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POSTER ABSTRACTS

906.OUTCOMES RESEARCH-MYELOID MALIGNANCIES

Disparities in the Enrollment of Racialized, Ethnic Minority, and Older Adults in Randomized Trials of Acute Myeloid Leukemia: A Systematic Review

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Introduction: There are significant racial and ethnic disparities in incidence and survival for patients diagnosed with hematologic malignancies. Understanding discrepancies in enrollment in randomized controlled trials based on race, ethnicity, and age is important to better understand access to care and clinical trial conduct.

Objective: To systematically review the literature on enrollment of racialized, ethnic minority, and older adults in randomized controlled trials (RCTs) of acute myeloid leukemia (AML) and to provide enrollment estimates and compare these to population characteristics.

Methods: MEDLINE was searched from inception through to June 2023. No restrictions based on language or publication date were used. Pairs of reviewers independently screened titles, abstracts, and full texts of records. Inclusion criteria were phase II and III RCTs of disease modifying therapy for AML in adults (≥ 18 years) reporting efficacy and safety outcomes. We excluded single arm trials, trials with unpublished results, conference abstracts, follow-up reports, subgroup/post-hoc/exploratory analyses, and supportive care trials, except those evaluating disease-modifying therapies and reporting clinical efficacy. A standardized form was pilot-tested and used to extract data related to trial characteristics. The proportion of trials reporting racial and ethnic subgroups (African American/Black, Asian, American Indian/Alaskan native, Native Hawaiian or other Pacific Islander, White, Hispanic), and age ≥ 65 were determined. For US trials, we calculated the enrollment incidence ratios (EIRs), the ratio of trial proportions of members of a racial and ethnic subgroup divided by US population-based incidence in the corresponding racial and ethnic subgroup using the Surveillance, Epidemiology, and End Results (SEER 20) database. We conducted a random-effects meta-analysis to pool EIRs.

Results: After screening 7,759 titles and abstracts and 157 full texts, we included 90 studies, of which 14 (15%) were US trials. Overall, there were 21 (23.3%) trials that reported race or ethnicity and 26 (28.9%) that reported the enrollment proportion of ≥ 65 years. Of the trials with data on race or ethnicity, 15 (71.4%) had data on African American/Blacks, 21 (100%) Whites, 14 (66.7%) Asian or Pacific Islanders, 2 (9.52%) American Indian and Alaskan Native, 4 (19.0%) Hispanics. Of trials reporting on race, 176 (3.6%) of participants were African American/Black, 360 (7.2%) Asian or Pacific Islander, 5 (0.1%) American Indian and Alaskan Native, 3,914 (79.6%) White, and 39 (0.8%) Hispanic. Of the 14 US trials, 4 (28.6%) reported race and 4 (28.6%) reported enrolled proportion of older adults. Hispanic patients (EIR 0.20; 95%CI 0.07 to 0.59, $I^2=86\%$), and Asian patients (EIR 0.24; 95%CI 0.07 to 0.86, $I^2=77\%$) were significantly underrepresented while White patients (EIR 1.33, 95%CI 1.07 to 1.66, $I^2=99\%$) were significantly overrepresented. Confidence intervals were wide for EIR of Black patients (EIR 0.96, 95%CI 0.42 to 2.2, $I^2=91\%$).

Conclusion: Most trials did not report data on race and ethnicity or on enrollment proportion of participants ≥ 65 years. Only a small proportion of trial participants were from racial and ethnic minority groups. Hispanic and Asian patients were significantly underrepresented while White patients were overrepresented.

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