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Original Article

Impact of temporary protective ileostomy on intestinal function and quality of life after a 2-year follow-up in patients submitted to colorectal segmental resection for endometriosis

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Precis: temporary protective ileostomy after colorectal segmental resection for deep infiltrating endometriosis does not appear to worsen intestinal function and quality of life at 2-year follow-up, compared to immediate recanalization

Journal Pre-proof

Abstract

Study Objective: To compare 2-year follow-up intestinal function and quality of life (QoL) between women with temporary protective ileostomy (PI) and recanalization and women without PI after colorectal segmental resection for deep infiltrating endometriosis (DIE).

Design: prospective observational exploratory study.

Setting: Tertiary level referral Center of minimally invasive gynecologic surgery.

Patients: Consecutive patients subjected to laparoscopic colorectal resection and PI because of DIE between January 2015 and January 2018; an equal number of women without PI were matched according to age and anamnestic findings to serve as controls.

Interventions: Realization of a protective ileostomy or immediate recanalization in patients subjected to laparoscopic colorectal resection.

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Measurements and Main Results: 36 patients were considered for the analyses: 18 in PI group and 18 in non-PI group. Baseline intestinal function and quality of life were evaluated using two validated questionnaires. The main reasons for ileostomy were: colpotomy (66.7%), ultra-low bowel anastomosis (27.8%), concomitant ureteroneocystostomy and positive Michelin test (5.6%). The mean interval between first and second surgery in PI group was 3.7 ± 1.7 months. Perioperative severe complications included one stenosis of colorectal anastomosis in one woman in PI group and one perianastomotic abscess in non-PI group, but were overall comparable between the two groups. At 2-year follow-up from recanalization, bowel function and QoL improved from baseline with no statistical difference between the groups (KESS delta: 5.9 ± 9.3 in PI group vs 7.7 ± 10.2 in non-PI group, $p = .6$; GIQLI delta: 16.0 ± 27.5 vs 19.2 ± 24.7 , $p = .7$).

Conclusions: Temporary PI after colorectal resection for DIE does not seem to influence patients' bowel function and QoL at a median follow-up from recanalization of 2-year.

Keywords: colorectal resection, deep infiltrating endometriosis, ileostomy, laparoscopy

Introduction

Deep infiltrating endometriosis (DIE) is an aggressive disease that penetrates under the peritoneal surface of affected tissue, infiltrating pelvic structures and organ walls [1–3]. The prevalence of bowel endometriosis ranges between 5.3% and 12% of patients with endometriosis, with rectum and rectosigmoid colon accounting for up to 72% of cases [4,5]. The involvement of the lower gastrointestinal tract causes some of the most debilitating features of endometriosis, including chronic pelvic pain, dyspareunia and digestive symptoms like diarrhea, constipation and dyschezia [5–7]. Laparoscopic surgery is the best therapeutic option to treat bowel DIE and colorectal segmental resection is one of the main surgical techniques normally employed [8,9]. Although effective, segmental bowel resection is highly complex and carries a considerable complication rate burden [10,11], including rectovaginal fistula and anastomotic leak, with a rate of 0-10% and 0-14% respectively, often requiring additional surgery [12,13]. The creation of a protective ileostomy (PI) may reduce the occurrence of these complications, even though no definite agreement on the role of PI exists [10,14]. Moreover, data supporting the realization of PI are mostly based on studies concerning colorectal cancer, which cannot easily be transposed to young, otherwise healthy patients [15–17]. PI itself may carry additional complications, such as stoma necrosis, prolapse, stenosis, peristomal hernia or fistula, with a morbidity rate up to 40% and a consistent negative impact on patients' QoL [18]. Up to date, few data are available on the impact of loop-ileostomy after its closure on bowel function and quality of life of young endometriotic patients. [19–22]

This study aims therefore to compare, at a median follow-up from recanalization of 2 years, intestinal function and QoL between women with temporary protective ileostomy (PI) and subsequent recanalization and women without PI after colorectal segmental resection for DIE. Secondly, we evaluated endometriosis-related symptoms and perioperative complication rates among the two groups.

Materials and Methods

For this prospective observational exploratory study, local ethic committee approval was obtained beforehand (IRB approval number: 149/2014/O/Oss).

Between January 2015 and January 2018, all reproductive-aged patients submitted to laparoscopic colorectal segmental resection because of symptomatic DIE were inserted into a prospective database at our referral center. Exclusion criteria for the present study were previous bowel surgery, history of other bowel pathological conditions (i.e., inflammatory bowel diseases, celiac disease) or multiple bowel resections. Patients respecting exclusion criteria with a protective ileostomy were selected as the Study Group. Maintaining a ratio of 1:1, an equal number of matched women without a PI were singled out to serve as the Control Group. Controls were chosen based on age, BMI, ultrasonographic findings, infertility, previous abdominal surgeries, symptoms and pre-surgical hormonal therapy.

During preoperative evaluation, anamnestic data were recorded, including age, BMI, infertility, previous surgery and hormonal therapy for endometriosis. The severity of pain symptoms (dysmenorrhea, ovulation pain, dyschezia, dysuria, dyspareunia and chronic pelvic pain) was evaluated on the Numerical Rating Scale (0 – no pain – 10 greatest pain). Information on baseline intestinal function using two validated questionnaires, the Knowles-Eccersley-Scott-Symptom Questionnaire (KESS) and The Gastrointestinal Quality of Life Index (GIQLI), was also acquired. The KESS is an 11-item tool for diagnosis of constipation. It uses four-to-five-point Likert scales that are scored on an unweighted linear integer scale. Total score ranges from 0 (no symptoms) to 39 (high symptom severity). A cut-off score of ≥ 10 indicates constipation [23]. The GIQLI is a 36-item multidimensional scale covering symptoms and physical, emotional and social dysfunctions relating to gastrointestinal diseases or their treatments. It is based on a five-point Likert scale, where 4 points are given to the most desirable option and 0 points to the least desirable option. The sum of the points gets total GIQLI score, defined abnormal if < 125 [24]. All patients were submitted to transabdominal and transvaginal ultrasound and in some cases to Magnetic Resonance

Imaging. Data on the location and size of endometriotic implants were recorded for each woman.

Surgical technique

All procedures were performed by highly experienced surgeons, two gynecologic and two dedicated colorectal surgeons, following the same technique [25,26]. All additional procedures (adhesiolysis, ovarian cystectomy and excision of other implants of endometriosis) were carried out prior to any bowel surgery. The ureters were bilaterally isolated and, if necessary, freed from fibrotic or endometriotic tissue and the retroperitoneal spaces were developed in order to mobilize the rectum. All procedures were carried out avoiding damage of hypogastric nerves and pelvic plexus and the ligation of superior and middle rectal arteries. Segmental recto-sigmoid resection was done using linear stapler 12 cm under the involved tract. The bowel tract was exteriorized outside the abdomen through a small incision (3 cm) at the point of the suprapubic trocar and it was excised. End-to-end or latero-terminal anastomosis was performed using a circular stapler. Bowel integrity was tested by filling the pelvic cavity with warm saline solution and insufflating air rectally or using methylene blue through the anus (Michelin test).

All patients with bowel involvement by the disease were preoperatively informed and counseled regarding the risk of bowel resection and temporary ileostomy. In particular, when the risk of major rectal complications was present according to preoperative or intraoperative findings (ultra-low rectal resection, associated posterior colpotomy or ureteroneocystostomy, positive Michelin test), a protective ileostomy was considered. The final decision was made at time of surgery.

During surgery, data on the site and distance from anus to anastomosis site (sigmoid colon, rectosigmoid junction or rectum), as well as the realization of a PI and the reasons why it was performed were recorded. Concomitant surgical procedures (i.e. hysterectomy,

adnexectomy, ovarian cystectomy) and data on perioperative complications rate (according to the Clavien-Dindo classification of surgical complications) [27] and length of hospital stay were noted for each patient.

Patients with PI were subjected to barium enema and/or rectosigmoid endoscopy 6 weeks after surgery, to check on the healing process of the colorectal anastomosis. Among PI group, during the stoma closure, perioperative complications rate and length of hospital stay were recorded again.

One year after recanalization, and every year since, all women underwent a thorough follow-up evaluation, which included a gynecological examination and a transabdominal and transvaginal ultrasound. Data on endometriosis-related symptoms and their severity, and on post-surgical hormonal therapy were recorded for each patient. Long-term intestinal function was also assessed at every interview, based on the KESS and the GIQLI questionnaires.

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Statistical analysis

Results were expressed as mean \pm SD, for normally distributed variables, or as number and percentage, for categorical variables. We compared the characteristics of patients by chi-square or Fisher's exact tests for categorical variables. Unpaired Student's t-test or Mann-Whitney test were used to compare continuous parametric and non-parametric variables respectively between different groups. Paired Student's t-test or Wilcoxon signed-rank test were used to compare continuous variables among the same group. A P-value of <0.05 was considered significant for all tests.

All statistical analyses were performed using the Statistical Package for the Social Sciences software (IBM SPSS v. 25, SPSS Inc.). Since this investigation was conceived as an exploratory study, no power-analysis was performed.

Results

A total of 154 consecutive patients was subjected to laparoscopic colorectal segmental resection for DIE during the study period. Among those, 18 women received a PI. Among all patients submitted to colorectal segmental resection without PI, 18 matched cases on age and risk factors for rectal complications were selected.

Demographic and anamnestic data on endometriosis-related symptoms were similar between the PI group and the control group. Women frequently complained of dyschezia, with a comparable degree of severity between the two groups (6.0 ± 3.4 in the PI group vs 4.2 ± 2.8 in the non-PI group, $p = 0.09$). Baseline intestinal function was comparable between the two groups, as measured by the KESS (13.1 ± 6.0 in the PI group vs 15.2 ± 7.7 in the control group, $p = 0.37$) and the GIQLI questionnaires (101.2 ± 18.7 vs 99.4 ± 21.0 , $p = 0.80$) (Table 1).

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A protective ileostomy was realized because of a concomitant posterior colpotomy in 12 patients (66.7%), an ultra-low resection in 5 patients (27.8%), and concomitant ureteroneocystostomy plus positive Michelin test in 1 woman (5.6%). Macroscopic eradication of endometriosis was obtained in all cases. A histological confirmation of the diagnosis of endometriosis was obtained in all women, and all colorectal specimens had negative macroscopic resection margins. Detailed perioperative data are listed in Table 2.

Overall perioperative complications rate was 16.7% and 22.2% in the PI- and non-PI group respectively. All complications recorded belong to Grade II (3 patients vs 2 patients) and Grade III (1 vs 1 patients) according to the Clavien-Dindo classification, with no statistical difference between the two groups ($p = 0.67$ and $p = 1.0$ respectively). In particular, 2 patients in the PI group and 1 woman in the non-PI group were diagnosed with severe anemia ($Hb < 8$ g/dL or anemia-related symptoms onset), requiring transfusion of 2 units of packed red blood cells. One patient in each group presented with persistent fever ($>38.3^{\circ}\text{C}$)

and required prolonged intravenous antibiotic therapy, with complete resolution of symptoms.

One woman in the non-PI group presented with persistent low-grade fever, pelvic pain in the left lower abdominal quadrants and loss of appetite. A CT scan detected a 3x2 cm pelvic abscess adjacent to the colorectal anastomosis, with no evidence of contrast leakage. The patient was immediately subjected to percutaneous CT-guided drainage of the abscess and placed on intravenous antibiotic therapy. She was discharged ten days after rehospitalization, with no clinical or diagnostic evidence of pelvic fluid collections.

No complications requiring re-intervention under general anesthesia occurred and no secondary ileostomies were performed. Mean hospital stay was 6.8 ± 4.2 days in PI-group and 6.1 ± 2.0 days in non-PI group ($p = 0.51$). The mean interval between first and second surgery in PI group was 3.7 ± 1.7 months. No intraoperative complications arose during the second intervention and mean hospital stay was 3.3 ± 1.7 days. One patient in the PI group presented at colonoscopy a significant stricture at the level of the colorectal anastomosis and was therefore subjected to repeated endoscopic mechanical dilations of the stenotic tract, with complete resolution of symptomatology.

At a median follow-up from recanalization of 2-year, bowel function and QoL greatly improved from baseline in each group, as well as pain symptoms related to endometriosis (Tables 3 and 4). Furthermore, there was a significant improvement in the KESS score both in the PI group (13.1 ± 6.0 vs 7.2 ± 5.4 , $p = 0.02$) and the control group (15.2 ± 7.7 vs 7.5 ± 6.0 , $p = 0.006$), whereas the GIQLI questionnaire showed higher scores in both groups, but without statistical relevance (101.2 ± 18.7 vs 117.2 ± 19.8 , $p = 0.9$ in the PI group; 99.4 ± 21.0 vs 118.6 ± 20.4 , $p = 0.2$ in the control group). No statistical difference was detected between the two groups. Moreover, the delta score between preoperative and postoperative results of the KESS and GIQLI questionnaires did not show statistical difference between the PI group and the non-PI group (KESS delta score: 5.9 ± 9.3 vs 7.7 ± 10.2 , $p = 0.6$; GIQLI

delta score: 16.0 ± 27.5 vs 19.2 ± 24.7 , $p = 0.7$) (Tables 3 and 4).-No significant differences were detected in post-surgical hormonal therapy use between the two groups.

Discussion

This is one of the few prospective-designed studies to evaluate intestinal function in women subjected to colorectal resection for endometriosis, and the first to focus on the functional outcomes of temporary loop ileostomy in endometriotic patients.

Based on our preliminary results, a protective ileostomy does not seem to worsen patients' bowel function and quality of life after 2 years follow-up from recanalization. Additionally, the improvement of endometriosis-related symptoms appears comparable between women with a PI and patients subjected to immediate recanalization, a finding in line with available literature [22]. The low complication rate together with good clinical and functional outcomes suggest that PI is safe and feasible in most situations judged to be at high risk for anastomosis-related complications.

The surgical management of deep infiltrating endometriosis of the colorectum represents a challenge for the gynecologic surgeon. Literature is rich in data concerning the various surgical techniques that may be adopted, although no definite guidelines have been realized yet [17,21-22]. It is well established that segmental rectal resection carries greater surgical risks than a conservative approach in terms of anastomotic leakage, fistula, bowel obstruction, hemorrhage and abscess [28-31]. From the analysis of several studies, Mereu et al. report an incidence of anastomotic leakage ranging from 0% to 10.3%, and of rectovaginal fistula ranging from 0% to 14.3% [32]. In a systematic review, De Cicco [33] et al. found an overall complication rate of 22.2% after segmental surgery, similar to 17.7% and 20.9% described by Mabrouk et al.[31] and Abo et al.[34]), respectively.

The evidence supporting the realization of a loop ileostomy is mainly based on studies concerning patients with rectal cancer [15-17], but these data should be transposed with

caution to endometriotic patients. Surgery for rectal cancer differ greatly from colorectal excision for endometriosis: firstly, endometriotic patients are younger, healthier and with low or normal BMI; secondly, the management of a malignancy often require a more radical surgery with excision of mesorectum and ligation of rectal vessels. In addition, presurgical irradiation of the pelvis is another important risk factor for anastomotic-related complications, especially leakage, whose incidence is reportedly higher in oncologic patients [12,35–38].

With no studies clearly demonstrating a real evidence of improved outcomes in endometriotic patients subjected to a PI, its role is still mostly undefined. This is highlighted by the fact that the rate of defunctioning stoma creation varies greatly among gynecologic surgeons: Brouwer et al. [12] report a 5% rate, Mabrouk et al. [31] 6.5%, Akladios et al. [35] 9.7%, Ruffo et al. [10] 14.5%, and Bonin et al. [28] 27.3%. In a recent case-series, Roman et al. [29] illustrated that among 56 French facilities, the rate of stoma differed considerably, ranging from 0% to 97.5%, being relevantly higher in facilities with higher rates of segmental resection. Conversely, other surgeons systematically perform a defunctioning ileostomy to protect a low rectal anastomosis [39].

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A protective ileostomy could have a helpful role in case of colpotomy, ultra-low rectal anastomosis, ureteroneocystostomy and positive Michelin test, which represent the most important risk factors for major rectal complications [10,14,35]. Moreover, according to a recent study by Ledu et al. [22], temporary stoma seems to successfully prevent anastomotic leakage. On the other hand, in a recent retrospective study, Bonin et al. [28] demonstrated that one patient out of 12 required a secondary surgical procedure because of stoma-related complications, with an overall complication rate of 38.6%. The most frequent complications were wound infection (13.5%), delayed healing and abdominal wall hernia (5.5% respectively) and urinary infections (4.3%). However, this study considered mostly patients subjected to a colostomy, which entails a higher risk of infectious complications, stoma prolapse and postoperative hernia of the abdominal wall [40].

Although the small sample size and the lack of randomization, strengths of our study include its novelty, its prospective design and the adoption of validated questionnaire for the assessment of patients' bowel function and quality of life. Given the paucity of prospective data on this issue, this exploratory study was conceived to help plan larger, multicentric trials.

Conclusion

Protective temporary ileostomy does not seem to worsen patients' bowel function after 2 years follow-up from recanalization, nor did it seem to lower the improvement rate of symptoms and quality of life compared to immediate recanalization. Also, complication rate was not significantly different between patients with and without PI. However, more prospective, randomized trials are necessary to further investigate the exact role of PI in young patients subjected to colorectal segmental resection for DIE.

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Table 1. Demographic and anamnestic characteristics.

	PI Group (18 pt)	Non-PI Group (18 pt)	p
Age (years)	36.8 ± 2.4	38.4 ± 5.6	NS
BMI (Kg/m ²)	23.2 ± 4.4	22.8 ± 3.3	NS
Previous abdominal surgery	8 (44.4%)	10 (55.5%)	NS
Infertility	6 (33.3%)	3 (16.7%)	NS
Presurgical hormonal therapy	10 (55.5%)	12 (66.7%)	NS
KESS score	13.1 ± 6.0	15.2 ± 7.7	NS
GIQLI score	101.2 ± 18.7	99.4 ± 21.0	NS
Endometriosis-related symptoms			
Dysmenorrhea	6.2 ± 3.7	7.7 ± 3.1	NS
Dyspareunia	5.1 ± 3.1	2.9 ± 3.4	NS
Chronic pelvic pain	4.8 ± 3.9	2.7 ± 3.7	NS
Dyschezia	6.0 ± 3.4	4.2 ± 2.8	NS
Dysuria	1.6 ± 2.7	3.8 ± 3.7	NS

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Table 2. Surgical procedures and perioperative outcomes during first intervention.

	PI Group (18 pt)	Non-PI Group (18 pt)	p
Concomitant surgical procedures			
Hysterectomy	7 (38.9%)	5 (27.8%)	NS
Posterior colpotomy	12 (66.7%)	11 (61.1%)	NS
Ureteral resection, ureteroneocystostomy	1 (5.6%)	2 (11.1%)	NS
Uterosacral ligament resection	13 (72.2%)	14 (77.8%)	NS

Ureterolysis	18 (100%)	16 (88.9%)	NS
Adnexal procedure	9 (50%)	12 (66.7%)	NS
Positive Michelin test	1 (5.6%)	0	NS
Conversion to laparotomy	0	0	NA
Colic resection site			
Recto-sigmoid junction	3 (16.7%)	4 (22.2%)	NS
High and low rectum (> 5 cm from dentate line)	10 (55.6%)	9 (50%)	NS
Ultra-low	5 (27.8%)	5 (27.8%)	NS
Post-operative complications			
Grade II complications			
Blood transfusion	2 (11.1%)	1 (5.6%)	NS
Isolated hyperpyrexia	1 (5.6%)	1 (5.6%)	NS
Grade IIIa complications			
Pelvic abscess	0	1 (5.6%)	NS
Anastomotic stenosis	1 (5.6%)	0	NS
Length of hospital stay	6.8 ± 4.2	6.1 ± 2.0	NS

Table 3. Post-operative assessment at a mean follow-up of 2 years.

	PI Group	Non-PI Group	p
	(18 pt)	(18 pt)	
KESS score	7.2 ± 5.4	7.5 ± 6.0	NS
GIQLI score	117.2 ± 19.8	118.6 ± 20.4	NS

KESS Delta score	5.9 ± 9.3	7.7 ± 10.2	NS
GIQLI Delta score	16.0 ± 27.5	19.2 ± 24.7	NS
Post-surgical hormonal therapy	8 (44.4%)	9 (50%)	NS
Endometriosis-related symptoms			
Dysmenorrhea	0.7 ± 2.2	0.9 ± 2.2	NS
Dyspareunia	0	0.3 ± 1.2	NS
Chronic pelvic pain	0.7 ± 1.6	1.2 ± 2.3	NS
Dyschezia	0	0.6 ± 1.7	NS
Dysuria	0	0.1 ± .5	NS

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Table 4. Endometriotic symptoms, KESS and GIQLI: preoperative vs postoperative results.

Item	Study Group	Pre-operative	Post-operative	p
Dysmenorrhea	PI	6.2 ± 3.7	0.7 ± 2.2	0.001
	Non-PI	7.7 ± 3.1	0.9 ± 2.2	0.001
Dyspareunia	PI	5.1 ± 3.1	0	0.001
	Non-PI	2.9 ± 3.4	0.3 ± 1.2	0.02
Chronic Pelvic Pain	PI	4.8 ± 3.9	0.7 ± 1.6	0.002
	Non-PI	2.7 ± 3.7	1.2 ± 2.3	NS
Dyschezia	PI	6.0 ± 3.4	0	0.001

	Non-PI	4.2 ± 2.8	0.6 ± 1.7	0.002
Dysuria	PI	1.6 ± 2.7	0	0.03
	Non-PI	3.8 ± 3.7	0.1 ± .5	0.003
KESS questionnaire	PI	13.1 ± 6.0	7.2 ± 5.4	0.02
	Non-PI	15.2 ± 7.7	7.5 ± 6.0	0.006
GIQLI questionnaire	PI	101.2 ± 18.7	117.2 ± 19.8	NS
	Non-PI	99.4 ± 21.0	118.6 ± 20.4	NS
KESS score >10 (n of patients)	PI	11 (61.1%)	5 (27.8%)	NS
	Non-PI	12 (66.7%)	7 (38.9%)	