Black and White Patients With Inflammatory Bowel Disease Show Similar Biologic Use Patterns With Medicaid Insurance

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Background: Prior studies have identified racial disparities in the treatment and outcomes of inflammatory bowel disease (IBD). These disparities could be secondary to differences in biology, care delivery, or access to appropriate therapy. The primary aim of this study was to compare medication use among Medicaid-insured black and white patients with IBD, given uniform access to gastroenterologists and therapies.

Methods: We analyzed Medicaid Analytic eXtract data from 4 states (California, Georgia, North Carolina, and Texas) between 2006 and 2011. We compared the use of IBD-specific therapies, including analyses of postoperative therapy among patients with Crohn disease (CD). We performed bivariate analyses and multivariable logistic regression, adjusting for potential confounders.

Results: We identified 14,735 patients with IBD (4672 black [32%], 8277 with CD [58%]). In multivariable analysis, there was no significant difference in the odds of anti-tumor necrosis factor use by race for CD (adjusted odds ratio [aOR] = 1.13; 95% confidence interval [CI], 0.99-1.28] or ulcerative colitis (aOR = 1.12; 95% CI, 0.96-1.32). Black patients with CD were more likely than white patients to receive combination therapy (aOR = 1.50; 95% CI, 1.15-1.96), and black patients were more likely than white patients to receive immunomodulator monotherapy after surgery for CD (31% vs 18%; $P = 0.004$).

Conclusions: In patients with Medicaid insurance, where access to IBD-specific therapy should be similar for all individuals, there was no significant disparity by race in the utilization of IBD-specific therapies. Disparities in IBD treatment discussed in prior literature seem to be driven by socioeconomic or other issues affecting access to care.

Key Words: disparities, race, Crohn disease, ulcerative colitis, Medicaid, postoperative therapy

INTRODUCTION

Although inflammatory bowel disease (IBD) has historically been viewed as a condition that predominantly affects white patients in Western Europe and North America, more recent data indicate increasing rates of Crohn disease (CD) and ulcerative colitis (UC) among previously low-incidence populations.[1] Epidemiologic data regarding the incidence and prevalence of IBD among racial groups in the United States are relatively limited given that many of the largest evaluations were performed in populations that were predominantly white.[2-4] Emerging literature also suggests that the genetic determinants of IBD may differ by race.[5] Underlying biological differences may lead to phenotypic differences in disease expression, as black patients have been suggested to have increased rates of perianal disease,[6-9] upper gastrointestinal tract CD,[9] penetrating disease,[10] and higher rates of proctitis or left-sided UC.[11, 12]

Prior studies have suggested that black patients are more likely to experience higher rates of IBD complications including hospitalizations and mortality when compared with non-Hispanic white and Hispanic populations.[13] Among patients undergoing IBD-related surgery, black patients are at increased risk for death and serious morbidity, yet this elevated risk is not explained by traditional perioperative factors.[14] In addition, although black race has been associated with an increased risk of complications related to IBD,[6] in some analyses black patients with CD were less likely to receive infliximab than white patients.[15]

Previously shown disparities in outcomes between black and white patients with IBD could exist for multiple reasons,

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including underlying biological and genetic differences, alternative settings or methods of care delivery, and unequal access to providers and medications. Since the Affordable Care Act provisions went into effect in 2014, insurance coverage has improved for minority populations.[16] However, according to U.S. Census data, in 2017, black patients were still more likely to be uninsured (10.6%) than non-Hispanic white patients (6.3%). As of 2017, black patients were also more likely to use government insurance coverage than were non-Hispanic white patients (44.1% vs 36.6%).[17] These disparities in insurance coverage have been shown to drive important differences in access to care.[18] In addition, even when insured, IBD patients reported difficulty in finding sufficient insurance coverage, and many reported delays in care because of cost concerns.[19]

To better understand the role that access to specialty care and therapies plays in disparities by race in IBD, we designed this study using data from the Medicaid Analytic eXtract (MAX) files from 4 states to analyze medication utilization patterns among black and white patients with IBD. In designing this study, we hypothesized that when access to specialty care and IBD-specific medications is equal, there would be no disparities in medication utilization between black and white patients. We believed that the MAX data was an ideal source for this analysis, given that black and white patients would have similar baseline socioeconomic status at the time of Medicaid enrollment, that all patients would have insurance coverage, and thus that they would have a similar network of gastroenterologists and therapies available via coverage with Medicaid insurance in an individual state. Notably, data regarding race and ethnicity in the MAX data are self-reported, showing the validity of this factor in this unique administrative dataset.

METHODS

We performed a retrospective cohort study evaluating medication use patterns among patients with UC and CD and Medicaid insurance between 2006 and 2011.

Data Source

Medicaid is the joint insurance program provided by states and the federal government to low-income and disabled individuals in the United States. The Centers for Medicare & Medicaid Services and its contractors compile data into a consistent and research-friendly format known as the MAX data.[20] The MAX data files contain enrollment information and final action claims for all Medicaid beneficiaries and are available for analysis on a state-by-state basis. For this study, MAX data from 4 states were analyzed (California, Georgia, North Carolina, and Texas) for 2006 to 2011. For 2011, 100% of data samples were available from North Carolina and Georgia but 15% of data samples from California and Texas were used. For all other years, 100% of data samples were used.

Study Population

All patients aged ≥18 years and <64 years with at least 6 months of continuous health plan enrollment were eligible for inclusion in these analyses. We used an age of 64 years as the upper age limit to avoid the possibility of missing data because of Medicare dual eligibility (which begins at age 65). We identified cases of UC and CD using a previously reported definition for use with administrative databases.[21] Patients were required to have at least 3 health care contacts, on different days, associated with an ICD-9 Clinical Modification diagnosis code for UC (556.xx) or CD (555.xx). Alternatively, patients could have at least 1 claim for UC and CD and at least 1 pharmacy claim for any of the following medications: balsalazide, mesalamine, olsalazine, sulfasalazine, azathioprine, mercaptopurine, methotrexate, adalimumab, certolizumab pegol, infliximab, or enteral budesonide. For patients who had claims for both UC and CD, disease assignment was made according to the majority of the last 9 claims, or the majority of total claims if there were fewer than 9 claims. Any patient with a concomitant diagnosis of rheumatoid arthritis, ankylosing spondylitis, psoriasis, or psoriatic arthritis was excluded as these diagnoses could represent competing indications for anti-tumor necrosis factor (anti-TNF) therapy. Race was defined using the existing structure of the MAX data, where white and black race are defined categorically and Hispanic ethnicity is a modifier. For these analyses we evaluated only non-Hispanic white and non-Hispanic black patients.

Exposure of Interest

Our primary aim was to compare medication use patterns among black and white patients with IBD. Using pharmacy claims, we evaluated the use of the following medications as monotherapy: adalimumab, azathioprine, certolizumab, infliximab, mercaptopurine, and methotrexate. In addition, we evaluated therapy use by class (aminosalicylates, anti-TNFs, thiopurines, and immunomodulators [thiopurines and methotrexate] where appropriate). Finally, we evaluated the use of combination therapy using an anti-TNF therapy with an immunomodulator. In a secondary analysis, among patients with CD undergoing intestinal resection, we evaluated the use of the same therapies for the postoperative management of CD.

Follow-Up

For each patient with IBD, the follow-up period began with the first claim with a diagnosis code defining UC or CD. Follow-up continued until any of the following censoring events: death, discontinuation or loss of Medicaid coverage, or the end of the study period. Time accrued on monotherapy began with the first claim for an IBD-specific therapy and continued until the last claim for the same therapy. Where individual patients had claims for multiple agents, each time period contributed individually to the total duration of time on monotherapy. Time

accrued on combination therapy began on the first date when both therapies had active claims. Follow-up continued until any of the following events: loss or discontinuation of Medicaid coverage for more than 1 month, age >65 years, or death. For any patient who had multiple periods of Medicaid coverage during the study period, only the first time period was used.

Covariates of Interest

In addition to therapy use patterns, we also compared baseline demographic characteristics, the Elixhauser Comorbidity Index Score,[22] and measures of health care resource utilization, including IBD-related surgeries and hospitalization. Patients with CD who underwent intestinal resection were identified using ICD-9 codes for intestinal resection (Supplemental Table 1).

Statistical Analysis

We used descriptive statistics to summarize baseline demographic and available clinical characteristics. Continuous variables are reported as means with accompanying SD, and categorical variables are reported as raw values with percentages. Continuous variables were compared using *t* tests and Wilcoxon rank-sum testing, and categorical variables were compared using Fisher exact and $\times^2$ testing as appropriate. Bivariate and multivariable logistic regression models were used to evaluate the relationship between race and IBD-specific medications. Logistic regression was used in all analyses of utilization patterns to control for potential confounders including differences in utilization of medication regimens. All covariates included in the multivariable analyses were identified a priori based on prior association with clinical disease activity, the disease course in IBD, or suspected influence on resource utilization. For all analyses, 2-sided *P* values ≤0.05 were considered statistically significant. All analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC).

RESULTS

We identified 14,735 patients with IBD, of whom 8277 (58%) had CD. Of the 14,735 patients, 4672 (32%) were black and 9459 (64%) had received at least 1 IBD-specific medication during the study period (Table 1). The median age was 41 (interquartile range = 29-51), and there were 9665 female patients (66%). The median follow-up time for patients in the study was 641 days (interquartile range = 281-1249). Among all patients in the cohort, the median follow-up time of black patients was significantly longer than that of white patients (665 days vs 629 days; $P < 0.001$). There was no significant difference in the follow-up time when comparing black and white patients who underwent an intestinal resection for CD. When examining the state of residence, the largest proportion of patients was from California (46%) and the smallest proportions were from Georgia and Texas (16% each).

In the evaluation of medication use patterns, black patients were more likely than white patients to use several classes of medications for the treatment of CD (Table 2), including an increased use of immunomodulators (25% vs 19%; $P < 0.001$), which was driven by an increased use of azathioprine (11% vs 9%; $P < 0.001$) and mercaptopurine (14% vs 9%; $P < 0.001$). Black patients with CD were also more likely than white patients to use anti-TNF therapy (25% vs 20%; $P < 0.001$). Although combination therapy was used by a minority of both black and white patients with CD, black patients were more

TABLE 1. Comparison of Demographic and Clinical Characteristics Among Patients With CD and UC in MAX (CA, GA, NC, TX) Stratified by Race

	White		Black	
	n = 10,063		**n = 4672**	
	n	**%**	**n**	**%**
Female	6508	65	3157	68
Age (median, IQR)	39	27-51	35	24-48
Type of IBD				
CD	5585	56	2692	58
UC	4478	44	1980	42
State of **r**esidence				
California	4125	41	1102	24
Georgia	1504	15	1360	29
North Carolina	2988	30	1511	34
Texas	1446	14	699	15
Elixhauser Comorbidity Index Score[22] (median, IQR)	2	1-4	2	1-5

IQR indicates interquartile ratio.

TABLE 2. Medication Use Among Black Patients With CD Compared With White Patients With CD in the MAX (CA, GA, NC, TX)

	Black (n = 2692)		White (n = 5585)		Adjusted OR[a] (95% CI)
	n	%	n	%	
Aminosalicylate[b]	1192	44	2373	42	1.04 (0.93-1.15)
Immunomodulator	684	25	1052	19	1.37 (1.20-1.56)
Azathioprine	308	11	490	9	
Mercaptopurine	369	14	529	9	
Methotrexate	59	2	105	2	
Anti-TNF therapy	681	25	1131	20	1.13 (0.99-1.28)
Adalimumab	119	4	217	4	
Certolizumab	38	1	65	1	
Infliximab	594	22	950	17	
Combination therapy[c]	138	5	193	3	1.50 (1.15-1.96)
Thiopurine	125	5	169	3	
Methotrexate	17	0.6	28	0.5	
Prednisone	1184	44	2189	39	1.07 (0.96-1.19)
Budesonide	212	8	485	9	0.78 (0.64-0.95)

[a]Odds ratio adjusted for age, sex, state of residence, and Elixhauser Comorbidity Index Score;[22] odds of use by black patients compared to use by white patients (reference group).
[b]Includes mesalamine, balsalazide, and sulfasalazine.
[c]Combination of anti-TNF and thiopurine or methotrexate.

likely than white patients to use the combination of an anti-TNF and an immunomodulator (5% vs 3%; $P < 0.001$).

Among patients with UC, similar patterns were also shown: Black patients were significantly more likely than white patients to utilize immunomodulators (15% vs 13%; $P = 0.006$) and anti-TNF therapies (20% vs 15%; $P < 0.001$; Table 3). Black patients with UC were also more likely to use combination therapy with an anti-TNF and an immunomodulator (3% vs 2%; $P = 0.018$) and were more likely to be treated with prednisone than white patients with UC (42% vs 37%; $P < 0.001$).

In a multivariable analysis adjusting for potential confounders, the odds of receiving anti-TNF therapy among black patients with CD compared to white patients with CD were similar (adjusted odds ratio [aOR] = 1.13; 95% confidence interval [CI], 0.99-1.28]. After adjusting for sex, age, state of residence, and Elixhauser Comorbidity Index Score,[22] there was also no difference in the odds of receiving anti-TNF therapy among black patients with UC compared to white patients with UC (aOR = 1.12; 95% CI, 0.96-1.32; Table 3). When evaluating the use of combination therapy, we found that black patients with CD were more likely to receive combination therapy than white patients with CD, even after adjusting for potential confounders (aOR = 1.50; 95% CI, 1.15-1.96; Table 2). However, there was no difference in the odds of receiving combination therapy after adjustment for confounders among patients with UC (Supplemental Table 2).

Among the 8277 patients with CD, 398 (5%) had undergone an intestinal resection with appropriate follow-up to allow for the assessment of postoperative therapy use. Following an intestinal resection for CD, black patients were significantly more likely than white patients to initiate immunomodulator monotherapy (31% vs 18%; $P = 0.004$; Fig. 1). There was no significant difference in the overall use of anti-TNF monotherapy (20% vs 17%; $P = 0.436$) or the use of combination therapy with an anti-TNF and an immunomodulator (1% vs 3%; $P = 0.123$). In a comparison of the median time to initiation of therapy after an intestinal resection for CD, black patients initiated anti-TNF monotherapy significantly earlier than white patients (52.0 days vs 104.0 days; $P = 0.027$). There was no significant difference in the time to initiation of immunomodulator monotherapy (33.0 days vs 64.5 days; $P = 0.052$) or combination therapy (55 days vs 122 days; $P = 0.212$).

DISCUSSION

In this study of patients with Medicaid insurance from 4 states, we found no disparities in the use of IBD-specific medications among black patients with UC or CD when compared with use among white patients. The higher rates of combination therapy in black patients with CD likely show appropriate care given that prior studies have found higher rates of complicated disease phenotypes in black patients with IBD.[6-9] In addition, among patients undergoing surgery for CD who were treated with anti-TNF monotherapy in the postoperative setting, black

TABLE 3. Medication Use Among Black Patients With UC Compared to White Patients With UC in the MAX (CA, GA, NC, TX) Stratified by Race

	Black (n = 1980)		White (n = 4478)		Adjusted OR[a] (95% CI)
	n	%	n	%	
Aminosalicylate	1098	55	2489	56	0.98 (0.87-1.10)
Immunomodulator	304	15	573	13	1.08 (0.90-1.29)
Azathioprine	169	9	305	7	
Mercaptopurine	129	7	277	6	
Methotrexate	23	1	56	1	
Anti-TNF therapy	387	20	679	15	1.12 (0.96-1.32)
Adalimumab	48	2	104	2	
Infliximab	356	18	603	13	
Combination therapy[b]	61	3	94	2	1.19 (0.80-1.78)
Thiopurine	58	3	83	2	
Methotrexate	5	0.3	18	0.4	
Prednisone	835	42	1653	37	1.06 (0.94-1.20)

[a]Odds ratio adjusted for age, sex, state of residence, and Elixhauser Comorbidity Index Score;[22] odds of use by black patients compared to white patients (reference group).
[b]Includes mesalamine, balsalazide, and sulfasalazine.
[c]Combination of anti-TNF and thiopurine or methotrexate.

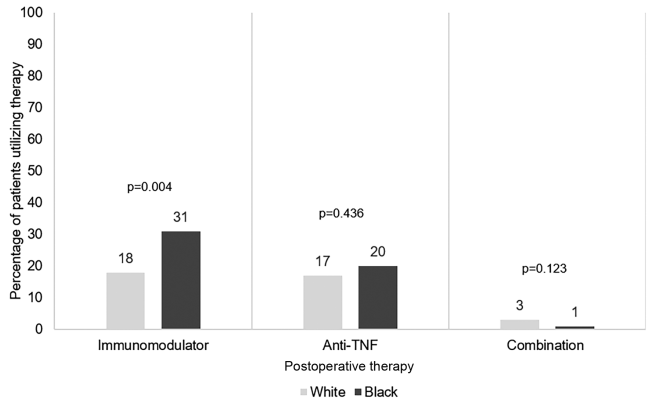

FIGURE 1. Postoperative therapies for CD among patients in the MAX (CA, GA, NC, TX) stratified by race (n = 398).

patients initiated these therapies more quickly after surgery than white patients. By focusing our analysis on a population of patients that had similar insurance coverage for therapies and specialty providers, we aimed to better understand the role that access to specialty care plays in disparities and IBD-related outcomes among patients of different races.

The underlying etiology of prior differences in care between black and white patients with IBD is not well defined. Given that genetic differences between patients with IBD from different races have been identified, there may be underlying biological differences that explain more complicated disease courses. In previously published studies, black patients were less likely to use important medications such as infliximab.[15] These previously reported disparities may also have been influenced by difficulties with access to specialists,[15] leading to increased rates of emergency department visits,[15, 23, 24] higher morbidity related to surgery,[14] and higher IBD-related mortality.[13] In our study, however, when patients had the same insurance coverage (through state-level Medicaid programs), allowing for the same access to medications and specialists, these disparities were not evident. Understanding the drivers of any underlying disparities becomes even more important when considering the changing demographics of the population in the United States, where the percentage of nonwhite groups is increasing and the incidence of IBD is increasing across all races and ethnicities.[25]

The MAX data are an ideal source to begin to analyze treatment utilization patterns with respect to access to care. We expected that within each of the 4 states represented in this study, black and white patients would have similar socioeconomic qualifications to be eligible for the study. We also assumed that black and white patients would have similar access to hospital facilities and providers that accept Medicaid insurance and the same pool of available medications within a state Medicaid insurance plan for a given year. These important assumptions allowed for the analysis of treatment patterns among patients with uniform insurance coverage, uniform treatment availabilities, and a relatively similar pool of providers for a given time period. We believe that these conditions allowed for a more direct comparison of racial differences in treatment utilization. Although multiple geographic regions and a racially diverse population are represented, the MAX data from these

4 states are not a nationally representative database. However, other large databases have existing limitations including the predominantly older population represented in Medicare data, the uneven geographic representation and potential lack of race or ethnicity information in commercial administrative claims data, and the lack of medication-related data in sources such as the Healthcare Utilization Project and the Nationwide Inpatient Sample.[26]

Among patients with Medicaid insurance in the 4 states analyzed, no significant differences in therapy use were identified when comparing black patients with white patients. In fact, black patients with CD were more likely to use combination therapy, even after we controlled for multiple potential confounders. We were motivated to pursue an analysis of the role that access to care plays in IBD-related outcomes based on prior work from the Sinai-Helmsley Alliance for Research Excellence (SHARE) cohort.[6] In an evaluation of treatment patterns among 7 academic IBD centers, black patients were found to be more likely to initiate an anti-TNF therapy during a longitudinal follow-up.[6] These findings from a multicenter cohort contrasted with prior publications, including a 2010 study by Nguyen et al[15] that found that black patients with CD were less likely to receive infliximab than white patients and that black patients with UC were less likely to utilize immunomodulators. In the analysis from the SHARE cohort,[6] black patients were more likely to show complications at baseline and in follow-up, indicating that access to specialty care may be critical in the initiation of appropriate therapy. However, the patients in the SHARE cohort were all treated in major academic medical centers and thus therapy patterns may not be reflective of the experience of patients treated by diverse community physicians. In addition, patients in the SHARE cohort had a variety of types of insurance coverage (or may have been uninsured), and our rationale for using the MAX data was to examine treatment patterns among patients with a uniform insurance status.

Although Sofia et al[27] found no difference in medication utilization patterns when comparing black and white patients with UC and CD, black patients with CD in that study were significantly more likely to undergo IBD-related surgery. Given the potential for a complicated phenotype, early initiation of combination therapy seems warranted in many black patients with CD. However, our study was not an inception cohort, so our finding regarding the increased use of combination therapy among black patients with CD could also represent the sequential addition of anti-TNF therapy among a group of patients with prior loss of response to immunomodulator monotherapy.

In our study, a minority of patients with CD underwent an ileal or ileocolonic resection and had an adequate follow-up period to allow for the assessment of postoperative therapy. In addition, all treatment in the study period analyzed (2006-2011) occurred before the publication of the current guidelines for the postoperative management of CD,[28] in which postoperative therapy with biologics and/or a thiopurine is recommended among patients with high risk factors. However, we did not find significant differences in the postoperative utilization of therapies when comparing black and white patients with CD, with the exception of an increased use of immunomodulator therapy among black patients.

Access to care, particularly the access provided by appropriate insurance coverage, seems to be critical in achieving IBD-related outcomes. In prior studies using data from the Nationwide Inpatient Sample, white and Asian patients with IBD were more likely to have commercial insurance than black and Hispanic patients.[26, 29] The role that these factors play in clinical outcomes is difficult to quantify, but in other studies of inpatients using data from the Healthcare Utilization Project, black patients had significant differences in the number of days to colectomy after admission[30] and an increased length of stay among pediatric patients.[31] Our study is unique in that it levels the access to resources. In fact, for example, Medicaid supports transportation to visits and pharmaceutical benefits often at zero cost for individual patients, which may actually improve access for those with this insurance.

This study used longitudinal data from 4 states with diverse Medicaid populations, allowing for a large evaluation of the treatment patterns for CD and UC. However, our study does have limitations. Given that these are retrospective data obtained from Medicaid billing, we do not have access to important clinical information such as disease severity at the time of treatment initiation, disease phenotype, smoking status, testing results such as endoscopic severity or imaging findings, or important laboratory information to compare between treatment groups. Prior evaluations have shown that black patients are more likely to have complicated disease presentations, including perianal disease,[6-9] but we could not quantify these differences. We did not perform specific analyses by geographic location, including a comparison of urban or rural treatment patterns. Given that we were aggregating data from 4 states across the United States, we chose to perform all analyses at the individual patient level and not to analyze by state or other geographic comparator. Similarly, we did not evaluate outcomes at the level of the treating provider or medical center. Although our primary interest in this study was to evaluate patients with uniform insurance coverage at the state level, we realize that this study is only representative of the Medicaid population of the 4 states analyzed and thus may not be representative of other insurance coverage plans.

In conclusion, among patients with Medicaid insurance from California, Georgia, North Carolina, and Texas, we found no significant disparities in the use of IBD-specific medications when comparing black and white patients with CD and UC. Although there may be underlying genetic and even phenotypic differences among patients with IBD from different races and ethnicities, ensuring appropriate access to insurance coverage

and ultimately access to gastroenterologists and IBD specialists may significantly improve outcomes and racial disparities among minority populations. These findings imply that changes in health policy to improve access to appropriate therapy would aid significantly in these efforts.

SUPPLEMENTARY DATA

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

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