エルロチニブは肺がん患者の生存率を改善することが明らかになった（Abstract #: LBA8002）

ATLAS：ベバシズマブ維持療法にエルロチニブを追加することにより進行非小細胞肺がん患者の予後が改善する

ATLAS: Adding erlotinib to bevacizumab maintenance therapy in patients with advanced non-small cell lung cancer improves outcomes

化学療法とベバシズマブによる初回治療後に、ベバシズマブによる維持療法にエルロチニブを追加することによりベバシズマブ単独投与と比較し、非小細胞肺がん患者の進行が遅延したとの研究結果が、ある国際研究チームにより第45回American Society of Clinical Oncology学会で発表された。この二重盲検phase IIIトライアルは768人の患者をベバシズマブとエルロチニブまたはベバシズマブとプラセボを投与する群に無作為に割り付けた。患者は全員がファーストライン治療として4クールの化学療法とベバシズマブ投与を受けていた。進行の認められなかった患者に対してはその後ベバシズマブを継続し、プラセボかエルロチニブを投与する群に無作為に割り付けた。このスタディはこのトライアルの二回目に計画されたデータの中間解析を報告したものであり、有意な有効性の改善がエルロチニブ群において認められた。エルロチニブ群の患者はがん進行のリスクが29%低かった。無増悪生存期間中央値はエルロチニブとベバシズマブ併用群で4.8ヵ月であり、ベバシズマブープラセボ投与群では3.7ヵ月であった。両群ともに想定外の副作用は認められなかった。これらの結果を基にトライアルは予定より早く中止された。

Full Text

An international team of researchers has shown that adding erlotinib to bevacizumab maintenance therapy after initial treatment with chemotherapy and bevacizumab in patients with advanced non- small cell lung cancer delays disease progression better than bevacizumab alone.

"There is ongoing interest among medical oncologists about the potential role of maintenance therapy for patients with advanced non-small cell lung cancer," said Vincent A. Miller, M.D., Associate attending Physician on the Thoracic Oncology Service at Memorial Sloan-Kettering Cancer Center and lead author of the study, known as ATLAS. "Bevacizumab is a core component of the treatment of advanced non-small cell lung cancer (NSCLC), and we've shown here we can delay progression with the addition of a targeted agent, erlotinib. Critical future work will try to determine which patients will get the greatest benefit from this combination, based in large part on the identification of genetic biomarkers."

Maintenance therapy, a relatively new concept in NSCLC, refers to the continuation of one or more agents of a chemotherapy regimen but not the whole regimen to delay progression of disease and potentially improve survival after patients have received several months of stronger standard chemotherapy, which can carry significant side effects. This is the first study to show that adding erlotinib to maintenance therapy with bevacizumab delays disease progression in patients who have already received bevacizumab as part of their initial chemotherapy. Both bevacizumab and erlotinib have fewer side effects than traditional cytotoxic chemotherapy.

Previous research has shown that bevacizumab along with chemotherapy improved progression-free and overall survival among patients with advanced, metastatic, or recurrent non-squamous NSCLC when compared to chemotherapy alone. In that study, bevacizumab was continued after chemotherapy until disease progression. The purpose of the current study was to determine if progression could be further delayed by the addition of erlotinib.

In this randomized, double-blind, phase III trial, 768 patients were randomized to receive bevacizumab plus erlotinib or bevacizumab plus placebo. All patients had already received four cycles of chemotherapy and bevacizumab as first-line therapy. Patients who had not progressed then continued bevacizumab and were blinded and randomized to receive placebo or erlotinib.

This study reports the results of the trials second planned interim analysis of the data, which identified a statistically significant improvement in efficacy, favoring the erlotinib group; the trial was stopped early based on these findings. Patients in the erlotinib group experienced a 29 percent reduced risk of disease progression. Median progression-free survival was 4.8 months for patients in the erlotinib plus bevacizumab group, compared with 3.7 months for patients in the bevacizumab-placebo group. There were no unexpected side effects in either arm.

ASCO2009特集