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Patient Groups Untested in Cancer Immunotherapy Trials Found to Also Benefit

CHICAGO (May 30, 2019) — Immunotherapy is a revolutionary cancer treatment, but it was unknown if cancer patients with HIV or viral hepatitis could also reap the benefits of this therapy because they had been excluded from most clinical trials.

In an “encouraging” study to be presented June 1 at the 2019 ASCO Annual Meeting in Chicago by Georgetown Lombardi Comprehensive Cancer Center, physicians say these patients along with African Americans, who were underrepresented in the trials, actually benefit at the same rate as patients tested in the clinical trials.

“(‘Real-world outcomes of underrepresented patient populations treated with immune checkpoint inhibitors: African American descent, poor ECOG performance status, and chronic viral infections” Abstract 2587 – Sat. June 1, 8:00 – 11:00 am; Hall A, Poster #231)

The immunotherapies examined are specifically known as immune checkpoint inhibitors (ICIs), which take the brakes off the immune cells — originally activated by exposure to the cancer — so that the person’s immune system can attack the cancer.

“Oncologists want to give their patients the best possible care, so some prescribe checkpoint inhibitors without knowing if the treatment will work in the setting of immunodeficiency caused by HIV or liver inflammation caused by viral hepatitis,” says the study’s lead investigator, Neil J. Shah, MD, a fellow at Georgetown Lombardi’s clinical partner, MedStar Georgetown University Hospital.

“What we found is good news for both patients and oncologists. We have strong data, from real world cancer care, that immunotherapy is as beneficial and safe for this group of patients as it is for other cancer patients,” he says.

Shah added that this study lays the groundwork for examining underrepresented patients in cancer clinical trials on both a national and international basis.
In this study, the investigators examined records from 765 patients treated with ICIs for various malignancies from 2011 to 2018 at five MedStar Health hospitals (MedStar Health is Georgetown’s clinical partner). These patients were either infected with HIV, hepatitis B, hepatitis C, were African American, or had a low ECOG performance status preventing them from participating in trials. The ECOG performance status measures the patient’s functional status from 0-4, with 0 being fully active and able to carry on all pre-disease activity without restriction and 4 being bedridden.

In the interest of minimizing complications stemming from co-morbidities most clinical trials include only patients with good functional status (ECOG 0 or 1) or those without concomitant illnesses such and HIV or viral hepatitis.

African-Americans were included in this analysis because, based on a variety of factors, clinical trials often have an under representation of minorities relative to the real-world experience.

Patients with lung cancer, melanoma and kidney cancer usually respond best to ICI therapy and that trend was reflected in the study of the underrepresented populations.

“This retrospective analysis of patient databases from five MedStar Health hospitals of populations receiving ICIs for their advanced cancers was reassuring in establishing that these groundbreaking treatments appeared to be safe and effective in patient populations that have typically been under represented or excluded from clinical trials,” says Michael Atkins, MD, deputy director of Georgetown Lombardi and the senior author on this work.

“These results will likely influence the care of such patients who make up a significant proportion of patients with cancer within the Washington area as well as in other major cities across the U.S. and around the world,” he says.

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In addition to Shah and Atkins, co-authors of the study include Georgetown Lombardi members Chul Kim, MD, MPH; Subha Madhavan, PhD; and Stephen V. Liu, MD; and MedStar Health residents Matthew Blackburn, MD, Michael Cook, MD, and Athanasios Bikas, MD. Other authors include Georgetown’s Anas Belouali, MS, MedStar Health’s William J. Kelly, MD; and Michael T. Sezran, MD, from MedStar’s Internal Residency Program.

The study was funded by Georgetown University Medical Center.

Atkins reports that he has served on advisory boards for BMS, Merck, Novartis, Arrowhead, Pfizer, Galactone, Werewolf (with stock options), and Fathom. He is a consultant for BMS, Merck, Novartis, Pfizer, Genentech-Roche, Exelixis, Eisai, Aveo, Array, ImmunoCore, Iovance, Newlink, Surface, and Cota.

**About Georgetown Lombardi Comprehensive Cancer Center**

Georgetown Lombardi Comprehensive Cancer Center is designated by the National Cancer Institute (NCI) as a comprehensive cancer center. A part of Georgetown University Medical Center, Georgetown Lombardi is the only comprehensive cancer center in the Washington D.C. area. It serves as the research engine for MedStar Health, Georgetown University’s clinical partner. Georgetown Lombardi is also an NCI recognized consortium with John Theurer Cancer Center/Hackensack Meridian Health in Bergen County, New Jersey. The consortium reflects an integrated cancer research enterprise with scientists and physician-researchers from both
locations. Georgetown Lombardi seeks to improve the diagnosis, treatment, and prevention of cancer through innovative basic, translational and clinical research, patient care, community education and outreach to service communities throughout the Washington region, while its consortium member John Theurer Cancer Center/Hackensack Meridian Health serves communities in northern New Jersey. Georgetown Lombardi is supported in part by a National Cancer Institute Cancer Center Support Grant (P30CA051008). Connect with Georgetown Lombardi on Facebook (Facebook.com/GeorgetownLombardi) and Twitter (@LombardiCancer).

About Georgetown University Medical Center
Georgetown University Medical Center (GUMC) is an internationally recognized academic health and science center with a four-part mission of research, teaching, service and patient care (through MedStar Health). GUMC’s mission is carried out with a strong emphasis on public service and a dedication to the Catholic, Jesuit principle of cura personalis -- or “care of the whole person.” The Medical Center includes the School of Medicine and the School of Nursing & Health Studies, both nationally ranked; Georgetown Lombardi Comprehensive Cancer Center, designated as a comprehensive cancer center by the National Cancer Institute; and the Biomedical Graduate Research Organization, which accounts for the majority of externally funded research at GUMC including a Clinical and Translational Science Award from the National Institutes of Health. Connect with GUMC on Facebook (Facebook.com/GUMCUpdate), Twitter (@gumedcenter).