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A two paramedian vaginalincisions versus the standard longitudinal incision of trans-obturator tape procedure for the management of stress urinary incontinence: A randomized controlled trial

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Abstract: Purpose: To evaluate the rate of success and the migration of tape in a modern surgical approach using 2 paramedian vaginal incisions compared to the standard longitudinal incision of the trans-obturator tape procedure. Methods: A randomized clinical trial was performed including 100 SUI patients; they were divided into 2 groups representing the two paramedian vaginal incisions versus the longitudinal vaginal incision. The clinical outcomes and tape location were assessed at 3,6 and 12 months following operation. Results: Forty-eight patients in group 1 underwent the classical surgical technique while the two paramedian incisions reflecting group 2 were made in 42 patients. The cure rate in group 1 was 70.8%, while only 6% of the cases showed no improvement compared to 78.6% cure rate in group 2, and 4% of cases showed no improvement. The incidence of tape migration was 52.1% in group 1 while no migration was noted in group 2. Failure to complete cure was associated with tape migration in 6 cases of group 1 representing 32 % of the total tape migration, these results were significant to correlate migration with failure to complete cure, also De novo urgency was seen to be associated with proximal tape migration. Conclusion: The 2 paramedian vaginal incisions provide greater stabilization and less tape migration, that enhances the rate of success. Trial registration number: the trial was registered at clinicaltial.gov with trial registration number: NCT04571346, date: 1st of October 2020, retrospectively registered.
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Keywords: Stress urinary incontinence, trans-obturator tape, tape migration, sling procedure, voiding dysfunction.

1. Introduction:

The involuntary leakage of urine secondary to a rise in intra-abdominal pressure like coughing or sneezing through an incompetent urethra is represented by stress urinary incontinence (SUI), it may be associated with intrinsic sphincter deficiency, detrusor muscle over activity or pelvic organ prolapse.(1,2)

Different treatment modalities are available ranging from lifestyle modification, pelvic muscle training, medications up to surgery. Mid urethral sling operations remain the definitive therapy for SUI that involves restoring the urethral support which is performed with various surgical techniques using different types of mechs.(3–5)

Both the tension and position of the tape in the trans-obturator tape (TOT) are related to the surgical outcome where recurrence of symptoms is correlated to tape migration in more than half of the cases, despite being initially placed at the mid-urethral zone that usually occurs 1 year after surgery(3,6,7), this could be assessed by trans-labial ultrasound (8,9).

Pirtea et al. showed more success in tape migration than the standard procedure using a transverse versus the standard vertical incision in TOT procedure. However, the transverse incision was associated with 18% tape migration rate. (10)

We have developed a novel technique involving two paramedian vaginal incisions that enable further stabilization of the tape by avoiding the dissection along the entire urethra, guaranteeing intact overlying tissues and building a tunnel among the 2 incisions for the tape, supporting normal undissected tissues proximally and distally.

We aim through our study to evaluate the rate of success of TOT and migration of tape against the

standard vertical incision utilizing our novel surgical technique.

2. Methods:

Adult female patients complaining of SUI were eligible for our study, 90 patients were selected for our study, between January 2016 and February 2018 at the department of urology, Ain-shams University hospitals. These patients were randomized into 2 groups utilizing closed envelopes organized by the ethical committee of the department; group 1 was the classic TOT protocol, while group 2 was the method of 2 paramedian vertical incisions. The type of intervention was blinded to patients. Before the operation, informed consent was obtained for all patients. Careful assessment, involving history taking, stress test analysis and urodynamic review, was conducted. Our study removed patients with neurological disorder, pelvic organ prolapse, prior urethral surgery or pelvic floor surgery.

Using silicon-coated polypropylene tape inserted into the mid-urethral part, the TOT procedure was performed. A classical vertical vaginal incision was made in group 1, proximal to external urethral meatus, with dissection along the axis of the urethra to the mid-urethral region, which is defined by the vaginal palpation of the urethral catheter balloon at the neck of the bladder, although two paramedian incisions in group 2 were made 1 cm long in the anterior vaginal wall 2 cm apart parallel to the urethra until the mid-urethral portion was found, a contact was made in this region among the two incisions 1 cm wide creating a tunnel where the tape was positioned, this approach offers healthy tissues that are proximal and distal to the tape, allowing more stability and fewer migration (figure 1). As the standard outside-in tension-free technique trans-obturator procedure, the remainder of the procedure was carried out(11). Trans-labial ultrasound was done at the end of each procedure to evaluate the tape position and ensure its ideal position.

Patients were assessed and followed up regarding operative time, postoperative pain, hospital stay and perioperative morbidities like visceral injury or hemorrhage. The continence after surgery was assessed by the patient's symptoms and cough stress test after 3,6 and 12 months after surgery. No symptoms and negative cough stress test was considered a cure and surgery success, while improvement or worsening of symptoms was considered according to the patient's symptoms before and after surgery regarding urine leak with stress like walking, walking up or downstairs, cough, sneezing or jogging. Patients were evaluated for symptoms of de novo urgency or pelvic pain. Trans-labial ultrasound was used to evaluate the site of the tape and its clinical correlation. Urodynamic study was performed for every symptomatic patient to confirm the diagnosis of stress urinary incontinence.

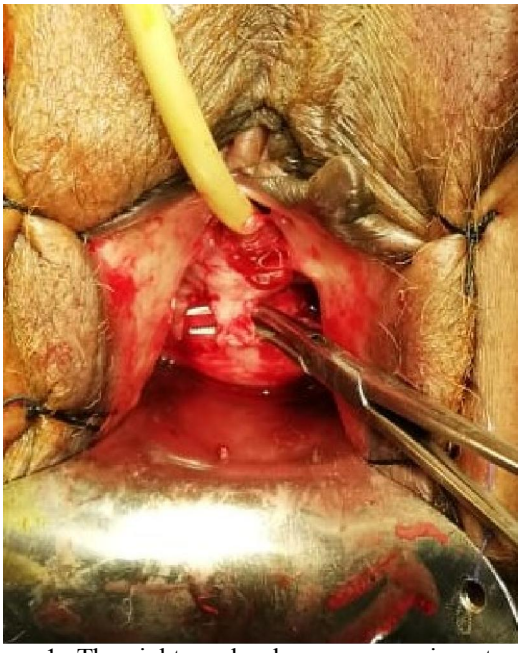

Figure 1: The right angle clamp passes via a tunnel created among the two paramedian incisions

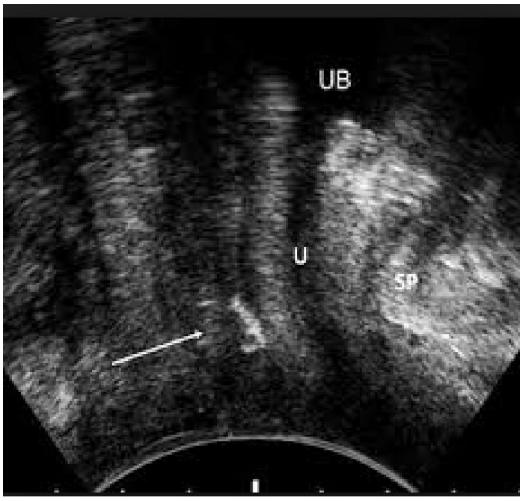

Figure 2: Trans-labial ultrasound demonstrating the placement of the mid-urethral tape

Trans-labial ultra sound Technique is the investigation of choice for tape evaluation regarding the urethral position, the urethral tape cannot be assessed by X-ray or MRI but could be visualized by ultrasound (9,11,12) A 7-MHz curvilinear transducer was used on the perineum in lithotomy position with filled bladder and empty rectum combined with an endo-vaginal probe for proper assessment of the site of the tape (figure 2).

Ethical considerations: The study was approved by our Research Ethical Committee with approval No. (FMASU R51/2019)

Statistical analysis: The data has been analyzed utilizing SPSS version 17.0, the chi-square or fisher's extract test has been utilized to analyze categorical variables, and the continuous variable has been analyzed utilizing the Student t-test or the Mann-Whitney U test. A P value below 0.05 has been found to be statistically significant. Sample size calculation was done utilizing the STATA program, setting alpha error at 5% and power at 80%.

3. Results:

A total number of 100 patients underwent surgical intervention for SUI randomly allocated into 2 groups. A total number of 48 and 42 patients completed a 12 month follow up in groups 1 and 2 respectively, where 10 patients did not complete the follow up in the outpatient clinic as shown in (figure 3).

The mean age in our study was 55 and 56 years in group 1 and 2 respectively, body mass index was 34 kg/m2 in both groups. The mean operative time was 33.46 ± 4.64 minutes for group 1 and 42.98 ± 10.38 minutes in group 2, there is no considerable blood loss or any intraoperative complications in both groups.

Continence evaluation at three months, the cure rate in group 1 became 70.8 %, 22.9 % saw symptom improvement, whereas only 3 instances reflecting 6 % of group 1 displayed no enhancement, whereas in group 2, the cure rate became 78.6 %, 16.7 % saw symptom improvement, whereas only 2 instances reflecting 4 % displayed no enhancement. At 1 year follow up, 5 cases in group 1 showed recurrence of symptoms compared to 1 case in group 2 representing 10% and 2% respectively while the cured rate showed no change over 12 months of follow up as shown in (table 1). Although continence results were better in the new technique compared to the standard one, it was not statistically significant in the overall success rate as shown in (Table 1).

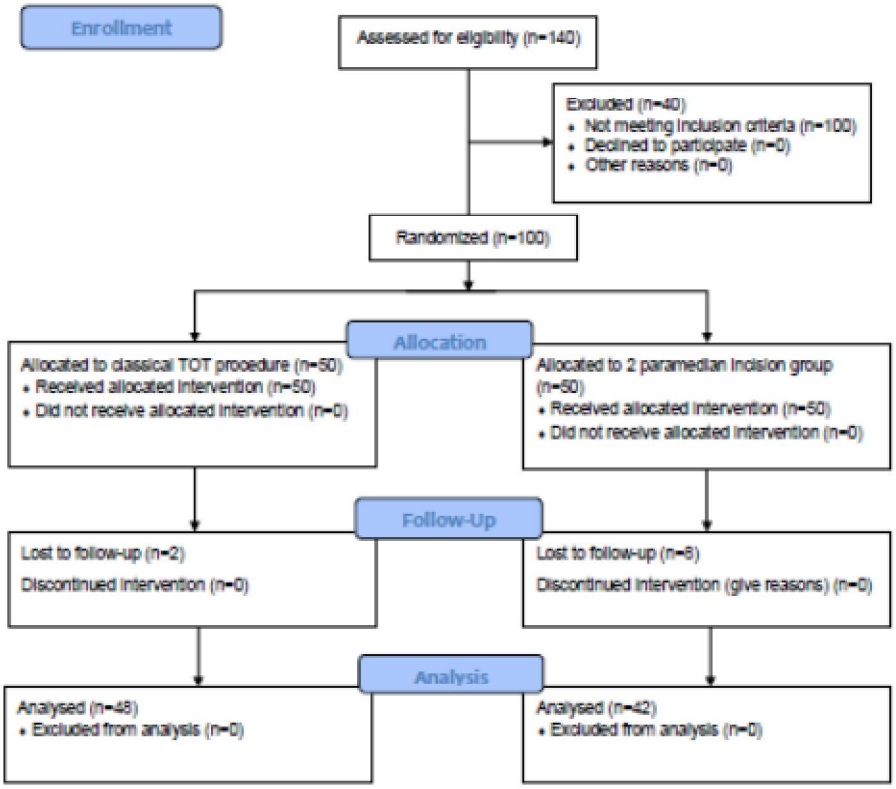

Figure 3: CONSORT Flow Diagram

In both groups, no postoperative urinary retention has been observed in our patients; De Novo urgency was shown in 10 cases of group 1 and 3 cases in group 2 representing 20% and 7% respectively. However, these results were not statistically significant. In group 1, only one instance of vaginal deterioration was identified following 1 month of surgery requiring the removal of the synthetic tape.

Trans-labial sonographic evaluation of the tape position was done to assess the tape position and its clinical correlation during the same period of follow up. For group 1, tape position at 3 months wasmid

urethral in 43 cases representing 89.6% of cases, while at 12 months, mid-urethral tape represents 47.9% of cases. 41.1% of instances indicated proximal or distal tape migration. For group 2, no migration was noted up to 12 months postoperative as shown in (Table 2). These findings with P-value have been statistically significant (0.02).

Clinical correlation of tape migration was evaluated in group 1 and it showed that failure to complete cure was associated with tape migration in 6out of 25 cases of group 1 representing 32 % of the total tape migration at one year follow up with a statistically significant difference. De Novo urgency noted 10 cases of group 1 compared to 3 cases in group 2 as shown in (Table 3). All cases of De Novo urgency in group 1 showed proximal tap migration as shown in (Table 4).

Table 1: Overall success rate

Overall success Rate	3 months			6 months			12 months		
	Group1 (n= 48)	Group2 (n=42)	P-value	Group1 (n= 48)	Group2 (n=42)	P-value	Group1 (n= 48)	Group2 (n=42)	P-value
No improvement	3 (6.3%)	2 (4.8%)	0.7 (NS)	3 (6.3%)	2 (4.8%)	0.17 (NS)	3 (6.3%)	2 (4.8%)	0.4 (NS)
Improved	11 (22.9%)	7 (16.7%)		6 (12.5%)	7 (16.7%)		6 (12.5%)	6 (14.3%)	
Cured	34 (70.8%)	33 (78.6%)		34 (70.8%)	33 (78.6%)		34 (70.8%)	33 (78.6%)	
Recurrence of symptoms	0 (0.0%)	0 (0.0%)		5 (10.4%)	0 (0.0%)		5 (10.4%)	1 (2.4%)	

P-value > 0.05: Non-significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant- Chi-square test.

Table 2: Assessment of Tape migration

Tape position	3 months			6 months			12 months		
	Group1 (n= 48)	Group2 (n=42)	P-value	Group1 (n= 48)	Group2 (n=42)	P-value	Group1 (n= 48)	Group2 (n=42)	P-value
Mid urethra	43 (89.6%)	42 (100%)	0.06 (NS)	23 (47.9%)	42 (100%)	<0.01 (HS)	23 (47.9%)	42 (100%)	0.02 (S)
Proximal urethra	5 (10.4%)	0 (0.0%)		12 (25.0%)	0 (0.0%)		12 (25.0%)	0 (0.0%)	
Distal urethra	0 (0.0%)	0 (0.0%)		13 (27.1%)	0 (0.0%)		13 (27.1%)	0 (0.0%)	

P-value > 0.05: Non-significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant- Chi-square test.

Table 3: Clinical correlation Vs tape migration.

Clinical correlation Vs tape migration	3 months			6 months			12 months		
	No migration	Migration	P-value	No migration	Migration	P-value	No migration	Migration	P-value
No improvement	3 (10.7%)	0 (0.0%)	0.03 (S)	3 (10.7%)	0 (0.0%)	0.02 (S)	3 (10.7%)	0 (0.0%)	0.02 (S)
Improved	3 (10.7%)	8 (40.0%)		3 (10.7%)	3 (15.0%)		3 (10.7%)	3 (15.0%)	
Cured	22 (78.6%)	12 (60.0%)		22 (78.6%)	12 (60.0%)		22 (78.6%)	12 (60.0%)	
Recurrence of symptoms	0 (0.0%)	0 (0.0%)		0 (0.0%)	5 (25.0%)		3 (10.7%)	3 (15.0%)	

P-value > 0.05: Non-significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant- Chi-square test.

Table 1: Incidence of DiNovo urgency)

De novo urgency	No	Group 1	Group 2	P-value
	Yes	10 (20.8%)	3 (7.1%)	0.03

P-value > 0.05: Non-significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant.

4. Discussion:

TOT that was initially described by Delrome in 2001 as the treatment of choice in management SUI(12), which was later modified by De Leval in 2003 with inside-out technique as a safer technique to avoid urethral or bladder injury (13).

The curative effect of the sling procedures depends mainly on the mechanical compression on the urethra and narrowing the gap between the pubis of the symphysis and the tape, as well the position of the tape compared to the urethraespecially in the middle portion of the urethra which is important for the continent mechanism(3,7,14,15)

Our technique includes two paramedian incisions in the anterior vaginal wall, each 1 cm long in the anterior vaginal wall 2 cm away parallel to the urethra until the mid-urethral portion is identified by palpating the catheter balloon through the vagina, then contact among the 2 incisions 1 cm broad in this region was made, forming a tunnel to put the tape, Unlike the standard technique with greater tissue dissection in the peri-urethral space which undermines the tape stabilization, we minimized dissection along the urethra to hold intact tissues proximal and distal to the tape to stabilize and avoid tape migration with this technique.

Continence was assessed following 3 months of surgery, suggesting a cure rate of 70.8% in group 1 relative to 78% in group 2, 22% and 16% of patients reported enhancement in their symptoms in group 1 and 2 respectively, and the failure rate has been almost the same in both groups, reflecting 3 patients in the standard technique and 2 patients in our technique. The 1-year follow-up of our patients following surgery revealed symptom repetition in 5 patients in the standard technique, reflecting 10% of patients, and 1 instance in our technique, reflecting 2.4% of instances.

However, no statistically significant results were obtained.

Trans-labial ultrasound was used to assess the mid urethra positioning of the tape intraoperative and to evaluate the migration of tape during the follow-up period. In contrast to a migration rate of 52.1 % in group 1, our technique showed no tape migration for 1 year follow-up, reflecting the standard technique that mostly happened in the first six months, on assessing the clinical correlation of the migration of tape on failure to cure and recurrence of symptoms. We noticed that 32% of the cases with tape migration showed a recurrence in their symptoms or failure to cure in the standard technique with a statistically significant difference.

In our study, De Novo emergency was assessed revealing an occurrence rate of 20.8% in group 1 relative to 7% in group 2, both reacted well to behavioral and pharmacological treatment, it has been noted that the clinical emergency status was associated with the location of the tape, thus appearing with the more proximal position of the tape.

In both groups, no postoperative urinary retention has been reported in our patients. Compared to 1 instance in the standard technique, pelvic pain has been observed in 4 instances in our technique and only one instance of vaginal deterioration has been experienced in group 1 following 2 months of operation that involved tape elimination.

Tape location was evaluated by ultrasound in previous studies that showed variable positioning of the tape, it is believed that proximal placement of the tape is associated with a De Novo urgency (3,15), Bougusiewicz et al. 2014, evaluated 141 patient underwent TOT and concluded that the highest failure rate was associated with proximal placement of the tape and the optimum site of placement to be at the middle and distal portion of the urethra (15). In our study, distal urethral migration showed a higher recurrence rate while proximal placement was associated with a higher rate of urgency.

Yand et al. 2012, reported that tape outside the middle portion of the urethra is associated with a higher rate of urgency and other voiding dysfunction (8). Pirtea et al. 2015, evaluated 51 patients who underwent TOT placement with a transverse incision versus the longitudinal aiming for more stabilization of the tape, their technique showed more stabilization rate compared to the standard technique with no tape migration in 82.1% of cases using their new technique (10). We adopted the same principle with a new surgical technique that showed no migration of the tape.

In contrast with the 40 % migration rate in the standard technique, our novel technique shows no tape migration according to our study 30 % that show repetition of symptoms could be related to tape migration, particularly distal migration. Clinically associated to tape positioning in the proximal urethra and near the bladder neck, post-surgery urgency was observed. A larger sample size is needed to detect statistically significant results in the cure rate after surgery.

Despite we used synthetic slings in our study that is still allowed to be used according to our local health care regulation, we did not report any case of dyspareunia or deep pelvic pain in any of both techniques. In our study, synthetic slings showed a significant success rate with no impact on sexual life. This raises a question regarding the superiority of natural slings over synthetic one that demands tissue retrieval first and longer operation time. We do recommend from our study to re-evaluate the use of

synthetic slings compared to natural ones on a wider scale.

Conclusion:

The tape migration was associated with recurrence of symptoms especially in distal tape migration while the appearance of De Novo urgency was seen in some cases of proximal tape migration.

We strongly believe that the 2 paramedian vaginal incisions type provides more tissues support proximal and distal to the tape, which enables for more stability and less tape migration that enhances the procedure's success rate reducing symptom recurrence.

Declaration:

Ethical approval and consent to participate:

The research was accepted by the Research Ethics Committee of the Ain Shams University Faculty of Medicine, Cairo, Egypt, with approval No. (FMASU R51/2019)

Trial registration number:

The trial was registered at clinicaltial.gov with trial registration number: NCT04571346, date: 1st of October 2020, retrospectively registered.

Consent for participation:

Written consent was obtained from all patients before participation

Consent for publication:

Written consent was obtained from all patients and approved by the ERB

Sample size calculation:

It was done according to results from the previous study done by Pirtea et al.2015(10) that compared a new horizontal incision versus the standard vertical incision in tape procedure and it showed that 20% of cases have tape migration, while it's assumed to be less than 5% among our new technique from previous a pilot study. Base on this, 35 cases per group will be needed considering a 10% dropout rate. We involved 100 patients instead to avoid a higher drop rate.

Availability of data and materials:

On fair request, the datasets used and/or analyzed during the present research are accessible from the corresponding author.

Competing interest:

No competing interests to declare

Funding:

We received no fund in our study.

Abbreviations:

Stress urinary incontinence (SUI)
trans-obturator tape (TOT)

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