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MANAGEMENT OF HIGH GRADE POSTERIOR VAGINAL WALL PROLAPSE ASSOCIATED WITH STRAINING TO DEFECATE USING A SINGLE INCISION POSTERIOR VAGINAL MESH KIT (ELEVATE®): A ONE YEAR FOLLOW-UP STUDY

Hypothesis / aims of study

Prosthetic procedures using vaginal mesh kits have been proved to be effective in the repair of vaginal wall prolapse (1). Nevertheless, these techniques need transobturator and transgluteal passage of needles that may cause vessel and organ injuries, that may be serious. In order to overcome these complications, a single incision technique for the treatment of posterior vaginal wall prolapse has been recently marketed. This procedure (Posterior Elevate®) uses a single incision of the posterior vaginal wall to transfix the sacro-spinous ligament with self-fixating tips without transgluteal passages, thus reducing possible lesion to vascular structure and to the ano-rectum. Aim of this study was to evaluate the effectiveness and safety of Posterior Elevate in the treatment of high grade rectocele associated with difficulties in defecation.

Study design, materials and methods

In this prospective study, we enrolled 22 patients affected by posterior vaginal wall prolapse and straining to defecate. Inclusion criteria were: high grade posterior vaginal wall prolapse (3-4 stage; AP=/>3; BP=/>3) as diagnosed by PoP-Q staging and x-ray (rectocele ≥ 3 cm); straining to defecate with a preoperative Wexner score >19 and ≤ 27; eligibility for surgical procedures (ASA ≤ 2). Exclusion criteria were: obstructed defecation, contraindication to surgical procedures (ASA > 3); diabetes; rectal intussusceptions; immunodeficiency. All patients signed an informed consent. Before the procedure, patients underwent gynecologic and proctologic examinations, pelvic ultrasonography and defecography and Wexner score and QoL questionnaire were completed. All patients received spinal anesthesia, perioperative antibiotic prophilaxy, and underwent single incision Posterior Elevate implant. Operative times, blood loss, and intraoperative complications were recorded. Three, 6 and 12 months after the procedure, PoP-Q score, Wexner score, QoL questionnaire and the onset of complications were reviewed. Data distribution was assessed with the Shapiro-Wilk's test. PoP-Q scoring displayed a non-normal distribution and differences in the values observed at the follow-up up visit were evaluated using the Wilcoxon test. The other variables displayed a normal distribution and a Student's t test for coupled samples was used. Statistical significance was set for a p value of .05

Results

All patients were available at the 12 months follow-up visit. Mean age was 58.9 years (range 45-69), BMI was 26.5 ± 5.3 kg/m^2, 18 patients (81.8%) were postmenopausal and none was on hormonal replacement treatment. Ten patients (45.4%) had urinary incontinence and 6 (27.3%) urinary urgence. Eleven patients (50%) underwent associated procedures (5 Perigee for anterior vaginal wall prolapse, 5 Monarc and 4 Miniarc for stress urinary incontinence). Mean operative time was 17.6 ± 7.3 minutes and mean blood loss 60 ± 26.5 ml. During the procedure, no bleeding > 200 ml was observed and the only complications recorded were two vaginal lesions (9.1%). Short term complications (one week) were two vaginal infections (9.1%), two perineal pain with difficulties in walking (9.1%). We did not observed any case of vaginal or rectal mesh erosion. At the 12 months follow-up we recorded a total of 3 recurrences (13.6%). PoP-Q score was significantly lower at the first follow-up visit in comparison with preoperative values (median 0 [range 0-2] vs. 3 [range 3-4]; p < .001) and remained unchanged at the second and third follow-up visits (Table 1). Wexner score was significantly reduced 3 months after the procedure in comparison with baseline values (8.0 ± 2.4 vs. 24.2 ± 2.7; p < .0001) and remained low at 6 and 12 months after the procedure (8.1 ± 3.2 and 7.0 ± 1.3). QoL questionnaire showed that all patients were unsatisfied and had sexual dysfunctions. Three months after the procedure, 12 patients were very satisfied (54.5%) and 9 satisfied (40.9%), while only one was unsatisfied (4.5%) and three had sexual dysfunctions (13.6%). Six months after surgical intervention, 13 patients were very satisfied (59.1%) and 8 satisfied (36.4%), while one was unsatisfied (4.5%) and two had sexual dysfunction (13.6%). At the last follow-up visit (12 months), 16 patients were very satisfied (72.7%) and five satisfied (22.7%), while one was unsatisfied (4.5%) and two reported sexual dysfunction (18.2%). Objective cure rate three months after the procedure was 90.9%, while subjective cure rate was 86.4%. Objective cure rates at 6 and 12 months follow-up were 90.9%, while subjective cure rates were 81.8% for both follow-up visits.

Table 1. Pop-Q scores.

Basal	3 months	6 months	12 months
3	0	0	0
3	0	0	0
3	1	1	1
3	1	1	1
3	0	0	0
3	0	0	0
4	1	1	1
4	0	0	0
3	2	3	1

Table 2. Wexner scores.

Basal	3 months	6 mo.	12 mo.
19	7	6	6
24	7	7	7
27	7	7	7
26	8	7	7
24	7	7	7
26	8	7	7
22	6	6	6
25	8	6	6
25	16	20	7

3	0	0	0
4	1	1	1
4	0	0	0
4	0	0	0
4	1	1	1
4	1	1	0
4	0	0	0
4	0	0	1
3	0	0	1
3	0	0	0
4	1	1	0
3	0	0	0
3	0	0	1

18	4	4	4
25	9	9	9
26	9	9	9
26	11	10	10
28	8	9	9
24	11	11	6
26	8	7	7
25	8	7	7
23	5	6	7
25	7	7	7
28	10	10	7
22	7	10	6
19	6	6	6

Interpretation of results

This procedure yielded a high cure rate, both objective and subjective, with a low failure rates. The intraoperative complication rate was very limited and no visceral or vessel injuries nor heavy bleeding were recorded. Post-operative complications were few and were represented by perineal pain and vaginal infections. We observed three recurrences (13.6%) and no vaginal or rectal erosions.

Concluding message

Posterior Elevate proved to be effective and safe in the treatment of high grade posterior vaginal wall prolapse associated with straining in defecation, with excellent anatomical and functional results after one year. A higher number of patients are needed to further explore the incidence of recurrences and intra- and post-operative complication rates, but this study seems to indicate a good performance of this device.

References

1. Moore RD, Miklos JR. Vaginal repair of cystocele with anterior wall mesh via transobturator route: efficacy and complications with up to 3-year follow-up. Adv Urol 2009; epub 24/8/2009.

Specify source of funding or grant	**None**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require ethics committee approval because	**Patients underwent diagnostic and surgical procedure indicated for their pathology**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**