EARLY OUTCOME OF TOT SURGERY FOR URINARY INCONTINENCE IN SULAIMANI TEACHING HOSPITAL

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ABSTRACT

Background

Female urinary incontinence is a major health issue affecting about 30% of adult women and majority of them is stress type. Transobturator tape (TOT) technique is relatively safe and associated with minimum complication rate.

Objectives

To identify the safety, success rate and efficacy of TOT procedures performed for female patients with stress urinary incontinence.

Patients and Methods

A prospective study included thirty patients with history of urinary incontinence (22 patients with stress type and 8 patients with mixed type UI). They underwent TOT procedure in Sulaimani teaching hospital under general or spinal anesthesia; they were collected over a year from June 2014 to June 2015, all of them referred from urological clinic with history of stress or mixed urinary incontinence. The response of TOT surgery was assessed in both subjective and objective ways, using the ICIQ-UI short form and both cough stress test and Q-tip test (before and after surgery), 20 of them had urodynamic study before surgery to confirm the diagnosis, follow up done at one week, three months and six months postoperatively.

Results

A total of 30 females with mean age (48.8±9.51) years, Mean number of deliveries for studied females was (4.9±2) deliveries. Main type of urinary incontinence among studied females was stress urinary incontinence (73, 3%); followed by mixed urinary incontinence (26, 7%), all of them were from Sulaimani city and its peripheries. In this study; we found that the success rate is 80% (considering both objective and subjective outcome) which is comparative to similar studies. The early complications were mainly perineal (groin) and upper thigh pain, while the late complications were the development of de novo detrusor over activity, there were no vaginal or urethral erosions.

Conclusion

Transobturator tape (TOT) is an efficient and safe way of managing stress urinary incontinence with high success rate and short hospitalization with minimum and simple early complications.

Keywords: *Urodynamic, Transobturator tape (TOT), Stress urinary incontinence.*

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INTRODUCTION

Urinary incontinence (UI): is a major health issue results in psychological and medical morbidity, significantly impacting health-related quality of life in a manner similar to other chronic conditions, in addition to its cost because of repeated UTI, skin problems and cost of laundry diapers and pads [1].

The most common type of UI is: Stress urinary incontinence (SUI); defined as, the involuntary leakage of urine on effort or exertion. The vast majority of stress incontinence occurs in women after middle age (with repeated vaginal deliveries and obstructed labor due to trauma, aging, or obesity). SUI is thought to be caused by two major anatomical deficits; hypermobility of the sphincteric unit and intrinsic sphincteric deficiency [2]. The second type is Urge urinary incontinence (UUI); defined as the symptomatic complaint of involuntary leakage accompanied by or immediately preceded by urgency. It can present in different symptomatic forms e.g. as frequent small losses between micturitions or as a catastrophic leak with complete bladder emptying [3]. Detrusor over activity: is a urodynamic observation characterized by involuntary detrusor contractions during the filling phase of the bladder, which may be spontaneous or provoked and can consequently cause UI, [4]. The third type is mixed urinary incontinence (MUI), is defined as the symptomatic complaint of involuntary leakage of urine associated or immediately preceded by urgency and synchronous with exertion, effort, sneezing, or coughing [3]. Other types of urinary incontinence include: nocturnal enuresis, continuous incontinence, and overflow incontinence [4]. International studies show a gradual increase in the prevalence of female UI during adulthood to 30 %, stabilizing between the ages of 50 and 70 years, before rising again. Approximately 50% of women suffer stress incontinence, 11% urgency incontinence and 36% of mixed type [5]. Diagnosis of female urinary incontinence accomplished by several measures starting with history using a validated patient-completed questionnaire (e.g.: ICIQ-short form UI) shown in figure [3], physical examination, pad testing, stress cough test and urodynamic study [6].

The role of urodynamic study (UDS) includes discriminating between different types of urinary incontinence, diagnosing the severity, and identifying concomitant complicating factors such as outlet obstruction, detrusor hypo-activity, and detrusor over-activity [7]. While the diagnosis and optimal treatment of LUTD requires a careful history and objective evaluation, it has been demonstrated that urinary symptoms are not specific in predicting the dysfunction involved in the patient's incontinence [8–9]. Uroflowmetry measures urinary flow time, flow rate, voided volume, and average flow rate, post-void residual (PVR) measures the quantity of urine remaining in the bladder after voiding [9]. Preoperative uroflowmetry showing voiding abnormalities such as valsalva voiding or low flow rates may predict abnormal symptomatic voiding dysfunction postoperatively [10]. Pressure flow study (PFS) measures the relationship between pressure in the bladder and urine flow rate during emptying and, hence, provides information about detrusor contractility and bladder outlet obstruction, it is recommended to investigate voiding dysfunction, specifically in those patients who had previous incontinence surgery and those with high residual urine volume [11]. Complex single-channel and multichannel (Cystomyography) CMG requires specialized, expensive equipment, and training to properly interpret the findings [13].

Management of female stress urinary incontinence is either conservative or surgical: Surgical treatment using midurethral sling procedures, these procedures include: tension-free vaginal tape (TVT) and Transobturator tape (TOT). Materials used as sling constituent include: autografts, allografts, xenografts and more recently, synthetic variants (figure 2) [14]. Delorme (2001); initially described the placement of synthetic polypropylene mesh using the trans-obturator tape (TOT) approach. This technique was described as being relatively facile and associated with fewer complications than retropubic approaches, it was also thought that the procedure does not require cystoscopy, in those individuals, a functional kinking of the urethra during stress events is noted to occur when the tape is placed at the midurethra, in relatively long-term follow-up (3 years); For successful implantation of the TOT, an understanding of surgical anatomy of the pelvic floor, including the surrounding neurovascular structures, pelvic and perineal anatomy, and the obturator foramen is crucial to provide surgical success and minimize morbidity [14]. Transobturator (Outside-In) is when the patient is placed in the dorsal lithotomy position with legs in hyperflexion (120 degrees), a small vertical vaginal incision is created over the midurethra, and dissection is carried out laterally to the ischiopubic ramus, a puncture incision is made in the obturator foramen at the level of the clitoris in the leg using the tunneler (figure 4); the obturator

membrane is perforated, at which point resistance is noted by the operative surgeon using the non-dominant index finger and identifying the landmarks of ramus and the obturator internus muscle, the surgeon turns the tunneler in a medial orientation and advances it on the tip of the index finger and brings it out through the vaginal incision, the synthetic material is then attached to the tunneler and brought out through the inner thigh stab wound. The procedure is then repeated on the contralateral side, an1 8-Fr Foley catheter was introduced urethrally and maintained for 2–4 days, according to the circumstances of surgery, a vaginal pack, soaked with povidine iodine, was inserted at the end of surgery and held for 1 day for sterilization and to avoid hematoma formation [14]. The procedure shown in figure 1.

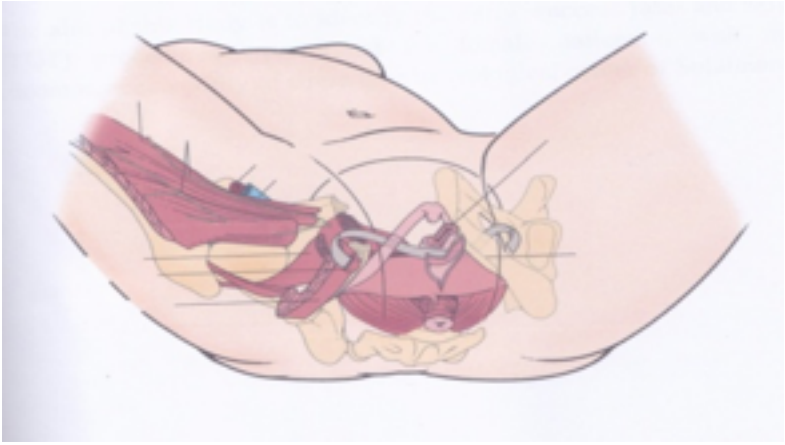

Figure 1. Midurethral sling as placed by the trans-obturator approach [14].

Aim of Study

The aim of this study is to identify the early success rate and safety of (TOT) procedures performed for female patients with urinary incontinence, majority of stress type in urological center of Sulaimani.

PATIENTS AND METHODS

A prospective observasional study included thirty patients with history of urinary incontinence (22 of stress type and 8 of mixed type) have undergone trans-obturator tape procedure (TOT) in Sulaimani teaching hospital were seen over a year from June 2014 to June 2015. All of them were referred from urological clinic with history of stress urinary incontinence and failure of conservative treatment.

All these patients were assessed by full history, Physical examination, routine investigations including: urinalysis, complete blood count, renal function test ,viral screen, urine culture, abdominal ultrasonography, KUB, diagnostic cystoscopy and cough stress test with Q-tip test (is an office test to evaluate the adequacy of anatomic support to the bladder neck and to determine an abnormal urethrovesical angle). were done for every patient, 20 of these patients had a urodynamic study due to either the history was inconclusive or indicated mixed type, and this UDS included cystometry and flowmetry prior to surgical intervention. The patient-completed questionnaire ICIQ-Urinary Incontinence short form (International Consultation on Incontinence Modular Questionnaire) which provides a brief and robust measure to assess the impact of symptoms of incontinence on quality of life and outcome of treatment. It was used for every patient before and after surgery to assess initial symptoms and patient-reported outcome following intervention.

The Inclusion criteria of this study were stress urinary incontinence, whether in a pure form or a major component of mixed urinary incontinence. While the exclusion criteria were a mild degree of UI, history of previous surgery for UI, neurological lower urinary tract dysfunction (neurogenic voiding dysfunction), Urge urinary incontinence, active vaginal infection or UTI, concomitant genitourinary prolapsed (cystocele more than grade one), a significant post void residual volume, male patients with UI.

The follow-up visits were scheduled at one week, one month, three months, and six months thereafter. The primary outcome was the cure of SUI, as shown by significant dryness as perceived by the patient (no more use of pads) and also determined by using ICIQ-UI short form and both cough stress test and Q-tip test before and after surgery; i.e. the patients were assessed

in both subjective and objective ways. Patients with a concomitant cystocele included in the study were only those with grade 1, because this type usually requires no further gynaecological intervention. The relatively new macroporous polypropylene tape (synthetic tape) inserted through the Transobturator route, the ideal sling material should be inert, not carcinogenic, non-inflammatory, with enough strength and flexibility, not modifiable by the ingrowth of tissue, and affordable.

Statistical analysis: patients' data entered using computerized statistical software; Statistical Package for Social Sciences (SPSS) version 20 was used. Descriptive statistics presented as (mean ± standard deviation) and frequencies as percentages. Multiple contingency tables conducted and appropriate statistical tests performed. In all statistical analysis, level of significance (p value) set at ≤ 0.05 and the result presented as tables.

Figure 2. The tape of midurethral sling surgery (TOT).

ICIQ-UI Short Form

Initial number | CONFIDENTIAL | DAY MONTH YEAR Today's date

Many people leak urine some of the time. We are trying to find out how many people leak urine, and how much this bothers them. We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the PAST FOUR WEEKS.

1 Please write in your date of birth: DAY MONTH YEAR

2 Are you *(tick one)*: Female ☐ Male ☐

3 How often do you leak urine? *(Tick one box)*

never	0
about once a week or less often	1
two or three times a week	2
about once a day	3
several times a day	4
all the time	5

4 We would like to know how much urine you think leaks.
How much urine do you usually leak (whether you wear protection or not)?
(Tick one box)

none	0
a small amount	2
a moderate amount	4
a large amount	6

5 Overall, how much does leaking urine interfere with your everyday life?
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**
not at all — a great deal

ICIQ score: sum scores 3+4+5 ☐☐

6 When does urine leak? *(Please tick all that apply to you)*

- never – urine does not leak
- leaks before you can get to the toilet
- leaks when you cough or sneeze
- leaks when you are asleep
- leaks when you are physically active/exercising
- leaks when you have finished urinating and are dressed
- leaks for no obvious reason
- leaks all the time

Thank you very much for answering these questions.

Figure 3. International Consultation on Incontinence Modular Questionnaire, (ICIQ- Urinary Incontinence Short Form) [16].

Figure 4. Obtryx TM System-Halo, Handles of Transobturator Midurethral System; Boston Scientific Corporation (Made in USA), the surgical device used in TOT surgery.

RESULTS

A total of 30 females with urinary incontinence were included in present study with mean age 48.8 years, 40% of them were between 40-49 years, as shown in table (1).

Mean number of deliveries was (4.9±2) deliveries, 21 patients had less than or equal to 5 deliveries and 9 patients had more than 5 deliveries, as shown in table (2).

Main type of urinary incontinence among studied females was stress urinary incontinence (73.4%); followed by mixed urinary incontinence (26.6%), table 3.

There was a significant decrease in Q-tip test mean after TOT surgery for studied females with urinary incontinence ($p<0.001$). A significant decrease was observed in ICIQ questionnaire mean of studied females after TOT surgery. All these findings were shown in table 4.

Table 1.Distribution of age of patients.

Variable	No.	%
Age Mean±SD (48.8±9.51 years)		
<40	5	16.7
40-49	12	40.0
50-59	9	30.0
≥ 60	4	13.3
Total	30	100.0

Table 2. Parity table for patients.

Variable	No.	%
Para Mean±SD (4.9±2deliveries)		
≤ 5 deliveries	21	70.0
>5 deliveries	9	30.0
Total	30	100.0

Table 3. Types of incontinence patients.

Variable	No.	%
Stress urinary incontinence	22	73.4
Mixed urinary incontinence	8	26.6
Total	30	100.0

Table 4. Distribution of Q-tip test and ICIQ-UI SF means before and after TOT surgery.

Variable	ICIQ Before Surgery	ICIQ After Surgery	Q-tip Before Surgery	Q-tip After Surgery
Mean± SD	15.40±2.044	2.70±4.632	49.83±16.582	18.17±15.227
P value	<.001	.003	<.001	<.001

UDS for female patients with urinary incontinence included in this study before TOT surgery revealed that 40% of them had normal cystometry, with pelvic hypermobility and sphincteric weakness and 26.7% of them had bladder over activity and sphincteric weakness. The other 10 patients were having pure stress incontinence, so UDS were not done for them. The results show that 9 of these 10 pure stress incontinence patients who didn't undergo UDS were continent after TOT surgery, and only one patient still incontinent up to the end of the study, as in table (5).

Depending on patients history (using ICIQ-UI SF) after 6 months follow up and by objective measures using Q-tip test and cough test, 24 patients with urinary incontinence were continent after TOT surgery and 6 patients were incontinent as shown in table (6).

Complications after TOT surgery after one week follow up were absent among 11 patients, on the other hand, the main observed complications for TOT surgery were perineal and upper thigh pain (43.4%), genital infection (6.6%), suprapubic pain and dysuria (UTI) (6.6%), urine retention (3.35%) and hematuria (3.35%), as shown in table (7).

The complications recorded at the end of the study show that the perineal and upper thigh pain was the most common (36.7%), while (53.3%) had no complications and only (10%) of them exhibit features of de novo urge incontinence.

Table 5. Urodynamic Diagnosis Results before TOT Surgery

Urodynamic Diagnosis	No.	%
Normal Cystometry+ pelvic hypermobility+ Sphincteric Weakness	12	40.0
No UDS	10	33.3
Bladder Over activity + Sphincteric weakness	8	26.7
Total	30	100.0

Table 6. Outcome of TOT surgery after six months.

Variable	No.	%
Continent	24	80
Incontinent	6	20
Total	30	100.0

Table 7. Complications of TOT Surgery.

	After 1 Week		After 3-6 Months	
	Frequency	**Percent**	**Frequency**	**Percent**
No Complication	11	36.7	16	53.3
Perineal Pain	13	43.3	11	36.7
Genital Infection	2	6.7	0	0.0
UTI	2	6.7	0	0.0
Hematuria	1	3.3	0	0.0
Urine Retention	1	3.3	0	0.0
Urge Urinary Incontinence	0	0.0	3	10.0
Total	30	100.0	30	100.0

DISCUSSION

In this study, we collected the early results of thirty TOT surgeries in Sulaimani teaching center. All the TOT operations in this study were performed by the (outside-in) technique, using the Obtryx type tunneler, which is a matter of the surgeon's preference and experience.

The developement of the urge UI component after TOT surgery might be because in patients with MUI, the frequent appearance of urine in the proximal urethra will easily induce reflex detrusor contractions, whilst the absence of urinary leakage, after sling surgery might decrease this reflex [17].

Initial results in our study with the midurethral sling technique approximated 80% success rates, while in (Ulmsten et al, 1996), a prospective multicenter trial that included 130 women with genuine SUI who were observed for 1 year revealed success rates of 91% [14], 7% were considered improved, and only 2% were deemed failures, complication rates were low, including one bladder perforation and one wound infection. voiding dysfunction was also relatively low, with 1 patient experiencing retention for 12 days, which resolved spontaneously, and 3 patients with less than 3 days of voiding dysfunction (regarding catheterization) [14]. Success rates ranging from 81% to 90% have been reported at more than 3 years [14],Ulmsten and associates (1999) reported an 86% success rate in 50 women at 3 years [14], Olsson and Kroon (1999) reported 90% success in 51 women at 3 years[14], Doo and colleagues (2006) [14] evaluated long-term efficacy and safety of this procedure among 134 Korean women; the overall 5-year success rate was 94.9%, with an 86.6% patient satisfaction rate, although success rates between 1 and 5 years were similar (97.7% and 94.9%), the cure rate decreased from 90.1% to 76.9%. Nilsson and coworkers [14] reported success rates of 84.7% at 5 years and 81.3% at 7 years in a consistent cohort of 90 women. Since the initial description by Delorme in 2001 [14], continence rates have been reproducibly satisfactory although follow-up has in general been short. Reported continence rates range from 80.5% to 96% on the basis

of a variety of subjective (questionnaire and quality of life single-item assessment) and objective (cough stress test, uroflowmetry, physical examination) measures [14].

The early cure rate reported by Issam S. Al-Azzawi (2014), was 95% for TOT, this result is comparable and even higher than other studies on TOT. This high cure rate might be attributed to the proper selection of patients and meticulous technique, especially in placing the sling in the correct place and in a tension-free manner. The two failures in the TOT group were all early in the experience, in patients with a preoperatively severe type of SUI, and all were related to insertion of the sling with an incorrect tension [18].

TOT surgery have less incidence of postoperative retention of urine and voiding difficulties, return to normal activities is earlier, postoperative groin pain is reported at higher levels than most other complications and is usually resolved within two months of follow-up [19]. We found that our results were close to other studies in high success rate 80% considering both objective and subjective cure rate and that findings were changeable with time. The process of fibrosis will increase the chance of tightness of the tape and increase the continence degree, so some of our patients who did this surgery noticed an improvement and disappearance of both the stress incontinence and the complications after TOT surgery.

Most of our patients (more than 80%), were free from genital infection and residual incontinence by prescribing medicines, especially those with elements of mixed type incontinence. This improvement achieved within one or two weeks after surgery, the genital and upper thigh pain decreased with time and it was the most common complication reported in this study. Although there is a higher risk of damage to the obturator vessel tributary and the vagina, we did not record any vascular injury in this study, one patient with hematuria is recorded due to bladder injury by the surgical device which is improved completely 3 days postoperatively and only 3 patients with persistent urge incontinence were recorded until the end of this study.

Conclusion

Trans-obturator tape (TOT) is an efficient and safe procedure with high success rate and short hospitalization period with minimum and simple early complication rates, in addition to short operative time, with no post operative bleeding recorded. TOT surgery require proper patient selection and it is preferable to do urodynamic study to confirm the diagnosis before surgery

Recommendation

We recommend continuing the follow up of our TOT patients discussed in this research and prepare another study about final results of this type of surgery especially after 3 years depending on our early results.

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