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CLINICAL ARTICLE

Long-term functional outcomes following mesh-augmented posterior vaginal prolapse repair

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ABSTRACT

Objective: To assess long-term patient-centered functional outcomes following posterior vaginal wall repair using mesh implants. *Method:* The present prospective telephone interview study enrolled a cohort of women who had undergone posterior vaginal wall repair with mesh between January 1, 2006 and February 28, 2009, at a single center in Israel. Patients were asked to report long-term outcomes, and demographic, clinical, intraoperative, and postoperative follow-up data were retrieved from patients' medical files. Multivariable logistic regression models were used to asses associations between baseline characteristics and long-term outcomes. *Results:* In total, 102 patients were contacted, with 80 (78.4%) at 61–83 months after surgery agreeing to participate. A recurrence of prolapse symptoms was reported by 14 patients (18%) (12 required a corrective procedure), mesh had been removed from two patients owing to erosion/extrusion, and two others had undergone removal of granulation tissue. Long-term, bothersome symptoms were reported by 13 (16%) patients. Parity and previous hysterectomy were associated with lower odds of long-term adverse outcomes, and the location of the apical (C/D) pelvic organ prolapse quantification point and a change in its position following surgery were associated with increased odds of adverse outcomes. *Conclusion:* The long-term adverse-outcome rate was low for patients who underwent posterior vaginal mesh augmentation. These results highlight the importance of apical support for good long-term functional outcomes.

1. Introduction

Rectocele is the most common manifestation of posterior pelvic floor defects, and is often accompanied by constipation and incomplete rectal emptying [1]. Longstanding constipation and increased abdominal pressure can lead to or worsen posterior wall prolapses. Conversely, if not treated properly, rectocele can worsen intestinal syndromes. Advancing age, menopause, perineal surgery, certain congenital perineal defects, and multiparity are risk factors for rectovaginal septum relaxation, changes in the rectal angle, and rectocele [1].

The cumulative risk for requiring pelvic organ prolapse surgery by 80 years of age is 12.6% and the age-specific annual risk has been shown to progressively increase, reaching 3.8 per 1000 women at 70 years of age [2,3]. In the USA, the prevalence of rectocele in women ranges from 12.9% to 18.6% and the average annual incidence is estimated to be 5.7 cases per 100 patient years [4,5].

The aim of surgical rectocele repair is to relieve symptoms that are relevant to the failing anatomic support of the posterior vaginal compartment. Colorectal surgeons frequently operate through an endoanal approach whereas gynecologists usually perform repairs using a transvaginal approach. There are two main methods of transvaginal rectocele repair: the traditional posterior colporrhaphy, and site-specific repair. Both methods can include a biologic graft or synthetic mesh [6].

It has been suggested that mesh augmentation presents no clear advantage in comparison with standard repair [7]. Moreover, transvaginal mesh repair could be associated with adverse outcomes including erosion/extrusion and infection. Additionally, concerns have been raised regarding potential long-term outcomes such as dyspareunia, chronic pelvic pain, and vaginal distortion, which can even occur in the absence of frank extrusion [8,9]. Vaginal mesh erosion and recurrent rectocele incidence rates of approximately 30% and 22%, respectively, have been reported in the literature [10].

Studies of mesh augmentation have mostly assessed anatomical outcomes using pelvic organ prolapse quantification (POP-Q) scores

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and not quality of life [11,12]. Although surgeons tend to focus on anatomical outcomes when defining surgical success, patients are more concerned with functional outcomes [13]. FDA warnings regarding adverse events following transvaginal mesh implantation have led to a call for increased surveillance and reporting of outcomes [14].

The aim of the present study was to assess the long-term functional outcomes of patients who had undergone mesh-augmented posterior vaginal wall prolapse repair.

2. Methods

The present prospective telephone interview study, performed in January 2015, was designed to assess the long-term functional and adverse outcomes among a cohort of women who had undergone posterior vaginal wall repair with mesh implantation at Assuta Medical Center, Rishon LeZion, Israel. The local institutional review board approved the study and oral informed consent for participation was obtained from participants during telephone interviews.

Patients were eligible for inclusion if they who had undergone posterior vaginal wall mesh augmentation for symptomatic posterior vaginal wall prolapse between January 1, 2006 and February 28, 2009. All potential participants were contacted by telephone and asked to participate in the present study.

Prior to surgery, routine history, and general and gynecological physical examinations were performed for each patient. The vaginal examination performed for site-specific prolapse was consistent with the recommendations of the International Continence Society outlined in the POP-Q system. The indication for the primary surgery was symptomatic posterior wall prolapse. Patients underwent a standardized procedure performed by one surgeon (M.N.) and were clinically assessed 1–3 months after surgery in the outpatient clinic. Follow-up continued thereafter with patients' primary care physicians and patients only returned to the study institution if they requested to.

All patients had 1 g of a first-generation cephalosporin administered intravenously 30 minutes before surgery. Iodine antiseptic wash was applied to the surgical site prior to beginning surgery. The surgical technique has been described in detail previously [11]. Briefly, a 50 mL 0.9% saline hydro-dissection was performed at the mid-line of the posterior vaginal wall. A longitudinal incision was made, including the full thickness of the fibromuscular wall of the vagina. A sub-fascial lateral dissection towards the pelvic side wall followed, continuing to the iliac spine and then to the mid-portion of the sacrospinous ligament. The needle guide and the mesh arm used this point thereafter. The other pair of arms was directed through the para-rectal fossa for reconstruction of the posterior compartment. Following this, a partially absorbable mesh implant (Gynecare Prolift; Ethicon, Summerville, USA) was placed and flattened, and the vaginal wall was re-sutured using one layer of running absorbable sutures; the vagina was closed without any resection of vaginal tissue. Additional procedures were only performed if indicated.

Patients who agreed to participate in telephone interviews were asked to provide details of any long-term adverse outcomes, mesh-related complications, and pelvic floor symptoms. Additionally, demographic, clinical, intraoperative, and postoperative follow-up data were retrieved from patients' medical records. The primary outcome was a composite measure of recurrent prolapse (any compartment), stress urinary incontinence (SUI), overactive bladder syndrome (defined as urgency with or without incontinence, usually with frequency, nocturia and dyspareunia), and defecatory dysfunction. The secondary outcome measure was any recurrent surgeries performed.

All statistical analyses were performed using SPSS version 22.0 (IBM, Armonk, NY, USA). Continuous variable data with normal distributions were expressed as mean ± SD; comparisons between groups were made using the Student *t* test. Continuous variables not normally distributed and ordinal variables were presented as medians with inter-quartile ranges and statistical analyses were performed using the Mann–Whitney *U* test. Categorical data were presented as absolute numbers and percentages, and differences were analyzed using the χ^2 and Fisher exact tests, as appropriate. A multivariable logistic regression model was used to evaluate associations between baseline characteristics and long-term symptoms. Variable selection during multivariable modeling was based on clinical and statistical significance. Final parsimonious models were reported. A second multivariate model was constructed to predict repeat operations. A two-sided $P < 0.05$ was considered statistically significant.

3. Results

Of the 102 eligible patients identified from the study institution records, 80 (78%) consented to participate in telephone interviews. Baseline demographic and clinical characteristics of participants in the present study are detailed in Table 1. Almost half the participants had previously undergone a hysterectomy and 36 (45%) had undergone surgery for either a previous pelvic organ prolapse or SUI. POP-Q stage III rectocele was recorded for 76 (95%) patients.

Intraoperative data from posterior vaginal mesh augmentation surgeries are presented in Table 2; all but four procedures were performed under general anesthesia, with the remaining participants receiving regional anesthesia. All patients underwent concurrent procedures; however, only two underwent a concomitant hysterectomy. Treatment with tension-free vaginal tape for SUI was recorded for 37 (46%) patients. Only two patients experienced immediate postoperative complications, which were considered mild (de novo fecal urgency).

Baseline and intraoperative characteristics were also compared between patients who participated in the present study and those who had undergone posterior vaginal mesh augmentation surgery

Table 1
Preoperative patient characteristics (n = 80).[a]

Variable	Value
Age, y	61.53 ± 11.41
Parity	3 (2–3)
Previous hysterectomy	39 (49)
Previous pelvic organ prolapse surgery	24 (30)
Previous SUI surgery	12 (15)
Major health problems	27 (34)
Hypertension	16 (20)
Diabetes mellitus	5 (6)
Rheumatic disease	2 (3)
Malignancy	2 (3)
Hypothyroidism	4 (5)
Asthma	3 (4)
Coronary heart disease	3 (4)
Depression	16 (20)
Other	5 (63)
POP-Q Ba domain	1.50 ± 1.86
Stage	
I	9 (11)
II	22 (28)
III	47 (59)
IV	0
POP-Q C/D domain	4.04 ± 3.03
Stage	
I	2 (3)
II	13 (16)
III	63 (79)
IV	0
POP-Q Bp domain	4.32 ± 1.81
Stage	
I	1 (1)
II	1 (1)
III	76 (95)
IV	0

Abbreviations: SUI, stress urinary incontinence; POP-Q, Pelvic organ prolapse quantification.
[a] Values are given as mean ± SD, median (range), or number (percentage).

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