

# Tailoring Stress Incontinence Surgery

“How to install proper diagnostic work-up and individualised treatment”

**Roderick Marijn Houwert**

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“How to install proper diagnostic work-up and individualised treatment”  
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# Tailoring Stress Incontinence Surgery

“How to install proper diagnostic work-up and individualised treatment”

## Stress Incontinentie Chirurgie op Maat

“Handleiding voor een eenduidige work-up en persoonlijk behandelplan”  
(met een samenvatting in het Nederlands)

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# Content

<b>Chapter 1</b>	<b>9</b>
Introduction and Aim of the thesis	
<b>Chapter 2</b>	<b>17</b>
Predictive value of urodynamics on outcome after mid-urethral sling surgery for female stress urinary incontinence	
<b>Chapter 3</b>	<b>37</b>
Risk factors for failure of retropubic and Transobturator mid-urethral slings	
<b>Chapter 4</b>	<b>55</b>
When to perform urodynamics before mid-urethral sling surgery for female stress urinary incontinence?	
<b>Chapter 5</b>	<b>69</b>
Outcome and complications of retropubic and transobturator mid-urethral slings translated into Surgical Therapeutic Indices	
<b>Chapter 6</b>	<b>88</b>
Perspectives by patients and physicians on outcomes of mid-urethral sling surgery	
<b>Chapter 7</b>	<b>103</b>
TVT-O versus Monarc after 2 – 4 years follow-up: a prospective comparative study	
<b>Chapter 8</b>	<b>119</b>
General discussion	

<b>Chapter 9</b>	<b>131</b>
How to tailor stress incontinence surgery	
<b>Chapter 10</b>	<b>135</b>
Summary and Conclusions	
<b>About the author</b>	<b>141</b>
<b>Dutch Summary / Nederlandse samenvatting</b>	<b>145</b>
<b>Dankwoord</b>	<b>153</b>

Tailoring Stress Incontinence Surgery: "No fixed prices!"



# **Chapter 1**

Introduction and Aim of the thesis

## **INTRODUCTION**

This thesis deals with two important clinical questions: which diagnostic work-up is necessary and which surgical treatment is the most beneficial when considering surgical treatment for Stress Urinary Incontinence (SUI).

Stress urinary incontinence is defined as the complaint of urine leakage upon physical effort or exertion, coughing or sneezing [1]. After SUI, the most common other forms of urinary incontinence are urge urinary incontinence (UUI) and mixed urinary incontinence (MUI). UUI is defined as leakage of urine preceded by a strong desire to void, while MUI is the condition when both SUI and UUI exist together [1].

The large Norwegian Epicont Study shows that 26% of the female population is affected by urinary incontinence [2]. Data from the Netherlands show prevalence rates between 26 and 57% [3,4]. Of these women 50% suffered from SUI and a further 40% of MUI [2]. Therefore SUI represents a major health issue among women.

Important treatment options for SUI are conservative measures like medical treatment and pelvic floor physiotherapy, and surgery. Even with conservative treatment, the overall lifetime risk for women of SUI surgery is no less than 4% in the United States [5]. Therefore, surgical treatment of SUI is an important cornerstone in the treatment for women with SUI.

## **CONTROVERSIES IN DIAGNOSTIC WORK-UP FOR SURGICAL TREATMENT OF SUI**

The conventional diagnostic work-up before considering surgery for SUI consists of assessment of medical history, performing an urogynecological examination and carrying out urodynamic investigation (UDI).

UDI consists of several separate procedures, assessing bladder storage and evacuation function [6]. The investigation is usually started with a free flowmetry. Flowmetry is the measuring of urinary flow without any catheter present and assessment of residual urine. It is followed by cystometry. This is the simultaneous measurement of the intravesical and intrarectal pressure while the bladder is filled through a catheter at a speed of 50 ml/min. Next, the pressure-flow relationship is determined through simultaneously measuring the urinary flow and detrusor pressure. Then a urethral pressure profilometry is performed, which is the simultaneous measurement of intra-urethral and intravesical pressure while the urethral catheter is withdrawn through the urethra at a speed of 1 mm/s [7].

Surgical treatment is then selected based on results of the diagnostic work-up. However, knowledge on the relationship between

diagnostic procedures like medical history, urogynecological examination and UDI on the one hand and the outcome of treatment on the other hand is lacking. Furthermore, one is faced with the fact that UDI is not one single procedure but, as mentioned before, consists of several separate diagnostic investigations. These investigations all have their own sensitivity and specificity with regard to establishing a diagnosis. It is therefore not surprising that this traditional work-up may lead to contradictory results. For example, urodynamic SUI is found in only 70% of women having complaints of SUI [6]. Furthermore, our own preliminary data analysis showed that cure rates of women without urodynamic SUI were equal to women with urodynamic SUI.

The need for pre-operative UDI is often justified by the consideration that pre-existing detrusor overactivity (DO; involuntary detrusor contraction [1]) may either be a contra-indication for surgery or the reason that surgery has at least a worse prognosis [8]. However, conventional UDI fails to detect DO in 53-62% of the women with UUI symptoms [9-11].

The necessity of UDI was recently quite prominently addressed in a Cochrane review [8]. The conclusion in this review is that there is not enough evidence to show that women with pre-treatment UDI are less likely to be incontinent after treatment than women who did not have urodynamic testing. These observations challenge the reliability of UDI and the necessity of performing UDI in all women.

These considerations indicate that it is not one single diagnostic property that establishes a diagnosis. In fact, not much is even known about how these diagnostic entities relate to successful treatment.

## **SURGICAL TREATMENT FOR SUI BY MID-URETHRAL SLINGS**

Mid-urethral sling (MUS) procedures are currently the gold standard of surgical treatment for SUI [12]. They were the first incontinence procedures that were designed on a previously well-defined pathophysiological theory: the Integral Theory and the Hammock Hypothesis [13,14]. Both theories have in common that a connective tissue band underneath the middle part of the urethra (located between the back part of the urethra and the anterior vaginal wall) supports the backside of the urethra during moments of sudden rise of the intra-abdominal pressure. Contraction of the horseshoe-shaped urethral muscles that are located in the anterior wall of the urethra, causes the urethra to be pushed against this connective tissue band and consequently, the urethra is closed. The Integral Theory also emphasizes

## Chapter 1

the importance of the support function of the pubo-urethral ligaments which connect the urethra to the backside of the pubic symphysis.

After the development of Intravaginal Sling Plasty, the first generally accepted MUS procedure is the Tension-free Vaginal Tape (TVT) introduced by Ulmsten et al. in 1996 [15,16]. TVT is a polypropylene tape that runs from underneath the middle part of the urethra behind the pubic bone and in front of the bladder to the lower abdominal wall. Follow-up data after 10-12 years show cure and improvement rates of respectively 77 and 20% [17].

As no surgical treatment is free of complications, gradually these also became evident for TVT. Due to the blind passage through the retropubic space bladder perforations, vessel lesions and even bowel injury have been described [18]. Postoperative voiding difficulty and de novo urgency or urge incontinence are regarded the most important functional complications [19,20].

In order to address these complications of TVT, other modifications were developed. In 2001 Delorme introduced the TransObturator Tape procedure (TOT), a new method of inserting a polypropylene tape with a high success rate for curing SUI [21]. The tape runs from underneath the urethra through the left and right obturator membrane onwards to the upper inner side of the thigh.

There are two basic techniques for performing TOT: "Inside - Out" (TVT-O) described by de Leval and "Outside - In" described by Delorme [21,22]. These techniques do not only differ in the way the needle is placed and carried forward, but also in the different designs of the introducer. After the introduction of the "Outside-In" technique by Delorme in 2001 several other similar procedures were developed. Among them is Monarc, which, like TVT, is a monofilament macroporous polypropylene mesh. It has shown similar and equally good short-term to medium-term success rates as TVT-O [23,24].

The advantage of the obturator approaches is that blind passage of the introducer in the retropubic space is avoided. Therefore, theoretically, the risk of bladder or bowel perforation is minimized [19]. Because the outcome of many incontinence procedures tends to decline over time, a disadvantage of TOT procedures is the lack of long-term outcome [25]. Furthermore, comparative trials with long-term follow-up between different obturator procedures are lacking.

After TOT procedures gained popularity and comparison to TVT became available, it was hypothesised that differences in individual characteristics of women may exist that influence success rates of TVT and

TOT procedures [26-28]. This hypothesis should be investigated and therefore an essential goal of research is identification of these characteristics.

### **SOME CONSIDERATIONS ON OUTCOME PARAMETERS OF SUI SURGERY**

Incontinence surgery is considered elective surgery. A primary goal for elective surgery is to improve patient-related Quality of Life [29]. Therefore it is important to assess opinions and expectations of women regarding possible outcomes of MUS procedures. So far, this topic has not yet been fully investigated.

### **CONCLUSIONS**

There are significant flaws in current diagnostic work-up for MUS procedures. Knowledge on the relationship of diagnostic procedures like medical history, urogynecological examination and UDI to the outcome of treatment is missing. Patient preferences are unknown and long-term results of TOT procedures are lacking. These flaws obstruct a proper diagnostic work-up and individualized surgical treatment of female SUI.

### **AIM OF THE THESIS**

The aims of this thesis are:

1. To perform an in-depth analysis of the current diagnostic modalities and correlation to successful outcome of mid-urethral sling (MUS) procedures.
2. To develop instruments for selecting the best surgical procedure based on the different properties of MUS procedures, women's individual characteristics and women's preferences.
3. To present our data on medium-term outcome of Transobturator Tape (TOT) procedures Monarc and TVT-O.

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## *Introduction and Aim of the thesis*

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## Chapter 2

### Predictive value of urodynamics on outcome after mid-urethral sling surgery for female stress urinary incontinence

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## ABSTRACT

**Objective:** the aim of this study was to evaluate the value of urodynamic investigation (UDI) in the pre-operative work-up of mid-urethral sling (MUS) surgery and to identify risk factors for failure after three different MUS procedures.

**Study design:** retrospective cohort study. 437 women who underwent a TVT, Monarc or TVT-O procedure without other simultaneously performed urogynecological surgery were included. Pre-operative data were collected from the medical files. Patients who reported any amount of leakage were considered failures. The mean follow-up of the study population was 14 months.

**Results:** after multivariate analysis, mixed urinary incontinence (MUI) ( $p = 0.04$ ), previous incontinence surgery ( $p = 0.022$ ) and detrusor overactivity (DO) ( $p = 0.02$ ) were significantly related to failure of MUS procedures. There were no predictive urodynamic parameters for failure in patients with MUI or previous incontinence surgery.

**Conclusions:** the standard use of UDI in the pre-operative work-up of MUS surgery needs to be revisited.

## **INTRODUCTION**

Mid Urethral Sling (MUS) surgery has become the golden standard for the surgical treatment of female Stress Urinary Incontinence (SUI) since the introduction of the Tension-Free Vaginal Tape (TVT) in 1995 by Ulmsten [1]. In the mean time MUS surgery has evolved and multiple less invasive procedures were developed like the Transobturator Tape procedures.

The development of mid-urethral slings has been based on new insights by clearly defined pathophysiological theories [2-3]. However, diagnostic techniques like urodynamic investigation (UDI) hardly changed in the last two decades. In current urogynecological practice, UDI is routinely performed before SUI surgery. This strategy is recommended in both gynecological and urological guidelines [4,5].

The need for pre-operative urodynamics is often justified by the consideration that pre-existing detrusor overactivity (DO) may either be a contra-indication for surgery or at least carries a worse prognosis [6]. Therefore UDI is performed to detect factors that may unfavorably influence the outcome of the operation or confirm the diagnosis.

However a recent Cochrane review concluded that there was not enough evidence to show whether women with pre-treatment urodynamics were less likely to be incontinent after treatment than women who did not have urodynamic testing [6]. Moreover, UDI is a stressful event for the patient and not without side-effects such as dysuria, urinary tract infections and even pyelonephritis [7]. Furthermore UDI is an expensive and time consuming investigation.

The aim of this study was to evaluate the predictive value of UDI in the pre-operative work-up of MUS procedures.

## **MATERIAL AND METHODS**

In this study, standardized data collected systematically from 437 patients were retrospectively analyzed. All women had symptoms of predominant SUI. 343 women (79%) had symptoms of pure SUI and 94 women (21%) had symptoms of mixed urinary incontinence (MUI). In women with MUI, anti-cholinergic medical treatment was given before surgical treatment was considered and did not alleviate their symptoms.

All patients underwent UDI before TVT, Monarc or TVT-O procedures. Urodynamic stress-incontinence was found in 336 (77%) patients whereas detrusor overactivity (DO) was observed in 27 (6%) patients. No other urogynecological surgery was simultaneously performed. The mean follow-

## Chapter 2

up of the included patients was 14 months (range 2-34 months). The baseline characteristics of the study population are shown in table 1.

Pre-operative the following patient characteristics were collected from the medical files: age, parity, menopausal status, history of SUI or MUI, voiding pattern (easy or difficult micturition: straining to void), voiding frequency (daytime and nighttime), complaints of vaginal prolapse, anorectal function and previous urogynecological surgery (anti SUI or prolapse). From physical examination, the cough stress test, urethral hypermobility and pelvic organ prolapse data were collected.

The definitions used are according to the recommendations of the International Continence Society [8]. A history of SUI was defined as the statement of the patient of involuntary leakage during physical activity, coughing or sneezing; Urge urinary incontinence (UUI) was defined as the statement of the patient of involuntary leakage when experiencing a feeling of urgency. MUI was considered to be present if both SUI and UUI were reported. Nocturia was defined as a micturition frequency > 1 during sleep. Pelvic organ prolapse was assessed according to Baden-Walker classification, grade  $\geq 2$  was defined as pelvic organ prolapse [9].

Multichannel urodynamic investigation was performed in all women according to the recommendations of the International Continence Society and followed by cystoscopy [8,10]. During the initial visit and after the cystoscopy a cough-stress test was performed in supine position. SUI was objectified by a positive cough-stress test and, if negative, by a one-hour pad test. In only 15 patients (3%) the incontinence needed to be objectified by a pad test due to a negative cough stress test.

The TVT (Gynecare, Ethicon Inc, Sommerville, New Jersey, USA) procedure was performed as described by Ulmsten [1]. The Monarc (American Medical Systems, Minneapolis, USA) tape was inserted through the "outside-in" route as using the technique recommended by the manufacturer. The "inside-out" procedure was performed as described by de Leval [11] and a TVT-O (Gynecare, Sommerville, New Jersey, USA) tape was inserted. Cystoscopy was performed after all TVT procedures.

TVT operations were carried out under local anesthesia using 0,25% prilocaine and/or systemic administered propofol. TVT-O and Monarc procedures were all performed under general anesthesia. All women received pre-operative antibiotics and this was continued for 7 days. All procedures were performed in the St. Elisabeth Hospital.

Post-operative postvoid residual urine was defined in this study as a postvoid residual urine of more than 150 ml identified by ultrasound

scanning of the bladder or catheterization and necessity of postoperative catheter use for more than 24 hours. Patients who were unable to micturate postoperatively were also included in this group.

Cure of SUI is defined as the statement of the woman of not experiencing any loss of urine upon physical exercise. Patients reporting any amount of leakage were considered failures. Although not available at the moment that that data collection took place, we adhered to the recommendations of IUGA on outcome measures [12].

Statistical analyses were performed with SPSS (Windows version 13,0). Continuous variables were compared using unpaired t-test and dichotomous variables were compared using Chi-square test or Fisher's exact test when appropriate. The minimum level of significance was 0,05. Subsequently, multivariate logistic regression analyses were used to determine clinical parameters that independently predicted outcomes after MUS surgery. Each multivariate analysis included all parameters with a p-value < 0.1 in the univariate analyses.

Although data were retrospectively collected, we performed a power calculation in order to determine whether from this dataset any reliable and statistical valid conclusions could be drawn. In order to find differences with medium effect size between women who were cured and not cured, and with an alpha of 0.05 and a power of 0.80, the group "not cured" should at least consist of 87 women to perform the above mentioned tests. The overall cure rate was 79.9% or 349 women and 88 women were not cured. Therefore this study has sufficient power.

All patients were included in prospective studies investigating the outcome of the TVT (Dutch TVT database) and afterwards the Transobturator Tapes (Monarc and TVT-O) as surgical treatment for female SUI. Both studies were approved by the Medical Ethical Committee of the St. Elisabeth Hospital Tilburg. Data gathered during both studies were retrospectively analyzed.

## **RESULTS**

In table 2 the relationship between data from medical history, physical examination, urodynamic investigation and the outcome on SUI cure is listed. Of the total group of 437 patients, 349 were cured (79%). Of the 257 patients who underwent a TVT procedure, 213 were cured (83%). The cure rates after TVT-O and Monarc were respectively 77% (n = 73) and 74% (n = 63). These differences in cure rates are not statistically significant ( $p = 0.095$ ).

## Chapter 2

After univariate analysis MUI, difficult micturition, nocturia, previous incontinence surgery, low maximum cystometric capacity (MCC) and the presence of DO were significantly related to failure. After multivariate analysis MUI ( $p = 0.042$ ), previous incontinence surgery ( $p = 0.022$ ) and the presence of DO ( $p = 0.024$ ) were significantly related to failure. The urge component in the MUI group ( $n = 94$ ) was cured in 55 patients (62%).

Table 3 shows the relationship between medical history, physical and urodynamic examination data and postoperative micturition. Only parameters with an univariate  $p$ -value  $< 0.1$  are shown. In 105 patients (24%) post-operative residual urine or urinary retention occurred. After multivariate analysis only mean age ( $p = 0.032$ ) appeared to be related. When a difference was made between the 25 patients with urinary retention and the 80 patients with postvoid residual urine  $> 150$  ml, the same results were found.

In table 4 the relationship between medical history, physical and urodynamic examination data and complications after 14 months are described. These complications include de novo obstructive micturition ( $n=26$ , 6%), de novo urgency ( $n=24$ , 5%) and de novo UUI ( $n=21$ , 5%). Only parameters with an univariate  $p$ -value  $< 0.1$  are shown.

After multivariate analysis none of the parameters was significantly related to de novo obstructive micturition.

The absence of urodynamic stress incontinence ( $p = 0.008$ ) and a low MCC ( $p = 0.003$ ) appeared to be risk factors for de novo urgency after multivariate analysis. MCC below 200 ml ( $p = 0.044$ ) and the absence of stress incontinence at UDI ( $p = 0.017$ ) were risk factors for de novo UUI after multivariate analysis.

Table 5 shows the results of UDI in patients with MUI and previous incontinence surgery separately. None of the urodynamic parameters has any predictive value for failure.

### COMMENT

The aim of the study was to assess the predictive value of UDI investigation on the outcome of MUS procedures for female SUI. In very recent recommendations of IUGA, multichannel urodynamic studies are recommended especially in patients with MUI and patients who have symptoms or signs of voiding difficulty. However, in patients whose predominant symptom is SUI, UDI may not be necessary [12]. This conclusion is shared by Farrell et al [13].

In this study, DO was related to failure of MUS procedures and significantly more diagnosed in the MUI group ( $p = 0,001$ ). The SUI cure rate in the DO group was 60% (16/27) compared to 81% (333/410) in the patients without DO. Literature is inconsistent about the influence of DO on cure rate. Kuo et al [14] compared patients with normal detrusor functions, DO and detrusor underactivity. All patients underwent a pubovaginal sling procedure. The investigators found that patients with DO had a significantly higher cure rate of SUI than patients in the other groups. But despite the higher cure rate, the satisfaction rate was considerably lower compared to the normal detrusor group due to a higher rate of postoperative urge incontinence.

In their review Lai et al [15] found that pre-operative DO was cured consistently by  $\geq 50\%$  with colposuspension and slings. They concluded that pre-operative DO does not appear to significantly worsen the outcome of surgical treatment of SUI for women. Their cure rates for patients with DO equal our results. Nevertheless their conclusion seems to be contrary to results of MUS surgery found in literature. Cure rates of 80% have been showed for TVT procedures after 7 years [16] and although the Transobturator Tape procedures are relatively new, 2 year follow-up results seem to equal results after one year with estimated cure rates of approximately 80% [17]. Therefore 50% cure rate in the DO group seems to be much lower than the results accomplished in the average population after MUS surgery. The question remains whether the pre-operative diagnosis of DO influences management. For the 6% of the patients with DO, the only consequence would have been better counseling about the post-operative cure rate (from 80 to 60%). Anyhow patients might still want to be operated with DO, if they are properly counseled about their post-operative prospects. 60% cure rate in patients with DO is still an obvious improvement for patients who daily suffer from episodes of incontinence.

Anamnestic risk factors for failure in this study were MUI and previous incontinence surgery. Nevertheless, the SUI cure rate in patients with MUI in this study was still 67% (63/94) and the SUI cure rate in patients with previous incontinence surgery was 56% (22/39).

The relation between pre-operative MUI and failure of incontinence surgery is well known. Kulseng-Hansen et al [18] performed a large prospective trial investigating cure rates in patients with MUI 7 to 38 months after a TVT procedure. They found average subjective cure rates of 60.0% after 7 months and 53.8% after 38 months. Other studies showed that subjective cure rates in patients with MUI after TVT procedures are ranging

between 85% after one year and declined up to 30% after 6-8 years [19,20]. The results of the above mentioned studies are generally consistent with our findings.

Several authors have demonstrated that previous incontinence surgery is associated with lower cure rates of SUI procedures [21,22]. In their study, Meschia found a 72% cure rate in patients who underwent previous incontinence surgery versus 89% in the patients without a history of surgical treatment of SUI [22]. On the other hand high success rates have been established with the TVT procedure in this group of patients. Rezapour et al [23] investigated the influence from previous incontinence surgery in 34 patients who underwent a TVT procedure and presented 82% cure rates after 5 years. In our study the cure rate in patients with previous incontinence surgery is 56% versus 82% in the group without previous incontinence surgery. Therefore both this study and results found in literature indicate that previous incontinence surgery is an obvious risk factor for failure. Future counseling of this group of patients seems appropriate.

Post-operative voiding dysfunction in our study was only predictable by age. Almeida et al [24] found pre-operative post-voiding residual higher than 100 ml predictive of postoperative voiding dysfunction. In our study, this parameter was not significant but there were only 7 patients with pre-operative postvoid residual higher than 100 ml, so this group is too small to draw conclusions. Other urodynamic parameters described in literature are maximum free flow less than 12 ml or voiding with no or minimal detrusor contraction [25].

In this study de novo urgency and de novo UUI both occurred significantly more in women when SUI could not be diagnosed during urodynamic investigation. We could not find evidence in literature to support our findings. Therefore it may be an coincidental finding.

Our results also indicate that a low MCC might be a risk factor for de novo urgency. When a cut-off point was calculated,  $MCC < 400$  ml would be a risk factor for de novo urgency. Because 400 ml is a quite normal capacity, the clinical implications of this finding are marginal. Furthermore 383 ml (the MCC in the de novo urgency group) is quite a normal bladder capacity too.

Summarized these results are not strong enough to justify pre-operative UDI in all patients, especially when the negative aspects of UDI (costs, a delay in surgery, risk of infection and patient discomfort) are taken into account. Therefore further investigation is recommended.

Our results clearly indicate lower SUI cure rates after MUS procedures in patients presenting with MUI or previous incontinence surgery. Therefore

UDI would be indicated in patients with MUI or previous incontinence surgery. However none of the urodynamic parameters predicted failure in both groups of patients (table 5). Moreover the predictive value of urodynamic parameters for post-operative functional complications was marginal in our population. Therefore it is important to assess if information acquired from UDI can not be obtained in other, less invasive ways. Predictive value of disease specific questionnaires have been investigated with excellent results [26,27]. Therefore with an adequate anamnesis supported by validated questionnaires, patients with MUI can be properly identified and counseled about their prospects after MUS surgery without the necessity of UDI.

This type of study may be subject to bias because patients who did not undergo surgery, were not included. This may limit the interpretation of the diagnostic power of urodynamic investigation. However, the aim of the study was to determine the predictive value of UDI on outcome after surgery. Furthermore it is interesting to determine in a large group of patients what standard urogynecological history-taking and urogynecological physical examination contributes to the outcome of stress incontinence surgery.

We did not collect all the parameters we studied from each patient as can be seen in table 1. The most pronounced missing data are nocturia (n = 33, 8%) and MUCP (n = 59, 14%), the latter mostly because of unreliable measurement during UDI. Therefore we accepted that the power of results concerning principally nocturia and MUCP are a little lower than results of the other parameters. We did not exclude these patients because the other parameters might still have prognostic influence and valuable information would be lost if we excluded them all.

The main endpoint of this study is cure of SUI. A recent meta analysis [28] concluded that both “inside-out” and “outside in” procedures are equally effective in curing female SUI compared to TVT procedures. With no differences between these techniques we feel it was methodologically appropriate to combine these groups concerning cure of SUI. The same meta analysis showed that retropubic and transobturator slings have different post-operative obstruction rates and therefore voiding may be influenced. By not analyzing each type of sling separately, this study may be subject to bias regarding the listed functional complications.

Although the definition of failure used in this study is subjective, it does provide information about the experience of the patient over a longer period of time contrary to more objective investigations like a post-operative stress test, pad test or UDI. Those investigations merely reflect a

## Chapter 2

measurement at one point in time. Therefore we feel that our definition of failure (and cure) is valid to use.

Our relative low cure rates are more likely due to our definition of cure. Women who reported improvement of symptoms (but not completely dry) were considered as failure. However, improvement was observed in 64 patients (15%). If cure and improvement rates are taken together, 95% of the patients found their symptoms to be improved/cured after 14 months.

Advantages in this study are the large number of women and a standardized urogynecological work-up. A consistent treatment strategy was followed where MUS procedures were not combined with other urogynecological procedures, thereby excluding the bias of concomitant surgery. In this way we are able to study whether the outcome could be influenced by making treatment decisions on urogynecological anamnesis, physical examination and urodynamic investigation without any other source of bias. Furthermore, all patients were treated in one clinic, which may enhance the consistency of the results.

Despite the described limitations and taking the advantages of this study design into account, we feel that this study may contribute to our understanding and value of standard urogynecological work-up in women in whom stress incontinence surgery is considered.

### **CONCLUSION**

MUI and previous incontinence surgery are risk factors for failure of MUS surgery. DO was the only predictive urodynamic parameter for failure of MUS procedures. In this study only 6% of the patients had DO and would have benefited from UDI. Therefore the standard use of UDI in the pre-operative work-up of MUS surgery needs to be revisited.

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## Chapter 2

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## Predictive value of urodynamics

<b>Table 1. Baseline characteristics of study population</b>			
Part 1: medical history & physical examination			
		included in analyses	missing values
Number of women		437	
<b>Medical history</b>			
Age	(years, mean $\pm$ SD)	51,1 $\pm$ 10,4	
Type of Incontinence (n)	SUI	343 (79%)	
	MUI	94 (21%)	
Menopausal status (n)	premenopausal	244 (56%)	
	postmenopausal	193 (44%)	
Parity (number of vaginal deliveries)	nulliparous	18 (4%)	11(3%)
	multiparity	408 (93%)	
Pelvic floor physiotherapy prior to surgery (n)	performed	388 (88%)	2 (1%)
	not performed	47 (11%)	
Daily micturition frequency	(n; mean,SD)	8 $\pm$ 3	35 (8%)
	$\leq$ 8	282 (64%)	
	$>$ 8	120 (28%)	
Micturition (n)	easy	422 (96%)	2 (1%)
	difficult	13 (3%)	
Nocturia (n) <sup>1</sup>	present	228 (52%)	33 (8%)
	absent	176 (40%)	
Prolapse complaints (n)	present	29 (7%)	4 (1%)
	absent	404 (92%)	
Defaecation problems (n)	present	17 (4%)	5 (1%)
	absent	415 (95%)	
Straining for defaecation (n)	present	25 (6%)	5 (1%)
	absent	407 (93%)	
Previous incontinence surgery (n)	present	39 (9%)	
	absent	398 (91%)	
Previous prolapse surgery (n)	present	99 (23%)	
	absent	338 (77%)	
<b>Physical examination</b>			
Cough-stress test	loss of urine	422 (97%)	
	no loss of urine	15 (3%)	
Cystocele (n)	grade $<$ 2	425 (97%)	
	grade $\geq$ 2	12 (3%)	
Rectocele (n)	grade $<$ 2	431 (99%)	
	grade $\geq$ 2	6 (1%)	
Prolapse of uterine cervix of vaginal vault (n)	grade $<$ 2	433 (99%)	
	grade $\geq$ 2	4 (1%)	
Urethral hypermobility (n)	grade $\geq$ 1	8 (2%)	
	grade 1 or more	429 (98%)	

## Chapter 2

<b>Table 1. Baseline characteristics of study population</b>			
Part 2: urodynamic investigation & surgical procedure			
		included in analyses	missing values
Number of women		437	
<b>Urodynamic investigation</b>			
Maximum bladder capacity	(ml, mean ± SD)	427 ± 125	4 (1%)
number of women with MCC < 200 ml		7 (2%)	
number of women with MCC ≥ 200 ml		426 (97%)	
Urodynamic stress incontinence (n)	present	336 (77%)	
	absent	101 (23%)	
Detrusor overactivity (n)	present	27 (6%)	
	absent	410 (94%)	
MUCP	(cm H <sub>2</sub> O, mean ± SD)	49 ± 30	59 (13%)
	MUCP < 20 cm H <sub>2</sub> O (n)	41 (10%)	
	MUCP ≥ 20 cm H <sub>2</sub> O (n)	337 (77%)	
Qmax	(ml/s, mean ± SD)	24,4 ± 9,9	14 (3%)
	Qmax < 15 ml/s (n)	46 (11%)	
	Qmax ≥ 15 ml/s (n)	377 (86%)	
Postvoid residu	(ml, mean ± SD)	10 ± 25	
	> 100 ml (n)	7 (2%)	
	≤100 ml (n)	430 (98%)	
<b>Surgical procedure</b>			
TVT-O		85 (20%)	
Monarc		95 (21%)	
TVT		257 (59%)	
Simultaneous surgical procedure*			
yes		24 (5%)	
no		413 (95%)	

\* non-urogynecological

## Predictive value of urodynamics

Part 1: medical history		Univariate analysis			Multivariate analysis	
		not cured (n = 88)			OR [95% CI]	p-value
<b>Medical history</b>						
Age	mean ± SD (years)	52.0 ± 10.7		0.367 (*1)		
Type of Incontinence (n)	SUI	57 (17%)	2.47 [1.47-4.13]	<b>0.000 (*2)</b>	1.87 [1.02-3.40]	<b>0.042</b>
	MUI	31 (33%)				
Menopausal status	premenopausal	51 (21%)	0.90 [0.56-1.44]	0.654 (*2)		
	postmenopausal	37 (19%)				
Parity	nulliparous (n)	3 (17%)	0.80 [0.23-2.81]	1.000 (*3)		
	multiparity (n)	82 (20%)				
Pelvic floor physiotherapy prior to surgery (n)	performed	81 (21%)	0.66 [0.29-1.54]	0.335 (*2)		
	not performed	7 (15%)				
Daily micturitation frequency	mean ± SD (n)	8 ± 3		0.430 (*1)		
	≤ 8	53 (19%)	1.03 [0.60-1.77]	0.930 (*2)		
	>8	23 (19%)				
Nocturia (n) <sup>1</sup>	present	21 (29%)	1.99 [1.11-3.56]	<b>0.019 (*2)</b>	1.51 [0.79-2.89]	0.216
	absent	57 (17%)				
Micturition (n)	easy	81 (19%)	3.61 [1.18-11.03]	<b>0.017 (*2)</b>	2.64 [0.74-9.36]	0.133
	difficult	6 (46%)				
Prolapse complaints (n)	present	7 (24%)	0.78 [0.32-1.88]	0.574 (*2)		
	absent	80 (20%)				
Defaecation problems (n)	present	4 (24%)	0.81 [0.26-2.56]	0.758 (*3)		
	absent	83 (20%)				
Straining for defaecation (n)	present	3 (12%)	1.91 [0.56-6.52]	0.441 (*3)		
	absent	84 (21%)				
Previous incontinence surgery (n)	present	17 (44%)	3.56 [1.80-7.05]	<b>0.000 (*2)</b>	2.52 [1.15-5.56]	<b>0.022</b>
	absent	71 (18%)				
Previous prolapse surgery (n)	present	23 (23%)	0.79 [0.46-1.35]	0.383 (*2)		
	absent	65 (20%)				

Statistical analysis: \*1. student t-test (two-sided); \*2. X2 test; \*3. Fishers exact test; statistically significant differences are highlighted

## Chapter 2

Part 2: physical examination & urodynamic investigation						
		Univariate analysis			Multivariate analysis	
		not cured (n = 88)	OR [95% CI]	p-value	OR [95% CI]	p-value
<b>Physical examination</b>						
Cough-stress test	loss of urine	85 (20%)				
	no loss of urine	3 (20%)	0.99 [0.27-3.59]	1.000 (*3)		
Cystocele (n)	grade < 2	86 (20%)				
	grade ≥ 2	2 (17%)	0.79 [0.17-3.69]	0.761 (*3)		
Rectocele (n)	grade < 2	85 (20%)				
	grade ≥ 2	3 (50%)	4.07 [0.81-20.52]	0.099 (*3)	4.71 [0.66-33.74]	0.123
Prolapse of uterine cervix of vaginal vault (n)	grade < 2	87 (20%)				
	grade ≥ 2	1 (25%)	1.33 [0.14-12.90]	1.000 (*3)		
Urethral hypermobility (n)	grade ≥ 1	2 (25%)				
	no hypermobility	86 (20%)	1.33 [0.26-6.70]	0.665 (*3)		
<b>Urodynamic investigation</b>						
Maximum cystometric capacity	mean ± SD (ml)	403 ± 125		<b>0.050 (*1)</b>	1.00 [0.99-1.01]	0.873
	MCC < 200 ml (n)	5 (71%)				
	MCC ≥ 200 ml (n)	82 (19%)	10.49 [2.00-55.01]	<b>0.004 (*3)</b>		
Urodynamic stress incontinence (n)	present	69 (21%)				
	absent	19 (19%)	0.90 [0.51-1.58]	0.705 (*2)		
Detrusor overactivity (n)	present	11 (41%)				
	absent	77 (19%)	2.97 [1.33-6.66]	<b>0.006 (*2)</b>	2.91 [1.15-7.32]	<b>0.024</b>
Maximum Urethral Closure Pressure	mean ± SD (cm H <sub>2</sub> O)	49 ± 29		1.000 (*1)		
	MUCP < 20 cm H <sub>2</sub> O (n)	9 (22%)				
	MUCP ≥ 20 cm H <sub>2</sub> O (n)	68 (20%)	1.11 [0.51-2.44]	0.790 (*2)		
Qmax	mean ± SD (ml/s)	25 ± 10		0.790 (*1)		
	Qmax < 15 ml/s (n)	12 (26%)				
	Qmax ≥ 15 ml/s (n)	75 (20%)	1.42 [0.70-2.88]	0.327 (*2)		
Postvoid residu	mean ± SD (ml)	13 ± 34		0.228 (*1)		
	> 100 ml (n)	3 (43%)				
	≤ 100 ml (n)	85 (20%)	3.04 [0.67-13.86]	0.149 (*3)		

Statistical analysis: \*1. student t-test (two-sided); \*2. X2 test; \*3. Fishers exact test; statistically significant differences are highlighted

## Predictive value of urodynamics

<b>Tabel 3. Post-operative residual urine or urinary retention</b>						
		Univariate analysis			Multivariate analysis	
		present				
		n =105 (24%)	OR [95% CI]	p- value	OR [95% CI]	p- value
<b>Medical history</b>						
Age	mean ± SD (years)	53,5 ± 11,4		<b>0.006 (*1)</b>	1.03 [1.01-1.05]	<b>0.032</b>
Nocturia (n) <sup>1</sup>	present	24 (33%)	1.77 [1.02-3.09]	<b>0.041 (*2)</b>	1.52 [0.84-2.73]	0.168
	absent	73 (22%)				
Prolapse complaints (n)	present	3 (10%)	0.34 [0.10-1.15]	0.076 (*3)	0.45 [0.13-1.53]	0.200
	absent	102 (25%)				

Statistical analysis: \*1. student t-test (two-sided); \*2. X2 test; \*3. Fishers exact test; statistically significant differences are highlighted

## Chapter 2

Table 4. Functional complications after 14 months						
		Univariate analysis			Multivariate analysis	
		present				
		n =26 (6%)	OR [95% CI]	p- value	OR [95% CI]	p- value
<b>De novo obstructive micturition</b>						
<b>Medical history</b>						
Nocturia (n) <sup>1</sup>	present	8 (11%)				
	absent	17 (6%)	2.32 [0.96-5.60]	0.056 (*2)	1.84 [0.70-4.82]	0.215
<b>Urodynamic investigation</b>						
Maximum bladder capacity	(ml, mean ± SD)	386 ± 86		0.081 (*1)	0.99 [0.99-1.01]	0.308
Urodynamic stress incontinence (n)	present	25 (7%)	0.12 [0.02-0.93]	<b>0.015 (*3)</b>	0.17 [0.02-1.26]	0.082
	absent	1 (1%)				
Qmax	(ml/s, mean ± SD)	20 ± 6		<b>0.050 (*1)</b>	0.96 [0.91-1.02]	0.193
<b>De novo urgency</b>						
		present				
		n = 24 (5%)	OR [95% CI]	p- value	OR [95% CI]	p- value
<b>Medical history</b>						
Type of Incontinence (n)	SUI	23 (7%)				
	MUI	1 (1%)	0.15 [0.02-1.12]	<b>0.038 (*3)</b>	0.17 [0.02-1.35]	0.095
<b>Urodynamic investigation</b>						
Maximum cystometric capacity	mean ± SD (ml)	383 ± 136		0.075 (*1)	0.99 [0.99-1.00]	<b>0.003</b>
Urodynamic stress incontinence (n)	present	12 (4%)	3.64 [1.58-8.38]	<b>0.001 (*2)</b>	3.64 [1.40-9.44]	<b>0.008</b>
	absent	12 (12%)				
Maximum Urethral Closure Pressure	mean ± SD (cm H <sub>2</sub> O)	62 ± 38		<b>0.042 (*1)</b>	1.01 [0.99-1.02]	0.082
<b>De novo urge urinary incontinence</b>						
		present				
		n = 21 (5%)	OR [95% CI]	p- value	OR [95% CI]	p- value
<b>Urodynamic investigation</b>						
Maximum cystometric capacity	MCC < 200 ml (n)	2 (29%)	8.57 [1.56-47.05]	<b>0.041 (*3)</b>	6.11 [1.05-35.58]	<b>0.044</b>
	MCC ≥ 200 ml (n)	19 (5%)				
Urodynamic stress incontinence (n)	present	11 (3%)	3.25 [1.34-7.89]	<b>0.006 (*2)</b>	3.00 [1.21-7.42]	<b>0.017</b>
	absent	10 (10%)				

Statistical analysis: \*1. student t-test (two-sided); \*2. X2 test; \*3. Fishers exact test; statistically significant differences are highlighted

## Predictive value of urodynamics

		Univariate analysis			
		cured n= 63 (67%)	not cured n = 31 (31%)	OR [95% CI]	p-value
<b>Mixed Urinary Incontinence</b>					
<b>Urodynamic investigation</b>					
Maximum cystometric capacity	mean ± SD (ml)	390 ± 108	394 ± 127		0.856 (*1)
	MCC < 200 ml (n)	1 (50%)	1 (50%)	2.10 [0.13-34.83]	0.548 (*3)
	MCC ≥ 200 ml (n)	61 (68%)	29 (32%)		
Urodynamic stress incontinence (n)	present	54 (67%)	27 (33%)	0.89 [0.25-3.15]	1.000 (*3)
	absent	9 (69%)	4 (31%)		
Detrusor overactivity (n)	present	7 (54%)	6 (46%)	1.92 [0.59-6.30]	0.276 (*2)
	absent	56 (69%)	25 (31%)		
Maximum Urethral Closure Pressure	mean ± SD (cm H <sub>2</sub> O)	48 ± 30	44 ± 26		0.616 (*1)
	MUCP < 20 cm H <sub>2</sub> O (n)	6 (55%)	5 (45%)	1.77 [0.49-6.38]	0.378 (*2)
	MUCP ≥ 20 cm H <sub>2</sub> O (n)	51 (66%)	24 (34%)		
Qmax	mean ± SD (ml/s)	22 ± 8	24 ± 12		0.298 (*1)
	Qmax < 15 ml/s (n)	6 (50%)	6 (50%)	2.33 [0.68-7.97]	0.168 (*2)
	Qmax ≥ 15 ml/s (n)	56 (70%)	24 (30%)		
Postvoid residu	mean ± SD (ml)	12 ± 29	18 ± 45		0.460 (*1)
	> 100 ml (n)	1 (67%)	2 (33%)	4.28 [0.37-49.09]	0.252 (*3)
	≤ 100 ml (n)	62 (68%)	29 (32%)		
<b>Previous incontinence surgery</b>					
<b>Urodynamic investigation</b>					
Maximum cystometric capacity	mean ± SD (ml)	403 ± 77	386 ± 134		0.620 (*1)
	MCC < 200 ml (n)	0	1 (100%)	n.a.	0.436 (*3)
	MCC ≥ 200 ml (n)	22 (58%)	16 (42%)		
Urodynamic stress incontinence (n)	present	20 (63%)	12 (37%)	4.17 [0.70-24.94]	0.205 (*3)
	absent	2 (14%)	7 (86%)		
Detrusor overactivity (n)	present	19 (58%)	14 (42%)	1.36 [0.34-7.75]	1.000 (*3)
	absent	3 (50%)	3 (50%)		
Maximum Urethral Closure Pressure	mean ± SD (cm H <sub>2</sub> O)	40 ± 18	46 ± 28		0.431 (*1)
	MUCP < 20 cm H <sub>2</sub> O (n)	4 (50%)	4 (50%)	1.39 [0.29-6.58]	0.709 (*3)
	MUCP ≥ 20 cm H <sub>2</sub> O (n)	18 (58%)	13 (42%)		
Qmax	mean ± SD (ml/s)	24 ± 8	22 ± 9		0.481 (*1)
	Qmax < 15 ml/s (n)	2 (40%)	3 (60%)	1.93 [0.28-13.16]	0.644 (*3)
	Qmax ≥ 15 ml/s (n)	18 (56%)	14 (44%)		
Postvoid residu	mean ± SD (ml)	9 ± 24	14 ± 39		0.610 (*1)
	> 100 ml (n)	1 (50%)	1 (50%)	1.31 [0.08-22.62]	1.000 (*3)
	≤ 100 ml (n)	21 (57%)	16 (43%)		

Statistical analysis: \*1. student t-test (two-sided); \*2. X2 test; \*3. Fishers exact test; statistically significant differences are highlighted  
n.a. = could not be determined



## Chapter 3

### Risk factors for failure of retropubic and transobturator mid-urethral slings

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## ABSTRACT

**Objective:** The aim of our study was to identify and compare risk factors for failure of retropubic and transobturator procedures.

**Study design:** Retrospective cohort study. Women with predominant stress urinary incontinence (SUI) who underwent a retropubic (n=214) or transobturator tape procedure (n=173) were included. Women reporting any amount of urine leakage during stress after 2 and/or 12 months were considered as failures.

**Results:** Risk factors for failure were mixed urinary incontinence (MUI) (OR 3.7 [1.5-9.1]) and the observation of detrusor overactivity (DO) at urodynamics (OR 8.6 [1.9-39.4]) in the retropubic group. Reporting a history of previous incontinence surgery (OR 3.9 [1.3-11.7]) and a low mean urethral closure pressure (MUCP) at urodynamics (OR 14.5 [1.5-139.0]) were risk factors for failure in the transobturator group.

**Conclusion(s):** Women with previous incontinence surgery or a low MUCP might benefit more of a retropubic sling whereas a transobturator procedure might be preferable in women with MUI or DO.

## **INTRODUCTION**

The Burch colposuspension has long been the operation of first choice for female stress urinary incontinence (SUI). In 1996 suspension by the Tension-free Vaginal Tape (TVT) was introduced and has gradually replaced the colposuspension [1]. In a randomized controlled trial TVT appeared to be as effective as colposuspension, but with lesser complications and faster recovery [2].

In 2001 Delorme introduced suspension by a TransObturator Tape (TOT). Thereafter several other TOT techniques were developed. There are two different types of TOT procedures: "Outside-In" (Monarc) and "Inside-out" (TVT-O). Both techniques have similar cure and complication rates [3,4].

Several studies have compared retropubic with transobturator procedures [5-8]. While in general these studies indicate that cure rates are similar, there is evidence that in certain subgroups of patients the outcome after TOT may be different from TVT [9-11].

Obturator procedures seem to be somewhat more effective in patients with mixed urinary incontinence (MUI) [9-10] whereas Miller et al [11] showed that in women with a maximum urethral closure pressure (MUCP) < 42 cm H<sub>2</sub>O, a Monarc procedure is 6 times more likely to fail compared to a TVT procedure. This indicates that perhaps certain patient characteristics can help to select the optimal mid-urethral sling in patients undergoing stress incontinence surgery.

In this study pre-operative data were used to identify and compare statistically significant risk factors for failure of retropubic and transobturator mid-urethral sling procedures.

## **MATERIAL AND METHODS**

Standardized data collected systematically from 387 patients were retrospectively analyzed. Data were collected in a large teaching hospital in the Netherlands at which the TVT procedure was introduced in 1998. In 2004 increasingly more frequent a transobturator approach was selected based on reported advantages of avoiding the retropubic route and faster recovery of the patients. We performed either a Monarc or TVT-O procedure. Both Monarc and TVT-O are in this study referred as TOT. Indications for all types of mid-urethral slings were similar.

Since 1998 data were consistently collected of all consecutive patients undergoing either TVT, Monarc or TVT-O. For this study we only report on women who did not undergo concomitant surgical procedures. We

### Chapter 3

also excluded patients who did not show up for their follow-up visits at 2 or 12 months after surgery.

The definitions used are according to the recommendations of the International Continence Society [12]. A history of SUI was defined as the statement of the patient of involuntary leakage during physical activity, coughing or sneezing. A history of UUI was defined as the statement of involuntary leakage preceded by a strong sense of urgency. A history of MUI was defined as a combination of SUI and UUI. Nocturia was defined as a micturition frequency  $> 1$  during sleep. Pelvic organ prolapse was scored according to Baden–Walker classification [13].

Multichannel urodynamic investigation was performed in all women according to the recommendations of the International Continence Society and followed by cystoscopy [14,15]. During the initial visit and after the cystoscopy a cough-stress test was performed in supine position. SUI was objectified by a positive cough-stress test and, if negative, by a standard ICS one-hour pad test. We presumed SUI to be present based on medical history combined with the positive cough stress test in women who demonstrated no urodynamic SUI.

The TVT (Gynecare, Ethicon Inc, Sommerville, New Jersey, USA) procedure was performed as described by Ulmsten [1]. The Monarc (American Medical Systems, Minneapolis, USA) tape was inserted through the “Outside-in” route as using the technique recommended by the manufacturer. The “Inside-out” procedure was performed as described by de Leval [16] and a TVT-O (Gynecare, Sommerville, New Jersey, USA) tape was inserted. Cystoscopy was performed after all TVT procedures and in women with TOT procedures only in case of suspected bladder perforations.

TVT operations were carried out under local anesthesia using 0,25% prilocaine and/or systemic administered propofol. Monarc and TVT-O procedures were all performed under general anesthesia. Proper placement and tensioning of the tape was done by checking the easy passage of a Metzenbaum scissor between the tape and the backside of the urethra in all procedures and modes of anesthesia. All procedures were performed or supervised by the last author (HV). This surgeon (HV) has an extensive experience in pelvic floor surgery and has performed over 500 retropubic and transobturator mid-urethral slings.

Although not available at the moment that data collection took place, we adhered to the recommendations of IUGA on outcome measures [17]. Cure of SUI was defined as the statement of the woman of not experiencing any loss of urine during physical activity, coughing or sneezing. Patients

reporting any amount of leakage during physical activity, coughing or sneezing were considered failures.

Continuous variables were compared using unpaired t-test and dichotomous variables were compared using Chi-square test. Fisher's exact test was used if cross tabs had a cell with an expected frequency < 5. Subsequently, multivariate logistic regression analysis was used to determine clinical parameters that independently influenced outcome after mid-urethral sling surgery. Multivariate analysis included all parameters with a  $p$ -value < 0.10 in the univariate analysis.

To make sure a group is large enough to perform Chi-square analysis or Fisher's exact test, this group must consist of at least 165 patients with an  $\alpha$  of 0,01 and power of 0,90 to establish medium effect size [18]. In the smallest group (Monarc and TVT-O), 173 patients were included. Therefore this study is sufficiently powered to perform the above mentioned analyses. A  $p$ -value of less than 0.05 was considered to be statistically significant. Statistical analysis was performed with SPSS (Windows version 13,0).

All patients were included in prospective studies investigating the outcome of the TVT (Dutch TVT database [19]) and afterwards the transobturator tapes (Monarc and TVT-O) as surgical treatment for female SUI. Both studies were approved by the Medical Ethical Committee of the St. Elisabeth Hospital Tilburg.

## **RESULTS**

In this period 465 patients met the inclusion criteria. 28 women (6%) did not return for any postoperative visit, in 37 women only data from the 2 months postoperative visit and from 13 women only data from 12 months postoperative visit were available. Therefore 78 (17%) patients were left out of this analysis and this study population contains 387 women (214 TVT, 90 Monarc and 83 TVT-O procedures). There were no statistically significant differences in pre-operative data between patients who underwent a Monarc or TVT-O procedure.

Pre-operative data are listed in table 1. A history of pure SUI was reported by 302 women (78%) whereas 85 women (22%) had a history of MUI. In women with MUI, anti-cholinergic medical treatment was given before surgical treatment was considered and did not alleviate their symptoms. The majority (89%) of the patients underwent pre-operative pelvic floor physiotherapy.

### Chapter 3

The age of the TVT group was higher than of the TOT group. The TVT group had more prolapse symptoms ( $p = 0.01$ ) and less need to strain for defecation ( $p = 0.002$ ). The TVT group contained significantly more patients with a positive cough stress test ( $p = 0.02$ ).

Findings at urodynamic investigation showed a lower mean maximum cystometric capacity (MCC) for the TVT group. Stress incontinence during urodynamic investigation was more absent in the TOT group ( $p < 0.001$ ) and there were significantly more patients with a MUCP  $< 20$  cm H<sub>2</sub>O in the TVT group ( $p = 0.001$ ).

Table 2 shows outcome after 2 and 12 months for both groups. There were no statistically significant differences in SUI cure rates between TVT and TOT after 2 and 12 months. The cure rates after Monarc and TVT-O procedures were respectively 74% ( $n = 67$ ) and 76% ( $n = 63$ ). These differences in cure rates were not statistically significant ( $p = 0.8$ ).

After 12 months, 48 (12%) patients reported symptoms of MUI. In this group 19 patients developed de novo UUI, in 21 patients the UUI was the same as before surgery and in 8 patients the UUI did improve but was not cured after surgery. No statistically significant differences between both groups were found.

In table 3 the relationship between data from medical history, physical examination, urodynamic investigation and the outcome on SUI cure is listed. All parameters from table 1 were tested for statistical significance but only parameters with an univariate  $p$ -value  $< 0.1$  are shown. If parameters were significant in the TVT group, they are also shown for the TOT group for comparison and vice versa.

In the TVT group MUI, nocturia, previous incontinence surgery and detrusor overactivity (DO) at urodynamic investigation appeared to be related to failure after univariate analysis. After multivariate analysis MUI (OR 3.7 [1.5-9.1]) and DO (OR 8.6 [1.9-39.4]) appeared to be independent risk factors.

In the TOT group previous incontinence surgery, a mean maximum cystometric capacity (MCC)  $< 200$  ml, and a MUCP  $< 20$  cm H<sub>2</sub>O were significantly associated with a lower cure rate after TOT procedures. After multivariate analysis previous incontinence surgery (OR 3.9 [1.3-11.7]) and a MUCP  $< 20$  cm H<sub>2</sub>O (OR 14.5 [1.5-139.0]) were significantly related to an unfavorable outcome. Because all 3 patients with a MCC  $< 200$  ml were not cured an odds ratio could not be calculated.

## **DISCUSSION**

Our study shows that risk factors for failure of mid-urethral slings differ between retropubic and transobturator procedures. While the presence of MUI and DO appear to negatively affect the outcome of TVT, previous incontinence surgery and a low MUCP predict failure of TOT procedures. The results of this study may help physicians to make an individualized selection of mid-urethral sling procedures.

The strength of our study is that data were collected in one single center ruling out variation in diagnostic work-up or surgical procedure. Furthermore we only included patients who did not undergo concomitant surgical procedures. One could argue that a randomized trial would have a higher scientific value. However, in a randomized trial, patients with risk factors for failure (previous incontinence surgery, DO or a low MUCP) are often excluded. In this retrospective analysis, patients were only excluded if they missed their follow-up appointment or underwent other simultaneously performed urogynecological surgery. Therefore our results apply to patients from daily clinical practice and our design is par excellence capable of determining risk factors for failure.

The decision to analyze “Outside-in” and “Inside-out” transobturator slings as one group is supported by the results of comparative studies indicating that cure and complication rates of these transobturator tape procedures are similar at one year after surgery [3,4].

Nevertheless, there are also limitations to the design of this study. First there are differences in patient characteristics between both groups that may be explained by an evolution in indication over time. However, multivariate regression analysis allowed us to correct for differences in patient characteristics.

When we started to perform TVT procedures (1998), it was common knowledge that SUI should be objectified by urodynamic investigation before considering surgical treatment. Therefore most patients (85%) in the TVT group were urodynamic stress incontinent.

During the following years more evidence came available about the possible unreliability of urodynamics in objectivating SUI, especially in patients with MUI, due to the artificial situation during the investigation [20,21]. Acting on this insight, we presumed SUI to be present based on medical history combined with the positive cough stress test in women who demonstrated no urodynamic SUI.

Because patients in the TOT group were operated from October 2004 - December 2006, absence of urodynamic SUI was higher in this

group. Cure rates were not influenced by this decision because 77.9% of the patients without urodynamic SUI were cured, compared to 77.8% of the patients with urodynamic SUI ( $p = NS$ ).

Furthermore, outcome measurements were not based on validated questionnaires but on a standardized interview which is more subject to interpretation. However, as almost all patients were operated and followed-up by the same gynecologist, a wide variation in interpretation of the outcome is unlikely to exist.

Some studies suggest that results of patients with MUI or DO might be better after TOT procedures but never reached significant results [9-10]. Our study was the first to show that these factors have statistically significant prognostic value for an improved outcome of a TOT. In comparison with TOT, the sling axis of the TVT is more perpendicular to the urethral axis, creating more circumferential compression of the urethra. This might implicate that TOT is theoretically less obstructive. Therefore TOT is less likely to exacerbate leakage with DO and might perform better in women with MUI or DO.

Previous incontinence surgery is a known risk factor for failure of both retropubic and transobturator tape procedures [22,23]. Nevertheless after multivariate analysis, previous incontinence surgery appeared to be an independent risk factor only in the TOT group. The explanation might be that patients with previous incontinence surgery benefit from restoring pubo-urethral ligament support and increased urethral resistance as provided by the TVT. Therefore patients with previous incontinence surgery might benefit from a TVT procedure, although the number of patients is too small to draw definite conclusions.

Our results indicate that patients with a MCC < 200 ml have a worse outcome after TOT procedures. However as only three patients met this criterion we prefer not to draw firm conclusions from this observation.

A low MUCP also appears to be related to lower success rates after TOT procedures. Miller et al. concluded that in women with a MUCP < 42 cm H<sub>2</sub>O, the Monarc procedure was nearly 6 times more likely to fail than retropubic TVT at 3 months after surgery [11]. A very recently published prospective randomised trial has shown that TVT is more effective in patients with intrinsic sphincter deficiency compared to TOT [24].

Both TVT and TOT are based on the Hammock Hypothesis and the Integral Theory [25-27]. However, the difference is that TOT only restores endopelvic fascia against which the urethra is compressed, while TVT is thought to additionally restore pubo-urethral ligament support. Furthermore

the less-acute axis of the TOT may not provide adequate support in the intrinsic sphincter deficiency group suffering from more severe compromise of the urethral closure and support mechanism [24]. We state that this explains the lower success of transobturator surgical approach in patients with low a MUCP. Despite the small number of patients in this study, our results confirm this finding.

A recent meta analysis [4] concluded that both “Outside- in” and “Inside-out” procedures are equally effective in curing female SUI compared to TVT procedures. Our cure rates are a little lower than in the studies mentioned in this meta analysis. This could be explained by the more ambitious definition of cure applied in this study. We defined cure as the statement of the woman of not experiencing any loss of urine during physical activity, coughing or sneezing. Although subjective, it constitutes a recording of the experience of the woman over a longer period in time, while more objective parameters like a cough-stress test, a pad test or postoperative urodynamic investigation are just recordings at one moment in time. We realize however that in a small number of patients it is quite possible that “failures” are actually reporting the symptom of urge incontinence rather than the diagnosis of genuine stress incontinence. To demonstrate this difference, objective testing would be required.

Although cure rates may be lower than those reported in literature, the number of patients that reported improvement were similar. If cure and improvement rates are taken together, 97% of the patients in the TVT and 92% of the patients in the TOT group found their symptoms to be improved after surgery.

In a previous study we demonstrated the limited value of pre-operative urodynamics with respect to outcome of mid-urethral sling surgery in general. Based on our results we advised to revisit the standard use of pre-operative urodynamics in uncomplicated patients with bothersome SUI [28]. This has been done in this study. Although many urodynamic parameters have no correlation with success or failure of mid-urethral sling surgery, this study indicates that DO and a low MUCP may aid in selecting the proper mid-urethral sling procedure. It worthwhile that these findings are confirmed in further prospectively carried out investigations.

## **CONCLUSION**

Our study shows that based on history and urodynamic investigation it is possible to select the mid-urethral sling procedure that yields the best results. A transobturator approach appears to be beneficial in patients who

### *Chapter 3*

report mixed urinary incontinence or reveal detrusor overactivity at urodynamics and a retropubic procedure appears to be beneficial in patients with previous incontinence surgery or low mean urethral closure pressure at urodynamics. Ideally randomized trials comparing both surgical approaches in these subcategories of patients are performed to confirm our findings.

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## Risk factors for failure

<b>Table 1. Baseline characteristics of study population</b>					
Part 1: medical history					
		TVT		Monarc & TVT-O	<i>p</i> -value
		214		173	
Number of women		214		173	
<b>Medical history</b>					
Age	mean ± SD (years)	52,8 ± 10,7		49,2 ± 9,8	<b>0.001 (*1)</b>
Type of Incontinence (n)	SUI	171	80%	131	76%
	MUI	43	20%	42	24%
Menopausal status	premenopausal	112	52%	101	55%
	postmenopausal	102	48%	72	45%
Parity (number of vaginal deliveries; mean,SD)	nulliparous (n)	10	5%	8	5%
	multiparity (n)	198	95%	163	95%
Daily micturition frequency (n; mean,SD)	mean ± SD (n)	7 ± 2		8 ± 3	0.675 (*1)
	≤ 8	143	72%	112	71%
	> 8	55	28%	46	29%
Nocturia (n)	present	38	19%	29	18%
	absent	163	81%	128	82%
Micturition (n)	easy	206	96%	167	98%
	difficult	8	4%	4	2%
Prolapse complaints (n)	present	20	9%	5	3%
	absent	193	91%	166	97%
Defaecation problems (n)	present	6	4%	9	5%
	absent	208	96%	160	95%
Straining for defaecation (n)	present	5	2%	16	9%
	absent	209	98%	153	91%
Previous incontinence surgery (n)	present	19	9%	16	9%
	absent	195	91%	157	91%
Previous prolapse surgery (n)	present	55	26%	32	18%
	absent	159	74%	141	82%

Statistical analysis: \*1. student t-test (two-sided); \*2. Chi-square test; \*3. Fisher's exact test; statistically significant differences are highlighted

## Chapter 3

<b>Table 1. Baseline characteristics of study population</b>						
Part 2: physical examination & urodynamic investigation						
		TVT		Monarc & TVT-O		p-value
Number of women		214		173		
<b>Physical examination</b>						
Cough-stress test	loss of urine	211	99%	163	94%	<b>0.022 (*3)</b>
	no loss of urine	3	1%	10	6%	
Cystocele (n)	grade < 2	210	98%	167	97%	0.352 (*3)
	grade 2 or more	4	2%	6	3%	
Rectocele (n)	grade < 2	212	99%	170	98%	0.660 (*3)
	grade 2 or more	2	1%	3	2%	
Prolapse of uterine cervix of vaginal vault (n)	grade < 2	213	100%	171	99%	0.589 (*3)
	grade 2 or more	1	0%	2	1%	
Urethral hypermobility (n)	grade ≥ 1	210	98%	169	98%	1.000 (*3)
	no hypermobility	4	2%	4	2%	
<b>Urodynamic investigation</b>						
Maximum bladder capacity	mean ± SD (ml)	414 ± 127		442 ± 124		<b>0.030 (*1)</b>
	MCC < 200 ml	4	2%	3	2%	1.000 (*3)
	MCC ≥ 200 ml	208	98%	168	98%	
Urodynamic stress incontinence (n)	present	181	85%	116	67%	<b>0.000 (*2)</b>
	absent	33	15%	57	33%	
Detrusor overactivity (n)	present	11	5%	12	7%	0.457 (*2)
	absent	203	95%	161	93%	
MUCP	mean ± SD (cm H <sub>2</sub> O)	41 ± 22		60 ± 36		<b>0.000 (*1)</b>
	MUCP < 20 cm H <sub>2</sub> O (n)	26	14%	5	3%	<b>0.001 (*2)</b>
	MUCP ≥ 20 cm H <sub>2</sub> O (n)	157	86%	148	97%	0.516 (*1)
Qmax (ml/s, mean ± SD)	mean ± SD (ml/s)	24 ± 9		24 ± 9		
	Qmax < 15 ml/s	21	10%	21	12%	
	Qmax ≥ 15 ml/s	183	90%	150	88%	
Postvoid residu	mean ± SD (ml)	8 ± 23		13 ± 30		0.056 (*1)
	> 100 ml	2	1%	5	3%	0.250 (*3)
	≤ 100 ml	212	99%	168	97%	

Statistical analysis: \*1. student t-test (two-sided); \*2. Chi-square test; \*3. Fisher's exact test; statistically significant differences are highlighted

*Risk factors for failure*

<b>Table 2. Outcome after 2 respectively 12 months</b>						
	total	TVT		Monarc & TVT-O		p-value
	387	214		173		
<i>Outcome after 2 months</i>						
SUI cured	329	185	86%	144	83%	0.379 (*1)
SUI not cured	58	29	14%	29	17%	
<i>Outcome after 12 months</i>						
SUI cured	305	175	82%	130	75%	0.112 (*1)
SUI not cured	82	39	18%	43	25%	

Statistical analysis: \*1. Chi-square test

### Chapter 3

<b>Table 3. Comparison of risk factors for failure of retropubic and transobturator midurethral sling procedures after 12 months</b>					
Part 1: TVT					
	Not cured	UNIVARIATE ANALYSIS		MULTIVARIATE ANALYSIS	
		OR [95% CI]	p - value	OR [95% CI]	p - value
<b>TVT (n)</b>	39 (18%)				
<i>Medical history</i>					
Type of Incontinence (n)					
SUI	21 (12%)	5.14 [2.41-10.98]	<b>0.000 (*2)</b>	3.7 [1.5-9.1]	<b>0.004</b>
MUI	18 (42%)				
Nocturia (n)					
present	11 (29%)	2.36 [1.04-5.38]	<b>0.037 (*2)</b>	2.0 [0.8-5.0]	0.162
absent	24 (15%)				
Previous incontinence surgery (n)					
present	7 (37%)	2.97 [1.09-8.13]	<b>0.028 (*2)</b>	1.1 [0.3-4.9]	0.898
absent	32 (16%)				
<i>Physical examination</i>					
Cough-stress test (n)					
loss of urine present	37 (17%)	9.41 [0.83-106.47]	0.086 (*3)	7.9 [0.4-143.2]	0.160
no loss of urine	2 (67%)				
<i>Urodynamic investigation</i>					
Maximum bladder capacity (ml, mean ± SD)	381 ± 115		0.069 (*1)	1.0 [1.0-1.0]	0.918
number of women with MCC < 200 ml (n)	2 (50%)	4.62 [0.63-33.88]	0.155 (*3)		
number of women with MCC ≥ 200 ml (n)	37 (18%)				
Detrusor overactivity (n)					
present	6 (55%)	6.18 [1.78-21.45]	<b>0.001 (*2)</b>	8.6 [1.9-39.4]	<b>0.006</b>
absent	33 (16%)				
MUCP (cm H <sub>2</sub> O, mean ± SD)	44 ± 23		0.295 (*1)		
number of women with MUCP < 20 cm H <sub>2</sub> O (n)	4 (15%)	0.80 [0.26-2.51]	1.000 (*3)		
number of women with MUCP ≥ 20 cm H <sub>2</sub> O	29 (18%)				

Statistical analysis: \*1. student t-test (two-sided); \*2. Chi-square test; \*3. Fishers exact test; statistically significant differences are highlighted

## Risk factors for failure

<b>Table 3. Comparison of risk factors for failure of retropubic and transobturator midurethral sling procedures after 12 months</b>					
Part 2: Monarc & TVT-O					
	Not cured	UNIVARIATE ANALYSIS		MULTIVARIATE ANALYSIS	
		OR [95% CI]	p - value	OR [95% CI]	p - value
<b>Monarc &amp; TVT-O (n,%)</b>	43 (25%)				
<i>Medical History</i>					
Type of Incontinence (n,%)					
SUI	34 (26%)	0.78 [0.34-1.79]	0.555 (*2)		
MUI	9 (21%)				
Nocturia (n,%)					
present	9 (31%)	1.54 [0.63-3.74]	0.342 (*2)		
absent	29 (23%)				
Previous incontinence surgery (n,%)					
present	8 (50%)	3.49 [1.22-9.96]	<b>0.015 (*2)</b>	3.9 [1.3-11.7]	<b>0.015</b>
absent	35 (22%)				
<i>Physical examination</i>					
Cough-stress test (n,%)					
loss of urine present	42 (26%)	0.32 [0.04-2.60]	0.454 (*3)		
no loss of urine	1 (10%)				
<i>Urodynamic investigation</i>					
Maximum bladder capacity (ml, mean ± SD)	416 ± 131		0.106 (*1)		
number of women with MCC < 200 ml (n,%)	3 (100%)	(*4)	<b>0.014 (*3)</b>	(*4)	0.999
number of women with MCC ≥ 200 ml (n,%)	39 (23%)				
Detrusor overactivity (n,%)					
present	4 (33%)	1.56 [0.45-5.48]	0.496 (*3)		
absent	39 (24%)				
MUCP (cm H2O, mean ± SD)	52 ± 34		0.131 (*1)		
number of women with MUCP < 20 cm H2O (n,%)	4 (80%)	12.91 [1.40-119.37]	<b>0.015 (*3)</b>	14.5 [1.5-139.0]	<b>0.002</b>
number of women with MUCP ≥ 20 cm H2O	35 (24%)				

Statistical analysis: \*1. student t-test (two-sided); \*2. Chi-square test; \*3. Fishers exact test; statistically significant differences are highlighted  
 \*4. non calculable because there were no patients cured with MCC < 200 ml



## Chapter 4

### When to perform urodynamics before mid-urethral sling surgery for female stress urinary incontinence?

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## ABSTRACT

**Objective:** Development of a model that can predict in which group of women pre-operative urodynamics can be safely omitted.

**Methods:** 381 uncomplicated women who underwent pre-operative urodynamics were evaluated. A multivariate logistic regression model was developed based on medical history and physical examination predicting a high probability group of women with detrusor overactivity or a low (< 20 cm H<sub>2</sub>O) mean urethral closure pressure (MUCP) and therefore are likely to benefit from urodynamics.

**Results:** Women are likely to benefit from pre-operative urodynamics if they: 1) are 53 years of age or older; or 2) have a history of prior incontinence surgery and are at least 29 years of age; or 3) have nocturia complaints and are at least 36 years of age.

**Conclusion(s):** If urogynaecologists omitted pre-operative urodynamics in women in the low probability group, in our population, pre-operative urodynamics would be reduced by 29%.

## **INTRODUCTION**

Approximately 13% of the female population is affected by stress urinary incontinence (SUI) [1]. If conservative therapy fails, surgical treatment is considered the therapy of choice. The life-time risk that women will have surgical treatment for SUI is about 4% [2]. In current urogynecological practice, urodynamics are routinely performed before considering surgical treatment for SUI. This strategy is recommended in both gynecological and urological guidelines [3,4].

Recent studies have shown that the sensitivity of urodynamics to diagnose SUI is far from perfect, especially in women with mixed urinary incontinence (MUI) [5,6]. Therefore routine use of pre-operative urodynamics in all women with an indication for surgical treatment of SUI is debatable [7-9].

On the other hand, detrusor overactivity (DO) is a risk factor for failure of mid-urethral sling (MUS) procedures or at least carries a worse prognosis [9-11]. A recent study even suggested that better results might be obtained with Transobturator Tape (TOT) compared to retropubic Tension-free Vaginal Tape (TVT) in women with DO [12]. Another recently published prospective study showed that women with a low ( $< 20$  cm H<sub>2</sub>O) mean urethral closure pressure (MUCP) benefit from a retropubic TVT [13]. Therefore urodynamics can be used to select the proper MUS procedure.

Nevertheless, the indication for urodynamics needs to be more precisely determined considering the negative side effects (costs, a delay in surgery, risk of infection and patient discomfort). The aim of this study was to develop a model that can identify women for whom pre-operative urodynamics can be safely omitted.

## **MATERIAL AND METHODS**

This study is based on data from prospective studies investigating the outcome of the TVT and afterwards the transobturator tapes (Monarc and TVT-O) as surgical treatment for female SUI. Both studies were approved by the Medical Ethical Committee of the St. Elisabeth Hospital Tilburg.

Since 1998 data was collected consecutively on women undergoing either TVT, Monarc or TVT-O in the St. Elisabeth Hospital Tilburg. For this study we only report on women who did not undergo concomitant surgical procedures (like prolapse surgery). Excluded were women with missing values of DO or MUCP at urodynamics and women with neurological disorders or pre-existent voiding dysfunction.

## Chapter 4

Before surgery, each woman underwent a standardised urogynecologic work-up. The definitions used are according to the recommendations of the International Continence Society [14]. A history of SUI was defined as the statement of the women of involuntary leakage during physical activity, coughing or sneezing. A history of urge urinary incontinence (UUI) was defined as the statement of involuntary leakage preceded by a strong sense of urgency. A history of mixed urinary incontinence (MUI) was defined as a combination of SUI and UUI. Nocturia was defined as a micturition frequency  $> 1$  during sleep. Pelvic organ prolapse was scored according to the Baden–Walker classification [15].

Multichannel urodynamic investigation was performed in all women according to the recommendations of the International Continence Society and followed by cystoscopy [16,17]. During the initial visit and after the cystoscopy a cough-stress test was performed in supine position with standard volume.

Two groups were discriminated during outcome assessment. Theoretically, the group of women who did not reveal DO or a low MUCP at urodynamics, was expected not to benefit from pre-operative urodynamics. This group is referred to as 'urodynamically normal'. The second group consisted of women who revealed DO and / or low MUCP at pre-operative urodynamics and therefore are likely to benefit from urodynamics [9-13]. This group is referred to as 'urodynamically abnormal'.

The aim of the analysis was to develop a model which can predict a high probability group of urodynamically abnormal women using parameters from the medical history and findings at physical examination. First, the association between each diagnostic variable and abnormal urodynamics was quantified using logistic regression analyses. Subsequently, predictors that were univariately associated with the outcome (odds ratio with a  $p$ -value  $< 0.15$ ) were included in a multivariate logistic regression model to evaluate their independent contribution to the prediction of abnormal urodynamics. Predictors in the multivariate analysis with  $p$ -values  $\geq 0.10$  were excluded from the final model.

The Hosmer and Lemeshow test was applied to assess if the model adequately fitted the data [18]. The resulting model can be considered as a 'combined diagnostic test' including several diagnostic findings, with the estimated probability of presence of abnormal urodynamics as its test result.

The diagnostic value of the model was quantified using the area under the receiver operating characteristic (ROC) curve. The ROC curve shows the model's sensitivity against 1 minus its specificity for each cut-off

## *When to perform urodynamics*

value for the predicted probability of abnormal urodynamics above which the urodynamics of women are actually considered as abnormal. An area under the ROC curve of 0.5 implies that the discriminatory capacity of the model does not exceed chance levels (rendering it meaningless), whereas an area under the ROC curve of 1 implies a perfect discriminatory capacity [19].

With an area under the curve in-between 0.5 and 1, a cut-off predicted probability should be chosen that optimizes the balance between the number of women with normal urodynamics for whom unnecessary pre-operative urodynamics can be prevented, and the number of women with abnormal urodynamics who will erroneously be excluded from urodynamics.

In order to define pre-operative work-up guidelines, we subsequently assessed which combinations of parameter values of the predictors in the final model would suffice to increase a woman's predicted probability of abnormal urodynamics above the chosen cut-off value.

## **RESULTS**

A total of 437 women were operated in the St. Elisabeth Hospital Tilburg, The Netherlands and included in one of both studies from January 1998 until December 2006. This study population contained 381 women because 56 women (13%) with missing values of DO or MUCP at urodynamics were excluded.

Baseline characteristics are shown in table 1. All women had symptoms of predominant SUI. 294 women (77%) had symptoms of pure SUI and 87 women (23%) had symptoms of MUI. All women with MUI received anticholinergic treatment which did not alleviate their symptoms. Twenty-five (7%) women showed DO, 39 (10%) women showed low MUCP and 2 women showed both.

Table 2 shows uni- and multivariate analyses and regression coefficients ( $\beta$ ) of the association of findings from medical history and physical examination with abnormal urodynamics. The final model included age, previous incontinence surgery and nocturia.

The predicted probabilities of abnormal urodynamics derived from the model were used to generate a ROC-curve of the need for pre-operative urodynamics (Figure 1). The corresponding area under the ROC-curve was 0.65 (95% CI 0.58–0.72). The cut-off predicted probability of abnormal urodynamics was set at 0.12. Hence, all women with a predicted probability of abnormal urodynamics above 0.12 would be subjected to urodynamic procedures.

To formulate clinical decision rules (prediction model), combinations of values for age (continuous), previous incontinence surgery (yes/no) and nocturia (yes/no) were determined in order for the prediction model,  $\exp(0.031 * \text{age} + 0.743 * \text{previous incontinence surgery} + 0.525 * \text{nocturia} - 3.606)$ , to exceed this cut-off predicted probability of 0.12. Hence, women are likely to benefit from pre-operative urodynamics if they: 1) are 53 years of age or older; or 2) have a history of prior incontinence surgery and are at least 29 years of age; or 3) have nocturia complaints and are at least 36 years of age. This model fitted the data adequately (Hosmer and Lemeshow test p-value > 0.4).

This model, in our population, has a sensitivity of 90% (56/62) and a negative predictive value of 94% (95/101), as shown in table 3. Exclusion of the less predictive variable (nocturia) from this model significantly decreased the negative predictive value (the number of women with abnormal urodynamics who would erroneously be excluded from urodynamics, doubled from 6 to 12).

If urogynaecologists would decide not to demand for pre-operative urodynamics in women with a low probability of abnormal urodynamics, in our population, pre-operative urodynamics would be reduced by 29% (101/351).

## DISCUSSION

The aim of this study was to investigate whether the findings of DO or a low MUCP in women with predominant SUI can be predicted by information obtained from medical history and physical examination. In this group of women urodynamic results could have influenced pre-operative counselling and the choice of the surgical procedure [9-13]. Therefore this group of women might benefit from pre-operative urodynamics.

Simple decision rules (53 years of age or older, a history of prior incontinence surgery and at least 29 years of age, complaints of nocturia and at least 36 years of age) containing only variables from medical history had a high sensitivity (90%) and negative predictive value (94%). Therefore these rules accurately identify women in whom pre-operative urodynamics can be safely omitted. Nevertheless, before implementation of this model in clinical practice, the actual performance of these decision rules should be proven by using these rules in a new group of women with SUI and an indication for surgical treatment [20].

An important question is what are the consequences of missing DO or a low MUCP? For missing DO a consequence is too optimistic counselling

### *When to perform urodynamics*

for cure of SUI [9]. It is also known that persistence or worsening of the UUI after surgery negatively affects the outcome of MUS procedures [21,22]. Furthermore DO might play a role in predicting post-operative overactive bladder (OAB) symptoms [23]. There are indications that a TOT procedure might give better results in women with DO but these findings need to be confirmed in prospective randomised trials [12].

Missing a low MUCP on the other hand, might have more evident consequences. Schierliz et al found that women with a low MUCP performed significantly better after a TVT procedure compared with TOT [13]. Six months after surgery 21% had urodynamic stress incontinence in the TVT group compared with 45% in the TOT group. Furthermore nine women in the TOT group underwent repeat sling surgery compared with none in the TVT group. These findings were confirmed in other studies [24-26]. In conclusion missing DO does not influence surgical treatment but a low MUCP should influence choice of suspension.

Because surgeries have irreversible outcome, high sensitivity of the decision rules was regarded most important and resulted in a conservative cut-off for predicted probability of abnormal urodynamics of 0.12. This implicates that urodynamics are performed if the model predicted a chance of abnormal urodynamics above 12%. The chosen cut-off generated the optimal balance between the number of women with normal urodynamics for whom unnecessary pre-operative urodynamics can be prevented, and the number of women with abnormal urodynamics who will erroneously be excluded from urodynamics.

The area under the curve of 0.65 is not very high. However, the discriminative power of the investigated diagnostic test (urodynamics), an invasive investigation with considerable side-effects, is not undisputed itself in uncomplicated women [7-9]. Therefore the AUC of 0.65 seems acceptable for this research question.

Women who revealed DO or low MUCP at pre-operative urodynamics were combined in one group in this study. Separate models predicting DO or a low MUCP were substantially worse compared with this final model. Little evidence exists of other urodynamic parameters influencing treatment modus or outcome in uncomplicated women with an indication for surgical treatment of SUI [21]. Therefore in this study we made the premise that only women with DO or a low MUCP might benefit from urodynamics.

A possible drawback of this model are women with voiding dysfunction. Voiding dysfunction can be present without symptoms and

without a pre-existing history. These group would not be properly identified by the presented model. However as patients with known pre-existing voiding dysfunction and post voiding bladder retention of more than 150 ml were already excluded from this study, this group is likely to be very small.

The strength of this study is the large number of women treated in the same clinic. Therefore the same work-up was used to evaluate symptoms and score findings at physical examination. We did not collect all the parameters we studied from each woman as can be seen in table 1. The most pronounced missing data are micturition frequency (8%) and nocturia (8%). We did not exclude these women because the other parameters might still have prognostic influence and valuable information would be lost if they were excluded.

The variables decided upon are drawn from the patients' history and demographics. This contrasts with many of the earlier papers which have looked at clinical features and other simple tests which are non-invasive and may be helpful. Therefore this paper aims to introduce a new concept for approaching the difficult subject of pre-operative urodynamics, their validity and their role, and stimulate the development of other models for discrimination.

## **CONCLUSION**

Women without neurological disease or pre-existing voiding dysfunction and with an intention for surgical treatment of stress urinary incontinence (without concomitant prolapse surgery) are likely to benefit from pre-operative urodynamics if they: 1) are 53 years of age or older; or 2) have a history of prior incontinence surgery and are at least 29 years of age; or 3) have nocturia complaints and are at least 36 years of age. The presented decision rules achieved a very high negative predictive value (94%) while still eliminating the need to perform urodynamics in 29% of the women. Before implementation in clinical practice, these rules should be validated.

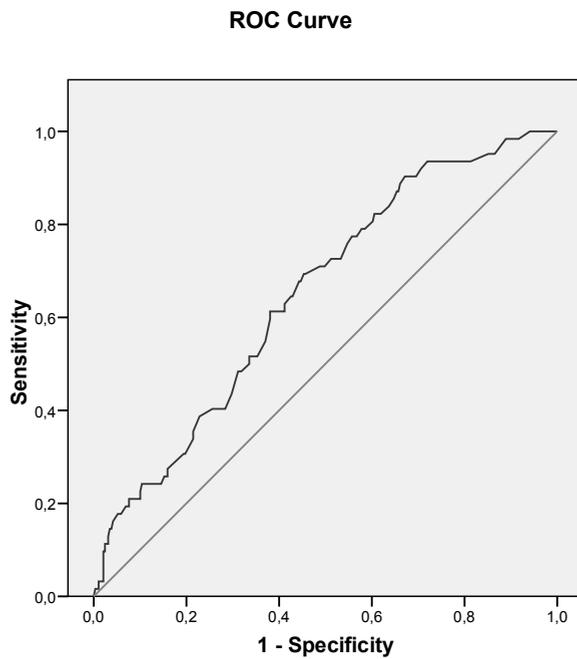
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Figure 1: ROC curve of prediction model



## Chapter 4

<b>Table 1. Characteristics of study population</b>					
		included in analyses	%	missing values	%
Number of women		381			
<b>Medical history</b>					
Age (years)	mean $\pm$ SD	51 $\pm$ 10			
Type of Incontinence (n)	SUI	294	77%		
	MUI	87	23%		
Menopausal status (n)	postmenopausal	168	44%		
Parity (n)	nulliparous	16	4%	10	3%
Micturition frequency (n)	> 8	109	29%	32	8%
Nocturia (n) <sup>1</sup>	present	202	53%	30	8%
Prolapse complaints (n)	present	24	6%	4	1%
Defaecation problems (n)	present	16	4%	5	1%
Straining for defaecation (n)	present	22	6%	5	1%
Previous incontinence surgery (n)	present	39	10%		
Previous prolapse surgery (n)	present	85	22%		
<b>Physical examination</b>					
Cough-stress test	no loss of urine	15	4%		
Cystocele (n)	$\geq$ grade 2	9	2%		
Rectocele (n)	$\geq$ grade 2	6	2%		
Prolapse of uterine cervix of vaginal vault (n)	$\geq$ grade 2	4	1%		
Urethral hypermobility (n)	$\geq$ grade 1	5	1%		
<b>Urodynamics</b>					
DO and / or low MUCP		66	17%		

1. Nocturia is defined as a micturition frequency of more than once during sleep.

## When to perform urodynamics

<b>Table 2. Uni - and multivariate analysis and regression coefficients</b>							
		'urodynamically abnormal'	UNIVARIATE ANALYSIS		MULTIVARIATE ANALYSIS		
			OR [95% CI]	p - value	$\beta$	OR [95% CI]	p - value
Patients (n)		66					
<b>Medical history</b>							
Age (years, mean $\pm$ SD)		55 $\pm$ 11	1.05 [1.02-1.07]	<b>0.000 (*1)</b>	0.031	1.03 [1.00-1.06]	<b>0.025</b>
Type of Incontinence (n)	MUI	23	2.10 [1.18-3.73]	<b>0.011 (*2)</b>			
Menopausal status (n)	postmenopausal	38	1.93 [1.13-3.31]	<b>0.015 (*2)</b>			
Parity (n)	nulliparous	3	1.14 [0.31-4.10]	0.741 (*3)			
Micturitation frequency (n)	> 8	25	1.63 [0.93-2.88]	0.089 (*2)			
Nocturia (n)	present	44	2.03 [1.12-3.68]	<b>0.018 (*2)</b>	0.525	1.69 [0.91-3.13]	0.096
Prolapse complaints (n)	present	2	0.41 [0.09-1.79]	0.279 (*3)			
Defaecation problems (n)	present	2	1.51 [0.34-6.82]	0.748 (*3)			
Straining for defaecation (n)	present	3	1.37 [0.39-4.78]	0.788 (*3)			
Previous incontinence surgery (n)	present	13	2.73 [1.31-5.64]	<b>0.005 (*2)</b>	0.743	2.10 [0.95-4.64]	0.065
Previous prolapse surgery (n)	present	21	0.55 [0.30-0.98]	<b>0.041 (*2)</b>			
<b>Physical examination</b>							
Cough-stress test (n)	no loss of urine	0	(*4)	0.084 (*3)			
Cystocele (n)	$\geq$ grade 2	2	1.38 [0.28-6.77]	0.658 (*3)			
Rectocele (n)	$\geq$ grade 2	1	0.95 [0.11-8.30]	0.966 (*3)			
Prolapse of uterine cervix of vaginal vault (n)	$\geq$ grade 2	0	(*4)	1.000 (*3)			
Urethral hypermobility (n)	$\geq$ grade 1	64	3.25 [0.53-19.85]	0.208 (*3)			
<b>Intercept final model</b>					- 3.606		

$\beta$  = regression coefficient

Statistical analysis: \*1. student t-test (two-sided); \*2. Chi-square test; \*3. Fishers exact test; statistically significant differences are highlighted

\*4. non calculable

## Chapter 4

<b>Table 3. Estimated results of prediction model</b>					
Prediction model: perform UDI?	Observed				total
	urodynamically		urodynamically		
	abnormal'	% [95% CI]*	normal'	% [95% CI]*	
yes	56	23 [18-28]	194	77 [72-82]	250
no	6	6 [3-12]	95	94 [88-97]	101
Total	62		289		351

\* 95% CI: 95% confidence interval

**Prediction rules (perform urodynamics if):**

- 1) age 53 years or older; or
- 2) history of previous incontinence surgery and age  $\geq$  29 years; or
- 3) nocturia and age  $\geq$  36 years

## Chapter 5

# Outcome and complications of retropubic and transobturator mid-urethral slings translated into Surgical Therapeutic Indices

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**ABSTRACT**

**Objective:** To determine and compare Surgical Therapeutic Indices (STI's) of the retropubic TVT and two transobturator tapes Monarc and TVT-O.

**Study design:** Retrospective cohort study. Patients with predominant stress urinary incontinence (SUI) who underwent a retropubic (TVT, n=257) or transobturator tape procedures (TOT, n=180) were included. STI's for both groups were calculated by dividing cure by complication rate at respectively 2 and 12 months.

**Results:** Two months after surgery the STI is significantly higher after TOT whereas 12 months after surgery results of STI's are equal. The explanation is more durable cure rates and declining long-term side effects after TVT procedures.

**Conclusion(s):** Both surgical approaches seem to have their own benefits. Based on the STI, the balance between cure rate and complications is on the short term in favor of TOT but on the long term similar for TOT and retropubic TVT.

## **INTRODUCTION**

Nowadays mid-urethral sling (MUS) procedures are considered the “gold standard” for surgical treatment of female stress urinary incontinence (SUI) [1]. Due to the broad assortment of MUS procedures, it is important to choose the right surgical procedure for each individual patient.

Several studies indicated that retropubic and obturator tape procedures are equally effective in curing female SUI at one year after surgery [2-7]. Due to small numbers, comparison of medium-term complications between studies is difficult and statistical significance is never reached. Moreover functional complications are often not or marginally described because the primary endpoint of most studies is cure.

For preoperative counseling purposes the concept of the benefit/risk ratio is often used. Benefit is defined as cure of incontinence and risk as the potential for surgical complications. In pharmacology, the benefit/risk ratio of medication is expressed through a therapeutic index. The therapeutic index describes the ratio of desired effect to toxic effect of a certain drug. Farrell et al applied this concept to incontinence surgery and first described the Surgical Therapeutic Index (STI) [8].

The STI is defined as the ratio between the cure and complication rate. The complication rate is calculated by summing complications associated with the performed surgical procedure at a defined moment in time [8,9]. The higher the STI, the safer the procedure. Urogynecological counseling can be improved by using STI's because they are comprehensible for patients and different MUS procedures can be easily compared by using STI's.

Therefore the aim of this study was to determine and compare STI's of the retropubic TVT and two transobturator tapes Monarc and TVT-O.

## **MATERIAL AND METHODS**

Prospectively collected data from all consecutive patients undergoing TVT, Monarc or TVT-O procedures in a large teaching hospital in the Netherlands were analyzed. Included were all patients operated by one of these procedures between January 1998 and December 2006. Patients undergoing concomitant surgical procedures were excluded, as were patients who did not show up for both postoperative visits after 2 and 12 months. Selection of surgical procedures was not affected by indication for surgery.

The definitions used are according to the recommendations of the International Continence Society (ICS) [11]. A history of SUI was defined as

the statement of the patient of involuntary leakage during physical activity, coughing or sneezing. A history of urge urinary incontinence (UUI) was defined as the statement of involuntary leakage preceded by a strong sense of urgency. A history of mixed urinary incontinence (MUI) was defined as a combination of SUI and UUI. Nocturia was defined as a micturition frequency > 1 during sleep. Pelvic organ prolapse was scored according to Baden-Walker classification [12].

Multichannel urodynamic investigation was performed in all patients according to the recommendations of the International Continence Society and followed by cystoscopy [13,14]. During the initial visit and after the cystoscopy a cough-stress test was performed in supine position. We presumed SUI to be present based on medical history combined with the positive cough stress test in patients who demonstrated no urodynamic SUI.

The TVT (Gynecare, Ethicon Inc, Sommerville, New Jersey, USA) procedure was performed as described by Ulmsten [15]. The Monarc (American Medical Systems, Minneapolis, USA) tape was inserted through the "Outside-in" route as using the technique recommended by the manufacturer. TVT-O (Gynecare, Sommerville, New Jersey USA), an "Inside-out" procedure, was performed as described by de Leval [16]. Cystoscopy was routinely performed after all TVT procedures and only in case of bloody stained urine after TOT procedures (which did not happen).

TVT operations were carried out under local anesthesia using 0,25% prilocaine and/or systemic administered propofol. TVT-O and Monarc procedures were all performed under general anesthesia. Monarc and TVT-O procedures are in this study referred as to Transobturator Tape (TOT).

Intra- or postoperative hemorrhage was defined as blood loss of more than 300 ml. Postvoid residual urine in the immediate postoperative period was defined as a postvoid residual urine of more than 150 ml identified by ultrasound scanning of the bladder or catheterization. Postoperative urinary retention was defined as the impossibility to void for which an indwelling catheter for more than 24 hours was necessary.

Follow-up of patients was at 2 and 12 months postoperative. Urinary symptoms and other symptoms were assessed at both visits. We adhered to the recommendations of IUGA on outcome measures [17]. Cure of SUI was defined as the statement of the woman of not experiencing any loss of urine upon physical activity, coughing or sneezing. Patients reporting any amount of leakage were considered failures. De novo UUI was defined as the development of postoperative UUI while absent prior to surgery. Voiding difficulty was defined as the report of difficult micturition. Furthermore tape

## *Surgical Therapeutic Index*

release, vaginal mesh erosion, dyspareunia and groin pain were evaluated. The complication rate for the STI was calculated by summing all complications associated with the performed surgical procedure at respectively 2 and 12 months. STI's for both groups were calculated by dividing cure by complication rate at respectively 2 and 12 months. STI's were calculated for Monarc and TVT-O as one combined group.

A second STI was calculated based on severity of the complications. The severity factor for de novo UUI and voiding difficulty was based on the Quality of Life (QoL) analysis of the Dutch TVT database [18,19]. The mean IIQ-7 values pre-operative, after 2 and 12 months for patients reporting de novo UUI and voiding difficulty were analyzed. Patients with de novo UUI showed factor 2 and 4 less improvement in QoL after respectively 2 and 12 months compared to patients without de novo UUI. Patients with voiding difficulty showed factor 2 less improvement in QoL after 2 and 12 months compared to patients without voiding difficulty. These factors were rounded to the nearest integer to improve practical application. The factor 2 for tape release is based on common sense.

The factors were used as severity factor in the following way: the number of patients reporting de novo UUI after 2 months was multiplied by 2 and after 12 months by 4. The number of patients reporting voiding difficulty after 2 and 12 months was multiplied by 2. For tape release the severity factor was used in the same way as for voiding difficulty.

Continuous variables were compared using unpaired t-test and dichotomous variables were compared using Chi-square test. Fisher's exact test was used if cross tabs had a cell with an expected frequency < 5. To compare dichotomous variables during time, the Mc Nemar test was used. A p-value of less than 0.05 was considered to be statistically significant. STI's were compared by their 95% confidence intervals (CIs), after correction for bias and using accelerated non-parametric bootstrapping, drawing 1000 samples of the same size as the original sample separately for each group and with replacement. The bootstrapping approach was used to generate the 95% CIs and to use the non-overlap of the respective CIs as a means of identifying statistically significant differences. Statistical analysis was performed using SPSS (Windows version 16.0).

All patients were participating in prospective studies investigating the outcome of TVT (Dutch TVT database) and at a later stage the Transobturator Tapes (Monarc and TVT-O) as surgical treatment for female SUI. Both studies had been approved by the Medical Ethical Committee of the St. Elisabeth Hospital Tilburg.

## RESULTS

465 patients met the inclusion criteria. 28 patients (6%) did not return for any postoperative visit and were left out of this analysis. From the included patients, 37 failed to show up for the 2 months postoperative visit and 13 patients failed to show up for the 12 months postoperative visit.

Pre-operative data are listed in Table 1. This study population contains 437 patients (257 TVT, 95 Monarc and 85 TVT-O procedures). A history of pure SUI was reported by 343 patients (78%) whereas 94 patients (22%) had a history of MUI. Anti-cholinergic medical treatment was given in patients with MUI before surgical treatment was considered and did not alleviate their symptoms. The majority of the patients (89%) underwent pre-operative pelvic floor physiotherapy. The age of the TVT group was higher than of the TOT group and stress incontinence during urodynamic investigation was more absent in the TOT group ( $p < 0.001$ ). There were no statistically significant differences in pre-operative data between patients who underwent a Monarc or TVT-O procedure (data not shown).

Cure rates of both groups are listed in Table 2. There were no significant differences in cure rate after 2 and 12 months. Cure rates after TVT procedures were more lasting ( $p = 0.029$ ).

Bladder perforations occurred in 9 patients (4%) in the TVT group versus none in the TOT group ( $p = 0.01$ ). Post-operative more urinary retention occurred in the TVT group ( $p = 0.003$ ). Hospital admission was longer after TVT procedures 1,7 versus 1,4 days ( $p = 0.03$ ) where patients treated in day care were scored as 1 day hospital admission. The number of patients who were treated in day care was not different ( $p = 0.2$ ).

After 2 months there were significantly more patients with voiding difficulty in the TVT group ( $p < 0.001$ ). However this difference was no longer present after 12 months and all patients voided without catheterization. In the follow-up period, there were 4 cases of tape erosion which all occurred in the TOT group ( $p = 0.04$ ).

Table 3 shows results of the obturator tapes Monarc and TVT-O separately. Except for voiding difficulty after 2 months ( $p = 0.043$ ), no statistically significant differences were observed.

In Table 4 the complication rates adjusted with the severity factor are shown. This table, as well as table 2, shows the decrease in complication rate after TVT and the increase in complication rate after TOT procedures over time.

The actual STI's of Table 5 were calculated directly from the data of Table 2 and of Table 4 (for severity adjustment). The STI after 2 months is

significantly higher in the TOT group. After 12 months, no significant differences between STI's of both procedures were observed. In the second STI (adjusted for severity) the same results were found.

#### **COMMENT**

The STI of TOT procedures was significantly higher compared to TVT procedures after 2 months. Nevertheless a significant decrease of SUI cure rate was observed in the TOT group in the period between 2 and 12 months. Through a decreasing cure rate and an increasing complication rate, the STI of TOT procedures decreased.

The more stable SUI cure rates after TVT procedures are confirmed by the number of patients who underwent a second incontinence procedure: 2 second incontinence procedures were performed due to failure in the TVT group, compared to 6 second incontinence procedures in the TOT group. Stable SUI cure rates and the decreasing complication rates after TVT procedures explain the increasing STI of TVT procedures.

After 11 years of follow-up excellent results of TVT procedures are described, even when dealt with an ageing population [20]. Until this moment long-term follow-up of TOT procedures is still unknown. Satisfying results of 3 year follow-up studies are reported but long-term comparative trials between both approaches are eagerly awaited [21,22].

The results of our study differ from the only other study where STI's of TVT and TOT procedures were compared [9]. Jeon et al found that differences in complication rates between TVT and TOT increased over time, favoring the TOT procedure. In our study the exact opposite is shown. The explanation might be better cure rates after TOT procedures in their study and the absence of tape erosions in their TOT group.

Bladder perforation and postoperative urinary retention did occur more frequently after TVT. This might have cost a longer hospital stay after TVT procedures. Without cystoscopy, no bladder perforations after TOT may underestimate the actual number. However, as none of the patients in the TOT group reported any symptoms of a bladder perforation post-operatively, the occurrence of bladder perforations is very unlikely.

These findings are consistent with the results of two recent published meta-analyses [2,3]. It is however important to assess the clinical impact of these complications. A recent study [23] found no differences in postoperative urinary tract infections, hematomas, voiding dysfunction or objective or subjective cure rates in patients who had cystotomy (bladder perforation) after TVT compared with those who did not. Although bothering,

bladder perforations with the TVT inserter apparently do not result in any clinically significant morbidity. Postoperative urinary retention in our study did not lead to a higher rate of voiding dysfunction in the TVT group after 12 months. Therefore both short-term complications are unlikely to influence results after 12 months.

Two months after surgery there were more patients with postoperative voiding difficulty in the TVT group. In comparison with TOT, the sling axis of the TVT is more perpendicular to the urethral axis, creating more circumferential compression of the urethra. This implies that TVT is theoretically more obstructive. Increased obstruction with more urethral compression and hence increased urethral resistance may lead to increased voiding difficulty after retropubic TVT procedures. Five patients in the TVT group and 1 patient in the TOT group required tape release due to voiding difficulty (the other patients in the TOT group underwent tape release due to persistent UUI). Twelve months after surgery similar rates of voiding difficulty in both groups were reported. Our results are confirmed by Dietz et al, who also found that symptoms of voiding dysfunction after TVT decrease over time [24].

Tape erosions tend to occur more frequently after TOT procedures [2]. A long-term follow-up study of TVT showed no erosions after eleven years [20]. This study confirms these findings: all erosions occurred after a TOT procedure (3 after a Monarc and 1 after a TVT-O procedure). All erosions required excision under local anesthesia. Nevertheless, 3 of the 4 patients were cured of SUI.

The strength of this study is the large number of patients, treated in the same clinic with the same diagnostic work-up and evaluation of outcome used in all patients. Procedures were not combined with other urogynecological surgery and nearly all surgery was performed by one author (HV). Therefore differences in surgical method of the procedures are unlikely.

Nevertheless, there are also limitations to the design of this study. First there are differences in baseline characteristics between the groups. This may be due to the different time frame in which these patients were operated. TVT was the first available treatment option and later, when TOT became available, we switched to TOT. One could argue that patients without urodynamic SUI ( $n = 90$ ; 23%) should not be operated. However the cure rate in this group was 77,9% after 12 months compared to 77,8% in patients with urodynamic SUI ( $p = NS$ ). Therefore the absence of urodynamic SUI did not influence cure rate.

The aims of this study were to introduce the STI and compare generations of mid-urethral slings. Therefore we combined Monarc and TVT-O in one group (TOT): second generation of MUS procedures. The decision to analyze Monarc and TVT-O as one group, did not influence our conclusions as the tendency of the STI's of the obturator tapes is comparable. Due to the increased size of the combined obturator group, a more reliable comparison with TVT can be presented.

Besides voiding difficulty after 2 months, no differences were observed between both procedures. We have no explanation for this difference. Furthermore several other studies indicated that cure and complication rates of Monarc and TVT-O are similar after one year [2,10].

Outcome measurements were not based on validated questionnaires but on a standardized interview which is more subject to interpretation. However, as the follow-up of nearly all patients was done by the same gynecologist (HV), differences in interpretation seem unlikely.

Success rates of incontinence surgery can be widely variable and are largely dependant upon the definition of cure or the outcome measure used [25]. Due to our ambitious definition of cure, our cure rates are a little lower than the results presented in other studies [2-7]. However our improvement rates were in agreement with these other studies: 97% of the patients in the TVT and 92% of the patients in the TOT group found their symptoms to be improved after surgery.

A drawback of using the "old-fashioned" STI is that the seriousness of the complications is not taken into account [8,9]. Therefore groin pain, although bothering, contributed equally to the complication rate as voiding difficulty which required tape release. In this study an effort is made to introduce a severity factor. Through the use of severity factors, the STI's of both approaches in this study decreased but differences became more evident. Although subjective, severity factors might play an important role in judging complications.

The severity factors for voiding difficulty and de novo UUI are based on patients who underwent a TVT procedure [18,19]. Ideally all patients would have completed QoL questionnaires and results could be compared between groups of patients with a certain complication, stratified for type of MUS procedure. Therefore an important goal for further research is to determine the impact of the different complications and develop a severity index for complications.

For global use of STI a standardized definition of cure is crucial. Furthermore all investigators need to report the same complications in a

## Chapter 5

standardized STI. Only when world-wide standardized definitions are used, can STI's of different studies be objectively compared.

Nevertheless the STI is a reliable indicator of success because cure as well as complications have been taken into account. We developed a "severity factor" for complications, which estimates the impact of the different complications on patient related quality of life. As a result the STI's are capable of providing a complete overview of postoperative outcome after incontinence surgery.

### **CONCLUSION**

TOT procedures are performing significantly better in the short-term but in the long- term this difference disappeared. Both surgical approaches seem to have their own benefits and patients can be given a choice between the two approaches. Based on the STI the benefit/risk of TVT and TOT is comparable on the long term but in favor of TOT on the short term.

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## Surgical Therapeutic Index

<b>Table 1. Baseline characteristics of study population</b>						
		<b>TVT</b>		<b>Monarc &amp; TVT-O</b>		<b>p-value</b>
Number of women		257		180		
<b>Medical history</b>						
Age (years)	mean ± SD	52 ± 11		49 ± 10		<b>0.001 (*1)</b>
Type of Incontinence (n)	SUI	206	80%	137	76%	0.311 (*2)
	MUI	51	20%	43	24%	
Daily micturitation frequency (n)	mean ± SD	7 ± 2		8 ± 3		0.675 (*1)
	> 8	72	30%	48	30%	0.884 (*2)
Nocturia (n)	present	43	18%	29	18%	0.973 (*2)
Previous incontinence surgery (n)	present	22	9%	17	9%	0.750 (*2)
Previous prolapse surgery (n)	present	65	25%	34	19%	0.116 (*2)
<b>Physical examination</b>						
Cystocele (n)	≥ grade 2	5	2%	7	4%	0.221 (*2)
Rectocele (n)	≥ grade 2	3	1%	3	2%	0.694 (*3)
Prolapse of uterine cervix of vaginal vault (n)	≥ grade 2	1	0%	3	2%	0.311 (*3)
<b>Urodynamic investigation</b>						
Urodynamic stress incontinence (n)	present	215	84%	121	67%	<b>0.000 (*2)</b>
Detrusor overactivity (n)	present	15	6%	12	7%	0.723 (*2)

Statistical analysis: \*1. Student t-test (two-sided); \*2. Chi-square test; \*3. Fisher's exact test; statistically significant differences are highlighted

## Chapter 5

<b>Table 2. Outcome &amp; complications after TVT and TOT</b>						
	total	TVT		Monarc & TVT-O		p- value
<i>Comparison between groups</i>						
Cured after 2 months		217	88%	147	83%	0.162 (*1)
Cured after 12 months		182	81%	132	75%	0.131 (*1)
<i>Comparison within groups #</i>						
Cured after 2 months		185	86%			0.121 (*2)
Cured after 12 months		175	82%			
Cured after 2 months				144	83%	<b>0.029 (*2)</b>
Cured after 12 months				130	75%	
<i>Intra-operative complications</i>						
bladder perforation	9	9	4%	0	0%	<b>0.011 (*3)</b>
fausse route needle introducer	5	3	1%	2	1%	1.000 (*3)
hemorraghe	1	1	1%	0	0%	1.000 (*3)
<i>Post-operative complications</i>						
> 150 ml postvoid residual urine	80	50	20%	30	17%	0.458 (*1)
urinary retention	25	22	9%	3	2%	<b>0.003 (*3)</b>
<i>Complications after 2 months</i>						
de novo UUI	13	11	4%	2	1%	0.083 (*3)
voiding difficulty	63	50	20%	13	8%	<b>0.000 (*1)</b>
vaginal mesh erosion	1	0		1	1%	0.447 (*3)
tape release	0	0		0		
dyspareunia	2	2	1%	0		0.512 (*3)
groin pain	0	0		0		
<b>Summing</b>	79	63	26%	16	9%	
<i>Complications after 12 months</i>						
de novo UUI	19	10	5%	9	5%	0.576 (*1)
voiding difficulty	22	15	6%	7	4%	0.386 (*1)
vaginal mesh erosion	4	0		4	2%	<b>0.037 (*3)</b>
tape release	7	5	2%	2	1%	0.473 (*3)
dyspareunia	2	0		2	1%	0.193 (*3)
groin pain	2	0		2	1%	0.193 (*3)
<b>Summing</b>	56	30	13%	26	15%	

# The Mc Nemar test is calculated only for patients who did show up on both post-operative visits  
 statistical analysis: \*1. Chi-square test; \*2. Mc Nemar test; \*3. Fisher's exact test;  
 statistically significant differences are highlighted

## Surgical Therapeutic Index

<b>Table 3. Comparing Monarc &amp; TVT-O</b>						
	total	Monarc		TVT-O		p- value
<i>Comparison between groups</i>						
Cured after 2 months		74	80%	73	86%	0.334 (*1)
Cured after 12 months		69	74%	63	76%	0.794 (*1)
<i>Comparison within groups #</i>						
Cured after 2 months		73	81%			0.263 (*2)
Cured after 12 months		67	74%			
Cured after 2 months				71	85%	0.077 (*2)
Cured after 12 months				63	76%	
<i>Intra-operative complications</i>						
bladder perforation	0	0		0		
fausse route needle introducer	2	1	1%	1	1%	1.000 (*3)
hemorraghe	0	0		0		1.000 (*3)
<i>Post-operative complications</i>						
> 150 ml postvoid residual urine	30	15	16%	15	18%	0.738 (*1)
urinary retention	3	0		3	2%	0.103 (*3)
<i>Complications after 2 months</i>						
de novo UUI	2	2	2%	0	0%	0.498 (*3)
voiding difficulty	13	3	3%	10	12%	<b>0.043 (*3)</b>
vaginal mesh erosion	1	1	1%	0		1.000 (*3)
tape release	0	0		0		
dyspareunia	0	0		0		
groin pain	0	0		0		
<b>Summing</b>	16	6	7%	10	12%	
<i>Complications after 12 months</i>						
de novo UUI	9	6	5%	3	5%	0.503 (*3)
voiding difficulty	7	3	6%	4	4%	0.709 (*3)
vaginal mesh erosion	4	3	3%	1	1%	0.623 (*3)
tape release	2	1	1%	1	1%	1.000 (*3)
dyspareunia	2	1	1%	1	1%	1.000 (*3)
groin pain	2	2	2%	0		0.499 (*3)
<b>Summing</b>	26	16	17%	10	12%	

# The Mc Nemar test is calculated only for patients who did show up on both post-operative visits  
 statistical analysis: \*1. Chi-square test; 2\*. Mc Nemar test; 3\*. Fisher's exact test; statistically  
 significant differences are highlighted

Chapter 5

<b>Table 4. Complication rates adjusted with the severity factor.</b>						
	TVT			Monarc & TVT-O		
	SF	2 months	12 months	SF	2 months	12 months
de novo UUI	2 & 4	22	40	2 & 4	4	36
voiding difficulty	2	100	30	2	26	14
vaginal mesh erosion	1	0	0	1	1	4
tape release	2	0	10	2	0	4
dyspareunia	1	2	0	1	0	2
groin pain	1	0	0	1	0	2
<b>Summing</b>		124	80		31	62

SF = Severity factor

## Surgical Therapeutic Index

<b>Table 5. Surgical Therapeutic Indices</b>		
	TVT	Monarc & TVT-O
<i>STI</i>		
after 2 months (95% CI)	3.4 (2.8 - 4.3)*	9.2 (6.0 - 17.2)*
after 12 months (95% CI)	6.1 (4.5 - 8.9)	5.1 (3.7 - 7.6)
<i>STI (adjusted for severity) #</i>		
after 2 months (95% CI)	1.7 (1.4 - 2.1)*	4.7 (3.1 - 8.9)*
after 12 months (95% CI)	2.3 (1.6 - 3.4)	2.1 (1.5 - 3.5)

# as shown in table 3

Statistical analysis: bootstrapping; \* statistically significant differences



## Chapter 6

### Perspectives by patients and physicians on outcomes of mid-urethral sling surgery.

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## ABSTRACT

**Objective:** To determine patient expectations regarding wanted and unwanted sequels of mid-urethral sling (MUS) procedures and to identify mismatches during the physician-patient information exchange prior to MUS procedures.

**Study design:** A patient preference study (40 patients) and a questionnaire study with 20 experts as control group. Seventeen different sequels, defined by an expert team, were evaluated.

**Results:** Both patients and expert physicians ranked cure and improvement of SUI as most important goals of treatment.

De novo UUI, requiring post-operative intermittent self-catheterisation and dyspareunia were considered to be the most important complications by patients.

Time to resume work after the operation and dyspareunia were among the highest rated sequels in the patient group compared to re-operation and intra-operative complications in the expert group.

**Conclusion(s):** No differences were found in the five most important outcome parameters. In pre-operative counselling and future clinical trials time to resume work and dyspareunia should be regarded.

## **INTRODUCTION**

Mid-urethral sling (MUS) procedures are currently the “gold standard” of surgical treatment for female stress urinary incontinence (SUI) [1]. Cure rates, failure rates and possible complications of different MUS procedures are well-known and thoroughly investigated [2,3]. Traditionally, the physician informs the patient prior to surgery about the positive and negative effects to be expected. The information processed by the physician is the selection from all available evidence that he considers of relevance to the patient.

Little is known about how patients value the exchanged information and what additional pieces of information patients would like to see exchanged such as the length of hospital stay or time to resume work after the operation. Consequently, little is known about how congruent the expectations of physicians and patients about the course after surgery are.

Medical evaluations that incorporate subjective reporting run the risk of discrepant perceptions between the patient and the physician [4]. For instance, patients and physicians differ considerably by the rating of the severity of urinary incontinence prior to treatment [5]. Also clinicians tend to be more optimistic when considering outcome following incontinence surgery when compared to patients [6]. Discrepancies between expectations, both in a positive and negative sense, may influence how patients appraise their process of recovery after surgery and perhaps even how they rate the improvements in quality of life to be achieved by MUS procedures.

This study aims to identify mismatches during the physician-patient information exchange prior to MUS procedures by looking at how patients value the information potentially exchanged and whether physicians are aware of those values.

## **MATERIALS AND METHODS**

A preference study (patients) and a questionnaire study (physicians) were conducted to meet the study objectives. Forty consecutive patients were asked to participate in this investigation and none of these patients objected. All patients visited the outpatient department in Tilburg or The Hague with complaints of predominant SUI. Patients who underwent previous MUS procedures were excluded. The patients interviewed came for the first time or returned after pelvic floor physiotherapy or drug treatment. They had not discussed surgery in our departments. We provided all patients with similar amounts of information before the interviews.

A history of SUI was defined as the statement of the patient of involuntary leakage during physical activity, coughing or sneezing; Urge

urinary incontinence (UUI) was defined as the statement of the patient of involuntary leakage when experiencing a feeling of urgency. MUI was considered to be present if both SUI and UUI were reported. Nocturia was defined as a micturition frequency > 1 during sleep.

All patients agreed to a structured interview with one of the authors (MH, DM and PV). To construct the interview, an expert panel consisting of 3 urogynecologists, was asked to identify the most prevailing positive (wanted) and negative (unwanted) outcomes associated with MUS surgery. The expert panel was asked to list as many important outcomes as possible after MUS surgery. If an outcome was selected by one of the members of the expert panel, the outcome was investigated in the structured interview (table 1).

Definitions of the outcome parameters used in the interview were in accordance with the recommendations of the International Continence Society [7]. Incidences were based on our previous study investigating risk factors for failure of MUS procedures [8]. Cure of SUI was defined as not experiencing any loss of urine during physical activity, coughing or sneezing. Improvement was defined as any amount of leakage during physical activity, coughing or sneezing but a substantial gain compared to the pre-operative situation. Long-term results available was explained to patients as the availability of 11 years follow-up as described for Tension-free Vaginal Tape [9]. For Transobturator Tapes, on the other hand, only 3 years follow-up results are available [10]. Re-operation in 1 year was described as a result of failure of the surgical procedure to cure SUI.

Before starting the interviews, the 3 interviewers agreed on how to conduct the interview and synchronize the information offered to the patients. Before the interview, patients were asked to imagine that they would undergo surgical treatment for their incontinence. During the interview the outcome parameters were discussed with and explained (if necessary) to the patients by the investigators. Successively, patients were asked to score the outcome parameters for relative importance. A 100 point scoring scale was used to rate the relative importance from 0 (=totally unimportant) to 100 (= utmost importance). Patients were asked to score on five points punctual. The basic format of the structured interview is provided in appendix 1.

To identify possible differences in relative importance between patients and physicians, we sent a questionnaire modification of the structured interview by email to 25 opinion-leaders (experts) in the field of urogynecology in the Netherlands and Belgium. Experts were defined as gynecologists or urologists who on weekly basis treat patients with SUI. This

expert panel was used as the comparison group. The experts were asked to score the 17 outcome parameters for the relative importance they thought would represent the opinion of their patients. The same 100 point scale was used for scoring.

Mann-Whitney U-tests were performed to compare the scores of patients and experts for each of the 17 outcome parameters. A  $p$ -value of less than 0.05 was considered to represent statistical significance. The primary goal of this study was to determine patient expectations regarding possible outcomes after MUS surgery. Cure and improvement of SUI are likely to be ranked among the top five most important outcome parameters after MUS procedures. Therefore we also selected the 5 'other' most important outcome parameters in each group and ranked a 'Top 7'.

Statistical analysis was performed with SPSS (Windows version 15.0). This study was approved by the Medical Ethical Committee of the St. Elisabeth Hospital.

## **RESULTS**

Baseline characteristics of the patient population are described in table 2. All patients with MUI were pre-dominantly stress incontinent. Two patients underwent previous incontinence surgery (Burch colposuspension).

Table 3 shows the results of the investigated outcome parameters in the patient and expert groups. Twenty (80%) experts returned the questionnaire.

No differences were found in the five most important outcome parameters. Both patients and experts ranked cure and improvement of SUI as most important outcome parameters. Also the importance of long-term follow-up results is recognised in both groups. Most relevant complications for patients were de novo UUI, post-operative intermittent self-catheterisation, and dyspareunia.

Differences in 'Top 7' were: time to resume work after the operation and dyspareunia in the patient group and re-operation and intra-operative complications in the expert group. Although both patient and experts ranked cure and improvement as most important outcomes, patients' raw values were higher than the ones from the experts ( $p < 0.01$  and  $p = 0.02$  respectively). Patients valued time to resume work after the operation as more relevant than experts ( $p < 0.01$ ).

## DISCUSSION

The aims of this study were to determine patient expectations regarding possible wanted and unwanted outcomes of MUS procedures and identify possible mismatches during the physician-patient information exchange prior to MUS procedures. The experts were asked to score the outcome parameters in the opinion of their patients. Although not totally natural, physicians expect themselves to think for their patients in daily practice. As might be expected, cure and improvement of SUI were considered the most important outcome parameters after MUS procedures. Most relevant complications for patients were de novo UUI, requiring post-operative intermittent self-catheterisation, and dyspareunia.

An important goal of this study was to find differences between patients and physicians. Before elaborating on this issue, it is reassuring that patients and physicians agree on the most important issues like cure, improvement and functional complications.

A remarkable difference is that patients are generally more concerned about parameters which influence quality of life (time to resume work after the operation, dyspareunia) while experts tend to overestimate the value of more technical parameters (risk on re-operation and risk on intra-operative complications). An explanation for this difference could be found during the interviews. In general patients told us that they might be willing to accept the risk of intra-operative complications or a re-operation to solve their incontinence problem if counseled properly.

As SUI is a significant quality of life issue and treatment is usually elective, it is imperative to determine patient's expectations of outcome [11]. Treatment options can be adjusted to patient preferences and pre-operative counseling can be improved. Therefore expanding knowledge of patient expectations may improve treatment results. Furthermore outcome parameters which are considered important by patients should become main goals of studies investigating results of MUS surgery.

Other studies addressing expectations of women being evaluated for lower urinary tract symptoms used different measures of bother and quality of life including the Incontinence Quality of Life (QoL) Measurement and the King's Health Questionnaire [12,13]. These QoL questionnaires do not always contain the relevant questions and, contrary to this study, might fail to identify which outcome parameters are important for patients. In this study outcome parameters from daily clinical practice were used and women were asked to add important outcomes if missing. Therefore results of this study

provide a complete overview of women's expectations regarding counseling before MUS surgery.

A possible drawback of the study design is that only 3 experts selected the rated outcome parameters. However both patients and experts were asked if they missed important outcome parameters in the presented list. None of the patients or experts missed an important outcome parameter. Therefore it is plausible that the most important outcome parameters were scored. Another drawback of this study is that the patients were interviewed by 3 different persons which might induce a bias. However, as a structured interview was used, little opportunities were available for the interviewers to influence patient scores.

Another possible disadvantage of this study design is that patients could theoretically score all parameters equally (for example 50). To assess the presence of such response patterns at individual patient level in the present data set, we analyzed the scoring range for each participant. We calculated the differences between the highest and the lowest score for each patient. The range of these differences was 40 (minimal) -100 (maximal). Therefore the response patterns indicate considerable differentiation in valuation by individual patients.

A possible bias are differences between patients. Some patients asked many questions about possible consequences of the discussed outcome parameters, others did not. However, in common daily practice these differences between patients are also present.

Two patients had previous colposuspensions, which might be a source of bias as their expectations would have been altered by having previous, failed incontinence surgery. However as they underwent surgery in the eighties (1984, 1988) and for more then 20 years remained continent, surgery did not fail in their perception.

A formal power analysis was considered inappropriate in absence of any useful prior data on relative weights attached to MUS outcome parameters by patients and by experts asked to reflect on patients' opinions. The included number of 40 patients and 20 experts and the application of distribution-free statistics of ranks however, should be sufficient to generate a first assessment of potential mismatches. For instance, although patients and experts ranked cure and improvement equally high, the differences in absolute valuations (medians: 100 versus 97; 100 versus 93 respectively) suggest that experts should realize that the importance of cure and improvement cannot be overestimated.

SUI is more common in young and middle-aged women, who are more likely to work and to be sexually active [14]. Results of our study indicate that patients considered both parameters of significant importance. Currently no data are available about time to resume work after the operation and consequently this parameter should be an important outcome parameter in future clinical trials.

It has been largely demonstrated that urinary leakage can have a dramatic effect on the quality of female sexual life, and it can even lead to a complete lack of sexual activity in a high proportion of cases [15]. Our results confirm these findings and show that patients consider sexual function very important. Therefore, physicians should not underestimate the impact of the surgical procedure on the sexual well-being of the patient.

Another important observation is that the availability of long-term results (> 10 years) are recognised as an important parameter by both patients and experts. Nowadays patients want to know if the recommended surgical procedure achieved satisfying long-term results. Therefore, it is remarkable that obturator tapes are performed on large scale while little evidence is available of results after only 3 years of follow-up [10,16]. Furthermore, follow-up of the available prospective comparative trials between obturator tapes and the current “gold standard” (Tension-free Vaginal Tape) does not exceed a one year period [2,3,16]. Results of this study once again emphasise the need for long-term trials of obturator tapes.

## **CONCLUSION**

Experts and patients agree on the importance of cure and improvement of SUI, de novo UUI and post-operative intermittent self-catheterisation as potential complications as well as recognising the importance of long-term follow up data. Time to resume work after the operation and dyspareunia were among the highest rated sequels in the patient group compared to re-operation and intra-operative complications in the expert group. In pre-operative counselling and future clinical trials time to resume work after the operation and dyspareunia should be regarded.

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## Chapter 6

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## **APPENDIX 1**

### BASIC FORMAT OF THE INTERVIEW

Q1: How important on a scale from 0-100 do you consider being counselled about the possibility of intra-operative complications?

E1: Intra-operative complications are side-effects during the surgical procedure which occur unexpectedly like bladder or urethral injury, bleeding or perforation of the bowel. Our previous results indicated that these complications occurred in 5% of the patients who underwent surgery.

Q2: How important on a scale from 0-100 do you consider being counselled about the duration of the hospital admission?

E2: Our former study indicated that most patients go home the same day or stay one night.

Q3: How important on a scale from 0-100 do you consider being counselled about the possibility of post-operative urinary retention?

E3: Urinary retention is the impossibility to void for which an indwelling catheter for more than 24 hours is necessary. In most cases the indwelling catheter can be removed within 3 days. Our former study indicated that this condition occurred in 5% of the patients.

Q4: How important on a scale from 0-100 do you consider being counselled about expected cure rates after the surgical procedure?

E4: Cure is defined as absolutely no loss of urine during coughing sneezing or physical activity. Normally 80% of the patients are cured after one year.

Q5: How important on a scale from 0-100 do you consider being counselled about improvement after the surgical procedure?

E5: Improvement is defined as sometimes loss of urine during coughing sneezing or physical activity. However the situation is improved compared to the situation pre-operatively. Normally 95% of the patients report improvement after one year.

Q6: How important on a scale from 0-100 do you consider being counselled about the availability of long term results of a surgical procedure?

E6: For example there are 2 basic surgical procedures. For the first procedure, Tension-free vaginal Tape, are results available 11 years after surgery. For the second procedure, Transobturator Tape, are results available after 3 years.

Q7: How important on a scale from 0-100 do you consider being counselled about time to resume work after the surgical procedure?

E7: Our former studies showed that nearly all patient resumed work after 6 weeks. The majority was able to return to work after 2 weeks.

Q8: How important on a scale from 0-100 do you consider being counselled about the possibility of voiding difficulty after the surgical procedure?

E8: Voiding difficulty is defined as micturition that becomes more difficult as a result of the operation. Normally micturition takes longer, in rare cases the tape needs to be removed. Our former studies indicated that voiding difficulty occurred in 6% of the patients.

Q9: How important on a scale from 0-100 do you consider being counselled about the possibility of de novo urge urinary incontinence after the surgical procedure?

E9: Urge incontinence is described as loss of urine preceded by feelings of (strong) urgency. In some cases the stress incontinence is cured but after the operation urge incontinence develops. Our previous studies indicated that de novo urge incontinence occurred in 6% of the patients.

Q10: How important on a scale from 0-100 do you consider being counselled about the necessity to use medication to remain continent after the operation?

E10: Our previous studies indicated that 5% of the patients needed daily medication to remain continent.

## Chapter 6

Q11: How important on a scale from 0-100 do you consider being counselled about the duration of post-operative pain medication?

E11: Our previous studies indicated that patients needed post-operative medication for maximal 2 weeks.

Q12: How important on a scale from 0-100 do you consider being counselled about the possibility of post-operative groin pain?

E12: In some cases groin pain develops after the operation. Normally groin pain resolves within 6 weeks, but in our population 2 cases are known where groin pain existed after 6 months.

Q13: How important on a scale from 0-100 do you consider being counselled about the possibility of dyspareunia?

E13: Dyspareunia is pain or discomfort during sexual intercourse. In our population 1% of the patients developed dyspareunia after the operation.

Q14: How important on a scale from 0-100 do you consider being counselled about the possibility of post-operative intermittent self-catheterisation?

E14: Post-operative intermittent self-catheterisation is necessary when a patient is unable to micturate spontaneously after the operation. Patients are learned to perform the catheterisation at home. In our population self catheterisation was necessary in 1% of the patients.

Q15: How important on a scale from 0-100 do you consider being counselled about the possibility of a re-operation in one year?

E15: A re-operation in one year is necessary if the first operation fails. In our population 2% of the patients needed a re-operation within one year.

Q16: How important on a scale from 0-100 do you consider being counselled about the possibility of developing a urinary tract infection after the operation?

E16: In our population 1% of the patients developed a urinary tract infection.

Q17: How important on a scale from 0-100 do you consider being counselled about the possibility of a tape erosion?

E17: When the tape protrudes through the vaginal wall it is called an erosion. When an erosion occurs, the protruding part of the tape needs to be removed. Tape erosions occurred in 2% of our patient population.

Q: question

E: explanation

*Perspectives by patients and physicians*

<b>Table 1. Investigated outcome parameters</b>	
	<b>Incidence*</b>
Intra-operative complications	5%
Duration of hospital admission	1 day versus longer
Post-operative urinary retention	5%
Cured of SUI after 1 year	80%
Improvement of SUI	95%
Long term results available	> 10 years
Time to resume work after the operation	6 weeks
Voiding difficulty	6%
De novo UUI	6%
Necessity of medication to remain continent	5%
Duration of post-operative pain medication use	2 weeks
Groin pain	1%
Dyspareunia	1%
Post-operative intermittent self-catheterisation	2%
Re-operation in 1 year	2%
Urinary tract infection	1%
Tape erosion	2%

\* own results described in reference 8

## Chapter 6

<b>Table 2. Baseline characteristics of patient population</b>			
Age (years, mean (range))		55	(33 - 78)
Parity (n, mean (range))		2	(0 - 4)
Type of incontinence (n (%))	SUI	32	80%
	MUI	8	20%
Frequency of incontinence (n (%))	daily episodes	38	95%
	weekly episodes	2	5%
Duration of incontinence (months, mean (range))		49	(3 - 120)
Daily micturition frequency (n, mean (range))		8	(3 - 15)
Nocturia (n (%))		12	30%
Underwent pelvic floor physiotherapy (n (%))		24	60%
Used medication for incontinence (n (%))		8	20%

## Perspectives by patients and physicians

	Patient Scores			Expert Scores			p-value*
	median	interquartile range	rank	median	interquartile range	rank	
Intra-operative complications	65	[30 - 80]		65	[40 - 90]	7	0.65
Duration of hospital admission	55	[11 - 98]		28	[20 - 48]		0.09
Post-operative urinary retention	55	[21 - 84]		60	[50 - 74]		0.56
Cured of SUI after 1 year	100	[100 - 100]	1	97	[81 - 100]	1	<b>&lt; 0.01</b>
Improvement of SUI	100	[90 - 100]	2	93	[80 - 100]	2	<b>0.02</b>
Long term results available	80	[71 - 100]	5	75	[50 - 88]	5	0.06
Time to resume work after the operation	75	[50 - 100]	6	40	[20 - 60]		<b>&lt; 0.01</b>
Voiding difficulty	70	[33 - 80]		70	[60 - 80]		0.45
De novo UUI	90	[63 - 100]	3 # 4	75	[60 - 90]	4	0.16
Necessity of medication to remain continent	30	[10 - 60]		35	[20 - 50]		0.98
Duration of post-operative pain medication use	35	[10 - 60]		30	[10 - 56]		0.73
Groin pain	50	[20 - 70]		35	[20 - 50]		0.38
Dyspareunia	73	[45 - 90]	7	58	[40 - 70]		0.10
Post-operative intermittent self-catheterisation	90	[63 - 100]	3 # 4	80	[63 - 90]	3	0.14
Re-operation in 1 year	65	[21 - 80]		65	[50 - 90]	6	0.29
Urinary tract infection	28	[10 - 60]		20	[10 - 30]		0.07
Tape erosion	50	[10 - 80]		60	[30 - 80]		0.31

(\*) Mann Whitney U test

# ex aequo



## **Chapter 7**

TVT-O versus Monarc after 2 – 4 years follow-up: a prospective comparative study.

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**ABSTRACT**

**Objective:** The aim of this study was to compare outcome and quality of life (QoL) of TVT-O and Monarc Transobturator Tapes after 2-4 years.

**Study design:** Prospective comparative study. Participants (n = 191) were assigned to either a TVT-O (n= 93) or a Monarc (n = 98) procedure. Cure of stress incontinence (SUI) was defined as the statement of the woman of not experiencing any loss of urine upon physical exercise.

**Results:** Cure rates after 2-4 years were 72% for TVT-O and 65% for Monarc, while improvement was observed in respectively 12% and 21% ( $p = 0.3$ ). There was a statistically significant improvement in Quality of Life but no differences were found between both procedures.

**Conclusion(s):** After a 2-4 years follow-up period, both procedures were equally safe and effective in curing SUI.

## **INTRODUCTION**

Until recently, the Burch colposuspension was the standard procedure for the treatment of female Stress Urinary Incontinence (SUI) [1, 2]. Since its introduction in 1995 Tension-free Vaginal Tape (TVT) became the new “gold” standard in the surgical treatment of SUI. TVT has been proven to be as effective as the Burch colposuspension with success rates ranging from 84 to 95%, but has less side effects and complications [3-5]. In 2001 Delorme introduced Transobturator Tape (TOT) with a high success rate [6]. This sling is also located underneath the mid-urethra, but runs laterally through the obturator membrane to the upper part of the thigh.

There are two basic techniques for performing TOT: “Outside - In” described by Delorme [6] and “Inside - Out” (TVT-O) described by de Leval [7]. These techniques do not only differ in the way the needle is placed and carried forward, but also in the different designs of the introducer. After the introduction of the “Outside-In” technique by Delorme in 2001 several other similar procedures were developed. Among them is Monarc, which consists like TVT-O of a monofilament macroporous polypropylene mesh and which has shown similar and equally good short-term to medium-term success rates as TVT-O [8,9].

However, until now there is little evidence that one technique is superior to the other. Furthermore no comparative trials are published with follow-up longer than 1 year. Therefore the aim of this study is to compare outcome and the quality of life results of two existing different TOT procedures “Inside - Out” (TVT-O) and “Outside - In” (Monarc) for the treatment of SUI after 2 – 4 years follow-up.

## **MATERIAL AND METHODS**

Between October 2004 and December 2006, 191 consecutive women with an indication for surgical treatment of SUI underwent either the TVT-O or the Monarc procedure. This study was approved by the Medical Ethical Committee of the St. Elisabeth Hospital as part of a multicentre study on the outcome of Transobturator Tape as treatment for predominant female SUI.

Included were 93 women with a TVT-O and 98 women with a Monarc procedure. Women who did not show up for their 2-4 years follow-up visit first received a questionnaire and, if they did not reply, were later contacted by one of the investigators (MH).

Excluded were women with recurrent and difficult to treat urinary tract infections, significant and predominantly symptoms of urge urinary incontinence, post voiding bladder retention of more than 150 ml, bladder

## Chapter 7

capacity of less than 100 ml and physical or mental impairment to adequately register outcome results or complications.

A standardized urogynecological history and physical examination was performed preoperative, after 2 months, 1 year and after 2 to 4 years. Pre-operative multichannel urodynamic investigation was carried in all women according to the International Continence Society standards [10,11].

All women were asked to complete the short version of the Incontinence Impact Questionnaire (IIQ-7) and the Urogenital Distress Inventory (UDI-6) before and at the above mentioned postoperative intervals. These questionnaires are internationally accepted as valid disease-specific QoL instruments and are sensitive to change [12]. They have been translated into Dutch language and validated [13]. The questionnaires were anonymously entered in a database and researchers were blinded to the individual results of these questionnaires. The total score of the IIQ-7 and UDI-6 was transformed to a scale from 0-100 (a higher score indicates more bother).

Women were informed and agreed that, on the basis of the availability of the TOT supplies on the day of surgery, they were assigned to either a TVT-O or a Monarc procedure just before surgery was to take place. The "Inside-out" procedure was performed as described by de Leval [7] and a TVT-O (Gynecare, Sommerville, New Jersey, USA) tape was inserted. The Monarc (American Medical Systems, Minneapolis, USA) tape was inserted through the "Outside-in" route as using the technique recommended by the manufacturer. Both procedures use a monofilament, macroporous polypropylene tape, which is placed under the urethra without any tension. Surgery was not accompanied by other urogynecological procedures.

All procedures were carried out under general anesthesia and hence no intra-operative cough stress test was performed. Cystoscopy was performed only in case of encountering bloody urine. All women received pre-operative antibiotics and this was continued for 7 days postoperative. All procedures were performed in the St. Elisabeth Hospital Tilburg, The Netherlands.

We adhered to the recommendations of IUGA on outcome measures [14]. Cure of SUI was defined as the statement of the woman of not experiencing any loss of urine upon physical exercise. Other definitions in this study are in accordance with the terminology of the International Continence Society [10].

Continuous variables were compared using unpaired t-test and dichotomous variables were compared using Chi-square test. Fisher's exact

test was used if cross tabs had a cell with an expected frequency < 5. The minimum level of significance was 0.05. Statistical analyses were performed with SPSS (Windows version 16.0).

## **RESULTS**

After 2-4 years follow up, 161 (84%) women were available for evaluation. The TVT-O group consisted of 75 women compared to 86 women in the Monarc group. The mean follow-up of the TVT-O group was 38 months (range 12-53 months) and 39 months (range 12-53 months) in the Monarc group. For their 2-4 years follow-up control 76 (47%) women visited our outpatient department, 51 (32%) women answered a questionnaire by mail and 34 (21%) women answered a telephonic questionnaire by one of the investigators (MH). The response rate of the QoL questionnaires was 92%, 81%, 81% and 70% respectively prior to, 2 months and 1 year postoperatively and after 2-4 years. There were no differences in method of follow-up or response rate of QoL questionnaires between both groups.

Pre-operative data are listed in table 1. No differences between both groups were observed. In women with mixed urinary incontinence (MUI) anti-cholinergic medical treatment was given before surgical treatment was considered and did not alleviate their symptoms. The majority (89%) of the women underwent pre-operative pelvic floor physiotherapy.

Surgical data are depicted in table 2. No concomitant urogynecological surgery was performed, but in 15 women (8%) surgery was combined with non-urogynecological procedures. There are no differences in surgery time, amount of blood loss and type of anesthesia between TVT-O and Monarc.

Outcome data are presented in table 3. The cure rate for TVT-O was 72% after 2-4 years compared to 65% in the Monarc group while improvement was observed in respectively 12% and 21% ( $p = 0.3$ ). Pre-existing urge incontinence resolved in 7 women (32%) after TVT-O and 8 women (31%) after Monarc ( $p = 1.0$ ). De novo urge incontinence developed in 2 cases in the TVT-O group versus 4 cases in the Monarc group ( $p = 0.2$ ).

Both the IIQ-7 and UDI-6 demonstrated a statistically significant increase in QoL decrease in impairment caused by symptoms of SUI after 2 months, 1 year and 2-4 years in both TOT groups.

Any complications are presented in table 4. No major intra-operative complications occurred. After 2 months voiding difficulty was more observed in the TVT-O group. Tape release was carried out in 1 women in the TVT-O group, because of vaginal pain and a superficial located and palpable tape.

She remained continent. In one other women tape release was indicated for voiding difficulty. Afterwards voiding became normal and they remained continent.

There were 5 cases of vaginal erosion which were all excised under local anesthesia and all remained continent afterwards. In 5 women after TVT-O and in 4 women after Monarc a second anti-incontinence procedure was performed ( $p = 0.5$ ). As second incontinence procedures Tension-free Vaginal Tape (7x), Tension-free Vaginal tape Secur (1x) and Remeex system (1x) were performed. The stress incontinence was resolved in all 9 women. In one other woman a stitch was placed under the mid-urethra under local anesthesia after which her already improved SUI disappeared.

## DISCUSSION

This report comprises a large comparative study of both procedures with the longest follow-up until now. The main objective of this study was to compare outcome and complications for an “Inside-Out” versus an “Outside-In” transobturator approach. The second objective was to evaluate results of both obturator approaches after 2-4 years follow-up. We did not found significant differences between both approaches. Approximately 85% of the women found their symptoms to be improved after 2-4 years, which are satisfying results.

Most studies comparing TVT-O and Monarc have a short follow-up time and differ with respect to definitions of success. Deboinance compared 50 TVT-O procedures to 50 Monarc procedures in a prospective observational study [15]. With a definition of cure as being continent at postoperative urodynamic assessment, 47 (94%) women with TVT-O and 45 (90%) with Monarc were cured after one year. Lee et al prospectively compared 100 women who underwent either a TVT-O ( $n = 50$ ) or a TOT (Dow Medics, Korea,  $n = 50$ ) procedure and defined cure as a negative cough stress test and no reports of urine leakage during stress [16]. Equal cure rates for TVT-O and TOT were found: 86% versus 92% one year after surgery. Liapsis et al followed 114 women who were prospectively randomized to TVT-O or Monarc for one year [17]. Cure was defined as a negative cough stress test during multichannel urodynamic investigation and a one hour pad test giving a weight of less than one gram. Cure rate in the TVT-O group was 87% (53 of 61 women) and 90% (48 of 53 women) in the Monarc group. Subjective cure was remarkably lower: 80% in the TVT-O group versus 77% in the Monarc group.

Not many studies have investigated the medium-term results (> one year) of obturator tapes. Waltregny et al followed 91 women prospectively after a TVT-O procedure with a minimum follow-up of 3 years [18]. Cure of SUI was defined by the disappearance of subjective SUI, as assessed by a SUI symptom scale score equal to 0. Disappearance and improvement of SUI was observed in 88% and 9% of the women respectively. Wang et al found a 83% cure rate 36 months after a TVT-O procedure. The clinical outcome was regarded as cured when the cough test was negative at the follow-up visit. Their results were based on 30 women with a 36 months follow-up.

Above mentioned comparative studies show as presented in this study that both TVT-O and Monarc are equally effective in curing SUI after one year [15-17]. On longer follow-up our results are lower compared to the mentioned studies [18,19]. This might be due to our definition of cure. We intentionally used the statement of women about losing urine upon physical exercise. Although this is a subjective parameter, it does give information about the experience of women over a longer period of time. This may provide more or different information than objective parameters like a post-operative stress test, pad test or urodynamic investigation which just reflect a measurement at one point in time. We realize however that in a small number of women it is quite possible that "failures" are actually reporting the symptom of urge incontinence rather than the diagnosis of genuine stress incontinence. To demonstrate this difference, objective testing would be required.

Our strict definition of success, being no loss of urine at all, may be unrealistic compared to the occurrence of incontinence and experience of women in the normal population. Becoming fully continent after TVT is not synonymous with being satisfied. A number of operated women still leaked postoperatively but were satisfied. These were mostly women with severe incontinence who experienced substantial improvement, the incontinence being reduced to an acceptable degree. This corroborates the finding that women can cope with a certain degree of incontinence for which therapy is not warranted [20]. However for scientific purposes, it is perhaps better and gives accurate insight in cure and improvement rates. For counseling purposes to women the improvement rate is also of importance. In our study with a long follow-up of 2 to 4 years 72% of women with a TVT-O were cured and another 12% improved, while in the Monarc group these numbers are respectively 65% and 21%. This indicates that most women are still much better off after these incontinence procedures.

In determining success another important parameter is the improvement in quality of life. In our study QoL parameters improved significantly in both groups and no differences were found between the two procedures. In general, the improvement observed after both procedures seems comparable to QoL improvement after a TVT procedure [3].

Other functional changes are related to the development of de novo urge incontinence and voiding difficulty or the resolution of these symptoms. The risk for developing de novo urge incontinence seems to be equal after Monarc and TVT-O procedures. This observation is confirmed by the other comparative studies [15-17]. The number of women reporting voiding difficulty after 2 months is higher in the TVT-O group. There's no explanation for this difference. Latthe's results [21] indicate that voiding difficulty was less for combined TVT-O and TOT tapes compared to the retropubic TVT procedure. On subgroup analysis they found no differences between the procedures by either obturator route.

Anatomical complications like bladder or urethra injury or bleeding of more than 300 ml did not occur in this study. Furthermore the 3 remaining complications in this study (2 accidental fausse routes and 1 premature cutting of the tape) are relative minor incidents. Both TVT-O and Monarc have substantial lower intra-operative complication rates than TVT, but no differences between both procedures are observed [21].

When TVT-O and Monarc became available there was some evidence that one procedure could be less safe than the other. Ahtari et al. [22] showed by cadaveric dissection that TVT-O runs more closely to the obturator canal, making TVT-O more prone to possible injury of the obturator nerve and vessels. We did not find any obturator nerve or vessel injury and apparently this theoretical risk does not exist in clinical practice.

Although the number of women is too small to draw conclusions, there seems to be a little higher erosion rate in the Monarc group. These results are confirmed by other publications but a significant difference was never reached, mostly due small patient numbers [21]. Nevertheless, the postoperative complication rate in our study population is low and no differences between both procedures were observed.

Advantages of this study are the large number of women with only 16% loss to follow up after 2-4 years. Other advantages are a strict outcome parameter, a consistent treatment strategy where procedures were not combined with other urogynecological treatments, the standardized urogynecological work-up (including urodynamic investigation) and the fact that all women were treated in one clinic by two urogynecologists and

## *TVT-O versus Monarc*

residents (always with supervision and the presence of these urogynecologist during surgery).

The draw-back of this study may be the bias in follow-up results. Not all women visited our outpatient department for the follow-up procedure. There may be a difference in the results of women visiting our outpatient department compared to women answering questionnaires by mail or telephone. Nevertheless the use of interviews by telephone allowed us to minimise the loss to follow-up.

This study shows equal clinical cure rates and improvement in quality of life for both TVT-O and Monarc as a surgical treatment for stress urinary incontinence on the long run. Nevertheless, while longer follow-up data of TVT are now available [23] longer follow-up than 4 years is still mandatory.

### **CONCLUSION**

After a 2-4 years follow-up period, both procedures were equally safe and effective in curing female SUI.

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	<b>TVT-O</b>	<b>Monarc</b>	<b>p- value</b>
Number of women (n,%)	93 (49%)	98 (51%)	
<b>Medical history</b>			
Age (years, mean $\pm$ SD)	49,2 $\pm$ 8,9	49,5 $\pm$ 10,3	0.8 (*1)
Type of incontinence (n,%)			
SUI	74 (80%)	74 (76%)	
MUI	19 (20%)	23 (24%)	0.6 (*2)
Parity (number of vaginal deliveries; mean,SD)	2 $\pm$ 1	2 $\pm$ 1	0.8 (*1)
multiparous (n,%)	84 (90%)	92 (94%)	0.7 (*3)
Menopausal status (n,%)			
premenopausal	51 (55%)	58 (59%)	
climacterial	9 (10%)	6 (6%)	0.5 (*2)
postmenopausal	33 (35%)	34 (35%)	
Severity of incontinence (daily episodes) (n,%)	79 (85%)	79 (81%)	0.6 (*2)
Pelvic floor physiotherapy prior to surgery (n,%)			
performed	82 (88%)	88 (90%)	0.5 (*3)
Previous incontinence surgery	8 (9%)	9 (9%)	1.0 (*2)
Previous prolapse surgery	19 (22%)	15 (16%)	0.3 (*2)
<b>Physical examination</b>			
urethral hypermobility (n,%)	80 (86%)	90 (92%)	0.3 (*2)
urinary incontinence on coughing (n,%)	62 (67%)	67 (68%)	1.0 (*2)
vaginal wall prolaps (grade 1 or more) (n,%)	25 (27%)	24 (24%)	0.7 (*2)
<b>Urodynamic investigation</b>			
maximum bladder capacity (ml, mean $\pm$ SD)	443 $\pm$ 121	433 $\pm$ 130	0.6 (*1)
number of women with urodynamic SUI (n,%)	61 (66%)	64 (65%)	0.9 (*2)
number of women with detrusor overactivity (n,%)	5 (6%)	7 (7%)	0.7 (*2)
maximum urethral closure pressure (cm H2O, mean $\pm$ SD)	59 $\pm$ 31	64 $\pm$ 43	0.5 (*1)
number of women with MUCP < 20 cm H2O (n,%)	5 (5%)	1 (1%)	0.1 (*3)

statistical analysis: \*1 Students t-test (two-sided); \*2 Chi-square test; \*3 Fisher's exact test

TVT-O versus Monarc

<b>Table 2. Surgery characteristics</b>			
	<b>TVT-O</b>	<b>Monarc</b>	<i>p</i> -value
Length of surgery (minutes; mean ± SD, range)	16 ± 5 [10-34]	16 ± 6 [10-30]	0.9 (*1)
Amount of blood loss (ml; mean ± SD, range)	55 ± 53 [0-300]	62 ± 42 [0-250]	0.3 (*1)
Type of anesthesia (n,%)			
general	85 (91%)	84 (86%)	0.2 (*2)
spinal	8 (9%)	14 (14%)	
Simultaneous performed secondary surgical procedure			
hysteroscopic endometrial ablation / myoma resection	2	2	
introital plasty		2	
sterilization	4	2	
LLETZ	1		
cystoscopic resection of bladder endometriosis		1	
inguinal hernia repair	1		

Statistical analysis: \*1. Student-t test (two sided); \*2 Chi-square test

## Chapter 7

<b>Table 3. Outcome of TVT-O and Monarc procedures</b>					
	TVT-O	$p$ - value within TVT-O group	Monarc	$p$ - value within Monarc group	$p$ - value between groups
<b>Stress Urinary Incontinence (SUI)</b>					
2 months after surgery					
- no SUI	76 (85%)		78 (83%)		
- improved	7 (9%)		12 (13%)		0.4 (*2)
- unchanged	6 (7%)		4 (4%)		
12 months after surgery					
- no SUI	66 (77%)		73 (77%)		
- improved	13 (15%)		16 (17%)		0.9 (*4)
- unchanged	7 (8%)		6 (6%)		
2-4 years after surgery					
- no SUI	54 (72%)		56 (65%)		
- improved	9 (12%)		18 (21%)		0.3 (*4)
- unchanged	12 (16%)		12 (14%)		
<b>Quality of life analysis</b>					
Incontinence Impact Questionnaire (IIQ-7, mean $\pm$ SD)					
- prior to surgery	56 $\pm$ 21		51 $\pm$ 22		0.1 (*3)
- 2 months after surgery	11 $\pm$ 20	<b>0.0 (*1)</b>	13 $\pm$ 21	<b>0.0 (*1)</b>	0.6 (*3)
- 12 months after surgery	13 $\pm$ 21	<b>0.0 (*1)</b>	11 $\pm$ 19	<b>0.0 (*1)</b>	0.7 (*3)
- 2-4 years after surgery	11 $\pm$ 28	<b>0.0 (*1)</b>	12 $\pm$ 20	<b>0.0 (*1)</b>	0.6 (*3)
Urodynamic Distress Inventory (UDI-6, mean $\pm$ SD)					
- prior to surgery	45 $\pm$ 17		45 $\pm$ 16		0.7 (*3)
- 2 months after surgery	17 $\pm$ 18	<b>0.0 (*1)</b>	16 $\pm$ 17	<b>0.0 (*1)</b>	0.7 (*3)
- 12 months after surgery	16 $\pm$ 20	<b>0.0 (*1)</b>	16 $\pm$ 17	<b>0.0 (*1)</b>	0.9 (*3)
- 2-4 years months after surgery	17 $\pm$ 18	<b>0.0 (*1)</b>	17 $\pm$ 17	<b>0.0 (*1)</b>	1.0 (*3)
<b>Urge Urinary Incontinence (UUI)</b>					
prior to surgery present					
- UUI resolved, 2 months after surgery	12 (55%)		14 (54%)		0.7 (*4)
- UUI resolved, 12 months after surgery	13 (59%)		17 (65%)		0.5 (*4)
- UUI resolved, 2-4 years after surgery	7 (32%)		8 (31%)		1.0 (*4)
prior to surgery absent					
- de novo UUI, 2 months after surgery	0		2 (4%)		0.5 (*2)
- de novo UUI, 12 months after surgery	3 (4%)		6 (6%)		0.5 (*2)
- de novo UUI, 2-4 years after surgery	2 (3%)		4 (5%)		0.2 (*2)

Statistical analysis: \*1. Wilcoxon Signed Ranks Test, pre-operative compared to postoperative situation within one group  
\*2. Fisher's exact test; \*3. Student-t test (two-sided); \*4 Chi-square test; statistically significant differences are highlighted

TVT-O versus Monarc

<b>Table 4. Complications and Second incontinence procedures</b>			
	<b>TVT-O</b>	<b>Monarc</b>	<i>p</i> -value
<b>Intra-operative complications (n,%)</b>			
bleeding > 100 ml (1)	4 (4%)	5 (5%)	0.9 (*1)
fausse route (within vagina)	1 (1%)	1 (1%)	0.6 (*1)
second TOT procedure (2)	0	1 (1%)	1.0 (*1)
<b>Postoperative complications 2 months (n,%)</b>			
voiding difficulty	10 (12%)	3 (3%)	<b>0.03 (*1)</b>
vaginal erosion	0	1 (1%)	1.0 (*1)
<b>Postoperative complications 12 months (n,%)</b>			
voiding difficulty	4 (5%)	3 (4%)	0.7 (*1)
vaginal erosion	1 (1%)	3 (3%)	0.6 (*1)
tape release	1 (1%)	1 (1%)	1.0 (*1)
dyspareunia	1 (1%)	1 (1%)	1.0 (*1)
persisting pain in thigh	0	2 (2%)	0.5 (*1)
<b>Postoperative complications 2-4 years (n,%)</b>			
voiding difficulty	3 (4%)	5 (6%)	0.7 (*1)
vaginal erosion (3)	1 (1%)	4 (5%)	0.4 (*1)
dyspareunia	1 (1%)	0	1.0 (*1)
persisting pain in thigh	0	1 (1%)	1.0 (*1)
<b>Second incontinence procedures (n,%)</b>			
< 1 year after primary procedure	3 (4%)	3 (4%)	
> 1 year after primary procedure	2 (2%)	1 (1%)	
<b>total</b>	<b>5 (6%)</b>	<b>4 (5%)</b>	<b>0.5 (*1)</b>

Statistical analysis: \* 1 Fisher's exact test

(1) range 150 - 300

(2) second procedure performed within the same surgery session due to accidentally premature cutting of the tape

(3) total erosions after 2-4 years of follow-up



# **Chapter 8**

## General Discussion

## INTRODUCTION

In this thesis the work-up for mid-urethral sling surgery is critically evaluated. In the first part the value of urodynamics with respect to outcome and complications is investigated. An effort is presented to sharpen the indication of pre-operative urodynamics based on risk factors for failure of different mid-urethral slings. Subsequently, the Surgical Therapeutic Index is presented to select the optimal procedure based on both cure and complications. Furthermore patient expectations regarding wanted and unwanted sequels of mid-urethral sling procedures are investigated and compared with expert findings in the field of urogynecology. Finally, long-term follow-up of two different Transobturator Tapes is provided. Therefore this thesis provides a complete view of the current knowledge, work-up and surgical treatment of female stress urinary incontinence by means of mid-urethral sling surgery.

## REMARKS ON THE STUDY DESIGN AND PARAMETERS USED IN THIS THESIS

### *Design of the studies in this thesis*

In this thesis different mid-urethral sling procedures are compared. However, the baseline characteristics of the women in the Tension-free Vaginal Tape and Transobturator Tape group were different. This may be due to the different time frame in which these women were operated. Tension-free Vaginal Tape was the first available treatment as of 1998 and no other form of mid-urethral sling procedures existed at that time. When Transobturator Tape procedures became available in 2004, a switch to Transobturator Tapes was made. Although they had already been introduced in 2001, the reason to change to Transobturator Tapes not earlier than 2004 was primarily based on the fact that the tapes that became available in 2004 had the same biological and biomechanical properties as Tension-free Vaginal Tape. In order to compare both groups and correct for possible differences in baseline characteristics, multivariate regression analysis was used

Studies investigating risk factors are often conducted on databases from prospective trials. However, in prospective trials women with previous incontinence surgery, detrusor overactivity or a low mean urethral closure pressure are often excluded [1-3]. This causes a gap in evidence as these women may need a personally tailored treatment. In our retrospective analyses, women were only excluded if they missed their follow-up appointment or underwent other simultaneously performed urogynecological surgery. Therefore our results apply to women in the common daily clinical

## *General Discussion*

practice and our design is par excellence capable of determining risk factors for failure.

The value of pre-operative urodynamics is evaluated in women who underwent a mid-urethral sling procedure. Thus a possible bias was introduced because women who did not undergo surgery, were not included in our analyses. However medical records from patients who underwent urodynamic investigation for predominant stress urinary incontinence from January 1998 until December 2006 and did not undergo a mid-urethral sling procedure (n = 95) were investigated. The majority of these patients had a significant improvement after pelvic floor physiotherapy or anticholinergic medication. Furthermore, in none of these patients surgery was cancelled based on results of the urodynamic investigation. Therefore the bias is negligible.

We did not collect all the parameters we studied from each woman. Data were missing because the attending physician did not collect all data investigated and sometimes measurements of the urodynamic investigation were unreliable. We did not exclude these women because the other parameters might still have prognostic influence and valuable information would be lost if we excluded them all.

The strengths of the studies in this thesis are the large number of women and the standardized urogynecological work-up. A consistent treatment strategy was followed where mid-urethral sling procedures were not combined with other urogynecological procedures (i.e. prolapse surgery), thereby excluding the bias of concomitant surgery (which in itself might have a beneficial effect on incontinence). As nearly all procedures were performed by one surgeon (alone or supervising residents), differences in surgical technique of the procedures are unlikely.

### ***Outcome parameters***

In this thesis a strict outcome parameter for success is used namely the report of the woman of having no stress urinary incontinence at all after surgery, whereas improvement of stress incontinence symptoms are considered as failure. It is a clear definition of the parameter with the advantage of having no debate between cure and improvement. In most publications cure and improvement are listed together and this sometimes makes comparison of data awkward.

Although the definition of failure used in this study is subjective, it does provide information about the experience of the women over a longer period of time contrary to more objective investigations such as a post-

operative stress test, pad test or the urodynamic investigation. Those investigations merely reflect a measurement at one point in time. We realize, however, that in a small number of women it is possible that "failures" are actually reporting the symptoms of urge incontinence rather than those of stress incontinence. To demonstrate this difference, objective testing would have been required.

From expectations of women after incontinence surgery it is known that the majority expects a significant improvement [4]. Therefore the strict outcome parameter used in this thesis is not realistic for counseling women in common urogynecological practice and should be strictly used for scientific purposes. So when comparing success of incontinence surgery in this thesis to other studies or to women in common urogynecological practice, improvement rates must be added to the cure rate.

### **CURRENT VALUE OF PRE-OPERATIVE UROGYNECOLOGICAL WORK-UP**

It is remarkable that nowadays state-of-the-art treatment modalities such as mid-urethral slings exist for the treatment of stress urinary incontinence, but that the diagnostic procedures for deciding on this treatment are still based on long-existing and almost unchanged diagnostic concepts. Therefore we analyzed the value of the current diagnostic work-up and especially the importance of what was once considered the gold standard for diagnosing incontinence, the urodynamic investigation.

The main goals of urodynamic investigation in current urogynecological practice are to confirm the diagnosis or detect factors that may influence the outcome unfavorably. However, due to the invasive nature of urodynamic investigation, it is stressful for the patient and not without side-effects such as dysuria, urinary tract infections and even pyelonephritis [5]. Furthermore urodynamics are expensive, time consuming and not available in every clinic. This makes a critical appraisal of urodynamic investigation necessary.

The ability of urodynamics to confirm the true diagnosis is under debate [6,7]. An important observation of this thesis is that cure rates of patients with and without urodynamic SUJ were equal (chapters 3 & 5). As mentioned before urodynamic investigation reflects a measurement at one point in time, contrary to a patient's history of stress incontinence. Therefore value should also be attached to patient history and a patient should not be denied a surgical procedure based on absence of urodynamic stress incontinence. This observation reinforces the debate about the ability of pre-

## *General Discussion*

operative urodynamic investigation to confirm the diagnosis of stress incontinence.

Apart from the discussion about the value of urodynamic investigation in establishing a correct diagnosis, the results of urodynamic investigation should be related to the outcome of stress incontinence surgery. A recent Cochrane review concluded that there was not enough evidence to show that women with pre-treatment urodynamic investigation were less likely to be incontinent after treatment than women who did not have urodynamic testing [8]. The relationship between results from urodynamic investigation and cure or complications after MUS procedures is poor [9]. Detrusor overactivity and a low mean urethral closure pressure (< 20 cm H<sub>2</sub>O) seem to be the only predictive results which directly interfere with success of an operation [8;10-12]. Our results confirm these findings.

In this thesis we continue to elaborate on the use of urodynamic investigation for predicting outcome of stress incontinence surgery by introducing a new concept on its use : determining the best surgical procedure in a given woman's individual situation. Urodynamic investigation can be used as a tool to select the proper mid-urethral sling procedure. Different procedures have (?) different urodynamic risk factors: a Transobturator Tape procedure appears to be beneficial in patients who reveal detrusor overactivity at urodynamic investigation whereas a Tension-free Vaginal Tape procedure appears to be beneficial in patients with a low mean urethral closure pressure.

The incidence of patients (with detrusor overactivity or a low mean urethral closure pressure) is 17% in our population and they might benefit from this new application of urodynamic investigation. Therefore we investigated if patient characteristics might help in selecting which patients may benefit from pre-operative urodynamic investigation. Applying simple decision rules, obtained from medical history, a reduction in pre-operative urodynamics of 29% could be gained in our population with a 94% negative predictive value. However, the area under the curve of 0.65 in the receiver-operator curve of this screening method can still be improved. Further investigation is necessary to determine the indication for pre-operative urodynamic investigation more precisely.

### **RISK FACTORS**

Our study was the first to show that mixed urinary incontinence has statistically significant prognostic value for an improved outcome of a Transobturator Tape compared to Tension-free Vaginal Tape. In comparison

with the Transobturator Tape procedures, the sling axis of the Tension-free Vaginal Tape is more perpendicular to the urethral axis, creating more circumferential compression of the urethra. More compression of the urethra, and hence obstruction, is related to the development of detrusor overactivity. Therefore Transobturator Tapes, being theoretically less obstructive, are less likely to exacerbate urinary leakage and might perform better in women with mixed urinary incontinence and detrusor overactivity.

Previous incontinence surgery is a known risk factor for failure of both Tension-free Vaginal Tape and Transobturator Tape procedures [13,14]. Nevertheless, after multivariate analysis, previous incontinence surgery appeared to be an independent risk factor only in the Transobturator group. The explanation might be that patients with previous incontinence surgery benefit from restoring pubo-urethral ligament support and increased urethral resistance as provided by the Tension-free Vaginal Tape. Our results indicate that this increased urethral resistance is also advantageous to women with an intrinsic sphincter deficiency.

Therefore women with previous incontinence surgery or low urethral closure pressure might benefit from a Tension-free Vaginal Tape procedure whereas patients with mixed urinary incontinence or detrusor overactivity are better off with a Transobturator Tape procedure.

## **COMPARING TENSION-FREE VAGINAL TAPE AND TRANSOBTURATOR TAPE**

In the absence of risk factors the choice for either Tension-free Vaginal Tape or Transobturator Tape is not easy to make. Therefore, we introduced two instruments which may aid women and physicians alike in making this choice. The first instrument is the Surgical Therapeutic Index and the second is an analysis of women's preferences for the outcome of mid-urethral sling surgery.

### ***Surgical Therapeutic Index***

In this study the Surgical Therapeutic Index is described which simultaneously compares cure and complications of MUS procedures. We introduced the "severity factor" in a second STI, which estimates the impact of the different complications on patient-related quality of life. The Surgical Therapeutic Indices are a means of providing a complete overview of postoperative outcome (cure and complications) after incontinence surgery.

Several studies indicate that Tension-free Vaginal Tape and Transobturator Tape procedures are equally effective in curing female SUI at

## *General Discussion*

one year after surgery [1,2,15-18]. However, we found the results of Tension-free Vaginal Tape to be more lasting after one year compared to Transobturator Tape procedures. These findings were reinforced by the increased number of re-operations due to failure in the Transobturator Tape group. After 11 years of follow-up, excellent results of Tension-free Vaginal Tape procedures are described, even when an ageing population is taken into consideration. [19]. Satisfying results of 3 year follow-up studies are reported after Transobturator Tape procedures but the number of trials is minimal [20]. At present, long-term follow-up of Transobturator Tape procedures is still unavailable and comparative trials between Tension-free Vaginal Tape and Transobturator Tape do not exceed one year follow-up [1,2,15-17].

As far as complications are concerned, two months after surgery there were more patients with postoperative voiding difficulty in the Tension-free Vaginal Tape group. However, twelve months after surgery similar rates of voiding difficulty in both groups were reported. Our results are confirmed by Dietz et al, who also found that symptoms of voiding dysfunction after Tension-free Vaginal Tape decrease over time [21].

Intra-operative complications are not included in the Surgical Therapeutic Index, but may be of importance in assessing the best procedure. In our studies bladder perforation and postoperative urinary retention did occur more frequently after Tension-free Vaginal Tape procedures. This might have resulted in a longer hospital stay. These findings are consistent with the results of two recently published meta-analyses [15,16]. It is worthwhile to note that these bladder perforations, although disturbing at the moment they occur, are minor in severity if recognized in time and treated properly.

The Surgical Therapeutic Indices indicate that Transobturator Tape procedures are performing significantly better in the short-term but more stable cure rates and well-known long-term results after Tension-free Vaginal Tape are observed. There are also differences in type and frequency of several complications. Therefore both surgical approaches seem to have their own benefits and the Surgical Therapeutic Index may aid patients in making a choice between the two surgical modalities.

### **Women's and physician's preferences**

As SUI is a significant quality of life issue and treatment is usually elective, it is imperative to determine patient's expectations of outcome [22]. Treatment options can be adjusted to patient preferences and pre-operative counseling can be improved. Therefore increasing the knowledge of patient expectations may improve treatment results.

In this thesis patient expectations regarding wanted and unwanted sequels of mid-urethral sling procedures were investigated. Furthermore, we aimed to identify mismatches during the physician-patient information exchange prior to surgery. It is reassuring that patients and physicians agree on the most important issues like cure, improvement and functional complications. We found the time after which work could be resumed following the operation and dyspareunia to be important outcomes in the patients' opinions which might be undervalued by physicians. These outcome parameters should be introduced as outcome parameters of studies investigating results of mid-urethral sling surgery.

### **TRANSOBTURATOR TAPES: TVT-O VERSUS MONARC**

Throughout this thesis we emphasized the need for having at least medium – or, even better, long-term outcome data of mid-urethral sling surgery. Due to the fact that the second generation of mid-urethral sling procedures were introduced not that long ago, long-term data of these procedures are not available yet. Nevertheless, we like to recognize the importance of having medium-term follow-up of Transobturator Tape procedures and we therefore presented our three-year data of TVT-O and Monarc.

No differences were found between TVT-O and Monarc procedures after one year [3,15,16,23,24]. Our results confirmed these findings and even after 3 years both procedures performed similarly. In our study as well as in literature, Monarc procedures might have a tendency towards a higher erosion rate [15]. However, patient numbers are too small to draw reliable conclusions. Therefore choice of obturator procedure must depend on the preference and experience of the surgeon.

### **FUTURE**

This thesis showed the relative value of pre-operative urodynamics in women with an indication for mid-urethral sling surgery. However, the indication of pre-operative urodynamics should be further sharpened as only a minor part (17% in our population) benefited from this investigation.

## *General Discussion*

To optimize individualized treatment, prospective comparative trials between Tension-free Vaginal Tape, Transobturator Tape and third generation mid-urethral sling procedures are needed to confirm the risk factors found in this study. Our results once again emphasize the need for long-term follow-up of surgical procedures before implementation in common clinical practice.

Surgical Therapeutic Indices may be implemented in common urogynecological practice as they provide a complete overview of both cure and complications of a surgical technique. Women's expectations should be part of the common urogynecological work-up and should be recognized as outcome parameters in scientific research.

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## **Chapter 9**

### How to Tailor Stress Incontinence Surgery

## **HOW TO TAILOR STRESS INCONTINENCE SURGERY?**

One important goal of this thesis was to develop a guideline for selecting the optimal mid-urethral sling technique for the treatment of stress urinary incontinence. A flow diagram is presented with four steps for choosing the diagnostic procedure and the best suited MUS procedure.

Step 1 is, with reference to history and physical examination, based on current (Dutch) national and international guidelines [1,2]. It forms the basis for the diagnostic work-up. The value of various urogynecological parameters from these guidelines was evaluated in chapter 2.

Step 2 makes it possible to adjust additional invasive investigations to the individual need of the incontinent woman. This is based on the research depicted in chapters 2 and 4 of this thesis.

Step 3 lists an inventory of risk factors for failure of mid-urethral sling procedures which may result from the additional investigation of step 2. The basis for this step is presented in chapter 3 of this thesis.

Step 4 follows after assessing possible risk factors for failure. If these risk factors are present, advice on how to counsel women and how to handle is offered in chapter 3. If no risk factors are present, the opinion of women is of even greater importance. As both women and physicians have stated that outcome data are the first important parameter in choosing the surgical incontinence procedure, outcome studies on Tension-free Vaginal Tape like the long- and medium-term data presented by respectively Nilsson [3] and Schraffordt [4] can be considered. For Transobturator Tape procedures the results are listed in chapter 7. Next to this, other aids may be the Surgical Therapeutic Index (chapter 5) and the results of women's and physicians' preferences (chapter 6).

## HOW TO TAILOR STRESS INCONTINENCE SURGERY (Without simultaneous prolapse surgery)

### Step 1

**Perform a standard urogynecological history and physical examination including a validated quality of life questionnaire and voiding diary in order to determine to intent for a surgical treatment**

### Step 2

**Decide on the necessity of additional urodynamic investigation (chapters 2 and 4)**

Decision may be based on these women's characteristics:

- presence of neurologic disorders
- presence of pre-existent voiding dysfunction
- age 53 years or older
- having a history of prior incontinence surgery and at are least 29 years of age
- having nocturia complaints and being at least 36 years of age

### Step 3

**Determine whether risk factors for failure are present (chapter 3)**

These factors are the presence of:

- a history of previous incontinence surgery
- mixed urinary incontinence
- detrusor overactivity on the urodynamic investigation
- a maximum urethral closure pressure below 20 cm H<sub>2</sub>O (ISD) on the urodynamic investigation

### Step 4

**No risk factors for failure are present  
(chapter 5,6,7)**

Decision to choose for either a TVT procedure or TOT procedure is to be discussed with the patient. Helpful means are:

- Outcome data
- Surgical Therapeutic Index
- Women's and physician's preferences

**Risk factors for failure are present  
(chapter 3)**

- Mixed urinary incontinence and/or detrusor overactivity present: perform a TOT procedure
- Previous incontinence surgery and/or ISD present: perform a TVT procedure

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# **Chapter 10**

## Summary and Conclusions

## SUMMARY

In this thesis a different principle to determine the value of diagnostic parameters and to install the proper, individualized, surgical treatment for stress urinary incontinence is presented. It is based on the prognostic value of various diagnostic parameters with reference to a successful outcome of mid-urethral sling surgery. The emphasis of the diagnostic process is therefore not only on accurate diagnosis, but also on correct treatment. Next to prognostic values an effort is also presented to determine which individual surgical treatment is the most appropriate considering outcome, complications and women's preferences for a surgical technique.

**Chapter 1** consists of an introduction and describes the aim and outline of the thesis. The aims of the studies presented in this thesis were:

1. To perform an in-depth analysis of the current diagnostic modalities and correlation to successful outcome of mid-urethral sling procedures.
2. To develop instruments that help in selecting the best surgical procedure based on the different properties of mid-urethral sling procedures, women's individual characteristics and women's preferences.
3. To present our data on medium-term outcome of Transobturator Tape procedures TVT-O and Monarc.

In **chapter 2** we evaluate the value of urodynamic investigation in the pre-operative work-up of women with predominant stress incontinence and identified risk factors for failure and complications after three different mid-urethral sling procedures.

A retrospective cohort study was performed. Pre-operative data from medical history, physical examination and urodynamic investigation were collected from the medical files. Women who reported any amount of urine leakage were considered failures.

After multivariate analysis, mixed urinary incontinence (Odds ratio (OR) 1.87 [95% confidence interval (CI) 1.02 - 3.40]), previous incontinence surgery (OR 2.52 [CI 1.15 - 5.56]) and detrusor overactivity (OR 2.91 [CI 1.15 - 7.32]) were significantly related to failure of mid-urethral sling procedures. There were no predictive urodynamic parameters for failure in women with mixed urinary incontinence or previous incontinence surgery. Age appeared to be a risk factor for post-operative urinary retention (OR 1.03 [CI .01 - 1.05]). Mean cystometric capacity below 200 ml (OR 6.11 [CI 1.05 - 35.58]) and the absence of stress incontinence at the urodynamic

## *Summary and Conclusions*

investigation (OR 3.00 [CI 1.21 – 7.42]) were risk factors for de novo urge urinary incontinence (UUI).

In **chapter 3** a comparison is made between the risk factors for failure of Tension-free Vaginal Tape and Transobturator Tape procedures. A retrospective cohort study was performed. Pre-operative data from medical history, physical examination and the urodynamic investigation were collected from the medical files. Women reporting any amount of urine leakage 12 months after the operation were considered as failures.

Risk factors for failure were mixed urinary incontinence (OR 3.7 [CI 1.5 - 9.1]) and the observation of detrusor overactivity at urodynamics (OR 8.6 [CI 1.9 - 39.4]) in the Tension-free Vaginal Tape group. A history of previous incontinence surgery (OR 3.9 [CI 1.3 - 11.7]) and a low (< 20 cm H<sub>2</sub>O) mean urethral closure pressure at urodynamics (OR 14.5 [CI 1.5 - 139.0]) were risk factors for failure in the Transobturator group.

In **chapter 4** a model is presented that can differentiate between women who might benefit from pre-operative urodynamics and women in whom pre-operative urodynamics can be safely omitted. The model is based on the urodynamic risk factors found in chapter 4: detrusor overactivity for Tension-free Vaginal Tape and / or low mean urethral closure pressure for Transobturator Tape procedures. Therefore results of pre-operative urodynamics may aid in selecting the proper mid-urethral sling procedure.

With multivariate logistic regression a model was developed based on medical history and physical examination to predict a high probability group of women with detrusor overactivity and/or a low mean urethral closure pressure. Women with neurologic disorders or pre-existent voiding dysfunction were excluded.

The final model includes age, previous incontinence surgery and nocturia. The corresponding area under the receiver operating characteristic curve is 0.65 (CI 0.58 - 0.72). The following decision rules could be formulated: women are likely to benefit from pre-operative urodynamics if they: 1) are 53 years of age or older; or 2) have a history of prior incontinence surgery and are at least 29 years of age; or 3) have nocturia complaints and are at least 36 years of age.

In **chapter 5** the concept of the Surgical Therapeutic Index is introduced. The Surgical Therapeutic Index is defined as the ratio between the cure- and complication rate. The complication rate is calculated by adding up

complications associated with the performed surgical procedure at a defined moment in time. Furthermore a severity factor was introduced based on the Dutch TVT Database to rate the severity of complications [1,2]. The aim of this chapter is to determine and compare Surgical Therapeutic Indices of the retropubic Tension-free Vaginal Tape and two Transobturator Tapes, Monarc and TVT-O.

A retrospective cohort study was performed. Data from medical history, physical examination, the urodynamic investigation and follow-up visits were collected from the medical files. Follow-up of women was at 2 and 12 months postoperatively. Cure of stress urinary incontinence was defined as the patient's statement of not experiencing any loss of urine upon physical activity, coughing or sneezing. Surgical Therapeutic Indices of Monarc and TVT-O were analyzed as one group based on studies that showed no differences in cure and complications between both procedures after one year [3-6].

There were no significant differences in cure rate between the Tension-free Vaginal Tape and the Transobturator Tape procedures after 2 and 12 months. Cure rates after Tension-free Vaginal Tape procedures were more lasting compared to the Transobturator Tape procedures ( $p = 0.03$ ).

Bladder perforations occurred in 9 women (4%) in the Tension-free Vaginal Tape group versus none in the Transobturator Tape group ( $p = 0.01$ ). Post-operative urinary retention occurred more often in the Tension-free Vaginal Tape group ( $p = 0.003$ ). Hospitalization was longer after Tension-free Vaginal Tape procedures 1,7 versus 1,4 days ( $p = 0.03$ ). Nevertheless, the number of women who were treated in day care was not different ( $p = 0.2$ ).

After 2 months there were significantly more women with voiding difficulty in the Tension-free Vaginal Tape group ( $p < 0.001$ ). However this difference was no longer present after 12 months and all women voided without catheterization. In the follow-up period, there were 4 cases of tape erosion which all occurred in the Transobturator Tape group ( $p = 0.04$ ).

Surgical Therapeutic Indices after 2 months were significantly higher in the Transobturator Tape group. After 12 months, no significant differences between Surgical Therapeutic Indices of both procedures were observed.

**Chapter 6** describes a patient preferences study (40 patients) and a questionnaire study with 20 urogynecological experts. This study was conducted to identify mismatches during the physician-patient information exchange prior to mid-urethral sling procedures by looking at how patients

## Summary and Conclusions

value the information potentially exchanged and whether physicians are aware of those values. Sixteen important possible effects – wanted and unwanted- of incontinence surgery (outcome parameters) were investigated.

Both patients and experts ranked cure and improvement of stress incontinence as most important outcome parameters. De novo urge urinary incontinence, post-operative intermittent self-catheterization and dyspareunia were regarded by patients as the most important complications. Period of absence from work after the operation and dyspareunia were among the highest rated sequels in the patient group compared to risk of a re-operation and risk of intra-operative complications in the expert group. Patients rated the time after which work could be resumed more relevant than experts ( $p < 0.01$ ).

In **Chapter 7** we compared outcome and quality of life of TVT-O and Monarc Transobturator Tape procedures after 2-4 years. A prospective cohort study was conducted. Participants ( $n = 191$ ) were assigned to either a TVT-O ( $n = 93$ ) or a Monarc ( $n = 98$ ) procedure. Cure was defined as the statement of the woman of not experiencing any loss of urine upon physical effort.

There were no differences in surgery time, amount of blood loss and type of anesthesia between TVT-O and Monarc procedures and no major intra-operative complications occurred.

Cure rates after 2-4 years were 72% for TVT-O and 65% for Monarc, while improvement was observed in respectively 12% and 21% ( $p = 0.3$ ). There was a statistically significant improvement in quality of life but no differences were found between both procedures.

Pre-existing urge incontinence resolved in 7 women (32%) after TVT-O and 8 women (31%) after Monarc ( $p = 1.0$ ). De novo urge incontinence developed in 2 cases in the TVT-O group versus 4 cases in the Monarc group ( $p = 0.2$ ). There were 5 cases of vaginal erosion which were all excised under local anesthesia and all patients remained continent afterwards. In 5 women after TVT-O and in 4 women after Monarc a second anti-incontinence procedure was performed ( $p = 0.5$ ).

## CONCLUSIONS

- Mixed urinary incontinence and detrusor overactivity are risk factors for failure of Tension-free Vaginal Tape procedures.
- Previous incontinence surgery and a low mean urethral closure (< 20 cm H<sub>2</sub>O) pressure are risk factors for failure of Transobturator Tape procedures.
- Women are likely to benefit from pre-operative urodynamics if they: 1) are 53 years of age or older; or 2) have a history of prior incontinence surgery and are at least 29 years of age; or 3) have nocturia complaints and are at least 36 years of age.
- The Surgical Therapeutic Index is capable of providing a complete overview of postoperative outcome after incontinence surgery.
- Based on the Surgical Therapeutic Index, the balance between cure rate and complications is in favor of Transobturator Tape procedures in the short term, but in the long term it is similar for Transobturator Tape procedures and Tension-free Vaginal Tape procedures.
- Patients and physicians agree on the most important outcome parameters of incontinence surgery like cure, improvement and functional complications.
- Period of absence from work after operations and dyspareunia should be regarded in pre-operative counselling and future clinical trials based on women's preferences.
- After 2-4 years, no significant differences are found in cure rate and complications of two Transobturator Tape procedures Monarc and TVT-O

## **About the author**

## **CURRICULUM VITAE**

Roderick Marijn Houwert was born on November 28th 1981 in Utrecht, the Netherlands. He graduated from secondary school (Christelijk College, Zeist) in the year 2000 and the same year he enrolled in the medical program of the University of Utrecht.

During his study, he was an active member of the Utrechtsch Studenten Corps and the Utrechtsche Studenten Roeivereniging Triton, with whom he participated in the Ringvaart Regatta in 2005.

Several internships abroad, including in Suriname and on the island of Aruba, finally lead him to the St. Elisabeth Hospital in Tilburg. There, under the inspiring supervision of Dr. H.A.M. Vervest, the foundation of this thesis was laid by spending many hours in the hospital's archives collecting his patients' database.

After completion of his medical degree in the fall of 2008, he started as a resident in the gynaecology department in the St. Elisabeth Hospital, in combination with the continuation of his doctoral program on stress urinary incontinence surgery at the Wilhelmina Child's Hospital in Utrecht (Prof. dr. H.W. Bruinse).

In the past two years, the author of this thesis was rewarded the prestigious Prof. van Buchem award for conducting the best scientific research among all residents of the St. Elisabeth Hospital and held several presentations at meetings of the International UroGynaecological Association (IUGA) in Mexico and Taiwan.

Despite the primary interest in female pathology, the final stages of medical school were spent in the orthopedic surgery department of the St. Antonius Hospital in Nieuwegein. His career interests rapidly transferred to joints and bones and an ultimate career change took place. While finishing his thesis the author successfully applied for a residency in orthopedic surgery. He will start with his 2 years of training in general surgery in the Diakonessen Hospital Utrecht (Dr. G.J. Clevers) on the 1<sup>st</sup> of January 2010, followed by 4 years of orthopedic surgery starting at the Medisch Centrum Haaglanden in The Hague (Prof. dr. R.G.H.H. Nelissen and Dr. E.R.A. van Arkel).

Olivier van der Meijden and Stephanie Winters (paranymphes)

**PERSONAL NOTE TO THE AUTHOR**

Dear Marijn,

This thesis is the product of solely 12 months of hard and tenacious work. Though 3 months later than firstly expected, your good friend Niek will probably not hold this against you after reading his own copy of your fantastic result. We are very proud of the way you have achieved your goal and wish you all the best in your future career.

Your paranymphs,

Joost Dijkshoorn  
Anne den Hartog  
Olivier van der Meijden  
Joost Overgaauw  
Stephanie Winters



# Nederlandse Samenvatting

## *Nederlandse Samenvatting*

Dit proefschrift gaat over de diagnostiek en chirurgische behandeling van incontinentie urinae, ongewild urineverlies, bij vrouwen. De onderwerpen in dit proefschrift zijn: 1) welk onderzoek is voorafgaand aan een operatie noodzakelijk; 2) wat zijn de factoren die van invloed zijn op het resultaat van de operatie; 3) welke type operatie is het meest geschikt; en 4) wat vinden vrouwen belangrijk als uitkomst van de operatie?

Incontinentie bij vrouwen is een veelvoorkomend probleem dat de kwaliteit van leven in belangrijke mate beïnvloed.

Er zijn drie belangrijke vormen van incontinentie. De eerste vorm is stress incontinentie waarbij urineverlies optreedt bij lichamelijke inspanning zoals bijvoorbeeld fietsen of traplopen. De tweede vorm is urge incontinentie waarbij ongewild urineverlies optreedt bij een gevoel van ernstige aandrang. De derde vorm is gemengde incontinentie: een combinatie van bovengenoemde vormen.

Naar schatting komt incontinentie voor bij 1 op de 4 vrouwen. Ongeveer de helft van deze vrouwen heeft stress incontinentie, 10% urge incontinentie en 40% gemengde incontinentie.

Voorafgaand aan een incontinentieoperatie is het advies volgens de richtlijnen van zowel de Nederlandse Vereniging van Obstetrie en Gynaecologie als de Nederlandse Vereniging voor Urologie om urodynamisch onderzoek te verrichten.

Urodynamisch onderzoek is een onderzoek naar de functie van de blaas en afsluitmechanisme van de plasbuis (urethra). Het is een invasief onderzoek. Door middel van dunne slangetjes die druk kunnen meten (catheters) en die ingebracht worden via de plasbuis en de endeldarm, kan onderzoek worden verricht naar de functie van de blaas en de urethra. Tevens wordt nagegaan of urineverlies optreedt als gevolg van een abnormale functie van de blaas of als gevolg van lichamelijke inspanning.

Urodynamisch onderzoek wordt door veel vrouwen als belastend ervaren. Bovendien is urodynamisch onderzoek duur, tijdrovend, niet overal beschikbaar en kunnen complicaties optreden zoals een blaasontsteking en in zeldzame gevallen een nierbekkenontsteking.

Recent onderzoek heeft aangetoond dat er niet altijd een goede overeenkomst is tussen de uitkomst van urodynamisch onderzoek en het resultaat van de operatie. Daarom is in dit proefschrift de waarde van het urodynamisch onderzoek voorafgaand aan incontinentiechirurgie onderzocht

met als doel om vrouwen te identificeren waarbij urodynamisch onderzoek achterwege kan blijven voorafgaand aan een incontinentiechirurgie.

De gouden standaard in de incontinentiechirurgie is de Tension-free Vaginal Tape (TVT). Een voorloper van deze methode werd in 1995 voor het eerst beschreven door Ulmsten en Papa Petros. Bij deze operatie wordt via de vagina een kunststof (polypropyleen) bandje onder en naast de urethra geplaatst en via uitsteekopeningen achter het schaambeentje langs, via de buikwand naar buiten geleid. Op momenten van drukverhoging in de buik wordt de urethra tegen het bandje dichtgedrukt.

In 2001 werd de Transobturator Tape (TOT) geïntroduceerd door Delorme als alternatief van de TVT. Hierbij is de insteekopening van het bandje niet in de vagina maar in de liezen. Daarna komt het bandje, evenals bij de TVT, midden onder de urethra te liggen. Problemen tijdens de operatie, zoals het doorprikken van de blaas dat kan voorkomen bij de TVT, worden in theorie door deze methode (TOT) vermeden.

Er zijn verschillende vormen van TOT procedures. Bij de Monarc is de procedure zoals hierboven beschreven, bij de TVT-Obturator (TVT-O) is de insteekopening onder urethra en de uitsteekopening in de liezen. Eigenlijk is een TVT-O het omgekeerde van een Monarc procedure.

Tot op heden is het resultaat van deze TOT procedures na meer dan 2 jaar nog niet onderzocht. Bij incontinentiechirurgie wordt vaak alleen het resultaat van de ingreep onderzocht en blijven complicaties onderbelicht. Een methode waarbij tegelijkertijd genezing en complicaties wordt onderzocht, ontbreekt.

Doordat er twee verschillende technieken zijn (TVT en TOT), is er onderzoek mogelijk om te bepalen welke techniek het beste is voor welke patiënt. In dit proefschrift is daarom onderzoek gedaan naar risicofactoren van beide technieken voor het niet slagen van een operatie.

Incontinentie is een hinderlijke maar niet levensbedreigende aandoening. Bij de chirurgische behandeling is het dan ook van belang de verwachtingen van vrouwen ten aanzien van de operatie te kunnen herkennen. Ook is het belangrijk om te weten of deze verwachtingen overeenkomen met de verwachtingen van de behandelend artsen. Hierover is eigenlijk nog weinig bekend.

Bovengenoemde hiaten maken verdieping van de huidige kennis over het gehele traject van incontinentiechirurgie noodzakelijk. Het doel van dit

proefschrift was dan ook om het gehele traject van incontinentiechirurgie te onderzoeken en waar nodig te verbeteren.

In **hoofdstuk 1** worden de achtergrond en de onderzoeksvragen van dit proefschrift beschreven. Deze onderzoeksvragen zijn:

- 1) De huidige diagnostiek voorafgaand aan incontinentiechirurgie evalueren en de relatie tussen deze diagnostiek en een succesvolle uitkomst van de operatie onderzoeken.
- 2) Instrumenten ontwikkelen waarmee de beste incontinentieprocedure kan worden gekozen op basis van eigenschappen van de procedure en eigenschappen van de patiënt.
- 3) Verwachtingen van patiënt ten aanzien van een operatie onderzoeken.
- 4) Middellange follow-up (2 tot 4 jaar) beschrijven van de TOT procedures TVT-O en Monarc.

In **hoofdstuk 2** zijn risicofactoren voor het niet slagen van incontinentiechirurgie en risicofactoren voor complicaties onderzocht. Tevens is de waarde van het urodynamisch onderzoek voorafgaand aan incontinentiechirurgie geëvalueerd.

Alle gegevens die voor de operatie van de patiënt waren verkregen uit het vraaggesprek (anamnese), het lichamelijk onderzoek en het urodynamisch onderzoek zijn hiervoor gebruikt. Bij patiënten die minimaal 1 jaar na de operatie nog klachten hadden van urineverlies bij lichamelijke inspanning, zelfs minimaal, werd de operatie beschouwd als “niet geslaagd”.

Na analyse van deze data kwamen 3 risicofactoren naar voren voor het niet slagen van de operatie: gemengde incontinentie, eerder ondergane incontinentiechirurgie en onwillekeurige blaascontracties gepaard gaande met urineverlies tijdens het urodynamisch onderzoek (detrusor overactiviteit).

Hogere leeftijd was gerelateerd aan een verhoogde kans op niet uit kunnen plassen na de operatie (blaasretentie). Een blaascapaciteit kleiner dan 200 ml vastgesteld tijdens het urodynamisch onderzoek of het niet aan kunnen tonen van stress incontinentie bij het urodynamisch onderzoek waren risicofactoren voor het ontstaan van urge incontinentie na de operatie.

Het urodynamisch onderzoek had geen voorspellende waarde voor het resultaat van de operatie in de groep patiënten met gemengde incontinentie of eerder ondergane incontinentiechirurgie. De conclusie van

deze studie was dat het standaard uitvoeren van urodynamisch onderzoek voorafgaand aan incontinentiechirurgie moet worden herzien.

In **hoofdstuk 3** zijn risicofactoren voor het niet slagen van de operatie tussen TVT en TOT procedures vergeleken.

Alle gegevens die voor de operatie van de patiënt waren verkregen uit het vraagesprek (anamnese), het lichamelijk onderzoek en het urodynamisch onderzoek zijn hiervoor gebruikt. Bij patiënten die minimaal 1 jaar na de operatie nog klachten hadden van urineverlies bij lichamelijke inspanning, zelfs minimaal, werd de operatie beschouwd als “niet geslaagd”.

Gemengde incontinentie en detrusor overactiviteit waren risicofactoren voor het niet slagen van een TVT procedure. Eerder ondergane incontinentiechirurgie en een lage afsluitdruk van de urethra vastgesteld bij urodynamisch onderzoek, waren risicofactoren voor het niet slagen van TOT procedure.

Hieruit concludeerden wij dat anamnese en urodynamisch onderzoek van waarde zijn bij de keuze tussen beide procedures.

**Hoofdstuk 4** is een vervolg op de bevindingen uit hoofdstuk 2 en 3. We hebben een model ontwikkeld dat aangeeft welke vrouwen baat hebben bij urodynamisch onderzoek en bij welke vrouwen urodynamisch onderzoek achterwege kan blijven.

De basis van het model is het gegeven dat als er sprake is van detrusor overactiviteit en/of een lage afsluitdruk van de urethra dit consequenties heeft voor de operatie (hoofdstukken 2 en 3). Op basis van gegevens uit anamnese en lichamelijk onderzoek is onderzocht welke vrouwen een verhoogde kans hadden op detrusor overactiviteit of een lage afsluitdruk van de urethra.

Uit deze analyse kwamen leeftijd, eerder ondergane incontinentiechirurgie en 's nachts meer dan 1x naar de toilet moeten (nycturie) als voorspellende gegevens naar voren. Op basis van deze gegevens werden het volgende model ontwikkeld:

Vrouwen komen in aanmerking voor urodynamisch onderzoek als ze: 1) ouder zijn dan 53 jaar; of 2) eerder incontinentiechirurgie hebben ondergaan en tenminste 29 jaar oud zijn; of 3) klachten hebben van nycturie en tenminste 36 jaar oud zijn.

30% van de vrouwen valt niet in bovengenoemde groep en hebben een zeer kleine kans op detrusor overactiviteit en/of een lage afsluitdruk van de urethra. In deze groep kan dus het urodynamisch onderzoek achterwege

blijven. Voordat dit model wordt toegepast in de dagelijkse praktijk dient het beoordeeld te worden bij een nieuwe groep vrouwen met incontinentie.

In **hoofdstuk 5** wordt de Surgical Therapeutic Index (STI) geïntroduceerd. De STI is de ratio tussen het percentage patiënten dat genezen is na een operatie op een bepaald tijdstip en het percentage patiënten dat een complicatie heeft op hetzelfde tijdstip.

Omdat in de STI alle complicaties even zwaar worden meegeteld, hebben wij een “severity factor” toegekend aan verschillende complicaties. Deze “severity factor” is vastgesteld op basis van gegevens uit eerdere studies, waarin de kwaliteit van leven van patiënten met complicaties na incontinentiechirurgie is onderzocht. Met de STI hebben wij de resultaten van TVT en TOT procedures vergeleken.

Patiënten werden 2 en 12 maanden na de operatie onderzocht. Bij patiënten die na de operatie nog klachten hadden van urineverlies bij lichamelijke inspanning, zelfs minimaal, werd de operatie beschouwd als “niet geslaagd”.

In de TVT groep verschilde het aantal patiënten dat genezen was bij 2 maanden, niet significant van het aantal patiënten dat genezen was bij 12 maanden. Na TOT procedures zagen wij een significante daling van het aantal patiënten dat genezen was bij 12 maanden ten opzichte van het aantal patiënten dat genezen was bij 2 maanden. Hieruit concluderen wij dat resultaten na een TVT procedure meer stabiel zijn.

Tijdens een TVT operatie werd de blaas van de patiënt significant vaker doorgeprikt (9x versus niet in de TOT groep). Na de TVT operatie konden significant meer vrouwen niet uitplassen (22 vrouwen versus 3 in de TOT groep). Door deze problemen was de opnameduur in het ziekenhuis langer na een TVT procedure. Echter, het aantal vrouwen dat in dagbehandeling was geopereerd, verschilde niet.

Bij 2 maanden waren er meer vrouwen met plas (mictie) problemen in de TVT groep, echter bij 12 maanden was dit verschil verdwenen. In de TOT groep waren meer patiënten waarbij het bandje door de vaginawand heen kwam (tape erosie). Bij deze vrouwen moest dit deel van het bandje worden verwijderd.

Bij 2 maanden was de STI hoger in de TOT groep. Bij 12 maanden waren STI's nagenoeg gelijk. Er werd een duidelijke stijging in de STI van de TVT waargenomen en een daling in de STI van de TOT.

Concluderend hebben beide procedures hun voordelen en is de STI en goed instrument om resultaten van een operatie te evalueren omdat zowel kans op genezing als kans op complicaties wordt beoordeeld.

**Hoofdstuk 6** beschrijft onderzoek dat is gedaan naar de verwachtingen van vrouwen en behandelaars (experts op het gebied van incontinentie) van incontinentiechirurgie. Het doel van deze studie was om te onderzoeken of verwachtingen van vrouwen en behandelaars overeenkomen en indien afwijkend hiermee de voorlichting voor de operatie (counseling) te verbeteren.

17 mogelijke uitkomsten van incontinentiechirurgie zijn opgesteld door 3 experts. Deze uitkomsten zijn beoordeeld op een schaal van 0 (zeer onbelangrijk) tot 100 (extreem belangrijk) door 40 patiënten met incontinentie en 20 experts.

Patiënten en experts vonden genezing en verbetering na de operatie de belangrijkste uitkomstmaten. Beide groepen vonden urge incontinentie na de operatie en urineretentie waarvoor zelf-catheterisatie noodzakelijk is, de belangrijkste complicaties. Door beide groepen werd het belang van lange termijn resultaten onderstreept.

Verschillen tussen beide groepen waren dat patiënten de kans op pijn bij het vrijen (dyspareunie) en tijdsduur tot werkhervatting belangrijker vonden dan experts.

Het blijkt dat de mening van patiënten en experts over de belangrijkste verwachtingen van een incontinentieoperatie overeenkomen. In counseling en toekomstige studies naar het resultaat van incontinentiechirurgie, zouden de kans op dyspareunie en tijdsduur tot werkhervatting moeten worden opgenomen.

In **hoofdstuk 7** zijn resultaten van twee TOT procedures TVT-O en Monarc vergeleken op de middellange termijn (2 tot 4 jaar). Patiënten ondergingen een TVT-O procedure (93) of een Monarc procedure (98). Bij patiënten die na de operatie nog klachten hadden van urineverlies bij lichamelijke inspanning, zelfs minimaal, werd de operatie beschouwd als “niet geslaagd”.

Er waren geen verschillen tussen de duur van de operatie en complicaties tijdens de operatie.

Na 2 tot 4 jaar waren 72% van de vrouwen in de TVT-O groep genezen en 65% in de Monarc groep. Verbetering werd vastgesteld bij 12% in de TVT-O groep en 21% in de Monarc groep. Deze verschillen zijn statistisch niet significant. Kwaliteit van leven was in beide groepen

aanzienlijk verbeterd. Er waren geen significante verschillen tussen beide groepen in complicaties na 2 tot 4 jaar.

De conclusie van de studie is dat de resultaten van TVT-O en Monarc even goed en veilig zijn na een follow-up periode van 2 tot 4 jaar.

**In hoofdstuk 8** worden de bevindingen van dit proefschrift geanalyseerd en **hoofdstuk 9** beschrijft een schematische indeling van incontinentiechirurgie op maat. **Hoofdstuk 10** bevat de samenvatting en conclusies.

De conclusies van dit proefschrift zijn de volgende:

- Anamnese en urodynamisch onderzoek zijn van waarde bij de keuze tussen verschillende incontinentieoperaties.
- Vrouwen komen in aanmerking voor urodynamisch onderzoek als ze: 1) ouder zijn dan 53 jaar; of 2) eerder incontinentiechirurgie hebben ondergaan en tenminste 29 jaar oud zijn; of 3) klachten hebben van nycturie en tenminste 36 jaar oud zijn.
- De Surgical Therapeutic Index is bij uitstek het middel om succes van een operatie te bepalen: genezing en complicaties worden beoordeeld.
- De verwachtingen van een incontinentieoperatie van dokters en patiënten in de urogynaecologische praktijk komen goed overeen.
- De resultaten van Monarc en TVT-O procedures zijn na 2-4 jaar follow-up nagenoeg gelijk.

Dankwoord

## *Dankwoord*

De onderstaande personen verdienen een woord van dank voor hun hulp bij het tot stand komen van dit proefschrift.

Dr. H.A.M. Vervest, beste Harry, je bent waarschijnlijk de enige gynaecoloog in Nederland die op basis van zijn eigen patiënten een proefschrift heeft geschreven. Daarom is dit **ONS** proefschrift. Bedacht in Bangkok en afgerond op Aruba. Ik beloof je niet meer te bellen op zondagavond, althans niet over onderzoek.

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Boys van de Maliebaan en Rooseveltlaan + overige maatjes: vrijdag is voor jullie.

Lieve Glenda en Moon, was erg gezellig op Aruba. Glenda: "Tailoring stress incontinence surgery: no fixed prices!" Dank voor je altijd gastvrije onthaal + uitleg/opvoeding dat er meer is dan geneeskunde. Moon: smeer je in als je in de zon gaat liggen, vergeet niet dat je blank geboren bent!

Lieve Pa en Pom, ik beloof dat het niet meer over mijn promotie/de gynaecologie gaat aan de keukentafel (ik moet dit nog wel even aan ma doorgeven...). Fijn om altijd op zo'n warm nest te mogen terugvallen.

Lieve Lotje, dit proefschrift begint door en eindigt voor jou. Dat zegt genoeg. I'm indeed a lucky man!