INTRODUCTION

Stress urinary incontinence (SUI) is the most common type of incontinence in women, with 86% of incontinent women presenting with the symptom of SUI in either pure (50%) or mixed (36%) forms. Incontinent women have SUI when they complain of involuntary leakage of urine on effort, exertion, sneezing or coughing.[1] Many surgical procedures for relieving SUI have been introduced and most stabilize the bladder neck and/or urethra. In 1996, Ulmsten et al. proposed a new surgical technique called tension-free vaginal tape (TVT) for treatment of SUI.[2] Pioneered by Delorme, the transobturator tape approach (TOT) was developed with the aim to reduce side-effects of this retropubic sling procedure by not entering...
the space beyond the endopelvic fascia.[3] The mechanism of action of these sling procedures differ from that of the conventional slings that usually are placed beneath the bladder neck to elevate this area according to pressure transmission theory.[4] Using tension-free or low-tension slings, the bladder neck is not displaced backwards into the abdomino-pelvic pressure zone, but the defective pubo-urethral ligament is replaced. In addition, the defective connection between the urethra and vagina is restored and thereby the sub-urethral hammock reinforced or restored.[4] Another surgical technique was developed by De Leval in 2003, which allows the passage of the tape from inside to outside, with the use of newly designed specific surgical instruments is the Gynecare TVT obturator system techniques, which use a nonabsorbable monofilament polypropylene tape in a plastic sheath. Most of the available studies are about the short-term results of TOT procedure in the treatment of female SUI and few studies are available on the long-term.

The aim of the present study was to evaluate the long-term safety and efficacy of TOT procedure in the treatment of women with SUI by subjective and objective measures.

**PATIENTS AND METHODS**

A total 48 women with SUI underwent TOT procedure (25 patients treated with in-out technique using TVT obturator system by Gynecare, Ethicon, USA and the other 23 patients treated with out-in technique using Monarc subfascial hammock, AMS) during the period from December 2005 to February 2008 under spinal anesthesia. All patients were assessed before surgery by history, clinical examination, urine analysis, abdomino-pelvic ultrasonography, and urodynamic evaluation when indicated. Patients who required concomitant anterior or apical pelvic organ prolapse repair or both were excluded.

Early postoperative and 1-year evaluation data were retrieved from the patient’s medical files.

Patients were recruited for follow-up after a period ranged from 60 to 85 months (mean 71 months) postoperatively. Patients were subjected to the following assessment:

- A detailed history to detect any possible complications and the history included symptoms of urinary incontinence, frequency, nocturia, urgency, hesitancy and weak stream in addition to the presence of vaginal pain, dysparonia, vaginal discharge, suprapubic pain, or thigh pain
- Quality of micturition regarding strength, intermittency, deviation of stream, and postvoiding dribbling was also assessed
- Quality of life (QOL) of the studied patients was assessed postoperatively according to QOL questionnaire by McConnell 1994 [Appendix I][5]
- Physical examination searching for the presence of discharge, vaginal erosion, and chronic retention in addition to cough stress test
- Radiological evaluation included abdomino-pelvic ultrasonography to evaluate upper urinary tract and postvoid residual urine measurement
- Urodynamic tests including uroflowmetry. Cystometry and pressure flow study were performed in the presence of urge or obstructive symptoms, reduced Q max, or residual urine more than 100 ml.

**Treatment outcome**

The outcome of the procedure was evaluated depending on history and objective criteria from physical examination. Treatment outcome was categorized into:

- Cured: Patient reported no leakage with stress and she was very satisfied (score 0-1). On examination, there was no leakage with cough test
- Improved: Patient reported leakage only with severe exertion, using less number of pads/day, and she feels that she is improved (score 2-3). On examination, there was no SUI
- Failed: For patients not fulfilling the abovementioned criteria.

The long-term results were compared with the 1-year results obtained from the patients files postoperatively.

Appropriate statistical analysis were applied on the obtained data, and P value was considered as significant when <0.005 and highly significant when <0.001.

**RESULTS**

A total 48 female patients were enrolled in the study. Their mean age was 44.21 ± 7.52 (range: 30-58). The follow-up period ranged between 60 and 85 months (mean 71 months).

The success rate after 12 months postoperatively and at the last follow-up [Table 1].

Table 2 compares the QOL of the studied patients preoperatively, after 12 months postoperatively and at the last follow-up with significant improvement of the QOL after the procedure.

Estimation of postvoiding residual (PVR) urine revealed a statistically nonsignificant increase between PVR preoperatively, after 12 months, and at the last follow-up, and the details are shown in Table 3.
Uroflowmetry performed for the evaluable patients revealed a statistically nonsignificant decrease in the Q max during the follow-up evaluation as shown in Table 4.

Preoperatively, filling cystometry for the studied women showed normal bladder capacity, sensation, and compliance with the absence of uninhibited detrusor contraction with stress leak.

De novo urgency occurred in three patients (6.25%) after 1 year, and their filling cystometry demonstrated uninhibited detrusor contractions. One patient of them with anticholinergic therapy (oxybutynin 2-4 tablets/day) and the urgency persisted in other two patients (4.16%) for 6 years.

No cases recorded with vaginal erosion. No cases recorded with postoperative urinary retention. Three cases developed postoperative voiding difficulty after 1 year, and one of them her complaint persist after 5 years. The patient with persistent complaint had peak flow 18 ml/s preoperatively, 13 ml/s after 1 year and 5 years postoperatively with postvoid residual urine 70 ml and detrusor pressure of 55 cm Hg at Q max.

DISCUSSION

The main goal of the surgical treatment of SUI is to restore a perfect continence with minimal morbidity. Although it is effective and easy to perform, the retropubic placement of sub-urethral TVT has been associated with a number of peri-and post-operative complications including bowel, vascular, and bladder injury but also dysuria, urinary retention and de novo urge 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 while preserving an intact retropubic space.[6]

Delorme et al. described the transobturator approach to place the tape suburethrally between the two obturator foramens from outside to inside, which is an excellent alternative to the retropubic approach that reduces complications.[7]

Another transobturator technique was developed to allow the passage of the tape from inside to outside obviating any complications.[8]

In our study, 48 women with genuine SUI underwent the TOT procedure (25 patients treated with in-out technique and the other 23 patients treated with out-in technique).

Follow-up of the studied patients revealed that 39 patients (81.25%) had been cured, 5 (10.42%) improved, 4 (8.33%) were considered a failure after 12 months follow-up versus 38 patients (79.15%) cured, 5 (10.42%) improved, and 5 (10.42%) were considered a failure after 71 months mean follow-up with no statistically significant difference between the two groups. Several studies have results comparable to our results. In a study by Groutz et al. on 61 women with SUI-treated with TOT, 45 patients (74%) had been cured, 5 (10.42%) improved, and 5 (8.33%) were considered a failure after 12 months follow-up versus 38 patients (79.15%) cured, 5 (10.42%) improved, and 5 (10.42%) were considered a failure after 71 months mean follow-up with no statistically significant difference between the two groups. Several studies have results comparable to our results. In a study by Groutz et al. on 61 women with SUI-treated with TOT, 45 patients (74%) had been cured, 5 (10.42%) improved, and 5 (8.33%) were considered a failure after 12 months follow-up versus 38 patients (79.15%) cured, 5 (10.42%) improved, and 5 (10.42%) were considered a failure after 71 months mean follow-up. Furthermore in a study by Angioli et al. on 32 women with SUI treated with TOT, 72% cured, 18% improved and 10% failure with 5 years mean follow-up.[9] Furthermore Cheng and Liu in their study on 103 women with SUI treated with TOT found 87.4% cured, 4.6% improved, and 8% failure with 5 years mean follow-up.[11]

In the present study, there is a significant improvement in the QOL score among the treated patients during the early and late follow-up, which is comparable to studies done by Schierlitz et al. and Ballester et al.[12,13] Furthermore Cheng and Liu in their study on 103 women with SUI treated with TOT found Table 1: The success rate of the procedure early and after 71 months mean follow-up

| Success rate (%) | Chi-square |
|------------------|------------|
|                  |            |
| Cured            |            |
| 12 months        | 39 (81.25) |
| 71 months        | 38 (79.15) |
|                  | 0.124      |
|                  | 0.939      |

Table 2: Patients quality-of-life

| Quality of life | Paired t test |
|-----------------|---------------|
| Range           |               |
| Preoperative    |               |
| 5-6             | 5.411±0.237   |
| Comparison with preoperative |            |
| After 12 months | 0-2           |
| Median (IQR)    | 1.07±0.964    |
| Comparison with preoperative |            |
| After 71 months | 0-3           |
| Median (IQR)    | 1.265±0.437   |

Table 3: Assessment of PVR

| PVR (ml) | Wilcoxon signed ranks test |
|----------|---------------------------|
| Range    | Median (IQR)              |
| Preoperative | 0-25           |
|           | 10 (5)               |
| Comparison with preoperative |            |
| After 12 months | 0-50           |
| Median (IQR)    | 15 (10)            |
| Comparison with preoperative |            |
| After 71 months | 0-70           |
| Median (IQR)    | 12.5 (5)           |

PVR: Postvoiding residual, IQR: Interquartile range

Table 4: Evaluation of maximal flow rate

| Q max | Paired t test |
|-------|---------------|
| Range | Mean±SD      |
| Preoperative | 16-33         |
|           | 21.451±7.15  |
| Comparison with preoperative |            |
| After 12 months | 13-31         |
| Median (IQR)    | 19.421±6.875 |
| Comparison with preoperative |            |
| After 71 months | 13-26         |
| Median (IQR)    | 19.044±7.55  |

SD: Standard deviation
that, incontinence severity degree and QOL scale scores were largely improved after the operation \( (P < 0.001) \) while no difference was found between years 1 and 5 \( (P = 0.11 \) and \( P = 0.09 \) respectively).\(^{[11]}\)

In the present study, no patient developed postoperative urinary retention. There was no significant difference in the mean \( Q \) max and postvoid residual urine measured preoperatively, at 12 months postoperatively and at the last follow-up (mean 71 months) postoperatively. In the study done by Cheng and Liu, they concluded that the severity of obstructive symptoms and postvoid residual volumes at 5 years were not improved compared with 1 year after the procedure \( (P = 0.10 \) and \( P = 0.33 \) respectively).\(^{[11]}\) Morey et al. stated that the position of the transobturator sling replaces the damaged pubourethral 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 TVT, therefore not only is this more anatomic and natural, it also makes sense that there are fewer problems with urinary dysfunction such as urinary obstruction.\(^{[14]}\)

In our study, de novo urgency occurred in three patients (6.25%) after 1 year, one of them improved after 1 year with anticholinergic therapy (oxybutinin 2-4 tablets/day) while the urgency persisted in other two patients (4.16%) for 6 years. It is difficult to determine why these patients develop postoperative urgency; it is thought that the symptoms are due to a combination of degree of obstruction and irritative symptoms due to the presence of the sling. Theoretically, TOT should carry little if any risk of producing urgency as it is expected to provide a tension-free support and thus minimize the chance of producing any obstruction.\(^{[15]}\) Recent reports on de novo urgency after TOT suggests that de novo urgency develops in 2.5-8% of patients.\(^{[6,11,16]}\)

**CONCLUSIONS**

Transobturator tape procedure appeared to be safe and effective minimally invasive procedure for treatment of SUI with good long-term outcome. Studies on a larger series of patients are required to confirm the results obtained from the present study.

**Appendix 1: Quality of life questionnaire**

| Delighted | Pleased | Mostly | Mixed | Mostly Dissatisfied | Unhappy | Terrible |
|-----------|---------|--------|-------|---------------------|---------|---------|
| satisfied (satisfied and not satisfied) |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 |

If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that?

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