

Midurethral sling procedure (Tension free Vaginal Tape –Obturator) in the management of female stress Urinary incontinence

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Abstract —Urinary incontinence is a common condition affecting 20 to 40% of older women. Sufferers tend to become social recluses, not wanting to socialize for fear of embarrassment and ridicule. Tension-free vaginal tapes have revolutionized the treatment of female Stress urinary incontinence. The aims of this prospective observational study were to determine efficacy and post operative complications of Tension free vaginal tape – Obturator (TVT-O) after minimum one year follow up. Between March 1st 2006 and January 1st 2009, 30 patients with clinical diagnosis of moderate to sever SUI and mixed with predominant Stress incontinence who fulfill the inclusion and exclusion criteria underwent TVT-O Procedure. Preoperative and post operative evaluation included physical examination, post void residual measurement, post operative complications, severity of urinary stress incontinence, and quality of life questionnaires (QoL). 50% of women were menopause, their mean age was 52±11.105 year, their mean body weight was 81.066±13.59 kg, and their mean parity was 5.53±2.58. Three cases had anterior vaginal wall prolapse (grade 2 and 3 cystocel), anterior colporrhaphy was done for them before TVT-O procedure. No significant intra and post operative complications were observed. One year minimum follow up revealed a highly significant difference between pre and post operative stress incontinence severity grades and QoL scale scores (P value <0.001). The TVT-O procedure is a safe and efficient treatment of female SUI, with a high cure rate after a minimum one year follow up and a low post-operative complications and no risk to intra-abdominal organ injury.

Keywords- Female stress incontinence, Quality of life, sub urethral sling, TVT-O, IIQ- Short Form 11Q-7

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I. INTROUCTION

Urinary incontinence (UI) is a very common condition, especially in Women, and affects almost all aspects of everyday life, influencing not only affected individuals but also their families [1]. The two most common types of urinary incontinence are stress urinary incontinence (SUI), the involuntary loss of urine resulting from increased abdominal pressure (such as with a cough or Valsalvas maneuver), and the urge incontinence, the involuntary loss of urine after an unwanted contraction of the detrusor muscle. Some patients have mixed incontinence with both types of condition [2]. The prevalence of UI increases with age, with a typical rate in young adults ranging from 20-30%, reaching 30-40% around middle age, with a further increase in older age 30-50 % [3]. Stress urinary incontinence (SUI) is the predominant type of incontinence affecting approximately 50% of incontinent women [4].

Despite its common occurrence and often seemingly obvious causes, female urinary incontinence requires a thorough and thoughtful evaluation for its proper diagnosis and treatment. With rare exceptions, urinary incontinence is the result of failure of the sphincter mechanism to resist bladder pressure encountered during daily activities. This may be the result of sphincter failure, over activity of the bladder detrusor muscle or both. In uncomplicated cases, the diagnosis is usually based on an evaluation in the office. Urodynamic and cystoscopic study may be helpful in complex, resistant and recurring cases of urinary incontinence of any cause. Most cases of incontinence may be classified as stress, urge or mixed urinary incontinence. Treatment of stress urinary incontinence focuses on supplementing the urethral continence mechanisms, particularly the urethral supports and periurethral striated muscle function [5].

The frequency of both types of urinary incontinence increase with age, with peaks in prevalence around menopause and after the age of 65 years [1], [6]. Obesity and multiparity are recognized risk factors for stress incontinence. Even so, many nulliparus teenage women, especially athletes, have episodes of stress incontinence at time s of increase physical activity [7]. The degree to which incontinence bothers a woman may vary, depending on her activity level. Many women adjust their activity to reduce the frequency of leakage, which may adversely affect other health and quality-of-life measures [2].

Stress urinary incontinence is a common condition affecting approximately 20% of adult women causing substantial individual (quality of life) and economic (119 million Euro/year spent on incontinence pads in the Netherlands)

burden. Pelvic floor muscle training is regarded as first line treatment, but only 15-25% of women will be completely cured. Approximately 65% will report that their condition improved, but long term adherence to treatment is problematic. In addition, at longer term (2-15 years) follow-up 30-50% of patients will end up having surgery [8].

Over 200 surgical procedures to treat stress urinary incontinence have been reported in the medical literature [9]. In the past decade, surgery of (SI) has made a huge progression with the introduction of minimally invasive surgical techniques. The Tension-free Vaginal Tape (TVT) and Tension-free Vaginal Tape Obturator (TVT-O) are the most frequently performed procedures. In both cases, a small incision is made under the mid urethra through which a polypropylene mesh is placed without tension under urethra. If abdominal pressure increases, the urethra is compressed to the tape and incontinence is restored. An advantage of these procedures is that they can be performed in day-care [10]. However, although minimal invasive, stress incontinence surgery carries a risk of complications. Major complications are extremely rare with an incidence of 0.007% for bowel perforation and 0.012% for vascular injury [11]. The most common complication of bladder perforation during the procedure (approximately 3-6% for TVT and below 1% for TVT-O) is easily recognized during the procedure itself and carries no long-term morbidity. Adverse outcome of surgery in terms of the development of new symptoms may be a bigger concern. Voiding difficulties and symptoms of an overactive bladder are reported in 6% of cases. TVT procedure introduced by Ulmsten [12] is now considered by many surgeons to be the gold standard surgery for female SUI [13]. This surgical technique, which uses retro pubic route for the insertion of the tape, has been shown to be effective over a period of 7 years, with objective and subjective cure rate of 80%. Although the TVT procedure appears to be safe and efficacious at long-term, complications resulting from the penetration of the surgical device into pelvic organs, nerves, and vessels have been reported [14].

In 2001, while in search of a simplified version of the procedure, Delorme [15], described the TOT technique (trans-obturator-tape). The main advantages of such technique are more anatomical position of the tape than with TVT, the fact that needles do not pass through the retro pubic space, it entails less operative blood loss, do not involve abdominal incisions, is associated with a decreased risk of urinary bladder and intestinal injuries and does not require cystoscopy. Thus, TOT merged as an easier to perform and faster to achieve surgical technique when compared to TVT [16].

In 2003, Jean de Leval during an attempt to further simplify the procedure, described TVT-O. The TVT-O procedure is even closer to the concept of minimally invasive surgery than its predecessors TVT and TOT [17]. It is advocated that this inside-out approach results in a more precise placement of the tape and this may further minimize the potential risks of perforation of the bladder and urethra that may happen with outside-in approach [18].

II. OBJECTIVES

The aims of the study were to assess:

- 1-The Subjective and objective improvement of urinary incontinence after TVT-O sling operation.
- 2-The Subjective improvement in quality of life.
- 3-To determine early and late complications associated with TVT-O procedure.

III. PATIENTS AND METHODS

Between March 1st 2006 and January 1st 2009, 30 women with moderate to severe pure stress or mixed urinary incontinence with no previous anti-incontinence surgery, were enrolled in the study. TVT-O surgery done for them in Maternity teaching hospital, Erbil city, North of Iraq, Kurdistan region. This procedure conducted in our hospital for the first time and it is the only area in Kurdistan region that this type of operation was performed. All the patients gave verbal consent.

Because women may be reluctant to talk about their incontinence, clinicians should routinely ask their female patients if they are bothered by their incontinence symptoms [19].

Reasons for not seeking treatment include the perception that incontinence is not sufficiently severe to warrant treatment, embarrassment, the belief that incontinence is an inevitable consequence of child-bearing and/or aging, lack of knowledge about the different treatment options that are available [20].

All women with urinary incontinence (pure stress or mixed) who were offered a surgical treatment were candidates with the following criteria:

Age between 32-80 years, clinical diagnosis of urinary incontinence, positive cough test, and residual bladder of more than 100ml, grade 2 and 3 cystocele, a verbal consent for the operation. Contraindications to anesthesia, pregnancy, neurogenic bladder, or active urinary or vaginal infection were excluded from study.

The procedure was explained to the patients and a formal consent was obtained from all the participants.

Preoperative evaluation included detailed history, age, weight, parity, menopausal state, hormone replacement therapy, previous hysterectomy or genital prolapse surgery, day time frequency/ nocturia, the patient asked about how many times accidental leak of urine onto the clothing or under wear or pad in the last week, symptoms of SUI during coughing, sneezing lifting, exercise. Symptoms of urgency (sudden strong desire to pass urine that the patient couldn't reach the toilet in time).

As part of the initial evaluation, patients were asked to complete a 2-to3-day urinary diary (Fig 1), in which they document frequency of leakage episodes, amount, and types of fluids being consumed. Evaluation of stress incontinence using such a diary is often helpful to clinicians for two reasons. First, compared to simple interview questions, the diary is a more reliable diagnostic tool for establishing the frequency and type of incontinence episodes. Second, the diary can help to tailor behavioral management [21].

Time	Urinate in toilet	Leaking Accident	Reason for Accident	Fluid Intake (type,
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				amount)
6 a.m.				
7 a.m.				
8 a.m.				
9 a.m.				
10 a.m.				
11 a.m.				
12 noon				
1 p.m.				
2 p.m.				
3 p.m.				
4 p.m.				
5 p.m.				

INSTRUCTIONS

1. In the 1st column mark an (X) every time you urinate into the toilet.
2. In the 2nd column mark an (X) every time you accidentally leaked urine.
3. If an accident occurred, indicate the reason or circumstances surrounding the accident in the third column. For example, "coughed", "bent over", "sudden urge".
4. Under "Fluid Intake" describe the type (coffee, tea, apple juice, etc.) and Amount (1/2 cup, 1 quart, 8 oz., etc) of fluid you consumed.
5. Circle the time when you got up in the morning and when you went to bed.
6. Record the number and type of pads used.
7. Under "Notes" write any additional information you would like to include. For example, type and dose of medication you may be on for your urinary incontinence.

Fig.1 . Example of a urinary diary.

The urodynamic test was not used in this study because it is not available in our locality, beside the sensitivity, specificity and predictive value for diagnosis and predicting outcome in female urinary incontinence has not been proved [10].

Affection of involuntary urine loss on the quality of life (activities, relationships, feelings, emotional health) was assessed using Incontinence Impact Questionnaire- Short FormIIQ-7(Table 1), item responses are signed values of 0 for (not at all),1 for slightly, 2 for (moderately), and 3 for (greatly). The average score of items responded to is calculated. The average, which ranges from 0 to 3, is multiplied by 33 1/3 to put scores on a scale of 0 to 100, with higher scores indicating greater impact on daily life.

Table 1
Incontinence Impact Questionnaire- Short Form 11Q-7

	Not at all	Slightly	Moderately	Greatly
(1)Ability to do household chores (Cooking, housecleaning, laundry) ?	0	1	2	3
(2)Physical recreation such as walking, swimming, or other exercise?	0	1	2	3
(3)Ability to travel by car or bus more than 30 minutes from home	0	1	2	3
(5)Participation in social activities outside your home	0	1	2	3
(6)Emotional health (nervousness, depression , etc.)	0	1	2	3
(7)Feeling frustrated	0	1	2	3

Item 1 and 2= physical activity, Item 3 and 4=travel, item 5= social/ relationships, item 6 and 7= emotional health [23]

While low scores reflected minimal distress or impact on patients quality of life.

General examination and investigation was done for all patients, most of them being menopause to determine fitness for anesthesia. Cardiovascular system, respiratory system, urinary tract system. Vulval examination done to exclude active vulvovaginal infection and if it was present treatment was prescribed for them after the results of culture and sensitivity was obtained. For all menopausal ladies Vagifem® 10mcg (Estradiole vaginal tablets), were prescribed for them to use it before and after the procedure as a part of improving the vulvovaginal area due to estrogen deficiency. Vagifem® is a registered trade mark of Novo Nordisk FemCare AG.

Physical examination of the cases includes a stress cough test, urinalysis, the severity of urinary incontinence was classified according to the Stamey incontinence score (grade 0, continent; grade 1, loss of urine with sudden increases in abdominal pressure (coughing, sneezing, laughing); grade 2, leaks with lesser degrees of physical stress, such as walking, standing erect from a sitting position, or sitting up in bed; grade 3, total incontinence— urine is lost without any relation to physical activity or position) [22].

Cystocele was graded using the Baden-Walker halfway system [23] as shown in Table 1: cases with grade 2 and 3 cystocele, anterior colporrhaphy done for them before application of the TVT-O sub urethral sling.

TABLE I
BADEN – WALKER HALFWAYSESTEM FOR
GRANDING PROLAPSE

Grade 0: Normal position for each respective site
Grade 1: Descent halfway to the hymen
Grade 2: Descent to the hymen
Grade 3: Descent halfway past the hymen
Grade 4: Maximum possible descent for each site.

The International Continence Society (ICS) define UI as “any leakage or involuntary loss of urine”. “Urge UI is the complaint of involuntary leakage accompanied by or immediately preceded by urgency”. Stress UI is the complaint of involuntary leakage on effort, exertion, sneezing, or coughing. Mixed UI is the complaint of involuntary leakage associated with urgency as well as with exertion, effort, sneezing, or coughing [24].

All operations were performed under general anesthesia with the patients in lithotomy position with thighs flexed at a 120° angle. After the vagina was prepared with povidium, folly's catheter gage 16 was inserted to the bladder and fixed there. The TVT-O (Gynecare, Johnson and Johnson, Spreitenbach, Suisse) procedure were performed in accordance with the technique described by de Leval [], where a paraurethral dissection plane is made from a suburethral incision to the obturator foramin. The obturator membrane is punctured, an inducer is passed along the passage made, the spiral trocar of the TVT-O device is guided along the introducer through the obturator foramin. The trocar of the TVT-O device is guided along the introducer through the obturator membrane before being rotated out through the groin incisions (made at plane 2 cm above the urethral meatus at a point 2cm lateral to labial crural folds). Once the trocar is pulled through and the correct tension has been achieved, the plastic cover over the tape is removed. An instrument between the tape and urethra ensures that the mesh remains tension free. Lateral vaginal fornices are checked for breaches in the vaginal epithelium at the conclusion of the procedure to avoid paraurethral vaginal mesh erosion.

The mesh end in the inner aspect of the thigh was cut there and the exit point was covered with a small piece of plaster, while the vaginal skin was sutured using 2 or 3 interrupted 3/0 vicryl suture material.

Operative time estimated from incision start time to closure stop time. Intra operative bleeding volume was calculated by weighing blood stained gauzes.

Per-operative complications (vaginal perforation, haemorrhage, vesical or urethral perforation) and early post operative complications (inner aspect of thigh pain, haematoma, dysurea, infection) and late post operative complication (perineal pain, dysparonia, and de novo urge incontinence) were collected in the charts.

Follow up evaluation done at 1, 6, and 12 months, and yearly thereafter included:

In all these visits patients were assessed by history taking and Physical examination for any signs of infection , recurrence of SUI symptoms , any other urinary symptoms , examination also done for any evidence of mesh erosion. Physical examination done with a cough test, post void

residual volume (PVR) measurement, and scoring of the severity of incontinence symptoms, QoL with Incontinence impact Questionnaire-Short form 11Q-7.

Cough test done with the patients in the supine and standing positions with a comfortably full bladder.

Surgical outcome was evaluated by the cough stress test and symptoms of incontinence. The out come was divided into 3 groups, including cured, improved, and failed. The patients were regarded cured of SUI if they had a negative cough test result and there were no reports of urine leakage during stress (objective and subjective cure). Patients were considered to have improved if they had no leakage on the cough test but may have had some occasional leakage during stress. In patients who did not full fill these criteria regarded as failed.

Data for all patents including the study were collected using a specially designed questionnaire that consisted of three parts. The first part was designed to involve the patients demographic characteristics and obstetric history: (age, parity, menopausal state , years of menopause, sexual activity, use of any hormone replacement therapy, history of any gynecological operation like anterior colporrhaphy or hysterectomy), and types of incontinence after history taking and physical examination.

The second part of the questionnaire involved severity of stress urinary incontinence assessed by Stamy incontinence scoring, and was completed twice before and after the procedure (TVT-O)

The third part involved assessment of quality of life using IIQ-Short Form IIQ-7, and this questionnaire was also filled twice before and after the operation.

Sexual intercourse was forbidden for 2 months after the operation for sexually active women in the study group as instructed by the company.

The trial has been approved by the scientific committee in department of obstetrics and Gynecology, medical college-Hawler medical university, and by the scientific department of maternity teaching hospital.

Data analysis was performed using the SPSS (Statistical Package for Social Science, Version 15). Parameters were given as frequency distribution, mean \pm SD, and the comparison between pre and post operative readings regarding severity of SUI and QoL scores were done using t.test. P value \leq 0.05 regarded statistically significant.

IV. RESULTS

Between March 1st 2006 and January 1st 2009, 30 women with clinical diagnosis of moderate to sever pure SUI or Mixed with predominant SUI, who fulfilled inclusion and exclusion criteria were enrolled in the trial and underwent TVT-O procedure.

The characteristics of the women who were enrolled in the study are summarized in Table 2. 50% of the women were menopause and were not on hormone replacement therapy.

Their mean age of patients was 52 \pm 11.1years (range 32-78), their mean body weight was 81.066 \pm 13.59 kg (range58-125), mean parity was 5.53 \pm 2.589 (range 0-12) placed them in a grand multiparus category. The indication for TVT-O surgery was stress urinary incontinence with pure stress

urinary incontinence in 26(86.7%), and mixed urinary incontinence in 4 women (13.3%). TVT-O was the only surgery in 26 patients and was associated with another surgical intervention (anterior colporrhaphy) in 3 women, 2 of them had grade 2 cystocele and one case with grade 3, all had concurrent anterior colporrhaphy before the application of TVT-O sling operation. All the cases had no any history of previous gynecological surgery except one case who presented with stress urinary incontinence following abdominal hysterectomy for benign abnormal uterine bleeding.

The mean operation time and bleeding during operation are summarized in Table 3. The range blood loss during operation was (25-200ml), the mean blood loss was 13.3 ± 12 ml, and the mean operation time were 11.2 ± 2.33 minutes for all cases including the anterior repair for cases of cystocele.

No significant intraoperative complications were observed, 3 patients (3.3%) complained of pain in the inner aspect of thigh and 1 patient (3.3%) with superficial dyspareunia, post operatively both were managed with simple analgesia and the pain disappears completely 1 month after the operation. Following removal of catheter post surgery one patient had urine retention, she required recatheterization using Foley catheter, she voided well after removal of the catheter 48 hours later.

There were 3 cases with mixed stress incontinence preoperatively and one case de novo urge incontinence and nocturnal enuresis, for all of them antimuscarinic drug (Tolterodine tablet) 2.5 mg twice daily was prescribed; all of them were reviewed 4 weeks after the procedure, all were asymptomatic. None of the patients required blood transfusion during or after operation, there was no bladder perforation or vagina erosion in the current trial. One year minimum follow up was available (range 1-3 years) for all the patients. The cure rate (objective and subjective cure) was 83.3% and the incontinence events were improved in 3 cases (10%), while the procedure was regarded failed only in one case.

All the patients who underwent TVT-O only procedure discharged home in the same day (90%) of the cases. Comparing the severity of incontinence and impact of incontinence on quality of life before and after the operation most patients reported a significant decrease in incontinence severity and improvement in quality of life after the operation (P value < 0.001).

TABLE II
CHARACTERISTICS OF SAMPLE SIZE

Characteristics	Range	mean \pm SD
Age (year)	32-80	52 \pm 11.105
Weight (Kg)	58-125	81.066 \pm 13.59
Parity	0-12	5.53 \pm 2.58
Menopause		15(50%)
Sexual activity		25(83%)
Pure stress incontinence		26 (86.7%)

Mixed stress incontinence		4 (13.3%)
*Cystocele (grade 2&3)		3 (10%)
*Previous hysterectomy		1 (3.3%)

Anterior vaginal wall prolapse (bladder)*
Hysterectomy=removal of the uterus abdominally or vaginally

TABLE III
INTRA AND POST OPERATIVE OUTCOMES

Outcomes	range	mean \pm S
Blood loss (ml)	25-200	13.3 \pm 12
Operative time (mint)	13-10	11.2 \pm 2.33
Post operative thigh pain		3 (10%)
Short- term voiding difficulty		1 (3.3%)
De novo urgency		1 (3.3%)
De novo dyspareunia		1 (3.3%)

TABLE IV
CURE RATE

Outcome	No. (%)	Outcome	No. (%)
Cured		25 (83.3%)	
Improved		3 (10%)	
Failed		2 (6.7%)	
Total		30 (100%)	

TABLE V
PRIMARY OUTCOME MEASURES

Measures	Preoperative	postoperative	T. test	P. Value
Incontinence severity grades	2.26 \pm 0.44	0.26 \pm 0.63	13.994	0.001
Quality of life score	28.166 \pm 6.086	78 \pm 16.16	16.779	0.001

There are no any data available regarding the effect of vaginal delivery following the application of TVT-O for female complaining of SUI and yet not completing their

family size, so the recorded advice in the manual of the tape is to deliver the women abdominally if she gets pregnant after TVT-O procedure. 2 female in the current study get pregnant 6 months after the procedure and were delivered by Caesarean Section and both of them are doing well after the operation.

V. DISCUSSIONS

Tension-free vaginal tapes have revolutionized the treatment of female SUI [12]. The TVT procedure has recently replaced Burch colposuspension as the gold standard surgical procedure for treatment of SUI. A systemic review of seven randomized trials of TVT or laparoscopic Burch colposuspension for treatment of SUI showed no significant difference of the two procedures in the rate of complications and subjective cure rates at 18 months but the objective cure rates was in favor of the TVT procedure [25]. While TVT have proven to have long-term efficacy [26], their introduction via a retro pubic route has been associated with a number of perioperative or postoperative complications resulting from penetration of the tape or supporting needle in the bladder, urethra, bowel, nerves, or vessels [27]. Transobturator tape was introduced as a purportedly safer procedure of equal effectiveness to TVT [28].

Surgery remains the cornerstone of treatment of women with a diagnosis of severe SUI and also of those who have failed to improve using conservative methods [29]. Patients in current study complaining from moderate to severe incontinence were obese, grand multiparous, 50% were menopause while 50% of cases were middle age group, and with no history of HRT use. The risk factors for stress incontinence are parity (vaginal delivery greater risk than Cesarean section), diabetes, high body mass index (overweight and obese), high waist-to-hip ratio/ increased waist circumference, family history, smoking, chronic obstructive pulmonary disease, hysterectomy, and white race [19]. A cross-sectional study conducted in France by Andrea L, et al 2009, also revealed that incontinent women were older, had a higher BMI, and had more children than continent women [30].

The mean operative time (11.2 ± 2.33 min) was comparable with a study conducted in the Second Department of Gynecology, Medical University of Lublin Poland, by Tomaz R, et al [31], to compare the clinical efficacy of TVT slings versus TVT-O operations for the surgical treatment of female SUI, the mean operation time was (12 ± 4 min) in TVT-O group.

The mean intra operative bleeding was 33.3 ± 12 ml, this was in agreement with a study done by Nerli R, et al. in Belgaum, India [32], where TVT-O in comparison to TVT in a prospective trial with a minimum 12 month follow up was done on 36 patients, the mean intra-operative bleeding in TVT-O group was 37.2 ± 4.53 ml.

Short term voiding difficulty, De novo urgency, and De novo dyspareunia was 3.3% for each post operative outcome; these outcomes were less than in the same study by Nerli R, et al, where 16% of their cases complicated by De novo urgency and short term voiding difficulty. Voiding dysfunction is a common concern after sling surgery. In contrast to the often prolonged period of incomplete bladder emptying observed after retro pubic colposuspensions,

spontaneous voiding is generally achieved rapidly with midurethral sling placement.

The development of de novo urgency following midurethral sling placement is a concern. This symptom is reported in 0-26% of patients, and is attributed to obstructive or locally irritative causes [33]. Mid urethral sling placement is, however, more likely than traditional sling procedures to alleviate preoperative urgency and irritative symptoms [34]. When de novo urgency does occur, it is typically treated with dietary and behavior modification and anticholinergic therapy [35].

In a study done by Nader et al in Darwin hospital, Australia, where TVT-O procedure done for 25 women the short term complication was groin pain in two women (8%) which completely resolved by 6 weeks post surgery. Of the women who had their surgery in the morning 86% were discharged on the same day (within 10 hours). The only woman on the morning list that was discharged the following day, the delay in her discharge was planned preoperatively due to her medical history [36], this was in comparable with the current study where inner aspect of the thigh pain developed in 10% of the cases and treated with simple analgesia and resolved completely one month post surgery and only one case developed retention of urine who discharged home after 48 hours. There was no post operative bladder perforation, abscess formation, or vaginal erosion in current study.

The cure rate in this study was 83.3%, and 10% improvement rate, while only 6.7% with failure rate, these results were in agreement with that in a study done by Waltergny and colleagues where the outcomes with a minimum of 3 years follow-up were reported following transobturator TVT placement in 91 patients with SUI. In this patient cohort, 88% of patients were cured, and a further 9% improved. Again these outcomes remained stable, with no significant differences in the cure rate being observed when compared with outcomes seen at 1 year follow-up [37]. Our findings were also in agreement with a study done by Lee et al [38]. Prospectively they compared the efficacy and safety of TVT and TOT inside-out for female SUI. The rate of cure was 86.8%, improvement 6.6%, and failure 6.5% in the TVT-O group.

Nerli et al, conducted a trial on 36 women with stress urinary incontinence, they were alternatively assigned to the TVT group (18) or the TOT group, the surgical results in two groups were similar. The cure rate was 88.8% in both the groups and so was the improved rate in both the groups [32].

There was a statistically significant difference between patients self evaluated incontinence severity scores and QoL scores before and after the TVT-O sling operation (P value < 0.05); these findings were in agreement with a study done by David W, et al [14], [39], a prospective observational trial designed to assess the safety and efficacy of TVT-O procedure for female SUI was conducted on 253 patients, most patients reported a significant decrease in incontinence severity and improvement in quality of life.

In another study conducted in Department of Urogynecology, Royal Women's Hospital, Australia by Lim J et al, where TVT-O technique was performed on a population of 100 consecutive women. Three standardized QOL questionnaires were completed preoperatively at 6 and 12 months postoperatively. These were the Short Urogenital

Distress Inventory (SUDI), the Short Incontinence Impact Questionnaire (SIIQ), and the European Quality of Life Questionnaire (EuroQol). Quality of Life analysis by the three standard methods showed a significant improvement in mean SUDI, SIIQ, and EuroQol scores at both 6- and 12 months follow up [17].

VI. CONCLUSION

1-TVT-O procedure is associated with a low short term complication; its long term safety and effectiveness remain to be determined.

2-It is a simple procedure with a low risks and can be recommended as a gold standard for management of cases with SUI in Maternity teaching hospital and our locality.

3-Despite the suggested simplicity of surgical kits use, specific training is recommended prior to the use of this procedure.

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