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Research Article

Mesh-Related Complications of the Mid-Urethral Sling in Diabetic Women with Stress Urinary Incontinence

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Abstract

Objective: In recent years, synthetic mesh has become a popular pelvic floor reconstruction surgery tool. However, in some cases, complications following the use of mesh require further investigation. This study investigates the mesh-related complications of mid-urethral sling (MUS) among diabetic patients.

Materials and Methods: This retrospective cohort study was performed in the urology department of a referral teaching hospital. Of a total 320 clinical records of women undergoing MUS with synthetic meshes for stress urinary incontinence (SUI) treatment from 2013 to 2019, we collected the mesh-related reported complications of diabetic patients and analyzed using SPSS/ 21 software.

Results: Among 320 women who had undergone MUS with synthetic meshes, 46 cases out of 51 diabetic patients met our inclusion criteria. The mean age was 58.23 (7.72) years. Ten patients underwent tension-free vaginal tape (TVT) implantation, and the others underwent implantation of Trans-obturator tape (TOT) method. We followed the patients for 36.89 ± 11.33 months (range 12 - 60 months). Our results showed that the common complications after MUS surgery were *denovo* urgency UI (UUI) (19.57%) and mesh sensation (17.39%). Besides, we evaluated the satisfaction rate after the procedure as a secondary outcome, which indicated that 36 cases out of 46 (78.2%) diabetic patients had a high satisfaction rate during 12 - 60 months.

Conclusion: The common complications after MUS surgery in diabetic women were *denovo* UUI, and mesh sensation. It can be concluded that, with careful and principal surgery and appropriate post-operative care, there will be no high risk in MUS surgery using mesh for diabetic patients.

Keywords: *Surgical Mesh; Midurethral Sling; Diabetes Mellitus; Urinary Incontinence, Stress*

Introduction

Stress urinary incontinence (SUI) is a common problem in women, even among young females [1]. According to the international continence society (ICS), SUI is a complaint of involuntary loss of urine on effort or physical exertion, including sporting activities, or on sneezing or coughing. A cough stress test (CST) is recommended in evaluating female patients to identify the signs of SUI. Conservative treatment with pelvic floor muscle training and lifestyle modification is the first line of management, and mid-urethral sling procedures are considered the 'gold standard' treatment of SUI [2,3].

The prevalence of UI was 53.4% among the women, and 40% of it was stress UI. International Consultation on Incontinence Questionnaire - Short Form shows that urinary incontinence negatively impacts the quality of life [4].

SUI treatment is essential to increase life expectancy and improve the quality of life. Procedures utilizing native tissue had a high recurrence rate and could restore only 50% of the preoperative tissue strength. Reconstructive surgery that s synthetic mesh in a sub-urethral sling to treat SUI is known as a standard procedure. Since one-third of those undergoing pelvic floor reconstruction surgery without using a mesh had a recurrence, attention was drawn to new approaches [5].

It has been observed that the amount of collagenolytic activity in the connective tissue matrix of women with SUI is increased compared to other subjects. Available information suggests that the factors contributing to collagen loss are not confined to the pubocervical fascia, but they are systemic processes that involve even ineffective tissues in the pelvic organ tolerance. Collagenolytic activity in explant skin biopsy cultures and pubocervical fascia in healthy continent women was lower than in those with SUI. This evidence suggests an increased collagenolysis in the etiology of weakened pelvic floor support of the lower genitourinary tract in SUI [6].

In light of the above, the synthetic mesh in sub-urethral sling has become a common tool for pelvic floor reconstruction surgery in stress urinary incontinence in recent years.

Despite these benefits, there have been numerous reports of complications in patients treated with mesh. As a result of these reports, the US Food and Drug Administration issued warnings about mesh's effects in 2008 and 2011 [7]. Complications of mesh are mainly manifested in the forms of erosion, infection [8], retraction [9,10], dyspareunia [11] and pain [12]. The International Urogycological Association (IUGA) and the International continence society (ICS) in a joint study classified the effects of external prostheses (mesh, implants, etc.) as [3] exposure or conditions in which the mesh is obvious, visible and accessible; extrusion or gradual withdrawal from the body or tissue; and perforation or anomalous cavity to the hollow or visceral organ. Infections may occur with erosion or alone. Various pathogens such as gram-positive aerobic and anaerobic bacteria are involved in this condition [8]. In retraction**,** the tissue's shrinkage surrounding the mesh is very common, and the contact area may be reduced to as much as 40% of the initial area after surgery [9,10].

Dyspareunia can be caused by erosion, infection, retraction, or even severe fibrosis, and a study showed that at a three-year interval, 6.2% of patients treated with SUI develop this complication [11]. Although the specific risk factors for mesh infection are not fully understood, several pre-operative patient-related factors such as aging, smoking, diabetes, obesity, and autoimmune diseases may impact the development of mesh-related complications, including exposure or even infection [12]. Among the mentioned risk factors, lifestyle factors and morbidities such as diabetes are crucial. What makes diabetes even more important is that diabetes is more prevalent among older women, who are more prone to SUI disorders. According to the US Centers for Disease Control and Prevention, the incidence of diabetes is about 4% at ages 18 to 44, and it increases to 17% at ages 45 to 64, and 25% at ages 65 and over [13]. In diabetes patients' hyperglycemia is thought to cause dysfunction of the immune response. Therefore, diabetic cases are known to be more susceptible to infections. Besides, nerve damage and reduced blood flow to the extremities increase the body's vulnerability to infections and tissue damage. Referring to the present studies, it has been observed that no studies have been performed on the complications of using the synthetic mesh in diabetic patients. Accordingly, the present retrospective study attempted to investigate the complications of using synthetic meshes in diabetic patients referred for SUI treatment from 2013 to 2019.

Materials and Methods

This retrospective cohort study was performed in the urology department of a referral teaching hospital, and we evaluated the clinical records of diabetic patients who underwent mid-urethral sling (MUS) surgery to treat SUI using polypropylene mesh Obtryx™ II Transobturator MUS or Knotless Incontinence Mesh of Neomedic from 2013 to 2019 after the proposal approval by regional ethic committee.

Inclusion and exclusion criteria

We included all medical records of patients with DM for at least five years and SUI treated with MUS using synthetic meshes from 2013 to 2019. The patients whose symptoms were not in the definition of SUI or unclear diabetes mellitus (DM) diagnosis were excluded from the study. In addition, patient dissatisfaction with continuing cooperation was the other exclusion criteria.

The severity of SUI was classified according to Ingelmann-Sundberg. According to this classification, grade I incontinence is defined as urine loss during coughing, sneezing, pressure and laughing. Grade II is urine loss during lifting, running, climbing stairs, and grade III is urine loss during standing without physical activity [14].

The diagnostic criteria of DM were considered as occasional plasma glucose value of ≥ 200 mg/dl (≥ 11.1 mmol/l), fasting plasma glucose of ≥ 126 mg/dl (7.0 mmol/l) (fasting time 8 - 12h), OGTT 2-h value in venous plasma ≥ 200 mg/dl (≥ 11.1 mmol/l) [15].

Outcome measures

Our primary outcome was mesh-related complications, including mesh sensation, pain, erosion, mash palpation, and infection. The secondary outcome was the patient's satisfaction after the procedure.

Data collection

Of a total of 320 medical records, only the medical records of DM patients were selected for data extraction in terms of post-operative complications. After recording all hospital file information, we contacted the patients. Then we explained the research objectives and obtained their informed consent to participate in the study. They were asked about the parameters in the data extraction checklist, including age, duration of diabetes, type of surgery, complication before and after surgery, UI recurrence, mesh sensation, pain, erosion, mash palpation and infection.

For this purpose, the demographic characteristics, including age, and medical history, were collected. In the first step, the medical records of non-diabetic patients were excluded. The results of urethral hypermobility and stress test recorded in the medical history were collected, too.

To assess the patient's satisfaction with treatment, we used a visual analogue scale (VAS) with a scoring system of 0-100. A score between 0-25 was considered "Poor", between 26-50 "Moderate", 51-75 "High" and higher than 75 an "Excellent" satisfaction. The obtained data were analyzed by SPSS/version 21 software.

Results

The clinical records of 320 patients who underwent MUS surgery for SUI treatment in the urology department from 2013 to 2019 were studied. Fifty-one cases (17%) were diabetic, and their mean age was 58.23 (± 7.72) years. The patients under investigation had diabetes for at least five years during the follow-up. Figure 1 shows the flow diagram of the study.

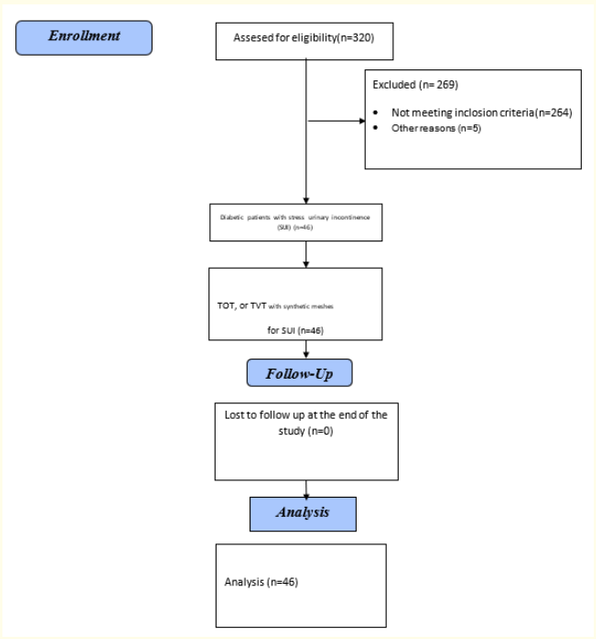

Figure 1: *Flowchart of study.*

Pre-operation, the most common symptoms were stress incontinence (54.4%), frequency (25.7%), urge incontinence (14.17%), and nocturia (5.7%).

Of a total of 320 cases, 51 patients had diabetes. Five patients were excluded because of the lack of contact information, loss to follow-up, and finally, 46 cases were included in this study. Ten subjects underwent implantation of TVT, and the majority of women underwent implantation of TOT. In MUS surgery, we used polypropylene mesh Obtryx™ II Transobturator MUS or Knotless Incontinence Mesh of Neomedic in our procedures. The mean age of patients was 57.5 (± 8.0). Of those, 11 (23.91%) cases had SUI grade III, and the rest 35 cases (76.08%) had grade I and II of SUI.

The all patients' blood glucose levels were regulated during the surgery. However, during the long-term follow-up period, we didn't know about their blood glucose levels either it was well-controlled or poorly.

We followed the patients for 36.89 ± 11.33 months (range 12 - 60 months).

The results showed that out of 46 cases in synthetic mesh, the common adverse events were *denovo* UUI and mesh sensation.

Table 1 shows the observed complications.

Type of complication	Number	Frequency (%)	Age (Mean ± SD)
Denovo urgency UI	9	19.57%	59.8 (7.22)
Mesh sensation	8	17.39%	62.8 (9.83)
Pain	6	13.04%	58.75 (8.14)
Frequency	5	10.87%	56.33 (15.31)
Erosion	3	6.52%	57.3 (7.8)
Mesh palpation	1	2.17%	48.0 (0.0)
Infection	1	2.17%	64.0 (0.0)

Table 1: *The frequency of mesh-related post- mid-urethral sling operative observed complications in the study.*

In terms of patient satisfaction after the procedure, most cases were satisfied with the treatment. The frequency of patients' satisfaction with treatment is listed in table 2.

Patient's satisfaction	Poor (0 - 25)	Moderate (26 - 50)	High (51 - 75)	Excellent (76 - 100)
Frequency	1 (2.17%)	9 (19.57%)	16 (34.78%)	20 (43.48%)

Table 2: *Patient's satisfaction with treatment.*

Discussion and Conclusion

Our results showed that among 320 women who had undergone MUS surgery with synthetic meshes, 51 cases were diabetic, and 46 patients had eligibility criteria. Ten subjects underwent implantation of TVT, and the remained women underwent implantation of TOT method. During the follow-up period, the common complications after MUS surgery were *denovo* UUI, and mesh sensation. Infection, mesh palpation, and erosion were less common complications. Nowadays, the different outcomes associated with varying types of the sling are unclear, and *denovo* urgency and UUI may be observed in some patients with no previous evidence of storage symptoms after placement of a MUS [16].

In the study of Lo., *et al*. in the general population (diabetic or non-diabetic), the recurrence rate of SUI was approximately 10% [17]. Barski., *et al*. [18] in retrospective review of 388 patients with MUS, showed that the most common complications are overactive bladder (52%), obstructive micturition (45%) and SUI recurrence (26.03%). In addition, dyspareunia in 5.67% and pain in 13.91% were reported. Hampel., *et al*. [19] showed *denovo* urge in 65% of women that were developed MUS surgery (44 cases in TVT and four in TOT). Renezeder., *et al*. [20] followed 118 cases of MUS and transvaginal mesh for 27 months. *Denovo* urgency rate were (46.6%), dyspareunia (41.5%), and mesh erosion (37%).

Abed., *et al*. studied 110 articles that included 11,785 patients and noted that the mean incidence of graft erosion was 10.3% [21]. After surgery, the reported mesh erosion rate for female SUI was 0 - 7.3% [22]. In the present study, erosion was present in only three diabetic cases (6.52%), consistent with previous studies. Compared to the 0 - 21% incidence reported in various randomized control trials and prospective studies published on POP surgeries by vaginal approach, this was low [9]. Several studies have documented a link between mesh erosion after female pelvic floor reconstruction and DM [23-25]. Mesh erosion may result from peripheral neuropathy, micro vasculopathy, and decreased immune function caused by hyperglycemia [26].

A comparison of concomitant diabetes between erosion and no erosion groups was made in 13 studies. The meta-analysis showed that concomitant DM was significantly more common in patients with mesh erosion than in the no erosion group (OR 1.87, 95% CI 1.35 - 2.57, $P < 0.001$). This result indicated that concomitant DM was a significant risk factor [27].

In the Brill study [28] the prevalence of erosion in non-diabetic patients was 30%, and 15% for infection. The average prevalence of erosion was reported to be around 10% in the Falagas' study. In both diabetic community and the general population, erosion directly relates to infection. They reported erosion as the most common complication, while it is the least prevalent in the study population. Compared to the current study, the prevalence of these complications was lower in the statistical population treated with TOT or TVT, where the erosion was 6.5% and infection was 2.1%.

The prevalence of erosion in this study is lower than the median value reported in the Falagas (10%) [10], or Brill's study (30%) [28].

Mesh infection may be associated with or without vaginal mesh exposure. Various pathogens have been implicated, including Gram-positive and Gram-negative aerobic and anaerobic bacteria, and incidence ranges from 0 - 8% [26]. Only one case (2.2%) had infection post-procedure in our survey.

After using synthetic mesh for pelvic floor reconstruction, chronic pelvic pain often presents a serious problem [12]. Groin and thigh pain is a potential problem of MUS placement, especially transobturator slings. It has been reported in up to 40% of patients after transobturator sling placement [29]. A recent meta-analysis revealed more common in the inside-to-outside transobturator approach [30]. Its incidence can be decreased by newly introduced mini-slings, which reported a lower incidence of pain ranging from 0 to 3.3% only. About 13% (6 out of 46) of our diabetic patients experienced pain. Suppose initial conservative management with anti-inflammatory medications fails to relieve pain. In that case, a few patients may need mesh removal with its attendant risk of recurrence of pelvic floor defect. In the case of pain, a comparison with the Shah., *et al*. study [9] shows that the incidence of this complication in diabetic patients undergoing synthetic mesh surgery is comparable to that in those experiencing the same type of surgery. Finally, according to our results, it can be seen that more than 78% of patients have over-average satisfaction with the treatment by synthetic mesh.

Although our results showed that the outcomes of mesh-related complications are comparable with the non-diabetic normal population in the previously mentioned studies, one of our limitations was the lack of a control arm. Therefore, we recommend conducting a survey to compare mesh-related complications in diabetic and healthy control patients. Since our cases were referred with a complaint of pure SUI, and according to the guidelines, for the patients with pure SUI, the urodynamic study is not mandatory; therefore, we had no urodynamic evaluation before surgery. However, in the cases with urodynamic study it is recommended to evaluate the correlation

between urodynamic bladder sensation findings and sense-related complication e.g. mesh sensation, pain. Besides the other limitations of this study, including retrospectively data collection as well as unavailability of some cases, one of the strengths of our study was the long-term follow-up of diabetic patients. Further studies on the MUS surgical outcomes on diabetic patients and comparing the control arm results are recommended.

In the diabetic population, *denovo* urgency UI, and mesh sensation were more prevalent than other complications. Compared to previous studies on the complications of using the synthetic mesh, the prevalence of complications in diabetic patients didn't differ from other subjects. Besides, in more than 75% of patients, the satisfaction rate with treatment was above average. It can be hypothesized that with proper patient selection, precise and routine MUS surgery, and appropriate post-operative care, synthetic mesh in diabetic patients with SUI may not be very risky.

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Conflict of Interest Statement

The authors have no conflicts of interest to declare that are relevant to the content of this article.

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