

A pilot comparative study between transobturator Tape (TOT) versus vaginal polypropylene mesh in management of patients with stress urinary incontinence in Egyptian women

Abstract

Aim of work: To assess the efficiency of vaginal polypropylene mesh as a cheaper alternative to Obtape.

Patients and methods: Forty qualified patients were subjected to history, examination and investigations including urodynamic studies and the patients were divided into two groups each containing twenty patients. Group 1 underwent the procedure using OB TAPE LG (Mentor Corporation-USA) and Group 2 did the procedure using a polypropylene mesh (Ethicon). Follow-up was done at one and six months post-operatively by clinical exam and by urodynamics (after 6 months only).

Results: Age, parity, duration of disease, mode of delivery, menopausal status, associated anterior vaginal wall repair and pre-operative urodynamics were similar in both groups. Success rate was 95% in the mesh group and 90% in the OBTAPE LG (Mentor Corporation- USA) and mean operative time was 18.5minutes for the mesh and 17.5minutes for the OBTAPE LG (Mentor Corporation-USA). After 6 months follow-up complications did not differ greatly between the two groups except for mesh erosion which was three cases with Obtape and none with the mesh. Post-operative urodynamics showed significant improvement in cystometric capacity in mesh ($P<0.001$) and ob Tape ($P=0.05$), maximum urethral closure pressure in mesh ($P=0.01$) and obtape ($P=0.03$), maximum urethral closure pressure at stress in mesh ($P=0.04$) and obtape ($P=0.007$) and pressure transmission in mesh ($P=0.01$) and obtape ($P=0.05$).

Conclusion: Transobturator approach is a safe minimally invasive surgical technique. The use of vaginal mesh for this operation can provide a cheaper alternative for poorly resourced hospital settings. Further studies are needed to properly assess the efficiency of vaginal mesh for this surgical technique.

Keywords: stress incontinence, treatment, vaginal mesh

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Abbreviations: TVT, tension free vaginal tape; BMI, body mass index calculation; TOT, transobturator tape

Introduction

Stress urinary incontinence is defined as the involuntary loss of urine on effort, coughing or sneezing.¹ It is the commonest form of urinary incontinence with an estimated prevalence of 8% to 33%.² The etiology of urinary incontinence was poorly understood until the integral theory of female urinary incontinence,³ followed by the hammock theory⁴ were published. All sling procedures use the principle of supporting the urethra and the bladder in a hammock, which provides both elevation and partial compression of the urethra with a success rate of approximately 80 % and an improvement rate of 90% with little reduction in continence over time.⁵

Delorime⁶ advocated the transobturator approach to avoid the complications associated with the retropubic approach with high success rate and few peri-operative complications. Those results were also shown in other studies using this approach as was the study done by Dargent et al.⁷ In spite of the good results of sling operations

especially the transobturator approach, these kinds of operations are still not popular in Egypt as it is in the developed world due to the price of the tape that can't be afforded by most patients due to their low income and lack of medical insurance in a huge sector of the population. Therefore, the aim of our pilot study was to try to provide an acceptable cheaper alternative to those patients.

Patients and methods

This prospective pilot study was done at 6th October and Al-Azhar University Hospitals. Ninety three patients complaining of stress incontinence were initially recruited for the study of which forty patients met the inclusion criteria which were patients with stress incontinence who failed to respond to conservative management in the form of pelvic floor exercises or mixed stress incontinence and overactive bladder and had no previous surgery for stress incontinence. Exclusion criteria included any other form of urinary incontinence including cases with pure overactive bladder, neurological lesions such as spina bifida and transient causes of urinary incontinence such as urinary tract infection.

All patients were subjected to detailed history, general, body mass index calculation (BMI) abdominal, neurological and local examination including stress tests to demonstrate urinary leakage. Investigations performed included urinalysis and urodynamic studies in the form of cystometry, uroflowmetry and urethral pressure profile, in addition to routine pre-operative investigations in the form of full blood count, liver function tests, kidney function tests, chest x-ray and ECG to those above 40years. Pre-operatively cases with mixed stress incontinence and overactive bladder received anti-cholinergic medications for 4-6weeks to avoid worsening of the symptoms of overactive bladder post-operatively.

The qualified patients were divided randomly into two groups each containing twenty patients. Group 1 underwent the procedure using OB TAPE (Mentor Corporation-USA) which is made of extruded thermally-bonded, non-woven, non-knitted polypropylene fibers giving it good resistance to traction and tearing. The cost of the tape was 1800 L.E. (equivalent to \$225). Group 2 underwent the procedure using a polypropylene mesh (Ethicon) which is divided into 10pieces each piece measuring 10x1cm. A polygalactyline (Vicryl10) is passed through each edge of the tape to help in attaching the tape to the instrument. All instruments are kept in povidone iodine to avoid infection. The whole mesh costs 450L.E. divided into 10pieces, each costing 45 L.E. (equivalent to approximately \$5.50). We used the corkscrew needle for the procedure.

Surgical technique

Under regional or local anesthesia (according to patient's preference) the patient is placed in lithotomy position. Disinfection of the anterior abdominal wall and thighs from the level of the umbilicus to the knees was done with povidone iodine. A Foley Catheter was inserted to empty the bladder. A small 2cm. vertical incision in the anterior vaginal wall was done starting from 1cm. below the urethral meatus. Sharp dissection of the vaginal wall from the periurethral fascia until reaching the inferior pubic ramus, then a finger is introduced to palpate the internal edge of the ischiopubic ramus and the upper-inner corner of the obturator foramen. A small vertical incision is made over the skin covering the upper inner corner of the obturator foramen which corresponds to the meeting of a horizontal line at the level of the clitoris with a vertical line at the level of the genitofemoral fold, this incision is the point of entry of the corkscrew needle. The left index finger was introduced into the vaginal incision on the patient's left side while holding the right-side needle and introducing its tip perpendicular to the above mentioned point on the patient's left side from outside to inside. The thumb of the left hand was placed on the outside curve of the need legently pushing it until the tip penetrated the obturator membrane and muscles and the needle was rotated so that the tip follows the posterior surface of the pubic ramus. The rotation was continued using the left index finger to guide the needle tip to exit from the vaginal incision. One end of the sling was then attached to the needle tip and the needle was pulled in the opposite direction using a reverse rotation of the needle until its exit from the same entry point. The same steps were repeated on the opposite side and the operator made sure that the tape lied flat beneath the mid-urethra. A forceps was placed between the mesh and the urethra and tension was adjusted using the cough test. The mesh was trimmed at the level of the subcutaneous tissue. The skin incisions were closed so that the suture didn't involve the edges of the mesh. Vaginal incision was closed with interrupted Vicryl 2/0 sutures.

Early ambulation was encouraged and the patients were

encouraged to void and post voiding residual urine was measured by ultrasound and the patient was discharged if the post voiding residual urine was 50c.c. or less. The patients were discharged on analgesics and given instructions to avoid heavy exercise, straining and sexual intercourse for one month. Follow-up was done one and six months post-operatively it included clinical assessment, urodynamic studies (after 6months only) and urine analysis+culture and sensitivity if needed.

Statistical analysis

The data were coded, entered and processed on an IBM-PC compatible computer using SPSS (version 11). P value less than 0.05 was considered the cut-off value for significance. Chi-square test X² was used to test the association variables for categorical data. Fisher exact test in table containing values less than 5. Student's t-test was used to assess the statistical significance of the difference between two population means in a study involving independent samples. Paired t-test was used to assess the statistical significance of the difference between two population means in a study involving matched or paired samples.

Results

Group 2 (mesh) had 14 postmenopausal cases and 6cases who had concomitant anterior repair while, group 1 (obtape) had 13cases postmenopausal and 7cases who had concomitant anterior repair. P value was 0.8 for postmenopausal status and 0.75 for cases who did concomitant anterior repair both were non-significant. Group 1 had 17cases who had vaginal delivery while, group 2 to had 16cases.

The mean operative time was 18.5minutes in the mesh group and 17.5minutes in the obtape group which was statistically insignificant while the mean blood loss was 40ml. in the mesh group and 50ml. in the tape group except in the cases complicated by hemorrhage which were between 200 and 500ml. Operative complications in group 2 (mesh) were 1case of urethral injury, 1case of vaginal injury and 2cases of hemorrhage which didn't require blood transfusion. Group 1(obtape) had 1case of urethral injury, 1case of vaginal injury and 1case of hemorrhage not requiring blood transfusion. There was no statistically significant difference between the 2groups as regards complications.

The mean ambulation time was 11.4hours for both groups and the mean hospital stay was 2.1days for mesh group and 1.9day for ob Tape. The results of the follow-up after 6months in the mesh group revealed 17cases (85%) complete cure, 2cases (10%) improved and 1 case (5%) failed. Two cases had post-operative urgency, 2cases had coital incontinence, and one case had post-operative nocturia. There were no cases of de novo urgency, post-operative retention, urinary tract infection or graft rejection in this group.

The results of follow-up after 6 months in the ob Tape group revealed 16cases (80%) complete cure, 2cases (10%) improved and 2cases (10%) failed. One case had post-operative urgency, 2cases had coital incontinence, 1 case had post-operative nocturia and 3 cases had graft rejection.

Discussion

Urinary incontinence is a common world-wide problem. The condition is not a life threatening one, however, it is disturbing both socially and psychologically. El-Azab et al.,⁸ in their cross-sectional

community based study on Egyptian women estimated the prevalence of stress and mixed incontinence to be 14.8% and 25% respectively. Based on ‘‘the integral theory’’ Ulmsten et al.,⁹ developed the tension free vaginal tape (T.V.T.) operation which was a revolutionary concept in the treatment of stress incontinence. However, due to its associated complications, Delorme and co-workers⁶ advocated the trans-obturator route to preserve the retropubic space.

The current study compares the vaginal mesh as a cheaper alternative with Obtape. Factors such as age, parity, duration of disease, mode of delivery, menopausal status, associated anterior vaginal wall repair and pre-operative urodynamics were similar in both groups (Table 1) & (Table 2). The current study reported a success

rate of 95% (dry and improved cases) in the vaginal mesh group and a success rate of 90% (dry and improved cases) in the Obtape group which was similar to other studies done by.^{6,10}

The mean operative time in the current study was 18.5minutes for the vaginal mesh and 17.5minutes for the Obtape which was close to the studies done by^{6,7} as they had a mean time of 17 minutes. Mean ambulation were similar in both groups and mean hospital stay was insignificantly different between both groups the latter being relatively long as compared to most studies due to associated surgeries done in some patients, however, it was more or less similar to the mean hospital stay in the study done by Kdous et al.¹¹

Table 1 Comparison between the two groups as regards age, parity and disease duration showed statistically insignificant difference

	Mesh	Mesh	Obtap	Obtap		
	Mean	SD	Mean	SD	T	P
Age	46.63	9.23	44.9	8.55	0.75	0.45
Parity	3.2	1.79	3.4	1.38	-0.48	0.63
Disease duration	4.93	2.18	4.7	1.13	2.12	0.46

Student’s t test

Table 2 Comparison between the 2 groups regarding pre-operative urodynamic parameters

	Mesh	Mesh	Obtap	Obtap		
	Mean	SD	Mean	SD	t	P
1 st Desire to Void	142.63	23.01	138.6	18.45	0.75	0.457
Cystometric Capacity	387.27	80.18	423.9	72.02	1.86	0.06
Compliance	66.9	68.45	65.2	17.26	0.13	0.896
Max. Closure Pressure	86.23	9.92	83.87	14.34	0.744	0.46
Max. Closure Pressure at Stress	-37.1	18.61	-38.1	13.26	0.24	0.811
Functional Length (mm)	19.8	4.34	19.87	4.22	0.06	0.952
Pressure Transmission	54.6	13.87	52.9	11.14	0.523	0.603
Q-max	27.17	5.77	27.1	5.51	0.05	0.96
Residual Volume (ml)	29.4	19.57	28.37	9	4.078	0.92
Leak Point Pressure	95.5	17.36	94.17	9.38	4.904	0.93

Complications

Most of the complications that occurred in the current study didn’t differ much between the two groups. All immediate complications were detected and managed intra-operatively and were close to the rate of complications reported in the studies done by.^{10,12} However, mesh erosion which was not found in the vaginal mesh group but was found in three cases of the Obtape group-which necessitated cutting of the extruded part. In spite of this, the three cases remained continent. A possible explanation of this finding may be the difference in pore sizes which are smaller in the Obtape than in the polypropylene mesh. The current study is not the only study which stated this finding other studies also showed that Obtape had relatively high incidence of erosion as the study done by Yamada et al.,¹³ even higher than TVT-O (Gynecare).¹⁴ In spite of this the transobturator approach has the advantage of lower intra-operative complications than those reported by Zilbert et al.,¹⁵ in the retropubic approach such as vascular and

bladder injuries the later complication necessitating the routine use of cystoscopy to detect it which is not the case in the transobturator approach.

Post-operative cystometry done 6 months after the operation showed a statistically significant improvement as compared to pre-operative values in the mean cystometric capacity more in the vaginal mesh group (P less than 0.001) as compared to the Obtape group (P=0.05) which was also statistically significant but less than the vaginal mesh group a possible explanation to this finding is that the vaginal mesh has more degree of elasticity than the Obtape. Other cystometric parameters as 1st desire to void and cystometric compliance were not significantly different than pre-operative values (Table 3).

The current study shows statistically significant changes in most parameters of urethral pressure profile namely maximum

closure pressure, maximum closure pressure at stress and pressure transmission between pre-operative and 6months post-operative values in both groups, however, the functional length of the urethra didn't significantly change (Table 4).

Table 3 Comparison between cystometric data pre-operative and 6months post-operative. There is a statistically significant difference between pre and post-operative 1st cystometric desire and cystometric capacity in both groups, however, cystometric compliance was not significantly changed in both groups

		Pre-op. mean	Pre-op. SD	Post-op. 6 months mean	Post-op. 6 months SD	P value
1 st cystometric Desire	Mesh	142.63	23.01	151.13	16.42	0.09
1 st cystometric Desire	Obtape	138.6	18.45	141.57	15.45	0.18
Cystometric Capacity	Mesh	387.27	80.18	413.2	71.79	< 0.001
Cystometric Capacity	Obtape	423.9	72.02	452.87	68.79	0.03
Cystometric Compliance	Mesh	66.9	68.45	59.53	21.75	0.49
Cystometric Compliance	Obtape	65.2	17.26	65.33	16.56	0.95

Table 4 Comparison between urethral pressure profile pre-and 6months post-operative. There is a statically significant difference between pre-operative and 6months post-operative urethral closure pressure, maximum closure pressure at stress and pressure transmission.

		Pre-op. mean	Pre-op. SD	6 months post-Op. mean	6 months post-Op. SD	P value
Max. Closure Pressure	Mesh	86.23	9.92	87.67	9.67	0.01
Max. Closure Pressure	Obtape	83.87	14.34	87.47	13.15	0.03
Max. Closure Pressure at Stress	Mesh	37.1	18.61	30.97	20.36	0.04
Max. Closure Pressure at Stress	Obtape	38.1	13.26	31.7	14.01	0.007
Functional Length (mm)	Mesh	19.8	4.34	20.07	4.21	0.06
Functional Length (mm)	Obtape	19.87	4.22	20.23	3.87	0.05
Pressure Transmission	Mesh	54.6	13.87	58.53	15.95	0.01
Pressure Transmission	Obtape	52.9	11.14	53.93	10.26	0.05

Conclusion

The current study concludes that the transobturator approach is a safe minimally invasive surgical technique and that the use of vaginal mesh for this operation can provide a cheaper alternative for poor resourced hospital settings, however, the two main drawbacks were having to disinfect each strip of vaginal mesh before using it, in addition to, the small number of patients in our study, therefore, we recommend further studies to be done to properly assess the efficiency of vaginal mesh for this surgical technique.

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Conflict of interest

The author declares no conflict of interest.

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