

Efficacy of minimally invasive surgery Tension Free Trans-Obturator Tape in management of women with stress urinary incontinence at Maternity Teaching Hospital, Erbil city

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Abstract

Background and Objectives :Stress urinary incontinence (SUI) is consider the most common type of urinary incontinence in female; and is associated with high impact on patient 's hygienic, emotional and social life. This study was conducted to determine the effectiveness of tension free sub-urethral sling procedure(TOT) in the treatment of women SUI and any intra-operative and/or post-operative complication.

Patient and method:A prospective observational study was done in gynaecological out-patient clinic and operative theater of Maternity Teaching Hospital in Erbil city, Kurdistan region, Iraq, from 1st of February 2016 to 1st of February 2017 on 30 women with pure or mixed SUI. Follow-up done up to six weeks postoperative. Preoperative and postoperative assessment of severity of incontinence and its impact on Quality of Life (QoL) done by using specific questionnaire. Data were analyzed using Statistical Package for Social Sciences (SPSS, version 19)

Results: Majority of women (76.7%) were cured after the operation and the rest (23.3) were improved. The mean operation time was $14.03 + 2.025$ minutes, ranging from 11 to 18 minutes. The mean blood loss during the operation was $67.47 + 20.163$ ml, ranging from 40 to 115 ml .The QoL score after the operation (0.286) was significantly less than the pre-operative score (69.2) ($p < 0.001$). (

Conclusion: TOT procedure is an effective, safe and simple surgical treatment of female SUI with high success rate and low risks and complications.

Key words: Stress incontinence, Sub urethral sling, Quality of life, Urinary incontinence, Vaginal erosion

Introduction:

Urinary incontinence (UI) is a common symptom experienced by significant numbers of adult women. Stress urinary incontinence (SUI) is the most frequently encountered type and affects around 50% of incontinent females. (1) SUI is defined by the International Continence Society as a leak or loss of urine caused by sneezing, coughing, exercising, lifting or physical activity (2).

UI is a distressing and common problem, which may have a high impact on patient's quality of life. as it may cause depression, anxiety, work impairment, and social isolation. (3,4) coital incontinence affects more than one-third of all female urinary incontinent female (UI) women, and can contribute to incontinence-related sexual dysfunction. (5-7)

Female UI is often remains undetected and undertreated, (8,9) because women may refuse to initiate discussions about their urinary symptoms and urinary incontinence due to embarrassment, fear of surgery, and/or lack of knowledge about treatment options (10).

Management options for SUI include conservative and surgical treatments. Midurethral slings are a relatively new treatment option, but have become the procedure of choice for many women. The first midurethral sling was placed by passing trocars with mesh through the retropubic space (Transvaginal tape(TVT) (11). Trans obturator tape (TOT) slings were introduced in 2001 with the goal of avoiding some of the complications of retropubic insertion (eg, bladder perforation, vascular injury, bowel injury). Trans obturator slings are placed by passing trocars with mesh through obturator canal and avoiding the retro pubic space completely. The TOT would theoretically have the same anti-incontinence outcomes as the TVT. Significant complications are rare with this type of surgery. However, there is no surgery without risk and complications. (12) The most important benefits of the TOT as compared with other sling procedures is the less incidence of *de novo* urge/urge incontinence(13).There is no more change in patient's sexual life as regards pleasure and frequency of intercourse and/or pain during penetration, whereas there is a significant decrease in coital incontinence(14).

According to the best knowledge of the researchers this is the first time to conduct this operation using out in suburithral tape for women with stress incontinence in Maternity Teaching Hospital, Erbil city to determine its efficacy and complications related to its use.

Aims of study

The primary goal of the study was

with the secondary goal of assessing the

safety and efficacy of the TOAllow-up of six weeks .

1) To determine the effectiveness and success rate of Tension Free Trans- Obturator vaginal Tape (TOT) procedure in the treatment of women with stress urinary incontinence

2) To detect any intra-operative and/or post-operative complications and to assess the quality of life of the patients before and after the procedure

Patients and Methods

The protocol and the study design were approved by the scientific council of Obstetrics and Gynecology / Iraqi Board for Medical Specialization. A prospective observational study was conducted on 30 women presented with urinary incontinence to gynecology outpatient clinic in Maternity Teaching Hospital, Erbil city, Kurdistan region, Iraq from February 2016 to December 2016. Formal verbal consent was taken from all women participated in this study, TOT procedure performed under general or spinal anesthesia to all of them

The study included women with SUI or mixed UI of any age group, having no contraindications for anesthesia, women having cystocele were classified according to the Baden and Walker classification in to grade 1, 2 and 3 (15) and accepted to participate in the trial

Patients were excluded if they had a small bladder capacity (<300 mL) or, had any neurological pathology affecting the bladder, on antipsychotic treatment, having history of radio- or chemotherapy, having any serious medical condition like complicated diabetes mellitus, bronchial asthma, ischemic heart disease, having active urinary or vaginal infections, women who have previous surgery for stress urinary incontinence and if the patient refused to participate in the research.

Stress urinary incontinence defined as involuntary loss of urine on coughing, laughing, sneezing, climbing stairs, or other physical activities. Urge urinary incontinence of involuntary loss of urine accompanied by or immediately preceded by urgency. Mixed urinary incontinence is the complaint of involuntary loss of urine associated with urgency and also during exertion, sneezing and any increased intrabdominal pressure causes (2).

The preoperative evaluation of the women included a detailed medical history, general, focused neurological examination, and detailed pelvic examinations .Vaginal examination done when the bladder was full and empty to assess the presence of pelvic organ prolapse and determine their degree.

Bladder stress test was done when the bladder being comfortably full the patient was checked for incontinence when the patient in lying in dorsal position and repeated with the patient standing by asking to cough and confirming the presence of incontinence by visualization of urine coming out the urethra during staining (16).

Each patient was investigated by mid-stream urine analysis and if infection was there then culture and sensitivity was requested for them

Abdomino-pelvic ultrasonography was used in all patients to evaluate the kidneys and bladder, and to exclude the presence of a significant PVR by repeating the ultrasound after asking the patients to empty the bladder and the ultrasound was repeated.

The severity of urinary incontinence was classified according to the Stamey incontinence score; to grade 1,2,and 3 (17) . The assessment done twice before and after TOT procedure.

Anterior colporrhaphy done for cases with grade 2 and 3 cystocele; after taking formal agreement, before application of the TOT procedure.

Affection of involuntary urine loss on the quality of life (activities, relationships, feelings and emotional health) was assessed using Incontinence Impact Questionnaire-Short Form IIQ-7 (18).

The body mass indexes (BMI) were: Underweight <18.5 kg/m², normal weight 18.5-24.9 kg/m², overweight 25-29.9 kg/m² and obese as ≥ 30 kg/m² (19).

All participants were treated using TOT outside-in sling (Monarc), AMS company, Minnetonka, USA.

The patients were operated on under anesthesia and placed in the exaggerated lithotomy position, urine was evacuated using Foley catheter (18-F). A small midline vaginal incision was made 1cm below the external urethral meatus and the para-urethral space was opened. Bilateral skin punctures were made in the genitofemoral fold at the level of the clitoris. The tape was then applied using 'out-in' technique vaginal incision was closed using 3-0 vicryl sutures.

The time taken for the surgical procedure was recorded for every patient in minutes starting from skin incision to closure of it (the time needed for anterior colporrhaphy was not recorded). The amount of blood loss at the surgery was assessed by using pre-weighed pack and calculating their difference in weight before and after surgery.

Intra-operative complications as: (vaginal wall injury, bleeding, bladder or urethral perforation) and early post-operative complications (thigh pain, short term voiding difficulty, hematoma, dysuria, or infection) and late post-operative complication (perineal pain, dyspareunia, and de novo urge incontinence) were recorded.

Postoperative analgesia and pain killers were used. Twenty four hours after the surgery patients were discharged home after confirming that they have passed urine freely.

All patients were given an advice at the time of discharge to use chair-style toilet seat only and avoid squat position and preventing intercourse and lifting heavy things for 4 weeks. They were also advised on an adequate fluid intake so as to avoid urinary tract infections and also avoid constipation.

Evaluation of women done by direct interview and physical examinations 1 week and 6 weeks after surgery. At the follow-up visits, they were asked about, any pain or other complaint, and their satisfaction with the surgical result. Surgical outcome was evaluated by the bladder stress test and symptoms of incontinence. The patients were regarded cured of SUI if they had a negative bladder stress test and there were no reports of urine leakage during stress (objective and subjective cure). Patient's improvement was considered when she had no leakage of urine on the cough test; but may have had some occasional leakage of urine during stress.

Data were analyzed using the Statistical Package for Social Sciences (SPSS, version 19). Means were calculated for numerical variables, and proportions were calculated for categorical variables. Wilcoxon ranked-sign test was used to compare the mean ranks of quality of life before and after the operation. A p value of ≤ 0.05 was considered statistically significant.

Results: Thirty women participated in the study. Their mean age was 54.9 ± 6.7 years, ranging from 44 to 66 years. The median was 54 years. Only 26.7% aged less than 50 years. The majority (76.7%)

had five or more children. None of the women had normal weight, only 26.7% were over-weight, and the rest were obese. The majority of the women (93.3%) had history of vaginal deliveries, and the rest had history of both vaginal and abdominal deliveries (delivery by cesarean section), i.e. all of them had history of vaginal deliveries, as mentioned in Table 3.1. The same table shows that two thirds of the sample was menopausal women, and 83.3% were sexually active. Results showed also that none of the women were on hormonal replacement therapy.

Table 1. Basic characteristics of the studied sample.

Variables	Categories	No.(%)	Mean \pmSD
Age (years)	< 50	8(26.7)	54.9 \pm 6.7
	50-59	12(40)	
	\geq 60	10(33.3)	
Parity	< 5	7(23.3)	5.7 \pm 1.7
	\geq 5	23(76.7)	
BMI	27-29	8(26.70)	32.4 \pm 3.2
	30-34	16(53.3)	
	\geq 35	6(20.0)	
MOD	Vaginal	28(93.3)	
	VD and c/s	2(6.7)	
Menopause	No	10(33.3)	
	Yes	20(66.7)	
Sexual activity	No	5(16.7)	
	Yes	25(83.3)	

BMI: Body mass index, Mod : Mode of delivery

The majority of patients (86.7%) got pure stress incontinence, and only 13.3% had mixed type. Examination showed that 70% had cystocele, and none of them had vault prolapse. Only two patients had history of operations, which were for vaginal repair (Table 2). Patients with cystocele were classified into grade 1 (9 patients), grade 2 (9 patients), and grade 3 (3 patients).

Table 2. Distribution of patients by type of stress incontinence, presence of cystocele, vault prolapse, and history of operations.

Variables	Categories	No.(%)
Type of stress incontinence	Pure	26(86.7)
	Mixed	4(13.3)
Cystocele	No	9(30)
	Yes	21(70)
Vault prolapse	No	30(10)
	Yes	0(0)
Previous operation	No	28(93.3)
	Yes	2(6.7)

Table 3 shows very clear improvement in the quality of life of patients after the operation. The table shows down grading in the impact on quality of life of all the seven indicators, as in general the activities of the majority of patients returned back to normal after the operation.

Table 3 : Shows the Impact of the stress incontinence on the indicators of the quality of life, before and after the TOT operation.

		Pre-op. impact		Post-operative impact					
		No.	%	Not at all		Slightly		Total	
Indicators	severity	No.	%	No.	%	No.	%	No.	%
Ability to do household chores	Slightly	10	33.3	10	100	0	0	10	100
	Moderately	19	63.3	19	100	0	0	19	100
	Greatly	1	3.3	1	100	0	0	1	100
Physical recreation	Moderately	14	46.7	14	100	0	0	14	100
	Greatly	16	53.3	10	62.5	6	37.5	16	100
Entertainment	Moderately	24	80.0	23	95.8	1	4.2	24	100

activities	Greatly	6	20.0	4	66.7	2	33.3	6	100
Ability to travel more than 30 minutes	Slightly	3	10.0	3	100	0	0	3	100
	Moderately	17	56.7	17	100	0	0	17	100
	Greatly	10	33.3	8	80	2	20	10	100
Participation in social activities outside home	Slightly	1	3.3	1	100	0	0	1	100
	Moderately	18	60.0	16	88.9	2	11.1	18	100
	Greatly	11	36.7	6	54.5	5	45.5	11	100
Emotional health (nervousness & depression)	Slightly	8	26.7	8	100	0	0	8	100
	Moderately	17	56.7	17	100	0	0	17	100
	Greatly	5	16.7	5	100	0	0	5	100
Feeling frustrated	Slightly	12	40.0	12	100	0	0	12	100
	Moderately	17	56.7	17	100	0	0	17	100
	Greatly	1	3.3	1	100	0	0	1	100

Table 4 shows that the majority (76.7%) of patients cured after the operation and the rest were improved. The intra-operative complications reported in only one patient (3.3%) who developed vaginal wall injury. In day one post-operatively, 16.7% developed thigh pain, and 3.3% developed short term voiding difficulty. All the complications disappeared on week 6 post operatively. None of the patients needed blood during the operation.

Table 4. Operation success and complications.

Variables	Categories	No.	%
Success of operation	Improved	7	23.3
	Cured	23	76.7
Intra-operative complications	No	29	96.7
	Yes	1	3.3
Day 1 complications	None	24	80.0
	Thigh pain	5	16.7
	Short term voiding difficulty	1	3.3
Week 1 complications	None	28	93.3

	Thigh pain	1	3.3
	Infection	1	3.3
Week 6 complications	None	30	100.0
Intra-operative need for blood	None	30	100.0
Total		30	100

The mean (\pm SD) of operation time was 14.03 ± 2.025 minutes, ranging from 11 to 18 minutes. The mean (\pm SD) of blood loss was 67.47 ± 20.163 ml, ranging from 40 to 115 ml (Table 5).

Table 5. Details of operation time and blood loss.

	Mean	SD	Minimum	Maximum	Median
Operation time (minutes)	14.03	2.02	11	18	14.0
Blood loss (ml)	67.47	20.16	40	115	64.5

The severity of SI was much improved post-operatively, where all the 18 patients of grade 2 pre-operatively, converted to grade 0 after the operation. Five patients (41.7%) of the grade 3 converted to grade 0 after the operation (Figur 1).

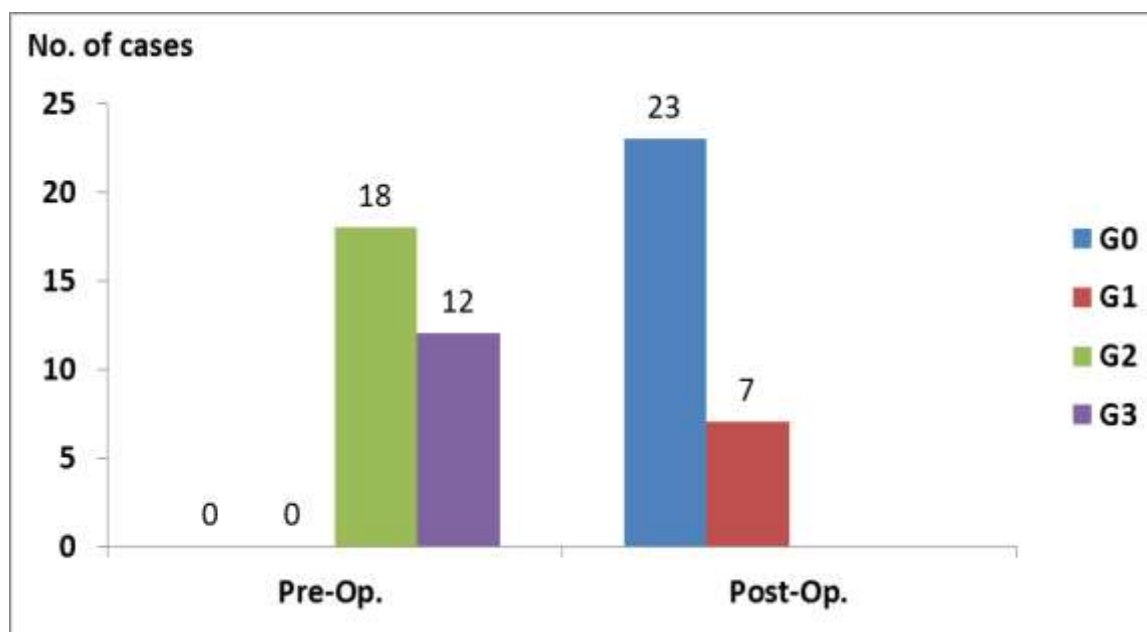


Figure 1: shows the comparison between pre and post-operative severity of SUI.

The QoL score significantly improved after the operation. The score after the operation (0.286) was significantly less than the pre-operative score (69.2) ($p < 0.001$) as shown in table 3.7.

Table 6. Pre and post-operative scores of quality of life (QoL)

Pre-operative score (100)		Post-operative score (100)		P*
Mean	SD	Mean	SD	
69.206	11.780	.286	.539	< 0.001

*By Wilcoxon Signed Ranks Test.

Discussion

The results of a recent large multicenter trial have confirmed excellent outcomes and a low rate of complications to be expected after treatment with MUS (20).

In current study; the majority of patients operated on for stress urinary incontinence (pure and mixed UI) were 54.9 + 6.7 years, only 26.7% aged less than 50 years. Published articles on the mean age of women with SUI and operated on were all around this age group (21, 22). The majority of participants were grand multipara and the vaginal delivery was the predominant mode of delivery. All the women in current study were either obese or over weight. Ghanbari et al conducted a study on women also operated on for SI where the mean parity was also 5 ± 0.66 , and the BMI was $28 + 1.5$. (23). Two thirds of the women included in this study were menopausal women with none of them on HRT, and the majority was sexually active. In Al alaf study where TVT-O procedure (inside-out) was conducted to determine the effectiveness of a sling procedures in treating female SUI; 50% of patients were menopause, and 83% were sexually active. (24).

There was a very clear improvement in the quality of life of patients after the operation in this study; as in general the activities of the majority of patients returned back to normal after the operation. This was in accordance to researched done by Taweel et al and Moore et al (21, 22)

Mean operative time for conduction the suburethral tape insertion in published articles is different from 12 to 25 minutes (22, 25)

Magon N et al reported a mean intra-operative blood loss of $76.78 \pm \text{ml}$ (26) while the mean blood loss was reported by Taweel et al to be $57 \pm 22 \text{ml}$ (21)

The mean blood loss in the current study was $67.47 \pm 20.16 \text{ ml}$.

The intra-operative complications reported in only one woman who developed vaginal wall injury, (which was identified at the time of insertion of TOT needle in the surgery, the needle removed immediately and then reinserted without any complications). Unrecognized, vaginal wall injury may cause mesh extrusion for that reason, it is important to check the lateral vaginal wall after passing the tunneler through transobturator foramen. All studies and researches that reviewed TOT alone or with comparison with the TVT mid-urethral sling procedures demonstrated vaginal wall injury and/or mesh extrusion during or after TOT insertion .(27-29)

There was no any case of bladder injury in current study for that reason intraoperative cystoscopical examination was not performed. Several cases of bladder injury were reported by Sivanesan and colleagues, (30) Abdel-Fattah and colleagues after performing 390 cases of TOT by different routes, found that the lower urinary tract injury may occur with the outside-in technique. (31)As they reported that; women who underwent concomitant vaginal surgeries, were on risks of bladder injuries; while women underwent secondary procedures were at risk of urethral injuries. They recommend performance of cystoscopy in all cases that associated with pelvic surgery, previous retro pubic surgery, presence of prolapse, or in cases where there is difficulty in the insertion of the tapes. (30, 31)

In day 1, 16.7% developed thigh pain which was managed effectively by simple analgesia, and 3.3% developed short term voiding difficulty that was improved after catheterization for 24 hours.

The majority of women cured after the operation and the rest were improved. These results similar to a study reported by Waltergny and colleagues where the outcomes with a minimum of 3 years follow-up were (88.4%) of patients were cured and (9.3%)were improved.(32)(

The QoL score was greatly improved after the TOT procedure. Post-operative score was (0.286), which was significantly less than the pre-operative score (69.2) , There was a more statistically difference between incontinence severity scores and QoL scores of women before and after the TOT surgical technique , these results were similar to a study performed by David W, et al, whom assess the safety and efficacy of TOT technique for women with SUI and reported a significant decrease in continence severity and improvement in quality of life among women included in that study(33)

One of the limitations of this study was that the urodynamic test was not used being not available in the hospital and other governmental hospitals in Erbil city; also the specificity, sensitivity and predictive value for diagnosis and predicting outcome in women with urinary incontinence has not

been analyzed. Although more than 2 third of participant were totally cured and 23. % was improved. The time period for following the patients post-operatively was up to six weeks; so evaluation of long-term morbidity and / or long-term patient satisfactory was limited.

In post-operative period; the majority of patients(86.7%) assessed directly by physical examination in gynecological out-patient clinic ;and this regarded as a power for the study while the remainder (13.3%) of patients assessed indirectly by calling them and history taking rather than direct physical examination being either far away from the hospital or due to some social reasons that limit their attendance for the hospital .

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