An evaluation of outcomes and complications of patients undergoing mid-urethral tapes insertion for stress urinary incontinence at a tertiary institution

Dr C Maistry

SUBMITTED IN PARTIAL FULFILLMENT OF THE ACADEMIC REQUIREMENT FOR THE DEGREE OF THE FELLOWSHIP OF THE COLLEGE OF OBSTETRICS AND GYNAECOLOGISTS OF SOUTH AFRICA FCOG (S.A)

Dedication

This dissertation is dedicated to a number of people without whom I may never have believed myself capable of completing this mammoth task.

First and foremost, My Lord, Jesus Christ, who has been an enduring rock and source of strength. His word was my refuge throughout this journey, and will continue to be, into my future.

My parents, Devi and Stanley, whose love, encouragement, and constant prayer, enabled me to believe in myself enough to undertake this task.

My ever-present pillar of support Sanjeev, for the words of encouragement and help, during those long hours of research and work.

My sister, Charlotte for her support and encouragement at any and all time, despite being in a similarly gruelling battle with academia, and the demands of medicine.

To Earl who has taken the time to support and assist me in overcoming the obstacles along the path to fulfilling this dream.
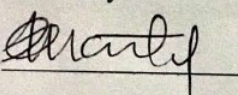
My sincerest thank you.

DECLARATION

I, Charlene Maistry, do hereby declare that the work on which this dissertation is based on is my own original work, under the supervision and mentorship of Dr S Ramphal. This dissertation has not been previously submitted to any other colleges. Where use was made of the work of others it was duly acknowledged in the text

Candidate

Dr Charlene Maistry

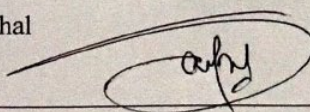Signature _____   **Date** _2/11/2016_

Department of Obstetrics and Gynaecology

Nelson R. Mandela School of Medicine

University of KwaZulu-Natal, Durban

Supervisor

Dr S Ramphal

Signature _____   **Date** _2/11/2016_

Head of Urogynaecological Unit

Inkosi Albert Luthuli Central Hospital

Department of Obstetrics and Gynaecology

Nelson R. Mandela School of Medicine

University of KwaZulu-Natal, Durban

Acknowledgements

Dr S Ramphal, Head of Urogynaecological Unit, Department of Obstetrics and Gynaecology, Inkosi Albert Luthuli Central Hospital, University of Kwa Zulu - Natal for his inspirational and exceptional mentorship with my research commentary. I am eternally grateful for his valuable time, advice and constructive criticism.

I am grateful to the following regulatory bodies for approval to do my thesis.

- The management of Inkosi Albert Luthuli Central Hospital

- The Kwa Zulu – Natal Department of Health

- The Biomedical Research Ethics Committee (BREC), UKZN

Abstract

Introduction

Midurethral sling procedures have become the gold standard surgical procedure for the management of stress urinary incontinence in most centres globally and at present it is the most common surgical intervention for stress urinary incontinence at Inkosi Albert Luthuli Central Hospital (IALCH).

The two approaches with midurethral slings at IALCH is the retropubic tension free vaginal tape (TVT) and the transobturator tape (TOT). However, success rate, intra-operative and post-operative complications following the use of these tapes for urinary incontinence has not been evaluated in our setting.

Aim

An evaluation of outcomes and complications of patients undergoing mid-urethral tapes for stress urinary incontinence in IALCH.

Methods

Data was extracted from a retrospective chart review of patients who underwent mid-urethral tape insertion for the management of stress urinary incontinence at the institution between 1st January 2004 and 31st December 2013. Success was defined by self-reported absence of symptoms, no leakage episodes at 6 months and 1 year. Demographic data, urodynamic data, Kings College Questionnaire, patient outcomes and complications were evaluated.

Results

One hundred and twenty one patients were identified with stress urinary incontinence (SUI) and mixed urinary incontinence (MUI) with predominant stress urinary incontinence (SUI). Urodynamic stress urinary incontinence was diagnosed in one hundred and one (83.5%) patients and twenty (16.5%) with mixed incontinence. Transobturator midurethral tape was performed in 110 patients and tension free vaginal tape in 11 patients.

Twelve months post surgery, the cumulative objective and subjective cure rates in the TOT group and the TVT group were 95.5% and 81.8 % and 91.8% and 90.9% respectively.

Conclusion

At the end of twelve months our cumulative objective and subjective cure rates in the TOT group and the TVT group were 95.5% and 81.8 % and 91.8% and 90.9% respectively. Success of SUI surgery was defined as having no postoperative stress urinary incontinence, no voiding dysfunction, improvement or no alteration in frequency and urgency symptoms.

The overall results of our study indicate that midurethral tape surgery is a safe and efficacious intervention with reasonable cure rates and low complication rates and is associated with a low morbidity.

List of Tables

List of Figures

Fig 1: Two types of mid-urethral sling tapes

Fig 2: Graphical representation of the number of stress urinary incontinence managed at IALCH

Fig3: Graphic representation showing the urinary incontinence in the different age groups

Fig 4: Graphical representation of frequency of urine loss at stress

Abbreviations

BMI	body mass index
CS	caesarean section
GA	general anaesthesia
IALCH	Inkosi Albert Luthuli central hospital
ICS	International Continence Society
MUS	mid-urethral slings
NVD	normal vaginal delivery
RP	retropubic
Pdet	detrusor pressure
SD	standard deviation
SUI	stress urinary incontinence
TO	transobturator
TOT	transoburator tape
TVT	transvaginal tape
UUI	urinary incontinence
UTI	urinary tract infection

Table of contents

Chapter One: Background and literature review

Chapter Two: Methodology

Chapter Three: Results

Chapter Four: Discussion

Chapter Five: References   67

Chapter Six: Annexures

Background and Literature Review

1.0 Introduction

Urinary incontinence is a common condition that can severely effect a women's quality of life. Urinary incontinence is divided into three types namely stress urinary incontinence, urge incontinence and overflow incontinence. Stress urinary incontinence (SUI) is the most common type of urinary incontinence which is defined by the International Continence Society (ICS) as the complaint of involuntary loss of urine on sneezing, coughing, laughing or physical exertion which is objectively demonstrated and is associated with social and hygienic stresses. Stress urinary incontinence occurs when the intra-abdominal pressure exceeds the maximum urethral pressure in the absence of detrusor contractions (Haylen et al., 2010; Abrams et al., 2002). Stress urinary incontinence is estimated to affect up to 35% of adult women worldwide (Lubber et al., 2004).

1.1 Epidemiology

The reported prevalence of SUI is variable, but several studies suggest that it may be as high as one in four adult women (Harding and Thorpe.,2008). Epidemiological studies show a prevalence of SUI of 26.5% in women between 35 and 64 years of age (Fenner et al., 2008) and 41% in those older than 65 years (Goode et al., 2008). Other studies describe a prevalence of 49.6% in women over 20 years of age (Dooley et al., 2008) and 45% in those that are between 30 and 90 years (Melville et al., 2005). The prevalence of SUI increases with age (Melville et al., 2005; Anger et al., 2006; Danforth et al., 2006) and therefore, this condition will become extremely common with the aging population.

The risk factors most frequently highlighted include among others: advanced age, high body mass index (BMI), white race, parity, menopause, hysterectomy, and co-morbidities such as depression and diabetes (Fenner et al., 2008; Goode et al., 2008).

1.2 Classification of urinary incontinence

About one half of women reporting urine leakage are diagnosed with pure SUI and approximately 30% exhibit mixed urinary incontinence (Hunskaar et al., 2004; Minassian et al., 2003). The major types of urinary incontinence according to the International Continence Society (ICS) is as follows:

Table 1: Urinary incontinence: Types

Symptom	Description
Stress	Involuntary leakage on effort or exertion, or on sneezing or coughing
Urge	Involuntary leakage accompanied by or immediately preceded by urgency
Mixed	Involuntary leakage associated with urgency and also with exertion, effort, sneezing, or coughing
Functional	Untimely urination because of physical disability, external obstacles, or problems in thinking or communicating that prevent a person from reaching a toilet
Overflow	Unexpected leakage of small amounts of urine because of an overfilled bladder
Transient	Leakage that occurs temporarily because of a condition or situation that will pass (eg infection, medication)

1.3 Stress Urinary Incontinence

Stress urinary incontinence is the involuntary loss or leakage of urine from the urethra during increases in intra abdominal pressure which is characterised by involuntary urine loss during coughing, laughing and sneezing. (International Continence Society) Urinary incontinence may worsen during sports activities. Leakage is more common while standing than while lying down (e.g. at night).

1.4 Classification of stress incontinence (Harding and Thorpe., 2008)

Stress incontinence can be sub-classified according to the system originally described by Green and Thomas (1968) and modified by Blaivas (1984). These are:

Type 0: A good history of stress incontinence is obtained. During video urodynamic study the vesical neck and proximal urethra are closed at rest, being situated at or above the superior margin of the pubic symphysis. During stress (cough or strain) although the vesical neck and proximal urethra open, no leakage is observed.

Type 1: The vesical neck is closed at rest, and is situated at or above the inferior margin of the pubic symphysis. During stress manoeuvre with increased abdominal pressure, the vesical neck and proximal urethra open and descend 2 cm and urinary incontinence is demonstrated. A cystocoele is also present.

Type 2a: The vesical neck is closed at rest and above the inferior margin of the pubic symphysis. During stress the vesical neck and proximal urethra descend >2 cm and urinary incontinence is demonstrated. A cystocoele is also present.

Type 2b: At rest the vesical neck is closed but is situated below the inferior margin of the pubic symphysis. During stress there is further descent, the proximal urethra opens and urinary incontinence is demonstrated.

Type 3: At rest the vesical neck and proximal urethra are open, despite the absence of a detrusor contraction, there is obvious leakage of urine, which is either gravitational or associated with a minimal increase in intravesical pressure.

The above classification for stress urinary incontinence is that by Harding and Thorpe modified by Blaivas. Other classifications includes Intrinsic Sphincter Deficiency (ISD) and Urethral Hypermobility. The term ISD was originally coined by McGuire et al. in the urology literature from the 1980s and was used to describe a severe form of stress urinary incontinence, equating it to an earlier term "type 3 urinary incontinence" reported by Blavais. The International Urogyneacologic Association (IUGA) and International Continence Society (ICS) joint report ignores the diagnosis of ISD. Urethral hypermobility refers to too much

movement of the urethra, causing it to drop below the pelvic floor muscles during certain activities. This may or may not cause urine leakage.

1.5 Stress Incontinence: Pathophysiology

The aetiology of stress urinary incontinence is multifactorial and is based on complex pathophysiological mechanisms. Several hypotheses have been proposed to explain the pathophysiology. These include the Enhorning Theory, Hammock Hypothesis Theory and Integral Theory.

Goran Enhorning (1961) introduced the "Trampoline Theory" or "Enhorning's Theory", which suggested that the proximal urethra is an intra-abdominal organ capable of receiving transmitted intra-abdominal pressure. In women with SUI with urethral hypermobility, the proximal urethra cannot receive transmitted abdominal pressure which is needed for the normal sphincteric mechanism, and therefore urine is lost with stress. Enhorning (1961) postulated that stress urinary incontinence is attributed to the following factors:

a) Descent of the bladder neck and upper part of the urethra below the pelvic floor outside the intraabdominal zone.

b) Loss of urethrovesical angle.

c) Axial rotation of the urethra, urethral hyper mobility.

d) Intrinsic sphincter defect.

However this theory did not explain all patients with SUI, as there are patients with significant urethrocele but who remain continent. The next postulate was the hammock hypotheses introduced by De Lancey (1994), which states that the pelvic floor muscles and fasciae act as a hammock supporting the bladder neck, and the upper part of the urethra. Urethral closing pressure, depends upon transmission of pressure to the bladder neck and proximal urethra against the rigid support of the pelvic floor muscles, fasciae and the anterior vaginal wall.

More recently Petros and Ulmsten (1993) introduced the Integral theory which is based on 3 criteria:

a) The pubococcygeus muscle lifts the anterior vaginal wall to compress the urethra.

b) The pelvic floor muscles draw the hammock upwards closing the bladder neck.

c) The anterior vaginal wall must be tough, and not lax.

Currently the Integral Theory is the one that is most accepted by clinicians.

A number of epidemiological studies have been published on the role of childbirth in the development of urinary incontinence. (Rortvei et al.,2003) reported a doubling in the risk of incontinence in women having vaginal delivery compared to caesarean section. In a questionnaire based study, (Lukacz et al.,2006) reported a significance difference in the occurrence of stress incontinence in eight hundred and two (18%) of the four thousand four hundred and fifty eight women delivered vaginally compared to four hundred and ninety (11%) who delivered by caesarean delivery. There has also been reports of the protective effect of caesarean section in preventing both stress and urge incontinence (Casey et al., 2005). Further risk factors for stress urinary incontinence include age, obesity, chronically increased abdominal pressure, chronic cough, constipation, occupational risk, urinary symptoms, childbirth, pregnancy, hysterectomy, menopause, diuretic therapy, smoking, diabetes mellitus, chronic obstructive pulmonary disease, ethicnicty, spinal cord trauma, and pelvic floor injury.

1.6 Investigations

The National Institute For Health and Care Excellence(NICE guidelines guidance.nice.org.uk/cg171) on "urinary incontinence" recommends that a detailed history is taken to evaluate and categorise urinary incontinence. A general examination should include abdominal and pelvic assessment of pelvic floor muscle tone, the woman's BMI, blood pressure, urinalysis, haematology, bladder diary and urodynamic studies. Urodynamic studies still remain a controversial investigation in the assessment of patients with stress urinary incontinence. Current NICE guidelines recommend urodynamic studies to be performed when conservative treatment fails , in patients with complex symptoms or failed previous surgery. A bladder diary is given to the patients. When the diagnosis is SUI, management options include conservative and surgical.

1.7 Urge incontinence

Urge incontinence or symptoms of an overactive bladder are uncontrolled urine loss associated with a strong desire to void, which is often a very sudden and rapid event that occurs without any warning. (International Continence Society).

1.8 Mixed incontinence

Mixed incontinence is the combination of symptoms of both stress incontinence and urge incontinence. Affected patients experience mild-to-moderate urine loss with physical activities (stress incontinence). At other times, they experience acute urine loss without any antecedent warning (urge incontinence). Urinary frequency, urgency, and nocturia complement urge incontinence symptom complex.

1.9 Continuous incontinence

Continuous incontinence is the complaint of continuous leakage of urine with a sense of incomplete emptying, slow-flowing urine, and urinary dribbling (International Continence Society).

1.10 Midurethral slings

There are two main types of midurethral synthetic sling procedures: retropubic and transobturator (TOT). The retropubic technique is often referred to as TVT, for "tension-free vaginal tape", the first procedure that was introduced. Both types of slings are made of polypropylene mesh, an open-weave material that stays in place without sutures while scar tissue grows around and through it. The choice of TVT versus TOT depends on many factors and is a decision that should be made jointly by patient and surgeon.

Mid-urethral sling procedures have superseded the Burch Colposuspension as the treatment of choice in managing SUI, the former having the advantage of shorter operating time, with many procedures being performed on an outpatient basis (Nilsson et al., 2008). Surgical intervention

of these two procedures has been shown to have an equivalent success rate of cure of greater than 77% and low rates of complication in a general population (Richter et al., 2010).

Fig 1: Two types of mi-urethral slings tapes
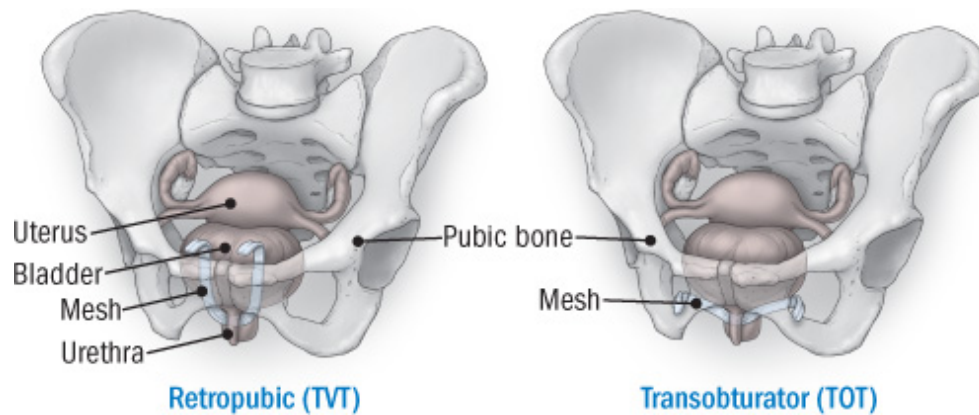
Source: American Urogyneacologic Society; www.mypelvichealth.org

1.11 Benefits of mid-urethral slings over Burch Colposuspension

- Short surgical procedure usually takes less than 30 minutes to perform
- Shorter hospitalisation time
- Recovery time generally quicker than other procedures for SUI
- Less post operative pain
- Faster return to normal activities

1.12 Risks associated with mid-urethral slings

Mid-urethral slings are not free of complications and, although rare, some of these complications can be challenging. Some complications occur intra-operatively, whereas others appear in the early or late postoperative period. Several intra-operative and postoperative complications have been described with mid-urethral slings (Novara et al., 2008). Liapis et al.,2002 reported   cure rates of 87% with TVT with the following complications, perforation of bladder 3.7 – 23 %, bleeding 0.8-3.3%, voiding difficulty 1.5-17%, de novo urgency 2.5-25%. Similarly Richter et al.,2010   reported complications associated with TOT, mesh erosion (<0.5%), infection, long-term pain.

Table 2: Classification of complications of midurethral tape surgery

_____

Intra-operative complications

Hemorrhagic complications

Urinary tract injury

Postoperative complications

Infectious complications

Vaginal tape extrusion, urethral, and intravesical tape erosion

De novo voiding dysfunction

Urinary retention

High post void residual and emptying symptoms

De novo urgency

_____

1.13 Tension free vaginal tape (TVT)

Ulmsten and Petros (1995) introduced an effective minimally invasive option with low postoperative morbidity for surgically managing SUI, the "tension-free vaginal tape" (TVT). TVT is the most studied sling, has comparable success rate to colposuspension (Ward et al., 2004) but is still associated with voiding disorders persisting beyond the immediate post-operative period.

Classical retropubic TVT (retropubic route) involves the passage of polypropylene mesh tape covered with a plastic sheath from a vaginal incision (either side of mid-urethra), passage of the needle behind the symphysis pubis and exiting of the needle on the anterior abdominal wall (suprapubic area).

It involves placement of a polypropylene tape in a tension free manner in the midurethra without elevation of the bladder neck and without fixation of proximal ends of supportive tape. Over the years the use of this procedure has become widespread throughout the world. In the early twentieth century it was considered the gold standard in the management of stress urinary

incontinence. A 10 years follow-up of Ulmsten's original series (TVT) found an objective cure rate of 90% and its efficacy was found to be equivalent to that of colposuspension (Ulmsten et al.,1993).

Use of the tension free vaginal tape is based on the following principles:

1. It is a mid urethral rather than a bladder neck suspension.

2. It is a knitted polypropylene mesh (45cm x 1.1cm x 0.7cm) sling

3. It is not sutured or anchored to any structure (pubic bones, ligaments, or rectus sheath)

4. It is therefore considered tension free (reduces incidence of voiding difficulties)

5. The newer tension free sling devices are not anchored but instead suspended through the retropubic space, hence the name.

1.14 Advantages of TVT

Transvaginal tape has several advantages compared with Burch Colposuspension. These include minimal surgical trauma, shorter hospital stay, use of local or regional anaesthetics, low cost and shorter operating time (Ulmsten et al.,1993).

1.15 Disadvantages of TVT

TVT is associated with a range of potential complications, in particular bladder perforation 3.7-23% appears to occur more frequently (Richter et al., 2010), development of urinary retention and difficulties with micturition following surgery 1.5-17% (Novara et al., 2008). A recent large, multicentre trial demonstrated that 2.7% of women undergoing retropubic tape insertion sustained voiding dysfunction requiring surgery (Richter et al., 2010). The potential problem with synthetic tape is erosion of the tape material into the bladder, urethra or vagina which occurs at a rate of less than 1% (National Institute of Clincal Excellence: NICE., 2003). New onset symptoms of urgency and detrusor overactivity have also been reported following use of TVT (Cetinel and Tarcan., 2013).

1.16 Transoburator tape (TOT)

The transoburator-type sling, which avoided the risks of bladder, bowel and major vascular injury was developed by Delorme in 2001, which avoids the Cave of Retzius and intrabdominal region.

Transobturator sling can be carried out in two ways namely the "outside in" technique example in the Monarch system and the "inside out" technique example the TVT obturator technique.

The transobturator route was researched and developed by Delorme in 2001 with the aim to reduce complications like bladder, bowel and vascular injuries. His technique involved the outside in approach. The transobturator route was further modified by the inside out technique by (Jean de Leval.,2003) and this gained widespread acceptance. Jean de Leval felt that by placing the tape from the miduretrhra and working your technique away from the urethra achieved a higher mid-urethral placement as compared to the outside in technique. The advantages of the transobturator route are that it provided safe needle passage avoiding the retropubic space hence eliminating bladder, bowel and vascular injures. Midurethral tape procedures have gained popularity in the last decade due to its diminished invasiveness, short operative time, brief hospitalization period.

The procedure has a success rate of 85–90 per cent in the short term and 60–70 per cent in the long term. Furthermore, a meta-analysis has further shown equivalence in terms of cure between the transobturator (TOT) and retropubic placement (TVT) of mid-urethral slings (Fong and Nitti., 2010).

1.17 Advantages of transobturator approach to retropubic approach
• It avoids the retropubic area, thus decreasing the risk of bowel perforation and vascular injury.
• It requires less operative time.
• The transobturator route is believed to mimic the natural support system in the pelvic floor better than the TVT.

1.18 Complications of Transobturator Tape

23

Postoperative groin pain is reported more frequently with the transobturator route (2.2 %) and is usually resolved within two months of follow-up (Laurikainen et al., 2007).

Although it avoids the retropubic area, there is a higher risk of damage to the obturator vessel tributary and the vagina (0.9%): (Bonnet et al.,2005; Darai et al., 2007). There is a higher risk of vaginal erosion with the TOT (7.6%) than with the TVT approach. Furthermore groin abscesses (1.9%) have been reported with TOT (Robert et al., 2007).

1.19 Treatment Options for Stress Urinary Incontinence

 Treatment options for stress urinary incontinence (SUI) in women are designed to prevent the involuntary loss of urine from the urethra during increases in intra abdominal pressure that occur during physical activity, coughing, sneezing and laughing. No single procedure or intervention is optimal for all patients. Since a variety of treatment options are available, it is possible to tailor therapy to the desires and needs of the individual patient.

The key to an optimal therapeutic outcome is an accurate diagnosis combined with the selection of an appropriate intervention that is acceptable to the patient after controlling for confounding for multiple factors.

1.20 Non-pharmacological therapy

- Lifestyle modifications (caffeine, alcohol and fluid management)
- Bladder training
- Pelvic floor exercise
- Weight loss in obese women

1.21 Pharmacological therapy

Pharmacologic therapy has been recently used, with varying success rates, for the treatment of SUI in women and includes fesoterodine, duloxetine, topical oestrogens.

While the literature reports a small benefit, the risk of side effects are a concern and includes nausea and headaches (Shamliyan et al.,2012).

1.22 Surgical

Many surgical procedures have been described for the treatment of SUI.

Surgical treatment remains the most effective therepeutic option and approximately 200 different surgical procedures have been described (Virkud et al., 2011).

Since their introduction in 1996, tension-free midurethral slings (MUS) have been proven to have long-term efficacy and safety and is considered the gold standard treatment of female stress urinary incontinence.

The European Association of Urology Guidelines and International Consultation on Incontinence recommends that retropubic and transoburator midurethral slings (MUS) be considered as the first line surgical treatment option for female SUI management after the failure of conservative measures (Lucas et al., 2012; Abrams et al., 2013).

The ultimate aim of surgery is to alleviate symptoms of stress urinary incontinence, avoid the onset of new urinary symptoms, avoid complications and to maintain continence for long periods of time.

Historically all efforts were focused on the bladder neck. Several options were innovated such as the Marshall-Marchetti–Krantz Cysto-Urethropexy (MMK) procedure which was first described in 1949 (Virkud et al., 2011). It is a transabdominal suspension technique of the vesico-urethral junction or bladder neck onto the periosteum of the pubic symphysis. This procedure was related with many complications such as damage to the sphincter mechanism, development of osteitis pubis, overcorrection of the elevation of bladder neck. This led to the development of the Burch Colposuspension which was introduced by John Burch in 1961. He described it as an alternative transabdominal technique in which the urethral wall and pubic bone remain untouched.

For years, the standard surgical treatments for stress incontinence were the Burch procedure (which supports the bladder neck and urethra with sutures running internally from the vagina to the pubic bone through an abdominal incision) and the fascial sling (which supports the upper urethra with a sling made of the patient's own tissue). These treatments were usually effective, but they required hospitalization, general anaesthesia, and substantial recovery time and they carried all the risks of major surgery. A long-term series demonstrated excellent durability (Alcalay et al., 1995; Drouin et al., 1999). Lapitan et al. (2003) reviewed 33 trials that involved a total of 2,403 women, who underwent open retropubic colposuspensions and found an overall cure rate between 68.9% and 88.0%. They reported that the overall continence rates were approximately 85-90% within the first year and 70% after five years of treatment.

With technological advancements and improvements with equipment and instrumentation the Laparoscopic Burch procedure was first introduced and reported by Vancaillie and Schuessler (1991). The Laparoscopic Burch was regarded as being less invasive, associated with reduced morbidity but was associated with longer surgical time and a steep learning curve. The other drawback was that it required a skilled surgeon and was associated with a steep learning curve to master the procedure. In an attempt to find a procedure with a shorter operative surgical time and reduced morbidity the TVT was introduced (Lapitan et al.,2003).

Urethral bulking agents

Injectable therapy using bulking agents composed of synthetic materials, bovine collagen, or an autologous substance augments the urethral wall by creating artificial cushions in the urethra submucosa, improving urethral coaptation, increasing urethral resistance to urinary flow and hence preventing urinary leakage. Injection of bulking agents to treat a dysfunctional urethra is a minimally invasive method of correcting intrinsic sphincteric deficiency (ISD) and can be performed as an outpatient procedure. They can be injected transurethrally or pararurethrally with or without cystoscopic guidance. The ideal agent for injection should be long lasting, hypoallergenic and non migratory and should cause the least inflammatory response (Bradley et al.,2015).

A Cochrane review of periurethral injection therapy for urinary incontinence in women in 2007 and reprinted in 2009 concluded that there is still an unsatisfactory basis for the use of urethral bulking agents as a first line treatment for SUI. It also suggested that transurethral route resulted

in fewer complications than paraurethral administration. The success rate was lower than synthetic slings and colposuspension and that it was inferior to open surgery at 12 months but with a better safety profile and a lower morbidity rate. The review recommended other surgical procedures as first line treatment for women who are fit for surgery and injectable therapy reserved for those who have extensive co-morbidity and are not fit for surgery (Cochrane database systematic review.,2012).

Artificial Sphincters

Foley described an artificial sphincter in 1974, that was an externally non urethral cuff attached to a pump kept in the patients pocket. This is an implantable device which compromises of an inflatable cuff, a balloon to regulate pressure and a control pump. Essential characteristics of an ideal patient for artificial urinary sphincter include motivation, manual dexteritiy, relativily normal detrusor, absence of urinary tract infection, failure of alternative means of incontinence control, and realistic expectations. It can be placed vaginally or abdominally where the cuff surrounds the bladder neck, the balloon is placed in the pelvis and the pump is placed in the labium majoris. There seems to be a higher infection rate with vaginal placement, hence most surgeons choose the abdominal route. The largest study of artificial urinary sphincter in the literature reports that 90% of patients have a functional artificial urinary sphincter in place at a mean follow up of 5 years, with a 28% revision rate(Sajadi et al.,2015).

1.23 Rationale

In 2003 the Urogynaecological Unit at Inkosi Albert Luthuli Central Hospital was established and protocols for Urogynaecology referrals from surrounding hospitals were instituted. All

patients attending the urogynaecology clinic for stress incontinence were fully evaluated with a detailed history and clinical examination and urodynamic studies. Patients were interviewed with a structured questionnaire according to the Kings College incontinence questionnaire (Linda Cardozo et al.,1997). Women with history of SUI were evaluated with baseline investigations which included midstream urine, frequency and voiding chart (bladder diary), Q tip test. Q tip test was done in the majority of patients. The cotton swab or Q tip test uses a sterile lubricated cotton or Dacron swab, which is inserted into the urethra just until the end of the urethra and beginning of the trigonum of the bladder. The patient is asked for valsalva provocation. If the angle of the Q tip rotates more than thirty degrees, a urethrovesical hypermobility is probable. A positive test contributed to diagnosis of SUI in women. If symptoms persisted after 4 months of conservative management (behavioural modification, pelvic floor rehabilitation and physiotherapy) they were then subjected to urodynamic studies. In selected cases perineal ultrasound was done. If stress urinary incontinence was demonstrated on urodynamic studies then patients were offered midurethral tape procedures. The midurethral tape in our institution is done as an inpatient procedure under general anaesthetic. If the patient has associated prolapse, all corrective surgery were performed at the same time. Patients were then evaluated 7-10 days post operation, then monthly thereafter 6 monthly intervals for a year and then annually if there are no associated problems. At each visit symptoms were assessed addressing urinary symptoms, overactive bladder signs and symptoms and voiding dysfunction.

Currently mid-urethral tapes, (tension free vaginal tape and transobturator tape), are being used to treat patients for stress urinary incontinence at Inkosi Albert Luthuli Central Hospital. The reported success rate with the TVT and TOT is variable worldwide. There is a paucity of data on the use of these tapes in our setting. Success rates following the procedure, intra-operative and post operative complications, and new symptoms have not been evaluated.

1.24 Aim

An evaluation of outcomes and complications of patients undergoing mid-urethral tapes for stress urinary incontinence in a tertiary institution

1.25 Objectives

Primary objectives

- To evaluate the intra-operative and postoperative complications in women undergoing mid-urethral tapes for stress urinary incontinence at IALCH.

- To evaluate the objective and subjective success following mid-urethral tapes in this cohort of patients.

- To compare the outcomes of patients at IALCH who underwent MUT with that of documented literature.

- To evaluate patients who underwent MUT when the only indication was urodynamic stress incontinence.

Secondary objectives

- To evaluate the patient profile in women undergoing mid-urethral tapes.

- To evaluate the urodynamic data prior to mid-urethral tape surgery.

Chapter 2: Methodology

2.0 Research design

A retrospective chart review of patients who underwent insertion of TVT or TOT were evaluated between 1st January 2004 and 31st December 2013. All patients were identified from the surgical records at the Urogynaecology Unit, IALCH Durban, South Africa.

2.1 Study population

Included women presenting with urodynamic stress incontinence and urodynamic mixed incontinence who underwent midurethral tapes as surgical intervention.

2.2 Sampling and Data collection

IALCH is a fully computerised hospital and all patient records are on a computerised database. Data from the medical records of patients was extracted and recorded on a structured data form. This database was initially Medicom and was changed to Sorian database in 2010. This data included demographic (age, race, BMI, marital status, education, occupation, residence, referral site) and clinical data as follows: parity, menopausal status, hiv status, medical and surgical history, urinary symptoms, quantification of pelvic organ prolapse if coexisted with stress urinary incontinence and diagnosis. Patients were interviewed with a structured questionnaire according to the Kings College incontinence questionnaire. Surgical notes of surgery for type of SUI, surgery for prolapse, route of surgical intervention, intraoperative complications, duration of follow up, post operative evaluation of outcome at each post surgical visit was evaluated. Urodynamic studies were also recorded preoperatively (Annexure 1).

2.3 Inclusion and Exclusion criteria

All women who underwent midurethral tapes for urodynamic stress incontinence and urodynamic mixed incontinence were included in this study.

Exclusion criteria included mixed urinary incontinence with a predominant stress component, urge or overactive bladder, perineal, urethral or urinary tract infections, pregnancy and neurogenic bladder.

2.4 Definition of Cure

Success of SUI surgery was defined as having no postoperative stress urinary incontinence, no voiding dysfunction, improvement or no alteration in frequency and urgency symptoms. Voiding was considered normal if the patient passed urine without straining and the residual volumes did not exceed 50mls.

Objective cure rate was determined by a cough stress test with a reasonable full bladder during follow-up pelvic examination. Subjective cure was recorded as the absence of leaking with coughing, laughing, sneezing, or exertion. Symptoms of overactive bladder (urgency, frequency, nocturia, and urge incontinence) were recorded. Subjects were included with a minimum of 1 year follow-up.

2.5 Anthropometric measurements

 Body mass index (BMI) was calculated as the ratio of weight (kg) to height (m) squared (kg/m^2). Maternal age was analyzed as a categorical variable to account for a potential nonlinear relationship and categorized as less than 45 years, 45-50 years, 51-55 years, 56-60,61-65 years and more than 65 years or older. For purposes of this study, being overwieght was defined as a body mass index $\geq$ 30 kg/m2.   Race was categorized as Indian, Black, Coloured and White.

2.6 Statistical analysis

Data was entered into a computer database using Microsoft Excel and imported on SPSS (The Statistical Package for Social Sciences, version 22) for analysis. The data was analyzed using descriptive statistics with the use of frequency, tables, percentages and cross-tabulation and results are presented as mean ± SD, range. Student t test was used for continuous variables and chi square test for categorical variables. A p-value < 0.05 was considered statistically significant.

2.7 Regulatory Approval

The study was approved by the BREC (Biomedical Research Ethics and Committees) - BE 502/14 , Postgraduate Education and Research Office (student number: 200267651) Nelson R

Mandela, School of Medicine, University of Kwa Zulu - Natal and IALCH administration office by the Hospital management of the IALCH Hospital administration.

Data sheet used for recording all data from patient medical files together with approvals from BREC, Postgraduate Education and Research Office, IALCH administration, and KZN Department of Health are shown in Annexure 1, 2, 3, 4,5 and 6.

Chapter 3: Results

3.0 Introduction

A total of one hundred and twenty one patients were identified from the Sorion and Medicom database. One hundred and one (83.5%) patients were diagnosed with pure urodynamic stress urinary incontinence and twenty (16.5%) patients had mixed urinary incontinence with a predominant stress urinary component. One hundred and nineteen (98.3%) were new cases and two (1.7%) were recurrent stress urinary incontinence. There were eleven (9.1%) retropubic insertions (TVT) and one hundred and ten (90.9%) TOT insertions. The annual number of stress urinary incontinence patients managed at IALCH is shown in Table 3 and graphically depicted in Figure 2.

Table 3: Number of SUI managed yearly at the study site over the 10 year the study period

Year	Number	Percentage
2004	2	1.7
2005	18	14.9
2006	18	14.9
2007	17	14.0
2008	18	14.9
2009	10	8.3
2010	8	6.6
2011	9	7.4
2012	11	9.1
2013	10	8.3

Figure 2: Graphical representation of the number patients with stress urinary incontinence managed yearly at the study site over the 10 year study period
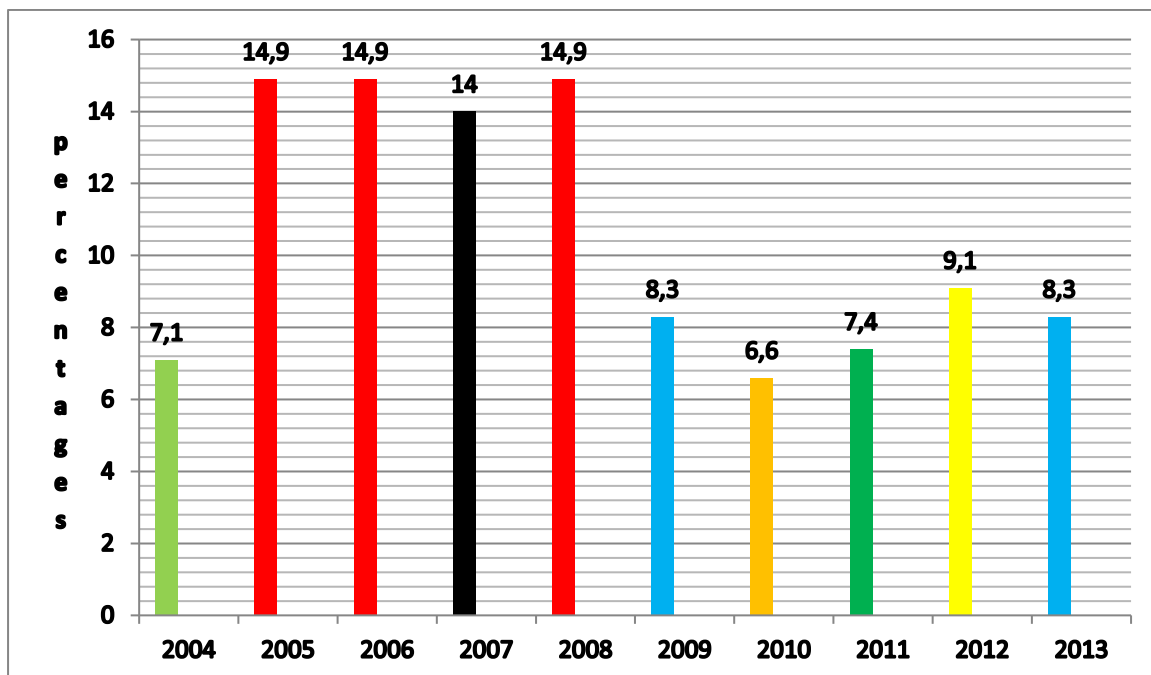
3.1 Baseline demographic data are summarized in Table 4 and are as follows:

Table 4: Demographic details

Variable	Number (n=121)	Percentage
Age (years)		
<45	11	9
45- 50	29	23.9
51- 55	31	25.6
56-60	36	29.8
61-65	9	7.4
>65	5	4.1
Race		
Indian	76	62.8
Black	25	20.6
White	15	12.3
Coloured	5	4.1
Body mass index(kg/m^2)		
Normal	10	8.3
Overweight	43	35.5
Obese	68	56.2
Referred		
Level 1 – district hospital	4	3.3
Level 2 – regional hosptial	114	94.2
Level 3 – tertiary hospital	3	2.5
Parity		
1	18	14.9
2	48	39.7
3	35	28.9
4	12	9.9
≥5	8	6.6

3.1.1 Age

The age distribution of MUT insertion increased linearly significantly up to 60 years and was more common in the 45 - 60 year age group. Results are graphically shown in Figure 3.

Figure 3: Graphic representation showing the urinary incontinence in the different age groups
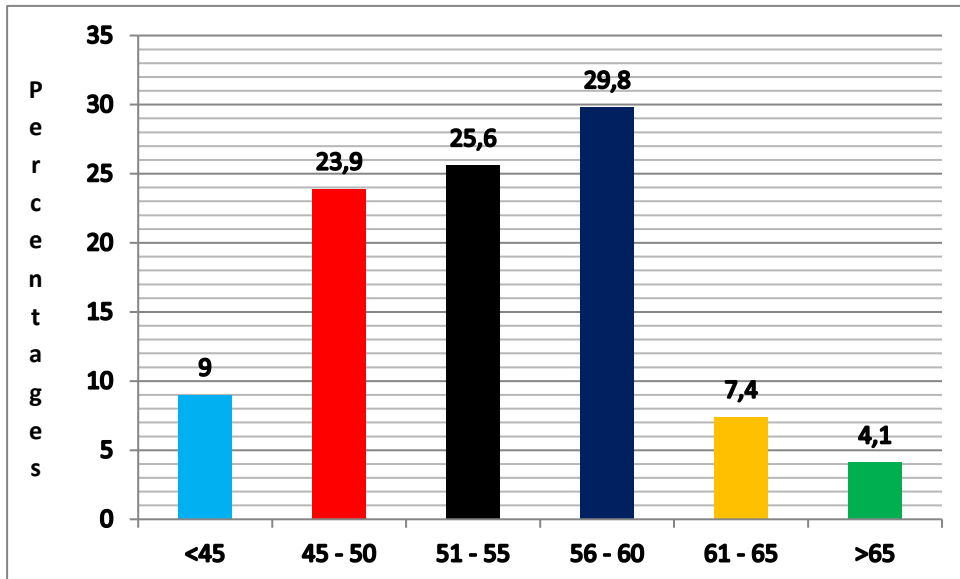
3.1.2 Menopausal status

One hundred and one (83.5%) were postmenopausal. Twenty two (21.8%) of postmenopausal women took hormonal replacement therapy.

3.1.3 Parity

The median parity was three (range: 1-7). The incidence of SUI was 100% in all parity groups. None were nulliparous. Data on parity is shown in table 4.

3.1.4 Mode of delivery

The delivery pattern is shown in Table 5. The majority had normal vaginal deliveries 86.6% in their first delivery and 80.2% in subsequent deliveries, 7.4% had assisted vaginal deliveries at the first delivery and 5.8% had assisted deliveries in their subsequent deliveries. The ventouse extraction was the commonest assisted delivery technique. This is depicted Table 5.

Table 5: Mode of delivery

Mode of delivery	1st delivery	Subsequent deliveries
Vaginal delivery		
Normal delivery	105 (86.8%)	97 (80.2%)
Assisted	09 (7.4%)	7 (5.8%)
Forceps	4 (80%)	1 (14.3%)
Vacuum	5 (20%)	6 (85.7%)
Caesarean delivery	7 (5.8%)	17 (14%)

3.1.5 Body mass index

The majority of patients 56.2% in our cohort were obese followed by 35.5% being overweight. The incidence of stress urinary incontinence was 100% in all BMI categories.

The results of BMI are summarized in Table 4.

3.1.6 Race

The predominant race group was Indian (n=76; 62.8%) followed by black African (n=25; 20.6%), Whites (n=15; 12.3%) and Coloureds (n=5; 4.1%).

3.1.7 Referral pattern

One hundred and fourteen (94.2%) of the patients that required MUT insertion were referred from level 2 regional hospitals.

3.1.8 Selected variables

3.1.9 Marital status

Majority were married eighty one (66.9%) eight (6.6%) patients were single, sixteen (13.2%) were divorced and sixteen (13.2%) were widowed. Marital status is shown in Table 6.

3.1.10 Educational status
This is shown in Table 6.

3.1.11 Occupation

 Ninety eight (81%) were unemployed.

3.1.12 Residence

Seventy (57.9%) of the patients resided in urban area and fifty one (42.1%) in semi rural areas.

3.1.13 HIV status
Two patients (1.7%) were HIV positive and both were on antiretroviral treatment.

Table 6: Social characteristics of selected variables

Variable	Number (n=121)	Percentage
Marital status		
Single	8	6.6
Married	81	66.9
Divorced	16	13.2
Widowed	16	13.2
Education status		
Primary	48	39.7
Secondary	51	42.1
Tertiary	2	1.7
No formal education	20	16.5
Occupation		
Employed	23	19
Unemployed	98	81
Residence		
Semi-rural	51	42.1
Urban	70	57.9
HIV status		
Negative	119	98.3
Positive	2	1.7
Menopausal status		
Pre-menopausal	20	16.5
Postmenopausal	101	83.5
HRT treatment	22	21.8

3.14 Medical history

Seventy three (60.3%) of the women had concomitant medical disorder. Diabetes, hypertension was the most common co-morbid problem. The major and minor co-morbidities are shown in Table 7 and Table 8

Table 7: Co-morbidities

Co-morbidities	Major
Hypertension	23 (31.5%)
Hypertension + asthma	1 (1.4%)
Hypertension + IHD	2 (2.7%)
Diabetes	21 (28.8%)
Diabetes + hypertension	16 (21.9%)
Diabetes + arthritis	2 (2.7%)
Hypertension + Diabetes + IHD	4 (5.5%)
Hypertension + Diabetes + asthma	2 (2.7%)
Hypertension +diabetes + IHD + asthma	1 (1.4%)
Tuberculosis	1 (1.4%)

IHD- ischaemic heart disease

Table 8: Minor Co-morbidities

Minor Co-morbidities
Depression 7 (41.2%)
Hypothyroidism 4 (23.5)
Parkinson 1 (5.9%)
Bells palsy 1 (5.9%)
Psoriasis 1 (5.9%)
Gout 1 (5.9%)
Scoliosis 1 (5.9%)
Sinusitis 1 (5.9%)

3.15 Surgical history

Seventy (57.9%) patients had undergone previous surgery. Fifty (71.4%) had undergone only gynaecological surgery and twenty (16.5%) had undergone only non-gynaecological surgery. This is shown in Table 9.

Table 9: Previous surgical history

Gynaecological surgery (n=50)		Non gynaecological surgery (n=20)	
Bilateral tubal ligation	10(8.2%)	Nephrectomy	1(0.82%)
Hysterectomy	35(28.9%)	Tonsillectomy	4(3.03%)
Ovarian cystectomy	2(1.65%)	Thyroidectomy	5(3.3%)
Polypectomy	1(2 %)	Appendectomy	4(4.13%)
Cystectomy	2(1.65%)	Cholecystectomy	4(4.13%)
		Mastectomy	1 (0.82%)
		Spinal surgery	1(0.82%)

3.16 Urinary symptoms on presentation

Symptoms of both stress urinary incontinence and overactive bladder were addressed on history. Ninety eight (81%) had pure stress urinary incontinence and twenty three (19%) were of the mixed urinary incontinence Table 10.

Table 10: Urinary symptoms

Variable	Number (%)
Clinically pure SUI	**98 (81%)**
Stress urinary incontinence	
Mixed urinary incontinence	**23 (19%)**
Stress urinary incontinence/urgency/ urge urinary incontinence	16 (69.6%)
Stress urinary incontinence/urgency	3 (13%)
Stress urinary incontinence/nocturnal enuresis	2 (8.7%)
Stress urinary incontinence/urgency/ urge urinary incontinence/nocturnal enuresis	2 (8.7%)

3.17 Factors affecting leakage of urine

Factors affecting leakage of urine are listed in Table 11. Physical effort and exercise was the most common factor affecting the leakage of urine.

Table 11: Factors affecting leakage of urine

Factors affecting leaking of urine	Number (%)
Single	
Physical effort / exercise	95 (78.5%)
Coughing and sneezing	20 (16.5%)
Multiple	
Physical effort / exercise/coughing/sneezing/no clear reason	3 (2.5%)
Physical effort / exercise/coughing/sneezing/before reaching toilet	2 (1.7%)
Physical effort / exercise/coughing/sneezing/intense urge	1 (0.8%)

3.18 Frequency of urine loss at stress

The frequency of urinary incontinence during stress episodes resulting in leakage is shown in Table 12 and graphically represented in Figure 4. The most common listed frequency of urine loss at stress was several times a day

Table 12: Frequency of urine loss at stress episodes in all patients

Frequency of stress episodes	Frequency (%)
Several times a day	105 (86.77%)
Once a week	4 (3.3%)
2-3 times a week	5 (4.1%)
Once a day	1 (0.8%)
Leaks continuously	6 (4.9%)

Figure 4: Graphical representation of frequency of urine loss at stress
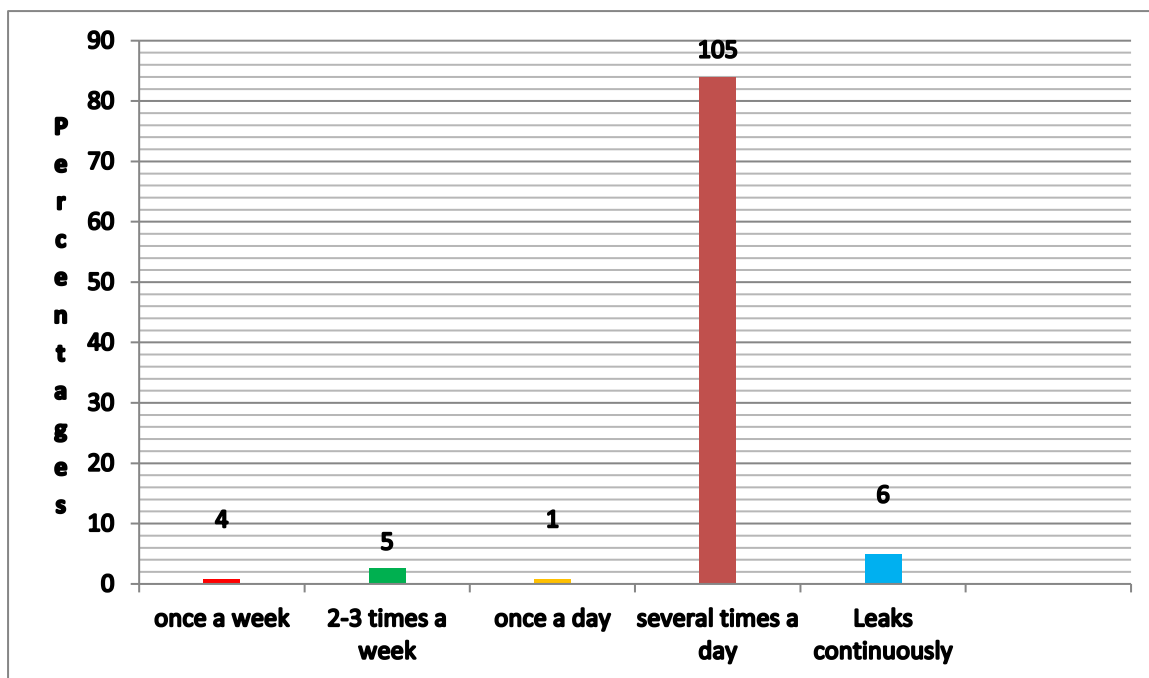
3.19 Bowel dysfunction

Bowel dysfunctions are shown in Table 13. Thirty two (26.4%) complained of constipation, four (3.3%) had diarrhoea and one (0.8%) had faecal incontinence. One patient had diarrhoea and faecal incontinence

Table 13: Bowel dysfunction

Bowel dysfunction	Number (n=121)	Percentage
Single		
Constipation	32	26.4
Diarrhoea	4	3.3
Faecal incontinence	1	0.8
Multiple		
Diarrhoea + faecal incontinence	1	0.8

3.20 Examination

On examination seventy five (62%) had oestrogenised vulvas. Stress urinary incontinence was demonstrated in one hundred and seventeen (96.7%) patients, thirty one patients (25.7%) had associated prolapsed. The examination results are shown in Table 14.

Table 14: Examination

Variable	Number (n=121)	Percentage
Vulva –estrogensied	75	62.0
SUI demonstrable	117	96.7
Q TIP test		
Positive	115	95
Negative	6	5
Associated prolapse	31	25.7
Prolapse		
Anterior	11	9.1
Middle	2	1.6
Posterior	11	9.1
Anterior + Posterior	7	5.7

Table 15: Investigations

Laboratory investigations results are shown in Table 15.

Variable	Data
Hb (g/dl)	
Mean	12.4 ± 1.3
Median	12.7
Range	9.8 – 16.6
Platelets (10^3)	
Mean	294.2 ± 76.8
Median	300
Range	44 – 515
Frequency voiding chart (amount leaked)	80 (73.4%)
Radiology VCU vesico urethal angle straight	71 (65.1%)
Radiology VCU vesico urethal angle not straight	4 (3.7%)

3.21 Urodynamics

Urodynamic studies were performed on all patients. UDS in the unit includes non invasive uroflowmetry, filling and voiding cystometrogram and urethral profile pressure. The urodynamics results are shown in Table 16.

Table 16: Urodynamics

Variable	Data
Non invasive uroflowmetry	0
Qmax	
Mean	30.1 ± 12.3 ml/sec
Voided volume	
Mean	406.8 ± 196.6 ml
Voided time	
Mean	33.4 ± 21.2 ml/sec
Qavg	
Mean	18.2 ± 11.6 ml/sec
Residual	
Mean	36.9 ± 33.3 ml

3.22 Cystometrogram details

The cystometrogram results are shown in Table 17.

Table 17: Cystometrogram details (voiding and filling)

Variable	Data
First sensation	
Mean	128.3 ± 63.3 ml
Maximum cystometrogram capacity	
Mean	409.7 ± 149.2 cm H20
Detrusor overactivity	4 (3.7%)
Stress urinary incontinence,	121 (100%)
Pdet at onset of micturition	
Mean	25.9 ± 14.5 cmH20
Pdet at Qmax of micturition	
Mean	32.9 ± 6.0 cmH20
Pdet at end of micturition	
Mean	27.4 ± 16.9 cmH20

3.23 Urethral pressure details

The mean (SD) maximal urethral closure pressure and functional urethral length was 73.5 ± 48.2 cmH20 and 21.8 ± 13.1 mm respectively as represented on table 18.

Table 18: Urethral pressure details

Variable	Data
Maximal urethral closure pressure	
Mean	73.5 ± 48.2 cmH2o
Functional urethral length	
Mean	21.8 ± 13.1 mm

Twelve months after the operations, the cumulative cure rates in the TVT group and the TOT group were 95.2% and 82.7%, respectively (p = 0.009).

3.24 Additional gynaecological surgery

Thirty one (25.6%) patients had additional gynaecological surgical procedures. There were nineteen cases with one additional surgical procedure, eleven patients with two surgical procedures and one patient that had three procedures. In the TVT group there were five cases with two additional surgical procedures (45.5%) and six cases with one additional surgical procedure (54.5%). Among the TOT treated patients there was one additional surgical procedure in thirteen patients (65%), two in six patients (30%) and three in one patients (5%). The overall success rate in those patients that underwent additional gynaecological surgery was 81%. The most common additional surgeries for both surgical techniques are listed in Table 20

Of significance one hundred and twenty one patients underwent additional surgery and ninety only had MUT, success and failure are shown below in table 19.

Table 19: Outcomes in all patient undergoing MUS placement only

Additional Gynaecological Surgery					MUS Placement Only	
Outcomes	TVT n=11	%	TOT n=20	%	TOT n=90	%
Success	9	81.8 %	16	80.0%	89	98.9%
Failure	2	18.2%	4	20.0%	1	1.1%
Overall Success Rate		81.8%		80.0%		98.89%

Table 20: Additional gynaecological surgical procedures

Type of surgery	TOT	TVT
Vaginal hysterectomy	2	
Laparoscopic assisted vaginal hysterectomy	2	
Anterior repair	5	4
Posterior repair	4	2
Laparoscopic assisted vaginal hysterectomy/ant repair	3	2
Vaginal hysterectomy/ant repair/uterosacral vault suspension	1	
Vaginal hysterectomy/ant repair	1	1
Laparoscopic assisted vaginal hysterectomy/post repair	1	
Anterior and posterior repair	1	2

Table 21: Complications

Complications	Number (n=121)	%
Intraoperative		
Anaesthetic complications	0	0
Intraoperative bleeding	0	0
Bladder perforation	0	0
Bowel injury	0	0
Urethral injury	0	0
Vascular injury	0	0
Failure	0	0
*Immediate post operative within 24 hours		
Anaesthetic complications	0	0
Post operative voiding - residual < 100 ml	120	99.
Post operative voiding - residual > 100ml	1	2
Retropubic heamatoma	0	0.8
Vulvovaginal heamatoma	0	0
Vaginal laceration	0	0
**Late post operative >24hours but <2 weeks		
Single		
Backache	9	7.4
Thigh pain	8	6.1
Early therapeutic failure	1	0.8
Urinary tract infection	2	1.6
***Delayed complications > 2 weeks and < 1 month		
Single		
Thigh pain	7	5.7
Backache	9	7.4
Urgency	1	0.8
Urinary tract infection	3	2.4
Voiding dysfunction + thigh pain new onset	3	2.4
Urinary tract infection + backache	2	8.3
Backache	17	14

3.25 Intraoperative

There were no intraoperative complications (aneasthetic complications, intraoperative bleeding, bladder perforation, bowel injury, urethral injury, vascular injury).

3.26 Immediate post operative within 24 hours

There was no bleeding or injury noted following removal of the catheter after 24 hours only one patient had post operative voiding - residual > 100 ml (0.8%).

3.27 Late post operative >24 hours but <2 weeks

Twenty one (17.3%) patients reported the following complications at follow up, nine patients backache, three patients reported thigh pain and one patient early therapeutic failure while five reported backache and thigh pain and three patients reported backache thigh and groin pain.

3.28 Delayed complications > 2 weeks < 1 month

Three patients reported thigh pain and nine experienced backache. Two patients had symptoms of urinary tract infection and one had associated urgency. Three reported a slower urinary stream (voiding dysfunction), five had associated thigh pain, and two had symptoms of urinary tract infection and seventeen experienced associated backache.

3.29 Objective and subjective outcomes

Objectively cure was determined by a cough stress test with a reasonable full bladder during follow-up pelvic examination. Subjective cure was recorded as the absence of any symptoms of leaking with coughing, laughing, sneezing, or exertion. Symptoms of overactive bladder (urgency, frequency, nocturia, and urge incontinence) were recorded. Subjects were included with a minimum of 1 year follow-up. Objective and subjective outcomes are shown in Table 22 and Table 23 respectively.

Table 22: Objective outcomes at 1 year

Outcomes	n=121	%
Cough Stress test positive	8	6.6
Symptoms of overactive bladder	6	4.9
Cough stress test negative	107	88.4

Table 23: Objective and Subjective cure rate for TOT and TVT at 1 year

Procedure	Cure Rate Objective	Cure Rate Subjective
TOT	95.5	91.8
TVT	81.8	90.9

3.30 Follow up details

Postoperative long term evaluation was carried out after 6 months and 1 year. All the patients attended the follow up visits at 6 month and at 12 months.

3.31 Complications at follow up visits

Complications reported by the patients at follow up visits at 6 months and one year are shown in Table 24. There was no difference in the number of complications observed with TVT placement compared with TOT placement (16 vs 15; p=0.7).

Table 24: Complications reported by the patients at follow up visits at 6 months and 12 months

Complications	TVT	TOT	Percentage
Complications at 6 months			
Symptoms of overactive bladder	3	2	4.1
Symptoms of urinary tract infection	1	3	3.3
Erosion exposure	1	0	0.8
Dyspareunia	2	0	1.6
Backache	3	7	8.3
Complications at 1 year			
Symptoms of overactive bladder	4	2	4.9
Symptoms of urinary tract infection	2	1	2.5
Erosion exposure	0	0	0
Dyspareunia	0	0	0
Backache	0	0	0

Chapter 4: Discussion

4.0 Discussion

Stress urinary incontinence is a common condition with increasing prevalence worldwide. Midurethral sling procedures have become the gold standard surgical procedure for the management of stress urinary incontinence in most centres globally and at present it is the most common surgical intervention for SUI at IALCH. However, this procedure is not without its complications. It is therefore important that surgeons performing these procedures are able to manage intra-operative complications and poor post-operative complications appropriately as they impact considerably on the patient's quality of life. In the patients that underwent midurethral tapes 83.5% had urodynamic SUI and 16.5% had mixed urinary incontinence with SUI being the predominant component. These findings are consistent with other studies (Harrison and Memel.,1994 ; Constanini and Lazzerri.,2007).

In our study overall complication rate was minimal. To our knowledge, this is the first study in South Africa addressing complications associated with MUT use at these time periods 6 months and 1 year. All other studies observed complications intraoperatively and complications seen after the procedure were grouped as postoperative complications.

In our cohort of patients there was no intraoperative surgical anaesthetic complications, intraoperative bleeding, bladder perforation, bowel injury, urethral injury, vascular injury and failure which is in accordance with other studies (Cho et al., 2011; Sola et al., 2007) but is at variance with other studies which reported bladder (3.2%) and vaginal perforation (1.6%) locally (Chrysostomou., 2012) and worldwide (Brubaker et al., 2011; Kristensen et al., 2010). The study by Chrysostomou was conducted at Johannesburg Hospital, and included seventy nine patients with stress urinary incontinence who underwent TOT procedure. All cases were done by a single surgeon. Intra-operative complications were observed which included two bladder perforations and two vaginal perforations.

Although bladder injury is the most common intraoperative complication reported with the retropubic TVT occurring in 3.8% to 9.7% of cases there were no such injuries in our study cohort. There were also no cases of vascular or visceral injuries in our study. These results are consistent with the findings of other studies pertaining to transobturator sling procedures (Cho et al., 2011; Sola et al., 2007). In the literature immediate complications after surgery with

TVT reported by Abouassaly et al, identified urinary retention, pelvic haematoma and suprapubic wound infection as complications (Abouassaly et al., 2004). However based on the literature bladder perforations are shown to increase with the TVT, as the needle passes through the retropubic space. However the majority of patients in our study had the transobturator approach which avoids the bladder and the vascular plexus. In view of the small number of patients in our study cohort complications were not detected due to sample size being small in the TVT group.

In our study, immediate post operative phase (within 24 hours) there were no identified retropubic heamatomas, vulvovaginal heamatomas, and vaginal bleeding. Following removal of the catheter one patient had a post operative voiding residual > 100ml. The patient was found to be diabetic and had urodynamic risk factors for voiding dysfunction. The patient had an increasing residual volume following emptying of the bladder and decreasing detrusor pressure on voiding with a decreased Qmax. The patient was managed with continuation of the Foleys catheter for a further 72 hours, following removal of the catheter the patient voided 200ml, the residual volume was 400ml. This patient was subsequently managed with physiotherapy and was satisfied.

In our late post operative evaluation (>24hours and < 2 weeks) nine patients reported backache, eight patients had thigh pain, one patient had an early therapeutic failure with history of still having symptomatic stress urinary incontinence. Patients with backache and thigh pain were managed with analgesia and anti-inflammatory drugs and at two weeks the pain settled in all patients accept one. Our observations were congruent with the reported literature with TOT (Lee et al., 2007; Abdel-fattah et al., 2010; Moore et al., 2007). Furthermore, (Abouassaly et al.,2004) reported that late complications in their study using TVT included de novo urgency, persistent suprapubic discomfort and intravaginal tape exposure. In one study, no late postoperative complications were noted (Waltregny and De Leval., 2009). In a study conducted at Johannesburg hospital, one tape erosion was detected at the 1-year follow-up, and there were two failures at the 6-month and 1-year follow-up. One case of urge incontinence was observed at the 6-week follow-up (Chrysostomou.,2012).

In our cohort delayed post operative evaluation (> 2 weeks and < 1 month) three patients had thigh pain, one patient urgency and two patients had urinary tract infections. Specific to thigh

pain and backache it was possibly due to the positioning of the patient and the increasing abduction, this was however shown to improve on taking analgesics.

At the 6 month postoperative review five patients were identified with overactive bladder symptoms, four with UTI, one with mesh exposure, two with dyspareunia. However when this cohort of patients were analysed specific to retropubic and transobturator routes, although the numbers are small (TVT 11 patients and TOT 110 patients) overactive bladder symptoms were paralleled in the retropubic route. This can be explained on the basis that the retropubic route is more obstructive than the transobturator route. Mesh exposure and dyspareunia was noted with the TVT. The patients were managed with premarin topical cream and antibiotics for 3 months. Post commencement of treatment the tissue had epitheliased. At the 1 year post operative review no complications were noted. Our results indicate that TVT procedure is a safe treatment for female SUI.

Our comparison of short term complications in patients with MUT placement only compared to patients with MUT placement + additional surgeries showed no significant clinical difference. These are in accordance to an earlier study comparing SUI patients managed with TVT having additional surgery and with TOT having additional surgery (Sola et al., 2007). When MUT placement was compared with the MUT and additional surgery there was not much difference in intraoperative, postoperative and delayed complications as shown in Table 21. Documented literature comparing outcomes and complications found no difference in subjective failure between the transobturator and retropubic approaches of midurethral tapes in patients with SUI.

In our study, women who underwent concomitant surgery during mid-urethral sling placement procedure for urinary incontinence, post-operative urinary tract infection was the most common complication observed compared to those who had mid-urethral sling placement insertion only. Complications included urinary tract infection and backache. Eleven patients had retropubic TVT and one hundred and ten patients underwent transobturator tape procedures. No patients required recatheterisation or self catheterisation prior to discharge from hospital. In our study cohort the percentage of proportion is higher in the TVT compared to the TOT, which makes it difficult to make recommendations.

Recent systemic reviews and metanalysis of MUT reported higher rates of bladder perforations and voiding dysfunction with retropubic procedures compared to TOT procedure. (Brubaker et al.,2012). The higher incidence of urinary tract infections in the retropubic group may be related to the higher rate of voiding dysfunction. Data from both the SISTER and TOMUS Trials demonstrate a higher incidence of UTI following surgery for stress urinary incontinence. Specific to backache when subanalysed between the TVT/TOT groups, more backache was noted with the TOT route. (Marc A Lucky; Paul Irwin.,2012) Documented in the literature this could be explained by the course of the tape through various anatomical structures resulting in irritation and inflammation of the muscle tissue. (Costa P and Grise.,2004). In view of the small numbers of TVT's that were performed in the unit (only eleven cases) it was not statistically feasible to compare the two groups hence much of the data with regard to outcomes will be in the TOT group.

In our cohort of patients transobturator midurethral tape was performed in 110 patients and tension free vaginal tape in 11 patients. Twelve months post surgery, the cumulative objective and subjective cure rates in the TOT group and the TVT group were 95.5% and 81.8 % and 91.8% and 90.9% respectively. A recent multicentre, randomized equivalence trial by Richter et al, comparing outcomes TVT and TOT slings at 12 months showed that objectively assessed success rates with both approaches met the prespecified criteria for equivalence. A systematic review and meta-analysis comparing transobturator and retropubic tapes by Latthe et al, also found no difference in subjective cure rate at 12 months

Gynaecological surgeries especially hysterectomy is a frequently mentioned risk factor for the development of stress urinary incontinence (Altman et al., 2007; Lakeman et al., 2010; Menezes et al., 2010). In a 3 year follow up of one hundred and eighty three patients who were continent previously underwent gynaecological surgery primarily hysterectomy (vaginal, abdominal and total), forty (22%) patients developed SUI (Lakeman et al., 2011). These authors using their prediction model also demonstrated a linear association between the probabilities of developing SUI with continuous variables, body mass index, age and parity. Furthermore, the number of vaginal deliveries in the past did not seem to influence the risk of developing SUI. In our audit, fifty patients had undergone gynaecological surgeries and twenty had non gynaecological surgery. There were thirty five hysterectomies.

In our unit patients are subjected to urodynamic studies prior to anti incontinence surgery. Urodynamic studies from our cohort of patients were demonstrated in all patients and four (3.7%) had detrusor overactivity in combination with SUI. In our unit all patients with failed conservative therapy and mixed urinary symptoms are subjected to urodynamic studies prior to anti incontinence surgery. SUI was demonstrated in all patients during the filling phase of ctystometrogram and four patients had detrusor overactivity in combination with urinary incontinence 3.7%. Urodynamic studies assists in the choice of midurethral tape used. Patients with reduced MUCP are subjected to retropubic tapes. None of the patients pre operatively had voiding dysfunction. Of interest our Qmax mean was 30.1ml/sec, mean voided volume was 406.8ml, and mean residual was 36.9ml.

During voiding CMG the average pressure at onset of micturition was 25.9, mean Pdet at Qmax 32.9 and mean Pdet at end was 27. These pressures highlight that the patient is generating detrusor pressure on voiding and can explain the low incidence of voiding dysfunction post surgery. The mean MUCP of 73cmH2o which is a reasonable value resulted in many of our patients undergoing Transobturator tape procedure which may explain the high surgical success rate. In a study by (Pietersand et al., Is TOT as effective as TVT in patients with borderline maximum urethral closure pressure), it was identified that patients with a MUCP < 43 had six times higher failure rate with TOT route as compared to the retropubic route.

The prevalence of SUI varies with age. In our cohort of patients stress urinary incontinence was lowest in the age group <45 years, peaked in the age group 45-60 years and subsequently decreased in age groups over 65 years.

A 1995 review on the prevalence of stress incontinence in the general population summarized 11 studies conducted with a mixed population of females of various ages and a variety of causes of incontinence. The prevalence is relatively low early in life, has a peak around the time of menopause, and then rises steadily between the ages of 60 and 80 years. (Victor W Nitti.,2001)

In a large Norwegian study on the epidemiology of SUI the authors found an increasing prevalence during young adult life, a broad peak around middle age, and then a steady increase in the elderly. The decreased prevalence observed in our study in the age groups greater than

60 may be due to the fact that the older generation accept urinary incontinence as part of the normal ageing process, may be ignorant of the availability of treatment modalities, or are embarrassed to present with these complaints. In another study conducted on elderly women aged between 70 to 79 years, the prevalence of stress urinary incontinence of 27% for White women and 14% for Black women was observed (Jackson et al., 2004). Two other studies that addressed women in the age groups 37 to 54 years and 40 to 69 years indicated that the leakage of urine was more prevalent among White and Hispanic women than among Black and Asian women (Thom et al., 2006; Danforth et al., 2006).

In our audit, one hundred and one patients were postmenopausal who were diagnosed either with stress urinary and mixed urinary incontinence (predominant component being stress) and were managed with mid-urethral tapes as the surgical intervention. The prevalence of stress urinary incontinence increased linearly with age. A major contributing cause in women > 65 years is overactive bladder.

The diversity of our population provided us a unique opportunity to examine differences in urinary incontinence among four major ethnic groups of patients attending Inkosi Albert Luthuli Central Hospital, Kwazulu Natal. In our cohort of patients the largest number were Indians. This maybe representative of the large number of Indian population that reside in the Durban Metropolitan area. It was not surprising that the black population was the second highest proportion in our cohort.

In a study by Richard Bump addressing SUI in different racial groups he established according to demographic data that the prevalence of SUI was lowest in the Black population due to the patient profile that serviced that hospital.

In an epidemiological study which included Black and White women, aged between 35 and 64 years, the prevalence of urinary incontinence was higher among the White women than the Black women (Fenner et al.,2008; Anger et al., 2006).

Overweight and obesity were common in our patient demographic profile. A high proportion of patients in our cohort were of the obese category. These findings are congruent with several studies which have reported that a higher BMI is a risk factor for SUI (Hunskaar et al., 2008). Obesity is a modifiable condition, and it has been reported that with loss of weight, resolution

of some types of SUI may occur (Hunskaar et al., 2008, Botlero et al., 2009) found that obesity was a significant risk factor for both stress and mixed urinary incontinence. (Khong and Jackson et al., 2008) also highlighted that urinary incontinence could be attributed to the accumulation of extra weight in the midsection, which may put pressure on the bladder and predispose to developing urinary incontinence.

There is conflicting views on the role of mode of delivery and the occurrence of SUI. In our cohort of patients majority had normal vaginal deliveries 86.8% and 80.2% in subsequent deliveries, of significance 7.4% has assisted vaginal deliveries and 5.85% has assisted deliveries in the subsequent deliveries. A number of studies showed that the prevalence of SUI was more prevalent in women who delivered by vaginal delivery compared to caesarean section (Zhu et al., 2010; Van Brummen et al., 2006) while others studies (Herrmann et al., 2009; McKinnie et al., 2005) showed that mode of delivery did not play any role in the prevalence of urinary incontinence.

An association between stress urinary incontinence and co-morbid diseases such as diabetes, connective tissue disorders and hypertension has been reported previously in other studies (Danforth et al., 2006; Barclay et al., 2009). The remaining disorders reported by patients during history taking in our audit were classified as 'others', because it was considered that they did not constitute significant data as the factors predisposing to urinary incontinence. A number of studies have shown that stress urinary incontinence is associated with depression, particularly in the older age and in patients with an urge component (Viktrup et al., 2005; Melville et al., 2002; Dugan et al., 2000). In our study seven patients were identified with depression. It is well known that SUI is associated with depression, although it was not volunteered by our patients.

4.1 Limitations

This study had several limitations. This study was not a randomized controlled study, but a single centre retrospective study. The number of patients in the TVT group was lower than that in the TOT group. This was also one of the limitations of a retrospective study. A relatively short follow-up duration is another limitation of this study. A number of important data was missing from the medical files. In addition, urinary incontinence information was based on self-report. The reliability and validity of self-reported incontinence may be questionable. The follow up period was too short. It is difficult to know, for example, whether the observed racial disparities in the prevalence of SUI are due to real differences or to differences in reporting the urinary dysfunction among the various ethnic and racial groups, since SUI can be reported differently by ethnic and racial groups according to the accepted cultural norms.

In this study, both TVT and TOT were performed contemporarily by a single experienced surgeon. This is the strength of our study because it increases the objective comparability. Therefore, previous conflicting results of TVT and TOT comparative studies might also have been affected by the risk of same bias.

4.2 Conclusion

At the end of twelve months our cumulative objective and subjective cure rates in the TOT group and the TVT group were 95.5% and 81.8 % and 91.8% and 90.9% respectively. There were no intraoperative complications in our study cohort and at the end of twelve months four patients had overactive bladder in the TVT group and two patients in the TOT group (4.9%). The overall results of our study indicate that midurethral tape surgery is a safe and efficacious intervention with reasonable cure rates and low complication rates and is associated with a low morbidity.

4.3 Recommendations

Although obesity and diabetes maybe independent modifiable risk factors for incontinence, future research is needed to further examine the threshold above which body weight increases risk in diabetic women, such information is critical to setting future targets for treatment and prevention intervention. Further study is needed with greater number of patients in each racial group including a need to follow patients for longer duration. In addition, further studies with a larger group of patients to clarify the effect of co-morbidities on urinary incontinence. Furthermore, for a more definite conclusion, further study in a larger population and a randomized controlled trial are required.

Chapter 5: References

References

Haylen BT, de Ridder D, Freeman RM (2010). An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. Neurourol Urogyn, 29, p. 4–20.

Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U.(2002) The standardisation of terminology of lower urinary tract function: report from the standardisation sub-committee of the international continence society. Am J Obstet Gynecol, 187,p.116–26.

Rortveit G, Daltveit AK, Hannestad YS.(2003) Norwegian epincont study. Urinary incontinence after vaginal delivery or caesarean section. N Engl J Med, 348,p. 900-907

Harding CK and Thorpe AC.(2008) Surgical treatment for stress urinary incontinence. International Journal of Urology, 15,p. 27–34

Fenner DE, Trowbridge ER, Patel DL, Fultz NH, Miller JM, Howard D.(2008) Establishing the prevalence of incontinence study: racial differences in women's patterns of urinary incontinence. J Urol, 179,p.1455-60.

Goode PS, Burgio KL, Redden DT, Markland A, Richter HE, Sawyer.(2008)population based study of incidence and predictors of urinary incontinence in black and white older adults. J Urol, 179,p.1449-53.

Dooley Y, Kenton K, Cao G, Luke A, Durazo-Arvizu R, Kramer H.(2008) Urinary incontinence prevalence: results from the National Health and Nutrition Examination Survey. J Urol, 179,p.656-61.

Melville JL, Katon W, Delaney K, Newton K.(2005) Urinary incontinence in US women: a population-based study. Arch Intern Med, 165,p.37-42.

Anger JT, Saigal CS, Litwin MS.(2006) Urologic diseases of America Project. The prevalence of urinary incontinence among community dwelling adult women: results from the National Health and Nutrition Examination Survey. J Urol,175,p.601-4.

Danforth KN, Townsend MK, Lifford K, Curhan GC, Resnick NM, Grodstein F. (2006)Risk factors for urinary incontinence among middle-aged women. Am J Obstet Gynecol,194,p.339-45.

Ragins AI, Shan J, Thom DH, Subak LL, Brown JS, Van Den Eeden SK. (2008)Effects of urinary incontinence, comorbidity and race on quality of life outcomes in women. J Urol, 179,p.651-5.

Hunskaar S, Lose G, Sykes D, Voss S.(2004) The prevalence of urinary incontinence in women in four European countries. Br J Urol Int, 93,p. 324–30.

Minassian VA, Drutz HP, Al-Badr A.(2003) Urinary incontinence as a worldwide problem. Int J Gynaecol Obstet, 82,p.327–38

Green TH and Thomas H Jr.(1968) The problem of urinary stress incontinence. Obstet Gynaecol Surv,23,p. 603–34.

Blaivas JG.(1984) Classification of stress urinary incontinence. Neurourol Urodyn, 2,p. 103.

Enhorning G.(1961) Simultaneous recording of intra- 17. vesical and intra-urethral pressure. A study on urethral closure in normal and stress incontinent women. Acta Chir Scand Suppl, 276,p.1-68.

DeLancey JO.(1994) Structural support of the urethra 44. as it relates to stress urinary incontinence: the hammock hypothesis. Am J Obstet Gynecol,170,p. 1713-20.

Petros PE, Ulmsten UI.(1993) An integral theory and 41. its method for the diagnosis and management of female urinary incontinence. Scand J Urol Nephrol Suppl, 153,p.1-93.

Lukacz ES, Lawerence JM, Contreras R.(2006) Parity, mode of delivery and pelvic floor disorders. Obstet Gynecol, 107,p. 1253-1260

Casey BM, Schaffer JL, Boom SL.(2005) Obstetric antecedents for postpartum pelvic floor dysfunction. Am J Obstet Gynecol, 192,p. 1655-1662

Qaseem A, Dallas P, Forciea MA, Starkey M, Denberg TD, Shekelle P.(2014) for the Clinical Guidelines Committee of the American College of, Physicians.. Nonsurgical Management of Urinary Incontinence in Women: A Clinical Practice Guideline from the American College of Physicians. Annals of Internal Medicine,161,p.429–440.

Shamliyan, T; Wyman, JF; Ramakrishnan, R; Sainfort, F; Kane, RL.(2012) Benefits and harms of pharmacologic treatment for urinary incontinence in women: a systematic review. Annals of Internal Medicine,156,p.861–74.

Virkud A.(2011) Management of stress urinary incontinence. Clin Obstet Gynecol, 25,p.205-216.

Lucas MG, Bosch RJ, Burkhard FC, Cruz F, Madden TB, Nambiar AK, Neisius A, de Ridder DJ, Tubaro A, Turner WH, Pickard RS.(2012) European Association of Urology.EAU guidelines on assessment and nonsurgical management of urinary incontinence. Euro Urol, 2,p.1130-42.

Marshall FV, Marchetti AA, Krantz KE.(1949) The cor- 11. Rection of stress incontinence by simple vesicourethral suspension. Surg Gynecol Obstet,88,p.509-518.

Burch JC.(1961) Urethrovaginal fixation to Cooper's 12. Ligament for correction of stress incontinence, cystocele, and prolapse. Am J Obstet Gynecol,81,p. 281-90.

Vancaillie TG and Schuessler W.(1991) Laparoscopic bladder neck suspension. J Laparoendosc Surg, 1,p.169 –173.

Alcalay M, Monga A, Stanton SL.(1995) Burch colposuspension: 10-20 year follow up. Br J Obstet Gynaecol,102,p.740–745.

Drouin J, Tessier J, Bertrand PE, Schick E. (1999)Burch colposuspension: long-term results and review of published reports. Urology, 54,p.808–814.

Lapitan MC, Cody DJ, Grant AM.(2003) Open retropubic colposuspension for urinary incontinence in women. Cochrane Database Syst Rev, CD002912.

Nilsson CG, Palva K, Rezapour M, Falconer C.(2008) Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence. Int Urogynecol J,19,p.1043–1047.

Richter HE, Albo M, Zyczynski H, Kenton K, Norton PA, Sirls LT.(2010) Retropubic versus transobturator midurethral slings for stress incontinence. N Engl J Med, 362,p.2066–76.

American Urogynaecological Society: www: mypelvichealth.org accessed on 12 April, 2015

Ulmsten U and Petros P.(1995) Intravaginal slingplasty (IVS): an ambulatory surgical procedure for treatment of female urinary incontinence. Scand J Urol Nephrol, 29,p.75-82.

Ward KL, Hilton P; (2004)UK and Ireland TVT trial group. A prospective multicentre randomized trial of tension-free vaginal tape and colposuspension for primary urodynamic stress incontinence: 2-year follow-up. Am J Obstet Gynecol, 190,p.324–31.

Novara G, Boscolo-Berto R, Secco S, Cavalleri S, Ficarra V, Artibani W.(2008) Complication rates of tension-free midurethral slings in the treatment of female stress urinary incontinence: a systematic review and meta-analysis of randomized controlled trials comparing tension-free midurethral tapes to other surgical procedures and different devices. Euro Urol,53,p.288–308.

Çetinel B and Tufan Tarcan T.(2013) Management of Complications after Tension-Free Midurethral Slings. Korean J Urol, 54,p.651-659

National Institute for Clinical Excellence (2003), Technology Appraisal Guidance No.56: Guidance on the use of tension-free vaginal tape (Gynecare TVT) for stress incontinence, NICE London, ISBN 1842572768

Delorme E.(2001) Transobturator urethral suspension: mini-invasive procedure in the treatment of stress urinary incontinence in women. Prog Urol,11,p.1306-1313.

de Leval J. (2003) Novel surgical technique for the treatment of female stress urinary incontinence: transobturator vaginal tape inside-out. Euro Urol, 44,p.724–30

Fong EDM and Nitti VW.(2010) Mid-urethral synthetic slings for female stress urinary incontinence. Br J Urol Int, 106,p.596-608.

Laurikainen E, Valpas A, Kivela A, Kalliola T, Rinne K, Takala T, Nilsson C.(2007) Retropubic compared with transobturator tape placement in treatment of urinary incontinence: a randomized controlled trial. Obstet Gynecol, 109,p.4–11.

Bonnet P, Waltregny D, Reul O, deLeval J.(2005) Transobturator vaginal tape inside out for the surgical treatment of female stress urinary incontinence: anatomical considerations. J Urol, 173,p.1223–8.

Darai E, Frobert J, Grisard-Anaf M, Lienhart J, Fernandez H, Dubernard G.(2007) Functional results after the suburethral sling procedure for urinary stress incontinence: a prospective randomized multicentre study comparing the retropubic and transobturator routes. Euro Urol,51,p.795–802.

Giberti C, Gallo F, Cortese P, Schenone M. (2007)Transobturator tape for treatment of female stress urinary incontinence: objective and subjective results after a mean follow-up of two years. Urology, 69,p.703–7.

Cindolo L, Salzano L, Rota G, Bellini S, D'Afiero A. (2004)Tension-free transobturator approach for female stress urinary incontinence. Minerva Urol Nefro,56,p.89–98.

Roumeguere T, Quackels T, Bollens R, deGroote A, Zlotta A, Bossche MV, Schulman C. Trans-obturator vaginal tape (TOT) for female stress incontinence: one year follow-up in 120 patients. Euro Urol

Robert M, Murphy M, Birch C, Swaby C, Ross S.(2006) Five cases of tape erosion after transobturator surgery for stress incontinence. Obstet Gynecol, 107,p.:472–4.

Miranda V, Pineda R, Lovatsis D, Alarab M, Drutz H.(2012) Efficacy and Safety of Tension-Free Vaginal Tape Compared With Transobturator Tape Among Obese Women With Stress Urinary Incontinence: A Retrospective Cohort Study. JOGC,p.755-759

Luber KM. (2004) The definition, prevalence, and risk factors for stress urinary incontinence. Rev Urol, 6,p.S3-S9.

Herrmann V, Scarpa K, Palma PC, Riccetto CZ.(2009) Stress urinary incontinence 3 years after pregnancy: correlation to mode of delivery and parity. Int Urogynecol J Pelvic Floor Dysfunct,20,p.281-8.

Zhu L, Lang J, Liu C.(2010) Epidemiological study of urge urinary incontinence and risk factors in China. Int Urogynecol J,21,p.589-93.

Lee KS, Han DH, Choi YS.(2007) a prospective trial single blinded study comparing tension free vaginal tape and transobturator vaginal tape inside-out for surgical treatment for female stress incontinence: 1 year follow up. J Urol,177,p.214-218

Abdel-fattah M, Ramsay I, Pringle S.(2010) randomized prospective single blinded study comparing inside out vs outside in transoburator tapes in the management of urodynamic stress incontinence ; a one year outcomes from E-TOT study. Br J Obstet Gynecol, 117,p.870-878

Dugan E, Cohen S, Bland DR.(2000) The association of depressive symptoms and urinary incontinence among older adults. J Am Geriatr Soc, 48,p.413–416.

Melville JL, Walker E, Katon W, Lentz G, Miller J, Fenner D.(2002) Prevalence of comorbid psychiatric illness and its impact on symptom perception, quality of life, and functional status in women with urinary incontinence. Am J Obstet Gynecol. 187,p.80–87.

Viktrup L, Koke S, Burgio KL, Ouslander JG.(2005) Stress urinary incontinence in active elderly women. South Med J, 98,p.79–89.

Torrisi g, Mininni G, Bernasconi F.(2012) A prospective study of pelvic floor dysfunction related to delivery. Euro J Obstet Gynaecol Reprod Biol,160,p.110-115

Jackson RA, Vittinghoff E, Kanaya AM, Miles TP, Resnick HE, Kritchevsky SB.(2004) Urinary incontinence in elderly women: findings from the health, aging, and body composition study. Obstet Gynecol, 104,p.301-7.

Thom DH, Van den Eeden SK, Ragins AI, Wassel-Fyr C, Vittinghof E, Subak LL.(2006) Differences in prevalence of urinary incontinence by race/ethnicity. J Urol,p.259-64.

Danforth KN, Townsend MK, Lifford K, Curhan GC, Resnick NM, Grodstein F.(2006) Risk factors for urinary incontinence among middle-aged women. Am J Obstet Gynecol, 194,p.339-45.

Botlero R, Davis SR, Urquhart DM, Shortreed S, Bell RJ.(2009) Age-specific prevalence of, and factors associated with, different types of urinary incontinence in community-dwelling Australian women assessed with a validated questionnaire. Maturitas, 62,p.134-139

Khong S, Jackson S.(2008) Obesity and Urinary Incontinence. Menopause International, 14,p.53-56

Barclay L.(2009) Urinary Incontinence Highly prevalent in overweight, obese women with type 2 Diabetes. New England Journal of Medicine,p.481-490

Moore RD, Gamble K, Miklos JR.(2007) Tension-free vaginal tape sling for recurrent stress incontinence after transobturator tape sling failure. Int Urogynecol J Pelvic Floor Dysfunct,18,p.309-13.

Harrison GL, Memel DS.(1994) Urinary incontinence in women, its prevalence and its management in a health promotion clinic. Br J Gen Prac,44,p.149-152.

Raza-Khan F, Graziano S, Kenton K, Shott S, Brubaker L. (2006)Peripartum urinary incontinence in a racially diverse obstetrical population. Int Urogynecol J Pelvic Floor Dysfunct,17,p.525-530.

Hannestad YS, Rortveit G, Sandvik H, Hunskaar S.(2000) A community-based epidemiological survey of female urinary incontinence – the Norwegian EPINCONT Study. J Clin Epidemiol,55,p.1150-1157.

Hunskaar S.(2008) A systematic review of overweight and obesity as risk factors and targets for clinical intervention for urinary incontinence in women. Neurourol Urodyn,27,p.749-757.

Danforth KN, Townsend MK, Lifford K, Curhan GC, Resnick NM, Grodstein F.(2006) Risk factors for urinary incontinence among middle-aged women. Am J Obstet Gynecol,194,p.339-345.

Chaliha C, Digesu A, Hutchings A, Soligo M, Khullar V. (2004)Caesarean section is protective against stress urinary incontinence: An analysis of women with multiple deliveries. BJOG,111,p.754-755.

McKinnie V, Swift SE, Wang DO.(2005) The effect of pregnancy and mode of delivery on the prevalence of urinary and fecal incontinence. Am J Obstet Gynecol ,193,p.512-517.

Kim HG, Park HK, Paick SH, Choi WS.(2016) Comparison of Effectiveness between Tension-Free Vaginal Tape (TVT) and Trans-Obturator Tape (TOT) in Patients with Stress Urinary Incontinence and Intrinsic Sphincter Deficiency. PLoS One, 11,p.156-159.

Richter HE, Albo ME, Zyczynski HM, Kenton K, Norton PA, Sirls LT.(2010) Retropubic versus transobturator midurethral slings for stress incontinence. N Engl J Med,362,p.66–76.

Novara G, Artibani W, Barber MD, Chapple CR, Costantini E, Ficarra V.(2010) Updated systematic review and meta-analysis of the comparative data on colposuspensions, pubovaginal slings, and midurethral tapes in the surgical treatment of female stress urinary incontinence. Eur Urol,58,p.218–38.

Araco F, Gravante G, Sorge R, Overton J, De Vita D, Sesti F, Piccione E.(2008) TVT-O vs TVT: A randomized trial in patients with different degrees of urinary stress incontinence. Int Urogynecol J,19,p.917–26.

Fenner DE, Trowbridge ER, Patel DA, Fultz NH, Miller JM, Howard D, DeLancey JO.(2008) Establishing the prevalence of incontinence study: racial differences in women's patterns of urinary incontinence. J Urol,179,p.1455-60.

DeLancey JO. (1994) Structural support of the urethra as it relates to stress urinary incontinence: the hammock hypothesis. Am J Obstet Gynecol,170,p.1713–172

Rezapour M, Falconer C, Ulmsten U.(2001) Tension-free vaginal tape (TVT) in stress incontinent women with intrinsic sphincter deficiency (ISD)—a long-term follow-up. Int Urogynecol J Pelvic Floor Dysfunct,12,p.12–14.

Hunskaar S., Arnold E.P. and Burgio K. (2000) Epidemiology and natural history of urinary incontinence, Int. Urogynecol. J. Pelvic Floor. Dysfunct,11,p. 301-319

. Berghmans L.C., Hendriks H.J and Bo K.(1998) Conservative treatment of stress urinary incontinence in women: a systematic review of randomized clinical trials, Br. J. Urol,82p. 181-91

Hunskaar S., Arnold E.P. and Burgio K.(2000) Epidemiology and natural history of urinary incontinence, Int. Urogynecol. J. Pelvic Floor. Dysfunct,11,p. 301-319

Herbruck L.F.(2008) Urinary Incontinence in the Childbearing Woman, Urol. Nurs,28,p. 163-171