P0419 -  Racial inequalities in multiple sclerosis research participation: underreporting and underrepresentation (ID 1751)

Speakers: H. Onuorah

Authors: H. Onuorah, A. Lucas, O. Charron, A. Montague, A. Crispino, A. Aguirre, V. Kallhoff, T. Hall, E. Meltzer, L. Freeman

Presentation Number: P0419
Presentation Topic: Epidemiology

Abstract

Background

MS affects minority communities differently with more rapid disability accumulation described in African American and Hispanic patients. These patients are also negatively impacted by social determinants of health further worsening disparities in outcomes. To best care for minority patients, the safety and efficacy of MS treatments in these populations must be known and reliably reported.

Objectives

To evaluate how representation of minority patients in manufacturer-sponsored phase 3 trials is reported in medical journals and on patient- and healthcare provider (HCP)-facing websites for approved disease-modifying therapies (DMTs). To assess the representation of minority patients in DMT trials and trends over time.

Methods

The Medline and clinicaltrials.gov databases were searched from 1995 to 1 June 2020, to identify manufacturer-sponsored phase 3 trials for FDA-approved MS DMTs. We explored how race and ethnicity were reported in the trial outcomes publications. Using studies where information was available, we analyzed representation of minority patients. Additionally, we reviewed patient-and HCP-facing websites of available DMTs to assess the availability of information on racial representation in trials. Finally, we searched for publications presenting either post-hoc analyses of clinical trial data or post-marketing studies aiming to evaluate safety and efficacy of DMTs in minority patients.

Results

A total of 41 phase 3 trials were reviewed, among which 14 (34%) did not report race, 15 (37%) reported race as proportion of white participants only, and 12 (29%) reported detailed information on race. People identifying as black were underrepresented in all trials, with decreased representation over time. Ethnicity was only reported in 1/41 publication, and trends in representation of Hispanics could not be assessed. No patient- or HCP-facing website reported demographic data on race and ethnicity. Four post-hoc analyses and three post-marketing studies that addressed DMT efficacy and safety in minority patients were found.

Conclusions

Race is underreported in phase 3 trial outcomes publications for MS DMTs and race/ethnicity representation is omitted from patient- and HCP-facing websites. When available, data show that minority patients are underrepresented in MS trials. Finally, few post-marketing studies assessed safety and efficacy of DMTs in minority patients.
populations. The availability of this information is crucial for patients and their HCPs to make informed decisions about their care.