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Is Intestinal Diversion an Effective Treatment for Distal Crohn's Disease?

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Background: Fecal diversion with an ileostomy is selectively used in cases of medically refractory Crohn's proctocolitis or advanced perianal disease. The aim of this study was to evaluate clinical improvement after fecal diversion in Crohn's disease (CD) and factors associated with clinical improvement.

Methods: A retrospective chart review of adult CD patients undergoing ileostomy formation for distal disease between 2000 and 2019 at 2 CD referral centers was conducted. The primary outcome was the rate of clinical improvement with diversion that allowed for successful restoration of intestinal continuity. Secondary outcomes included the rate of clinical and endoscopic improvement after fecal diversion, ileostomy morbidity, need for subsequent total proctocolectomy and end ileostomy, and factors associated with a clinical response to fecal diversion.

Results: A total of 132 patients with a median age of 36 years (interquartile range, 25–49) were included. Mean duration of disease was 16.2 years (10.4) years. Indication for surgery was medically refractory proctocolitis with perianal disease (n = 59; 45%), perianal disease alone (n = 24; 18%), colitis (n = 37; 28%), proctitis (n = 4; 3%), proctocolitis alone (n = 4; 3%), and ileitis with perianal disease (n = 4; 3%). Medications used before surgery included corticosteroids (n = 59; 45%), immunomodulators (n = 55; 42%) and biologics (n = 82; 62%). The clinical and endoscopic response to diversion was 43.2% (n = 57) and 23.9% (n = 16). At a median follow-up of 35.3 months (interquartile range, 10.6–74.5), 25 patients (19%) had improved and had ileostomy reversal, but 86 (65%) did not improve, with 50 (38%) undergoing total proctocolectomy for persistent symptoms. There were no significant predictors of clinical improvement.

Conclusions: The use of a "temporary" ileostomy is largely ineffective in achieving clinical response.

Key Words: fecal diversion, ileostomy, Crohn's proctocolitis, Crohn's perianal fistulizing disease

Introduction

Crohn's disease (CD) continues to increase in incidence for unknown reasons, now affecting up to 1 million people in the United States alone.[1,2] Despite the advent of biologic therapy with infliximab in 1998[1] and more recently, small molecule inhibitors in clinical trials, up to 60% to 80% of CD patients will require an intestinal resection for medically refractory disease. In patients with proctocolitis, a bowel resection includes a proctocolectomy with a permanent end ileostomy. Similarly, patients with perianal fistulizing disease, comprising nearly a quarter of all Crohn's patients,[2] are largely refractory to biologic therapy[3,4] with up to 90% requiring an operative intervention. Unfortunately, the list of operative interventions, including chronic seton placement,[4,5] rectal mucosal advancement flaps,[5,6] and ligation of intersphincteric fistula tract (LIFT) procedures,[7,8] are largely ineffective, and up to 40% of patients eventually undergo proctectomy with a permanent stoma for perianal disease.[9–11]

Intestinal diversion with loop ileostomy formation has been used as a less invasive, reversible surgical treatment strategy in medically refractory CD patients with distal disease, including proctocolitis and perianal fistulas.[12] It has been proposed that removal of the fecal stream in combination with optimized medical management can reduce disease burden, allowing for mucosal healing and closure of perianal fistula tracts.[13] However, the short-term and long-term efficacy of fecal diversion and risk factors for clinical response to diversion remain poorly described and controversial. Although 1 study of fecal diversion for medically refractory Crohn's proctocolitis suggested diversion with a "rescue ileostomy" was successful in reducing the morbidity of the inevitable later need for colectomy, it included too few patients to investigate the efficacy of diversion for colon salvage.[14] For perianal fistulizing disease, fecal diversion seems to improve quality of life scores,[15] and a handful of studies have suggested effective perianal healing,[16] but a meta-analysis of more recent studies reported restoration of intestinal continuity with perianal healing in only 17% of patients.[12]

Several studies have noted a lack of durable clinical remission with a diverting ileostomy for distal CD.[12] Interestingly, however, the use of a diverting ileostomy continues to increase in the United States for perianal CD.[17] Previous reports of fecal diversion for distal CD are largely from series limited by small sample size[15,18–21] and data before the introduction of

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biologic therapy.[13, 16, 22] We therefore aimed to combine data from 2 large inflammatory bowel disease (IBD) referral centers in the era of biologics to define the rate of clinical improvement with a diverting ileostomy and better understand the factors associated with a clinical improvement. We hypothesized that fecal diversion is not an effective treatment strategy, as has been previously proposed, even in the era of biologic therapy.

METHODS

After institutional review board approval, a retrospective chart review of all adult (≥18 years old) CD patients undergoing an ileostomy between January 1, 2000, and January 1, 2019, at Cleveland Clinic, Cleveland, Ohio, and Cedars-Sinai Medical Center, Los Angeles, California, was conducted. Patients were included if they underwent intestinal diversion alone with an ileostomy for distal CD including proctocolitis, colitis alone, proctitis alone, or perianal disease including anal canal stenosis, perianal fistula, or rectovaginal fistulas. Patients undergoing additional operative intervention such as simultaneous bowel resection or strictureplasty or a resection with primary anastomosis in which diversion was performed to protect the anastomosis were excluded.

Data collected included patient demographics, duration of CD, medications before diversion, serum laboratory values at the time of diversion, indication for diversion, clinical response after diversion, endoscopic response following diversion, morbidity of fecal diversion related to ileostomy complications, need for more definitive operation after diversion with total proctocolectomy and end ileostomy, and final clinical status at the date of last follow-up. The primary outcome was the rate of clinical improvement with the ability to successful restore intestinal continuity. Secondary outcomes included clinical response to diversion defined as improvement in clinical symptoms upon diversion, endoscopic response to diversion defined as improvement in mucosal inflammation on repeat endoscopy post-fecal diversion, clinical improvement but unable to reverse the ileostomy, ileostomy morbidity, need for more definitive surgical intervention with total proctocolectomy and end ileostomy, and factors associated with clinical improvement.

Statistical Analysis

All relevant demographic, disease phenotype, and outcomes were presented as mean (standard deviation), median (25th, 75th percentiles), or frequency (percent). Univariate analyses were conducted to examine the association between patient characteristics and improvement. The *t* test or nonparametric Wilcoxon rank sum tests was used for continuous factors, χ^2 test or Fisher exact test was used for categorical variables, and Wilcoxon rank sum tests was used to compare ordinal factors between patients with and without clinical improvement. All comparisons were made at a significance level of 0.05, and all analyses were performed with R version 3.6.1.

RESULTS

A total of 132 adult CD patients who underwent a diverting loop ileostomy for distal CD were included in the analysis. The median age at the time of surgery was 36 years (interquartile range [IQR], 25–49 years), and 65 (49%) were female. The median body mass index (BMI) was 22.7 (IQR, 20.1, 27.8), and 19 (14.4%) were actively smoking at the time of surgery. Twenty-five (18.9%) had a family history of inflammatory bowel disease. Patients were diagnosed with CD at a median age of 25 years (IQR, 17–35), with a total CD disease duration at the time of ileostomy a mean of 16.2 years (SD, 10.4 years). A small number of patients had concomitant extraintestinal manifestations of CD, including polyarthritis (n = 13; 9.85%), pyoderma gangrenosum (n = 1; 0.76%), and iritis (n = 1; 0.76%; Table 1).

Patients were diverted for medically refractory proctocolitis and perianal disease (n = 59; 44.7%), colitis alone (n = 37; 28%), perianal fistulizing disease alone (n = 24; 18.2%), proctitis alone (n = 4; 3.0%), and terminal ileitis with perianal disease (n = 4; 3.0%). Nearly one third of patients diverted had concurrent small bowel disease in the ileum. At the time of fecal diversion, 59 (44.7%) had been exposed to corticosteroids within 4 weeks of surgery, 55 (41.7%) were exposed to an immunomodulator within 4 weeks of surgery, and 82 (62.1%) were exposed to a biologic within 12 weeks of surgery.

Preoperative serum laboratories showed most patients had adequate serum protein levels and were not severely anemic at the time of fecal diversion (Table 2).

After fecal diversion, 32 patients (24.2%) experienced stoma morbidity, with the most common being a peristomal abscess requiring drainage (n = 8; 6.1%), parastomal hernia (n = 7; 5.3%), and stomal prolapse (n = 7; 5.3%). The clinical response to diversion was 43.2% (n = 57), and the endoscopic response to diversion, assessed in 67 patients, was 23.9% (n = 16). In these initial clinical and endoscopic responders, 23.9% (n = 16) relapsed with recurrence of symptoms. At a median follow-up of 35.3 months (IQR, 10.6–74.5), the final clinical status was that 25 patients (18.9%) had improved and were able to establish restoration of intestinal continuity with ileostomy reversal. Another 21 patients had clinical improvement but had not yet reversed their ileostomy. Thus, a total of 65.2% (n = 86) did not improve with fecal diversion and had persistent perianal disease (21.2%), had colitis (n = 7; 5.3%), had proctitis (n = 1; 0.76%), still had the

Table 1. Patient Demographics

	N = 132
Age at surgery, in years	36.0 (25.0;49.0)
Sex: Female	65 (49.2%)
BMI (kg/m^2)	22.7 (20.1;27.8)
Tobacco use at surgery	
Never	89 (67.4%)
Quit	24 (18.2%)
Active	19 (14.4%)
Age of onset of CD, in years	25.0 (17.0;35.0)
Total CD disease duration, in years	16.2 (10.4)
Family history of inflammatory bowel disease	25 (18.9%)
Any extraintestinal manifestations of IBD	
No	117 (88.6%)
Polyarthritis	13 (9.85%)
Pyoderma gangrenosum	1 (0.76%)
Iritis	1 (0.76%)

First numerals in parenthetical phrases with semicolons denote IQR.

Table 2. Disease Phenotype

	N = 132
Crohn's Disease Location	
Proctocolitis + perianal disease	59 (44.7%)
Colitis	37 (28.0%)
Perianal disease alone	24 (18.2%)
Ileitis with perianal disease	4 (3.03%)
Proctitis	4 (3.03%)
Proctocolitis	4 (3.03%)
Concurrent small bowel disease	40 (30.3%)
Any corticosteroids within 4 weeks of surgery	59 (44.7%)
Immunomodulator within 4 weeks of surgery	55 (41.7%)
6 mercaptopurine	30 (22.7%)
azathioprine	12 (9.09%)
methotrexate	13 (9.85%)
Any biologic within 12 weeks of surgery	82 (62.1%)
Adalimumab	28 (21.2%)
Infliximab	16 (12.1%)
Certolizumab	12 (9.09%)
Ustekinumab	13 (9.85%)
Vedolizumab	13 (9.85%)
Preoperative albumin	3.70 (3.10;4.10)
Preoperative WBC	8.68 (6.50;11.3)
Preoperative hemoglobin	11.1 (1.95)
Preoperative hematocrit	35.6 (5.82)
Preoperative platelet	358 (293;457)

First numerals in parenthetical phrases with semicolons denote IQR.

Table 3. Surgical Outcomes

	N = 132
Follow-up (months)	35.3 (10.6;74.5)
Morbidity of Stoma:	
No	100 (75.8%)
Peristomal abscess requiring drainage	8 (6.06%)
Parastomal hernia	7 (5.30%)
Prolapse	7 (5.30%)
Leaking	4 (3.03%)
Pyoderma gangrenosum	2 (1.52%)
Bleeding	1 (0.76%)
Granuloma	1 (0.76%)
Necrosis	1 (0.76%)
Retraction	1 (0.76%)
Clinical Response to Diversion	57 (43.2%)
Endoscopic Response to Diversion	53 (53.0%)
Relapse in the Initial Clinical/Endoscopic Responders	16 (23.9%)
Patient Clinical Status at Date of Last Follow-up	
Colitis	7 (5.30%)
Persistent perianal disease	28 (21.2%)
Proctitis	1 (0.76%)
Stoma in place	21 (15.9%)
Total proctocolectomy and end ileostomy	50 (37.9%)
Improved	46 (34.8%)
Improved andstoma closed	25 (18.9%)

First numerals in parenthetical phrases with semicolons denote IQR.

ileostomy in place (n = 21; 15.9%), or had undergone a total proctocolectomy with end ileostomy due to persistent symptoms (n = 50; 37.9%; Table 3).

There were no identified risk factors for clinical improvement with fecal diversion, such as age, sex, BMI, tobacco use, disease duration, family history of IBD, extraintestinal manifestations, location of CD, concurrent small bowel disease, prefecal diversion medications, prefecal diversion serum laboratories, or initial clinical and endoscopic response to diversion (Table 4). When comparing CD patients diverted for medically refractory luminal disease (ileitis, colitis, proctitis, proctocolitis) with CD patients who were diverted for isolated perianal fistulizing disease and CD patients diverted for simultaneous proctocolitis with perianal fistulizing disease, there were no significant differences in the rate of clinical response with diversion (Table 5) or rate of subsequent total proctocolectomy and end ileostomy (Table 6).

Discussion

Despite biologic therapy, the majority of CD patients with distal disease including proctocolitis and perianal fistulizing disease will require surgical intervention.[3, 4] Though local perianal surgery may be effective in select patients with isolated perianal disease, the majority of operative interventions for distal CD results in a proctectomy and permanent stoma—an operation the majority of patients resist until all other medical and surgical options have proven ineffective. Fecal diversion with a loop ileostomy presents a less invasive and potentially "temporary" treatment strategy that allows the fecal stream to be diverted away from the areas of most severe disease. Early series suggested this was an effective treatment strategy for distal CD.[23, 24] However, more recent data have suggested that restoration of intestinal continuity occurs in a limited number of patients.[9, 16, 19, 21, 25] In the largest multicenter series to date, we found that only a third of patients improved with fecal diversion, and of these, only half had successful restoration of intestinal continuity.

Fecal diversion for Crohn's colitis in the biologic drug era remains largely unstudied, with series reporting data from the 1960s and 1970s.[23, 24] One recent study of a rescue ileostomy for medically refractory ulcerative colitis and Crohn's colitis included 14 patients with CD. Although the study reported that a rescue ileostomy avoided an emergent colectomy and decreased complication rates with the patients' subsequent colectomy, there were too few patients included to understand whether this was an effective treatment strategy for colon salvage.[14] In our series of 45 patients (34%) with isolated Crohn's colitis and/or proctitis without perianal fistulizing disease, 19 (42.2%) had clinical improvement with fecal diversion, which was not significantly different than those with isolated perianal fistulizing disease (37.5%) or proctocolitis with perianal fistulizing disease (25.4%). Of the 26 patients that did not respond, 15 (58%) have since undergone a proctocolectomy and end ileostomy in our study follow-up period, suggesting that a temporary ileostomy is really only a bridge to more definitive surgery.

The use of fecal diversion for perianal fistulizing disease has been evaluated in a greater number of series; although again, these have been limited by representing single-center

Table 4. Univariate Analysis Across Clinical Improvement

	ALL	Improvement	Nonimprovement	*P*
	N = 132 (100%)	N = 46 (34.8%)	N = 86 (65%)	
Age at surgery	36.0 (25.0;49.0)	37.0 (27.0;47.5)	35.5 (24.2;49.0)	0.65
Sex: Female	65 (49.2%)	21 (45.7%)	44 (51.2%)	0.67
BMI	22.7 (20.1;27.8)	21.5 (19.5;27.8)	23.0 (20.2;28.4)	0.60
Tobacco use at surgery				0.400
Never	89 (67.4%)	33 (71.7%)	56 (65.1%)	
Quit	24 (18.2%)	8 (17.4%)	16 (18.6%)	
Active	19 (14.4%)	5 (10.9%)	14 (16.3%)	
Age onset of CD	25.0 (17.0;35.0)	25.5 (17.0;34.0)	25.0 (17.0;35.0)	0.923
Total CD disease duration	16.2 (10.4)	17.1 (10.7)	15.7 (10.3)	0.47
Family history of inflammatory bowel disease	25 (18.9%)	8 (17.4%)	17 (19.8%)	0.92
Any extraintestinal manifestations of IBD				1.000
Iritis	1 (0.76%)	0 (0.00%)	1 (1.16%)	
No	117 (88.6%)	42 (91.3%)	75 (87.2%)	
Polyarthritis	13 (9.85%)	4 (8.70%)	9 (10.5%)	
Pyoderma gangrenosum	1 (0.76%)	0 (0.00%)	1 (1.16%)	
Crohn's Disease Location				0.070
Colitis	37 (28.0%)	17 (37.0%)	20 (23.3%)	
Ileitis + perianal disease	4 (3.03%)	3 (6.52%)	1 (1.16%)	
Proctitis	4 (3.03%)	2 (4.35%)	2 (2.33%)	
Proctocolitis	4 (3.03%)	0 (0.00%)	4 (4.65%)	
Proctocolitis + perianal disease	59 (44.7%)	15 (32.6%)	44 (51.2%)	
Perianal disease alone	24 (18.2%)	9 (19.6%)	15 (17.4%)	
Concurrent small bowel disease	40 (30.3%)	18 (39.1%)	22 (25.6%)	0.16
Any corticosteroids within 4 weeks of surgery	59 (44.7%)	23 (50.0%)	36 (41.9%)	0.48
Any biologic within 12 weeks of surgery	82 (62.1%)	27 (58.7%)	55 (64.0%)	0.69
6 mercaptopurine within 4 weeks of surgery	30 (22.7%)	10 (21.7%)	20 (23.3%)	1.000
Azathioprine within 4 weeks of surgery	12 (9.09%)	1 (2.17%)	11 (12.8%)	0.06
Methotrexate within 4 weeks of surgery	13 (9.85%)	4 (8.70%)	9 (10.5%)	1.000
Preoperative serum albumin	3.70 (3.10;4.10)	3.70 (3.45;4.00)	3.60 (3.10;4.10)	0.56
Preoperative serum hematocrit	35.6 (5.82)	35.7 (6.23)	35.5 (5.64)	0.83
Preoperative serum hemoglobin	11.1 (1.95)	11.2 (2.46)	11.1 (1.79)	0.81
Preoperative serum WBC	8.68 (6.50;11.3)	8.10 (5.99;10.5)	8.95 (6.54;11.6)	0.46
Preoperative serum platelet	358 (293;457)	319 (262;448)	372 (311;463)	0.07
Clinical response to diversion	57 (43.2%)	40 (87.0%)	17 (19.8%)	<0.001
Endoscopic response to diversion	53 (53.0%)	32 (82.1%)	21 (34.4%)	<0.001
Relapse in initial responders	16 (23.9%)	4 (10.8%)	12 (40.0%)	0.01

First numerals in parenthetical phrases with semicolons denote IQR.

Table 5. Clinical Response Based on Crohn's Disease Phenotype

	ALL	Improved	Nonimproved	*P*
	N = 128 (100%)	N = 43 (33.6%)	N = 85 (66.4%)	
Crohn's Disease Site[a]				0.18
Luminal disease	45 (35.2%)	19 (42.2%)	26 (57.8%)	
Perianal disease alone	24 (18.8%)	9 (37.5%)	15 (62.5%)	
Proctocolitis + perianal disease	59 (46.1%)	15 (25.4%)	44 (74.6%)	

[a]Luminal disease included colitis, proctitis and proctocolitis; perianal disease included perianal disease alone and perianal disease with proctocolitis

case series with small sample sizes before the era of biologics. Initial series from the 1960s to 1990s suggested that, if diverted, reversal of the ileostomy should not be performed due to the lack of sustained remission upon restoration of intestinal continuity.[13, 22–24, 26, 27] More recent data in the 2000s has reported variable success rates.[9, 16, 19, 21, 25] A sys-

Table 6. Total Proctocolectomy with End Ileostomy Based on Crohn's Disease Phenotype

	ALL	NON TPC EI	TPC EI	*P*
	N = 128 (100%)	*N = 79 (33.6%)*	*N = 49 (66.4%)*	
Crohn's Disease Site[a]				0.11
Luminal disease	45 (35.2%)	30 (66.7%)	15 (33.3%)	
Perianal disease alone	24 (18.8%)	18 (75.0%)	6 (25.0%)	
Proctocolitis + perianal disease	59 (46.1%)	31 (52.5%)	28 (47.5%)	

[a]Luminal disease included colitis, proctitis, and proctocolitis; perianal disease included perianal disease alone and perianal disease with proctocolitis

tematic review and meta-analysis including many of these studies (n = 556) found that 64% of patients experienced an early clinical response with perianal healing.[12] However, only 17% of patients had a successful restoration of bowel continuity; and of these patients, 27% required rediversion or multiple subsequent interventions to treat their fistulas. Ultimately, 42% of patients required a proctectomy, suggesting diversion was not an adequate long-term treatment strategy.[12] Regardless, temporary diversion is still used as a treatment strategy to improve patients' quality of life, allow patients to "practice" having an ileostomy, and bridge them to a more definitive permanent ileostomy. However, it is important to consider that even though clinicians see this as a less definitive, less invasive approach, many patients do not respond clinically or endoscopically and may continue to suffer from symptomatic disease requiring ongoing perineal surgery and immunosuppressive medications until they are physiologically optimized and emotionally ready to accept a total proctocolectomy. In our series, we found only 37.5% of patients with isolated perianal fistulizing disease had clinical improvement, with the majority having worsening symptoms and 25% eventually undergoing a proctocolectomy for symptom resolution.

If we could predict which patients comprise the one third who do improve, use of a diverting ileostomy would be a much more effective treatment approach. Limited studies have investigated risk factors for failure of diversion with an ileostomy. One series of 97 patients followed for 16 years from the first diagnosis of CD reported that patients with complicated perianal disease, colorectal resection, and fecal incontinence were at highest risk for permanent fecal diversion.[9] Another series of 138 diverted patients found proctitis and the need for loose seton placement was associated with the need for permanent diversion.[28] Similar to these single-center series, the largest cohort of patients (n = 556) from the previously mentioned systematic review found proctitis was a significant risk factor for unsuccessful restoration of intestinal continuity.[12] Unfortunately, despite being a larger series, we were unable to identify any significant risk factors for clinical improvement, limiting our ability to selectively use fecal diversion as an effective treatment strategy. Interestingly, though the rates of nonimprovement (74.6%) and need for subsequent total procotocolectomy with end ileostomy (47.5%) were not significant among Crohn's phenotypes in our series, those patients with perianal fistulizing disease *and* panproctocolitis had the highest rates of nonimprovement and subsequent proctocolectomy with end ileostomy. This suggests that those with combined luminal and perianal fistulizing disease may be the least likely to respond to a management strategy of fecal diversion, and a more definitive approach should be taken initially.

One might predict that the use of biologics would have a synergistic effect on mucosal healing with fecal diversion. However, the addition of biologics to fecal diversion has not been shown to improve the clinical success of fecal diversion. In 2 series including patients from the era of biologic therapy, both reported no difference in successful restoration of intestinal continuity in patients treated with biologic therapy vs those not exposed to biologic therapy.[19, 28] In our own series, 62% of patients were exposed to biologic therapy prefecal diversion; and regardless of the majority being exposed to biologics, there was no difference in clinical improvement if exposed to biologic therapy or not. Similarly, we found no difference in clinical improvement if exposed to corticosteroids or immunomodulators. In the aforementioned series of rescue ileostomy for refractory colitis, of the 14 CD patients, 3 were able to achieve colon salvage with restoration of intestinal continuity, and all 3 were biologic naïve at the time of their rescue ileostomy.[14] Thus, perhaps biologic-naïve patients would be the cohort to have improved outcomes with fecal diversion if exposed to biologic therapy for the first time after fecal diversion. However, this was not investigated in this series but could be considered in future prospective evaluation.

Although this represents the largest series to date, including data from 2 IBD referral centers, there are limitations worth mentioning. First, this is a retrospective chart review of CD patients, which inherently limits the ability to collect data that may have been accessible if assessed in a prospective manner. For example, endoscopy after diversion was not routinely performed at a particular time point after fecal diversion. Thus, we do not have the endoscopic disease response at 3, 6, or 12 months after diversion. We also do not have consistent clinical and endoscopic assessment with validated scoring systems such as the Crohn's disease activity index or simple endoscopic severity score for Crohn's disease. In addition, the optimal end point in this situation is (improvement in) patient quality of life, which is the proximate rationale for pursuing fecal diversion, and the retrospective nature of this study precluded assessment of quality of life. Second, our results may not be applicable to other centers that might see less severe or more severe distal CD. Third, we do not have follow-up past 75 months, during which time more patients may have had either improvement with restoration of intestinal continuity or worsening disease with total proctocolectomy and end ileostomy.

In conclusion, the use of a diverting ileostomy for distal Crohn's disease is largely ineffective, with the majority of patients having persistent disease or requiring a more definitive total proctocolectomy.

Conflicts of Interest

AL and PF areconsultants for Takeda. SH is a consultatnt for Shinogi and Takeda.

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