Chapter 9

Summary, conclusions, general discussion & recommendations for future research

Summary

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

Further, this chapter comprehends the aims and outline of this thesis.

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

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

a survey of complications of the TVT procedure as published in the English scientific literature is presented.

In total 809 women participated in this study. Their mean age was 51.3 +/-10.4 (range 20-82) years and mean parity was 2.4 +/-1.1. The overall intra operative complication rate was 6.2%. Bladder perforation was the most common complication (n=28, 3.5%). In all cases it was diagnosed during the procedure. In all but one case the tape was reinserted and an indwelling catheter was placed, at follow-up none of these patients suffered any problems. There were no urethral lesions. Severe blood loss (>300ml) occurred in 10 cases. In one case the internal iliac vein was lacerated and a laparotomy followed.

The total incidence for postoperative complications was 20.9% (N=169). In this group there were 30 patients (3.7%) with a combination of more than one complication. A temperature rise (> 38°C) was diagnosed in 1 (0.1%) case. Tape erosion was found in 2 (0.2%) cases in two year follow-up. In 121 (14.9%) cases an indwelling bladder catheter was needed for more than 24 hours. In 13 (1.6%) of these patients the TVT tape had to be cut because of voiding difficulty, erosion, or infection.

Previous prolapse surgery was a risk factor for complications (OR 2.86, CI 1.15 - 7.11). We found more intra operative complications in patients with general anesthesia than local analgesia with sedation (OR 4.14, CI 2.01- 8.53). The postoperative complication rate in the 25 teaching hospitals was 24% and 16% in the 13 local hospital(OR 0.55, CI 0.35- 0.85). The learning curve is short and more postoperative complications were found in the second ten patients operated by one surgeon (OR 1.94, CI 1.14 − 3.29). Spinal analgesia gives less postoperative complications than local analgesia with sedation (OR 0.35, CI 0.13 − 0.92).

In **chapter 3** we presented the results of a multicenter study on the long-term outcome of TVT. The focus of this report is on the pre and intraoperative factors influencing the success of the TVT procedure for SUI. This is a prospective cohort study of 809 patients. In 28 teaching hospitals and 13 local hospitals, 54 gynecologists and urologists participated. Hundred and thirty-one women had previous incontinence or prolapse surgery. In this group there were nine patients who had undergone two prior incontinence procedures and one patient who had undergone three prior incontinence procedures (Burch, re-Burch and hysterectomy with concomitant Raz sling procedure).

Before treatment and two years postoperatively the following question from the Urogenital Distress Inventory (UDI) for stress urinary incontinence was selected to define success or failure: "do you experience urinary leakage during physical activity, coughing or sneezing?". Secondary outcome measurement was the outcome of the doctors question "do you leak during physical activity, coughing or sneezing?" asked at two year follow-up. As tertiary outcome measurement both questions were combined. Women who had answered to be dry in the written questionnaire as well as to the oral question at two year follow-up were defined to be a success.

The response rate was 78.7%. The success rate on outcome measurement 1 was 66%. The success rate was significant higher in all analyses when the surgeons had per-

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

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

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

sling procedure). There were 16 cases with a history of both prolapse and incontinence surgery. In this group, one woman had undergone an Burch colposuspension twice; one woman had undergone a Stamey suspension followed by a Burch colposuspension. Sixty-five women had a history of prolapse surgery only. Two women had undergone prolapse surgery twice. The primary outcome measurement were the IIQ and UDI scores.

According the recommendation of the ICS, the question "Do you experience urinary leakage during physical activity, coughing or sneezing?" was selected from the UDI, as secondary outcome measure to define success or failure for SUI [2]. Women who have a lower score on the UDI question score post operatively were considered to be improved.

A significant improvement was found for all outcome measurements, which shows that TVT is a successful treatment in secondary cases for recurrent incontinence and/or prolapse. The research group (N=131) was compared with control group without previous urogynecological surgery (N=687). A difference between the UDI scores of the two groups was found at twelve months and at twenty-four months follow-up (p=0.011 & p=0.018 respectively). The improvement of the group with prior surgery was encouraging, because in this group the preoperative UDI scores were significantly higher than for the other groups, indicating more preoperative bother. The quality of life scores are equally good for both groups after 3 years follow-up.

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

This is a prospective cohort study of 610 participants. Excluded were women in whom no urodynamic investigations prior to TVT were performed, women of whom the presence of detrusor over activity (DO) was not listed and women who had detrusor over activity on their preoperative urodynamic investigation. Urge incontinence and OAB wet symptoms developed in 11% and 3% respectively and give less improvement on the quality of life scores. The presence of preoperative frequency (odds ratio 2.64; 95% CI, 1.16-6.03) and rectocele (odds ratio 2.39; 95% CI, 1.15-4.99) were independent factors for the development of irritative symptoms postoperative. Nevertheless, these women still had significant improvement in their quality of life compared to the preoperative situation. This is probably due to cure of their stress incontinence. This study showed a *de novo* rate for urge incontinence after 2 months and 3 years of 6.3% and 10.9% respectively and *de novo* OAB wet of 1.6% and 3.2%.

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

(UDI-6) were used to measure the results of the TVT procedure (preoperative, at two, six, twelve and twenty-four months postoperative). Fifty-nine patients with concomitant prolapse surgery were compared with 687 women with TVT only. The surgical procedures performed concomitant to the TVT were: vaginal hysterectomy for uterine descent (n=7), anterior repair (n=15), posterior repair (n=28) and anterior with posterior repair (n=9). Of these 59 patients 15 women underwent prior surgery, 6 women had prior prolapse repair: 3 women a vaginal hysterectomy, 5 underwent a colporrhaphy anterior, 3 women a colporrhaphy posterior. One woman underwent a sacrocolpopexy and rectopexy. Seven women underwent previous incontinence surgery, all underwent a Burch colposuspension. One woman underwent a re-Burch and one women underwent a Marchall-Marchetti-Kranz (MMK) suspension after a Burch. Two women underwent both prior incontinence and prolapse surgery: one Burch colposuspension with a colporrhaphy anterior and colporrhaphy posterior and one women a MMK with abdominal hysterectomy with colporrhaphy anterior and posterior. The IIQ/UDI mean scores decrease statistically significant in both groups after the TVT, indicating a significant improvement in quality of life.

Both IIQ and UDI mean scores decreased statistically significant after TVT after two months. Thereafter, no statistical difference was found when comparing the changes between two and six, six and twelve months and twenty-four months follow-up in the UDI scores. The mean IIQ and UDI scores of women with concomitant pelvic surgery were compared with the mean IIQ and UDI scores of women without prior surgery. After a follow-up of two years a statistical significant difference in UDI & IIQ scores could be identified (p=0.019). Nevertheless, this study shows that the procedure in conjunction with prolapse surgery can safely be performed with good results .

In **chapter 8** we report on the prevalence of voiding difficulties after TVT in the immediate postoperative period and on the long-term with the aid of reports of women, measurement of objective measurements, and with the use of validated quality of life questionnaires. For this study women in whom no urodynamic investigation prior to TVT was performed (n = 106) were left out of the analysis. This left 703 women for this study. The follow-up period was 3 years.

The first outcome measure was the need of postoperative catheterization. Secondly, women were asked if voiding went easy or difficult. Thirdly, the following question of the short form of the Urogenital Distress Inventory (UDI-6) informing about difficulty in emptying the bladder, was used. A woman was considered to experience voiding difficulty if she replied positively to the question: "do you experience difficulty emptying your bladder?". The fourth outcome measurement was the maximum flowrate and the fifth was the amount of postvoid residual urine.

Postoperative catheterization due to urinary retention was necessary in 81 (11.5%) of women. Of these 81 women 66% voided normal within 2 days, 95% within 10 days, while in 4 women (5%) catheterization up to 90 days was needed. The mean length of catheterization was 5.07 (± 12.5, median 2) days. Tape revision or adhaesi-

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

CONCLUSIONS

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

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

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

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

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

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

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

GENERAL DISCUSSION

Methodological considerations

Urogenital symptoms can be assessed objectively or subjectively. While both have different advantages, they also have some major drawbacks. Objective test available are urodynamic investigations, pad tests and bladder diary. In 2002 Soroka et al[3] published a systematic review on pad tests, which showed a significant variability and repeatability of the pad test. Using a bladder diary, patients may register time of voiding and voided volume for a few days. This provides valuable information in initially detecting frequency, urgency and urge incontinence because it offers a quantitative measure of the symptomatic degree of motor urgency[4]. However, the accuracy of the self-reported diary is point of discussion[5-7]. Urodynamic testing has been the "golden standard" to assess urogenital symptoms for a long period, but it also has its limitations. The test-retest reproducibility and validity in several urodynamic tests are not convincing[8] and because urogenital symptoms may fluctuate[9] the assessment may be done on an asymptomatic day. *The bladder* is a notoriously bad witness, and the symptoms of frequency, nocturia and urgency may arise because of hypersensitivity of the bladder stretch but also may occur when the bladder contracts inappropriately due to detrusor over activity. Conventional urodynamic investigation fails to detect detrusor over activity in 62-74 percent of the women with frequency and/or urgency symptoms and in 53-62 percent of the women with urge incontinence symptoms[10-15]. Therefore, a normal urodynamic investigation cannot disprove the accuracy of a patient's history of urge incontinence, urgency and urge incontinence[16]. Subjective symptoms can be measured with self-report questionnaires or in a personal interview. Khan et al looked whether the method of administration of questions changed the outcome[17]. They authors concluded that postal questionnaire responses had a better relationship with urodynamics, both for urodynamic stress incontinence and detrusor overactivity, than interview-assisted questionnaire responses. The International Continence Society (ICS) also uses definitions based on subjectively measured symptoms. But according to the ICS, using a questionnaire without objective assessment does not allow an accurate diagnosis of genuine stress incontinence or detrusor overactivity. The symptom of stress incontinence may be sensitive in predicting genuine stress incontinence, but there is a false-positive rate[18].

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

ing from 0 (no bother) to 100 (maximum bother).

Disease specific health related quality of life scores assessing the impact of pelvic floor symptoms were obtained from the Incontinence Impact Questionnaire (IIQ)[21, 22]. The impact of pelvic floor symptoms were measured on five domains; emotional functioning, physical functioning, social functioning, mobility and embarrassment. The scores on the domains range from 0 to 100. A high score indicated that a person's well-being on that particular domain is negatively affected.

The application of quality of life instruments to women preoperative and postoperative assessing urogenital symptoms enables a measurement of the impact of symptoms on lifestyle. Contrary to objective measurements which record a health status at just one specific moment, subjective parameters like symptoms and quality of life measurements can record the impression of a woman's health situation over a period of time. The main part of our results has to be viewed from this symptom-based point of view. Another reason to focus on symptom and quality of life based parameters is that it is merely impossible to perform objective measurements (like urodynamic investigations) in a large cohort of 809 women.

Design of the study

Randomized controlled trials are the best way to address differences between surgical procedures, when an effective randomization takes place. But to investigate the occurrence of for example complications with a very low prevalence a large cohort study is more appropriate. The same is true for prognostic factors.

At the start of our trial only few publications had appeared. A proper power analysis should be based on outcome differences generated by prior publications. At the time when this study was designed, such publications did not exist. In retrospect we believe that for all outcome measures the amount of 809 women included in this study was sufficient.

Another point of discussion is the length of follow-up. As Black and Downs have demonstrated the outcome of many incontinence procedures decline over time[23]. The WHO Consultation on Incontinence has defined that a follow-up of 2 years is considered long-term follow-up. We adhered to this definition and even more, we followed all women for three years.

However, a longer follow-up also leads to a greater drop out rate. In our study the drop out rate after 3 years for the follow-up in clinic is 20-30%, depending on which variable was used.

A fourth methodological problem is how to define the women who are lost to follow-up. Normally, no information at all is gathered from those patients who were failed to follow-up in clinic and the incorrect assumption is often made that these women perform the same as the attendees. Hilton suggests in his article; "Trials of surgery for stress incontinence-thoughts on the 'Humpty Dumpty principle'", to consider these non-attendees as failures[24]. In this study though we had information via the separately send postal questionnaires. We found a small difference between the groups who did and did not show up in clinic but did fill in the questionnaires. The improvement rates in the "lost to follow-up" group (chapter 4) is 5.4%-8.6% lower,

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

Outcome

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

Quality of life

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

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

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

Complication rates

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

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

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

RECOMMENDATIONS FOR FUTURE RESEARCH

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

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