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Demographic Disparities in Clinical Trial Enrollment of US Patients with Newly-Diagnosed Multiple Myeloma

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Background: Racial, ethnic and gender disparities impact the real-world reproducibility of clinical trials leading to drug approvals for hematologic malignancies. Interestingly, a prior abstract (Boisclair et al., 2022) has shown an equitable enrollment between US demographic groups in frontline trials for newly-diagnosed non-Hodgkin lymphoma. Although disparities in multiple myeloma (MM) trial participation have been oftentimes demonstrated, prior studies (Kanapuru et al., 2022; Alqazaqi et al., 2022) predominantly involved patients with relapsed/refractory MM (RRMM). To further assess this gap, we conducted a cross-sectional analysis of US demographic representation in phase II or III trials for newly-diagnosed MM (NDMM).
Methods: Clinicaltrials.gov was searched for completed NDMM trials with a recruitment period between 01/01/2007-12/31/2020. Studies limited to phase I data (n=10), enrolling <30 patients (n=35), including RRMM or other malignancies (n=18), and/or recruiting outside the US (n=93) were excluded. We subdivided patients according to gender, race, and ethnicity. For each subgroup, total new cases of MM from 2007-2020 were identified via the Surveillance, Epidemiology and End Results (SEER) Cancer Statistics Explorer Network, with subsequent calculation of a trial enrollment fraction (TEF; number of trial enrollees divided by incident US cases). Pearson's chi-square test was used to compare TEF between subgroups, yielding odds ratio (OR) and 95% confidence interval (95%CI) values, with $P<0.05$ deemed significant.
Results: Among the 194 trials found on initial review, 25 met the established criteria for inclusion (Figure 1). All studies (n=3,559) described the participants' gender, while only 18 (72%; n=3,129) reported race and 9 (36%; n=2,319) reported ethnicity. Overall, women showed a significantly lower TEF compared to men (OR, 0.88; 95%CI, 0.82-0.94; $P<0.001$). When compared to White Americans, TEF was significantly lower for African Americans (OR, 0.71; 95%CI, 0.64-0.78; $P<0.001$) and Asian Americans/Pacific Islanders (AAPIs; OR, 0.64; 95%CI, 0.22-0.41; $P<0.001$). In studies reporting ethnicity, TEF was significantly lower for Hispanics compared to non-Hispanics (OR, 0.18; 95%CI, 0.14-0.24; $P<0.001$).
Conclusion: Our cross-sectional analysis reveals an underrepresentation of women, African Americans, AAPIs, and Hispanics in NDMM trials conducted around the US. These findings are complementary to the enrollment disparities previously shown in RRMM trials. Through the implementation of a comprehensive diversity plan, MM trials must include a more inclusive representation of the US population affected by this blood cancer. Such an approach will not only enhance the external validity of these trials but also mitigate the impact of ascertainment bias and promote healthcare equity.

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