Immune therapy after surgery lowers relapse risk in patients with high-risk melanoma

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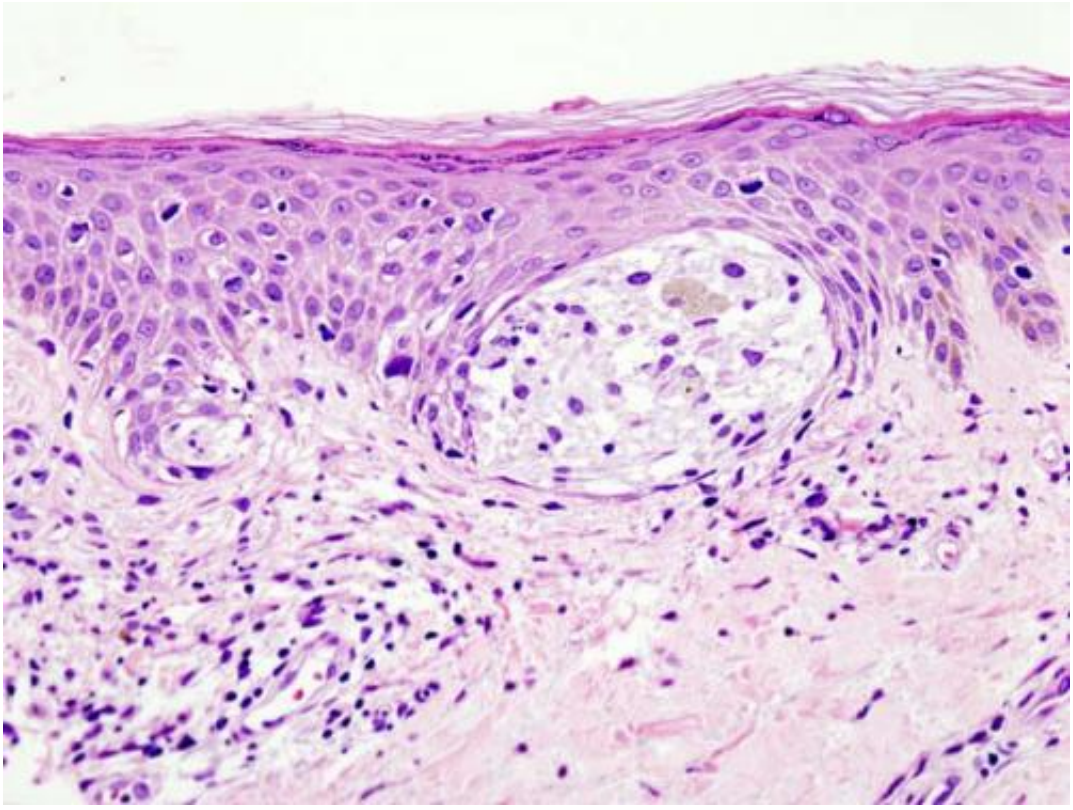

Melanoma in skin biopsy with H&E stain—this case may represent superficial spreading melanoma. Credit: Wikipedia/CC BY-SA 3.0

Patients with high-risk melanoma who had a course of pembrolizumab after their surgery had a longer time before their disease recurred than patients who got either ipilimumab or high-dose interferon after surgery. These findings of a large SWOG Cancer Research Network clinical trial,

S1404, will be presented at the ASCO annual meeting June 6, 2021.

Researchers also measured overall survival and found no statistically significant difference in overall survival rates between the two groups of patients three and one-half years after the last patient enrolled to the trial. They did find, however, that patients taking pembrolizumab had fewer serious side effects than those treated with either high-dose interferon or ipilimumab.

The S1404 trial is sponsored by the National Cancer Institute (NCI), part of the National Institutes of Health (NIH), designed and led by the SWOG Cancer Research Network, and conducted by the NIH-funded National Clinical Trials Network (NCTN).

Kenneth F. Grossmann, MD, Ph.D., of the Huntsman Cancer Institute at the University of Utah Medical Center and chair of SWOG's Melanoma Committee, was lead investigator on the study. He spoke about the pembrolizumab treatment that was tested: "The recurrence-free survival advantage and improved safety profile over the previous standard of care make this therapy a continued standard for treating patients with high-risk resected melanoma."

Noting that overall survival measures were not significantly different between the two arms, Grossmann said, "The overall survival analysis was performed at a pre-defined time point with only approximately 50% of events needed for a fully powered analysis. We suspect that effective use of PD-1 blockade and other improved therapies for stage IV disease improved outcomes of relapsing patients on the control arm such that overall survival was not different between the two groups."

Grossmann added that further data to come from this trial will include studies to evaluate pre-treatment predictors of whether patients are likely to benefit from treatment and quality of life studies to better understand

the impact of relapse in patients with high-risk resectable melanoma.

The study randomized 1,345 adult patients with stage III or IV melanoma who had undergone surgery to remove their tumors. Patients were assigned at random to either the pembrolizumab arm or the control arm. Those on the control arm decided with their physicians whether to follow a course of high-dose interferon or a course of ipilimumab, both of which are approved by the FDA for use in treating these patients.

Pembrolizumab, an immunotherapy drug known as a PD-1 inhibitor, was chosen for the trial because of its comparatively low toxicity and its activity in metastatic disease. Another trial has also since shown a recurrence-free survival benefit for the drug when compared to a placebo. High-dose interferon and ipilimumab, which were standard of care treatments for these patients at the start of the study, often come with serious side effects. As the S1404 researchers had expected, toxicity was lower in patients on the pembrolizumab arm. Among patients taking high-dose interferon, roughly 72% had severe side effects (grade 3 or higher adverse events). The rate of such side effects was about 58% for those on ipilimumab, but it was only about 32% for patients on pembrolizumab.

Provided by SWOG Cancer Research Network