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# Trans Obturator Tape (TOT) Procedure in cases of Stress Urinary Incontinence: Patients' Satisfaction and Cure Rates (Retrospective Analysis)

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## **Abstract**

**Background:** Stress urinary incontinence (SUI) is the involuntary escape of urine on exertion or physical effort, including sports activities, or on coughing or sneezing, affecting the women's health-related quality of life, either the psychological well-being or physical activity.

**Aim of the Work:** To assess the rates of cure, complications, and patient's satisfaction after doing a Trans-obturator tape (TOT) procedure in patients with stress urinary incontinence (SUI).

**Patients and Methods:** This retrospective study was conducted at at the Urogynecology Department, Ain Shams University Maternity Hospital from June 2022 till January 2023 and performed on a total of 79 women who underwent trans-obturator tape (TOT) procedure for treatment of female urinary incontinence in the last four years in urogynecology department.

**Results:** As regards Follow-up postoperatively, our study results revealed that cure rate and satisfaction rate were 55.7% and leak and Unsatisfaction were reported in 44.3% of cases and the cases with urine leak and unsatisfaction significantly had higher age as well as more frequent hypertension, pelvic prolapse and urinary positive culture as well as longer hospital stay. In addition, diabetes mellitus is significantly associated with leak. The total ICIQ-SF scores and IIQ-7 were 0 in all patients after the surgery while before the surgery, the ICIQ-SF scores and IIQ-7 were missed which is the disadvantage the retrospective study design of the current study.

**Conclusion:** Our study showed that the TOT procedure is effective in the treatment of pure SI and Mixed incontinence with high success rates, high patient satisfaction and the least complications.

**Keywords:** Trans Obturator Tape - Stress Urinary Incontinence - Tension Free Vaginal Tape.

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## **Introduction**

Stress urinary incontinence is a gynecological condition that negatively affects the woman life either psychologically, and quality of life. however, it is more prevalent in older women, particularly amongst those in institutionalized care. <sup>1</sup>

The predisposing factors include multiple vaginal deliveries, constipation, increased BMI, chronic cough, old age, menopause. <sup>2</sup> The Diagnosis depends on the clinical assessment, symptoms (frequency and triggering factors) and to assess the effect of SI by QOL (quality of life) questionnaire. Different urodynamics studies confirm the diagnosis and help in assessing degree of incontinence <sup>3</sup>

Modification of lifestyle is a crucial step in the treatment of SUI and includes diet modifications, weight reduction, cessation or decrease smoking , regular pelvic floor muscle training for at least 3 month. <sup>4</sup>

When conservative treatment fails, the surgical treatment is resorted in the form of mid urethral slings. <sup>5</sup>

The most common performed procedures now for treating SUI are the mid urethral slings are currently TOT and tension free vaginal tape (TVT) on top of these procedures. <sup>6</sup>

The common point of mid urethral sling operations is the use of mesh material passed under the urethra. <sup>7</sup>

Based on the "Integral Theory" by Petros and Ulmsten <sup>8</sup>, the retro pubic tapes (TVT) were released and introduced in 1996. Their role was to imitate the pubo urethral ligament and became widely adopted. <sup>9</sup>

Taking into consideration the complications associated with the retro pubic approach (Bladder injury, Injury of the major vessels, Bowel Injury, Postoperative Voiding difficulties and low patients' satisfaction) Delorme et al. <sup>10</sup> promoted the TOT outside and de Leval <sup>11-12</sup> the TOT inside

out approach based on the "Hammock Hypothesis". <sup>9</sup>

Aim of the Work: To assess the rates of cure, complications, and patients' satisfaction after doing a Trans-obturator tape (TOT) procedure in patients with stress urinary incontinence (SUI).

## **Patients and Methods**

After ethical committee approval and informed consent from the patients, this retrospective study was conducted at tertiary care hospital at Urogynecology Department, Ain Shams University Maternity Hospital from June 2022 till January 2023 and performed on a total of 79 women who underwent trans-obturator tape (TOT) procedure for treatment of female urinary incontinence in the last 4 years in urogynecology department.

### **Study population:**

All women who undergone transobturator tape (TOT) procedure for treatment of female urinary incontinence in the last 4 years in urogynecology department, Ain Shams University Maternity hospital.

### **Inclusion criteria:**

Being aged above 18 years, and patient with stress urinary incontinence (SUI) and stress predominant mixed urinary incontinence (MUI).

Stress Urinary Incontinence (SUI) diagnosed by urodynamic study was defined as the involuntary leakage of urine during increased abdominal pressure, in the absence of a detrusor contraction (Detrusor Overactivity Incontinence "DOI"). <sup>13</sup>

### **Exclusion criteria:**

Having a neurogenic bladder, history of urethral reconstruction, history of anti-incontinence surgery, and being aged below 18 years.

### **Sample size:**

Şik et al. <sup>14</sup> reported proportion of objective

cure rate after TOT of 88.5%. A sample size of at least 79 cases produces a two-sided 95% confidence interval with a width equal to 0.200 when the sample proportion is 0.880. Sample size calculation produced a sample size of a minimum of 79 patients achieving 80% power and x error at 0.05.

**Study procedure:**

The patient files in the urogynecology unit as well as other units in the hospital were reviewed & the following data were collected: Age, Parity, & BMI, associated medical conditions like Diabetes Mellitus, Hypertension, Chronic Obstructive Pulmonary Disease, Chronic Kidney Disease, Chronic Lung Disease, Chronic Constipation, Abdominal Ascites and Swellings, pre operative preparation, urine analysis, urine culture, results of urodynamic study, and associated prolapse assessed by POPQ system.

Primary outcome

**1. Cure rate:**

Defined as a self-reported absence of symptoms, no treatment over two years. We used the Arabic version of the International Consultation of Incontinence Questionnaire Short Form (ICIQ-UI-SF) to assess urinary incontinence before surgery and at two years postoperatively. 15

Its validation revealed that the assessment

of the internal consistency was excellent, with the Cronbach's alpha coefficient of 0.97 (95% CI: 0.88-0.98). 16-17

**2. Patient satisfaction "satisfaction rate"**

We used the Arabic version of the IIQ-7 (Incontinence Impact Questionnaire) to evaluate generalized health-related quality of life (physical activity, social relationships, travel, and emotional health). 18-19

The IIQ (incontinence impact questionnaire) was used in this study for QOL assessment 20. It was composed of 30 questions. 21

**3.Recurrence rate at 2 years**

**Secondary outcome:**

Injury to (bladder, urethra, obturator vessels), post-operative retention of urine & intermittent self-catheterization, duration of hospital stay, vaginal erosion, and female sexual dysfunction (dyspareunia).

**Statistical analysis:**

The Statistical Package for Social Sciences (SPSS, V. 22) was used for coding, tabulation, and analysis of study data. Quantitative data were expressed by mean and SD, while qualitative data were described by number and percentage.

Shapiro-Wilk test was used to check normal distribution. We used Chi-Square and Fisher’s Exact test to compare different groups. P value < 0.050 was considered significant.

**Results**

I) Descriptive statistics of the studied cases

**Table (1): Baseline demographic characteristics and comorbidities among the studied cases**

Characteristics	Mean±SD	Range
Age (years)	46.3±10.0	27.0–70.0
BMI (kg/m <sup>2</sup> )	32.4±4.7	20.5–48.9
Parity	4.0 (3.0–5.0)	0.0–8.0
	<b>n</b>	<b>%</b>
Diabetes mellitus	17	21.5%
Hypertension	18	22.8%

<b>Constipation</b>	50	63.3%
<b>Chronic liver disease</b>	13	16.5%
<b>Asictes</b>	4	5.1%
<b>Chronic kidney disease</b>	1	1.3%
<b>Chronic obstructive pulmonary diseases</b>	0	0.0%
<b>Pelvic prolapse</b>	57	72.2%

**Total=79**

Table (1) showed that: among the studied cases; pelvic prolapse & constipation were the most frequent comorbidities (72.2% and 63.3% respectively).

**Table (2): Baseline urine analysis among the studied cases**

<b>Characteristics</b>	<b>n</b>	<b>%</b>
<b>Red blood cells</b>	3	3.8%
<b>Pus cells</b>	46	58.2%
<b>Epithelial cells</b>	15	19.0%
<b>Red cells</b>	6	7.6%
<b>Calcium oxalate</b>	17	21.5%
<b>Uric acid</b>	2	2.5%
<b>Amporphus</b>	9	11.4%
<b>Positive culture</b>	21	26.6%

**Total=79**

Table (2) showed that: among the studied cases; pus cells were detected in 58.2% of the studied cases, 26.0% had positive culture.

**Table (3): Operative findings among the studied cases**

<b>Characteristics</b>	<b>n</b>	<b>%</b>
<b>Visceral injury</b>	2	2.5%
<b>Vaginal erosions</b>	1	1.3%
	<b>Median (1st - 3rd IQ)</b>	<b>Range</b>
<b>Hospital stay (days)</b>	2.0 (1.0–3.0)	1.0–14

**Total=79. IQ: Interquartiles.**

Table (3) showed that: among the studied cases; visceral injury and vaginal erosions were uncommon (2.5% and 1.3% respectively).

**Table (4): Postoperative complications among the studied cases**

<b>Complications</b>	<b>n</b>	<b>%</b>	
<b>Urine retention</b>	4	5.1%	
<b>Dyspareunia</b>	27	34.2%	
<b>Recurrence</b>	13	16.5%	
<b>Time to recurrence (Total=13)</b>	<b>1-6 months</b>	7	53.8%
	<b>7-12 months</b>	4	30.8%
	<b>13-18 months</b>	2	15.4%

**Total=79**

Table (4) showed that: among the studied cases; dyspareunia was the most frequent complication (34.2%), while recurrence and urine retention were (16.5% and 5.1% respectively).

Majority of recurrence occurred in the 1<sup>st</sup> 6-months (53.0%), followed by 2<sup>nd</sup> 6-months (30.8%), then 3<sup>rd</sup> 6-months (15.4%).

**Table (5): International Consultation of Incontinence Questionnaire Short Form (ICIQ UI SF) findings among the studied cases**

Characteristics		n	%
<b>Leak</b>		35	44.3%
<b>How often</b>	<b>Never</b>	44	55.7%
	<b>About once a week or less often</b>	3	3.8%
	<b>2 or 3 times a week</b>	5	6.3%
	<b>About once a day</b>	14	17.7%
	<b>Several times a day</b>	12	15.2%
	<b>All the time</b>	1	1.3%
<b>How much urine</b>	<b>None</b>	44	55.7%
	<b>A small amount</b>	21	26.6%
	<b>A moderate amount</b>	8	10.1%
	<b>A large amount</b>	6	7.6%
<b>When</b>	<b>Never</b>	44	55.7%
	<b>Before you can get to the toilet</b>	7	8.9%
	<b>When you cough or sneeze</b>	7	8.9%
	<b>When you are asleep</b>	8	10.1%
	<b>When you are physically active/exercising</b>	6	7.6%
	<b>When you have finished urinating and are dressed</b>	3	3.8%
	<b>For no obvious reason</b>	2	2.5%
	<b>All the time</b>	2	2.5%
		<b>Median (1<sup>st</sup> -3<sup>rd</sup> IQ)</b>	<b>Range</b>
<b>Interfere with activity</b>		0.0 (0.0–3.0)	0.0–10.0
<b>Total ICIQ score</b>		0.0 (0.0–8.0)	0.0–20.0

**Total=79. IQ: Interquartiles.**

Table (5) showed that: among the studied cases; leak was reported in less than half of cases (44.3%).

**Table (6): Incontinence Impact Questionnaire-Short Form (IIQ-7) findings among the studied cases**

Characteristics		n	%
<b>Affect household activities</b>	<b>Not at all</b>	55	69.6%
	<b>Slightly</b>	13	16.5%
	<b>Moderate</b>	7	8.9%
	<b>Greatly</b>	4	5.1%

<b>Affect physical recreational activities</b>	<b>Not at all</b>	52	65.8%
	<b>Slightly</b>	17	21.5%
	<b>Moderate</b>	4	5.1%
	<b>Greatly</b>	6	7.6%
<b>Disrupt your prayer schedule</b>	<b>Not at all</b>	57	72.2%
	<b>Slightly</b>	10	12.7%
	<b>Moderate</b>	10	12.7%
	<b>Greatly</b>	2	2.5%
<b>Affect ability to do social activities</b>	<b>Not at all</b>	52	65.8%
	<b>Slightly</b>	17	21.5%
	<b>Moderate</b>	5	6.3%
	<b>Greatly</b>	5	6.3%
<b>Affect ability to travel</b>	<b>Not at all</b>	59	74.7%
	<b>Slightly</b>	10	12.7%
	<b>Moderate</b>	3	3.8%
	<b>Greatly</b>	7	8.9%
<b>Experience frustration</b>	<b>Not at all</b>	49	62.0%
	<b>Slightly</b>	18	22.8%
	<b>Moderate</b>	8	10.1%
	<b>Greatly</b>	4	5.1%
<b>Affect emotional health</b>	<b>Not at all</b>	53	67.1%
	<b>Slightly</b>	15	19.0%
	<b>Moderate</b>	4	5.1%
	<b>Greatly</b>	7	8.9%
<b>Unsatisfaction</b>		35	44.3%
		<b>Median (1st - 3rd IQ)</b>	<b>Range</b>
<b>Total score</b>		0.0 (0.0–19.0)	0.0–95.2

**Total=79. IQ: Interquartiles.**

Table (6) showed that: among the studied cases; unsatisfaction was reported in less than half of cases (44.3%).

**Table (7): Comparison according to recurrence**

<b>Characteristics</b>	<b>Recurrence (Total=13)</b>	<b>No recurrence (Total=66)</b>	<b>p-value</b>
<b>Age (years)</b>	54.5±6.9	44.7±9.8	<b>^0.001*</b>
<b>BMI (kg/m<sup>2</sup>)</b>	34.2±5.8	32.0±4.5	<b>^0.129</b>
<b>Parity</b>	4.0 (3.0–5.0)	4.0 (3.0–5.0)	<b>△0.634</b>
<b>Diabetes mellitus</b>	7 (53.8%)	10 (15.2%)	<b>§0.005*</b>
<b>Hypertension</b>	4 (30.8%)	14 (21.2%)	<b>§0.479</b>
<b>Constipation</b>	7 (53.8%)	43 (65.2%)	<b>§0.533</b>
<b>Chronic liver disease</b>	2 (15.4%)	11 (16.7%)	<b>§0.999</b>
<b>Asictes</b>	0 (0.0%)	4 (6.1%)	<b>§0.999</b>

<b>Chronic kidney disease</b>	0 (0.0%)	1 (1.5%)	§0.999
<b>Pelvic prolapse</b>	11 (84.6%)	46 (69.7%)	§0.334
<b>Red blood cells</b>	2 (15.4%)	1 (1.5%)	§0.069
<b>Pus cells</b>	11 (84.6%)	35 (53.0%)	#0.035*
<b>Epithelial cells</b>	4 (30.8%)	11 (16.7%)	§0.256
<b>Red cells</b>	0 (0.0%)	6 (9.1%)	§0.582
<b>Calcium oxalate</b>	8 (61.5%)	9 (13.6%)	§0.001*
<b>Uric acid</b>	0 (0.0%)	2 (3.0%)	§0.999
<b>Amporphus</b>	3 (23.1%)	6 (9.1%)	§0.162
<b>Positive culture</b>	7 (53.8%)	14 (21.2%)	§0.034*
<b>Visceral injury</b>	1 (7.7%)	1 (1.5%)	§0.304
<b>Vaginal erosions</b>	0 (0.0%)	1 (1.5%)	§0.999
<b>Hospital stay (days)</b>	2.0 (2.0–3.0)	2.0 (1.0–3.0)	△0.827

^Independent t-test. △Mann Whitney. §Fisher's Exact test. \*Significant.

Table (7) showed that: Cases with recurrence significantly had higher age and more frequent diabetes mellitus, pus cells, calcium oxalate and positive culture.

**Table (8): Comparison according to urine retention**

<b>Characteristics</b>	<b>Retention (Total=4)</b>	<b>No retention (Total=65)</b>	<b>p-value</b>
<b>Age (years)</b>	47.8±14.2	46.2±9.9	^0.765
<b>BMI (kg/m<sup>2</sup>)</b>	30.4±5.1	32.5±4.7	^0.380
<b>Parity</b>	5.0 (4.0–5.0)	4.0 (3.0–5.0)	△0.538
<b>Diabetes mellitus</b>	1 (25.0%)	16 (21.3%)	§0.999
<b>Hypertension</b>	1 (25.0%)	17 (22.7%)	§0.999
<b>Constipation</b>	4 (100.0%)	46 (61.3%)	§0.291
<b>Chronic liver disease</b>	0 (0.0%)	13 (17.3%)	§0.999
<b>Asictes</b>	1 (25.0%)	3 (4.0%)	§0.191
<b>Chronic kidney disease</b>	0 (0.0%)	1 (1.3%)	§0.999
<b>Pelvic prolapse</b>	4 (100.0%)	53 (70.7%)	§0.572
<b>Red blood cells</b>	0 (0.0%)	3 (4.0%)	§0.999
<b>Pus cells</b>	2 (50.0%)	44 (58.7%)	§0.999
<b>Epithelial cells</b>	1 (25.0%)	14 (18.7%)	§0.577
<b>Red cells</b>	1 (25.0%)	5 (6.7%)	§0.276
<b>Calcium oxalate</b>	1 (25.0%)	16 (21.3%)	§0.999
<b>Uric acid</b>	0 (0.0%)	2 (2.7%)	§0.999
<b>Amporphus</b>	1 (25.0%)	8 (10.7%)	§0.390
<b>Positive culture</b>	1 (25.0%)	20 (26.7%)	§0.999
<b>Visceral injury</b>	2 (50.0%)	0 (0.0%)	§0.002*
<b>Vaginal erosions</b>	1 (25.0%)	0 (0.0%)	§0.051
<b>Hospital stay (days)</b>	1.5 (1.0–4.5)	2.0 (1.0–3.0)	△0.674

^Independent t-test. △Mann Whitney. §Fisher's Exact test. \*Significant.

Table (8) showed that: Cases with urine retention significantly had more frequent visceral injury.

**Table (9): Comparison according to dyspareunia**

Characteristics	Dyspareunia (Total=27)	No dyspareunia (Total=52)	
Age (years)	43.2±8.6	47.9±10.4	^ <b>0.047*</b>
BMI (kg/m <sup>2</sup> )	32.1±5.9	32.5±4.1	^0.722
Parity	4.0 (3.0–5.0)	4.0 (3.0–5.0)	△0.398
Diabetes mellitus	5 (18.5%)	12 (23.1%)	#0.640
Hypertension	2 (7.4%)	16 (30.8%)	# <b>0.019*</b>
Constipation	22 (81.5%)	28 (53.8%)	# <b>0.016*</b>
Chronic liver disease	6 (22.2%)	7 (13.5%)	§0.350
Asictes	2 (7.4%)	2 (3.8%)	§0.603
Chronic kidney disease	0 (0.0%)	1 (1.9%)	§0.999
Pelvic prolapse	20 (74.1%)	37 (71.2%)	#0.784
Red blood cells	1 (3.7%)	2 (3.8%)	§0.999
Pus cells	16 (59.3%)	30 (57.7%)	#0.983
Epithelial cells	3 (11.1%)	12 (23.1%)	#0.198
Red cells	2 (7.4%)	4 (7.7%)	§0.999
Calcium oxalate	10 (37.0%)	7 (13.5%)	# <b>0.016*</b>
Uric acid	0 (0.0%)	2 (3.8%)	§0.056
Amporphus	6 (22.2%)	3 (5.8%)	§0.999
Positive culture	7 (25.9%)	14 (26.9%)	#0.924
Visceral injury	2 (7.4%)	0 (0.0%)	§0.114
Vaginal erosions	1 (3.7%)	0 (0.0%)	§0.342
Hospital stay (days)	2.0 (1.0–2.0)	2.0 (1.0–3.0)	△0.137

^Indepdent t-test. △Mann Whitney. #Chi square test. §Fisher’s Exact test. \*Significant.

Table (9) showed that: Cases with dyspareunia significantly had lower age as well as more frequent constipation and urinary calcium oxalate, while less frequent hypertention.

**Table (10): Comparison according to cure**

Characteristics	Leak (Total=35)	Cure (Total=44)	p-value
Age (years)	50.7±9.8	42.8±8.8	^< <b>0.001*</b>
BMI (kg/m <sup>2</sup> )	33.4±6.0	31.6±3.3	^0.110
Parity	5.0 (3.0–5.0)	4.0 (3.0–5.0)	△0.152
Diabetes mellitus	12 (34.3%)	5 (11.4%)	# <b>0.014*</b>
Hypertension	14 (40.0%)	4 (9.1%)	# <b>0.001*</b>
Constipation	25 (71.4%)	25 (56.8%)	#0.181
Chronic liver disease	5 (14.3%)	8 (18.2%)	#0.643
Asictes	2 (5.7%)	2 (4.5%)	§0.999
Chronic kidney disease	0 (0.0%)	1 (2.3%)	§0.999
Pelvic prolapse	30 (85.7%)	27 (61.4%)	# <b>0.016*</b>
Red blood cells	2 (5.7%)	1 (2.3%)	§0.581
Pus cells	23 (65.7%)	23 (52.3%)	#0.229



<b>Epithelial cells</b>	9 (25.7%)	6 (13.6%)	#0.174
<b>Red cells</b>	4 (11.4%)	2 (4.5%)	§0.398
<b>Calcium oxalate</b>	11 (31.4%)	6 (13.6%)	#0.056
<b>Uric acid</b>	1 (2.9%)	1 (2.3%)	§0.999
<b>Amporphus</b>	3 (8.6%)	6 (13.6%)	§0.724
<b>Positive culture</b>	15 (42.9%)	6 (13.6%)	#0.003*
<b>Visceral injury</b>	2 (5.7%)	0 (0.0%)	§0.193
<b>Vaginal erosions</b>	1 (2.9%)	0 (0.0%)	§0.443
<b>Hospital stay (days)</b>	3.0 (2.0–3.0)	2.0 (1.0–3.0)	△0.006*

^Independent t-test. △Mann Whitney. #Chi square test. §Fisher's Exact test. \*Significant.

Table (10) showed that: cases with urine leak significantly had higher age as well as more frequent hypertension, diabetes mellitus, pelvic prolapse and urinary positive culture as well as longer hospital stay.

**Table (11): Comparison according to satisfaction**

<b>Characteristics</b>	<b>Unsatisfied (Total=35)</b>	<b>Satisfied (Total=34)</b>	<b>p-value</b>
<b>Age (years)</b>	49.7±9.5	43.5±9.7	^0.006*
<b>BMI (kg/m<sup>2</sup>)</b>	33.1±6.2	31.8±3.2	^0.272
<b>Parity</b>	5.0 (3.0–5.0)	4.0 (3.0–5.0)	△0.152
<b>Diabetes mellitus</b>	11 (31.4%)	6 (13.6%)	#0.056
<b>Hypertension</b>	13 (37.1%)	5 (11.4%)	#0.007*
<b>Constipation</b>	25 (71.4%)	25 (56.8%)	#0.181
<b>Chronic liver disease</b>	5 (14.3%)	8 (18.2%)	#0.643
<b>Asictes</b>	3 (8.6%)	1 (2.3%)	§0.317
<b>Chronic kidney disease</b>	0 (0.0%)	1 (2.3%)	§0.999
<b>Pelvic prolapse</b>	30 (85.7%)	27 (61.4%)	#0.016*
<b>Red blood cells</b>	2 (5.7%)	1 (2.3%)	§0.581
<b>Pus cells</b>	24 (68.6%)	22 (50.0%)	#0.096
<b>Epithelial cells</b>	8 (22.9%)	7 (15.9%)	#0.434
<b>Red cells</b>	3 (8.6%)	3 (6.8%)	§0.999
<b>Calcium oxalate</b>	11 (31.4%)	6 (13.6%)	#0.596
<b>Uric acid</b>	1 (2.9%)	1 (2.3%)	§0.999
<b>Amporphus</b>	4 (11.4%)	5 (11.4%)	§0.999
<b>Positive culture</b>	15 (42.9%)	6 (13.6%)	#0.003*
<b>Visceral injury</b>	2 (5.7%)	0 (0.0%)	§0.193
<b>Vaginal erosions</b>	1 (2.9%)	0 (0.0%)	§0.443
<b>Hospital stay (days)</b>	2.0 (2.0–3.0)	2.0 (1.0–3.0)	△0.018*

^Independent t-test. △Mann Whitney. #Chi square test. §Fisher's Exact test. \*Significant.

Table (11) showed that cases with unsatisfaction significantly had higher age and more frequent hypertension, red blood cells and urinary positive culture as well as longer hospital stay.

## **Discussion**

The estimated prevalence of female stress urinary incontinence is nearly 16% in women aged 30–60. <sup>22</sup> Lifestyle modifications, bladder training, and pelvic floor exercises are considered initial conservative management. If failed to improve the QOL, the role of surgery is to treat the SI. <sup>23</sup>

Synthetic mid-urethral sling techniques have minimized operative times and complication rates for treating female urinary incontinence. The safety and efficacy of TOT (trans-obturator tape procedure) in treating SUI has been proven since 2001. <sup>24</sup>

Since Stress urinary incontinence in women's lives represents major conflict and may be associated with impaired quality of life and satisfaction, evaluating the effectiveness of trans-obturator tape (TOT) in treating female SUI was highlighted as a main point of interest. <sup>23</sup>

Our analysis was based on the data of 79 women who underwent the trans-obturator tape (TOT) procedure for treating female urinary incontinence in the last four years in the urogynecology department.

As regards the demographic characteristics, the current study results revealed that the mean age of the patients was  $46.3 \pm 10.0$  years, BMI was  $32.4 \pm 4.7$  kg/m<sup>2</sup> and the parity was 4.0 (3.0–5.0) which were multiparous. The Pelvic prolapse & constipation were the most frequent associated comorbidities (72.2% and 63.3% respectively). Pus cells were detected in 58.2% of the studied cases. However, 26.0% had positive culture.

To the best of our knowledge, there is a paucity of studies in literature in Egypt evaluating the rates of cure, complications and patients' satisfaction after doing a trans-obturator tape (TOT) procedure in patients with stress urinary incontinence, and that represents a strong point of our study.

Magon and Chopra <sup>22</sup> conducted a prospective experimental study that enrolled 59 patients who applied TOT in treating female SI. Their study revealed that the mean age was 46.2 years and 84.7% were multiparous women. This is consistent with Taweel and Rabah <sup>25</sup> who reported that the mean age of patients was  $52 \pm 9$  years (range 34–70 years). Moore and Miklos <sup>26</sup> in their study had patients with an average age of  $56.8 \pm 11.7$ . Kaelin-Gambirasio et al. <sup>27</sup> in their study of 233 patients, the average age was  $57.9 \pm 13.2$  years.

Natale et al. <sup>23</sup> conducted a single-center prospective study that enrolled 136 patients and revealed that a mean age of 59 years, BMI was  $27.22 \pm 2.8$  kg/m<sup>2</sup> and the parity was 2.0 (0.0–6.0).

As regards the operative complications, our study results revealed that visceral injury (2 cases) and vaginal erosions (1 case) were uncommon (2.5% and 1.3% respectively). Furthermore, Dyspareunia was the most frequent complication (34.2%), while recurrence and urine retention were (16.5% and 5.1% respectively). The majority of recurrence occurred in the 1st 6-months (53.0%), followed by 2nd 6-months (30.8%), then 3rd 6-months (15.4%). The patients' average hospital stay after the operation was two days (range=1.0–3.0).

Our study results reported that Cases with dyspareunia significantly had lower age and more frequent constipation and urinary calcium oxalate, while less frequent hypertension (p value= 0.047, 0.019, 0.016, 0.016), respectively.

In concordance with our results, Magon and Chopra <sup>22</sup> revealed intraoperative injury of the bladder in 1 case and intraoperative injury of the urethra in 1 patient. Twenty-seven patients (45.8%) were discharged within the first day of surgery, Thirty patients (50.8%) were discharged within third day of surgery, and only two patients (3.4%) had to

stay hospitalized for more than three days due to bladder/ urethral injury. The average stay was 1.6 days in this study.

The average stay in the study of Purnichescu et al. 28 was 1.6 days and was 2.2 days in study of Kaelin-Gambirasio et al. 27

Yonguc et al. 24 conducted a retrospective study that enrolled 126 women who underwent TOT to evaluate long-term cure rates and late complication rates after treatment for female stress urinary incontinence (SUI) with trans-obturator tape (TOT) procedure and reported an overall complication rate was 11.1%. Vaginal erosion was recorded in 2 patients (1.6%), one treated by local estrogen cream and the other by mesh removal. Two patients had dyspareunia and two cases of urinary retention (one treated by prolonged urethral catheterization and the other by tape incision).

Our study results reported that Cases with recurrence significantly had higher age and more frequent diabetes mellitus, pus cells, calcium oxalate, and positive culture (p value= 0.001, 0.005, 0.035, 0.001, 0.034), respectively. In contrast, Cases with urine retention significantly had more frequent visceral injury (p value= 0.002).

In line with our results, Natale et al. 23 suggested that elderly cases developed more storage symptoms. Detrusor instability (due to DM or UTI) was significantly associated with recurrent SI (P = 0.038), and parity of more than two was significantly associated with recurrent SI (P = 0.023).

Our results agree with the study of Gleason et al. 29, who demonstrated significantly lower success rates in Mixed Urinary Incontinence patients compared to those with Stress Urinary Incontinence (64% vs 85%, P < .001) proofing the association of DM and UTI risk factors for the recurrence and the failure of the operation.

On the contrary, Ayhan et al. 30 showed that patients with low parities, especially those

with less deliveries, had significantly a higher success rates following SI surgery.

As regards Follow-up postoperatively, our study results revealed that the cure rate and satisfaction rate were 55.7% and leak and Unsatisfaction were reported in 44.3% of cases and the cases with urine leak and unsatisfaction significantly had higher age as well as more frequent hypertension, pelvic prolapse and urinary positive culture as well as longer hospital stay. In addition, diabetes mellitus is significantly associated with leak. The total ICIQ-SF scores and IIQ-7 were 0 in all patients after the surgery while before the surgery, the ICIQ-SF scores and IIQ-7 were missed which is the disadvantage the retrospective study design of the current study.

Patient satisfaction is a very important issue in incontinence surgery, since it quantitates the effect of the treatment on the patient's QoL. 24

In agreement with our findings, Magon and Chopra 22 revealed that total success rate of trans-obturator sling fixation in the study was 93.2% (95% CI: 86.4–99.5). A total of 51 patients which constituted 86.4% of patients were completely satisfied with the surgical outcome, whereas 4 patients (6.8%) were partially satisfied and an equal number of patients, i.e., 4 were unsatisfied with the surgical outcome, the same patients in whom the surgery was not successful. Yonguc et al. 24 reported that the aging process brought about more UUI symptoms during 5 years compared to baseline.

Natale et al. 23 reported that the objective cure rate was 87.1% (97 patients). In 2017, Serati et al. 31 reported the objective cure rates of TOT, in a group of 160 women with uro-dynamically proven pure SUI with a follow-up of 10 years and showed an objective outcome of 92%. In 2019, Zhang et al. 32 published data on a group of 73 uncomplicated SUI patients who underwent TOT with a follow-up of 12 years and

reported an objective cure rate of 82.2% and a subjective satisfaction rate of 80.8%. These cure rates are higher than in our study due to the larger sample size and prospective study design which are different from our study.

Yonguc et al.<sup>24</sup> revealed that the cure rate and satisfaction rate were 89.6% and 92% respectively and reported that the mean ICIQ-SF scores of the 126 patients before surgery were 15.7 (SD  $\pm$  3.1). At first year, of the 126 patients, 109 patients had 0 score that were accepted as subjective cure and the remaining 17 patients had a mean score of 10.1 (SD  $\pm$  4.6) from ICIQ-SF.

Also, Cheng and Liu<sup>33</sup> reported patient satisfaction rates at 1 and 5 years as 78 and 69%, respectively, whereas Richter et al.<sup>34</sup> reported a 90% patient satisfaction rate for 12-month follow-up.

One of the most important and not well recognized advantages of the TOT as compared with other mid-urethral sling procedures is the lower rate of de novo urge/urge incontinence. In the trans-obturator approach, the path of the tape, crossing the obturator foramen, muscle, and fascia, reproduces the natural sub-urethral suspension by reinforcing the rotational pivot point, restoring continence while sparing the retropubic space. Sparing the retropubic space may preserve any periurethral nerve fibers that may be associated with urethral function and stability.<sup>35</sup> Second, the TOT is associated with a lower risk of urethral obstruction as compared with other mid-urethral sling procedures. The trans-obturator sling procedure spares the retropubic space and thus also eliminates the risk of major bowel, neural, and vascular complications which have been reported with the TVT.<sup>24</sup> In our study, there was no incidence of de novo urgency/urge incontinence, while Natale et al.<sup>23</sup> observed de novo urgency in 7.3% and de novo Urge urinary incontinence (UI) in 4.1% of the studied patients. Also, Yonguc et al.<sup>24</sup> reported that two patients (1.6%) had de novo urge symptoms confirmed

with urodynamic studies (UDS). Forty-one patients (32.5%) whose UI symptoms continued after surgery and 2 patients who had de novo urgency were treated with antimuscarinic agents.

Another important advantage of TOT is that since it is not possible anatomically to over tighten the tape, there is hardly any reported incidence of urinary retention because of mechanical obstruction, whereas obstructive voiding dysfunction is the most commonly reported complication of some other mid urethral sling placements like TVT.<sup>23</sup> In the present study, no patient developed urethral obstruction while Yonguc et al.<sup>24</sup> reported that five patients (3.9%) were diagnosed with recurrent SUI and had obstructive urinary symptoms with increased residual urine.

#### **The strength points of this study:**

The strength points of this study are that its setting at a single tertiary care center and it is the first study in Ain Shams Maternity Hospital to assess the rates of cure, complications and patients' satisfaction after doing trans obturator tape (TOT) procedure in patients with stress urinary incontinence (SUI). The postoperative complications, satisfaction, and objective cure rates were comprehensively evaluated with standardized methods; we used questionnaires, that were validated in our language.

#### **The limitations of the study:**

The limitations of the study are worthy of mention, firstly by its retrospective nature which can be associated with missed clinical information of patients. Secondly, relatively smaller sample size relative to the previous studies, not being a multicentric study and this represents a significant risk of publication bias. Thirdly, the relatively short-term follow-up of patients postoperatively as most of the previous studies tracked outcomes for 3 years postoperatively, which may underestimate the incidence of recurrence of de novo SUI, or mesh erosion.

Although there have been studies quoted in the literature which have followed up patients for almost up to 3 years after TOT application, it is still felt desirable that larger trials with bigger sample size and with a longer duration of follow-up for evaluating long-term success of TOT are required.

Further, comparative trials comparing TOT with other surgical options available for treatment of SUI shall be able to give it its right place of honor in the treatment of SUI. It has all the potential to be the new Gold Standard in the treatment of female SUI.

### **Conclusion**

As evident from the current study, TOT procedure is one of the effective minimally invasive alternatives for the treatment of pure SUI and MUI in long term with low complication rates, high cure rates, fast recovery and good patient satisfaction for SUI in short term in a retrospective point of view, although our study has limitations about the time period in which the patients were followed.

The present study can burden the knowledge and shed some light on future prospective studies with larger sample sizes demonstrating the long-term outcomes of TOT.

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