A PROSPECTIVE STUDY ON OUTCOME OF TENSION FREE TRANS OBTURATOR TAPE FOR FEMALE STRESS URINARY INCONTINENCE

Dissertation submitted in partial fulfilment
of the requirement for the degree of

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DEPARTMENT OF UROLOGY,
GOVERNMENT ROYAPETTAH HOSPITAL,
KILPAUK MEDICAL COLLEGE,
CHENNAI

DECLARATION

I solemnly declare that this dissertation **"A PROSPECTIVE STUDY ON OUTCOME OF TENSION FREE TRANS OBTURATOR TAPE FOR FEMALE STRESS URINARY INCONTINENCE"** was proposed by me in the Department of Urology, Kilpauk Medical College and Govt. Royapettah Hospital, Chennai under the guidance and supervision of **Prof.K.THIYAGARAJAN, M.S.,M.Ch. (Urology), D.N.B (Urology)** Professor and Head of the Department of Urology, Kilpauk Medical College and Govt. Royapettah Hospital,Chennai and **Prof. V. SELVARAJ, M.S., M.Ch. (Urology),** Additional Professor, Department of Urology, Kilpauk Medical College and Hospital,Chennai

This Dissertation is submitted to the Tamilnadu Dr. M.G.R. Medical University, Chennai in partial fulfilment of the University requirements for the award of degree of M.Ch Genitourinary Surgery.

Place : Chennai

Date :

BONAFIDE CERTIFICATE

This is to certify that this dissertation entitled *"***A PROSPECTIVE STUDY ON OUTCOME OF TENSION FREE TRANS OBTURATOR TAPE FOR FEMALE STRESS URINARY INCONTINENCE"** submitted by **Dr. J. SIVABALAN,** appearing for **M.Ch (Urology)** degree examination in August 2010 is a bonafide record of work done by him, under my guidance and supervision in partial fulfilment of requirement of the Tamilnadu Dr. M.G.R. Medical University, Chennai. I forward this to the Tamilnadu Dr. M.G.R. Medical University, Chennai, Tamilnadu, India.

Prof. V. SELVARAJ,
M.S., M.Ch. (Urology)
Addl. Professor. Dept. of Urology
Kilpauk Medical College and Hospital
Chennai – 600 010.

Prof.K.THIYAGARAJAN,
M.S.,M.Ch. (Urology), D.N.B. (Urology)
Professor and Head of the
Department of Urology,
Government Royapettah Hospital,
and Kilpauk Medical College,
Chennai

THE DEAN
Kilpauk Medical College & Hospital
Chennai – 600 010.

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CONTENTS

CHAPTER NO.	TITLE	PAGE NO
1	INTRODUCTION	1
2	AIM OF STUDY	3
3	REVIEW OF LITERATURE	4
4	MATERIALS AND METHODS	43
5	RESULTS AND OUTCOME	54
6	DISCUSSION	56
7	CONCLUSION	61
8	BIBLIOGRAPHY	62
9	MASTER CHART	

INTRODUCTION / BACKGROUND

Stress Urinary Incontinence is defined as the involuntary loss of urine from the urethra during physical activities that increase the intra abdominal pressure in the absence of detrusor activity. It is the major proportion of cause of urinary incontinence. SUI can develop through two mechanisms; hyper mobility - significant displacement of the urethra and bladder neck during exertion and intrinsic sphincter deficiency(ISD).These two conditions can coexist in women.

As stated by the American Urologic Association consensus statement in 2001, there are only 2 procedures that are proven to have effective long-term cure rates for the treatment of stress urinary incontinence (SUI). These procedures are the abdominal Burch Colposuspension and the sling procedure that is completed vaginally.

However, in the past, the sling procedure was far from standardized. There have been multiple different descriptions using different materials for the sling (fascia from the patient, cadaveric fascia or dermis from humans or animals, synthetics, etc), different anchoring points, and different methods to adjust the tension of the sling. In many cases patients had to undergo general anesthesia, were in the hospital for several days, required a catheter to drain the bladder and many patients suffered high rates of voiding dysfunction following these slings.

However the introduction of the tension-free vaginal tape procedures to the United States in the late 90's revolutionized the treatment of SUI. It introduced a standardized sling procedure that could be completed safely in 20 minutes under local anesthesia, utilizing 3 very small incisions with minimal dissection, a cough test for individual tension patient adjustment and excellent cure rates. Over 500,000 of these procedures have been completed worldwide.

AIM OF STUDY

To study the efficacy of TOT in Stress Urinary Incontinence

To analyse immediate and late complications

Compare the results

REVIEW OF LITERATURE

The prevalence of incontinence may be significantly underestimated since physicians rarely ask patients about the problem and the patients seldom initiate discussion about incontinence with the physician. Older patients may assume that urinary incontinence is a normal consequence of aging. The prevalence of urinary incontinence in a community is as high as 30% Some patients do not disclose the incontinence because of fear of invasive testing. Incontinence may be genuine stress incontinence, detrusor instability or mixed incontinence. DIAPPERS - (Delirium, Infection, Atrophic urethritis / vaginitis, Restricted mobility and Stool impaction) summarizes the functional causes**.** The inability to control the urine is most unpleasant and distressing problem. Incontinence does not lead to death but it causes substantial debility, social seclusion, psychological stress, and economical burden. Although involuntary loss of urine is not a normal part of ageing, it often becomes a clinical problem for the ageing women due to trauma of child birth, development of acute and chronic illnesses, loss of estrogenic stimulation at menopause, weaker pelvic support, and diminished amount of normal homeostatic reserve available to cope with stresses placed on the bladder.

Since the inception of the pubovaginal sling approximately a century ago, experimentation has continued with multiple types of slings

composed of different materials using different suspension techniques. Materials used as sling constituents have included autografts, allografts, xenografts, and, more recently, synthetic variants. Methods of anchoring these slings have also undergone development and advancement; however, the ideal method of suspension remains to be completely defined. Sling placement was classically described at the level of the bladder neck in an effort to correct urethral hypermobility and enhance pressure transmission invoked by intra-abdominal straining.

However, competing theories arose initially as suggested by Zaccharin in the 1960s and DeLancey in the 1990s (Zaccharin, 1968 ; DeLancey, 1994). In these theories, the importance of the pubourethral ligaments and their function in maintaining the integrity of urinary control furthered the concept of the importance of the midurethral mechanism for preservation of urinary incontinence under stress circumstances. These findings further demonstrate the fact that hypermobility is a secondary finding noted in association with incontinence but not causative of the condition of effort-related urinary loss (stress incontinence).

Petros and Ulmsten, using these theories, proposed a unifying concept now known as the midurethra theory (previously the integral theory) (Petros and Ulmsten, 1993). They postulated that injury arising from surgery, parturition, ageing, or hormonal deprivation lead to weakening or damage of the pubourethral ligaments, impairing

midurethral function and anterior urethral wall support, thus resulting in urinary incontinence. They theorized that this damage was not only a ligamentous injury but also a representation of weakening of the pubococcygeal muscles at the level of the midurethra. It has been shown that weakness of soft tissue in this area and specifically connective tissue can contribute to urinary incontinence (Ulmsten et al, 1987).

THE TENSION-FREE VAGINAL TAPE PROCEDURE

Transvaginal taping was developed using the concepts of the integral theory. The provisions of this operation include a minimally invasive approach, which would supplement the diminished midurethral mechanism and produce the ingrowth of new host tissues after implantation for purposes of further supplementing support introduced by the procedure. As initially described, the procedure was performed under local anesthesia to allow ambulatory delivery of the intervention.

What does 'tension-free' mean?

Tension-free slings are used to treat stress urinary incontinence caused by urethral hypermobility and intrinsic sphincter deficiency. In this approach, a synthetic transvaginal suburethral sling is placed through the retropubic space without using suspension sutures. The sling is held in place by the friction between the mesh and the tissue canals created by the metallic needle passers. Scar tissue later fixes the mesh, preventing migration. Because the sling is not anchored to the pubic bone,

ligaments, or rectus fascia, it is considered "free of tension." The result is a midcomplex urethral support that limits urethral descent, improves the stabilization mechanism generated by pubourethral ligaments and levator ani muscles, and reinforces support of the backboard vaginal hammock.

Initially, several types of material were evaluated until the final material was chosen, a synthetic polypropylene monofilament mesh with pore size under 150 μm. Also, this material allowed optimal migration of host inflammatory components (leukocytes and macrophages) into the mesh for purposes of infectious surveillance and host wound healing (imbibition and inosculation). It was found that this material was optimal for inciting fibrous tissue ingrowth. This type of mesh is known as a type 1 mesh and has previously been described in the general surgical literature as being favorable from the standpoints of its mechanical properties (stretch and elasticity) (Dietz et al, 2001, 2003). Efforts have been made to standardize the procedure by incorporating certain technical approaches and safety features for purposes of avoiding injury to surrounding structures.

To date, more than 400,000 of these procedures have been performed worldwide.

The Procedure

The device consists of two specially curved 5-mm-diameter insertion needles that are attached to a 40-cm segment of polypropylene tape that is 11 mm wide. The tape is covered with a clear plastic sheath, which protects the tape from contamination and allows easy passage through host tissues. A rigid catheter guide is placed in the bladder with an 18 French Foley catheter to help deflect the bladder away from the locale of needle path insertion. An ergonomic handle is attached to the insertion needles for actual placement of the needles during the procedure. This handle is reusable and sterilizable.

The midurethra sling procedure (transvaginal tape) is performed with the patient in the dorsal lithotomy position with a significant degree of flexion (70 degrees or more) of the thighs, the patient under parenteral sedation with local anesthetics placed in the region of insertion of the device (vaginal wall and retropubic space). Approximately 5 mL of local anesthetic is injected into the vaginal area as well as into the planned suprapubic insertion skin sites. For placement of retropubic local anesthesia, another 20 mL of local anesthetic agent is injected into the area along the posterior aspect of the pubic bone to the level of the urogenital diaphragm. Additional vaginal infiltration includes approximately 10 mL injected on either side of the urethra to the level of the urogenital diaphragm.

After appropriate anesthesia, two small suprapubic stab incisions are created just above the level of the symphysis pubis, approximately 2 cm lateral to the midline. A third midline vaginal incision approximately 1.5 cm wide is created approximately 1.5 cm from the external meatus of the urethra, between that structure and the bladder neck.

After the vaginal incision is created, minimal dissection is performed using Metzenbaum scissors under the vaginal flaps on either side to elevate the vaginal epithelium from the underlying periurethral tissue to the level of the pubocervical fascia, which is not perforated. The tension-free vaginal tape (TVT) needle is then placed in the dissection tunnel immediately beneath the vaginal epithelium on one side of the urethra with the needle tip situated in close proximity to the lower rim of the pubic ramus. Using controlled pressure, the needle is elevated through the endopelvic fascia, into the space of Retzius, through the rectus muscles and through the previously created suprapubic skin incision. During this maneuver, the needle is kept in close contact with the intrapelvic surface of the pubic bone in order to avoid perforation of the lower urinary tract and also to avoid intraperitoneal entry. Tactile contact ensures direct apposition of metal to bone, as does slow graded pressure during needle advancement.

Simultaneous deflection of the lower urinary tract is accomplished during insertion using the catheter guide and catheter with pelvic viscera deflected away from the side of needle insertion. The same maneuver is

performed contralaterally so that each needle exits through the appropriate skin incision. Cystoscopy is performed to exclude needle penetration of the lower urinary tract. The use of a 70-degree lens is essential, as is complete distention of the bladder with irrigant to exclude subtle tangential injury. If perforation is noted, the needle is withdrawn and passed once more in the same area in an effort to avoid further perforation. Once cystoscopy has demonstrated no evidence of bladder injury, the tape is brought through the incisions and tension adjustment of the tape is performed. Tension adjustment is most commonly performed by inserting either a surgical instrument (clamp) or a metallic sound between the tape and urethra while the covering plastic sheath is removed from the field. The tape is set to tension such that with the bladder full to 300 mL of saline and the patient now aroused and asked to cough, no incontinence occurs during the stress maneuver. Redundant tape is then excised at the level of the suprapubic skin incisions and all incisions are closed. The procedure may also be performed under regional or general anesthesia according to the surgeon's preference. Outcome data support the incorporation of midurethral sling techniques with concomitant vaginal prolapse repairs.

Results

In reviewing the extensive results reporting for the midurethral sling, several caveats must be entertained. Outcomes are reported in varying fashions using different tools, lengths of follow-up, and overall

definitions of success and failure. These factors should be kept in mind when attempting to cross-compare different groups and procedural nuances.

Initial results with the midurethral sling technique approximated 80% (author-defined) success rates (Ulmsten et al, 1996). A subsequent prospective multicenter trial that included 130 women with genuine stress incontinence (GSI) who were observed for 1 year revealed success rates of 91% (Ulmsten et al, 1998). Seven percent were considered improved and only 2% deemed failures. Complication rates were low, including one bladder perforation and one wound infection. Voiding dysfunction was also relatively low, with one patient experiencing retention for 12 days, which resolved spontaneously, and three patients with less than 3 days of voiding dysfunction (regarding catheterization), which the authors defined as a short-term voiding problem.

On the basis of these findings, further studies were then embarked upon. Nilsson and Kuuva (2001) evaluated 161 consecutive TVT operations in cases of which 28% had failed prior incontinence surgery, 11% had intrinsic sphincteric deficiency (ISD), and 37% had mixed incontinence. At 16 months mean follow-up, the overall objective cure rate was 87% with 7% significantly improved and another 5% considered failures.

Bladder injury rate at the time of insertion was 3.7%, and 4.3% of women experienced short-term de novo voiding dysfunction. Urge symptoms arising after surgery occurred in 3% of women, yet 80% of the women who had preoperative urgency symptoms had relief of those symptoms at their 16-month visit. No serious complications were noted.

Long-term results mirror the short-term experience with this procedure. Success rates ranging from 81% to 90% have been reported at more than 3 years. Ulmsten (1999) reported an 86% success rate in 50 women at 3 years. Olsson reported 90% success in 51 women at 3 years (Olsson and Kroon, 1999). Nilsson reported success rates of 84.7% at 5 years (Nilsson et al, 2001) and 81.3% at 7 years (Nilsson et al, 2004) in a consistent cohort of 90 women. These long-term studies have attempted to evaluate risk factors for declining effectiveness. There does appear to be a tendency for higher failure rates to be associated with advancing age at the time of procedure and also with diminished urethral function (intrinsic sphincter deficiency). Notable, the long-term studies demonstrate an absence of signs of long-term tissue erosion or other complications related to material insertion.

The most stringent evaluation of this technique has occurred in four randomized controlled clinical trials that have compared it with the colposuspension procedure. The most meticulously designed trial was that of the UK/Ireland cooperative group, which compared TVT with open colposuspension. One hundred seventy-five women underwent TVT

and 169 underwent Burch suspension. Clinical follow-up was continued for 24 months. A variety of outcome measures including subjective and objective measures were utilized. Overall cure rates noted in the study were lower than other reported cure rates, with 63% of TVT patients and 51% of colposuspension patients being cured (Ward and Hilton, 2004).

Comparator Tabulation of Outcomes Obtained with the Tension-Free Vaginal Tape and Burch Procedure in a Randomized Analysis

	Tension-Free Vaginal Tape (%)	**Colposusp-ension (%)**
Objective cure		
1-hour pad test	81	67
Negative urodynamic studies + pad test	73	64
Subjective cure		
No stress incontinence	59	53
No incontinence	36	28
Response to procedure		
Satisfied	85	82
Recommend	84	82

From Ward K, Hilton P: A prospective multicenter randomized trial of tension-free vaginal tape and colposuspension for primary stress incontinence. Two-year follow-up. Am J Obstet Gynecol 2004;190:324-331.

Three other randomized trials have been performed: one that compared TVT with laparoscopic colposuspension using mesh (Valpas et al, 2004), another that used laparoscopic colposuspension with Gortex sutures as the comparator (Persson et al, 2002), and a third that used laparoscopic colposuspension with polyfilament polyester sutures as the comparator technique to TVT (Paraiso et al, 2004). Valpas and Persson reported results at 12 months, and Paraiso reported outcomes at 18 months. The results of the laparoscopic trials revealed TVT cure rates in the range of 86% to 97%, with colposuspension rates ranging from 57% to 100%, depending on the reporting method.

There was no apparent difference between procedures in the Persson trial, but Paraiso and Valpas noted significant differences in success in the two study groups. These trials noted no other apparent differences between techniques other than that the TVT group recovered more rapidly and had a lower need for subsequent urogenital prolapse procedures than the colposuspension group.

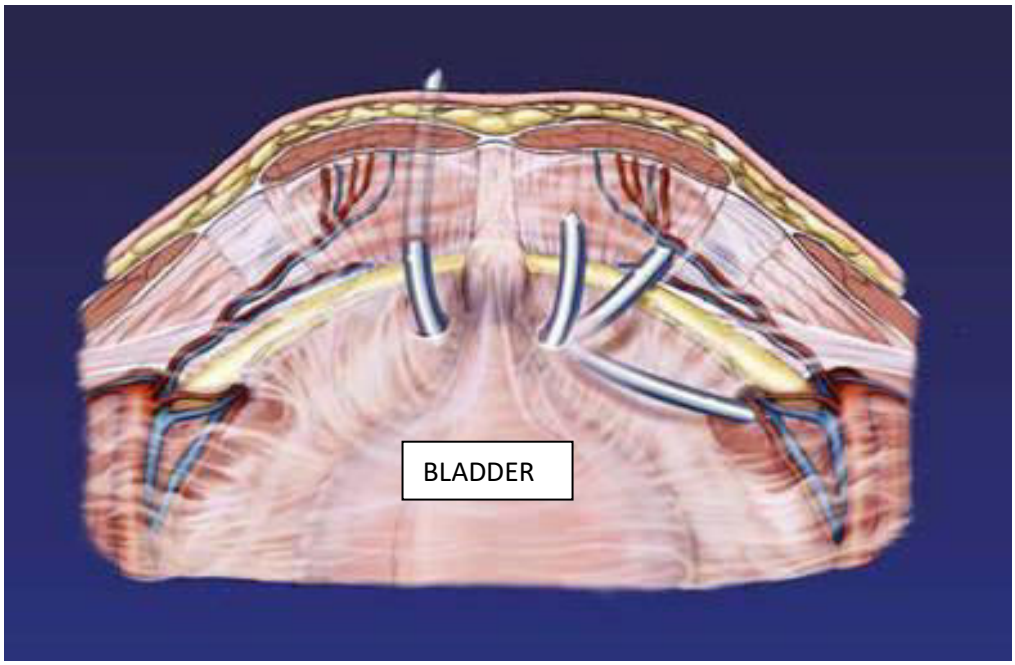
Complications

Despite its relative safety, the tension free vaginal tape procedures require the blind passage of needles through 2 small incisions in the abdomen just above the pubic bone. The retropubic space that the needle has to pass through to get to these abdominal incisions is also a very vascular space with venous plexuses and the potential for injury to large

blood vessels in the pelvis. Secondary to this and the areas that the needle has to pass to place the mesh tape, there is potential for complications such as injury to the bladder, intestines, or nerves in the pelvis and/or abdomen. All of these injuries have been reported in the literature. Secondary to this, physicians in Europe began investigating to find a safer approach to place the mesh tape sling.

Risks of Retropubic Needle Passage

-Bladder injury,Bowel injury,Major vascular injury,Nerve injury



Passage of Retropubic Needles for TVT, etc.

The needle on the left shows a safe passage, the needle on the right shows potential injury to abdominal wall vessels or pelvic vessels or nerve. Despite its relative safety, the tension free vaginal tape procedures require the blind passage of needles through 2 small incisions in the

abdomen just above the pubic bone. The retropubic space that the needle has to pass through to get to these abdominal incisions is also a very vascular space with venous plexuses and the potential for injury to large blood vessels in the pelvis. Secondary to this and the areas that the needle has to pass to place the mesh tape, there is potential for complications such as injury to the bladder, intestines, or nerves in the pelvis and/or abdomen.

TRANSOBTURATOR SLINGS

Subsequent to the development of the TVT, it was recognized that the transobturator (TOT) tape was a viable method for correction of SUI. Since Ulmsten's initial article in 1996, there has been extensive acceptance of the various midurethral sling technologies.

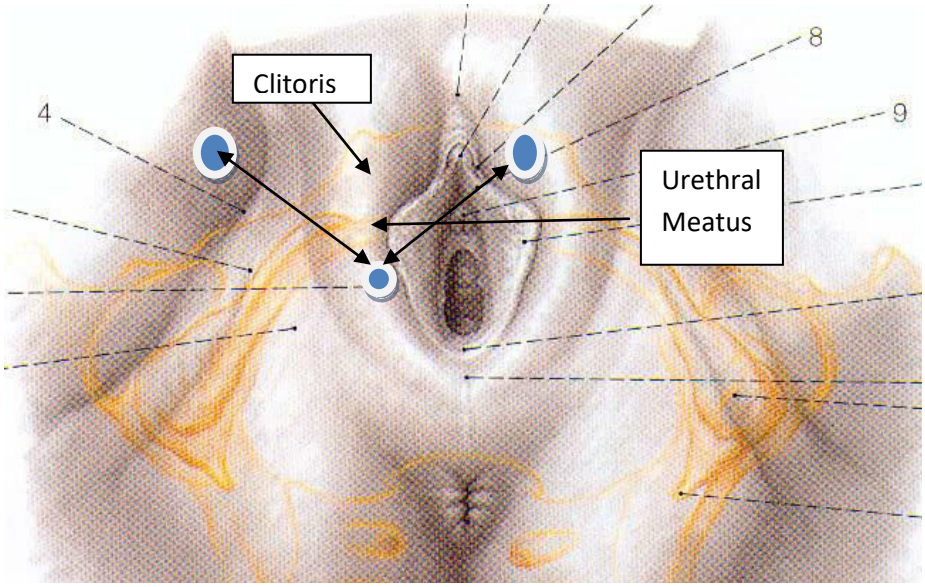
In Europe, as of 2005, approximately 83.9% of all procedures are midurethral-type synthetic slings, of which 26.9% are TOT (de Tayrac and Medelenat, 2004). Since the initial description of the TOT approach, numerous other similar TOT approaches have been noted.

The goal of the minimally invasive surgical procedure should be to provide acceptable long-term efficacy comparable to that of more standard methods as well as a relatively low incidence of long-term complications, Delorme (2001) initially described the placement of synthetic polypropylene mesh using the TOT approach. The technique was described as being relatively facile and associated with fewer

complications than retropubic approaches. It was also thought that the procedure did not require cystoscopy.

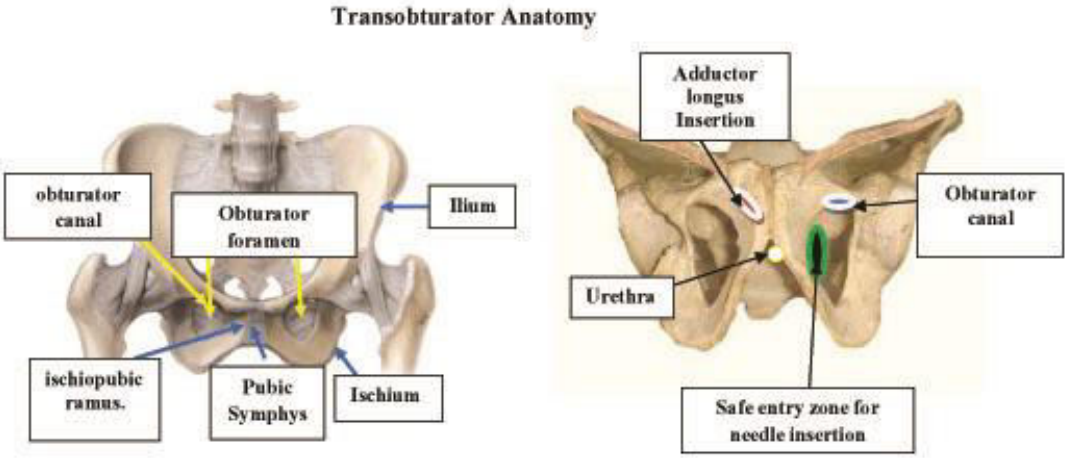
Advantages of Transobturator Approach

-Safer, faster, more efficient -Decreased risk of: -Bowel Injury -Bladder Injury -Major Bleeding -No Retropubic Needle Passage -No Abdominal Incisions - More Anatomic Position of Tape



The double arrows show the final position of the transobturator sling placement. The blue circles in the groin are where the small stab incisions are made to place the polypropylene mesh tape sling

Transobturator Anatomy



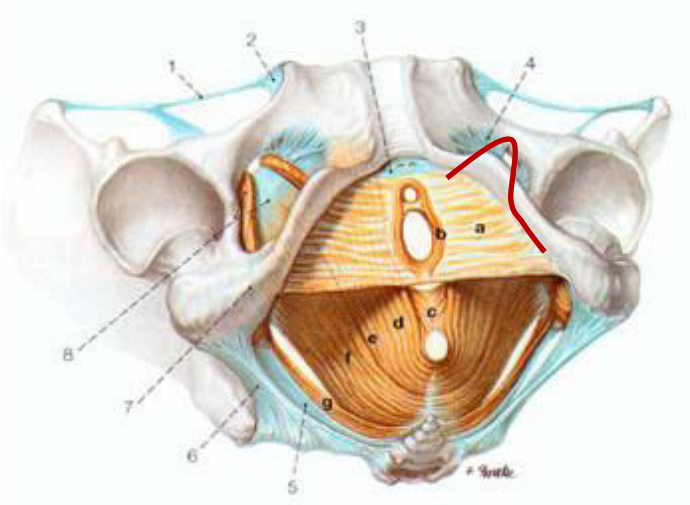
OBTURATOR ANATOMY

The obturator foramen is covered by a thick membrane called the obturator membrane. The external and internal obturator muscles cover this membrane. It is a very safe space anatomically, ie there are no major vascular or nerve structures near the ischiopubic ramus. This is the area that the needle is passed for the sling placement. As can be visualized by the drawing, the obturator canal is very lateral and superior to the ischiopubic ramus, this is the area that the obturator nerve and vessels transverse the needle to place the TOT sling is passed through the groin incision, the obturator membrane and around the descending ischiopubic ramus (the area marked in green in the above diagram). A small incision is made vaginally as well and the needle is guided throughout its course with a finger placed in the vaginal incision, thus protecting the urethra and making it safer than just a “blind” needle passage. The mesh tape is

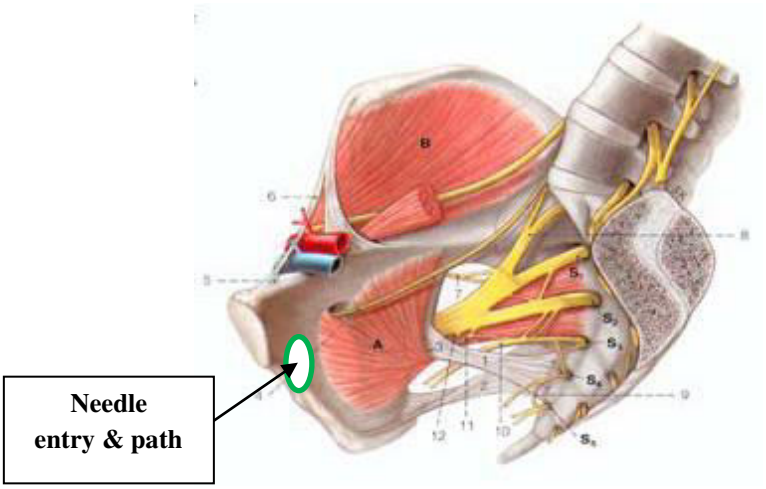
then attached to the needle and brought back through the incision The obturator vessels and nerve coming through the canal are far away from the surgical field, thus making injury very unlikely.

The TOT needle used to place the sling has minimal blind passage making it very safe, additionally neither the needle nor the sling has to be passed through the abdominal wall like traditional slings

TOT Needle Passage



demonstrates the positioning of the needle passage in the Monarc transobturator sling, made by American Medical Systems. This is just one of the types of TOT slings currently on the market.



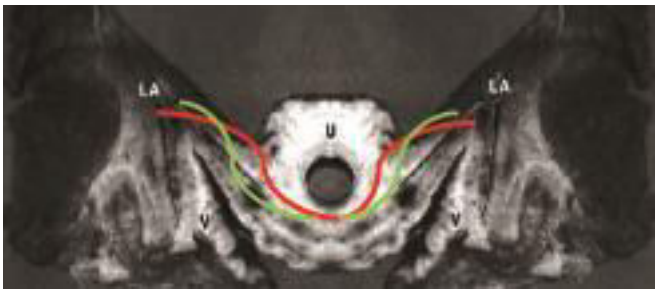
Demonstrates the passage of the needle viewed from the inside of the pelvis. Again a very safe area to pass the needle through to place the sling. This area is below the fascia of the bladder and therefore the retropubic space is never entered and the bladder remains very protected with this approach.'

TOT Mimics Normal Anatomy

The transobturator sling forms a subfascial hammock of support under the urethra. This mimics the normal position of the pubourethral ligament. This is the ligament that typically provides the backboard of support to help prevent urinary leakage with stress events such as coughing, laughing, sneezing, exercising, etc. When this ligament is damaged or stretched out secondary to childbirth, aging, chronic straining, etc, stress urinary leakage may ensue. The position of the transobturator sling reproduces the natural position of this ligament and in a sense replaces the damaged ligament with a permanent mesh tape that

provides the support needed to prevent leakage the angle of the TOT sling is much less acute than the traditional pubovaginal sling procedures such as the TVT, therefore not only is this more anatomic and natural, it also makes sense that there is less problems with urinary dysfunction such as urinary obstruction.

MRI that demonstrates the position of the TOT sling is almost identical to the natural position of the pubourethral ligament.



The TOT sling (red) is shown in this MRI to mimic the natural position of the pubourethral ligament (green) which is the ligament known to be responsible for maintaining continence.

Operative Technique

Operative technique varies with insertion method. Various procedures using similar insertion methods represent relatively similar technique.

Not only does implantation technique affect overall success of the sling, but also the type of mesh or tape implanted has a substantive effect

upon overall results. Mesh properties have been shown to have a significant effect upon local inflammatory response and ingrowth of local fibrous tissues (collagen, neovascularity) and subsequent integration of these tapes into host tissues. These differences in properties are felt to affect the risk of erosion and subsequent infection and other vaginal and local complications. There are intrinsic differences between the various meshes that have been used for the TOT approach. The ObTape and UraTape meshes are polypropylene material but are small-pore, knitted and thermally bonded with an approximately 15-mm silicone component that is immediately suburethral in location after implantation. A second-generation obturator tape developed by the Mentor Corporation is known as the Aris TOT; it has a larger 200-μm pore size that allows improved tissue ingrowth with less encapsulation. The ObTryx, TVT-O, Monarc, I STOP, and Urotex-TO are large-pore open knit polypropylene meshes. A unique obturator mesh is the BioArc, which, like the suprapubic variety, has a biologic graft material that is sutured on either end to the polypropylene tape. The biologic material actually occupies a suburethral position (deLeval, 2003 ; Delorme et al, 2003).

-- Devices and Descriptions

Company	*Brand Name*	*Mesh Material*	*Pore Size (m)*
Mentor	ObTape	Prolene, 15-mm silicone	50
	UraTape	Prolene, 15-mm silicone	50
	Aris	Polypropylene	200
AMS	Monarc	Knitted polypropylene	Large, open knit
	BioArc	Polypropylene with biologic suburethral component	Large, open knit
GyneCare	TVT-Obturator	Polypropylene	Large, open knit
Bard	Uretex-TO	Polypropylene	Large pore
Boston Scientific	ObTryx	Polypropylene with detangled suburethral segment	Large pore, >100
			>75, low weight/area
CL Medical, France	I STOP	Monofilament prolene	weave

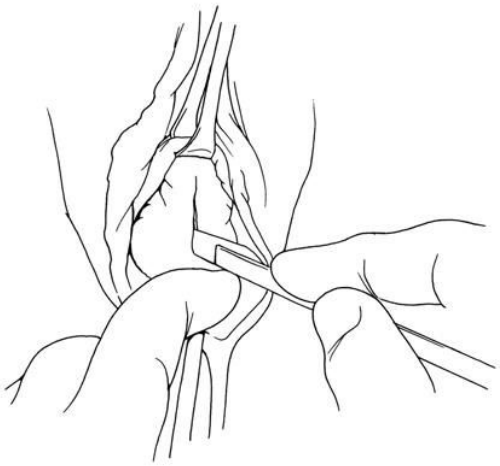
Transobturator Outside In

The patient is placed in the dorsal lithotomy position with legs in hyperflexion (120 degrees). A small vertical vaginal incision is created as with the TVT over the midurethra, and dissection is carried out laterally to the ischiopubic ramus. A puncture incision is made in the obturator

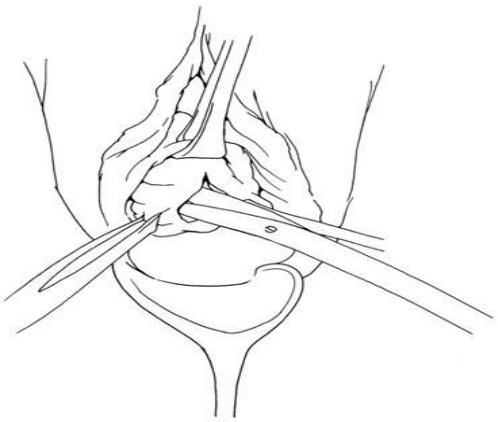
foramen at the level of the clitoris in the leg using the tunneler; the obturator membrane is perforated, at which point resistance is noted by the operative surgeon. Using the nondominant index finger and identifying the landmarks of ramus and the obturator internus muscle, the tunneler is turned in a medial orientation and advanced on the tip of the index finger and brought out through the vaginal incision.

Inspection is carried out at this point to exclude inadvertent penetration of the vaginal fornix or associated urinary structures. The synthetic material is then attached to the tunneler and brought out through the inner thigh stab wound. The procedure is then repeated on the contralateral side. Tension is set on the tape by passing a clamp between the tape and urethra such that a surgical clamp can be passed easily between these two structures. Excess material is then cut at the skin puncture site and the incisions are closed according to the surgeon's preference. This approach is used by the following devices: ObTape, UraTape, Aris TOT, Monarc, BioArc TO, Uretex-TO, ObTryx, I STOP.

Surgical Synopsis-TOT Sling



Step 1. Small incision is made under the urethra

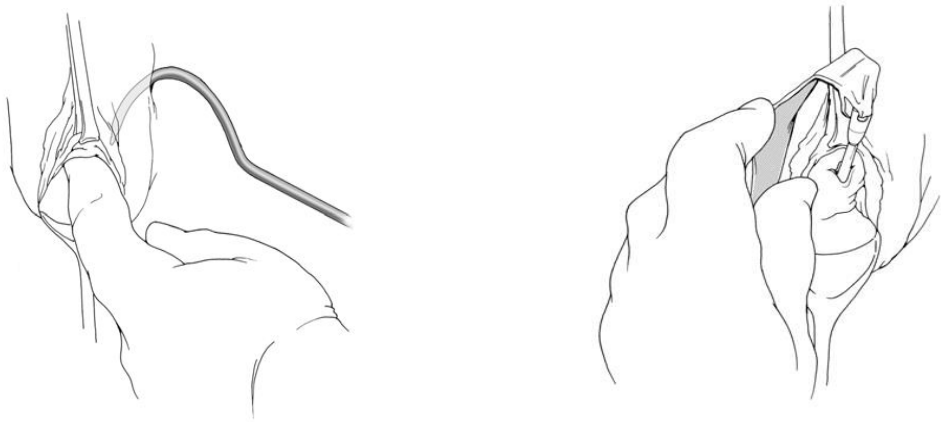


Step2. Vaginal epithelium is dissected free

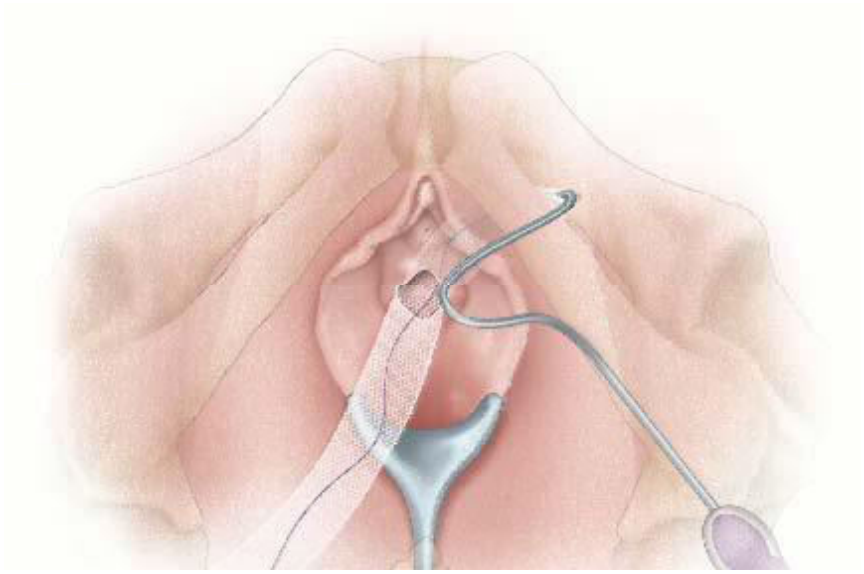
Step 3 Area of groin incision located 1 cm inferior to adductor longus tendinous insertion (level of clitoris)

Step 4: Figner placed in vaginal incision to guide needle. Needle placed in groin incision and passed.

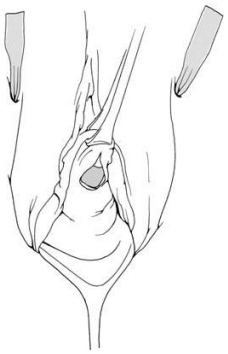
Then the needle is passed through the groin incision, through the obturator membrane and muscles and brought into the vaginal incision.

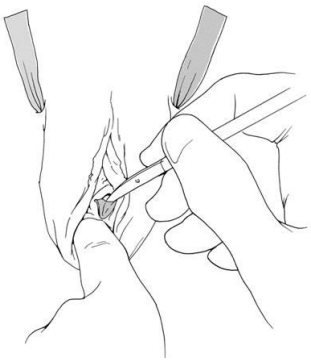


Step 5. The needle is brought through the vaginal incision and the tape is attached to the needle with the connector.



Step 6. Connected tape is then brought back through the groin incision



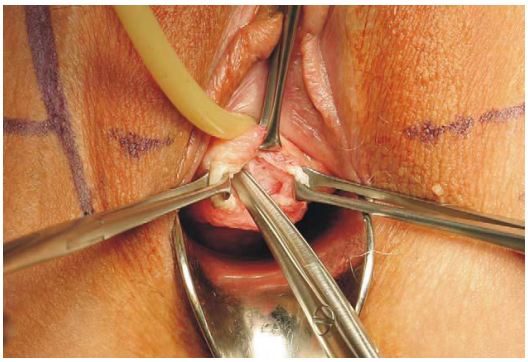


Step 7. Needle and tape is passed on the opposite side. Tape is then adjusted with an intra-operative cough test and adjusted until no leakage occurs. Excess mesh is cut off at the groin incisions and these are closed with steri-strips and vaginal incision is closed with absorbable suture

TOT inside out

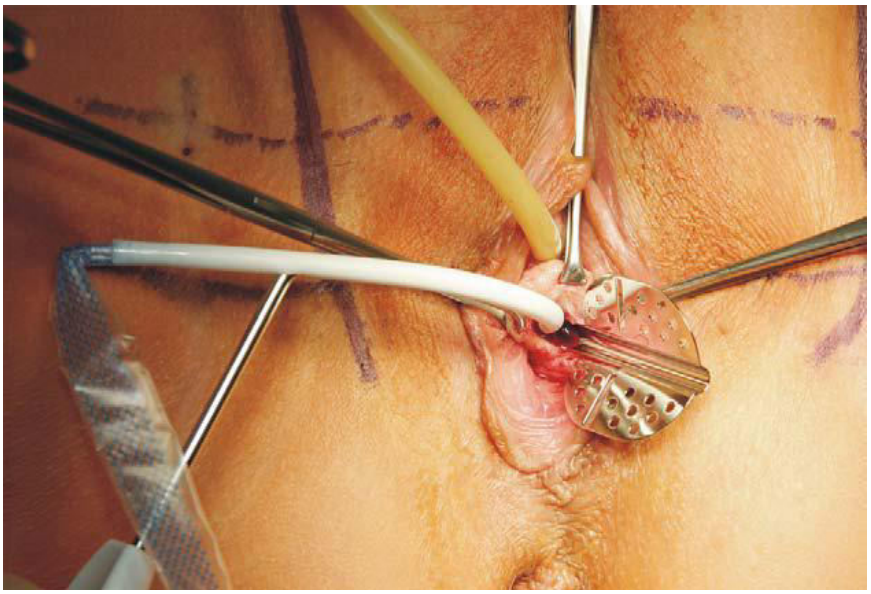
The patient is placed in the gynaecological position with thighs in hyperflexion. After the usual preparation of the patient a urethral catheter is inserted into the bladder, which is emptied. Then the local or regional anaesthesia is performed. The anterior vaginal wall is incised at a length of 1 cm and at a distance of 1 cm proximally to the urethral meatus. This step is followed by introducing fine dissection scissors through the initial dissection pathtowards the upper part of the ischio-pubic ramus on a horizontal plane with a 45degree angle to the urethral sagittal plane. Once the upper part of the ischio-pubic ramus is reached, the obturator membrane is perforated with the tip of the scissors. An introducer, with the open side of its gutter facing the surgeon, is pushed along the preformed dissection canal until it reaches and perforates the obturator membrane. The distal end of the tube mounted onto the spiral segment of

the needle is gently slipped along the gutter of the introducer in order to pass through the obturator foramen . Then the introducer is removed. After the tube has appeared at the previously determined skin exit point , the tube is pulled off from the supporting needle, which is removed. The same technique is applied at the other side. Next the ends of the tape are cut, the tape is aligned under the middle of the urethra, creating space and avoiding any tension of the tape by introducing curved scissors under the tap thus creating a small loop of 5 mm. The plastic sheaths are then removed simultaneously. The tape ends are cut in the subcutaneous layer and the incisions are closed. Postoperative indwelling catheterisation is done in regional anesthesia patients. Catheter removed on the next day.

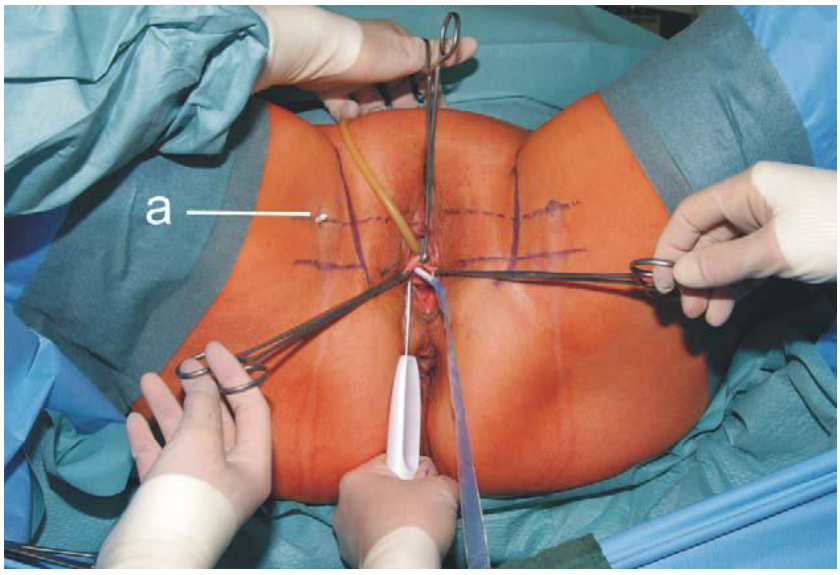


Median sagittal incision of the vaginal wall. Introduction of fine dissection scissors towards the upper part of the ischio-pubic ramus to perforate the obturator membrane.

Gynecare TVT-O special device.

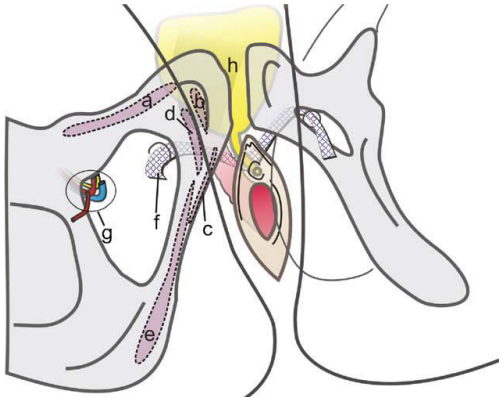


The introducer is pushed along the preformed dissection canal until it perforates the obturator membrane. The tube mounted onto the spiral segment of the needle is slipped along the gutter of the introducer so as to pass through the obturator foramen



The tube appears at the previously determined skin exit point a. The skin exit points are identified by tracing a horizontal line at the

level of the urethral meatus and a second line parallel and 2 cm above the first line. The exit points are located at the second line 2 cm outside of the genitofemoral folds.



Schematic drawing of the position of the TVT-O, important neighbouring structures and insertion points of the adductor muscles of the thigh: a, musculus pectineus; b, musculus adductor longus; c, musculus gracilis; d, musculus adductor brevis; e, musculus adductor magnus; f, tape; g, canalis obturatorius with the obturator nerve, artery and vein; h, vesicarinaria.

Results

Since the initial description by Delorme in 2001 , continence rates have been reproducibly satisfactory although follow-up has, in general, been short Reported continence rates range from 80.5% to 96% on the basis of a variety of subjective (questionnaire and quality of life single-item assessment) and objective (cough stress test, uroflowmetry, physical examination) measures.

Outcomes with Transobturator Techniques

Study	N	Follow-up	Cured/Improved/Failed	Assessment of Outcome	Patients' Age	Pure SUI	Mixed UI	ISD	Previous Anti-Incontinence Surgery	Prehysterectomy	Concomitant Prolapse Repair
Delorme et al, 2003	150 (32w/ 1 year f/u)	17 mo (13-29)	90.6%; 9.4%; 0	Cough stress test; uroflow	64 (50-81)	14 (44%)	18 (56%)	5 (15.6%)	5 (15.6%)	5 (15.6%)	0
Costa et al, 2004	183	7 mo (1-21)	80.5%; 7.5%; 12%	Cough stress test/questionnaire	56yr (29-87)	53%	27.30 %	10 (MUCP <20 cm H_2O); 5.4%	14.20%	25.70%	26 (14.2%)
de Tayrac et al, 2004	30	12 mo	90%; 3.3%; 6.7% 92% objective cure; 97% subjective;	Cough stress test/questionnaire	54.7	27	3	4	4	2 (4 previous prolapse sx)	None
Cindolo et al, 2004	80	4 mo (1-8)	96% overall satisfaction	Questionnaire/quality of life instrument	56 (39-79)	62 with + Q-tip test (78%)	22 (28%)	NA	16 (20%)	NA	None
Mellier et al, 2004	94	12.8 mo (2-20)	95% cured; 4%; 1%	Telephone based Questionnaire	58.1 (± 9.3)	94 (100 %) defined on three-grade scale	12 (13%) preop urgency	26 (28%) MUCP < 30	28 (30%)	17 (18%)	None
Queimadelos et al, 2004	47	18 mo	45/47 (96%)	Questionnaire	55 (40-69)	47	0	3	NA	NA	0
Krauth et al, 2005	604 (140 w/1 year f/u)	1-3 mo in 572; 1yr in 140	85.5% satisfied at 1yr	Subjective questioning	57	47.30 %	52.70 %	Not reported	Not reported	Not reported	8%

Efficacy

Efficacy analyses have included heterogeneous groups of patients including those in whom prior procedures failed, those who had concomitant prolapse, and those with mixed incontinence. Delorme (2001) noted that 15.6% of his patients had ISD, and Mellier and colleagues (2004) diagnosed 28% of their patients with ISD. Despite these diverse populations of patients, relatively similar results were obtained. However, no preoperative predictors of outcomes using either clinical or urodynamic parameters were established to determine overall results of these procedures. Therefore, the effect of mixed incontinence, ISD, and concomitant prolapse on surgical outcomes for this intervention are unknown. Prospective studies are needed to answer these questions.

Two nonrandomized studies have compared TOT with TVT procedures and have found no significant difference in postoperative voiding dysfunction, complications, or overall continence. There was a tendency toward more bladder injuries (10% versus 0%) and hemorrhage (10% versus 2%) with the suprapubic as compared with the TOT approach, but this did not reach statistical significance (de Tayrac et al, 2004 ; Mellier et al, 2004).

Complications of the Transobturator Approach

Despite the minimally invasive nature of these procedures, peri- and postoperative complications have been reported with a variety of techniques.

Bladder perforation appears to be the most common complication associated with any midurethral sling, with a 2% to 11% risk with the suprapubic approach. Although initial reports described the risk with the TOT approach as being negligible, the risk of bladder injury is now identified as associated with this sling insertion technique.

-- Complications Associated With TOT Techniques

Study	N	Adverse Events
Delorme et al, 2003	32	None reported
de Leval, 2003	107	One superficial vein thrombosis with abscess; ?(27/107) 15.9% transient thigh pain
Domingo et al, 2005	65	Nine vaginal mesh erosion
Costa et al, 2004	183	Three vaginal erosion; two urethral erosion; one bladder perforation; one vaginal perforation; two urethral perforation
de Tayrac et al, 2004	30	Six uncomplicated UTI; one obturator hematoma
Cindolo et al, 2004	80	One vaginal erosion with inguinal abscess

Study	N	Adverse Events
Mellier et al, 2004	94	2% intraop hemmorhage (300 mL); one urethral perforation
Queimadelos et al, 2004	47	None reported
Krauth et al, 2005	604 (140 with 1-year Follow-up	0.3% vaginal erosion; 2.5%UTI; 0.5% bladder perforation; 0.33% vaginal perforation; 2.3% perineal pain

Minaglia and colleagues (2004) reported three cases of intraoperative bladder injury while performing the TOT insertion method. They identified all injuries intraoperatively because of their utilization of cystoscopy as an adjunct to all insertion procedures. All injuries were managed with catheter placement for 1 week postoperatively, and these authors noted no complications after sling removal and reinsertion at that same setting.

To date, no case of bladder injury when performing the TOT by the inside-out approach has been reported using the TVT-O (Hermieu et al, 2003 ; Whiteside and Walters, 2004).

Domingo and coauthors (2005) reported a relatively high incidence of vaginal erosion in their series using either the ObTape or UraTape. They attributed their erosion rate to the characteristics of the particular mesh that they utilized, with the reduced pore size and other mechanical

properties of that particular material. They noted a slightly increased risk of erosion with the ObTape (15-mm silicone-coated portion), 19% versus 12% compared with the UraTape, and they felt that this was most likely due to reduction in pore size and higher degree of encapsulation. They also concluded that synthetic mesh with larger pore sizes facilitates vascular and tissue ingrowth, optimizing mesh incorporation. Tape erosion was usually managed by removal by the transvaginal approach alone or combined with the transobturator approach. They noted continence rates of 78% (despite tape removal in their series) (Domingo et al, 2005).

Postoperative voiding dysfunction has been noted to occur in 0% to 20.6% of patients following TVT (Pesschers et al, 2000). The incidence following TOT procedures varies between 2.1% and 6.7%. There appears to be no significant difference in postoperative voiding dysfunction between the TVT and TOT in nonrandomized studies (Mansoor et al, 2003 ; de Tayrac et al, 2004). Urinary retention also appears to be not significantly different. The rate of obstructive symptoms after the TOT midurethral sling varies between 1.5% and 15.6% of patients. This phenomenon is usually transient and managed with short-term intermittent catheterization, although occasionally symptoms mandate tape release. Long-term retention after TVT is a rare complication (0.6% to 3.8%) and can be expected in the TOT population as well (deTayrac et al, 2004). Removal of the tape, in most cases, improves the patient's

symptoms. There has been some anecdotal experience with downward displacement of the tape under local anesthesia to provide symptomatic relief in patients with persistent voiding dysfunction (Ozel et al, 2004).

Nonetheless, the overall risk of postoperative voiding dysfunction after the TOT is relatively low. Another bothersome complication, unique to the TOT approach, is that of postoperative leg pain. de Leval (2003) described 15.9% of patients with temporary groin pain that resolved after the second postoperative day. Similarly, Krauth and associates (2005) reported 14 cases (2.3%) of patients with postoperative perineal groin pain. They also noted it to be transient and responding to nonsteroidal anti-inflammatories in all but one case. They hypothesized that the etiology of the pain was either subclinical hematoma or a transient neuropathic phenomenon. They recommended that persistent leg pain that does not respond to conservative measures should prompt an investigation to exclude the possibility of erosion, which has been reported in several case reports (Mahajan et al, 2006).

Infection-related complications have included thigh abscess requiring drainage (Goldman, 2005) and an infected obturator hematoma also requiring exploration and drainage (Game et al, 2004).

DEFINITION OF URINARY INCONTINENCE

The International Continence Society (ICS) defines the symptom of urinary incontinence as **"**the complaint of any involuntary loss of urine"

Stress urinary incontinence. The symptom is the complaint of involuntary leakage on exertion or on sneezing or coughing. The sign is the observation of involuntary urinary loss from the urethra synchronous with exertion, sneezing, or coughing.

Urodynamic stress incontinence is noted during urodynamic testing (filling cystometry) and is defined as the involuntary leakage of urine during increases in abdominal pressure in the absence of a detrusor contraction.

Urge urinary incontinence. The symptom is the complaint of an involuntary leakage accompanied by or immediately preceded by urgency. The sign is the observation of involuntary urinary loss from the urethra that is accompanied by or immediately preceded by urgency. Detrusor overactivity incontinence is incontinence related to an involuntary detrusor contraction during urodynamics.

Mixed urinary incontinence. The complaint of an involuntary leakage of urine associated with urgency and also with exertion, effort, sneezing, or coughing.

EPIDEMOLOGY OF URINARY INCONTINENCE

Urinary Incontinence in Women

Urinary incontinence is more prevalent in women than in men, making gender itself a risk factor. prevalence ranged from 5% to 72% among community-dwelling women Hunskaar and colleagues (2005) summarized available epidemiologic data and concluded that incontinence does show increasing prevalence during young adult life (20% to 30%), a broad peak around middle age (30% to 40%), and then a steady increase in elderly women (30% to 50%). In young and middle-aged women, stress incontinence predominates and in older women mixed incontinence is most common. Over all age groups, stress incontinence is most common (49%) followed by mixed incontinence (29%) and pure urge incontinence (21%).

Risk factors for the development of urinary incontinence are age, parity, route of delivery, and obesity have been the most rigorously studied risk factors. Incontinence during pregnancy has a prevalence of 31% to 60% but it resolves in most cases. It has long been suspected that there is an association of urinary symptoms, including incontinence, with menopause.

Sphincteric Mechanism and Anatomic Support

Traditionally, the urethral sphincter is considered to be composed of two components: the internal sphincter, which represents a direct continuation of the detrusor smooth muscle, and the striated external sphincter. The principles underlying the function of a sphincter are (1) watertight apposition of the urethral lumen, (2) compression of the wall around the lumen, (3) structural support to keep the proximal urethra from moving during increases in pressure, (4) a means of compensating for abdominal pressure changes (pressure transmission), and (5) neural control. Thus, normal sphincteric function is the result of an integrated interaction among all these factors.

Management of Incontinence Caused by Sphincteric Dysfunction (Stress Incontinence).

Rehabilitative Techniques: Behavior Modification, Pelvic Floor Muscle Training, and Electrical Stimulation , conservative techniques including decreasing fluid intake, dietary and lifestyle changes, and programmed voiding by the clock have been used to treat SUI and seem to make common sense, especially in less severe and bothersome cases.

After these techniques, PFMT is next in the line of conservative management for SUI. The rationale for PFMT in the treatment of SUI is to improve strength or timing, or both, of the pelvic floor muscle contraction. Several randomized studies have shown that PFMT is better

than no treatment for women with SUI It appears that the most intensively supervised PFMT programs produce the best results, Until recently, pharmacologic treatment has been largely confined to α-adrenergic agonists and estrogens.However, a review of randomized and quasi-randomized studies by the Agency for Health Care Policy and Research (1992) and the Cochrane database suggests that there is only weak evidence to suggest that any α-adrenergic agent is better than placebo. Agents that inhibit the uptake of serotonin and norepinephrine have also been used to treat SUI. Estrogens have been used empirically to treat incontinence in women at least since the report of Salmon and colleagues

Urethral Bulking Agents

Urethral bulking agents have been used for decades to treat SUI in women. Urethral bulking agents probably work by augmenting the submucosal layer of the urethra and increasing the compressive force inward toward the urethral lumen. They have no effect on urethral mobility. A variety of substances have been reported to be safe and effective including bovine glutaraldehyde cross-linked collagen , carbon-coated zirconium beads polytetrafluoroethylene, polydimethylsiloxane elastomer, dimethyl sulfoxide in ethylene vinyl alcohol, and autologous tissues such as fat and cartilage. These agents are usually injected in a retrograde fashion using cystoscopic guidance or special delivery systems. In most cases, periurethral injections are simple office procedures, which may be accomplished with the patient under local anesthesia.

Surgery for Stress Incontinence in Females

Surgical treatment of sphincteric incontinence may be divided into sling procedures, suspension procedures (transvaginal and retropubic), and sphincter prostheses. The choice of procedure depends upon several factors, including (1) the underlying condition—degree of urethral mobility and leak point pressure, (2) available outcome data on various procedures, (3) surgeon preference and expertise, and (4) patient-related factors such as age, comorbid conditions, desire for a fast recovery, and avoidance of potential complications.

In 1997, the AUA Stress Urinary Incontinence Clinical Guideline Panel concluded that patients should be informed of the available surgical alternatives and the estimated risks and benefits of each procedure, including complications and how they would be treated.

As far as evaluating individual procedures, although much of the available data was inadequate, the panel concluded that retropubic suspensions (e.g., colposuspension) and slings were the most efficacious procedures for long-term success. These procedures had 84% and 83% cure/improvement rates at a minimum of 4 years of follow-up.

In the decade since the AUA Stress Urinary Incontinence Panel guidelines were published, midurethral tension-free synthetic slings such as the tension-free vaginal tape (TVT) have become the most popular procedures worldwide for the treatment of female SUI. Available short-

and intermediate-term prospective data suggest that these procedures give comparable results to traditional pubovaginal sling and colposuspension with cure rates in the 80% to 94% range; however, there is some concern about serious complications during the learning curve and the long-term consequences of urethral and vaginal erosions of the sling material.

The artificial urinary sphincter (AUS) has been used to treat SUI in women. Because of the high success rates of sling surgery and retropubic suspensions, the AUS is rarely used in women. In cases of mixed incontinence with a predominant stress component, successful surgical correction of stress incontinence has been shown to cure or improve urge incontinence in 50% to 93% of cases.

MATERIALS AND METHODS

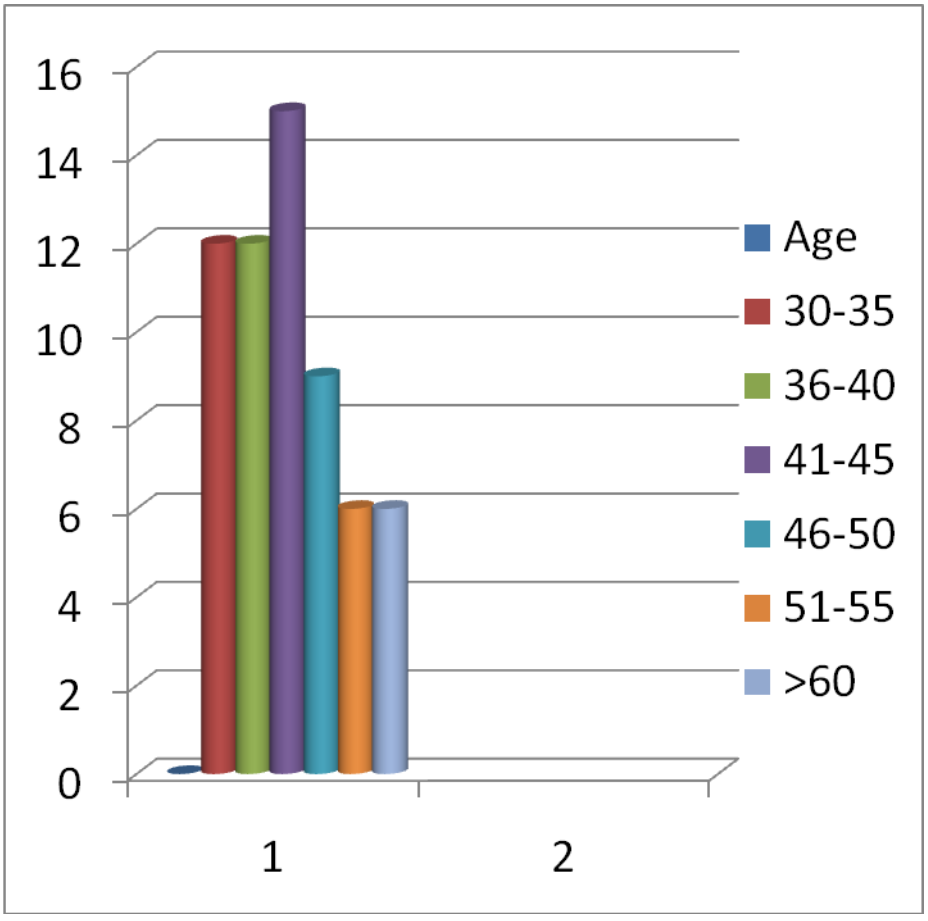
All female patients with SUI who underwent TOT procedure from September 2007 to March 2009 were included .The study was prospective study, conducted in Department of Urology, GRH and KMCH.

Total number of patients included in this study were 60.

Age distribution

30-35 years - 12; 36-40 years - 12; 41-45 years - 15;

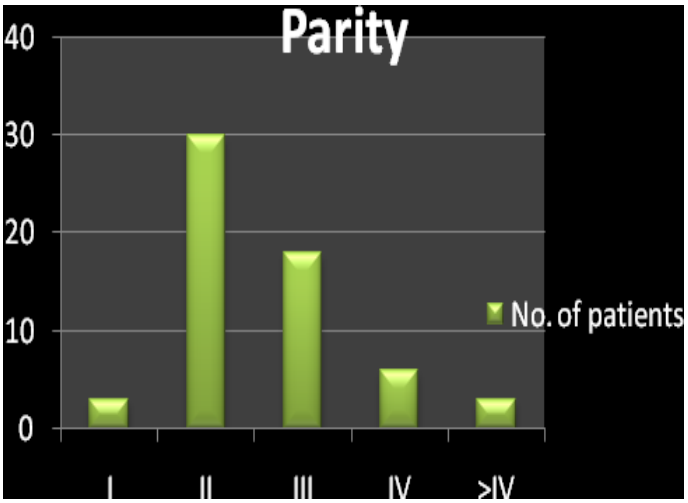
46-50 years - 09; 51-60 years -06; >60 years - 06.



All patients were evaluated with history including bladder diary pre operative. International Consulation on continence Questionnaire and Urogenital Distress Inventory. physical examination including pelvic examination, urinalysis, urodynamic studies

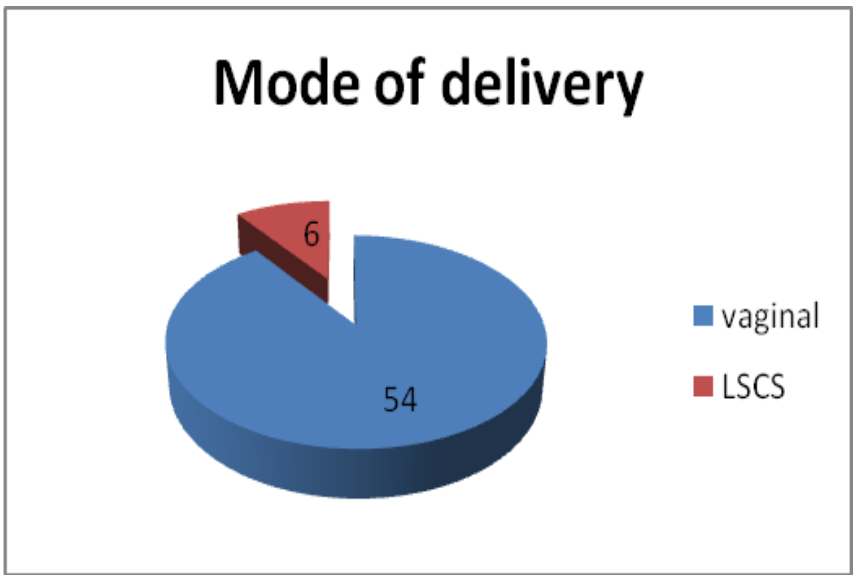
Parity

Parity	No. of Patients
1	3
2	30
3	18
4	6
> 4	3



Mode of delivery

Vaginal 54 LSCS 6



Menstrual status

Premenopausal 25 Post menopausal 35

Comorbid illness

Obesity	20	Bronchial asthma	7
Diabetes	12	Hypertension	06

International Consulation on continence Questionnorie

1. How often do you leak urine?

0 Never 1 About once a week or less often

2 Two or three times a week 3 About once a day

4 Several times a day 5 All the time

2..How much urine do you usually leak (whether you wear protection or not)?

0 None 1 A small amount 2 A moderate amount 3 A large amount

3. Overall, how much does this interfere with your everyday life?

ring a number between 0 (not at all) and 10 (a greatdeal)

0 1 2 3 4 5 6 7 8 9 10
not at all a great deal

4. When does urine leak?

Never – urine does not leak Leaks before you can get to the toilet

Leaks when you cough or sneeze Leaks when you are asleep

Leaks when you are physically active/exercising

Leaks when you have finished urinating and are dressed

Leaks for no obvious reason

Leaks all the time

Urogenital Distress Inventory

How much are you bothered by: ("X" one for each question)

	Not at all	Slightly	Moderately	Greatly
1. Frequent urination?	□	□	□	□
2. Urine leakage related to the feeling of urgency?	□	□	□	□

3. Urine leakage related to physical activity, coughing, or sneezing? □ □ □ □

4. Small amounts of urine leakage drops? □ □ □ □

5. Difficulty emptying your bladder? □ □ □ □

6. Pain or discomfort in the lower abdominal or genital area? □ □ □ □

Bladder diary

Time	Amount and type of fluid in	Time	Amount of Urine released	Comments to leakage,urge,pain,etc

Clinical features

Patient with pure stress leak 70%

Patients with SUI & UI 30%

Associated conditions

Cystocele - 4 Rectocele - 1

Fibroid uterus - 2 Vault prolapse - 3

Prolopse uterus - 2

Investigations

USG ABD KUB with post void residual urine.

Urine c/s

UDE in 18 cases with more of irritative voiding symptoms

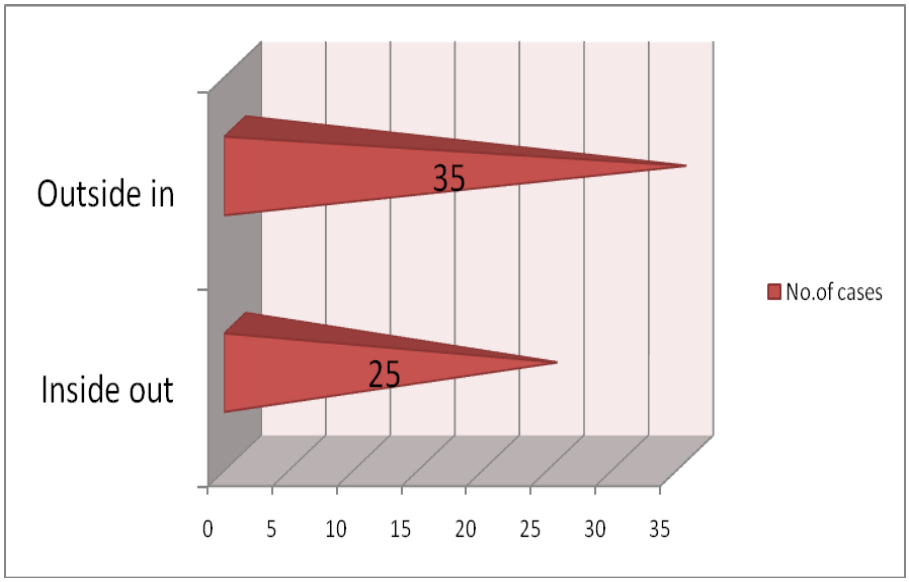
The history of SUI and bother some symptoms with the demonstration of SUI during physical examination or urodynamic studies constituted an indication for the TOT procedure.

Patients with pure urge incontinence were excluded

All patients were required to have a minimal follow-up of 12 months.

We defined the cure of SUI as the disappearance of subjective and objective SUI using Urogenital Distress Inventory and negative cough test on physical examination at 1week,6 months and 1 year.

PROCEDURE



INSIDE OUT APPROACH –TOT

Introducer

Under SA the patient is placed in dorsal lithotomy position.

Intra operative cystoscopy done

Stab incisions are created approximately 2 cm superior to the horizontal line level with the urethra and 2 cm lateral to the labial folds 2cm mid urethral incision vertically begins 1 cm from external urethral meatus.

The intoducer passes at 45 degree angle and perforate the obturator membrane and exits through the stab incision.

The procedure repeated on the opposite side

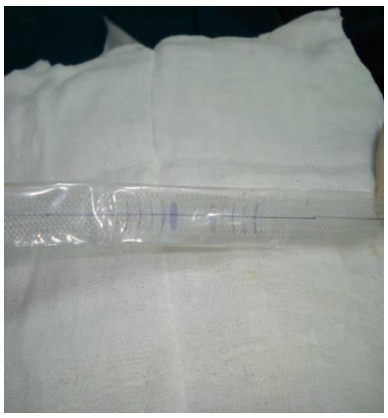
All plastic covering sheaths are then removed

Excess material excised.

Maintaining no tension upon the sling.

Vaginal incision and stab incision closed.

OUTSIDE IN APPROACH-TOT



The patient is placed in the dorsal lithotomy position.

A small vertical vaginal incision is created over the mid urethra

A puncture incision is made at the level of the clitoris in the obturator foramen

The needle passed via stab incision

The needle is turned in a medial orientation and advanced on the tip of the index finger & brought out through the vaginal incision.

Intraoperative cystoscopy done

The synthetic material is then attached to the needle and brought out through the stab wound.

The procedure is then repeated on the contralateral side.

Maintain no tension on the tape by passing a curved scissors between the tape and urethra. Excess material is then cut at the skin puncture site and the incisions are closed Foley Catheterisation done, removed on the next day.

Associated repair done simultaneously for four cystocele and one rectocele. Trial vaginal hysterectomy done for 2 fibroid uterus patients, both are about 14-16 week size, mobile uterus. 2 vaginal hysterectomy

for prolopse uterus patients.3 vault prolopse patients underwent Bilateral sacro spinous colpo suspension.

Assessment of outcome

- Cough stress test
- Subjective questionnaire

We defined the cure of SUI as the disappearance of subjective and objective SUI using in Urogenital Distress Inventory and International Consultation on continence Questionnaire score and negative cough test on physical examination after 1week, 1and 12 months.

RESULTS AND OUTCOME

50 patients under spinal anaesthesia 10 patients under IV Sedation

The mean operative time was 12 min (6–30) in cases of isolated SUI treatment.

The catheterisation time was 0.9 day (0–2).

No significant blood loss occurred in any cases

	Outcome 1 month	**Outcome** 1 year
Cured	93%	80%
Improved	4%	12%
Failed	3%	8%

At one month, 93% of patients (56/60) were cured and 3.5% (2/60) of persistent voiding dysfunction with de novo urgency or urge incontinence who needed simple follow up.

Perineal pain was observed in 1 patient (2.5%) – Lasted for 3 months

Post operative leg pain in 4 patients (7%) - Lasted for 2 to 6 months

No vaginal erosion was observed at this point.

No perioperative complications noted

2 urinary retention after removal of the catheter on post-operative day 1, one for 15 days and the other one not recovered ,patient advised splitting of the tape under mid urethra..Patient was not willing , hence self catheterisation was taught.

Two lower urinary tract infections were observed in the immediate post-operative period.

At one year, 48 of 60 patients (80%) were clinically cured from their stress incontinence and an additional 12% were also improved.

All patients answered adequately to questionnaire

Complications

Bladder injury	-	nil
Vaginal erosion	-	nil
Voiding dysfunction		
Irritative symptoms	-	two
Obstructive symptoms	-	two
Post operative perineal pain	-	one
Post operative leg pain in	-	four
Infection		
Thigh abcess	-nil	
Infected obturator hematoma	-nil	
lower urinary tract infections	- two	
Vascular,Nerve injury	-nil	

DISCUSSION

The main goal of the surgical treatment of Stress Urinary Incontinence is to restore a perfect continence with minimal morbidity. Although it is effective and easy to perform, the retropubic placement of suburethral tension-free vaginal tape has been associated with a number of peri and post-operative complications including bowel, vascular and bladder injuries , and but also dysuria, urinary retention and de *novo* symptoms. Most complications appear to be related to the blind upward vaginal passage of the trocars in the retropubic space.

The perineal approach reproduces the natural support of the urethra as clearly explained by the Hammock hypothesis of de Lancey while preserving an intact retropubic space. Delorme et al. described the trans-obturator approach as an excellent alternative to the retropubic approach that reduces complications.

In our series, no lower urinary tract injuries were seen. A Vertical incision is made in the anterior vaginal wall at the level of the mid urethra, hydro dissection facilitate easy dissection.The anterior vaginal wall is reflected off the underlying peri urethral tissue. A finger placed in the dissected vaginal space guards the urethra from the needle.

Regarding post-operative complications, the 2 urinary retention occurred most probably due to excessive tension on the tape. In case of

obstructive voiding difficulties, it is firmly recommended to release the tape within the first week. The most important issue is that the tape must be adjusted without any tension nor any contact with the urethra.

To avoid vaginal erosion, a deep incision of the Halban fascia on the midline of the vagina must be done associated with a cautious closure of the vaginal mucosa.

The non-woven polypropylene mono filament with macropores allow good fibroblasts colonisation of the tape which is essential in preventing erosion and local infection.

TOT is not associated in our experience with the risk of severe injuries confirming the interest of the perineal approach and the procedure is nowadays usually performed in day care setting . We do not have a clear explanation for the persistent perineal pain in some patients, but it was not due to obturator nerve trauma, as the distance between the zone for needle insertion and the obturator canal is approximately 3.5 to 4 cm with no neuro-vascular elements in contact with the tape and it settled with analgesics.

Pelvic Floor Musle Training is usually performed in our department as the initial approach. In case of insufficient response, or in patients with very significant leak surgery is recommended. Despite its limitations, pre-operative physiotherapy could perhaps improve long term efficacy of the surgical procedure.

We have done associated cystocele and rectocele repair simultaneously.Trial vaginal hysterectomy done for 2 fibroid uterus patients,both are about 14-16 week size, mobile uterus with minimal descent 2 vaginal hysterectomy for prolopse uterus patients.3 vault prolopse patients underwent Bilateral sacro spinous colpo suspension.

At one month, results concerning continence are excellent and comparable to other results obtained with the TVT procedure in world wide publications.

At one year, the cure rate is 80% and 12% of the patients are significantly improved Longer follow up will confirm or refute this trend. De *novo* symptoms such as urgency or urge incontinence were observed in 2 patients only This confirms data published in previous studies with TOT .These results are much lower compared with those on TVT® . Noteworthy pre-operative urgency and urge incontinence disappeared in 97% of cases without anticholinergic drugs. The trans-obturator route considerably limits de *novo* symptoms, probably due to the horizontally placed tape below the urethra with no tension between the two ischiopubic rami.

Nevertheless, questionnaire shows excellent results regarding the different dimensions scores. This is very important when assessing functional results.

Complications associated with TOT-other studies

Study	N	Adverse Events
▪ Delorme et al, 2003	32	None reported
▪ Domingo et al, 2005	65	Nine vaginal mesh erosion
▪ de Tayrac et al, 2004	30	6 uncomplicated UTI; 1 obturator hematoma
▪ Cindolo et al, 2004	80	One vaginal erosion with inguinal abscess
▪ Mellier et al, 2004	94	2% intra op haemorhage (300 ml); one urethral perforation
▪ Queimadelos et al, 2004	47	None reported

Comparision with other studies

Study	N	Age	Follow up	Cured	Improved	Failed	Assessment of out come
Delorme et al,2003	150	50-81	17 months	90.6%	9.40%	0	cough stress test. uroflow
de Tayrac et al, 2004	30	54.7	12 months	80.5%	7.50%	12%	cough stress test. questionaire
mellier et al, 2004	94	58.1+/-9.3	12.8 months	95%	4%	1%	questionaire
Our study	60	30-63	1-12 months	80%	12%	08%	cough stress test. questionaire

CONCLUSION

- Trans obturator tape is a simple, effective and safe procedure for the treatment of female stress urinary incontinence confirmed after 1 year of follow-up.
- It offers increased safety.
- The post-operative morbidities associated with this technique are minimal and manageable.
- Evaluation of the results after a longer follow-up period is needed.
- The learning curve is simple and easy.

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MASTER CHART

Sl No	Name	Age	Sex	IP No	Presentation	Diagnosis	Urine c/s	USG	UDE	Procedure	Outcome
1	Rani	30	F	5372	Stress leak	SUI	NG	Normal		TOT-Outsidein	Cured
2	Poongothai	36	F	5674	Stress leak+UI	MI	NG	Normal	Leak demonstrared	TOT-Outsidein	Cured
3	Padma	41	F	6012	Stress leak	SUI	NG	Normal		TOT Outsidein	Cured
4	Jeya lakshmi	46	F	6298	Stress leak	SUI	Proteus	Normal		TOT Outsidein	Failed
5	Anjalai	32	F	6987	Stress leak+UI	MI	E.coli	Normal	Leak demonstrared	TOT Outsidein	Improved
6	Kannagi	38	F	7098	Stress leak	SUI	NG	Normal		TOT Outsidein	Cured
7	Indumathi	44	F	8765	Stress leak	SUI	NG	Normal		TOT Outsidein	Cured
8	Fathima	50	F	9125	Stress leak	SUI	NG	Normal		TOT Outsidein	Cured
9	Valarmathi	34	F	9543	Stress leak	SUI	NG	Normal		TOT inside out	Cured
10	Eswari	37	F	10234	Stress leak	SUI	NG	Normal		TOT inside out	Cured
11	Kannika	42	F	10765	Stress leak+UI	MI	NG	Normal	Leak demonstrared	TOT Outsidein	Cured
12	Jasmine	51	F	11256	Stress leak	SUI	NG	Normal		TOT inside out	Cured
13	Thayammal	49	F	11754	Stress leak	SUI	NG	Normal		TOT Outsidein	Cured
14	Chitra	35	F	12478	Stress leak	SUI	NG	Normal		TOT inside out	Cured
15	Navamani	37	F	13012	Stress leak+UI	MI	NG	Normal	Leak demonstrared	TOT-Outsidein	Cured
16	Kalyani	43	F	13653	Stress leak	SUI	NG	Fibroid Uterus		TOT inside out	Improved
17	Vijayalakshmi	53	F	13978	Stress leak	SUI	NG	Normal		TOT-Outsidein	Improved
18	Shanthi	33	F	14238	Stress leak+UI	MI	NG	Normal	Leak demonstrared	TOT-Outsidein	Cured
19	Lalitha	40	F	14295	Stress leak	SUI	NG	Normal		TOT inside out	Cured
20	Panjali	44	F	14839	Stress leak	SUI	NG	Normal		TOT-Outsidein	Cured
21	Valli	47	F	15378	Stress leak	SUI	NG	Normal		TOT inside out	Cured
22	Ramya	32	F	15289	Stress leak+UI	MI	NG	Normal	Leak demonstrared	TOT-Outsidein	Cured
23	Andal	39	F	15673	Stress leak	SUI	E.coli	Normal		TOT inside out	Cured
24	Muniyammal	45	F	15987	Stress leak	SUI	NG	Normal		TOT-Outsidein	failed
25	Porkodi	31	F	16342	Stress leak	SUI	NG	Normal		TOT inside out	Cured
26	Angammal	36	F	16543	Stress leak+UI	MI	NG	Normal	Leak demonstrared	TOT-Outsidein	Cured
27	Pachaiammal	55	F	16598	Stress leak	SUI	NG	Normal		TOT inside out	Cured
28	Noorjahan	61	F	17123	Stress leak	SUI	NG	Normal		TOT-Outsidein	Improved
29	Suseela	63	F	17298	Stress leak+UI	MI	NG	Normal	Leak demonstrared	TOT-Outsidein	Cured
30	Backiyam	37	F	17689	Stress leak	SUI	NG	Normal		TOT inside out	Cured
31	Geetha	30	F	894820	Stress leak+UI	MI	NG	Normal	Leak demonstrared	TOT-Outsidein	Improved
32	Parvatham	43	F	895690	Stress leak	SUI	NG	Normal		TOT inside out	Cured
33	Vani	46	F	896785	Stress leak+UI	MI	NG	Normal	Leak demonstrared	TOT-Outsidein	Cured

Sl No	Name	Age	Sex	IP No	Presentation	Diagnosis	Urine c/s	USG	UDE	Procedure	Outcome
34	Latha	40	F	897213	Stress leak	SUI	NG	Normal		TOT-Outsidein	Cured
35	Shakilabanu	32	F	897779	Stress leak+UI	MI	NG	Normal	Leak demonstrared	TOT inside out	failed
36	Anita	44	F	898654	Stress leak	SUI	NG	Normal		TOT-Outsidein	Improved
37	Jenneth	41	F	898765	Stress leak	SUI	NG	Normal		TOT inside out	Cured
38	Sangeetha	33	F	899345	Stress leak+UI	MI	Klebsiella	Normal	Leak demonstrared	TOT-Outsidein	Cured
39	Nirmala	39	F	902345	Stress leak	SUI	NG	Normal		TOT-Outsidein	Cured
40	Abirami	45	F	903786	Stress leak	SUI	NG	Fibroid Uterus		TOT-Outsidein	Improved
41	Mangai	48	F	904378	Stress leak	SUI	NG	Normal		TOT inside out	Cured
42	Mariammal	57	F	904987	Stress leak	SUI	NG	Normal		TOT-Outsidein	Cured
43	Perumayammal	44	F	905615	Stress leak+UI	MI	NG	Normal	Leak demonstrared	TOT inside out	Cured
44	Sridevi	35	F	906435	Stress leak	SUI	NG	Normal		TOT inside out	Cured
45	Kalarani	40	F	907432	Stress leak+UI	MI	NG	Normal	Leak demonstrared	TOT-Outsidein	Cured
46	Vijaya	43	F	907865	Stress leak	SUI	NG	Normal		TOT inside out	Cured
47	Damayanthi	64	F	908234	Stress leak	SUI	NG	Normal		TOT inside out	Cured
48	Shanmugapriya	61	F	909876	Stress leak	SUI	NG	Normal		TOT-Outsidein	failed
49	Anuradha	47	F	912347	Stress leak	SUI	NG	Normal		TOT inside out	Cured
50	Gokila	31	F	913678	Stress leak	SUI	NG	Normal		TOT inside out	Cured
51	Priya	37	F	914589	Stress leak+UI	MI	NG	Normal	Leak demonstrared	TOT-Outsidein	Improved
52	Sitalakshmi	41	F	914987	Stress leak	SUI	NG	Normal		TOT-Outsidein	Cured
53	Shanthana lakshmi	50	F	915324	Stress leak	SUI	NG	Normal		TOT inside out	Cured
54	Manimegalai	46	F	915786	Stress leak+UI	MI	NG	Normal	Leak demonstrared	TOT-Outsidein	Cured
55	Kowsalya	43	F	916875	Stress leak	SUI	NG	Normal		TOT inside out	Cured
56	Sharmila	54	F	917654	Stress leak+UI	MI	NG	Normal	Leak demonstrared	TOT-Outsidein	Cured
57	Kalpana	61	F	918564	Stress leak	SUI	NG	Normal		TOT inside out	Cured
58	Shifa	43	F	919765	Stress leak+UI	MI	NG	Normal	Leak demonstrared	TOT-Outsidein	Cured
59	Jeyanthi	55	F	919876	Stress leak	SUI	NG	Normal		TOT inside out	Cured
60	Mookkammal	63	F	921456	Stress leak	SUI	NG	Normal		TOT-Outsidein	Cured

PATIENT PROFORMA

Age 20-30

31-40

41-50

51-60

>60

Duration of symptoms

<3 months

4-12 months

1-3 years

>3 years

Presenting complaint

Leakage with cough,sneeze, lifting heavy objects

Leakage with the desperate desire to void

Leakage without warning

Frequency

Urgency

Nocturia

Burning Micturition

Haematuria

Strain to void

Intermittent (stop-start)

Flow is prolonged

Post void dribble (Pt getsup from the toilet thinking she is empty but urine tricklesout as she walks away)

Need to revoid

History for prolopse uterus

Something coming down in the vagina

Anal incontinence if present for flatus or faeces

Any duspareunia

H/O Drug therapy

Alpha Blockers (provokes Stress Incontinence)

Diuretic therapy

Chronic Dry Cough with ACE inhibitor provoke SI

Psychotrophic Drugs (Lithium,Serotonin reuptake inhibitors) overflow incontinence

Previous surgical history in related to incontinence

History for bacterial cystitis

->3 proven episodes of cystitis in last 5 years

-Any investigation to exclude stone

-cystoscopy

History for Interstitial cystitis

-Supra pubic pain worse with full bladder, relieved by voiding,frequency 10 – 20 times,5-10 nocturia

Co morbid conditions

COPD/Brochial Asthma

HT/Diuretics

Obesity

Menstruating/Menopausal

Obstetric Details

Duration of labour Normal or prolonged

Weight of the baby <3 kg,3-4kg,>4 kg

Mode of delivery Labour normal

LSCS after prolonged labour

LSCS

PN complications PPH

CPT

Frequency Volume Chart

Date/Time	Fluids takenin	Amout of urine passed	When you leak

How bad is the problem

How often do you leak urine(All the time,daily,2-3 times weakly,weakly or less).

How much urine do you leak(A little bit,moderate amount,large amount).

How much does it affect your daily life(on a scale of 1-10)

Clinical Examination

Abd

Any mass that increase intra abd pressure may cause incontinence

Inspection of vulva

Healthy pink skin like appearance-pre menopausal women

Shiny glistening red epithelium-Post menopausal atrophy

Cracks or fissure like lesion bet labia majora &minora

Urethral caruncle (indicates oestrogen deprivation)\

Any cystocele or Rectocele

Perineum for signs of post obstetric perineal deficiency

Stress leak

Part the labia and ask the patient to void

Stress leak -Short spurt of urine that occurs during the height of the cough effort

Urge leak - An instant after the cough but a large prolonged urine leak is seen due to detrusor contraction

Speculum examination

Sims speculum examination

Bimanual examination, palpate the urethrae

Pelvic Floor muscle Contraction

Grading 0-Nil

1-Muscle on stretch-flicker

2-Week squeeze with 2 second hold

3-5 second hold

4-7 second hold

5-10 second hold

PR

Basic Neurological Examination