New HPV-related throat cancer treatment uses less radiation and spares most patients from chemotherapy

December 21 2021

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Low-dose radiation at 50 Gy without chemotherapy following transoral surgery (TOS) led to very high survival and outstanding quality of life in

patients with human papillomavirus-positive (HPV+) throat cancer and at medium risk for recurrence. The *Journal of Clinical Oncology* has published the final results of the randomized phase 2 trial E3311 showing that 94.9% of such patients were alive and disease-free three years later and had an excellent quality of life after this less intense treatment. The approach preserved patients' swallowing and voice functions and spared them unnecessary short-term toxicities. The trial continues to follow patients to measure long-term survival and quality of life over five years. The ECOG-ACRIN Cancer Research Group (ECOG-ACRIN) designed and conducted the trial with funding from the National Cancer Institute, part of the National Institutes of Health.

"For intermediate-risk patients—those with uninvolved surgical margins, less than five involved nodes, and less than 1mm extranodal extension—postoperative radiation therapy at 50 Gy without chemotherapy appears sufficient," said senior author Barbara A. Burtness, MD, professor of medicine and co-leader of the Developmental Therapeutics Research Program at Yale Cancer Center, chair of the ECOG-ACRIN Head and Neck Committee, and chair of the ECOG-ACRIN Task Force on Advancement of Women.

In E3311, 359 participants with HPV-related oropharyngeal (throat) cancer all underwent transoral surgery (TOS) and were assigned to treatment based on individual risk factors for recurrence. The intensity of any additional treatment they received was based on factors known to predict whether the cancer is likely to spread or return, such as the size of the original tumor, the extent of cancer in neck lymph nodes, and others.

"The E3311 findings are building a strong case that usual postoperative high-dose radiation and chemotherapy may not be necessary for all patients," said first author Robert L. Ferris, MD, Ph.D., director of the UPMC Hillman Cancer Center in Pittsburgh, PA.

Only high-risk patients were assigned to chemotherapy, along with usual high-dose radiation (66 Gy, Arm D). Patients at low risk were observed and received no additional treatment (Arm A). Patients at intermediate risk were randomized to one of two arms to receive radiation alone, both at doses lower than usual (Arm B, 50 Gy or Arm C, 60 GY).

After three years of follow-up, the E3311 trial showed two-year progression-free survival rates above 90% across all four groups: 96.9% for Arm A; 94.9% for Arm B; 96% for Arm C; and 90.7% for Arm D. Between Arms B and C, the progression-free survival rates were statistically the same, a strong indicator that radiation alone at 50 Gy was safe and effective for patients at intermediate risk.

E3311 is the first multi-center study of transoral surgery in head and neck cancer.

Surgeons and patients widely favor the organ-preservation approach of TOS. The surgeon uses this sophisticated, computer-enhanced system to guide the surgical tools and see an enhanced view of the cancer and surrounding tissue. The E3311 trial collected prospective, multi-institutional data with meticulous and ongoing evaluation of surgeon expertise. There was a low incidence of positive margins and minimal oropharyngeal bleeding from TOS. This high level of surgical quality assurance demonstrated that the procedure could be performed safely.

"The surgeon credentialing and quality assurance process developed to support the E3311 trial provide standards for future transoral head and neck surgical oncology trials and improve their validity," said Dr. Burtness. "Our results may also apply to other surgical disciplines and clinical trials."

E3311 provides quality of life data from the patients' own perspectives.

This trial used validated patient-reported outcome (PRO) scoring. Although a consistent decline in quality of life and swallowing scores was observed during treatment, these recovered to baseline in Arms A, B, and C. Scores following treatment in Arm D were slightly lower than baseline. Quality of life is important to measure because, in general, patients with HPV-related throat cancer experience profound, acute decreases in physical functioning and quality of life from open surgery, chemotherapy, and radiation treatments.

More information: Robert L. Ferris et al, Phase II Randomized Trial of Transoral Surgery and Low-Dose Intensity Modulated Radiation Therapy in Resectable p16+ Locally Advanced Oropharynx Cancer: An ECOG-ACRIN Cancer Research Group Trial (E3311), *Journal of Clinical Oncology* (2021). DOI: 10.1200/JCO.21.01752

Provided by ECOG-ACRIN Cancer Research Group

Citation: New HPV-related throat cancer treatment uses less radiation and spares most patients from chemotherapy (2021, December 21) retrieved 26 April 2024 from https://medicalxpress.com/news/2021-12-hpv-related-throat-cancer-treatment-patients.html

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