Black and Latino People Are Underrepresented in Cirrhosis Clinical Trials

Black people make up only 6% and Latino people make up 5% of participants in cirrhosis trials in the United States.

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Black and Latino people are greatly underrepresented in clinical trials of therapies for cirrhosis, despite their disproportionate representation among people with cirrhosis in the United States, according to findings presented at the AASLD Liver Meeting.

Over time, chronic hepatitis B, hepatitis C, fatty liver disease, heavy alcohol use and other causes can lead to serious complications including liver cirrhosis, or advance scarring. Cirrhosis is especially prevalent among racial and ethnic minorities. But minorities and women continue to be underrepresented in clinical trials.

Paige McLean Diaz, MD, and Nneka Ufere, MD, of Massachusetts General Hospital, and colleagues characterized sex, race and ethnicity in randomized clinical trials for people with cirrhosis. They carried out a systematic review of clinical trial published in leading medical journals that enrolled adults with cirrhosis. They also compared the distribution of clinical trials in the United States relative to cirrhosis rates by sex, race and ethnicity in the general U.S. population.

Some 133 studies were included in the analysis, with a total of 20,870 participants. Only 15 of these trials were conducted in the United States, with the remaining 118 trials being international.

Enrollment data on sex were available for all U.S. based trials and 99% of international trials. Women made up 31% of all study participants. For U.S. based trials, female enrollment (33%) in trials was similar to the proportion of cirrhosis cases among women in the population (27%).

Enrollment data on race and ethnicity were available for only 9% of all trials. The eight U.S. trials with such data available included a total of 2,644 participants. Most trials that included Latino individuals conflated their Latino or Hispanic ethnicity with race.

In the U.S. cirrhosis trials, 83% of participants were white, 6% were Black, 5% were Latino, 0.6% were Asian and 5% belonged to other races or ethnicities. But Black and Latino individuals account

for far more of the cirrhosis cases in the United States, 29% and 34%, respectively.

Only two trials included information on American Indian/Alaska Native or Native Hawaiian/Pacific-Islander participants—a group that has high cirrhosis-related mortality, Ufere noted at an AASLD media briefing.

“There was significant underreporting of race and ethnicity of participants in cirrhosis [randomized clinical trials],” the researchers concluded. “Barriers to clinical trial enrollment of racial and ethnic minority patients with cirrhosis should be systematically investigated to improve representation.”

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