Novel technique for the treatment of stress urinary incontinence

Early experience

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ABSTRACT

The objectives of this study were to evaluate the efficacy of an in situ anterior vaginal wall sling, reinforced with polypropylene mesh, in the treatment of stress urinary incontinence (SUI).

Methods: Seventeen patients with mean age of 51.29 years (range: 27-73) underwent surgery for SUI from August 2006 to August 2007 at Osmaniye State Hospital, Osmaniye, Turkey. Two out of 17 patients gave history of previous anti-incontinence surgical intervention, while the remaining were primary cases. In situ anterior vaginal wall sling, reinforced with semi-size monofilament polypropylene tape (size of the mesh was similar to size of in situ sling), was used as an anti-incontinence procedure. The mean follow-up period was 9.29 months (range: 4-16).

Results: In situ anterior vaginal wall sling reinforced with polypropylene mesh was successful in 16 (94.1%) patients, 14 of them were cured, and 2 had clinical improvement. There was no report of preoperative urethral, bladder, or bowel injury. One patient developed postoperative urinary retention that resolved after decreasing the tension of the suspension sutures, and one patient had suprapubic wound sepsis treated by oral antibiotics and anti-inflammatory drugs. No postoperatively significant post-voiding residue was detected.

Conclusion: The early results of this technique are encouraging. It is easy to learn, economical, with a good success rate. Urethral erosion is less likely to occur due to the presence of intervening vaginal mucosa. In the future, a prospective study recruiting a larger number of patients undergoing this technique with long-term follow-up is recommended.
Tension-free vaginal tape (TVT) represents the well-established surgical procedure for the treatment of stress urinary incontinence (SUI). The technique described by Ulmsten in 1996, which is based on a midurethral Prolene tape support, is accepted worldwide as an easy to learn, effective, and safe surgical technique with low incidence of complications. However, the reported failure rate following TVT procedure was 5-15%, and other possible alternative techniques were developed. Another well-known complication is a bladder outlet obstruction, which has a negative influence on patients rehabilitation. Bladder penetration, bowel injury, intra-operative bleeding, and post-operative infection are examples of reported complications. In one of the largest studies, Kuuva et al reported that the percentages of postoperative complications after anti-incontinence surgery were: 2.3% for urinary retention, 3.8% for bladder perforation, 0.07% for urethral erosion, and 0.8% for wound infection. Similarly, Neuman et al reported 8% of bladder perforation, 5% of voiding dysfunction, 2.7% of therapeutic failures after TVT procedure. The place of urodynamic study in patients with pure SUI is not universally accepted. While some studies emphasize its importance, others are not in support of its routine use before anti-incontinence surgery. In this study, the efficacy of a new surgical technique utilizing in situ anterior vaginal wall sling, reinforced with polypropylene mesh for the treatment of pure SUI is evaluated.

Methods. This prospective trial included 17 female patients with a mean age of 51.29 years (range: 27-73) who were planned for surgery due to SUI from August 2006 to August 2007, at Osmaniye State Hospital, Osmaniye, Turkey. The diagnosis of SUI was based on positive stress test, and the presence of urethral hypermobility confirmed by cotton swab test. The SUI was defined as involuntary leakage on effort, exertion, sneezing or coughing, and urge incontinence was defined as the complaint of involuntary leakage accompanied by, or immediately preceded by urgency. Urethral hypermobility was assessed with Q-tip test. The degree of cystocele was assessed according to the Baden-Walker classification. Cystocele of various degrees were observed in 10 patients; grade III in 2, grade II in 5, and grade I in 3 patients. Urodynamics were performed only for 7 (41.2%) patients who did not define pure stress incontinence. All patients included in the study were diagnosed to have pure stress incontinence and showed no benefit of anti-cholinergic therapy. Any patient that suffered from urodynamically documented urge incontinence was excluded from the study. No patient received preoperative pelvic floor muscle training for the treatment of SUI. Two out of 17 patients gave a history of previous anti-incontinence surgical intervention. One patient underwent a retropubic procedure of unknown nature, and another one underwent transobturator tension-free vaginal tape. All patients were informed about the operation and consent was obtained from the patients. Ethical approval was obtained from the hospital for this study. The operation was performed under spinal or general anesthesia. In the lithotomy position, 18 F Foley catheter was inserted to evacuate the bladder. Then, a placard-shaped incision was made in the anterior vaginal wall (Figure 1), and dissection of the vaginal flap was carried out to prepare midurethral in situ anterior vaginal wall sling (Figure 2). The length of midline incision at anterior vaginal wall was determined according to the degree of cystocele. The dissection at the lateral side of the in situ sling was carried out until the index finger could be easily felt from the suprapubic area. Semi-size monofilament polypropylene mesh (I-STOP CL Medical, France) was prepared, then at the lateral side of the placard incision, 2 suspension sutures of 1/0 polypropylene were inserted in the flaps and the mesh (Figure 3), and passed lateral to the urethra. Two fixation sutures were placed at the lower and upper edges of the in situ sling to keep the mesh over the sling (Figure 3). A small transverse incision of 4.5 cm was made over the symphysis pubis without cutting the rectus fascia. Before fixation of the suspension sutures to the symphysis pubis peristomeum, the bladder was filled with 250-300 ml isotonic solution, and manual pressure was applied to the suprapubic area to test for leakage, thus adjusting the tension of the sutures. Then, closure of the placard incision followed over the in situ sling. Per-operative cystoscopy was performed in each patient to exclude urethral or bladder injury. All patients were hospitalized for 24-48 hours. An 18 F Foley catheter was left for 7 days. The vaginal sponge was placed at the end of the operation, and removed 24 hours later. Operative time varied from 45-90 minutes (mean 60 minutes). Postoperatively, patients were advised to avoid sexual intercourse and carrying heavy weights for 2 months. The mean follow up period of patients was 9.29 months (range: 4-16). The postoperative follow up schedule was 1, 3, 6 months, and then every 6 months. It included clinical history for possible urinary leakage, 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. Cure of SUI after the procedure was defined as the absence of complaint of leakage, and the absence of leakage on stress testing. Improvement was defined as no urine loss on stress plus patients report of some leakage but overall satisfaction. Therapeutic failure was defined as sustained SUI.
anesthesia. This resulted in spontaneous voiding shortly after one day of catheterization. No intra-operative bleeding, bladder or intestinal penetration was observed. Two patients (11.7%) had asymptomatic vaginal tape erosion detected during the gynecological examination at the first month postoperatively, and a conservative approach (watchful waiting) was adopted. One patient had temporary urgency without urge incontinence, starting at the third week postoperative, and improved on anti-muscarinic for 3 weeks. There was no clinically significant PVR urine detected by real time abdominal ultrasound after the catheter removal. One patient had wound sepsis in the form of suprapubic tenderness and redness, which was treated by oral antibiotics and anti-inflammatory drugs for one week.

Discussion. The integral theory of incontinence and the basis of midurethral sling procedure was developed by Petros et al.\textsuperscript{15} The current view in incontinence surgery is in favor of pubovaginal fascial sling over traditional abdominal colposuspension techniques, as the results of the former are much better long term regarding efficacy, morbidity, hospital stay, and cost to public health care.\textsuperscript{16-18} However, many publications reported no significant differences between various midurethral sling procedures.\textsuperscript{19,20} In a recent study, we reported encouraging results using the placard technique, utilizing \textit{in situ} sling of anterior vaginal wall for the treatment of SUI, especially in patients with average BMI.\textsuperscript{21} In the current description, a slight modification by supporting the \textit{in situ} vaginal sling with semi-size mesh was adopted, aiming to increase the efficacy of the surgical procedure. Cost effectiveness and low risk of urethral or bladder erosion are the most important potential advantages of this technique. The length of the mesh used in our technique is 2 cm (>15 times less than the length of the same mesh [I-STOP] used for TVT). Urethral erosion is theoretically less likely to occur due to the presence of vaginal mucosa between the mesh and urethra. The success of curing SUI by this technique is also related to the good feasibility of cystocele correction. Cystocele was reported to be one of high risk factors for persistence of stress incontinence.\textsuperscript{22} Modest long-term success is one of the dilemmas that face the patients undergoing anti-incontinence surgery. The overall 5-year cure rate for anti-incontinence surgery was reported to be 76.8%.\textsuperscript{23,24} With this technique, we hope that long term success is achieved as the urethra is supported by the \textit{in situ} sling and semi-size mesh, and no relaxation in the suspension sutures is expected. The patient who did not benefit from the surgery was diabetic and obese (BMI=44.98). Obesity and co-morbid diseases are among factors (high BMI, urge incontinence, low leak point pressure, high grade

Results. The surgical technique used in this study was successful in 16 (94.1%) patients, as 14 of them were cured, and 2 patients had clinical improvement. The ages of these 2 patients were 73 and 69 years, and the later was diabetic. One patient (5.8%) did not benefit from the surgery (64-year-old, diabetic, body mass index [BMI]=44.98). One patient (5.8%) had urinary retention that was not resolved after a further 5 days of catheterization, therefore, the tension of suspension sutures was relieved in the theater under...
incontinence, severe grade of cystocele) that may have a negative impact on cure rate after anti-incontinence surgery. Preoperative PVR determination is recommended for any women with voiding dysfunction or history of recurrent urinary tract infection. In our study, all patients (7 patients) who underwent urodynamic evaluation had no detected PVR, and the remaining females had no history of inadequate bladder emptying, so it is difficult to comment on the effect of preoperative PVR volume on the clinical outcomes of the technique. Due to the low number of patients included in the study, it is difficult to evaluate the statistical correlation between the failure of the technique and the development of certain complications (urgency, retention) with certain risk factors such as age, BMI, parity, menopausal status, diabetes mellitus, the presence of cystocele, and previous incontinence surgery. The use of this procedure in secondary cases of SUI seems to be acceptable. Out of 2 patients, who were “re-do”, both were cured. However, performing this technique for secondary cases may carry some difficulties in preparing the in situ sling due to fibrosis because of the previously surgeries. To reduce the rate of vaginal erosion, enough dissection at the lateral side of the in situ sling is recommended. The high rate of vaginal erosion in our study may be due the low number of patients who were included in the study. In conclusion, early therapeutic results of this technique are encouraging. The cost-effectiveness and the low risk of urethral erosion are the most important considerations of this technique. Long-term success is expected, hoping that relaxation of the suspension sutures is less likely. Long term follow up and larger sample size are required to enable drawing solid conclusions regarding this operative procedure.

References