MedicalXpress

Erlotinib maintenance therapy prolongs survival in patients with the most common form of lung cancer

May 19 2010

Erlotinib maintenance therapy given after platinum-based chemotherapy is well tolerated, significantly improves progression free survival (PFS), and increases overall survival in patients with advanced non-small-cell lung cancer (NSCLC). Wherever possible, erlotinib maintenance therapy should be considered for patients who do not have disease progression after first-line chemotherapy, concludes an Article published Online First in the *Lancet Oncology*.

About 85% of lung cancers are NSCLC, and nearly half of these patients are diagnosed with advanced disease and receive only chemotherapy. Currently, first-line chemotherapy regimens offer a modest overall survival of 8-10 months, and most patients with NSCLC have disease progression within 2-3 months of their final chemotherapy cycle. Maintenance therapy given immediately after first-line treatments has been shown to delay progression and increase survival. Erlotinib is an established second-line treatment for NSCLC with proven effectiveness and acceptable toxicity, and might improve outcomes when given as maintenance therapy in these patients.

To provide more evidence, Federico Cappuzzo from Ospedale Civile di Livorno, Italy, and international colleagues did a phase 3 trial (SATURN) to assess erlotinib as first-line maintenance therapy in 889 patients who had received four cycles of platinum-based chemotherapy and whose disease had not progressed. Patients were randomly assigned

to erlotinib (438) or placebo (451) until disease progression, unacceptable toxicity, or death.

Findings showed that erlotinib significantly improved PFS (12.3 vs 11.1 weeks) and overall survival (12.0 vs 11.0 months). PFS was also significantly longer in patients with epidermal growth factor receptor (EGFR) mutations who were treated with erlotinib compared with placebo, with 90% reduction in the risk of progression.

The treatment was generally well tolerated, and side effects were mild to moderate, the most common being skin rash and diarrhoea. However, serious adverse events were more common in patients being treated with erlotinib (11%) than with placebo (8%). Additionally, there were no significant differences reported in quality of life between the two groups.

These results add to the evidence that giving treatment immediately after first-line chemotherapy ensures that more patients, who might otherwise be unsuitable for further treatment because of rapid disease progression and increased symptom burden, have the opportunity to benefit from effective therapy.

The authors conclude: "The acceptable tolerability profile of erlotinib, together with proven efficacy in all patient subgroups and oral dosing, distinguishes erlotinib from other agents in this setting, and could provide greater treatment choice for clinicians."

In a Comment, Thomas E Stinchcombe from the University of North Carolina and Suresh S Ramalingam from Emory University say that "maintenance therapy with erlotinib represents an important modality to improve patient outcomes in advanced NSCLC", reflected by the recent approval of erlotinib as maintenance therapy by the US Food and Drug Administration and the European Medicines Agency based on these

results. However, they caution that these findings highlight that "robust responses and prolonged PFS outcomes with EGFR tyrosine kinase inhibitors are limited to patients with an EGFR mutation", whilst the benefit to patients with EGFR wild-type is modest.

Provided by Lancet