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Transobturator tape surgery for stress urinary incontinence: an assessment of quality of life before and after surgery from the patient's perspective

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CHAPTER 1: INTRODUCTION

1.1 Background:

Stress urinary incontinence (SUI) is a psychologically, emotionally and physically debilitating disease in a woman's life. The International Continence Society defines urinary incontinence as 'a condition in which involuntary loss of urine is a social or hygienic problem.' This definition shows that urinary incontinence is a symptom that affects multiple aspects of a woman's life negatively including interpersonal relationships, social interaction, careers, health and psychological wellbeing [1].

It is estimated that about 15% to 30% of women of all ages suffer from urinary incontinence[2]. However, these figures are just the tip of the iceberg as urinary incontinence is largely under estimated. Approximately 1 in 4 women with urinary incontinence consult a health care worker [3]. The possible reasons for this may be that women are embarrassed about their condition and that there is simply not enough awareness about the available treatment. One of the options in the treatment of SUI is the placement of a transobturator mid urethral tape (TOT) as first described by Delorme in 2001. This procedure involves the mid urethral placement of tape to support the proximal urethra and bladder neck. Although this is a popular procedure, there is very little data on patient satisfaction. There have been several short and long term studies demonstrating objectively the efficacy of the TOT procedure. While these are essential measures, they do provide very little information about the impact of urinary incontinence in a woman's life before and after the procedure.

Quality of life is a very subjective and is an abstract term[2]. To measure this, a well validated disease specific questionnaire will be used called the King's Health Questionnaire. This study intends to evaluate the patient's "quality of life" and the impact of urinary incontinence on multiple aspects of a woman's life from the patient's perspective before and after the procedure.

1.2 Definition of Research Question

1.2.1 Problem Statement

Urinary incontinence has a detrimental effect on a woman's quality of life. Although this condition is not life threatening it does however contribute to morbidity [2.] The trans-obturator tape is a safe and effective way to treat stress urinary incontinence. The primary goal of the treatment is to improve a woman's quality of life. To measure the true success of an operation, a well validated disease specific quality of life questionnaire is used called the King's Health Questionnaire. This questionnaire will be used before and after the operation. Not only will one be able to assess the quality of life but also in a subtle way the post-operative complications which contributes to the overall success.

1.2.2 Justification for the Study

- Stress urinary incontinence negatively affects the quality of life (QOL) of a woman. It affects the woman's health, psychological state, interpersonal relationships and ability to perform family and career responsibilities. The primary aim of the procedure is to bring

an improvement to the woman's QOL. So the best way to assess the outcome of the procedure is to ask the woman.

- Treatment of SUI has economic considerations. Incontinence has larger financial implications such as personal cost to the patients and state. There is no data available for South Africa but recent USA data estimates are $16 billion dollars annually [4].
- There is no South African study that prospectively determines the impact of the TOT procedure on a woman's quality of life. In the past subjective outcomes have been reported by the opinion of the doctor and not the women whom have had the operation.
- South African literature lacks evidence of prospective trials regarding the TOT procedures. It is important to have prospective trials to eliminate potential bias in results.
- The findings from this study could justify current and future departmental policies on continence treatment.
- The outcomes and suggestions from this study could serve as a basis for future studies.
- This study uses a well validated and reliable questionnaire to assess the subjective effect on quality of life (QOL) which have been inconsistently assessed in other studies.

1.2.3 Aim of the Study

To determine if the TOT procedure improves the quality of life for women with SUI by using a validated survey – the King's Health Questionnaire.

1.2.4 Objectives:

1.2.4.1 Primary Objectives

To determine the effect of urinary incontinence before and after the TOT procedure on the different aspects of a woman's quality of life using the KHQ domains.

To determine the change in patient reported urinary symptoms post operatively using the KHQ.

1.2.4.2 Secondary Objectives

To assess the impact on QOL and the operative subjective symptom change of the TOT procedure.

To evaluate the outcomes of the urgency symptom post operatively in patients with pre-operative urgency.

To determine if the change in post-operative urinary incontinence correlates with personal relationships (sexual function).

1.2.5 Definition of Terms:

The following definitions were used according to the International Urogynecological Association (IUGA)/International Continence Society (ICS) in the study:

Urinary Incontinence: a condition in which involuntary loss of urine is a social or hygienic problem.

Stress urinary incontinence: complaint of involuntary loss of urine on effort of physical exertion, sneezing or coughing.

Urgency urinary incontinence: complaint of involuntary loss of urine associated with the urge to void immediately preceding or accompanied by involuntary leakage of urine. The amount of leakage ranges from a few drops to a completely soaked pad.

Mixed urinary incontinence: complaint of involuntary loss of urine associated with urgency and with effort or physical exertion or when sneezing or coughing.

Overactive bladder (OAB, urgency) syndrome: This is a syndrome used to describe urinary urgency, usually accompanied by frequency and nocturia, with or without urgency urinary incontinence, in the absence of urinary tract infection (UTI) or other obvious pathology.

Stress urinary incontinence with urgency symptoms: These patients had stress urinary incontinence (based on history and examination). On pre operative questioning this group of women had varying degrees of urgency. Essentially this group was very similar to the mixed urinary incontinence but did not have urodynamic testing as it was not practically available the day prior to the procedure. This group was still considered as uncomplicated SUI.

Urodynamic stress incontinence: noted during filling cystometry as the involuntary leaking of urine during increased abdominal pressure without a detrusor contraction.

Validity: Assesses the robustness of the model used to measure or analyse the data.

Reliability: the extent to which the test produces the same results on repeated trials.

Urodynamic studies: functional test of the lower urinary tract predominantly utilising natural filling of the urinary tract and reproducing the subject's normal activity.

Subjective cure rate: improvement in QOL by more than 90% post operatively

Pelvic organ prolapse (POPQ) stage II: Most distal portion of the prolapse is 1 cm or less proximal to or distal to the plane of the hymen.

CHAPTER 2 - LITERATURE REVIEW

2.1 Methodology for Literature review

2.1.1 Design of literature review

The literature research was conducted through Pubmed and the Cochrane Collaboration databases. The following search terms used were: (SUI OR stress urinary incontinence and TOT OR transobturator tape and QOL OR quality of life and King's Health Questionnaire). Only English articles were included. The reference list of identified articles were searched for through the University of the Witwatersrand eJournal portal. Appropriate articles cited by other authors were also reviewed. There were no studies located through a Cochrane review.

2.2 Prevalence of Stress Urinary Incontinence (SUI):

2.2.1 The Global Scenario:

SUI is a common problem in women. A large study involving a validated severity index in Norway between 1995 and 1997 was conducted on 27 936 women. Twenty-five percent of the participants had urinary incontinence. Out of these women, 50% had SUI[9]. The prevalence of urinary incontinence varies depending on the definition and age of the women. A systemic review reported a range of 16.2% to 69.2% [5].

The prevalence of SUI could be largely underestimated. Approximately 1 in 4 women with urinary incontinence consult a health care worker [3]. The speculated reasons for this are:

- Women are embarrassed
- They think that it's a normal part of aging
- Very few health care clinics have the specialties to deal with this.

Urinary incontinence is very costly. The most recent estimate of annual cost was $16 billion (1995 U.S. money terms) [4]. This is greater than the annual cost of breast, ovarian, cervical and uterine cancer combined [62]. According to the National Institute for Health and Excellence (NICE) guidelines, the estimated current cost to the National Health Service is £233 million annually [6].

More than 50% of the cost of urinary incontinence (UI) is because of routine care, pads, linen, protection and laundry [4].

2.2.2 The South African Scenario:

There is very little data available about the prevalence of incontinence in South Africa and other developing countries.

A study in Kwazulu Natal involving 100 women between the age of 21 to 70 years, the prevalence of UI was 35.4% [7]. Of these women 62.9% had SUI [7].

Another study done in Bloemfontein in 2010 showed that 27.5% of women had UI [8]. Of these women 34.6% reported that UI did not interfere with their lives. While 11.5% reported severe interference [8].

2.3 The risk factors are:

Age: The prevalence of urinary incontinence increases with age. The reason for this is that elderly people have reduced urinary flow rates, increased urinary residuals, higher filling pressures, reduced bladder capacity and lower maximum voiding pressures [3]. The Norwegian EPICONT study showed that 65% of women between the ages of 45 and 49 years had SUI [9].

Race:

A large cross sectional study in Michigan, USA, was done between 2002 and 2004 to determine racial differences in urinary incontinence. The prevalence for black and white women was 14.6% and 33% respectively. The risk factors for urinary incontinence were similar in the white and black groups[10] .One possible reason for this is that leiomyomata is

more common in black women. This may predispose some women to SUI by applying pressure to the bladder. In the SWAN (study of women's health across the nation) study comprising 3302 women between the ages of 42 and 52 years, it was found that uterine leiomyomata is 1.81 times higher in black women compared to white women [11].

Pregnancy:

During pregnancy, marked physiological changes occur. There is an increase in renal plasma flow and glomerular filtration rate. Also, the growing gravid uterus compresses on the bladder. SUI is common during pregnancy.[3]

Childbirth:

Vaginal delivery might result in injury to the pelvic floor and nerves. In a case-control study, 20% of women had a Levator Ani Muscle (LAM) defect seen on MRI. Seventy-one percent of women with on LAM defect had SUI. These LAM defects were not seen in nulliparous women[12]. There has been a proportional relationship between the increase in parity and the severity of urinary incontinence [3]. The *Term Breech Trial* assessed urinary incontinence after elective caesar as well as planned vaginal birth. Three months postpartum, the women in the elective caesarean group had less urinary incontinence than in the vaginal birth group (4.5% compared to 7.3% respectively) [11]. However this showed no significant difference between the two groups at 2 years postpartum[13.] So although a caesarean section can be proposed as a strategy to prevent U.I, it is highly controversial and long-term follow up shows no significant differences in outcome.

Menopause:

Studies have shown that due to the lack of oestrogen there is an increase in symptoms of urinary incontinence following menopause with 50% of patients complaining about SUI.[3] However it is also known that oestrogen does not treat SUI. This shows that UI is multifactorial.

2.4 Pathophysiology of SUI

The principle of continence is a dynamic process whereby the pressure in the urethra must be greater than the bladder pressure at rest as well as during times of increased intra-abdominal pressure to prevent leaking.

The anatomical structures responsible for preventing SUI during episodes of raised intra-abdominal pressure can be separated into sphincteric and supportive systems [14].
These 2 systems have been referred to as the *stress continence control system* originally suggested by Dr. Ashton-Miller [14].

2.4.1 Sphincteric System: (Intrinsic sphincter deficiency (ISD))

Leakage of urine occurs when there is a poor coaptation of the urethra. This causes low preoperative urethral closure pressure [15].

The normal closure of the urethra is maintained by outer striated circular muscle and inner longitudinal muscle surrounding a mucosal vascular core. This vascular plexus forms a watertight seal by closure of the mucosal layer.

Loss of this urethral closure pressure is probably caused by age related degeneration or neurological injury by vaginal delivery. In these women with low urethral closure pressure, good results have been achieved with sling procedures such as the transobturator tape [15].

2.4.2 Supportive System: (urethral hypermobility)

Bonney first gave an account of this system in the 1920s. However, it was Delancey who described the nature of the supporting anatomical structures. Delancey's theory is that these structures provide a back stop effect or 'kinking' of the urethra to be pressed shut against by rises in intra-abdominal pressure [16].

These supporting structures are the Levator ani muscles (LAM's), arcus tendineus fascia pelvis (band of endopelvic fascia medial to (LAM)) and the anterior vaginal wall. According to the hypothesis connective tissue laxity in the vagina or its supporting ligaments is the main cause for stress symptoms[16].

The combination of these above structures forms a hammock like effect in which the urethra can be compressed shut against the supporting structures during a rise in intra-abdominal pressure [15].

When there is damage to the supporting structures, the result is hypermobility of the urethrovesical junction causing the bladder neck to move downwards and backwards. The urethrovesical angle becomes more obtuse. This results in subsequent leakage of urine during rises in intra-abdominal pressure [15].

These 2 systems often coexist with varying degrees of disruption of normal urethral and pelvic floor anatomy [17]. There are women with hypermobility of the urethra that do not leak urine on effort. It is plausible to conclude that all women with SUI must have some degree of ISD. There are very few women that have pure anatomically induced incontinence without some degree of intrinsic sphincter deficiency. In this study, we did not distinguish between urethral hyper mobility and ISD. Women that have both hyper mobility of the urethra (from an anatomical defect in the supportive layer) and damage to the sphincter closure mechanism will benefit from the TOT procedure even if hyper mobility of the urethra is the only clinical sign because the TOT will assist in correcting the urethral sphincter closure pressure [15].

2.4.3 The role of the TOT in Mixed urinary incontinence (predominant stress urinary symptoms)

Mixed urinary incontinence presents with both symptoms of stress urinary incontinence and urge urinary incontinence. This presents a challenge as there are two co-existing pathologies. Although the TOT procedure is the gold standard for SUI, there is great variation in the cure rate of mixed urinary incontinence (MUI). The post-operative course of MUI is unpredictable as the urge component might resolve, persist or worsen.[18] The cure rate for MUI is better in a group of women with predominant SUI symptoms in comparison to a group of women with predominant overactive bladder symptoms[19]. Women with MUI were treated with anticholinergics, pelvic floor muscle exercises and bladder training. If the predominant and bothersome stress symptoms persisted after the above treatment then the TOT procedure was recommended. The TOT surgery can result in improvement in overactive bladder symptoms in some women, but may also worsen the symptoms. Thus, careful counseling regarding expectations of treatment is imperative. Women were counseled that surgical success rates were slightly lower in women with mixed incontinence compared to women with pure SUI.

In the study, patients with over active bladder (OAB) symptoms were included.

The proposed mechanism of MUI:

- Urine entering the proximal urethra could be an initiating factor for urgency and result in a secondary episode of detrusor overactivity (stressed induced detrusor overactivity) [20, 21].

- Open bladder neck or an incompetent bladder neck under conditions of raised intra-abdominal pressure may result in reflex detrusor overactivity [21].
- There is a possibility that mixed symptoms might be due to a more severe form of stress component rather than two coexisting pathologies[22].

The possible explanations why the TOT procedure might improve the urge component:

- The TOT procedure prevents urine from entering the upper posterior urethra with increases in intra- abdominal pressure which prevents the reflex urgency [22, 23].
- The TOT might stabilise urethral overactivity by providing kinking support instead of pressure when closing the urethra [24].
- Stress urinary incontinence might be misperceived as an urgency event. In some individuals SUI may falsely present as MUI due to the significant urgency component associated with spontaneous urinary loss.
- Urinary frequency is superimposed over this scenario as a behavioral response to the bothersome urinary symptoms [20, 21].

2.5 The transobturator tape procedure

2.5.1 History of the TOT

The transobturator tape (TOT) was first described by Delorme in 2001. Since then it has been shown to be a safe and successful procedure.

A prospective multi-centric study involving 183 women with SUI underwent a TOT procedure. The mean follow up was 7 months. At the 1 year follow up, 80.5% of women were symptom free and 7.5% of the women improved. The peri-operative complication rate was 2.2% and 3.3% of women had postoperative urinary retention[25].

The TOT is the modification of the tension free vaginal tape (TVT) designed to avoid the risk of bladder, bowel and vascular injury [11]. These structures are avoided by passing a trocar through the obturator membrane along the ischiorectal fossa and avoiding the pelvic cavity [11].

The incidence of bladder outlet obstruction (BOO) is rare and more common in the TVT procedure. The incidence ranges from 2.3% to 27% after the TVT [26]. BOO causes urinary retention, high residual urine volumes and de novo urgency and frequency. It is thought to be caused by insertion of the tape with tension under the distal urethral angle.

The cough test at the time of the procedure was avoided in the study as a guide of tape placement. As this adjustment is thought to increase the tension caudo-urethrally especially if the patient is in the trendellenburg position as the urethral area is at its highest point rather than tension free. A study by Low showed that there was no difference in outcome between a positive cough test and a negative cough test.[27]

2.5.2 Procedure Technique used in the study [28]:

The surgical technique used was originally described by Delorme but with local modifications by the study surgeon (Dr A.C).

The patient is placed in lithotomy position with the hips flexed to 120 degrees [28].

A bladder catheter is inserted. This helps identify the urethra during the vaginal dissection.

The trocar insertion site is marked lateral to the inferior ischiopubic ramus. The insertion point is not fixed as it depends on the depth of the lateral vaginal fornix. It must be at least 1cm above the horizontal line at the level of the urethra meatus and below the horizontal line at the level of the clitorus[28].

A finger is placed in the vaginal incision between the middle and lower third of the urethra[28].The vaginal epithelium and underlying periurethral fascia is bluntly separated in the direction of the inferior pubic ramus. If the index finger is in the incision, and the thumb is at the nearest point of the genito-crural fold, one may determine the entry point[28.]

A trocar is passed from the genito-crural fold through the obturator membrane and muscle (keeping it close to the ischiopubic ramus) and directed towards the urethral meatus[28].

The trocar is then guided through the vaginal incision. Check the lateral vaginal fornix for any perforation[28].

The tape is inserted through the eye of the needle and brought through the obturator foramen by reversing the trocar.

The procedure is repeated on the other side and the tape is left tension-free under the mid urethra [28]. The tape must not be twisted and should lie flat under the urethra. The vagina incision and inner thigh skin incisions can now be sutured closed.

2.5.3 Bladder Care

A local modification in the technique is that the patient is not discharged the same day but rather stays overnight so that the urinary catheter can be clamped the following day post-operatively and removed on the second post-operative day. This is done in order to retrain the bladder to feel the sensation to urinate. The patient is then discharged as long as the post void residual (PVR) volume is less than 100 ml [28].

2.5.4 Inside-out technique

There is also an inside-outside method (TVT-O) described by De Leval et al. This is a modified technique of the TVT. It is a method that allows the trocar and tape to be passed from the inside through the obturator foramen to the outside [29]. This also reduces the risk of bladder and urethra damage. However there are very few studies showing long term safety of this method [29]. There is minimal quality of life data. This method wasn't used in this study.[29]

Five different tapes were used in the study. These tapes were IVS-O Tyco, Aris Mentor-Porges, Monarc AMS, Obtryx Boston Scientific and Intramesh Cousin [28]. These tapes were all synthetic and made from polypropylene macroporous monofilament (Type 1). These tapes are recommended by the National Institute for Health and Clinical Excellence (NICE) guidelines [6]. Tape complications such as erosion have been associated with Obtape® device.[30]. This tape was not used in the study.

2.6 The use of special investigations

2.6.1 Urodynamic Studies (UDS)

An urodynamic study is a functional test of the lower urinary tract. The aim is to produce the patient's symptoms and objectively explain the pathology. The main disadvantages of urodynamic testing are that it is expensive, time-consuming, and causes patient discomfort.

A comparative review study by Shamliyan showed that once a clinical diagnosis of SUI was made, there were no statistically significant differences in continence improvement or treatment failure between groups of women who did or did not have baseline urodynamic diagnosis [31].

According to the NICE guidelines, if a clear clinical diagnosis of SUI was made then UDS was not recommended

In a study by Nager, 655 women underwent UDS following a positive stress test. Ten percent of the women did not demonstrate urodynamic stress incontinence (USI). The reasons for this could be the inability of the patient to relax or faulty equipment.

If 10% of patients with a positive stress test cannot demonstrate USI, then the stress test is more sensitive than UDS [32].

UDS was not included in this study for pure stress in continence as the evidence shows that if the symptoms of SUI are clearly demonstrated by a positive cough test, then UDS is not necessary.

Urodynamic testing may be useful when symptoms are not consistent with physical examination findings or in women with complicated incontinence scenarios. The group of women with stress urinary incontinence and a sensation of urgency is controversial. They most definitely were considered for urodynamic studies. However these symptoms were noted on the admission prior to the procedure, at which point urodynamic testing was not available due to the time constraint. However none of these symptoms were noted to be complicated SUI. The patients with mixed urinary incontinence all had urodynamic studies. All complicated women with SUI (history and positive cough test) that needed urodynamic studies were excluded from the study. This included neurogenic lower urinary tract dysfunction (example due to spinal cord injury and multiple sclerosis), pregnancy, mixed urinary incontinence with predominant overactive bladder symptoms.
A suspicion of a non-stress aetiology of urinary incontinence, suggested by the following components of the clinic evaluation:
Leakage of urine without exertion, especially while standing
Nocturia (≥2 episodes per night)

Persistently elevated post-void residual volume (PVR) (≥50 mL)

Urinary stress test with leakage that is delayed and difficult to stop

Women with these findings may have overflow incontinence, intrinsic sphincter deficiency, or other systemic or local causes of incontinence (example urethral diverticulum and urethral mobility problems).This also included women with pure detrusor overactivity demonstrated by cystometry.

Urodynamic testing was done on all the patients included in the group of mixed urinary in continence as well as the two patients with previous incontinence surgery. These two patients with prior anti-incontinence surgery had urodynamic testing that displayed stress urinary incontinence. There was no evidence of detrusor overactivity and they had normal voiding parameters.These two patients had failed sling procedures performed by another surgeon. The patients most likely had the tension free vaginal tape inserted evident by old marks abdominally (superior to the pubic bone)

2.6.2 Cystoscopy

Bladder complications are rare among the TOT procedures. It is however a common problem with the TVT. The incidence reported with the TVT is between 0.8% and 21% [26].

Dargent reported in 2002 that there were no bladder injuries in 71 women undergoing the TOT procedure of which cystoscopy was performed intra-operatively [33].

The author Deval recommends that there is no need to perform cystoscopy when a TOT procedure is performed [26].

2.7 Impact of SUI on the quality of Life

2.7.1 The Quality of life (QOL) is multidimensional:

- Psychological: There is a direct relationship between urinary incontinence and depression. A cross sectional study in the USA between 1991 and 1996 consisting of 5701 women between the ages of 50 and 69 years showed that women with urinary incontinence were 80% more likely to have depression according to the diagnostic and statistical manual of mental disorder (DSM) than continent women[34].

- Exercise: Urinary incontinence is an obstacle to exercise. A study of 3364 women showed that women with severe incontinence were 2.6 times more likely not to exercise than continent women to avoid leakage [35].

- Sexual function: Urinary incontinence causes reduced sexual function in sexually active women. In a cross-sectional study of 216 women, 48% reported sexual dysfunction according to the female sexual function index (FSFI) [36].

- Health: Urinary incontinence causes poor health, as there is a high incidence of bacterial infection, fungal infection, cellulites, ulcers and skin excoriation[37].

Quality of life is difficult to quantify as there is no defined progression or biochemical measure. Although quality of life is subjective, clinical parameters have shown to be in keeping with subjective findings. The success of treatment cannot only be judged on the objective findings alone but also on the quality of life.

Kelleher showed that QOL scores does correlate with a women's response to treatment[2]. According to the Incontinence Quality of Life Questionnaire (IQOL) and the global perception of Improvement and Incontinence Impact questionnaire, improvements are perceived by women at a 70% reduction in urinary frequency. Clinical success is perceived by women when episode frequency is reduced by 50% or more[2].

2.7.2 Two types of QOL of questionnaires.

Generic: This is used to measure broad range of health problems rather than subtle changes in a system [38]. This type of questionnaire is insensitive and unresponsive to changes in treatment [38].

Disease specific: This is more sensitive to issues affecting the patient with a specific medical condition [38]. An example of this is the King's Health Questionnaire used in the study.

2.8 King's Health Questionnaire (KHQ)

2.8.1 Validation of the King's Health Questionnaire

To measure a patient's satisfaction with the TOT procedure for SUI, a survey would need to be used. Although there is no internationally accepted questionnaire for urinary incontinence, the KHQ has been developed to access the quality of life for women with UI [25]. The KHQ was developed in 1997. It provides a thorough assessment of the impact of UI on QOL. It has been translated into many languages including South African English, Afrikaans and isiXhosa[39]. It also has a great sensitivity over time and is useful in measuring UI before and after a procedure. This study uses a comprehensive quality of life survey as the primary outcome. The KHQ has 21 questions that assess 9 different domains of QOL impairment (Appendix F).These domains are in four sections:

Section one: *general health perceptions and incontinence impact.*

Section two: *role limitations, physical and social limitations, personal relationships, emotions, sleep and energy.*

Section three: assesses *severity measures* associated with UI.

Section four: assesses how much each *urinary symptom* affects the patient. The symptoms are rated on a separate scale of 'a little,' 'moderately 'and 'a lot.'

Section 1 to 4 have a four point likert rating score. The total score is between 0 to 100. The higher the score the worse the outcome of QOL. In the study section 1-3 was analysed as QOL and section 4 was analysed as subjective symptoms.

2.8.2 Psychometric testing

The reasons for choosing the KHQ for assessing quality of life in this study are as follows:

- KHQ is a good screening tool for SUI and MUI symptoms.
- KHQ has 21 questions covering all aspects of health, physical, social and emotional problems related to UI [25].
- This is a grade A questionnaire and is highly recommended [40]. This means that the questionnaire has gone through rigorous published testing and is valid, reliable and responsive to psychometric testing [40].
- The questionnaire is suitable for the study population since it is easy to answer accurately and understandable.
- It has a high power to detect significant results.
- It has a good re-test value. The KHQ showed that clinically meaningful changes were associated with a 5 point score post operatively as compared before the operation[2].
- The questionnaire is printed in large print so that it can be read easily.

CHAPTER 3: METHODOLOGY

3.1 Research Methodology

3.1.1 Study design:

The study was a prospective cohort study.

Prospective:

Women would complete the preoperative KHQ before the TOT procedure. They then would be followed forward in time (6-24 months) until the postoperative KHQ was completed.

Cohort:

Women that completed the KHQ are followed prospectively after the TOT procedure for 6-24 months to determine the outcome of the quality of life questionnaire (KHQ) postoperatively. As well as any existing relationships with specific variables. The researcher did not randomize the patients into any groups. The patients were objectively assessed as having SUI by the clinic doctors prior to the questionnaire. However the data was analysed after completion of the post operative questionnaire into 3 groups for statistical ease and interpretation.

3.1.2 Study setting:

The study recruited patients that were operated on at Charlotte Maxeke Academic Johannesburg hospital (CMAJH) in Parktown, Johannesburg. This hospital represents a low to middle income urban population. Any women with SUI symptoms that would be undergoing a TOT procedure were included in the study.

3.1.3 Study population and period:

Women with SUI completed the KHQ on admission before the TOT procedure and again between 6 months and 2 years post operatively. The questionnaire was obtained from the NICE guidance website (guidance.nice.org.uk). Permission was obtained from the author of the questionnaire for use in this study.

This study enrolled women from January 2010 and completed the follow up questionnaire in June 2013. The research protocol was submitted and approved by the ethics committee

– number M120483. This included an amendment to include data collecting from January 2010 before the ethics approval. Permission to conduct the study was obtained from the CEO of the hospital – Dr. Selebano.

3.1.4 Primary data set:

All the patients with stress urinary incontinence were offered surgery if conservative management failed. The conservative options included pelvic floor exercises and anticholinergics. The diagnosis of SUI was made clinically by performing a positive cough test on physical exam and urine testing. UDS were not done for women with pure uncomplicated stress urinary incontinence as it was not freely available and there was certainty about the diagnosis objectively by demonstrating a positive cough test. However the patients with mixed urinary in continence had urodynamic testing. The patients with mixed urinary incontinence has predominant stress symptoms-subjectively and demonstrated a positive cough test. The urge symptoms were uncomplicated as they responded to anticholinergics. The patients with SUI and MUI were given a date for admission from the clinic.

Women with mixed urinary incontinence were counseled that the symptom of urgency might remain after the operation. The women were also told that they will need to continue anticholinergics. The KHQ (including consent and data sheet) took place in the ward on admission of the patient. All the TOT procedures were done by the same surgeon (Dr. AC). The KHQ was repeated between 6 months to 2 years later either at the follow up

outpatient clinic or telephonically. The patient's information was confidential and a study number was assigned to each patient.

If a patient reported a problem after the TOT procedure, she would be asked to return to the outpatient's clinic for a full workup. This workup included history taking, cough test, post void residual volume test (PVR) and urine analysis.

If the cause was infectious then it would be treated with antibiotics. If the residual volume was more than 100 ml without infection then UDS would be performed. All local complications were classified according to terminology from the International Urogynaecological Association (IUGA).[41]

3.1.5 Sample size:

77 patients were recruited from January 2010 – December 2012.The follow up was completed in June 2013. This sample size was calculated using an Engine Room for Excel.

3.2 Study Criteria

3.2.1 Inclusion criteria

The following patients were included in the study:

- Pure stress urinary incontinence
- Stress urinary incontinence and sensation of urgency*
- Uncomplicated MUI with a predominant stress component.

* There was a small group of patients that were initially categorised as SUI by the unit doctors by the initial workup (pelvic examination,demonstrating a positive cough test and excluding urinary tract infection). However, after completion of the pre-operative questionnaire on admission, these patients had significant SUI but also answered positively to the presence of sensation of urgency and urge urinary incontinence. These patients were included in the Study and analysed separately because these symptoms were only elicited after answering the questionnaire. The questionnaire was done on admission so it was not feasible to perform urodynamic studies as the procedure was the following day.This was a unique group and the data was analysed separately. All the patients with MUI had urodynamic studies.

3.2.2 Exclusion criteria

The following patients were excluded from the study:

- Urgency predominant mixed urinary incontinence
- Urge/overactive bladder.The treatment includes lifestyle modification, exclusion of infection, bladder training and anti-muscarinics
- Complicated mixed urinary incontinence. If OAB symptoms did respond to anticholinergics
- Urodynamic studies demonstrating bladder sensation abnormalities
- Any condition that causes an overactive bladder
- Perineal skin and urethral infection

- Urinary tract infection
- Pelvic organ prolapse beyond (ICS-POPQ) stage 11 in any vaginal component
- Inability to get into lithotomy position
- Pregnancy
- Neurogenic bladder
- Any patient not willing to give informed consent

3.3 Study Variables:

The variables that have been chosen to be studied were those that were known risk factors for SUI, namely:

Demographic data:

- Age
- Basal metabolic index(BMI)
- Smoker
- Race

Obstetric history:

- Parity and Gravidity

- Number of vaginal deliveries.

Gynaecological history:

- Previous hysterectomy.
- Previous surgery for incontinence
- Previous surgery for prolapse
- Menopausal status

Type of incontinence:

- SUI
- SUI and urgency
- MUI(predominant stress component)

3.4 Data Collection:

The data sheet (appendix D) and Kings Health Questionnaire (appendix F) was filled out on admission of the patient before the TOT procedure and 6 months to 2 years post-operatively at the follow up visit or telephonically. The clinical variables used in the data sheet included surgery date, age, parity, gravidity, menopausal status, height, weight, basal metabolic index (BMI), smoker, previous surgical history, type of incontinence and problems after the TOT procedure. Written or telephonic consent was obtained (appendix E). Every patient was assigned a study number which was used on the data sheet and questionnaire so that the patient could not be identified. On a separate sheet the study numbers were listed with the patients' names, contact numbers and date of operation.

Information collected from the Kings Health Questionnaire consisted of 9 different domains including '*general health perceptions, incontinence impact, role limitations, physical limitations, social limitations, personal relationships, emotions, sleep, energy and severity measures'.* The patients answered questions relating to each domain (refer to appendix F-KHQ).Each domain consists of questions which are used to assess a certain aspect of QOL. For example, the variable *Role limitations* consist of 2 questions.
Does your bladder problem affect your household tasks? (cleaning, shopping etc.)
Does your bladder problem affect your job, or your normal daily activities outside the home?

3.5 Data Analysis:

3.5.1 Calculating Sample Size

To prove statistically that there is a change in quality of life and subjective symptoms by at least 5 percent. The number of patients was chosen so that a two-sided 95% confidence interval for a single proportion would allow at least a 5% change. This was done using the two tailed test .The sample size of 67 patients was required to achieve an 80% power to detect a significant post-operative change. Engine Room for Excel was used to perform the power calculation.

3.5.2 Analysis of primary outcomes

The data was captured and analysed with Excel (2010).No patient identifying clinical variables were included. Variables were coded to assist with the analysis. Categorical variables were assigned a code of 1 or 0.The code 1 meant that the variable was present in the study patient and 0 meant that the variable was absent. The categorical variables were smoking, menopausal status, SUI, MUI, SUI with sensation of urgency, previous operations (previous incontinent surgery, trans-abdominal hysterectomy, anterior repair, posterior repair and Posterior intra-vaginal sling), concomitant procedures (vaginal hysterectomy, anterior repair and posterior repair) and postoperative complications (intra peritoneal complications, urinary tract infection, groin pain, tape erosion, sling failure, de novo urgency). The race was assigned a code of 1=black, 2=white, assigned the relative number. Comparisons of continuous variables were done by the Student t-test. The frequencies, means, medians and ranges were calculated for the data variables. There was no missing data. Analytical statistics were done using Chi squared and Fischer's exact test. A p-value < 0.05 was accepted as indicating statistical significance. A p-value <0.01 was considered as highly significant. Logistic regression models were used to determine the objectives between baseline and 12 months as there was minimal change in QOL between 6-24 months.

It was found that the 6 month results correlated with the 2 year results. The data for each objective was analysed in three different groups being SUI, SUI and urgency and MUI.

3.5.3 Analysis of secondary outcomes

The subjective operative change was determined by separately analysing the symptoms and the QOL part of the KHQ. Subjective operative change was graded by comparing the operative change (post-operative-pre operative). The operative change was graded into 5 percentile groups *cure* = > 90%, *near cured* = 75-90%, *improved* = 0-74%, *no change* = 0% and *worse* = < 0%.

The change in post-operative urgency was graded into 4 groups being *disappeared* = 100%, *improved* = 80-99%, *no change* = 0%, and *worse* = < 0%.

3.5.4 Analysis of the type of incontinence

The women were classified into two groups being SUI and MUI (predominant stress component) objectively performing an uro-gynaecological exam and cough stress test (cough provocation). Subjective urgency urinary incontinence(UUI) was determined when patients responded positively ‘a little’, ‘moderately’ or ’a lot’ to the question, ’Do you have a strong and difficult time to control desire to pass urine? Women that were classified objectively as SUI, but had subsequent subjective UUI were then classified and analysed as a separate group to avoid any potential bias to the study. So the objectives were analysed in 3 groups being SUI, SUI and urgency and MUI. The data was analysed when the answer to the above urgency question was negative preoperative but positive postoperative, the women were then considered to have subjective de novo overactive bladder syndrome.

3.6 Ethical Considerations

Ethical clearance was obtained from the Human Research Ethics Committee (HREC). The clearance number was M 120483 (appendix 1). Ethical approval was obtained to use collected data from 2010 before Ethical clearance. Permission to perform the study at the hospital was obtained from the CEO Dr. Selebanou (appendix 2).

3.7 Funding

The study had no direct costs associated with it besides printing and telephone calls. This was borne by the researcher.

CHAPTER 4: RESULTS

In this chapter, results are presented for baseline data as well as both primary and secondary objectives of this study.

4.1 Baseline Data

4.1.1 Patient exclusion

In total 76 patients were operated on. There were nine (11.8%) patients excluded. This included seven patients that did not return for the follow up visit. One of the non-contactable patients died 6 months post operatively from pulmonary hypertension. One patient had a neurogenic bladder. One patient did not consent to be involved in the study.

4.1.2 Patient characteristics

The study included 67 patients. The mean age was 57.3(SD-11.4) years. The age range was 27-75 years. The average parity was 2.9 (n= 191). Of which 2.8 (n=185 normal vaginal deliveries) were normal vaginal deliveries and the average of 0.1 (n=6 caesarian section deliveries) caesarian sections. Nulliparity applied to one (1.49%) woman. The women consisted of 15(22.4%) black, 43(64.2%) white, 4(6%) coloured and 6(9%) Indian. Sixty one (91%) were in menopause. The mean BMI was 30.2(18.7-50.8). Seventeen (25%) of the women had a smoking history. Six (10%) of the patients were premenopausal and 61(90%) patients were post-menopausal. There were 4(6%) patients with MUI.

Patient Characteristics	(N=67)
Age, mean yrs (sd)	57.3 (11.4)
Race, n (% of total)	
Black	15 (22.4)
White	43 (64.2)
Coloured	4 (6)
Indian	6 (9)
Parity, mean (sd)	2.9 (1.5)
Normal Vaginal Deliveries, mean (sd)	2.8 (1.5)
Number of Caesarian Sections, mean (sd)	0.1 (0.5)
Menopause, n (%)	61 (91)
BMI: kg/m2, mean (range)	30.2 (18.7-50.8)
Smoking History, n (%)	17 (25)
Stress UI, n (%)	50 (75)
Stress UI with sensation of urgency, n (%)	13 (19)
Mixed UI, n (%)	4 (6)

Table 4.1: Baseline characteristics of the study patients

The distribution for urinary incontinence patients in the different age groups:

The mode for SUI is in the 50-59 age group. The MUI group's patients' ages were 35, 49, 66 and 74. In the SUI and urgency sensation group 12(92%) patients are over the 50 years of age.

The mean age for the SUI group was 56 (CI=53.2-58,3) , MUI group 54 (CI=53.6-58.5) and the SUI and urgency group was 62.5 (CI=58.7-66.3) The youngest patient is 27 years old. The oldest patient is 75 years old.

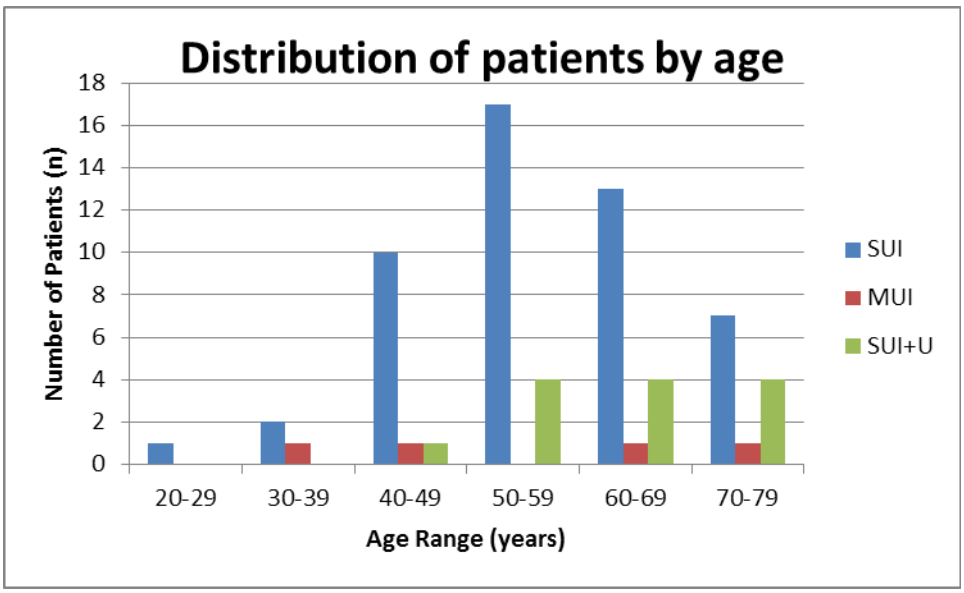


Figure 4.1: Histogram showing the age distribution (years) of the three types of incontinence.

4.1.3 Types of incontinence

There were 50 (75%) patients in the SUI group, 4 (6%) patients in the MUI group and 13 (19%) patients in the SUI and urgency group.

4.1.4 Previous surgery

Sixteen (23.9%) women have never been operated on before. Two (3%) patients had recurrent SUI and had previously undergone an anti-incontinence procedure. Twenty-seven (40%) women previously had a total abdominal hysterectomy. Ten (15%) women had previously had a vaginal hysterectomy. Six women previously had an anterior repair and 1(1%) woman had a posterior repair. Ten (15%) women previously had an appendectomy and 5(7%) women had a cholecystectomy.

Previous Surgery	(N=67)
Anti-Incontinence Procedure, n (%)	2 (3)
Total Abdominal Hysterectomy, n (%)	27 (40)
Vaginal Hysterectomy, n (%)	10 (15)
Anterior Repair, n (%)	6 (9)
Posterior Repair, n (%)	1 (1)
Appendectomy, n (%)	10 (15)
Cholecystectomy n (%)	5 (7)

Table 4.2: Previous surgery

4.1.5 Concomitant surgery

The TOT was combined with other procedures in twenty-three (34%) women. Five (7%) women had a vaginal hysterectomy. Fourteen (21%) women had an anterior repair. Three (4%) women had a posterior repair. One (1%) woman had a posterior intra-vaginal sling. Total concomitant surgeries were 46 (69%).

Concommitent Surgery	(N=67)
Vaginal Hysterectomy, n (%)	5 (7)
Anterior Repair, n (%)	14 (21)
Posterior Repair, n (%)	3 (4)
Posterior Intra-Vaginal Sling, n (%)	1 (1)

Table 4.3: Concomitant surgery

4.2 Post-operative Complications

Six (9%) women had postoperative urinary tract infection (UTI). Two (3%) women had groin pain. There was no erosion of the tape, intra peritoneal complications such as perforation, sepsis, haematoma, de novo overactive bladder (OAB).There was 1(1%) sling

failure and 1(1%) woman who had an urinary tract infection that needed hospital admission for antibiotics (Amikacin).

Surgery	
Post-Operative Problems	**(N=67)**
Urinary Tract Infection on Follow-up, n (%)	6 (9)
Groin Pain, n (%)	2 (3)
Erosion, n (%)	0
De Novo Urgency UI, n (%)	0
Sling Failure, n (%)	1 (1)
Perforation of Bladder, Vagina and Urethra, n (%)	0
Admission for Urinary Tract Infection, n (%)	1 (1)

Table 4.4 Post-operative problems

4.3 Primary outcome results

4.3.1 Comparing pre-operative and post-operative changes in the KHQ

Table 4.5 shows the mean values (p= < 0.0001) for all the patients in each group under each domain.

KHQ Variables (mean)	Pre-Op (p<0.0001)			Post-Op (p<0.0001)		
	SUI	SUI + Urgency	MUI	SUI	SUI + Urgency	MUI
General Health Perceptions	29	40	50	14	23	6
Incontinence Impact	91	92	83	6	8	33
Role Limitations	78	77	58	7	3	17
Physical Limitations	70	67	63	7	5	38
Social Limitations	34	43	39	0	3	14
Personal Relationships	36	12	75	10	1	37
Emotions	70	78	58	7	5	19
Sleep/Energy	45	47	75	8	1	50
Severity Measures	59	62	60	7	7	23

Table 4.5 Operative KHQ results classified by type of incontinence showing the mean score for the different KHQ variables

Women with MUI scored worse in all the domains except personal relationships. The mean score of the KHQ for each variable is shown preoperatively and postoperatively in the Graph 4.7. The X axis corresponds to the key (KHQ variables) on the right side of the graph. While the Y axis shows the mean score (0 - 100). The most relatively improved variable is *incontinence impact* of 89%. The least improved is *general health perception* of 52%. The most absolute improved in post-operative success is *social limitation*.

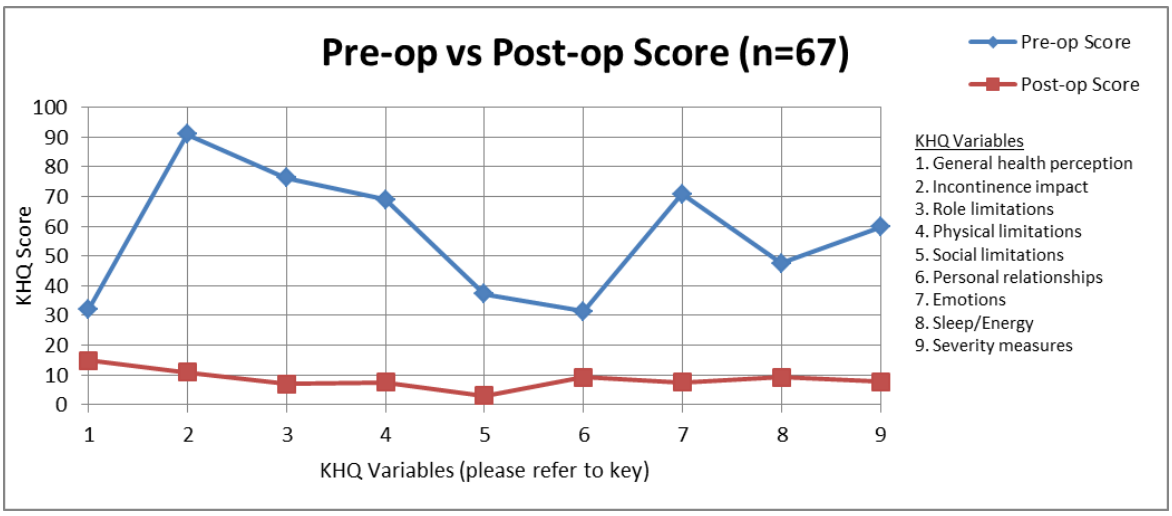


Figure 4.2 Graph: Comparing the change in operative KHQ results

There were 50 patients in the SUI group. The figure 4.4 measures the mean score for the patients in each KHQ variable. The relative best improvement is social limitations of 100%. The relative least improved is general health perceptions of 52%. The absolute best improvement is incontinence impact of 85%. The least improvement in absolute terms is general health perception of 15%.

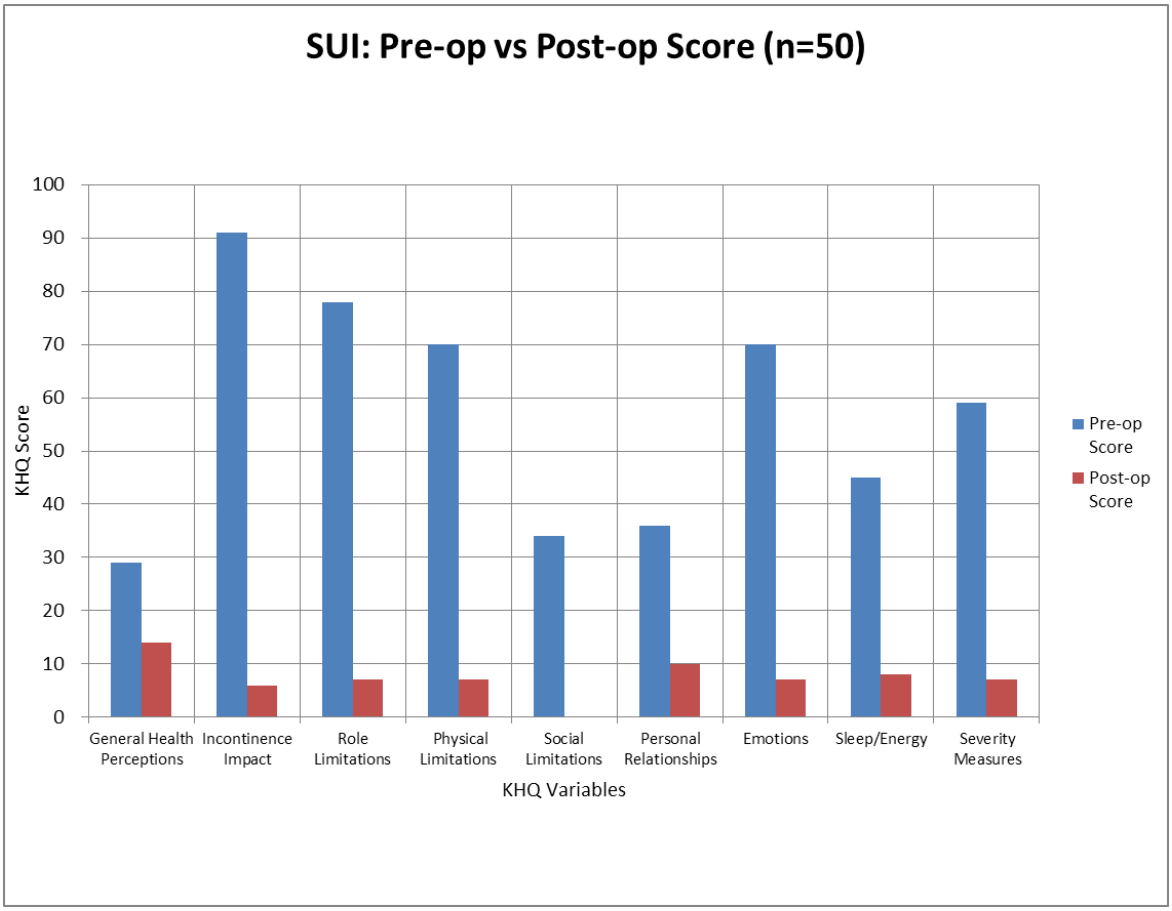


Figure 4.3: Graph showing Pre-operative and post-operative change for SUI

There were 13 patients in the SUI and urgency group. The figure 4.4 measures the mean score for the patients in each KHQ variable. The relative best improvement is social limitations of 96%. The relative least improved is general health perceptions of 43%. The absolute best improvement was incontinence impact of 84%. The least improvement for absolute terms was personal relationships of 11%.

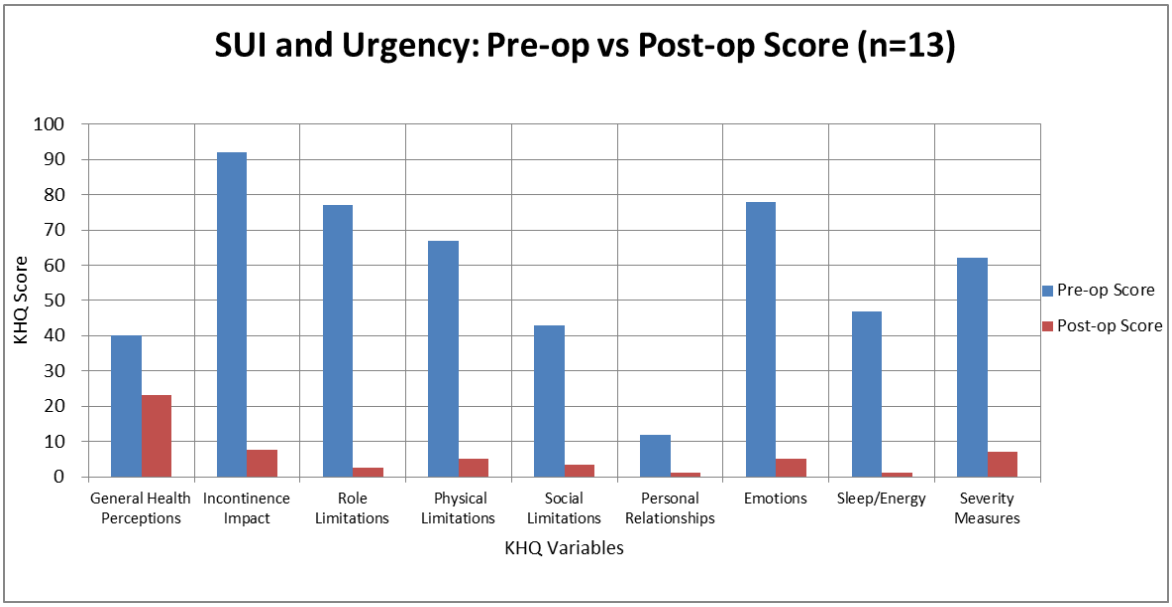


Figure 4.4 Graph: Pre-operative and post-operative change for SUI and urgency

There were 4 patients in the MUI group. The figure 4.5 measures the mean score for the patients in each KHQ variable. The relative best improvement is general health perceptions of 88%. The relative least improved is sleep/energy of 33%. The absolute best improvement was incontinence impact of 50% and the absolute least improvement was physical limitations and sleep/energy of 25%.

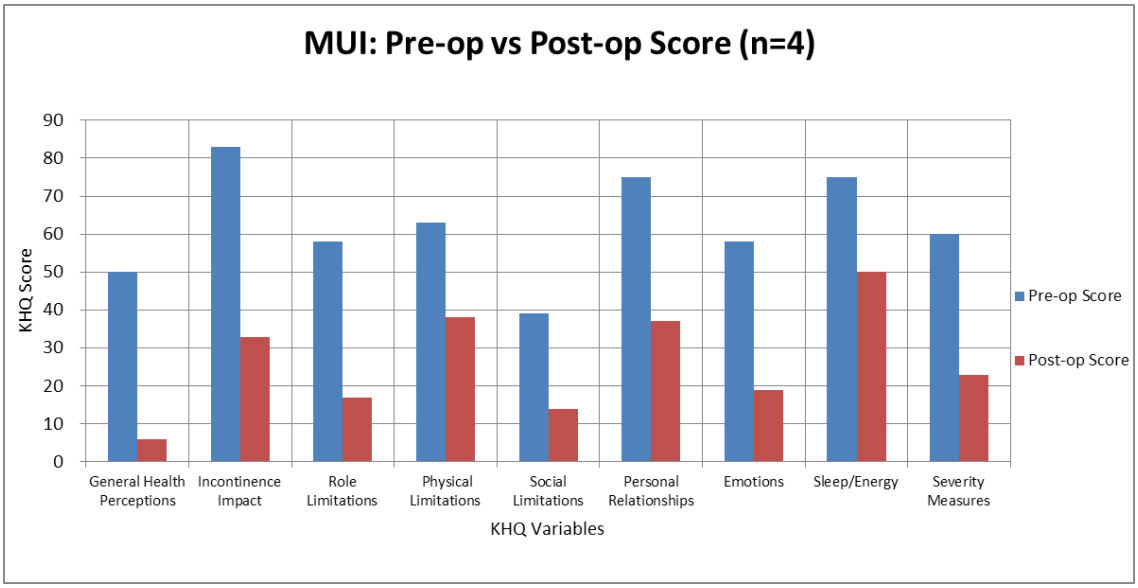


Figure 4.5 Graph: Pre-operative and post-operative change for MUI

4.3.2 Comparing pre-operative and post-operative changes in the Symptoms

Table 4.6 shows the mean values (p= < 0.0001) for all the patients in each group under each KHQ symptom.

KHQ Symptoms (mean)	Pre-Op (p<0.0001)			Post-Op (p<0.0001)		
	SUI	SUI + Urgency	MUI	SUI	SUI + Urgency	MUI
Frequency	77	21	9	18	4	7
Nocturia	53	14	10	16	6	6
Urgency	0	16	8	0	3	7
Urge UI	0	4	7	0	0	4
Stress UI	149	39	11	17	0	2
Nocturnal Enuresis	7	1	1	3	0	1
Intercourse Incontinence	38	1	1	8	1	1
Urinary Tract Infection	19	6	5	14	1	3
Bladder Pain	9	5	3	2	2	1
Difficulty Urinating	2	0	0	3	1	0

Table 4.6 Operative KHQ results classified by type of incontinence showing the mean score for the different KHQ symptoms.

Table 4.6 shows the comparative change in each variable before and after the surgery. The values given are the mean patient score for that variable. The higher the mean score for each variable, the worse the average patient level is for that variable.
An example is *incontinence impact* which had an average score in the SUI pre-op group of 91 and an average post op score of 6. Therefore, the average patient improved significantly with respect to this variable.

Graph 4.6 shows the operative change in symptoms for the SUI group. The greatest improvement was in the stress symptom of 89%.

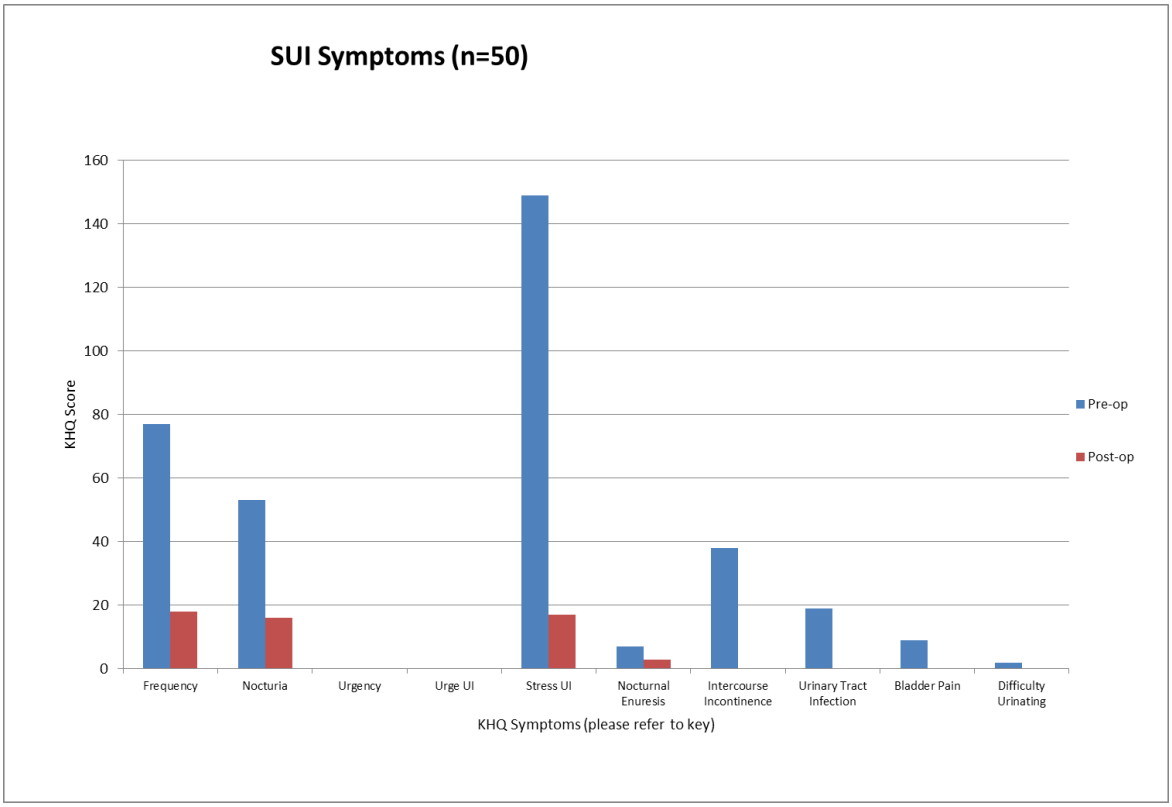


Figure 4.6 Graph: Pre-operative and post-operative changes in symptoms for SUI

Graph 4.7 shows the operative change in symptoms for the SUI and urgency group. The relative and absolute greatest improvement was for *stress* symptom which reduced to nil. There was an overall improvement in all the other symptoms except intercourse incontinence which stayed the same. Only 2 patients had urinary leakage during intercourse.

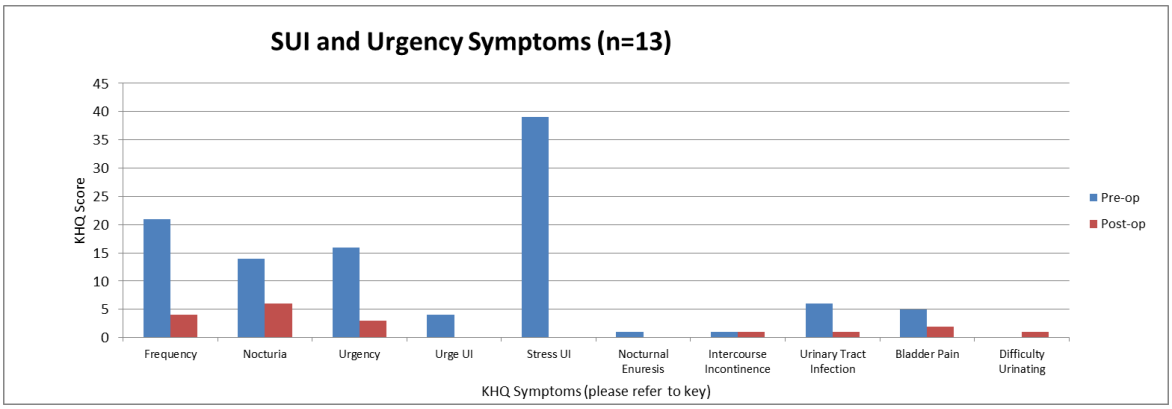


Figure 4.7 Graph: Pre-operative and post-operative changes in symptoms for SUI and urgency

Graph 4.8 shows the operative change in symptoms for the MUI group. The relative greatest improvement was for stress symptoms by a reduction of 82%. There was no improvement in nocturnal enuresis and intercourse incontinence.

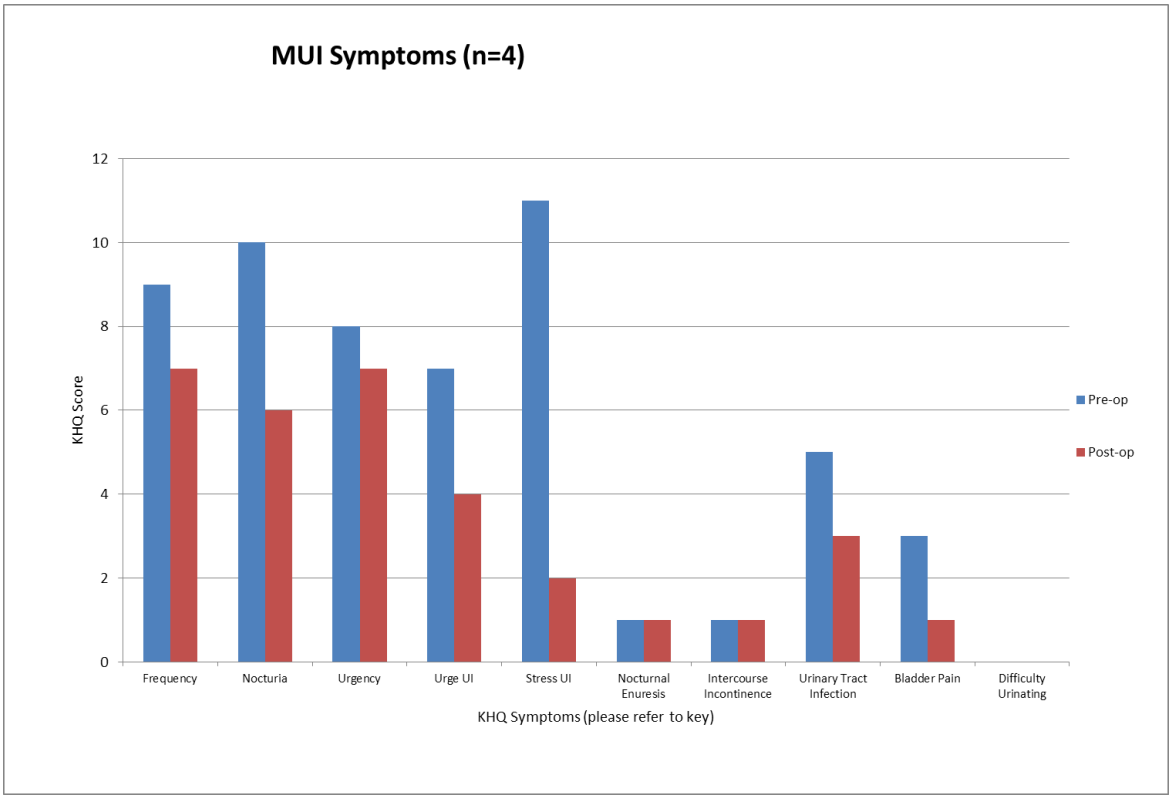


Figure 4.8 Graph: Pre-operative and post-operative changes in symptoms for MUI

Graph 4.9 shows the comparison for the mean change in QOL and symptoms for all the patients. The points on the left show the mean change and the points on the right show the respective standard deviation (SD) of the mean reduction for each of the three groups.

SUI quality of life (QOL) group and the SUI (and urgency) QOL group had the greatest reduction in mean score. The two groups also showed low SD of the mean reduction. The MUI symptoms had the lowest mean reduction.

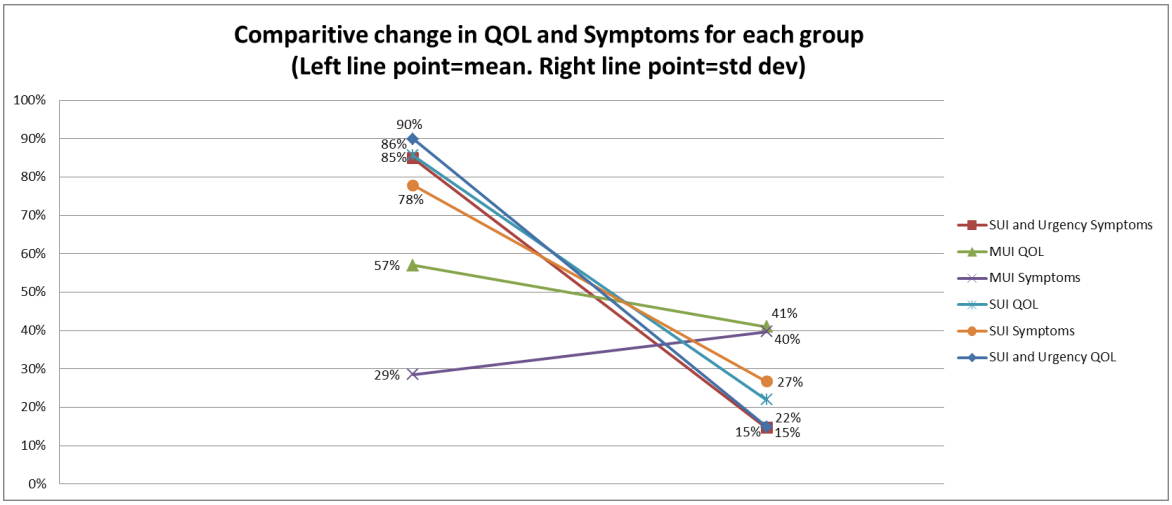


Figure 4.9 Graph: Total score correlation between QOL and symptomatic operative change expressed in mean score (left) and SD (right) for each group.

4.4 Secondary Outcome Results

4.4.1 Subjective QOL and symptom change in each group

The pie chart 4.10 shows that 62% of the SUI group were cured, 18% near cured, 18% improved. No patients worsened.

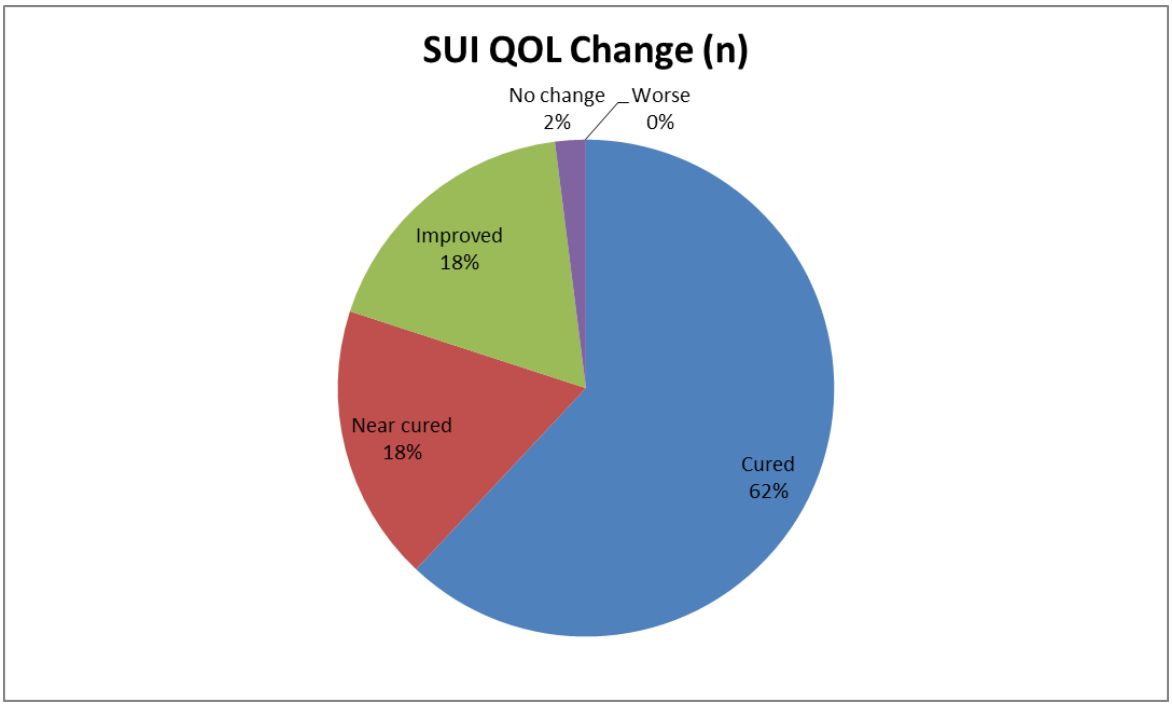


Figure 4.10 Pie chart: Subjective KHQ quality of life cure rate in the SUI group

The pie chart 4.11 shows that 42% of the SUI group were cured, 24% near cured, 34% improved. No patients worsened.

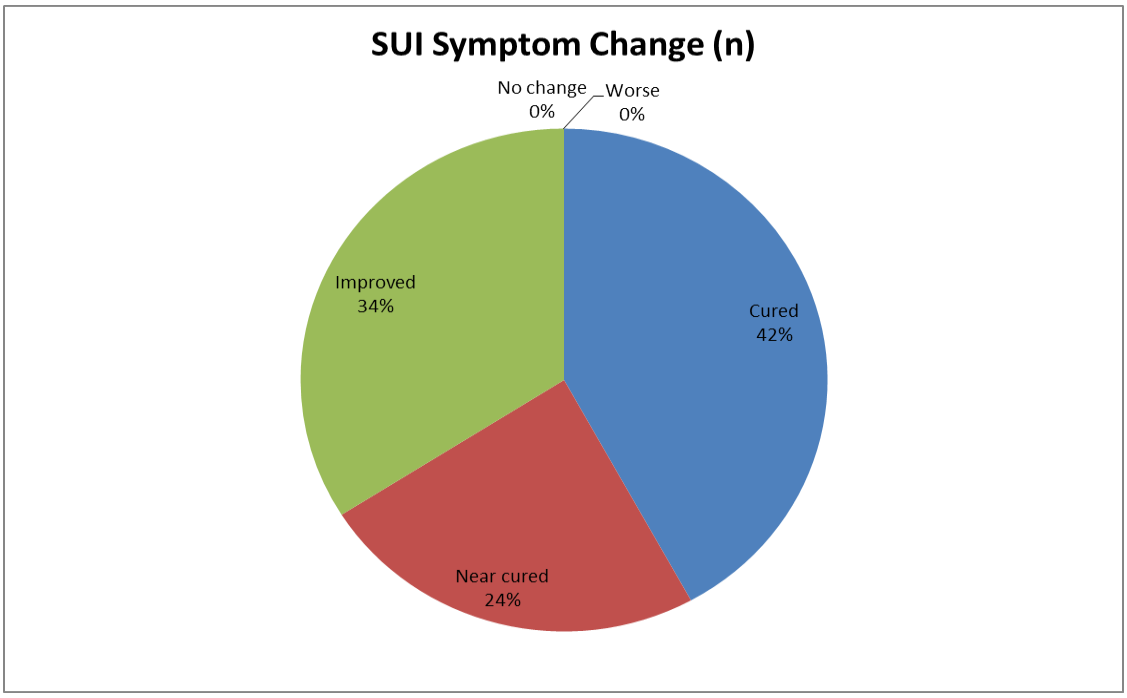


Figure 4.11 Pie chart: Subjective cure rate of symptoms in the SUI group

The pie chart 4.12 shows that 10(77%) patients in the SUI and urgency group were cured, 2(15%) patients were near cured, 1(8%) patient improved. No patients worsened.

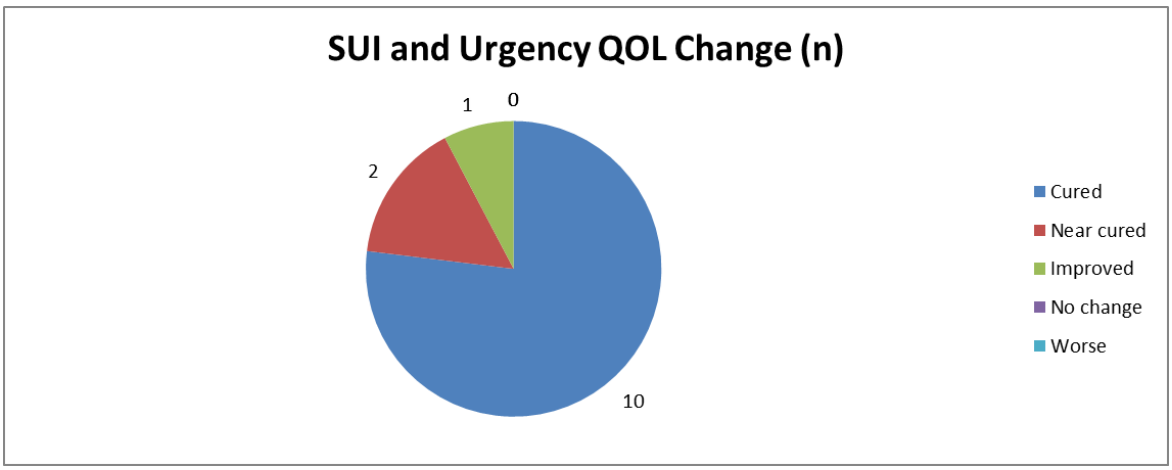


Figure 4.12 Pie chart: Subjective KHQ quality of life cure rate in the SUI and urgency group

The pie chart 4.13 shows that 5(38%) of the SUI and urgency group were cured, 7(54%) near cured, 1(8%) improved. No patients worsened.

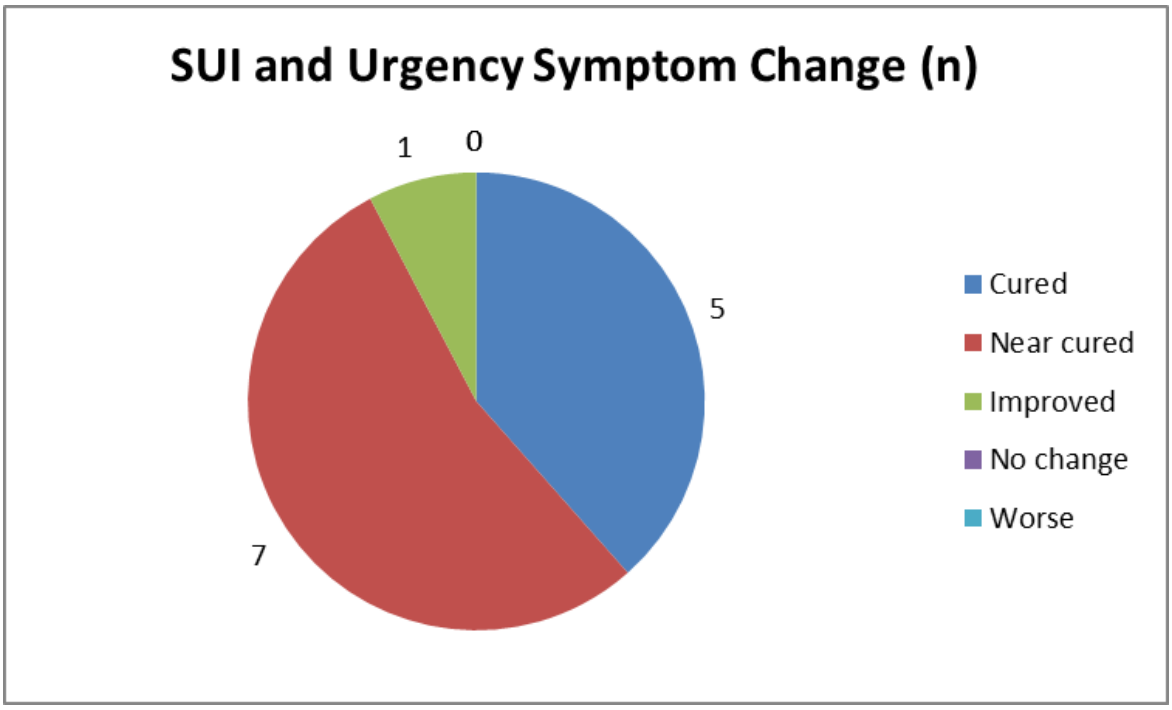


Figure 4.13 Pie chart: Subjective cure rate of symptoms in the SUI and urgency group

The pie chart 4.14 shows that 25% of the MUI group were cured, 25% near cured, 50% improved. No patients worsened.

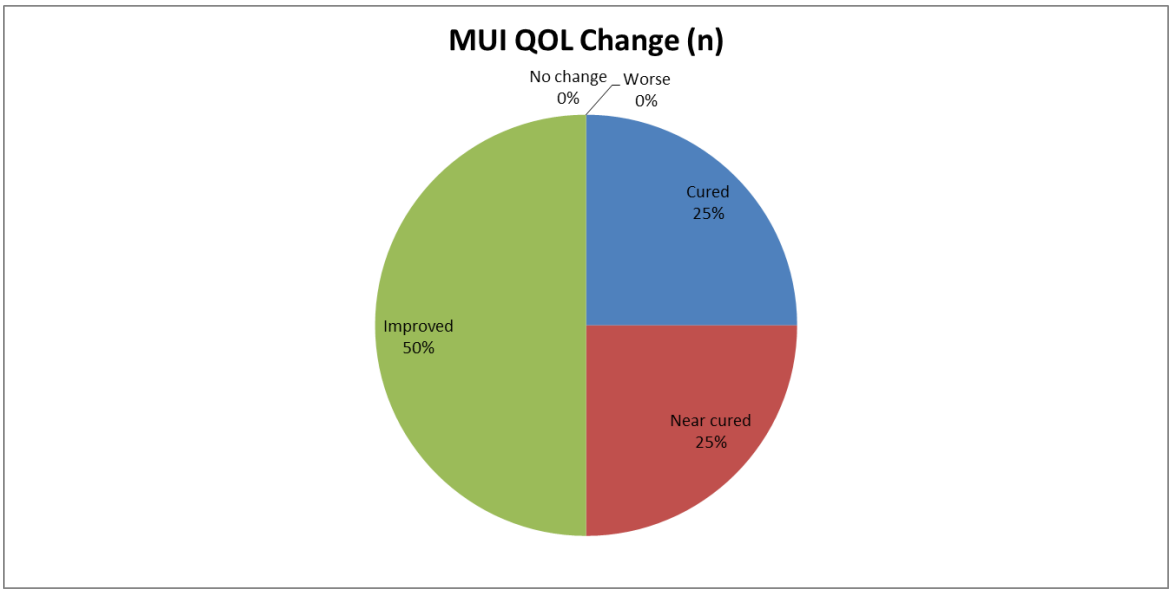


Figure 4.14 Pie chart: Subjective KHQ quality of life cure rate in the MUI group

The pie chart 4.15 shows that none of the MUI group were cured, 25% near cured, 50% improved and 25% of patients worsened.

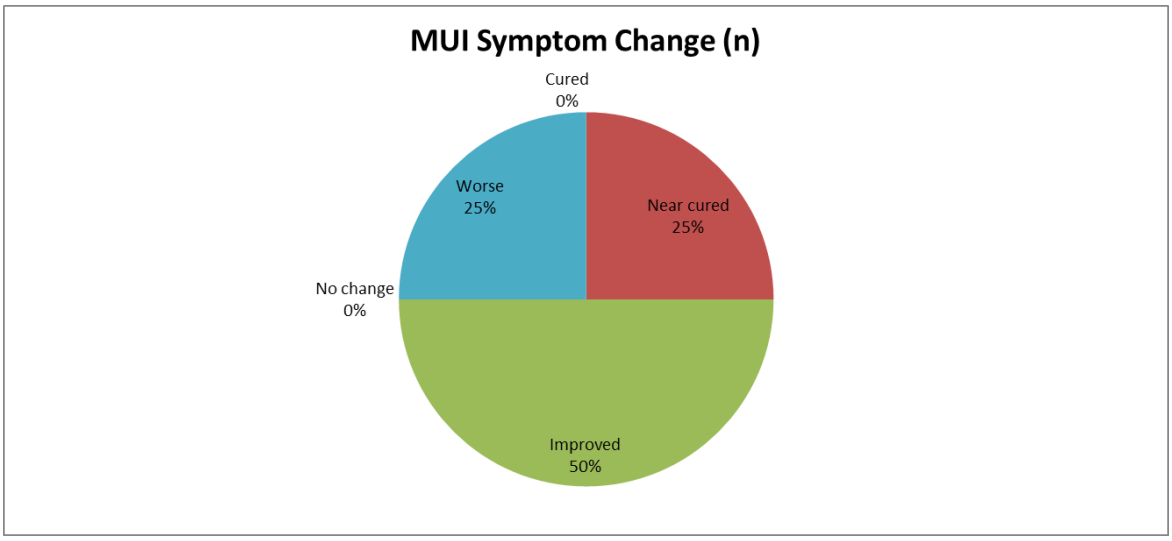


Figure 4.15 Pie chart: Subjective cure rate of symptoms in the MUI group

Graphs 4.16, 4.17 and 4.18 show a reduction in both the QOL cure rate score as well as the symptom cure rate score for each person in each group:

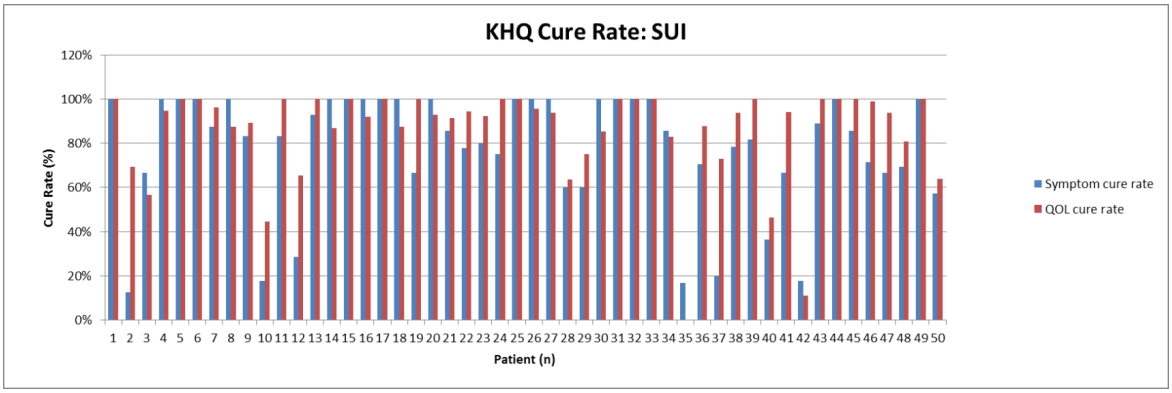


Figure 4.16 Graph: KHQ cure rate for both symptoms and QOL in the SUI group for each patient

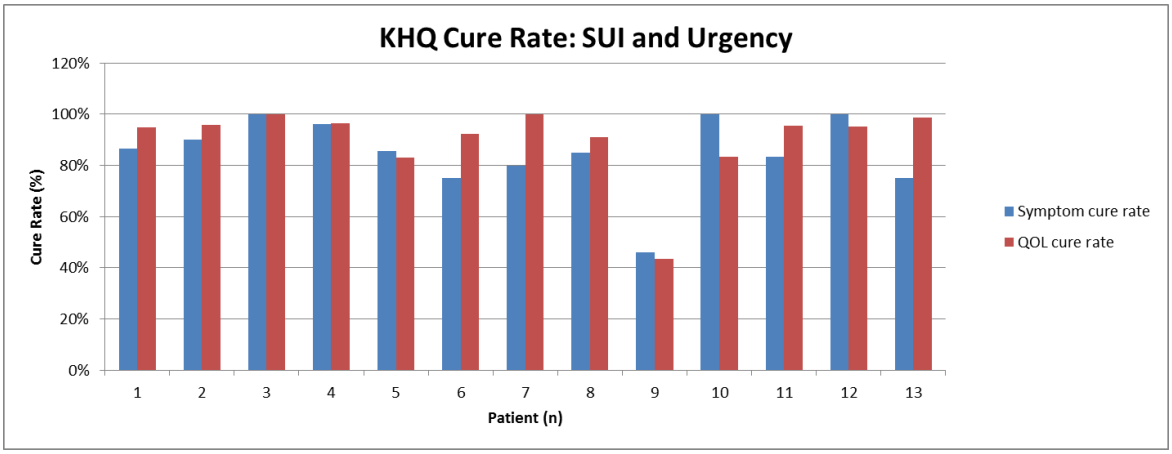


Figure 4.17 Graph: KHQ cure rate for both symptoms and QOL in the SUI and urgency group for each patient

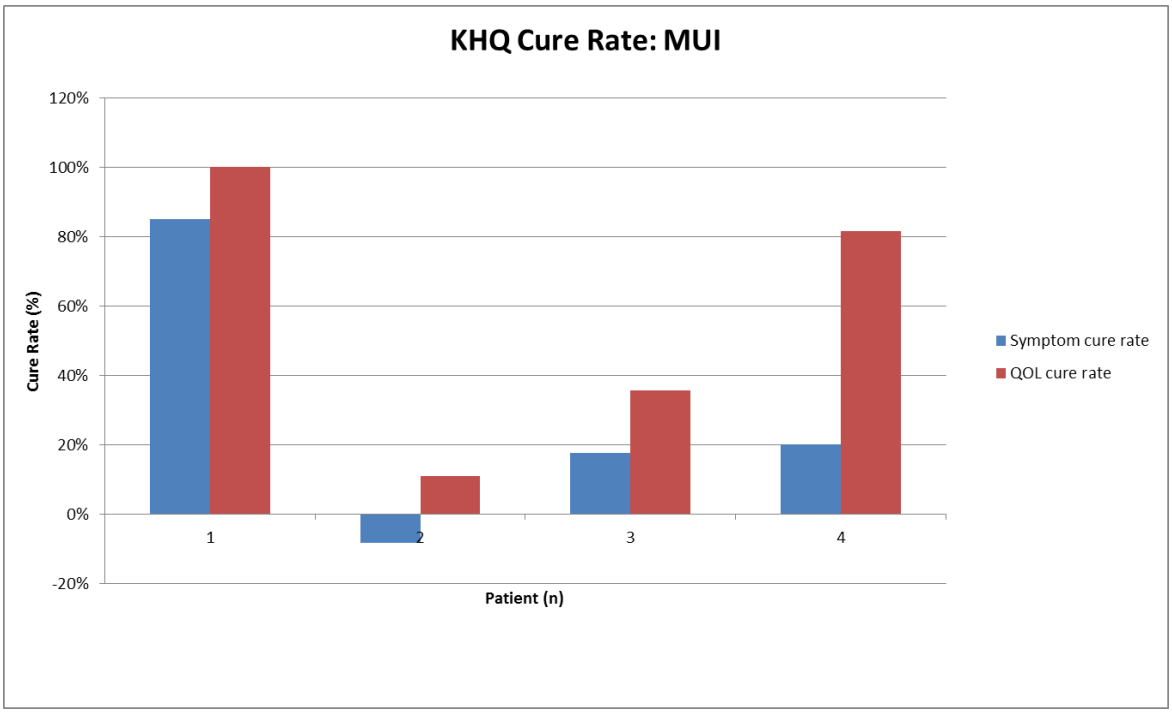


Figure 4.18 Graph: KHQ cure rate for both symptoms and QOL in the MUI group for each patient

Those patients who experienced an improvement greater than 75% in symptoms for each group - SUI,SUI and urgency and MUI - was 66%, 92% and 25% respectively.

Those patients who experienced an improvement greater than 75% in QOL for each group - SUI,SUI and urgency and MUI - was 80%, 92% and 50% respectively.

4.4.2 Outcome of urgency symptoms post operatively in patients with pre-operative urgency.

In the SUI (and urgency) group 9 (69%) of the 13 patients were cured, 1(8%) patient improved, 3(23%) remained the same and no patients worsened.

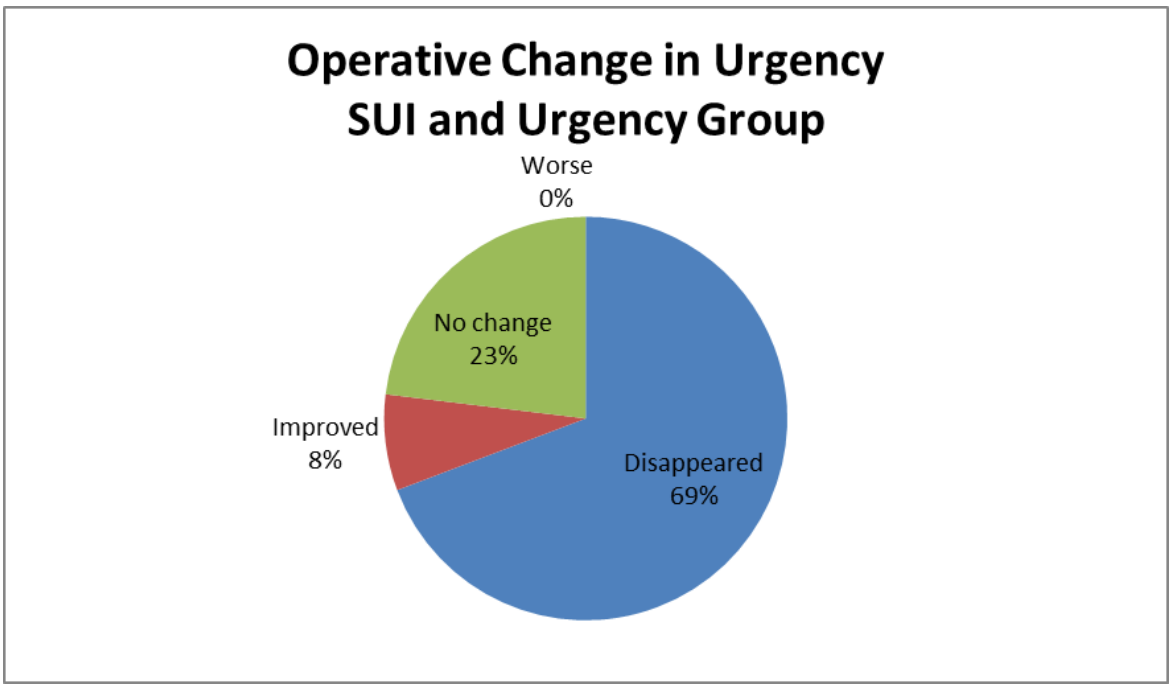


Figure 4.19 Pie graph: Operative change in urgency in the (SUI with urgency sensation) group.

In the MUI group 1(25%) of the 4 patients were cured, none improved, one remained the same and 2(50%) patients worsened

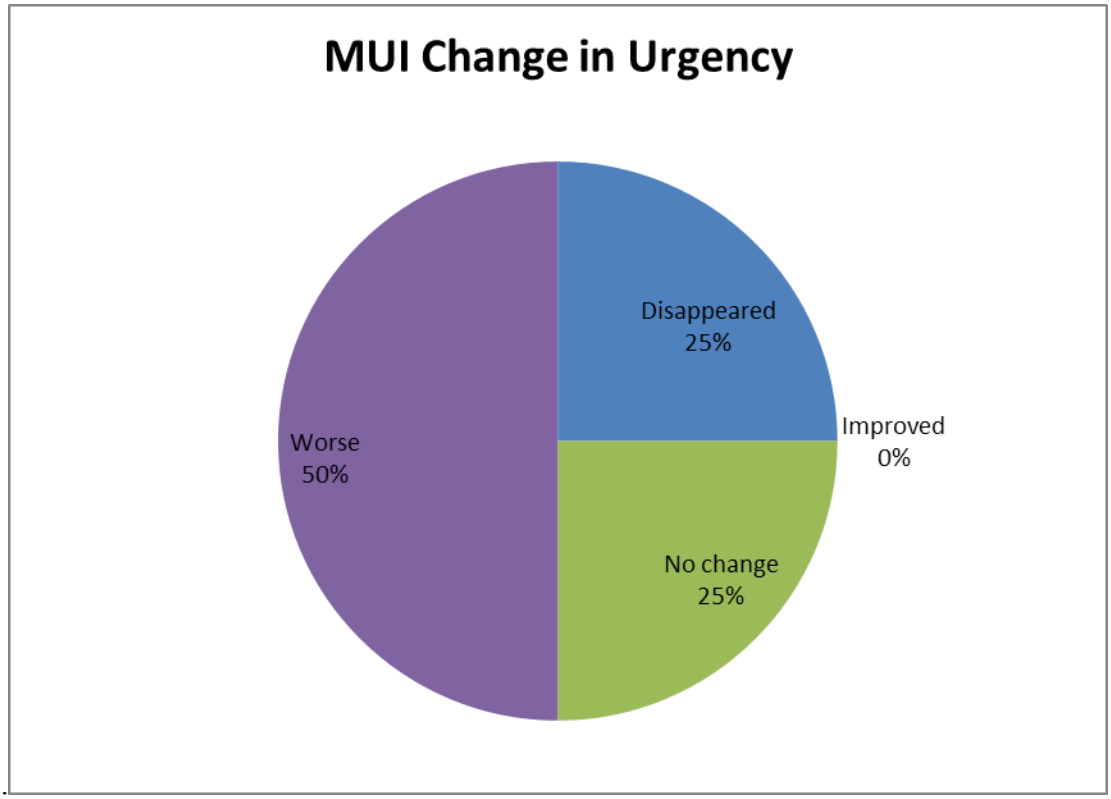


Figure 4.20 Pie graph: Operative change in urgency in the MUI group.

4.4.3 Comparing post-operative change in urinary incontinence and sexual function

The bar chart 4.21 shows the average reduction for all the patients in each group for the symptom of intercourse incontinence and personal relationships.

MUI has a greater reduction in intercourse incontinence than in personal relationships.

The SUI group had the greatest overall reduction in mean score compared to the other two groups. Overall personal relationships reduced more than urinary intercourse in mean score.

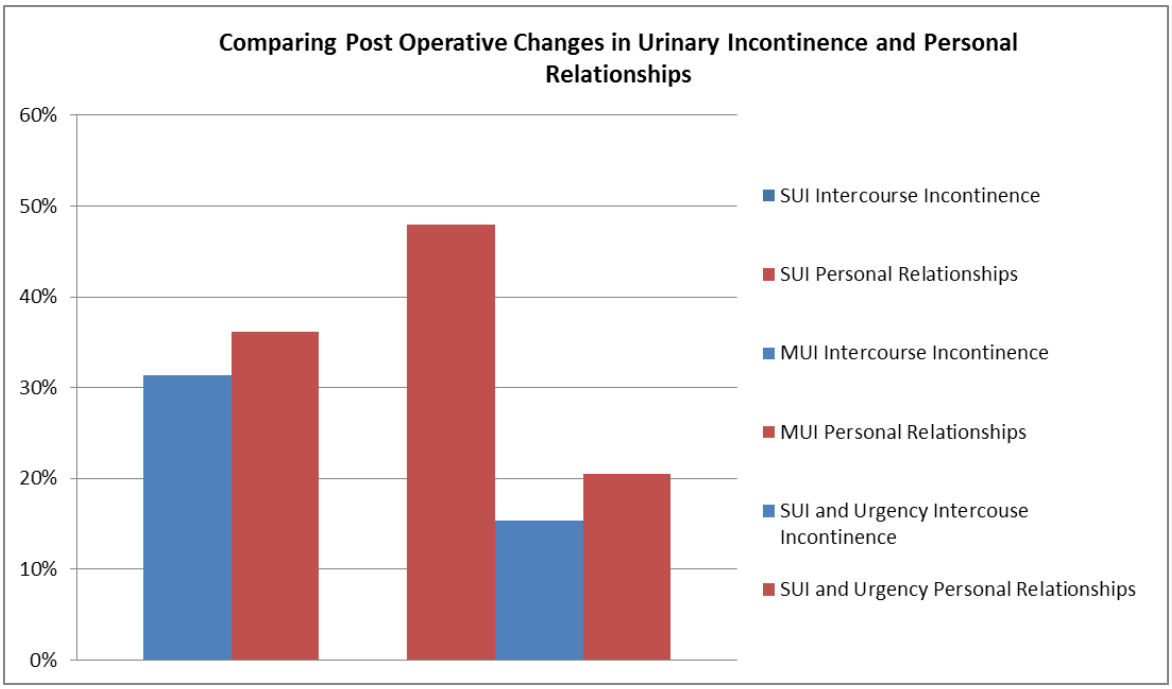


Figure 4.21 Bar chart: Comparing the operative changes of urinary incontinence and personal relationships in the three groups.

CHAPTER 5 - DISCUSSION

5.1 Difficulties encountered

5.1.1 The SUI with a sensation of urgency group

Patients were initially classified as SUI objectively. After answering positively to the presence of urgency and/or urge symptoms, these patients were put into a separate group of 'SUI with the sensation of urgency'. There were 13 patients in this group. This discrepancy shows that there is an inconsistency about how MUI is diagnosed. The discrepancy in the grouping could be as a result of the definition. MUI is defined as the

involuntary loss of urine associated with the sensation of urgency and associated with exertion, effort, sneezing or coughing[41]. Urge urinary incontinence is the complaint of involuntary leakage accompanied by or immediately preceded by urgency [41]. Further complicating the definition of MUI is that SUI may also be perceived as an urgency event [42]. A study showed that for women seeking surgical treatment for SUI, the majority were classified into the MUI group when using subjective measures[42]. The prevalence ranged from 50% to 93% depending on the questions used and severity selected. However when using objective measures only 8% of women were diagnosed with having MUI [42]. This illustrates how the definition and severity of symptoms can affect the classification and outcome of studies. A study by Chou et al suggested that patients might mistake the urge component for the 'fear of leaking'[43]. This adds to the discrepancy between the subjective and objective diagnosis. Not surprisingly, the subjective classification yields a higher prevalence rate of MUI then using objective measures. For this reason the data for this group was separately analysed as SUI with a sensation of urgency. This group was sufficiently powered to provide robust evidence to comment on the primary and secondary outcomes. This group responded similarly to the SUI group with QOL and symptom change.

5.1.2 Subjective cure rate

In previous studies, the subjective cure rate was calculated with less stringent criteria. There is no universally accepted calculation for cure rate. In this study the subjective cure rate was determined by using the total (n=67) 'cure' score for the QOL component of the

KHQ. The current literature shows that the subjective cure rate is 70-80%. The subjective cure rate in all the studies is always lower than the objective cure rate. A study by Deval et al had a 77.5% subjective cure rate and an 89.9% objective cure rate [44]. A TVT trial study showed that a subjective cure rate of less than 30% while more than 60% of patients would have been cured objectively based on the absence of urodynamic SUI or a negative pad test [45, 46]. Another TVT study showed that the objective cure rate was 89.3% and the subjective cure rate was 66%. The lower subjective value was attributed to the patients with de novo urge symptoms [47].

While the objective cure rate is determined by a negative cough test and more stringently by a pad weight test, very few studies have used the subjective outcomes as the primary objective. The success rates in this study are lower than most other studies published for the TOT procedure. However most studies report success rates based on poorly defined samples of patients with non-validated outcome measures. These studies often include 'patient improvement' in the definition of the cure rate.[11] To further illustrate the issue of the non standardised definition of the cure rate whereby the cure rate percentage is lower than current literature. A cohort study of 442 women showed that 28% of women reported complete continence 3 months post operatively and 18% reported incontinence once a month or less. One year post operatively 68% would recommend the surgery to a friend [11, 48].

5.2 Potential Biases in the study

5.2.1 Selection bias

A special group of 13 patients of SUI with a sensation of urgency was created because the patients were initially classified as SUI objectively (positive cough test). However during completion of the questionnaire, the patients had a sensation of urgency. These patients did not have urodynamic evaluation as the symptom of urgency were noted on admission, the day prior to the operation. These patients had varying degrees of the symptoms of a little to moderate on the likert scoring system. This was a unique group of individuals. To avoid any selection bias, these 13 patients were placed into a separate group. The two other groups were SUI and MUI (predominant stress symptoms). To help ensure external validity, the study patients were similar to the clinic patients in which the study results will apply.

5.2.2 Measurement bias

The KHQ was used to measure the subjective QOL and subjective symptom change post operatively. This measurement tool is thoroughly validated, reliable and responsive to re-test.[2]

5.2.3 Interviewer bias

Every patient was interviewed pre and post operatively. Whenever possible the interviewer ensured that the patient filled out the questionnaires themselves to avoid verbal and non-verbal cues.

5.2.4 Response bias

The patients with preoperative sensation of urgency were counseled about the symptoms which might remain or worsen post operatively and that the stress symptom would be surgically treated.

It is important that the patients understood this as they might be dissatisfied post operatively and that the operative change in QOL might remain inadequate.
It is possible that patients might respond a certain way to please the researcher. The KHQ helped avoid any loaded questions, but rather used clear, precise and short questions.

5.3 Concomitant surgery

In 34% of women, the TOT procedure was combined with repair of other pelvic defects and repaired at the vaginal level.This is a larger number compared to other studies In the study by Costa et al 13% of patients had concomitant pelvic repair surgery.[49] This shows that other pelvic procedures can be performed without compromising the cure rate. Fourteen women (21%) had an anterior repair at the same time as the TOT procedure was performed. Anterior repair was performed by inserting sutures in the weakened pubocervical fascia (without suburethral plication) and removing the redundant lax vaginal tissue.The anterior repair is rather a procedure of choice for repair of midline, or central, anterior vaginal wall defects and/or to reduce the volume of the anterior wall. It was not used to aid or alleviate any symptoms of SUI but rather done concomitantly to

treat the anterior wall defect at the time as the SUI procedure.In the past Kelly- Kennedy plication sutures or suburethral plication has been used to treat SUI but with low success rates.

5.4 Patient exclusion

Out of the 76 patients that had the TOT procedure, a total of 9 (11.8%) were excluded. Of the excluded patients, 7 of the 9 patients did not return for follow up visit. These patients were non contactable. One of the non-contactable patients died six months post-operatively from pulmonary hypertension. One patient had a neurogenic bladder and agreed to self-intermittent clean catheterisation. One patient did not consent to be involved in the study.

5.5 Post-operative complications

Six (9%) of the women had post-operative UTI. They had symptomatic dysuria and no voiding difficulties. Two patients were admitted for two days of antibiotic treatment. The other 4 patients were treated as out patients with antibiotics. All six women had a prior history of UTI. The incidence of UTI is in keeping with current literature of 3.1-22%.[50] The incidence of UTI appears to be lower with a TOT procedure as the tape is placed on the posterior surface of the mid-urethra allowing an obtuse curve between the obturators preventing voiding obstruction.

An explanation for the women with UTI in the study could be a possible prior decrease in urinary flow and an element of an under active bladder. However no pressure flow urodynamics was performed so this cannot be confirmed.

There were 2(3%) women whom had groin pain. One woman's groin pain resolved spontaneously after three months. The other woman had unilateral inner groin pain. This burning sensation was not relieved by amitriptyline. The pain resolved after partial removal of the tape and continence was preserved. Injury to the ilioinguinal nerve and rarely the obturator nerve has been described. The ilioinguinal nerve supplies the sensory innervation to the skin over the groin, inner thighs and labius majus. The incidence of groin pain has been reported in 3(1.5%) women out of 204 women following the TOT procedure [50].

In the study, no patients developed de novo urgency. The prevalence of de novo urgency in other studies shows an incidence of 16.6% (4-29%). It also occurs more frequently after previous incontinence surgery[51]. In this study, two (3%) women had repeat anti incontinence surgery.[51] De novo urge incontinence has been reported in 0.8-25.9% of women in the literature [52].

One patient had wound sepsis. The patient was admitted for 5 days on antibiotics. The patient did not require tape removal. To date, studies have shown that there have been few reports of infection following the tape removal.[50]

One patient had a sling failure which was managed by inserting a new sling.

5.6 Discussion of Primary Objectives

5.6.1 The change in QOL

There was a general improvement in all areas of the KHQ quality of life in all groups of patients post operatively. In the SUI group the social limitations improved 100% and incontinence impact improved by 93%. In the MUI group there was a 60% improvement in the incontinence impact. Patients in the SUI grouped scored better for incontinence impact. Women with SUI are more able to adapt and learn avoidance strategies such as shopping mall toilet mapping. The MUI patients scored worse in this area because of the unpredictable nature and the difficulties adapting. Most women in all the groups considered their general health perception to be good but scored the worst in incontinence impact on their life pre operatively. This shows that urinary incontinence is a major impedance to good QOL. Patients with MUI scored the worst post operatively in physical limitations because of the unpredictable nature of urgency. Patients with MUI showed the least improvement in personal relationships. The mean operative change in the score showed an 87% improvement in the SUI group, 58% in the MUI group and 89% in the SUI with a sensation of urgency group. The SUI with a sensation of urgency group had a similar response to the SUI group. The literature supports this study showing that women with mixed symptoms reported a higher degree of impact on daily activities, social life and

mental symptoms. More women with mixed symptoms reported an insult on the overall quality of life compared to stress symptoms [18].

5.6.2 The change in operative symptoms

The KHQ covers 10 urinary symptoms.

The SUI group and SUI with urgency had a reduction in the stress symptoms of 89% and 100% respectively, while the MUI group improved by 82%. In the MUI group there was an improvement in urgency of 12.5% and urge urinary incontinence by 43%. There was no de novo urgency and de novo urge urinary incontinence.

In the SUI with sensation of urgency group, urge urinary incontinence disappeared while the urgency symptom was reduced.This could suggest that urgency is caused by an inflow of urine into the urethra, activating parasympathetic sensory nerves and causing the urgency sensation. However urine leakage is prevented by the TOT procedure.

The possible explanations why the TOT procedure might improve the urge component:

- The TOT procedure prevents urine from entering the upper posterior urethra with increases in intra- abdominal pressure which prevents the reflex urgency [22, 23].
- Stress urinary incontinence might be misperceived as an urgency event. In some individuals SUI may falsely present as MUI due to the significant urgency component associated with spontaneous urinary loss.
- Urinary frequency is superimposed over this scenario as a behavioral response to the bothersome urinary symptoms [20, 21].

5.7 Discussion of Secondary objectives

5.7.1 Cure rate

The impact of QOL cure rate was determined as well as the subjective symptom improvement (10 symptoms graded as a little, moderately and a lot). The impact of QOL cure rate was analysed separately to the symptoms. The QOL was calculated for each incontinent group as well as a total cure rate score. In this study the QOL cure rate as well as the subjective symptom cure rate was defined as a more than 90% post-operative improvement based on the KHQ score. The literature shows no accepted calculation for cure rate. Other studies have defined the positive operative change as simply improvement or failure, or asked the patient if she leaks after coughing, or use of validated and non-validated questionnaires, or visual analogue scales, or telephone interviews and self-reports. A randomised control trial comparing different surgical slings for SUI showed that only 21 out of 76 trials used a validated questionnaire to evaluate the subjective cure rate[45]. This multitude of different questions makes comparisons very difficult. A standardised assessment of subjective cure rate is strongly recommended. In a study using the UDI-6 and IIQ-7 questionnaire, the subjective cure rate was 26 women (41%) and 12 (19%) respectively, this shows internal inconsistencies in the definitions of cure rate.[30]

The TOT is effective in patients with MUI as there is a dramatic improvement in their QOL. The SUI and urgency group had the greatest QOL cure rate (>90% improvement) of

77%. The subjective symptom change was 38.5%. The MUI group had a QOL cure rate (>90% improvement) of 25%, while none of the subjective symptoms were cured. This shows the impact of urinary incontinence on the QOL. The SUI group had a 62% QOL cure rate (>90% improvement) and a 42% subjective symptom cure rate.

5.7.2 Post-operative urgency

There have been a limited number of studies on the change of urgency postoperatively. In a study by Tomoe, the sensation has been reported to get better after the TOT.[53.] The cure rate is analysed by including all the patients with pre-operative urgency. In our study, the MUI and SUI with a sensation of urgency groups had a total of 17 patients.

There was a 59% (n=10) cure rate (disappearance) of urgency and a 6% (n=1) improvement. In a prospective multi-centric study, there was a 45% cure rate and a 31% improvement in the MUI group.[53.] In another prospective multi-centric study there was 56.3% disappearance of urgency[49.] The cure rate of urgency seemed better than other studies.

The SUI with a sensation of urgency alone had a 69% disappearance of urgency and 8% improvement. No patients worsened.This group did better than the MUI group. There were no patients with de novo urgency.

The role of anticholinergics:

Anticholinergics are used for the treatment of urge urinary incontinence.They are thought to act primarily by increasing bladder capacity and decreasing urgency by blocking basal release of acetylcholine during bladder filling. The type of antimuscarinic used was Oxybutinin at a dose of 5mg twice per day. The study patients with mixed urinary incontinence continued to use anticholinergics. Three women (75%) continued to use anticholinergics at the same dose preoperatively. One woman (25%) continued to use anticholinergics at half the dose used pre operatively. No women with true SUI were given anticholinergics post operatively.

5.7.3 Relationship between urinary leakage during intercourse and the effect on personal relationships

In a study by Temml et al, 25% of women had impairment of their sexual life by urinary incontinence.[54] Intercourse incontinence is a common embarrassing problem with the prevalence ranging between 10% to 56% of women with incontinence.[55.]

Patients with urgency (MUI n=4 and SUI with sensation of urgency n=13) had a significant reduction in urinary leakage but less so in personal relationships than the SUI group. There was an 86% reduction in intercourse incontinence in the SUI group and no reduction in the MUI group. There was a 69% improvement in personal relationships in the SUI group. It is good to know that urinary incontinence improves, but it seems even

better that personal relationships improve after the TOT procedure.[56] The effects of the TOT on sexual function have been studied but are still inconsistent. A prospective study of 54 women showed that the TOT procedure has a positive effect on women's sexual function by reducing urinary leakage and pain during or after sexual activity.[56.] This helps improve a woman's body image by treating urinary incontinence.[57, 58.] However TOT procedures have a risk of neurovascular injuries. Sexual function might worsen by developing dyspareunia after the suburethral sling procedure.[59] De novo dyspareunia might happen by the position of the tape such as in the vaginal narrowing, para urethral banding or erosions.[59] Caruso et al studied the effect of clitoral blood flow after the TVT and TOT procedure using colour doppler ultrasonography. Clitoral blood flowed negatively after the TVT, whereas it was not affected by the TOT.[60] The TOT is an anatomically safer approach. However the vaginal anatomy is altered and this might result in vaginal narrowing. Elzevier et al reported that 10% of partners that underwent the TOT procedure reported vaginal narrowing causing dysparaenia.[61]

5.8 Strengths and Limitations of the study

5.8.1 Strengths of the Study

- Prospective design. This eliminates recall bias.
- Long term follow up between 6 months to 2 years (dependent on timing of the procedure).
- Completion of a well validated questionnaire.

- First South African study to assess the patient reported outcomes of the TOT procedure.
- Same surgeon (AC) operating on all the patients.
- Inclusion of a unique group of patients with stress urinary incontinence with a sensation of urgency

5.8.2 Limitations of the Study

- Women could be a source of potential bias when answering the questions.
- Inconsistent definitions of affect of quality of life cure rate and subjective symptom cure rate make it difficult to compare cure rate results with other studies.
- Single researcher carrying out all postoperative interviews.
- Interview administered which might lead to patient answering bias.
- Including patients with SUI and urgency.
- No urodynamic studies performed on patients with SUI due to time constraint and limited resources
- Lack of objective cure measurements and depending solely on subjective outcomes.
- Longer follow up time would be favourable.
- In the analysis of the quality of life variables of the KHQ and symptoms, not only the absolute pre to post-operative changes but also the relative operative changes were calculated. This was done to control for the differences in pre-operative variables and symptoms.

- The MUI group was small in number consisting of four women. This is not sufficiently robust to determine a credible outcome. The MUI group responded less favorably to the TOT procedure compared to the SUI (with sensation of urgency). The SUI was a unique group that was analysed separately.
- The study did not explore the role of anticholinergics in quality of life and symptom relief other than specifically focusing on specific overactive bladder symptoms. It is possible that this aided in improving the QOL by alleviating some of the symptoms. On the flip side, anticholinergics need to be tailored specifically to the patient and are dictated by a side effect profile, tolerability, medical co-morbidities and age.

CHAPTER 6 - CONCLUSIONS

6.1 Conclusion

Most studies on the TOT procedure have focused on objective cute rate, complication and technique but less so on women's fundamental outcome. This study evaluates the QOL of women before and after the TOT procedure. It shows that the TOT procedure significantly improves the quality of life. The study provides first hand insight into operative outcomes using a well validated questionnaire. It also raises the question of the need of a standardised cure rate.

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Dr Hayley Jacobson

CLEARANCE CERTIFICATE	**M120483**
PROJECT	Transobturator Tape Surgery for Stress Urinary Incontinence: An Assessment of Quality of Life \before and After Surgery from the Patient's Perspective
INVESTIGATORS	Dr Hayley Jacobson.
DEPARTMENT	Department of Obstetrics & Gynaecology
DATE CONSIDERED	04/05/2012
DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 22/06/2012 **CHAIRPERSON** .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor : Dr Frank

DECLARATION OF INVESTIGATOR(S)
To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...

Human Research Ethics Committee (Medical)
(formerly Committee for Research on Human Subjects (Medical))
Secretariat: Research Office, Room SH10005, 10th floor, Senate House • Telephone: +27 11 717-1234 • Fax: +27 11 339-5708
Private Bag 3, Wits 2050, South Africa

University
of the Witwatersrand,
Johannesburg

10 October 2012

Dr Hayley Jacobson
Department of Obstetrics
& Gynaecology
CM Johannesburg Academic Hospital
University

Sent by e-mail to: hjacobson@netactive.co.za

Dear Dr Jacobson

RE: **Protocol M120483: 'Transoburator Tape Surgery for Stress Urinary Incontinence: An Assessment of Quality of Life before and After Surgery from Patients' Perspective'**

This letter serves to confirm that the Chairman of the Human Research Ethics Committee (Medical) has reviewed and approved the following amendment on the abovementioned protocol as detailed in your undated letter:

- Request to include data collected prior to ethics application since January 2011

Thank you for keeping us informed and updated.

Yours sincerely,

Anisa Keshav
Secretary
Human Research Ethics Committee (Medical)

University
of the Witwatersrand,
Johannesburg

Human Research Ethics Committee (Medical)
(formerly Committee for Research on Human Subjects (Medical)

Secretariat: Research Office, Room SH10005, 10th floor, Senate House • Telephone: +27 11 717-1234 • Fax: +27 11 339-5708
Private Bag 3, Wits 2050, South Africa

25 March 2013

Dr Hayley Jacobson
Department of Obstetrics & Gynaecology
CM Johannesburg Academic Hospital
University

Sent by email to: hjacobson@netactive.co.za

Dear Dr Jacobson

RE: Protocol M120483: 'Transoburator Tape Surgery for Stress Urinary Incontinence: An Assessment for Quality of Life: Before and After Surgery from the Patient's Perspective

This letter serves to confirm that the Chairman of the Human Research Ethics Committee (Medical) has approved your request to 'include patient data that has been collected from January 2010' as detailed in your letter dated 13 March 2013.

Thank you for keeping us informed and updated.

Yours sincerely,

Anisa Keshav
Secretary
Human Research Ethics Committee (Medical0

University of the Witwatersrand

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
FACULTY OF HEALTH SCIENCES
ASSESSORS MEETING

CANDIDATE: Dr Hayley Jacobson

Date of Assessor Group Meeting: 23/10/2012 ~~School~~/ Department / ~~Division~~: Obstetrics/Gynaecology

Yes ✓ | No | Is the research question clearly identified and described?

Comments:

~~Yes~~ | No | Not entirely

Is the design of the study and methods used appropriate for the research question being asked?

Comments:

(1) Grade the anatomical abnormalities (RCOG)
(2). Suggest delay to follow-up questionnaire to 3 or 6 months (6 weeks too early) - even
(3) Consider telephonic interview
(4). Needs paired analysis of data.
(5) e.g. paired t-test, McNemar's test,

Is the study feasible within:

i. the applicant's resources? Yes | No
ii. the departments resources? Yes | No
iii. the time frame? Yes | No

Do you recommend:

i. shortening / lengthening of the protocol? Please specify and explain.

ii. the appointment of a co-supervisor? Yes [ ] No [✓]

Nominee/s :

Overall recommendation regarding the protocol :

i. revision of the protocol to the Supervisor (if HOD approval is also required, please specify):
(**Candidates**: one copy, list of corrections, supervisor approval letter – submit to PG Office) Yes [✓] No [ ]

ii. revision of the protocol to the satisfaction of the Assessor Group:
(**Candidates**: six copies, list of corrections, supervisor approval letter – submit to PG Office) Yes [ ] No [✓]

iii. revision of the protocol and resubmission of the revised protocol to the next Assessor Group Meeting:
(**Candidates**: six copies, list of corrections, supervisor approval letter – submit one copy to PG Office / 5 to school assessor group administrator/ for PhD all six copies to be submitted to the PG Office) Yes [ ] No [✓]

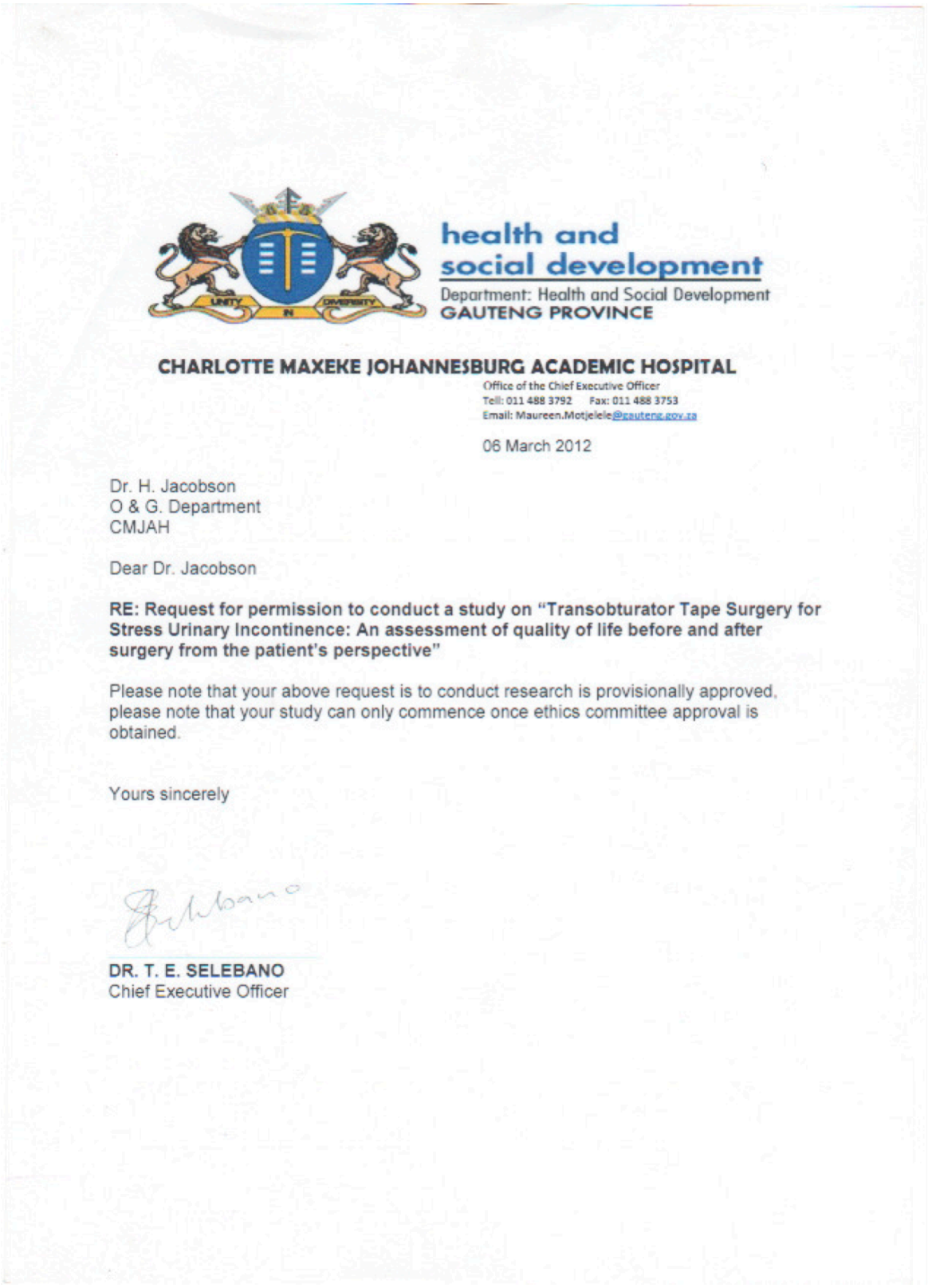
iv. candidate goes ahead: Yes [ ] No [✓]

Assessor Names and Signatures :

Prof F. Guidozzi
Dr Y. Adam
Dr R. Nyakoe
Dr M. Patel
Prof E. Buchmann

23/10/12
Date

Assessor Group Chair



health and social development
Department: Health and Social Development
GAUTENG PROVINCE

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

Office of the Chief Executive Officer
Tell: 011 488 3792 Fax: 011 488 3753
Email: Maureen.Motjelele@gauteng.gov.za

06 March 2012

Dr. H. Jacobson
O & G. Department
CMJAH

Dear Dr. Jacobson

RE: Request for permission to conduct a study on "Transobturator Tape Surgery for Stress Urinary Incontinence: An assessment of quality of life before and after surgery from the patient's perspective"

Please note that your above request is to conduct research is provisionally approved, please note that your study can only commence once ethics committee approval is obtained.

Yours sincerely

DR. T. E. SELEBANO
Chief Executive Officer

Datasheet-Baseline data:

Date:

Study number:

Date of procedure:

The following information below is relevant as at the date of the procedure:

Age:

Parity: Gravidity:

Menopausal:

Height: Weight: BMI:

Smoker:

Previous surgical history:

Stress urinary incontinence:

Mixed urinary incontinence:(Predominant SUI symptoms)

Problem(s) after TOT procedure:

- **Intra-peritoneal problems**
- **Urinary tract infection**
- **Pain**
- **erosion**
- **other**

Consent for the study of transobturator tape surgery for stress urinary incontinence: an assessment of quality of life before and after surgery from the patients's perspective

Hello, my name is Dr Jacobson. I am doing research as part of my training to become as specialist Obstetrician-Gynaecologist. I would like to invite you to participate in a study that requires you to answer a few questions before and after the operation that you will be having at CMAJH to correct the problem with urine leakage.

Why does urine leak?

Urine is stored in the bladder. The bladder works like a balloon. The urine empties through the urethra. The urethra is like a pipe connected to the bladder. Urine leakage occurs when the urethra is weak. Such weakness may be caused by damage to the muscles, nerves and the floor of the bladder. This can occur during child birth, aging, weight gain, hysterectomy (removal of womb) and coughing a lot.

What is a transobturator tape procedure?

This is the operation performed to treat the urine leakage. The tape is inserted underneath the urethra in order to support the urethra, as the supporting structures of the urethra are weak.

How do we know if this is a good operation?

The best way to measure the success of the operation is to ask women before and after the operation about how this urine problem affects their life. After asking many women about their lifestyle before and after the operation, we can determine the effectiveness of this operation based on their answers to these questions.

How can you help?

We will ask you a few questions on your admission for the operation. After 6 months, when you come in for your routine follow-up, we will ask you the same questions again. The questionnaire will take 10 minutes in total.

Your answers will be treated confidentially. If you do not wish to answer any of the questions, you may feel free to withdraw at any time without any consequences to yourself.

Please note, there is no reimbursement for participating in this study.

If we have deemed your operation to be unsuccessful during the course of this survey, we will ask you to come into the hospital for a full examination by the doctor that did your operation and possible re-attempt at relieving your symptoms, if that is what you want.

If you have any questions, feel free to ask me now. Alternatively you can reach me on (071) 682 0106.

You may also call the doctor performing the operation, Dr Chrysostomou, on (083) 324 4122.

Do you agree to take part in the survey?

Thank you

Participant name: _____

Person obtaining consent: _____

THE KING'S HEALTH QUESTIONNAIRE

1. How would you describe your health at the present?

Please tick one answer

- Very good ⬭
- Good ⬭
- Fair ⬭
- Poor ⬭
- Very poor ⬭

2. How much do you think your bladder problem affects your life?

Please tick one answer

- Not at all ⬭
- A little ⬭
- Moderately ⬭
- A lot ⬭

Please turn the page

Below are some daily activities that can be affected by bladder problems. How much does your bladder problem affect you?

We would like you to answer every question. Simply tick the box that applies to yo

3. ROLE LIMITATIONS	1 Not at all	2 Slightly	3 Moderately	4 A lot
A. Does your bladder problem affect your household tasks? (cleaning, shopping etc)	○	○	○	○
B. Does your bladder problem affect your job, or your normal daily activities outside the home?	○	○	○	○

4. PHYSICAL/SOCIAL LIMITATION	1 Not at all	2 Slightly	3 Moderately	4 A lot
A Does your bladder problem affect your physical activities (e.g. going for a walk, running, sport, gym etc)?	○	○	○	○
B. Does your bladder problem affect your ability to travel?	○	○	○	○
C. Does your bladder problem limit your social life?	○	○	○	○
D. Does your bladder problem limit your ability to see and visit friends?	○	○	○	○

5. PERSONAL RELATIONSHIPS	0 Not Applicable	1 Not at all	2 Slightly	3 Moderately	4 A lot
A. Does your bladder problem affect your relationship with your partner?	○	○	○	○	○
B. Does your bladder problem affect your sex life?	○	○	○	○	○
C. Does your bladder problem affect your family life?	○	○	○	○	○

6. EMOTIONS	1 Not at all	2 Slightly	3 Moderately	4 Very much
A. Does your bladder problem make you feel depressed?	○	○	○	○
B. Does your bladder problem make you feel anxious or nervous?	○	○	○	○
C. Does your bladder problem make you feel bad about yourself?	○	○	○	○

7.SLEEP/ENERGY	1 Never	2 Sometimes	3 Often	4 All the time
A. Does your bladder problem affect your sleep?	○	○	○	○
B. Does your bladder problem make you feel worn out and tired ?	○	○	○	○

8.Do you do any of the following?	If so how much? 1 Never	2 Sometimes	3 Often	4 All the time
A. Wear pads to keep dry?	○	○	○	○
B. Be careful how much fluid you drink ?	○	○	○	○
C. Change your underclothes because they get wet?	○	○	○	○
D. Worry in case you smell?	○	○	○	○

We would like to know what your bladder problems are and how much they affect you ? From the list below choose only those problems that you have at present. Leave out those that don't apply to you.

How much do they affect you?

FREQUENCY: going to the toilet very often

1. A little ○ 2.Moderately ○ 3. A lot ○

NOCTURIA: getting up at night to pass urine

1. A little ○ 2.Moderately ○ 3. A lot ○

URGENCY: a strong and difficult to control desire to pass urine

1. A little ○ 2.Moderately ○ 3. A lot ○

URGE INCONTINENCE: urinary leakage associated with a strong desire to pass urine

1. A little ○ 2.Moderately ○ 3. A lot ○

STRESS INCONTINENCE: urinary leakage with physical activity eg. coughing, running

1. A little ○ 2.Moderately ○ 3. A lot ○

NOCTURNAL ENURESIS: wetting the bed at night

1. A little ○ 2.Moderately ○ 3. A lot ○

INTERCOURSE INCONTINENCE: urinary leakage with sexual intercourse

1. A little ○ 2.Moderately ○ 3. A lot ○

WATERWORKS INFECTIONS

1. A little ○ 2.Moderately ○ 3. A lot ○

BLADDER PAIN

1. A little ○ 2.Moderately ○ 3. A lot ○

Thank You For Your Time

To Calculate Scores

PART 1

1) General Health Perceptions

Very good	1
Good	2
Fair	3
Poor	4
Very poor	5

Score = ((Score to Q1 – 1)/4) x 100

2) Incontinence Impact

Not at all	1
A little	2
Moderately	3
A lot	4

Score =((Score to Q2 – 1)/3) x 100

PART 2

Individual scores as recorded at the top of each column of possible responses

3) Role limitations

Score =(((Scores to Q 3A + 3B) – 2)/6) x 100

4) Physical limitations

Score =(((Scores to Q 4A + 4B) – 2)/6) x 100

5) Social limitations

[If 5C >/= 1] Score =(((Score to Q 4C + 4D + 5C) – 3)/9) X 100

6) *Personal relationships*

[If 5A+5B >=2]Score =(((Scores to Q 5A + 5B) – 2)/6) x 100

[If 5A+5B =1] Score =(((Scores to Q 5A + 5B) – 1)/3) x 100

[If 5A+5B =0] Treat as missing value

7) *Emotions*

Score =(((Score to Q 6A + 6B + 6C) – 3)/9) X 100

8) *Sleep / energy*

Score =(((Scores to Q 7A + 7B) – 2)/5) x 100

9) *Severity measures*

Score =(((Scores to Q 8A + 8B + 8C + 8D) – 4)/12) x 100

PART 3

Scale	*score*
Omitted	0
A little	1
Moderately	2
A lot	3

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