

# Nivolumab immunotherapy safe, feasible during chemoradiation for adv. head and neck cancer

February 13 2018

---

Analysis of a clinical trial, RTOG Foundation 3504, finds that nivolumab immunotherapy can be administered safely in conjunction with radiation therapy and chemotherapy for patients with newly diagnosed local-regionally advanced head and neck cancers. All patients in the trial were able to complete curative-intent radiation therapy even with the addition of the PD-1 inhibitor to platinum-based chemotherapy, and maintenance immunotherapy to one year was found to be feasible. The study will be presented today in an online news briefing and at the 2018 Multidisciplinary Head and Neck Cancers Symposium in Scottsdale, Arizona.

"Patients diagnosed with cancers in the mouth and throat often are diagnosed at advanced stages of disease and relapse within two years," said Maura Gillison, MD, PhD, lead author of the study and a professor of thoracic/head and neck medical oncology at the University of Texas MD Anderson Cancer Center in Houston. "We previously found that [nivolumab](#) improves survival for patients who experience head and neck cancer relapse after platinum chemotherapy. Thus, we are compelled to evaluate whether adding immunotherapy to the initial treatment of head and neck cancer could prevent these relapses from happening."

"In this trial, we evaluated the safety and feasibility of adding immunotherapy to curative-intent [cisplatin](#) and radiation therapy, a treatment that is already quite taxing for patients due to side effects. We

found that it is possible to add nivolumab immunotherapy to cisplatin treatment without compromising radiation delivery, and patients were also able to tolerate continuing immunotherapy for up to a year."

RTOG 3504 was designed to evaluate the safety of adding nivolumab to standard treatment options for local-regionally advanced head and [neck cancer](#), and the current analysis reports early safety data for the two cohorts who received weekly or high-dose cisplatin chemoradiation therapy. Twenty patients with newly-diagnosed intermediate-risk HNSCC (p16+, oropharynx T1-2N2b-N3/T3-4N0-3, >10 pack-years smoking; or T4N0-N3, T1-3N3, ?10 pack-years) (65% of patients) or high-risk HNSCC (oral cavity, larynx, hypopharynx, or p16(-) oropharynx, stage T1-2N2a-N3 or T3-4N0-3) (35% of patients) were enrolled. Median patient age was 56 years (range 35-76), and most patients were male (70%) and Caucasian (85%). Most patients were in advanced stages of disease (80% T3-4 and 45% N2-3) and were former smokers (55% >10 pack-year smokers).

Patients received nivolumab in addition to chemoradiation with either weekly or high-dose cisplatin. Ten patients were enrolled in each treatment group; eight and nine patients from the weekly and high-dose cohorts, respectively, were evaluable for this analysis.

All patients in both treatment groups completed radiation therapy. Additionally, 15 of 17 patients received at least 70 percent of their prescribed dose of platinum chemotherapy; cisplatin was stopped for two patients for an allergic reaction and for cholecystitis not related to nivolumab. Immunotherapy was discontinued for three patients due to known side effects of nivolumab, including blurred vision, diarrhea and joint pain.

Most patients were able to both start and continue nivolumab following first-line treatment. On the weekly cisplatin arm, five of the eight

evaluable patients received 10 doses of concurrent nivolumab and two patients received nine doses. On the high-dose cisplatin arm, five of the nine evaluable patients received seven doses and three patients received six doses. Six of the first eight patients enrolled in the trial completed a year of nivolumab therapy; other patients in the study continue to receive treatment, but the trial was designed to evaluate the first eight enrolled.

Nivolumab was tolerated well by patients in both treatment groups. No [patients](#) in either cohort experienced dose-limiting toxicities, which were defined as grade 3 or higher nivolumab-related adverse events not resolved within four weeks, [radiation therapy](#) delays of more than two weeks, or an inability to receive at least 70 percent of prescribed chemotherapy.

On the weekly cisplatin arm, there was one case each of anaphylaxis and cholecystitis, though neither was attributable to nivolumab. Grade 3 side effects attributable to the immunotherapy on this arm included three cases of decreased white blood cell count (two leukopenia, one lymphopenia) and one case each of fatigue, loss of appetite, lipase elevation, mucositis and adrenal insufficiency. On the high-dose cisplatin arm, grade 3 side effects related to nivolumab included one case each of diarrhea, lipase elevation and amylase elevation. There were no grade 4 or 5 side effects on either [treatment](#) arm.

**More information:** The abstract, "Safety evaluation of nivolumab (Nivo) concomitant with platinum-based chemoradiotherapy (CRT) for intermediate (IR) and high-risk (HR) local-regionally advanced head and neck squamous cell carcinoma (HNSCC): RTOG Foundation 3504," will be presented in detail during the Plenary Session at the 2018 Multidisciplinary Head and Neck Cancers Symposium in Scottsdale, Arizona.

Provided by American Society for Radiation Oncology

Citation: Nivolumab immunotherapy safe, feasible during chemoradiation for adv. head and neck cancer (2018, February 13) retrieved 6 May 2024 from

<https://medicalxpress.com/news/2018-02-nivolumab-immunotherapy-safe-feasible-chemoradiation.html>

|  |
|--|
| <p>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.</p> |
|--|