Background

Due to limited inclusion of PLWH in most ICI clinical trials, there is a paucity of evaluating their safety and efficacy in this unique population, especially among PLWH and metastatic NSCLC.

Methods

In this retrospective, international multi-center study, we identified 64 HIV positive (HIV+) patients and 117 matched HIV negative (HIV-) controls with metastatic NSCLC. At each institution, we treated with ICI between January 2015 and October 2021 at 16 institutions in the U.S. and Europe. We matched patients in a 1:2 ratio by age, sex, class of ICI, use of concurrent chemotherapy, and number of prior lines of systemic therapy. We estimated overall survival (OS) and progression-free survival (PFS) by the Kaplan-Meier method. When the proportional hazards assumption was violated, we used restricted mean survival time (RMST) to compare survival outcomes. We fitted a linear regression model with RMST as outcome and HIV infection (status) as predictor, adjusting for race, ECOG performance status, histology, smoking status and PD-L1 expression. We compared categorical variables using chi-square tests.

Results

In our cohort, median age was 60 years, 77% were males, 61% received ICI as 1st line therapy, 89% received anti-PD-1 based therapy, and 46% received concurrent chemotherapy. Blacks/African Americans were more represented among HIV+ vs. HIV- patients (42% vs 23%, p < 0.01). At baseline, HIV+ patients had a median CD4 count = 386 cells/mL (range: 6 – 1,721), 19/31 had undetectable HIV viral load (VL) while 12/31 had a median detectable VL ≥ 60 copies/mL (range: 10 – 223,408). Grade ≥ 3 immune-related adverse events occurred in 11% HIV+ vs. 9% HIV- patients. Overall response rate was similar between both groups (28% HIV+ vs. 37% HIV-, p=0.25). Comparing HIV+ vs. HIV-, the adjusted RMST difference within 42 months was 1.75 months (95% CI: -4.13, 7.63, p=0.56) for OS, and 0.35 months (95% CI: -4.83, 5.53, p=0.90) for PFS (figures 1 and 2). In addition, the 24-month OS rates were 41.7% for HIV+ vs. 42.9% for HIV- patients while the 24-month PFS rates were 18.1% HIV+ vs 18.7% HIV- patients.

Conclusions

In this matched cohort study, PLWH and metastatic NSCLC had similar toxicity profiles and clinical outcomes to HIV-counterparts receiving ICI supporting their use in PLWH and their inclusion in clinical trials. Larger
prospective studies are needed to inform a broader usage of ICI among PLWH presenting with other cancer types, low CD4 counts (i.e., <200 cells/μL) and high VL.

Ethics Approval Our study was exempt from institutional review board (IRB) review at DFCI (Protocol #21-342) and was approved by local IRBs at participating sites per institutional policy, according to the principles of the Declaration of Helsinki.