"MEDICAL THERAPY IN REFRACTORY IBD: WHEN ENOUGH IS ENOUGH?"

Ulcerative colitis

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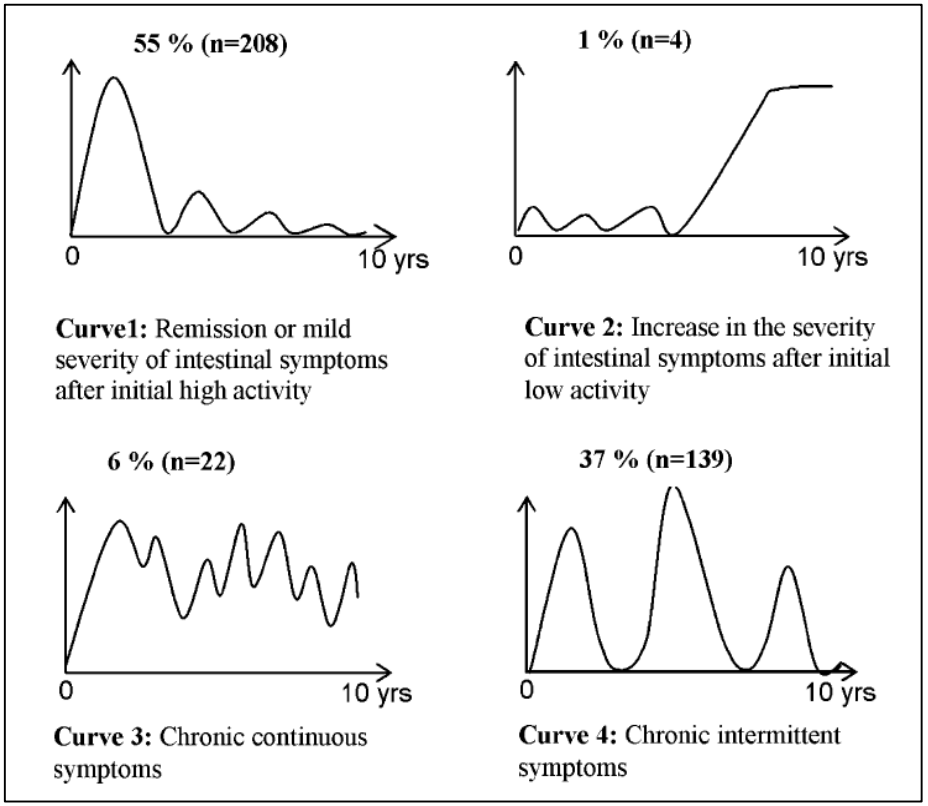
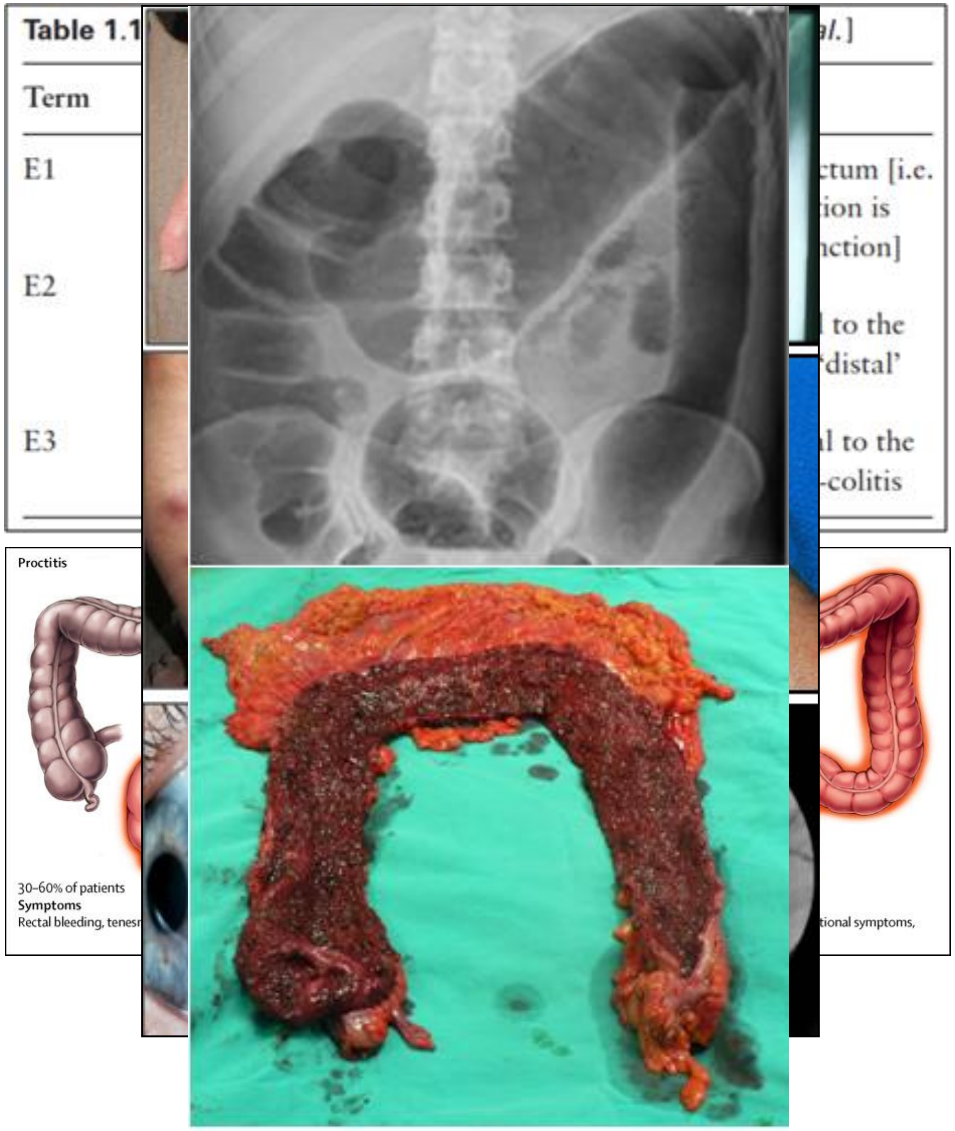
ULCERATIVE COLITIS





Solberg IC et al. Scand J Gastroenterol 2009;44:431-440

ULCERATIVE COLITIS

Table 5 Colectomy rates in acute severe and moderate-to-severe ulcerative colitis reported in the literature

Type of study	Patient population	Follow up	Colectomy rates	Reference
Randomised, controlled trial	ASUC	3 months	7/24 (29%) – infliximab 14/21 (67%) – placebo *P* = 0.017	Järnerot *et al*.[7]
Randomised controlled trial	ASUC	24 months	11/24 (46%) – infliximab 16/21 (76%) – placebo *P* = 0.008	Gustavsson *et al*.[11]
Randomised, controlled trial	ASUC	98 days	12/57 (21%) – infliximab 10/58 (17%) – ciclosporin	Laharie *et al*.[8]
Randomised, controlled trial	Moderate-to-severe UC	54 weeks	10% – infliximab 17% – placebo *P = 0.02*	Sandborn *et al*.[3]
Retrospective observational study	Moderate-to-severe UC	33 months	21/121 (17%) – infliximab	Ferrante *et al*.[4]
Retrospective observational study	Moderate-to-severe UC	15 months	7/38 (18%) – infliximab	Russo *et al*.[12]
Retrospective observational study	Moderate-to-severe UC	205 days	11/48 (23%) – adalimumab (39/48 previous infliximab)	García-Bosch *et al*.[13]

ASUC, acute severe ulcerative colitis; UC, ulcerative colitis.

Subramaniam K et al. Intern Med J. 2014 ;44:464-70

ULCERATIVE COLITIS

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ASUC, acute severe ulcerative colitis; UC, ulcerative colitis.

Subramaniam K et al. Intern Med J. 2014 ;44:464-70

IBD TREATMENT-THE HISTORY

1955

BRITISH MEDICAL JOURNAL

LONDON SATURDAY OCTOBER 29 1955

CORTISONE IN ULCERATIVE COLITIS

FINAL REPORT ON A THERAPEUTIC TRIAL

BY

S. C. TRUELOVE, M.D., M.R.C.P. AND L. J. WITTS, M.D., F.R.C.P.

Nuffield Department of Clinical Medicine, Radcliffe Infirmary, Oxford

With the co-operation of Professor R. E. TUNBRIDGE and Dr. G. WATKINSON (Leeds), Dr. F. AVERY JONES and Dr. RICHARD DOLL (North-west London), Professor T. L. HARDY and Dr. C. R. ST. JOHNSTON (Birmingham), Dr. W. I. CARD and Dr. MAXWELL WILSON (Edinburgh), and Sir JOHN TAYLOR (Medical Research Council)

In a preliminary report (Truelove and Witts, 1954) we have given the immediate results of a controlled trial of cortisone in the treatment of chronic ulcerative colitis. In the present paper it is intended to fill in some of the details about the immediate results and to report on the subsequent progress of the patients. The trial was confined to typical cases of chronic ulcerative colitis which would normally be expected to require at least six weeks' treatment in hospital, and patients with regional colitis, ileitis, or proctitis were not included. A total of 213 patients received treatment. Of these, three have been rejected from the analysis of results for the following reasons: one patient proved to be suffering from carcinoma of the colon, one had had a colostomy, and in the third the records were inadequate. Of the remaining 210 patients, 109 received cortisone and 101 received the dummy preparation.

Diagnosis.—The diagnosis was established by the following criteria: (1) History. (2) Character of stools. (3) Sigmoidoscopy (in very ill patients, proctoscopy was regarded as sufficient). (4) Barium enema, except when the patient was gravely ill. (5) Absence of known pathogens in the stools.

First Attacks and Relapses.—First attacks and relapses were handled separately in the design of the master sheets because previous work suggested that their prognosis might be different. Physicians were asked to classify the illness as a relapse when the patient had previously had an attack of bloody diarrhoea without evidence of a specific infection such as bacillary dysentery. In patients with the chronic continuous form of the disease the illness was classified as a relapse if the symptoms had lasted more than two years.

General Principles of Treatment.—In addition to the special tablets, patients received full therapy along the lines thought best by the physician in charge of them. The following general principles of treatment were agreed upon: (1) High protein, low residue diet with vitamin supplements. (2) Maintenance of water and electrolyte balance, if necessary by intravenous infusion. (3) Blood transfusions to maintain haemoglobin above 70%. (4) Sulphonamides and antibiotics at the discretion of the physician in charge. (5) Rectal instillations, likewise at the discretion of the physician in charge. (6) Surgery should not normally be required during the period of trial, and would usually imply that the patient had failed on medical treatment. (7) Other forms of treatment at the discretion of the physician in charge of the patient.

Dosage.—The actual dosage of cortisone used in the 109 patients who received it was as follows:

100 mg. a day for six weeks	38	patients
100 mg. a day for two to three weeks, followed by smaller doses of 50–75 mg. a day	38	,,
Doses exceeding 100 mg. a day	17	,,
Therapy for less than six weeks	16	,,

The patients in whom therapy was stopped before completion of the six-weeks period fell into two categories: first, those who were deteriorating on treatment; secondly, some of the patients who went into a remission rapidly after beginning cortisone.

PART A: SHORT-TERM RESULTS

The effect of treatment was assessed by placing patients into three categories at the end of six weeks' treatment. In the majority this was the *conclusion* of their treatment; a minority during the second half of the trial received treatment for a longer period than six weeks, and for convenience in assessing the results their condition at the end of six weeks has likewise been taken. In some patients the specific therapy was stopped before six weeks had passed, as noted above, and their condition has been assessed at the time when treatment was stopped. The three clinical categories were as follows:

Clinical Remission.—One or two stools a day without blood. No fever. No tachycardia. Haemoglobin normal or returning towards normal. E.S.R. normal or returning towards normal. Gaining weight. To be included in this category the patient was expected to show all the above features. In the great majority all these data were included in the records, but in some the data for haemoglobin, E.S.R., or weight were incomplete. In such cases all the available data had to conform to this schedule.

No Change or Worse.—Self-explanatory.

Improved.—All intermediate cases.

The results for the whole group are shown in Fig. 1 and Table I, which demonstrate that the patients receiving cortisone enjoyed a clear-cut advantage over the patients on

2019

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 SEPTEMBER 26, 2019 VOL. 381 NO. 13

Ustekinumab as Induction and Maintenance Therapy for Ulcerative Colitis

B.E. Sands, W.J. Sandborn, R. Panaccione, C.D. O'Brien, H. Zhang, J. Johanns, O.J. Adedokun, K. Li, L. Peyrin-Biroulet, G. Van Assche, S. Danese, S. Targan, M.T. Abreu, T. Hisamatsu, P. Szapary, and C. Marano, for the UNIFI Study Group*

ABSTRACT

BACKGROUND

The efficacy of ustekinumab, an antagonist of the p40 subunit of interleukin-12 and interleukin-23, as induction and maintenance therapy in patients with ulcerative colitis is unknown.

METHODS

We evaluated ustekinumab as 8-week induction therapy and 44-week maintenance therapy in patients with moderate-to-severe ulcerative colitis. A total of 961 patients were randomly assigned to receive an intravenous induction dose of ustekinumab (either 130 mg [320 patients] or a weight-range–based dose that approximated 6 mg per kilogram of body weight [322]) or placebo (319). Patients who had a response to induction therapy 8 weeks after administration of intravenous ustekinumab were randomly assigned again to receive subcutaneous maintenance injections of 90 mg of ustekinumab (either every 12 weeks [172 patients] or every 8 weeks [176]) or placebo (175). The primary end point in the induction trial (week 8) and the maintenance trial (week 44) was clinical remission (defined as a total score of ≤2 on the Mayo scale [range, 0 to 12, with higher scores indicating more severe disease] and no subscore >1 [range, 0 to 3] on any of the four Mayo scale components).

RESULTS

The percentage of patients who had clinical remission at week 8 among patients who received intravenous ustekinumab at a dose of 130 mg (15.6%) or 6 mg per kilogram (15.5%) was significantly higher than that among patients who received placebo (5.3%) (P<0.001 for both comparisons). Among patients who had a response to induction therapy with ustekinumab and underwent a second randomization, the percentage of patients who had clinical remission at week 44 was significantly higher among patients assigned to 90 mg of subcutaneous ustekinumab every 12 weeks (38.4%) or every 8 weeks (43.8%) than among those assigned to placebo (24.0%) (P=0.002 and P<0.001, respectively). The incidence of serious adverse events with ustekinumab was similar to that with placebo. Through 52 weeks of exposure, there were two deaths (one each from acute respiratory distress syndrome and hemorrhage from esophageal varices) and seven cases of cancer (one each of prostate, colon, renal papillary, and rectal cancer and three nonmelanoma skin cancers) among 825 patients who received ustekinumab and no deaths and one case of cancer (testicular cancer) among 319 patients who received placebo.

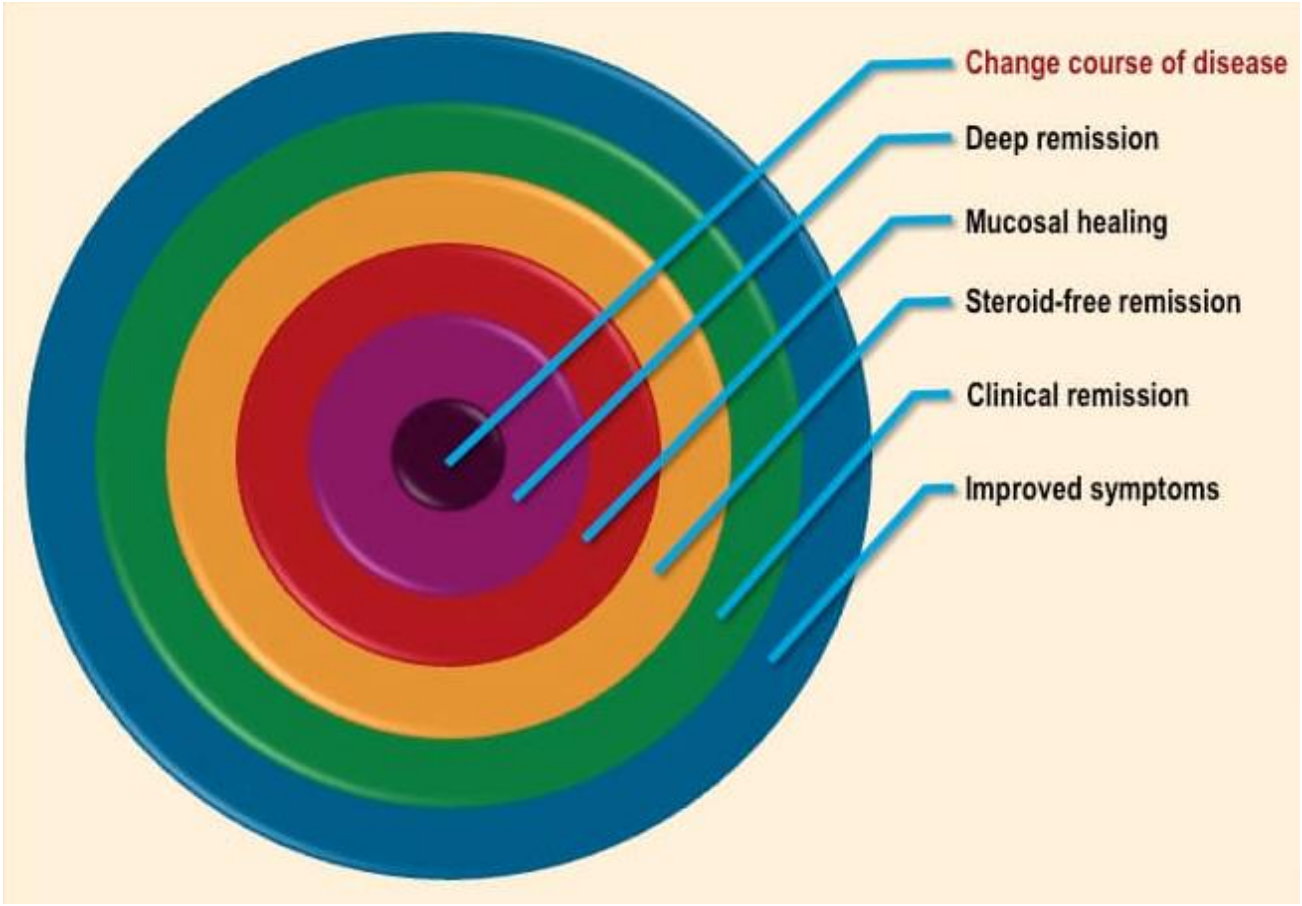
CONCLUSIONS

Ustekinumab was more effective than placebo for inducing and maintaining remission in patients with moderate-to-severe ulcerative colitis. (Funded by Janssen Research and Development; UNIFI ClinicalTrials.gov number, NCT02407236.)

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Address reprint requests to Dr. Sands at the Dr. Henry D. Janowitz Division of Gastroenterology, Icahn School of Medicine at Mount Sinai, 1 Gustave L. Levy Pl., Box 1069, New York, NY 10029, or at bruce.sands@mssm.edu.

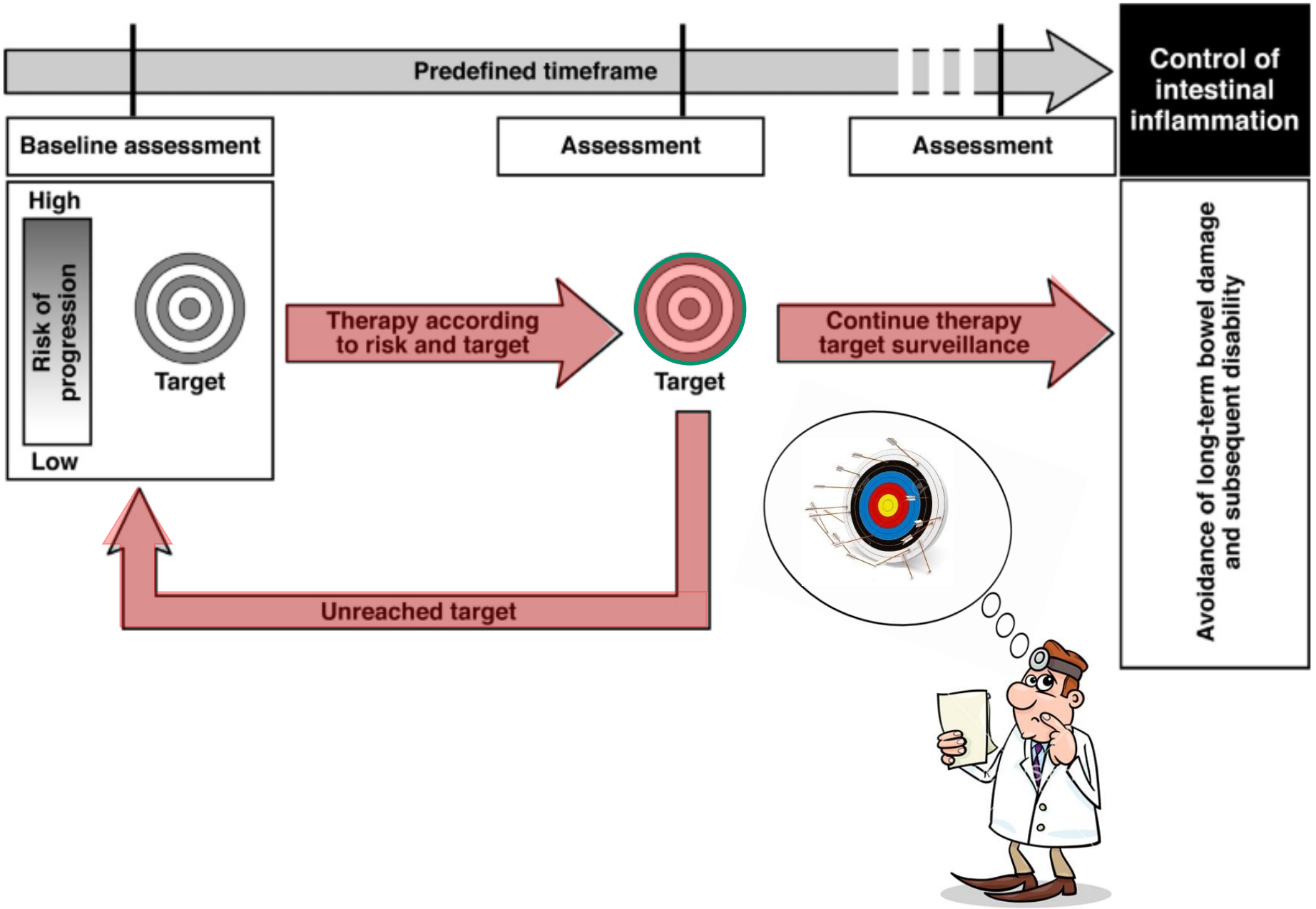
*Members of the UNIFI Study Group are listed in the Supplementary Appendix, available at NEJM.org.

N Engl J Med 2019;381:1201-14.
DOI: 10.1056/NEJMoa1900750

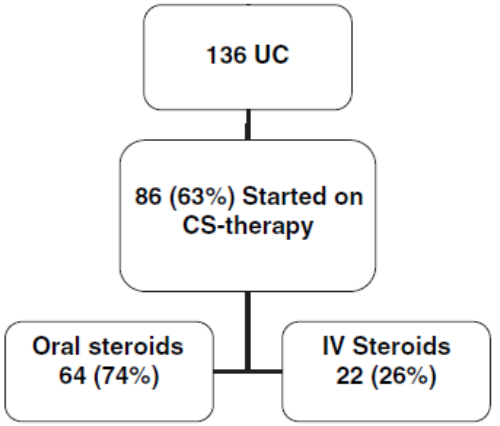


1979	1980	1993	1994	1995	1998	2005
Sulfasalazine Steroids	Antibiotics AZA/6-MP	5-ASA	Budesonide	MTX	Infliximab	Second generation biologics

TREAT TO TARGET



The efficacy of corticosteroid therapy in inflammatory bowel disease: analysis of a 5-year UK inception cohort



Outcome at 30 days

Outcome at 1 year

Table 2. Indications of surgery for UC

UC	$n = 18$
Failure to respond to corticosteroids in acute severe disease (corticosteroid resistance)	8
Toxic dilatation	1
Perforation/major haemorrhage	0
Chronic continuous symptoms (corticosteroid dependency)	9

15 (18%)

Prolonged response 47 (55%)

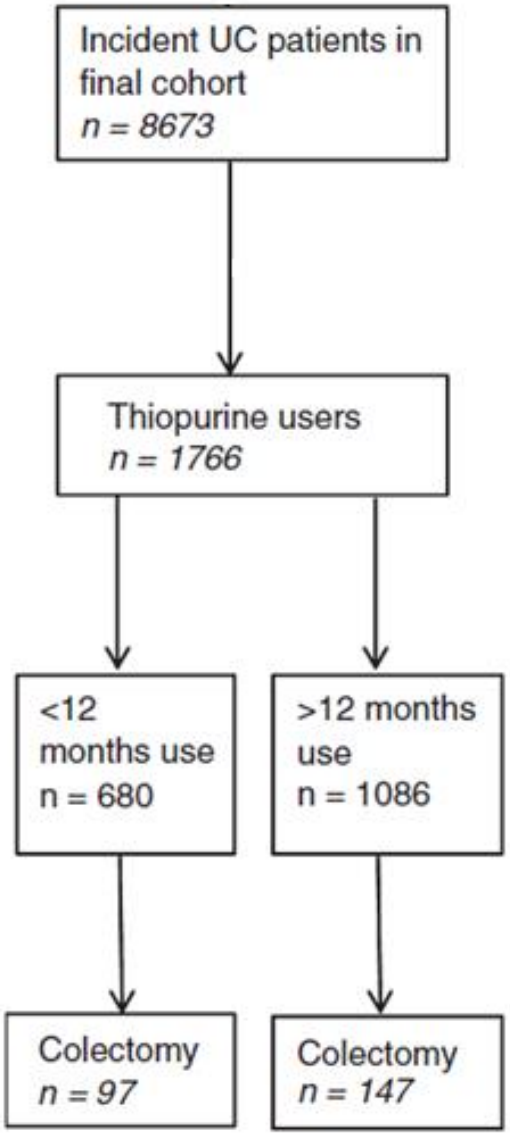
CS dependent 15 (17%)

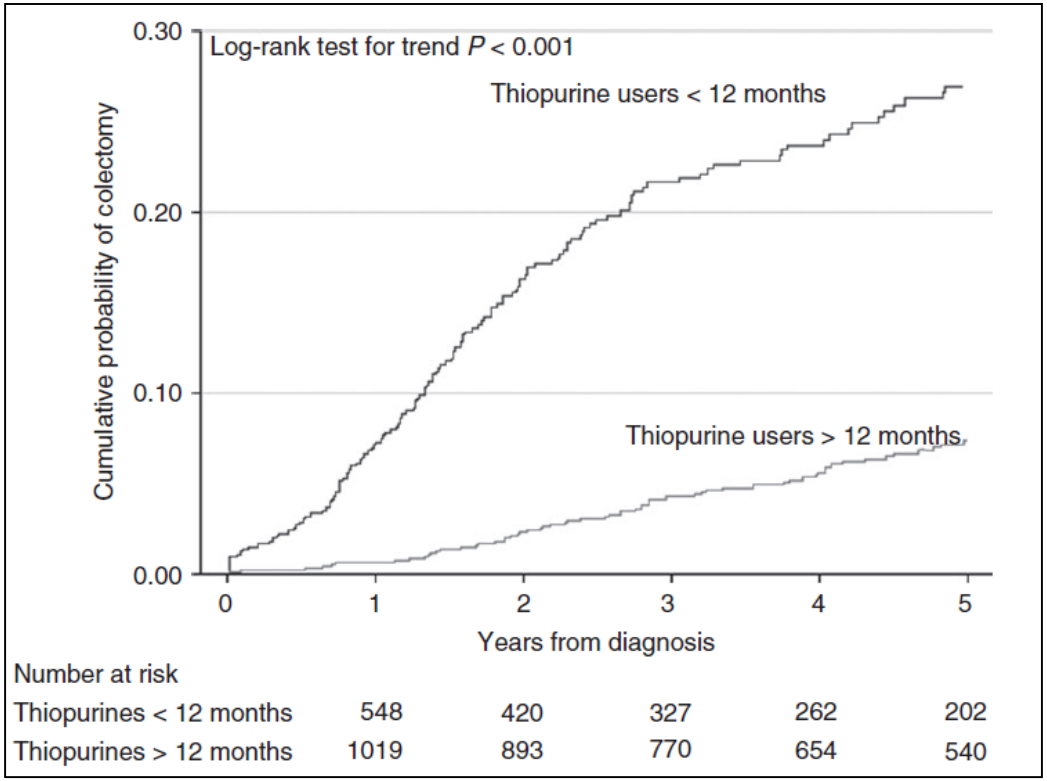
Surgery 18 (21%)

Lost to follow up 6 (7%)

Ho GT et al. Aliment Pharmacol Ther 2006;24:319-30

The impact of timing and duration of thiopurine treatment on colectomy in ulcerative colitis: a national population-based study of incident cases between 1989–2009





Chhaya V. et al. Aliment Pharmacol Ther 2015; 41: 87–98

Infliximab in Steroid-dependent Ulcerative Colitis: Effectiveness and Predictors of Clinical and Endoscopic Remission

126 steroid-dependent UC patients were studied: 36 retrospectively and 90 prospectively enrolled.

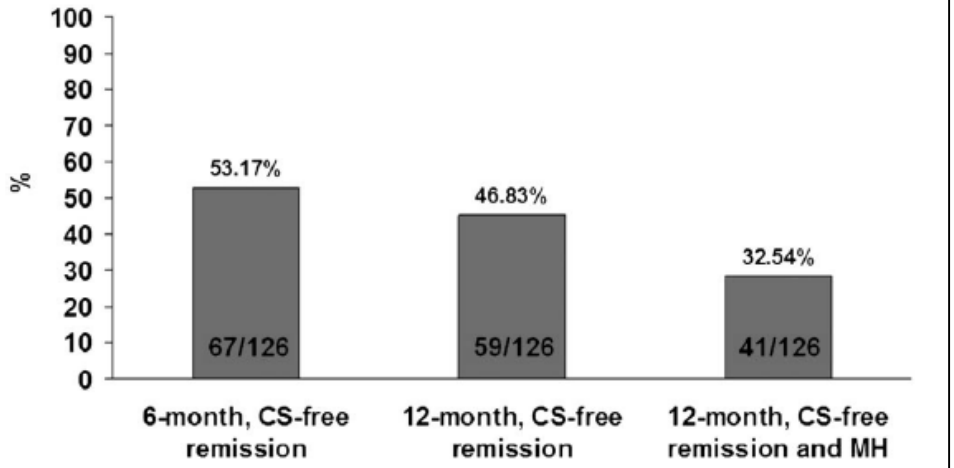
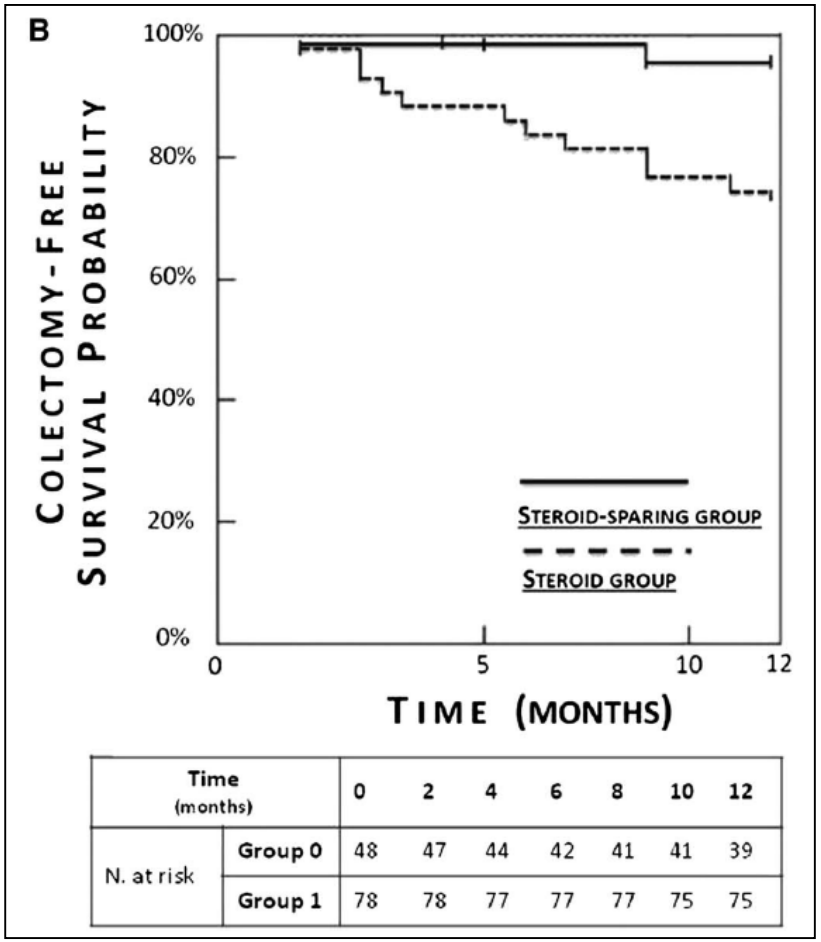


FIGURE 1. Rate of steroid-free clinical remission at 6 and 12 months and steroid-free clinical remission and MH at 12 months. CS, corticosteroid.



Time (months)		0	2	4	6	8	10	12
N. at risk	Group 0	48	47	44	42	41	41	39
	Group 1	78	78	77	77	77	75	75

Armuzzi A. et al. Inflamm Bowel Dis 2013;19:1065–1072

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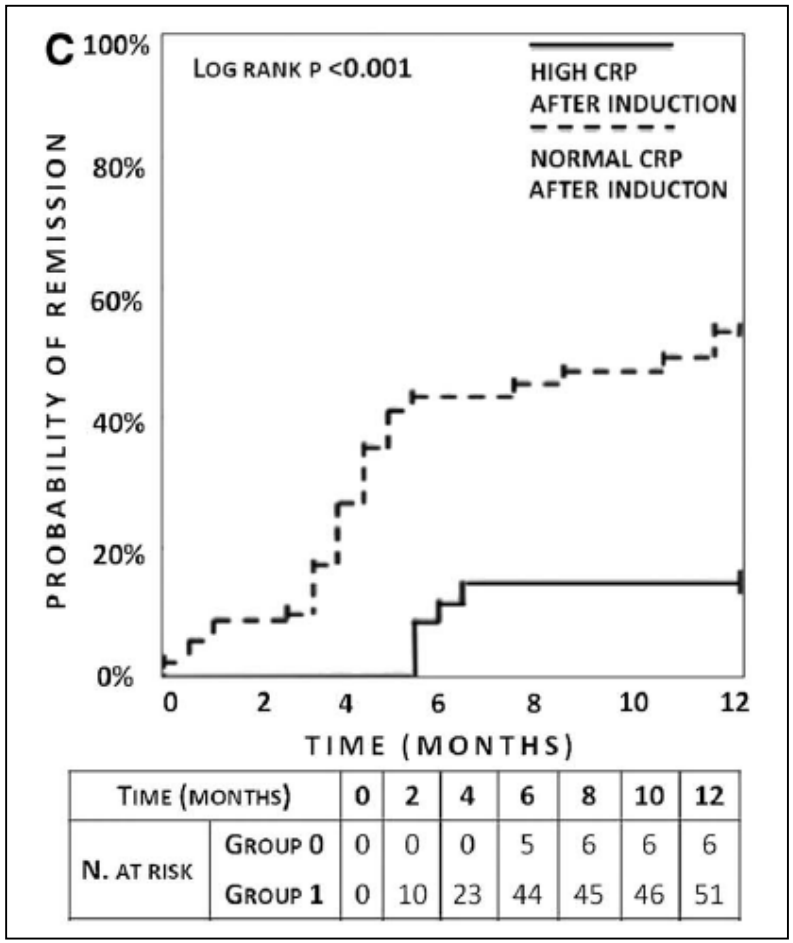


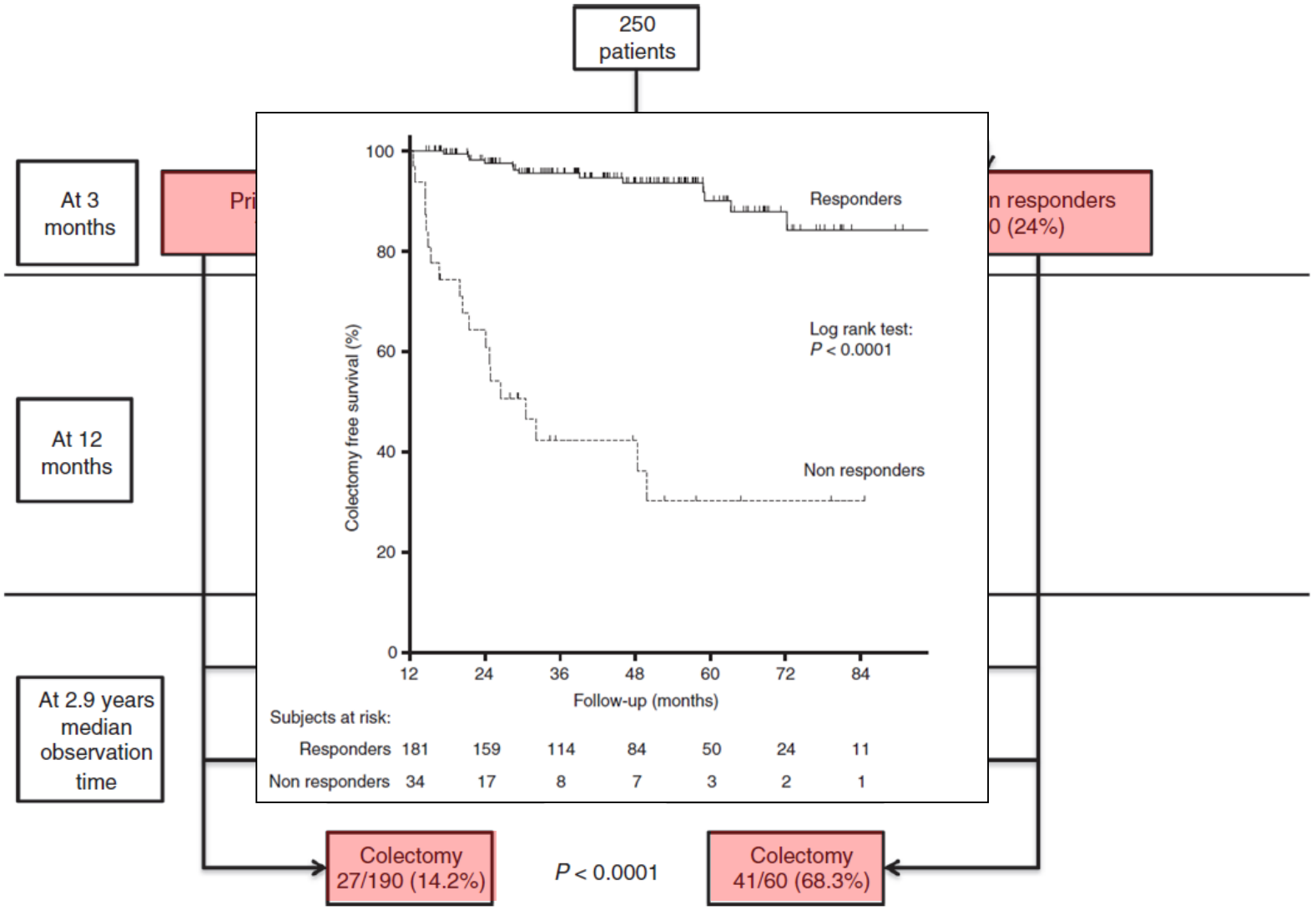
TIME (MONTHS)		0	2	4	6	8	10	12
N. AT RISK	GROUP 0	0	0	0	5	6	6	6
	GROUP 1	0	10	23	44	45	46	51

TABLE 5. Predictors of Steroid-free Clinical Remission and MH at 12 Months

Variable	OR	95% CI	*P*
Sex	1.0	0.37–2.74	0.99
Age (<median)	2.7	0.92–7.87	0.07
IFX + AZA	2.2	0.75–6.63	0.15
IM naive	3.6	1.30–10.04	0.01
CRP drop after induction	6.0	1.57–22.93	0.009

Armuzzi A. et al. Inflamm Bowel Dis 2013;19:1065–1072

Long-term outcome of infliximab treatment in chronic active ulcerative colitis: a Swedish multicentre study of 250 patients



Angelison L. et al. Aliment Pharmacol Ther 2017; 45: 519–532

A Panel to Predict Long-term Outcome of Infliximab Therapy for Patients With Ulcerative Colitis

Data from 285 patients with refractory UC treated with infliximab were collected. During a median follow-up period of 5 years, 61% of patients relapsed and 20% required colectomy.

Table 2. Predictive Factors of Relapse-Free Survival

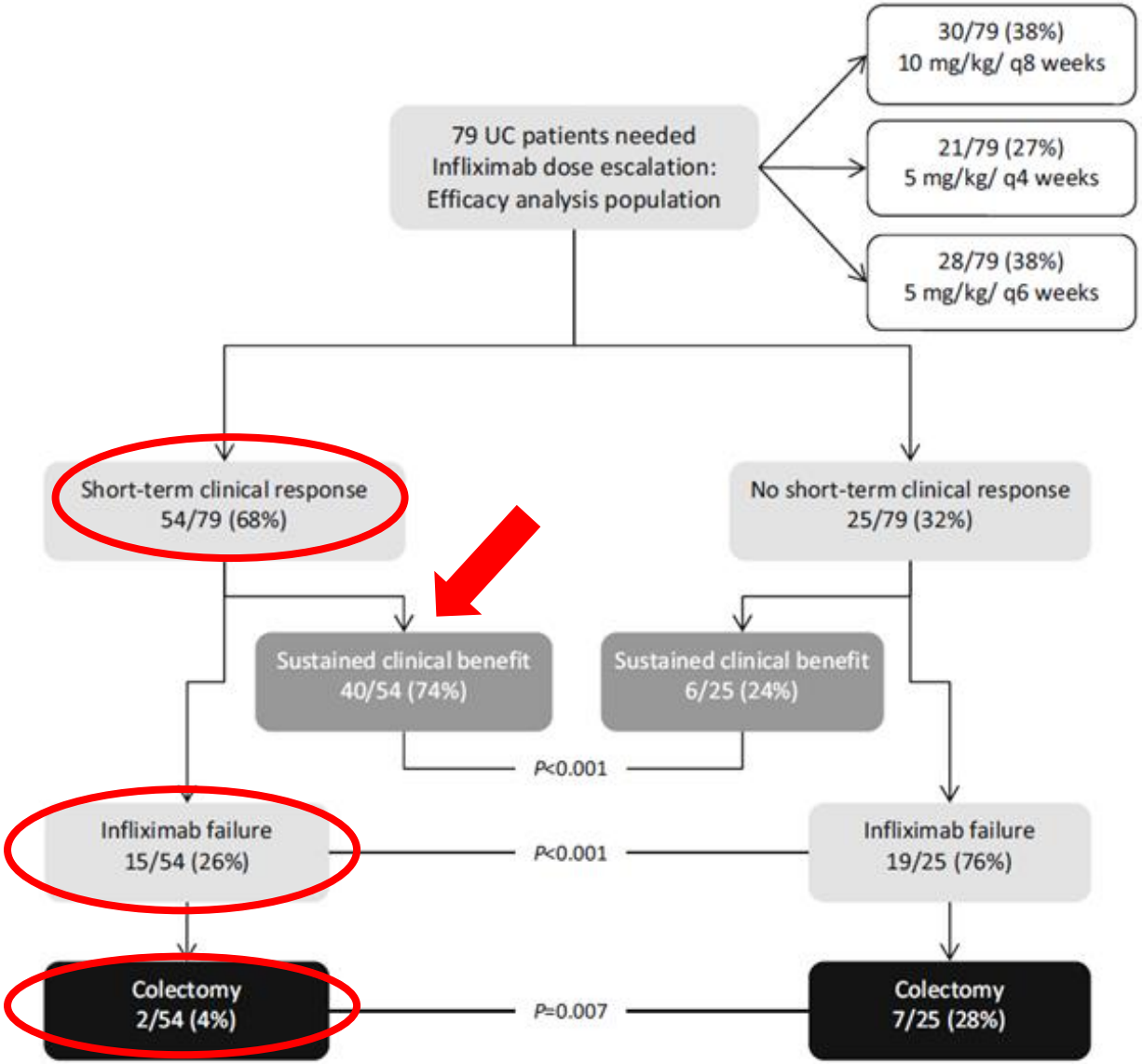
	Univariate analysis (n = 184)	Multivariate analysis (n = 146)	
	Log-rank *P* value	OR (95% CI)	*P* value
Short-term complete clinical response	<.001	3.75 (2.35–5.97)	<.001
Short-term CRP level normalization	.014		
Short-term mucosal healing	<.001	1.87 (1.17–2.98)	.009
pANCA negative	.052	1.96 (1.23–3.12)	.005

Table 3. Predictive Factors of Colectomy-Free Survival

	Univariate analysis (N = 285)	Multivariate analysis (n = 195)	
	Log-rank *P* value	Odds ratio (95% CI)	*P* value
Short-term clinical response	<.001	7.74 (2.76–21.68)	<.001
Short-term CRP level normalization	.010		
Short-term mucosal healing	<.001	4.02 (1.16–13.97)	.028
Disease duration ≥ 2 y	.026		
Baseline CRP level ≤ 5 mg/L	.009	2.95 (1.26–6.89)	.012
Baseline albumin level ≥ 35 g/L	.025	3.03 (1.12–8.22)	.029
No extensive colitis	.053		
Mayo endoscopic subscore < 3	.027		
No previous need for intravenous CS	.016		

Arias MT et al. Clin Gastroenterol Hepatol 2015;13:531-8

Infliximab Dose Escalation as an Effective Strategy for Managing Secondary Loss of Response in Ulcerative Colitis

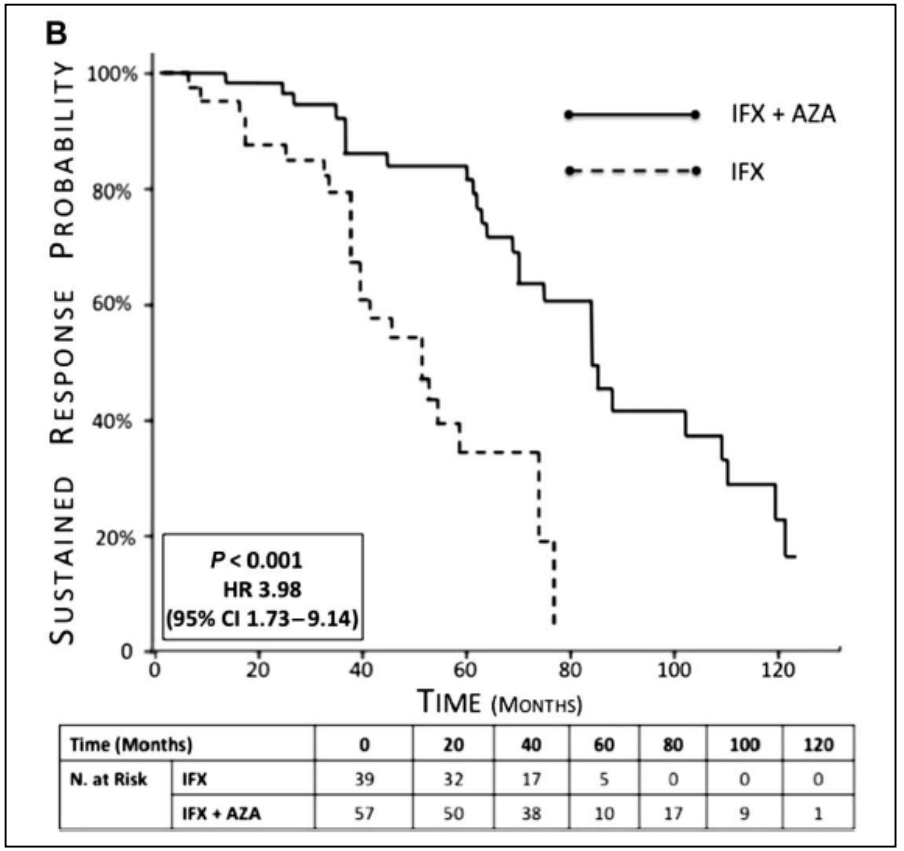


Taxonera C. et al. Dig Dis Sci (2015) 60:3075–3084

Long-term Combination Therapy with Infliximab Plus Azathioprine Predicts Sustained Steroid-free Clinical Benefit in Steroid-dependent Ulcerative Colitis

TABLE 1. Patients' Characteristics at Baseline

Patients	N = 126
Sex	71 F; 55 M
Age, median (IQR), yr	36.5 (28–50)
Active smoking status, n (%)	19 (15.1)
Duration of disease, median (IQR), yr	4 (2–8)
Extension of disease, n (%)	
E1	9 (7.2)
E2	40 (31.7)
E3	77 (61.1)
Extraintestinal manifestations, n (%)	24 (19.0)
Median partial Mayo score (IQR)	6 (5–7)
Endoscopic Mayo score, n (%)	
1	6 (4.8)
2	56 (44.4)
3	64 (50.8)
Median Mayo score (IQR)	9 (8–10)
Concomitant CS, n (%)	88 (69.8)
Prednisone dose, median (IQR), mg/d	25 (15–30)
IM naive, n (%)	57 (45.2)
Combination therapy (IFX + AZA), n (%)	71 (56.3)
Mesalamine, n (%)	
Oral	102 (80.9)
Topical	56 (44.4)
CRP, median (IQR), mg/L	11.4 (5.6–26.6)

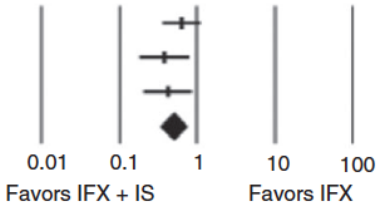


Armuzzi A. et al. Inflamm Bowel Dis 2014;20:1368–1374

Systematic review with meta-analysis: infliximab and immunosuppressant therapy vs. infliximab alone for active ulcerative colitis

Forest plot for infliximab versus infliximab and immunosuppressant in ulcerative colitis patients at 4 to 6 months

Study	Remission rate		Statistics for each study				MH odds ratio and 95% CI
	IFX	IFX + IS	MH OR	Lower limit	Upper limit	*P*-value	
ACT 2 2009	37/139	37/102	0.64	0.37	1.11	0.11	
Armuzzi 2013	22/55	45/71	0.39	0.19	0.79	0.01	
SUCCESS 2014	17/77	31/78	0.43	0.21	0.87	0.02	
	76/271	113/251	0.50	0.34	0.73	0.001	



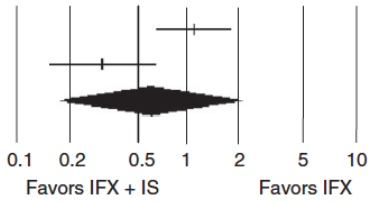
Test for heterogeneity: ($P = 0.49$) $I^2 = 0.0\%$

Test for overall effect: $Z = -3.65$ ($P < 0.0001$)

Figure 2 | Forest plot of the meta-analysis comparing infliximab (IFX) vs. infliximab and immunosuppressant (IS) in ulcerative colitis patients at 4–6 months.

Forest plot for infliximab versus infliximab and immunosuppressant in ulcerative colitis patients at 12 months

Study	Remission rate		Statistics for each study				MH odds ratio and 95% CI
	IFX	IFX + IS	MH OR	Lower limit	Upper limit	*P*-value	
ACT 2 2009	42/118	42/125	1.09	0.64	1.85	0.74	
Armuzzi 2013	17/55	42/71	0.31	0.15	0.65	0.00	
	59/173	84/196	0.60	0.17	2.06	0.41	



Test for heterogeneity: ($P = 0.01$) $I^2 = 86.4\%$

Test for overall effect: $Z = -0.82$ ($P = 0.414$)

Figure 3 | Forest plot of the meta-analysis comparing infliximab (IFX) vs. infliximab and immunosuppressant (IS) in ulcerative colitis patients at 12 months.

Christophorou D et al. Aliment Pharmacol Ther 2015; 41: 603–612

The Addition of an Immunosuppressant After Loss of Response to Anti-TNFα Monotherapy in Inflammatory Bowel Disease: A 2-Year Study

Among 630 patients treated with anti-TNFα from October 2014 to October 2016, 46 (7.3%) added an IM.

Variable	N = 46
Type of disease, n (%)	
Crohn's disease	33 (71.7)
Ulcerative colitis	13 (28.3)
Line of anti-TNFα therapy, n (%)	
First	10 (21.7)
Second	34 (73.9)
Third	2 (4.4)
Experienced to the IM used in combination therapy, n (%)	13 (28.3)
Time between start of anti-TNFα therapy and addition of IM, median (interquartile range), mo	7 (13.5)

Variable	N = 46
Combination therapy, n (%)	
IFX + AZA	11/46 (23.9)
IFX + 6-MP	5/46 (10.9)
IFX + MTX	12/46 (26.1)
IFX + MMF	3/46 (6.5)
TOTAL IV	**31/46 (67.4)**
ADA + AZA	2/46 (4.3)
ADA + MTX	8/46 (17.4)
GOL + AZA	2/46 (4.3)
GOL + MMF	3/46 (6.5)
TOTAL SC	15/46 (32.6)

Macaluso FS et al. Inflamm Bowel Dis. 2018 ;24:394-401

The Addition of an Immunosuppressant After Loss of Response to Anti-TNFα Monotherapy in Inflammatory Bowel Disease: A 2-Year Study

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END OF FOLLOW-UP

PATIENTS ON COMBINATION THERAPY: N=21

Steroid-free remission: 15 (32.6%)

Clinical response: 6 (13.0%)

CD: 10 steroid-free remission (9 IV +1 SC)

4 clinical response (3 IV + 1 SC)

UC: 5 steroid-free remission (3 IV + 2 SC)

2 clinical response (1 IV + 1 SC)

COMBINATION THERAPY SUCCESS: 21/46 (45.7%)

CD: 14/33 (42.4%); UC: 7/13 (53.8%)

IV: 16/31 (51.6%); SC: 5/15 (33.3%)

Macaluso FS et al. Inflamm Bowel Dis. 2018 ;24:394-401

Contents lists available at ScienceDirect

Digestive and Liver Disease

journal homepage: www.elsevier.com/locate/dld

Alimentary Tract

Adalimumab in active ulcerative colitis: A "real-life" observational study

Italian Group for the Study of Inflammatory Bowel Disease, Alessandro Armuzzi[a,*], Livia Biancone[b], Marco Daperno[b], Alessandra Coli[b], Daniela Pugliese[a], Vito Annese[b], Annalisa Aratari[b], Sandro Ardizzone[b], Paola Balestrieri[b], Fabrizio Bossa[b], Maria Cappello[b], Fabiana Castiglione[b], Michele Cicala[b], Silvio Danese[b], Renata D'Incà[b], Pietro Dulbecco[b], Giuseppe Feliciangeli[b], Walter Fries[b], Stefania Genise[b], Paolo Gionchetti[b], Stefano Gozzi[b], Anna Kohn[b], Roberto Lorenzetti[b], Monica Milla[b], Sara Onali[b], Ambrogio Orlando[b], Luigi Giovanni Papparella[b], Sara Renna[b], Chiara Ricci[b], Fernando Rizzello[b], Raffaello Sostegni[b], Luisa Guidi[a], Claudio Papi[b]

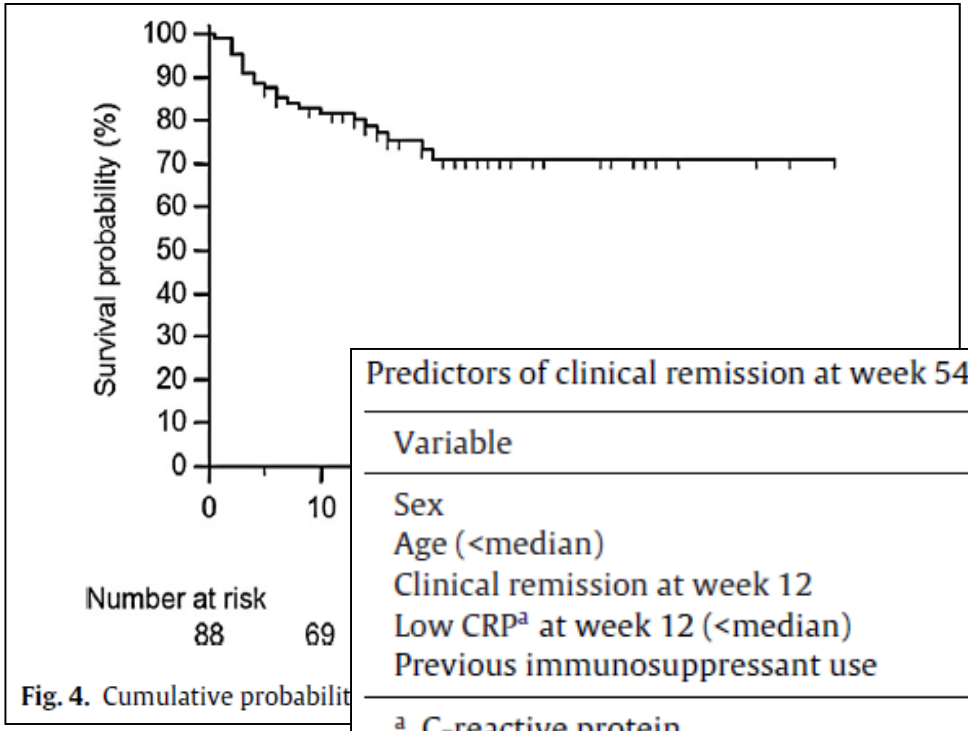
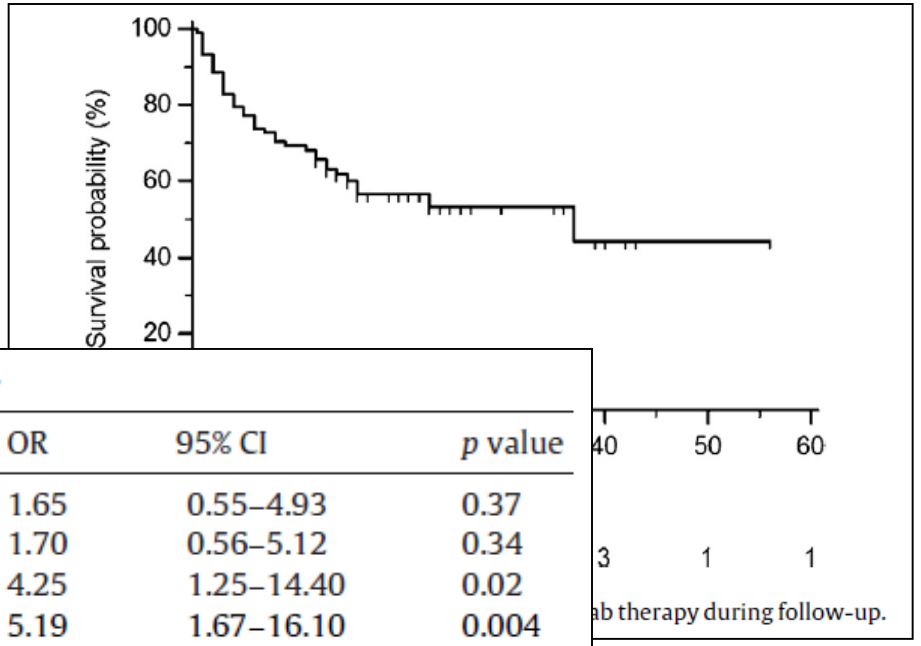


Fig. 4. Cumulative probabilit



4%, 36.4% and

Predictors of clinical remission at week 54.

Variable	OR	95% CI	*p* value
Sex	1.65	0.55–4.93	0.37
Age (<median)	1.70	0.56–5.12	0.34
Clinical remission at week 12	4.25	1.25–14.40	0.02
Low CRP[a] at week 12 (<median)	5.19	1.67–16.10	0.004
Previous immunosuppressant use	0.20	0.06–0.64	0.007

[a] C-reactive protein.

Effectiveness of adalimumab for the treatment of ulcerative colitis in clinical practice: comparison between anti-tumour necrosis factor-naïve and non-naïve patients

263 patients (87 naive and 176 previously exposed to anti-TNFα from the ENEIDA registry).

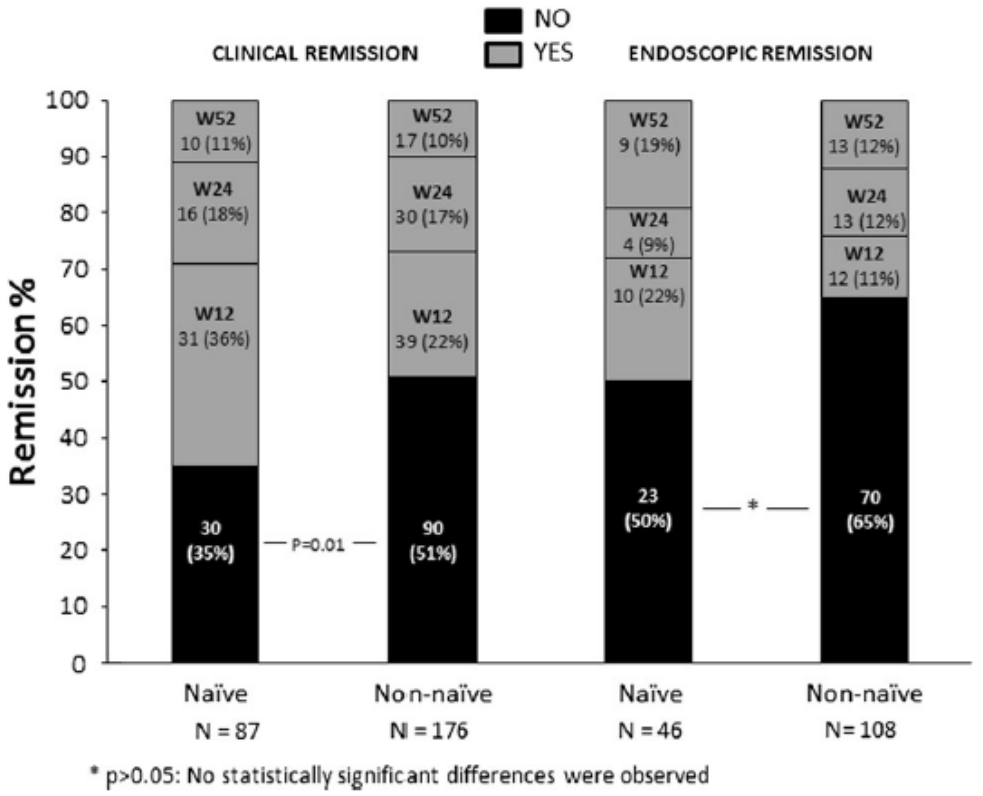


Fig. 2 Rates of clinical and endoscopic remission and time point of achievement during 1 year of adalimumab treatment. Results are expressed as absolute number (percentage)

Iborra M et al. (GETECCU). J Gastroenterol 2017;5:788-799

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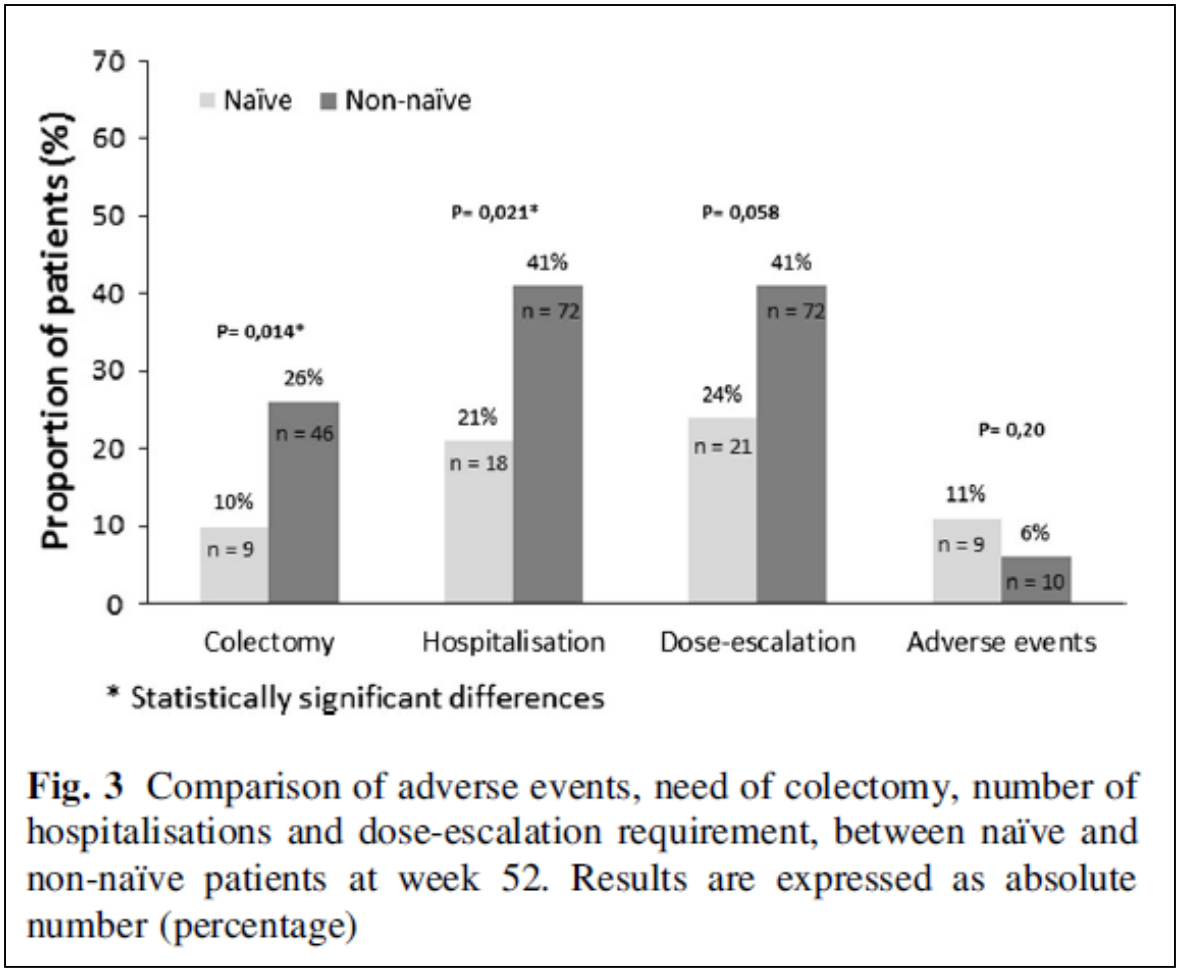

Fig. 3 Comparison of adverse events, need of colectomy, number of hospitalisations and dose-escalation requirement, between naïve and non-naïve patients at week 52. Results are expressed as absolute number (percentage)

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Effectiveness of adalimumab for the treatment of ulcerative colitis in clinical practice: comparison between anti-tumour necrosis factor-naïve and non-naïve patients

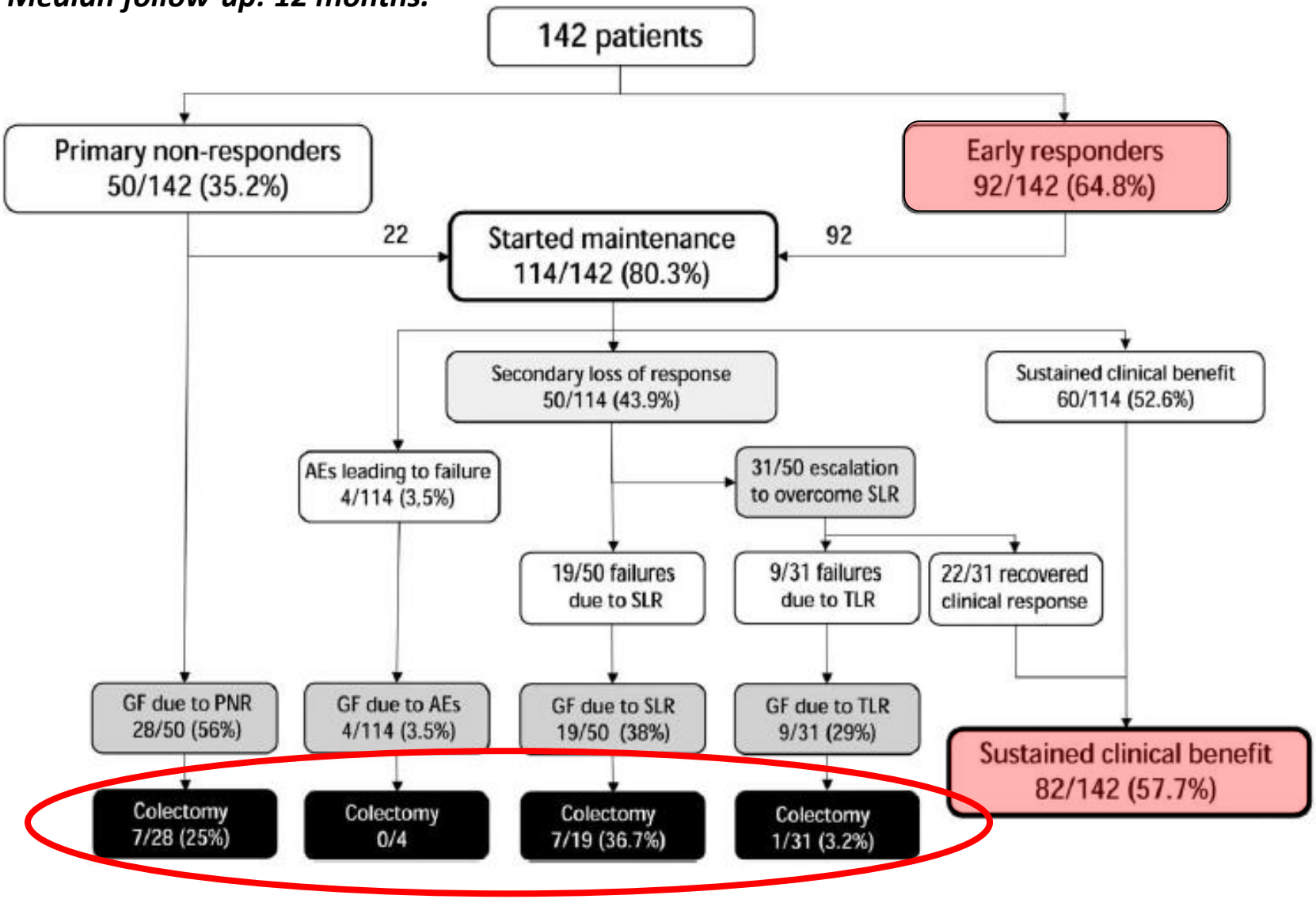
263 patients (87 naive and 176 previously exposed to anti-TNFα from the ENEIDA registry).

Variable	OR	95 % CI	*p* value
Predictors of clinical response			
Primary failure (patients previously exposed to anti-TNF)	0.22	0.06–0.77	0.015
Intolerance to first anti-TNF	0.37	0.12–0.99	0.042
Severe disease	0.36	0.14–0.93	0.049
Predictors of clinical remission			
Primary failure (patients previously exposed to anti-TNF)	0.25	0.06–0.85	0.034
Severe disease	0.31	0.08–0.98	0.026
Predictors of endoscopic remission			
Severe disease	0.32	0.07–0.99	0.015

Iborra M et al. (GETECCU). J Gastroenterol 2017;5:788-799

Clinical Outcomes of Golimumab as First, Second or Third Anti-TNF Agent in Patients with Moderate-to-Severe Ulcerative Colitis

Median follow-up: 12 months.



Taxonera C. et al. Inflamm Bowel Dis 2017;0:1–9

Clinical Outcomes of Golimumab as First, Second or Third Anti-TNF Agent in Patients with Moderate-to-Severe Ulcerative Colitis

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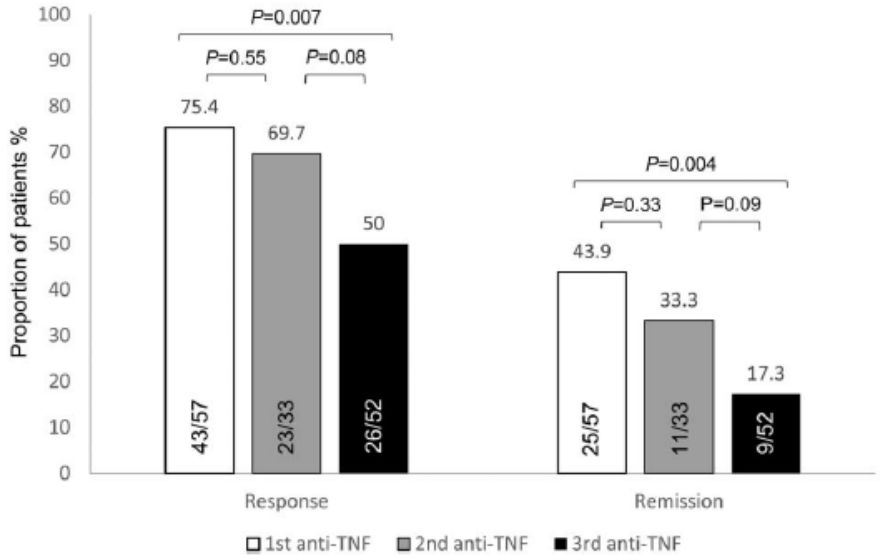


FIGURE 2. Proportion of patients with clinical response or remission at week 8: differences between patients treated with golimumab as first, second, or third anti-TNF agent.

TABLE 2. Multivariate Analysis of Factors Associated with Golimumab Failure

	Adjusted Hazard Ratio	95% CI	*P*
Short-term response			
No	1		
Yes	0.21	0.12–0.37	<0.001
Golimumab maintenance, mg q4wk			
50	1		
100	1.83	1.08–3.11	0.02

TABLE 3. Multivariate Analysis of Factors Associated with Colectomy

	Adjusted Hazard Ratio	95% CI	*P*
Short-term response			
No	1		
Yes	0.21	0.07–0.68	0.009
Concomitant IM			
No	1		
Yes	0.28	0.08–0.89	0.03

Taxonera C. et al. Inflamm Bowel Dis 2017;0:1–9

Effectiveness and Safety of the Sequential Use of a Second and Third Anti-TNF Agent in Patients With Inflammatory Bowel Disease: Results From the Eneida Registry

Median follow-up: 19 months.

1122 patients switched to a second anti-TNF drug → **300 UC**

71 patients switched to a third anti-TNF due to primary failure, secondary failure or intolerance to the second anti-TNF

39 patients achieved remission

24 patients remained on remission at the end of follow-up

2%

500 patients achieved re

273 patients remained on re the end of follow-u

24%

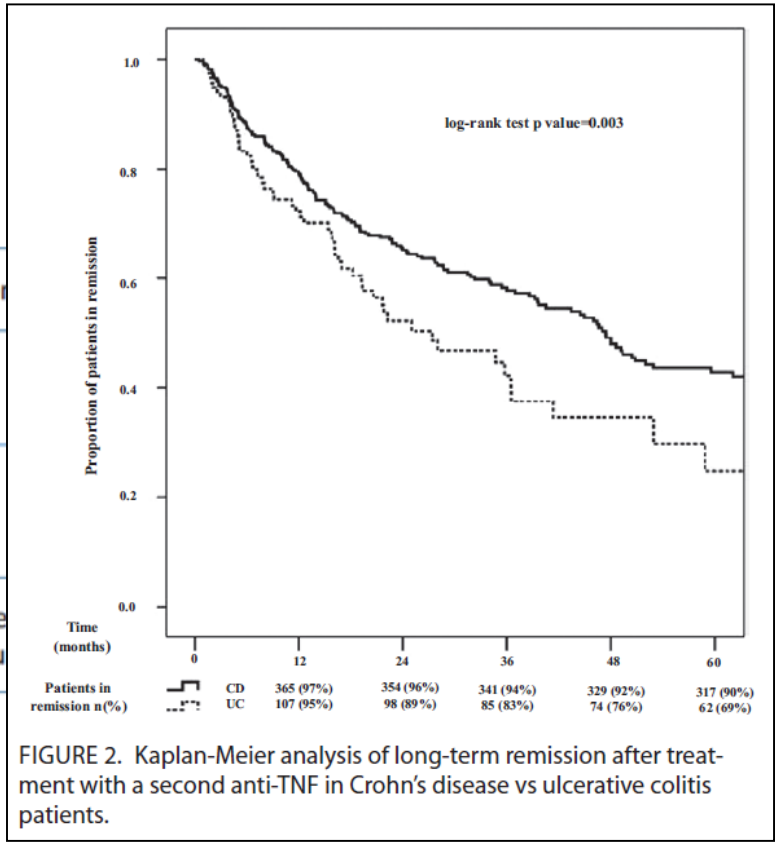


FIGURE 2. Kaplan-Meier analysis of long-term remission after treatment with a second anti-TNF in Crohn's disease vs ulcerative colitis patients.

Casanova MJ et al. Inflamm Bowel Dis 2019 [Epub ahead of print]

Effectiveness and Safety of the Sequential Use of a Second and Third Anti-TNF Agent in Patients With Inflammatory Bowel Disease: Results From the Eneida Registry

TABLE 2. Multivariate Analysis of Factors Associated With the Probability of Achieving Remission With the Second Anti-TNF

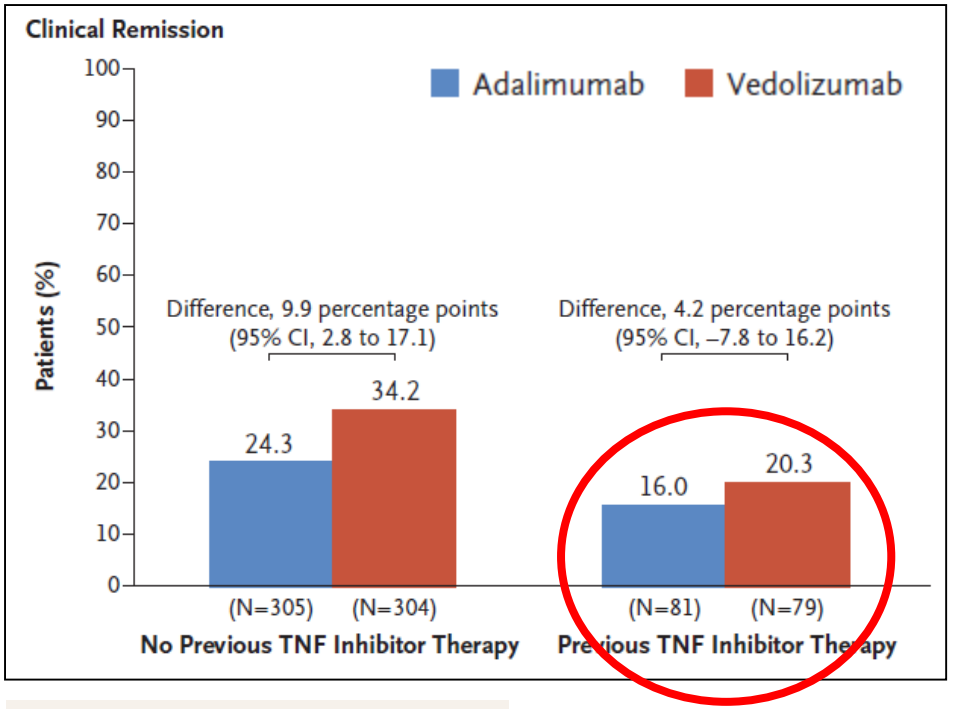
Factors	OR	95% CI	*P* Value
Concomitant IMMs	0.5	0.4–0.7	<0.0001
To withdraw the first anti-TNF due to a primary failure (vs intolerance)	0.6	0.4–0.9	0.007
To withdraw the first anti-TNF due to secondary failure (vs intolerance)	0.6	0.5–0.9	0.003
Sex	0.84	0.7–1.1	0.1
Age at diagnosis	0.9	0.9–1	0.1
Smoking history	1.1	0.9–1.5	0.4
Type of IBD (UC vs CD)	0.9	0.7–1.3	0.5
Extraintestinal manifestations	0.9	0.7–1.2	0.5
Duration of disease	1	0.99–1.001	0.9

Casanova MJ et al. Inflamm Bowel Dis 2019 [Epub ahead of print]

Vedolizumab versus Adalimumab for Moderate-to-Severe Ulcerative Colitis

Table 1. Demographic and Disease Characteristics of the Patients at Baseline.*

Characteristic	Adalimumab (N=386)	Vedolizumab (N=385)
Age — yr	40.5±13.4	40.8±13.7
Male sex — no. (%)	216 (56.0)	234 (60.8)
White race — no. (%)†	341 (88.3)	345 (89.6)
Body weight — kg	73.4±18.4	72.7±17.0
Current smoker — no. (%)‡	23 (6.0)	19 (4.9)
Duration of ulcerative colitis — yr§	6.4±6.0	7.3±7.2
Total score on the Mayo scale¶	8.7±1.5	8.7±1.6
Fecal calprotectin level — μg/g‖	2771±4064	2929±5920
Previous treatment with a TNF inhibitor with documented reason for discontinuation — no. (%)	81 (21.0)	80 (20.8)
Previous therapy with a TNF inhibitor with documented failure — no. (%)	79 (20.5)	72 (18.7)
Inadequate response	40 (50.6)	36 (50.0)
Loss of response	29 (36.7)	24 (33.3)
Side effects	3 (3.8)	7 (9.7)
Missing data	7 (8.9)	5 (6.9)
Concomitant use of medications for ulcerative colitis — no. (%)		
Corticosteroids only**	140 (36.3)	139 (36.1)
Immunomodulators only††	100 (25.9)	101 (26.2)



Efficacy Outcomes at Week 52

Sands BE et al. N Engl J Med. 2019;381:1215-1226

Vedolizumab versus Adalimumab for Moderate-to-Severe Ulcerative Colitis

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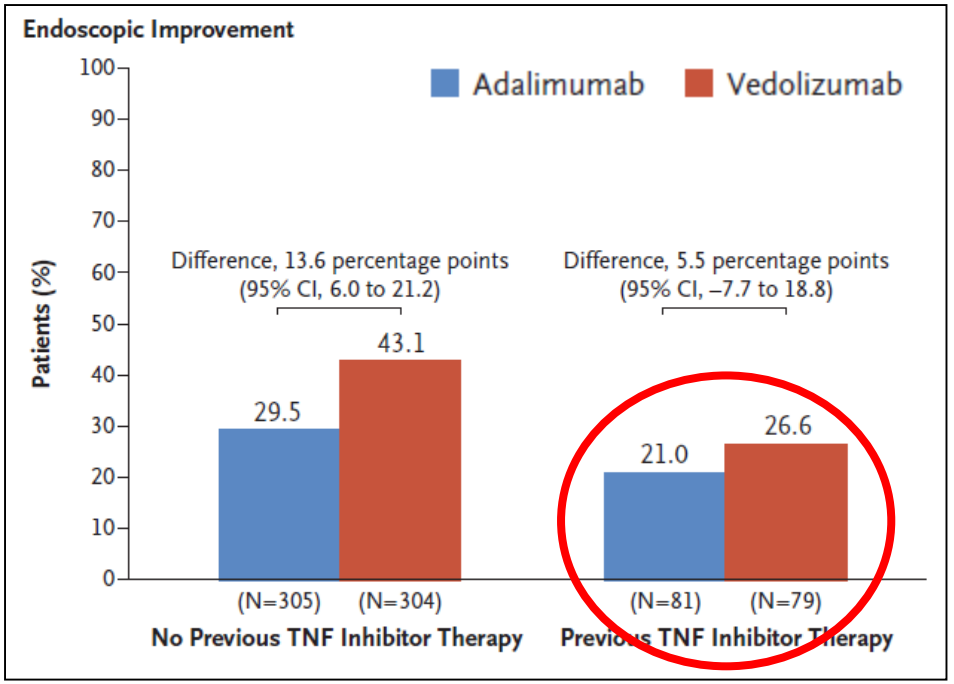


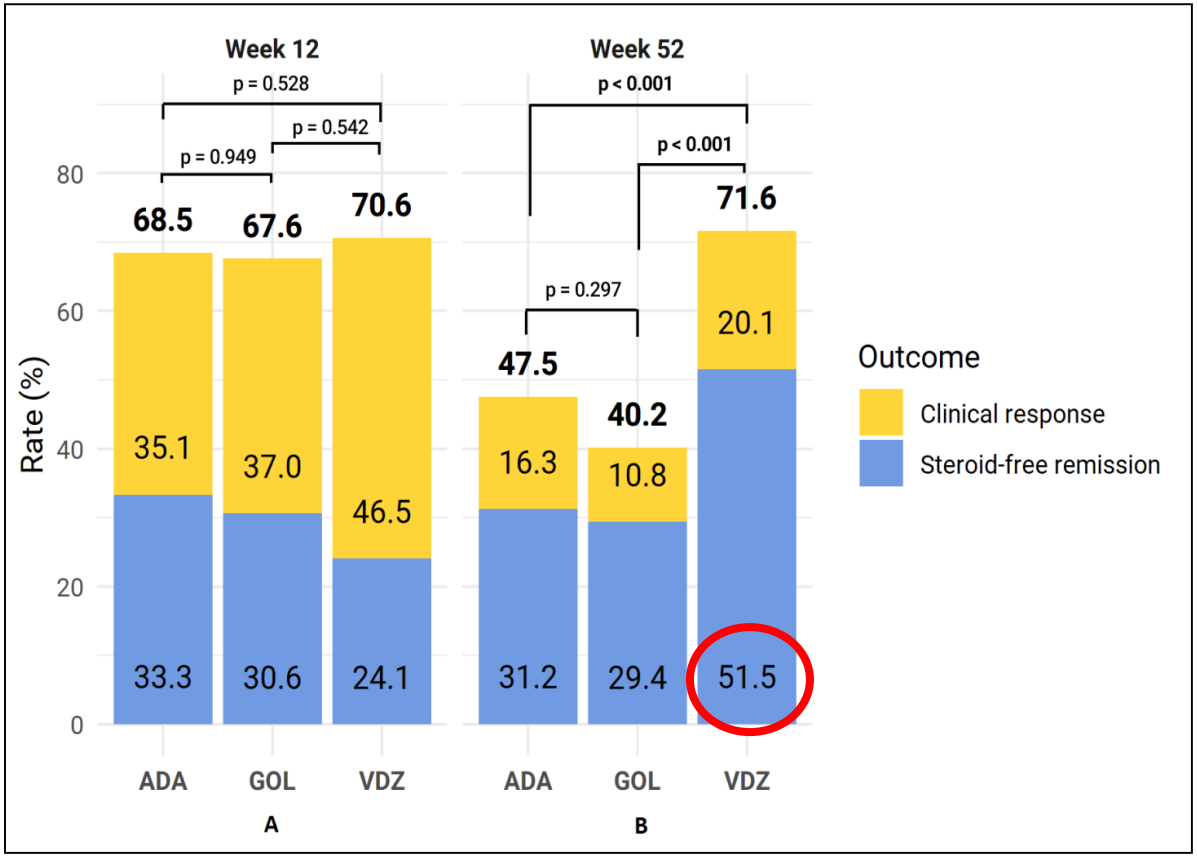
Efficacy Outcomes at Week 52

Sands BE et al. N Engl J Med. 2019;381:1215-1226

A Propensity Score Weighted Comparison of Vedolizumab, Adalimumab, and Golimumab in Patients with Ulcerative Colitis: Real-Life Data from the Sicilian Network for Inflammatory Bowel Disease (SN-IBD)

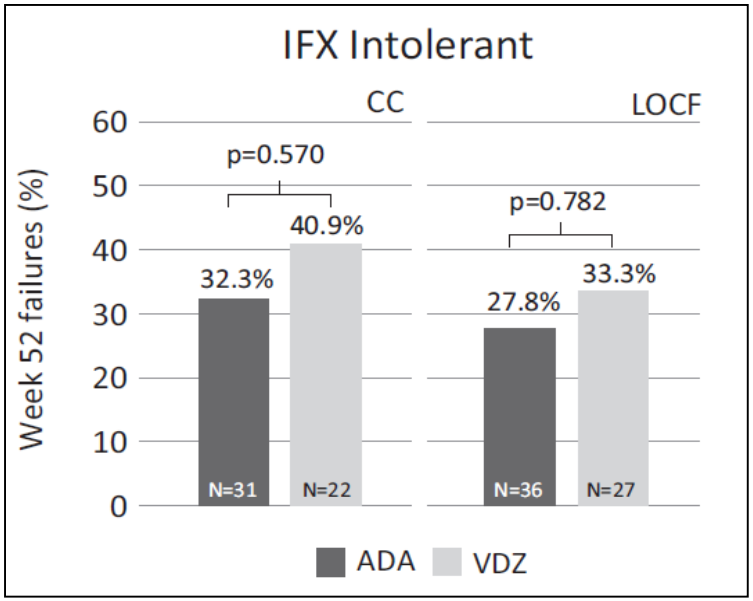
Fabio Salvatore Macaluso, Marco Ventimiglia, Walter Fries, Anna Viola, Maria Cappello, Barbara Scrivo, Antonio Magnano, Dario Pluchino, Salvatore Camilleri, Serena Garufi, Roberto Di Mitri, Filippo Mocciaro, Giovanni Magrì, Concetta Ferracane, Michele Citrano, Francesco Graziano, Carmelo Bertolami, Sara Renna, Rosalba Orlando, Giulia Rizzuto, Mario Cottone, Ambrogio Orlando.

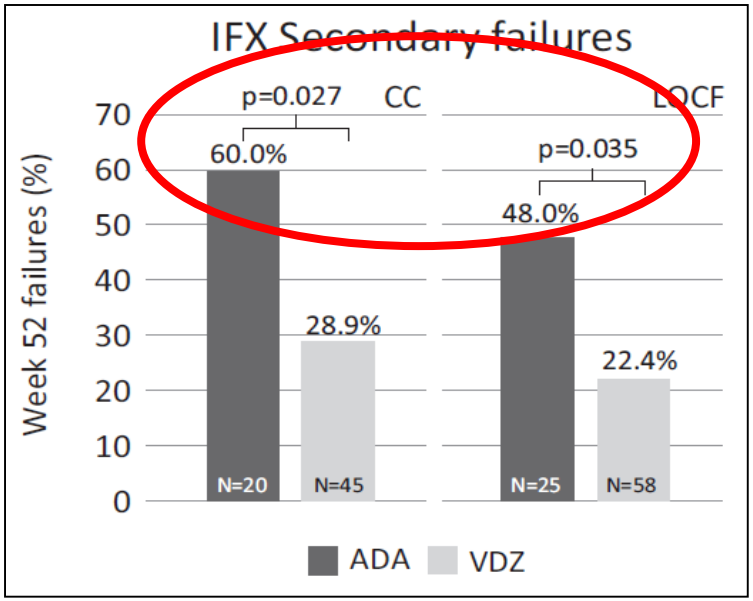
Data of 463 consecutive UC patients treated with VDZ (187), ADA (168), and GOL (108) from June 2015 to December 2018 were extracted from the cohort of the SN-IBD. A three-arms propensity score-adjusted analysis was performed to reduce bias caused by imbalanced covariates at baseline.

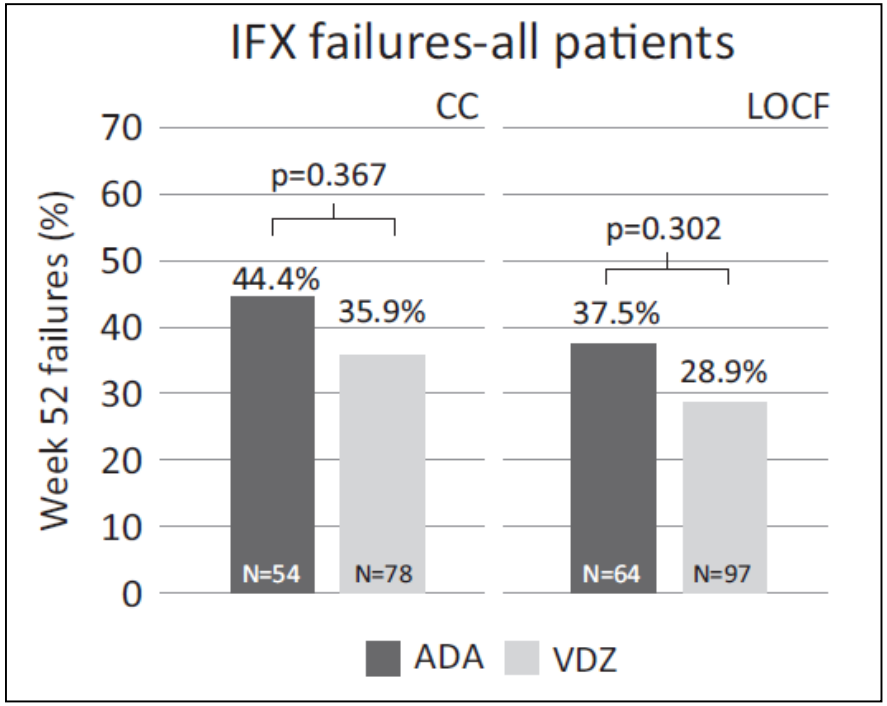


UEGW 2019: poster presentation. Submitted

Comparative Efficacy of Vedolizumab and Adalimumab in Ulcerative Colitis Patients Previously Treated With Infliximab







Favale A et al. Inflamm Bowel Dis 2019;25:1805-1812

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 SEPTEMBER 26, 2019 VOL. 381 NO. 13

Ustekinumab as Induction and Maintenance Therapy for Ulcerative Colitis

B.E. Sands, W.J. Sandborn, R. Panaccione, C.D. O'Brien, H. Z
L. Peyrin-Biroulet, G. Van Assche, S. Danese, S. Targan, M
and C. Marano, for the UNIFI Stu

Table 1. Demographic and Clinical Characteristics at Baseline in the Induction Trial (Randomly Assigned Patients).*

Characteristic	Placebo (N=319)	Ustekinumab	
		130 mg (N=320)	6 mg/kg† (N=322)
Total Mayo score‡	8.9±1.6	8.9±1.6	8.9±1.5
Score of 6–10, indicating moderate disease — no./total no. (%)	263/319 (82.4)	271/320 (84.7)	276/321 (86.0)
Disease limited to left side of colon — no./total no. (%)	167/316 (52.8)	183/318 (57.5)	168/320 (52.5)
Medications for ulcerative colitis taken at baseline			
≥1 Medication — no. (%)	283 (88.7)	290 (90.6)	294 (91.3)
Aminosalicylates — no. (%)	207 (64.9)	215 (67.2)	238 (73.9)
Corticosteroids — no. (%)	157 (49.2)	173 (54.1)	168 (52.2)
Median dose (IQR) — mg/day	20.0 (10.0–20.0)	20.0 (10.0–20.0)	20.0 (10.0–20.0)
Immunomodulator — no. (%)**	89 (27.9)	93 (29.1)	89 (27.6)
No history of disease refractory to treatment with biologic agents — no. (%)	158 (49.5)	156 (48.8)	156 (48.4)
Had not received biologics	151 (47.3)	145 (45.3)	147 (45.7)
Had received biologics but did not have documented treatment failure	7 (2.2)	11 (3.4)	9 (2.8)
History of treatment failure with biologics — no. (%)††	161 (50.5)	164 (51.2)	166 (51.6)
Only TNF antagonist	112 (35.1)	107 (33.4)	106 (32.9)
Vedolizumab	49 (15.4)	57 (17.8)	60 (18.6)
≥1 TNF antagonist, regardless of vedolizumab	159 (49.8)	162 (50.6)	164 (50.9)
Any TNF antagonist and vedolizumab	47 (14.7)	55 (17.2)	58 (18.0)

Sands BE et al. N Engl J Med 2019;381:1201-14

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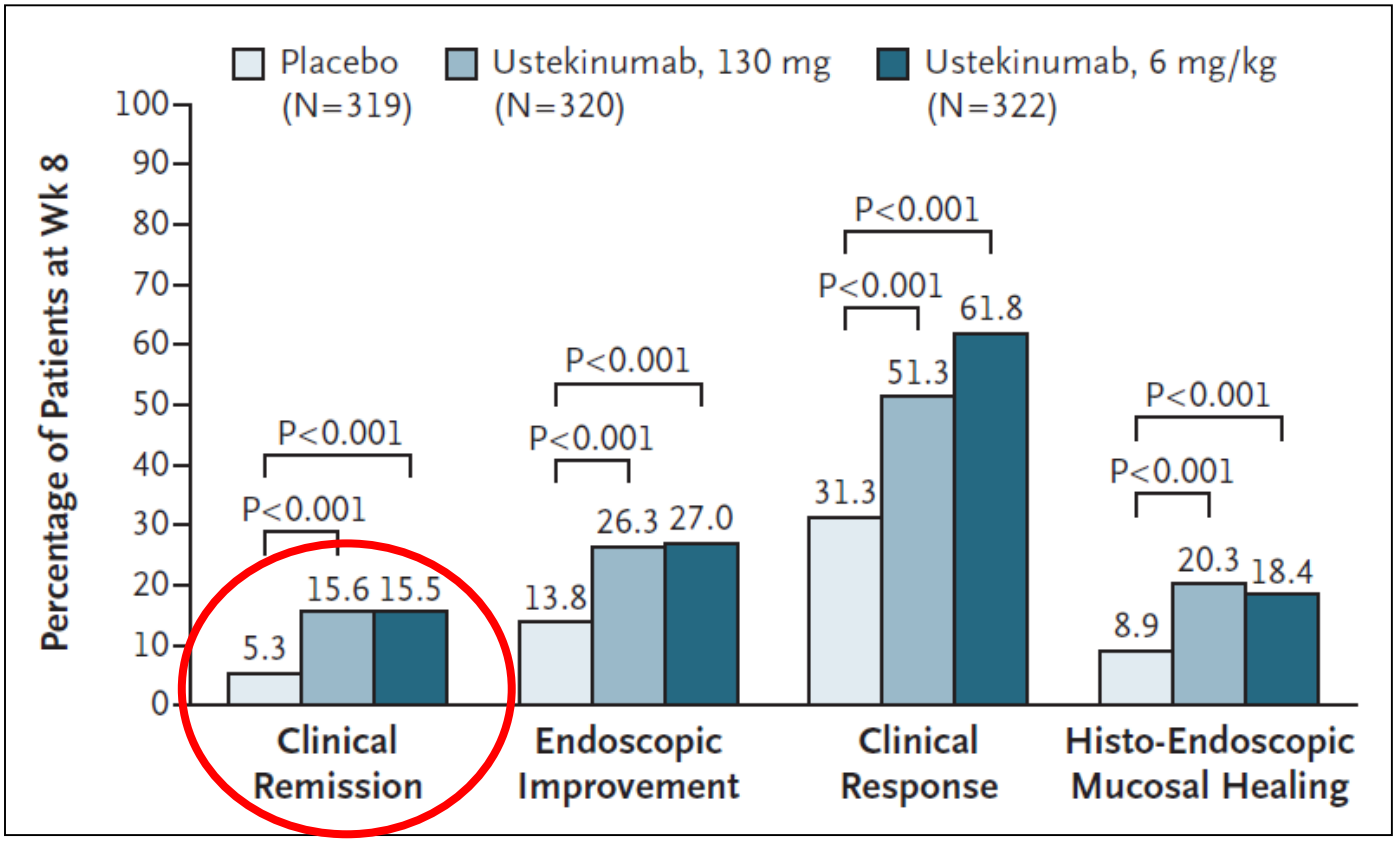

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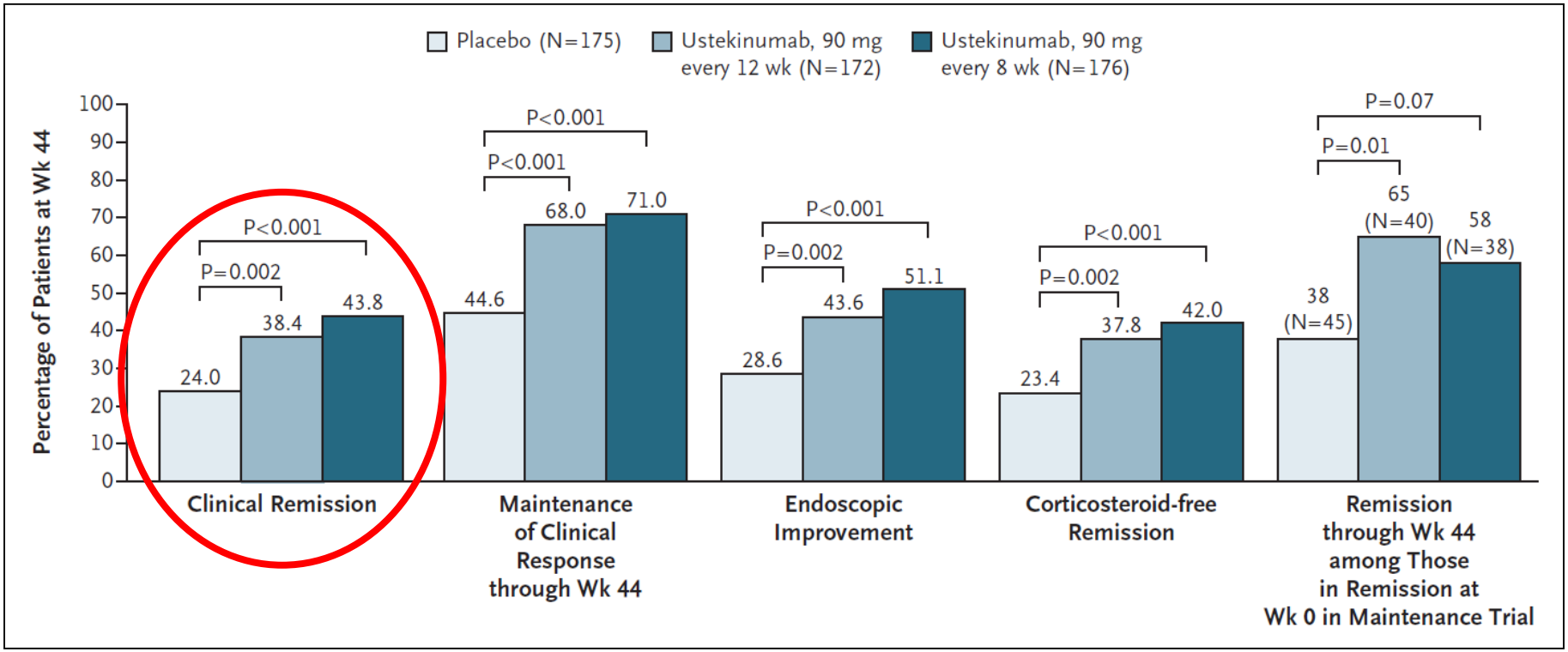

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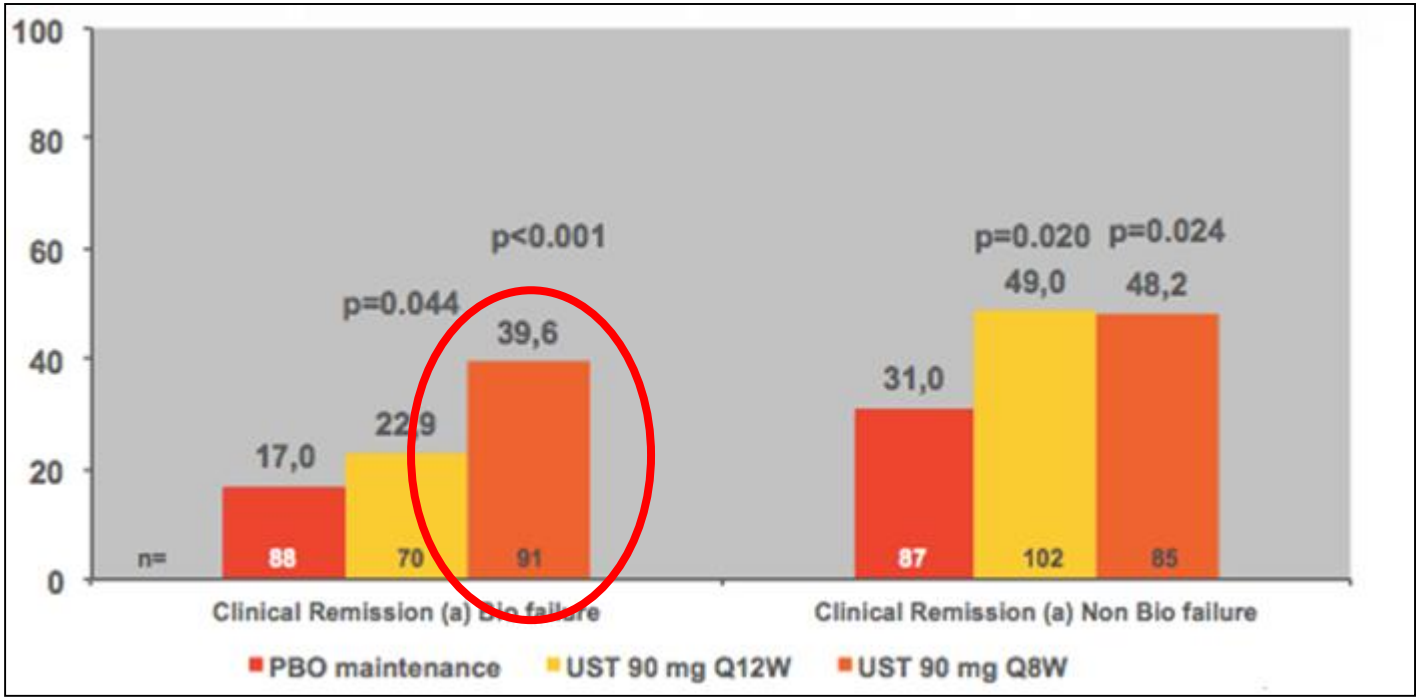

Sands BE et al. N Engl J Med 2019;381:1201-14

ORIGINAL ARTICLE

Tofacitinib as Induction and Maintenance Therapy for Ulcerative Colitis

William J. Sandborn, M.D., Chinyu Su, M.D., Bruce E. Sands, M.D., Geert R. D'Haens, M.D., Séverine Vermeire, M.D., Ph.D., Stefan Schreiber, M.D., Silvio Danese, M.D., Brian G. Feagan, M.D., Walter Reinisch, M.D., Wojciech Niezychowski, M.D., Gary Friedman, M.D., Nervin Lawendy, Pharm.D., Dahong Yu, M.D., Ph.D., Deborah Woodworth, M.B.A., Arnab Mukherjee, Ph.D., Haiying Zhang, Ph.D., Paul Healey, M.D., and Julian Panés, M.D., for the OCTAVE Induction 1, OCTAVE Induction 2, and OCTAVE Sustain Investigators*

Table 1. Baseline Demographic and Disease Characteristics of the Patients in the OCTAVE Induction 1, OCTAVE Induction 2, and OCTAVE Sustain Trials.*

Characteristic	OCTAVE Induction 1		OCTAVE Induction 2		OCTAVE Sustain		
	Placebo (N=122)	Tofacitinib, 10 mg (N=476)	Placebo (N=112)	Tofacitinib, 10 mg (N=429)	Placebo (N=198)	Tofacitinib, 5 mg (N=198)	Tofacitinib, 10 mg (N=197)
Extent of disease — no./total no. (%)§¶							
Proctosigmoiditis	19/122 (15.6)	65/475 (13.7)	16/111 (14.4)	67/428 (15.7)	21/198 (10.6)	28/196 (14.3)	33/196 (16.8)
Left-sided colitis	37/122 (30.3)	158/475 (33.3)	39/111 (35.1)	149/428 (34.8)	68/198 (34.3)	66/196 (33.7)	60/196 (30.6)
Extensive colitis or pancolitis	66/122 (54.1)	252/475 (53.1)	56/111 (50.5)	211/428 (49.3)	108/198 (54.5)	102/196 (52.0)	103/196 (52.6)
Total Mayo score‡‖	9.1±1.4	9.0±1.4	8.9±1.5	9.0±1.5	3.3±1.8	3.3±1.8	3.4±1.8
Partial Mayo score‡‖	6.5±1.2	6.3±1.2	6.4±1.2	6.4±1.3	1.8±1.4	1.8±1.3	1.8±1.3
C-reactive protein — mg/liter‡							
Median	4.7	4.4	5.0	4.6	1.0	0.7	0.9
Range	0.1–82.5	0.1–208.4	0.2–205.1	0.2–156.0	0.1–45.0	0.1–33.7	0.1–74.3
Oral glucocorticoid use at baseline — no. (%)‡	58 (47.5)	214 (45.0)	55 (49.1)	198 (46.2)	100 (50.5)	101 (51.0)	87 (44.2)
Previous treatment with TNF antagonist — no. (%)§	65 (53.3)	254 (53.4)	65 (58.0)	234 (54.5)	92 (46.5)	90 (45.5)	101 (51.3)
Previous treatment failure — no. (%)§**							
TNF antagonist	64 (52.5)	243 (51.1)	60 (53.6)	222 (51.7)	89 (44.9)	83 (41.9)	93 (47.2)
Glucocorticoid	98 (80.3)	350 (73.5)	83 (74.1)	303 (70.6)	151 (76.3)	145 (73.2)	149 (75.6)
Immunosuppressant††	83 (68.0)	360 (75.6)	75 (67.0)	301 (70.2)	129 (65.2)	143 (72.2)	141 (71.6)

Sandborn WL et al. N Engl J Med 2017;376:1723-36

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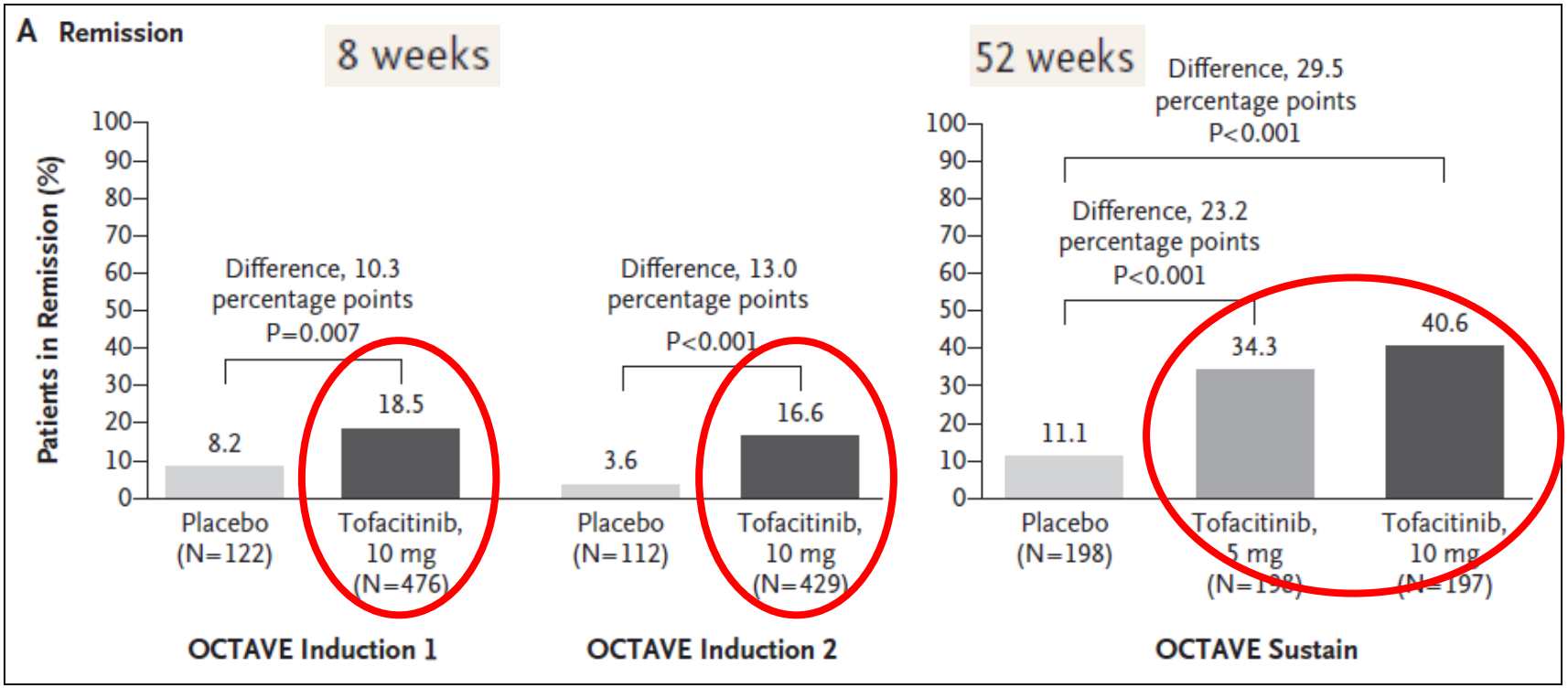

Sandborn WL et al. N Engl J Med 2017;376:1723-36

ORIGINAL ARTICLE

Tofacitinib as Induction and Maintenance Therapy for Ulcerative Colitis

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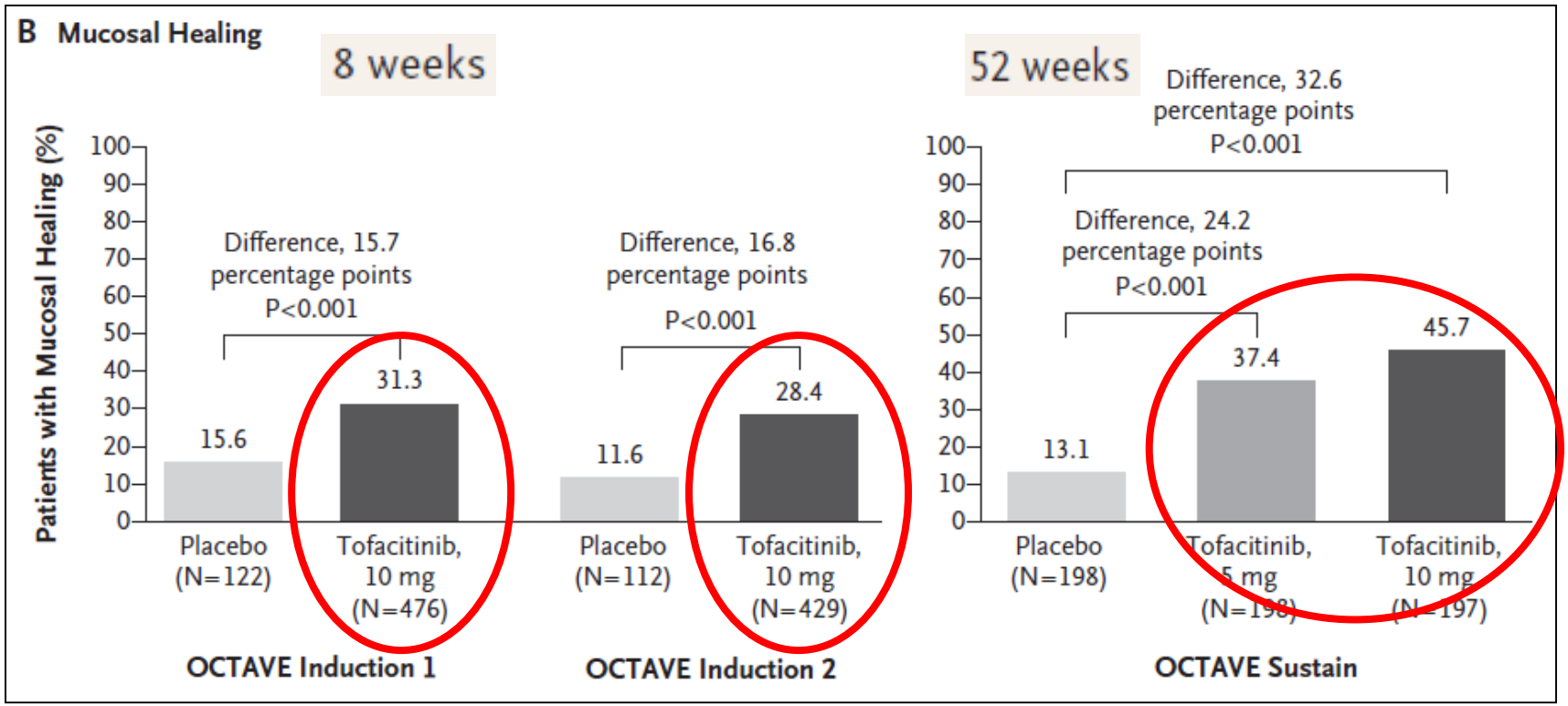
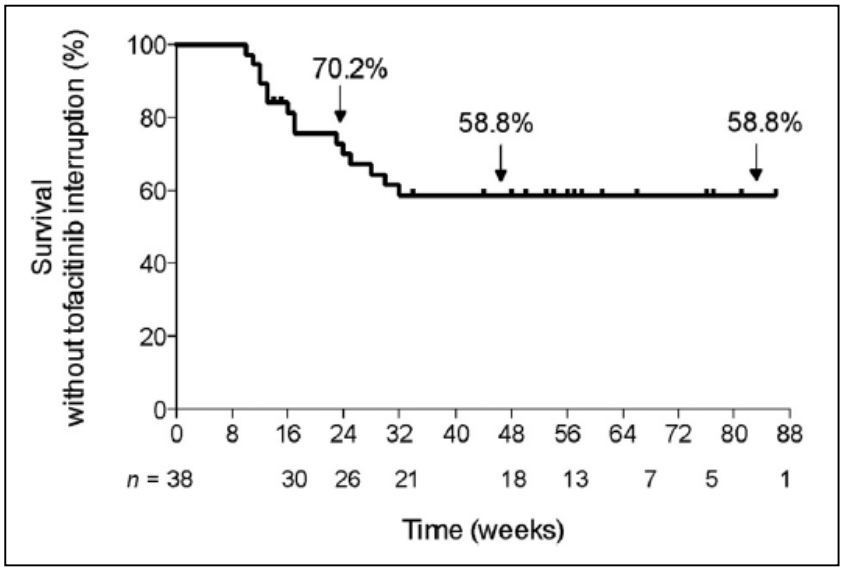


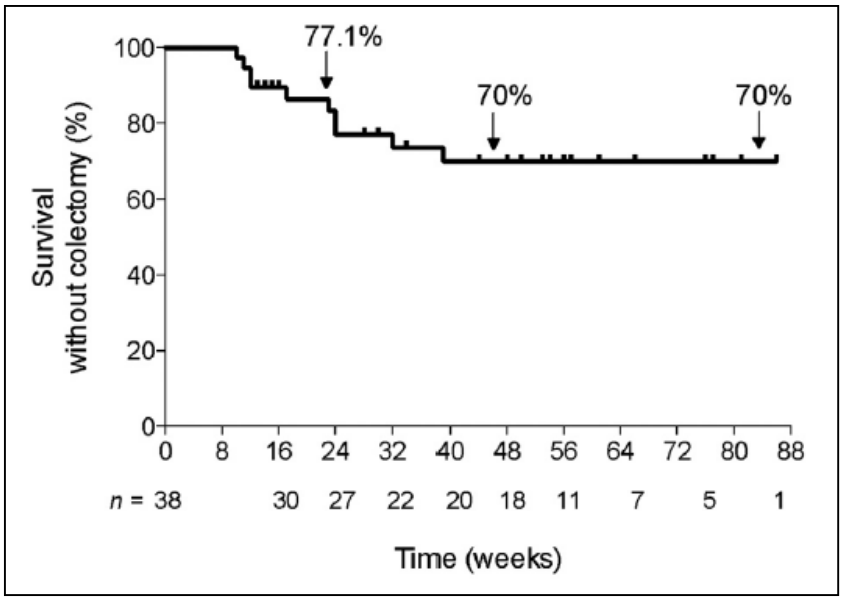
Sandborn WL et al. N Engl J Med 2017;376:1723-36

Real-world evidence of tofacitinib effectiveness and safety in patients with refractory ulcerative colitis

Population characteristics in the tofacitinib cohort ($n = 38$).

	Tofacitinib $n = 38$
Baseline demographics and medical history:	
Age, yr.	41 (28–52)
Women, No. (%)	15 (39.5%)
Medical history: No. (%)	
Appendectomy	4 (10.5%)
Abdominal surgery	1 (2,6%)
Current smoking	3 (7.9%)
Smoking cessation	8 (21%)
Family history of IBD	9 (23.7%)
Baseline characteristics of UC:	
Duration of disease, median, yr.	7 (5–11.8)
Age at diagnostic, median, yr.	29.5 (13–73)
Extent of disease, No. (%)	
Proctitis	3 (7.9%)
Left-sided colitis	13 (34.2%)
Extensive colitis/pancolitis	22 (57.9%)
Total Mayo score	9 (7–10)
Partial Mayo score	6 (5–8)
UCEIS score	5 (4–6)
C-reactive protein—mg/L, median	11 (5.5–19.3)
Hemoglobin—g/dL, median	12.8 (11.7–14)
History of treatment at baseline	
Oral steroids, No. (%)	20 (52.6%)
Previous treatment with TNF antagonist	38 (100%)
Previous treatment with vedolizumab	38 (100%)
Previous treatment with ustekinumab	4 (10.5%)
Previous treatment with cyclosporine	1 (2.6%)
Previous treatment failure	
Immunosuppressant	36 (94.7%)
Non-response to anti-TNF	31 (81.6%)
Loss of response to anti-TNF	19 (50%)
≥2 anti-TNF	27 (71%)
Number of previous treatment lines	
3	11 (28.9%)
4	19 (50%)
5	8 (21.1%)





Lair-Mehiri L et al. Dig Liver Dis 2019 [Epub ahead of print]

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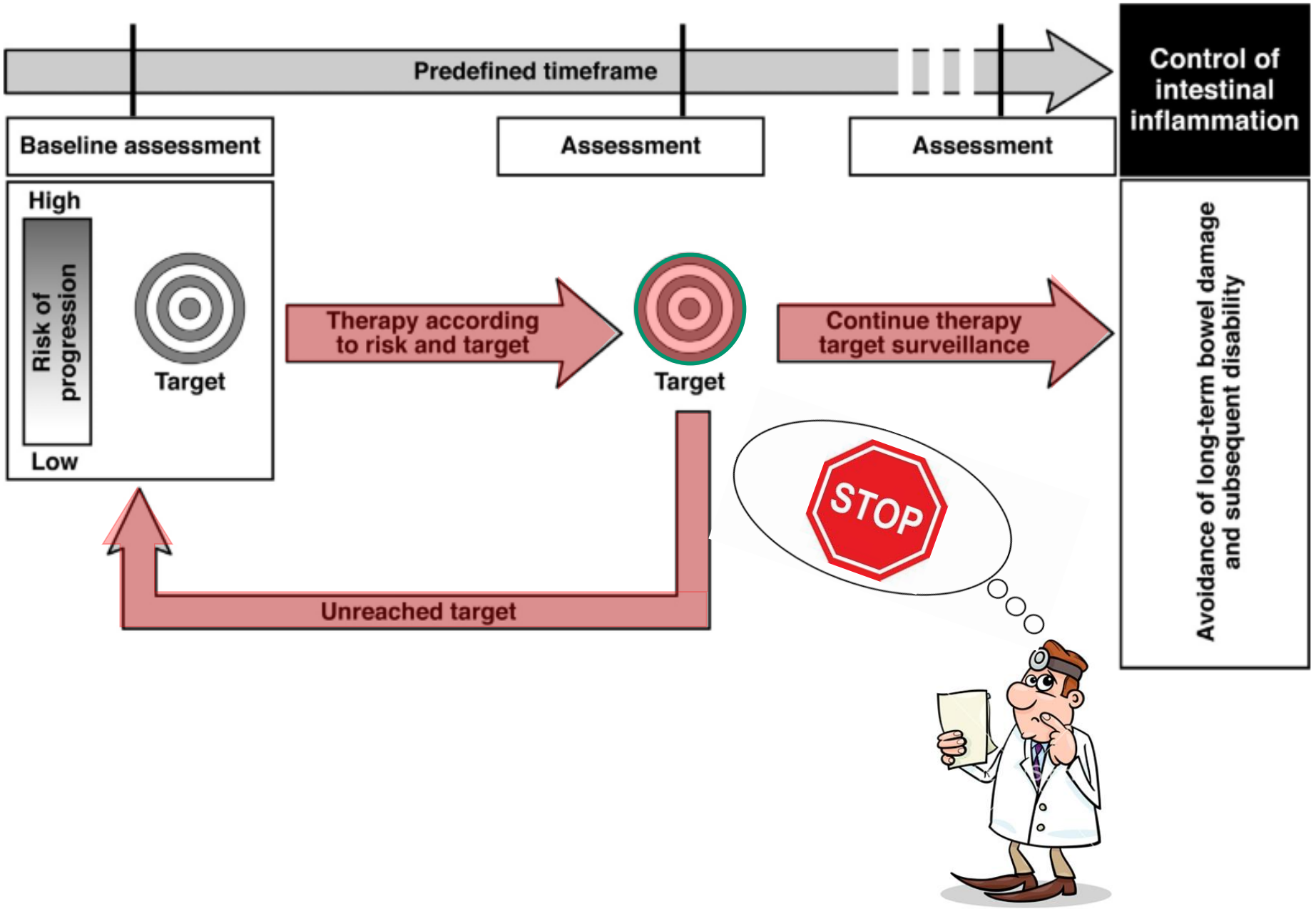
Adverse events in the tofacitinib group ($n = 38$).

	Tofacitinib $n = 38$
Adverse event, No. (%)	14 (36.8%)
Asthenia, No. (%)	4 (10.5%)
Myalgia, No. (%)	2 (5.3%)
Hypercholesterolemia	3 (7.9%)
Paresthesia, No. (%)	1 (2.6%)
Infectious adverse event, No. (%)	9 (23.7%)
Dental infection	3 (7.9%)
Upper respiratory tract infection	3 (7.9%)
Pyelonephritis	1 (2.6%)
Herpes zoster	3 (7.9%)
Anastomotic rectal abscess	1 (2.6%)
Toxic thyroid adenoma	1 (2.6%)
Serious infection, No. (%)	5 (13.2%)
Any serious adverse event, No. (%)	6 (15.8%)
Colectomy, No. (%)	10 (26.3%)

Lair-Mehiri L et al. Dig Liver Dis 2019 [Epub ahead of print]

TREAT TO TARGET



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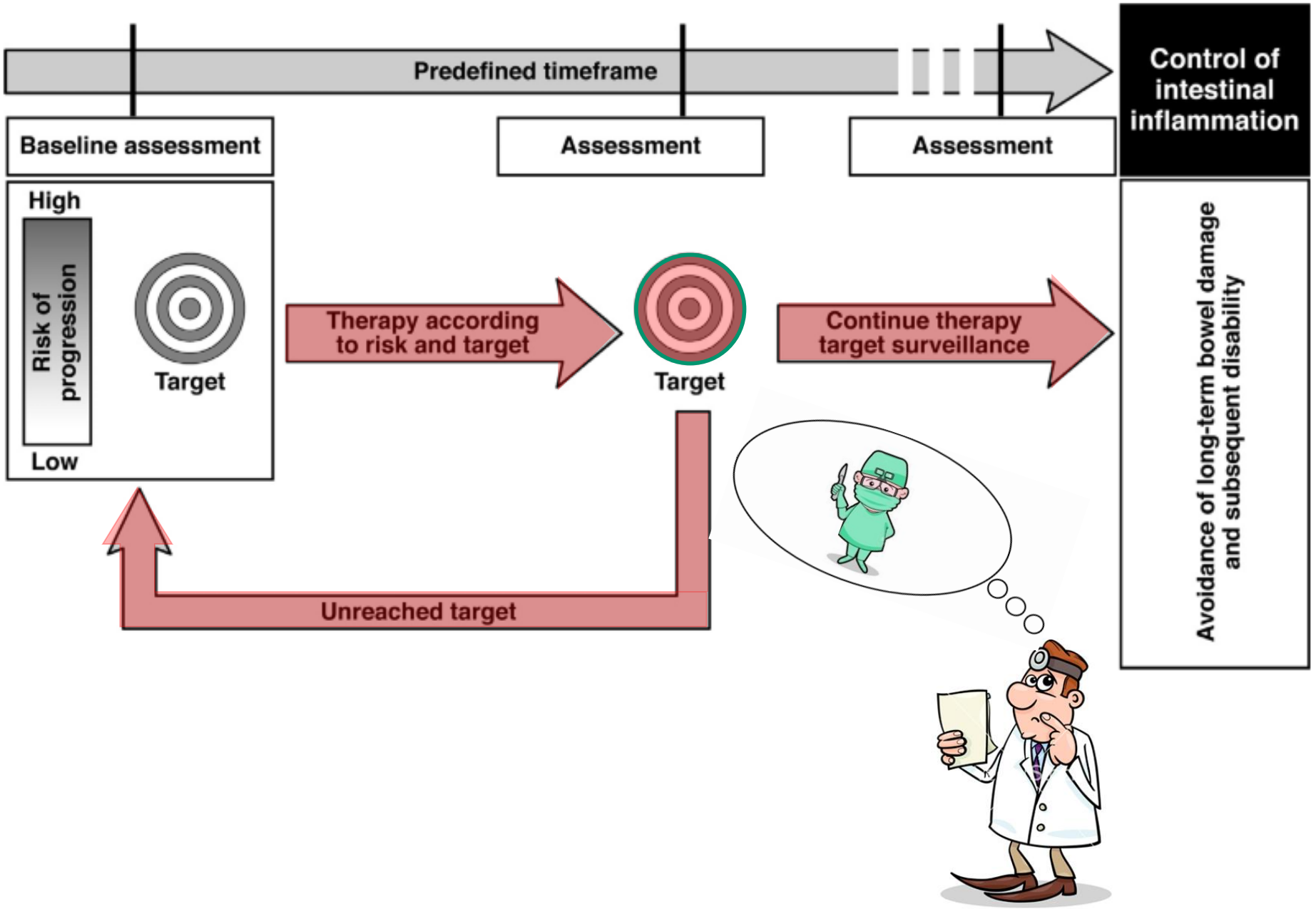


Impact of anti-TNF-alpha therapy on colectomy rate and indications for colectomy in ulcerative colitis: comparison of two patient cohorts from 2005 to 2007 and from 2014 to 2016*

Cohort 1 (2005–2007)	Cohort 2 (2014–2016)
129	133

Table 2. Number of colectomies for ulcerative colitis in years 2005–2007 and 2014–2016.

	2005–2007		2014–2016
Number of colectomies	129		133
Person years (pyrs) with ulcerative colitis	14979 (4993 × 3)	***p<.001***	25983 (8661 × 3)
Colectomies per 1000 pyrs (95% CI)	8.6 (7.2–10.2)		5.1 (4.3–6.1)

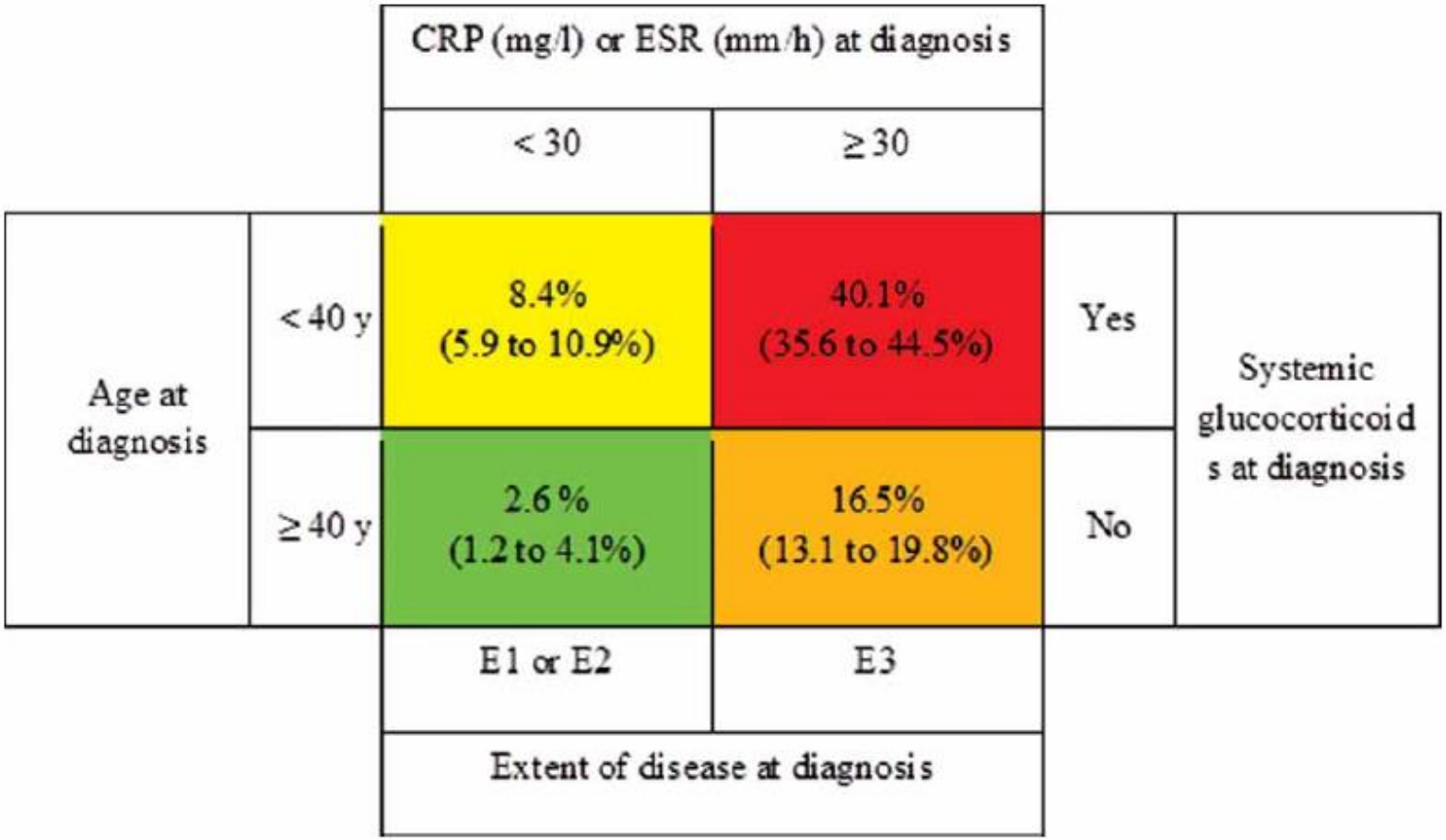
Table 3. Indications for colectomy in the two cohorts.

	Both cohorts	Cohort 1 (2005–2007)	Cohort 2 (2014–2016)	*p* Value (CI 95%)
Indication for colectomy, *n* (%)				
Refractory to medical therapy	208 (79.4)	102 (79.1)	106 (79.7)	.900
Dysplasia	38 (14.5)	21 (16.3)	17 (12.8)	.422
Cancer	7 (2.7)	3 (2.3)	4 (3.0)	.732
Others	9 (3.4)	3 (2.3)	6 (4.5)	.331
Histopathological findings, *n* (%)				
Dysplasia	42 (16.0)	28 (21.7)	14 (10.5)	.014
Cancer	12 (4.6)	6 (4.7)	6 (4.5)	.957
Emergency or urgent surgery, *n* (%)	24 (9.2)	11 (8.5)	13 (9.8)	.726
Fulminant colitis, *n* (%)	18 (6.9)	7 (5.4)	11 (8.3)	.363

Kolehmainen S et al. Scand J Gastroenterol 2019;54:707-711

Risk matrix model for prediction of colectomy in a population-based study of ulcerative colitis patients (the IBSEN study)

A cohort of 519 UC patients diagnosed between 1990 and 1994 has been followed for 10 years, 49 patients were colectomized.



Solberg IC et al. IBSEN Study Group. Scand J Gastroenterol 2015;50:1456-62

A User-Friendly Prediction Tool to Identify Colectomy Risk in Patients With Ulcerative Colitis

A retrospective study on UC patients reviewed from January 2017 to December 2017. Cases (115) had total proctocolectomy (TPC) performed for refractory UC after January 2008, controls (325) had no prior UC surgery.

TABLE 3. Multivariable Prediction Model for TPC in UC

Variable	Coefficient	Odds Ratio	OR 95% LCL	OR 95% UCL	*P*
Intercept	0.02				0.99
Albumin, g/dL	–1.06	0.35	0.15	0.78	0.01
Mayo endoscopic subscore >1	1.17	10.30	4.35	24.37	<0.01
9-point Mayo score >5	0.95	6.63	2.70	16.27	<0.01
Corticosteroid use in last 6 mo	0.64	3.61	1.50	8.70	<0.01

Dalal RS et al. Inflamm Bowel Dis. 2019;25:1550-1558

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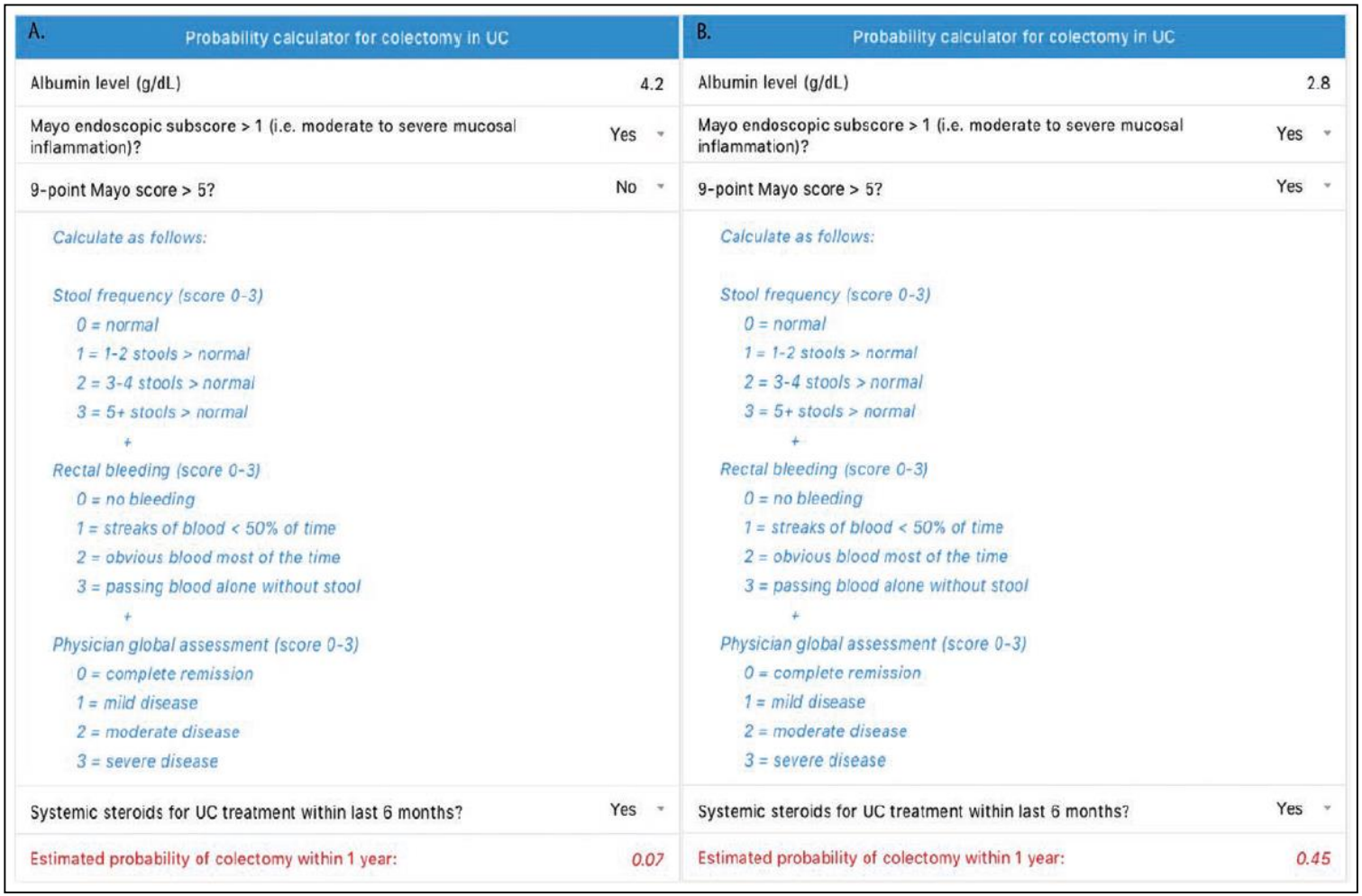

A. Probability calculator for colectomy in UC

Albumin level (g/dL)	4.2
Mayo endoscopic subscore > 1 (i.e. moderate to severe mucosal inflammation)?	Yes
9-point Mayo score > 5?	No

Calculate as follows:

Stool frequency (score 0-3)
0 = normal
1 = 1-2 stools > normal
2 = 3-4 stools > normal
3 = 5+ stools > normal
+
Rectal bleeding (score 0-3)
0 = no bleeding
1 = streaks of blood < 50% of time
2 = obvious blood most of the time
3 = passing blood alone without stool
+
Physician global assessment (score 0-3)
0 = complete remission
1 = mild disease
2 = moderate disease
3 = severe disease

Systemic steroids for UC treatment within last 6 months?	Yes
Estimated probability of colectomy within 1 year:	0.07

B. Probability calculator for colectomy in UC

Albumin level (g/dL)	2.8
Mayo endoscopic subscore > 1 (i.e. moderate to severe mucosal inflammation)?	Yes
9-point Mayo score > 5?	Yes

Calculate as follows:

Stool frequency (score 0-3)
0 = normal
1 = 1-2 stools > normal
2 = 3-4 stools > normal
3 = 5+ stools > normal
+
Rectal bleeding (score 0-3)
0 = no bleeding
1 = streaks of blood < 50% of time
2 = obvious blood most of the time
3 = passing blood alone without stool
+
Physician global assessment (score 0-3)
0 = complete remission
1 = mild disease
2 = moderate disease
3 = severe disease

Systemic steroids for UC treatment within last 6 months?	Yes
Estimated probability of colectomy within 1 year:	0.45

Dalal RS et al. Inflamm Bowel Dis. 2019;25:1550-1558

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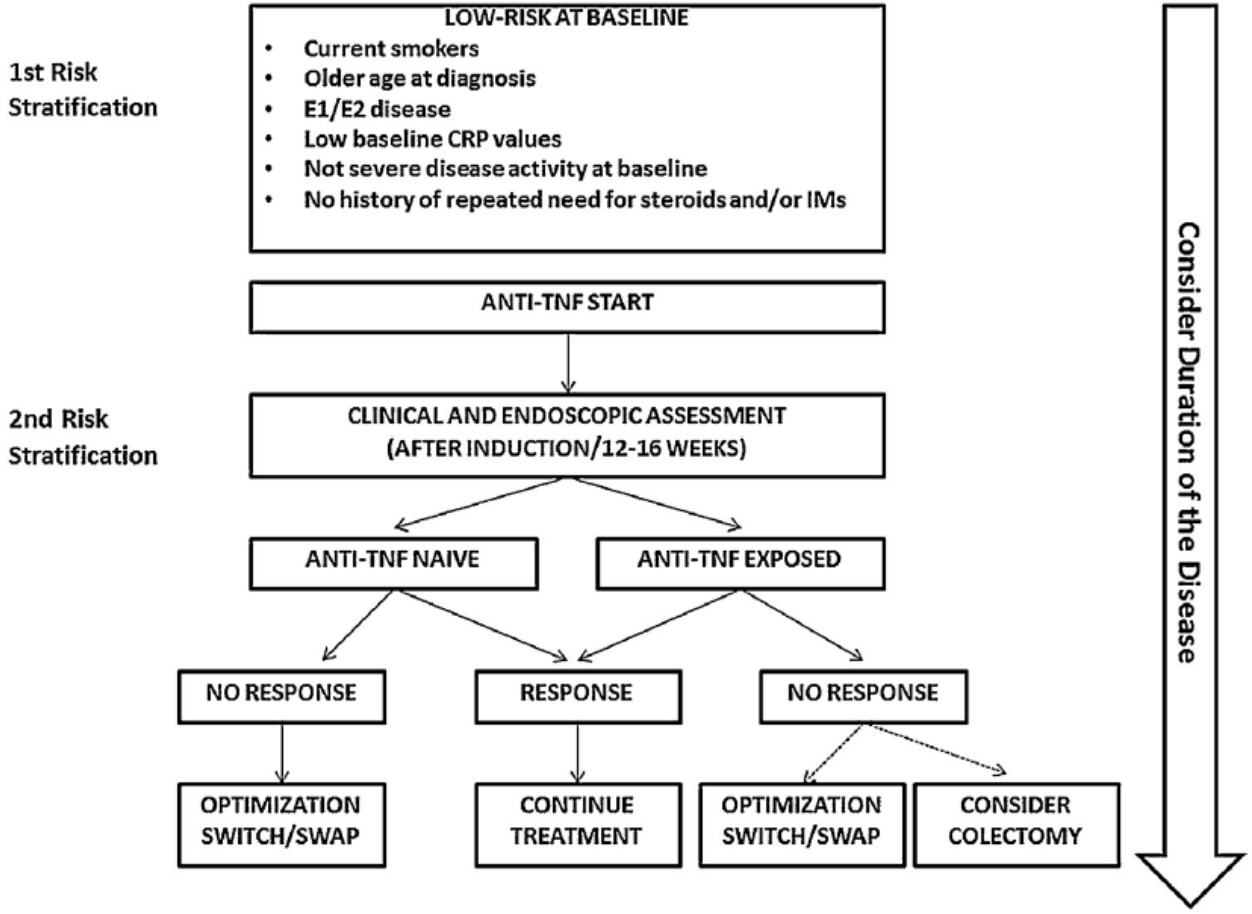
Review Article

Risk factors and timing for colectomy in chronically active refractory ulcerative colitis: A systematic review

Fabio Salvatore Macaluso[a,*], Flaminia Cavallaro[b], Carla Felice[c], Marta Mazza[d], Alessandro Armuzzi[c], Paolo Gionchetti[d], Maurizio Vecchi[e], Ambrogio Orlando[a]

70 studies were included in the qualitative synthesis. Several factors were found to be associated with a higher or reduced risk for colectomy, including variables at baseline, previous medical history, and factors arising during therapy with biologics.



Macaluso SF et al. Digestive and Liver Disease 51 (2019) 613-620

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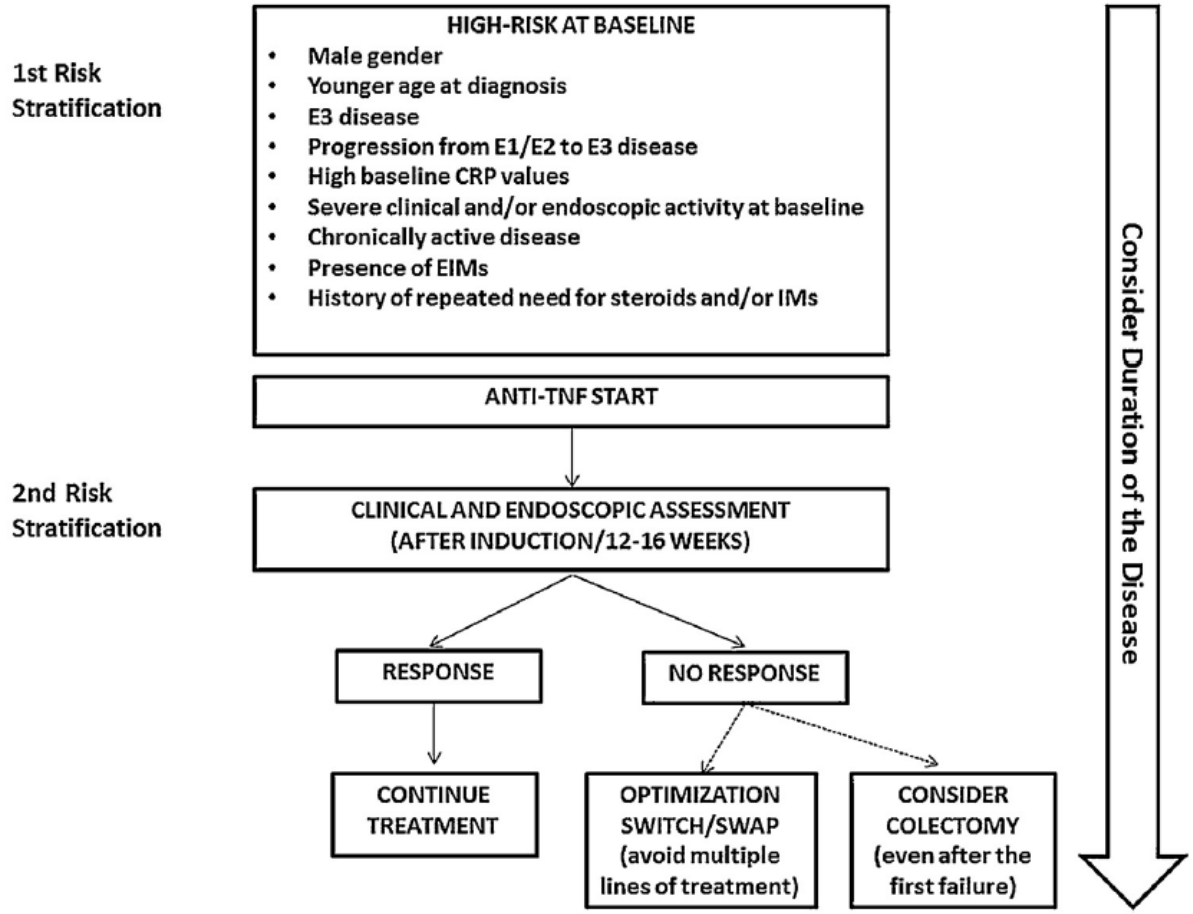

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