A STUDY OF INSIDE OUT TRANSOBTURATOR TAPE FOR THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE

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GOVT. STANLEY MEDICAL COLLEGE & HOSPITAL

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CERTIFICATE

This is to certify that the dissertation titled **"A STUDY OF INSIDE OUT TRANSOBTURATOR TAPE FOR THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE"** is the bonafide original work of **Dr.A.K.JAYARAJ,** in partial fulfillment of the requirements for M.Ch. Branch – IV (Urology) Examination of the Tamil Nadu DR. M.G.R Medical University to be held in AUGUST 2013.

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DECLARATION

I, **Dr.A.K.JAYARAJ,** solemnly declare that dissertation titled **"A STUDY OF INSIDE OUT TRANSOBTURATOR TAPE FOR THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE"** is a bonafide work done by me at Government Stanley Medical College and Hospital during November 2010 to February 2013 under the guidance and supervision of **Prof .Dr. V. Selvaraj, M.S., M.ch. (Urology)** Professor and Head, Department of Urology, Government Stanley Medical College and Hospital, Chennai.

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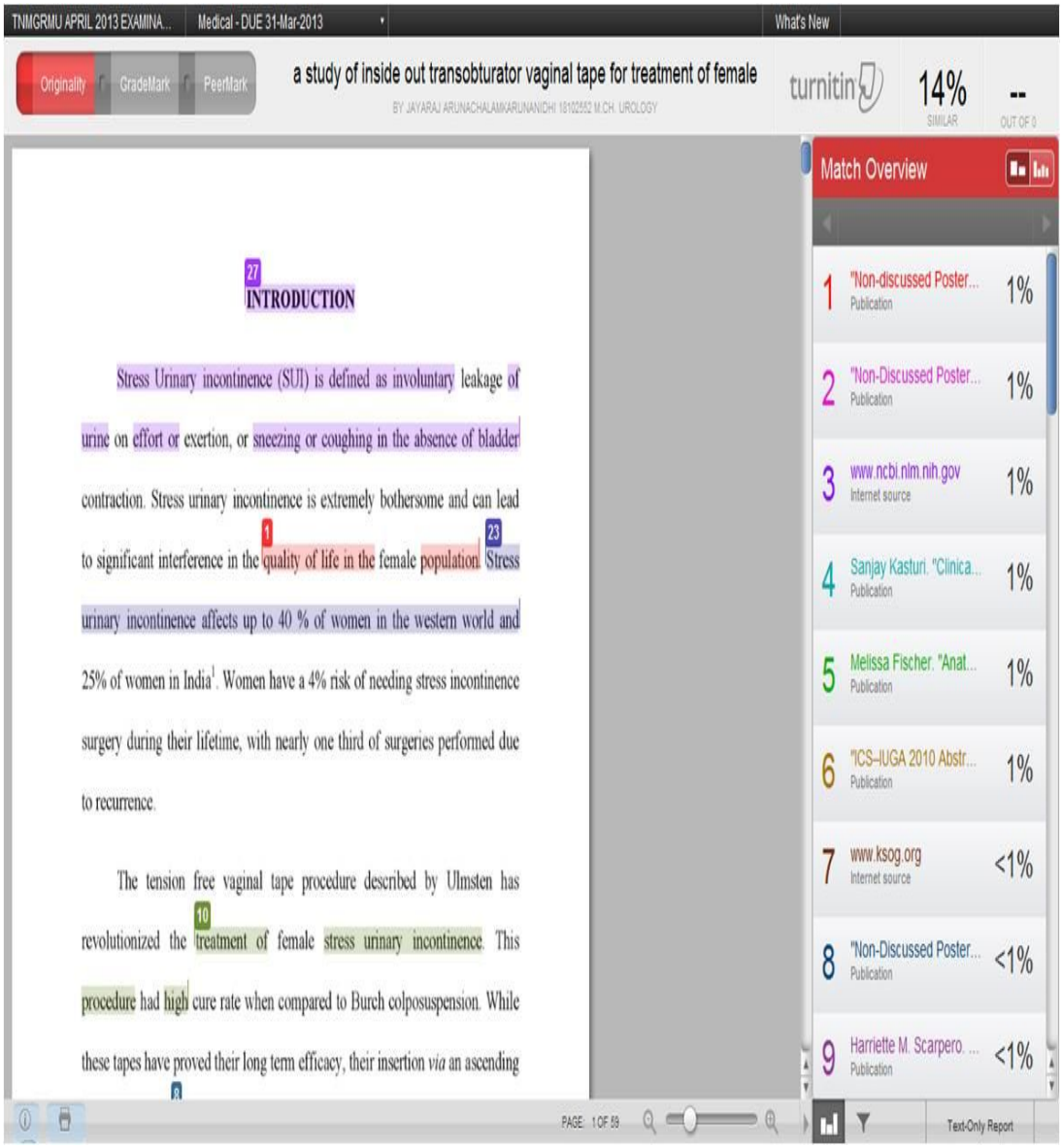
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a study of inside out transobturator vaginal tape for treatment of female
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INTRODUCTION
Stress Urinary incontinence (SUI) is defined as involuntary leakage of urine on effort or exertion, or sneezing or coughing in the absence of bladder contraction. Stress urinary incontinence is extremely bothersome and can lead to significant interference in the quality of life in the female population. Stress urinary incontinence affects up to 40 % of women in the western world and 25% of women in India[1]. Women have a 4% risk of needing stress incontinence surgery during their lifetime, with nearly one third of surgeries performed due to recurrence.
The tension free vaginal tape procedure described by Ulmsten has revolutionized the treatment of female stress urinary incontinence. This procedure had high cure rate when compared to Burch colposuspension. While these tapes have proved their long term efficacy, their insertion via an ascending
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INSTITUTIONAL ETHICAL COMMITTEE, STANLEY MEDICAL COLLEGE, CHENNAI-1

Title of the Work : A Study of Inside out Transobturator Vaginal Tape for the treatment of Female Stress Urinary Incontinence

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The request for an approval from the Institutional Ethical Committee (IEC) was considered on the IEC meeting held on 12.10.2011 at the Modernized Seminar Hall, Stanley Medical College, Chennai-1 at 2PM

The members of the Committee, the secretary and the Chairman are pleased to approve the proposed work mentioned above, submitted by the principal investigator.

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CONTENTS

INTRODUCTION

INTRODUCTION

Stress Urinary incontinence (SUI) is defined as involuntary leakage of urine on effort or exertion, or sneezing or coughing in the absence of bladder contraction. Stress urinary incontinence is extremely bothersome and can lead to significant interference in the quality of life in the female population. Stress urinary incontinence affects up to 40 % of women in the western world and 25% of women in India[1]. Women have a 4% risk of needing stress incontinence surgery during their lifetime, with nearly one third of surgeries performed due to recurrence.

The tension free vaginal tape procedure described by Ulmsten has revolutionized the treatment of female stress urinary incontinence. This procedure had high cure rate when compared to Burch colposuspension. While these tapes have proved their long term efficacy, their insertion *via* an ascending or descending retropubic approach has been associated with number of intraoperative complications.

The transobturator approach was first described by DeLorme in 2001 for placement of midurethral vaginal tape with the objective of avoiding retropubic area. It consists of insertion of the tape through a skin incision in the thigh into the obturator foramen towards the urethra. Cadaveric dissections by various authors have proved this procedure is

safer but complications like lower urinary tract injuries, vaginal tears and groin haematoma have been noted[2].

In 2003, a modified transobturator (inside out) approach was described to improve the intraoperative safety profile of the obturator approach. In this inside out transobturator method, the needle serially passes through the infra-urethra area, the obturator foramen, and the inguinal area. Various studies involving cadaveric dissections has shown the transobturator tape was very much away from the pudendal nerve, obturator vessels and nerve, and the femoral vesslels. The risk of lower urinary tract injury or other visceral injury is negligible with this approach when compared to tension free vaginal tape or outside in transobturator approach.

aims & objectives

AIMS AND OBJECTIVES

1) To evaluate the efficacy of inside out transobturator tape in the treatment of female stress urinary incontinence.

2) To determine the influence of inside out transobturator tape on objective and subjective cure rate and quality of life in patients with stress urinary incontinence.

3) To assess the postoperative complications and thus the safety of this procedure.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

Epidemiology of stress urinary incontinence

Stress urinary incontinence (SUI) is extremely bothersome and can lead to significant interference in the quality of life in the female population. It is defined clinically as “involuntary loss of urine on effort or exertion, or sneezing or coughing”[3]. This sign may be reproduced by the clinician on examination. In addition to this, urodynamic observations may be undertaken to provide more precise although more invasive evaluations of incontinence. This is typically not required as women may be characterised as suffering from stress urinary incontinence by symptoms and signs alone and conservative measures undertaken to help treat the condition. However, if there is disparity in symptoms or surgical intervention is contemplated urodynamics is currently considered beneficial.

The urodynamic definition of incontinence proposed by the International Continence Society is “the involuntary leakage of urine during increased intrabdominal pressure, in the absence of a detrusor contraction”. This is referred to as *urodynamic stress urinary incontinence*. It is in contradistinction to urge urinary incontinence, whereby a sudden desire to void occurs which cannot be deferred. This

often shows detrusor overactivity during urodynamic testing. Occasionally both types of incontinence can occur simultaneously[4].

The definitions above were only coined by International Continence Society (ICS) in the year 2002. Prior to this the definitions of stress urinary incontinence were varied and thus reports of the prevalence of stress incontinence are variable. Hampel *et al* has reported the overall prevalence of urinary incontinence to be 16% in patients younger than 30 years and 29% in women between 30 to 60 years. It is more common in young and middle-aged women, who are more likely to work and to be sexually active whereas mixed urinary incontinence is predominant in older women[5]. Among all women the incidence of stress urinary incontinence, mixed incontinence and pure urge incontinence are 49%, 29% and 21% respectively[6]. Moreover, it is believed that more than half of women suffering from stress urinary incontinence are embarrassed by the condition, are unable to mention it to their healthcare provider or may even accept some incontinence as part of the ageing process.

Incontinence may be characterised by the impact caused by the symptoms on quality of life, by questionnaires like the Incontinence Impact Questionnaire[7]. As a measure of severity, the most widely used indexes are the Sandvik Severity Index, the ICIQ-UI SF index and Incontinence Quality of Life (I-QOL). These have been validated[8].

Anatomy of the pelvic floor

Female pelvic anatomy is a complex combination of muscles, ligaments, nerves, and blood vessels that act dynamically to provide support for the urethra, bladder, uterus, and rectum. An understanding of normal mechanisms of pelvic support is essential in the evaluation of women with stress urinary incontinence.

Bone

Passive support of the pelvic floor is provided by the bony structures, which act as anchors for the important muscular and fascial structures comprising the pelvic floor. The pubic rami, ischial spines, and sacrum represent the anchoring points of the true bony pelvis, which is made up of pubis, ilium, ischium, sacrum, and coccyx. The pelvic floor is diamond-shaped with the pubic symphysis and sacrum at the anterior and posterior apices while the ischial spines serve as lateral anchors[9].

Connective tissue

The fascia overlying the pelvic floor musculature plays a critical role in pelvic support. The abdominal portion of the fascia is referred to as endopelvic fascia and represents a continuation of the abdominal transversalis fascia. The levator ani muscle is covered superiorly and inferiorly by a fascial layer. The two fascial layers split at the levator hiatus to cover the pelvic organs that traverse it.

The pubourethral ligaments are a condensation of levator fascia connecting the inner surface of the inferior pubis to the midportion of the urethra and prevent its descent. This ligament along with the pubourethralis muscle supports the urethra and forms the midurethral complex[10].

The urethropelvic ligaments are composed of a two-layer condensation of levator fascia, which provides the most important anatomic support of the bladder neck and proximal urethra to the lateral pelvic wall. The lateral fusions of the levator and periurethral fascia provide important, elastic musculofascial support to the bladder outlet, thereby maintaining passive continence in women. Voluntary or reflex contractions of the levator or obturator musculature increase the tensile forces across these ligaments, increasing outlet resistance and continence[8].

The pubocervical fascia is a continuous sheet of connective tissue support from pubic symphysis to cervix, including the periurethral, perivesical, and endopelvic fascia, which fuse to support the bladder to the lateral pelvic wall. It is continuous distally with the periurethral fascia and proximally with the uterine cervix and cardinal ligament complex.

Musculature

The striated musculature comprising the pelvic floor acts as a supporting structure for the visceral contents of the abdominopelvic cavity as well as a dynamic organ involved in maintenance of urinary and fecal continence. The pelvic diaphragm is composed of the levator ani and coccygeus muscles. The levator ani muscle group and its fascia provide the most critical support for the pelvic viscera, acting as the true muscular pelvic floor.

The levator ani group is composed of the pubococcygeus, ischiococcygeus, and iliococcygeus, named according to their origin from the pelvic sidewall. This broad sheet of muscular tissue extends from the undersurface of the pubic symphysis to the pelvic surface of the ischial spines, taking origin from the tendinous arc laterally[9].

Midline apertures in the levator ani group, collectively referred to as the levator hiatus, allow passage of the urethra, vagina, and rectum. Adjacent fascial attachments provide support to these pelvic viscera as

they exit the pelvis, fashioning a “hammock” of horizontal support. The bladder, proximal vagina, and rectum rest on the levator floor and become coapted against it during periods of increased intra-abdominal pressure. Resting tone of the levator muscle, as well as reflex and voluntary contraction, acts to pull the vagina and rectum forward, thereby preventing incontinence of both urine and stool. These active mechanisms of pelvic floor support maintain both urinary and fecal continence.

Mechanisms of Urethral Continence in Women

Bladder outlet resistance in women is attained by several factors working together to provide continence at rest and during stress manoeuvres. Urethral anatomy, including functional length and elastic closure, is an important determinant of continence. In addition, activity of the muscular pelvic floor with its associated connective-tissue elements helps to maintain outlet resistance when there is increase in intraabdominal pressure[10]. The anatomic position of the urethra is another factor contributing to continence.

Urethral Length

The distance between internal meatus and external urethral meatus in a female determines anatomic length. Congenital anomalies and traumatic injuries may result in significant urethral loss with subsequent incontinence. Functional urethral length is determined by

urethral pressure profilometry where the total urethral length is assessed by urethral pressure exceeding bladder pressures. The clinical utility of urethral length has not been consistently proven. Funnelling of the bladder neck and proximal urethra during straining cystography is seen in up to 50% of continent women [13].

Furthermore, surgical incision of the bladder neck and Y-V plasty do not cause incontinence in women with otherwise normal outlets. In addition, resection of the distal one-third of the urethra does not produce incontinence. However, despite these observations, a critical length of healthy urethra is necessary to provide the coaptation for passive continence and continence during increases in abdominal pressure. Bladder neck suspensions may restore functional urethral length, thereby improving continence.

Urethral Closure

The urethra is made up of three functional anatomic components that result in an elastic, dynamic conduit with mucosal coaptation. The urethral mucosa is a transitional epithelium with numerous infoldings that allow distensibility and closure with excellent coaptation. Beneath the mucosa is a spongy tissue made up of vascular networks analogous to the corpus spongiosum in the male. Surrounding the spongy tissue is a thin musculofascial envelope, the periurethral fascia, which appears as

a glistening white membrane. These three components create a coaptive seal[11].

Urethral closure is also affected by surrounding connective tissue structures. The pubourethral ligaments provide stability to the midurethra, especially during increases in intraabdominal pressure. In addition, the tensile strength of urethropelvic ligament along with the adjacent levator muscle facilitates compression of the proximal and midurethra. Finally, the striated musculature of the midurethral complex adds resting tone to the urethra, further effecting closure.

Surrounding the sphincteric unit is skeletal musculature that provides an important additional mechanism for urethral closure. The striated musculature provides resting urethral tone as well as an involuntary reflex contraction in response to stress that increases coaptation. Furthermore, voluntary contraction also helps to prevent loss of urine by improving urethral closure[12]. These mechanisms increase urethral resistance, as measured by leak point pressures, but may not directly affect urethral pressures

Pelvic Floor Activity during Increased Intra-Abdominal Pressure

Female continence is maintained during increases in intraabdominal pressure by several distinct mechanisms. Abdominal pressure is passively transmitted to the proximal urethra followed by an active contraction of the striated external sphincter musculature.

Furthermore, the suburethral supportive layer, made up of periurethral fascia, anterior vaginal wall, and levator ani muscles, provides a firm backboard against which the urethra is compressed rapidly during increases in intra-abdominal pressure. Both the levator musculature and the urogenital diaphragm undergo reflex contraction, resulting in increased midurethral pressure. Furthermore, voluntary contraction of the levator and obturator muscles increases tension on the urethropelvic ligaments. These factors act in concert to promote urethral continence during changes in position and abdominal pressure.

Anatomic Position

Both the bladder neck and the urethra are normally maintained in a high retropubic position relative to the more dependent bladder base, creating a valvular effect. They are supported by a musculofascial layer that suspends these structures from the pubic bone and pelvic sidewalls, thereby preventing their descent during increases in intra-abdominal pressures. A limited degree of bladder base rotation against a well-supported urethra occurs with increased abdominal pressures, further creating a valvular effect between these two structures. Furthermore, direct transmission of intra-abdominal forces to a well-supported proximal urethra increases its resistance and promotes coaptation[12]. This complex set of compensatory mechanisms in a normal healthy woman

allows maintenance of sufficient outlet resistance to promote continence, especially during episodes of abdominal stress such as coughing, sneezing, walking, and straining.

Any process that results in deterioration of these mechanisms can result in incontinence. Urethral function can be compromised by atrophy of its spongy tissue secondary to menopausal hormonal deficiency, altered neuromuscular function, or intrinsic damage from surgery, radiation, or trauma. In addition, a weakening of the levator musculature impairs the compensatory increases in midurethral pressures during stress. Although these physiologic changes can adversely impact on continence, the most common etiology of impaired outlet resistance in women is the loss of anatomic support of the bladder neck and urethra.

Relaxation of the pelvic floor as well as weakening of the urethropelvic ligaments and midurethral complex produces significant posterior and downward rotation of the urethra as well as bladder neck. The anatomic repositioning of these structures to a more dependent pelvic position eliminates the valvular effect. Sudden increases in intra-abdominal forces facilitate funneling and opening of a poorly supported bladder outlet. The extra-abdominal location of the poorly supported proximal urethra and the loss of the backboard of strong normal support of the urethropelvic ligaments do not allow effective transmission of abdominal forces. Although such anatomic changes can lead to

incontinence, urethral hypermobility does not always correlate with incontinence.

Many asymptomatic women with urethral hypermobility on physical examination do not report urinary incontinence. Thus, the anatomic position of the urethra alone does not correlate with the degree of incontinence. A component of intrinsic sphincter deficiency must be present along with these anatomic changes to create incontinence[11]. The factors responsible for pelvic floor relaxation rarely affect isolated anatomic areas. Thus, stress urinary incontinence resulting from urethral and bladder neck hypermobility is often accompanied by associated defects of pelvic support.

The identification of these concomitant defects is crucial to planning effective therapy, with restoration of pelvic support, anatomic vaginal axis, and outlet resistance. Defects in pelvic support can be organized according to their effects on various pelvic organs and structures, in order to allow a more systematic approach to treatment planning. The vaginal compartment contains a confluence of urinary, genital, and bowel organs. The goal of pelvic reconstructive surgery is to restore both anatomy and function. However, the restoration of anatomy does not always correlate with restoration of function.

Risk factors

Age: Increasing age was accepted as one of the risk factors for urinary incontinence. Stress urinary incontinence increases up to the age of 50, thereafter it is followed by little increase in the levels of prevalence. The mechanism in these cases may be the effect of the loss of muscle tone, long term effects of denervation injuries sustained during childbirth or changes in hormonal status leading to alterations in collagen in paravaginal tissues. However, it has proved difficult to show a link between natural menopause and increasing risk of stress urinary incontinence. Also the evidence for hormone replacement therapy does not show it to reduce the risk of the development of stress urinary incontinence as evidenced by two randomized control trials[14].

Heredity: Prevalence of stress urinary incontinence was almost three times higher (20.3% vs. 7.8%) in first-degree female relatives of women with stress urinary incontinence themselves[14]. These data suggest that there may be familial transmission of traits that can lead to an increased incidence of stress urinary incontinence.

***Obesity*:** Obesity has been cited as a risk factor for stress urinary incontinence, with women who have a higher body mass index displaying higher rates of stress incontinence. Women in the highest quartile of body mass index are two to four times more likely to have urinary incontinence than those in the lowest quartile[14]. This is

postulated to be consequent upon the existence of a greater abdominal pressure and/ or laxity in support tissues caused by chronic strain.

Hysterectomy: Data on the risk, hysterectomy confers on the development of subsequent urinary incontinence are conflicting. In one large, systematic review of the literature published from 1966 to 1997, Brown and colleagues constructed a summary estimate of the increased odds for development of urinary incontinence in women who undergo hysterectomy[15]. They found that among women 60 years of age, those who had a history of hysterectomy had an odds ratio of 1.6 compared to those without such a history. There was not a similar increase in odds for women younger than 60. They concluded that urinary incontinence following hysterectomy might not be seen until many years after the procedure.

Pregnancy and Parity: Several studies suggest that parity is associated with increased risk of stress urinary incontinence. Investigators have documented incidence rates for urinary incontinence occurring after pregnancy as high as 26% at 6 months, although most women recover continence with time. Possible explanations for this relationship lie in pelvic floor denervation due to compression during pregnancy and delivery and stretching or tearing of pelvic floor connective tissue and musculature during pregnancy and delivery[16].

In a prospective study 305 primiparas by Vikrup et al, has concluded that 32% had stress urinary incontinence during pregnancy. On followup, 19% of the continent women postpartum had stress urinary incontinence 5 years later, whereas female with stress urinary incontinence postpartum had an incidence of 92%. In another prospective study 344 nulliparous pregnant women were grouped into vaginal delivery and caesarean delivery groups. It was found that vaginal delivery group had stress urinary incontinence 18 times more than that of caesarean delivery group. Epidemiological studies have shown approximately half of all women develop transient urinary incontinence during pregnancy and post partum the prevalence of urinary incontinence is still 9-31%[18].

Smoking: Some evidence links stress urinary incontinence and urge incontinence with cigarette smoking in women. In a case control study, Bump and McClish examined 606 women with known smoking history (current, former, or never) and recorded the results of urodynamic tests for the 322 women who were incontinent. Urinary incontinence was significantly more prevalent in current and former smokers than in nonsmokers[19].

Medical Co-morbidities: Medical co-morbidities, such as, the length of time with type II diabetes mellitus have been found to confer increased

risk of stress urinary incontinence[20]. Other co-morbidities presenting risk include neurological disorders and connective tissue disorders.

GRADING OF STRESS URINARY INCONTINENCE

Grade I: Incontinence occurs only with severe stress, such as coughing, sneezing, etc.

Grade II: Incontinence with moderate stress, such as rapid movement or walking up and down stairs.

Grade III: Incontinence with mild stress, such as standing. The patient is continent in the supine position.

Evaluation of stress urinary incontinence

The history, physical examination, and simple office testing may establish a preliminary diagnosis on which a clinician may begin treatment or may serve as an excellent screening tool to determine which individuals require further evaluation. If a complex or recurrent problem is present, surgery is planned, or the patient's symptoms do not improve with initial treatment, specialized tests such as complex urodynamics should be employed to definitively establish diagnosis. Urogenital, gastrointestinal, musculoskeletal, neurologic, and endocrinologic factors may affect pelvic floor disorders, and a comprehensive history and physical examination begins the process of evaluating these conditions[21].

Bladder Diary

Bladder diaries assist in providing quantitative data on urinary frequency, voiding intervals, the volume of continent voids, and the number of incontinent episodes. They also enable the clinician to better understand triggers of incontinence such as coughing, exercises, valsalva, or strenuous activity. The diary may help to establish voiding patterns that can help clinicians select appropriate behavioural interventions, and may also serve as a baseline of symptom severity for assessment of treatment efficacy.

The cotton tip applicator test (Q-Tip)

A sterile applicator with a small piece of cotton at its tip is introduced to reach the bladder neck. The angle between the applicator and the horizontal is measured. The patient then strains maximally using the valsalva manoeuvre. The rotational movement of the bladder neck around the symphysis pubis causes the Q-tip to move in a cranial direction. The angle of the Q-tip is measured relative to the horizontal using an orthopedic goniometer. A change of greater than 30 degrees is thought to represent a hypermobile urethra. This test does not establish the diagnosis of stress incontinence and does not add any extra information to the history and examination. However, it is thought by some clinicians to indicate the most appropriate continence procedure when urodynamic stress incontinence has been diagnosed and may predict failure after incontinence surgery[22].

Stress test

This test is performed in a moderately full bladder. The patient in the lithotomy position, the two labia is separated, and the patient is asked to cough. If there is leakage of urine, and stress urinary incontinence is demonstrated.

Boney (Marshall) test

It is indicated in case of a positive stress test associated with a cystocele, to know if incontinence is due to descent of bladder neck or weakness of the sphincter. The index and middle fingers are placed on both sides of the urethra to elevate the bladder neck upwards. If no urine escapes on stress it means that the incontinence is due to descent of the bladder neck, but if urine still escapes it means weakness of the sphincter.

Yousef test

This test is indicated in case of a negative stress test associated with a large cystocele to diagnose hidden stress incontinence. The cystocele is reduced, the cervix is grasped with a volsellum and pushed upward, then the patient is asked to cough. If urine escapes, it indicates that the patient was continent because of kinking of the urethra.

Urodynamics

The need for pre-operative urodynamics is often justified by the consideration that pre-existing detrusor overactivity (DO) may either be a contra-indication for surgery or at least carries a worse prognosis. Therefore urodynamics is performed to detect factors that may unfavourably influence the outcome of the operation or confirm the diagnosis. The indications for urodynamic evaluation in patients with stress urinary incontinence are 1)to define incontinence when history in unclear 2)when planned for invasive or surgical treatment 3)failed conservative therapy 4)patients with mixed incontinence 5)failed anti-incontinence surgery.

Videourodynamic evaluation in women with stress incontinence provides information on the position and behaviour of the pelvic floor and urethra during stress and voiding[22]. Cystocoeles are also easily diagnosed on video studies. It may be possible to demonstrate a change in symptomatic and urodynamic status after repositioning of the prolapsed organ. Abdominal leak point pressure and maximum urethral closure pressure are helpful in categorizing the patients with stress urinary incontinence into anatomical and instrinsic sphincter deficiency types of incontinence.

Treatment of stress urinary incontinence

Non surgical treatments

The National Institute of Clinical Excellence (NICE)[24] recommends lifestyle changes such as weight loss and supervised pelvic floor exercises as first line therapy for the treatment of stress urinary incontinence. Failing this, electrical stimulation and biofeedback may be used. However, in one study, electrical stimulation has not shown to be effective compared to sham treatments in patients with the ability to contract pelvic floor musculature. Conversely, Castro *et al*. reported benefit in patients receiving treatment via pelvic floor muscle training, peripheral stimulation or vaginal support devices. The subjective improvements were of the range of 54-58% for all three treatment modalities compared to 21% in an untreated group[25]. However, the urodynamic parameters stayed the same which may suggest a placebo effect.

Pelvic floor exercises have been shown to improve symptoms stress urinary incontinence of and have also been recommended for prevention of pelvic organ prolapse in nulliparous women prior to pregnancy. Moderate weight loss has been shown to decrease stress urinary incontinence symptoms.

The studies have shown that women with stress urinary incontinence had lower resting urethral pressures when compared to continent women[26]. Therefore, pharmacological methods to increase urethral pressure seem logical. Urethral tone is maintained by the release

of noradrenaline on to the alpha adreno-receptors. Many different alpha adreno-receptor agonists have been used to treat stress urinary incontinence. The most widely used were ephedrine and norephedrine. Alhasso *et al*. reviewed the evidence for alpha adreno-receptor agonists and found limited evidence to recommend their routine use[27]. Beta adreno-receptor antagonists have been postulated to enhance alpha adrenoreceptor action by beta adrenoreceptor blockade. However, the clinical benefit of this has not been sufficiently reported.

Duloxetine, a serotonin nonadrenaline reuptake inhibitor has been licensed for the medical management of women with stress urinary incontinence. It is understood to work on the urethral rhabdosphincter. Both noradrenaline and serotonin are thought to lead to enhanced contraction of the sphincter via a potentiating effect on glutamate. Women taking Duloxetine for eight weeks were found to have a significantly higher mean urethral pressure profile, maximal urethral closure pressure but not functional urethral length. A randomized control trial in 533 women found Duloxetine to significantly decrease incontinence episode frequency in 64% of women at a dose of 80mg/day. At that dose 15% of women discontinued the drug due to non severe side effects most commonly nausea[28]. Further clinical trials have also led to this conclusion. Higher doses have been associated with psychiatric disorders which has limited its popularity.

Oestrogens have a significant role in maintaining continence in women. In addition to oestrogen receptors existing in the vagina, levator muscles, ligaments and fascia, oestrogen plays an important role in the maintenance of a positive urethral pressure. Exogenous oestrogens have been shown to reduce collagen concentration and decrease collagen cross linking in urogenital tissues[17].

As lack of collagen is thought to be a cause for pelvic floor disorders, many researchers have attempted to inject collagen para-urethrally, to act as a urethral bulking agent. A Cochrane review found peri-urethral collagen injections for stress urinary incontinence to have a reasonable short term cure, but a multicentre randomised trial found a 19% reduced success rate with collagen injection compared to surgery[29].

Other urethral bulking agents have been used ranging from autologous fat, carbon particles, calcium hydroxyapetite, ethylene vinyl calcohol copolymer, dextranomer and silicone based Macroplastique. The latter has been found to have the greatest efficacy over the others.

Macroplastique is a urethral bulking agent involving injection of cross-linked polydimethylsiloxane. It is a soft, flexible implant, which upon implantation is encapsulated in fibrin. The carrier gel is absorbed leaving the fibrous capsule, which is thought will not migrate. Recently Ghoniem *et al.* reported a multicentre single blinded randomized control trial comparing collagen injection to Macroplastique[30]. The cure rate at 1

year was 36.9% of patients in the Macroplastique group compared to 24.8% in the collagen group. The risk of urinary retention was 3.2 and 6.6% and urethral erosion was 0.8 and 1.6 % respectively. Given the cure rates are less than that reported for surgery; many surgeons would not use bulking agents as first line. However, it may be considered for use as second line after failed surgery. Moreover, if used as a first line treatment, many note an adverse effect on consequent surgical intervention.

Surgical treatment

The aims of the corrective surgeries are compressing the outlet, repositioning or restoring the sphincteric unit to higher intraabdominal location, provide backboard and coaptation at rest.

Anterior colporrhaphy with bladder neck plication

Anterior colporraphy is inidicated in patients with cystocele, if there is associated stress urinary incontinence. The plication sutures provide support to and/or elevate the urethra and/or bladder neck. Many variations of the procedure exist. Meta-analysis has reported the success rate of this procedure to be in the region of 67.8-72%. The serious complications are seen is 1% and the detrusor overactivity is seen in 6%. At five years the continence rate was found to decline to just 37%, thus making this procedure unpopular[31].

Retropubic suspension procedures

In these procedures, bladder neck displacement and urethral hypermobility are corrected by resuspending endopelvic fascia to various fixed points in retropubic space. In Marshall-Marchetti-Krantz procedure, the sutures are placed in the endopelvic fascia along the urethra and then into the periosteum along the back of pubic symphisis. The cure rate was 88% and the improvement was seen in more than 91% of the patients, but the risk of osteitis pubis had been reported in three percent of the patients.

Burch Colposuspension is a longstanding effective treatment. The sutures are placed in the endopelvic fascia along the bladder edge down to bladder neck and fixed to the illiopectineal ligament of Cooper. This procedure is highly effective and appears to remain so with time. It is reported as having a continence rate of 83-87% at one year[32]. A 51% objective cure rate has been reported at two years by Ward and Hilton in a multicentre randomised trial. At five years the authors reported a 90% negative pad-test amongst women in the colposuspension arm of the trial[33]. Complications reported from this study showed a rate of 39.8% of pelvic organ prolapse after this procedure and reoperation rates for incontinence of 3.4%.

In Paravaginal repair, the endopelvic fascia is reattached to arcus tendineus bilaterally with precaution to avoid injuring obturator neurovascular bundle. Turner Warwick has introduced the vagino-

obturator shelf procedure which is intermediate between classic Burch & Paravaginal repair. The endopelvic fascia is sutured to fascia over obturator internus.

Laparoscopic Colposuspension

Laparoscopic colposuspension is the most popular of the laparoscopic incontinence procedures. As in open colposuspension, sutures are inserted into the paravaginal tissues on either side of the bladder neck and then attached. The results are conflicting until longer studies are available no conclusions can be drawn. Various studies suggests that the results are surgeon-dependent

Needle suspension procedure

Needle suspension procedures use suspending sutures and patch materials to suspend the bladder neck, usually from bone anchors placed in the pubic bone or from the rectus fascia. These are seldom used due to poor success rates. Though these procedures had initial success rate, but on long term followup the risk of failure was greater than retropubic suspension procedures[34].

Pubovaginal slings

Pubovaginal slings have been used for many years. Price described the first rectus fascia sling in 1933. The sling is placed beneath the bladder neck and the amount of tension on the sling requires an individualized approach. A sling which is too tight may lead to

urinary retention and conversely a sling that is too loose may lead to recurrence. Tissue may be obtained from many different sources such as autografts, allografts and xenografts.

The success rates of pubovaginal slings vary according to the type of material used. The success reported with cadaveric fascia is mixed, ranging from 33 to 93%. The rectus fascia sling has a success rate of approximately 80% depending on the level of patient selection and follows up. The success rates with porcine dermis have been found to be 54% at 36 months follow up. However, Abdel-Fattah *et al*. found no difference in improvements in cure, defined by improvements in quality of life, between porcine dermis and Tension free transvaginal tape[35].

Tension-free Transvaginal tape (TVT)

Mid-urethral sling (MUS) procedures are currently the gold standard of the surgical treatment for stress urinary incontinence. They were the first incontinence procedures that were designed on a previously well-defined pathophysiological theory: the Integral Theory and the Hammock Hypothesis. Both theories have in common that a connective tissue band underneath the middle part of the urethra (located between the back part of the urethra and the anterior vaginal wall) supports the backside of the urethra during moments of sudden rise of the intra-abdominal pressure. Contraction of the horseshoeshaped urethral muscles that are located in the anterior wall of the urethra

causes the urethra to be pushed against this connective tissue band and consequenltly, the urethra is closed. The Integral theory also emphasizes the importance of the support function of the pubo-urethral ligaments which connect the urethra to the backside of the pubic symphysis.

Tension-free Vaginal Tape (TVT) was introduced by Ulmsten et al. in 1996. Trans Vaginal tape is a polypropylene tape that runs from underneath the middle part of the urethra behind the pubic bone and in front of the bladder to the lower abdominal wall[36]. Follow-up data after 10-12 years show cure and improvement rates of respectively 77 and 20%.

Due to the blind passage through the retropubic space bladder perforations, vessel injury and even bowel injury have been described. Postoperative voiding difficulty and de novo urgency or urge incontinence are regarded the most important functional complications.

Transobturator vaginal tape

In order to address the complications of tension free transvaginal tape, other modifications were developed. In 2001 Delorme introduced the Transobturator tape procedure, a new method of inserting a polypropylene tape with a high success rate for curing stress urinary incontinence. The tape runs from underneath the urethra through the left and right obturator membrane onwards to the upper inner side of the thigh[36].

There are two basic techniques for performing transobturator tape: “Inside - Out” (TVT-O) which was described by de Leval and “Outside - In” (TOT) described by Delorme. Both these procedures differ not only on the direction of needle and also differ on the type of surgical equipments like introducer. After the introduction of the “Outside-In” technique by Delorme in 2001 several other similar procedures were developed. Among them is Monarc, which, like transvaginal tape, is a monofilament macroporous polypropylene mesh. It has shown similar and equally good short-term to medium-term success rates as TVT-O.

The advantage of the obturator approaches is that blind passage of the introducer in the retropubic space is avoided. Therefore, theoretically, the risk of bladder or bowel perforation is minimized. A metanalysis procedure comparing transobturator approaches with retropubic colposuspension has shown objective cure and improvement was comparable in both the techniques[32]. The incidence of postoperative complications like lower urinary tract injuries, visceral injury were less with transobturator approach except for the groin pain which was more than 15% in the immediate postoperative period. Groin pain was transient and the patients were pain free during the follow up.

Complications

Complications of stress urinary incontinence surgery may be divided into intraoperative and postoperative. Intraoperative complications involve injury to organs, vessels and nerves. The injury may occur to:

- Urethra: This is a rarely reported complication. It may occur during transvaginal dissection or trocar placement. Failure to recognise this leads to the risk of urethrovaginal fistula development and sling erosion/infection.
- Bladder: Bladder injury varies with the surgical approach. Albo *et al*. reported more injuries with colposuspension compared to sling procedures. At meta-analysis the risk of bladder perforation is less with transobturator tape compared to transvaginal tape[37].
- Ureter: Ureteric injury is very uncommon, but the ureter may be kinked during a Burch colposuspension. The position of the midurethral sling makes it extremely unlikely for the ureters to be encountered.
- Blood vessels: Multiple blood vessels traverse the deep pelvis; these are at risk in the obturator fossa and pelvic side walls. The iliac vessels and vascular pedicle of the bladder are at risk especially during blind passage of trocars or needles.

- Bowel: Bowel injury is very rare, only being reported in case reports. It can happen during dissection in the retropubic area for colposuspension or pubovaginal sling or during trocar passage for a midurethral sling.
- Nerve injury: Injuries to nerves may occur during harvest of rectus fascia or during trocar movement in the pelvis.

Postoperative complications

- Voiding dysfunction and urinary retention- symptoms range from difficulty voiding to complete retention and/ or urge incontinence. Post-op voiding difficulties lasting more than four weeks occur in 4-8% of burch colposuspension procedures and 3-11% of sling procedures[38]. Permanent retention is rare and can occur in five percent of patients. Similarly five percent of women who underwent midurethral sling procedures may require a surgical treatment during the followup period.
- Infection- multiple case reports of pelvic abscesses have been reported post stress urinary incontinence surgery
- Vaginal extrusion and urinary tract erosion- extrusion implies the presence of sling in the vaginal cavity and erosion refers to the appearance of sling in the urinary tract. Extrusion rates have been found to be higher with multifilament slings as opposed to

monofilament. The risk of extrusion with monofilament slings is less than 5%. The risk of erosion is reported to be less than 1%.

Outcome measures of stress urinary incontinence surgery

Comparable scientific assessment is necessary in the evaluation of stress urinary incontinence surgery, to allow comparison between procedures and guide best practice. The commonly used methods of both objective and subjective assessment are discussed below. Any outcome measure must be reliable, valid, interpretable and responsive to change.

Objective measures:

- Urodynamics- has been found not to show stress urinary incontinence in 15% of women with primary stress urinary incontinence. Post operatively, Azam *et al*. demonstrated almost 40% of women, who complained of persisting stress urinary incontinence, did not show leakage on urodynamics[39]. Although urodynamics is the gold standard for the objective assessment of this condition, its reliability is not proven.
- Cough stress test- may be used to assess cure, but may not be used to assess improvement[41]. Prior to commencing the test, bladder volume, number and force of coughs should be standardized. However, currently no standards exist.

- Pad tests- have been used to objectively define cure, using a cut off depending on the test duration and standardization. The 1 hour, 24 hours and 72 hours pad test have been validated[40].
- Bladder diaries- have been shown to be a reliable measure but rely on the duration of the test and are currently not standardized.

Subjective measures:

- ICIQ questionnaire- is a modular questionnaire which has been validated, shown to be reliable and is used in many research studies. The ICIQ modular questionnaire is an amalgamation of other existing questionnaires. The modules range from core symptom modules, quality of life modules and optional modules.
- Satisfaction outcomes- ascertain from patients their satisfaction from a certain intervention. This relies heavily on patient goals and expectations and Norton has shown a reduction of leaks by 50% does not entail a 50% improvement in satisfaction[42].

MATERIALS & METHODS

MATERIAL AND METHODS

Study Design: Prospective study

Duration: September 2011 to May 2013

Setting: Govt. Stanley Medical College and Hospital, Chennai.

Inclusion Criteria:

1) Patients in the age group between twenty five to eighty five years.
2) Clinical as well as urodynamic diagnosis of stress urinary incontinence.
3) Positive pad test, stress-test.

Exclusion Criteria:

1) Detrusor overactivity or impaired bladder contractility.
2) Post void residual urine 100 ml or greater.
3) Pregnancy.
4) Neurological pathology.
5) Active urinary or vaginal infection.

Methodology:

A total of 25 patients with stress urinary incontinence in Government Stanley Hospital during the period November 2010 to January 2013 were asked to participate in this prospective study. All the women underwent a standardized preoperative evaluation including detailed incontinence history regarding duration and severity of stress urinary incontinence. All the patients underwent pelvic examination, a stress-test in upright position and a short term pad test.

Urodynamic tests such as pressure flow study was performed in all patients for diagnosis of stress urinary incontinence and discrimination from urge incontinence. Urodynamic evaluation was done using Laborie and Medical Measurement System urodynamic device. A sterile 8 French dual channel cystometry catheter was placed into the urethra and a rectal catheter with 5 ml balloon was placed into the rectum. The urinary bladder was filled with saline solution at the rate of 50 ml/min and the patient was asked to cough after each 100 ml filling. Urinary incontinence occurring in this time was detected and the diagnosis of stress incontinence was made. Abdominal leak point pressure was measured in all patients and recorded.

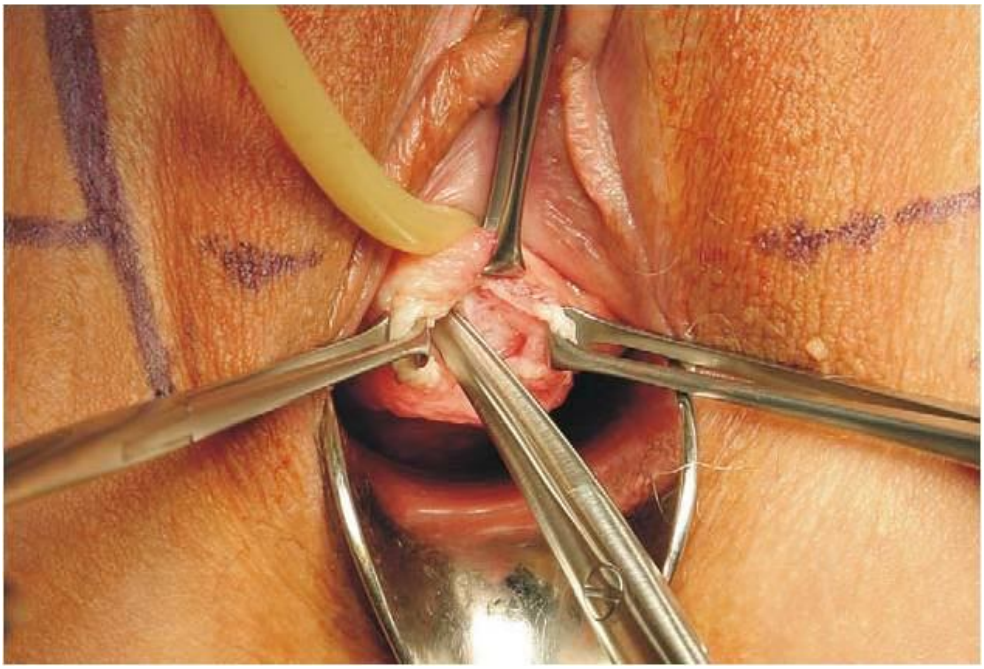
All patients were administered parentral first generation cephalosporin preoperatively for antibacterial prophylaxis. The inside out transobturator procedure was performed as described by Leval. All

patients were administered regional (spinal) anesthesia. Cystoscopy was performed to evaluate the bladder and urethra after the procedure. The duration of the procedure, cystoscopy and any additional operations, if performed, were recorded. All patients were monitored with the Foley catheter for bladder drainage for 48 hours. Postoperative follow-up was done at six weeks, three and six months. The objective cure was evaluated with a negative stress-test and 24-hour pad test. The subjective cure was also evaluated based on satisfaction of the patient with the procedure.

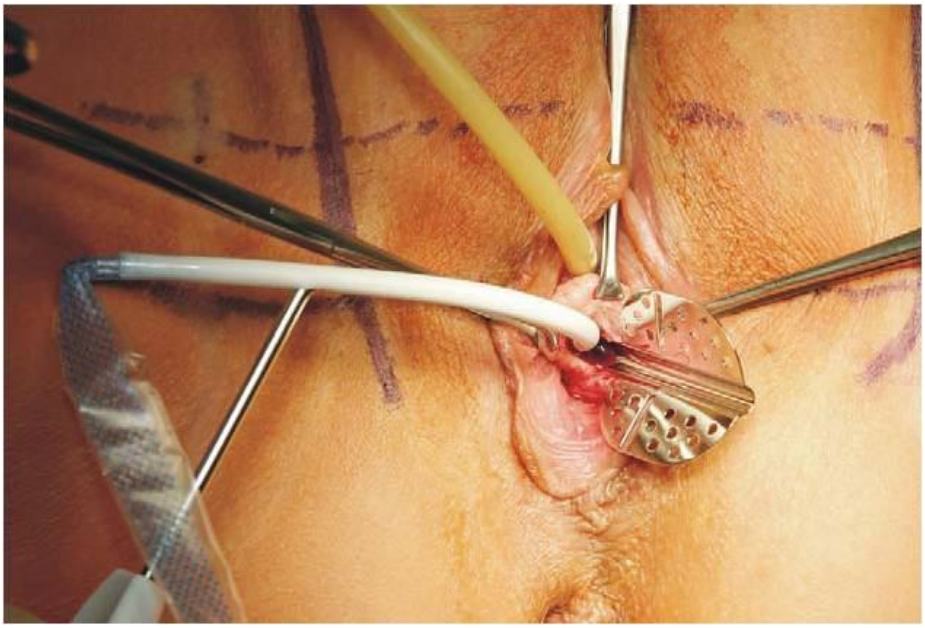
The influence of inside out transobturator tape on quality of life of the patients was evaluated with the Incontinence Quality of Life (I-QOL) pre- and postoperatively.

TVT-O DEVICE: HELICAL PASSER WITH ATRAUMATIC WINGED GUIDE

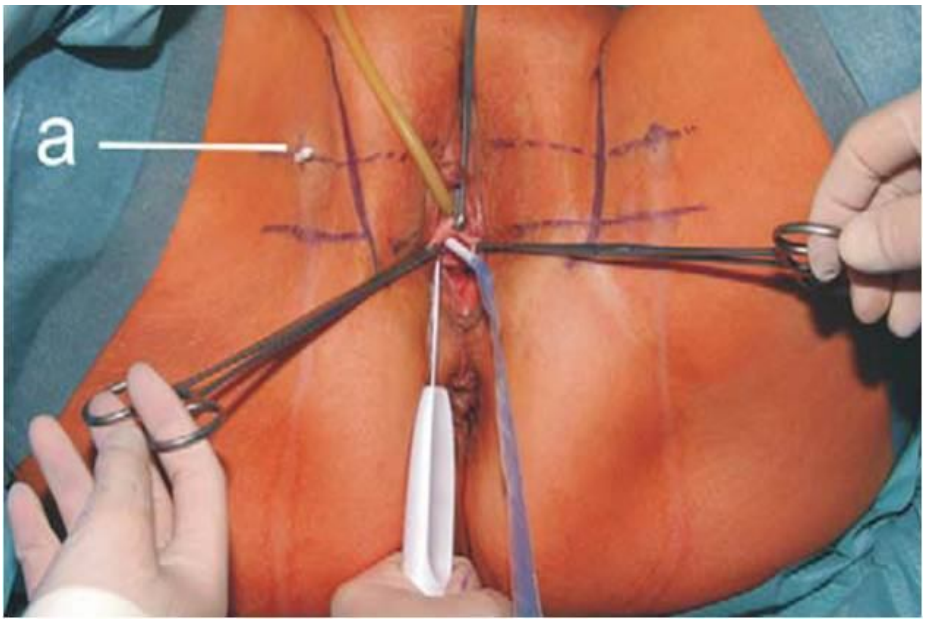
INCISION OF VAGINAL WALL AND PARAURETHRAL SPACE DISSECTION WITH FINE SCISSORS



WINGED INTRODUCER PUSHED ALONG DISSECTED SPACE UNTIL IT PERFORATED THE OBTURATOR MEMBRANE



HELCIAL PASSER APPEAR AT THE PREVIOUSLY DETERMINED SKIN EXIT POINT

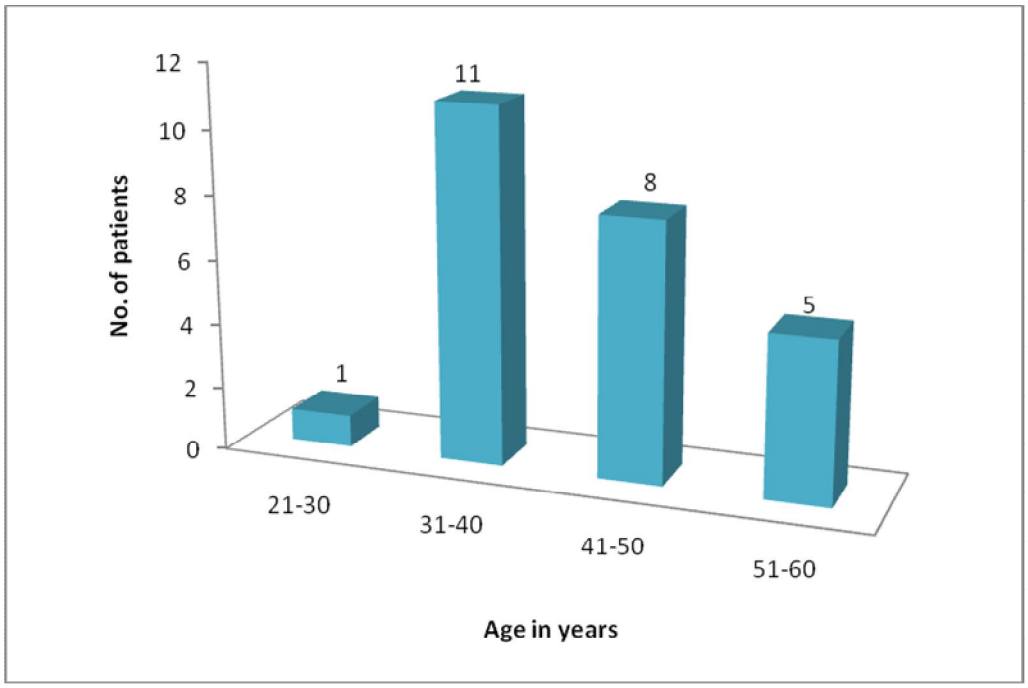


RESULTS

RESULTS

AGE DISTRIBUTION

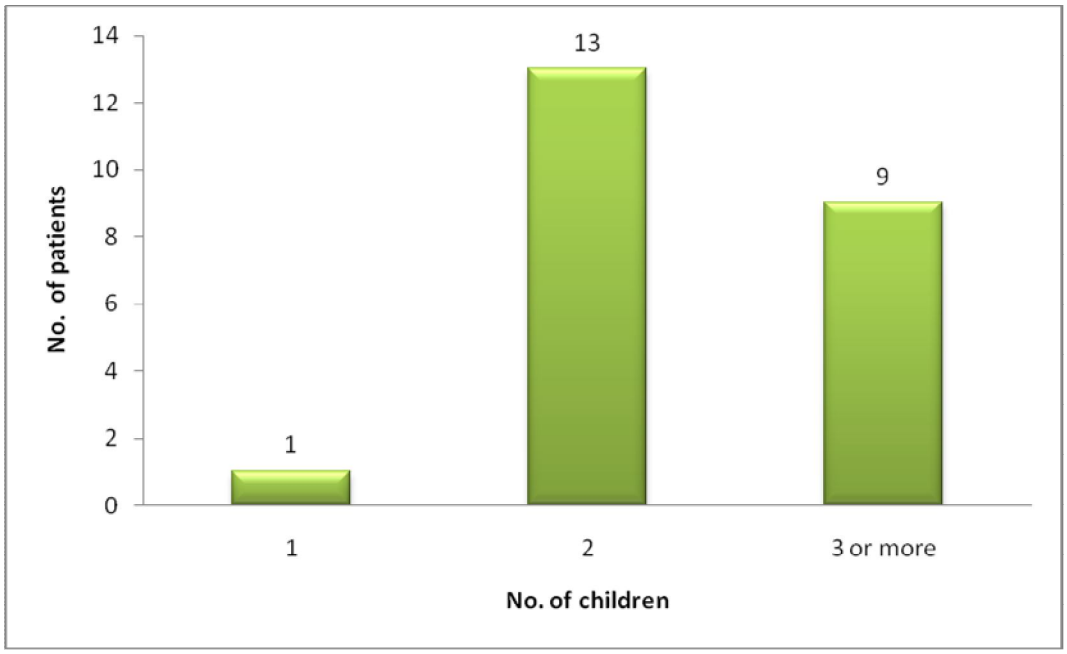
Age in years	Number of patients	Percentage of Total
21-30	1	4%
30-40	11	44%
41-50	8	32%
>50	5	20%



A total of 25 patients with stress urinary incontinence were admitted in the present study. The average age of the patient was 42.08 ± 8.49 years.

PARITY

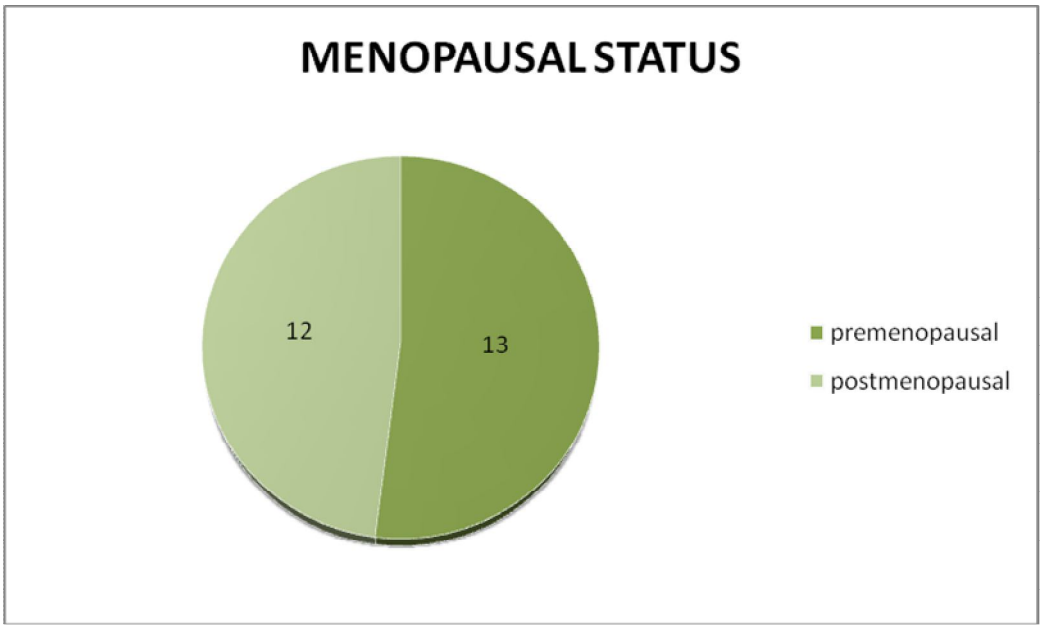
Parity	Number of patients
1	1
2	13
>2	11



The mean parity of the patients with stress urinary incontinence was 2.52 ± 0.77 (Mean ±SD). The data collected indicated that the women with 2 children had more Stress Urinary Incontinence

MENOPAUSAL STATUS

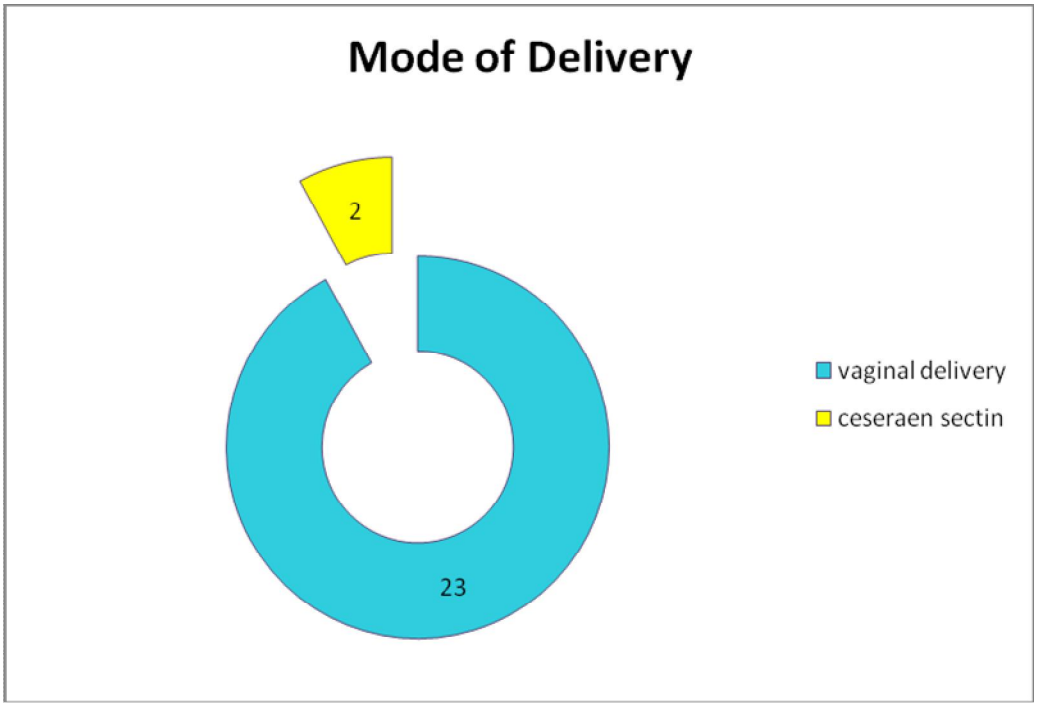
Menopausal status	Number of patients	Percentage of total
Pre menopausal	13	52%
Post menopausal	12	48%



Around thirteen patients (52%) with stress urinary incontinence were premenopausal and 12 patients out of twenty five were postmenopausal.

MODE OF DELIVERY

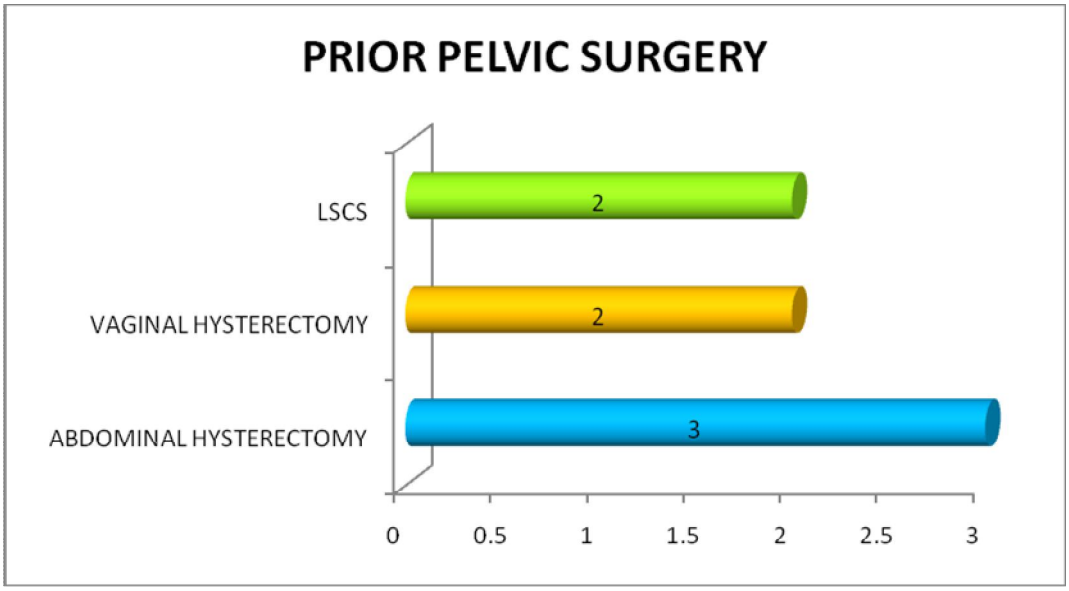
Mode	Number of patients
Vaginal delivery	23
Caesarean section	2



23 patients in this study underwent vaginal delivery and 2 patients had undergone caesarean section. Women who have had vaginal deliveries were found to have a higher association with stress urinary incontinence.

PREVIOUS PELVIC SURGERIES

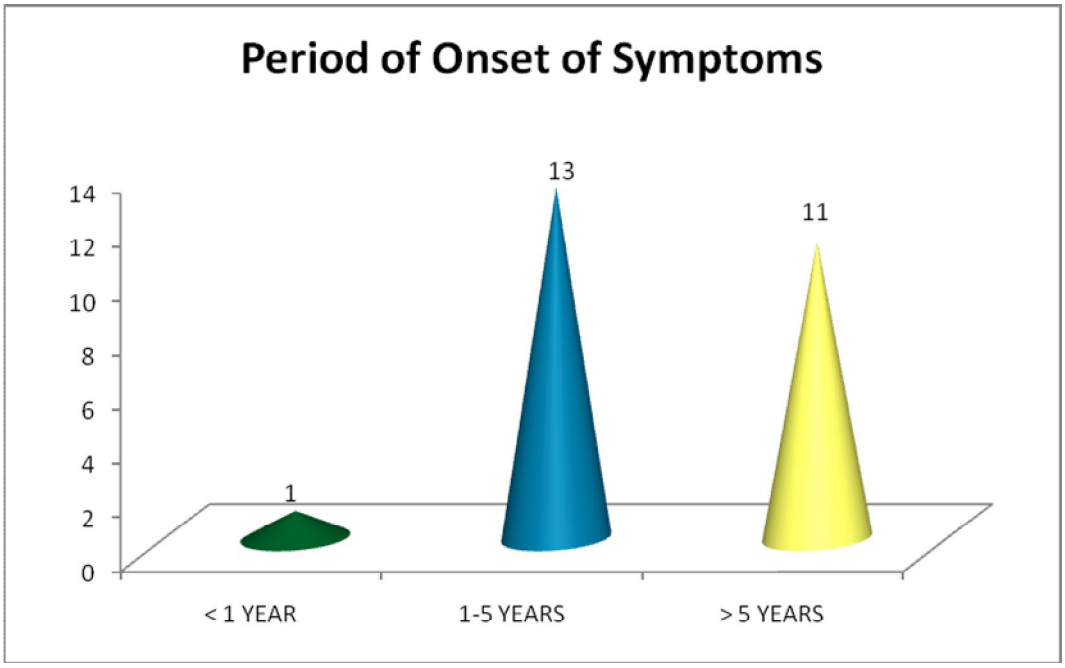
Prior pelvic surgery	Number of patients
Abdominal hysterectomy	3
Vaginal hysterectomy	2
Caesarean section	2



Seven patients with stress urinary incontinence had undergone previous pelvic procedures; three patients had previous history of abdominal hysterectomy, two patients had undergone a vaginal hysterectomy and two patients had undergone a caesarean section.

PREOP CLINICAL PARAMETERS

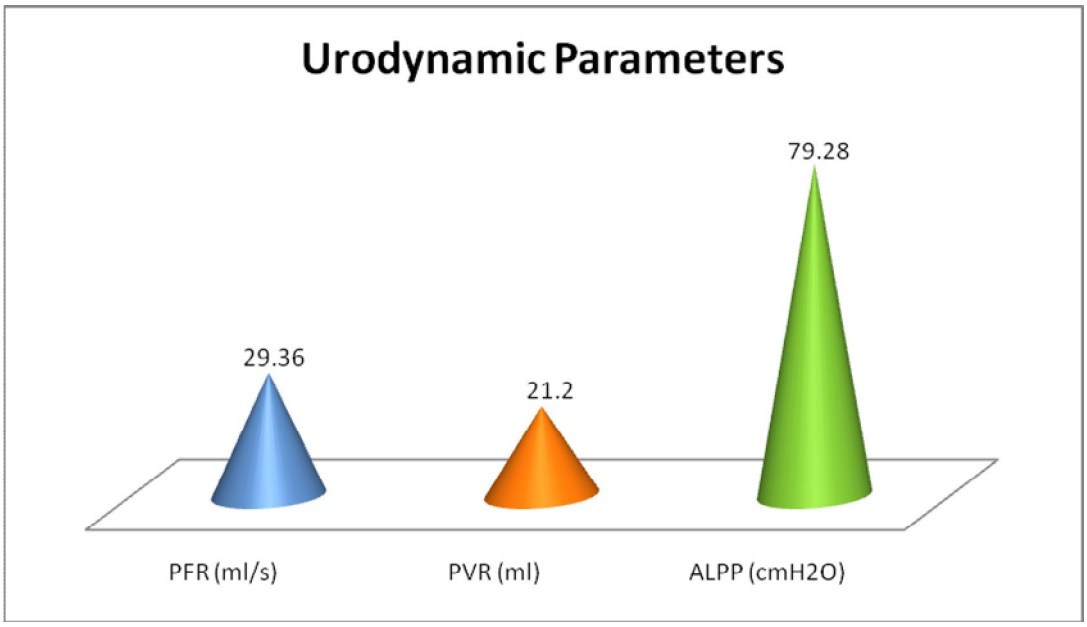
Preop clinical parameters	Mean ± S.D
Symptom duration (years)	4.56 ± 1.75
SUI grade (range 1-3)	2.24 ±0.52



The average symptom duration noted in patients with stress incontinence was 4.56 years, ranging from one year to eight years. Average stress urinary incontinence grade was 2.24 (range 1-3).

PREOPERATIVE URODYNAMIC PARATMETERS

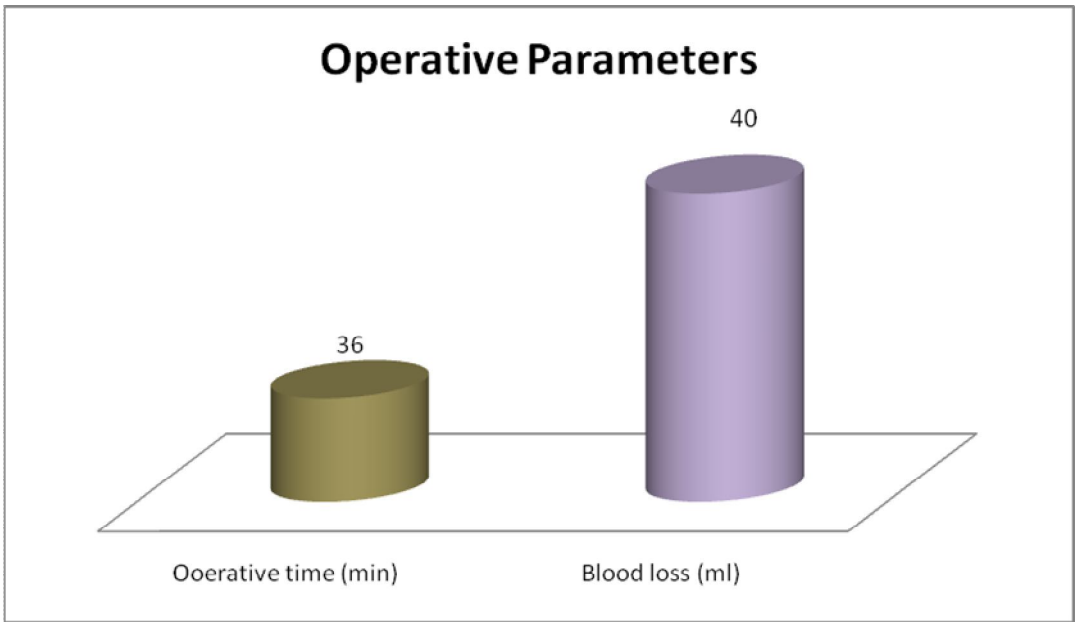
Preoperative urodynamic parameters	Mean ± S.D
Peak flow rate (ml/sec)	29.36 ±_2.65
Postvoid residual urine (ml)	21.2 ± 12.01
Abdominal leak point pressure (cmH_2O)	79.28 ± 6.75



The peak flow rate of the patients with stress urinary incontinence observed was 29.36 ml/second, and the post void residual urine measured by ultrasound abdomen was 21.2 ml. The abdominal or valsalva leak point pressure measured by pressure flow study was 79.28 cmH_2O.

OPERATIVE PARAMETERS

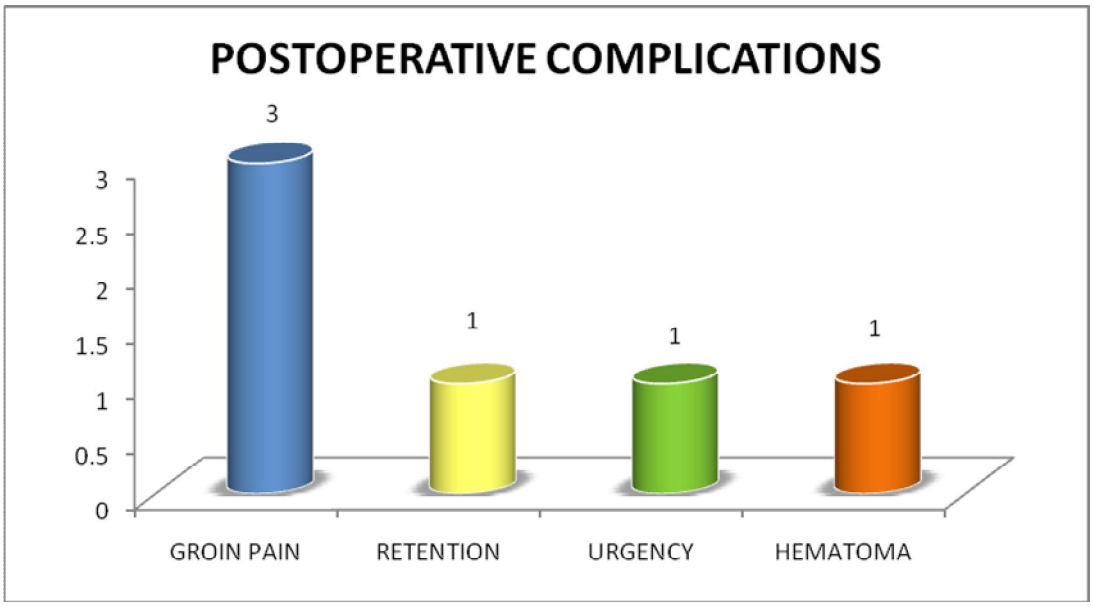
Procedural parameters	Mean ±S.D	Range
Operative time	36 ± 6.12	25 – 45 min
Blood loss	40 ± 9.12	10 – 40 ml
Hospital stay	3.08	2 – 4 days



The mean operating time of inside out transobturator approach was 36 minutes (range 25 to 45 minutes). The average blood loss during this procedure was 40 ml. The average duration of stay in the hospital during this study was only 3 days. All the patients underwent cystoscopy to detect any intraoperative complications - urethral or bladder injury.

POSTOPERATIVE COMPLICATIONS

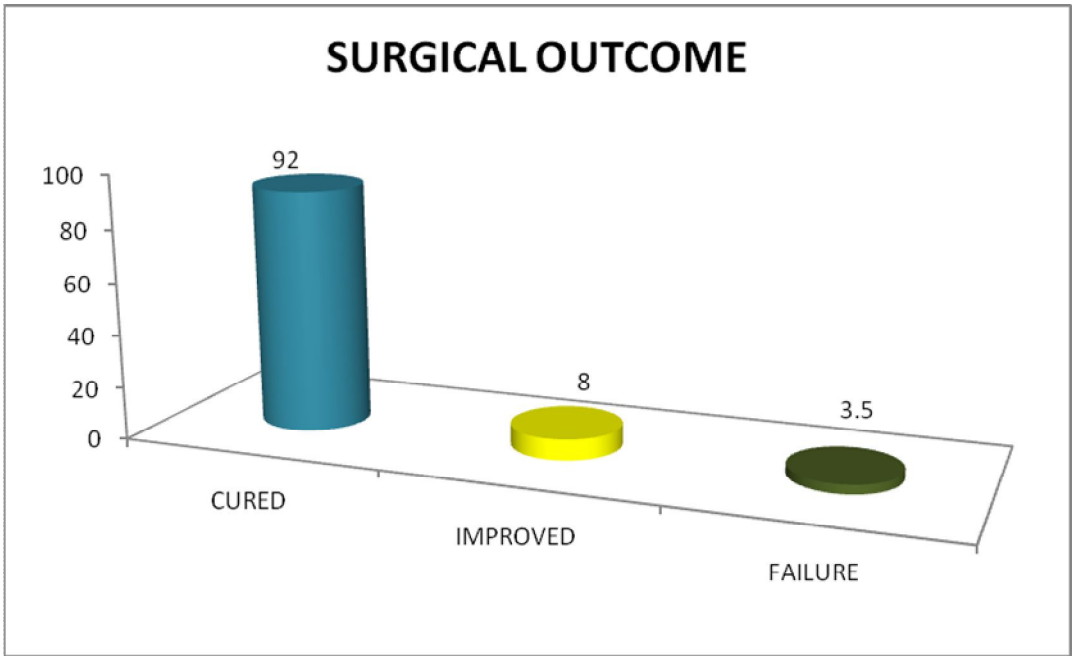
Complications	Number of patients (%)
Groin pain	3 (12%)
Retention	1 (4%)
Urgerncy	1 (4%)
Hematoma	1 (4%)



Following removal of the catheter post procedure one patient developed retention of urine requiring recatheterisation, but she had no voiding dysfunction after removal of catheter after one week. Groin pain was noted in 3 women during postop period. One patient developed wound hematoma and one patient had urgency and she was treated with antimuscarinics and on regular follow-up. Other serious postoperative complications like vaginal / urethral erosion, urinary tract infection, fistula, etc was not noted in the present study.

SURGICAL OUTCOMES

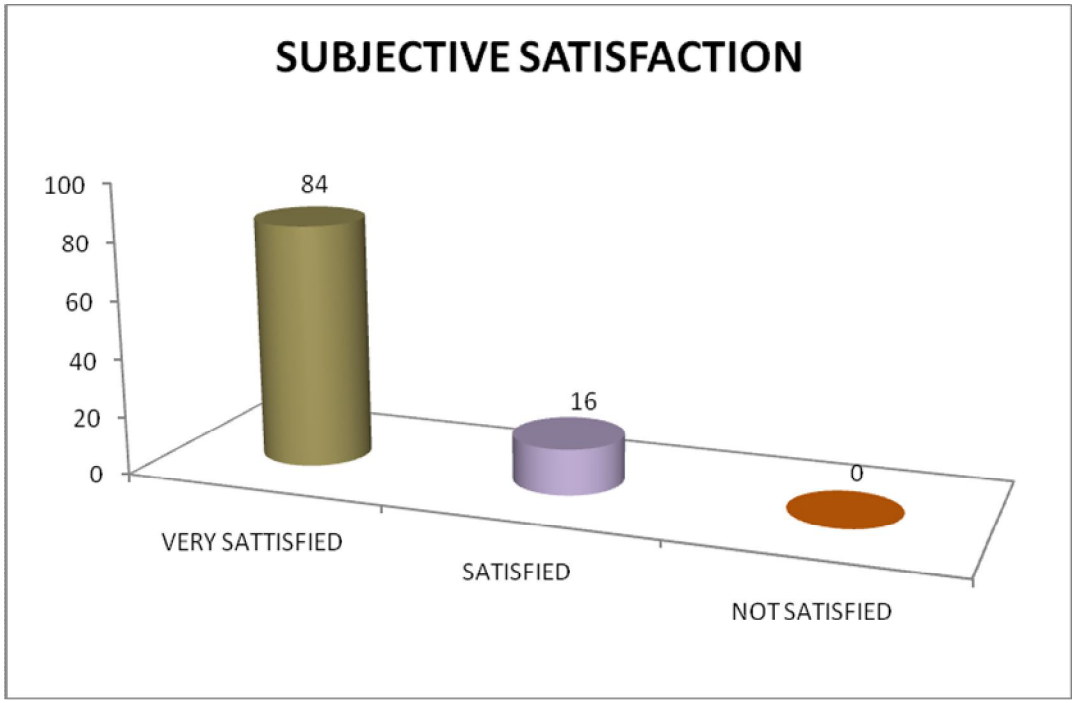
Surgical outcome	Number of patients (%)
Cure	23 (92%)
Improved	2 (8%)
Failure	-



Surgical outcome following inside out transobturator repair was assessed and categorized as cured, improved and failure of the procedure. It was based on list of questionnaires, stress test and pad tests. The results of this study are as follows – cured 92% , improved 8%, and there was no failure in this approach

SUBJECTIVE OUTCOME

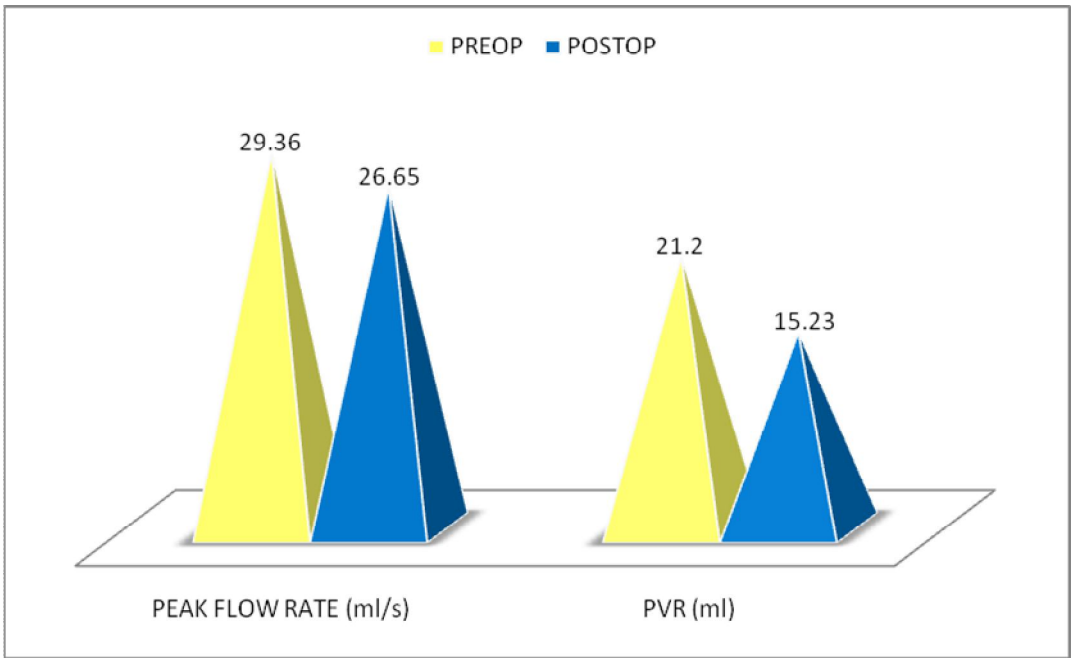
Subjective satisfaction	Number of patients (%)
Very satisfied	21 (84%)
Satisfied	4 (16%)
Not satisfied	-



The rate of satisfaction of the inside out transobturator approach was assessed during followup. 21 patients (84%) were very much satisfied with the procedure and 4 patients (16%) were satisfied with the procedure.

FOLLOWUP

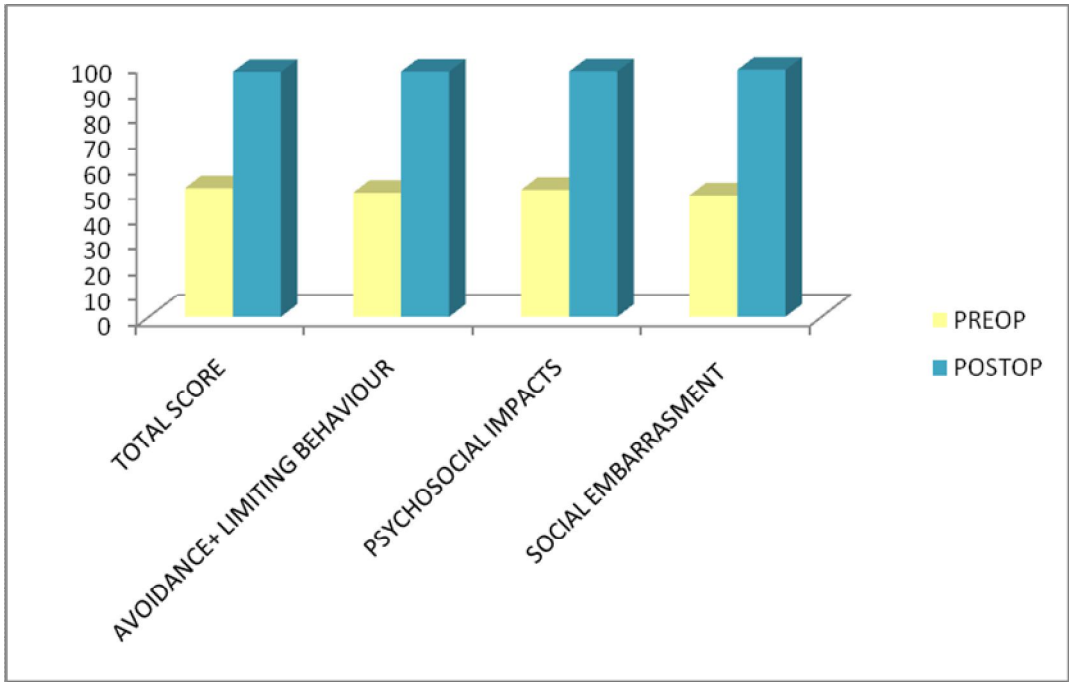
FOLLOWUP	PREOP	POSTOP
Peak flow rate (ml/s)	29.36 ± 2.65	26.65 ± 2.12
Post void residual urine (ml)	21.2 ± 12.01	15.23 ± 6.01



At 6 months follow-up, postoperative assessment of peak flow rate and the residual urine was done. The mean peak flow rate during the follow up was 26.65 ± 2.12, the mean post void residual urine during the follow-up was 15.23 ± 6.01.

I-QOL (QUALITY OF LIFE)

I-QOL SCORES	Preop (Mean ± SD)	Postop (Mean + SD)
Total	51.52 ± 5.49	96.84 ± 1.43
Avoidance + limiting behaviour	49.2 ± 5.52	97 ± 1.58
Psychosocial impacts	50.36 ± 6.76	97.04 ± 1.54
Social embarassment	48.16 ± 5.19	97.68 ± 1.97



All the patients in this study were evaluated using International Quality of Life Questionnaires and the scores were converted to 0 to 100 scale. Scoring was obtained both preoperatively and postoperatively during the follow-up.

DISCUSSION

DISCUSSION

The tension free vaginal tape procedure described by Ulmsten has revolutionized the treatment of female stress urinary incontinence. Ulmsten's theory is based on the concept that the urethral continence mechanism is controlled by the interplay of three anatomical structures and their associated function: the tension of the pubourethral ligaments, the muscular activity of the pubococcygeus and levator ani, and the condition of the suburethral vaginal hammock.

While these tapes have proved their long term efficacy[44], their insertion *via* an ascending or descending retropubic approach has been associated with number of intraoperative complications including bladder perforations, urethral injuries, retropubic hematoma formation, and rarely, complications with significant consequences such as injury to bowel, major blood vessels and nerves[40].

The transobturator approach was first described by DeLorme in 2001 for placement of midurethral vaginal tape with the aim of sparing pelvic space. In this outside in approach the needle is passed through a skin incision in the thigh fold, through the inferior-medial aspect of the obturator foramen, the anterior recess of the ishiorectal fossa under the levator muscles, and through the pubocervical fibromuscular tissue to exit a suburethral incision. The tape was then withdrawn through the

same path. The same procedure was performed on the opposite side to form the midurethral sling[45].

Initial data have demonstrated similar cure rates when compared to traditional retropubic placement with a lower incidence of bladder injury. The results from various clinical studies supported by cadaver dissections have demonstrated the injuries to the bladder, urethra, and vagina. Noteworthy, bladder perforations have been observed despite the recommended use of a large lateral para-urethral dissection to allow the introduction of a finger, employed to guide the tunneler. Therefore, systematic intra-operative cystoscopy may be needed while performing this procedure, in particular for avoiding unrecognized bladder or urethral perforations.

In an attempt to further improve upon the intraoperative safety profile of an obturator approach, de Leval had described an inside out transobtuator technique of tape placement with a helical passer that begins at the vaginal incision, follows the same path and exists the skin 2 cm lateral to the thigh fold thus earning it the “inside-out” designation.

The surgical device consists of stainless helical passer, polyethylene plastic tubes, stainless tube introducer and a polypropylene mesh. In order to determine the anatomical trajectory of the inside out transobturator tape and the neighbouring structures, de Leval et al. have performed cadaver dissections. These studies demonstrated that the tape

had followed the following consistent path: it penetrated from the suburethral space into the anterior recess of the ischio-rectal fossa, limited medially and cranially by the levator ani muscle, caudally by the deep transverse muscle, and laterally by the internal obturator muscle. The tape then perforated the obturator membrane and muscles and exited at the skin level after passing through the adductor muscles and sub-cutaneous tissues[45].

The transobturator tape was at a significant distance away form pudendal nerve, the obturator nerve and vessels, and the femoral vessels. The obturator vascular structures were also carefully dissected. Dissections consistently showed that the anterior branch of the obturator artery lied on the external rim of the ischio-pubic ramus, and was thus protected by this bony structure from being injured by the insertion of the tape[47].

Like the outside in approach (TOT), the inside out (TVT-O) tape passes from the midurethral level to obturator and thigh regions, and thus avoiding the pelvic cavity. The urethra and vaginal walls are under direct view[47]. The TVT-O tape is inserted into a rigorously perineal space, without traversing the levator ani muscle or its tendinous arch, making cystoscopy unnecessary, when properly performing the surgical procedure.

Spinosa and Dubuis (2005)[48] followed up 117 patients who underwent inside out transobturator approach for 16.3 months, and the complete and partial subjective cure rates were found as 92.3% (n:108) and 4.2% (n:5), respectively. Overall, four patients stated that their condition did not change. In another study that 120 patients were followed up for one year, 80% patients reported that they were completely dry and 12% reported that they had recovered almost totally. The initial reports of this inside out approach are encouraging suggesting a similar efficacy with no reported adverse events. Long term data demonstrating sustained efficacy of the transobturator approach has been demonstrated by various clinical studies.

Stress Urinary Incontinence was more commonly seen in younger women in this our study that is comparable to prevalence seen in other clinical studies. The higher level of physical activity seen in younger women than that of older women could be the reason. The average age of the patients was 42.08 years, whereas in a study conducted by Swift and Ostergard, average age was 59.8 years[49].

The mean parity, the number of children women had in our study was 2.52. The data collected indicated that the women with 2 children had more stress urinary incontinence, but the fact that almost half of the study population had only two children must be taken into consideration[50].

In our study stress urinary incontinence was equal amongst premenopausal women (52%) and postmenopausal women (48%) similar to the results by Fultz et al[51].

Patients with vaginal delivery were found to have a higher association with stress urinary incontinence. As shown in present work, women who had vaginal deliveries more likely to develop stress urinary incontinence than patients who had caesarean section. In a prospective study by in 344 nulliparous women it has shown that vaginal delivery has 18 times increased risk of urinary incontinence in a year when compared to caesarean delivery[50].

In this study 12% of patients had undergone abdominal hysterectomy and 8% vaginal hysterectomy compared to 25.4% and 9.6% respectively quoted by Bidmead et al[52].

There is latency from onset of symptoms to help-seeking in women with stress urinary incontinence. From the data gathered, it appears that most people tended to seek treatment between one and five years from the onset of their symptoms. There could be several reasons as to why people wait and as to why some people wait longer than others, ranging from personal to economical to logistical issues[50].

The present study shows that of women with stress incontinence had 4%, 68%, 28% grade1,2,and 3 respectively while Teleman et al reported that only 20% had occasional episodes of incontinence and 80% were incontinent all the time[53].

The mean procedural time was 36 minutes including an additional cystoscopy. This was similar to mean operative time of transvaginal tape as reported by Abouassaly et al[54]. The average intraoperative blood loss in the present study was 36 ml, and no patient had blood loss greater than 100 ml. Various studies[50] have shown the average blood loss during transvaginal tape procedure was significant and around 2% to 5% of patients had blood loss greater than 100 ml.

De Leval in his study of around 100 patients with stress urinary continence has demonstrated the absence of bladder or urethral injuries and no vascular (hematoma or bleeding) or neurologic complications[55]. The present study has demonstrated that no patient had signs and symptoms of vaginal, urethral, or bladder injury or erosions; or persistent pain during the 6 months follow-up period. The rate of urinary retention and hematoma is similar to the prospective study by Waltregny et al.

The postoperative groin pain was seen in 4 (16%) patients in this study. The cause for the postoperative pain with this procedure was due to a less predictable, more lateral passage of the needle and thus a closer exit to the obturator nerve in the groin. Most of the patients settled with oral analgesics and they were pain free during the follow-up at 3 months[57].

Denovo urge symptoms are commonly seen in patients undergoing surgical management for stress urinary incontinence.

DeNeval[58] in his study has demonstrated that urge symptoms disappeared or decreased in 72.8% and 6%, respectively, among the 33 patients who suffered from this condition pre-operatively. No change in urge symptoms was noted in five patients (15.2%) and six out of 96 patients developed de novo urge incontinence (6.25%). The incidence of de novo urgency is more common with transvaginal tape when compared to transobturator tape because of proximity of the tape to the bladder which can penetrate and irritate the bladder. In transobturator approach the tape is subfascial and avoids the retropubic space. In the present study postoperative urgency was seen in one patient.

The present study showed an objective cure rate of 92% and there was no failure of the procedure. On subjective assessment 84% of patients were very much satisfied with the procedure and 16% were satisfied with the procedure during the follow-up. De Neval[58] in his study of inside out transobturator approach among 108 patients with more than 6 months follow-up, 98 were cured (90.7%), 4 improved (3.7%) and 6 failed (5.6%).

The results from inside out approach showed a significant improvement between preoperative and postoperative assessment scores for health related quality of life (I-QOL). All the patients who had undergone this procedure reported improvement in the total score as well as the subscale scores – avoidance and limiting behaviour, psychosocial impact and social embarrassment (Incontinence – Quality

of Life score). This result was comparable to other midurethral tapes which also have shown improvement in quality of life.

Waltregny et al[59] (2006) found complete cure rate of 91% after TVT-O procedure on one-year follow up. A significant improvement was also detected in the quality of life and severity of incontinence in most patients. In another study follow up of four months, the objective and subjective cure rates were found to be 92 and 97%, respectively. An improvement was observed in the quality of life of 96% patients (Cindolo et al., 2004)[60]. In an additional study including 94 patients with a mean of 12.8 months of follow up, the cure rate was found to be 95% (Mellier et al., 2004)[61].

CONCLUSION

CONCLUSION

The inside out transobturator approach (TVT-O) is an effective and safe technique for the treatment of female stress urinary incontinence. The anatomical and functional mechanism of continence is restored with this minimally invasive approach. The position of the transobturator tape is similar to that of the natural hammock supporting the urethra, respects the orientation of muscle fibres better than the tension free transvaginal tape operation, and the dissection is less extensive, making tape migration less likely to occur. The para-urethral subvaginal dissection is less extensive with the inside-out route and the learning curve of this approach appears to be quicker.

There are several proven advantages concerning the feasibility of the inside out transobturator technique compared to the transvaginal tape procedure: the short duration of the operation; the low risk of urethral and bladder lesion, making cystoscopy redundant; the absence of risk of bowel lesion; the low risk of haemorrhage. Initial and long term results appear to suggest a cure rate similar to that of the transvaginal tape procedure and outside in transobturator approach with decreased incidence of complications.

On conclusion, the inside-out transobturator technique is simple, quick, and safe. It allows the accurate passage of the tape with minimal

dissection, protection of the urethra and avoiding the pelvis. There have been no reported urethra or bladder injuries, and no bowel or neurological complications. Post-operative continence rates are similar to the transvaginal tape procedure on short-term follow-up. In the future more randomized studies are necessary comparing the various midurethral slings and to further establish efficacy and safety of inside out transobturator vaginal tape.

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PROFORMA

PROFORMA

Name:

Age/ Sex:

Hospital No:

Date of Admission:

Date of Surgery:

Date of Discharge:

Presenting History:

- Incontinence – aggravated by stress
- Urgency
- frequency of micturition
- pain – suprabubic or dysuria
- haematuria
- altered bowel habits
- chronic cough

Past History:

- recurrent urinary tract infections
- drug intake
- previous pelvic surgery
- known DM/HT/PTB

Obstetric History:

- Parity
- Mode of Delivery
- Forceps or breech delivery

Clinical Examination:

General Examination:

Abdominal Examination:

PV:

PR:

IQOL questionnaire:

INVESTIGATIONS:

Basic Investigations:

- Urine routine
- Urine C/S
- Renal Parameters
- Ultrasound KUB: post void residual urine assessment

Bladder diary:

Cystoscopy:

Urodynamic Evaluation:

PROCEDURE:

- Date of surgery:
- Anaesthesia:
- Findings:
- Operative time:
- Blood loss:

Post op Period:

- Retention of urine
- Voiding dysfunction
- Urgency
- Groin pain
- Wound hematoma
- Tape erosion/extrusion
- Urinary tract infection

Follow-up:

MASTER CHART

SLNo	Name	Age	Parity	Menopause	Pelvic Surgery	Mode of Delivery	IQOL-T	IQOL-A	IQOL-P	IQOL-S	Symptom Duration	Grade	Peak Flow Rate	PVR	ALPP	Operative time	Blood loss	Hospital stay	Pain	Retention	Hematoma	Urgency	Post void residue	Peak flow rate	Cured	Improved	Failed	Very Satisfied	Satisfied	Not Satisfied	IQOL-T	IQOL-A	IQOL-P	IQOL-S
1	Kothanayaki	36	2		-	VD	68	65	64	60	3	2	32	20	82	40	50	3					nil	28		x			x		96	95	96	96
2	Krishnaveni	45	3	x	-	VD	52	50	55	52	6	2	28	30	74	35	30	2					20	24	x			x			98	98	98	100
3	Jayanthi	59	4	x	AH	VD	49	45	49	40	3	2	29	nil	86	45	50	3	x				10	26	x			x			100	100	100	100
4	Noorjahan	59	3	x	-	VD	46	43	40	48	5	3	31	10	88	30	40	4					nil	28	x			x			98	98	98	100
5	Thilaka	54	2	x	-	VD	50	48	53	48	6	2	26	nil	72	25	30	3					20	24	x			x			97	98	96	100
6	Karpagam	45	2		-	VD	46	52	49	52	4	3	28	30	78	35	40	3					20	24	x			x			96	95	96	96
7	Alamelu	32	2		-	VD	55	58	66	52	3	2	34	40	82	40	30	4					10	28	x			x			98	98	98	100
8	Sivakami	36	2		AH	VD	52	45	51	44	4	2	34	20	78	50	60	4	x				10	26	x			x			97	98	98	96
9	Krishnaveni	32	2		LSCS	CS	47	45	42	44	4	2	31	10	70	30	40	3					10	30		x			x		94	95	94	96
10	Maliga	52	3	x	-	VD	52	48	51	44	7	2	32	20	64	35	30	3					nil	25	x			x			98	98	98	100
11	Radha	35	2		-	VD	51	48	46	48	2	3	28	30	86	40	40	3					10	26	x			x			96	95	96	96
12	Thenmozhi	38	3		VH	VD	53	48	49	48	3	2	26	20	80	35	50	2					20	29	x			x			97	98	98	96
13	Rama	36	2		-	VD	64	60	62	54	6	2	28	20	92	30	40	3					20	26	x			x			98	98	98	100
14	Chitra	40	2		-	VD	45	45	40	40	3	3	31	30	80	25	30	3					10	28	x			x			98	98	98	100
15	Sheela	44	2	x	LSCS	CS	52	50	55	52	8	2	24	nil	84	40	50	4			x		20	26	x			x			97	98	98	96
16	Vedhanayaki	38	3		-	VD	53	50	53	48	3	3	32	30	78	35	50	3					nil	25	x			x			96	95	96	96
17	Kumari	41	1		-	VD	54	50	48	54	4	2	26	30	84	45	40	3					30	24	x			x			96	95	96	98
18	Sakunthala	46	4	x	VH	VD	48	45	47	40	7	3	29	20	76	35	50	3	x			x	20	32	x			x			98	98	98	100
19	Chandra	42	3	x	-	VD	50	48	53	48	6	2	28	30	82	40	40	3					20	28	x			x			97	98	98	96
20	Esther	28	2		-	VD	46	53	49	52	3	1	31	20	86	30	30	3		x			10	29	x			x	x		94	95	94	96
21	Ayesha begum	36	4	x	-	VD	44	43	40	40	6	3	26	nil	76	40	50	3					20	24	x			x			96	95	96	96
22	Muniammal	49	2	x	AH	VD	57	55	52	52	4	2	32	20	84	35	30	3					10	28	x			x			97	98	98	96
23	Sundari	46	3	x	-	VD	52	45	51	44	1	2	28	30	80	30	40	3	x				nil	26	x			x			97	98	98	96
24	Chellammal	51	3	x	-	VD	49	43	45	52	8	2	31	40	66	40	30	3					10	24		x			x		94	95	94	96
25	Ramani	32	2			VD	53	48	49	48	5	2	29	30	74	35	30	3					10	28	x			x			98	98	98	100

IQOL-T : incontinence quality of life score total **IQOL-A** **Avoidance and limiting behaviour** **IQOL-P** **Psychosocial impact** **IQOL-S** **Social embarrassment** **PVR** **Post void residual urine** **ALPP** **Abdominal Leak Point Pressure**