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Biologic-naïve Patients with Crohn's Disease are More Likely to Achieve Mucosal Healing than Biologic-experienced Patients: TARGET-IBD Real World Cohort

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Introduction

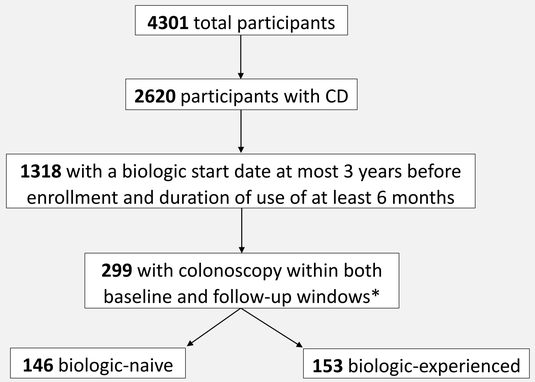
- Therapeutic targets in Crohn's disease (CD) have evolved from clinical remission to endoscopic remission or mucosal healing (MH).
- Clinical trials have suggested that biologic-naïve (Bio-N) patients have higher rates of MH than biologic-experienced (Bio-E) patients who have failed/been intolerant. However, the degree to which this holds true in clinical practice is unknown.
- The aim of this study was to assess factors associated with MH in a real-world CD cohort starting biologic therapy.

Methods

- TARGET-IBD is an observational study of IBD patients receiving care at 36 clinical sites in the US (23 academic and 13 community).
- Patients enrolled July 2017-November 2020 were eligible for analysis if they had active CD at enrollment, started a biologic at most ≤3 years prior, had a baseline colonoscopy ≤12 months prior to biologic start, were on the biologic ≥6 months, and had a follow-up colonoscopy 2-18 months after biologic start while still on the biologic.
- Presence of inflammation, erosion, ulceration, stricture and/or fistula, was assessed at baseline and follow-up for ascertainment of MH defined as:
  a. Normal colonoscopy among patients with any of these abnormalities
  b. Steroid-free normal colonoscopy among patients with any of these
  c. Resolution of inflammation, erosion or ulcerations
- Standard statistical methods were used to compare baseline demographic and clinical factors by previous biologic use (Bio-N/Bio-E). Logistic regression was used to estimate odds ratios (ORs) and 95% confidence intervals (CIs) of MH in relation to the factors.

Results

Figure 1. Flow diagram of TARGET-IBD cohort eligible for analysis



*Baseline window: 12 months prior to biologic start
Follow-up window: 2-18 months after biologic start (and participant must still be on the biologic)*

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Table 1. Characteristics of CD Participants by Previous Biologic Exposure

	Bio-N (N=146)	Bio-E (N=153)	Total (N=299)	P-value
Median age at diagnosis (min–max)	28 (8–76)	22 (6–65)	25 (6–76)	0.001
Median age at biologic start (min–max)	35 (8–78)	37 (13–73)	36 (8–78)	0.50
Female	78 (53.4%)	89 (58.2%)	167 (55.9%)	0.41
Race				
White	125 (85.6%)	131 (85.6%)	256 (85.6%)	0.75
Black/African American	10 (6.8%)	13 (8.5%)	23 (7.7%)	
Other/not reported	11 (7.5%)	9 (5.9%)	20 (6.7%)	
Hispanic or Latino ethnicity	5 (3.4%)	5 (3.3%)	10 (3.3%)	0.94
Median BMI (kg/m^2)[1] (min-max)	25 (14–50)	26 (18–54)	25 (14–54)	0.89
Smoking status				
Never smoker	100 (68.5%)	99 (64.7%)	199 (66.6%)	0.23
Current or former smoker	42 (28.8%)	53 (34.6%)	95 (31.8%)	
Unknown	4 (2.7%)	1 (0.7%)	5 (1.7%)	
Median duration of disease (years)[2] (min-max)	2 (0–57)	11 (0–47)	6 (0–57)	<.001
History of IBD Surgery, n (%)	31 (21.2%)	67 (43.8%)	98 (32.8%)	<.001
History of Non-Perianal Fistula, n (%)[3]	8 (5.5%)	10 (6.5%)	18 (6.0%)	0.70
History of Perianal Disease, n (%)[4]	44 (30.1%)	55 (35.9%)	99 (33.1%)	0.29
Severe Disease, n (%)[5]	64 (43.8%)	94 (61.4%)	158 (52.8%)	0.002
Location of Crohn's Disease, n (%)[6]				
Colon	21 (14.4%)	24 (15.7%)	45 (15.1%)	0.10
Ileocolon	59 (40.4%)*	81 (52.9%)	140 (46.8%)	
Ileum	42 (28.8%)	30 (19.6%)	72 (24.1%)	
Not Reported	24 (16.4%)	18 (11.8%)	42 (14.0%)	
Crohn's Disease Phenotype, n (%)[7]				
Inflammatory (B1)	61 (41.8%)*	35 (22.9%)	96 (32.1%)	<.001
Stricturing (B2)	31 (21.2%)	23 (15.0%)	54 (18.1%)	
Fistulizing (B3)	35 (24.0%)	48 (31.4%)	83 (27.8%)	
History of Surgery (unknown whether B2 or B3)	19 (13.0%)*	47 (30.7%)	66 (22.1%)	
Number of prior biologics used among Bio-E, n (%)				
1	NA	67 (43.8%)	NA	--
>1	NA	86 (56.2%)	NA	

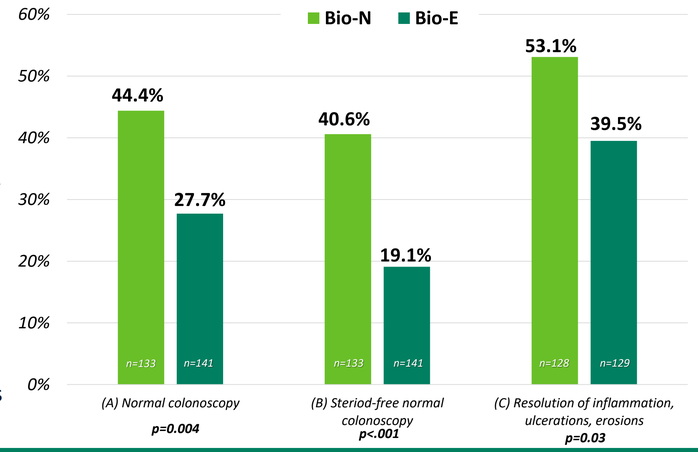
*[1]Most recent BMI from at or before biologic start [2]Duration of disease calculated as the difference in years between diagnosis and biologic start [3]History of non-perianal fistula based on endoscopy and imaging [4]History of perianal disease based on physical exam, and imaging [5]Severe disease defined as history of IBD surgery, non-perianal fistula or perianal disease [6]Based on most recent location of disease at time of biologic start [7]Derived using data up to biologic start date. B2/B3 includes participants with history of surgery for whom it is unknown whether their disease phenotype is stricturing or fistulizing. *Statistical significance at the 5% level observed between characteristic in Bio-N vs. Bio-E groups. (Note: P-values for categorical variables are from the Cochran-Mantel-Haenszel general association test, and p-values for continuous variables are from the Kruskal-Wallis test)*

Figure 2. Rates (Proportion) of Mucosal Healing, Bio-N vs. Bio-E:

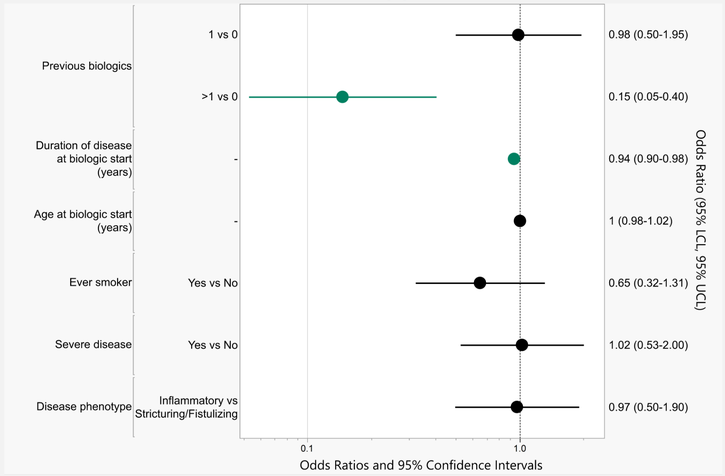
(A) Normal colonoscopy

(B) Steroid-free normal colonoscopy

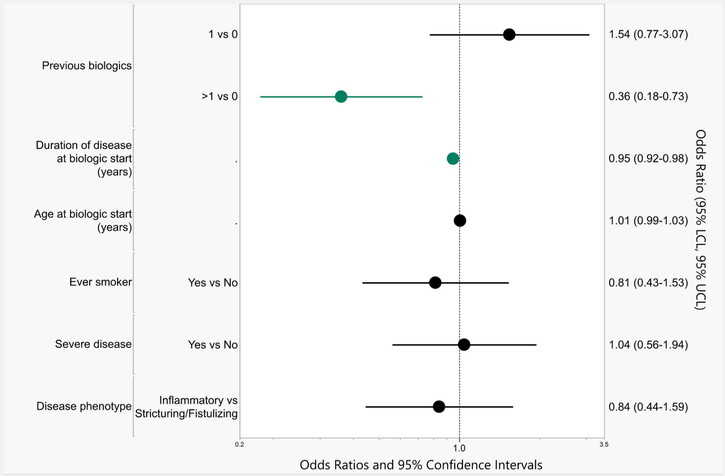
(C) Resolution of inflammation, ulcerations, erosions



Model 1 Outcome: Normal colonoscopy, steroid-free



Model 2 Outcome: No inflammation or ulcerations/erosions



Variables mutually adjusted for all others in model

Conclusions

- **Consistent with observations from clinical trials, Biologic-Naive patients in a real-world CD cohort were significantly more likely to achieve MH than Biologic-Experienced patients.**
- **Prospective analyses are underway to determine if specific sequencing of biologic drugs may impact these findings.**