investigations have been performed. Krissi et al measured the distance between the tension-free vaginal tape and the iliofemoral vessels. The distance between the tape and the major vessels was 55 - 56 mm (Krissi et al 2003).

After transobturator tape outside-in technique Fernandez et al showed that the lateral bladder wall was the structure closest (11-12 $\pm$ 4.6 mm) to the tape at the passage through the obturator foramen. They found that the distance from the obturator tape to the iliac vessels was 42-43$\pm$10-11mm suggesting a low risk of vascular injury (Fernandez et al 2008).

2.7.3.3.5 The role of MRI in assessing female incontinence

Magnetic resonance imaging is a promising diagnostic tool having excellent soft tissue contrast and multiplanar acquisition. It allows investigation of the three compartments of the female pelvic floor without any ionizing radiation. Proper validation of the method however is lacking. MRI studies have involved small sample sizes and differences are difficult to compare because of differences in examination and evaluation routines. On the other hand the cost of dynamic MRI is higher than that of ultrasonography, and MRI is less easily available (Dalpiaz et al 2006).

Figure 2.7.3. Pubococcygeal reference line

2.8 Treatment alternatives

2.8.1 Conservative treatment of stress urinary incontinence

2.8.1.1 Lifestyle changes

Conservative treatment options for SUI can be divided into three categories: lifestyle changes, physiotherapy and pharmacological treatment. Lifestyle changes, as weight loss, giving up smoking or treating chronic conditions such as cough and constipation might have a beneficial effect on UI, since they are clearly associated with it (Hannestad et al. 2003). Weight loss in obese women has been shown to improve incontinence symptoms and quality of life (Bump et al. 1992, Subak et al. 2009). Inspite of reports indicating that high caffeine intake is related to detrusor instability (Arya 2000), which in turn may cause urinary incontinence, no association between coffee and incontinence has been found in cross-sectional studies (Burgio et al.1991, Brown et al. 1999).

2.8.1.2 Pelvic floor muscle training

Pelvic floor exercises first developed by Kegel 1948 form the basis of conservative therapy of SUI. Kegel´s cure rate was 84% after pelvic floor muscle training (Kegel 1948). Pelvic floor muscle training is recommended as first line treatment for stress and mixed UI in women (Hay-Smith et al 2006, Wilson 2005).

The role of biofeedback in pelvic floor muscle training is controversal. In a randomized study by Mørkved et al. no significant difference was found between simple PFT and biofeedback (BF) groups in cure or improvement rates (67% and 65%) (Mørkved et al.2002). In a Finnish randomized study pelvic floor muscle activity was increased and urine leakage was decreased after three months of training and improvement was significantly better in the biofeedback group than in the PFMT alone group (Aukee et al. 2003). Women with insufficient or no awareness of how to contract their pelvic floor muscles might benefit from adjuvant biofeedback therapy (Berghmans et al. 1998). The role of transversus abdominis muscle training alone or combined with PFMT is also unclear. At present there is insufficient evidence for the use of transversus abdominis muscle training instead of or in addition to PFMT for women with UI (Bø et al. 2009). There is insufficient evidence to determine whether pelvic floor muscle training during pregnancy is effective at preventing urinary UI in childbearing women.

The PFMT effect seems greater in women with pure stress urinary incontinence and in those who participate in supervised PFMT program for at least three months (Dumoulin et al. 2010). After five years organized pelvic floor muscle training, incontinence was significantly increased assessed by pad test and a leakage index. Seventy-five percent of the women showed no leakage during a cough stress test and 70% were satisfied (Bø et al. 1996). The benefit of intensive pelvic floor muscle training seen after 6 months was not maintained 15 years later. Long-term adherence to training was low (Bø et al. 2005).

Based on available evidence pelvic floor muscle training is probably no better than available pharmacotherapy, though there are fewer side effects and it is more cost-effective (Brunenberg et al 2006) and can therefore be recommended as a first-line conservative treatment alternative. It is important to counsel patients regarding realistic expectations and to schedule follow-up visits so that they can be offered effective treatment if pelvic floor muscle training fails. To clarify the clinical role of PFMT larger, well-designed, well-powered RCTs are needed (Brostrom et al. 2008).

2.8.1.3 Pharmacological treatment

Pharmacological treatment of SUI is designed to increase intraurethral closure forces by acting on smooth or striated muscle sphincter tone. Phenypropanolamin α-adrenoreceptor agonists have a limited efficacy and side effects caused by these drugs restrict their clinical use.

There are only a few pharmacological treatment options for SUI. Duloxetine is the first licensed drug developed for SUI. It is a combination of norepinephrine and serotonin reuptake inhibitor and has proven to be effective in the treatment of female SUI (Cardozo et al. 2005).In a Cochrane review the conclusion was that duloxetine reduced the frequency of incontinence episodes and improved quality-of-life scores (Mariappan et al. 2007). We know relatively little about how women decide on whether they want surgery or medical therapy, but the majority of women initially offered drug therapy will eventually undergo surgery for their incontinence. The most limiting factor of duloxetine usage is poor tolerance of adverse symptoms appearing at the recommended dose. The mechanism of duloxetine and its correct place in a treatment schedule is uncertain.

Local estradiol relieves vaginal dryness, dysuria and dyspareunia without endometrial hyperplasia (Henriksson et al. 1996), but does not decrease the

number of stress urinary leakage episodes or the amount of leakage (Cody et al. 2009).

2.8.2 Surgical treatment

2.8.2.1 Methods to stabilize the bladder neck

The first sling operation for treatment of female urinary incontinence was invented by Giordano (1907). He tried to create a sphincter by wrapping the urethra with the gracilis muscle. In 1910 Goebell reported on a method where the pyramidalis muscles were used as a sling from above (Schulz et al 2006). Frangenheim 1914 extended the often too short pyramidalis muscles by a strip of the rectus fascia (Schulz et al 2006). Stoeckel (1917) further developed the method by adding a vaginal approach in order to be able to place the sling at the bladder neck with less risk of bladder injury (Schulz et al 2006). Further modifications and improvements of the combined pubo-vaginal sling principle have been presented by Aldridge 1942 and McGuire 1978(Schulz et al 2006). These pubo-vaginal slings were major invasive procedures with high risk of intra- and post-operative complications.

In an attempt to minimize the invasiveness of incontinence surgery Pereyra developed in 1959 the first bladder neck suspension method, which later on was modified in many ways by Stamey in1973 and Raz in 1981 (Schulz et al 2006). The needle suspension operations were the first less invasive surgical operations for female urinary incontinence, in which the bladder neck was elevated by sutures placed at the bladder neck by specially designed needles brought down to the bladder neck from above. Later follow-up of the cure rates revealed poor performance and as fistulation around the sutures appeared to an unacceptable rate, the method was largely abandoned.

A paper by Marshall, Marchetti and Krantz entitled The correction of stress incontinence by simple vesicourethral suspension was publiced in 1949 (Marshall et al 1949). This operation was recommended for patients whose first operation had failed. In this method the whole urethra was fixed to the pubic bone. The Marshall-Marchetti-Krantz procedure was associated with problems of osteitis pubis and difficulties in retaining sutures in the periosteum. To solve these problems Burch suggested that the bladder neck could be stabilized by colposuspension where the vaginal wall is sutured to Cooper´s ligament (Burch 1961). The objective success rate of this colposuspension operation range from 68 to 95.6%. A Cochrane review

of open retropubic colposuspension revealed a slow decline in cure to 70% after 5 years follow-up. Voiding problems such as de novo urgency and urinary retention were common after colposuspension (Lapitan et al 2009). Development of enterocele or rectocele has been recognized as a relatively common potential postoperative complication of the colposuspension procedure (Ward and Hilton 2008). Despite these risks the open Burch colposuspension procedure has been the gold standard of female stress urinary incontinence surgery for years.

2.8.2.2 Methods to stabilize the mid-urethra

The Tension-free vaginal tape (TVT) procedure was introduced by Ulmsten and co-workers in 1995 (Ulmsten and Petros 1995). The TVT procedure was developed on the basis of the mid-urethral theory. The goal was to create a minimal invasive technique performed under local anesthesia, in order to facilitate same-day discharge. The basic aim was to develop a standardized procedure with intra-operative testing of proper adjustment of the tape by a cough stress test (Ulmsten et al. 1996) (Fig 2.7.1).

Several sling materials were tested and the final tape chosen was a synthetic polypropylene monofilamentous mesh (type 1), with a pore size between 75 and 150 microns, which allows the in-growth of fibrous tissue, leucocytes and macrophages to avoid bacterial colonization. Another goal of the standardized operations was to facilitate training of doctors to perform the procedure. Local anesthesia in addition to enabling same-day discharge was also utilized as a safety measure in that it created an element of hydro-dissection of the tissues, which facilitates passage of the tape into the appropriate layers of tissue, thus avoiding possible complications. It also allows the intra-operative cough test to be performed, which helps in adjusting the tape tension to be loose enough, thus avoiding postoperative voiding difficulties.

This ambulatory technique has become the most popular female incontinence operation since the late 1990´s. It has excellent long-term results, it is easy to perform and the complication rate is low. After 11 years 90% of the women involved have been reported to have both a negative cough stress test and a negative pad test being objectively cured (Nilsson et al. 2008). In Austrian and Finnish registers of complications associated with the TVT procedure, rates have been low (Tamussino et al. 2001,Kuuva et al. 2002). The most common intra-operative

complication of bladder perforation was seen at rates of 3.8 and 2.7 respectively in the Finnish and the Austrian reports. The most common post-operative complication related to TVT is voiding difficulties seen at a rate ranging between 2.5 and 19.7 % (Karram et al. 2003, Abouassaly et al. 2004 (8-17%).

Soon after introduction of the tension-free vaginal tape procedure, several copies and modifications were presented. The IVS® sling using a type III multifilament, miniporous polypropylene mesh as the tape material, was introduced as in the TVT procedure with a vaginal approach retropubically through the abdominal wall. The IVS procedure has been found to be associated with an up to 24 % rate of sling erosion and fistulation, requiring tape removal (Lim et al. 2005). The Sparc procedure involves an abdominal approach retropubically aiming at the mid-urethra. The tape material is a type I polypropylene mesh. The Sparc procedure is associated with a higher rate of bladder perforation and tape protrusion than the TVT procedure (Lord et al. 2006, Tseng et al. 2005).

Retropubic placement of the tape has been associated with a potential risk of bladder injury and very rarely bowl and blood vessel injuries. To avoid these kind of complications a different route of tape placement was first introduced by Delorme in 2001. In his technique mid-urethra tapes are brought from the inner aspect of the thighs through the obturator membrane to support the mid-urethra, an “outside-in” technique (Delorme et al. 2001). DeLeval presented his “inside-out” technique in 2003, in which the tape was placed at the midurethra and then brought through the obturator membrane to exit at the inner aspect of the thighs (deLeval 2003) (Fig 2.7.2). These obturator approaches avoid intra-abdominal structures and thus potential injuries of the same. The methods, however, have been associated with abscesses and hematomas of the obturator region and groin pain (Zumbe et al. 2008, Latthe et al. 2010).

In order to further decrease the invasiveness of an incontinence operation so called mini-sling or single-incision sling procedures have been launched. The first of the kind was the TVT-Secure®, after which several modifications have been introduced. The short sling tapes are fixed to the obturator membrane or the urogenital diaphragm by different anchoring systems. Despite high expectations the mini-sling procedures still have some complications with lower objective and subjective cure rates compared with TVT (Basu et al. 2010).

2.8.3. Comparison of different surgical procedures

2.8.3.1 Randomized clinical trials comparing traditional procedures with TVT

The introduction of new surgical procedures for treatment of SUI requires basic research on materials as well as randomized prospective clinical studies or multicenter databases to identify long-term outcomes and complications. Up to May 2010 only 5 RCT:s have been published comparing TVT with the traditional colposuspension operation. The largest one by Ward and Hilton included 14 centers in the UK and Ireland and follow-up times of 2 and 5 years (Ward et al. 2004, 2008). There was no statistical difference between the objective cure rates (66-75%) versus (57-69%) respectively, but there was a significantly more rapid recovery after TVT surgery. The operation time and hospital stay were shorter in the TVT group. Moreover, the colposuspension group more often needed later surgery for urogenital prolapsed, whereas bladder perforation was more common in the TVT group.

There are only 4 trials in which laparoscopic colposuspension and TVT have been compared. Valpas et al. found that TVT was more effective than laparoscopic colposuspension (Valpas et al. 2004).

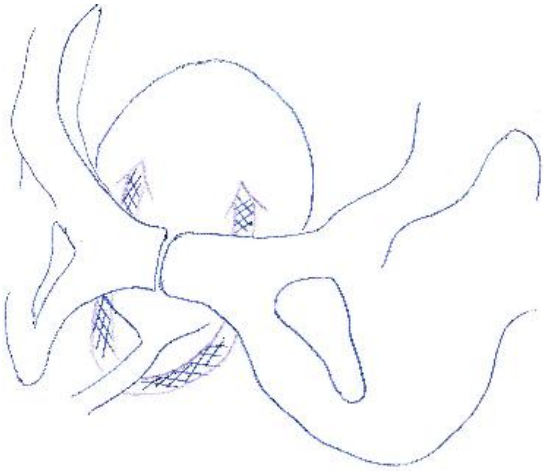


Figure 2.7.1 Tension-free vaginal tape (TVT)

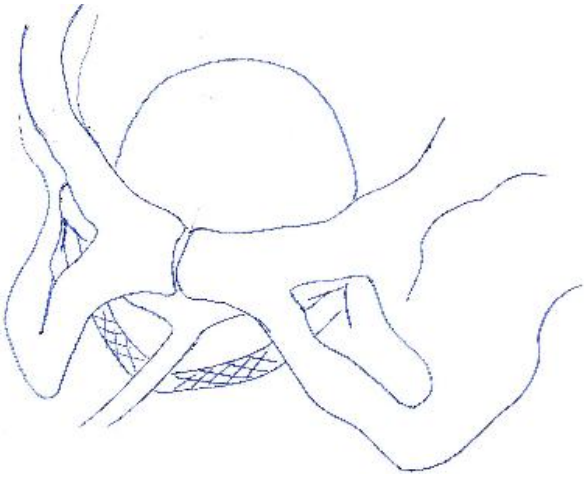


Figure 2.7.2 Tension-free vaginal tape obturator (TVT-O)

2.8.3.2. TVT versus retropubic modifications

According to the latest Cochrane review the retropubic bottom-to-top route was more effective than top-to-bottom route with fewer voiding dysfunctions, bladder perforations and tape erosions. Monofilament tapes were associated with significantly higher objective cure rates compared with multifilament tapes and fewer tape erosion (1.3% versus 6%) (Ogah et al. 2009).

2.8.3.3. TVT versus obturator methods

The latest Cochrane review (2009), covering 62 trials involving 7100 women showed that obturator slings were less favorable than the retropubic route in terms of objective cure (84% versus 88%), although there was no difference in subjective cure rates. The obturator sling was associated with fewer cases of voiding dysfunction, blood loss and bladder perforation (0.3% versus 5.5 %) and there was a shorter operation time.

3. AIMS OF THE STUDY

The primary aim of the present study was to compare two different mid-urethral sling operations for the treatment of female stress urinary incontinence and to image the behavior of the mid-urethra in healthy volunteers, in stress urinary incontinent patients after mid-urethral sling operation, by using dynamic MR imaging.

Specific aims were:

1. to compare rates of cure and complications of the tension-free vaginal tape (TVT) with those of the tension-free vaginal tape obturator (TVT-O) procedure after one and three year of follow-up

2. to image the behavior of the mid-urethra in healthy volunteers and in stress urinary incontinent women by dynamic MR imaging

3. to evaluate the change in behavior of the mid-urethra of stress urinary incontinent women before and after TVT or TVT-O procedures by dynamic MR imaging and compare the postoperative results with conditions in healthy volunteers

4 SUBJECTS AND METHODS

4.1 PATIENTS

4.1.1 Patient population in Studies I and II

The patient population of Studies I and study II were recruited into a prospective, randomized, multicenter study carried out in seven clinical centers in Finland (four university hospitals and three central hospitals) for the purpose of comparing two different mid-urethra sling procedures: the TVT and the TVT-O. Two hundred and seventy-three women were recruited between March 2004 and November 2005. The trial was approved by the Ethics Committee of Helsinki University Central Hospital and written informed consent to participate was obtained from each patient. Inclusion criteria were a history of stress urinary incontinence, an indication for surgical treatment of stress urinary incontinence, a positive cough stress test and a detrusor instability score (DIS) of seven or less. The exclusion criteria were previous incontinence surgery, a residual urine volume >100 ml, any anomaly of the lower urinary tract, current urinary tract infection (UTI) or more than three UTI episodes within the past year, urogenital prolapse of more than second degree (Baden and Walker 1972), BMI>35 kg/m2, previous pelvic radiation therapy, active malignancy, anticoagulant therapy, hemophilia, neurological disease that may be associated with bladder disorders, anticholinergic or duloxetine medication, lack of informed consent or immobility.

Sample size calculation was performed assuming that a 10% difference in cure rate and/or a 10% difference in complication rates would be clinically significant. An assumed cure rate of 95% for the TVT procedure a 70% power to show a 10% difference, would require a sample size of 260 patients, with 130 in each arm. The investigators called an independent randomization center located in Helsinki. Randomization was performed by computer-generated random allocation in a ratio of 1:1 in balanced blocks of 4.

4.1.2 Patient population in Studies III and IV

Studies III and IV were prospective observational trials carried out at the Kuopio University Hospital. In Study III, sixteen healthy volunteers and 42 women with stress urinary incontinence underwent dynamic MRI at rest, during pelvic floor contraction, coughing and voiding. All the stress urinary incontinent women had positive cough stress test and a Detrusor Instability Score of seven or less suggesting absence of urgency urinary incontinence. Acceptance for the studies was obtained from Kuopio University Hospital Ethics Committee and each patient gave written informed consent.

The exclusion criteria were previous incontinence surgery, urogenital prolapse of more than second degree according to Baden-Walker classification, current urinary tract infection (UTI) or more than three UTI episodes within the past year, active malignancy, previous radiation therapy, any neurogenic disease associated with bladder disorders, immobility of the patient and inability to understand the purpose of the study.

In Study IV the 40 stress urinary incontinent women recruited into Study III who had undergone preoperative dynamic MRI underwent a mid-urethral sling operation. Dynamic MRI was performed postoperatively at rest, and during pelvic floor muscle contraction, straining, coughing and voiding. The first twenty women underwent a TVT operation, and the following twenty women underwent a TVT-O procedure. The characteristics of all study populations are presented in Table 5.1.

4.2 METHODS

4.2.1 Surgical procedures

4.2.1.1 Tension-free vaginal tape procedure

The tension-free vaginal tape procedure was performed according to Ulmsten et al. (1996). All patients in Studies I and II were operated under local anesthesia using prilocain and adrenalin diluted to 0.25%. Single doses of prophylactic antibiotics(cefuroxime 1.5g or metronidazole 500 mg) were given to the patients intra-operatively. Commercial TVT kits were used (TVT Gynecare, Ethicon, Somerville, NJ, USA). Cystoscopy using a 70 degree lens was carried out twice during the TVT operation in order to detect bladder injury. An intraoperative cough stress test was performed with a bladder filled with 300 ml of saline. The tape was adjusted to a

tension allowing only a few drops of saline to escape on vigorous coughing. The bladder was emptied at the end of the operation by catheterization. Within 3 hours after the operation the women were asked to void and residual urine volumes were measured by ultrasonography (Fig 2.7.1).

4.2.1.2 Tension-free vaginal tape obturator procedure

The tension-free vaginal tape-obturator procedure was performed as described by de Leval (2003). The procedure was performed under local anesthesia using diluted (0.25%) prilocain and adrenalin and the same principles regarading prophylactic antibiotics were followed as for the TVT procedure. Commercial TVT-O kit were used (Gynecare, Ethicon, Johnson & Johnson,Somerville, New Jersey, USA). The TVT-O procedure is a ´inside–out´ technique. Cystoscopy was carried out only once during the TVT-O operation. Tape adjustment and postoperative residual urine volume measurements were undertaken in the same manner as with the TVT procedure (Fig 2.7.2).

4.2.2 Outcome measures

4.2.2.1 24-h pad test (Study I –II)

A 24-hour pad-weighing test was used as an objective measure of the amount of urinary leakage. Women were provided with pre-weighed pads to be used for 24 hours. After use the pads were weighed by the women themselves using scales also provided by the clinics. The weight difference was used as an objective measurement of the amount of urine leakage. The patients were provided with specific diaries for entering the weight data. A weight gain of more than 8 grams was regarded as a positive pad-test (Victor et al. 1987).

4.2.2.2 Cough stress test (Studies I –IV)

A cough stress test was used as another objective sign of urinary leakage. The cough stress test was performed with the women in a semilithotomy position or if necessary in a standing position with a comfortable filled bladder (200-300 ml). Leakage from the urethra was registered during repeat vigorous coughing. The

subjects were regarded as objectively cured if the postoperative cough test was neagative: no leakage (Studies I, II, IV).

4.2.2.3 UISS (Studies I , II, IV)

The Urinary Incontinence Severity Score (UISS) questionnaire, which is a disease specific quality-of-life questionnaire, includes ten questions on the impact of urinary incontinence on everyday activities, was used before and after the operations (Appendix 1) (Mäkinen et al. 1992b). The UISS has been validated in Finnish (Stach-Lempinen et al. 2001). Lower UISS scores indicate higher quality of life.

4.2.2.4 DIS (Studies I, II, IV)

The Detrusor Instability Score (DIS) questionnaire consists of ten questions related to detrusor instability symptoms. Each question is scored from 0 to 2. A score sum of ≤ 7 indicates absence of urgency urinary incontinence. Higher scores indicates increased risk of the presence of urgency symptoms (Appendix 2) (Kauppila et al. 1982).

4.2.2.5 Visual analoque scale (VAS) (Study I-II)

A Visual Analog Scale (VAS) measure a person´s subjective perception of a certain condition, for instance the degree of bother caused by urinary symptoms. VAS has been shown to be responsive and sensitive to treatment interventions and to changes over time (Stach-Lempinen et al. 2001). The VAS used in the present studies had a scale of 0 to 100, where 0 represented no urinary problems and 100 unbearable urinary complaints (Appendix 3).

4.2.2.6 UDI-6 (StudiesI-II) and IIQ-7 (Studies I-II)

The Urogenital Distress Inventory short form (UDI-6) consists of six questions concerning the prevalence of urinary incontinence and the bother it causes (Appendix 3). Urgency symptoms before and after intervention and the rate of de novo urge symptoms were assessed.

The Incontinence Impact Questionnaire (IIQ-7) was designed to assess all forms of incontinence on quality of life. The short form of the questionnaire consists of seven questions. Each question is scored from 0 to 3. The lower IIQ-7 scores indicate higher quality of life (Appendix 4).

4.2.2.7 Euro-Quality of life and thermometer-like scale (Studies I-II)

The Euro Quality of life-5D (EQ-5D) is a general quality-of-life questionnaire. The questions include information on mobility, self-care, usual everyday activities, pain or other complaints, anxiety and depression, every question having three graded options. The thermometer-like scale (0-100) assesses general health perception at the current moment. The patient draws a line indicating the state of her current health- 100 represents the best health state and zero the worst imaginable health state (Appendices 5 and 6)(Rabin et al. 2001).

4.2.3 Dynamic MR Imaging (Studies III- IV)

Dynamic magnetic imaging was performed at rest, when contracting pelvic floor muscles and during straining, coughing and voiding. The women received detailed instructions on how to relax, contract their pelvic floor muscles, cough and strain. Imaging was performed in a supine position with the legs slightly apart and a pillow under the knees to add comfort. Bladder volume was controlled by transvaginal ultrasonogaphy to be 200-300 ml. The vagina and the rectum were opacified with sonographic gel, 50 ml and 100 ml respectively, to facilitate identification of the lining of the vagina and the rectum.

A reference line from the lower border of the symphysis pubis to the sacrococcygeal joint was used. The distance of the rectal wall and the most distal part of the cervix uteri from the reference line were measured. All measurements were done in all sequences, i.e. at rest, when contracting pelvic floor muscles, during straining, coughing and voiding.

Urethral length and the coordinates of the mid-urethra were measured. Mid-urethral movements were calculated using the following formula: vector length = $\sqrt{[(x_2 - x_1)^2 + (y_2 - y_1)^2]}$ where x_1 and y_1 represent coordinates at rest, and x_2 and y_2 during different maneuvers. In order to obtain as accurate a measure of the midpoint of the urethra as possible, two different ways of measurement were tried. Firstly at a distance of 15 mm from the bladder neck by assuming that the functional length of a normal urethra is on average 30 mm, and secondly by identifying the midpoint of the measured total length of the urethra. An attempt to identify funneling of the bladder neck was also performed (Study III).

The coordinate origo was placed on the inferior tip of the symphysis pubis and the vertical axis of the symphysis pubis served as the y-axis while the x-axis was perpendicular to it. The images were displayed in coronal, axial and transversal planes during rest, at maximal straining and during maximal pelvic floor contraction. Thereafter dynamic imaging was performed in a sagittal plane during coughing and voiding.

Images were acquired on a 1.5T scanner (Magnetom Vision, Siemens, Erlangen, Germany) with a phased array body coil. To define a reference line between the sacrococcygeal joint and the lower border of the symphysis pubis a sagittal scan was acquired (Flash, TR 120.2 ms, TE 4.1 ms, flip angle 80, matrix 140x256, slice thickness 5 mm, 10 slices). For the dynamic scans a T1/T2-weighted gradient echo pulse sequence was used (TRUE_FISP, TR 6.46 ms, TE 3.05 ms, flip angle 70, matrix 256x256, slice thickness 5 mm, one slice a second for 30 seconds) in the mid-sagittal plane. The dynamic scans were obtained at rest, when contracting pelvic floor muscles and during straining, coughing and voiding.

All measurements were independently performed by two experienced radiologists. Interobserver reproducibility was tested by the method of Bland and Altman (Bland and Altman1986). A difference (±2 SD) between two measurements >10 mm was considered clinically significant.

The randomized studies (I and II) have been registered at http://www.ClinicalTrials.gov and the identification number is NCT00379314. The observational studies (III-IV) have also been registered at http://www.ClinicalTrials.gov (identification number NCT00747370.

4.2.4 Statistical methods

The Statistical Package for Social Sciences (SPSS for Windows 9.0, 11.0 and 14.0 Chicago, IL, USA) was used for statistical analysis. For analysis of continuous variables, the paired samples t-test or Wilcoxon test were used to calculate statistical differences between groups. The Chi-squared or Fisher`s test were used for categorical variables. A p-value ≤0.05 was considered to indicate statistical significance.

5 RESULTS

5.1 Clinical outcome in Studies I and II

5.1.1 Cure rates

Two hundred and sixty-seven patients of the originally randomized 273 underwent the allocated operation: 136 in the TVT group and 131 in the TVT-O group. After randomization 6 patients dropped out. Four patients refused operation and one patient cancelled because of an eye operation at the same time as the intended incontinence operation. In one patient the TVT-O procedure was technically impossible and the operation was altered to a TVT operation. The data on this patient was disregarded. At the 1-year follow-up visit 134 TVT and 131 TVT-O patients were available. Between the one-year and the three-year follow-up visits only 10 patients were lost to follow-up. At the three-year follow-up visit 96% of the patients were evaluated: 131 in the TVT group and 126 in the TVT-O group. The flowchart concerning Studies I and II is illustrated in Figure 5.1.

The objective cure rates in Studies I and II are summarized in Table 5.2. In (randomized) Study I the cure rate after 1-year follow-up was 95.5% in the TVT patients and 93.1% in the TVT-O patients. After 3 years of follow-up the cure rate was 94.6% in the TVT group and 89.5% in the TVT-O group.

As assessed by the pad test (<8g/day), 90.2% of TVT patients and 95.3% of the TVT-O patients were cured at the 1-year follow-up visit. At the 36-month follow-up visit 91.7% and 93.8% in the TVT and the TVT-O group respectively were cured.

The subjective cure rates measured by the condition-specific QoL questionnaires were similar in both groups. At the one and three-year follow-up visits the subjective cure rates were significantly improved compared with the preoperative situation. General health was assessed by the EuroQoL-5D. The Euro quality of life index improved in the TVT group significantly from the baseline value of 0.855, to 9.01 at the one-year visit and 0.870 at the 3-year follow-up visit. In the TVT-O group the baseline index improved, correspondingly, from 0.876 to 0.933 and to 0.895 at the 1-year and 3-year follow-up visits respectively. The EQ-5D thermometer-like VAS scale also improved significantly in both groups, with no difference between the groups.

In the TVT group 90% were completely satisfied with the operation at the 1-year and 3-year follow-up visits, whereas 93% and 91.2% of the TVT-O patients were completely satisfied with the operation at the 1-year and 3-year follow-up visits.

Most of the patients were ready to recommend the operation to a friend: 97% and 98.4% of the TVT patients and 96% and 95.2% of the TVT-O patients at the 1- and 3-year follow-up visits, respectively.

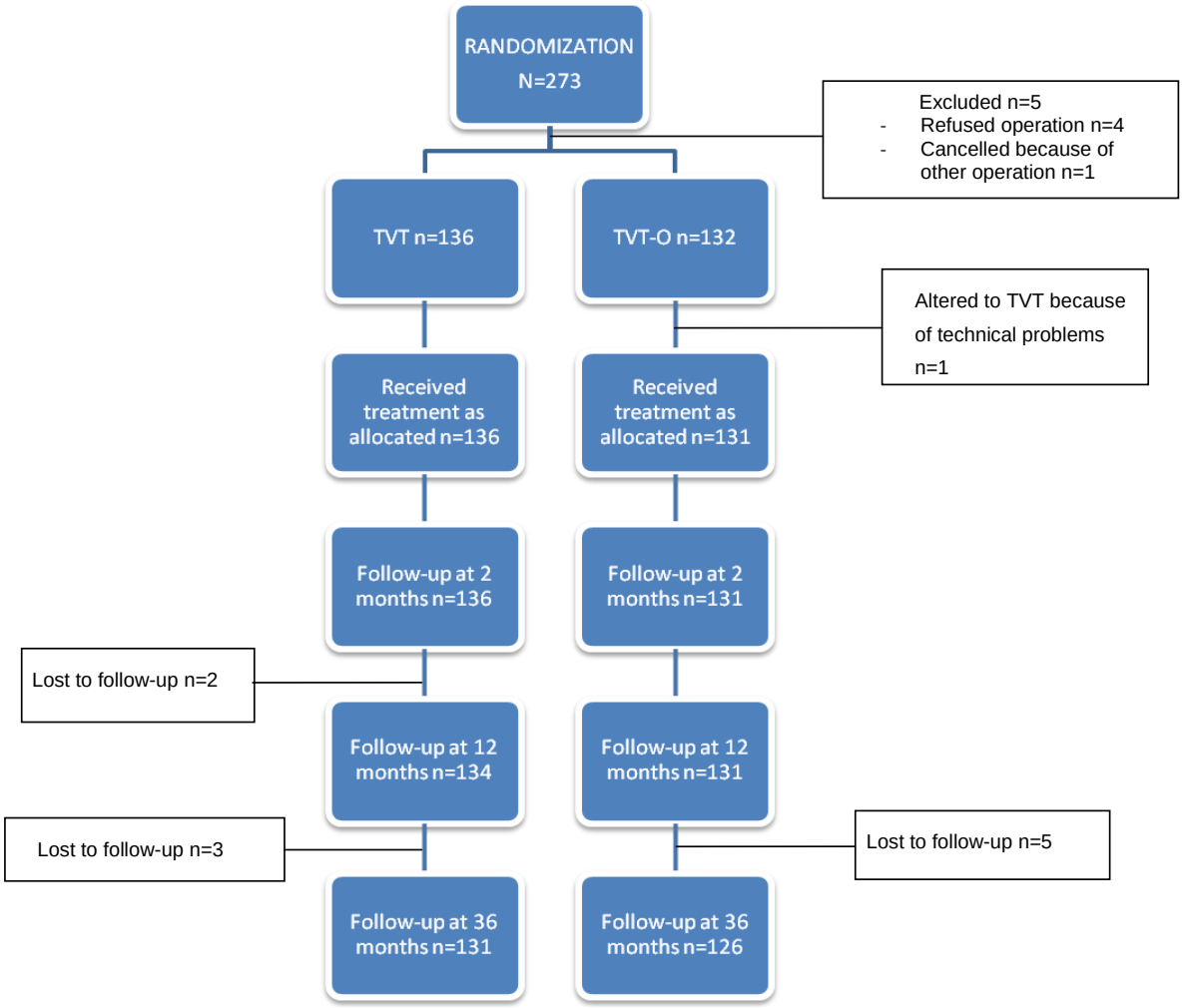


Figure 5.1 Flow of patients though the trial

5.1.2 Complications

All patients had a detrusor instability score (DIS) of seven or less preoperatively. The de novo urgency rate, defined as new symptoms of frequency or urgency of moderate or severe degree in the UDI-6 or a DIS of > 7 was 1.5% in the TVT group and 2.3% in the TVT-O group at the one year follow-up visit. At the 36 months follow-up visit de novo urgency was found in 9.2% of the patients in the TVT group and 5.6% in the TVT-O group with no difference between the groups.

The frequencies of voiding difficulties requiring repeat catheterization between the 2 and 12-month follow-up visits were 0.7% and 1.5% in the TVT and TVT-O groups respectively. One patient had retention problems after a TVT-O operation and division of the tape was performed twice: 1 year 4 months and 1 year and 7 months after the operation, but the patient developed de novo urge symptoms. One woman in the TVT group and two in the TVT-O group needed anticholinergic treatment at one year of follow-up. Three women in the TVT group and none in the TVT-O group used anticholinergic treatment at the 36-month follow-up visit.

One TVT-O patient was found to have tape extrusion at the 1-year follow-up visit and tape resection was performed, which resulted in recurrence of incontinence and a TVT reoperation was performed. Neither vaginal erosion nor tape extrusion were found in any of the patients at the 36 month follow-up visit.

Two TVT patients were not satisfied with the result of the operation at one year of follow-up and underwent reoperation with a repeat TVT. Of the total of three women who underwent reoperation, one was lost to follow-up at 36-month. The other two patients were continent (negative cough stress test result) at the 36-month follow-up visit.

At the 12- and 36-month follow-up visits antibiotic treatment for urinary tract infections had been needed in 14.2% and 15.4% of the patients, respectively, in TVT group and correspondingly in 16.8% and 17.6% in the TVT-O group. One patient in the TVT group and five in the TVT-O group needed long-term prophylactic antibiotics treatment for recurrent urinary tract infections between the 1- and 3-year follow-up visits.

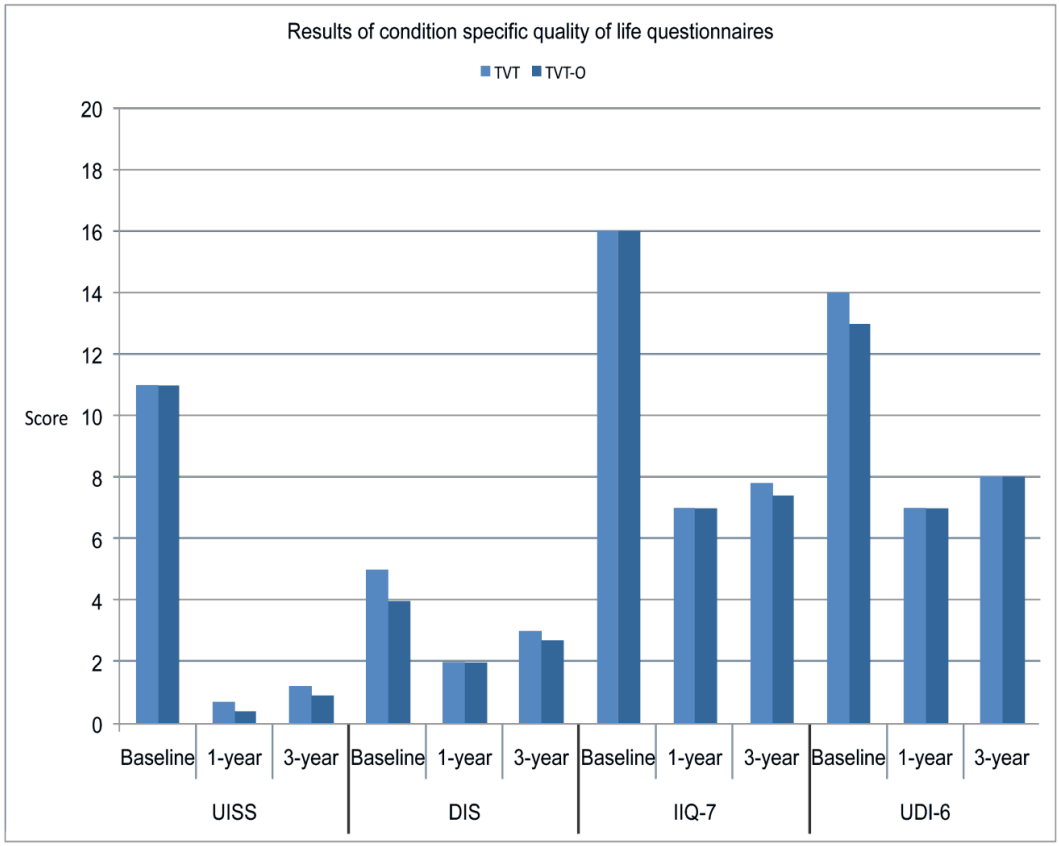
Table 5.1 Demographics of the women in Studies I -IV

	Studies I & II		Studies III & IV	
	TVT	**TVT-O**	**Healthy Volunteers**	**Stress Incontinent Women**
Number of patients	I Study 134/ II Study 131	I Study 131/ II Study 126	15	40
Age (mean ± SD)	53±10	54±10	41± 5.8	51.0±8.5
Parity median (range)	2 (0-6)	2 (0-7)	3 (0-2)	2(0-6)
Number of menopausal women n(%)	71 (52)	78 (60)	4 (27)	8 (20)
Number of women on HRT n(%)	50 (37)	50 (38)	4 (27)	11 (27)
BMI (mean ± SD) kg/m^2	26±3	26±4	24.1±3	26.4±5

Table 5.2 Objective cure rates at 1-year and 3-year follow-up

	TVT group 1-year follow-up	TVT-O group 1-year follow-up	TVT group 3-year follow-up	TVT-O group 3-year follow-up
Negative cough stress test	95.5%	94.6%	93.1%	89.5%
Pad test (<8g/day)	90.2%	95.3%	92.7%	94.1%

Figure 5.4 Results of condition-specific quality of life questionnaires



5.2 Clinical outcome in Studies III and IV

Fifteen healthy volunteers and 40 stress urinary incontinent women underwent dynamic MRI. Table 5.1 shows the demographics of the volunteers and stress urinary incontinent women. One volunteer and two incontinent women were not able to complete the imaging as a result of claustrophobia caused by the MRI equipment. Moreover, in Study IV, four patients (one patient in the TVT group and three patients in the TVT-O group) refused to undergo the postoperative MR imaging for the same reason.

5.2.1 Location of the mid-urethra

In (imaging) Study III we measured the length of the urethra at rest. There was no difference between the length of the urethra in healthy volunteers and incontinent women (p=0.87). We tested two different ways of determining the mid-point of the urethra. First, we measured a distance of 15 mm from the bladder neck by assuming that the functional length of a normal urethra is on average 30 mm. Secondly we identified the mid-point of the measured total length of the urethra. The measurements did not differ from each other. As the bladder neck could be more precisely determined, a distance of 15 mm from the bladder neck was used for the midpoint of the urethra in Studies III and IV.

The precise location of the mid-urethra was plotted on the x- and y-coordinate (Schaer et al. 1999). The measurements were performed when contracting the pelvic floor, during coughing, straining and voiding. On contracting pelvic floor muscles the mid-point of the urethra rose significantly higher on the y-axis in the healthy volunteers than in the stress incontinent women. After the mid-urethral sling operation the incontinent women could elevate their mid-urethra higher than before the operation. However, healthy volunteers were able to elevate their mid-urethra even higher than the operated women. The mid-urethra moved significantly more towards the axis of the symphysis in incontinent women than in healthy volunteers during straining (Table 5.3) (Fig 6.3.1).

5.2.2 Pre- and post-operative location of the mid-urethra in stress urinary women

After the TVT and TVT-O operations the mid-urethra is more dorsal and higher than before the operation during straining, coughing and voiding. The mid-urethral sling operation corrects the mid-point of the urethra close to the location of healthy volunteers (Table 5.3) (Fig 6.3.2).

The total vector movement from rest to a state of contracted pelvic floor muscles was significantly (p=0.013) in healthy volunteers (5.3±1.8) than in stress incontinent women (3.8±2.1). After the mid-urethral sling operation the total vector movement was restricted during downward forces; straining, coughing and voiding (Table 5.4).

Table 5.4 Movements of the mid-urethra $\sqrt{[(x_2-x_1)^2 + (y_2-y_1)^2]}$

	before surgery (mm)	after surgery (mm)	significance p-value
during pelvic floor muscle contraction	4.8	3.6	0.3
straining	14.6	11.2	0.01
coughing	16.4	12.9	0.002
voiding	17.6	12.7	<0.001

Table 5.3 Cordinates of the mid-point of the urethra in healthy volunteers and in incontinent women before and after successful incontinence surgery

	The x coordinate Mean(mm)± sd	significance	The y coordinate Mean(mm)± sd	significance
Rest				
pre-operative	13.3 ±3.4	ns	-1.8 ±4.7	<0.05
postoperative	13.1 ±3.3		-0.1 ±4.7	
Volunteers	14.1 ±2.8	ns	0.6 ±3.4	ns
Pelvic floor contraction				
preoperative	14.5 ±3.2	ns	0.9 ±5.1	<0.05
postoperative	14.3 ±2.6		2.7 ±4.8	
volunteers	15.8 ±2.6	<0.05	4.7 ±3.2	ns
Straining				
preoperative	2.1 ±4.6	<0.05	-9.0 ±5.1	<0.05
postoperative	5.4 ±5.6		-7.1 ±4.9	
Volunteers	6.8 ±3.8	ns	-7.4 ±3.4	ns
Coughing				
preoperative	0.3 ±4.0		-9.1 ±5.6	ns
postoperative	3.6 ±5.8	<0.005	-8.0 ±4.3	
Volunteers	6.6 ±3.7		-8.3 ±4.1	ns
		ns		
Voiding				
preoperative	-0.5 ±6.5	<0.001	-9.3 ±4.5	0.001
postoperative	4.1 ±6.5		-7.5 ±4.3	
volunteers	1.7 ±6.4	ns	-7.6 ±3.9	ns

Table 6.1 RCT:s comparing TVT with TVT-O 2 month – 1 year

	obj (subj) cure rate		bladder injury		vaginal erosion		de novo urge		groin pain		UTI	
	TVT	TVT-O	TVT	TVT-O	TVT	TVT-O	TVT	TVT-O	TVT	TVT-O	TVT	TVT-O
Zullo et al 2007 TVT 35 TVT-O 37	89%	91%	6%	0	0	0	9%	0			2.7%	5.7%
Liapis et al 2006 TVT 46 TVT-O43	89% (73.9%)	90% (76.7%)	6.5%	0	2.2%	0	10.8%	13.9%			6.5%	2.3%
Laurikainen et al 2007 2 month TVT 136 TVT -O 131	98.5%	95.4%	0.7%	0	1.5%	2.3%	2.2%	2.3%	0	0.8%	8%	13%
Rinne et al 2008 1 year	95.5%	93.1%			0	0.8%	1.5%	2.3%	0	0.8%	14.2%	16.8%
Meschia et al 2007 6 months TVT 114 TVT-O 117	92% (92%)	89% (87%)	4%	0	2.5%	3%	2.5%	4%	0	5%	NR	NR
Araco et al 2008 TVT120 TVT-O 120	100%SUI1 100%SUI2*	100% SUI1 66% SUI2*	2%	0	0.9%	3%			0	6% postoper pain	NR	NR
Karateke et al 2009 TVT 81 TVT-O 83	88.9%	86.7%	3.7%	0	9.9%	7.2%	14.8%	12.0%	NR	NR	NR	NR
Wang W et al 2009 TVT 160 TVT-O 155	89.6%	89.8%	0	0	1.9%	2.1%	5.8%	4.1%	2.6%*	8.2%*	NR	NR

Table 6.2 RCT:s comparing TVT with TOT 2 month – 1 year

	obj (subj) cure rate		bladder injury		vaginal erosion		de novo urge		groin pain		UTI	
	TVT	TOT	TVT	TOT	TVT	TOT	TVT	TOT	TVT	TOT	TVT	TOT
Barry et al 2008 3 month TVT 82 TOT 58	78%	82.8%	8.5%*	0*	1.2%	5.2%	1.2%	0	1.5%	1.5%	13.4%	15.5%
Barber et al 2009 TVT 88 TVT-O 82	58.8%(79%)	62.3%(82%)	7%*	0*	5.6%	1.2%	NR	NR	2.4%	4%	1.3%	1.3%
Ross et al 2009 TVT 90 TOT 85	77%	81%	2.9%	0	1.1%	1.2%	NR	NR	5.6%*	15.3%*	NR	NR
Wang F et al 2010 TVT 70 TOT 70	92.8%	91.4%	4.3%	1.4%	1.4%	2.8%	4.3%	1.4%	4.2%	11.4%	NR	NR

SUI 1 mild incontinence, SUI 2 severe incontinence, * significance $p < 0.05$

Fig 6.3.1 a) The mid-urethra ★ during pelvic floor contraction in incontinent patients and healthy volunteers

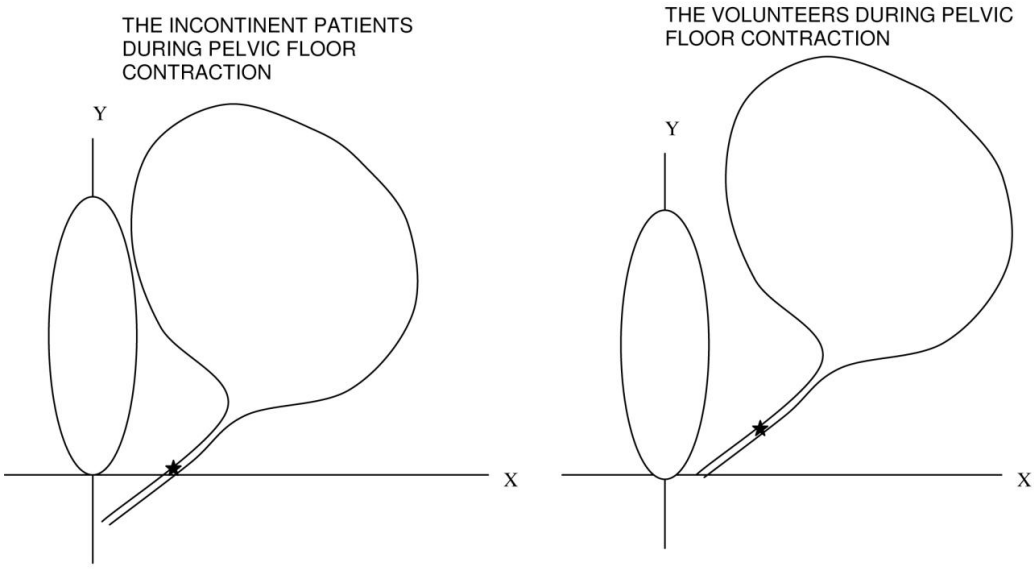


Fig. 6.3.1 b)The mid-urethra ★ during straining in incontinent patients and healthy volunteers

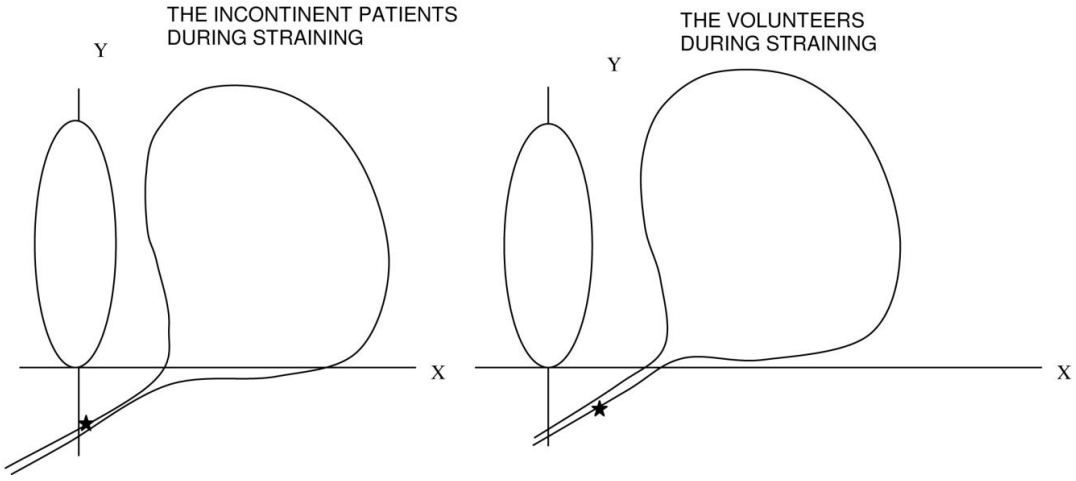


Fig 6.3.2 a) The middle urethra ★ during pelvic floor contraction before and after mid-urethral sling operation

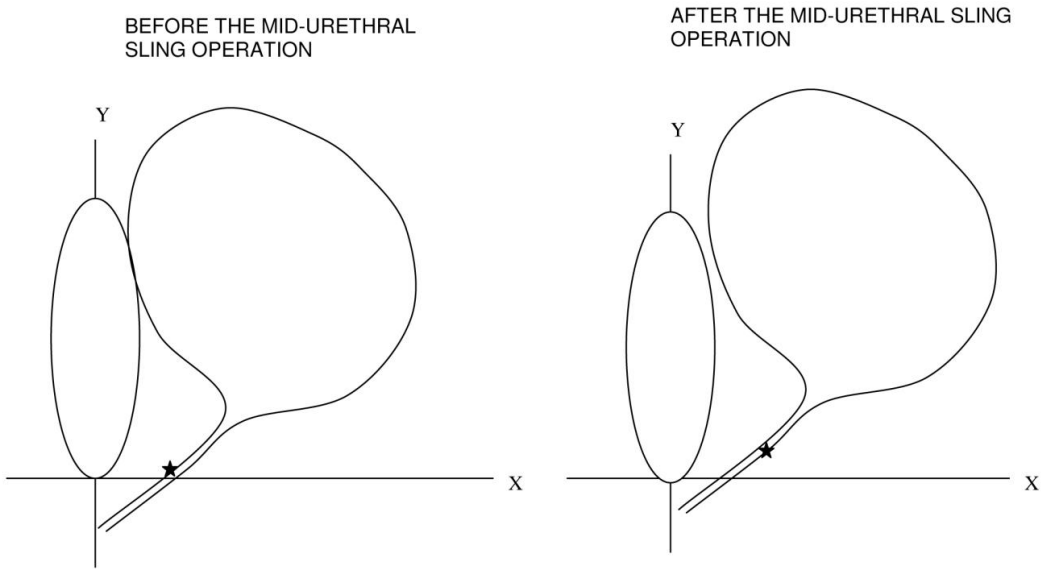


Fig. 6.3.2 b)The middle urethra ★ during voiding before and after mid-urethral sling operation

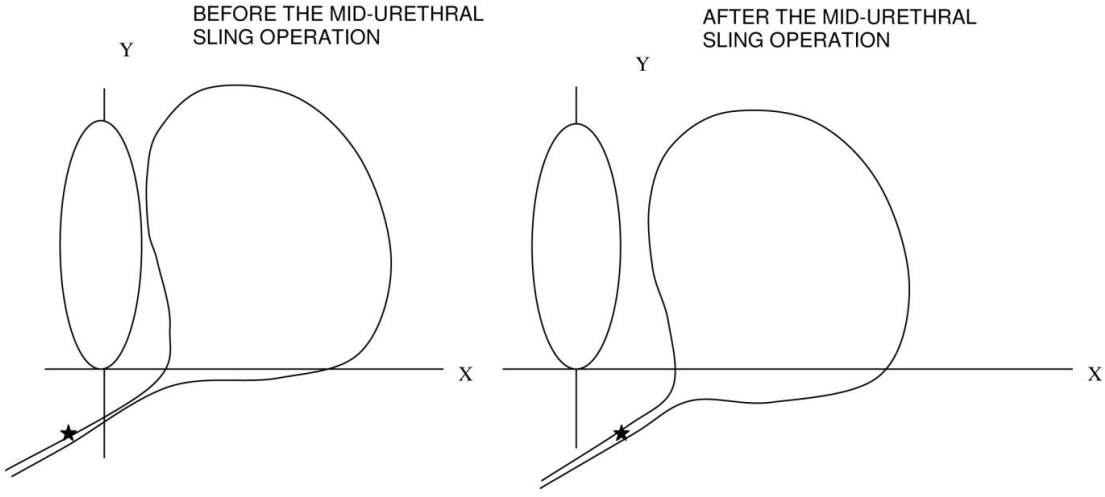


Table 6.3 Complications at 12 and 36 month follow-up

	TVT %		TVT-O %	
	12 month	**36 month**	**12month**	**36 month**
De novo urgency				
(no treatment)	1.5	9.2	2.3	5.6
anticholinergic treatment	0.7	2.3	0.8	0
Voiding difficulties	0.7	0	1.5	0.8
tape division	0	0	0	0.8
Tape erosion	0	0	0.8	0
tape resection	0	0	0	0.8
UTI				
(one or more antibiotics)	14.2	15.4	16.8	17.6
Recurrent UTI (long-term antibiotic)	2.2	0.01	3.0	3.9
Groin or thigh pain	0	0	0	0

no statistical significance between TVT and TVT-O group

6. Discussion

6.1 Cure rates associated with mid-urethral sling procedures

Introduction of new surgical procedures for treatment of female stress urinary incontinence requires basic research on safety and efficiency. The first modern mid-urethral sling procedure is the retropubic TVT operation, which has been extensively investigated in prospective clinical observational studies. The TVT has been compared with the former gold standard operation for stress urinary incontinence, the colposuspension operation, and found to be as effective but associated with a lower rate of complications (Ward et al.2004). The obturator approach for placement of a mid-urethral sling was introduced five years after the first publications on the retropubic mid-urethra sling procedure. The first obturator operation was an outside-in procedure and two years later an inside-out modification was launched. Nine years after developing the obturator technique 15 randomized controlled trials comparing TVT with transobturator procedures were found (Table 6.1 and Table 6.2). Our present randomized study was initiated in 2003 when no randomized comparisons between retropubic and obturator mid-urethra slings had been published. The present trial was designed to compare the retropubic TVT with the inside-out obturator technique (TVT-O) in terms of efficiency and complication rates.

We found that the objective cure rates, defined as negative stress test, at 2, 12 and 36 months of follow-up, were 98.5%, 95.5% and 94.6% respectively for the TVT patients and 95.4%, 93.1% and 89.5% respectively for the TVT-O patients. Our cure rates are in accordance with other randomized trials (Table 6.1). Only Araco et al. found a significant difference between the two procedures in women with more severe stress incontinence (Araco et al. 2008). The small difference in cure rates between our groups did not reached statistical significance. The trend towards a slightly steeper decline in cure rates in connection with the TVT-O procedure, however, raises concern about the future development of the obturator approach. In the latest Cochrane review (2009) there was a significant difference between the retropubic and transobturator routes in objective cure rates in favor of the retropubic route, while subjective cure rates where similar (Ogah et al. 2009).

Most of the randomized trials in which these two routes have been compared lack a sufficient number of patients. Only three of the trials (Meschia et al. 2007, Araco et al. 2008 and Karateke et al. 2009) have involved power calculations. Wang et al analyzed 300 patients, but no power analysis was reported (Wang et al. 2009). In the present multi-center, randomized study power analysis was performed (70% power) to show a 10% difference in either success rate or rates of complications. The required sample size was to be 260, with 130 in each group. At the 36-month follow-up visit we were able to evaluate 96% of the initial patients, 131 in the TVT group and 126 in the TVT-O group. Thus power still remained almost completely at three year postoperatively.

6.2 Complications

The traditional incontinence operations, the Marshall-Marchetti-Kranz procedure and Burch colposuspension as well as pubovaginal sling were associated with high complication rates including voiding dysfunction, urge symptoms and infections. To avoid these complications there was an attempt to develop less invasive anti-incontinence procedures. The first generation of less invasive surgical procedures involved needle suspension techniques (Pereyra 1959, Stamey 1973, Raz 1981), which were found to be associated with lower cure rates than the more invasive procedures and were also associated with fistula complications (Schulz et al. 2006).
The most common complications related to the mid-urethral sling procedures are bladder perforation, vaginal perforation, voiding dysfunction, urinary tract infections and postoperative hematoma. Bladder perforation rates ranged from 0% to 6.5% in the TVT procedure (Wang et al. 2009, Liapis et al. 2006). The vaginal perforation rate is low ranging from 0% to 3% in both procedures (Zullo et al. 2007, Meschia et al. 2007). However, vascular, bowel and nerve injuries have been reported as well as necrotizing fasciitis, ischiorectal abscess, urethrovaginal fistulas and even patient deaths. Deng et al. reported major complications after the TVT procedure based on an FDA register (Deng et al. 2007).They identified 32 vascular injuries, 33 bowel injuries, and 8 patient deaths after TVT placement.
In our randomized study the complication rate was low and no major complication was detected (Table 6.3). The bladder perforation rate was 0.7% in the TVT group and 0% in the TVT-O group, which might reflect the standard of the training our surgeons have had. The vaginal perforation rate was low: 1.5% in the TVT group

and 2.3% in the transobturator group; the results are in concordance with other RCT (Laurikainen et al. 2007). Only Karateke et al. found higher vaginal perforation rates: 9.9% in TVT group and 7.2% in the transobturator group (Karateke et al. 2009).

In the present study, de novo urgency, defined as new symptoms of frequency and/or urgency of moderate or severe degree in the UDI-6 or scores > 7 in the Detrusor Instability Scores (DIS) was found at rates of 2.2% and 1.5% at the 2-and 12-month follow-up visits in the TVT group. Accordingly, de novo urgency was found at a rate of 2.3% in the TVT-O group both at the 2-and 12-months follow-up visits.

At the three-year follow-up visit the rate of de novo urgency was 9.2% in the TVT group and 5.6% in the TVT-O group. This increase from the figures seen at one year postoperatively might reflect the effect of time, age and concomitant medical conditions than a late-onset effect of the mid-urethra sling operation. Among the reports on randomized trials, the highest incidence of de novo detrusor overactivity was found by Karateke et al: 14.8% in the TVT group and 12.0% in the TVT-O group (Karateke et al. 2009). De novo urge symptoms seem to vary from 0% to 15% in these randomized trials, with no significant difference between the groups. This finding is confirmed by the latest Cochrane review (2009).

Several studies have shown that the TVT induces dynamic compression of the mid-urethra (Zullo et al. 2007, Dietz et al. 2004). The rate of voiding difficulties after a TVT procedure has been reported to be between 1.4% and 9% (Lukacz et al. 2004), while it is between 2 and 13% after a TVT-O procedure (Lee et al. 2007, Mellier et al. 2004). Voiding difficulties requiring catheterization or division of the tape were rare in our study: 0.7% and 1.5% in the TVT and the TVT-O groups, respectively at 12-month of follow-up. Only one TVT-O patient needed tape division. The procedure was performed twice: at 1 year 4 months and at 1 year 7 months postoperatively. The retention problem was solved after the second division, but the patient developed de novo urgency symptoms. Similar low rates of voiding difficulties were found in two other randomized studies 2.8% and 3.9% in TVT group and 0% and 2.7% in TVT-O group (Zullo et al. 2007, Wang et al. 2009). No differences in the risk of developing postoperative voiding difficulties seem to exist between the retropubic and obturator mid-urethral sling procedures.

During the present trial antibiotic treatment for urinary tract infection was needed in 8%, 14.2% and 15.4% of the patients in TVT group and in 13%, 16.8% and 17.6% in the TVT-O group respectively registered at the 2-, 12- and 36- month follow-up visits. Between the 1- and the 3-year follow-up visits one TVT patient and five TVT-O patients needed long-term antibiotic treatment for recurrent urinary tract infections. During the same follow-up period (1year-3 years) two TVT and four TVT-O patients had post-void residual urine volumes >100 ml, but none of them had experienced urinary tract infections. The rate of urinary tract infections we found was marginally higher than those found in other randomized studies (Zullo et al. 2007, Liapis et al. 2006). No significant difference was found between the groups.

Postoperative pain was found significantly more often in the TVT-O group than in TVT group at the 2-month follow-up visit, 16% versus 1.5%, p=0.001. The TVT-O patients complained of groin pain, which in one patient lasted 2 months, but resolved later (Laurikainen et al. 2007). At later follow-up visits no groin pain was detected. Other randomized studies (Wang et al. 2009 et al., Ross et al. 2009) and meta-analyses (Long et al. 2009 and Novara et al 2010) have shown higher rates of thigh or groin pain related to the transobturator technique. In a randomized trial by But et al. in which two transobturator techniques were compared (the inside-out and the outside-in route), the number of patients complaining of postoperative groin pain was significantly greater in the inside-out (TVT-O) group than in the outside-in (TOT) group (But et al.2008). A possible explanation could be that the TVT-O trocar passes closer to the adductor muscles and the posterior branch of the obturator nerve than the TOT trocar.

Our study confirms the results of other middle-term follow-up studies, which show cure rates are equal with the retropubic and the obturator sling placement procedures. Both the objective and subjective cure rates were high after 36 months of follow-up. The complication rate was low, with no difference between the groups. Our results are similar to those in other randomized trials, with shorter follow-up times and mostly with fewer numbers of subjects enrolled (Meschia et al. 2007, Karateke et al. 2009, Wang et al. 2009).

For the treatment of female stress urinary incontinence both techniques are effective and safe. In cases of severe stress incontinence or in women with intrinsic

sphincter deficiency, the TVT procedure seems to function more effectively than the transobturator procedure (Schierlitz et al. 2008, Miller et al. 2006, Hsiao et al.2009).

6.3 MRI studies on the behavior of the urethra in healthy women and women with stress urinary incontinence

Earlier static MRI studies have shown typical anatomical differences between healthy and incontinent women. The thickness of the urethral sphincter has been found to be reduced and the configuration different (omega shape) in incontinent women than in healthy women. The results of several MRI studies have also shown a thinner and distorted levator ani muscle in incontinent women than in control women (Aronson et al. 1995, Tunn et al. 2005, Macura et al. 2006). MRI studies involving endourethral or endovaginal coils have revealed distorted periurethral or paraurethral supporting ligaments in incontinent women.

According to the findings of our present study there is a significant difference in urethral behavior between healthy volunteers and incontinent women as well as in the movement of the mid-urethra before and after mid-urethral sling operations (Figures 6.3.1. and 6.3.2). We were able to show that in incontinent women the rotation of the mid-urethra downwards during straining and coughing was more significant towards the vaginal introitus and towards the axis of the symphysis than in continent volunteers (Table 5.3). As far as we know, there is no other imaging study in which the location of the mid-urethrahas been investigated by means of dynamic MRI.

Ultrasonography has been used to image movements of the bladder neck. Our MRI findings are supported by the ultrasonographic findings by Howard et al. (2000), in which the bladder neck moves in a dorso-caudal direction during maximal straining when intra-abdominal pressure increases (Howard et al 2000). Dietz et al. found, however, a wide range in the mobility of the bladder neck in young continent women (Dietz et al. 2004). They could not detect any cut-off point between continent and incontinent women.

Childbirth is one of the main risk factors of developing stress urinary incontinence. Shek et al found that the mobility of the proximal urethra was significantly increased after childbirth. The distal part of urethra was consistently less mobile than the proximal part (Shek et al. 2008).

6.4 Urethral behavior before and after mid-urethral sling operation assessed by MRI

Urethral and bladder neck hypermobility have been considered to be important factors in the pathophysiology of stress urinary incontinence. The literature has been concentrating on bladder neck mobility, cotton swab angles, urethrovesical angles and bladder neck descent in relation to urethral mobility. The focus was on bladder neck hypermobility and its correction at the time when the gold standard of incontinence surgery was the colposuspension operation. Information on changes in urethral mobility after incontinence surgery is lacking in the literature. No information on the more distal parts of the urethra has been available. One could argue that of the use of different angles is irrelevant, since the urethra is not a strait tube during different functions.

The main philosophy behind the development of the TVT procedure was stabilization of the mid-urethra. Therefore we particularly wanted to concentrate our investigations on movement of the mid-urethra. Our results show that vector mobility of the mid-urethra during different functional tests became significantly more restricted after the mid-urethral sling operation compared with preoperative vector mobility and resembled more the findings in healthy volunteers. Our data is supported by similar findings from ultrasonographic studies (Masata et al. 2006, Shek et al. 2010).

Retrospective ultrasonographic studies have suggested that the mechanism of action of the TVT procedure is urethral kinking at the midpoint (Lo et al. 2001, Atherton et al. 2000). One ultrasonographic study did not reveal this urethral kinking (Virtanen et al 2002). Even the importance of correct mid-urethral location of the sling has been questioned (Kaum et al. 2002, Dietz et al. 2004). Available functional studies have not yet answered all questions regarding the mechanism of action of mid-urethra sling procedures.

The recent development of fast magnetic resonance imaging sequences allows noninvasive, radiation-free, rapid, high-resolution evaluation of the entire female pelvis within one examination. Studies utilizing such dynamic MRI techniques might in the future help identifying phenomena associated with the development of stress urinary incontinence and approaches needed to correct the condition.

6.5 The role of dynamic MRI

The main problem of dynamic studies of the female pelvic floor is the lack of proper standardization and validation of methods. Five different reference lines have been used in the literature. The most commonly used reference line is the pubococcygeal line, which is thought to approximate the location of the plate of levator muscles. Therefore, in this study we wanted to use a more precise x-y-coordinate system to assess the exact location of the mid-urethra. The bladder volume we preferred was 200-300ml, which is commonly used in ultrasonographic studies. We are aware of the lack of proper or objective assessment of the strength and degree of straining as well as the fact that our studies were performed in a supine position as a result of the nature of the MR equipment available. We consider that our findings agree with the idea that mid-urethral support is essential when dealing with SUI.

7. CONCLUSIONS

1. In the present randomized clinical multicenter study compared the retropubic TVT procedure with the transobturator TVT-O procedure for treatment of female urinary stress incontinence. At one and three years of follow-up no significant statistical or clinical difference in either cure rates or rates of complications was found.

2. In the dynamic MRI study compared the behavior of the mid-urethra of 15 healthy continent women with that of 40 urinary stress incontinent women during different maneuvers. Dynamic MRI revealed a difference between continent and incontinent women in the behavior of the mid-urethra.

3. The effect of anti-incontinence surgery via the TVT and the TVT-O procedures on the behavior of the mid-urethra was studied. Successful surgery resulted in significant changes in the behavior of the mid-urethra approaching the behavior seen in healthy volunteers.

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APPENDICES

ORIGINAL PUBLICATIONS I-IV

VIRTSANKARKAAMISEN HAITTA-ASTE

Pvm:

Nimi — Ongelma esiintynyt — kuukautta/vuotta

Henkilötunnus — Pituus — Paino — Ikä

Rastittakaa sopivin vaihtoehto ☒	**0**	**1**	**2**
1. Karkaako Teiltä virtsa ilman ponnistusta ja asennosta riippumatta (esim. makuulla)?	☐ Ei	☐ Joskus	☐ Hyvin usein
2. Esiintyykö virtsan karkaaminen (vasta) vähäisessä ponnistuksessa (esim. seisomaan noustessa, kävellessä)?	☐ Ei	☐ Joskus	☐ Hyvin usein
3. Karkaako Teiltä virtsaa (vasta) yht'äkkisissä, voimakkaissa ponnistuksissa (esim. aivastaessa, yskiessä, juostessa)?	☐ Ei	☐ Joskus	☐ Hyvin usein
4. Haittaavatko karkailuoireet jokapäiväisiä askareitanne (kaupassakäynti, ruoanlaitto, siivous, tms.)?	☐ Ei	☐ Joskus	☐ Hyvin usein
5. Onko oireistanne haittaa ansiotyössänne (asiakkaiden palveleminen, työsuoritukset, tms.)?	☐ Ei	☐ Joskus	☐ Hyvin usein
6. Pelkäättekö, että muut huomaavat vaivanne (haju, märkyys, tms.)?	☐ Ei	☐ Joskus	☐ Hyvin usein
7. Joudutteko luopumaan menoistanne (liikunta, kyläily, teatteri, kirkko, tms.)?	☐ Ei	☐ Joskus	☐ Hyvin usein
8. Haittaavatko karkailuoireet sukupuolielämäänne?	☐ Ei	☐ Joskus	☐ Hyvin usein
9. Aiheuttaako karkailu ulkosynnyttimienne ärtymistä?	☐ Ei	☐ Joskus	☐ Hyvin usein
10. Joudutteko käyttämään suojavaippoja tai -siteitä?	☐ Ei	☐ Joskus	☐ Hyvin usein

HAITTA-ASTE

%

VIRTSANKARKAAMISEN EROTTELUPISTEET

Nimi _____ Pvm: _____

Henkilötunnus _____

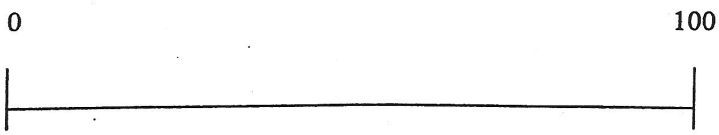
Rastittakaa sopivin vaihtoehto ☒	**0**	**1**	**2**
1. Montako kertaa käytte virtsalla päivisin?	☐ 5–7	☐ 8–10	☐ yli 10
2. Montako kertaa joudutte öisin nousemaan virtsalle?	☐ 0–1	☐ 2–3	☐ yli 3
3. Tuntuuko Teistä, että virtsarakkoon jää virtsaa WC:ssä käynnin jälkeen.	☐ Ei	☐ Joskus	☐ Usein
4. Aiheuttaako kiire tai jännitys Teille virtsaamispakkoa?	☐ Ei	☐ Lievä	☐ Voimakas
5. Karkaako Teiltä virtsaa ponnistamistilanteissa muulloinkin (esim. yskäisy, aivastus, nauru)?	☐ Kyllä	☐ Joskus	☐ Ajoittain
6. Karkaako virtsa välittömästi em. ponnistuksen yhteydessä?	☐ Kyllä	☐ En osaa sanoa	☐ Vasta ponnistuksen jälkeen
7. Tunnetteko virtsaamistarvetta ennen virtsan karkaamista?	☐ Ei	☐ Joskus	☐ Usein
8. Paljonko Teiltä karkaa virtsaa kerrallaan?	☐ Tippoja	☐ Liraus	☐ Virtsa alkaa valua
9. Pystyttekö virtsatessanne keskeyttämään virtsasuihkun?	☐ Kyllä	☐ Aika hyvin	☐ Ei onnistu
10. Onko Teillä ollut hoidettuja virtsatietulehduksia viimeisten kahden vuoden aikana?	☐ Ei	☐ 1–2	☐ yli 2/ kroonisesti

YHTEENSÄ ☐

VAS
Visual analog score

Kuinka hankala on virtsavaivanne (merkitkää rasti oheiselle janalle) ?

0 = ei lainkaan haittaa, 100 = hankalin kuviteltavissa oleva haitta



IIQ-7
Incontinence Impact Questionnaire - short form

Olkaa hyvä ja rastittakaa oireisiinne parhaiten sopiva ruutu:

Onko virtsankarkailu vaikuttanut:	**ei lainkaan**	**hieman**	**kohtalaisesti**	**suuressa määrin**
Kotiaskareisiinne				
Liikuntaharrastuksiinne				
Muihin harrastuksiinne				
Matkustamiseen (>30 min matka kotoa)				
Sosiaaliseen kanssakäymiseen				
Tunne-elämäänne (mm. hermostuminen, masentuneisuus)				
Aiheuttanut turhautumisen tunnetta				

UDI-6
Urogenital Distress Inventory - short form

Olkaa hyvä ja rastittakaa oireisiinne parhaiten sopiva ruutu:

Esiintyykö Teillä seuraavia oireita ja miten hankalina?	**ei lainkaan**	**hieman**	**kohtalaisesti**	**suuressa määrin**
Tihentynyt virtsaamistarve				
Virtsankarkailua, johon liittyy pakottava virtsaamistarve				
Virtsankarkailua liittyen ponnistustilanteisiin, yskimiseen tai aivastamiseen				
Virtsaa karkaa tipoittain, pieniä määriä				
Hankaluuksia tyhjentää rakkoa				
Kipuja alavatsalla tai ulkosynnyttimien alueella				

EQ – 5D
Terveyskysely
(Suomalainen versio)

Olkaa hyvä ja merkitkää rastilla (x), yksi rasti kunkin alla olevan ryhmän kohdalle, mikä seuraavista kolmesta väitteestä kuvaa parhaiten terveydentilaanne tänään:

Liikkuminen

( ) Minulla ei ole vaikeuksia kävelemisessä
( ) Minulla on jonkin verran vaikeuksia kävelemisessä
( ) Olen vuoteenomana

Itsestä huolehtiminen

( ) Minulla ei ole vaikeuksia huolehtia itsestäni
( ) Minulla on jonkin verran vaikeuksia peseytyä tai pukeutua itse
( ) En kykene peseytymään tai pukeutumaan itse

Tavanomaiset toiminnot

( ) Minulla ei ole vaikeuksia suorittaa tavanomaisia toimintojani (esim. ansiotyö, opiskelu, kotityö, vapaa-ajan toiminnot)
( ) Minulla on jonkin verran vaikeuksia suorittaa tavanomaisia toimintojani
( ) En kykene suorittamaan tavanomaisia toimintojani

Kipu tai vaiva

( ) Minulla ei ole kipuja eikä vaivoja
( ) Minulla on kohtalaisia kipuja tai vaivoja
( ) Minulla on ankaria kipuja tai vaivoja

Mieliala

( ) En ole ahdistunut enkä masentunut
( ) Olen melko ahdistunut tai masentunut
( ) Olen erittäin ahdistunut tai masentunut

Verrattuna keskimääräiset terveydentilaani viimeisten 12 kuukauden aikana, terveydentilani tällä hetkellä on

( ) Parempi
( ) Suunnilleen sama
( ) Huonompi

EQ – 5D
Terveyskysely
(Suomalainen versio)

Auttaaksemme Teitä arvioimaan kuinka hyvä tai huono jokin terveydentila on, olemme piirtäneet oheen lämpömittaria muistuttavan asteikon. Parasta terveydentilaa, jonka voitte kuvitella, merkitään siinä 100:lla ja huonointa 0:lla.

Pyydämme Teitä nyt merkitsemään oheiselle asteikolle, millainen on terveydentilanne tänään. Olkaa hyvä ja vetäkää alla olevasta laatikosta viiva siihen kohtaan asteikolle, joka parhaiten kuvaa tämänhetkistä terveydentilaanne.

Paras kuviteltavissa oleva terveydentila

Huonoin kuviteltavissa oleva terveydentila

Terveydentilani tänään

Kirsi Rinne

Comparison of Two Mid-Urethral Sling Operations and Their Effect on Urethral Mobility Assessed by Dynamic Magnetic Resonance Imaging

Female urinary incontinence is a common condition, which has high negative impact on quality of life and a major cost effect on the health care system. Permanent cure of stress urinary incontinence is achieved by anti-incontinence surgery. We compared the cure rates and complications of two mid-urethral sling operations (TVT and TVT-O). The mobility of female mid-urethra was assessed by dynamic magnetic resonance imaging.

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