Cetuximab, you're fired

Cetuximab has been combined successfully with chemotherapy in the treatment of cancers of an epithelial nature. Edward Kim, at the Levine Cancer Institute, and colleagues have reported the results of FLEX, a phase III trial in which cetuximab was evaluated in combination with both docetaxel and pemetrexed in patients with advanced NSCLC. Kim explains the design of the study: "both docetaxel and pemetrexed were approved as first-line treatments, limiting the eligibility of the study. This led us to adapt the design. Instead of excluding patients who had previously received docetaxel or pemetrexed, physicians could choose the chemotherapy arm and then the patient was randomly assigned to receive cetuximab or not."

The study enrolled 938 patients, 333 of whom received docetaxel (167 patients with cetuximab and 166 without) and 605 received pemetrexed (301 with cetuximab and 304 alone). Median overall survival with cetuximab and pemetrexed was 6.9 months compared with 7.8 months with pemetrexed alone, and 5.8 months for patients receiving cetuximab plus docetaxel versus 8.2 months in patients receiving docetaxel alone.

"Our study clearly indicates that cetuximab does not add benefit to chemotherapy in the second line for patients with NSCLC," states Kim. He also explains the importance of using the appropriate biomarker, particularly the immunohistochemistry score (H score), which provides an assessment of EGFR protein expression and response to treatment with cetuximab. "We observed no increased benefit with the use of the H score in a large cohort of patients. H-score is not a relevant biomarker for determining patients for cetuximab treatment and other biomarkers should be explored," he concludes.

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Original article Kim, D. S. *et al.* Docetaxel or pemetrexed with or without cetuximab in recurrent or progressive non-small-cell lung cancer after platinum-based therapy: a phase 3, open-label, randomised trial. *Lancet Oncol.* doi:10.1016/S1470-2045(13)70473-X