

Patients with high-risk melanoma had better quality of life on pembrolizumab than on standard immunotherapy regimens

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Patients with high-risk stage III-IV melanoma who received pembrolizumab after their surgery reported a better quality of life than patients who received the previous standard-of-care treatment with either ipilimumab or high-dose interferon. These findings were from a large clinical trial led by the SWOG Cancer Research Network and are reported in the journal *JAMA Oncology*.

Researchers on the trial, known as \$1404, had recently reported the primary clinical results of the study in *Cancer Discovery*, which showed that patients on the study's pembrolizumab arm had a longer time before their disease recurred than patients on either of the other two treatments. The new quality-of-life findings come from a planned analysis of patient-reported outcomes (PROs) collected during the trial. PROs provide patients the opportunity to directly report aspects of their <u>cancer</u> care experience, especially information about their symptoms and quality of life.

The lead author on the quality-of-life analysis was Joseph M. Unger, Ph.D., a SWOG health services researcher and biostatistician with Fred Hutchinson Cancer Center.

"When patients and their physicians are trying to assess the potentially complex tradeoffs between treatment efficacy and quality of life," Unger said, "it is vital that we rigorously account for the patients' own experience of their treatment. This information can be extraordinarily helpful for guiding decision-making between patients and physicians."



Patients on the S1404 study completed standard questionnaires to report on their quality of life at five time points during treatment and at 24 weeks and 48 weeks after they finished treatment. If their cancer recurred, patients were asked to complete one additional quality-of-life assessment at that time.

The primary endpoint for the quality-of-life analysis was the Functional Assessment of Cancer Therapy—Biologic Response Modifiers—Trial Outcome Index (FACT-BRM-TOI). This measure combines multiple domains of the experience of patients receiving immunotherapy treatment, including measures of their physical, social, emotional, functional, and cognitive well-being. Among patients on the trial who completed these PRO questionnaires, by 13 weeks after the start of treatment the mean scores between the arms had greatly diverged: the mean FACT-BRM-TOI score on the pembrolizumab arm was 90.3, while the mean score on the control arm was 80.6. Higher scores indicate better quality of life, and this difference of nearly 10 points was statistically significant and was considered clinically meaningful.

Primary clinical findings from the S1404 trial were reported in June of 2021, at the annual meeting of the American Society of Clinical Oncology. Those results showed that in patients with stage III or IV melanoma who had undergone surgery to remove their tumors, those treated with pembrolizumab after surgery lived significantly longer without a recurrence of their cancer (they had a 23 percent lower risk of relapse) than those treated with ipilimumab or high-dose interferon. The new findings now reported in *JAMA Oncology* indicate that those patients treated with pembrolizumab also, on average, experienced a significantly better quality of life.

This alignment of clinical benefit with quality-of-life benefits can be particularly important when doctor and patient are deciding whether to begin a course of treatment after a patient's surgery, known as adjuvant



treatment.

Senior author Sapna Patel, MD, chair of the SWOG melanoma committee and associate professor of Melanoma Medical Oncology at The University of Texas MD Anderson Cancer Center, compared these quality-of-life findings from \$1404 (also known as KEYNOTE 053) with findings from a recent study of adjuvant pembrolizumab in patients with stage III melanoma—the KEYNOTE 054 study. Five-year quality-of-life data from that study were presented at the ESMO 2022 Congress and published in *NEJM Evidence*.

"The KEYNOTE 054 team presented long-term health-related quality-of-life outcomes from their study of adjuvant pembro versus placebo," Patel said. "The investigators showed no difference in health-related quality-of-life scores at all time points throughout their study. This stands in contrast to S1404, where we found a notable difference in quality-of-life scores at all time points, including the primary end point at cycle 3.

"The key difference is that our study compared pembrolizumab to an active control which had substantial adverse impacts on quality of life. When compared back to back, the patterns of quality of life for <u>patients</u> on the pembro arms of both studies were quite similar.

"My interpretation is that quality-of-life scores may not be that different when treatment options have minimal severe side effects (pembro versus placebo, e.g. KEYNOTE 054). But when treatment options vary in their rates of severe toxicity or discontinuation due to side effects (S1404), quality-of-life scores may favor the less severe treatment.

"In the adjuvant setting, where cancer may already be cured with local maneuvers, we should consider the importance of <u>quality of life</u> when proposing treatments and attempt to minimize disruption to everyday



life."

More information: Effectiveness of Adjuvant Pembrolizumab vs High-Dose Interferon or Ipilimumab for Quality-of-Life Outcomes in Patients With Resected Melanoma A Secondary Analysis of the SWOG S1404 Randomized Clinical Trial, *JAMA Oncology* (2022). DOI: 10.1001/jamaoncol.2022.5486

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