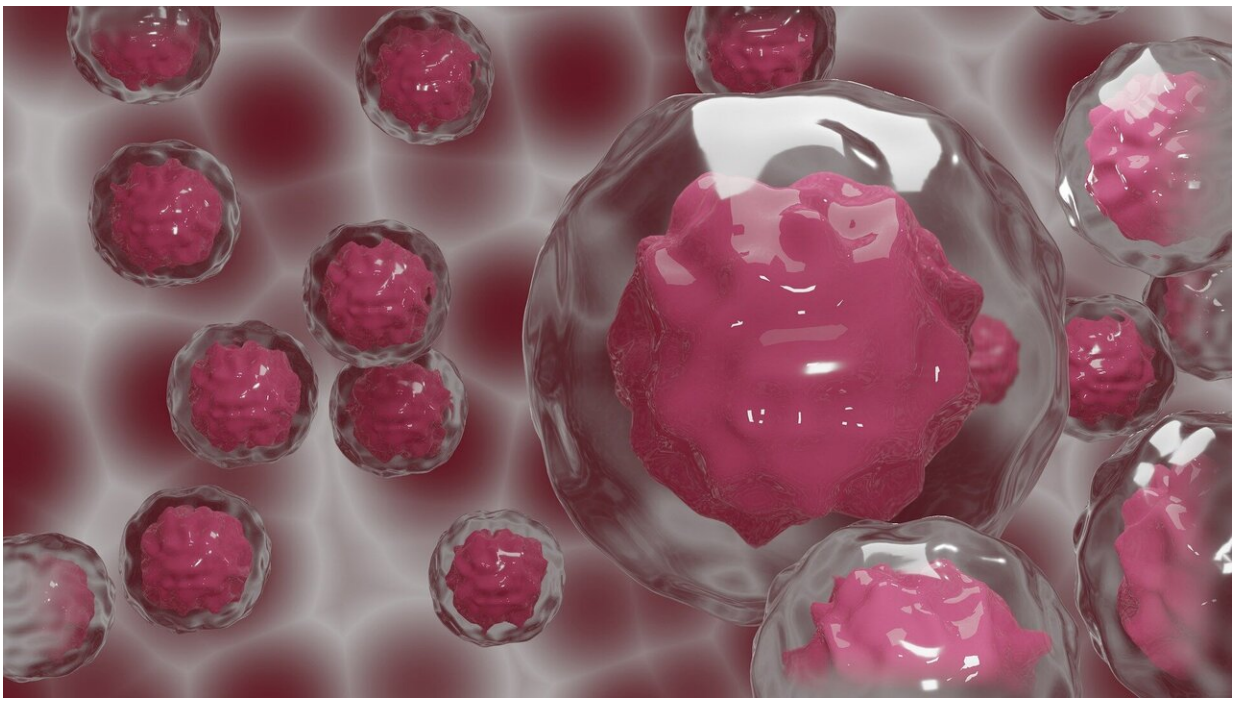
Immunotherapy before surgery induces complete response in more than half of patients with common skin cancer

September 12 2022



Credit: CC0 Public Domain

In an international, multicenter Phase II clinical trial led by The University of Texas MD Anderson Cancer Center, 63.3% of patients with stage II–IV cutaneous squamous cell carcinoma (CSCC) saw their tumors nearly or completely disappear when treated with

immunotherapy before surgery. The results were presented today at the European Society for Medical Oncology (ESMO) Congress 2022 and published in *The New England Journal of Medicine*.

The anti-PD1 therapy cemiplimab was well-tolerated, and the study met its primary endpoint with a pathologic complete response (pCR) rate of 50.6%, meaning no tumor cells were found at surgery. Another 12.7% of patients had a major pathological response (MPR), with less than 10% viable tumor found at surgery. The responses were confirmed by independent central pathologic review.

"These results represent the highest response rate to neoadjuvant anti-PD1 monotherapy in any solid cancer so far and likely are the start of a practice change for how we treat advanced, resectable cutaneous squamous cell carcinoma," said study principal investigator and lead author Neil Gross, M.D., professor of Head and Neck Surgery. "I'm excited to see how this new treatment approach impacts outcomes, including quality of life, as we continue long-term follow-up."

About 1 million people in the U.S. are diagnosed with CSCC each year, making it one of the most common forms of cancer. Most cases are easily treated by a dermatologist or primary care physician and do not require advanced care. However, most CSCCs occur in the head and neck regions—areas that receive heavy sun exposure—and, in the rare instances that they do grow and spread aggressively, they can affect the eyes, ears, nose and mouth.

The current standard of care, involving surgical excision and radiation, can be disfiguring and result in loss of important functions. Although not an endpoint of the study, the response to neoadjuvant (pre-surgical) immunotherapy enabled less invasive, function-preserving surgery in some cases.

In 2018, the Food and Drug Administration (FDA) approved cemiplimab for patients with metastatic CSCC who are not candidates for curative surgery or radiation. The drug was first studied in the neoadjuvant setting for operable disease in a single-institution phase II study at MD Anderson that Gross designed and led. The results were presented at the ESMO Congress 2019 and published in *Clinical Cancer Research* in 2021. The 75% pathologic response rate from 20 patients in that study prompted this international, multicenter study (NCT04154943) to confirm the drug's efficacy.

The single-arm study enrolled 79 patients in the U.S., Australia and Europe with operable stage II–IV CSCC to receive four doses of neoadjuvant cemiplimab followed by curative-intent surgery, with optional adjuvant radiation therapy. Patients had scans before surgery, but the imaging responses (6.3% complete response) underestimated pCR (50.6%). The overall response rate from imaging was 68.4%, with most responses classified as partial responses.

Sixty-seven patients (84.8%) were male and the median age was 73. Consistent with CSCC incidence, 87.3% of patients were white, and the head and neck region was the primary cancer site for 91.9% of patients.

Sixty-two patients received all four doses and 70 patients underwent surgery. Of the nine patients who did not have surgery, three declined because imaging showed their cancer responded to the immunotherapy, two were lost to follow-up/non-compliance, two had progressive disease and two experienced adverse events.

Overall, 14 patients (17.7%) experienced grade three or higher adverse events. The most common events of any grade were fatigue (30.4%), rash (13.9%), diarrhea (13.9%) and nausea (13.9%). Four patients died; one death, an exacerbation of cardiac failure, was considered related to treatment. There were no new safety signals for anti-PD1

immunotherapy treatment.

The research team will continue to follow the study participants and to report survival data and other outcomes when follow-up is complete. In the future, investigators hope to address still-unanswered questions about the optimal number of doses before surgery, which patients can safely avoid radiation and/or surgery, and how to predict which patients are most likely to respond to immunotherapy.

"I think where it's really going to make a huge difference is quality of life," Gross said. "If you can avoid radiation or have a smaller surgery, and you can keep your eye, ear or nose, that's a huge win for people. That's the excitement of this approach: the chance to make life so much better for our patients in the future."

More information: Abstract: 789O

Neoadjuvant cemiplimab for stage II to IV cutaneous squamous-cell carcinoma, *New England Journal of Medicine* (2022). DOI: 10.1056/NEJMoa2209813

Provided by University of Texas M. D. Anderson Cancer Center

Citation: Immunotherapy before surgery induces complete response in more than half of patients with common skin cancer (2022, September 12) retrieved 17 January 2023 from https://medicalxpress.com/news/2022-09-immunotherapy-surgery-response-patients-common.html

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.