Disparities in Age, Race, Gender, and Viral Infection Inclusion in Mantle Cell Lymphoma Trials: A Retrospective Enrollment Analysis

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Introduction

Mantle cell lymphoma (MCL) is a rare B-cell non-Hodgkin lymphoma (~6% of cases) with limited large prospective trials. Underrepresentation of elderly patients, women, racial/ethnic minorities, and those with HIV/hepatitis reduces the reliability and real-world applicability of findings. Inclusive recruitment strategies are needed to improve external validity.

Aim

- Evaluate demographic and clinical inclusivity in MCL trials, focusing on underrepresented populations.
- Assess and describe enrollment gaps in MCL trials compared to U.S. disease incidence to inform future trial design.

Objectives

- Review phase I–III MCL trials published between 2000–2023.
- Compare age, gender, and race/ethnicity representation to U.S. SEER incidence data.
- Assess eligibility criteria for patients with HIV, hepatitis B, and hepatitis C.
- Quantify representation using Enrollment Incidence Ratio (EIR).

Methods

- **Data Sources:** PubMed, ClinicalTrials.gov, ASCO, and ASH databases (2000–2023).
- **Inclusion Criteria:** Phase I–III trials with ≥5% MCL enrollment.
- **Exclusion Criteria:** Trials without race/ethnicity reporting.
- **Analysis:**
- SEER registry used for U.S. incidence rates.
- **Enrollment Incidence Ratio (EIR):** calculated as % enrolled in trials ÷ % incidence in SEER. EIR 0.8–1.2 = adequate representation; <0.8 = underrepresented; >1.2 = overrepresented.
- **Eligibility Review:** Documentation of HIV and hepatitis B/C inclusion or exclusion.

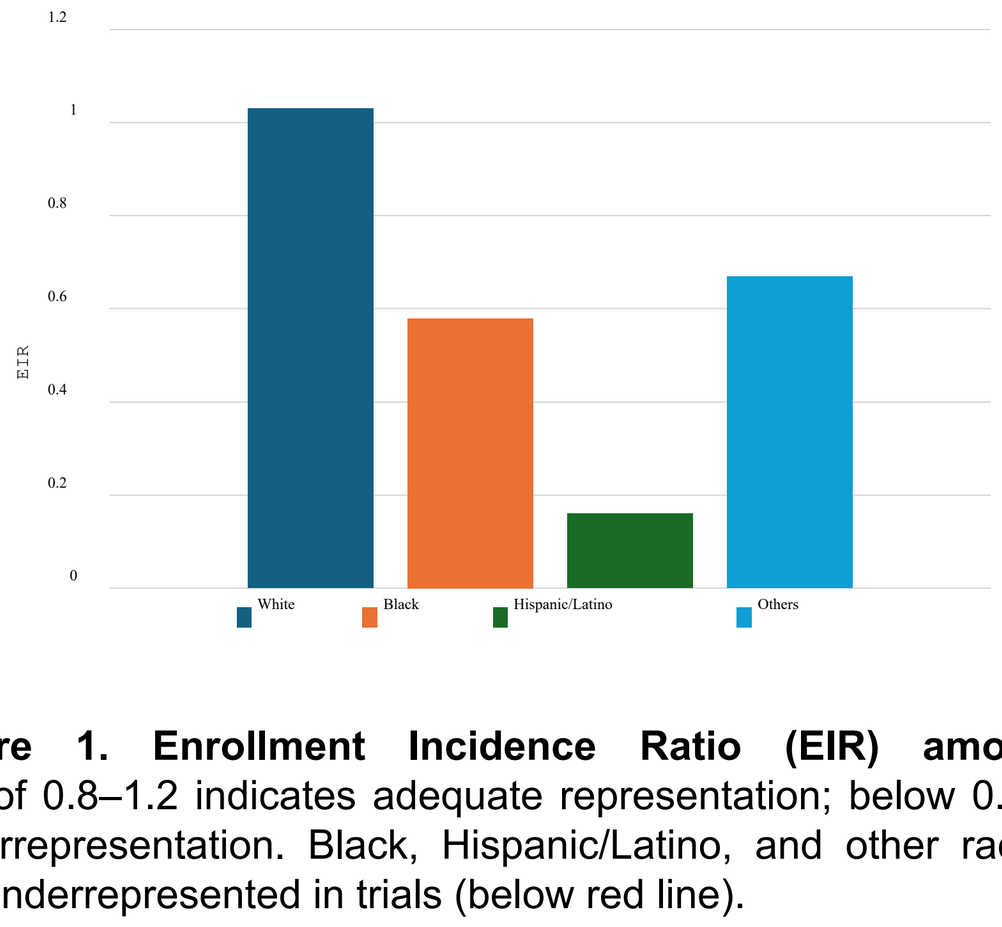


Figure 1. Enrollment Incidence Ratio (EIR) among races
EIR of 0.8–1.2 indicates adequate representation; below 0.8 indicates underrepresentation. Black, Hispanic/Latino, and other racial groups are underrepresented in trials (below red line).

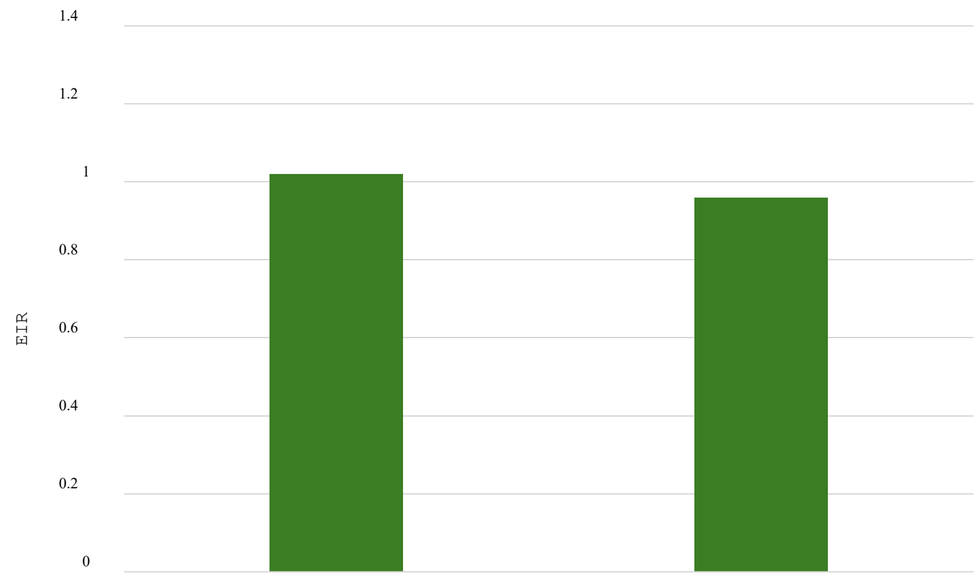


Figure 2. Enrollment Incidence Ratio (EIR) between genders
EIR of 0.8–1.2 indicates adequate representation. Both male and female participants are adequately represented in trials (within blue lines).

Results

- We identified 217 trials; only 41 (18.9%) reported race/ethnicity.
- 3,826 patients were enrolled: 3,173 (83%) White, 94 (2.5%) Black, 51 (1.3%) Hispanic/Latino, and 170 (4.4%) Other. White enrollment was adequately represented (EIR 1.03), but Black (EIR 0.58), Hispanic/Latino (EIR 0.16), and Other (EIR 0.67) were underrepresented.
- EIR for male (1.02) and female (0.96) patients were similar and adequately represented.
- EIR for age ≥65 years was 0.35, indicating underrepresentation.
- Of 41 trials, 30 (73.2%) excluded HIV patients, 18 (43.9%) allowed non-active hepatitis B, and 12 (29.3%) allowed non-active hepatitis C infection.

Summary

- Reviewed 217 phase I–III MCL trials (2000–2023).
- Only 18.9% reported race/ethnicity data.
- Black, Hispanic/Latino, and elderly patients were underrepresented.
- Majority of trials excluded HIV patients; many excluded non-active hepatitis B/C patients.

Discussion

- Limited demographic data disclosed by most MCL trials hinders understanding of trial inclusivity.
- We demonstrated systemic enrollment disparity in MCL trials.
- Disparities may arise from strict eligibility criteria and low minority recruitment.
- Excluding patients with controlled HIV/hepatitis further reduces real-world relevance.
- Improving representation requires broader eligibility criteria, targeted outreach, tailored education, and stronger regulatory measures.

References

- SEER database.

Yang F, et al. Enrollment representation of age, race, and ethnicity in ovarian cancer registrational clinical trials (2010–2020): An evaluation by the U.S. Food and Drug Administration. *J Clin Oncol.* 2023;41:e18527-e18527.