

TREATMENT OF POSTERIOR VAGINAL WALL PROLAPSE ASSOCIATED WITH ANORECTAL DYSFUNCTIONS USING A VAGINAL POLYPROPYLENE MESH KIT (POSTERIOR PROLIFT): ONE YEAR FOLLOW-UP STUDY

Hypothesis / aims of study

Anatomical support of the pelvic viscera is mainly provided by the levator ani muscle complex and connective-tissue attachments of the pelvic organs. Disruption, dysfunction, or structural alterations of one or both of these components may lead to loss of support and to pelvic organ prolapse. Anatomical alterations of the posterior compartment (posterior vaginal wall prolapse, or rectocele) are associated to functional alterations such as obstructed defecation or fecal incontinence. Correcting the anatomical defect should induce an improvement of defecatory function. Traditional posterior compartment repair are posterior colporrhaphy, midline fascial placcation and site-specific repairs. Although these techniques achieve good anatomical results, their recurrence and *de novo* dyspareunia rates appears to be relatively high (1). To overcome these problems, prosthetic procedures have been proposed, with good anatomical results and low recurrence rate. In order to standardize these technique and to improve safety and easier to perform, in the last year a number of vaginal mesh kits have been marketed (2). Aim of this study was to evaluate the anatomical result and the reduction of functional symptomatology in patients affected by high stage posterior vaginal wall prolapse and obstructed defecation treated with posterior repair using the posterior Prolift vaginal mesh kit system.

Study design, materials and methods

In this prospective study, we enrolled 20 patients affected by posterior vaginal wall prolapse and obstructed defecation. Inclusion criteria were: high grade posterior vaginal wall prolapse (3 stage; AP= \geq 3; BP= \geq 3) as diagnosed by PoP-Q staging and x-ray (rectocele \geq 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 prophylaxy, and underwent posterior Prolift implant following the technique described by Debodinance et al. (3). Operative times, blood loss, and intraoperative complications were recorded. Three, 6 and 12 months after the procedure, PoP-Q score, Wexner score 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 56 years (range 39-79), BMI was 27.4 ± 6.3 kg/m², 12 patients (60%) were postmenopausal and 3 (25% of postmenopausal women) were on hormonal replacement treatment. Mean operative time was 23.1 ± 6.3 minutes and mean blood loss 65.3 ± 26.5 ml. During the procedure, no bleeding > 200 ml was observed and the only complications recorded were two vaginal lesions. We observed one post-operative case (day one) of hematoma of the gluteus that did not need surgical intervention. We did not observe any case of vaginal or rectal mesh erosion. In this cohort, only one case of vaginal infection was observed. PoP-Q score was significantly lower at the first follow-up visit in comparison with preoperative values (median 0 [range 0-2] vs. 3 [3]; $p < .001$) 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 (7.1 ± 0.8 vs. 24.6 ± 2.8 ; $p < .0001$) and a further, significant reduction was observed 6 and 12 months after the procedure in comparison with the first follow-up visit (6.6 ± 0.6 and 6.5 ± 0.7 vs. 7.1 ± 0.8 ; $p = .03$).

Table 1. Pop-Q scores.

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

Table 2. Wexner scores.

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

3	1	1	0
3	1	1	1
3	0	0	0
3	0	0	0
3	1	1	1
3	0	0	0
3	0	0	1
3	0	0	0
3	0	0	0
3	0	0	0

23	7	7	6
25	7	7	7
28	8	7	7
28	8	8	8
22	6	6	6
28	7	6	6
25	6	6	6
24	6	6	6
25	7	6	6
28	8	6	6

Interpretation of results

In this study, we did not observed significant intraoperative complications, with low operative times and no significant blood loss. Furthermore, mid-term complications were absent, with no mesh erosion or dyspareunia. Anatomical correction was evident since the first follow-up visit and was preserved one year after the procedure, with no recurrences. Symptomatology was significantly reduced at the first follow-up visit and showed a further improvement six months after the procedure, indicating that the correction of the anatomical defect induced an improvement of the symptoms of anorectal function.

Concluding message

Repair of posterior vaginal wall prolapse in women with anorectal dysfunction with Posterior Prolift seems to be effective and safe. The number of patients studied is limited and thus no definitive conclusions may be drawn. Nevertheless, this cohort is very homogeneous and may represent a starting point for larger studies evaluating the effect of mesh repair of posterior vaginal wall prolapse on anorectal symptomatology.

References

1. Jelovsek J, Maher C, Barber MD. Pelvic organ prolapse. Lancet 2007; 369: 1027-1038.
2. 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.
3. Debodinance P, Berrocal J, Clavè H, Cosson M, Garbin O, Jaquetin B, Rosenthal C, Salet-Lizée D, Villet R. Evolution des idées sur le traitement chirurgical des prolapsus génitaux: Naissance de la technique TVM. J Gynecol Obstet Biol Reprod 2004; 33: 577-588.

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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 procedures indicated for their pathologies.
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes