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Full length article

Two years follow up of 270 patients treated by transvaginal mesh for anterior and/or apical prolapse

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ABSTARCT

Objective: The aim of this study was to assess the 1 and 2 years outcomes of transvaginal single incision mesh surgery (SIMS) for anterior pelvic organ prolapse (POP).
Material and methods: This was a prospective study including all patients from November 2008 to December 2012 who underwent SIMS for symptomatic anterior prolapse stage ≥2, according to the POP Quantification (POP-Q). Symptoms and quality of life were assessed using validated questionnaires: Pelvic Floor Distress Inventory (PFDI-20), Pelvic Floor Impact questionnaire (PFIQ-7), and Prolapse/Incontinence Sexual Questionnaire (PISQ-12). The main outcome was subjective success (question 3 of PFDI-20 score = 0). Safety, anatomic and functional outcomes were used as the secondary outcomes.
Results: A total of 270 patients were included in the study. Subjective success rate was 95,4% and 92,2% at 1 and 2 years. Objective success rate was 65,9%and 60,5% at 1 and 2 years. At 1 year, composite failure (subjective + objective) occurred for 11 patients (4,6%), 5 patients with direct recurrence and 6 with indirect recurrence. At 2 years, composite failure was reported for 14 patients (6,4%): 6 direct recurrences and 8 indirect recurrences. Re-treatment was performed in one case (0,4%). One case (0,4%) of asymptomatic mesh exposure occurred. The reoperation rate for mesh-related complications was 3%. We reported a de novo dyspareunia rate of 8,4%, 5,3% considered as mesh-related. A significant improvement was noted for symptoms and quality of life.
Conclusion: POP repair using SIMS is a safe and efficient treatment of anterior compartment prolapse in the medium term with a low rate of mesh-related complications. Longer-term follow-up is ongoing.

Introduction

Population-based epidemiologic studies report that 12,6% of women will undergo POP surgery by the age of 80 years [1,2].

Transvaginal surgery using native tissue have significant failure rate and mesh reinforcement was proposed to reduce this risk [3].

However, transvaginal mesh repair evolved as a topic of controversy regarding its morbidity leading to surgical revisions or debilitating sequelae [4]. This concern led to a United States Food and Drug Administration (FDA) public health notification in 2011 and classification of meshes to a class III product in 2015 leading to a decrease in mesh use [5,6].

Incidences of adverse events after mesh surgery vary dramatically between studies especially for vaginal exposure rate, from 0 to 29,7% with an overall rate of 10,3% [7]. It can be difficult to compare mesh-related complications because of heterogeneity of mesh materials and placements. However, considerable variability persists between studies using the same mesh kit [8–11]. These data support the hypothesis that mesh-related complications rate can be lower with an appropriate surgical technique.

We report in this study our experience of a transvaginal single incision mesh surgery using the Elevate Anterior&Apical® (EAA) kit (Astora) with at least 2 years follow-up.

Materials and methods

Study design and setting

This was a prospective, unicentric cohort study including all patients from November 2008 to December 2012 who underwent POP surgery using transvaginal SIMS for symptomatic anterior

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Table 1
Baseline characteristics.

Demographic data				Surgery procedure		
Age		65,8	±9,6	Time in surgery (min)	57,6	±23,2
Body Mass Index		24,9	±4	Hospital stays (days)	3	±1,3
Parity		2,4	(0–10)	Colpectomy (5–20 mm)	109	40,4%
Diabetes		23	8,5%	**Concurrent surgeries**		%
Current smokers		18	6,7%	**Posterior procedure**	**177**	**65,6**
Constipation		59	22%	Autologous procedure	124	46
Surgical history			%	Posterior fascia plication (PFP)	89	33
Continence surgery		23	8,5	Perineorrhaphy	26	9,6
Prolapse repair		31	11,5	PFP + perineorrhaphy	9	3,4
Hysterectomy		34	12,6	Elevate® Apical&Posterior	53	19,6
Preoperative anterior prolapse stage			%			
		13	4,8	**Sub-urethral sling**	**48**	**17,8**
	Stage 3	225	83,3			
	Stage 4	32	11,9	**Hysterectomy**	**59**	**21,8**

± standard deviation, () range.

prolapse. Procedures were performed by 2 experienced pelvic floor surgeons in transvaginal mesh surgery by transobturator route.

Surgical indication was symptomatic anterior prolapse stage 2 or more according to the POP quantification system (POP-Q) [8], isolated or associated with apical/posterior compartment prolapse. The first 21 patients were excluded, considered as the learning curve evaluated by LC-CUSUM charts for complications [13].

Preoperative evaluation

Pre-operative evaluation recorded patients' characteristics, prior surgical history and clinical examination using the POP-Q system. Patients were subjected to multichannel urodynamics, urinalyses, pelvic sonography and cervical smear before surgery.

Patients completed French version of Pelvic Floor Distress Inventory (PFDI-20), Pelvic Floor Impact Questionnaire (PFIQ-7) [14,15] and Prolapse/Incontinence Sexual Questionnaire if the patient was sexually active (PISQ-12) [16,17].

Surgical procedure

All patients provided informed consent for surgery. Women were operated with EAA®, as previously described by Moore. [10]. This mesh kit has been withdrawn from the market by the manufacturer and the results cannot be generalized for other devices.

Foley catheter and vaginal gauze pack were removed after 24 h. Patients used vaginal oestrogens, and avoid heavy lifting, sport or intercourse during 6 weeks.

A concomitant posterior procedure was performed, at surgeon convenience. Hysterectomy was performed in case of uterine pathology or cervical elongation. Vaginal incision was Crossen T-shape incision or dissection by single horizontal incision without vaginal trimming. A sub-urethral sling was implanted in case of overt SUI with normal uroflowmetry.

Postoperative evaluation

Post-operative follow-up was scheduled at 6 weeks, 6 months, 1 and 2 years. During follow-up visits, the surgeon who performed the procedure assessed POP-Q staging and mesh complication by vaginal examination. Patients complete PFDI-20, PFIQ-7 and PISQ-12 and additional satisfaction (5-point scale) and improvement (4-point scale) questionnaires.

Reported measures

Outcomes were assessed at 1 and 2 years postoperatively. The primary endpoint was subjective success, defined as the absence of vaginal bulge: negative response to the question 3 of PFDI-20 [18].

Secondary end points were anatomic outcomes, peri- and postoperative complications, reoperations and functional outcomes. Objective success was defined as overall (anterior, apical and posterior) POP-Q stages <2. Recurrence was classified as direct recurrence (anterior and/or apical compartment), or indirect recurrence (posterior compartment only). Reoperations over the 2-year follow-up period were distinguished as procedure-related, mesh-related (mesh, arms or anchors) or re-treatment (recurrent POP).

Subjective outcomes, assessed by specific PFDI-20 questions, were classified as de novo, persistent or cured. De novo symptoms were defined as a postoperative score of 2 or greater, given a baseline score ≤ 1 (no or no bothersome). When symptoms were pre-existing (score ≥ 2), they were considered cured when score was ≤ 1 postoperatively or persistent when ≥ 2. Dyspareunia was defined as a score ≤ 1 to the question 5 of the PISQ-12. De novo dyspareunia was defined as dyspareunia occuring after surgery in non dyspareunic patient. Mesh related dyspareunia was defined as dyspareunia+ provoked pain on mesh or arm area.

Composite failure was defined as subjective+ objective failure for the same patient.

Ethics and statistical methods

Ethic approval was obtained from the CCTIRS (n°14.487) and the Clinical Research Committee of our institution. For the analysis, we used the version 9.2 of SAS (Statistical Analysis Software). For each outcomes, the number of patient available for evaluation excluded the lost of follow-up and missing data. Qualitative variables were expressed as counts and percentages, as quantitative variables were expressed as means and standard deviations (SD), or range when mentioned. The Fisher's exact test was used for comparison of qualitative variables. The nonparametric Wilcoxon test on paired sample was used for comparison of preoperative and postoperative quantitative data. Differences were considered statistically significant when $p < 0,05$.

Results

270 patients were included from November 2008 to December 2012 in our institution. At 2 years, thirty-four patients (12,6%) were