

# Results of NRG-RTOG 0436 highlight need for biomarkers in treatment of esophageal cancer

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NRG-RTOG 0436 has determined that adding an epidermal growth factor receptor (EGFR) inhibitor to a chemo-radiation regimen does not improve overall survival for patients with locally advanced esophageal cancer treated in a non-operative manner. These results are reported in "Effect of the Addition of Cetuximab to Paclitaxel, Cisplatin, and Radiation Therapy for Patients with Esophageal Cancer - The NRG Oncology RTOG 0436 Phase 3 Randomized Clinical Trial," which was recently published in the *Journal of the American Medical Association (JAMA) Oncology*.

NRG-RTOG 0436 is a phase III clinical trial which was open to [patients](#) with biopsy-proven carcinoma of the esophagus. During the time period of 2008-2013, 344 patients were accrued to this trial and randomized between two treatments arms: standard chemo-radiation alone versus standard chemo-radiation with the addition of the EGFR inhibitor cetuximab.

"The addition of cetuximab to chemo-radiation yielded no significant benefit for the patients on the experimental treatment arm when compared to the standard treatment," stated the lead author, Mohan Suntharalingam, MD, MBA, the Marlene and Stewart Greenebaum Professor of Radiation Oncology at the University of Maryland School of Medicine and President and Chief Executive Officer of the University of Maryland Medical Center . "These results highlight the

need for predictive biomarkers in order to improve and refine the treatment of [esophageal cancer](#)."

All patients enrolled on NRG-RTOG 0436 received weekly cisplatin (50mg/m<sup>2</sup>) plus paclitaxel (25mg/m<sup>2</sup>), and daily radiation (50.4 Gy). Patients assigned to the experimental arm also received weekly cetuximab: day 1 (400mg/m<sup>2</sup>) and then weekly (250 mg/m<sup>2</sup>). Results indicated no significant improvement in overall survival between arms (24- and 36-month overall survival for experimental arm: 45% and 34% vs. standard arm: 44% and 28%). The incidence of grade 3/4/5 treatment-related adverse effects between experimental arm (46%/23%/4%) and the standard arm (50%/17%/1%), and the clinical complete response (cCR) rate between the experimental (56%) and the standard (58%) treatment arms also conveyed no substantial difference.

"Carcinoma of the esophagus causes over 400,000 fatalities worldwide every year, and most patients are at an advanced stage of the disease at presentation. The knowledge acquired from this study will ultimately impact how researchers approach [treatment](#) methods for this patient population in the future," says Walter J. Curran, Jr., MD, NRG Oncology Group Chair and Executive Director of the Winship Cancer Institute of Emory University. "Thank you to Dr. Suntharalingam, the NRG-RTOG 0436 study team, and all of the participating sites for their efforts."

**More information:** Mohan Suntharalingam et al, Effect of the Addition of Cetuximab to Paclitaxel, Cisplatin, and Radiation Therapy for Patients With Esophageal Cancer, *JAMA Oncology* (2017). [DOI: 10.1001/jamaoncol.2017.1598](https://doi.org/10.1001/jamaoncol.2017.1598)

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