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Risk factors for mesh erosion after vaginal sling procedures for urinary incontinence

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ABSTRACT

Objectives: To identify risk factors for mesh erosion in women undergoing vaginal sling procedures for urinary incontinence with synthetic meshes, and to estimate the incidence of mesh erosion after these procedures.

Study design: Retrospective study of women who underwent vaginal sling procedures between January 2007 and January 2013. In total, 1439 consecutive women with stress urinary incontinence were investigated. Five hundred and sixty-six (39.3%) women underwent a tension-free vaginal tape (TVT) procedure and 873 (60.7%) women underwent a transobturator tape (TOT) procedure. All procedures were performed using meshes of the same type and size. Women who experienced mesh erosion were defined as cases, and women who were not re-admitted or identified with mesh erosion during the study period were defined as controls. Demographics, operative techniques and outcomes were taken from medical records. Multivariate regression identified the odds of mesh erosion.

Results: Sixty-one of 1439 (4.2%) women were found to have mesh erosion in the postoperative period: 41 (67.2%) after TOT procedures and 20 (32.8%) after TVT procedures. The rate of mesh erosion was 4.7% in the TOT group and 3.5% in the TVT group, and this difference was significant ($p < 0.05$). Mean age, body mass index, current smoking, menopausal status and diabetes mellitus were significantly higher among cases than controls. Univariate analysis showed that length of vaginal incision >2 cm, recurrent vaginal incision for postoperative complications, and previous pelvic organ prolapse or incontinence surgery were significant risk factors for erosion. Multivariate analysis demonstrated that older age, diabetes mellitus, current smoking, length of vaginal incision >2 cm, recurrent vaginal incision for postoperative complications, and previous pelvic organ prolapse or incontinence surgery were independent risk factors for mesh erosion.

Conclusions: Mesh erosion following vaginal sling procedures is a frustrating complication with relatively low incidence. It was found to occur more often after TOT procedures than TVT procedures. Older age, diabetes mellitus, smoking, length of vaginal incision >2 cm, recurrent vaginal incision for postoperative complications, and previous vaginal surgery for pelvic organ prolapse or incontinence increased the risk of mesh erosion. Identification of risk factors may enable surgeons to prevent or minimize this complication.

Introduction

Stress urinary incontinence (SUI) is the most common type of urinary incontinence and is generally treated surgically [1,2]. Vaginal sling procedures have become the standard technique for the surgical treatment of SUI, in which synthetic mesh material is located suburethrally under the vaginal mucosa. The tension-free vaginal tape (TVT) procedure, developed by Ulmsten et al. in 1996, was one of the first retropubic midurethral sling procedures [3,4]. During this procedure, approaching the posterior pubic cavity may cause bladder perforation and vessel, nerve or bowel injuries. As such, the transobturator tape (TOT) procedure was developed more recently to minimize associated morbidity [5]. Studies have demonstrated that these procedures are very effective and have similar cure rates for SUI [6,7]. However, using synthetic tape material may have complications such as rejection, infection and erosion [8]. Hence, concerns about mesh complications have made these procedures controversial.

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A literature review undertaken by the US Food and Drug Administration found that mesh erosion through the vagina is one of the most common complications following transvaginal procedures that use meshes. Several factors contribute to the wide range of vaginal erosion rates, including patient characteristics (e.g. age and oestrogen deficiency), operative technique, implant size and specific properties of the graft material (e.g. pore size, stiffness, elasticity and basic tissue compatibility) [9]. This study aimed to identify the risk factors for mesh erosion in women undergoing vaginal sling procedures for SUI with synthetic meshes, and to determine the incidence of mesh erosion after these procedures.

Materials and methods

This retrospective study consisted of 1439 women who had undergone vaginal sling procedures for SUI at the Department of Obstetrics and Gynaecology, Zekai Tahir Burak Woman's Health Education and Research Hospital, Ankara, Turkey, from January 2007 to January 2013. Ethical approval was obtained from the regional hospital ethics committee. Five hundred and sixty-six women underwent TVT procedures and 873 women underwent TOT procedures. All procedures were performed using meshes of the same type (polypropylene monofilament) and size (1.1×40 cm). The TOT technique was performed in accordance with Delorme's description [5] of the outside-in technique, and the TVT technique was performed in accordance with Ulmsten's description [3,4] of the inside-out approach. All variables were collected from hospital records. Demographic variables included age, weight, height, gravida, parity, history of diabetes mellitus, smoking status, menopausal status, and previous hysterectomy or genital prolapse surgery. Pre-operatively, pelvic floor defects were determined using Baden–Walker's classification [10], and all patients underwent a stress test that was considered positive if leakage occurred concurrent with cough or valsalva manoeuvere in a supine position. Proximal urethral mobility was quantified using the *Q*-tip angle test. Patients with a hypermobile proximal urethra (*Q*-tip test angle $\geq 30^{\circ}$) and a positive stress test underwent a TOT procedure, and patients with a non-hypermobile urethra (*Q*-tip test angle $<30^{\circ}$) and a positive stress test who appeared to have intrinsic sphincter deficiency underwent a TVT procedure. Urodynamic evaluation and cystoscopy could not be performed systematically before surgery. Operative data collected from hospital records included operative technique, estimated blood loss, concomitant procedures and operative time. All procedures were performed by six senior surgeons. The thickness of dissection, location of incision, placement of mesh and closure of incision did not differ between the surgeons. Prophylactic antibiotics (cefazolin 2 g intravenously) were administered systematically. A urinary catheter was inserted for 24 h postoperatively for each patient, and removed on the first postoperative day. Postvoid residual urine was measured before each patient was discharged from hospital. Time from procedure to mesh erosion, location of mesh erosion and complications were also documented postoperatively. Mesh erosion was defined as any exposure of mesh upon visual inspection of the entire vagina at the postoperative speculum examination. Women who experienced mesh erosion during the study period were defined as cases, and women who were not re-admitted or found to have mesh erosion during the study period were defined as controls.

Data are presented as mean ± standard deviation or number and percentage. In order to examine risk factors, Student's *t*-test was used to compare means of continuous data, and Chi-squared test was used for analysis of numbers and percentages. Univariate regression analysis was performed for the variables. Variables showing statistical significance in the univariate logistic regression analysis were included in a multivariate analysis to determine independent risk factors. $p < 0.05$ was taken to indicate significance.

Results

During the study period, 1439 vaginal sling procedures for SUI were performed. Postoperative mesh erosion occurred in 61 patients (4.2%): 41 (67.2%) TOT and 20 (32.8%) TVT procedures. All mesh erosions were located in the midline.

The characteristics of the case and control groups are shown in Table 1. The mean ± standard deviation age of cases was significantly higher than that of controls (50.57 ± 8.33 vs 46.69 ± 7.34, respectively). Mean body mass index (BMI) was significantly lower in controls compared with cases (30.25 ± 2.64 vs 31.37 ± 3.62, respectively; $p = 0.035$). The proportion of cases reporting current smoking, menopausal status and diabetes mellitus was significantly higher compared with controls. The remaining parameters listed in Table 1 did not differ significantly between cases and controls.

Risk factor analysis, performed by univariate logistic regression, identified previous vaginal sugery for pelvic organ prolapse (POP) or urinary incontinence as a risk factor for mesh erosion [odds ratio (OR) 0.16, 95% confidence interval (CI) 0.06–0.45; $p < 0.001$ (Table 2)]. Length of vaginal incision >2 cm during surgery (OR 0.15, 95% CI 0.08–0.31; $p < 0.001$) and recurrent vaginal incision for complications (infection, urinary retention or bleeding) (OR 0.22, 95% CI 0.09–0.56; $p = 0.001$) were associated with increased risk of mesh erosion (Table 3).

The multivariate analysis found that the most important independent risk factors for mesh erosion were length of vaginal incision >2 cm (Wald = 20.94; $p < 0.001$) and diabetes mellitus (Wald = 11.03; $p = 0.001$) (Table 4). The risk of erosion increased with age; age >60 years (Wald = 9.52; $p = 0.020$) and age 50–60 years (Wald = 4.61; $p = 0.032$) were found to be significant independent risk factors. Previous vaginal surgery for POP or incontinence ($p = 0.042$), recurrent vaginal incision for postoperative complications ($p = 0.031$) and current smoking ($p = 0.030$) were also found to be significant risk factors for mesh erosion.

Mesh erosion occurred following 4.7% of TOT procedures and 3.5% of TVT procedures; the mesh erosion rate was significantly higher in patients who underwent a TOT procedure ($p = 0.042$). No significant differences were found between patients who underwent TOT procedures and patients who underwent TVT procedures in terms of demographic, pre-operative, intra-operative and postoperative status (Table 5). The length of mesh exposure was similar following both TOT and TVT procedures ($p = 0.354$). The most common symptoms of mesh erosion following both TOT and TVT procedures were hand feeling. Asymptomatic erosions detected during routine postoperative control inspections were at least (Table 5).

Table 1
Demographic parameters of groups.

	Cases ($n = 61$)	Controls ($n = 1378$)	p[a]
Age (years)	50.57 ± 8.33	46.69 ± 7.34	0.020
Parity (n)	3.23 ± 1.51	2.87 ± 1.21	0.081
Body mass index (kg/m^2)	31.37 ± 3.62	30.25 ± 2.64	0.035
Current smoking	29 (47.5)	369 (26.8)	0.006
Menopausal status	35 (57.4)	535 (38.8)	0.017
Diabetes mellitus	18 (29.5)	222 (16.1)	0.033
Asthma	12 (19.7)	276 (20.0)	0.937
Spontaneous vaginal deliveries	44 (72.1)	904 (65.6)	0.326
Sexual activity	41 (67.2)	1052 (76.3)	0.184

Data presented as mean ± standard deviation or n (%).
[a] $p < 0.05$ was considered as statistically significant.