

How Immunotherapy Impacts Populations Underrepresented in Clinical Trials

Real world data are encouraging regarding immunotherapy to treat metastatic lung cancer across racial and ethnic groups.

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New research in the December 2023 issue of [JNCCN—Journal of the National Comprehensive Cancer Network](#) finds patients treated with first-line immunotherapy for advanced non-small-cell lung cancer (NSCLC) showed similar results in terms of survival, progression-free survival, and treatment duration, regardless of race or ethnicity, even with differences in income and insurance. The clinical investigators focused on patients in under-represented groups who were typically less likely to be included in the immunotherapy clinical trials that have been conducted to date. They analyzed results from 248 patients treated with pembrolizumab [Keytruda] over a 9-year period between January 1, 2013 and June 1, 2022, with non-Hispanic Black, Hispanic, and Non-Hispanic White patients each accounting for an approximately equal percentage. Median overall survival was 16.8 to 26.3 months, similar to results previously reported in large prospective clinical trials.

“There has not been enough information on how immunotherapy affected racially- and ethnically-marginalized patients with lung cancer in the past, because they were not well-represented in most previous studies,” explained lead investigator Matthew Lee, MD, MPH, Assistant Professor of Oncology, [Montefiore Einstein Comprehensive Cancer Center](#) (MECCC). “The findings from this study could change how we take care of patients and plan future lung cancer studies to better include all patients. While immunotherapy has significantly improved survival for lung cancer patients overall, differences exist in its administration among individuals of different races and ethnicities. This finding could potentially promote the use of immunotherapy in more diverse patient populations.”

The study results included other notable findings. While race, ethnicity, income, and insurance status did not statistically impact survival, the investigators were surprised to find that higher BMI was associated with longer progression-free survival and shorter time to treatment discontinuation. They also determined that a worse ECOG Performance Status—a standardized tool for measuring how capably a patient can take care of themselves, do regular activities, or move around—was significantly more likely to result in poorer outcomes.

“This study highlights the potential importance of adjusting treatment approaches in clinical practice, particularly for patients with a poor ECOG performance status,” said senior researcher Haiying Cheng, MD, PhD, Associate Professor of Oncology and Member of the MECCC Cancer Therapeutics Research Program. “There is a clear need for future studies to include underrepresented patient groups in clinical trials to validate these findings and to better guide clinical practice.”

“This retrospective study provides valuable real-world information on the clinical outcomes of patients from underrepresented racial/ethnic groups undergoing immunotherapy for metastatic NSCLC,” commented Debora S. Bruno MD, MS, Assistant Professor of Medicine - Case Western Reserve University; Medical Director, Dahms Clinical Research Unit, University Hospitals - Cleveland Medical Center, Seidman Cancer Center at Case Comprehensive Cancer Center, who was not involved in this research. “Non-Hispanic Black and Hispanic individuals were gravely underrepresented in registrational immunotherapy trials for lung cancer. As a result, there is a paucity of prospective trial data on the efficacy and safety of this class of antineoplastic agents for such patients.”

Dr. Bruno, a Member of the NCCN Guidelines Panel for [Non-Small Cell Lung Cancer/Mesothelioma/Thymomas and Thymic Carcinomas](#), continued: “While it is certainly reassuring to see a lack of real world racial and ethnic disparities in clinical outcomes when patients receive adequate therapy for their disease, we must continue and strive for equitable representation for all patients in prospective oncology clinical trials.”

To read the entire study, visit [JNCCN.org](https://www.jnccn.org). Complimentary access to “[Similar Efficacy Observed for First-Line Immunotherapy in Ethnic Minority Patients With Metastatic NSCLC](#)” is available until March 10, 2024.

[This announcement](#) was originally published December 11, 2023, on the National Comprehensive Cancer Network website.