

The Impact of the Tension free Vaginal Tape-Obturator (TVTO) procedure on Incontinence Intensity & Quality of Life, Experience at King Hussein Medical Center

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ABSTRACT

Objective: To assess the benefits and complications of tension free vaginal tape-obturator surgical application after twelve months follow up.

Methods: This prospective investigation included 324 female patients, aged 41-62 years and diagnosed of moderate to severe pure or mixed stress urinary incontinence with mainly stress incontinence who were scheduled for tension free vaginal tape-obturator surgical application method at King Hussein hospital, King Hussein medical center, Amman, Jordan, during the period Jan 2009 - Jan 2014. Pre-operative assessment included intensity of stress urinary incontinence and post- void residual recording, while post- operative assessment included complications, intensity of urinary stress incontinence and quality of life. Incontinence impact scale on quality of life was used. The intensity of urinary incontinence was classified according to the Stamey incontinence score.

Results: Twenty eight cases (8.6%) experienced anterior vaginal wall prolapse (stage 2 and 3 anterior wall prolapse). There was a significant difference between pre- and post- operative stress urinary incontinence intensity and quality of life scores. ($P < 0.05$). No significant intraoperative complications were recorded but postoperatively 29 patients (8.95%) experienced pain in the inner part of the thigh. The cure rate was 81.5 % (264) and the incontinence episodes were improved in 35 cases (10.8%), while the procedure was labeled failed in 25 cases (7.7%).

Conclusion: The tension free vaginal tape-obturator surgical application method is a safe and beneficial management of female stress urinary incontinence with a significant success rate and reduced post- operative complications.

Key words: Female stress urinary incontinence, Quality of life, Sub urethral sling, Tension free vaginal tape-obturator.

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Introduction

Tension free vaginal tapes are used in the management of female stress urinary incontinence. Urinary incontinence is a very frequent problem in women.⁽¹⁾ The most frequent kinds of urinary incontinence are 'stress ' (the complaint of involuntary leakage

on effort or exertion, or on sneezing or coughing) and ' urge' (the complaint of involuntary leakage accompanied by or immediately preceded urgency).Mixed urinary incontinence includes both.⁽²⁾ The incidence of urinary incontinence increases with age, affecting 20-30% of young adults, 30-40% of

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middle aged and 30-50% of older aged.⁽³⁾ Stress urinary incontinence is the main kind of incontinence in 50% of incontinent females.⁽⁴⁾ Stress urinary incontinence can be managed by supplementing the urethral continence mechanisms, of urethral supports and periurethral striated muscle function.⁽⁵⁾

Obesity and multiparity are risk factors for stress incontinence. Nevertheless, many nulliparus teenage athletes' females have attacks of stress incontinence at periods of increased physical activity .⁽⁶⁾ Females may change their activity to decrease the incidence of urine loss, affecting quality of life.⁽⁷⁾ Stress urinary incontinence is distressing and personal condition that affects 20% of adult females and has often neglected financial implications . (119 million euro expenditure/year on incontinence pads in the Holland). Pelvic floor muscle training management may cure 15-25% of females and improve 65% of cases. At 2-15 years follow up, 30-50% of women will require surgery.⁽⁴⁾

The insertion of Tension free Vaginal Tape (TVT) and Tension free Vaginal Tape-Obturator (TVTO) are predominate minimally invasive operative techniques for the treatment of stress incontinence.⁽⁸⁾

Increasing the abdominal pressure will compress the urethra to the tape and continence is returned. Major complications are rare with a frequency of 0.007% for bowel perforation and 0.012% for vascular injury.⁽⁹⁾ The most frequent complication is bladder perforation; ranges from 3-6% for tension free vaginal tape and less than 1% for tension free vaginal tape -obturator, fortunately with no long term morbidity. Voiding problems and over active bladder are seen in 6% of women. Tension free vaginal tape technique introduced by Ulmsten, was the gold standered operation for women stress urinary incontinence,⁽¹⁰⁾ using retro pubic way for the application of the tape, with cure rate of 80%.

Delorme introduced the trans- obturator tape procedure. The important benefits of it are more anatomical site of the tape, needles don't pass via the retro pubic space, it causes less surgical blood loss, does not need abdominal incisions, has reduced risk of urinary bladder and intestinal injuries and does not need cystoscopy. Trans- obturator tape is simpler and faster to

achieve in comparison with tension free vaginal tape.⁽¹¹⁾

Jean de Leval introduced tension free vaginal tape-obturator. The tension free vaginal tape-obturator procedure (TVT-O) is more nearer to the understanding of minimally invasive surgery than tension free vaginal tape (TVT) and Trans- Obturator Tape (TOT).⁽¹²⁾ This inside -out technique causes more accurate application of the tape, reducing the risks of perforation of the bladder and urethra occurring with outside -in approach.

The objective of the investigation was to evaluate the management of urinary incontinence using the tension free vaginal tape- obturator sling operation, the enhancement of quality of life and to evaluate its complications.

Methods

Our prospective investigation included 324 female patients, aged 41-62 years , diagnosed of moderate to severe pure or mixed stress urinary incontinence with mainly stress incontinence , with no previous anti-incontinence surgery and who were scheduled for tension free vaginal tape-obturator surgical application method at King Hussein hospital, King Hussein medical center, Amman, Jordan, during the period Jan 2009 - Jan 2014. Informed written consent from all participants was obtained and approval from our ethical and research board review committee of Royal Medical Services. Patient selection criteria included positive cough test, urodynamic stable bladder with residual urine of less than 100 ml ,maximum flow rate more than 15ml/s,maximal cystometric capacity more than 300 ml, and stage 2 or 3 anterior vaginal wall prolapsed, . Exclusion criteria included pregnancy, neurogenic bladder and active urinary or vaginal infection. Pre-operative assessment included intensity of stress urinary incontinence post- void residual recording and urodynamic study (Table I), while post-operative assessment included complications, intensity of urinary stress incontinence and quality of life. Urgency is defined as the complaint of sudden compelling desire to pass urine, which is difficult to defer.⁽²⁾ Incidence of accidental urine leakage episodes and causes or

conditions of the accident as coughing, bending over or sudden urge must be recorded.

Incontinence impact scale on quality of life Questionnaire-Short Form11 Q-7 was used, indicating 0 for (not at all), 1 for mildly, 2 for moderately and 3 for greatly (Table II). The average score ranging from 0 to 3 is multiplied by 33 1/3 to include scores on a scale of 0 to 100 with higher scores indicating greater impact on daily life.⁽¹³⁾ The intensity of urinary incontinence was classified according to the Stamey incontinence score (grade 0, continent; grade 1, leakage of urine with sudden increases in abdominal pressure by coughing, sneezing or laughing); grade 2, leaks with lesser degrees of physical stress, such as walking, standing erect from a sitting position or sitting up in bed; grade 3, total incontinence, urine is lost without any relation to physical activity or position (Table I).⁽¹⁴⁾ Anterior vaginal wall prolapse was graded using Pelvic Organ Prolapse Quantification system (POP-Q)⁽¹⁵⁾ (Table II). Anterior colporrhaphy was performed for stage 2 and 3 anterior vaginal wall prolapse before application of the tension free vaginal tape obturator sub urethral sling (TVT -O).

All operations were performed under spinal anaesthesia with the patients in lithotomy position. Follys catheter gauge 16 was placed in the bladder and fixed. A 10mm incision was performed on the anterior vaginal wall under the mid urethra via which a polypropylene mesh of tension free vaginal tape- obturator sling was inserted without tension under the urethra. The trocar and the tape were carried through trans- obturator foramen, inside -out with a curved tunneling to the internal aspect of the thigh. Intraoperative complications (vaginal perforation, haemorrhage, vesical or urethral perforation), early post- operative complications (inner aspect of thigh pain, hematoma, dysurea and infection) and late post operative complications (perineal pain, de novo urge incontinence, and vaginal tape protrusion) were recorded.

Follow up assessment was performed at 1 and 12 months and yearly postoperatively (range 1-3 years). This included: cough test (Cough test was performed with the patients in the supine and standing positions with a comfortably full bladder. Surgical outcome was assessed by the

cough stress test and symptoms of incontinence), post void residual volume measurement and scoring of the intensity of incontinence symptoms and quality of life using incontinence impact scale.

The application outcome was divided into 3 groups, including cured, improved and failed. The patients were labelled cured of stress urinary incontinence if they had a negative cough test with no urine leakage during stress. Patients were labelled improved if they had a negative cough test but with some occasional leakage during stress. The other patients were labelled failed.

Comparison between pre and post operative recordings of intensity of stress urinary incontinence and quality of life scores were performed using t-test. A P- value of less than 0.05 was considered statistically significant.

Results

The demographics of the females participating in the investigation are shown in Table III. 44.8 % (145) of the patients were menopausal not on Hormone Replacement Therapy (HRT). The mean BMI was 28 Kg/m², mean parity was 4.6 and mean age was 48.3 years. Nineteen patients had grade 2 cystocele and 9 patients had grade 3. The mean surgical period and blood loss during surgery are demonstrated in Table IV.

No significant intraoperative complications were recorded, but 29 patients (8.95%) experienced pain in the inner part of the thigh assessed by visual analogue scale, this condition was treated with simple analgesics and the pain disappeared completely within one month of surgery. After removal of the catheter after operation, 8 patients (2.5%) needed recatheterization, and voided well after removal of the catheter 2 days later. Six (1.9 %) of patients experienced vaginal tape protrusion, they were managed conservatively without the need to remove the mesh.

Before surgery, there were 54 women with mixed stress incontinence. The cure rate was 81.5 % (264) and the incontinence episodes were improved in 35 cases (10.8%), while the procedure was considered as ' failed' in 25 cases (7.7%), (Table V). Most patients recorded a significant reduction in incontinence intensity

and improvement in quality of life postoperatively ($P < 0.05$), (Table VI).

Table I: Urodynamic Parameters

	Number	%
Stress Urinary Incontinence	270	83.3
Mixed Urinary Incontinence	54	16.6
Post void Residual PVR: mean+/-SD	18+/-7	
Abdominal leak point pressure test: mean+/-SD	130+/-26	
Maximal cystometric capacity: mean+/-SD	470+/-60	

Table II: Study assessment scales.

Stages of POP-Q system measurement	
Stage	Description
0	No prolapse is demonstrated
1	The most distal portion of the prolapse is more than 1 cm above the level of the hymen
2	The most distal portion of the prolapse is 1 cm or less proximal or distal to the hymenal plane
3	The most distal portion of the prolapse protrudes more than 1 cm below the hymen but protrudes no farther than 2 cm less than the total vaginal length (for example., not all of the vagina has prolapsed)
4	Vaginal eversion is essentially complete
Incontinence impact scale on quality of life	
0	Not at all
1	Mild
2	Moderate
3	great
Stamey incontinence intensity scale	
0	Continent
1	Leakage of urine with sudden increase in abdominal pressure
2	Leaks with lesser degree of physical stress
3	Total incontinence

Table III: Demographics of investigation patients.

DEMOGRAPHIC	
no	324
Age(yr)range(mean+/-SD)	41-62(48.3+/-8.5)
BMI ,kg/m ²	28+/-4
Parity(no)range(mean+/-SD)	2-7(4.6+/-1.5)
menopause	145(44.8%)
Pure stress incontinence	270(83.3%)
Mixed stress incontinence	54(16.7%)
Cystocele grade 2 and 3	28(8.6%)
Previous hysterectomy	9(27.8%)

Table IV: Intra and postoperative complications.

complication	
Blood loss(ml)range(mean+/-SD)	20-30(15.4+/-9)
surgical period (min)range(mean+/-SD)	10-20(15.6+/-3.6)
Postoperative thigh pain(mean+/-SD)	29(8.95%)
Short term voiding difficulty(mean+/-SD)	7(2.2%)
De novo urgency(mean+/-SD)	6(1.9%)
Vaginal tape protrusion	6(1.9%)

Table V: Tension free vaginal tape-obturator postoperative outcome.

outcome	No. (%)
success	264 (81.5)
improved	35 (10.8)
failed	25 (7.7)
Total	324 (100)

Table VI: Incontinence and quality of life after tension free vaginal tape-obturator application.

parameter	preoperative	postoperative	t-test	P-value
Incontinence intensity score	1.96+/-0.31	0.18+/-0.41	11.76	<0.05
Quality of life score	26.53+/-5.1	69.9+/-14.1	14.43	<0.05

Discussion

Stress urinary incontinence has been treated with various surgical techniques; it is defined as the involuntary loss of urine during increases in intra-abdominal pressure.⁽¹⁶⁾ The risk factors for stress incontinence are parity (vaginal delivery has more risk than cesarean section), diabetes mellitus, increased body mass index (overweight and obese), high waist to hip ratio/increased waist circumference, family history, smoking, chronic obstructive pulmonary disease, hysterectomy and white race.⁽¹⁷⁾ Women can be hesitant to discuss their incontinence and management if their incontinence is not significantly intense, they feel embarrassed, they believe that incontinence is an unavoidable result of child birth and/ or aging or have received minimal information regarding available treatment options.⁽¹⁷⁾

The mean surgical period in our study was (15.6+/-3.6 min), which was nearly similar to that of a study conducted in Poland (18) comparing the obturator approach (12+/-4 min) with classical retropubic approach (23+/-5 min) in the application of tension free vaginal tape for the treatment of stress urinary incontinence. The mean intra-operative blood loss in our study was 15.4+/-9 ml which is less than that of the obturator approach (37.2+/-4.53 ml) of a prospective comparative Indian study by Nerli R, et al in 2009.⁽¹⁹⁾

Short term voiding difficulty, and de novo urgency were 2.2%, and 1.9% for each respective post operative outcome; these outcomes were less than that of the Indian study,⁽¹⁹⁾ where 16% of their patients experienced postoperative de novo urgency and short term voiding difficulty. Vaginal tape protrusion was noticed in 6 (1.9%) patients, and were managed conservatively using antibiotics and care without the need to remove the tape mesh, this figure was less than that in a study by Tsivian A. *et al* in 2004⁽²⁰⁾ where they had 2.5% prutrosin rate and they had to remove one tape in their

management. Voiding difficulty is a frequent problem after sling surgery. Lengthened time of incomplete bladder emptying is recorded after retro pubic colposuspension. Spontaneous voiding is commonly observed shortly with mid urethral sling insertion.⁽²¹⁾ The appearance of de novo urgency after mid urethral sling insertion is a problem, which is recorded in 0-26% of patients and is caused by obstructive or locally irritative causes.⁽¹³⁾ Mid urethral sling insertion is more likely than conventional sling techniques to reduce preoperative urgency and irritative symptoms. De novo urgency is commonly managed with dietary and behaviour changes and anti cholinergic drugs.⁽¹³⁾ There was no retention of urine, bladder perforation in our investigation after surgery.

The success rate in this investigation was 81.5% and 10.8% improvement rate with only 7.7% failure rate. These outcomes were comparable with that in an investigation in 2006⁽²²⁾ where the results of three years follow up were recorded after trans- obturator tension free vaginal tape insertion in 91 patients with stress urinary incontinence. In this study, 88% of patients were cured and a 9% improved. These results kept with no significant differences in the cure rate when compared with results at one year follow up.⁽²²⁾ Our results were similar with another prospective investigation.⁽²³⁾ The efficiency and safety of tension free vaginal tape and trans- obturator tape inside- out for female stress urinary incontinence were tested. The rate of success was 86.8%, improvement 6.6% and failure 6.5% in the tension free vaginal tape- obturator group.

There was a significant difference between patients who had a self assessment of incontinence intensity scores and quality of life scores before and after the application of Tension free vaginal tape-Obturator approach (P < 0.05); these results were comparable with another study by Hiroki I, *et al* in 2011.⁽²⁴⁾

Conclusion

One year follow up of women with stress urinary incontinence managed with tension free vaginal tape-obturator surgical application is an efficient and safe procedure. Tension free vaginal tape-obturator method is correlated with a decreased short term complication. It is a simple technique with a reduced risk and can be advised as a gold standard for management of patients with stress urinary incontinence.

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