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Long-term outcome of synthetic mesh use in Iranian women with genital prolapse

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Keywords: Prolapse; Synthetic mesh; Outcome; Complications.

Abstract

Purpose: To evaluate the long-term outcome of synthetic mesh use in the treatment of women with Pelvic organ prolapse (POP).

Materials and Methods: We evaluated the outcome of synthetic mesh implantation by vaginal surgery method in 153 women (mean age of 53.66±9.31 years) with POP grade >2 in the anterior compartment. Demographic findings, baseline symptoms as well as subjective and objective outcome were recorded during the follow-up period of 36.89±11.33 months.

Results: POP relapse occurred in 3.3% indicative of 96.7% anatomical success rate. Patients' common baseline findings were frequency (72.5%), stress and urge incontinence (59.5% and 47.7%). Subjective outcome were vaginal pain (13.7%), dyspareunia (9.2%) and tension feeling (8.5%), while objective outcomes were mesh exposure (3.9%), urge incontinence (11.1%) and vaginal infection (1.3%). Stress incontinence was completely treated following surgery. There was significant improvement in dyspareunia, vaginal pain, urge and stress incontinence (all $p<0.001$) and fecal incontinence ($p=0.02$). After surgery, 88.42% were satisfied of the surgery outcome.

Conclusion: POP surgery with synthetic mesh has acceptable results, considerable improvement in symptoms and high rate of satisfaction during follow-up; however, side effects are not uncommon but tolerable.

Introduction

Pelvic organ prolapse (POP) including genital prolapse is common with incidence rate of 40 % of women aged 45-85 years in general population, but only 12% of them are symptomatic [1,2]. Conservative and different surgical methods have been proposed for vaginal prolapse repair [3]. However, there is an increased risk of recurrence regarding the surgery method and the type of materials used [4,5].

Transvaginal meshes have been introduced to increase the surgery efficacy and reduce the recurrence rate [6]. After using synthetic meshes, studies have reported increased success rate with lower morbidity in genital prolapse surgeries [7]. Although previous studies have indicated that prolapse repair surgery with synthetic meshes are very effective with low prolapse and high patient's satisfaction, there are several complications reported regarding mesh use including mesh exposure, pelvic pain, infection, bleeding, dyspareunia and with lower incidence, organ perforation [8].

Studies evaluating the long-term outcome of synthetic mesh use in vaginal prolapse surgery are few. In this study, we aim to evaluate the outcome and rate of complications following vaginal prolapse surgery using synthetic mesh among Iranian women.

Patients and Methods

In this cross-sectional study, 300 women with POP undergone vaginal surgery with synthetic meshes between 2011 and 2016 in Alzahra, Taleghani and Imam Reza tertiary hospitals, Tabriz, Iran were evaluated and among them 153 patients meeting inclusion criteria and not having exclusion criteria were included. Inclusion criteria were women between 40-80 years old, with POP stage 2-4 according to simplified POP-Q scoring scale undergone surgery with synthetic mesh implantation (Figure 1). Patients with genital malignancies, body mass index >40 kg/m^2, infection, history of

previous mesh implantation, collagen vascular disease and those with psychologic disease and no cooperation for maintaining mesh were excluded. Also, those patients not returning for follow-up visits were excluded. The surgeries were performed by two experienced urogynecologists (PB and SH). This study was approved by ethics committee of Tabriz University of Medical Sciences.

Mesh implantation was indicated when there was severe anterior prolapse stage >2 or accompanied with uterine or posterior prolapse. If there was concomitant apical prolapse, sacrospinous fixation was used. After surgery, patients were followed with routine visits every six months for at least one year. In each visit, full physical examination was performed.

Before implanting the mesh, a vertical incision at the anterior vaginal wall was made from the point below the bladder neck to the lowermost part of the prolapse. Diluted vasopressin solution was applied subcutaneous to reduce bleeding. With the Allis forceps securing incision margins, full-thickness blunt dissection was done for the pubo-cervical fascia laterally until reaching the sacrospinous ligaments. Dissection with 1–2 finger breadths further down from the ischial spines towards sacrum was done. All used meshes were from Neomedic International Company (Madrid, Spain).

For anterior prolapse, the mesh is placed by a Single Incision procedure through one single vaginal incision. In its anterior part, the mesh is fixed to the internal obturator muscles by its two pocket system arms, with no needles and no skin perforations. For posterior prolapse, the surgeon cut the middle and anterior arms, fixating the mesh posteriorly to the sacrospinous ligament and anteriorly to the elevator anus muscles. For sacrospinous ligament fixation, the ischial spine was palpated and taken as the reference to pinpoint the sacrospinous ligament, which extends from the ischial spine medially to the coccyx and the lower portion of the sacrum. The pararectal fascia was

penetrated, and the space was enlarged using blunt dissection; the rectum was retracted to the left using two Breisky-Navratil retractors, thereby exposing the sacrospinous ligament. No 1 non-absorbable suture (Prolene) was placed 2-2.5 cm medially to the ischial spine, and one end of the suture was passed through the vaginal vault; surplus tissue located in the posterior vaginal wall was excised, and the upper 1/3 of the vaginal mucosa was repaired. Following the vaginal vault repair, the vaginal vault was suspended from the right sacrospinous ligament by tying together the sacrospinous sutures located proximal to the apex of the vaginal vault. Lastly, posterior repair and perineoplasty were performed, which marked the end of the procedure.

Demographic findings, patients' symptoms and POP grade before surgery, improvement in symptoms and complications following mesh use were all recorded. Subjective outcome was considered as pain, dyspareunia and mass extrusion and objective outcomes were mesh exposure, tenderness and urinary incontinence.

Patients' satisfaction of the surgery was assessed using Likert scale of four (excellent, well, moderate, poor).

Statistical analysis

All data were analyzed using SPSS Statistics, Version 20 (IBM Corporation, New York). Results are expressed as mean ± SD or percentage. McNemar test was used to evaluate the improvement in symptoms before and after surgery. p values of less than 0.05 were considered statistically significant.

Results

Patients' baseline findings are demonstrated in **Table 1.** The most common symptoms were frequency, urge and stress incontinence, and dyspareunia. Posterior and uterine prolapse were mainly stage II, while anterior prolapse was mainly stage III. Patients

were followed for 36.89±11.33 months (range 12-60 months). All patients with fecal incontinence had posterior compartment prolapse and treated accordingly.

During follow-up, prolapse recurrence occurred in 5 cases (3.3%), one treated with sacrocolpopexy, one with vaginal surgery and another mesh implantation and one with pessary. Two other patients were treated conservatively. In the case treated with pessary, in first surgery just small piece of mesh was used for anterior compartment repair but the relapse was related to combined anterior and apical compartment, so we used Capio system with mesh and we removed the previous one as much as possible and very gently

Subjective outcomes were vaginal pain in 21 (13.7%), dyspareunia in 14 (9.2%) and tension feeling in 13 (8.5%). Mass extrusion was not reported in any of the cases. This tension was present in patients with higher prolapse grade and in the recent weeks after surgery which was later improved with no treatment in the following visits. Of 14 dyspareunia cases after surgery, 4 persisted after surgery and 9 cases was de novo after surgery. Ten cases of vaginal pain, were persistent after surgery and the other 11 cases were de novo.

Objective outcomes were mesh exposure in 6 cases (3.9%), urge incontinency in 17 cases (11.1%) and infection in 2 cases (1.3%). Urge incontinency persisted in 9 cases and not improved following surgery, while 8 new de novo cases occurred after surgery. All stress incontinency cases were improved after surgery.

Of 6 patients with mesh exposure, symptoms occurred between 13-27 months after surgery, four cases were mild exposure and treated with vaginal estrogen. Two cases returned with delay with complete mesh exposure, the extruded mesh part was removed and repaired. One of the cases with complete exposure had purulent vaginal

discharges and treated with proper antibiotics. At the final follow-up, all 6 patients were symptom free.

Using a Likert scale, the patients reported their satisfaction of the surgery as excellent in 54 cases (35.2%), well in 81 cases (52.9%), moderate in 14 cases (9.2%) and poor in 4 cases (2.6%). Most patients had well to excellent satisfaction of surgery.

Following surgery, there was significant improvement in dyspareunia, vaginal pain, urge and stress incontinence and fecal incontinence (**Table 2**).

Discussion

In this study, we evaluated the long term outcome of using synthetic mesh in the vaginal surgery of genitalia prolapse in 153 women between 40-80 years old. There was significant improvement in prolapse stage after surgery with only 3.3% of recurrence indicative of 96.7% anatomical success rate. Prolapse severity, urinary symptoms and fecal incontinence was significantly improved after surgery.

In many studies, successful treatment was considered as POP grade ≤1 after surgery. The reported success rate are > 80% and in the recent studies are more than 90-95% [9-14]. Similar to our findings, Hong and colleagues reported total anatomical success rate of 96.5% after 18 months follow-up [10]. It is even noted that regardless of recurrence of POP in some patients, they are mostly satisfied of the treatment due to the considerable improvement in symptoms [11-14]. Although some studies report that two years after mesh treatment, many women still report symptoms that negatively impact their quality of life [15].

Using synthetic meshes would accompany with some side effects which would limit its use. Recent guidelines has recommended mesh in patients after full risk evaluation and to be performed by an expert surgeon [16]. Reported side effects of mesh use are mesh erosion, dyspareunia, hematoma, urinary incontinence, etc [17].

Mesh exposure is a complication related to procedure, mesh type and atrophy after mesh implantation. Mesh exposure occurred in 3.9% of our patients. Four cases had mild exposure and treated with vaginal estrogen. Two cases with complete mesh exposure had the extruded part removed and repaired.

The reported rate of mesh exposure in short and long term follow-up are variable. Meyer and colleagues reported mesh exposure in 6% of patients in long term follow-up [18], which was higher than 2% in midterm follow-up [19]. Other studies have reported mesh exposure rate of 1-24% and mostly below 15% [9,18-23]. Fan and colleagues reported mesh exposure in 6 patients (13%) of which three meshes were removed [20]. Meyer and colleagues also reported that mesh exposure usually occurred in women with vaginal atrophy who stopped using vaginal estrogen [18].

Transvaginal mesh implantation had conflicting effects on sexual function in previous studies. Meyer and colleagues observed that this surgery has no adverse effects on sexual function in long term [18]. Dyspareunia occurred in 36% of their study patients. Alperin and colleagues also have reported dyspareunia in 28.9% of patients after surgery [9], while the reported rate in most studies are 2-20% [21-25].

In our study, dyspareunia persisted in 2.7% and de novo dyspareunia occurred in 6.5%. The rate of dyspareunia after mesh implantation is not completely determined. The rate of new dyspareunia after surgery is reported to be between 4.4 to 20% [25-29]. De novo dyspareunia could be due to mesh exposure or mesh shrinkage. Milani et al. evaluated 127 patients after mesh implantation with 61 of them sexually active and observed new dyspareunia in 2% of cases [26].

The main cause for this difference in the rate of dyspareunia could be due to the unwillingness of women to talk about their sexual relation in different areas, especially in religious countries such as ours. As in our study, older women did not

like to talk about their sexual relations and it is possible that the real rate of new dyspareunia be higher. However, this low rate of dyspareunia is considerable and indicative of efficacy of treatment with mesh.

In our study, stress incontinence was completely improved after surgery. Vaginal pain persisted in 6.5% and newly occurred in 7.2% and urge incontinence was persistent regardless of surgery in 5.9% and de novo in 5.2%. Patients considered their symptoms not severe and tolerable. Alperin and colleagues reported pelvic pain in 4% [(9)]. Fan and colleagues reported stress incontinence in 11% of patients that were mostly mild and treated conservatively [(20)].

We observed that 88.2% of patients were well to excellent satisfied of the treatment outcome. Fan and colleagues reported overall satisfaction of 91% [(20)]. The satisfaction rate in Song et al. study was 84.7% [(30)].

Limitations

This study had also some limitations; One weakness of our study is that our data were collected partly retrospectively and so some data were not available. However, this study has the power of rather good sample size and long term follow-up.

Conclusion

Genitalia prolapse surgery with synthetic mesh has acceptable results, considerable improvement in symptoms and high rate of satisfaction during follow-up; however, side effects are not uncommon but tolerable.

Conflicts of interest: The authors declare that they have no conflict of interest.

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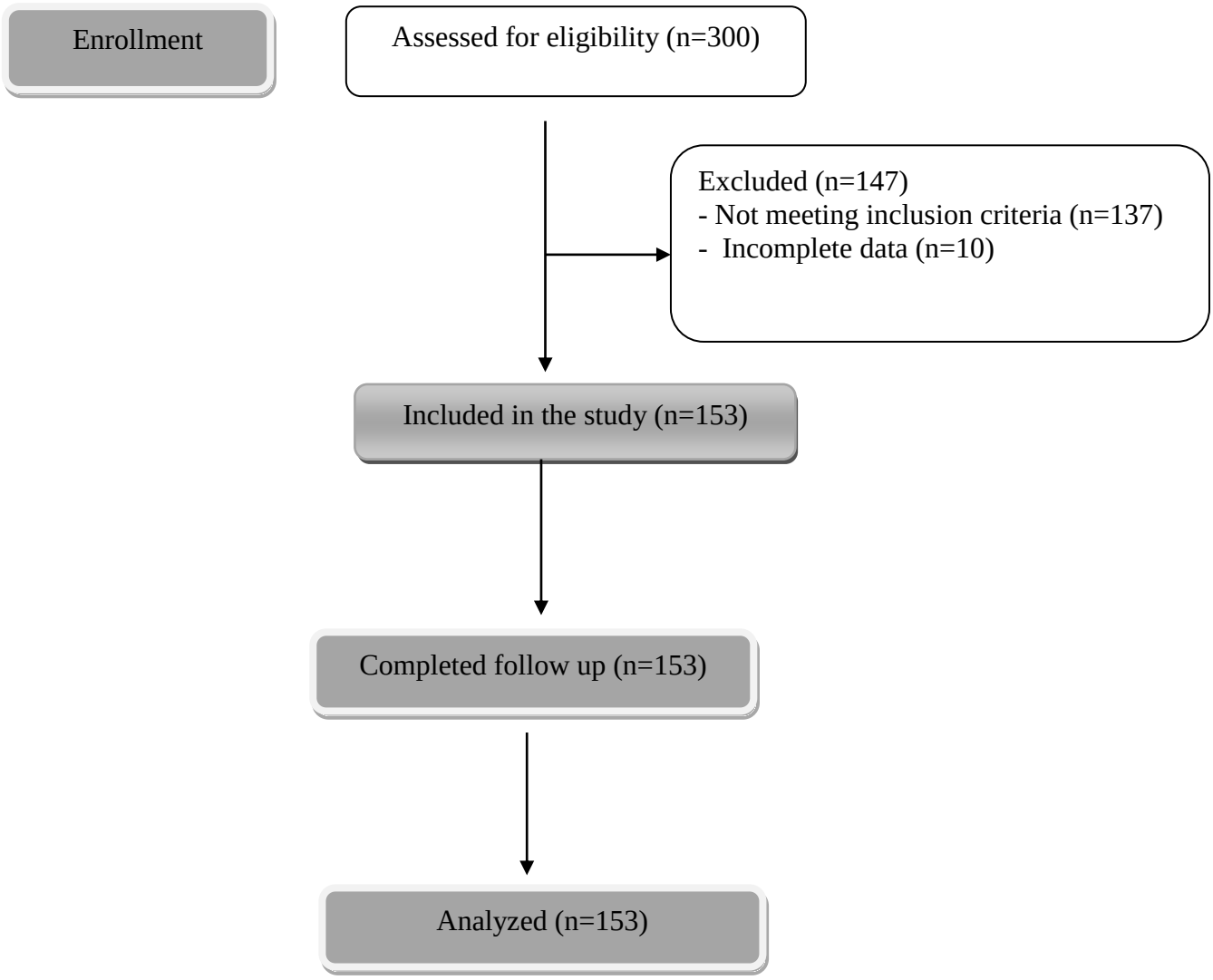

Figure 1. Flowdiagram of the study population.

Table 1. The grade of genitalia prolapse before Mesh Implantation in the study population

	Variables
Age (years)	**53.66±9.61**
Gravida	**4.56±1.94**
Parity	**4.18±1.80**
Hypertension	**8 (5.2%)**
Diabetes mellitus	**31 (20.3%)**
Symptoms	
Urge incontinence	**73 (47.7%)**
Stress Incontinence	**91 (59.5%)**
Urgency	**73 (47.7%)**
Frequency	**111 (72.5%)**
Urination problems	**37 (24.2%)**
Dyspareunia	**68 (44.4%)**
Vaginal pain	**56 (36.4%)**
Fecal incontinence	**5 (3.3%)**

Prolapse type[a]	**Stage I**	**Stage II**	**Stage III**	**Stage IV**
Uterine	**13 (8.5%)**	**88 (57.5%)**	**38 (25.18%)**	**14 (9.2%)**
Anterior	**11 (7.2%)**	**51 (33.3%)**	**91 (59.5%)**	**-------**
Posterior	**29 (19%)**	**108 (70.6%)**	**16 (10.5%)**	**-------**

[a] Data are presented as mean ±SD or number (percent)

Table 2. Comparing the symptoms before and after mesh implantation [a]

	Before surgery	After surgery	P value
Dyspareunia	**68 (44.4%)**	**14 (9.2%)**	**<0.001[b]**
Vaginal pain	**56 (36.6%)**	**21 (13.7%)**	**<0.001**
Urge incontinence	**73 (47.7%)**	**17 (11.1%)**	**<0.001**
Stress incontinence	**91 (59.5%)**	**0**	**<0.001**
Fecal incontinence	**5 (3.3%)**	**0**	**0.02**

[a] Data are presented as number (percent). [b] McNemar test was used.