



The 65th ASH Annual Meeting Abstracts

POSTER ABSTRACTS

637.MYELODYSPLASTIC SYNDROMES - CLINICAL AND EPIDEMIOLOGICAL

Race and Gender Representation in Myelodysplastic Syndrome Clinical Trials in the US: A Cohort Study

Sindhusa Veeraballi, MD¹, Ran Zhao², Megha Sai Konka³, Hetty E. Carraway, MD⁴, Moadh K. Mustafa Ali, MDMPH⁵, Aaron T. Gerds, MD MS⁶, Arooj Ahmed, MD¹, Anjali S. Advani, MD⁷, John C Molina, MDMD⁸, Sophia Balderman, MD⁸, Abhay Singh, MD MPH⁹, Sudipto Mukherjee, MDPhDMPH¹⁰

¹ Department of Translational Hematology and Oncology Research, Taussig Cancer Institute, Cleveland Clinic, Cleveland, OH

² Cleveland Clinic, Cleveland, OH

³ Department of Medicine, Kent State College of Podiatric Medicine, Independence, OH

⁴ Department of Hematology and Medical Oncology, Taussig Cancer Institute, Leukemia Program, Cleveland Clinic, Cleveland, OH

⁵ Leukemia Division, Taussig Cancer Center, Cleveland Clinic, Cleveland, OH

⁶ Leukemia Program, Department of Hematology and Medical Oncology, Cleveland Clinic, Cleveland, OH

⁷ Leukemia Program, Taussig Cancer Institute, Cleveland Clinic, Cleveland, OH

⁸ Department of Hematology and Medical Oncology, Taussig Cancer Institute, Cleveland Clinic Foundation, Cleveland, OH

⁹ Taussig cancer center, Cleveland Clinic, Cleveland, OH

¹⁰ Department of Hematology and Medical Oncology, Cleveland Clinic Taussig Cancer Institute, Cleveland, OH

Introduction:

Clinical trials in the US frequently under-enroll racial/ethnic minorities, and demographic reporting of minority enrollment is variable and often incomplete. Underrepresentation of minorities in clinical trials deprives these patients (pts) of the benefits of novel therapies and impacts the generalizability of clinical trial findings. Little is known about the disparities in enrollment of racial and ethnic minorities in myelodysplastic syndromes (MDS) clinical trials in the US and their trends over time.

Methods:

We used the aggregate analysis of ClinicalTrials.gov database to obtain records of interventional, randomized phase II and phase III studies conducted in US that reported completed results to the database using the search terms "myelodysplastic syndromes" or "MDS" with start and completion dates between January 1, 2000, to December 31, 2022. "Race/ethnicity" was adapted in accordance with US Census and Department of Health and Human Services guidelines and grouped into five categories for this analysis - White, Black/African American, American Indian or Alaska Native (AI/AN), Asian, and Other. We analyzed the reporting of race/ethnicity in clinical trials benchmarked with the passage of federal mandatory reporting requirements in September 2007 and January 2017. The proportions of enrollees by each racial group in all the MDS trials reporting on all 5 racial groups were computed for the entire study period and the distributions of these proportions were plotted in the density plots (Fig 1). Additionally, we calculated the odds ratios (OR) with 95% CI of enrollment by race and gender in clinical trials (Fig 2). All calculations were done using R version 4.2.0.

Results:

We identified 299 MDS clinical trials using our search criteria. After excluding phase I/II non-randomized clinical trials and trials with less than 20 pts, we included a total of 206 clinical trials (174 phases II & 32 phase III) for analysis. Of the 21,645 pts initially enrolled in the 206 trials, 20,709 pts with complete data were analyzed. With the institution of federal reporting requirements in the late 2000s, enrollment reporting by race and ethnicity has vastly improved, with 100% of MDS clinical trials reporting these demographics since 2017. In trials reporting race enrollment for all five groups, Whites had the highest enrollment proportions in all trials conducted within the study period, with a median enrollment of 85.8% (Fig 1). This level of clinical trial representation exceeded the estimates of proportion of Whites among the US population (70.3%, $p < 0.001$). In contrast, Blacks, AI/AN, Asian and other racial categories were significantly underrepresented relative to their US populations ($p < 0.001$). Figure 2 shows a forest plot of OR of enrollment by race and gender. Blacks, Asian and AI/AN had significantly lower odds of enrollment compared to Whites. Females had significantly higher odds of enrollment compared to males.

Conclusion:

Our analysis highlights substantial disparities in representation of racial minorities in MDS clinical trials in the US. Unless efforts are taken to systematically address these enrollment disparities, MDS outcomes for these historically disadvantaged groups will continue to lag due to incomplete understanding of biologic and individual factors that impact treatment effectiveness in these groups.

Disclosures Carraway: Astex Pharmaceuticals: Other; Agios: Consultancy, Speakers Bureau; Jazz Pharmaceuticals: Consultancy, Other: Travel, Accommodations, Expenses, Speakers Bureau; Daiichi: Consultancy; Genentech: Consultancy; Celgene: Research Funding; Syndax: Other: DSMB; Stemline Therapeutics: Consultancy, Speakers Bureau; AbbVie: Other; BMS: Consultancy, Research Funding, Speakers Bureau; Takeda: Other; Novartis: Consultancy, Other: Travel, Accommodations, Expenses, Speakers Bureau. **Mustafa Ali:** Daiichi Sankyo: Consultancy, Other: 10/19/2022 North Central Regional US Quizartinib/AML Advisory Board Not active (one-time occurrence). **Gerds:** AbbVie, Bristol Myers Squibb, Constellation Pharmaceuticals, GlaxoSmithKline, Kartos, Novartis, PharmaEssentia, Sierra Oncology: Consultancy; Accurate Pharmaceuticals, Constellation Pharmaceuticals, CTI BioPharma, Imago BioSciences, Incyte Corporation, Kratos Pharmaceuticals: Research Funding. **Advani:** Jazz: Honoraria, Membership on an entity's Board of Directors or advisory committees; Seattle Genetics: Research Funding; OBI: Research Funding; Kite: Honoraria, Other: consulting, Research Funding; Immunogen: Research Funding; Incyte: Research Funding; Glycomimetics: Membership on an entity's Board of Directors or advisory committees, Research Funding; Nkarta: Honoraria; Pfizer: Honoraria, Research Funding; Kura: Honoraria; Servier: Research Funding; MacroGenics: Research Funding; Beam: Honoraria; Taiho: Honoraria, Membership on an entity's Board of Directors or advisory committees; Amgen: Honoraria, Other: advisory board, Research Funding; Novartis: Honoraria, Membership on an entity's Board of Directors or advisory committees. **Singh:** Rigel: Other: Advisor or review panel participant. **Mukherjee:** Celgene (now BMS): Consultancy; BioPharm: Consultancy; EUSA: Honoraria; McGraw Hill Hematology Oncology Board Review: Honoraria; Bristol Myers Squibb: Honoraria; Celgene (now BMS): Honoraria; Aplastic Anemia and MDS International Foundation: Honoraria; EUSA: Other: Advisory Board; Genentech and AbbVie: Other: Advisory Board; Blueprint Medicines Corporation: Other: Advisory Board; Novartis: Other: Advisory Board; Bristol Myers Squibb: Other: Advisory Board; Celgene/Acceleron: Other: Advisory Board; Novartis: Consultancy; Bristol Myers Squibb: Consultancy; Celgene (now BMS): Research Funding; Novartis: Research Funding; Jazz Pharmaceuticals: Research Funding.

Figure 1: Race representation in US based MDS clinical trials: Enrollment data from clinicaltrials.gov

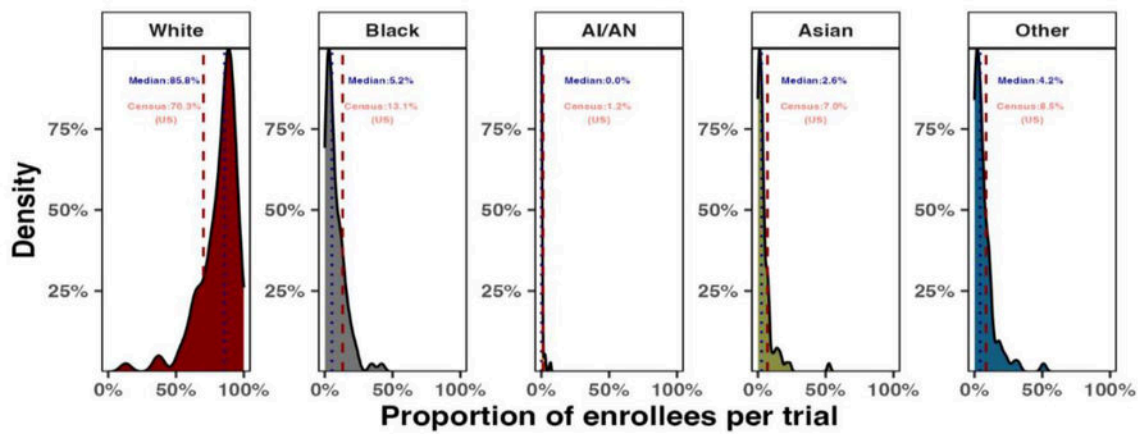


Figure 2: Forest plot of odds ratios of enrollment by race and gender in US MDS clinical trials

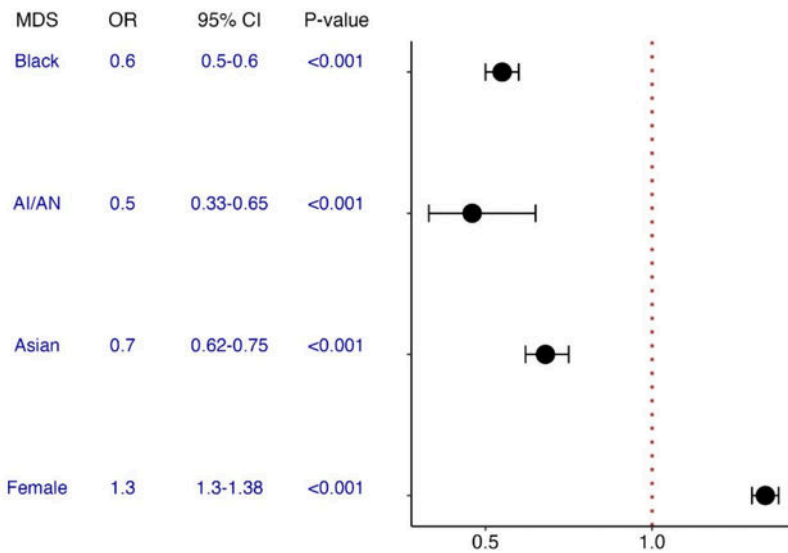


Figure 1

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