Patients with Head and Neck Cancers Do Not Benefit from the Addition of Cetuximab to Standard Chemoradiotherapy

The addition of cetuximab to treatment with cisplatin and radiotherapy did not improve the outcome of patients with locally advanced (non-metastatic) head and neck cancer (HNC) according to results of the phase III, RTOG 0522 clinical trial conducted by the Radiation Therapy Oncology Group (RTOG), which now carries out research as NRG Oncology. In a paper published online last week in the *Journal of Clinical Oncology*, the authors advise against the routine use of cetuximab with cisplatin and radiotherapy due to no improvement in tumor control or survival and an increase in acute side effects. As previous reports have shown, the RTOG 0522 trial results confirm that patients with human papillomavirus (HPV)-positive HNC have significantly better outcomes than patients with HPV-negative HNC.

The prognosis for patients diagnosed with locally advanced HNC is poor with approximately 50% of patients surviving more than 5 years. The addition of cetuximab, an epidermal growth factor receptor (EGFR) inhibitor, to chemotherapy with cisplatin and radiotherapy was identified as a promising treatment strategy. "Based upon sound clinical and biological evidence, we hypothesized the combination of cetuximab and cisplatin with radiotherapy would result in superior outcomes compared to cisplatin alone with radiotherapy. Both cetuximab and cisplatin are active agents in head and neck cancer and the combination has been shown to be more effective than a single agent for patients with recurrent or metastatic head and neck cancer. However, our hypothesis was proven to be wrong, which is why we do randomized trials," says Quynh-Thu Le, MD, chair of the NRG Oncology Head and Neck Cancer Committee and chair of the Department of Radiation Oncology at Stanford University. "What we learned from RTOG 0522 is that more treatment is not always better and that we cannot extrapolate data from the recurrent or metastatic setting to the locally advanced setting—especially when combined with radiotherapy."

Eight hundred and ninety-one eligible patients with stage III or IV HNC were enrolled at research sites in the United States, Canada and South Korea and randomly assigned to receive cisplatin with radiotherapy (Arm A = 447 patients) or cisplatin with radiotherapy plus cetuximab (Arm B = 444 patients).

"These study results provide definitive information to guide treatment decision making for patients with locally advanced head and neck cancer," says Walter J. Curran, Jr, MD, an NRG Oncology Group Chairman and Executive Director of the Winship Cancer Institute of Emory University in Atlanta. "This publication represents the prolific work of the NRG Oncology Head and Neck investigators who continue to advance our understanding of the best treatment for our patients."

NRG Oncology conducts practice-changing, multi-institutional clinical and translational research to improve the lives of patients with cancer. Founded in 2012, NRG Oncology is a Pennsylvania-based nonprofit corporation that integrates the research strengths of the National Adjuvant Breast and Bowel Project, the Radiation Therapy Oncology Group and the Gynecologic Oncology Group. The research organization seeks to carry clinical trials with emphases on gender-specific malignancies including gynecologic, breast, and prostate cancers and on localized or locally advanced cancers of all types. NRG Oncology’s extensive research organization is comprised of multidisciplinary investigators including medical oncologists, radiation oncologists, surgeons, physicists, pathologists, and statisticians and encompasses more than 1300 research sites located world-wide with predominance in the United States and Canada. NRG Oncology is supported primarily through grants from the National Cancer Institute (NCI) and is one of five research groups in the NCI’s National Clinical Trials Network.