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Full Length Research Paper

Trans-Obturator Sub-Urethral Sling Out-In and In-Out approaches in Female Stress Urinary Incontinence: Comparative study

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| ARTICLE INFORMATION | ABSTRACT |
|---|---|
| <p>Corresponding Author: M. M. Altoraky</p> | <p><i>Background: Trans-obturator sub urethral sling is considered treatment of choice for primary and uncomplicated female stress urinary incontinence, as it has the same efficacy of retro-pubic tension free vaginal tape (TVT) with fewer complications. There are two variations of trans-obturator sub-urethral sling procedures, out –in (TOT) and in-out (TVT-O) techniques. No comparison was done between the two approaches regarding safety, efficacy and patient satisfaction. Study Objectives: to evaluate the efficiency and safety of TVT-O versus TOT techniques followed by 3 years duration of follow up. Study design: prospective comparative study, carried out in urogynecology unit of the Gynecology and Obstetrics Department, Farwania Hospital, Kuwait for a period of 6 months with follow up period of 36 months post-operative. Study included 43 patients, divided into 2 groups. All patients underwent trans-obturator mid-urethral sling operation either TVT-O or TOT according to their group. Patient satisfaction, incidence of persistent symptoms, recurrence symptoms, incidence of recurrence of urinary symptoms, complications and incidence of groin pain were measured. Results: Patient satisfaction and efficacy: was measured in both groups which revealed (95.2%) in TOT group and (94.4%) in TVT-O group in TOT group: there was mesh erosion (4.0%), vaginal perforation (12.0%) bladder injury (8.0%) De novo urgency incontinence: (16.0%) while in TVT-O group there was mesh erosion (0%), vaginal perforation (0%) bladder injury (0) and De novo urgency incontinence (11.2%) while the Groin pain (mild pain and persist beyond two weeks) Was 16.7 % in TVT-O compared to (0%) percent in TOT group. Conclusion: trans-obturator in-out approaches (TVT-O) is more superior than out-in (TOT), regarding safety and morbidity</i></p> |
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| <p>Key words: TVT-O - female stress urinary incontinence- TOT- trans-obturator mid urethral sling.</p> | |

Introduction

Stress urinary incontinence (SUI) affects 4-35% of women¹; ².SUI occurs when an increase in intra -abdominal pressure exceeds urethral closure pressure, resulting in the involuntary leakage of urine. This may occur with exertion, sneezing, or coughing³.

Management options for SUI include conservative and surgical treatments. Mid-urethral slings are a relatively new treatment option but have become the procedure of choice for many women. The first mid-urethral sling, introduced in 1996, was placed by passing trocars with mesh through the retro-pubic space⁴,Retro-pubic mid-urethral slings are still commonly used, but trans-obturator slings were introduced in 2001 with the goal

of avoiding some of the complications of retro- pubic insertion (e.g., bladder perforation, vascular injury, bowel injury⁵,Trans-obturator slings are placed by passing trocars with mesh through obturator canal and avoiding the retro-pubic space completely. The sling lies under the mid-portion of the urethra at a less acute angle than the retro-pubic technique⁶.

There are two variations of trans-obturator mid-urethral sling procedures, which vary by direction of trocar insertion:

- Inside-out – The trocars are passed from a mid-urethral vaginal incision to exit through bilateral groin incisions (TVT Trans-obturator, often abbreviated as TVT-O).

- Outside-in – The trocars are passed from bilateral groin incisions to exit through a mid-urethral vaginal incision (often abbreviated as TOT).

7. Mild cases of urinary incontinence

The two types of trans-obturator procedures appear to be equally effective and have similar complication rates⁷.

One disadvantage of the outside-in approach is that it results in a larger vaginal incision and has a higher rate of vaginal perforation^{7,8}.

Urodynamic evaluation is not necessary for women with uncomplicated stress urinary incontinence (SUI)⁸.

Preoperative urodynamic evaluation is required in women with complicated SUI. These include women with a clinical diagnosis of SUI, who have one of the following characteristics:

- Prior continence surgery
- Prior pelvic radiation
- Neurogenic lower urinary tract dysfunction (e.g., due to spinal cord injury, multiple sclerosis)
- Suspicion of a non-stress etiology of urinary incontinence,

There are a few studies comparing the two variation of the trans-obturator approaches, the inside-out (TVT-O) and the out - inside (TOT) as a minimal invasive management of the primary and uncomplicated female stress urinary incontinence.

Materials and Methods

Study Objectives: this study is to evaluate efficiency and safety of TVT-O versus TOT as minimal invasive surgery in the primary and uncomplicated stress incontinence by 3 years duration of follow up.

Study design: this is prospective comparative study. *Settings:* it was carried out in urogynecology unit of the Gynecology and Obstetrics Department, Farwania Hospital, Kuwait for a period of 6 months starting from January 2014 to June 2014 with follow up period of 36 months post-operative. *Patients:* this study included 43 patients, divided into 2 groups according to the MUS used. Group (1) included 18 patients whom undergo TVT-O and Group (2) included 25 patients whom undergo TOT. The methodology included in this manuscript is approved by Farwaniya hospital institutional review board/ ethical committee. It is also approved by IRB.

Inclusion criteria

1. Pure stress urinary incontinence
2. Positive stress test
3. Positive office test
4. PVR less than 50ml
5. Completed family
6. Patient global impression of severity (Moderate and severe types)

Exclusion criteria

1. Mixed urinary incontinence
2. Pelvic organ prolapse
3. Voiding dysfunction
4. Previous incontinence surgery
5. Non-stress causes of urinary incontinence like fistula
6. Negative stress test

Interventions: All patients underwent trans-obturator mid-urethral sling operation either TVT-O or TOT according to their group.

First, all patients were evaluated by thorough history taking, physical examination, stress test and office test, post-void residual volume, as all cases were uncomplicated stress urinary incontinence the urodynamic test wasn't done, clinical examination, the nature of procedure and the principle behind it, counseling and basic patient information were done, and the patient quality of life was estimated patient global impression of severity questionnaire.

All patients underwent trans-obturator mid-urethral sling operation either TVT-O or TOT according to their group. Patients were treated surgically by TOT (25 patients) and TVT-O (18 patients)-sling procedure (trans-obturator mid-urethral sling), had the same pre-operative evaluation, and post-operative cystoscopy for documentation of intact bladder and urethra were done and recorded.

All surgical procedures were done by the same surgeon, the trans-obturator tape system was (TVT-O set and mesh was Gynecare (Ethicon, Johnson & Johnson) and TOT set, and mesh was, Obtryx II (Boston scientific Halo needle).

Procedure

A. Instrumentation:

- Trans-obturator tape system:
A polypropylene mesh tape (typically 40 cm long and 1 cm wide) covered by a plastic sheath and fixed to the helical trocar (TVT-O), and TOT tape system, the tape mesh i.e. separated from the delivery needle.
- Bladder (Foley) catheter (size 16 French)
- Cystoscope with 70 degrees, for evaluation of urinary bladder and urethra.

B. Patient preparation

- Patient set-up: patient in dorsal lithotomy
- Marking groin incisions: Mark the two-planned groin exit points at the level of the clitoris, 2 cm lateral to the Genito-femoral folds. Hydro dissection at the vaginal incision site and the path of the trocars, local anesthetic with epinephrine Fluid were injected into the vaginal wall and para-urethral.
- Sling placement

A. Inside-out (Fig. 1)⁹.

- vaginal incision, 1 cm proximal to the urethral meatus and 1 to 1.5 cm in length to accommodate the width of the sling in the appropriate location. Place Allis clamps on the lateral edges of the incision to provide exposure by retracting the vaginal mucosa laterally.
- Dissecting the tract for the trocar and mesh: the Metzenbaum scissors was used to perform a minimal dissection lateral to the mid-urethra, between the vaginal mucosa and the pubo-cervical fascia. The scissors were aimed towards the obturator foramen behind the inferior

pubic ramus. A winged was used then be introduced into the tract to guide the trocars into the obturator region.

vaginal incision. The vaginal sulci were inspected to ensure that they have not been compromised.

- Inserting the trocars: The trocars were inserted through the obturator foramen, posterior and medial to the obturator vessels. The trocars traverse the peri-urethral endopelvic fascia, obturator internus muscle, obturator membrane, obturator externus muscle, and exit out through the skin, just posterior to the adductor longus tendon^{4: 5}. Exit through the marked groin incisions, 2 cm lateral to the Genito-femoral folds at the level of the clitoris. The vaginal sulci are inspected to ensure that they have not been compromised and closure of the incisions⁴.
- Adjusting sling tension: The sling is tension-free and does not compress the urethra while the patient is at rest, Kelly clamp was inserted between the sling and the urethra while adjusting the sling tension. The mesh does not require suturing, it is held in by friction and then fibrosis.

B. Outside-in (Fig. 2)¹⁰

The unique steps of the outside-in⁵

- Mid-urethral vaginal incision
Make a vaginal incision, 1 cm proximal to the urethral meatus and 1 to 1.5 cm in length to accommodate the width of the sling and the surgeon's finger in the appropriate location. Place Allis clamps on the lateral edges of the incision to provide exposure by retracting the vaginal mucosa laterally.
- Dissecting the tract for the trocar and mesh:
The Metzenbaum scissors was used to perform a dissection lateral to the mid-urethra, between the vaginal mucosa and the pubo-cervical fascia. The scissors are aimed towards the obturator foramen behind the inferior pubic ramus. The operator's finger was placed into the tract created by the Metzenbaum scissors to the obturator foramen.
- Groin incisions and insertion of the trocars:
Bilaterally, 2 cm lateral to the Genito-femoral folds at the level of the clitoris. the trocars were passed through the groin incisions and rotate the trocars through the obturator membrane. The trocars traverse the skin, obturator externus muscle, obturator membrane, obturator internus muscle, peri-urethral endopelvic fascia, and out through the vaginal incision. The trocar was passed just posterior to the adductor longus tendon. A finger is placed via the vaginal incision through the tract to guide the trocars to avoid injury of the vaginal sulci. The trocars exit at the

Follow-up

Evaluation was done after 1, 3, 6, 12, 18, 24, 36 months.

Measurements: Patient satisfaction, incidence of persistent symptoms, recurrence symptoms, incidence of recurrence of urinary symptoms, complications (mesh erosion, vaginal perforation, bladder injury, De novo urgency incontinence, vascular and urethral injury) and incidence of groin pain were measured and compared between 2 groups.

Statistical analysis

Statistical analysis was done using Statistical Package of Social Science SPSS software 22 (SPSS Inc, USA, IL). The normality of data was first tested with Shapiro test. Qualitative data were described using number and percent. Association between categorical variables was tested using Chi-square test or Fischer exact test as expected cell count less than 5 while Paired groups were compared with Mc-Nemar test. Continuous variables were presented as mean ± SD for parametric data and median for non-parametric data. The two groups were compared with Student *t* test for parametric data and Mann-Whitney test for non-parametric data. For all above mentioned statistical tests, results was considered significant when $p < 0.05$.

Results

- Patient characteristics : age, parity, obesity, diabetes mellitus, and preoperative Questionnaire score are matched in studied groups as shown in (table 1).
- Patient satisfaction and efficacy: was measured in both groups which revealed (95.2%) in TOT group and (94.4%) in TVT-O group. Also, total efficacy was (78.3%) in TOT group and (94.4%) in TVT-O group as shown in (table 2) and (figure 1).
- Recurrence symptoms: was (12%) in TOT group compared to (5.6%) in TVT-O group as shown in (table 2 & 5).
- No vascular or urethral injury were recorded in both groups, as shown in (table 3) and (figure 2).
- The complications among studied groups: TOT group was mesh erosion (4.0%), vaginal perforation (12.0%) bladder injury (8.0%) De novo urgency incontinence: (16.0%) while in TVT-O group was mesh erosion (0%), vaginal perforation (0%) bladder injury (0%), De novo urgency incontinence (11.2%), groin pain which persist beyond two weeks was (16.7%) as shown in (table 4).
- Groin pain (mild pain and persist beyond two weeks) Was 16.7 % in TVT-O compared to (0%) percent in TOT group.



Fig. (1): Gynecare TVT obturator system⁹.



Fig. (2): Tension free vaginal tape¹⁰.

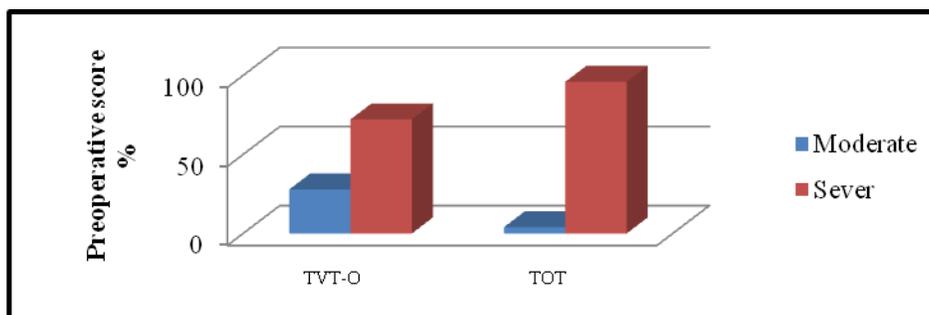


Fig. (3): Preoperative Questionnaire score among studied groups

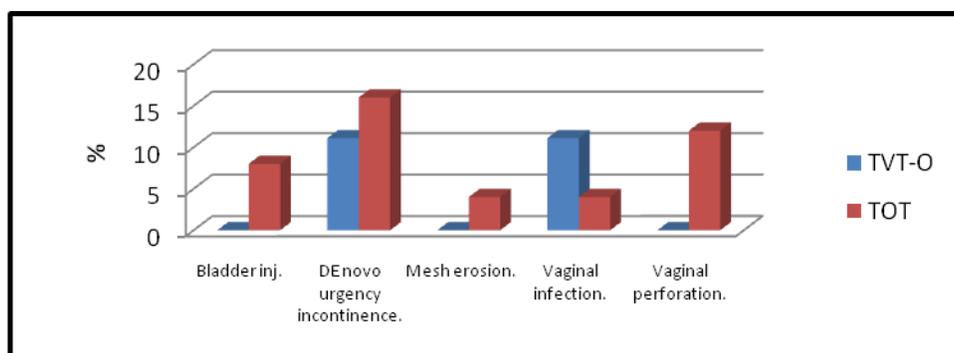


Fig. (4): Complications among studied groups

Table (1): Patients characteristics among the studied group

| Personal data | Midurethral sling | | P- value |
|---|-------------------|---------------|----------|
| | TVT-O (n=18) | TOT (n=25) | |
| Age / years | | | |
| Mean ± SD | 48.94±5.73 | 49.80±7.06 | 0.675 |
| Min-Max | 40–61 | 40–65 | |
| < 50 y | 11 (61.1%) | 13 (52.0%) | 0.820 |
| 50-60 y | 5 (27.8%) | 8 (32.0%) | |
| >60 y | 2 (11.1%) | 4 (16.0%) | |
| Parity | | | |
| Median (Min-Max) | 4.0 (2.0–6.0) | 4.0 (2.0–8.0) | 0.178 |
| P ≤ 3 | 6 (33.3%) | 7 (28.0%) | 0.707 |
| P >3 | 12 (66.7%) | 18 (72.0%) | |
| Diabetes mellitus | | | |
| Yes | 5 (27.8%) | 3 (12.0%) | 0.247 |
| No | 13 (72.2%) | 22 (88.0%) | |
| Οβεσιτυ | | | |
| Yes | 7 (38.9%) | 7 (28.0%) | 0.452 |
| No | 11 (61.1%) | 18 (72.0%) | |
| Preoperative Questionnaire score | | | |
| Moderate | 5 (27.8%) | 1 (4.0%) | 0.067 |
| Sever | 13 (72.2%) | 24 (96.0%) | |

Table (2): Patients satisfaction

| Patients satisfaction | Midurethral sling | | P- value |
|-----------------------|-------------------|------------|----------|
| | TVT-O (n=18) | TOT (n=25) | |
| After 1 month | | | |
| continent | 18 (100%) | 24 (96.0%) | 1.0 |
| persistent | – | 1 (4.0%) | |
| After 3 months | | | |
| continent | 18 (100%) | 23 (95.8%) | 1.0 |
| Recurrent | – | 1 (4.2%) | |

| | | | |
|------------------------|------------|------------|-------|
| After 6 months | | | |
| continent | 18 (100%) | 23 (100%) | – |
| After 12 months | | | |
| continent | 18 (100%) | 23 (100%) | – |
| After 18 months | | | |
| continent | 18 (100%) | 23 (100%) | – |
| After 24 months | | | |
| continent | 18 (100%) | 21 (91.3%) | 0.495 |
| Recurrent | – | 2 (8.7%) | |
| After 36 months | | | |
| continent | 17 (94.4%) | 20 (95.2%) | 1.0 |
| Recurrent | 1 (5.6%) | 1 (4.8%) | |
| ≠ P | $\Pi=1$ | $\Pi=1$ | |

Table (3): Complications among the studied groups

| Complications | Midurethral sling | | P- value |
|----------------------------------|-------------------|------------|----------|
| | TVT-O (n=18) | TOT (n=25) | |
| Vascular inj. | 0 (0.0%) | 0 (0.0%) | – |
| Bladder inj. | 0 (0.0%) | 2 (8.0%) | 0.502 |
| Urethral inj. | 0 (0.0%) | 0 (0.0%) | – |
| DEnourgency incontinence. | 2 (11.1%) | 4 (16.0%) | 1.0 |
| Mesh erosion. | 0 (0.0%) | 1 (4.0%) | 1.0 |
| Vaginal infection. | 2 (11.1%) | 1 (4.0%) | 0.562 |
| Vaginal perforation. | 0 (0.0%) | 3 (12.0%) | 0.252 |
| Total | 3 (16.7%) | 8 (32%) | 0.256 |

Table (4): Groin pain among studied groups

| Groin pain | Midurethral sling | | P- value |
|---------------------------|-------------------|--------------|----------|
| | TVT-O (n=18) | TOT (n=25) | |
| Day1 -2 weeks. | | | |
| No pain | 0 (0.0%) | 15 (60.0%) | <0.001* |
| Mild pain | 11 (61.1%) | 10 (40.0%) | |
| Moderate | 7 (38.9%) | 0 (0.0%) | |
| More than 2 weeks. | | | |
| No pain | 15 (83.3%) | 25 (100%) | 0.034* |
| Mild pain | 3 (16.7%) | 0 (0.0%) | |
| ≠ p | $\Pi=<0.001*$ | $\Pi=0.001*$ | |

Table (5): Persistent and recurrent symptoms among studied groups

| Symptoms | Midurethral sling | | P- value |
|----------------------------|-------------------|------------|----------|
| | TVT-O (n=18) | TOT (n=25) | |
| Persistent symptoms | | | |
| Yes | 0 (0.0%) | 1 (4.0%) | 1.0 |
| No | 18 (100%) | 24 (96%) | |
| Recurrent symptoms | | | |
| Yes | 0 (0.0%) | 3 (12.0%) | 0.252 |
| No | 18 (100%) | 22 (88.0%) | |

Discussion

the trans-obturator sub urethral sling surgery inside-out approaches (TVT-O) was more effective than the out-inside approach (TOT) (94.4%) and (78.3%) respectively both approaches (TVT- and TOT) were equally regarding patient satisfaction (94.4%) and (95.2%) respectively. Patients morbidity in TOT group were mesh erosion (4.0%), vaginal perforation

(12.0%) bladder injury (8.0%), compared to zero percent in TVT group , and the recurrent symptoms after TOT was 12% compared to 5.6 % in TVT-O group, and no vascular injuries was found in both variation The only aspect in which TOT is superior than TVT-O was groin pain , it was (16.7%) (mild groin pain which persist beyond 2weeks) Denovo urgency

incontinence was nearly equally statistically in both approaches (16%) in TOT compared to 11 % in TVT-O group. Compared to the study of^{11; 12} which showed bladder injury has been reported in (0-1%) and mesh erosion was (1.3%) in study of¹² vaginal perforation was (2%), (12%)¹³, the study of¹⁴, and also was agree with A systematic review of 32 studies (5 trials and 27 observational studies) that evaluated the incidence of de novo OAB reported de novo OAB rates of (8.7%) for the inside-to-outside approach and (11.2%) for outside-to-inside¹⁴. The incidence of vascular injury and urethral injury was (0%) in both groups and this was agreed with the study of^{15; 16} they documented that Vascular injury is uncommon during trans-obturator sling placement (0-3%). In TVT-O group there was Groin pain, (16%) and (0%) in TOT and this was agree with study of¹⁷ who documented that the Groin pain was (12-16%) with the TVT-O and also with the study of^{18; 19} who documented that the groin pain was more likely following inside-out placement of the sling.

Conclusion

Trans-obturator sub-urethral sling surgery inside-out approaches as a minimally invasive surgery proven that it was effective, safe with less and well tolerated morbidity.

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