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Some people with RA treated with immune checkpoint inhibitors for cancer have flare, most able to continue treatment

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A new study found that cancer patients with a pre-existing autoimmune disease receiving immune checkpoint inhibitors as treatment are likely to experience a flare. However, their rate of experiencing an immune related adverse event is at a rate similar to patients without an autoimmune disease. The study sought to determine the safety and efficacy of immune checkpoint inhibitors in patients with rheumatoid arthritis (RA). Details of this study will be presented at the 2019 ACR/ARP Annual Meeting (Abstract #1339).

Rheumatoid arthritis (RA) is the most common type of autoimmune arthritis. It is caused when the immune system (the body's defense system) is not working properly. RA is a chronic disease that causes joint pain, stiffness, swelling and decreased movement of the joints. Small joints in the hands and feet are most commonly affected. Sometimes RA can affect your organs, such as eyes, skin or lungs.

Immune checkpoint inhibitors have their own distinct adverse events, which are collectively referred to as "immune-related adverse events". These events can affect various organs in the body, may result in serious complications, and should be detected and treated promptly.

Immune checkpoint inhibitors have led to cures in some cancers. However, patients with pre-existing autoimmune diseases were largely excluded from clinical trials involving immune checkpoint inhibitors due

to the concern for increased adverse events. In clinical practice, some RA patients have been treated with immune checkpoint inhibitors, but the risks of toxicity and/or disease flare have not been clearly outlined. Researchers conducted a retrospective analysis evaluating the safety and efficacy of two immune checkpoint inhibitor therapies, anti-CTLA-4 and anti-PD-1, in patients with pre-existing autoimmune diseases treated from 2011 to 2018.

"Patients with RA are at a greater risk of certain cancers than the general population, yet they were excluded from groundbreaking trials evaluating immunotherapy for the treatment of malignancy due to fear of disease flare. However, patients with autoimmune diseases have the potential to benefit from the use of these therapies," says Sabina Sandigursky, MD, MS, instructor, Division of Rheumatology, at New York University Langone Medical Center, and the study's lead author. "Our data suggests that patients with RA may be treated with immunotherapy and attain rates of response that is similar to the general population at large with a 50 percent flare rate. There are ongoing clinical trials evaluating this question in a prospective nature."

The study's primary endpoints were incidences of immune-related adverse events and autoimmune disease flares. The study's secondary endpoint was overall survival.

Out of 84 patients with pre-existing autoimmune conditions who developed a malignancy and were treated with immune checkpoint inhibitor therapies, the researchers identified 22 patients with RA. Sixteen were female and six were male, with an average age of 67. Twenty of the patients had no evidence of active disease as indicated by their treating physician. Sixteen of the patients were receiving immunomodulatory therapy for their RA at the start of immune checkpoint inhibitors treatment, with eight patients receiving systemic corticosteroids and seven patients on methotrexate.

Patients' malignancies included seven with melanoma, seven with non-small cell lung cancer (NSCLC) and others. Thirteen patients were treated with pembrolizumab, nine with nivolumab and four with ipilimumab, all of which are currently approved immune checkpoint inhibitors.

Immune related adverse events (toxicity) occurred in seven patients (41 percent). The most common toxicities observed in the study were dermatitis in four patients (18 percent) and colitis in three (14 percent). Five patients temporarily discontinued immune checkpoint inhibitors therapy due to immune related adverse events and one required permanent ICI discontinuation. RA flares occurred in 12 (55 percent) patients, nine of whom received oral corticosteroid treatment for their flare. Immune checkpoint inhibitors were permanently discontinued due to RA flare in only one patient in the study. Overall, a flare, immune related adverse events, or both occurred in 16 (73 percent) of the 22 patients. The average overall survival for RA patients after starting immune checkpoint inhibitors therapy was 10.5 months.

Although this study cohort was small, the researchers concluded that results suggest that RA patients experience severe immune-related adverse events from immune checkpoint inhibitor therapy at a similar rate to the population of patients without autoimmune diseases.

"If validated in prospective clinical trials, this study's findings may open new treatment options for patients with autoimmune diseases and concurrent malignancy. A co-management approach between the oncologist and rheumatologist can help recognize and treat immunotherapy related toxicities if they do arise," says Dr. Sandigursky.

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