

Double Tension Adjustments with Novel Modification on Tension-Free Vaginal Tape

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Objective: To evaluate the results of novel modifications on tension-free vaginal tape (TVT) for the treatment of women with stress urinary incontinence (SUI).

Materials and Methods: Sixteen female patients (average age 49.29 years, range: 31-78) who underwent anti-incontinence surgery to correct their SUI in the period between June 2010 and August 2014 were included in the study. In situ anterior vaginal wall sling was prepared, and monofilament polypropylene tape passed below the in situ-sling and standard TVT procedure was performed. Both ends of the mesh in the suprapubic region were labeled with Vicryl sutures and left outside the wound. The middle of the mesh in the vaginal region were labeled with similar suture and left outside the vagina. Foley catheter was removed on the third postoperative day. The average period of follow-up was 8 months (range: 5-17).

Results: All patients benefited from the surgery; 15 (94%) of them completely cured and one patient clinically improved. Urinary retention was observed in one patient where the tension of the tape was reduced using adjustment sutures. No vaginal mesh erosion was detected during the gynecological examination postoperatively. No significant post-voiding residue was detected after catheter removal.

Conclusion: This technique gives feasible option to adjust the tension of the mesh in the early post-operative period in case of urinary retention. Presence of intervening in situ sling reduces the risk of vaginal erosions. Long-term success is expected because dislocation of the mid-urethral sling is less likely.

Keywords: female; quality of life; urinary incontinence; surgery; stress; outcome assessment; postoperative period; prospective studies.

INTRODUCTION

Since the initial description of tension-free vaginal tape (TVT) in 1995 by Ulmsten and Petros⁽¹⁾ for the treatment of stress urinary incontinence (SUI) in women, many approaches have been evolved.⁽²⁾ TVT which based on mid-urethral polypropylene, have become the most accepted technique for the treatment of type I and type II SUI in females.⁽³⁾ The cure rate of mid-urethral sling (MUS) appeared to decrease over time with an associated increase in the SUI recurrence rate.⁽⁵⁾ The overall 5-year cure rate for anti-incontinence surgery was reported to be 76.8%.⁽⁶⁾ Nilsson and colleagues reported excellent long-term success of 81.3% at 7 years follow-up.⁽⁷⁾ There is no definite cause for this reduction in the success rate of TVT over long-term follow-up. Many expected mechanisms may cause the reduction in long-term efficacy as the tape being loose, so that it becomes slacked with time or misplacement of mid-urethral tape.⁽⁸⁻¹⁰⁾ Loss of tensile property and relaxation of TVT tape are among the expected causes of reduction in the success rate at long-term follow-up.⁽¹¹⁾ Beside reduction in long-term success rate, MUS related complications are also present. Deng and col-

leagues investigated the incidence of MUS sling related complications in the American population and found they were underreported.⁽¹²⁾ There was a significant variation between the scientific reports in English literature and Food and Drug Administration (FDA), which collect four times as many as major complications.⁽¹²⁾ In a recent study we had introduced novel modification on TVT to overcome the dilemma of the reduction in long-term success rate and the results were promising.⁽¹³⁾ Here in we introduced further novel surgical modifications on TVT to achieve long-term success and avoid some complications of MUS, including; mesh erosion and postoperative urinary obstruction or incontinence.

MATERIALS AND METHODS

Study Population

Sixteen women (average age 49.3 years, (range: 31-71) who were diagnosed with genuine SUI underwent anti-incontinence surgery. Six patients were operated between June 2010 and August 2010 in Osmaniye state hospital in Turkey and another 10 patients were operated in An-Najah National University hospital in Palestine, between April 2013 and August 2014. SUI

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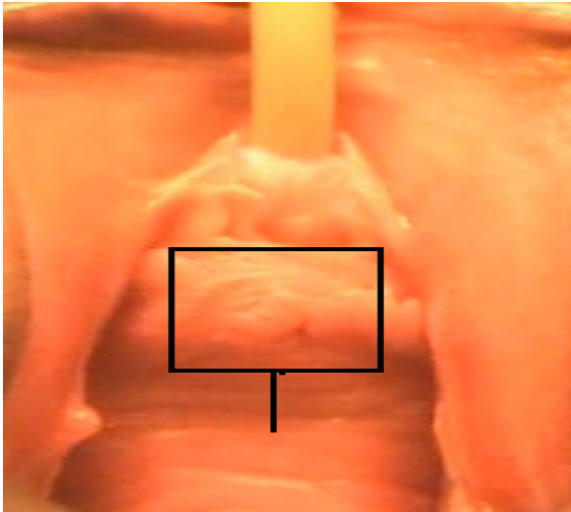


Figure 1. Schematic illustration of placard incision at the anterior vaginal wall.

was defined as unintentional loss of urine on physical movement or activity such as coughing, sneezing, or heavy lifting. The urodynamic evaluation showed stable bladder with normal volume and no detrusor over-activity. All cases were primary, except 3 patients who had anti-incontinence surgeries previously (the exact nature of the previous anti-incontinence surgeries was unclear). One of them had two previous unsuccessful anti-incontinence surgical interventions (vaginal approach without mesh), and another one had multiple pelvic surgeries with bladder and urethra rupture due to road traffic accident. This patient had severe form of SUI, with low bladder capacity (300 mL), and low leak point pressure at urodynamic study. Anti-cholinergic therapy was given for all patients before surgery and no

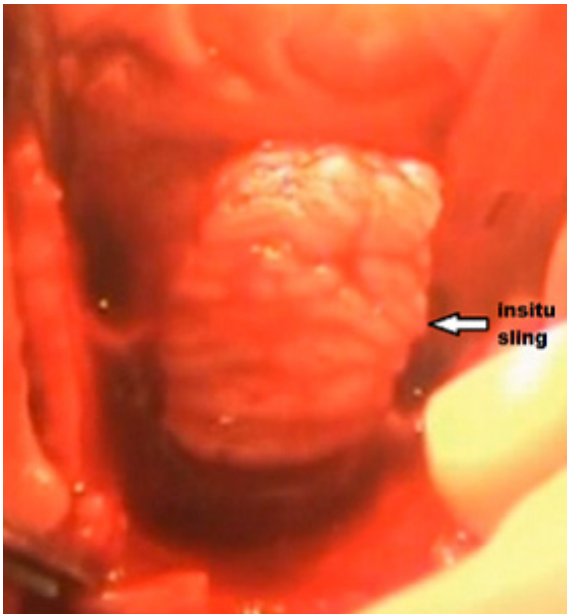


Figure 2. In situ sling prepared from anterior vaginal wall is shown.

benefit was seen.

Evaluations

Any patient who suffered from urodynamically documented urge incontinence was excluded from the study. Baden-Walker classification was used to evaluate the degree of cystocele.⁽¹⁴⁾ Cystocele was observed in only 4 patients: two patients with grade III and two patients with grade II.

Surgical Procedure

The patients were operated under spinal or general anesthesia. In the lithotomy position, an 18 French (F) Foley catheter was inserted to evacuate the bladder. In the anterior vaginal wall placard incision was done (**Figure 1**) and dissection was carried out to prepare a mid-urethral in situ anterior vaginal wall sling (**Figure 2**). According to the degree cystocele the length of mid-line incision at anterior vaginal wall was determined. Enough dissection at the lateral sides of in situ sling was performed till the index finger could be felt from the suprapubic region. No cauterization was done in the vaginal region. Monofilament polypropylene mesh (Vizcare, Istanbul, Turkey) passed through retropubic space as in the standard TVT operation and the mesh was passed between the mid-urethra and the in situ vaginal sling (**Figure 3**), doing so dislocation of the tape was avoided. Both ends of the tape in the suprapubic region were labeled with 2-0 Vicryl sutures and left outside the skin to increase the tension of the mesh in the early postoperative period in case of incontinence presence. Similarly the middle of the tape beside the in situ sling in the vaginal region was labeled with the same sutures and left outside the vagina to decrease the tension of the tape in the early post-operative period in case of urinary retention presence (**Figure 4**). Cystoscopy was done intra-operatively to rule out bladder or urethral perforation. The bladder was inflated with 300 mL normal saline and hand pressure was applied on the suprapubic region to define Valsalva leak point pressure and accordingly the tension of the tape was adjusted. The placard incision edges were sutured tightly over the in situ sling, leaving the tension adjustment sutures outside the wound (**Figure 4**). At the end of the surgery vaginal sponge with betadine solution and antibacterial cream was placed and left for one night.

Post-operative Period

Oral quinolones antibiotics (500 mg twice/day) were given for one week postoperatively. All patients were hospitalized for one day. An 18 F Foley catheter was left for average of 3 days. The operative time varied from 30-45 minutes. Sexual intercourse and lifting heavy loads were avoided for 2 months postoperatively. The postoperative follow-up schedule was 0.5, 1, 3, 6 months, and then every 6 months; including clinical history for possible urinary leakage, pelvic physical examination, stress test, and estimation of the post-voiding residue (PVR) volume (50 mL or less was considered insignificant). Real abdominal ultrasound was used to measure the PVR during the postoperative follow up. The patient was considered to be cured after surgery when there is absence of leakage with or without stress testing. Improvement was considered when there is no urine loss on stress plus patients report of some leakage but overall satisfaction. Therapeutic failure was defined as sustained SUI.

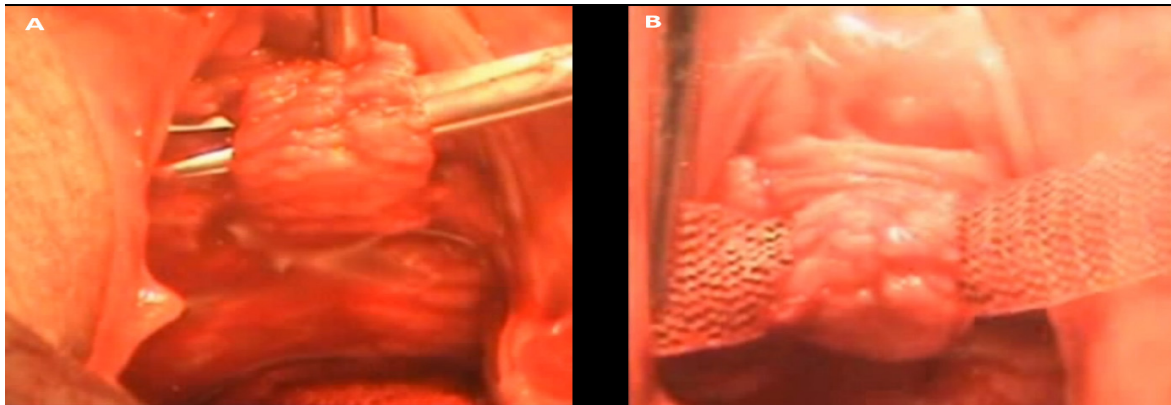


Figure 3. (A) Dissection below the in situ sling to pass the tape; (B) mid urethral tape passing below the in situ vaginal sling.

RESULTS

All patients benefited from the surgery; 15 (94%) of them completely cured and one patient clinically improved (78 year-old, grade III cystocele, history of cerebrovascular accident). Some urinary leakage occurred but satisfied overall. One patient (6%) had urinary retention (she had history of two anti-incontinence surgeries) after removal of Foley catheter. So a Foley catheter was re-inserted for one week more, but still the patient had urinary retention after the second removal of Foley catheter. Therefore a tension reduction of the sutures by pulling down external suspension suture (suture placed at the mid of the tape below the mid-urethra in the vagina (**Figure 4**) was enough to resolve urinary retention. Denovo urgency was performed in two patients, one of them had history of urgency symptoms before surgery and the other one was 71 years old and over obese. One of them gave a good response to anticholinergic therapy for three weeks; the other one (71-year old) partially benefited from anti-cholinergic therapy. No vaginal erosion was observed in any patient. There was no clinically significant PVR urine detected by real time abdominal ultrasound after catheter removal. The tension adjustment sutures were cut after one month

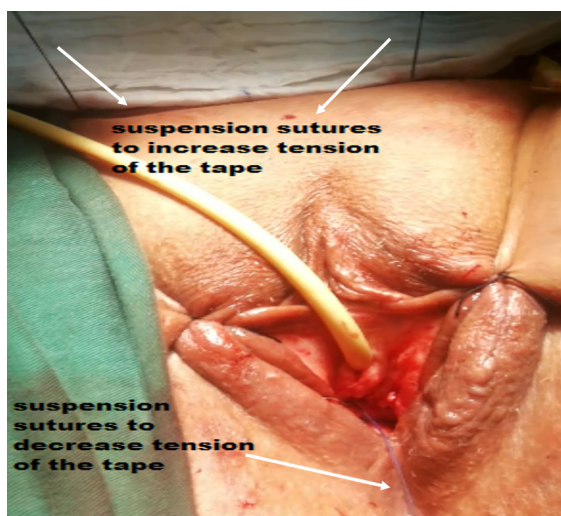


Figure 4. Tension adjustment sutures indicated by arrows in the suprapubic region and vagina.

postoperatively. The average follow-up period was 8 months (range: 5-17).

DISCUSSION

The safety and efficacy of TVT have been extensively investigated.⁽¹⁵⁾ However few studies have mentioned about the true incidence and prevalence of complications⁽¹²⁾ and even with their managements.⁽³⁾ Beside reduction in the long-term success rate,⁽⁵⁾ postoperative obstruction, bladder erosion, vaginal erosion, urethral erosion and denovo urgency are among the most common complications of anti-incontinence surgery. In the current description two modifications were adopted; passing the TVT mesh below the in situ vaginal sling to prevent the dislocation or misplacement of the tape and decrease the risk of vaginal erosion, the second modification was labeling the upper ends and the lower middle of mesh by Vicryl, thus the adjustment of the tape tension may be possible. In our study we tried to introduce solutions for the mechanisms that may cause decrement in the success rate on long-term follow-up. Dislocation of the tape from the mid-urethra was avoided by passing the tape below the in situ sling (**Figure 3**), so a long-term success is expected. In our recent published work, where mesh fixation with in situ sling were done, none of the patient who was continent after surgery suffered from any leakage at midterm follow-up.⁽¹³⁾ Low risk of vaginal erosion is also an expected result of the present technique. We had neither vaginal nor urethral mesh erosion. Generally 66% of erosions are discovered within the first 3 months after surgery, although recent series demonstrated the ongoing risk of vaginal surgery erosions even 5 years after surgery. Then we believe that our patients passed the critical period without having vaginal erosion as all patients were followed-up for more than 3 months. Passing the tape below the in situ sling, makes vaginal erosion less likely to occur because of the presence interposition vaginal mucosa. About 35% of the vaginal erosions present with no symptoms and usually discover on routine follow-up and not during symptomatic check. Similarly Kobashi and colleagues reported that in 90 women who had anti-incontinence surgery using polypropylene mesh, developed vaginal erosions but only one patient had symptoms such as pain during sexual intercourse.⁽¹⁶⁾ Surgical approach ranges from partial excision of the exposed mesh to surgical exploration for total graft re-

moval. Some authors believe that mesh erosion should be treated with complete mesh removal and regardless to erosion site, width, or local tissue.⁽¹⁷⁾ Vaginal erosion of synthetic material such as polyester and silicon slings should be also treated with mesh removal because epithelization over these materials rarely occur.^(12,18,19) In a recent study, a higher risk of vaginal erosion was found to be associated with hand-made sling (14.6%) than with commercial sling (1.6%).⁽²⁰⁾ In contrary to vaginal erosion, bladder erosion is serious complication, it is symptomatic and usually ends with calculus formation over the mesh. We do recommend intra-operative cystoscopy to verify the integrity of bladder. Open surgery was the valid management for the calcified eroded mesh in the bladder. We were the first who introduced the usage of the standard transurethral resection of the mesh as safe and simple way for the management of mesh bladder erosion,⁽²¹⁾ which was used and approved by many authors in a lot of publications.^(22,23) Urethral erosion following tape surgery is rare (0.03% to 0.8%) but potentially serious and symptomatic.⁽²⁴⁾ Surgical intervention is mandatory, but there is no consensus regarding the optimal management. The reconstructive procedures include: endoscopic tape removal and vaginal removal with urethral reconstruction with or without interposition of vascularized autologous tissue.⁽²⁴⁾ It is clear that tape anti-incontinence surgeries do have serious and sophisticated complications without standard approaches for management. Therefore save the patients from such complications is of utmost clinical value.

Postoperative urinary retention is a challenging complication of anti-incontinence surgery and there is no consensus-based approach for the management. In one of the largest studies, Kuuva and Nilsson reported that urinary retention after anti-incontinence surgery was 2.3%.⁽²⁵⁾ In our present study we had one patient (6.2%) with urinary obstruction after catheter removal and it was managed easily by reducing the tension of the mesh utilizing the adjustment suture at outpatient clinic. We believe that adjustment sutures are of much benefit especially for the beginner surgeons in the field of female anti-incontinence surgery. It is difficult to make definite comment regarding real possibility of adjusting the tension of the sutures as we have used it in one patient only. Early transient post-operative urinary retention may require intermittent sterile catheterization and in the majority of cases, urinary retention tends to solve within 12 weeks. If urinary retention persist for more than 12 weeks or significant PVR is present, then transvaginal urethrolysis may be done. Klutke and colleagues performed tape transaction without mesh resection for the treatment of postoperative persistent urinary retention.⁽³⁾ Similarly Volkmer and colleagues reported that women with persistent postoperative urinary retention stayed continent after mesh transaction, suggesting that mesh resection could damage the scar that replace the urethropubic ligaments and might result in urinary incontinence.⁽²⁶⁾ Either clean intermittent catheterization or sling transaction, they are not accepted procedure by the patients. In our technique, tension adjustment sutures give feasible option and fast solution for postoperative urinary retention.

We believe that patients with high risk factors for persistence of incontinence such as, obesity, old age, and high grade cystocele, history of failed anti-incontinence

surgery, diabetic, or presence of overactive bladder may be in need of tape tension adjustment. Therefore tension adjustment sutures may improve the success rate and expand the patients group who may benefit from anti-incontinence surgery. Our technique seems to be valid for secondary or complicated cases; none of the patients with history of previous vaginal or anti-incontinence surgery had recurrence of incontinence. However preparing vaginal in situ sling should be done carefully in such case as it is more difficult than in virgin cases. Standard MUS with these new modifications will keep it superior to all other kinds of anti-incontinence surgeries including vaginal sling and the new introduced single incision mini sling. In one of the recent meta-analysis of effectiveness and complications of MUS and mini slings, there was no evidence of significant difference in patients reported and objective cure rate between mini sling and MUS at midterm follow-up.⁽²⁷⁾ Mini sling was shown to have several complications similar to that of MUS.⁽²⁸⁾ Also TVT secure has already been withdrawn from clinical use and it is inferior to standard MUS.⁽²⁹⁾

CONCLUSIONS

Our modifications do improve the superiority of TVT and offer feasible solution for severe complications after anti-incontinence surgery including urinary retention and leakage of urine. Vaginal erosion is less likely to occur. Long-term success is expected as no dislocation of tape from the mid urethral is expected. Yet larger number of patients with longer follow up period is needed before final result can be drawn.

CONFLICT OF INTEREST

None declared.

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