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**Prevesical peritoneum interposition to prevent risk of rectovaginal fistula after en bloc
colorectal resection with hysterectomy for endometriosis: results of a pilot study.**

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1 **Abstract.**

2 **Objective:** To evaluate the risk of rectovaginal fistula after en bloc hysterectomy and
3 colorectal resection (H-CR) for endometriosis using prevesical peritoneum interposition.

4 **Study Design:** A retrospective study conducted at Tenon University Hospital, expert center in
5 endometriosis, from June 2016 to June 2018. Patients undergoing H-CR with prevesical
6 peritoneum interposition without protective defunctioning stoma were included.

7 **Results:** Of the 160 patients who underwent surgery with colorectal resection for
8 endometriosis during the study period, 27 had H-CR (15 with segmental and 12 with discoid
9 colorectal resection) and were included. The median age (range) was 45 years (41-47.5).
10 Eight patients (13%) were nulliparous. All procedures were performed by laparoscopy.
11 Parametrial resection was performed in 14 cases (52%). Associated bowel procedures were
12 ileocecal resection (n=5) and appendectomy (n=2). Median follow-up (range) was 14.6
13 months (10.5-20.2). Nine (33.3%) patients experienced intra- or postoperative complications
14 including one grade I, four grade II, two grade IIIA and two grade IIIB complications (Clavien-
15 Dindo classification). Seven patients (26%) experienced postoperative voiding dysfunction.
16 One suspicion of rectovaginal fistula associated with pelvic abscess was diagnosed 4 weeks
17 after surgery but not confirmed during a second operation.

18 **Conclusion:** Despite the small sample size, the present pilot study supports the practice of
19 prevesical peritoneum interposition to limit the risk of rectovaginal fistula in patients who
20 undergo H-CR for deep endometriosis.

21 **Keywords.**

22 Bowel endometriosis ; Colorectal resection ; Deep infiltrating endometriosis (DE) ;

23 Hysterectomy ; Rectovaginal fistula

Introduction.

Endometriosis is a benign gynecologic disorder defined by the presence of endometrial glands and stroma outside the uterus (1). It affects 3% of the general female population and about 10% of women of reproductive age (1,2). Bowel endometriosis is estimated to occur in 5.3% to 12% of women with endometriosis overall (3,4) but in as many as 35% of women with deep endometriosis (DE) managed in specialized centers (5).

The classic treatment of colorectal endometriosis is based on hormonal therapy (6). However, this approach is frequently associated with side effects and incomplete symptom relief and surgery is often required. In this specific setting, various surgical techniques have been advocated such as rectal shaving and discoid or segmental colorectal resection depending on the location, the size of the lesion and the multifocality (7–9).

For patients with no desire to preserve fertility and with associated uterine disorders including myomas and/or adenomyosis, radical surgery including en bloc hysterectomy and colorectal resection (H-CR) is an option. This approach improves symptoms and quality of life (10,11) and limits the risk of recurrence. Around 12% of patients with endometriosis require a hysterectomy (12).

In addition to the risk of voiding dysfunction, H-CR particularly involving the rectum and the recto-sigmoid junction exposes patients to the need for defunctioning stoma to limit the risk of rectovaginal fistula even if the effectiveness of this surgical procedure remains a matter of debate (13–15). Other surgical techniques have been suggested to reduce the risk of rectovaginal fistula such as omental flap interposition (epiploplasty). However, this procedure is not always feasible due to the anatomical characteristics of the omentum. Moreover, the efficacy of epiploplasty in the context of concomitant opening of the vagina and colorectal resection of endometriosis is questionable.

Therefore, the objective of this pilot study was to evaluate the potential role of prevesical peritoneum interposition between the vagina and the colorectum after H-CR for DE to limit the risk of rectovaginal fistula while avoiding systematic defunctioning stoma.

Material and Methods.

The present retrospective pilot study was based on the analysis of a prospective database of patients who underwent colorectal surgery for DE from June 2016 to June 2018 at Tenon University Hospital, Expert Center in Endometriosis (Paris), Sorbonne University. We identified all patients who had undergone H-CR with prevesical peritoneum interposition.

All the patients had given their informed consent for H-CR surgery after being informed about the risk of protective defunctioning stoma.

Preoperative Assessment of DE

DE was diagnosed clinically by two experienced surgeons (E.D. and S.B.) on the basis of the following criteria: visible dark blue nodules on the posterior vaginal fornix at speculum examination or infiltration associated with palpable induration at vaginal and digital rectal examination. Patients were then referred to the Department of Radiology for confirmation of the diagnosis. All the patients underwent transvaginal ultrasonography followed by magnetic resonance imaging (MRI) to assess the presence of colorectal lesions, the uni- or multifocality of bowel endometriosis, and location of associated DE lesions (2,13,16).

The anatomical locations of endometriosis and extent of colorectal endometriosis were also recorded especially evaluating external adenomyosis and the presence of uterine myomas. All the patients underwent pelvis ultrasonography, MRI, and rectal endoscopic sonography before surgery. DE was diagnosed according to the morphology of the lesions observed by imaging techniques and in accordance with previously described criteria (17–21). Colorectal endometriosis was defined as DE with infiltration of at least the rectal muscularis (14). Associated adenomyosis was defined as previously published by Bazot et al. (18). The ENZIAN classification was used to describe MRI distribution of lesions (22).

Surgical Procedure

All the patients received GnRH analogues for 3 months before surgery and were operated on under general anesthesia in the dorsolithotomy position. The abdominal and pelvic cavities were explored to identify all locations of endometriosis to evaluate the ENZIAN Score. All the colorectal resections were laparoscopically assisted and performed with the objective of complete resection, as previously described associating both hysterectomy and colorectal resection (13,23). Procedures included adnexal surgery (ovarian cystectomy or salpingo-oophorectomy); uterosacral ligament, parametrium, or vaginal resection; ureterolysis; and ureteral reimplantation when required. No omental flap interposition was used between the vaginal suture and rectal staple line.

To prevent the risk of rectovaginal fistula and to avoid protective defunctioning stoma, a prevesical peritoneum interposition was performed between the vaginal and digestive scars. For this procedure, the prevesical peritoneum was mobilized then sutured to the posterior vaginal wall by absorbable stitches over the vaginal suture.

For the colorectal resection, lesions under 3 centimeters in diameter underwent a discoid resection after removal of the exophytic portion keeping the infiltrating portion on the rectum. Discoid resection was then performed using an automatic transanal stapler (CDH33A, Endo-Surgery, Ethicon, France). The vagina was sutured with absorbable sutures.

For the segmental colorectal resection consisted of sectioning with endo GIA 60 by laparoscopy (Auto Suture; Tyco S.A., Elancourt, France) after mobilizing the rectum and left colon. The uterus was extracted by the vaginal route and the vagina then closed with absorbable sutures. The median suprapubic trocar was withdrawn and the incision enlarged to 3 cm to allow resection of the colorectum and placement of the anvil of the automatic stapler (CCEA forceps, Auto Suture; Tyco S.A., France).

Study Variables

Data including epidemiologic characteristics age, body mass index (BMI), previous surgery, details of radiologic and surgical findings were recorded from the patients' medical

records. The distribution of DE lesions was scored according to the ENZIAN classification. The size of the histological specimen was also recorded. All intra- and postoperative complications were recorded. In accordance with the Clavien-Dindo classification, complications were classified as minor when of grade I-II (deviation from the normal postoperative course without the need for surgical, endoscopic or radiological interventions) and major when of grade IIIa (requiring surgical, endoscopic or radiological intervention without general anesthesia), IIIb (requiring surgical, endoscopic or radiological intervention under general anesthesia), IV (life-threatening complication, including central nervous system complications or requiring intermediate or intensive care unit management) and V (death). In addition, de-novo voiding dysfunction requiring self-catheterization lasting more than 1 month was considered a major complication. The Ethical Review Committee (CEROG) approved this study (CEROG 2018-GYN-0201). Written informed consent was obtained from all patients.

Statistical Analysis

Quantitative variables were expressed in median and interquartile range (IQR) and nominal variables in proportion. Univariate analysis was performed using the Wilcoxon test for continuous variables and the Fisher exact test for categorical variables. All reported p values were 2-sided. The significance threshold was set at .05. All statistical analysis was performed using commercially available software JMP v.13.0.0 software © (SAS Institute Inc., Cary, NC, United-States).

Results.

Epidemiological and surgical characteristics of the population

During the study period, 160 patients with DE underwent surgery for colorectal endometriosis. Among them, 27 patients (16.8%) underwent an H-CR with prevesical peritoneum interposition.

The characteristics of the study population are summarized in Table 1. The median age was 45 years (IQR 41-47.5), and median BMI was 25.6 kg/m² (IQR 22.7-28.9). Thirty-seven percent of the patients (n=10) had a history of surgery for endometriosis: 19% (n=5) for DE and 26% (n=7) for ovarian endometriosis.

The main symptoms of the population were dysmenorrhea (96%), dyspareunia (63%), transit disorder (44%), chronic pelvic pain (44%), pain on defecation (26%) and dysuria (11%). Thirty percent (n=8) of the patients were nulliparous and 30% (n=8) had a prior history of IVF. The median gravidity was 1 (IQR 0-2) and the median parity was 1 (IQR 0-2).

According to the ENZIAN classification based on MRI description (Table 2), absence of vaginal involvement (A0) was found in 56% of the patients (n=15), involvement of the lateral compartment between 1 and 3 cm (B2) in 59% (n=16), and rectal involvement between 1 and 3 cm (C2) in 33% (n=9). Bladder endometriosis was described in one patient (4%), and ureter endometriosis in one patient (4%). Associated adenomyosis was found in 52% of the patients (n=14) and other intestine involvement (sigmoid, caecum, appendix and ileum) in 15%.

All procedures were performed by the laparoscopic route. Laparoscopic and MRI evaluation of the ENZIAN score were recorded (Table 2).

Segmental resection and discoid excision were performed in 15 (56%) and 12 patients (44%), respectively (Table 3). Ninety-three percent (n=25) of the patients underwent a torus or uterosacral ligament resection. Bilateral ureterolysis was performed for all the patients. Parametrial resection was performed in 14 cases (52%) (unilateral in six cases and bilateral in eight). Associated procedures were ovarian cystectomy in 12 cases (44%),

appendectomy in two (7%), ileocecal resection in five (19%), and a partial bladder resection in one (4%) (Table 3). No patients had primary protective defunctioning stoma. Endometriosis was confirmed by surgery and histology in all the patients. The median size of the rectal nodules on the histological specimen was 15 mm (IQR 10-25).

Surgical complications and follow-up

The median length of hospital stay was 7 days (IQR 6.5-10.5). Median follow-up was 14.6 months (IQR 10.5-20.2). **No patient was lost to follow-up.**

Nine (33.3%) patients experienced intra- or postoperative complications. One patient (3.7%) experienced a Clavien-Dindo grade I complication (parietal abscess), four (15%) a grade II complication (two urinary infections treated by antibiotics, one pelvic abscess requiring a treatment by antibiotics and one vesicovaginal fistula requiring a prolonged bladder drainage by a Foley catheter for 21 days), two (7.4%) a grade IIIA complication (pelvic abscess requiring radiological drainage, ureteral injury requiring a double-J stent), and two (7.4%) a grade IIIB complication requiring a second surgery (due to a hemorrhage linked to ureteral vessel injury in one case, and for multiple pelvic abscesses with suspicion of rectovaginal fistula in the other) (Table 4). No grade IV-V complications occurred.

The patient with a suspicion of rectovaginal fistula underwent both rectal shaving and colorectal resection associated with bilateral salpingectomy, bilateral ureterolysis and left parametrectomy. She experienced chest pain in the early postoperative period and was investigated by an angio CT scan. No emboli were detected but pneumothorax with mediastinal emphysema was found. As the patient did not have a diaphragmatic location of endometriosis or a high intraabdominal pressure, the presumed diagnosis was esophageal injury linked to the nasogastric tube. Thoracic drainage was performed with a favorable outcome. Scanner guided drainage of a pelvic collection was also performed on postoperative day 8. The patient was re-hospitalized 3 weeks after this procedure for vaginal discharge with complete vaginal dehiscence. CT scan exhibited multiple pelvis abscesses with suspicion of a rectovaginal fistula. A second surgery was required by laparoscopy with

conversion to laparotomy with extensive adhesiolysis, drainage of multiple pelvic abscesses and resection of 25 cm of the small bowel. No signs of rectovaginal fistula were found on rectal examination and intraoperative rectal blue test. Pathological analysis of the small bowel revealed an inflammatory reaction. A protective defunctioning stoma was performed. Three months later, the vagina had healed and the stoma could be closed after a CT scan confirmed absence of rectovaginal fistula.

Seven (26%) patients experienced postoperative voiding dysfunction and required self-bladder catheterization: five patients for less than 1 month, one for 45 days and one for 90 days).

Discussion.

This pilot study supports the practice of prevesical peritoneum interposition between the vagina and the colorectum after H-CR for DE as a simple and reproducible procedure which may avoid systematic digestive defunctioning stoma.

In a sub-analysis of a randomized study, H-CR was associated with a significant improvement in dysmenorrhea, dyspareunia and asthenia (10). A trend for improvement was found for diarrhea and back pain, while no improvement in constipation, bowel movement pain or cramping, and dyschesia was observed (10). No difference in urinary function was observed pre- and postoperatively (10). All the SF-36 quality-of-life items apart from physical functioning were significantly improved by surgery (10).

However, an important question that deserves to be addressed is whether our results reflect a real and reproducible benefit of prevesical peritoneum interposition in this setting or rather a coincidence due to the relatively low prevalence of the complication. We hypothesize the interest of this simple technique since we found no case of rectovaginal fistula after segmental or discoid colorectal resection in a subgroup of so-called high-risk patients. In these patients the rate of rectovaginal fistula can be as high as 10%, justifying the use of systematic protective defunctioning stoma for several authors (24). In the present study, the only case of suspected rectovaginal fistulae was observed after rectal shaving associated

with a segmental colorectal resection complicated by a pelvic abscess with subsequent vaginal dehiscence. No fistula was seen intraoperatively.

In a review published in 2008, Vercellini et al reported that the incidence of rectovaginal fistula after rectovaginal septum surgery (with and without colorectal resection) was between 2 and 10% depending on the series and the surgical procedure (25). In a meta-analysis of 49 series focusing on colorectal resection, Meuleman et al observed that the incidence of rectovaginal fistula was 2.7% after segmental resection and 0.7% for the mixed group composed of patients undergoing rectal shaving or discoid resection (26). Finally, in a recent systematic review of the literature involving 3079 colorectal resections, Balla et al reported similar results with 2.4% of rectovaginal fistula overall (2.8% for the open approach, 2.2% for the laparoscopic approach and 7.4% for the robotic approach) (27). However, despite the interest of these reviews, it is difficult to evaluate the true incidence of rectovaginal fistula in routine practice as most publications are from experienced teams and this could constitute a selection bias. In a French multicenter study involving 56 departments of gynecology with 1135 colorectal resections performed in 2015, Roman H. on behalf of the FRIENDS group reported a similar rate of rectovaginal fistula (28). However, a sub-analysis of data from the FRIENDS group by Bendifallah et al showed that this rate varied according to the hospital case volume: 4.95% of rectovaginal fistula for centers managing fewer than 10 procedures per year and 2.77% for centers with more than 40 procedures per year, with a significant cut-off at more than 20 procedures per year (29).

Several surgical procedures have been advocated to decrease the risk of rectovaginal fistulae after colorectal resection. Belghiti et al reported that protective defunctioning stoma was associated with a decrease in the number of rectovaginal fistulas in women undergoing partial colectomy and low colorectal resection for endometriosis from 27% to 15% but without reaching significance (13). However, in this specific setting, the new French guidelines for the management of colorectal endometriosis stated that, due to the lack of sufficient high-level evidence, no recommendation for a systematic protective defunctioning

stoma cannot be formulated (30). In a prospective randomized study including 126 patients, Agnifili et al suggested that omentoplasty seemed to be effective in lowering the rate and the severity of anastomotic leakage after colorectal surgery. However, they reported a high incidence of anastomotic leakage of 14.3% in the whole population (6.4% in the omentoplasty group vs 21.9% in the non-omentoplasty group) (14). Conversely, in a prospective randomized study of 712 patients undergoing colonic or rectal resection, Merad et al demonstrated that omentoplasty decreased neither the rate nor the severity of anastomotic failure (15). Finally, a meta-analysis showed that no statistically significant difference was found between the omentoplasty group and the no omentoplasty group in radiological anastomotic leakage (RR 0.76, 95% CI 0.41 to 1.40), death (RR 1.01, 95% CI 0.55 to 1.86), and repeat operation (RR 0.60, 95% CI 0.35 to 1.05) except for clinical anastomotic leakage (RR 0.36, 95% CI 0.16 to 0.78) (31). The authors stated that there was not enough evidence to say whether or not omentoplasty should be used to reduce anastomotic leakage after colorectal resection (31).

Despite the high feasibility rate of prevesical peritoneum interposition between the vagina and the colorectum, the technique is not feasible in patients undergoing partial colectomy with uterine conservation and is difficult in those with a concomitant bladder resection or with vesico-uterine fold endometriosis imposing extensive peritoneal resection. In this specific setting, several surgical techniques to minimize the risk of rectovaginal fistula have been advocated (13–15,31). For instance, some authors recommend a subtotal hysterectomy although this surgical option is associated with a risk of endometriosis recurrence requiring a second surgery (32,33). Another option is the use of a protective stoma. However, this technique is often poorly accepted by patients and requires a second surgery. Akladios et al suggested that, in the absence of partial colectomy, ileostomy may be omitted in patients with low colorectal anastomosis which were more than 5 cm from the anal verge, and with no adverse intraoperative events (34). After multivariate regression analysis and adjusting for major clinical, demographic, and surgical characteristics, Milone et

al underlined that the only factor associated with complicated cases was the distance of the endometriotic localization from the lower rectum (35). In a large series of patients undergoing colorectal resection for endometriosis, Belghiti et al confirmed that all rectovaginal fistulas occurred in patients with a low colorectal anastomosis ($p<.001$) and 88% in patients with a partial colectomy ($p<.001$) (13). Protective defunctioning stoma was associated with a decrease, albeit non-significant, in the number of rectovaginal fistulas in women undergoing partial colectomy and low colorectal resection (from 27% to 15%) (13). Data from randomized trials evaluating the contribution of epiploplasty in limiting the risk of digestive complications after colorectal resection in indications other than endometriosis, are controversial (14,15). However, in a meta-analysis, Hao et al emphasized that there is not enough evidence to claim whether or not epiploplasty should be used to reduce complication rates after colorectal resection (31).

From another point of view, it has been stated that this major complication can be avoided by leaving the uterus in situ (24), with the risk of postoperative recurrence due to incomplete removal of endometriosis (23). The most recent French guidelines suggest that hysterectomy is an option after failure of conservative medical and surgical therapies or in cases of associated uterine disorders such as myomas and external and internal adenomyosis (16,36). This may explain why more than half of our population operated on for colorectal endometriosis underwent an H-CR. Although highly selected, 19 of the 27 women (70%) in our series had had a previous pregnancy with a median gravidity of 1 (IQR 0-2) underlining our center's policy concerning radical hysterectomy.

Some limits of this pilot study deserve to be mentioned. First, the low sample size could imply a selection bias as our subgroup of patients were at high risk of complications due to associated disorders such as both internal and external adenomyosis (36,37). Second, comparison with the literature is difficult as few data have focused on this specific population. In a previous study, we found a high risk of complications in this subpopulation of patients with colorectal endometriosis (11). Third, our surgical procedure is not applicable in certain cases, for example: in patients with concomitant large bladder involvement or

299 extensive vesico-uterine fold involvement requiring removal of the prevesical peritoneum;
300 and in patients requiring a colectomy without associated hysterectomy which represents the
301 vast majority of patients with vaginal endometriosis.

302 Despite the small sample size, the present pilot study supports the practice of
303 prevesical peritoneum interposition to limit the risk of rectovaginal fistula in patients who
304 undergo H-CR for deep endometriosis. Further studies are necessary to confirm these
305 results and to identify good candidates for this simple technique.

306 Disclosure statement: The authors declare that they have no conflicts of interest and nothing
307 to disclose.

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Table 1. Epidemiological characteristics of the population.

<u>Characteristics</u>	<u>Population (n=27)</u>
Age median, years (IQR)	45 (41-47.5)
BMI median, kg/m2 (IQR)	25.6 (22.7-28.9)
History of prior surgery for endometriosis, n (%)	10 (37)
- Deep endometriosis	5 (19)
- Ovarian endometriosis	7 (26)
- Both	3 (11)
Symptoms related to endometriosis, n (%)	
- Chronic pelvic pain	12 (44)
- Dysmenorrhoea	26 (96)
- Dyspareunia	17 (63)
- Transit disorder	12 (44)
- Constipation	11 (41)
- Diarrhoea	4 (15)
- Pain at defecation	7 (26)
- Dysuria	3 (11)
- Pain when urinating	1 (4)
- Menorrhagia	3 (11)
Age at the first period, median, years (IQR)*	12.5 (12-13)
Gestity, median (IQR)	1 (0-2)
Parity, median (IQR)	1 (0-2)
Number of nulligest patients	8 (30)
Prior history of IVF	8 (30)
AMH value, mean, ng/mL **	0.56

* *Data missing for 2 patients*

** *Data available only for 5 patients*

Table 2 : MRI description of endometriotic lesions according to ENZIAN classification

ENZIAN classification	MRI evaluation	Laparoscopic evaluation
	Population n=27 (%)	Population n=27 (%)
<u>A (Rectovaginal space, Vagina)</u>		
A0	15 (56)	5 (18)
A1 (<1 cm)	3 (11)	13 (48)
A2 (1-3 cm)	5 (18)	5 (18)
A3 (>3 cm)	4 (15)	4 (15)
<u>B (Sacrouterine ligaments, Cardinal ligaments, Pelvic sidewall, External ureter, Compression)</u>		
B0	0 (0)	0 (0)
B1 (<1 cm)	4 (15)	0 (0)
B2 (1-3 cm)	16 (59)	20 (74)
B3 (>3 cm)	7 (26)	7 (26)
<u>C (Rectum)</u>		
C0	4 (15)	1 (4)
C1 (<1 cm)	6 (21)	7 (26)
C2 (1-3 cm)	9 (33)	11 (41)
C3 (>3 cm)	8 (31)	8 (31)
<u>Uterine and other types of extragenital deep infiltration endometriosis</u>		
F0	9 (33)	10 (37)
FA (Adenomyosis)	14 (52)	14 (52)

FB (Bladder)	1 (4)	1 (4)
FU (Ureter, intrinsic)	1 (4)	1 (4)
FI (Intestine, others (sigmoid, coecum, appendix and ileum))	4 (15)	4 (15)
FO (Other regions of localization: lung, diaphragm, inguinal region)	0 (0)	0 (0)

Table 3. Surgical procedures.

<u>Surgical characteristics</u>	<u>Population (n=27)</u>
Laparoscopic	27/27 (100)
Operating time, median, minutes (IQR)	200 (155-230)
Colorectal procedure, n (%)	
- Segmental resection	15 (56)
- Disc excision	12 (44)
Torus or uterosacral ligament resection, n (%)	25 (93)
Urétérolysis	27 (100)
- unilateral	0 (0)
- bilateral	27 (100)
Parametrial resection, n (%)	14 (52)
- unilateral	6 (22)
- bilateral	8 (30)
Ovarian ablation, n (%)	12 (44)
Ileo-caecal resection, n (%)	5 (19)
Appendicectomy, n (%)	2 (7)
Partial bladder resection, n (%)	1 (4)

Table 4 : Complications according to the Clavien-Dindo classification.

<u>Clavien-Dindo classification</u>	<u>Population n=27 (%)</u>
No complication	18 (66.7)
Grade I	1 (3.7)
Grade II	4 (15)
Grade IIIa	2 (7.4)
Grade IIIb	2 (7.4)
Grade IV-V	0