IMMUNOTHERAPY TRIALS LACK A BIOMARKER FOR INCLUSION: IMPLICATIONS FOR DRUG DEVELOPMENT

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Background Next-generation sequencing and other biomarkers have demonstrated the capability to identify potentially pathogenic molecular aberrancies. Immunotherapy checkpoint inhibitors (ICI) have benefited patients in almost every oncologic histologic type, age, sex, ethnicity, race, tobacco use and ECOG performance status (PS) were abstracted. We also assessed previous chemotherapy, radiation and targeted therapy utilization among all patients. The primary endpoints were progression free survival (PFS) and overall survival (OS) in those who have and have not received PRBCs. We then evaluated PFS and OS via a cox proportional hazards model that was adjusted for cancer type, age, PS, previous therapies and tobacco use.

Methods From January 2010 - June 2019, patients at Fox Chase Cancer Center who received a PRBC transfusion within 120 days of treatment with a CPI and with advanced NSCLC, UC and RCC were included. Patient demographics including age, sex, ethnicity, race, tobacco use and ECOG performance status (PS) were abstracted. We also assessed previous chemotherapy, radiation and targeted therapy utilization among all patients. The primary endpoints were progression free survival (PFS) and overall survival (OS) in those who have and have not received PRBCs. We then evaluated PFS and OS via a cox proportional hazards model that was adjusted for cancer type, age, PS, previous therapies and tobacco use.

Results 304 patients including 272 NSCLC, 24 UC and 8 RCC subjects were evaluated. 54 patients underwent a minimum of one PRBC transfusion during the pre-specified time period. Both median PFS (8.2 months versus 3.9) and overall survival (13.5 months versus 9.2 months) were improved in the non-transfused population compared to the transfused patients (PFS and OS: p<0.0001).

Conclusions For immunotherapy-based trials in 2019, <10% of patients expected to be enrolled would be selected by a biomarker for inclusion. Precision oncology continues to struggle in the era of ICI with an all-comers approach to patient selection and trial initiation. Selecting patients for trials based on biomarkers may help better identify responders to ICI.

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