Diplomarbeit

SLING DIVISION

Evaluation of the objective outcome and quality of life

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Graz, am 09.03.2017 *Anna Katharina Sophia Höllein eh*

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Abstract

Background: Midurethral sling procedures may cause long-term complications such as voiding dysfunction, groin pain and de novo urgency, which can lead to the indication of sling division. There is little literature available about stress urinary incontinence (SUI) rates and the quality of life (QoL) after sling division. The aim of this study was to analyse the postoperative objective and subjective outcome of a sling division and its impact on the QoL of these patients. Additionally, possible risk factors that could lead to a sling division were analysed.

Methods: Patients who underwent a sling division of a suburethral sling between 1999 until 2015 were invited for follow-up. For each case, two matching control patients were invited. A medical history was taken and urogynaecological as well as urodynamic examinations were performed. Objective SUI was defined as a positive stress test at bladder filling of 300 ml. Subjective SUI was defined when patients responded “yes” to the question: “Does urine leak when you are physically active, exert yourself, cough, or sneeze?”. Subjective success was assessed with the Patient’s Global Impression of Improvement (PGI-I) and the scores on a visual analogue scale (VAS) regarding the impact of incontinence. Patients completed the KING’s Health Questionnaire (KHQ), the Incontinence Outcome Questionnaire (IOQ) and the Female Sexual Function Index (FSFI).

Results: 15 patients were available for follow-up and completed the questionnaires. 13 women attended the clinical follow-up examination. The objective SUI rate was 33.3% in the sling division group and 11.1% in the control group. In comparison the subjective SUI rate was 53.3% in the sling division group and 16.6% in the control group. The sling division group has low subjective success, low QoL and a poor sexual health after the sling division. The type of sling procedure ($p = 0.038$), a concomitant surgery ($p = 0.048$) and a previous gynaecological surgery ($p = 0.031$) were identified as potential risk factors for sling division.

Conclusion: Poor subjective and objective outcome, low QoL and poor sexual health in women after sling division are shown in comparison to a control group.

Zusammenfassung

Hintergründe: Suburethrale Schlingen-OPs können Langzeit-Komplikationen wie Blasenentleerungstörungen, Schmerzen im OP-Areal sowie neu aufgetretene Dranginkontinenz hervorrufen, welche die Indikation zur Schlingendurchtrennung stellen können. Bisher gibt es wenig Literatur über Stressinkontinenzraten und Lebensqualität nach einer solchen Durchtrennung. Das Ziel dieser Arbeit war die Analyse der objektiven sowie der subjektiven Heilungsrate nach einer suburethralen Schlingendurchtrennung sowie der einhergehenden Auswirkung auf die Lebensqualität der Patientinnen. Zusätzlich wurde versucht, potentielle Risikofaktoren für die Notwendigkeit einer Schlingendurchtrennung zu identifizieren.

Methodik: Patientinnen, die sich zwischen 1999 und 2015 einer Schlingendurchtrennung unterzogen haben, wurden zu einer Studienuntersuchung eingeladen. Für jede Studienpatientin wurden zwei Kontrollpatientinnen eingeladen. Nach Anamneseerhebung wurden eine urogynäkologische und eine urodynamische Untersuchung durchgeführt. Objektive Stressinkontinenz wurde mittels eines positiven Stresstests bei einer Blasenfüllung von 300ml definiert, subjektive Stressinkontinenz durch die Bejahung der Frage „Verlieren Sie Harn bei sportlicher Aktivität, bei Anstrengung, Husten oder Niesen?“. Der subjektive Erfolg der Schlingen-OP wurde außerdem mittels der Frage des „Patient’s Global Impression of Improvement“ (PGI-I) und einer visuellen Analogskala (VAS) bezüglich der Beeinträchtigung durch Inkontinenz erhoben. Die Patientinnen füllten die Fragebögen „KING’s Health Questionnaire“ (KHQ), „Incontinence Outcome Questionnaire“ (IOQ) und „Female Sexual Function Index“ (FSFI) aus.

Ergebnisse: 15 Patientinnen wurden registriert und füllten die Fragebögen aus; davon waren 13 zur Studienuntersuchung vorstellig. Die objektive Stressinkontinenzrate war bei den Patientinnen die sich einer Schlingendurchtrennung unterzogen hatten 33.3% und 11.1% bei den Kontrollpatientinnen. Im Vergleich dazu war die subjektive Stressinkontinenzrate 53.3% bei der Studiengruppe und 16.6% bei der Kontrollgruppe. Auch der subjektive Erfolg, die Lebensqualität und die sexuelle Funktion waren bei den Frauen, die sich einer Schlingendurchtrennung unterzogen hatten, stark vermindert. Als potentielle Risikofaktoren für die Notwendigkeit einer

Schlingendurchtrennung konnten die Art der Schlingen-OP ($p = 0.038$), konkomitante OPs ($p = 0.048$) sowie vorrausgegangene gynäkologische OPs ($p = 0.031$) identifiziert werden.

Conclusio: Die subjektive sowie die objektive Heilungsrate, die Lebensqualität und die sexuelle Funktion nach einer Schlingendurchtrennung waren im Vergleich zur Kontrollgruppe herabgesetzt.

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List of Abbreviations

BMI	Body Mass Index
CI	Confidence Interval
cmH_2O	Centimetre of water
DGGG	Deutsche Gesellschaft für Gynäkologie und Geburtshilfe
FSFI-d	Deutsche Version Female Sexual Function Index
HRT	Hormone Replacement Therapy
ICS	International Continence Society
IOQ	Incontinence Outcome Questionnaire
kg	Kilograms
KHQ	KING'S Health Questionnaire
M.	Musculus
ml	Millilitres
mm	Millimetres
MUCP	Midurethral closure pressure
MUG	Medical University of Graz
OAB	Overactive bladder
PFMT	Pelvic floor muscle training
PGI-I	Patient`s Global Impression of Improvement
POP-Q	Pelvic Organ Prolaps Quantification
QoL	Quality of Life
SD	Standard deviation
SUI	Stress urinary incontinence
TVT	Tension free vaginal tape - retropubic
TVT-O	Tension free vaginal tape - obturator
UTI	Urinary tract infection
UUI	Urge urinary incontinence

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1 Introduction

"In a German saying it is told that laughing is the best medicine you can take in. But what if you can't laugh out loud light-hearted anymore, because of an illness that gives you an uncomfortable and insecure feeling?"

Urinary incontinence is a well-known condition that is studied, examined and treated in the medical subject of urogynaecology, a subfield of gynaecology and obstetrics. Up to 25% of women worldwide, especially the elderly, are affected by stress urinary incontinence (SUI) (1).

SUI is defined as the involuntary leakage during physical activity and everyday situations like sneezing, coughing or laughing that result in an increase of abdominal pressure. A weakening of the bladder muscles, especially the bladder sphincter, is the most common reason for SUI. The aetiology is multifactorial, but childbirth and ageing are the most common risk factors.

SUI has a huge impact on the quality of life (QoL), causing feelings of embarrassment and even leading to depression or work disability. In attempting to hide their problem, women often reduce their social contact and even limit their sexual relationship with their partner. Due to shame about their incontinence, patients seek medical help up to three to five years after the beginning of the symptoms. It is very important that health care professionals are sensible and question the patients without being intimidating, so that the condition can be diagnosed and treated as soon as possible (2).

The therapy for SUI includes conservative management as well as surgical therapies. As a first line treatment, pelvic floor muscle training (PFMT) as a conservative therapy can improve subjective and objective symptoms with varying success rates between 53-97% (3). A large prospective randomized trial showed that surgical therapies have a better outcome than PFMT (4). Nowadays the gold standard treatment for SUI is the midurethral sling procedure with subjective cure rates of up to 94% (5).

Currently there are different slings on the market, with Tension free Vaginal Tape (TVT) and TVT-Obturator (TVT-O) being the most common products (6). Adverse events are rare, however, postoperative complications can still occur, with voiding

dysfunction being the most common. It can even lead to urinary retention, which necessitates sling division.

In case of postoperative complications leading to sling division, patient counselling is difficult because data are lacking.

In the course of this diploma thesis we examined the objective and subjective outcomes in women who had undergone sling division for various reasons.

1.1 Urinary incontinence

1.1.1 Types of urinary incontinence

Urinary incontinence is defined as the loss of bladder control. There is an impaired function of the bladder's reservoir leading to an involuntary uncontrolled micturition. There are different types of urinary incontinence; for example urge urinary incontinence (UUI) with overactive bladder (OAB) symptoms, overflow incontinence, mixed incontinence and SUI, (7) with the latter being the main subject of this work.

1.1.1.1 OAB syndrome and UUI

The OAB syndrome is defined as a defect in the filling and the storage function of the bladder (7). Even if the bladder is not fully filled with urine, the women feel a strong and sudden need to urinate. During the filling episode, the bladder squeezes or even spasms and the bladder muscles have a higher activity, so the women feel a strong desire to void (8). If it also leads to an unwilling loss of urine it is called UUI.

1.1.1.2 Overflow incontinence

The overflow incontinence is defined as a loss of urine due to the cause of a higher pressure in the bladder than in the urethra, without any contractions of the detrusor muscle (7). The capacity limit of the bladder is exceeded due to a dysfunction of the bladder muscle (8).

1.1.1.3 SUI

Characteristic of SUI is the involuntary leakage during physical activity and everyday situations like sneezing, coughing or laughing due to an increase of abdominal pressure (7). The urethral closing mechanism is insufficient, possibly concurrent with a vaginal and rectal descensus and prolapse due to a weakness of the pelvic floor muscles (8).

1.1.1.4 Mixed urinary incontinence

The mixed incontinence is a combination of the symptoms of UUI and SUI.

1.1.2 Anatomy

The female lower urinary tract has a complex anatomy. The pelvic floor is the caudal layer of the abdominal cavity and the urethra, the vagina and the rectum pass through it. Consisting of the muscles and the perineal body, the pelvic floor gives stabilization to the urethral continence mechanism. It has to resist up to 100 cm water pressure, i.e. during coughing, to contain the continence (9). The pelvic floor also supports the bladder sphincter to control the voiding function.

1.1.2.1 The pelvic floor

Two diaphragms form the pelvic floor. Figure 1 shows the cranial view of the pelvic floor, obtained from “Waldeyer – Anatomie des Menschen” (10):

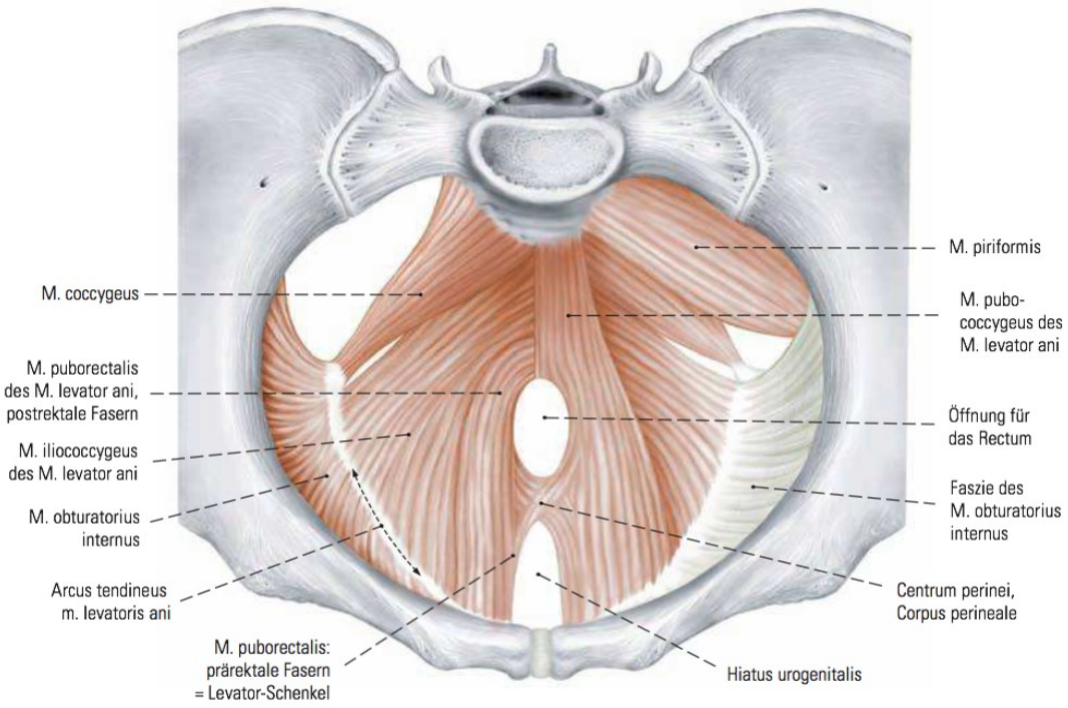

Figure 1: Cranial view of the pelvic floor, p. 1041 (10)

1.1.2.1.1 Pelvic diaphragm

Three muscles build the pelvic diaphragm: the levator ani muscle, the coccygeus muscle and the external anal sphincter (10).

The levator ani muscle is a funnel-shaped muscle-layer that forms the main structure of the pelvic floor and is made of three muscles: the puborectal muscle, the pubococcygeus muscle and the iliococcygeus muscle (see Figure 1). It has an anterior hiatus, the urogenital hiatus, through which the urethra and the vagina pass, and is mainly shaped by the puborectal muscle and the perineal centre. The posterior fibres of the puborectal muscle surround the second hiatus, through which the rectum passes (see Figure 1).

The pubococcygeus muscle stretches from the coccyges to the vaginal membrane and surrounds the rectum as well as the urethra and the vagina.

The iliococcygeus muscle forms the lateral layer of the levator ani muscle. It originates from the tendinous arch of pelvic fascia and stretches back to the anococcygeal ligament (10). The anococcygeal ligament is a fibrous cord and consists of fibres of the levator ani muscle and the external anal sphincter (8).

The coccygeus muscle is located behind the levator ani muscle. It originates from the sacrospinous ligament and the ischiadic spine and inserts on the caudal coccyges (8).

The external anal sphincter is subdivided into three layers. The subcutaneous part lies superficially and its fibres root into the skin around the anus. The superficial part consists of fibres that build two sagittal laminas between the anococcygeal ligament and the perineal centre and embed the rectum. The deep part surrounds the rectum circularly for 3 to 4 cm (10).

1.1.2.1.1 Urogenital diaphragm

The urethra and the vagina pass through the urogenital diaphragm, also known as the perineal membrane. It is a trapezoid-shaped fibrous layer between the symphysis and the two inferior pubic rami and seals the urogenital hiatus (see Figure 2) (8).

The superficial transverse perineal muscle is usually in the form of a bland muscle structure on both sides and is located on the dorsal part of the urogenital diaphragm (10).

The deep transverse perineal muscle is the main tissue of the urogenital diaphragm. It is passed through by the vagina and the urethra and stretches out from the ramus of the ischium until the inferior pubic ramus of both sides (10).
The external sphincter muscle of the female urethra is formed around it circularly and is the voluntary occlusion of the urethra.
The ischiocavernosus muscle originates from the ramus of the ischium and helps with the erection of the clitoris. The bulbospongiosus muscle originates from the perineal centre and inserts at the clitoris corps (10).
Figure 2 shows the bottom view of the pelvic floor, obtained from “Waldeyer – Anatomie des Menschen” (10):

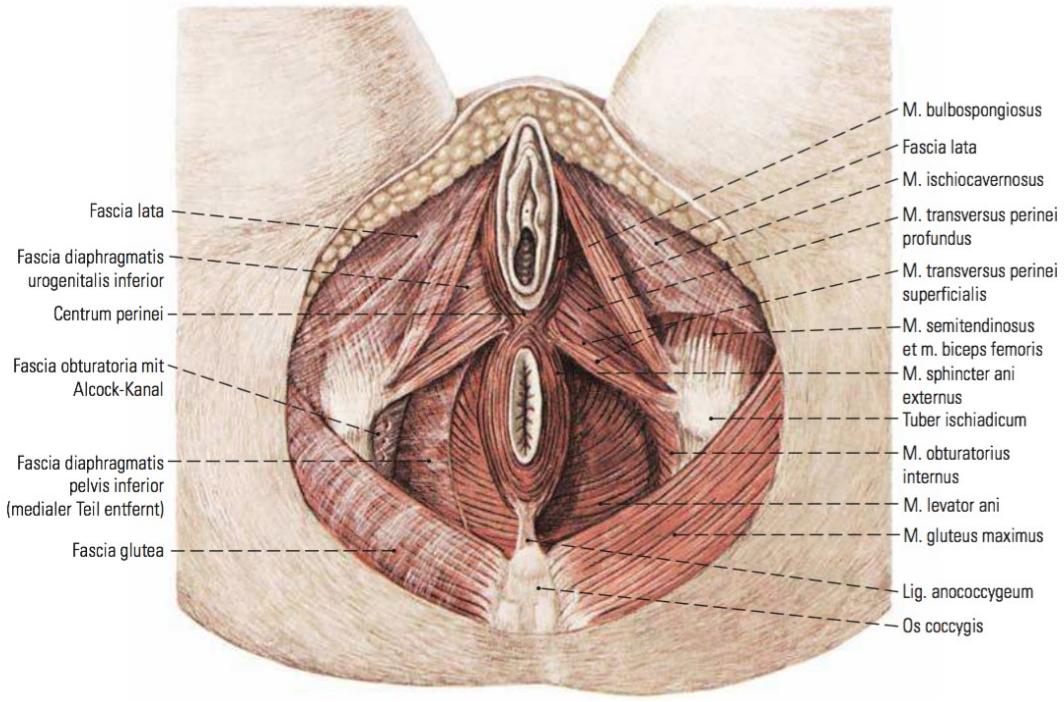

Figure 2: Bottom view of the pelvic floor, page 1042 (10)

1.1.2.2 Lower urinary tract

1.1.2.2.1 The Bladder

The bladder is located on the pelvic floor and sits between the symphysis, the uterus and the vagina. The bladder wall consists of three smooth muscle layers, which form the detrusor muscle: the outer longitudinal layer, the middle circular layer and an inner longitudinal layer (8). The urothelium is the hormone sensitive internal layer of the bladder, which makes it impermeable.

The bladder function is mainly urine storage; urine flows to the bladder through the two ureters, which insert at the fundus of the bladder, and leaves the body via the urethra (9). It has a storage capacity of up to 300 to 500 millilitres.
Around the insertion of the urethra is the funnel-shaped trigone of the bladder, which leads into the bladder neck, which in turn is the connection between bladder and urethra. The trigone only contains two muscle layers: an outer circular muscle layer and an inner longitudinal muscle layer. Fibres of the detrusor muscle are located in a specific order around the bladder neck to manage the continence and the voluntary voiding function.

1.1.2.2.1 The urethra

The urethra is about 2 to 3,5 cm long and has a urethral detrusor muscle: the urethral sphincter muscle (9).
The outer muscle layer of the urethra is the striated urogenital sphincter, also named the external sphincter muscle of the urethra. It consists of three striated muscles: the urethral sphincter muscle, the compressor urethrae and the urethrovaginal muscle. This external sphincter muscle is responsible for increase of pressure during physical activity to contain the continence and is supported by the pelvic floor (9).
Beneath that striated muscle layer, two smooth muscle layers are located, forming the internal sphincter muscle, which is a continuation of the detrusor muscle. The middle layer is arranged circularly around the urethra and the inner layer of smooth muscle is arranged longitudinally.

1.1.3 Physiology of voiding

The detrusor muscle has to manage the storage of urine as well as the voiding. The pelvic splanchnic nerves from the second, third and fourth sacral segments innervate the detrusor muscle (11). During the filling of the bladder, the distensible wall of the bladder and the nervous inhibition of the detrusor prevent an increase of pressure (8). The striated urogenital sphincter is located circularly around the urethra, is thickest in the middle of the urethra and can stabilize the pressure for a long time. By contracting, the pelvic floor muscles are a strong support if the

abdominal pressure rises (8). The autonomic nervous system controls the voluntary voiding function, which actually is a reflex process.

1.1.3.1 Voiding and reservoir function

The bladder can hold up to a maximum of 500 millilitres of urine. Voiding is a process with several steps that happen at the same time. Supraspinal and spinal reflexes control the voluntary micturition. During the filling period, an accommodation process ensures that the intravesical pressure remains constant by relaxing the detrusor muscle.

The parasympathetic nervous system supports that function and the sympathetic nervous system inhibits it (11).

The tonic contraction of the smooth muscle of the internal sphincter, controlled by the parasympathetic nervous system and the adrenoceptors, and the contraction of the striated muscles of the external sphincter manage the continence. The external sphincter muscle retains the continence at rest with a prolonged tonus of the slow-twitch fibres. During physical activity, the fast-twitch fibres of the external sphincter retain the continence by reacting very quickly to the increase of the abdominal pressure (11).

At a certain point of bladder filling, when the pressure surpasses the threshold, the pressure rises massively, which induces the micturition reflex. The parasympathetic nervous system gets activated resulting in contraction of the detrusor muscle. The internal sphincter opens passively and as a reflex the external sphincter goes limp, induced by the pudendal nerve. The cerebral inhibiting impulses on the pontine micturition center decrease, which results in starting the micturition reflex (11).

1.1.4 Aetiology and Causes

A weakening of the pelvic floor and the bladder muscles, especially the bladder sphincter, contributes to the involuntary loss of urine. Causes are multifactorial, which means the aetiology depends on many different aspects like genetics, lifestyle and the environment.

In women childbirth, obesity and ageing are the most common causes. In general, smoking and the occurrence of a cerebral insult can cause urinary incontinence. A

weak pelvic floor often correlates with vaginal and uterine descensus. A loosening of the pubourethral ligaments leads to damage in the transmission of the abdominal pressure and the urethra cannot withstand it with compression only, so it comes to an involuntary loss of urine.

1.1.4.1 Childbirth

Giving birth has a strong impact on the pelvic floor. All the muscles need to widen for the course of parturition. The foetus needs to travel all the way through the lesser pelvis. The strong muscle structure of the pelvic floor needs to be flexible for the head and body of the baby. In serial examinations it was shown that up to 50% of the examined women suffered from SUI during pregnancy (8). It is also common that women after delivery have a temporary incontinence, which can be controlled with bladder training and PFMT. There is a risk of persisting incontinence; and the number of incontinent women increases with the number of parity (12).

1.1.4.2 Neurological diseases and medication

Neurological diseases can lead to a dysfunction of the detrusor muscle, in particular a hyperreflexia of the detrusor muscle. Common diseases, such as Parkinson's disease, Alzheimer's disease, senile dementia, polyneuropathy, brain tumors and strokes, can cause UUI (8).

Also the intake of medication like anticholinergics, which have an inhibiting influence on the muscarinic receptors, contribute to declining of the tension of the vesical detrusor muscle. As consequence it leads to UUI.

1.1.4.3 Ageing

Ageing also plays a predominant role. The conjunctive tissue and the muscles loose their tenseness and decrease the stabilization of the urinary tract. Both the prevalence and the degree of severity increase in old age (12). Depending on the age, there is a difference in the distribution pattern (9). Mixed urinary incontinence and the OAB are especially present in elderly women, whereas the SUI is also common in younger women.

1.1.4.4 Obesity

Obesity changes the structure of the intraabdominal conjunctive tissue. The intraabdominal fat is also located in the lesser pelvis, which contributes to the decrease of the strength of that structure. Furthermore, the pressure on the pelvic floor due to the increased weight aids the development of SUI (12).

1.1.4.5 Smoking and menopause

Smoking leads to a higher level of carbon monoxide in the blood, which causes damage of the conjunctive tissue. This results in lesser perfusion and causes problems in the collagen synthesis (9).

Oestrogen deficiency, which occurs after menopause, has an impact on the appearance of incontinence (9).

1.1.5 Symptoms and level of severity of SUI

The main symptom is the involuntary leakage of urine. In addition, the anxiety of others smelling the urine loss and the constant inner tension trying to control the urine loss have a huge psychological impact on the patients. This can lead to depression and social denial (13). Moreover, people with urinary incontinence tend to be more prone to urinary tract infections (UTI).

Depending on the severity of SUI it can start with a dropping loss of urine till a gush of urine loss.

There are three levels of severity of SUI defined by Ingelmann-Sundberg (14):

I) Loss of urine during strong physical activity (jumping, coughing, sneezing, laughing)

II) Loss of urine during moderate physical activity (carrying, walking, climbing stairs)

III) Loss of urine during standing without physical activity

1.1.6 Diagnostics

1.1.6.1 Medical History

In the very first medical appointment, a detailed medical history of the woman should be taken. History should include age, weight, height, symptoms, pad usage, impairment of urine loss, parity, menopausal status and previous gynaecological treatment or surgeries. Additionally, concurrent diseases, current medication and previous therapies for incontinence are matters of interest. The patient should give an overview of the daily micturition and the drinking habit.

1.1.6.2 Gynaecological examination and Pelvic Organ Prolapse Quantification (POP-Q)

The gynaecological examination should start with the inspection of the outer female genital and an examination for any signs of a urogenital prolapse or haemorrhoids. By retracting the speculum, the patient is asked to cough or push, in order to see a potential prolapse, like a cystocele, urehtrocele, enterocele or rectocele (8). Following this the POP-Q as defined by the International Continence Society (ICS) is assessed (9). Six points and three measurements are assessed (see Figure 3). Two points are located on the anterior vaginal wall (Aa, Ba) and two on the posterior vaginal wall (Ap, Bp). Point C is defined as the most distal edge of cervix or the leading edge of the vaginal cuff (C); point D as the posterior fornix or the pouch of Douglas (D). The three measurements include the genital hiatus (gh), the perineal body (pb) and the total vaginal length (tvl) (15–17).

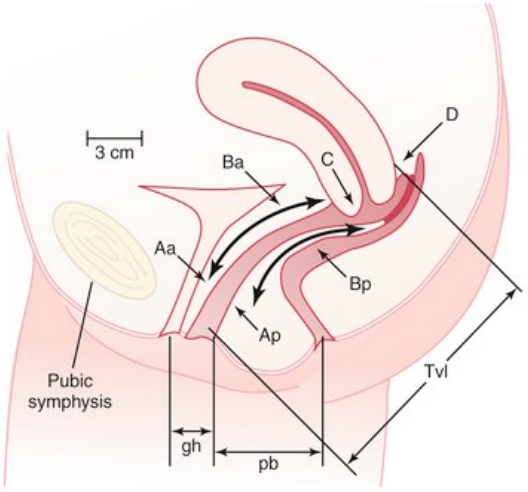

Figure 3: Side-view of female pelvis showing POP-Q measurements from (18)

The data from the POP-Q is recorded in a grid as shown in Table 1:

Table 1: Grid for measured data of POP-Q, reproduced from Bump et al. (16)

anterior wall **Aa**	anterior wall **Ba**	cervix or cuff **C**
genital hiatus **gh**	perineal body **pb**	total vaginal length **tvl**
posterior wall **Ap**	posterior wall **Bp**	posterior fornix **D**

Through bidigital examination, the pelvic floor and its function are tested. The patient is asked for a voluntary contraction of the pelvic floor and the strength and activity are sensed with the two fingers.

1.1.6.3 Urogynaecological examination

1.1.6.3.1 Urine analysis

For the urogynaecological examination, the urine has to be analysed to exclude a UTI possibly responsible for the urine loss.

1.1.6.3.2 Bladder sensation and cough stress test

A bladder filling is done with a catheter until a bladder sensation is felt – the maximum holding capacity is noted. Letting the patient cough on the gynaecological examination chair with a full bladder is known as an objective stress test. If no sign of incontinence appears, to escalate the objective stress test, the patient is asked to stand up and cough again whilst standing. If no urine leaks at a total bladder filling of 300 millilitres, the cough stress test is negative.

1.1.6.4 Urodynamic testing

Urodynamic testing are special examinations for the bladder and the urethra. Conclusions can be drawn, as to whether the problem is due to vesical or subvesical functional damage.

1.1.6.4.1 Cystometry

The cystometry is a standardized method to measure the relation between pressure and capacity during the bladder-filling period. The two-catheter method has one catheter for filling the bladder with saline and another that contains a pressure sensor. Simultaneously the abdominal pressure is measured with a vaginal or rectal catheter (9).

The detrusor pressure is then calculated by subtracting the abdominal pressure from the vesical pressure. With this method, involuntary contractions of the detrusor muscle during the filling period can be detected, which normally should not occur in a healthy patient. Involuntary detrusor contractions can be evidence of UUI (8).

1.1.6.4.2 Urethrocystoscopy

The urethrocystoscopy is indicated in case of urge symptoms, voiding dysfunction, recurrent UTIs or haematuria that are noticed by the patient (19). This is an endoscopic method to evaluate the inside of the urethra and the bladder, to detect any inflammation, swelling or tumour and to locate any bleeding, fistulas or foreign objects.

1.1.6.4.3 Urethral pressure profile

This diagnostic procedure measures the midurethral closure pressure (MUCP) and gives information about the urethral closure function (9). Steadily a catheter with a pressure transducer, as the one of the cystometry, is retracted through the urethra and the pressure is recorded constantly. The MUCP is calculated by subtracting the vesical pressure from the maximum pressure captured in the urethra. For a normotensive urethra the MUCP should be around (100 – age in years) cm H2O, or at least around 25 cm H2O. If the calculated pressure is below 20 cm H2O, it is a hypotensive urethra and the surgical treatment for SUI is known to have a bad outcome (9).

The functional length of the urethra is the length of the urethral detrusor muscle. The length corresponds to the section where the urethral pressure is higher than the vesical pressure, and the standard is more than 25 mm (9).

1.1.6.4.4 Uroflowmetry and residual urine volume

The patient is voiding into a funnel. The funnel is connected to a sensor, which can measure how much fluid is entering per time. A normal rate would be 20 ml/s. After voiding is completed the residual urine volume can be measured in order to check any incomplete voiding.

1.1.6.5 Imaging

A urogenital ultrasound is preferred to evaluate the bladder, the urethra and the pelvic floor muscles topographically and functionally. The two ultrasonographic methods, introitus and perineal, are done to detect any possible risk factors for the surgical treatment of SUI. The parameters assessed include length and mobility of the urethra, height of the vaginal sulcus, funneling of the urethra, avulsion of levator ani muscle or detection of urethral diverticulum. An urogynaecological ultrasound is important for planning the surgery because the above-mentioned parameters can have an impact on the outcome of the surgical treatment and facilitates correct implantation of the suburethral sling. Hence, preoperative ultrasound is an essential part of the clinical examination preoperatively (19).

After the surgical procedure the urogenital ultrasound is also a very effective diagnostic tool for evaluating failures of sling procedures, recurrent SUI, postoperative voiding dysfunction, dysuria, dyspareunia and de-novo UUI.

1.1.7 Therapy and Treatment of SUI

SUI can be treated in two different ways – with conservative treatment or with surgery. The following approach is based on the German guideline "Interdisziplinäre S2e-Leitlinine für die Diagnostik und Therapie der Belastungsinkontinenz der Frau" (19).

1.1.7.1 Conservative treatment

There are several options for the conservative way of treating SUI, such as weight-loss, physiotherapy, medication and medical aids. Weight-loss is recommended with at least a loss of 5% of weight, and is known to benefit up to 60% of the women with SUI (20).

Another option is the use of Duloxetine on an 80mg per day dose. It is a serotonin-norepinephrine reuptake inhibitor and is also licensed for depression and peripheral diabetic neuropathic pain. Duloxetine can have significant side effects like nausea, emesis, vertigo, obstipation, fatigue and insomnia. It is therefore recommended to start at a low dose so that the body can slowly adapt to it (21). As the side effects are limiting factors to daily life, a lot of women stop using the medication (22). Its indication is discussed controversially and it is hardly recommended anymore.

Use of pessaries and special incontinence tampons are also possible aids for SUI. They can be changed by the woman herself and should be worn during physical activity. At night, there should be a pause of usage in order to give rest to the vaginal mucous membrane.

A very effective method to treat SUI is PFMT. The idea is to strengthen the pelvic floor muscles to control the pelvic floor during physical activity. PFMT can significantly reduce SUI symptoms, however subjective improvement is higher with a midurethral sling surgery; 64.4% compared to 90.8% (4).

1.1.7.2 Surgical treatment

If all options for conservative treatment are exhausted, a surgical approach can be considered. The main surgical goal is to stabilize the urethra behind the symphysis (8).

1.1.7.2.1 Bulking agents

The urethra should remain closed during physical activity with the use of bulking agents, which are plumping up the urethral mucosa. Nowadays almost only polyacrylamide hydrogels, also known as “Bulkamid”, are used. These agents are injected periurethral to widen the urethral tissue. The injection gives volume to the urethral sphincter and as a consequence the urethra is constricted. It is known that the long-term response rates are not as good as the ones of the surgeries and a repeat injection is necessary (14).

1.1.7.2.2 Burch colposuspension

The Burch colposuspension is the oldest surgery with good long-term results (8,23). Thereby, after a small suprasymphyseal incision, the fibres of the rectus abdominis muscle are separated to get access to the neck of the bladder. With two non-absorbable sutures on each side, the paravaginal fascia gets attached to the Cooper`s ligament. Thereby the urethra gets pulled up, which results in increased stabilization (24). Later, due to the development of surgical techniques, the laparoscopic approach for the Burch colposuspension was introduced with similar good outcomes (25,26).

1.1.7.2.3 Midurethral slings

The current gold standard is midurethral slings. The continence rate is up to about 90% (27). The Tension free Vaginal Tape (TVT) introduced by Ulmsten in 1996 is a retropubic sling (see chapter “1.2.1. Retropubic sling”). The Transobturator Tape sling (TOT) and the Tension free Vaginal Tape – obturator (TVT-O) are transobturatoric slings (see chapter “1.2.2. Transobturatoric slings”) (28).

1.2 TVT and TVT-O

1.2.1 Retropubic sling

The TVT surgery can be performed in analgosedation and local anaesthesia, and is realised in lithotomy position. At the beginning the patient is catheterised. The two points where the sling needles exit are marked. This is just right above the symphysis, each about two centimetres from the median.

Through a small median anterior colpotomy at the level of the middle-section of the urethra, about one centimetre above the external urethral orifice, the urethra is edged off softly to reach the urogenital diaphragm by blunt dissection of the tissue. Using this access, the sling is placed around the middle-section of the urethra by softly bending the urethra with the cystoscopy to the contralateral side and the two ends are placed through the two marked incisions above the symphysis (see Figure 4).

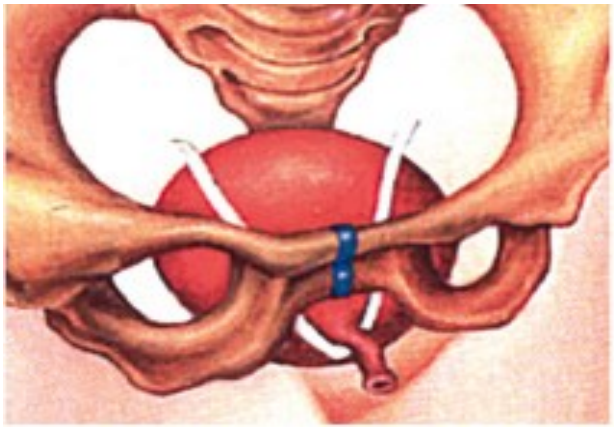

Figure 4: TVT sling reproduced from (28)

The sling has to be positioned tension-free around the urethra. Its purpose is to secure the urethra but not elevate or obstruct it. The two suprasymphyseal ends are trimmed to the skin. No further fixation is necessary, as the sling's texture is self-retaining. During sling placement the needles could come in contact with the bladder; therefore a cystoscopy is done to exclude injury of the bladder (29–31).

In a ten-year after TVT sling procedure follow-up study, 84% showed objective incontinence cure rate but only 57% subjective cure rate (32).

1.2.2 Transobturatoric slings

The TOT is an outside-in technique where the sling is placed through the obturator foramens under the urethra and the TVT-O is an inside-out technique also placed under the urethra but the ends exit through the obturator foramens (28). As the patients in this study did not undergo any TOT procedures, only the TVT-O procedure is explained further.

The TVT-O sling procedure was introduced by Delorme 2001 due to the complications that occurred during passing through the lesser pelvis with the TVT slings' needles (33,34). The sling is placed under the endopelvic fascia and therefore avoids intruding into the retro-pubic space. Fewer complications are reported in regard to bladder perforations (35). De Leval introduced the inside-out technique in 2003; this is the so-called TVT-O sling (36).

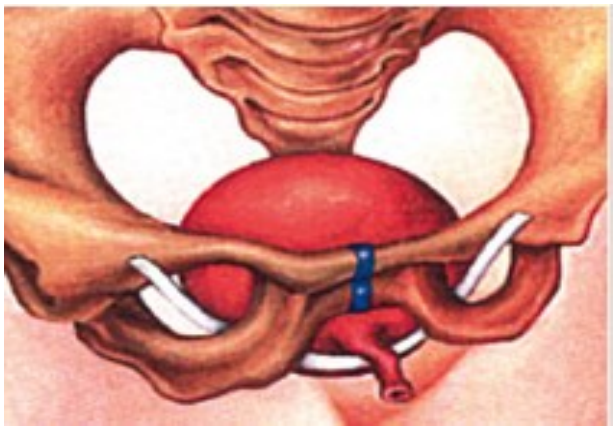

Figure 5: TVT-O sling reproduced from (28)

For optimal sling placement through the obturator foramens, the lithotomy position is extended to a hip flexion of 120°. The sling is placed like the retropubic sling through the anterior median colpotomy around the urethra but the two ends exit through the obturator foramen on each side (see Figure 5). A paraurethral blunt dissection to the pubic bone is done for reaching the obturator membranes on each side. Through these membranes the surgeon pushes through the TVT-O needles. Again, the sling is supposed to lie around the urethra without any tension (31,36).

In a ten-year after TVT-O sling procedure follow-up study, the objective incontinence cure rate, also measured with a cough stress test, was 69% and the subjective cure rate was 64% (37). This shows that the TVT and TVT-O surgeries result in a relatively good outcome and patients' satisfaction in the long-term.

1.2.3 Outcome and comparison of TVT and TVT-O sling surgeries

Three-months after the TVT or TVT-O sling surgeries it was shown that up to 87% of patients with TVT and 84% with TVT-O sling procedure had a negative cough stress test and a stable cystometry to 300 millilitres (35). There was zero percent of bladder perforation in the group of patients who underwent a TVT-O sling procedure in comparison to 3.9% of bladder perforation in the group who underwent a TVT sling surgery (35).

Similarly, a study with five-year follow-up after a TVT sling procedure showed very good outcome and patients' satisfaction. The negative cough stress test revealed the objective continence cure rate to be at 85% while the subjective cure rate was 59% (38).

Long-term follow-up studies of the TVT procedure showed objective cure rates of 84% to 90% and subjective cure rates of 57% to 77% after 10 to 11.5 years (32,39). No significant differences were found in another study comparing the TVT-O procedure with the TVT procedure (81,5% objective and 84% subjective cure rates) (40). Increasing age, concurrent prolapse surgery and preoperative intake of anticholinergics are associated with the reoccurrence of SUI (41).

1.3 Complications during and after TVT and TVT-O surgeries

1.3.1 Complications during operation

A common complication is the bladder perforation after a TVT (42). Management consists of antibiotics and by leaving a transurethral catheter for a couple of days. If a bladder perforation is missed, recurrent UTIs and urge symptoms can be a sign to recognize it (9,43,44).

Another intraoperative complication is bleeding due to vessel injury (45). Most of the bleeding can be handled conservatively by tamponing the wound. Extremely rare cases are mentioned where bigger vascular damage was done (45,46).

1.3.2 Postoperative and long-term complications

The most common postoperative complications are haematoma, pain in groin and thighs, vaginal perforation, mesh erosion, OAB and voiding dysfunction (47,48). Most of the time the haematoma resolves during the first postoperative days. In

only few cases, the haematoma have to be removed with a suprapubic catheter or surgically to allow normal voiding (49).

In case of mesh erosions, they should first be treated conservatively with oestrogen. Persisting erosions can be treated by refreshing the colpotomy or partial sling excision (46).

Pain in groin and thighs can be released with a partial excision or a complete sling division.

OAB symptoms were the main reason for dissatisfaction after a TVT sling procedure. This is shown in a ten-year follow-up study at the MUG. Of the 141 patients who were reachable for follow-up, 56 patients didn't feel cured after the sling implantation. The main reason for not feeling cured were OAB symptoms in 52% of those patients (50). OAB symptoms are mostly caused by urethral irritation due to the positioning of the sling and can be treated with PFMT, anticholinergic treatment or local oestrogens (9,51).

Voiding dysfunction occurs in up to 6% of the cases (52). If the voiding dysfunction persists or urinary retention occurs, a loosening of the sling or even a sling division can be necessary (49). Sling loosening is only possible within the first postoperative week and the old colpotomy can be used. Later on a sling division or a partial excision needs to be performed (9,53).

1.4 Current evidence about sling division

A complete sling removal has a higher risk of recurrent SUI than a partial removal of the sling or even just a sling loosening or incision (54,55). Unger et al. found an association between the necessity for a sling division after two previous sling surgeries (56). Also a history of pre-operative obstructive voiding symptoms has been associated with sling division. Additionally, retropubic slings had to be divided more often compared to other sling types. Concurrent surgeries can also contribute to the necessity of a sling division (57).

There is very little literature available about SUI rates and QoL after sling division. To date, there is no clinical study that reports the objective outcome and the QoL in women who underwent a sling division.

The aim of this study was to analyse the postoperative subjective and objective outcome in women after a sling division.

2 Methods

2.1 Goals

The aim of this cohort study is to evaluate the postoperative outcome after a sling division and the impact of the sling division on the QoL of these patients.

2.1.1 Main outcome parameter

The main outcome parameter was the objective incontinence rate after a sling division defined as a positive cough stress test at a bladder filling of 300 millilitres.

2.1.2 Secondary outcome parameters

A wide range of secondary outcome parameters was also assessed in the course of the study. One important outcome parameter was the subjective incontinence rate. Women were asked whether they considered themselves incontinent at time of follow-up.

Patient's satisfaction after a sling division procedure was also assessed with the PGI-I as described in chapter "2.5.2. Study examination". Also, two self-assessments regarding the severity of SUI and UUI were done with a visual analogue scale from 0 to 10.

Furthermore, patients were interviewed about the following parameters: any reoperations, medication, especially anticholinergics or the use of pads, UTIs during the last year, concurrent diseases, pain in the operative region, and OAB symptoms.

Additionally, risk factors that could have led to the sling division were searched for, such as previous gynaecological surgeries, concomitant surgeries, BMI or the MUCP.

The QoL after a sling division was assessed through the KING's Health Questionnaire (KHQ), see chapter "2.5.4.1. KHQ Questionnaire", and the Incontinence Outcome Questionnaire (IOQ), see chapter "2.5.4.2. IOQ Questionnaire". Sexual health was assessed using the Female Sexual Function Index (FSFI), see chapter "2.5.4.3. FSFI-d questionnaire".

2.2 Study population and design

The study population included patients who underwent a sling division of a TVT sling or a TVT-O sling procedure between 1999 and 2015.

Patients were identified using the institutional database of the Medical University of Graz (MUG), MEDOCs, and the operative reports, provided by the department of medical informatics of the MUG.

Inclusion criteria were any women who had to undergo sling division of a TVT sling or a TVT-O sling between 1999 and 2015, aged 18 to 88 years, with good German language skills and the ability to attend a clinical examination. Exclusion criteria were women who were older than 88 years, underwent a different sling surgery than TVT or TVT-O, as i.e. Remeex, or unwillingness to participate.

Patients were invited via mail, which included an invitation letter for a follow-up examination at the outpatient clinic of the "Universitätsklinik für Frauenheilkunde und Geburtshilfe – Landeskrankenhaus Graz". Every woman was asked to fill out three urinary incontinence specific questionnaires. Informed consent was obtained from all patients.

After identifying the study patients a control group was established by matching two control patients that underwent a sling surgery, without a sling division or any other sling related surgery. The control patients had to match in regard to the type of sling procedure, age and date of the sling implantation.

Some of the control patients were drawn out of the "Ten-year follow-up after the tension-free vaginal tape procedure" study (32). For these patients the clinical data was already present and only the questionnaires had to be obtained.

2.3 Time plan

The clinical examination took place between June 2015 and January 2016. On average 7 patients were invited per month, about two patients per week. The data was evaluated during summer and autumn of 2016. Data analysis was performed in November and December 2016.

2.4 Ethics vote

The Ethics Committee of the Medical University of Graz approved this study (EC-number: 27-211 ex 14/15).

2.5 Collection of data

For collection of the data, the medical history charts were reviewed and the data was collected in a Microsoft Excel file.

2.5.1 Clinical and demographic data

The medical history was retrieved from the MEDOCs system. The parameters were collected both before the initial surgery and before the sling division and included number of pads, any sensation of OAB, intake of anticholinergics, status of menopause, height, weight, BMI, number of deliveries, smoking, recent UTIs, sexual activity and dyspareunia, previous and concomitant gynaecological operations, previous incontinence operations besides TVT and TVT-O surgery, concomitant illness, vaginal erosions, pelvic organ prolapse quantification (POP-Q), data of an urogynaecological examination and data of an urodynamic evaluation. Urodynamic assessment included the measurement of the residual volume of urine, the first bladder sensation during bladder filling, the total capacity of the bladder, any involuntary contractions of the detrusor muscle, the MUCP and an objective cough stress test.

In regard to the surgery the exact information regarding the division including the indication and the type of the division was recorded.

2.5.2 Study examination

A detailed medical history was taken again during the follow-up appointment. In addition, patients were asked regarding pain in the groin or thighs and intake of painkillers, according to the study examination protocol.

The patient's global impression of improvement (PGI-I) was also assessed with the question "Check the number that best describes how your post-operative condition is now, compared with how it was before you had the surgery" with a scale from 1 to 7 (1 = very much better, 7 = very much worse). The scores 1 to 3

defined as subjective cure and improvement, a score of 4 defined as unchanged and the scores 5 to 7 defined as unimproved and worsened.
For the subjective incontinence rate, patients were asked if they leak urine when they cough, sneeze or laugh.
Also, the self-assessment of severity of the impairment of SUI and of UUI were measured with a visual analogue scale (VAS) from 0 to 10 (0 = no impairment, 10 = a lot impairment).
An urogynaecological examination was performed as described in chapter “2.5.3. Urogynaecological and urodynamic examination”.

2.5.3 Urogynaecological and urodynamic examination

The urogynaecological examination and urodynamic testing were performed as described in chapters “1.1.6.3. Urogynaecological examination” and “1.1.6.4. Urodynamic testing”. The examinations were done by attending surgeons from the department of gynaecology and obstetrics of the MUG. A standardized examination protocol was given to all of the examining doctors and included a POP-Q, the measurement of the residual urine volume, measurement of any detrusor actions, an assessment of the MUCP, an objective cough stress test and a cystoscopy if indicated.
The objective cure was defined by a negative cough stress test at a maximum bladder filling of 300 millilitres.

2.5.4 Questionnaires

The follow-up investigations included the completion of three questionnaires (see attachment). Patients who were not available for a clinical follow-up examination were asked to mail the questionnaires with a free of charge postal return envelope.

2.5.4.1 KHQ Questionnaire

The KHQ was validated for the assessment of the impact of incontinence on QoL with a survey of 32 questions. For the patients it is easy to complete and easy understandable. Therefore it is a good means for a follow-up study of women with urinary incontinence and women who underwent a urinary incontinence surgery.

There are two general questions about the general health perception and the incontinence impact and several subgroups to identify the affection of incontinence in different life settings like role limitations, physical limitation, social limitation, limitation of personal relationship, influence on emotions, sleep, energy, the severity of the incontinence and an appraisal of potential OAB symptoms.
The scores are calculated for each subgroup and can be from 0 to 100 points, whereas the lower the scores, the better the QoL of the patients.
For the patients of this study, a validated German version (58) of the survey was used.

2.5.4.2 IOQ-Questionnaire

The IOQ-Questionnaire is a survey with 26 questions that assesses the QoL after a surgical treatment for SUI.
There are four different subgroups regarding the postoperative outcome of symptoms and complications that occurred after the surgery, QoL and satisfaction after the surgery and another subgroup with demographic data. Additionally there is a single item question about pre-operative symptoms.
The scores are calculated for a large subgroup, the original scale of QoL and satisfaction, and nine single items. The scores can be from 0 to 100 points, whereby the lower the scores, the better are the outcome of the surgical treatment and the QoL of the patients.
For the patients of this study, again a validated German version (59) of the survey was used.

2.5.4.3 FSFI-d questionnaire

The FSFI-d is a questionnaire with 19 questions that assesses the female sexual function and dysfunction during the last four weeks.
There are six subgroups about desire, arousal, lubrication, orgasm, satisfaction and pain, each with two to four questions.
The minimum scores can be 0, 0.8 and 1.2 depending on the domain and the maximum score can be 6. There is a full-scale score with a minimum score of 2 and a maximum score of 36.

The lower the scores, the lower the sexual function. Scores of zero indicate no sexual activity at all.
For the patients of this study again a validated German version (60) of the survey was used.

2.5.5 Statistics

A basic statistical analysis was done in Microsoft Excel by calculating the mean, median, standard deviation and range.
Statistical analysis was performed with MATLAB 2016b (developed by MathWorks). Differences of preoperative parameters between sling division and control group, that could hint risk factors for a sling division, were analysed with a linear regression model.
The data from the follow-up examination are given descriptively and differences between the groups are shown in diagrams and charts.
The questionnaire data was analysed with descriptive statistics using Microsoft Excel.

3 Results

3.1 Data before sling implantation and sling division

3.1.1 Study population

In the operative reports, 34 patients underwent a sling division. From 9 of those 34 patients, the data was obtained through the study “Ten-year follow-up after the tension-free vaginal tape procedure” (32).

Of these 34 patients: 5 already passed away, 2 patients were too old for the inclusion criteria as the age limit was 88 years, 8 patients declined participation and 4 patients were lost for the follow-up examination (see Figure 6).

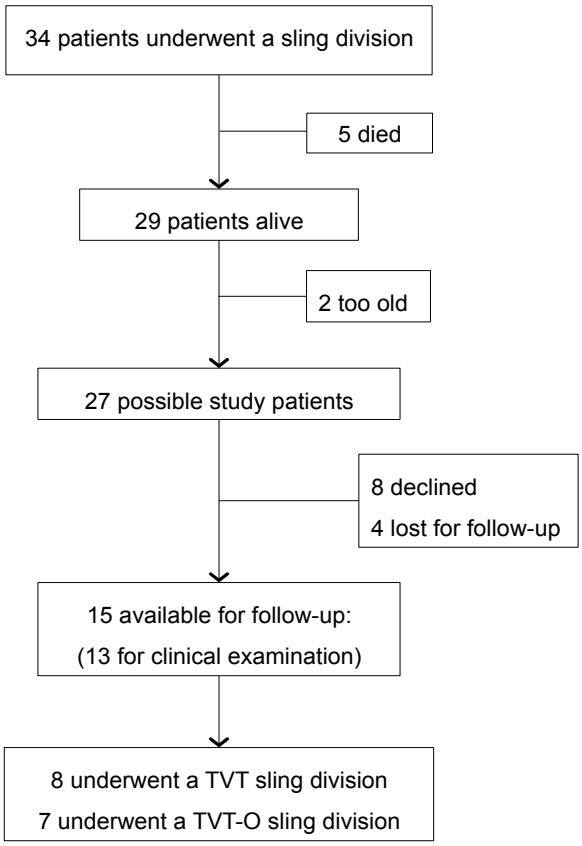

Figure 6: Flow chart of the sling division group

For each patient of the sling division group, two control patients were selected. 30 matching control patients were selected for the 15 sling division patients (see Figure 7).

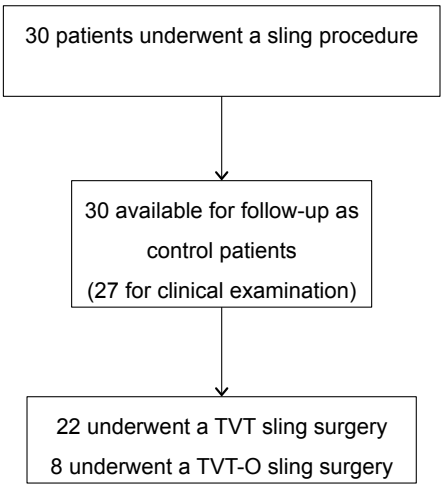

Figure 7: Flow chart of the control group

3.1.2 Demographic data and urodynamic data

Demographic data was collected from all patients and is shown in Table 2.
The women who underwent a sling procedure were mostly overweight to obese with a mean age of 58.3 years and a mean BMI of 30 kg/m^2.
At the time of sling implantation, the majority (91%) was postmenopausal, 55% without and 36% with a hormone replacement therapy (HRT) and only 9% were premenopausal.

Six out of 45 patients (13%) had had a previous incontinence surgery. 50% of those had undergone a Stamey procedure, 33% a Burch colposuspension and 17% a Peirera needle suspension. For the majority, the sling implantation was the first incontinence surgery.

A previous gynaecological surgery was documented for 19 out of the 45 patients (42%). This means that almost half of them already had cicatricial tissue in the lesser pelvis before the sling implantation. The most common preceded surgery was a vaginal hysterectomy including a colporrhaphy, which was done on nine out of 19 patients (47%) followed by vaginal hysterectomy in five out of 19 patients (26%). The other previous gynaecological surgeries were surgery for ovarian carcinoma, laparoscopic tubal sterilisation, C-section with postpartal tubal

sterilisation and adnexectomy, Wertheim-Meigs surgery and vaginal hysterectomy with colporrhaphy and adnexectomy.

Two thirds of the patients (30 patients) underwent a TVT sling procedure and one third (15 patients) underwent a TVT-O sling procedure. The suburethral slings used were from Ethicon; Gynecare TVT (Somerville, NJ) and Gynecare TVT-O (Johnson & Johnson).
For 15 of the 45 patients (33%), a concomitant surgery was planned. The main concomitant surgery was vaginal hysterectomy including colporrhaphy in 6 out of 15 patients (40%). Four out of the 15 patients had vaginal hysterectomy (27%), two out of 15 (13%) hysteroscopy with curettage. Colpoperineorrhaphy, laparoscopic adnexectomy with colpoperineorrhaphy and hysteroscopy were done only once.
These subtle structural and anatomic changes in addition to the sling implantation might have led to peri- and postoperative complications.

At the time before sling implantation, 42 patients had given birth 0 to 7 times with a median of 2. Five patients had not given birth at all and two patients had given birth to six or seven children. For three patients the parity was not recorded.

The range of pad usage per day varied from 0 to 10 with a median of 3 pads a day among 36 patients. Three patients reported no usage of pads at all and two patients reported usage of 9 or 10 pads a day.
Preoperatively, 10 out of 44 patients (23%) felt OAB symptoms and only one out of 31 patients had positive detrusor contractions.
The median of the residual volume of urine was 0 millilitres, indicating no obstruction to the majority. Only one out of the 20 examined patients had a residual volume of 235 millilitres.
The mean MUCP was 51 cm H_2O with a standard deviation of 26.8 cm H_2O (n = 26 patients). Three patients showed a low MUCP with 18 cm H_2O, 20 cm H_2O and 23 cm H_2O.

Table 2: Data at time before sling implantation of whole study population

Parameters	Whole study population
Age (years)	58.3 ± 5.8
BMI (kg/m^2)	30 ± 7.2
Menopausal status:	
Premenopausal	4 (9)
Postmenopausal	25 (55)
HRT	16 (36)
Parity	2 (0-7)
Type of sling procedure:	
TVT	30
TVT-O	15
Previous incontinence surgery	6 (13)
Stamey procedure	3 (50)
Previous gynaecological surgery	19 (42)
Vaginal hysterectomy+colporrhaphy	9 (47)
Concomitant surgery	15 (33)
Vaginal hysterectomy+colporrhaphy	6 (40)
Pads	3 (0-10)
OAB symptoms	10 (23)
Positive detrusor contractions	0
Residual urine (ml)	0 (0-235)
MUCP (cm H_2O)	51 ± 26.8

Data are expressed as mean ± SD or number (%) or median (range).

The minimum time between a sling implantation and the division of the sling was just a few days up to one month in 4 patients, as indicated by direct postoperative complications. The maximum was 81 months. Overall the time delay varied from zero to 2, 8, 11, 13, 22, 53, 56 and 81 months (see Table 3).

The main reason for a sling division was a foreign body sensation in five out of 12 patients (42%). Three out of 12 patients (25%) claimed voiding dysfunction and 2 patients reported OAB symptoms (17%). Pain and pain with foreign body

sensation were recorded for one of the 12 patients (8%), respectively. For three patients, the reason for sling division was not documented (see Table 3).

Table 3: Sling division patients – time in between and reason for sling division

Parameters	Sling division patients (n=15)
Time between sling implantation and division (months)	9.5 (0-81)
Reason for sling division	
Voiding dysfunction	3 (25)
Pain	1 (8)
Foreign body sensation	5 (42)
OAB	2 (17)
Pain and Foreign body sensation	1 (8)
Unknown reason	3 (25)

Data are expressed as median (range) or number (%).

3.2 Data at time of follow-up examination

Demographic parameters at time of follow-up are shown in Table 4.

Table 4: Data from follow-up examination structured in main and secondary outcome parameters, divided in sling division and control group

Parameters	Sling division group	Control group
Objective SUI rate	4 (33.3)	3 (11.1)
Subjective SUI rate	8 (53.3)	5 (16.6)
PGI-I (1-7)	4 (1-7)	2 (1-6)
VAS – SUI (0-10)	4 (0-10)	0 (0-7)
VAS – UUI (0-10)	7 (0-10)	2 (0-7)
Incontinence reoperation	4 (26.7)	1 (3.3)
Anticholinergic medication	5 (33.3)	4 (13.3)
Pad usage daily	11 (73.3)	11 (36.6)
UTIs	5 (35.7)	6 (20)
Concurrent disease	6 (40)	6 (20)
Pain	3 (20)	2 (6.7)
OAB Symptoms	8 (53.3)	12 (40)
MUCP (cm H_2O)	35 ± 10.8	47 ± 34.3

Data are expressed as mean ± SD or median (range) or number (%).

The results are analysed in the following chapters “3.3 Main outcome parameter – objective incontinence rate” and “3.4 Secondary outcome parameters”.

3.3 Main outcome parameter – objective incontinence rate

Four out of the 12 sling division patients who were available for follow-up had a positive clinical stress test. Thus, 33.3% were not cured (see Figure 8).

In comparison just three out of the 27 control patients had a positive clinical stress test. In that group only 11.1% were not cured based on that objective stress test (see Figure 8).

3.4 Secondary outcome parameters

3.4.1 Subjective incontinence rate

Through the self-assessment, meaning the patient's own judgement on it's continence, the subjective incontinence rate was assessed.

Eight out of 15 sling division patients and only five out of 30 control patients considered themselves as still suffering from SUI. Therefore 53.3 % of the sling division group and in comparison only 16.6% of the control group were considered as subjectively non-cured (see Figure 8).

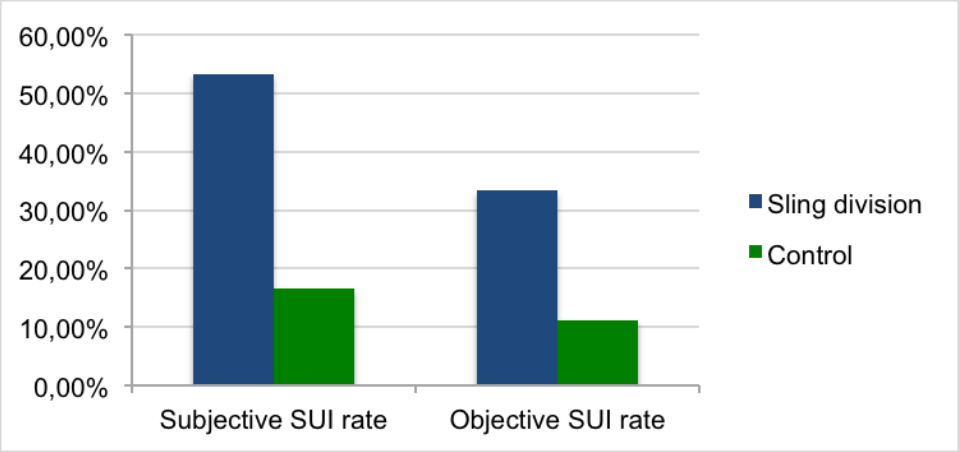

Figure 8: Comparison of subjective vs. objective incontinence rate

The PGI-I was also assessed. In the sling division group the median of the scores on the scale was 4 with a range of 1 to 7. In the control group the median of the scores was 2 with a range of 1 to 6 (see Table 5).

In the sling division group eight out of 15 patients (53.3%) reported that the condition was unchanged to worsened according to the PGI-I than before the sling surgery. 46.7% reported improvement according to the PGI-I.

In comparison to that, only six out of 27 patients in the control group (22.2%) reported an unchanged to worsened condition, but 77.8% of them reported improvement.

Table 5: PGI-I, VAS for SUI impairment and VAS for UUI impairment (excerpt from Table 4)

	PGI-I	VAS of SUI	VAS of UUI
Sling division group	4 (1-7)	4 (0-10)	7 (0-10)
Control group	2 (1-6)	0 (0-7)	2 (0-7)

Data are expressed as median and range.

53.3% of the patients in the sling division group considered themselves worse. In comparison, only 22.2% of the control group felt that way.

Also the self-assessments of severity of the impairment of SUI and UUI were assessed with a visual analogue scale (VAS) from 0 to 10 (0 = no impairment, 10 = a lot impairment).

On the VAS of SUI impairment, the sling division group had a median score of 4 with a range of 0 to 10. In the control group the median score was 0 with a range of 0 to 7 (see Table 5). On the VAS of severity of SUI impairment, 60% of the sling division group chose the numbers from 0 to 4 on the scale, in contrast to 88.9% of the control group that chose between 0 and 1 on the scale. This shows that the control group felt much less impairment from SUI.

In regard to VAS of UUI impairment, the sling division group had a median score of 7 with a range of 0 to 10. In the control group the median score was 2 with a range of 0 to 7. On the VAS of severity of UUI impairment, 40% of the sling division group chose between 0 to 1 on the scale and 61.1% of the control group chose the numbers from 0 to 3 on the scale. This shows that more patients from the control group tended to feel less impairment from UUI but with a wider range.

In the sling division group the highest VAS score for SUI and UUI was 10 while it was 7 in the control group.

3.4.2 Severity of urinary incontinence

Four out of the 15 sling division patients (26.7%) underwent an incontinence reoperation in comparison to just one out of the 30 control patients (3.3%). Five out of the 15 sling division patients (33.3%) were taking anticholinergic medication at that moment in comparison to just four out of the 30 control patients (13.3%).

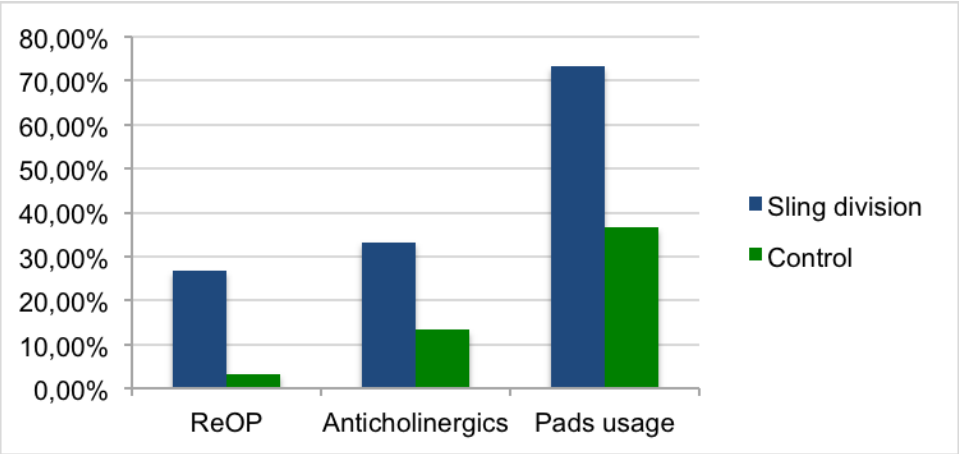

Figure 9: Severity measures taken to handle urinary incontinence, comparison of sling division and control group

11 out of the sling division group (73.3%) as well as out of the control group (36.6%) were using pads every day (see Figure 9). In the sling division group, the median number of pads a day was 2 with a range of 0 to 7 pads a day. In contrast the median number of pads a day in the control group was 0 with a range of 0 to 4 pads a day.

Figure 9 shows that the sling division group had better results suggesting that patients who underwent a sling division had worse outcomes than women who did not need sling division.

3.4.3 Current health condition

Figure 10 shows that the patients in the sling division group (35.7%) tended to be more prone to UTIs than the patients of the control group (20%). Also, patients who underwent a sling division (study patients 40%) suffered more often from concurrent diseases than patients who had none (control patients 20%).

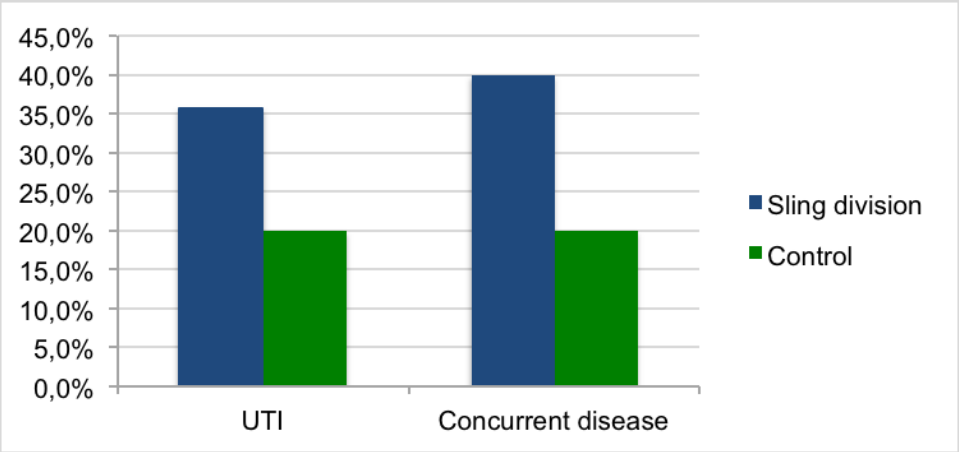

Figure 10: Current health condition,
comparison of sling division and control group

A few patients still suffered from pain in the operative area: 20% of the patients who underwent a sling division and 6.7% of the control group.

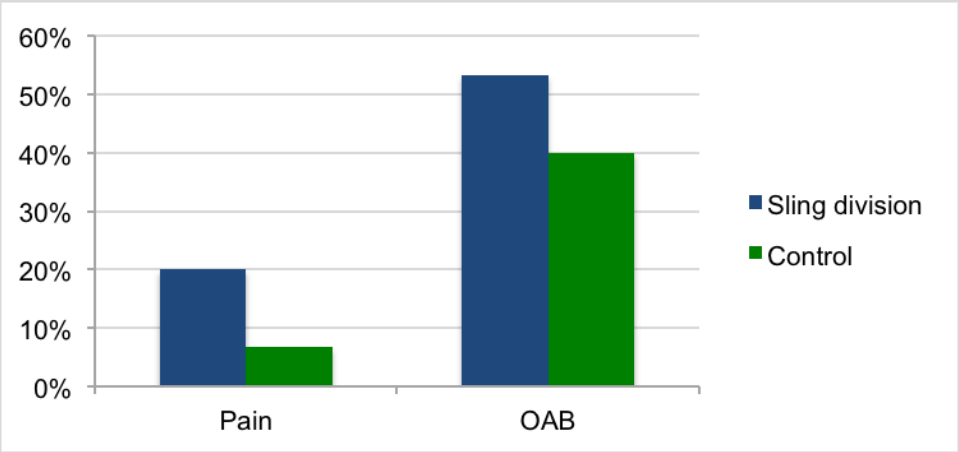

Figure 11: Long-term damage,
comparison of sling division and control group

More than half of the patients of the sling division group (53.5%) experienced OAB symptoms, whilst 40% of the control group also claimed OAB symptoms (see Figure 11).

Both preoperatively and at the follow-up examination, the MUCP was always lower in the sling division group than in the control group (see Table 6).

Table 6: MUCP compared preoperatively and in follow-up examination, divided in sling division and control group

	MUCP preop	MUCP follow-up
Division group	47 ± 12.5	35 ± 10.8
Control group	52 ± 30.6	47 ± 34.3

Data are expressed as mean ± SD.

As the mean of the MUCP was lower but still in normal range (see chapter 1.1.6.4.3.), it was considered as having no impact on the sling surgery and the need for sling division.

3.4.4 Potential risk factors

Differences between the sling division and the control group at the time before the sling implantation could give hints for potential risk factors that could lead to a sling division. As the data was not fully completed for all parameters and all patients, it was hard to draw substantial conclusions. Differences between the two groups are shown in Table 7.

Table 7: Pivotal differences between sling division group and control group

Parameters	Sling division group	Control group
Age (years)	59.9 ± 7.6	57.6 ± 4.7
BMI (kg/m^2)	31 ± 6.5	30 ± 7.6
TVT out of all sling procedures	8 (53)	22 (73)
Previous gynaecological surgery	8 (53)	11 (37)
Concomitant surgery	7 (47)	8 (27)
Previous incontinence surgery	2 (13)	4 (13)
OAB	5 (33)	5 (17)
Concurrent disease	2 (13)	2 (7)
Menopausal status		
Premenopausal	1 (6)	3 (10)
Postmenopausal	7 (47)	18 (60)
Postmenopausal + HRT	7 (47)	9 (30)
Anticholinergics	2 (13)	1 (3)
MUCP (cm H_2O)	47 ± 12.5	52.5 ± 30.6

Data are expressed as mean ± SD or number (%).

In a numerical computing environment called “MATLAB”, a linear regression model was used. This statistic model is used to show relationships between a dependent output variable and one or more independent input variables, on a linear basis. In this case, a lot of variables could not be used, because of their incompleteness among patients, as they would have decreased the usable number of samples drastically.
Therefore, the parameters parity, number of pads, residual volume and MUCP were taken out before the design of the regression model, leaving the following ones: age, BMI, type of sling procedure, previous gynaecological surgery, concomitant surgery, previous incontinence surgery, OAB symptoms, concurrent diseases, menopausal status and intake of anticholinergics.

The linear regression model was fitted for the given input variables with the goal (output variable) of leading to a sling division. Therefore sling division was coded as 1 and no sling division (the patients of the control group) was coded as 0, which gave a binomial distribution. Hence, a logistic function with a binomial distribution (see Figure 12) was used to see what variables tended more to lead to a sling division or not.

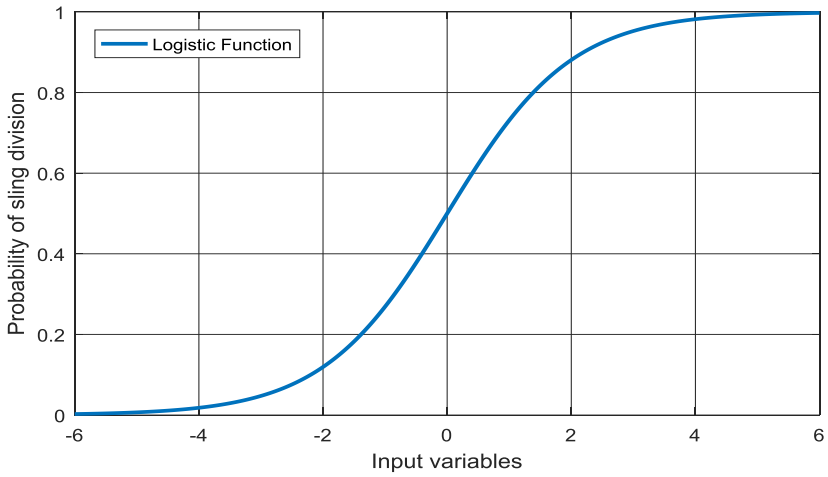

Figure 12: Logistic function with binomial distribution

This function is mathematically described by the polynomial shown in Figure 13.

$$\mathrm{P}(Y=1|X_i=x_i)=\frac{\exp(\beta_0+\beta_1X_1+\cdots+\beta_nX_n)}{1+\exp(\beta_0+\beta_1X_1+\cdots+\beta_nX_n)}$$

Figure 13: Polynomial for logistic function

The ß-coefficients could be interpreted as values of importance of the respective variables; the higher the ß-coefficient the more important was the variable for reaching the goal of a sling division.

A linear hypothesis test, in MATLAB called “coefTest”, was used on the resulting coefficients with a high p-Value. For the parameters BMI, previous incontinence surgery, concurrent diseases, anticholinergics and menopausal status, the resulting p-Value was too high and the F test recommended excluding these from the final model.

Then, the logistic linear regression model was fitted for the remaining variables age, type of sling procedure, previous gynaecological surgery, concomitant surgery and OAB. The results are shown in Table 8.

Table 8: p-Values and ß-coefficients computed using MATLAB

Variable (coding)	ß-Coefficient	p-Value
Age	0.101198547	0.169840326
Concomitant surgery (0=no, 1=yes)	1.908068508	0.047834026
Type of sling procedure (0=TVT, 1=TVT-O)	1.988678544	0.037763471
OAB	0.775212898	0.36465944
Previous gyn. surgery (0=no, 1=yes)	2.24777764	0.031427084

For the parameters concomitant surgery, type of sling procedure (where TVT-O was the goal that lead to sling division) and previous gynaecological surgery, the p-Values were less than 5%, indicating statistical significance. Also the ß-

coefficients were higher than those of the other parameters, pointing out a higher influence of the variables on the probability of a sling division.
For validation, the input parameters of all patients were fed into the model and the output was compared to known binary output “sling division”. The model could predict 78% of all patients’ sling division correctly.

The three selected variables were then used to calculate some predictions on an exemplary basis. Imagining a patient with an age of 58 (mean age of all patients) and no signs of OAB, the probabilities and confidence intervals (CI) could be calculated as shown in Table 9 (see coding for 0 and 1 in Table 8).

Table 9: Probabilities and confidence interval (CI) if no, one, two or all three parameters are present

Parameter	Presence of no parameter	Presence of one parameter	Presence of two parameters	Presence of all parameters
Concomitant Surgery	0	0	1	1
Type of Sling procedure	0	1	1	1
Previous gyn. surgery	0	0	0	1
Probability	2.8%	17.2%	58.3%	92.9%
CI	0.3% - 20.8%	3.5% - 54.4%	21.6% - 87.7%	48.1% - 99.5%

A certain trend could be seen. The presence of all three selected parameters increased the probability of a sling division and was therefore identified as a risk factor. On the contrary, a high CI was calculated for all cases in Table 9, meaning an exact prediction could not be done based on this model. Simply speaking, with this small study population no strong argumentation could be given. A much bigger study population with a higher number of samples could clarify the results and should be used.
Although initially assumed to be significant, the BMI or the MUCP did not show statistical significance.
As the set of data was too small, no further statistical investigation was done.

3.4.5 QoL after sling division and in control group

3.4.5.1 KHQ

The women were asked to fill out the KHQ questionnaire, the results are presented in Table 10.

The KHQ subscale scores were calculated for each patient and compared between patient groups using descriptive statistics.

Table 10: KHQ results

	Sling division group		Control group	
	Median (range)	n	Median (range)	n
General Health Perception	50 (25 – 75)	13	25 (0 – 100)	30
Incontinence Impact	33.3 (0 – 100)	13	33.3 (0 – 100)	30
Role limitation	58.3 (0 – 100)	14	16.7 (0 – 100)	29
Physical limitations	83.3 (16.7 – 100)	12	16.7 (0 – 66.7)	30
Social limitations	33.3 (0 – 100)	12	0 (0 – 66.7)	29
Personal relationships	16.7 (0 – 100)	4	0 (0 – 100)	18
Emotions	22.2 (0 – 100)	13	0 (0 – 100)	26
Sleep / energy	33.3 (0 – 83.3)	13	16.7 (0 – 100)	29
Severity measures	83.3 (0 – 100)	13	50 (0 – 100)	28

Data are expressed as median and range and numbers. Lower scores indicate better QoL.

It was recognisable that for all subgroups, except for one (“Incontinence Impact”), the sling division patients had a higher score than the control patients (see Table 10). This shows that the patients who had undergone a sling division had a worse QoL than the patients who did not.

The main differences were visible in the subgroups “Role limitations”, “Physical limitations” and “Social limitations”.

The highest difference was noticeable in the subgroup “Physical limitations”, where the scores differed from a median of 83.3 in the sling division group and a median of 16.7 in the control group (see Table 10). This shows how much more

the bladder problem affected the physical activities and the ability to travel of the patients who underwent a sling division.

Also, in the subgroup “Role limitation” the sling division group, with a median of 58.3, scored worse in comparison to the control group with a median of 16.7 (see Table 10). The difference indicated that the sling division group was much more impaired during household tasks, job and normal daily activities than the control group.

Another big impairment of the sling division group was shown in the subgroup “Social limitations”. The patients who underwent a sling division had a median score of 33.3, whereas the control group had a median score of 0 (see Table 10). The patients in the sling division group experienced a higher impact on their social life, visiting friends and their family life due to their bladder problem than the ones of the control group.

For “General Health Perception” the score of the sling division group with a median of 50 was higher than for the control group with a median of 25. The self-perception of health of the sling division patients was worse than of the control patients (see Table 10).

In addition, in the subgroup “Severity measures”, the sling division group again had a worse outcome than the control group. With a median of 83.3 compared to a median of 50, the sling division group took much more severity measures like wearing pads, restricting fluids, changing underclothes because they got wet and worrying about if they could smell due to their bladder problem.

The subgroups “Personal relationships”, “Emotions” and “Sleep/energy” did not show huge differences between the groups. The first-named subgroup also had a very low number of participating patients.

The control group had mainly low scores, which indicated a good subjective perception on QoL of the patients who did not undergo a sling division.

As the only exception, in the subgroup “Severity measures” also control-group patients scored a high value and tended to take measures to keep dry.

3.4.5.2 IOQ

The women were also asked to fill out the IOQ questionnaire with the results being shown in Table 11.

The scores were evaluated for each patient and an overall score for the single items and for a bigger subgroup (original scale of QoL and satisfaction) was done with the median and range or number and percentage and the number of patients who filled out that section.

Table 11: IOQ results

	Sling division group		**Control group**	
	Median (range) or number (%)	n	Median (range) or number (%)	n
Pain	0 (0 – 60)	11	0 (0 – 80)	30
Symptoms post-operative	25 (0 – 100)	12	0 (0 – 100)	30
OAB pre-operative	7 (70)	10	23 (82.1)	28
Change in OAB symptoms pre-/ post-operative	40 (0 – 100)	12	20 (0 – 80)	30
UTI	5 (38.5)	13	11 (37.9)	29
Other infection	4 (30.8)	13	10 (34.5)	29
Hospital Re-admission	8 (61.5)	13	2 (6.7)	30
Residual urine (ml)	37.5 (0 – 50)	12	0 (0 – 100)	30
Symptoms pre-operative	75 (25 – 100)	12	75 (0 – 100)	30
Original scale of QoL+satisfaction (Overall score)	52.5 ± 18.4	9	27.5 ± 24.9	25

Data are expressed as median (range) or number (%) except for the Overall score (mean ± SD). Lower scores indicate better outcome of surgical treatment and better QoL of patients.

Table 11 shows that in the majority of the single items and in the subgroup of QoL and satisfaction the sling division group reached higher scores than the control group. This implies that the patients who underwent a sling division had a worse outcome of the surgical treatment and a lesser QoL than the patients of the control group.

The main difference between the two groups could be seen in the subgroup of “Original scale of QoL and satisfaction”, where the mean score in the sling division group was higher with 52.5 compared to the control group with a mean score of 27.5. This shows that the patients who underwent a sling division tended to feel more tired, drained, lacking, irritable, snappy, depressed and tearful. Their self-perception of global health was worse; they felt more limited in daily activities and report bigger changes in their sex life and their feeling about their body. Additionally the satisfaction of the operation was less in the patients who underwent a sling division; the post-operative symptoms seemed to be worse, the time of recovery was longer than expected, they did not get enough information about the sling surgery, they felt worse than before sling implantation and they did not tend to recommend the sling surgery to friends.
The patients who underwent a sling division had more voiding problems than the patients of the control group with a median of 37.5 and 0, respectively.
Regarding the “Hospital Re-admission”, eight patients from the sling division group and only two patients from the control group had to be readmitted at the hospital due to the sling surgery, 61.5% compared to 6.7%, respectively. It should be mentioned that the high difference could come from the fact that the patients who underwent a sling division, answered with “yes” to the question if they had to be re-administered to hospital. Therefore this difference could be ignored.

The sling division group scored worse for the single question “Symptoms post-operative”, with a median of 25 compared to a median of 0 for the control group (Table 11).
Also the urge to void was more present in the sling division group than in the control group, with a median of 40 and 20, respectively.
The OAB symptoms and the loss of urine preoperatively had similar scores in both groups, which is reasonable.
Any occurrence of pain, a UTI or another infection was similar in both groups (see Table 11). With a median of 0, the patients had no pain within the last four weeks. About a third in both groups thought of having had a UTI or another infection since the sling surgery.

3.4.6 Sexual function after sling division and in control group

The German version of the FSFI (FSFI-d) was used to evaluate the sexual function after sling division and for comparison in the control group (see Table 12) and evaluated as for the other questionnaires.

Table 12: FSFI-d results

	Sling division group		**Control group**	
	Median (range)	n	Median (range)	n
Desire	1.2 (1.2 – 3)	8	2.4 (1.2 – 4.2)	23
Arousal	0 (0 – 3.9)	9	2.1 (0 – 5.4)	19
Lubrication	0 (0 – 4.2)	9	2.1 (0 – 6)	21
Orgasm	0 (0)	8	1.2 (0 – 6)	23
Satisfaction	0 (0 – 2.4)	4	2.8 (0 – 6)	16
Pain	0 (0)	7	0 (0 – 6)	21
Full-scale score	1.2 (1.2 – 2.4)	3	18.2 (1.2 – 31.8)	15

Data are expressed as median and range. Lower scores indicate lower sexual function. Scores of zero indicate no sexual activity at all.

As shown in Table 12 the patients who underwent a sling division tended to have lower scores or mainly scores of zero compared to the control group.
The median scores of both groups were not that high. That indicates that in both groups the women were either not sexually active anymore or had low sexual function.

The main difference was shown in the domain “Satisfaction”, where the median score of the sling division group was 0 but of the control group the median was 2.8. It has to be said that this domain was poorly filled out; therefore no strong conclusion could be drawn.
In the domains “Desire” and “Orgasm” just small differences were visible. In the domains “Arousal” and “Lubrication”, the sling division patients had median scores of zero and the control patients had median scores of 2.1 (see Table 12). This indicates that the sling division patients were not even sexually active anymore.

In the full-scale score the median of the sling division group was just 1.2. This was influenced by the many answers with a score of zero. This implies lower to no sexual function compared to the control group with a median of 18.2 (Table 12).
It has to be kept in mind that only the completely filled out questionnaires could be used for calculating the full-scale score, which had not been enough (only 3 sling division patients and 15 control patients) to allow a good comparison of the two groups.

4 Discussion

In the group of patients who underwent a sling division, the objective incontinence rate, determined by an objective clinical stress test, was 33.3%. This is not congruent with the subjective incontinence rate of 53.3%. In contrast in the control group the objective incontinence rate was 11.1% and the subjective incontinence rate 16.6%, respectively. Differences between subjective and objective SUI rate were therefore markedly higher in the sling division group than in the control group. According to the PGI-I, the subjective improvement rate was 46.7% in the sling division group and 77.8% in the control group.
There are many studies that show results for the short-term or long-term outcome of a sling surgery. However, there is only very little literature available for the outcome and the QoL after undergoing a sling division. So far there are no known studies that analysed the objective and subjective outcome after sling division. Kim-Fine et al. published a study on subjective outcome as determined with the PGI-I and showed an improvement rate of 41.8% of women who underwent a sling revision (55).

The low improvement rate of the patients who underwent a sling division is in line with the measures they are taking to handle the incontinence after division; 26.7% of these women in our study underwent an succeeding incontinence reoperation, 33.3% were taking anticholinergic medication and even up to 73.3% were using pads daily with a range of minimum 0 pads up to 7 pads a day.
Patients who did not undergo sling division took fewer measures to handle incontinence, which is congruent with their lower subjective and objective SUI rates. Only 3.3%, 13.3% and 36.6% of the control patients underwent incontinence reoperation, were taking anticholinergic medication or were using pads, respectively.

The current health situation of the sling division patients seemed to be worse compared to the control group. 35.7% of the women who underwent a sling division were prone to having UTIs and 40% of them had concurrent diseases. In comparison, only 20% of the women who did not undergo a sling division had UTIs within the last year and concurrent diseases.

In this study, sling division patients with failed sling surgery had a worse global health status, a lower immune system and therefore could have been more prone to sling failures.

In several studies it is shown that a low MUCP can lead to a sling failure (61,62). With a mean of 47 preoperatively and 35 postoperatively the MUCP values of the sling division patients were both times measured lower than in patients who did not undergo a sling division. But as the MUCP measures are still within a normal range, this does not imply a connection to a possible risk factor for sling division.

An important aspect of this study is the detection of potential risk factors that could lead to a sling division. Therefore the preoperative data of the sling division patients and of the control patients was fitted into a logistic regression model, with the goal of identifying the preoperative parameters, which are more common to lead to a sling division.
For the parameters “type of sling procedure” ($p = 0.038$), “concomitant surgery” ($p = 0.048$) and “previous gynaecological surgery” ($p = 0.031$), the p-Values were less than 5%, indicating statistical significance. When some predictions for these parameters were calculated on an exemplary basis, a certain trend could be seen:
The presence of all three selected parameters increased the probability (92.9%) of a sling division and was therefore identified as a risk factor. On the contrary, a high CI (48.1% – 99.5%) was given for this correlation, meaning an exact prediction cannot be done based on this model. To provide a strong argumentation, a much bigger study population with a higher number of samples should be used.
Nevertheless these results correlate with the results of other studies, where these parameters were shown to be associated with sling revision (40,56,57).
Similarly to our study, Molden et al. has shown that concomitant surgeries contribute to the indication of a sling division with a 95% CI of 2.16 – 11.05 ($p < 0.001$) (57). Furthermore, the retropubic sling type (TVT) has shown statistical significance ($p = 0.04$) with a 95% CI of 1.08 – 4.78. Also, pre-existing voiding symptoms were mentioned to lead to a sling division ($p = 0.004$) with a 95% CI of 1.32 – 5.79 (57).

Unger et al. searched for risk factors and described the contribution of preceded SUI surgeries to the indication of a sling division with a 95% probability with a CI of 2.1% – 9.5% ($p < 0.001$) (56).
In addition Athanasiou et al. showed that concomitant vaginal hysterectomy was correlated with subjective failure ($p = 0.02$) (40).

Three urinary incontinence specific questionnaires were used to elicit the QoL and the sexual health of the patients after a sling division. Only one study worked with questionnaires to evaluate lower urinary tract symptoms after midurethral sling revision. Parden et al. used follow-up questionnaires with PGI-I, Patient Satisfaction Questionnaire (PSQ), Medical, Epidemiological, and Social Aspect of Aging Questionnaire (MESA), Pelvic Floor Impact Questionnaire-7 (PFIQ-7), as well as the Pelvic Organ Prolapse Distress Inventory 6 (POPDI-6), and Urinary Distress Inventory 6 (UDI-6) subscales of the Pelvic Floor Distress Inventory-20 (PFDI-20) (63). The results of this study cannot be compared to the results of our study, as different questionnaires were used.
The QoL was assessed with the KHQ and the IOQ and in both surveys the women who had undergone a sling division produced scores that indicated a lower QoL and a worse outcome and satisfaction after sling surgery.
The sexual health was evaluated with the FSFI-d and showed low sexual function or no sexual activity at all for the patients after a sling division. Due to incomplete data and small sample size no conclusion can be drawn.
Overall, the QoL, the satisfaction of surgery outcome and the sexual health were worse in the sling division group. These results indicate that there are women who need further treatment or at least more information about further treatment to improve their QoL after the sling division. A failed sling surgery is already a burden, so we need stronger intentions to help these women, as their social, physical and role limitations are very impaired.

For managing recurrent or persistent SUI after sling failure, Scapero et al. described the options of shortening the pre-implanted sling or repetition of midurethral sling procedure, retropubic suspension, and pubovaginal sling surgery and also the use of bulking agents. Less invasive techniques are suggested in the literature (64); Lee et al. reported that, following injections of bulking agents as

treatment after failed sling surgery, the patients state a subjective cure rate of 34.8% (65). Although this is a low cure rate, in turn 92% of the women mentioned high satisfaction with this treatment, as it is a minimal invasive intervention and has a low complication rate (65).

The strengths of this study have to be pointed out. This is the first study to report on outcome after sling division, both objectively and subjectively evaluated. These data are a contribution to the current literature. Also there is new insight into a possible statistical correlation between risk factors and sling division.

It has to be mentioned that this study comes along with some limitation factors. The sample size is modest and the data incomplete. Especially, there is a lack of preoperative data making it difficult to conclude about the impact of the aforementioned risk factors. Additionally, the small sample size made further statistical investigations unappealing, which is mainly due to the low rate of necessity of sling division of 2.7% (56).
To achieve a higher number of study patients, multicenter studies will be inevitable in the future.

5 Conclusion

The comparison between patients who underwent a sling division and the control group shows a very poor outcome for the sling division group. The objective SUI rate for the sling division and the control group was 33.3% and 11.1%, respectively. The subjective SUI rate differed with 53.3% versus 16.6%. The difference of subjective and objective incontinence rate, 53.3% versus 33.3%, shows that the patients suffer subjectively much more than what can be demonstrated objectively.

Additionally, the patients who underwent a sling division scored low values in the PGI-I, the SUI VAS and the UUI VAS in comparison to the control group. This is verified with the higher number of severity measures the patients are taking to handle their bladder problem.

The type of sling procedure ($p = 0.038$), a concomitant surgery ($p = 0.048$) and a previous gynaecological surgery ($p = 0.031$) are potential risk factors that could lead to a sling division.

To summarize the results of the used questionnaires, the QoL, the satisfaction of surgery outcome and the sexual function are much lower for the patients that underwent a sling division.

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Appendix – Questionnaires

KHQ

Name: _____

Geburtsdatum: _____ Datum:_____

FRAGEBOGEN ZUM GESUNDHEITSZUSTAND
KING'S Health Questionnaire 1993

1. Wie würden Sie zur Zeit Ihren allgemeinen Gesundheitszustand beschreiben?
   - Sehr gut
   - Gut
   - Mittelmäßig
   - Schlecht
   - Sehr schlecht

2. Wie sehr wirkt sich Ihrer Meinung nach Ihr Blasenproblem auf Ihr Leben aus?
   - Überhaupt nicht
   - Ein wenig
   - Mäßig
   - Sehr

Bitte kreuzen Sie an, wie sehr Sie in den folgenden Bereichen im Alltag durch Ihr Blasenproblem beeinträchtigt sind!

	Einschränkungen bei Alltagsaktivitäten	Überhaupt nicht	Ein wenig	Mäßig	Sehr
3.	In welchem Ausmaß beeinträchtigt Sie Ihr Blasenproblem bei Ihren Aufgaben im Haushalt (z.B. Putzen, Einkaufen usw.)?				
4.	Beeinträchtigt Ihr Blasenproblem Ihre berufliche Arbeit oder Ihre üblichen täglichen Aktivitäten außerhalb des Hauses?				

	Körperliche/Soziale Einschränkungen	Überhaupt nicht	Ein wenig	Mäßig	Sehr
5.	Beeinträchtigt Ihr Blasenproblem Ihre körperlichen Aktivitäten (z.B. Spazierengehen, Laufen, Sport, Gymnastik)?				
6.	Beeinträchtigt Ihr Blasenproblem Ihre Fähigkeit zu reisen?				
7.	Schränkt Sie Ihr Blasenproblem im Kontakt mit Menschen ein?				
8.	Schränkt Ihr Blasenproblem Ihre Fähigkeit ein, Freunde zu treffen/zu besuchen?				

Bitte kreuzen Sie an, wie sehr Sie in den folgenden Bereichen im Alltag durch Ihr Blasenprobleme beeinträchtigt sind!

	Persönliche Beziehungen	Nicht vorhanden	Überhaupt nicht	Ein wenig	Mäßig	Sehr
9.	Beeinträchtigt Ihr Blasenproblem Ihre Beziehung zu Ihrem Partner?					
10.	Beeinträchtigt Ihr Blasenproblem Ihr Sexualleben?					
11.	Beeinträchtigt Ihr Blasenproblem Ihr Familienleben ?					

	Gefühlszustand	Überhaupt nicht	Ein wenig	Mäßig	Sehr
12.	Sind Sie wegen Ihres Blasenproblems deprimiert?				
13.	Sind Sie wegen Ihres Blasenproblems ängstlich oder nervös?				
14.	Beeinträchtigt Ihr Blasenproblem Ihr Selbstwertgefühl?				
	Schlaf/ Energie	Nie	Manchmal	Oft	Immer
15.	Beeinträchtigt Ihr Blasenproblem Ihren Schlaf?				
16.	Fühlen Sie sich wegen Ihres Blasenproblems erschöpft/müde?				
		Nie	Manchmal	Oft	Immer
17.	Tragen Sie Einlagen, um trocken zu bleiben?				
18.	Achten Sie darauf, wieviel Flüssigkeit Sie trinken?				
19.	Wechseln Sie Ihre Unterwäsche, wenn sie naß wird?				
20.	Haben Sie Angst zu riechen?				
21.	Ist Ihnen Ihr Blasenproblem peinlich?				

Wir möchten gerne erfahren, welche Blasenprobleme Sie haben und wie sehr Sie diese beeinträchtigen.

Wie sehr belasten Sie diese Probleme? Bitte zutreffendes ankreuzen!

	Ein wenig	Mäßig	Sehr	Nicht zutreffend
22. HÄUFIGKEIT: sehr oft zur Toilette gehen				
23. NÄCHTLICHER HARNDRANG: nachts aufstehen, um Wasser zu lassen				
24. Starker und schwer kontrollierbarer Drang, Wasser zu lassen				
25. Unwillkürlicher Harnabgang, verbunden mit dem starken Drang, Wasser zu lassen				
26. Unwillkürlicher Harnabgang bei körperlicher Aktivität, z.B. Husten, Niesen, Laufen				
27. Nächtliches Bettnässen				
28. Unwillkürlicher Harnabgang beim Geschlechtsverkehr				
29. Häufige Harnwegsentzündungen				
30. Blasenschmerzen				
31. Schwierigkeiten beim Wasserlassen				
32. Weiteres Blasenproblem Wenn ja, welches?_____				

VIELEN DANK!

IOQ

IOQ-FRAGEBOGEN

Wir sind interessiert zu erfahren, wie es Ihnen seit Ihrer Operation wegen Harnverlust (TVT) ergangen ist und wären Ihnen dankbar wenn Sie einen kurzen Fragebogen ausfüllen könnten. Alle Ihre Information werden streng vertraulich behandelt. Bitte beantworten Sie jede Frage und kreuzen Sie jene Antwort an, welche Ihre Situation am ehesten beschreibt. Zuerst möchten wir gerne wissen, ob Sie **in den letzten 4 Wochen** irgendwelche Probleme hatten, die mit dieser TVT-Operation in Zusammenhang stehen.

1. Wie viele Schmerzen hatten Sie während der **letzten 4 Wochen?**1.
   - 0 keine
   - 1 sehr wenig
   - 2 wenig
   - 3 mäßig
   - 4 stark
   - 5 sehr stark

2. Hatten Sie seit Ihrer TVT-Operation eine Harnwegsentzündung und mussten Sie wegen der Blasenbeschwerden Antibiotika nehmen? **ja** 1 **nein** 0

3. Hatten Sie seit Ihrer TVT-Operation irgendeine andere Entzündung, wegen der Sie Antibiotika nehmen mussten? **ja** 1 **nein** 0
   Wenn ja, wo war die Entzündung_____

4. Mussten Sie seit Ihrer TVT-Operation aus irgendeinem Grund, der mit **dieser Operation** zu tun hat, wieder ins Krankenhaus aufgenommen werden? **ja** 1 **nein** 0
   Wenn ja, was war der Grund , weswegen Sie im Spital waren?
   1_____
   2_____

5. Verglichen mit der Zeit vor der TVT-Operation, waren Sie **in den letzten 4 Wochen**:
   - 1 weniger erschöpft/müde/ausgelaugt?
   - 2 in etwa gleich?
   - 3 stärker erschöpft/müde/ausgelaugt?

6. Verglichen mit der Zeit vor der TVT-Operation, waren Sie **in den letzten 4 Wochen**:
   - 1 weniger gereizt?
   - 2 in etwa gleich?
   - 3 stärker gereizt?

7. Verglichen mit der Zeit vor der TVT-Operation, waren Sie **in den letzten 4 Wochen**:
   - 1 weniger deprimiert/weinerlich?
   - 2 in etwa gleich?
   - 3 stärker deprimiert/weinerlich?

8. Wieviel Probleme hat Ihnen der Harnverlust **vor der TVT-Operation** bereitet?
   - 1 keine
   - 2 ein wenig
   - 3 mäßig
   - 4 viele
   - 5 sehr viele

9. Wieviel Probleme hat Ihnen der Harnverlust **nach der TVT-Operation** bereitet?
   - 1 keine
   - 2 ein wenig
   - 3 mäßig
   - 4 viele
   - 5 sehr viele

Wir möchten auch gerne wissen, wie Ihr allgemeiner Gesundheitszustand und Ihre Lebensqualität in letzter Zeit war.

10. Würden Sie sagen Ihr Gesundheitszustand ist:
    1 ausgezeichnet
    2 sehr gut
    3 gut
    4 schlecht
    5 sehr schlecht

11. Wie ist Ihr Harnverlust **jetzt** im Vergleich mit der Zeit vor der TVT-Operation?
    1 viel besser
    2 etwas besser
    3 etwa gleich
    4 etwas schlechter
    5 viel schlechter

12. In welcher Weise war Ihre Leistungsfähigkeit im Alltag (Haushalt, Familie, Freizeit) **durch die TVT-Operation in der vergangenen Woche** verändert?
    1 verbessert
    2 kein Unterschied
    3 verschlechtert

13. In welcher Weise hat sich Ihr Sexualleben verändert?
    1 verbessert
    2 kein Unterschied
    3 verschlechtert
    4 nicht zutreffend

14. Hat sich die TVT-Operation auf die Art, wie Sie Ihren Körper wahrnehmen, ausgewirkt?
    1 ich fühle mich körperlich besser
    2 ich fühle mich körperlich etwa gleich
    3 ich fühle mich körperlich schlechter

15. War die Erholung von der Operation:
    1 schneller als Sie erwartet haben?
    2 in etwa so wie Sie erwartet haben?
    3 langsamer als Sie erwartet haben?
    4 wusste nicht wie lange es dauern würde

16. Bezüglich der Informatinonen über die TVT-Operation, hatten Sie:
    1 mehr Information als Sie wollten?
    2 ausreichend Information?
    3 weniger Information als Sie wollten?

17. Wie fühlen Sie sich **jetzt** im Allgemeinen im Vergleich mit der Zeit **vor** der TVT-Operation?
    1 viel besser
    2 etwas besser
    3 etwa gleich
    4 etwas schlechter
    5 viel schlechter

18. Wenn eine Freundin ähnliche Probleme (Harnverlust) hätte wie Sie vor der Operation, würden Sie Ihr diese TVT-Operation empfehlen?
    1 mit Sicherheit empfehlen
    2 wahrscheinlich empfehlen
    3 nicht sicher
    4 wahrscheinlich nicht empfehlen

19. Haben Sie derzeit Probleme mit der Entleerung Ihrer Blase?

1	keine
2	ein wenig
3	mäßig
4	viele
5	sehr viele

20. Hatten Sie vor der TVT-Operation vermehrten Harndrang?

ja	nein
1	0

21. Wie ist Ihr Harndrang **jetzt** verglichen mit der Zeit **vor** der TVT-Operation?

0	habe keinen Harndrang
1	viel besser
2	etwas besser
3	etwa gleich
4	etwas schlechter
5	viel schlechter

Abschließend wäre es hilfreich, wenn Sie einige allgemeine Fragen zu Ihrer Person beantworten könnten:

22. Wie alt sind Sie? _____ Jahre

23. Was ist/war Ihr Beruf, den Sie hauptberuflich ausüben/ausgeübt haben?
Berufsbezeichnung: _____

24. Leben Sie: (mehrere Anwortmöglichkeiten)

1	alleine
2	mit Ihrem (Ehe)Partner
3	mit Kindern
4	mit Familienangehörigen (Eltern, Geschwister, …)
5	andere (bitte angeben) _____

25. Was war der Grund für Ihre TVT-Operation? (Mehrfachantworten möglich)

1	Harnverlust
2	Harndrang
3	Gebärmuttersenkung/Vorfall
4	andere
5	weiß nicht

	ja	nein	weiß nicht
26. Nehmen Sie Hormone gegen Wechselbeschwerden?	1	0	2
Wenn ja, haben Sie diese Hormone vor der Operation genommen?	1	0	2

FSFI-d

Weiblicher Sexueller Funktionsindex (FSFI-d)

Bitte beantworten Sie diese Fragen, auch wenn Sie keinen Partner haben oder keinen Geschlechtsverkehr mehr haben.

Diese Fragen betreffen Ihre sexuellen Gefühle und Reaktionen **während der letzten 4 Wochen**. Bitte beantworten Sie die folgenden Fragen so ehrlich und präzise wie möglich. Ihre Antworten werden absolut vertraulich behandelt.

- **Sexuelle Aktivität** kann einschließen Zärtlichkeiten, Vorspiel, Masturbation und Geschlechtsverkehr (miteinander schlafen)
- **Geschlechtsverkehr** ist definiert als das Eindringen des Penis in die Scheide
- **Sexuelle Stimulation** schließt Situationen wie Vorspiel mit dem Partner, Selbstbefriedigung (Masturbation) oder sexuelle Fantasien ein.

Bitte kreuzen Sie **nur eine** Antwortmöglichkeit pro Frage an.

Sexuelle Lust oder **Interesse** bedeutet, den Wunsch nach sexuellen Erlebnissen zu haben, die Bereitschaft, sich vom Partner zu sexueller Aktivität anregen zu lassen oder erotische Vorstellungen und Fantasien zu haben.

1. Wie oft fühlten Sie sexuelle Lust oder Interesse (während der letzten 4 Wochen)?
   - x fast immer oder immer
   - x meistens (mehr als die Hälfte der Zeit)
   - x manchmal (etwa die Hälfte der Zeit)
   - x gelegentlich (weniger als die Hälft der Zeit)
   - x fast nie oder nie

2. Wie würden Sie die Stärke Ihrer sexuellen Lust einschätzen (während der letzten 4 Wochen)?
   - x sehr hoch
   - x hoch
   - x mittel
   - x niedrig
   - x sehr niedrig oder überhaupt nicht

3. Wie oft waren Sie sexuell erregt bei sexueller Aktivität oder Geschlechtsverkehr (während der letzten 4 Wochen)?
   - x keine sexuelle Aktivität
   - x fast immer oder immer
   - x meistens (mehr als die Hälfte der Zeit)
   - x manchmal (etwa die Hälfte der Zeit)
   - x gelegentlich (weniger als die Hälft der Zeit)
   - x fast nie oder nie

4. Wie würden Sie die Stärke Ihrer sexuelle Erregung bei sexueller Aktivität oder Geschlechtsverkehr einschätzen (während der letzten 4 Wochen)?
   - x keine sexuelle Aktivität
   - x sehr hoch
   - x hoch
   - x mittel
   - x niedrig
   - x sehr niedrig oder keine Erregung

5. Wie zuversichtlich waren Sie, sexuell erregt zu werden bei sexueller Aktivität oder Geschlechtsverkehr (während der letzten 4 Wochen)?
   - x keine sexuelle Aktivität
   - x sehr hohe Zuversicht
   - x hohe Zuversicht
   - x mittlere Zuversicht
   - x niedrige Zuversicht
   - x sehr niedrig oder keine Zuversicht

6. Wie oft waren Sie mit Ihrer sexuellen Erregung bei sexueller Aktivität oder Geschlechtsverkehr zufrieden (während der letzten 4 Wochen)?
   - x keine sexuelle Aktivität
   - x fast immer oder immer
   - x meistens (mehr als die Hälfte der Zeit)
   - x manchmal (etwa die Hälfte der Zeit)
   - x gelegentlich (weniger als die Hälft der Zeit)
   - x fast nie oder nie

7. Wie oft hatten Sie Lubrikationen (wurden Sie „feucht“) bei sexueller Aktivität oder Geschlechtsverkehr?
   - x keine sexuelle Aktivität
   - x fast immer oder immer
   - x meistens (mehr als die Hälfte der Zeit)
   - x manchmal (etwa die Hälfte der Zeit)
   - x gelegentlich (weniger als die Hälft der Zeit)
   - x fast nie oder nie

8. Wie schwierig war es, eine Lubrikation zu bekommen („feucht“ zu werden) bei sexueller Aktivität oder Geschlechtsverkehr (während der letzten 4 Wochen)?
   - x keine sexuelle Aktivität
   - x extrem schwierig oder unmöglich
   - x sehr schwierig
   - x schwierig
   - x etwas schwierig
   - x nicht schwierig

9. Wie oft konnten Sie die Lubrikation aufrecht erhalten („feucht“ bleiben) bis zum Ende der sexuellen Aktivität oder dem Geschlechtsverkehr (während der letzten 4 Wochen)?
   - x keine sexuelle Aktivität
   - x fast immer oder immer
   - x meistens (mehr als die Hälfte der Zeit)
   - x manchmal (etwa die Hälfte der Zeit)
   - x gelegentlich (weniger als die Hälft der Zeit)
   - x fast nie oder nie

10. Wie schwierig war es, die Lubrikation aufrecht zu erhalten („feucht“ zu bleiben) bis zum Ende der sexuellen Aktivität oder dem Geschlechtsverkehr (während der letzten 4 Wochen)?
    - x keine sexuelle Aktivität
    - x extrem schwierig oder unmöglich
    - x sehr schwierig
    - x schwierig
    - x etwas schwierig
    - x nicht schwierig

11. Wie oft erreichten Sie bei sexueller Stimulation oder Geschlechtsverkehr einen Orgasmus (Höhepunkt) (während der letzten 4 Wochen)?
    - x keine sexuelle Aktivität
    - x fast immer oder immer
    - x meistens (mehr als die Hälfte der Zeit)
    - x manchmal (etwa die Hälfte der Zeit)
    - x gelegentlich (weniger als die Hälft der Zeit)
    - x fast nie oder nie

12. Wie schwierig war es, bei sexueller Stimulation oder Geschlechtsverkehr einen Orgasmus (Höhepunkt) zu erreichen (während der letzten 4 Wochen)?
    - x keine sexuelle Aktivität
    - x extrem schwierig oder unmöglich
    - x sehr schwierig
    - x schwierig
    - x etwas schwierig
    - x nicht schwierig

13. Wie zufrieden waren Sie bei sexueller Stimulation oder Geschlechtsverkehr mit Ihrer Fähigkeit, einen Orgasmus (Höhepunkt) zu erreichen (während der letzten 4 Wochen)?
   - x keine sexuelle Aktivität
   - x sehr zufrieden
   - x mäßig zufrieden
   - x gleich zufrieden wie unzufrieden
   - x mäßig unzufrieden
   - x sehr unzufrieden

14. Wie zufrieden waren Sie mit dem Ausmaß an emotionaler (gefühlsmäßiger) Nähe zwischen Ihnen und Ihrem Partner bei sexueller Aktivität (während der letzten 4 Wochen)?
   - x keine sexuelle Aktivität
   - x sehr zufrieden
   - x mäßig zufrieden
   - x gleich zufrieden wie unzufrieden
   - x mäßig unzufrieden
   - x sehr unzufrieden

15. Wie zufrieden waren Sie mit der sexuellen Beziehung zu/mit Ihrem Partner (während der letzten 4 Wochen)?
   - x kein Partner
   - x sehr zufrieden
   - x mäßig zufrieden
   - x gleich zufrieden wie unzufrieden
   - x mäßig unzufrieden
   - x sehr unzufrieden

16. Wie zufrieden waren Sie mit Ihrem Sexualleben insgesamt (während der letzten 4 Wochen)?
   - x sehr zufrieden
   - x mäßig zufrieden
   - x gleich zufrieden wie unzufrieden
   - x mäßig unzufrieden
   - x sehr unzufrieden

17. Wie oft hatten Sie unangenehme Empfindungen oder Schmerzen **während** des Geschlechtsverkehrs (während der letzten 4 Wochen)?
   - x keine Versuche des Geschlechtsverkehrs
   - x fast immer oder immer
   - x meistens (mehr als die Hälfte der Zeit)
   - x manchmal (etwa die Hälfte der Zeit)
   - x gelegentlich (weniger als die Hälft der Zeit)
   - x fast nie oder nie

18. Wie oft hatten Sie unangenehme Empfindungen oder Schmerzen nach dem Geschlechtsverkehr **nach** dem Geschlechtsverkehr (während der letzten 4 Wochen)?
   - x keine Versuche des Geschlechtsverkehrs
   - x fast immer oder immer
   - x meistens (mehr als die Hälfte der Zeit)
   - x manchmal (etwa die Hälfte der Zeit)
   - x gelegentlich (weniger als die Hälft der Zeit)
   - x fast nie oder nie

19. Wie würden Sie die Stärke Ihrer unangenehmen Empfindungen oder Schmerzen während oder nach dem Geschlechtsverkehr einschätzen (während der letzten 4 Wochen)?
   - x keine Versuche des Geschlechtsverkehrs
   - x sehr hoch
   - x hoch
   - x mittel
   - x niedrig
   - x sehr niedrig oder keine