

## ELEVATE ANTERIOR AND APICAL AND ELEVATE APICAL AND POSTERIOR: SAFETY AND EFFICACY IN SURGICAL TREATMENT OF PELVIC ORGAN PROLAPSE.

### Hypothesis / aims of study

To assess the safety and efficacy of the Elevate® Anterior and Apical and Elevate® Apical and Posterior with IntePro® Lite™ support system (American Medical Systems, Minnesota, USA) in the repair of pelvic organ prolapse (POP). Here we present 8-months post procedure data.

### Study design, materials and methods

From October 2008 to February 2011, 23 women have been treated for pelvic organ prolapse using Elevate device:

- 6 Elevate® Anterior and Apical.
- 2 Elevate® Anterior and Apical and Miniarc™.
- 1 Elevate® Anterior and Apical and Apogee™.
- 1 Elevate® Anterior and Apical, Apogee™ and Miniarc™.
- 6 Elevate® Apical and Posterior.
- 1 Elevate® Apical and Posterior, Perigee™ and Miniarc™.
- 6 Elevate® Apical and Posterior and Perigee™.

We have evaluate the age, parity, presence of urgency, stress incontinence (SUI), prolapse degree, surgical time, stage time, early complication and late ones.

23 women were enrolled at the study, all of them completed 6-months follow-up. The primary outcome was treatment failure defined as > Stage II Baden-Walken anytime during follow-up. And it also considers subjects to be failures if they were re-operated for recurrent prolapse in the anterior or apical or posterior segments within 12 months from the initial implant, regardless of their 6 month and 12 month test results. Secondary outcomes were quality of life (QOL) measures using visual analogical scale (VAS). Statistical significance was assessed at P < 0.05.

### Results

Patient characteristics were: age 63.34yrs; parity 3.8; menopausal 21 (91.3%); prior hysterectomy 4 (17.39%), surgical time 66.52, stage time 6.39, follow up 7.2 months (6-18).

At baseline Stage:

- Cystocele: III: 16 (69.56%); II: 1 (4.34%); I: 3 (13.04%); 0: 2 (8.69%).
- Apical Prolapse: III: 14 (60.86%); II: 2 (8.69%); I: 2 (8.69%); 0: 3 (13.04%)
- Rectocele: III: 9 (39.13%); II: 4 (17.39%); I: 0; 0: 7 (30.43%)
- Urinary stress incontinence: 7 (30.43%)
- Urgency: 4 (17.39%)

Preoperatively 9 women had vaginal pessary during 7.88 months.

Early complications were: 3 urinary retention (13.04%) and 1 urinary tract infection (4.34%)

The anatomic success rate for the anterior compartment was 10/10 (100%) and for the apical and posterior compartment 9/13 (69%) and the VAS was 7.17 at 6 month follow up.

Of the 13 subjects who presented anatomic failure (13 posterior and 13 apical) only two complained of bulge symptoms and one subject need an Elevate anterior device and another woman has vaginal pessary since recurrence of apical prolapse.

Related adverse events reported at 6 and 12 months were mesh extrusion (1; 4.34%), urinary tract infection (1; 4.34%), transient buttock pain (1; 4.34%), de novo urinary stress incontinence (2; 8.64%); urgency recurrent (2, 8.64%).

### Concluding message

The Elevate Anterior and Apical and Posterior support procedure completed through a single vaginal incision and no external needle passes is effective treatment both anterior and apical prolapse or Apical and Posterior prolapse concomitantly with few complications. And we need more prospective studies to corroborate our results.

### Disclosures

**Funding:** We don't have any specify source of funding or grant. **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Ethics Committe of University Río Hortega Hospital of Valladolid, Spain **Helsinki:** Yes **Informed Consent:** Yes