Original Paper

Urologia Internationalis

Urol Int
DOI: 10.1159/000489636

Received: March 5, 2018
Accepted after revision: April 25, 2018
Published online: June 6, 2018

Pelvic Organ Prolapse Repair with Mesh: Mid-Term Efficacy and Complications

Laura Mateu Arrom[a] Carlos Errando Smet[a] Cristina Gutierrez Ruiz[a]
Pedro Araño[a] Joan Palou Redorta[b]

[a]Department of Female and Functional Urology, Fundació Puigvert, Barcelona, Spain; [b]Chairman, Department of Urology, Fundació Puigvert, Barcelona, Spain

Keywords
Pelvic organ prolapse · Pelvic floor dysfunction female · Complication · Prolapse recurrence · Mesh exposure

Abstract
Introduction: Our aim was to assess the efficacy and complications of pelvic organ prolapse (POP) correction with transvaginal mesh (TVM). ***Materials and Methods:*** We retrospectively assessed patients who had undergone a repair of an apical (primary or recurrent) or recurrent POP using TVM in our department since 2007. Meshes used were Prolift®, Elevate®, and Surelift®. Satisfaction with surgery was assessed on a 0–10 scale. ***Results:*** A total of 83 patients were included (33 Prolift®, 36 Elevate®, 14 Surelift®), with a mean age of 67.8 ± 9.7 years. Eighteen (21.6%) patients underwent a recurrent POP correction. Follow-up was 49 ± 34 months. Twelve (14.4%) symptomatic recurrences were identified, 3 of which required further surgery. Satisfaction was 8.7. Four (4.8%) vaginal exposures were detected, 2 of which required partial mesh removal. Three (3.6%) cases of dyspareunia and 1 (1.2%) case of mild pelvic pain were reported, which did not require further treatment. ***Conclusion:*** The use of TVM for apical or recurrent POP repair is effective and is associated with a high satisfaction rate while complications are infrequent.

Introduction

Pelvic organ prolapse (POP) is a major health issue in women affecting an estimated 1 in 9 women [1]. As surgical repair using native tissue is associated with a long-term failure rate of up to 20% [1], the concept of incorporating a synthetic material was adopted and the use of transvaginal mesh (TVM) spread [2]. A wide variety of mesh kits became available and initial studies showed high success rates with few complications [3].

E-Mail karger@karger.com
www.karger.com/uin

Laura Mateu Arrom
Department of Female and Functional Urology
Fundació Puigvert
C/Cartagena 340-350, ES–08025 Barcelona (Spain)
E-Mail lmateuarrom@hotmail.com

However, the rise in mesh placement was accompanied by increased reports of mesh-related complications [4], which prompted a Food and Drug Administration advisory panel investigation into the use of mesh in pelvic surgery [5]. A recent consensus statement of the European Urology Association and the European Urogynaecological Association on the use of implanted materials for treating POP and stress urinary incontinence (SUI) states that the use of TVM should be restricted to complex cases, such as when other surgical procedures have already failed, and it should be used only after extended patient counseling and only by expert surgeons in specialized departments [1].

In our department, TVM for POP correction has been used since 2004 which has led to a consolidated surgical technique allowing that, to date, it represents a common indication for these patients. Given the rise in litigation surrounding TVM use and the Food and Drug Administration advisory panel's conclusions, our aim was to review our results regarding the efficacy and complications of TVM for POP repair.

Materials and Methods

We retrospectively assessed the clinical records of patients who had undergone a repair of a POP using TVM in our department since 2007. Data collection was performed in ongoing, prospective fashion. Data collection and database use were approved by our institutional ethical review board.

The baseline evaluation included complete history, physical examination, and urodynamics, which were performed in accordance with the International Continence Society recommendations [6]. The degree of POP was quantified by using the Baden and Walker [7] system. TVM was offered to patients with symptomatic apical (primary or recurrent) or recurrent anterior or posterior POP stage ≥2. Patients with primary anterior or posterior POP were excluded from the study, as they are candidates for native tissue repair. Symptomatic POP was defined as any complaint relating to a bothersome vaginal bulge or other prolapse-related symptoms [8], confirmed by physical examination. The mesh kits used were Prolift® (Ethicon, Somerville, MA, USA) [9], Elevate® (American Medical System, Minnetonka, MN, USA) [10], and Surelift® (Neomedic International, Terrassa, Spain) [11], all of which are made of polypropylene and are classified as type 1 according to the Amid classification [12]. Surgical procedures were performed in accordance with previously reported techniques [9–11]. The mesh used in every case of this study was determined by commercial availability at the time of surgery. From 2007 to 2010, we used the Prolift® system. In 2010, the Elevate® was introduced while Prolift® was retired from the market. Elevate® remained in use until 2014, when it was withdrawn. Since then, the mesh kit used in our center has been the Surelift®.

Concurrent transobturator tape (TOT) placement was offered to patients with clinical or occult SUI assessed by urodynamics with a pessary in place, after discussing the related risks and benefits with the patient. No hysterectomies were performed at the time of mesh placement. Complications were classified according to the Clavien-Dindo classification [13].

Follow-up evaluation was carried out at 6 weeks and, in the absence of complications, at 6–9 months and annually thereafter. Outcomes were assessed by reviewing the clinical chart and by physical examination. POP recurrence was classified as asymptomatic anatomic (POP detected only by physical examination without the presence of prolapse-related symptoms [8]) or as symptomatic when patients cited the presence of prolapse-related symptoms [8]. Patients completed a 10-point satisfaction questionnaire (scale 0–10) in response to the question "How satisfied are you with the outcome of your treatment?". Urodynamic tests were repeated in patients who presented with urinary incontinence or symptoms suggesting voiding dysfunction after surgery. Obstruction was considered present when the maximum flow rate was under 15 mL/s and the detrusor pressure at the maximum flow rate was above 20 cm H_2O [14].

Statistical analysis was performed using SPSS® version 20.0. Results of qualitative variables are expressed as percentages and results of quantitative variables as mean and standard deviation. Comparison between different meshes was performed using the chi-square test for qualitative variables and the Kruskal-Wallis test for quantitative variables. p values <0.05 were considered statistically significant.

Results

A total of 83 women underwent POP repair with TVM. Their demographic characteristics are summarized in Table 1 and operative outcomes in Table 2. Mean follow-up was 49 months (±34); 59 (71.1%) patients had a follow-up >24 months while 3 had a follow-up <6 months for medical reasons unrelated to the surgery. Twenty four (28.9%) recurrences were identified after 19 (±18) months: 12 (14.4%) recurrences were asymptomatic while 12 were symptomatic, with 3 (3.6%) requiring further surgery (laparoscopic colposacropexy in 1 case and hysterectomy in 2 cases). At the time of follow-up, the satisfaction rating was 8.7/10. No differences between mesh kits were observed in terms of recurrence, need of further POP surgery, or satisfaction.

Eight (9.6%) patients presented complications related to the mesh, with no significant differences between the different mesh kits. Four patients (4.8%) presented vaginal exposure after 6.4 (±6) months; in 2 cases it was asymptomatic and 2 caused vaginal discharge and required partial mesh removal, performed under local anesthesia as an outpatient procedure. Three (3.6%) cases of dyspareunia were detected, none of which prevented sexual in-

Table 1. Patient demographics and characteristics

	Total	Prolift®	Elevate®	Surelift®	*p* value
Total, *n*	83	33	36	14	
Age, years	67.8±9.7	67.3±8.4	67.9±11.5	68.2±8	0.70
Body mass index, kg/m^2	27.2±4	26.9±3.3	27.8±4.7	26±3.3	0.57
Smoking	10 (12)	7 (21.2)	3 (8.3)	0 (0)	0.09
Vaginal deliveries	2.3±1.2	2.4±1	2.1±1.3	2.8±1.1	0.21
Postmenopausal	74 (89.1)	28 (84.5)	33 (91.7)	13 (92.8)	0.54
Chronic constipation	4 (4.8)	0 (0)	2 (5.5)	2 (14.3)	0.11
Chronic cough	7 (8.4)	5 (15.2)	2 (5.5)	0 (0)	0.16
Prior hysterectomy	21 (25.3)	10 (30.3)	8 (22.2)	3 (21.4)	0.69
Prior POP repair	18 (21.6)	7 (21.2)	8 (22.2)	3 (21.4)	0.99
Anterior POP	76 (91.5)	30 (90.9)	32 (88.9)	14 (100)	0.44
Anterior POP grade	3.2±1	3.3±1.2	2.8±0.9	2.8±0.5	0.79
Apical POP	82 (98.8)	33 (100)	35 (97.2)	14 (100)	0.52
Apical POP grade	3.2±0.8	30.7	3.2±0.9	2.8±1.1	0.39
Posterior POP	40 (48.2)	19 (57.7)	15 (41.6)	6 (42.6)	0.38
Posterior POP grade	2.2±1.1	2.1±1.2	1.8±1	1.6±0.9	0.17
Urinary urgency	4 (4.9)	2 (6.1)	2 (5.7)	0 (0)	0.07
Urge incontinence	20 (24.1)	12 (36.3)	4 (11.1)	4 (28.6)	0.05
Stress incontinence	21 (25.3)	9 (24.3)	10 (27.8)	2 (14.3)	0.56
Number of pads required	0.7±1.3	0.8±1.7	0.6±1	0.4±0.8	0.64
Detrusor over-activity	21 (25.3)	10 (30.3)	5 (13.8)	5 (35.7)	0.12
Occult stress incontinence	4 (4.8)	1 (3)	2 (5.5)	1 (7.1)	0.74

Continuous variables are expressed with mean ± SD and qualitative variables with *n* (%).
POP, pelvic organ prolapse.

Table 2. Operative outcomes

	Total	Prolift®	Elevate®	Surelift®	*p* value
Total	83	33	36	14	
Concurrent mid-urethral sling	17 (20.5)	7 (21.2)	8 (22.2)	2 (14.3)	0.82
Intraoperative complications	2 (2.4)	1 (3)	1 (2.7)	0 (0)	0.81
Clavien 1					
Bladder injury	2 (2.4)	1 (3)	1 (2.7)	0 (0)	
Operative time, min	139±34	151±35	135±38	153±20	0.05
Blood loss, mL	240±157	316±116	200±50	100±173	0.21
Spinal/general anesthesia	55 (66.3)/28 (33.7)	18 (54.5)/15 (45.5)	28 (77.7)/8 (22.2)	9 (64.3)/5 (35.7)	0.12
Length of stay, days	5.1±2.4	5.1±1.3	4.8±1.7	5.8±4.7	0.21
Postoperative complications	6 (7.2)	2 (6)	3 (8.3)	1 (7.1)	0.94
Clavien 2					
Phlebitis	1 (1.2)	1 (3)	0 (0)	0 (0)	
Urinary tract infection	1 (1.2)	0 (0)	0 (0)	1 (7.1)	
Pelvic hematoma (conservative management)	1 (1.2)	1 (3)	0 (0)	0 (0)	
Clavien 3a					
Non obstructive voiding dysfunction (temporary catheterization)	2 (2.4)	0 (0)	2 (5.5)	0 (0)	
Clavien 3b					
Pelvic hematoma (internal pudendalartery embolization)	1 (1.2)	0 (0)	1 (2.7)	0 (0)	

Continuous variables are expressed with mean ± SD and qualitative variables with *n* (%).

tercourse or required further treatment. One (1.2%) patient reported non-specific pelvic discomfort that did not limit daily life activities and required sporadic analgesic oral treatment.

Twenty-two (26.5%) patients reported SUI during follow-up, which was de novo in 14 (16.8%) cases. Five anti-incontinence procedures were required during follow-up. Four patients with de novo SUI required the placement of TOT, 3 of them during the first year of follow-up and 1 after 10 years. One patient with persistent SUI after TVM required a TOT at 1 year of follow-up. Other cases of SUI were mild and did not require further treatment.

Among 4 patients who presented urgency before surgery, the urgency persisted in 2 patients and became asymptomatic in 2. One case of de novo urgency was reported. Of 20 patients with urge urinary incontinence before surgery, 9 reported persistence of urge incontinence, 3 reported urgency without urge urinary incontinence, and 8 became asymptomatic. No cases of de novo urge urinary incontinence were detected. All patients with urgency or urge urinary incontinence after TVM who sought for treatment were managed with anticholinergics and none of them required further treatment.

Discussion

Several surgical techniques exist to treat apical prolapse, either vaginal or abdominal and with or without mesh placement. However, there are no guidelines on which technique is best [15]. In the largest randomized controlled study of the use of implanted materials for POP surgery, the authors concluded that the use of mesh is not associated with anatomic or clinical benefit while 14% of patients will present mesh exposure 2 years after TVM placement. [16] However, only women with primary anterior or posterior prolapse were included in this study, so the results are not generalizable to patients with apical or recurrent prolapse as patients included in our study. Although the results of several randomized controlled trials in patients with apical prolapse have shown greater benefits in terms of anatomic cure rate and prolapse-related quality of life in the mesh group [17], other authors have reported no differences regarding anatomic or symptomatic recurrences [18]. According to the latest Cochrane review [15], there is little or no difference between surgery with or without mesh in terms of awareness of prolapse and the need for repeat surgery for POP. However, the quality of studies included in the review was not optimal. Thus, the quality of the evidence is still low [15].

In our series, after a mean follow-up of 4 years, 28% of patients presented with anatomic recurrence. This rate is higher than that reported by other authors with a follow-up of 1 year, which ranged from 7.4 to 16.9% [17, 19]. However, half of the recurrences observed in our study were asymptomatic and only 3.6% of patients required further POP surgery, a rate closer to that reported by those authors [17, 19]. In fact, the self-reported satisfaction rate in our series was excellent: only 3 patients were unsatisfied (satisfaction <5) with surgery. Although the majority of per-operative complications observed in our study could be managed conservatively, we acknowledge that serious complications such as bleeding requiring arterial embolization can occur. Thus, in our opinion, prolapse repair with TVM should be performed in centers where these complications can be successfully managed.

The most frequently reported mesh-related complication is vaginal mesh exposure, with reported rates as high as 20% [17, 19]. However, in most cases, vaginal mesh exposures can be addressed largely through minimally invasive procedures [19–21]. In our series, only 4 (4.8%) mesh exposures were detected, one of them in a patient with previous history of TVM placement due to a vaginal vault POP. Moreover, only 2 exposures were symptomatic and were solved uneventfully after vaginal partial mesh removal under local anesthesia. We note that all such cases were diagnosed in the Prolift® group, possibly owing to the larger size of the mesh [22].

Regarding dyspareunia, the Cochrane review showed that there is little or no difference between vaginal surgery with or without mesh, which could be related to the vaginal approach, with rates of 4–5% [15]. In our series, a slightly lower dyspareunia rate was detected and it did not prevent sexual intercourse in any of the patients. Pain after vaginal mesh placement has also been reported in 3–10% of cases, and it can be serious and difficult to treat [22]. In this study, a lower rate of pelvic pain was detected, which was mild and did not restrict daily life activities. The limited number of cases with dyspareunia, pelvic pain, voiding dysfunction, and de novo urgency in our series could be due to our efforts to leave the mesh in place in a tension-free fashion.

Our study has some limitations. We acknowledge the limited number of patients included in this study and its retrospective nature. We did not analyze separately patients with recurrent prolapse and patients with primary prolapse, mainly due to the low number of patients with recurrent prolapse in each mesh group. The Baden-Walk-

er grading system was used because at the time of starting the study, POP-Q was not fully implemented in our department. In order to avoid using different assessment methods and to ensure the homogeneity of the population, we persisted with the Baden-Walker system records. Similarly, validated questionnaires to assess prolapse or other sexual or urinary symptoms were not in use in our department when the first TVM placements were performed; thus its results could not be included in the study. However, the satisfaction rating scale from 0 to 10 can be considered a reliable patient-related outcome, taking into account that objective anatomic evaluation of POP shows a poor correlation with patients' complaints [23].

According to our results, the use of TVM for POP repair is effective and is accompanied by a high satisfaction rate. Our results suggest that even though per-operative and mid-term complications may occur, they can largely be successfully managed in an outpatient setting. Thus we consider that, in experienced and specialized departments, these procedures are safe and can be considered for apical or recurrent POP repairs.

Disclosure Statement

None.

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