

Long-Term Outcomes of the Excluded Rectum in Crohn's Disease: A Multicenter International Study

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Background: Many patients with Crohn's disease (CD) require fecal diversion. To understand the long-term outcomes, we performed a multicenter review of the experience with retained excluded rectums.

Methods: We reviewed the medical records of all CD patients between 1990 and 2014 who had undergone diversionary surgery with retention of the excluded rectum for at least 6 months and who had at least 2 years of postoperative follow-up.

Results: From all the CD patients in the institutions' databases, there were 197 who met all our inclusion criteria. A total of 92 (46.7%) of 197 patients ultimately underwent subsequent proctectomy, while 105 (53.3%) still had retained rectums at time of last follow-up. Among these 105 patients with retained rectums, 50 (47.6%) underwent reanastomosis, while the other 55 (52.4%) retained excluded rectums. Of these 55 patients whose rectums remained excluded, 20 (36.4%) were symptom-free, but the other 35 (63.6%) were symptomatic. Among the 50 patients who had been reconnected, 28 (56%) were symptom-free, while 22 (44%) were symptomatic. From our entire cohort of 197 cases, 149 (75.6%) either ultimately lost their rectums or remained symptomatic with retained rectums, while only 28 (14.2%) of 197, and only 4 (5.9%) of 66 with initial perianal disease, were able to achieve reanastomosis without further problems. Four patients developed anorectal dysplasia or cancer.

Conclusions: In this multicenter cohort of patients with CD who had fecal diversion, fewer than 15%, and only 6% with perianal disease, achieved reanastomosis without experiencing disease persistence.

Lay Summary

Patients with distal Crohn's disease often undergo colon resection with a stoma to divert the intestinal stream from the rectum in hopes of achieving sufficient healing to allow ultimate re-establishment of intestinal continuity. Patients and practitioners alike should be aware of the long-term success rates of this procedure. Our retrospective study of 197 patients found that half required later proctectomy and an additional one-quarter remained symptomatic with excluded rectums. Only 14% remained symptom-free after reanastomosis, and only 6% if perianal disease was the initial surgical indication. These data provide estimation of long-term surgical outcomes.

Key Words: Crohn's Disease, Rectum, Surgery, Perianal disease

Introduction

Crohn's disease (CD) is a chronic progressing and debilitating disease.¹ Despite significant progress made in the treatment of CD, surgery remains an integral part of the overall treatment plan in patients with aggressive CD.² In some patients, exclusion of the rectum along with fecal diversion is needed as a temporary or permanent measure to control aggressive disease, including perianal complications.^{3,4}

CD patients who undergo a diverting ileostomy or colostomy often choose to keep this anatomy or may experience other delays in reconstructive operations, and hence may spend considerable periods of time with their rectums excluded from the intestinal stream.⁵ The fate of the excluded rectum is a particularly important issue because it determines the chance of a successful reconnection. Furthermore, carcinoma and other complications in the excluded rectal stump are persistent risks.^{6,7}

Previous studies of the fate of the excluded rectum in patients with CD have reported adverse outcomes including persistent disease activity, diversion proctitis, and dysplasia or cancer.⁸⁻¹² However, a number of these reports have experienced selection and recall bias, short-term follow-up, or exclusive focus on cancer. Furthermore, even those few studies that have avoided these pitfalls date mostly from the prebiologic era.

We therefore assembled a multicenter international cohort (Consortium to Assess the Prognosis of the Excluded Rectum) recording a full range of outcomes of excluded rectums in CD from the biologic era. Specifically, we have tabulated not only instances of cancer, but also other potential adverse results like bleeding, strictures, fistulae, abscesses, drainage, or other problems requiring local or systemic therapy, corrective operations, or even subsequent proctectomy.

Methods

This was a multicenter retrospective international cohort study that was approved by the Institutional Review Board at each respective institution. The cohorts were composed of CD patients followed at the respective institutions between 1990 and 2014, who had undergone diversionary surgery and who had retained excluded rectums for at least 6 months postoperatively. This latter stipulation was intended to eliminate most of those cases in whom a second-stage proctectomy or reanastomosis had been preplanned at the time of initial operation. Patients were identified using the International Classification of Diseases–Ninth Revision, International Classification of Diseases–10th Revision, clinical modification codes, and procedural codes. Patients who did not fulfill the inclusion criteria, who had ulcerative colitis or indeterminate colitis, or who did not have at least 2 years of postoperative follow-up were excluded. All but 2 of the patients had undergone colectomy at the time of the initial diversion.

The individual cohorts and numbers of cases from each center are outlined in [Table 1](#). As a group, these 8 centers constituted a Consortium to Assess Prognosis of the Excluded Rectum. Electronic medical records for all eligible patients were retrieved and reviewed by the study investigators to confirm eligibility of patients and to ascertain detailed medical and surgical data for each patient.

Variables

Baseline information was obtained from the medical charts including sex, smoking status, disease duration prior to diverting surgery, and duration of clinical follow-up. Disease characteristics prior to diverting surgery were collected including presence of perianal disease, presence of extraintestinal manifestation, prior exposure to azathioprine or 6-mercaptopurine, prior exposure to tumor necrosis factor inhibitors, prior exposure to vedolizumab, and prior history of bowel surgery. Disease localization and disease behavior prior to surgery were characterized based on the Montreal classification for CD.¹³ Age at time of diverting surgery was also recorded, and indications for diversion and rectal exclusion were assessed. Primary outcomes were determined at times of last follow-up, at least 2 years postdiversion. Rate of subsequent proctectomy, rate of rectal retention, outcomes of retained rectums whether excluded or reconnected, and symptoms reported in each group were reviewed and tabulated.

Statistical Analysis

We used categorical data in this study. All categorical variables were described in the form of proportions. Continuous variables were used for descriptive purposes and were reported as mean or median. As needed for continuous variables, comparisons were done using 2-sample *t* tests.

Results

A total of 197 patients meeting the inclusion criteria were identified across all academic institutions participating in this study. At Mount Sinai Hospital, 91 patients were found to meet inclusion criteria; 10 patients did not have sufficient follow-up data and were excluded, leaving a cohort of 81 patients. From the University of Chicago, 50 CD patients met the inclusion criteria. From the Humanitas University Rozzano Milano, 22 CD patients met the inclusion criteria. From the rest of the Mount Sinai Health System, excluding the main hospital, 69 CD patients were identified, of whom 21 met inclusion criteria. From Utrecht University, 6 CD patients met the inclusion criteria. From Weill Cornell Medical Center, 6 CD patients met the inclusion criteria. At the Northwell Health System, 9 CD patients were identified, of whom 6 met all inclusion criteria. From the NYU Health system, 5 CD patients met the inclusion criteria. Thus, overall, we identified 197 CD patients who had undergone fecal diversion, had retained an excluded rectum for at least 6 months, and had postoperative follow-ups of at least 2 years.

Baseline characteristics are listed in [Table 1](#). Baseline characteristics were very similar across all centers and are reported in detail as a Supplementary Table. Primary indications for diversionary surgery with rectal exclusion are shown in [Figure 1](#). About a third of the patients had undergone surgery for severe perianal disease 67 (34%), with another third for acute refractory bowel disease ($n = 75$, 38.5%); 35 (17.5%) for internal fistulas; 8 (4%) for bowel strictures; and 4 (2%) for known colon cancer.

Primary outcomes are outlined in [Figure 2](#). Of the 197 patients, 92 (46.7%) underwent subsequent proctectomy and the other 105 (53.3%) retained their rectums. With respect to the indication for subsequent proctectomy among the 92 patients who ultimately required this procedure, 39 (42.4%) patients needed

Table 1. Baseline characteristics of all patients that met inclusion criteria

General Characteristics	Overall Cohort (N = 197)
Sex	
Male	86 (44)
Female	111 (56)
Smoking status	
Current	21 (11)
Former	42 (21)
Never	115 (58)
Unknown	19 (10)
Localization of CD before surgery	
L1	11 (6)
L2	48 (24)
L3	129 (66)
Unknown	9 (5)
Disease behavior before surgery	
B1	28 (14)
B2	50 (25)
B3	101 (51)
Unknown	18 (9)
Perineal disease	125 (64)
History of bowel surgery	89 (45)
Extraintestinal manifestation	33 (17)
SPA	20
Erythema nodosum	4
Pyoderma gangrenosum	3
PSC	4
Uveitis	1
Episcleritis	1
CD duration before surgery, y	11.54 (0-31)
Previous exposure to tumor necrosis factor inhibitors	137 (70)
Previous exposure to azathioprine/6-mercaptopurine	111 (56)
Previous exposure to vedolizumab	14 (7)
Age at surgery, y	35.8 (13-80)
Follow-up period, y	9.2 (2-42)

Values are n (%), n, or median (interquartile range).

Abbreviations: CD, Crohn's disease; PSC, primary sclerosing cholangitis; SPA, spondyloarthritis.

subsequent proctectomy for worsening perianal disease, 21 (22.8%) for inadequate cancer surveillance in the rectal stump, 9 (9.8%) for severe anorectal stenosis, 9 (9.8%) on account of excessive soiling, 5 (5.4%) because of rectal bleeding, 3 (3.2%) owing to rectovaginal fistulas, 2 (2.2%) for persistent rectal pain, and 1 (1.1%) each for sexual dysfunction, rectal dysplasia, rectal cancer, and anal carcinoma.

With regard to the indication for initial diversion, patients in whom the indication for initial diversion was perianal disease, their likelihood of requiring subsequent proctectomy was 44 (66%) of 67 vs 48 (37%) of 130 among those who had undergone subsequent proctectomy for other indications ($P = .0001$). The details are outlined in Table 2.

Among the 44 patients who had undergone initial rectal exclusion for perianal disease and who had gone on to subsequent proctectomy, 30 (68%) required rectal excision for

ongoing perianal disease vs the other 14 (32%) whose subsequent proctectomy was performed for different reasons other than ongoing perianal disease ($P = .0008$).

Focusing on the 105 patients who retained their rectums, 50 (47.6%) had undergone reanastomosis and 55 (52.4%) continued to have their rectums excluded. Of those 50 patients who underwent reanastomosis, 22 (44%) were still symptomatic, while 28 (56%) were symptom-free at the time of last follow-up. Among the 55 patients who continued to have an excluded rectum, 20 (36.4%) were symptom-free, but the other 35 (63.6%) continued to experience problems: 16 (29%) had severe perianal disease, 8 (14.6%) had progressive fistulizing disease, 6 (11%) reported severe rectal discharge, 2 (3.6%) experienced severe sexual dysfunction, and 1 (1.8%) each had anal stenosis, chronic abdominal and pelvic pain, and anal carcinoma.

In summary, the goal of the original diversionary surgery to retain the rectum and be symptom-free was achieved in 48 (24.4%) of 197 patients, while 149 (75.6%) either ultimately lost their rectums or remained symptomatic with retained rectums, either reconnected or excluded.

Moreover, when considering the "ideal outcome" that patients and clinicians might wish for, to be symptom-free with a reconnected rectum, only 28 (14.2%) of 197 of patients ultimately achieved that outcome. On further analysis, we found that only 4 (5.9%) of 67 patients whose initial surgical indication had been perianal disease attained symptom-free reanastomosis, vs 24 of 130 (18.4%) whose initial diverting operation had been for other reasons attained symptom-free reanastomosis ($P = .017$).

Finally, it is noteworthy that 4 (2%) patients in our cohort developed neoplasia: 1 case of rectal dysplasia, 1 case of rectal carcinoma, and 2 cases of anal carcinomas. The patient who developed rectal dysplasia had undergone initial diversion for rectal cancer; the other 3 had no prior neoplasia in their backgrounds.

Discussion

In this international multicenter cohort of patients with CD and fecal diversion, almost half of those who carried a retained rectum for over 6 months ultimately required subsequent proctectomy, and fewer than 15% ever reached an outcome of reanastomosis without ongoing problems. All but 2 of the patients had undergone colectomy at the time of the initial diversion. Diversions without colectomy were performed only as temporizing measures and resulted in reanastomosis within 6 months in all but 2 patients. Hence, all but 2 of our 197 cases had subtotal colectomies at the time of diversion because simple diversion alone was not expected to definitively resolve their distal colonic disease or perianal lesions.

These data are not only generally consistent among our several different cohorts, but the proctectomy figures are also in substantial agreement with prior reports. For example, one such study followed 69 patients with CD who underwent diversionary surgery between 1962 and 1997 and found that 37 (54%) patients required subsequent proctectomy within 2 years.¹⁴ Five other studies of such cases have also reported subsequent proctectomy rates of 30% to 68%.^{3,15-18}

Most recently, our colleagues in Utrecht published a landmark study of 167 patients with CD (none included in the present study), in whom a rectal stump had been left in situ for more than 12 months. Among the 105 patients in their cohort who responded to a questionnaire, 44 (42%) had

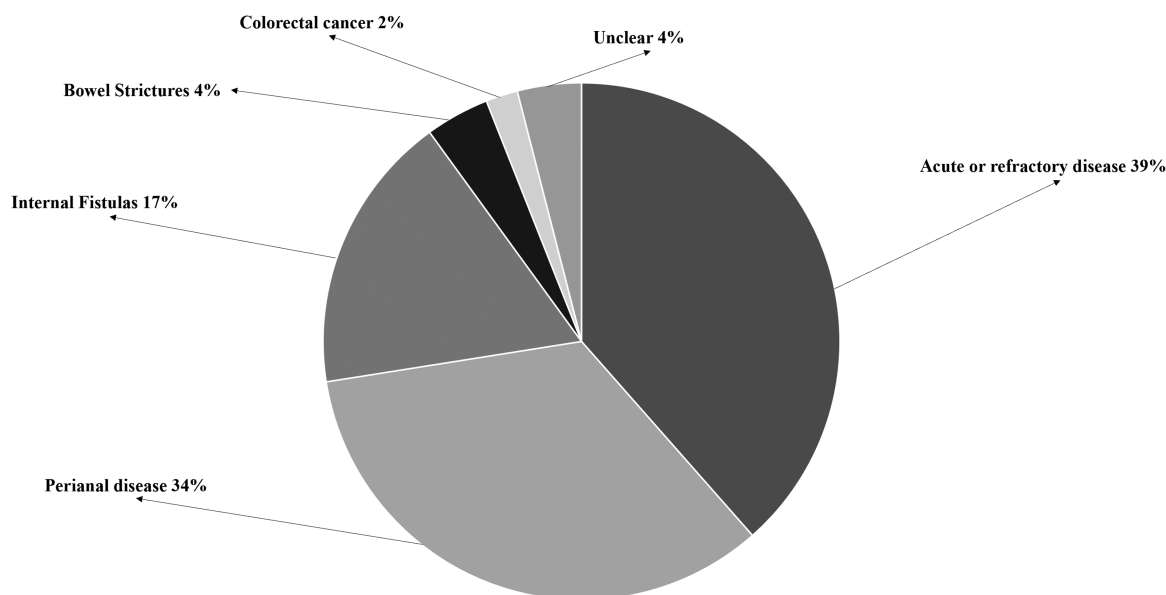


Figure 1. Primary indications for rectal exclusion.

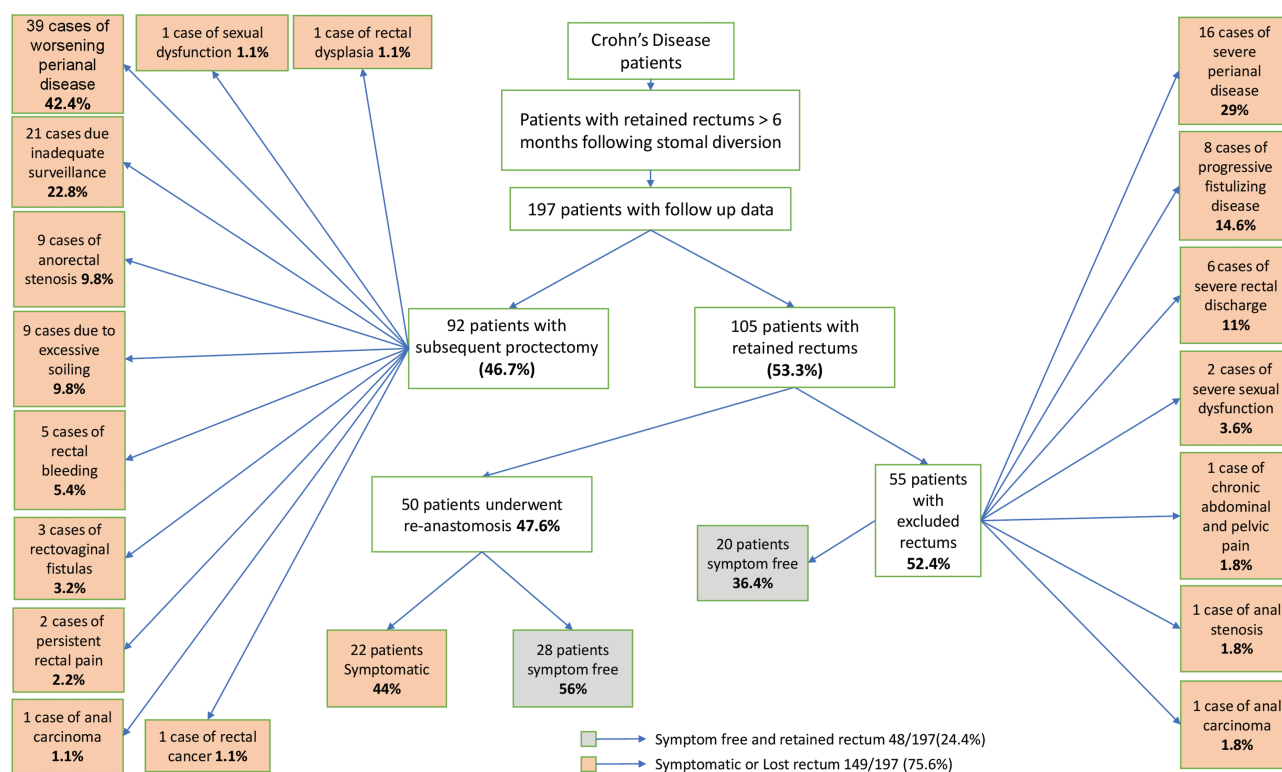


Figure 2. Primary outcomes for all patients who underwent diversionary surgery and who had retained excluded rectums for at least 6 months postoperatively.

undergone subsequent proctectomy.¹⁹ Our findings are also in line with those reported in a more recent study.²⁰

In addition to tabulating the ultimate rate of subsequent proctectomy in our series, we have also focused on the symptomatic outcomes of the individual patients. While about half of our total cohort were able to retain their rectums over the long term, only about half of those rectums remained symptom-free, including those reanastomosed and those permanently excluded. Of course, as the Utrecht group has

pointed out,¹⁹ many symptoms may simply reflect diversion proctitis and need not necessarily be disabling, but in this present series virtually all still required some ongoing treatment.

Equally noteworthy, it would appear from our data that the long-term fate of the excluded rectum depends to a significant extent on the original indication for the exclusion. The likelihood of requiring subsequent proctectomy was nearly twice as great when the initial reason for rectal diversion was

Table 2. Outcomes of patients who underwent diversion surgery for perianal disease vs those who underwent diversion surgery for all other indications

Indication for Diversion Surgery	Number of Patients	Subsequent Proctectomy Outcome	Retained Excluded Rectum Outcome	Reconnected Rectum Outcome	Percentage of Patients Who Underwent Subsequent Proctectomy
Mount Sinai Hospital					
Perianal disease	26	14	7	5	54%
All other indications	55	23	18	14	42%
University of Chicago					
Perianal disease	21	14	3	4	67%
All other indications	29	10	5	14	34%
Humanitas University Rozzano Milano					
Perianal disease	6	4	1	1	67%
All other indications	16	6	4	6	37%
Mount Sinai Health System					
Perianal disease	9	9	0	0	100%
All other indications	12	2	6	4	17%
Utrecht University					
Perianal disease	2	2	0	0	100%
All other indications	4	4	0	0	100%
Weill Cornell Medical Center					
Perianal disease	1	0	1	0	0%
All other indications	5	3	2	0	60%
Northwell Health system					
Perianal disease	2	1	0	1	50%
All other indications	4	0	3	1	0%
NYU Health system					
Perianal disease	0	0	0	0	0%
All other indications	5	0	5	0	0%
Total					
Perianal disease	67	44	12	11	66%
All other indications	130	48	43	39	37%

perianal disease, rather than for other indications ($P = .0001$). Moreover, if the indication for diversion had been perianal disease, the need for proctectomy was also dictated by perianal disease more than by other complications ($P = .0008$). With regard to the ideal outcome of ultimate restoration of bowel continuity without ongoing symptoms, the likelihood of such an outcome was lowest (5.9%) among patients who had had perianal disease as their initial surgical indications as compared with others (18.4%) ($P = .017$).

The strengths of this study are its multicenter design that included 8 major academic centers from the United States and Europe; the size of our overall cohort; the comprehensively inclusive and unselected composition of the databases, the uniformity of the selection criteria from the databases, the consistency of findings across the different cohorts, the inclusion of cases from the biologic era only, and the mean 10-year duration of the patient follow-up. This study, however, also entails substantial limitations. Prominent among them is the failure to include follow-up data on those patients who had undergone either early or delayed completion proctectomy, rendering it impossible to compare outcomes in patients with retained vs resected rectums. Also obvious is the inability to evaluate any of the medical therapies given to these patients, which might well have influenced their long-term outcomes. Moreover, other limitations of our study include its retrospective design, the small numbers in some of the subsets of the cohort, and the fact that most of the participating sites were tertiary referral centers, which might introduce selection bias. Nonetheless, our study provides real-life data for both patients and clinicians regarding the outcomes they can realistically anticipate from retention of excluded rectums for more than 6 months following initial diversionary surgery. It also calls attention to the presence of perianal disease as a relatively poor prognostic factor for the most desirable outcomes of rectal exclusion. Indeed, prior studies have likewise observed the low rate of successful restoration of bowel continuity following diversion for perianal CD.²¹

The neoplasia outcomes in 4 of these patients are important and are a reminder to clinicians that the retained but excluded rectum requires attention and monitoring. Future efforts will be needed to define how such surveillance would best be performed; in the meantime, a careful examination and individualized approach to follow-up seems prudent.

Conclusions

In our retrospective multicenter cohort study of CD patients with fecal diversion for over 6 months with an excluded rectum, fewer than 15%, and only 6% with perianal disease, achieved reanastomosis without experiencing disease persistence.

Supplementary Data

Supplementary data is available at *Inflammatory Bowel Diseases* online.

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Author Contribution

Research coordination and data extraction and consolidation at individual centers (A.D., A.R., N.N., C.T., A.C., A.M., E.C., M.M.C., M.S., F.D.L., N.B.D., J.t.H., M.R., E.E.). Advanced data analysis at individual centers (C.Y., M.M.C.H., D.L.). Supervising principal investigators at individual centers (D.T.R., A.S., S.D., B.O., K.S., J.A., E.S.). Oversight and consultation (J.-F.C.). Critical Review and editing of final manuscript (J.-F.C., D.T.R., K.S.S.). Principal investigator, overall data consolidation and analysis, manuscript author (G.K.). Research question, conception, design, analysis, and overall study supervision (D.B.S.).

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Conflicts of Interest

The authors have no conflicts of interest to disclose. The current manuscript, including related data and figures, has not been previously published and is not under consideration elsewhere.

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