

# Lack of Difference in Treatment Patterns and Clinical Outcomes Between Black and White Patients With Inflammatory Bowel Disease

Edward L. Barnes, MD, MPH,<sup>\*,†</sup> Bharati Kochar, MD, MSCR,<sup>\*,†</sup> Millie D. Long, MD, MPH,<sup>\*,†,‡</sup> Joel Pekow, MD,<sup>§</sup> Ashwin Ananthkrishnan, MD, MPH,<sup>¶</sup> Adjoa Anyane-Yeboah, MD,<sup>§</sup> Christopher Martin, MSPH,<sup>\*,‡</sup> Joseph Galanko, PhD<sup>‡</sup> Hans H. Herfarth, MD, PhD,<sup>\*,†,‡</sup> Michael D. Kappelman, MD, MPH,<sup>\*,†,‡</sup> and Robert S. Sandler, MD, MPH<sup>\*,‡</sup>

**Background:** Previous reports have shown differences in phenotypes among black patients with inflammatory bowel disease (IBD) compared with other racial groups, but prior studies were limited by small numbers of black patients and cross-sectional analyses. We used data from the Sinai-Helmsley Alliance for Research Excellence cohort to compare phenotypes and treatment patterns of black and white patients with IBD in a prospective study.

**Methods:** We compared phenotypes, IBD-specific therapies, and health care utilization among black and white patients with IBD. For all analyses, we performed bivariate analyses and multivariable logistic regression to adjust for potential confounders.

**Results:** Among 5537 patients with IBD, 314 (6%) reported black race. Black patients were more likely to report a Crohn's disease (CD)-related complication at baseline (adjusted odds ratio [aOR], 1.44; 95% confidence interval [CI], 1.06–1.95). Black patients with CD were more likely to develop a new abscess (aOR, 2.27; 95% CI, 1.31–3.93) and initiate an anti-tumor necrosis factor therapy during follow-up (aOR, 1.85; 95% CI, 1.09–3.14). Black patients with ulcerative colitis were more likely to have proctitis (24% vs 13%,  $P = 0.033$ ) at baseline. There were no differences in surgery or hospitalization rates during the follow-up period.

**Conclusions:** Black patients with CD demonstrated increased complications at baseline and during follow-up in this cohort. Despite more complicated disease, black and white patients with IBD were generally given the same medications and experienced similar rates of hospitalization and surgery during the study period. In our multicenter cohort, clinical outcomes among black and white patients with IBD were similar.

**Key Words:** race, Crohn's disease, ulcerative colitis, IBD-related surgery

## INTRODUCTION

Traditionally, inflammatory bowel disease (IBD) has been viewed as a condition that predominantly affects white patients in Western Europe and North America. Our information on IBD in nonwhite patients is limited, however, because

prior epidemiological studies were done in populations that were predominantly white. For example, some of the largest epidemiologic studies of IBD in the United States are from a population-based cohort in Olmsted County, Minnesota.<sup>1–3</sup> As of 2000, approximately 90% of the residents of Olmsted County were non-Hispanic white, whereas only 4% of residents were black.<sup>3</sup> In other large studies aimed at establishing the prevalence of IBD among different racial or ethnic groups, there has been wide variation in the reported prevalence of IBD among black patients in the United States.<sup>4,5</sup>

There has been a suggestion that black patients with Crohn's disease (CD) are more likely to have perianal disease<sup>6–8</sup> or upper gastrointestinal (GI) tract involvement.<sup>7</sup> In a separate single-center evaluation, black and Hispanic patients with CD treated with infliximab were more likely to demonstrate fistulizing perianal disease than white patients with CD.<sup>9</sup> One recent meta-analysis also demonstrated increased perianal disease among black patients with CD,<sup>10</sup> while suggesting the potentially critical interplay between genetics and environmental exposures on phenotype and the disease course.

In a nationally representative study using administrative databases, black patients were more likely to experience

Received for publications March 14, 2018; Editorial Decision April 9, 2018.

From the <sup>\*</sup>Division of Gastroenterology and Hepatology, <sup>†</sup>Multidisciplinary Center for Inflammatory Bowel Diseases, and <sup>‡</sup>Center for Gastrointestinal Biology and Disease, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina; <sup>§</sup>Section of Gastroenterology, Hepatology, and Nutrition, University of Chicago, Chicago, Illinois; <sup>¶</sup>Division of Gastroenterology, Massachusetts General Hospital, Boston, Massachusetts

Conflicts of interest: All authors report no relevant financial disclosures.

Supported by: This research was supported by grants from the National Institutes of Health (P30DK07634, T32DK07634) and by the Helmsley Charitable Trust.

Address correspondence to: Edward L. Barnes, MD, MPH, Division of Gastroenterology and Hepatology, University of North Carolina at Chapel Hill, Campus Box #7080, 130 Mason Farm Road, Chapel Hill, NC 27599-7080 ([edward\\_barnes@med.unc.edu](mailto:edward_barnes@med.unc.edu)).

doi: 10.1093/ibd/izy179

Published online 18 May 2018

IBD-related hospitalizations and demonstrated higher IBD-related mortality when compared with non-Hispanic white and Hispanic populations.<sup>4</sup> When evaluating utilization of other health care resources, multiple studies have demonstrated increased visits to the emergency department among black patients when compared with whites.<sup>11, 12</sup> Compared with white patients with IBD, black patients have also reported increased difficulty with access to specialists for management of their IBD in addition to increased concerns regarding the cost of their care.<sup>11</sup>

Given these underlying questions of potential differences in phenotype and medication/resource utilization, we aimed to compare patterns of disease distribution and medication use among black and white patients with IBD in the Sinai-Helmshley Alliance for Research Excellence (SHARE) cohort. The SHARE cohort was created from a national collaboration of 7 academic medical centers and contains extensive clinical and phenotypic data from patients with ulcerative colitis (UC) and CD. In contrast to most prior studies, SHARE followed patients prospectively. This prospective study design allows for both the comparison of disease phenotypes among black and white patients with IBD at enrollment and the opportunity to evaluate clinical outcomes and therapy utilization over time.

## METHODS

### Data Source

As previously described, SHARE is a multicenter prospective cohort study,<sup>13, 14</sup> with data collected for this study between January 1, 2012, and December 31, 2015. Patients were recruited from 7 US academic centers: Cedars-Sinai Medical Center, Massachusetts General Hospital, the Mayo Clinic, Mount Sinai, University of Chicago, University of North Carolina at Chapel Hill, and Washington University, Saint Louis. Consented patients provided demographic and clinical information, including past medical history, surgical history, family history, medication use, and extra-intestinal manifestations during a baseline interview with a study coordinator. Patients who were under the age of 18 years, those unable to understand or provide informed consent, and those who did not have a confirmed diagnosis of IBD in their medical records were excluded. Patients were followed prospectively using follow-up questionnaires that were similar to the baseline questionnaire. Follow-up questionnaires were administered every 12 months via telephone, the Internet, or during a subsequent clinic visit. In addition to updated information such as medication use and patient-reported outcomes (PROs), patients were asked if they had experienced a hospitalization (for any reason) or an IBD-related surgery on their bowel since their last visit.

### Outcomes of Interest

Patients were analyzed according to the phenotype of IBD, as defined by the Montreal classification.<sup>15</sup> Among patients with CD, a CD-related complication was defined by

the presence of a perianal fistula, fistulizing disease at another site, or a history of an abscess (abscess at any location). In a subanalysis, these complications were evaluated individually, given the potential differences in perianal and luminal complications. These CD-related complications were self-reported during baseline and follow-up assessments. In the baseline and prospective analyses of CD-related complications, penetrating and perianal complications were prioritized given prior literature, suggesting increased rates of these complications among black patients with CD.<sup>6-8</sup> In all therapy analyses, agents were analyzed by individual medications and by therapy groups (aminosalicylates, thiopurines, methotrexate, and anti-tumor necrosis factor- $\alpha$  [anti-TNF] therapies).

### Covariates

Disease characteristics, as defined by the Montreal classification,<sup>15</sup> were obtained from review of the medical record. A modified Harvey-Bradshaw Index (HBI) or Simple Clinical Colitis Activity Index (SCCAI) was completed during each study visit. Disease in remission was defined as an HBI of less than 5 (CD) or an SCCAI of 2 or less (UC).<sup>16, 17</sup> Several variables obtained from the baseline questionnaire were used in the analyses of therapy utilization, given their potential perceived influence on therapy decision (surgical history, time since diagnosis, smoking history, and disease phenotype). In the analysis of therapy utilization among patients with UC, only those patients without a history of IBD-related surgery were included.

### Statistical Analysis

Continuous variables were summarized using means and standard deviations and compared using Student *t* tests. Categorical variables were expressed as proportions and compared using Fisher exact and chi-square testing, as appropriate. Bivariate and multivariable logistic regression models were utilized to evaluate the odds of a CD-related complication among black and white patients with CD. Bivariate and multivariable logistic regression models were also used to evaluate the relationship between race and use of IBD-specific therapies among patients with CD and UC. All covariates included in the multivariable analyses were identified a priori based on prior association with clinical disease activity or disease course in IBD. In the analyses of therapy utilization among patients with UC, only patients without a history of IBD-related surgery were included. All statistical analyses were performed using SAS (version 9.4) statistical software (SAS Institute, Cary, NC, USA). The study protocol was approved by the institutional review boards of all participating institutions.

## RESULTS

A total of 5906 patients were evaluated in the SHARE Cohort (64% CD, 36% UC). When evaluated by racial group reported by the participant, 5223 patients reported white race (88%), 314 reported black race (5%), 116 reported Asian race

(2%), and 253 reported another racial group (4%). Of note, Hispanic ethnicity was reported as a modifier within the SHARE cohort, with 201 patients reporting Hispanic ethnicity. There was no difference in the number of patients reporting Hispanic ethnicity when comparing black and white patients (2% vs 2%,  $P = 0.828$ ). Those patients reporting black or white race ( $n = 5537$ ) represented the final population for all planned analyses. Of these 5537 patients, 4033 (73%) completed follow-up assessments. The median follow-up time for black and white patients enrolled in the SHARE cohort (interquartile range) was 23.6 (13.8–28.1) months and was not statistically significant between the 2 groups.

Black patients were significantly more likely to have a diagnosis of CD (75% vs 64%,  $P < 0.001$ ) and were more likely to be female (60% vs 52%,  $P = 0.008$ ) (Table 1). When evaluating demographics by center, 88% of black patients were treated at 4 of the 7 participating institutions (Supplementary Table 1). Although black patients with CD were more likely to report a history of an abscess (10% vs 5%,  $P = 0.015$ ), there were no significant differences in history of fistula or in phenotype as defined by Montreal classification of disease when comparing black and white patients with CD. Among patients with UC, however, black patients were significantly more likely to have proctitis (24% vs 13%), and were subsequently less likely to have pancolitis (46 vs 58%,  $P = 0.033$ ). There were no significant differences in extraintestinal manifestations of IBD when comparing black and white patients. Black patients with CD were significantly less likely to report use of a thiopurine before enrollment, (61% vs 72%,  $P = 0.003$ ), whereas black patients with UC were significantly less likely to report prior use of oral aminosalicylates (80 vs 89%,  $P = 0.011$ ) and methotrexate (0% vs 7%,  $P = 0.013$ ).

When comparing the odds of a CD-related complication (including perianal fistula, other CD-related fistula, or abscess) at the baseline visit, black patients were significantly more likely to demonstrate a complication in both the unadjusted (odds ratio [OR], 1.34; 95% confidence interval [CI], 1.10–1.81) and adjusted models (adjusted OR [aOR], 1.44; 95% CI, 1.06–1.95) when compared with white patients with CD (Table 2). In a secondary analysis evaluating perianal fistula, other CD-related fistula, and abscess as separate outcomes, only a history of an abscess at baseline among black patients with CD remained significant after adjusting for the same potential confounders (aOR, 2.07; 95% CI, 1.30–3.32). In the evaluation of the other complications, black patients demonstrated a nonsignificant increase in odds of perianal fistula (aOR, 1.30; 95% CI, 0.94–1.82) and other CD-related fistula (aOR, 1.44; 95% CI 0.84–2.45) when compared with white patients with CD.

In the follow-up period, black patients with CD were significantly more likely to develop a new abscess (aOR, 2.27; 95% CI, 1.31–3.93) or a new anal fissure (aOR, 1.76; 95% CI, 1.01–3.07) in both unadjusted and adjusted models (Table 3). Despite this increased frequency of abscess development among black

patients with CD, there were no significant differences in rates of IBD-related surgery after enrollment in the SHARE cohort when compared with white patients (aOR, 0.62; 95% CI, 0.37–1.05) (Table 4). Of note, only 1 black patient with UC underwent IBD-related surgery during the follow-up period; however, there were no significant differences when comparing black and white patients with UC (aOR, 0.18; 95% CI, 0.02–1.29). There were no differences in the number of hospitalizations during the follow-up period when comparing black and white patients with CD (aOR, 1.09; 95% CI, 0.80–1.48) or UC (aOR, 0.93; 95% CI, 0.51–1.70).

In the comparison of therapy utilization during the follow-up period, black patients with CD were more likely to be initiated on a new anti-TNF therapy after enrollment in the SHARE cohort (aOR, 1.85; 95% CI, 1.09–3.14) (Table 4). There was no statistically significant difference when comparing the initiation of a new anti-TNF between black and white patients with UC (aOR, 1.42; 95% CI, 0.55–3.69). When comparing the initiation of combination therapy, thiopurine monotherapy, and methotrexate monotherapy, there were no differences noted among black and white patients during the follow-up period. There were also no significant differences in the use of new steroid therapy.

## DISCUSSION

In an analysis of more than 5000 patients with IBD from 7 academic medical centers across the United States, we demonstrated that black patients with CD were more likely to experience complications related to CD at baseline, particularly the development of CD-related abscesses. However, black patients with CD and UC demonstrated no increase in frequency of surgery or hospital admission after enrollment in the SHARE cohort when compared with white patients with CD or UC. After enrollment in the SHARE cohort, black patients with CD were more likely to receive a new anti-TNF therapy than white patients with CD, perhaps indicating a recognition of the increased potential for disease complications or a reaction to increased complications such as abscess development. Overall, these findings suggest that despite potential underlying biologic differences or disease complications that may arise from environmental factors or access to care issues, if patients receive appropriate and tailored therapies, black and white patients with IBD may achieve similar long-term clinical outcomes.

Prior studies have indicated that black patients with CD are more likely to have complicated disease phenotypes, including increased perianal disease,<sup>6, 7, 9</sup> anal fissure,<sup>8</sup> and upper GI tract involvement.<sup>7</sup> In our analysis, we also demonstrated an increase in complications related to CD; however, black patients did not demonstrate an overall significant increase in stricturing or penetrating disease phenotypes, as defined by the Montreal classification of disease. The increase in complications may have been driven by self-report of a history of abscess during the baseline period, as this was the only outcome (of

**TABLE 1: Clinical and Demographic Characteristics of Patients in the SHARE Cohort, Evaluated by Racial Group**

	White (n = 5223)		Black (n = 314)		P
	No.	%	No.	%	
Age, mean (SD), y	41	15	41	15	0.547
Crohn's disease	3349	64	237	75	<0.001
Female sex	2725	52	188	60	0.008
Any history of smoking cigarettes	1666	33	85	28	0.070
Born in the United States	4908	95	296	95	0.990
Location of Crohn's disease					0.005
Ileal	841	26	57	24	
Colonic	635	19	67	28	
Ileocolonic	1815	55	115	48	
Behavior of Crohn's disease					0.549
B1, Nonpenetrating, nonstricturing	1582	48	107	45	
B2, Stricturing	946	29	69	29	
B3, Penetrating	778	24	63	26	
Location of ulcerative colitis					0.033
Proctitis	226	13	16	24	
Left-sided	522	30	21	30	
Extensive/pancolitis	1013	58	32	46	
History of extraintestinal manifestation <sup>a</sup>	243	5	16	5	0.718
Presence of a perianal fistula in patients with Crohn's disease	600	18	50	21	0.262
History of an abscess in patients with Crohn's disease	163	5	22	10	0.015
History of a fistula in patients with Crohn's disease	165	5	16	7	0.644
No. prior bowel surgeries in patients with Crohn's disease					0.503
0	1684	51	119	52	
1	1012	31	65	28	
2 or more	580	18	47	20	
Prior therapy, Crohn's disease					
Ever used oral steroids	2727	84	189	82	0.430
Ever used thiopurine	2349	72	140	61	0.003
Ever used methotrexate	601	19	38	17	0.451
Ever used anti-TNF	2379	71	167	70	0.851
Prior therapy, ulcerative colitis					
Ever used oral steroids	1570	86	59	79	0.070
Ever used oral aminosalicylates	1620	89	58	80	0.011
Ever used thiopurine	1019	56	38	52	0.484
Ever used methotrexate	125	7	0	0	0.013
Ever used anti-TNF	827	44	27	35	0.116
Ever used total parenteral nutrition	594	12	22	7	0.016
Ever used narcotic pain medications	2352	46	165	54	0.010
Ever used probiotics	1722	34	47	15	<0.001

those included in the composite) that was significantly different at baseline. In a retrospective evaluation of a multi-ethnic population from a county hospital, Malaty et al. also demonstrated no difference in CD phenotypes when comparing CD phenotypes among white, black, and Hispanic patients.<sup>16</sup> In a systematic review of manifestations of IBD among nonwhite

populations, between 16% and 24% of patients were reported to have fistulizing CD<sup>17</sup>; thus our population represents 1 of the highest frequencies of penetrating CD reported among black patients.

In our evaluation, black patients with UC were less likely to demonstrate extensive colitis when compared with white



**TABLE 2: Unadjusted and Adjusted Comparisons of Odds of a Crohn's Disease–Related Complication<sup>a</sup> Among Black and White Patients With Crohn's Disease at Baseline**

	Unadjusted Odds Ratio (95% Confidence Interval)	Adjusted Odds Ratio <sup>b</sup> (95% Confidence Interval)
Race		
White	Reference	Reference
Black	1.34 (1.10–1.81)	1.44 (1.06–1.95)
Female sex	0.92 (0.79–1.08)	0.92 (0.79–1.09)
Age, y		
18–30	0.75 (0.62–0.91)	1.09 (0.82–1.24)
31–50	Reference	Reference
51–70	0.80 (0.66–0.98)	0.73 (0.59–0.89)
>70	0.55 (0.32–0.95)	0.51 (0.29–0.88)
History of tobacco use	1.18 (1.00–1.39)	1.21 (1.02–1.44)
Time since diagnosis, y		
≤1	0.83 (0.56–1.24)	0.86 (0.58–1.29)
2–5	Reference	Reference
6–10	1.31 (0.99–1.73)	1.30 (0.98–1.73)
>10	2.10 (1.67–2.63)	2.26 (1.78–2.87)

<sup>a</sup>Disease complication defined by presence of perianal fistula, fistula in other location, or abscess.

<sup>b</sup>All variables included in the adjusted analysis are depicted above.

**TABLE 3: Odds of Crohn's Disease–Related Complications During the Follow-up Period Among Black Patients With CD Compared With White Patients With CD**

	Unadjusted Odds Ratio (95% Confidence Interval)	Adjusted Odds Ratio <sup>a</sup> (95% Confidence Interval)
New CD-related abscess	2.28 (1.33–3.93)	2.27 (1.31–3.93)
New luminal fistula	1.30 (0.69–2.44)	1.25 (0.66–2.35)
New anal fissure	1.77 (1.02–3.08)	1.76 (1.01–3.07)

<sup>a</sup>Adjusted for sex, age, tobacco use, and time since diagnosis.

patients with UC. Similar findings of an increase in proctitis among black patients with UC as compared with white patients with UC have been demonstrated in single-center studies.<sup>11, 18, 19</sup> In another single-center evaluation, Sofia et al.<sup>20</sup> demonstrated no difference in disease extent when comparing black and white patients with UC. The rate of proctitis in the SHARE cohort

was also higher than that reported in a large repository from the Inflammatory Bowel Disease Genetics Consortium.<sup>7</sup>

The existing literature suggests that disparities may exist in the utilization of medical therapies among black patients with IBD.<sup>11, 21–23</sup> Given the concerns regarding more aggressive phenotypes of CD in particular, we had a significant interest in the patterns of medication utilization and outcomes of patients after enrollment in the SHARE cohort. Prior retrospective studies have indicated that black patients with IBD were less likely to receive treatment with infliximab and other immunomodulators,<sup>21</sup> including in multivariable analyses adjusting for potential confounders.<sup>11</sup> In our analyses, black patients with CD were more likely to initiate a new anti-TNF during the follow-up period and demonstrated no disparities in terms of other medications utilized after enrollment during the follow-up period. When analyzing the entire population of patients with IBD, black patients were more likely to initiate an anti-TNF in the follow-up period but demonstrated no other significant differences in medication utilization.

In our prospective cohort study, all patients were treated at 1 of 7 participating academic institutions. In prior assessments of treatment patterns and outcomes of black patients with IBD, access to care has been recognized as a significant barrier to treatment and achieving goal outcomes.<sup>24</sup> In 1 single-center analysis, black patients with IBD reported greater difficulty obtaining referrals to specialists for IBD-related care and greater concerns regarding health care–related costs.<sup>11</sup> Additionally, in earlier multicenter cohort studies, the disparities in CD between black and white patients have been attributed to social and economic factors, and not underlying biological differences in the disease processes.<sup>25</sup> Our findings during the follow-up period would suggest that black patients receiving care at 1 of the participating institutions had similar frequencies of hospitalizations and IBD-related surgeries, despite higher rates of CD-related complications at baseline presentation.

Whether the differences in disease presentation at the time of enrollment in the SHARE cohort were due to underlying biologic differences or related to treatment decisions before enrollment remains unknown. Although black patients with CD were more likely to develop abscesses or anal fissures during the follow-up period, these complications alone did not seem to lead to increased resource utilization or worse outcomes. Our definition of IBD-related surgery was limited to surgeries on the bowel, and thus abscess drainage and other procedures were not evaluated in this study. However, given the similar rates of IBD-related surgery and hospitalization demonstrated, early recognition of the potential for increases in disease complications among black patients with IBD may be critical. This early recognition allows for appropriate intervention, including the use of anti-TNF monotherapy and combination therapy strategies where appropriate, and may lead to improved long-term outcomes.

**TABLE 4:** A Comparison of Health Care Resource Utilization During the Follow-up Period Comparing Black Patients With CD or UC With White Patients in Unadjusted and Adjusted Analyses

	Unadjusted Odds Ratio, CD (95% CI)	Adjusted Odds Ratio, <sup>a</sup> CD (95% CI)	Unadjusted Odds Ratio, UC (95% CI)	Adjusted Odds Ratio, <sup>a</sup> UC (95% CI)
IBD-related surgery	0.66 (0.39–1.11)	0.62 (0.37–1.05)	0.19 (0.03–1.38)	0.18 (0.02–1.29)
Hospitalization	1.14 (0.84–1.54)	1.09 (0.80–1.48)	0.96 (0.53–1.73)	0.93 (0.51–1.70)
Initiation of anti-TNF	1.83 (1.08–3.08)	1.85 (1.09–3.14)	1.65 (0.65–4.20)	1.42 (0.55–3.69)
Initiation of combination therapy	0.78 (0.24–2.52)	0.71 (0.22–2.30)	2.18 (0.50–9.42)	1.75 (0.40–7.78)
Initiation of a thiopurine	1.22 (0.61–2.44)	1.11 (0.55–2.25)	0.85 (0.20–3.54)	0.72 (0.17–3.04)
Initiation of methotrexate	1.29 (0.56–3.01)	1.24 (0.53–2.90)	2.51 (0.58–10.9)	2.29 (0.51–10.2)
New steroid therapy	2.05 (0.92–4.58)	2.07 (0.92–4.65)	N/A <sup>b</sup>	N/A <sup>b</sup>

<sup>a</sup>Adjusted for sex, age, tobacco use, time since diagnosis, and Montreal classification of disease at baseline.

<sup>b</sup>No black patients with UC received a new prescription for steroids during the follow-up period.

This cohort is among the largest multicenter populations of black patients with IBD that have been studied in the United States. However, this study does have existing limitations. At both the baseline assessment and during follow-up, CD-related complications such as abscess were self-reported. All patients enrolled in this study were evaluated and treated at academic medical centers, and thus their clinical course after enrollment in the SHARE cohort was likely influenced by access to multiple factors other than medical therapy, including but not limited to institutional support, nutritionists, and counselors. Additionally, because these are academic medical centers, many of the patients enrolled were likely referrals to the centers, and thus the clinical course of disease may have been well underway before enrollment in the cohort or initiation of a treatment plan at an individual center. Therapy decisions are likely influenced by both the patient and the provider, and although the providers are likely relatively constant in their practice patterns across each of the 7 medical centers in the SHARE cohort, we were unable to assess the factors that drove therapy decisions from the provider perspective. What does seem constant in our analyses is that black and white patients were offered similar therapies after enrollment in the SHARE cohort, with the only significant difference in treatment patterns being the increased use of anti-TNF therapy among black patients with CD after enrollment. Although we demonstrated no significant difference in the need for surgery among patients with CD and UC after enrollment, our median follow-up time was only 23 months, and the potential remains that significant differences in surgery rates may be demonstrated with longer follow-up.

In conclusion, using a multicenter cohort composed of patients from 7 academic medical centers in the United States, we have demonstrated significant differences in the disease presentation of black patients with CD and UC. Black patients with CD in particular were more likely to report a complication at baseline and were more likely to develop an abscess or

anal fissure during the follow-up period. However, following enrollment in the SHARE cohort, medication utilization patterns were similar among black and white patients with IBD, other than an increased use of anti-TNF therapies among black patients with CD. Additionally, there were no significant differences in hospitalization or surgery after enrollment in the SHARE cohort. Our study shows that although fundamental biological differences or environmental exposures may lead to variant phenotypic presentations of CD and UC between black and white patients, selection of appropriate therapies may overcome these differences, leading to similar long-term clinical outcomes.

## SUPPLEMENTARY DATA

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

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