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Original Research Article

Tension-free transobturator vaginal tape and autologous rectus fascia transobturator vaginal sling for the treatment of urinary stress incontinence: a prospective clinical study

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ABSTRACT

Background: A large proportion of adult women complain of urinary incontinence, which has considerable drawbacks on their quality of life and social incorporation in the community. Conservative measures had been tried for several decades but with limited efficacy in huge proportion of patients. Vaginal sling procedures, since it was introduced in medical field had achieved good success rates with low complication rates. However, they still cause problems. Since Ulmsten introduced the tension-free vaginal tape in 1995, it has become a popular method for surgical treatment of urodynamically proven USI. In this study, we are going to compare between tension-free Trans obturator vaginal tape (TVT-O) using synthetic polypropylene macro porous monofilament mesh and autologous rectus fascia Trans obturator sling.

Methods: 80 patients had stress urinary incontinence were randomly assigned to either group (1) who underwent insertion of synthetic tension free vaginal tape using (Aris- Transobturator Sling System) or group to (2) to whom autologous rectus fascia transobturator vaginal sling was applied.

Results: Objective and subjective cure rates were comparable in both groups, but patients in group (1) had shorter operative time and less duration of post-operative catheterization. Patients in group (1) were statistically more satisfied than patients in group (2).

Conclusions: Both techniques are effective in the treatment of female stress incontinence.

Keywords: Cough test, Stress urinary incontinence, Tension free vaginal tape, Urodynamic studies, Vaginal sling

INTRODUCTION

Stress urinary incontinence (SUI) is a common disorder affecting adult females due to weak mechanisms of urethral closure.^{1,2} Behavioral changes and pelvic floor muscle training are considered conservative nonsurgical options for treatment.³⁻⁵

Tension-free vaginal tape has become a popular method for surgical treatment of urodynamically proven stress incontinence (USI), since it was introduced by Ulmsten in 1995. The retro pubic approach of tension-free vaginal

tape (RT-TVT) procedure was widely accepted worldwide as the standard surgical treatment for SUI.⁶

Tension free vaginal sling procedures had achieved good long-term success together with lower complication rates; but they had some failure rate due to either excessive or failure to achieve the desired tension, which resulted in voiding difficulties or urinary leakage persistence, respectively.⁷

Transobturator route (TVT-O) was considered as the second-generation, utilizing either outside-in or inside-out approaches, so avoiding the passage into the retro pubic

space.^{8,9} TVT-Os were associated with significantly lower risk of visceral injuries, but they resulted in de novo storage symptoms.¹⁰

The third-generation vaginal sling, mostly described as single-incision mini-slings (SIMS), were first introduced in 2006 with the concept of a shorter tape, inserted through a single vaginal incision.¹¹

Autologous rectus fascia sling is considered equally effective as TVT regarding the cure of stress incontinence. Although fascial sling needs a longer time surgical procedure, but it is more economical.¹²

Few studies compared the use of the autologous rectus fascia using the transobturator route. Linder et al stated that autologous transobturator urethral sling placement appeared to be technically feasible with excellent short-term outcomes, but longer follow up and larger series are needed for validation.¹³

The autologous fascial pubovaginal sling was considered as a salvage procedure for recurrent stress incontinence after mesh erosion/exposure and/or bladder outlet obstruction in patients treated with prior transvaginal synthetic mesh for stress urinary incontinence.¹⁴⁻¹⁶

In this study, we are going to compare between tension-free trans obturator vaginal tape (TVT-O) using synthetic polypropylene macro porous monofilament mesh and autologous rectus fascia trans obturator vaginal sling as treatment modalities of female stress urinary incontinence.

METHODS

Type of the study is interventional.

Study design

Allocation is randomized, Endpoint Classification is Safety/Efficacy, Study intervention model is a 1:1 ratio by computer generated random number sequence, Masking is sequentially numbered sealed opaque envelopes and primary Purpose is treatment.

The present prospective comparative trial was conducted in Hai Jamma hospital. The protocol was approved by institutional research committee.

Eligibility

80 women diagnosed with stress urinary incontinence were recruited from the outpatient clinics in Hai Jamma hospital. The study was approved by the local research Ethics Committee and informed consent was obtained after full explanation of the study.

Inclusion criteria

Stress urinary incontinence, failure of conservative management, urethral hypermobility ≥ 45 degree change in the angle of urethra to horizontal line, a positive cough stress test when bladder capacity at 300 ml or more. urodynamic stress incontinence with abdominal leak point pressure of 60-90 cm H₂O, normal cystourethroscopy.

Exclusion criteria

Previous incontinence surgery, urinary tract infection (UTI) persistent or active UTI at the time of surgery, evidence or suspicious of urogynecological malignancies, Pelvic organ prolapse \geq grade II, history of neurogenic bladder, abnormal filling or voiding phase in the urodynamic study (low capacity, low compliance, or detrusor over activity, maximum flow rates of lower than 15 ml/s and residual urine of more than 100 milliliters) and abnormal cystourethroscopy findings.

Primary outcome

Cure rate of stress urinary incontinence at 4, 12 and 24 weeks postoperative by: negative cough stress test with a full bladder and Subjective means (IIQ scores) and a score less than 50 represent a good quality of life, between 50 and 70 moderate quality of life, and greater than 70 poor quality of life.

Secondary outcome

Length of operative time (incision to closure) Intraoperative complications (bleeding –bladder injury-urethral injury), Length of hospital stay, Post-operative urine retention: post voiding residual urine more than 100ml, De novo urge incontinence, Changes in voiding pattern, Patient satisfaction described on a visual analogue scale of 0–10, a visual analogue scale of 8–10 means patient satisfaction.

Enrollment

Study was started on May 2014 and completed on December 2015.

All patients underwent

Detailed history of urinary complains. The symptoms were scored according to the incontinence impact questionnaire (IIQ).¹⁷ Pelvic floor evaluation in the supine and standing position- the degree of pelvic floor weakness was scored according to the pelvic organ prolapse quantification system (POP-Q).¹⁸ Cough stress test, Q-tip test. Ultrasound scans of the urinary tract, complete blood count (CBC), renal function tests, urine analysis and culture.

Multi-channel urodynamic study. The technique, definitions and units of urodynamic measure conform to

the standard proposed by the international continence society and cystourethroscopy.¹⁹

Patients were randomly assigned to either group (1) who underwent insertion of synthetic tension free vaginal tape using (Aris- Transobturator Sling System, Coloplast A/S 3050 Humlebaek, Denmark) or group (2) to whom autologous rectus fascia transobturator vaginal sling was applied.

All procedures were performed by a single surgeon (M.A. Elserly), experienced in both techniques. All the procedures were performed on an in-patient setting under spinal anesthesia in both groups.

The TVT-O procedure was performed to patients in group (1) as described by Delorme E .8 In group (2): the autologous sling group, a transverse Pfannenstiel incision was made and a strip of anterior rectus fascia sheath with a size of approximately 1-1.5 cm wide and 10 cm long was dissected and prepared by applying four fixing prolene stitches on each of the 4 edges. One longitudinal midline incision of about 1-1.5 cm was made in the anterior vaginal wall mucosa at the level of mid urethra.

A sub mucosal sharp dissection was done in the direction of obturator foramen at about 45 degree from the mid line on each side. The harvested graft -anterior rectus fascia sheath -was inserted to the vaginal sub mucosal tunnel by using helical tunneler introduced from two skin incisions, one on each side. These skin incisions were made lateral to labia majora at the thigh crease at the same level of the base of the clitoris. The graft was manipulated by using the previously fixed prolene stitches. These prolene stitches were introduced in the eye on the tip of the helical tunneler then to the outside of the body at two skin incisions done before. Then the bladder was filled with 200ml sterile water. The graft was adjusted according to the patient leaking when asked to cough. The proper position is obtained when no leaking occurred when the patient coughed provided that no compression or kinking of the urethra had occurred.

Then each two ipsilateral ends of the four prolene stitches are tied together on each side at the skin incision made at the thigh crease.

In both groups, a 16-French Foley catheter was left in place for 24 hours postoperative. The catheter was removed after the patient can void, and the residual urine was less than 100 ml. In the case of bladder injury, the was left catheter in situ for 6-7 days in both groups.

The patients were followed-up regularly at one week, 12 and 24 weeks postoperative. The patients were evaluated by the cough stress test with a full bladder and IIQ scores. The women were asked to describe their satisfaction from the surgery, on a visual analogue scale of 0-10.

RESULTS

Comparison between the two studied groups as regards the demographic features and preoperative assessment parameters showed no statistical difference between patients in both groups as shown in Table 1.

Table 1: Comparison between the two studied groups as regards the demographic features of patients.

	Group 1 patients synthetic sling (n=39)	Group 2 patients autologous sling (n=41)	p
Age	45.2 ± 3.5	46.2 ± 3.4	0.206
Parity	3 (2-9)	3.7 (2-9)	0.984
Body mass index	27 ± 3.5	27 ± 3.6	0.961
Preoperative IIQ	62.2 ± 8.5	65.1 ± 8.5	0.065
Presence pelvic organ prolapse (n)	11 (28.2%)	10 (24.4%)	0.698
Preoperative maximum flow rate (ml/s)	30 9 13	29.8 8.7 11	0.513

Qualitative data were described using number and percent and was compared using Chi square test while normally quantitative data was expressed in mean±SD and was compared using student t-test, abnormally distributed data was expressed in median (Min. - Max.) and was compared using Mann Whitney test. *Statistically significant at p ≤0.05

All patients completed the full 24 weeks' duration of postoperative follow up. No patient needed intraoperative or post-operative blood transfusion. As shown in Table 2 statistical analysis of data showed that intraoperative bleeding (≥250 ml) was comparable in both groups.

The operative time required for completion of the surgical procedure in group (1) was statistically shorter than that needed in group (2), this could be explained by the time consumed while harvesting and preparing the rectus fascia graft.

As shown in Table 2, The mean duration of catheterization and hospitalization was lower in group (1) than in the group (2). While residual urine more than 100 ml and the need for intermittent self-catheterization were similar in both groups after 4 weeks follow up post-operative.

Surgical revision was done in 2 patients in group (1) due to mesh erosion and non-healing of vaginal mucosa overlying the synthetic vaginal sling.

De novo urge incontinence (self-reported by the patient and not proven urodynamically) was equal in both groups.

Table 2: Comparison between the two studied groups as regards the primary and secondary outcomes.

	Group 1 patients Synthetic sling (n=39)	Group 2 patients Autologous sling (n=41)	p
Negative cough stress (IIQ scores).	35(89.7%)	34(85.4%)	0.738
Length of operative time (incision to closure) min	48.5±8.1	51±7.7	0.155
Intraoperative bladder injury (n)	52(32-71)	109 (45-170)	<0.001*
Intraoperative bleeding (≥250 ml) (n)	3(7.7%)	2(4.9%)	0.671
Mean catheterization time, days	1(2.6%)	2(4.9%)	1.000
Post voiding residual urine more than 100ml (n)	3(1-4.5)	5(3-6)	<0.001*
Length of hospital stay days	2(5.1%)	3(7.3%)	1.000
De novo urge incontinence(n)	2(1-3)	5(2-7)	<0.001*
Changes in voiding pattern (n)	1(2.6%)	7(17.1%)	0.057
Patient satisfaction%	6(15.4%)	7(17.1%)	0.838
Postoperative maximum flow rate (ml/s)	31(79.5%)	23(56.1%)	0.026*
	27.2 7.9 8.7	26.9 7 6.5	0.275

Qualitative data were described using number and percent and was compared using Chi square test or Fisher Exact test, while normally quantitative data was expressed in mean ± SD and was compared using student t-test, abnormally distributed data was expressed in median (Min. - Max.) And was compared using Mann Whitney test. *Statistically significant at $p \leq 0.05$.

Comparison between preoperative and postoperative data on uroflowmetry (in the sitting position) showed some decrease in the maximum flow rate of both groups; but not statistically significant, as shown in Table 1 and 2.

The reported changes in the voiding pattern had been gradually noted during the late follow-up period, but it was not of significant impact on the women life. The mean maximum flow rate of these patients was normal.

DISCUSSION

The best material for a sling procedure remains controversial, because each type has its advantages and disadvantages. The ideal sling material should be inert, non-carcinogenic with enough strength and flexibility,

non-changeable by the ingrowth of tissue, and not expensive.²⁰

Autologous fascial slings have several advantages, including availability, minimal cost and being a natural material but getting a fascial graft from abdominal incision lengthens the operative and recovery time and increase the blood loss.²¹⁻²³

Few studies handled the same issue of this study i.e. comparison between synthetic tape and autologous sling through the transobturator route for treatment of female stress incontinence. In this study both methods showed comparable results as regards the cure rate of stress incontinence in both groups.

The transobturator route -outside-in technique was preferable in this study for both groups, because it is a rapid technique, with less possibility of bladder and other visceral injury than with the retro pubic approach, as reported in several studies.^{24,25}

Khan et al showed the same results when compared tension-free vaginal tape, xenograft and autologous fascial slings for the treatment of stress urinary incontinence.²⁶

There were two patients in this study in group (1) experienced mesh erosion which did not happen in the autologous vaginal sling group. This is similar to what have been observed by Blaivas et al who stated that the most common risks in patients with synthetic mid urethral sling (SMUS) included urethral obstruction requiring surgery, vaginal, bladder and/or urethral erosion requiring surgery and refractory chronic pain. These data were considered by them as minimal risks.²³

El Gamal et al did similar study using the transobturator route for insertion of hybrid sling which appeared to have good short-term efficacy and low cost.¹²

Linder et al published a study about the use of transobturator autologous midurethral sling procedure in 10 patients. They considered it technically feasible and, in the short term, effective. They recommended longer follow-up and larger series to validate this procedure which may become a suitable option for patients and surgeons concerned with potential mesh complications.¹³

In contrary to results of this study Webster et al reported a case of a 73 years old woman who underwent a pubovaginal sling using autologous rectus fascia for treatment of stress urinary incontinence (SUI). She developed urethral erosion following 2 weeks of clean intermittent catheterization (CIC). Visual internal urethrotomy (VIU) was performed to incise the sling and the prolene sutures were removed to eliminate any tension. Unlike synthetic slings, when autologous fascia is used, the tissue may be left in-situ. A minimally invasive approach may achieve an excellent result without the need for complex surgical repair.²⁷

CONCLUSION

Both tension-free transobturator vaginal tape and autologous rectus fascia transobturator vaginal sling have similar efficacy in the treatment of urinary stress incontinence.

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