

## AMERICAN COLLEGE OF GASTROENTEROLOGY

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## Studies Explore Racial Disparities in IBD Symptoms and Therapy

Provide New Insights on Infliximab Use, Disease Characteristics, Fistulizing Crohn's Disease

Las Vegas, NV (October 22, 2012) –Three separate studies presented today at the American College of Gastroenterology's (ACG) 77th Annual Scientific meeting in Las Vegas help to advance understanding of the differences between African American and Caucasian patients with Inflammatory Bowel Disease (IBD) and provide clinicians with new insight on how racial disparities involving disease characteristics, infliximab use, and fistulizing Crohn's disease may impact their patients—and their decisions on how best to manage the disease.

The incidence of inflammatory bowel disease (IBD) in non-Caucasian minority groups, including African-Americans (AA), appears to be increasing but there is limited understanding of phenotypic differences and outcomes by race, according to researchers from the University of Chicago who describe disease characteristics of both groups in a retrospective review, "Comparing Disease Characteristics between African-American and Caucasian Inflammatory Bowel Disease Patients."

"This study analyzed our large IBD registry and looked at the type of diseases seen in the African Americans (self-described) compared to Caucasians," said co-investigator David T. Rubin, M.D., FACG. "It is one of the largest studies of African Americans with IBD, and we identified a few important differences in this population. First, they were more likely to have extra-intestinal manifestations of their IBD, including joint pain and skin inflammation. Secondly, in the Crohn's patients, they were less likely to have small intestinal involvement."

For Crohn's disease (CD) patients, 797 Caucasians and 86 African Americans were identified. For ulcerative colitis (UC) patients, 345 Caucasians and 19 African Americans were identified. Among CD patients, African Americans had significantly higher rates of joint symptoms (31.2 percent vs. 20.1 percent) and pyoderma gangrenosum (3.5 percent vs. 1.1 percent) compared to Caucasian patients. African American Crohn's disease patients also had a significantly lower rate of ileal involvement (45.4 percent vs. 60.4 percent) compared to Caucasian patients, but no difference in rates of upper gastrointestinal, jejunal, colonic, or perianal disease.

Among UC patients, African Americans had significantly higher rates of extra-intestinal manifestations (EIMs) overall (42.1 percent vs. 20.8 percent), joint symptoms (26.3 percent vs. 12.1 percent), and pyoderma gangrenosum a necrotizing condition that causes skin ulcers (5.3 percent vs. 0.6 percent). There was no significant difference in disease extent.

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Researchers also reported no significant differences in medication usage, clinical trial enrollment, prevalence of dysplasia or cancer, surgical, family, or smoking histories between African American and Caucasian patients for either disease.

"We are moving towards personalizing our care of the IBD patient in a variety of important ways related to the severity and prognosis of the disease itself, specific inter-patient differences in response to therapies and potential side effects from the therapies, and importantly, understanding other differences in disease phenotypes – how the disease looks – that may be attributable to a variety of other factors, like race, geographic location in the world and even exposures that occur in the uterus before birth," Dr. Rubin said. "These findings are important since they can lead to focused genetic assessments in this population and help to define better treatment strategies for these individuals."

## Racial Differences in Fistulizing Crohn's Disease

Researchers from Mount Sinai School of Medicine explored racial differences in the prevalence of severe fistulizing perianal Crohn's disease in cross-sectional study of all adult patients with Crohn's disease treated with infliximab at The Mount Sinai Hospital between May 1 and December 31, 2011. In the study cohort, African Americans with Crohn's disease are significantly more likely than others, and Caucasians significantly less likely, to have severe fistulizing perianal disease.

Perianal disease is noted in up to one-third of patients with Crohn's disease (CD), according to co-investigator Pruthvi Patel, M.D. "In 2005, the Montreal Classification recognized that fistulizing perianal disease (FPD) represents a distinct phenotype from enteric fistulization," she said. "A growing body of literature suggests that there might be racial variations in the phenotypic manifestations of Crohn's disease but different studies have reached conflicting conclusions and few if any have specifically focused on perianal disease in adults with pre-specified criteria of severity."

Among all 333 CD on infliximab, 245 were Caucasian and 38 were African American, 48 were Hispanic and 6 were Asian. Of the 333 patients, 88 had FPD. 48 of these were Caucasians while 18 were African Americans. This demonstrates that African Americans are 1.87 times more likely than others to have FPD. On the other hand, Caucasians were significantly less likely than others to have FPD.

"These findings provide a platform to discuss the differences in Crohn's disease phenotype that may exist among various races, said Dr. Patel. "Knowledge about the burden of disease among racial groups may help early triage and management choices that will hopefuly improve the outcome on an individual basis."

In a third study, "Lower infliximab Use in African American Compared to Caucasian IBD Patients: Analysis of a Large U.S. Comparative Hospital Database," researchers from the University of Maryland School of Medicine suggest that African-American IBD patients were less likely to use infliximab therapy than Caucasian IBD patients after reviewing data from the Premier Perspective Comparative Database (PCD).

"During the last few decades, studies in numerous areas of medicine have revealed racial disparities in diagnosis and treatment, with African American patients often receiving inferior care to their Caucasian counterparts," said co-investigator Mark H. Flasar, M.D., MS. "Unfortunately, some more recent

analyses in the realm of inflammatory bowel diseases have suggested likewise disparities in use of medical resources, medication use, nutritional support therapies, and both the timing and type of surgery."

The study group included a total of 129,478 IBD patients treated at a hospital or hospital-based infusion center within the Premier Perspective database between January 1, 2005 and December 31, 2008. Of the 100,318 Caucasian patients, 55,033 (54.8 percent) had Crohn's disease and 37,719 (37.6 percent) had ulcerative colitis, while of the 10,279 African American patients, 6,032 (58.7 percent) had CD and 3,417 (33.2 percent) had UC.

Overall, a similar overall percentage of African American and Caucasian IBD patients got infliximab treatment (6.0 percent vs. 5.8 percent). Further, those who were treated seemed to get a similar and also appeared to get a similar average number of infusions (8.6 vs. 8.5). However, after adjusting for whether they had Crohn's disease or ulcerative colitis, as well as other factors such as gender and age, African Americans had a lower chance (about 12 percent lower) of getting infliximab treatment compared to Caucasian patients with IBD. Analyses limited to the 73,109 patients with moderate-to-severe disease revealed similar findings--about a 15 percent lower chance of getting infliximab treatment in African American compared to Caucasian IBD patients.

"It is important to note that these results represent the preliminary step in a larger and more detailed analysis, and should be interpreted with caution," said Dr. Flasar. "For instance, important factors which could influence the results such as severity of disease and important disease complications were not fully controlled for. On the other hand, at least preliminarily, these results lend some support to existing literature throughout medicine and within the realm of IBD with regards to issues of treatment disparities by race in the United States. It will be very interesting to see whether the results of our subsequent planned analyses remain consistent with the current findings," added Dr. Flasar.

## **About the American College of Gastroenterology**

Founded in 1932, the American College of Gastroenterology (ACG) is an organization with an international membership of more than 12,000 individuals from 80 countries. The College is committed to serving the clinically oriented digestive disease specialist through its emphasis on scholarly practice, teaching and research. The mission of the College is to serve the evolving needs of physicians in the delivery of high quality, scientifically sound, humanistic, ethical, and cost-effective health care to gastroenterology patients. <a href="www.gi.org">www.gi.org</a> View releases on other research breaking at the ACG meeting at <a href="http://gi.org/media/press-releases-for-acg-annual-scientific-meeting/">http://gi.org/media/press-releases-for-acg-annual-scientific-meeting/</a>

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