

Targeted Approach to Improve Diversity in Phase I Oncology Clinical Trials: A Single Institution Experience at the University of Colorado Cancer Center

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Abstract:

Background: Despite continued improvements in cancer outcomes, disparities persist between racial, ethnic, and socioeconomic groups. One potential driver is the lack of appropriate representation in clinical trials, including dose-finding studies. We implemented a set of initiatives including patient education and outreach, a Spanish-speaking bicultural clinic, and regular review of enrollment by race and ethnicity. To investigate the impact of these initiatives, we examined phase I clinical trial patient demographics and treatment outcomes before and after the intervention.

Methods: We performed a retrospective review of patients enrolled in 2018-2019 (cohort 1[C1], pre- intervention) and 2022-2023 (cohort 2[C2], post-intervention). We collected patient data including age, sex, race, ethnicity, language, insurance type, area deprivation index (ADI), body mass index (BMI), ECOG performance status, and tumor type. The differences between cohorts were evaluated with T-tests for continuous variables, the Chi-Square test for categorical variables, and the Fisher Exact test for categorical variables with low cell counts. Progression-free survival (PFS) and overall survival (OS) were calculated using the Kaplan-Meier method.

Hazard ratios and their associated p-values for univariable and multivariable models were derived using the cox proportional hazards method. For patient with colorectal cancers (CRC), the best-fitting multivariable model was selected using the Akaike information criterion.

Results: A total of 361 patients (C1 N = 209, C2 N = 152) were included. Overall, 52.4% of patients were Female. The most common tumor types were gastrointestinal (38.5%), sarcoma (12.2%), breast (10.8%) and lung (10.5%). Overall race was 85.0% White, 3.3% Asian, 1.4% Black with 9.1% of patients being ethnically Hispanic. In comparison, cancer incidence in Colorado was 92.8%, 1.6% and 3.3% and 10.0%, respectively. Following our intervention, there was a statistically significant increase in language preference other than English from 1.91% (4/209) in C1 to 6.58% (10/152) in C2 ($p = 0.028$) and in translated consents from 1.44% (3/209) to 5.92% (9/152) ($p = 0.033$). There was no statistically significant difference in race, ethnicity, insurance, or tumor type between C1 and C2, although there was an increase in Hispanic patients from 8.13% to 10.53%, trending towards significance. Median PFS was 2.83 months in C2 compared to 1.91 months in C1 (Hazard ratio (HR) = 0.72, 95% Confidence Interval (CI) 0.57-0.90, $p = 0.003$). By univariable analysis, ECOG 1 v. 0 was associated with inferior OS (HR:1.35, 95% CI 1.06-1.73, $p = 0.017$), and BMI of ≥ 18.5 v. < 18.5 was associated with superior OS (HR = 0.59, 95% C.I. 0.37-0.95, $p = 0.030$). A multivariable model of our most common tumor type, CRC ($n = 66$), revealed that ADI scores of 6-10 were associated with worse PFS and OS ($p = 0.022$ and $p = 0.001$, respectively) compared to ADI scores of 1-5.

Conclusion:

Our multi-faceted intervention resulted in an increase in enrollment of non-English speaking patients, however, there was not yet a statistically significant change in overall race and ethnicity. Our study confirms poorer clinical outcomes for patients with higher ADI scores.

Further research and intervention are warranted to mitigate disparities in clinical trial accrual and improve clinical outcomes for disadvantaged patients.