Racial and Ethnic Diversity in Inflammatory Bowel Disease Randomized Clinical Trials

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Background:

The prevalence of Inflammatory Bowel Disease (IBD) in non-White populations is rising[1]. Historically, inclusion of patients from underrepresented backgrounds in IBD randomized clinical trials (RCTs) has been poor[2]. It is unclear if representation has improved in the era of biologic medications. To address this, we conducted a systematic review of inclusions of race and ethnicity in Phase 2, 3 and 4 RCTs investigating biologic treatments in IBD.

Methods:

National and international trials were included if they investigated a biological treatment against at least one other unique treatment arm in patients with Crohn's Disease (CD), Ulcerative Colitis (UC) or both and included more than 50 patients with IBD. One reviewer screened articles for the inclusion criteria and extracted data. Percentages of participants of each race were compared over time through linear regression in R studio.

Results:

Of 111 RCTs that met inclusion criteria, 48.6% of studies did not include information on the racial breakdown of participants and 29.7% included demographics for one race (28 trials reported only White patients, 5 only Asian patients). 22.1% of RCTs represented multiple racial groups. Of these 24 studies, 100% reported White patients, 83.3% reported Black patients, 83.3% reported Asian patients, 16.6% reported Native or Pacific Island patients and 70.8% included patients defined as "Other" (most cases concurrent with reporting of Asian and Black patients).

Table 1: Percent of RCTs reporting racial and ethnic demographics, by time period and IBD subtype.

Races Reported	Percent of Studies (n=111)	Percent Pre-2010 (n=61)	Percent Post-2010 (n=50)	Crohn's Disease (n=67)	Ulcerative Colitis (n=45)
None	48.6 (54)	54.1 (33)	42.0 (21)	53.7 (36)	40.0 (18)
One	29.7 (33)	27.9 (17)	32.0 (16)	23.9 (16)	37.8 (17)
Asian Only	4.5 (5)	1.6 (1)	8.0 (4)	1.5 (1)	8.9 (4)
White Only	26.2 (29)	22.8 (14)	30.6 (15)	22.4 (15)	28.9 (13)
Multiple Races*	21.7 (24)	18.0 (11)	26.0 (13)	22.4 (15)	37.8 (17)
Two	3.6 (4)	6.6 (4)	0 (0)	1.5 (1)	6.7 (3)
Three	3.6 (4)	3.3 (2)	4.0 (2)	4.5 (3)	2.2 (1)
Four	13.5 (15)	8.2 (5)	20.0 (10)	13.4 (9)	13.3 (6)
Five	0.9 (1)	0 (0)	2.0 (1)	3.0 (2)	0 (0)
Average Racial Breakdown					
White	89.1	90.6	87.6	90.3	86.6
Black	2.6	2.7	2.4	5.2	2.1
Asian	7.6	8.4	7.0	5.6	9.9
NA/PI	0.7	0	0.6	0.5	0.6
Other	2.0	2.3	1.8	1.6	2.6
Reports Ethnicity	4.5 (5)	4.9 (3)	4.0 (2)	4.5 (3)	4.4 (2)
Average Hispanic/Latino	1.3	0.5	3.4	1.1	1.7

Across studies with reported racial demographics, participants were 89.1% White, 2.6% Black, 7.6% Asian, 0.7% Native or Pacific Islander (NA/PI) and 2.0% "Other". 4.5% of studies reported ethnicity, in which 1.3% of participants identified as Hispanic or Latino. There was a significant temporal decrease in the proportion of White participants (RR: 0.96 CI 0.92 - 0.99). There were no significant temporal trends in the participation of Black, Asian, NA/PI, "Other" and Hispanic or Latino patients.

Conclusions:

There is limited inclusion of race and ethnicity in RCTs and when documentation is present, it shows marginalized groups are underrepresented. Ongoing and future RCTs have an opportunity to 1) characterize the racial and ethnic demographics of participants and 2) increase recruitment of participants from underrepresented backgrounds to enhance the generalizability of RCT findings.

Works Cited:

1. Kaplan GG, Windsor JW. The four epidemiological stages in the global evolution of inflammatory bowel disease. Nature Reviews Gastroenterology & Hepatology 2021;18:56-66.

2. Sedano R, Hogan M, McDonald C, et al. Underrepresentation of Minorities and Underreporting of Race and Ethnicity in Crohn's Disease Clinical Trials. Gastroenterology 2022;162:338-340.e2.

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