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Original Article

Baseline severe constipation negatively impacts functional outcomes of surgery for deep endometriosis infiltrating the rectum: Results of the ENDORE randomized trial

Horace Roman[a,*], Michael Bubenheim[b], Emmanuel Huet[c], Valérie Bridoux[c], Chrysoula Zacharopoulou[d,e,f], Pierre Collinet[g], Emile Daraï[d,e,f], Jean-Jacques Tuech[c]

[a] Center of Endometriosis, Clinique Tivoli-Ducos, 33000, Bordeaux, France
[b] Department of Biostatistics, Rouen University Hospital, 76031 Rouen, France
[c] Department of Surgery, Rouen University Hospital, 76031 Rouen, France
[d] Department of Obstetrics and Gynecology, Tenon University Hospital, Assistance Publique Hôpitaux de Paris, Paris, France
[e] GRC-6 UPMC: Centre Expert en Endométriose (C3E), Université Pierre et Marie Curie, Paris, France
[f] Unité INSERM UMR_S 938, Université Pierre et Marie Curie, 75020 Paris, France
[g] Gynaecological Surgery Unit, Jeanne de Flandre Hospital, University Hospital of Lille, Lille, France

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ABSTRACT

Background: Predictive factors of functional outcomes after the surgery of rectal endometriosis are not well identified. Our recent randomized trial did not find significant differences between functional outcomes in patients managed by radical or conservative rectal surgery.
Objective: To identify preoperative factors which determine functional outcomes of surgery in patients with rectal endometriosis.
Study design: We performed a cohort study on the population of a 2-arm randomised trial, from March 2011 to August 2013. Patients were enrolled in three French university hospitals and had either conservative surgery by shaving or disc excision, or radical rectal surgery by segmental resection. The primary endpoint was the proportion of patients experiencing one of the following symptoms: constipation, frequent bowel movements, anal incontinence, dysuria or bladder atony requiring self-catheterisation 24 months postoperatively. Secondary endpoints were the values of the Knowles-Eccersley-Scott-Symptom Questionnaire (KESS), the Gastrointestinal Quality of Life Index (GIQLI), the Wexner scale, the Urinary Symptom Profile (USP) and the Short Form 36 Health Survey (SF36). A logistic regression model based on backward selection was used to screen for baseline factors that could impact the primary endpoint. A generalized estimating equations model for repeated measures was used to assess whether a trend could be observed over the follow-up period as regards gastrointestinal and quality of life scores.
Results: 60 patients with deep endometriosis infiltrating the rectum were managed by conservative surgery (27 cases) and segmental colorectal resection (33 cases). The primary endpoint was recorded in 26 patients (48.1% for conservative surgery vs. 39.4% for radical surgery, OR = 0.70, 95% CI 0.22–2.21). There was a significant improvement in values of all gastrointestinal, quality of life and urinary scores after surgery. Comparing patients with KESS scores < 10 (reference) to those with scores between 10 and 17 (OR = 2.1, 95%CI 0.4–12.2), as well as those with scores > 17 (OR = 11.1, 95%CI 2.2–20.5), revealed that the odds to record the primary endpoint are significantly higher in the latter group. Trend analyses suggest that the odds of an elevated KESS score are significantly higher at baseline than at 6 months, but significantly lower after 12 months.
Conclusions: Patients with severe preoperative constipation are less likely to achieve normal bowel movements after surgery for rectal endometriosis, using either radical or conservative rectal procedures.

Introduction

Surgical management of deep infiltrating endometriosis of the rectum has become a topic of increasing interest in gynecological

* Corresponding author at: Endometriosis Centre, Clinique Tivoli-Ducos, 91 rue Rivière, 33000 Bordeaux, France.
E-mail address: horace.roman@gmail.com (H. Roman).

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surgery, leading to much debate. We recently reported the main results of the first randomized trial comparing conservative rectal surgery by either shaving or disc excision to colorectal resection for large deep endometriosis infiltrating the rectum [1]. Although previous comparative observational studies have suggested better functional outcomes following conservative surgery [2], our trial did not show a statistically significant superiority of conservative surgery for mid-term functional digestive and urinary outcomes in this specific population of women with large involvement of the rectum. Conservative techniques were feasible in 92.6% of patients, and were associated with a lower risk of rectal stenosis requiring additional endoscopic or surgical procedures. However, 24 months after surgery, 48.1% of patients who had conservative surgery and 39.4% of patients who had colorectal resection presented one or more digestive or urinary functional symptoms, with no statistically significant relationship with the rectal procedure used to treat endometriosis [1].

To better understand these outcomes, we conducted a study assessing the postoperative evolution of digestive and urinary symptoms as well as baseline risk factors which could impact postoperative functional outcomes.

Methods

We conducted cohort study using the population enrolled in an unblinded, 1:1 parallel-arms, randomized controlled study [1] to assess the hypothetical superiority of conservative rectal surgery over segmental resection in the management of deep endometriosis infiltrating the rectum (ENDORE, NCT 01291576).

Eligible patients were over 18 and under 45 years of age and managed for deep endometriosis infiltrating the rectum up to 15 cm from the anus, measuring more than 20 mm in length, involving at least the muscular layer in depth, and up to 50% of rectal circumference. Between March 2011 and August 2013, patients were enrolled in three French referral centres, i.e. Rouen University Hospital, Tenon University Hospital, and Lille University Hospital. The trial's protocol, randomization process, surgical procedures, and the assessment of postoperative outcomes have recently been published in our previous article [1].

Patients filled in baseline questionnaires including questions on pelvic complaints related to endometriosis using Visual Analog Scale (VAS), bowel movements and bladder voiding, as well as the Knowles-Eccersley-Scott-Symptom Questionnaire (KESS) [3], the Gastrointestinal Quality of Life Index (GIQLI) [4], the Wexner scale [5], the Urinary Symptom Profile (USP) [6] and the Short Form 36 Health Survey (SF36) [7]. According to the trial's design, patients were followed-up at 6, 12, 18 and 24 month visits after surgery. Digestive and urinary outcomes were assessed using the same questionnaires used before surgery. Complete data were not recorded in women whose stoma was not yet closed at the time of the visit. The primary endpoint at 24 months post surgery was the proportion of patients experiencing one of the following symptoms: constipation (1 stool/>5 consecutive days), frequent bowel movements (>=3 stools/day), defecation pain, anal incontinence (involuntary loss of gas or stools), dysuria (USP score for dysuria >=1) or bladder atony requiring bladder voiding by self catheterisation. Secondary endpoints were the values of VAS, KESS, GIQLI, Wexner, USP, SF36 scores. This study was approved by the local Internal Review Board (N°CPP-SC 2010/006, the 22 October 2010).

Statistical analyses were carried out using SAS 9.3 software (Cary, NC). The population at the time of randomization, i.e. just before the intervention started, was described using median, first and third quartile (Q1 – Q3) if the characteristics had at least ordinal level and were not categorized. Fisher's exact test or its generalisation by Freeman and Halton was employed for categorical characteristics; otherwise, Wilcoxon's test for independent samples was used. As the analyses regarding the secondary aims are exploratory, each time the p-value was less than 0.05 the corresponding differences were considered to be significant.

To reach the principal aim of the present study, a logistic regression model was used to screen for potentially prognostic factors at baseline and those with a p-value < 0.05 in the univariate analysis were retained for the multivariable analysis based on backward selection.

To corroborate the findings, a secondary aim was to assess whether a trend could be observed over the follow-up period by means of the reported quality of life (SF36, GIQLI) or digestive problems (KESS, Wexner). Therefore, a generalized estimating equations (GEE) model for repeated measures was applied to test the hypothesis of no change against any change between time points [8]. In order to be able to distinguish between baseline and follow-up after surgery, the hypothesis was tested first globally, i.e. based on the declarations for all time points, and then on declarations after surgery only.

The trial was funded by the clinical research programme for hospitals (PHRC) in France and locally registered as 2009/069/HP by the sponsor. The funders had no role in the study design, data collection and analysis, decision to publish, or preparation of the manuscript. Randomized trial is registered with ClinicalTrials.gov, number NCT 01291576.

Results

Sixty patients were enrolled in the study: 55 in Rouen, 4 in Paris and 1 in Lille. Twenty-seven patients were randomly assigned to arm A (conservative surgery, all in Rouen) and 33 to arm B (radical surgery, 28 in Rouen, 4 in Paris and 1 in Lille). They were recruited from March 2011 to August 2013, and received surgery from March 2011 to October 2013. The patients attended clinical visits at the time of randomization (baseline) and at 6-month intervals for 2 years, with the last follow-up in October 2015. As no patient was either lost to follow-up or excluded, all 60 patients were analysed.

Analysis of primary outcomes revealed 13 patients in each group presenting primary endpoints 24 months after surgery (48.1 vs. 39.4%, OR = 0.70, 95%CI 0.22–2.21, P = 0.60) (Table 1). Each patient could report one or more symptoms. In the conservative surgery group, 3 patients (11.1%) reported constipation, 2 patients reported frequent bowel movements (7.4%), 5 patients reported defecation pain (18.5%) and 3 patients reported involuntary loss of gas (11.1%). In the radical surgery group, constipation was recorded in 3 patients (9.1%, P = 1), frequent bowel movements in 7 patients (21.2%, P = 0.17), defecation pain in 6 patients (18.2%, P = 1) and involuntary loss of gas or stools in 9 patients (27.3%, P = 0.19). As regards secondary outcomes, the values of KESS, GIQLI, Wexner, USP, SF36 and VAS scores were comparable between the 2 arms (Table 1).

Table 2 presents the assessment of functional outcomes at each postoperative visit (6, 12, 18 and 24 months postoperatively). Missing data correspond to patients whose stoma was not closed before the date of the assessment, thus functional outcomes could not be measured. Scores and proportions observed before surgery and during follow-up visits were compared and significant changes were observed over the whole period (Table 2, column "P including baseline"). However, except for the KESS score, no evidence of any change after surgery was found (Table 2, column "P disregarding baseline"). Hence, the population of treated patients improved significantly after surgery as regards primary outcomes, scores on standardized questionnaires and the evaluation of digestive and urinary function. Considering the KESS score at 6 months after surgery as reference, we observed

Table 1
Clinical assessment 24 months after surgery.

Parameter	Conservative surgery (n = 27)	Radical surgery (n = 33)	OR	95%CI	P
Assessment of digestive and urinary function					
Patients presenting primary outcome	13 (48%)	13 (39%)	0.70	0.22-2.21	0.60
GIQLI score	111 (97-135)	121 (99-128)	0.80	0.33-1.99	0.64
KESS score	10 (5-15)	9 (5-17)	1.10	0.46-2.67	0.83
Wexner score	0 (0-1)	0 (0-2)	2.10	0.71-6.22	0.23
USP of Dysuria	0 (0-1)	0 (0-0)	0.26	0.06-1.14	0.07
Short Form 36 Health Survey score	86 (64-92)	82 (62-87)	0.70	0.28-1.72	0.44
Short Form 36 Physical score	88 (60-96)	85 (70-92)	0.71	0.29-1.75	0.46
Short Form 36 Mental score	80 (61-90)	78 (58-82)	0.69	0.28-1.70	0.42

Data are n(%) or median (Q1-Q3); GIQLI: Gastrointestinal Quality of Life Index; KESS: Knowles-Eccersley-Scott-Symptom; USP Urinary Symptom Profile score (items 8–10 only):; VAS: Visual Analogue Scale.

Table 2
Assessment of digestive and urinary functional outcomes (values of primary outcome and standardised questionnaires) before surgery and at each postoperative visit.

	Baseline		6 months		12 months		18 months		24 months		P* including	P** disregarding
	N	Median (Q1-Q3)	N	Median (Q1-Q3)	N	Median (Q1-Q3)	N	Median (Q1-Q3)	N	Median (Q1-Q3)	baseline	baseline
Main outcome (yes)	60		60		60		60		60		<0.001	0.46
N/A	0		3		1		4		0			
No	4		34		31		35		34			
Yes	56		23		28		21		26			
SF 36	60	50 (42-62)	59	78 (61-88)	60	77 (62-90)	57	83 (62-91)	60	83 (62-91)	<0.001	0.52
OR vs. 6 month-visit		0.18		1		1.11		1.34		1.37		
P value vs. 6 month-visit		<0.001				0.61		0.22		0.16		
SF36 – Physical score	60	58 (41-66)	58	82 (70-92)	59	83 (57-94)	57	83 (62-91)	59	85 (70-95)	<0.001	0.54
OR vs. 6 month-visit		0.19		1		0.97		0.99		1.27		
P value vs. 6 month-visit		<0.001				0.88		0.96		0.30		
SF36 – Mental score	59	46 (30-63)	59	74 (51-86)	60	76 (55-88)	57	80 (56-89)	60	78 (58-87)	<0.001	0.20
OR vs. 6 month-visit		0.22		1		1.30		1.73		1.32		
P value vs. 6 month-visit		<0.001				0.25		0.03		0.22		
GIQLI	60	90 (83-105)	55	117 (105-125)	59	117 (104-127)	56	121 (100-130)	60	120 (97-129)	<0.001	0.36
OR vs. 6 month-visit		0.18		1		0.98		1.34		1.19		
P value vs. 6 month-visit		<0.001				0.93		0.20		0.44		
KESS	60	13 (8-18)	55	7 (3-11)	59	9 (6-16)	56	8 (4-17)	60	9 (5-16)	<0.001	0.004
OR vs. 6 month-visit		3.49		1		1.97		1.69		1.92		
P value vs. 6 month-visit		<0.001				<0.001		0.013		<0.001		
WEXNER	60	0 (0-3)	55	0 (0-1)	59	0 (0-1)	56	0 (0-1)	60	0 (0-1)	0.036	0.43
OR vs. 6 month-visit		2.75		1		1.43		1.49		1.29		
P value vs. 6 month-visit		<0.001				0.23		0.13		0.43		
Biberoglou & Behrman	60	4 (3-6)	60	0 (0-1)	60	1 (0-2)	58	1 (0-1)	60	1 (0-2)	<0.001	0.31
OR vs. 6 month-visit		41.2		1		1.49		1.11		1.24		
P value vs. 6 month-visit		<0.001				0.10		0.73		0.37		
USP	60	0 (0-2)	59	0 (0-0)	60	0 (0-0)	57	0 (0-0)	60	0 (0-0)	0.049	0.24
OR vs. 6 month-visit		2.02		1		1.06		1.02		0.68		
P value vs. 6 month-visit		0.038				0.86		0.94		0.14		

*P value of the comparison between values of scores at various times, including baseline assessment; **P value of the comparison between values of postoperative scores. Data are n(%) or median (Q1-Q3); GIQLI: Gastrointestinal Quality of Life Index; KESS: Knowles-Eccersley-Scott-Symptom; USP: Urinary Symptom Profile; SF 36: Short Form 36 Health Survey.

significantly more elevated values at all other follow-up visits, i.e. at 12 months (OR = 1.97), 18 months (OR = 1.69) and 24 months (OR = 1.92, Table 2).

Backward selection of the characteristics that appeared significantly associated with the primary outcome at 24 months (Table 3) yielded the KESS score at baseline as the sole factor significantly related to primary outcomes at the end of 24-month follow up.

Discussion

Our study suggests that severe preoperative constipation increases the likelihood of postoperative abnormal bowel movements. Surgical management of rectal endometriosis is followed by improvement in standardised gastrointestinal, urinary and quality of life scores, as early as 6 months after surgery. No further significant improvement was then observed from 6 to 24 months postoperatively. Conversely, constipation may be impaired from 6 to 24 months. Patients should receive this information prior to surgery for rectal endometriosis. Moreover, it may be useful in the decision of the shared therapeutic choice.

Our study has several limitations. The inclusion of only large infiltrations of the rectum does not allow the extrapolation of conclusions to small nodules of less than 2 cm in length. However, we chose to include only large nodules in the randomized trial due to the presumption that many surgeons would consider segmental resection to be an overtreatment in small rectal nodules. There were more patients enrolled in the first centre (Rouen) due to the presence of the primary investigator (H.R.). This unbalanced enrollment of patients may raise questions about the external validation of the study. As all surgeons were experienced in the management of rectal endometriosis, it is less likely that unbalanced enrollment of patients significantly impacted the study outcomes. The design of the trial was

Table 3
Univariate relationship between baseline factors and the presence of the main outcome 24 months after surgery.

	Patients without the main outcome N	Patients presenting with the main outcome at 24 months N	OR (95%CI)	P
Age*	34	26	1.1 (1-1.21)	0.04
Rectal nodule's largest diameter (mm)				0.80
<30	13	9	1	
30–40	10	10	1.4 (0.36-5.8)	
>40	11	7	0.92 (0.21-3.9)	
Distance from the anal verge to the inferior limit of rectal nodule	34**	24	1 (0.98-1.02)	0.73
Stenosis of rectal lumen				0.79
No	11	10	1	
Yes	23	16	0.77 (0.23-2.6)	
SF 36 score*	34	26	0.97 (0.93-1)	0.04
GIQLI score*	34	26	0.95 (0.91-0.98)	0.003
USP score				0.053
0	26	12	1	
1–3	5	7	2.96 (0.66-14.6)	
>=4	3	7	4.9 (0.92-34.4)	
KESS score				0.001
0–9	16	4	1	
10–17	13	7	2.1 (0.42-12.2)	
> = 18	5	15	11.1 (2.2-70.5)	
Wexner score				0.15
0	22	11	1	
1–3	4	8	3.9 (0.82-21.7)	
>=4	8	7	1.7 (0.42-7.2)	
How long were you able to defer defecation?				0.86
<5 min	4	5	1.6 (0.28-9.9)	
5 to 10 min	10	6	0.79 (0.18-3.2)	
10 to 15 min	3	2	0.88 (0.06-8.9)	
> 15 min	17	13	1	
Biberoglou & Behrman score*	34	26	1.4 (0.98-2.1)	0.06
Surgical procedure performed on the rectum				0.76
Shaving	6	4	1	
Disc excision	7	8	1.7 (0.26-11.9)	
Segmental colorectal resection	21	14	1 (0.19-5.7)	
Stomy				0.41
No	13	10	1	
Ileostomy	7	2	0.38 (0.03-2.6)	
Colostomy	14	14	1.3 (0.38-4.6)	
Hysterectomy				0.10
No	30	18	1	
Yes	4	8	3.2 (0.75-17)	
Operative time [min]*	254 (203;300)	290 (240;318)	1.01 (0.99-1.01)	0.08

* OR increase per unit; **Missing baseline data in 2 patients. Data are N or median (Q1-Q3); GIQLI: Gastrointestinal Quality of Life Index; KESS: Knowles-Eccersley-Scott-Symptom; USP: Urinary Symptom Profile (items 8–10 only); SF 36: Short Form 36 Health Survey.

unblinded, as specifically requested by the ethics committee. No patient had an a priori preference for one or other surgical procedure, and it was unlikely that surgeons influenced patients' answers to the questionnaires or the primary endpoint. The sample size enrolled in the randomized trial is small, and the statistical analysis could be impacted, as small differences could not reach the significany.

Our study also has several strengths. As patients were enrolled in a randomized trial, their follow-up was prospective and rigorous, leading to the absence of any patient lost definitively during follow-up. Only experienced gynecologic surgeons and general surgeons performed surgery. Four conservative procedures were used to treat patients allocated to the conservative surgery arm. However, we estimated that each conservative procedure would have a comparable impact on functional outcomes, as all four procedures allowed for systematic preservation of the mesorectum, with only limited variation of the length of rectum and the volume of rectal reservoir. Last but not least, the study focuses on a question of major interest in the dynamic topic of the management of deep endometriosis.

Previous studies assessed postoperative digestive function using standardised questionnaires and showed that complete removal of large deep endometriosis infiltrating the rectum does not guarantee the relief of digestive complaints [1,9,10]. However, predictive factors of abnormal bowel movements have not yet been identified. Riiskjaer et al observed that patients with anastomotic leakage were more likely to have postoperative anal incontinence [9], but we were not able to test this factor in our sample, as only 2 rectovaginal fistulas occurred in our patients [1].

In previous retrospective studies, we observed that surgery for rectal endometriosis may not significantly improve baseline constipation, regardless of the surgical technique used, i.e. rectal shaving [11,12], disc excision [13] or colorectal resection [2]. This information should be discussed preoperatively, particularly with patients for whom constipation is one of the symptoms indicating surgery. The mechanism of this symptom may be multifactorial. Constipation by slow stool progression through the left colon and rectum may be a result of the dysfunction of splanchnic nerves and inferior hypogastric plexus, by either deep endometriosis or excessively radical surgery [14–18]. Despite the use of nerve-sparing techniques [19], the function of the inferior hypogastric plexus and splanchnic nerves may not be systematically preserved, resulting in bowel and bladder function discomfort [14]. As patients with colorectal endometriosis may present preoperatively with rectal or bladder dysfunction [20], i.e. anal and urethral sphincter hypertonia, this discomfort may still be present postoperatively and may not be restored by complete removal of deep endometriosis. We found an immediate and significant

postoperative improvement in the scores used to assess main and secondary endpoints, which remained stable for up to 24 months (except for the constipation score). Both the overall and the gastrointestinal quality of life scores (SF36 and GIQLI) improved significantly within 6 months after surgery. Anal continence (Wexner score) also improved, and pelvic pain related to endometriosis (Biberoglou & Behrman score) was significantly reduced. Other authors reported similar trends in patients managed by colorectal resection for deep endometriosis by open route [21]. Together, all these results suggest that surgery is a valuable tool in the overall management of patients with colorectal endometriosis and suffering from gastrointestinal and painful complaints related to their deep endometriosis infiltrating the rectum.`

Our results demonstrate that surgery is followed by a significant improvement of overall parameters concerning the quality of life, gastrointestinal and urinary scores. This improvement was not only statistically significant, but also clinically relevant, as the reduction of the number of patients presenting the main outcomes decreased by more than 50%, while the median values of Biberoglou and Behrman, KESS and GIQLI scores improved by 75%, 50 and 30% respectively. All scores' variations were concordant with a general health improvement. Our findings are consistent with those previously reported by other teams, suggesting an overall benefit related to the surgery of deep endometriosis infiltrating the rectum [9,21].

It also should be emphasized that some patients presented preoperatively with discomfort related to subjective bladder voiding, revealed by abnormal values of the baseline USP score. Although nine patients presented immediate postoperative bladder dysfunction requiring self-catheterization for several weeks, the overall values of USP score significantly improved after surgery, suggesting a tendency towards the restoration of bladder function after surgery along with a regression of subjective dysuria.

In conclusion, our study suggests that baseline severe constipation is the main preoperative factor, which negatively impacts the functional outcomes of surgery for deep endometriosis involving the rectum. However, rectal surgery by either conservative procedures or segmental resection allows an overall significant improvement in pelvic pain, gastrointestinal complaints and discomfort related to subjective bladder voiding, particularly in patients free from severe constipation. This improvement was observed shortly after surgery and remained stable up to 24 months postoperatively, except for constipation. Our data suggest that symptomatic patients may benefit from laparoscopic surgery for deep endometriosis infiltrating the rectum with favorable functional outcomes.

Conflict of interest

The authors declare no competing interests related to this study.

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