

targeted therapy can delay recurrence of intermediate-stage lung cancer

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The targeted therapy gefitinib appears more effective in preventing recurrence after lung cancer surgery than the standard of care, chemotherapy. In a phase III clinical trial, patients with epidermal growth factor receptor (EGFR)-positive, stage II-IIIa non-small cell lung cancer (NSCLC) who received gefitinib went about 10 months longer without recurrence than patients who received chemotherapy. The study will be presented at the upcoming 2017 ASCO Annual Meeting in Chicago.

"Adjuvant gefitinib may ultimately be considered as an important option for stage II-IIIa lung cancer [patients](#) with an active EGFR mutation, and we may consider routine EGFR testing in this earlier stage of lung cancer," said lead study author Yi-Long Wu, MD, a director of the Guangdong Lung Cancer Institute, Guangdong General Hospital, Guangzhou, China. "We intend to follow these patients until we can fully measure overall survival as opposed to disease-free survival, which just measures disease recurrence."

Due to high chance of recurrence, the five-year survival for patients with stage II-IIIa NSCLC is only 40 percent. About 25 percent of all patients who are diagnosed with NSCLC are eligible to have surgery to remove the tumors with the hope of a cure. Among that group, about 30 percent or 140,000 people worldwide have an EGFR mutation in the tumor and may benefit from adjuvant treatment with EGFR-targeted therapy to reduce the chance of recurrence.

About the Study

Following surgery, 222 patients who had confirmed activating EGFR mutations in the tumor were randomly assigned to receive gefitinib or chemotherapy (vinorelbine plus cisplatin). Patients received gefitinib daily for 24 months or the standard therapy regimen every three weeks for four cycles. According to the authors, chemotherapy was given for a shorter period of time because it is usually not tolerated well for longer periods of time. All patients were followed for disease relapse for about three years.

"Two recent targeted therapy trials of adjuvant therapy did not show benefit in NSCLC, in part because they included stages I, II, and III of the disease in their design," said Dr. Wu. "The earlier trials only looked to see if patients showed overexpression, or over-activity, of EGFR, but not mutations in EGFR. Our trial recruited patients who had been confirmed to have activating EGFR mutations so we believe these reasons account for why other trials showed no benefit of a targeted therapy while ours did."

Gefitinib blocks the signaling through the EGFR and is only effective in cancers with mutated and overactive EGFR. It was initially approved by the FDA in 2003 as a third-line therapy for patients with advanced NSCLC, but it is now approved as initial therapy for advanced NSCLC with an EGFR mutation.

Key Findings

The median time to recurrence (disease-free survival) was 28.7 months for patients who received gefitinib and 18 months for those who received chemotherapy. There were 76 patient deaths (34.2 percent of all enrollees) during the trial period; 41 occurred in the gefitinib group

and 35 in the chemotherapy group.

Far fewer patients experienced severe side effects with gefitinib (12 percent) than with chemotherapy (48 percent). The most common serious side effect in the gefitinib group was elevated liver enzymes, whereas patients in the chemotherapy group had more severe quality of life concerns, including vomiting, nausea, low blood counts, and anemia.

Next Steps

As the researchers have a tissue repository from the surgically removed lung tumors, they plan to perform a comprehensive biomarker analysis looking for other potential biomarkers for [gefitinib](#) response or resistance, in addition to EGFR. Dr. Wu stated that a fuller analysis of treatment outcomes is also planned.

"This study identifies a subset of patients with [lung cancer](#) who can benefit from a targeted treatment that causes far fewer side effects than [chemotherapy](#)," said ASCO President-Elect Bruce E. Johnson, MD, FASCO. "It's also clear evidence that we can use precision medicine not only in patients with advanced [cancer](#), but also in those with earlier stage disease."

Provided by American Society of Clinical Oncology (ASCO)

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