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Trans-Obturator Tension Appliance Tape for failed Mid-Urethral Sling when and how?

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Abstract

Background & Objectives: Female urinary incontinence is a significant health issue affecting adult women, most suffering from stress incontinence. It affects the quality of life. Recurrence after surgery is difficult for the patients and the surgeon. There is no precise data to show how to treat failed Transobturator tape. Transobturator tape with tension may be an alternative method in applying proper tension in the mid urethra to correct the incontinence. We describe our experience to evaluated outcomes of the second mid-urethral sling with tension to treat recurrent incontinence after the failure of the first mid-urethral sling.

Methods: A prospective cohort study was conducted between Oct. 2012 to March 2019. A total of 16 patients with failed Transobturator tape surgery underwent second trans-obturator Mid-Urethral Sling surgery. Preoperative data and postoperative complications were recorded. All patients were followed for one year.

Results: Sixteen women after failed Mid-Urethral Sling surgery were evaluated. At a mean follow-up of 7.5 months, the cure rate was 62.5% (10 out of 16) patients. Partial cure (improvement) was achieved in 25% (4 patients out of 16) and failure in 2 patients, 12.5%. There were statistically significant improvements after surgery in the Q-tip test and the number of the pads.

Conclusion: Repeat Transobturator tape with tension treatment tends to result in good outcomes with a reasonable physician-determined success rate.

Key words: Recurrence Urinary Incontinence,Trans Obturator Tape,Persistent Incontinence, Mid-Urethral Sling.

Introduction

Urinary stress incontinence USI is a distressing condition that is widely underreported. It has negative impacts on a woman's social wellbeing and overall health[1]. Urinary stress incontinence USI is the most common form of urinary incontinence, reported by approximately 50% of the incontinent women.[2] A mid-urethral synthetic sling MUS procedure is considered the preferred effective treatment for female stress urinary incontinence USI [3] In a large randomized controlled study for the treatment of MUS, the rates of subjectively assessed success were 55.8% in the transobturator-sling patients.[4]Although the broad spectrum of options available, treatment of USI fails in 10–20% of patients, management of such recurrent Urinary stress incontinence USI is technically challenging to the surgeon and a frustrating problem for the patient.[5] Failed Urinary stress incontinence USI is defined as persistent incontinence (leakage within six weeks of a previous mid-urethral synthetic sling MUS procedure) and recurrent Urinary stress incontinence USI (leakage more than six weeks after the initial success of first mid-urethral

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synthetic sling MUS). The etiology of persistent or recurrent Urinary stress incontinence USI after surgery is unclear. Still, it may be related to improper adjustment of the tape, failure to fix the sling into place, or incorrect diagnosis of the form of incontinence.[6] To date, no consensus exists for the management of SUI in women with a previous failed mid urethral synthetic sling procedure. Several possible treatment options have been described in the literature. Although the documentation says, the repeat retropubic approach has a higher success rate than the repeat transobturator approach.[7]To date, however, there are incomplete data to determine whether cure rates differ significantly between the repeat retropubic and transobturator routes.[8] Repeat mid-urethral synthetic sling MUS surgery is safe and has an excellent short-term success rate, both objectively and subjectively, with reasonable patient-reported rates at one year of follow-up. A low maximal urethral closure pressure is the only independent predictor of failure.[9] Finally, the treatment depends on the experience and the expertise of the surgeon, but it appears most reasonable to offer a repeat mid-urethral synthetic sling MUS to women with recurrent SUI. Appropriate counseling of patients to set realistic outcomes is for symptomatic improvement than cure.[10]The Aim of the study was to evaluated outcomes of the second mid-urethral sling with tension to treat recurrent or persistent stress urinary incontinence after the failure of the first Transobturator mid-urethral sling.

Materials and methods

This is a prospective cohort study conducted in Sulaimania Teaching Hospital between Oct. 2012 to March 2019. After approval from the Medical College scientific and ethical committee, 16 patients with failed Trans-obturator tape TOT surgery underwent second trans-obturator tape sling surgery. Boston Scientific tape (Polypropylene mesh) was used. Inclusion Criteria was; recurrence stress incontinence, persistent SUI after surgery, time from the first operation for more than one year, no response to medical treatment or physiotherapy and had cystocele grade 1. Exclusion Criteria were neurogenic bladder dysfunction, recurrent, and unresolved Urinary tract infections. Neurological diseases, vesicovaginal fistula, pregnancy, cystocele grade 2and 3, and post voiding residual exceeded 100 ml. Preoperative evaluation included the patient's history, general, and genital examination to observe SUI and the site of the previous operation. The number of pads used per day, bodyweight measurement, cough stress test (Patient try to hold urine in the standing position with 250 ml bladder filling), Q-tip test, ultrasound to study bladder anatomy and residual amount, cystography, and flexible diagnostic cystoscopy were done. Multichannel urodynamic (using a Laborie 8 Fr double-lumen urodynamic catheter at a fill rate of 30 ml/min) and uroflowmetry study with measurement of urethral pressure profile UPP during cough stress to determine urethral closure pressure with detrusor pressure, Figure 1. The Valsalva leak point pressure (VLPP), a measure of the lowest abdominal pressure required to produce urine leakage, was recorded. Patients were considered to have SUI based on a Valsalva leak point pressure <60 cmH_2O or a maximum urethral closure pressure <20 cmH_2O or Zero urethral closure pressure with bladder pressure rises of less than 40 cmH2O. Patients were excluded cystometry had detrusor overactivity. Questionnaire of International Consultation on Incontinence (ICIQ Urinary Incontinence - Short Form) was used to evaluate the patient's condition before and after the surgery. The primary

outcome was determined after three months.

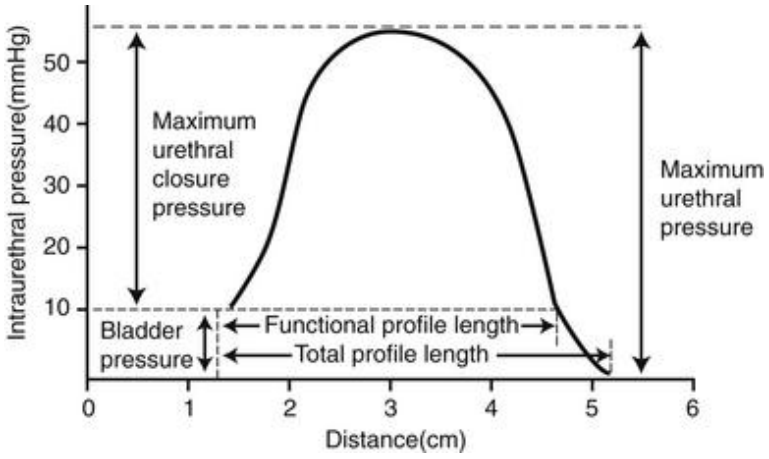

Figure :(1): Urethral pressure profile is a graphic presentation of pressure in the urethra.

All patients were operated on under spinal anesthesia and placed in the extended lithotomy position, with 1 g of third-generation cephalosporin givenat anesthesia. A 12-F Foley catheter was inserted into the bladder, and all urine was evacuated.Operative hydro-dissection was used to create a plan between the layer of the vagina and the urethra. A 2 cm midline anterior vaginal incision was made, and the para-urethral spaces were developed using blunt and sharp dissection. A Bilateral 5mm vertical skin incision was made in the internal surface of the thigh at the level of the clitoris. Scientific Polypropylene mesh(Obtyrx, USA) with specially designed helical passers attached to handles was used for insertion. Using out in technique and final adjustment of the tape carried out to raise the mid urethra by tightening it. All Intra-operative findings, immediate postoperative progression, and complications were recorded. Patients were followed at three months intervals up to 1 year—repeated Urodynamic used for failure conditions only. Outcomes of SUI as determined by using ICIQ-UI short form with both cough stress test and Q-tip test, complications like bleeding and pain were recorded. Success was defined as complete dryness as perceived by the patient (no more use of pads) during stress or minimal leakage, not requiring pads. Improvement was described as a reduction in number and amount of leakage with a minimum need for pads for about 50% or less. Failure of operation is defined as; recurrence of leakage after surgery with the need for pads without a reduction in the number or the amount of urine. The results were analyzed and compared with other studies. The data collection, entry, and coding were performed using Microsoft Excel Version 2016 (Microsoft Corporation, Redmond, WA). Besides, the "IBM SPSS Statistics version 25" was used for the analysis of the data, and both descriptive and inferential statistics were used. Furthermore, p-values of (≤ 0.05 and <0.001) were considered as statistically significant, and the Paired-Samples Student's T-Test was used to compare numerical independent and dependent variable pairs.

Results:

Of the 16 patients with Mean age 41.56± SD11.153, range (26-66), had recurrence SUI or failure of previous surgery. The preoperative patient's univariant analysis of;

age, BMI, time from first operations, Q Tip tests, pads, VLPP, ICQ- IU, shows statistically, no significances to predict factor for failure rate. Table (1).

Table (1). Baseline patients' characteristics (n=16) before surgery and Basic Monovariant analysis in both groups.

Variables Before operation	Both groups (Total) Mean ±SD	Successful Mean ±SD	Failed Mean± SD	P-Value*
Age (year)	41.5625± 11.53	41.14 ± 12.2	44.5 ± 6.36	0.284
Body mass index (kg/m*2)	27.038± 7.77	26.33 ± 7.55	31.95 ±10.53	0.877
Time from operation (years)	2.1125± 1.11	2 ± 1.1	2.9 ± 1.27	0.515
Q-Tip test (degree of angle)	54.06± 14.7	52.14 ±13.82	67.5 ± 10.67	0.468
Number of Pads	3.1±1.18	3 ± 1.04	4.5 ± 2.12	0.086
Valsalva leak-point pressure (VLPP) (cm H2O)	72.75± 18.3	70.64 ±19.34	87.5 ± 3.53	0.595
ICQ-IU Scors	13.68±1.56	13.92 ± 1.54	12 ± 1.41	0.163
Mean Residual Urine mL	22.5± 1.76	24.3 ± 1.24	32±5.65	0.344
Maximum Urethral closure pressure : MUCP (cmH2O)	47.3± 6.4	47.7±1.84	42±4.24	0.248
Maximum bladder capacity: MBC mL	376.5±4.4	377.4±5.1	349.55±54.44	0.673

SD = Standard deviation; * Measured by Paired-Samples T-Test (Student's T-Test).

After a Mean follows up of 7.5 months, the success rate was achieved by 62.5% with an improvement of 37.5% and a failure of 12.5%. Daily used pads reduced to 0-3 /day with $p < 0.01$. Ultrasound showed Mean post voiding residual urine in the preoperative period was 22.5 ml and 38.3 ml after the surgery with a p-value <0.05.Three, six, and twelve months Postoperative data groups of VLPP, ICQ-I.U, Q Tip test, pads show statistically significant improvement changes. Table (2).

Table (2). Patient data analysis before and after the second surgery.

Indicators	Mean ± SD	95% Confidence Interval for Mean		p- value
		Lower Bound	Upper Bound	
Q tip test Before operation	54.0±14.7	46.51	61.61	0< 0.001
Postoperative 3 months	25.3±18.1	15.32	35.30	
6 Months	28.1±14.6	20.05	36.19	
12 Months	28.1±20.4	16.86	39.38	

Pad Before operation Postoperative 3 months 6 Months 12 Months	3.1±1.18 0.6±0.98 0.8±1.1 0.6±1.1	2.53 0.14 0.19 0.01-	3.83 1.22 1.43 1.26	0< 0.001
VLPPCmH2O Before operation Postoperative 3 months	72.7±18.3 75.3±10.14	62.66 69.79	82.83 80.96	0.0185
ICQ-IU Before operation Postoperative 3 months 6 Months 12 Months	13.6±1.56 2.4±2.2 2.0±2.3 1.3±1.7	12.82 1.22 0.78 0.36	14.55 3.65 3.34 2.26	0< 0.001

The mean operation time was 45.96 ± SD8.20 min, range of (30.5-56). Minor bleeding and genital pain with groin in all the patients, urinary tract infection in one patient 6.25%, Urgency occurred in one patient 6.25%, and retention in one patient 6.25%, all happened in the success group.

Discussion

The management of recurrent incontinence can be quite tricky. With the failure rate of 6.5% and 6.7% in a study conducted by Tyrace[11], there are no clear-cut guidelines for a failed tension-free mid-urethral sling (MUS) procedure. The management of recurrent incontinence following sling surgery should follow a stepwise approach, with appropriate diagnostic studies, conservative treatment, if failed then surgery. In this study, with a mean follow-up of 7.5 months, the success rate was achieved in 62.5% with improvement (partial cure) in 37.5% and failure of 12.5%, close to a study done by Van Baelen. *et al.*, in 2009, after a mean follow-up of 16 months, there was a cure achieved in 55% of patients, improvement in 15%, and failure in 30%.[8] The same findings were observed in 2012 by JiYeon et al., who found that the cure rate was considerably higher in patients who underwent repeat MUS for a patient with persistent or recurrent SUI. The cure rate was higher in those who underwent repeat MUS than in those who underwent tape shortening, and the mono-variate analysis of preoperative factors showed that there were no risk factors associated with the cure rates in either group.[12] However, lower to a study done by Elaine *et al.* in 2010, ten women underwent repeat TOT after the failed first procedure with 80% success.[13]In 2007 Lee et al. operate on 31 female patients with a repeat mid-urethral sling for failed initial sling procedure; 29 patients were followed. The cure rate for the transobturator slings was 62.5% (10 of 16), respectively, a difference that did not quite attain statistical significance (p = 0.089) with the retropubic approach[14].In 2007; Nam *et al.* had a mean follow-up of 29.9 months after the second operation. Ten (71.4%) of 14 patients who had repeat MUS achieved full continence, while four patients (28.6%) had significant

improvement.[15] Our result showed a considerable increase in postvoiding residual urine, improvement in urge incontinence with a p-value < 0.05. Substantial improvement and feeling of wellbeing in the patient's ICQ-IU, Pad numbers, VLLP, and Q-tip test in the three months follow-up, as shown in table (2).

One of the most complex issues involved in performing sling operations is the ability to control the degree of tension. The term "tension-free" that the edges of the strap are not fixed. Controls are secondary and do not provide any specific guarantees.[16] Here in this study, we apply direct tension into the edges of the tape to raise the urethra aimed to increase the outlet resistance and better controls. In 2002, Villet advised increasing the strain on the previously established synthetic tape of women had a recurrence of urinary incontinence. The study found that there was completely absent tension in the earlier sling. After this manipulation, the tension in the band increased, which led to continent urine.[17] Although proper intervention and management of failure SUI are different from Patient to Patient. The repeated MUS is the most studied procedure, but recognizing failure and improvement are different between the patients and the physician. Many kinds of literature describe the secondary transobturator tape as inferior to secondary retropubic tape in women with recurrent SUI. Kobi Stav et al. found that the repeat retropubic approach was significantly more successful than the repeat transobturator approach (71% vs. 48%, p = 0.04),[18] because secondary TOT does not provide a proper angle of support to provide continence.[19] Walsh CA et al. did a retrospective study on repeat synthetic MUS surgery. They have demonstrated medium-term cure rates of 60–70%, which is lower than that achieved with primary surgery.[20] Till now, there are no randomized controlled trials to compare different surgical approaches for the treatment of the patient whose primary mid-urethral tape has failed. Whether to treat all in the same way or accordingly is a matter of debate.

Conclusion

Repeating TOT with tension after failed synthetic MUS treatment tended to result in good outcomes with a reasonable physician-determined success rate and acceptable minor morbidity.

Conflicts of interest

The author reports no conflicts of interest.

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