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ELEVATE ANTERIOR AND APICAL PELVIC ORGAN PROLAPSE REPAIR IS EFFECTIVE WHEN PERFORMED WITH UTERINE PRESERVATION: TWO-YEAR RESULTS

Hypothesis / aims of study

To evaluate efficacy of the Elevate® Anterior and Apical (EAA) with IntePro® Lite™ (American Medical Systems, Minnesota, USA) in the repair of pelvic organ prolapse (POP) when performed with or without uterine preservation.

Study design, materials and methods

One hundred forty-two women (age 63.9 ±9.8 years) with anterior vaginal prolapse and/or apical descent ≥ Stage II were enrolled at 16 investigational sites (10 US, 6 EU). All received transvaginal polypropylene mesh insertion with no external needle passes anchored bilaterally to the sacrospinous ligaments and obturator foramens.

The primary outcome was treatment failure defined as ≥ Stage II POP-Q during follow-up using the Last observed Failure Carried Forward (LFCF) method. The LFCF method carries forward a patient's objective failure at previous visits if their 24-month results were missing. It also considers subjects to be failures if they were re-operated for recurrent prolapse in the anterior or apical segments within 24 months from the initial implant regardless of their POP-Q test results.

Three sub-groups were analyzed: baseline prior hysterectomy (N=61); concomitant hysterectomy (N=29), and preserved uterus/no hysterectomy (N=51). One subject had a partial hysterectomy at baseline and was excluded from the analysis. Demographics, primary outcome and extrusion were compared between the groups. Kruskal-Wallis and Fisher Exact Test were used to compare differences between groups. A P value < 0.05 was considered statistically significant.

Results

The primary outcome of anatomic success for apical and anterior compartments shows significant and durable improvement at 24-months. The success for the apical compartment ranged between 93.8 – 100%. Success was slightly lower for the anterior compartment (70.8 – 89.1%). With respect to anatomic success for these two compartments, there was no statistically significant difference between the groups (Table 1). None of the patient's characteristics listed in Table 1 were found to be different between the three groups except for age. In addition, there was no difference in overall intra-operative complications (p=0.263). Mesh extrusion was found in all groups: 3/61 (4.9%) prior hysterectomy; 4/29 (13.8%) concomitant hysterectomy; and 1/51 (2.0%) uterus preserved (p=0.094). There appears to be a trend toward higher extrusion when a hysterectomy was performed with the EAA.

Interpretation of results

Anatomic success for anterior and apical prolapse and complications for the EAA do not appear to be significantly impacted when the uterus is removed or preserved during prolapse repair.

Concluding message

The results of this analysis show similar efficacy in patients with a prior hysterectomy, concomitant hysterectomy, or uterine preservation with the EAA procedure. There may be a trend toward increased mesh extrusion when a hysterectomy is performed. However, larger cohort studies are needed to determine if concomitant hysterectomy impact vaginal mesh extrusion.

Table 1	**Hysterectomy Group**			
	Baseline Hysterectomy (N=61)	**Concomitant Hysterectomy (N=29)**	**No Hysterectomy (N=51)**	**P Value**
Age				*<.001* [K]
Median (min - max)	69.4 (45.4 - 85.7)	60.3 (39.0 - 72.4)	62.8 (39.7 - 83.5)	
BMI group				*0.177* [F †]
Underweight (< 18.5) (%)	0 (0.0%)	1 (3.4%)	0 (0.0%)	
Normal (18.5 - 24.9)	23 (37.7%)	8 (27.6%)	20 (39.2%)	
Overweight (25.0 - 29.9)	23 (37.7%)	10 (34.5%)	24 (47.1%)	
Obese (>= 30)	15 (24.6%)	10 (34.5%)	7 (13.7%)	
Gravidity				*0.324* [K]
Median (min - max)	3 (0 - 10)	3 (1 - 6)	3 (0 - 15)	
Parity				*0.956* [K]
Median (min - max)	2 (0 - 6)	2 (1 - 6)	2 (0 - 11)	
History of Smoking				*0.147* [F †]

Table 1	Hysterectomy Group			
	Baseline Hysterectomy (N=61)	**Concomitant Hysterectomy (N=29)**	**No Hysterectomy (N=51)**	**P Value**
Non Smoker	43 (70.5%)	22 (75.9%)	34 (66.7%)	
Previous smoker	17 (27.9%)	4 (13.8%)	16 (31.4%)	
Current smoker	1 (1.6%)	3 (10.3%)	1 (2.0%)	
History of Diabetes				*0.914* [F †]
No Diabetes	56 (91.8%)	27 (93.1%)	48 (94.1%)	
Non-Insulin Dependent	5 (8.2%)	2 (6.9%)	3 (5.9%)	
Intra-Op Complication?				*0.263* [F †]
Yes (%)	3 (4.9%)	3 (10.3%)	7 (13.7%)	
No (%)	58 (95.1%)	26 (89.7%)	44 (86.3%)	
Extrusion				*0.094* [F †]
No (%)	58 (95.1%)	25 (86.2%)	50 (98.0%)	
Yes (%)	3 (4.9%)	4 (13.8%)	1 (2.0%)	
24M Apical Success				*0.621* [F †]
Success (%)	30 (93.8%)	21 (95.5%)	24 (100.0%)	
Fail (%)	2 (6.3%)	1 (4.5%)	0 (0.0%)	
Missing	29	7	27	
24M Anterior Success				*0.154* [F †]
Success (%)	43 (79.6%)	17 (70.8%)	41 (89.1%)	
Fail (%)	11 (20.4%)	7 (29.2%)	5 (10.9%)	
Missing	7	5	5	

[T]Exact test
[K]Kruskal-Wallis; [F]Fisher Exact test;

Disclosures
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2.Western Institutional Review Board
3.Northside Hospital IRB
4.Ethik Kommission Bayerischen Landesärztekammer
5.Medisch Ethische Commissie Academisch Medisch Centrum Universiteit van Amsterdam
6.Consorci Santari Integral
7.Leuven University Hospital
8.Allina Institutional Review Board Administrative Office **Helsinki:** Yes **Informed Consent:** Yes