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## Chapter 1

# Introduction and outline of the thesis

### THE HISTORY AND DEVELOPMENT OF THE TVT

The Tension-free Vaginal Tape (TVT) is a minimally invasive surgical procedure for the treatment of stress urinary incontinence. Since its development in 1996, over 900,000 procedures have been performed, making it one of the most commonly used interventions for Stress Urinary Incontinence (SUI).

The working mechanism is based on the mid-urethral support given by the tape and by the subsequent development of connective tissue. The theory behind this support mechanism originates from the Integral Theory, which was postulated in 1990 and 1993 by P.Petros and U.Ulmsten<sup>1,2</sup>. Petros was inspired by Dr Zacharin's anatomical studies of the ligaments and muscles around the urethra and the importance of these for control of urinary continence<sup>3</sup>. Petros observed that implantation of foreign material created scar tissue and that this could reinforce tissue. This led to the hypothesis that implantation of artificial tape would lead to enforcement of the pubourethral ligament and anchoring of the muscles needed for urethral closure. In 1986, Petros described the insertion of a mersilene tape in the position of the pubourethral ligament. Animal studies and later human studies<sup>4</sup> followed, but unfortunately tape erosion remained a major problem. This problem was largely solved with the introduction of the polypropylene mesh of which the first results were published in 1996<sup>5</sup>. In this first study, seventy-five patients underwent a new surgical procedure, later called the TVT procedure. The operation took place under local anesthesia and sedation and was performed with the aid of two metal needles.

Since this first publication, an enormous amount of scientific papers on TVT or TVT-like procedures have been published. Just before the first publications of the TVT in 1996, Black and Downs analyzed the outcome of 11 randomised controlled trials (RCT), 20 non-randomized trials/prospective cohort studies and 45 retrospective trials of incontinence procedures. They concluded that the methodological quality of the studies that reported on the effectiveness of surgery for SUI was poor<sup>6</sup>. The considerable variation in inclusion criteria, surgical management and assessment of outcome precluded any statistical meta-analyses. Additionally, they concluded that the value of surgery and the effectiveness of different procedures was unclear. While the criticism of Black and Downs is still applicable to some of the studies published

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

#### *Prevalence of urinary incontinence*

Several epidemiologic studies of urinary incontinence (UI) exist. The methodologies of these studies vary. This was because no consensus on the definition of UI existed at that time. Another issue in studying UI is that UI is a condition with many varied types, occurring in different age groups and different populations. Also the severity of incontinence is of importance as 'daily' leakage shows a lower prevalence compared to 'any' leakage. The different types of UI and the most important definitions as made by the International Continence Society (ICS)<sup>7</sup> are:

*Stress urinary incontinence:* is the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing.

*Urge urinary incontinence:* is the complaint of involuntary leakage accompanied by or immediately preceded by urgency.

*Mixed urinary incontinence:* is the complaint of involuntary leakage associated with urgency and also with exertion, effort, sneezing or coughing.

Prevalence is the proportion of a population having a disease at a point in time.

The prevalence of UI described in European studies varies between 12–45%<sup>8-19</sup>.

In the Netherlands, several studies have been performed to determine the prevalence of UI.

Rekers et al found an incontinence rate of 26.5% in 1299 women aged 35–79 years<sup>20</sup>.

Kok et al found an incontinence rate of 23.5% in a sample of 1049 women aged over 60 years and living in a community. Van der Vaart found an overall urinary incontinence rate of 43.7% in a random population of 1393 women, aged 20–45 years<sup>21</sup>.

Stress urinary incontinence has a prevalence of 50%, urge urinary incontinence of 10% and mixed incontinence of 40%<sup>8,22</sup>. Overall, stress urinary incontinence is the most prevalent type of urinary incontinence among women<sup>23,24</sup>. The prevalence of stress urinary incontinence decreases with increasing age, while urge incontinence increases with older age<sup>25-27</sup>.

#### *Impact of urinary incontinence*

Urinary incontinence has a profoundly negative impact on the quality of life of women<sup>28-31</sup>. Psychological impact like shame, depression, anxiety, embarrassment and loss of self-esteem are described<sup>32</sup>. The impact of urinary incontinence can be measured by assessing the life-style adjustments in patients suffering from UI. Daily activities, social activities, relationships and emotions can be affected. Most studies report on adjustments on shopping, visiting friends, sporting, traveling long distances (patients report only visiting places with known location of toilet facilities)<sup>20,33-35</sup>. Relationships may be affected due to incontinence during coitus<sup>20,35,36</sup>. Finally these adjustments can cause social isolation<sup>37</sup>.

Many women think that their incontinence is a normal result of pregnancy and aging. Others do not seek help because of embarrassment. Hannestad et al, in study

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

## ASSESSING THE OUTCOME OF INCONTINENCE SURGERY

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

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

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

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

Khan et al looked at whether the method of administration of questions, either by mail or by personal interview at the doctor's clinic, affected the outcome. The authors concluded that postal questionnaire responses had a better relationship with urodynamics, both for urodynamic stress incontinence and detrusor over-activity, than interview-assisted questionnaire responses<sup>54</sup>.

Several studies recently published have used quality of life to assess the outcome of the TVT. These studies show an overall improvement of quality of life after TVT<sup>28, 55-59</sup>.

## **TENSION-FREE VAGINAL TAPE**

### *Theories concerning the TVT*

The Integral theory describes the complex interplay of the specific structures involved in female urinary continence. The theory and studies sustaining the theory have almost all been published by Petros and Ulmsten<sup>1, 60</sup>.

According to the theory, stress and urge symptoms may both, for different reasons, derive from the same anatomical defect, namely a lax vagina. This laxity may be caused by defects within the vaginal wall itself, or its supporting structures for instance ligaments, muscles, and their connective tissue insertions. The vagina has a dual function. It mediates (transmits) the various muscle movements involved in bladder neck opening and closure through separate closure mechanisms. It also has a structural function, and prevents urgency by supporting the hypothesized stretch receptors at the proximal urethra and bladder neck. Altered collagen and elastin in the vaginal connective tissue or its ligamentous supports may cause laxity. This dissipates the muscle contraction, causing stress incontinence, and/or activation of an inappropriate micturition reflex ("bladder instability") by stimulation of bladder base stretch receptors. The latter is manifested by symptoms of frequency, urgency and nocturia, with or without urine loss.

An anatomical defect in the anterior vaginal wall results in a pubo-urethral ligament (PUL) and urethral or bladder neck closure dysfunction. This theory suggests that laxity in the suburethral vaginal wall (hammock) interferes with the function of the pubo-urethral ligament. The surgical intervention based on the integral theory to dissolve stress incontinence comprises the insertion of a tape around the urethra. The implantation of foreign material subsequently creates scar tissue that acts as an artificial peri-urethral ligament.

Secondly, the theory postulates that the suburethral hammock should be restored. Surgical intervention includes the excision of vaginal excess skin (vaginoplasty), anterior wall repair or a vaginal flap repair<sup>4, 60-62</sup>. This last part of the theory, the restoration of the hammock, is not commonly practiced by urologists and gynecologists.

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

of the urethra, the mucosal, the vascular tissues that surround the lumen and the connective tissue in the urethral wall.

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

#### *Surgical procedure of TVT*

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

#### *Anesthesia*

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

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

Overall the GA, RA or LA do not seem to have an influence on the outcome of the TVT procedure but more reliable data are necessary to strengthen this preliminary conclusion.

#### *Clinical efficacy*

The first publications on the TVT were published in 1998<sup>65, 66, 76</sup>. These studies were non-randomized, non-comparative studies with short follow-up. Ulmsten et al published their 3 year follow-up of 50 women in 1999<sup>77</sup>. The authors found a cure rate of 86% and concluded that the TVT operation was safe and effective. After this study more studies with a longer follow-up followed. The cure rates found in these studies varied between 66%-100%, subjective cure. Objective cure rates ranged from 67% to 100%<sup>69, 76, 78-85</sup>. The first large comparative studies started to emerge in 2001. Not all of these studies were randomized controlled trials, so heterogeneity of the groups may have influenced the results. Success rates between 86% and 96% were observed<sup>86-95</sup>.

The UK and Ireland group presented the first results of their randomized controlled trial (RCT) in 2002. Ward et al found a cure rate of 66% when the non- attendees were counted as failures. The cure for the attendees was 76%<sup>96</sup>. The success rates after 2 years follow-up were 65% and 87% respectively<sup>97</sup>. The reason to publish both outcomes has also been described by Hilton<sup>98</sup>. The most important findings of the RCT were that the cure rates after TVT compared with the Burch colposuspension were comparable, and that the intra- and postoperative complications of the TVT were lower. The problem with the study was that the number of patients needed for the assessment, as calculated before with a power analysis, were not achieved.

More and more RCT's were published after 2003, often with a short follow-up and small numbers of women. Comparison of TVT with different sling procedures, Raz, laparoscopic suspensions and open colposuspension showed equal or better results and less complications<sup>87-95, 99</sup> for the TVT.

Few studies have a longer follow-up of more than 4 years<sup>100-103</sup>. Jooma et al and Nilsson et al describe a stable success rate until 7 years follow-up. Holmgren et al describe a stable success rate for stress incontinence, however for 112 women with a

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

#### *Cost effectiveness*

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

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

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

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

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

Most complications are described in case reports, only two national prospective studies have been published recently<sup>111, 112</sup>.

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

Urethro-vaginal and cysto-vaginal fistulae have been described<sup>112, 116, 117</sup> but are

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uncommon complications.

Few case reports describe bowel perforations<sup>111, 118-121</sup>. Most perforations were recognized immediately postoperatively, mainly in very thin women and in women with prior pelvic surgery. Bafghi et al and Fouri et al each presented a case of a bowel erosion with a late clinical manifestation occurring several months after surgery<sup>122, 123</sup>.

Several case reports describe bleeding due to trauma to the perivesical venous plexus<sup>124</sup>, iliac artery<sup>125</sup> and vein<sup>126</sup>. Retropubic and vulval hematomas have been described.

Urethral injury can be caused by direct trauma with the introduction of the TVT needle or due to late migration of the tape<sup>115, 127</sup>. Haferkamp et al<sup>128</sup> advocate reconstructive urethral surgery, while others<sup>127, 129</sup> suggest endoscopic resection of the urethral penetrations.

Persisting postoperative pain after a TVT procedure is a rare complication. It may be due to trauma of bladder<sup>130</sup>, urethra<sup>131</sup>, a hematoma, tape erosion or tape rejection. Barrington et al reported a case in which the postoperative pain after TVT was caused by a densely adhered tape to the ileopectineal ligaments<sup>132</sup>. The pain resolved immediately after dissection and division of the tape. Duckett et al reported five cases (1%) of groin pain after a TVT procedure (n=450)<sup>133</sup>. Vervest et al published a case report where the tape inadvertently ran through a nervous structure causing retropubic pain<sup>134</sup>.

Tape erosion into the vagina has been described in publications as a late and very uncommon complication of the TVT<sup>135-138</sup>. Partial excision of the tape and the use of local estrogens is described as effective. Old age and post-menopausal status have been described as risk factors<sup>135</sup>. One comparative study compared the multifilament IVS procedure with the TVT. Glavind et al found more erosion in the multifilament group<sup>139</sup>.

Obstructive voiding has been described, however the rate seems lower after TVT than in the Burch procedure<sup>97</sup>. Excessive tension on the tape has been thought to provoke these symptoms but several articles describe other risk factors for the development of voiding disorder, namely preoperative ISD<sup>140</sup>, abnormal flow<sup>141, 142</sup>, urgency<sup>143</sup>, learning curve<sup>138</sup>, repeat surgery<sup>144-146</sup>, concomitant pelvic surgery<sup>142, 147</sup>. Obstructive voiding can also be a result of urinary tract infection<sup>147</sup>. Different options to resolve this complication have been described: tape excision<sup>111, 148-150</sup>, tension readjustment by downward traction of the urethra<sup>138, 151</sup> via the vaginal incision<sup>65, 111, 152</sup>, tape division<sup>152-154</sup> and interpositioning of another piece of tape<sup>155</sup>.

*Urge- and de novo urge incontinence, detrusor overactivity (DO) and mixed incontinence.*

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

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tion with SUI and the long-term results of the TVT on these symptoms should therefore be assessed.

Assessment of urge incontinence after TVT is difficult. Only a few large studies describe prospectively the long-term influence of the TVT on urge incontinence. The results of these published studies show a wide range in outcomes. Also a wide array of definitions were used to describe bladder function after the TVT procedure. This makes interpretation of these results difficult.

Two small (n=52 and n= 62 respectively) prospective studies showed de novo urge rates of 0-18%<sup>82,84</sup>. A large cross-sectional, questionnaire based study of 743 woman showed de novo urge incontinence in 6.7%<sup>102</sup>. This complication even increased after several years. This finding suggests that slow ingrowth of tissue in the tape possibly changes the surroundings of the urethra. This 'sclerosis' may induce urge incontinence. But we must not forget that age is also a confounding factor for urge incontinence. It is thought that this phenomenon is a result of atrophy of the bladder epithelium.

The improvement or cure rates of the TVT are often lower in patients with preoperative mixed incontinence than in patients with only stress incontinence, that is 42%-100%<sup>55, 69, 79, 81, 102, 158, 159</sup>. For patients with preoperative detrusor overactivity, the cure or improvement rates described are 33%-100%<sup>78, 79, 102, 159-161</sup>. Holmgren et al described a steadily decline to 30% cure rate, after 4-8 years follow-up, due to increasing urgency symptoms<sup>102</sup>. The reverse, a reduction of the urge component, has been described (up to 57% by Segal 2004)<sup>79, 82, 96, 97, 159, 161, 162</sup>. It is thought that this occurs due to the stability the tapes provides underneath the urethra, which inhibits the urge incontinence<sup>6, 60, 163</sup>.

Two large prospective comparative studies between the Burch colposuspension and the TVT showed de novo rates of detrusor overactivity (DO) of 7% and 17% after TVT and 9% and 14% after the Burch colposuspension<sup>86, 96</sup>.

#### *TVT and concomitant pelvic prolapse surgery.*

Co-existing urinary incontinence and pelvic organ prolapse has been reported in 15-80%<sup>164, 165</sup>. Choe et al and Bai et al reported that 60-63% of patients with urinary stress incontinence also had pelvic organ prolapse<sup>165, 166</sup>.

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

comfortably full bladder and no stress incontinence episodes having been reported verbally by the patient or noted in a voiding diary. Jomaa reported in 2001 on 32 women undergoing TVT and anterior and/or posterior colporrhaphy<sup>169</sup>

Success was defined as  $\leq 10$  g urine lost in a 24h pad test, no visible leakage at stress test, no anatomical defect and a patient satisfaction  $\geq 90\%$ . A 93% success rate was found. Lo et al found a success rate of 90.9% in 55 patients, part of the definition used to assess cure was a pad test<sup>170</sup>. In 2002 Soroka et al published a systematic review on pad tests which showed a significant variability and repeatability of the pad test<sup>171</sup>. Therefore studies using only the pad test as an outcome parameter should be treated with caution.

The results of all these studies are difficult to compare due to different definitions of success or cure.

#### *TVT in patients with prior pelvic surgery*

Burch colposuspension and sling procedures have been used in the past for women with recurrent stress incontinence. Success rates of 85-90% at 3-4 years follow-up are published but are associated with high complication rates such as significant urinary retentions and blood loss<sup>172-174</sup>. These complications are lower with the TVT procedure<sup>111</sup>.

Only few articles describe the outcome of the TVT after prior incontinence surgery<sup>58, 118, 146, 175-178</sup> and prolapse surgery<sup>78, 118</sup>. Most studies do not report a difference in success rates between primary and secondary cases of incontinence surgery<sup>80, 84, 179</sup>. The success rate of the secondary cases reported is 84%-89%, but objective judgment of these studies is complicated. The groups are small, the outcome parameters are all different, the definition of repeat or secondary surgery is not uniform and sometimes the statistical significance is not reported<sup>56, 58, 82</sup>.

#### *TVT with intrinsic sphincter deficiency*

Intrinsic sphincter deficiency (ISD) is defined as a urethra with a maximum closure pressure of less than 20 cm H<sub>2</sub>O. There is some controversy whether immobility (so called "fixed urethra") should also be included in the definition and whether ISD is defined as a low pressure, fixed urethra. This makes comparison of data in studies addressing the outcome of TVT in cases with ISD difficult to interpret. Furthermore, confounding factors like prior pelvic surgery and age may be introduced, which may be independent etiological factors for the development of ISD.

Most studies comparing women with low urethral sphincter closure pressure with women with normal closure pressures, show better cure rates for women with normal closure pressures<sup>180-182</sup>. Several studies do report differences between the two groups but do not report on the statistical significance<sup>56, 78, 82, 140</sup>. A few studies did not compare the results of women with or without ISD and reported on the results of the group with ISD only<sup>183-186</sup>. The reported cure rates are between 56% and 90%. Lower cure rates are reported in patients suffering from both ISD and an immobile urethra<sup>183, 187</sup>. One publication reports on a comparable high cure rate for both groups, ISD with immobility 83% and ISD without immobility 86%<sup>188</sup>.

### *TVT and sexual function*

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

### *TVT and pregnancy*

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

### *TVT in different age groups*

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

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

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

Prien-Larsen found comparable subjective and objective outcomes for women under and over 70 years<sup>199</sup>. In a comparative study of Gordon 157 women over 70 years and 303 younger women were assessed. The incidence of persistent postoperative SUI and persistent urge incontinence was similar in both age groups. However, de novo urge incontinence was significantly more common among elderly women (18% versus 4%,  $P < 0.05$ )<sup>200</sup>. Walsh et al compared 2 groups, namely 21 patients who were 70 years and older, and a control group of 46 patients younger than 70 years and assessed quality of life changes following TVT. In both groups the quality of life improved significantly<sup>59</sup>.

Alahdin et al looked at 3 age groups: 30-49 years, 50-69 years and 70-90 years. The cure rates were 84.9%, 81.3% and 85.3% respectively<sup>135</sup>. Abdel-Hady el et al found age over 70 years to be a risk factor<sup>201</sup>. In a non-comparative study in a patient group aged over 65 years, Lo et al found a success rate of 91% and de novo detrusor overactivity in 4%<sup>67</sup>. Sevestre et al, in a non comparative study in a group of 76 women over 70 years, found a 82% satisfaction rate but 21% rate of de novo urgency<sup>202</sup>. Liapis et al found in a group women aged between 65 and 86 years a satisfactory cure rate. However, in patients with significantly decreased bladder neck mobility (an angle  $< 20$  degrees on the Q-tip test), the success rates were lower<sup>203</sup>.

A review article about risk factors influencing the complication rates of TVT found prior anti-incontinence surgery and old age to be possible risk factors for postoperative overactive bladder symptoms<sup>204</sup>.

Wang et al found age not statistically significant in postoperative voiding dysfunction<sup>147</sup>.

#### *TVT in the obese patient*

Many articles have described the consequences of obesity in curing urinary incontinence. Dwyer et al describe a higher rate of stress and urge incontinence with an increased body mass index<sup>205</sup>. Kjolhede performed a long-term follow-up of women undergoing a Burch colposuspension. In this study preoperative obesity seemed to be a long-term risk factors for an adverse outcome<sup>206</sup>. Although outcome of TVT for an increasingly obese population seems interesting, not many articles have assessed specifically the outcome for this group.

Kinn et al<sup>78</sup> and Hung et al found a lower cure rate for obese women (BMI  $> 28$  kg/m<sup>2</sup> and 27.3 kg/m<sup>2</sup> respectively). A few other studies found comparable cure rates for normal BMI and obese women<sup>57, 207-209</sup>. Rafii et al found a higher rate of UI after TVT but this group had a higher rate of preoperative urgency<sup>208</sup>. In a comparative study between TVT and laparoscopic Burch colposuspension in obese women, the authors concluded TVT to be safer, more effective, and easier to perform<sup>207</sup>.

#### *TVT after radiotherapy*

Few studies report on the outcome of TVT after pelvic radiotherapy.

Ferrari et al found no specific complications or different success rate in women with a history of pelvic radiation<sup>118</sup>. Another study included 2 patients with pelvic beam radiation. One patient was found to be dry, the other patient is described as having

very slight leakage at stress<sup>82</sup>. Kinn et al also included 2 women with a history of pelvic radiation<sup>78</sup>. One patient was cured but showed a vaginal erosion of the tape. In the other patient the SUI was found to be worse after TVT. In a study of Al-Singary et al<sup>210</sup>, 87 women were evaluated. In 16 of these women TVT was considered to have failed and 2 of these women had a history of radiotherapy

In the Austrian national TVT registry, 8 patients with a history of radiotherapy were included but no success rates or specific complications were described<sup>111</sup>.

#### *TVT in patients with neuropathic bladder*

Patients with a neuropathic bladder have specific problems. In an upper motor neurone injury often a detrusor hyperreflexia exists combined with a weak external urethral sphincter. In lower motor neurone injury, an a non contractile bladder with a weak urethral sphincter exists. Stress incontinence in women with a neurogenic bladder is accompanied by either detrusor over- or under-activity. In women with hyperreflexia, suppressing the detrusor overactivity with anticholinergics may be indicated prior to TVT. Acontractility may indicate a need for permanent postoperative bladder drainage.

Hamid et al published an article describing the outcome of TVT in 11 patients with a neuropathic bladder and SUI<sup>211</sup>. They found a success rate of 92%. The authors warned that an exacerbation of pre existing hyperreflexia could be caused by the insertion of a TVT.

## **AIMS OF THE THESIS**

At the time of the initiation of this study, no large prospective cohort study had been performed. The aim of this study was to evaluate the outcome of TVT carried out by gynecologists and urologists in the Netherlands.

TVT was evaluated with a three year follow-up. At each follow-up a full urogynecological history, a physical examination and a cough-stress test was performed. Quality of life was separately assessed with disease specific health-related quality of life (HRQoL) questionnaire<sup>48 22</sup>.

The aims of the work presented in this thesis were:

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

## **OUTLINE OF THE THESIS**

To address the research questions we conducted the following studies.

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

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

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

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

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

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

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

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

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

Chapter 10 contains a summary in Dutch.

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