Observational Study Report

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Survey on the treatment reality of patients with *EGFR* gene mutation-positive non-small cell lung cancer

CSR Synopsis

AstraZeneca

STUDY REPORT SYNOPSIS

Survey on the treatment reality of patients with *EGFR* gene mutation-positive non-small cell lung cancer

Background/Rationale:

EGFR-TKI is now recommended by the clinical guidelines for lung cancer as 1st-line therapy for patients with *EGFR* mutation-positive non-small cell lung cancer (NSCLC).

Although the median survival time of Japanese patients with *EGFR* mutation-positive NSCLC tends to be prolonged with the range from 27.7 months to 46.9 months in several clinical trials for EGFR-TKI, the reason for such tendency has not been revealed.

Thus, this study, which clarifies survival of patients, patient characteristics, the prognostic factors, and treatment regimen of patients with *EGFR* mutation-positive NSCLC, was planned to provide useful information of treatment strategy for the patients in the future.

Objectives and Hypotheses:

The aim of this study was to investigate the real-world treatment regimens and survival of patients with *EGFR* mutation-positive advanced/recurrent NSCLC. The primary objective was to estimate overall survival (OS) of the patients. The secondary objectives were to determine prognostic factors, real-world treatment regimens, and efficacy of gefitinib treatment.

Methods:

Multicenter, non-interventional, retrospective observational study in Japan
Patients with *EGFR* mutation positive advanced/recurrent NSCLC were included, who commenced on 1st-line treatment between January 2008 and December 2012.
Patients who had a treatment history with the drug which was not approved by regulatory authority as of 31st December 2014 were excluded.

Patient characteristics were extracted from the medical records. These included all treatment history, survival status and so on.

For all patients, treatment regimen and estimation of survival time were investigated and the relationship between patient characteristics and prognostic factor was explored.

Results:

1) Patient characteristics

Overall, 1,660 patients were included in the study, but 4 patients did not fulfil the eligibility criteria; therefore, 1,656 patients were included in the full analysis set (FAS). Of these patients, 256 were alive, 1,140 were dead, and 260 were lost to follow-up at the end of December 2015.

Overall, 64.8% (1,073/1,656) of patients were female, and the median age was 67.0 years old. In total, 95.2 %(1,576/1,656) of all patients had adenocarcinoma, 66.7% (1,104/1,656) had stage IV disease. With regards to *EGFR* mutation, 50.1% (830/1,656) had deletion 19 and 41.5% (687/1,656) had L858R mutations. With regards to PS, 39.5% (654/1,656) had PS of 0, 41.1% (680/1,656) had PS of 1, 12.7% (210/1, 656) had PS of >1 and 6.8% (112/1, 656) were unknown. With regards to histology, 96.7% (897/928) of patients had adenocarcinoma. With regards to stage, 64.5% (599/928) of patients had stage IV disease.

2) Overall survival of all patients

The median overall survival (OS) was 29.70 months (95% CI; 28.13-31.40). In the result of multivariate Cox regression analysis of OS, age, histology, *EGFR* mutation type, stage, PS and smoking were identified as prognostic factors of OS.

3) Exposure Rate

Exposure rate*, which was a proportion of the each treatment category in a total treatment area (person-year) of all patients, was 61.47% for EGFR-TKI±α, 8.15% for platinum doublet±bevacizumab (BEV), 8.07% for other chemotherapy±BEV, and 22.24% for the untreated period.
*Exposure rate = person-years for the treatment group × 100 / total person-years