Lymphoma Researcher's Study Lends Support to Lower Barriers for CAR-T Treatment

University of Colorado Cancer Center's Manali Kamdar says improving access to CAR-T therapy is "a huge win for patients."

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Research led by University of Colorado Cancer Center member Manali Kamdar, MD, has contributed to a regulatory change that she says could broaden access to a form of CAR T-cell therapy for people with lymphoma.

"It's a huge win for patients" who previously had trouble accessing state-of-the-art therapy for certain types of lymphoma because of rules requiring them to stay close to a major medical facility for several weeks after treatment, Kamdar says.

Lymphoma is a cancer that starts in white blood cells that are part of the body's immune system. The most frequently occurring type, non-Hodgkin lymphoma, is one of the most common cancers in the United States.

Kamdar is an associate professor in the CU Department of Medicine's Division of Hematology, where she is clinical director of lymphoma services. Her findings were presented in May at the annual meeting of the American Society of Clinical Oncology (ASCO).

A revolutionary treatment

Kamdar's study focused on CAR T-cell therapies, an advanced, personalized form of treatment that uses a patient's own T cells, a type of immune cell, to fight cancer. These T cells are collected, modified in a lab to express chimeric antigen receptors (CARs) that target cancer cells, and then infused back into the patient to attack the disease.

These therapies are most often used to treat blood cancers, such as certain kinds of lymphoma, multiple myeloma, and leukemia, after other treatments haven't worked or stop working.

Lisocabtagene maraleucel, or liso-cel, is a form of CAR T-cell therapy that targets the CD19

antigen, a protein on the surface of cancer cells. It's a one-time infusion that's been approved for treatment of certain cases of large B-cell lymphoma when cancer has stopped responding to treatment (relapsed) or when cancer has continued to progress under treatment (refractory).

Kamdar says that CD19 CAR T-cell therapies "have revolutionized how we treat our patients with relapsed or refractory lymphomas. Patients who previously would have had no options are now able to live without lymphoma."

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Addressing an access issue

But some CAR T-cell therapies can cause "unique adverse events," Kamdar says — unusual reactions to a treatment that may be different from typical side effects. These adverse events include cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS), both of which can cause severe symptoms and are potentially life threatening.

Because of the risk of these events, U.S. Food and Drug Administration regulations previously required that most patients receive liso-cel therapy infusions at a large referral medical center capable of monitoring and treating CRS and ICANS, such as the CU Cancer Center, rather than at a community site that might be closer to their homes, Kamdar says. Also, patients were required to remain close to the center where they received their infusion for at least four weeks and were told not to drive for eight weeks after treatment.

Those rules have created logistical and socio-economic barriers for patients that have kept some eligible patients from receiving CAR T-cell therapies, Kamdar says.

"Although these treatments are transformative, they've only reached a certain section of the patient population that's able to relocate to a cancer center with their caregiver for four weeks, and who have someone who can drive them for eight weeks," she says. "We have people who are mill workers, factory employees, miners, and ranchers who can't be away for long periods. Clearly the access issue is huge."

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Rethinking the four-week mandate

Given previous research indicating that risk of severe CRS and ICANS is less with liso-cel that some other CAR T-cell therapies, Kamdar and colleagues set out to assess whether the four-week mandate was necessary for liso-cell treatment.

In their new study, Kamdar and her collaborators examined data from 1,579 patients who were treated with liso-cel, either as part of one of five clinical trials or as recorded in "real world"

registry data on standard-of-care treatment. The researchers looked at how many of the patients experienced CRS or ICANS and how severe they were.

They found that about half of these liso-cel treated patients had no occurrence of CRS and roughly two-thirds had no ICANS. When CRS or ICANS did occur, the effects were usually mild and lasted only a few days. And the vast majority of CRS or ICANS events happened within two weeks of liso-cell treatment.

Kamdar and her colleagues concluded that liso-cell treatment is generally safe, that the most serious side effects usually happen within the first two weeks after treatment and don't last very long, and that late adverse events are uncommon and don't require specialized treatment.

"This really called for us to rethink the four-week mandate, allowing us to keep the patients for a shorter period of time, thus decreasing the logistical and socio-economic burden that these patients often faced alongside their lymphoma," she says.

Fast action by the FDA

In June, the FDA reviewed all data and changed its rules requiring patients to stay near the center where they received their liso-cel infusion from four weeks to two weeks. And the eight-week driving ban was shortened to two weeks.

"When I presented this at ASCO, there was a lot of interest from regulators who were trying to figure out the data," Kamdar says. "We welcome this change, and now it's on us to disseminate this information everywhere, so that primary providers who send their patients to us know that they are not sending them to Denver for a month."

Kamdar says the FDA shift on liso-cell had an impact "right away" on some of her own patients. She adds: "My hope is that a year from now, we publish something new that shows that more people who need CAR T-cell therapy have had access across socioeconomic barriers."

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