



Real-World Efficacy of Aumolertinib in Patients With Advanced EGFR T790M-Positive Non-Small Cell Lung Cancer: A Multicentre Retrospective Cohort Study in Jiangsu Province, China

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ACCEPTANCE CODE

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BACKGROUND & OBJECTIVES

Background

Aumolertinib is a third-generation EGFR-TKI approved by the China NMPA in March 2020 for advanced NSCLC. Based on the single-arm, phase II APOLLO trial, it serves as a subsequent-line treatment for patients with an acquired EGFR T790M mutation following progression on prior EGFR-TKIs. The drug's subsequent inclusion in the NRDL has driven its widespread clinical utilization. Nevertheless, the lack of mature long-term clinical outcomes, coupled with the broader heterogeneity of real-world patient cohorts, limits the external validity of the initial trial data and poses ongoing financial risks for reimbursement decision-making.

Objective

To evaluate the long-term efficacy of aumolertinib in real-world routine clinical practice (Jiangsu Province, 2020–2026) and to compare real-world efficacy with that of the APOLLO clinical trial using the MAIC method.

METHODS

- Study Design:** Multicentre retrospective cohort, Jiangsu Province, China (2020–2026)
- Population:** Advanced T790M-positive NSCLC patients treated with aumolertinib
- Intervention:** Aumolertinib Real-World cohort
- Comparison:** Aumolertinib Clinical Trial (APOLLO) cohort
- Outcome:** Overall Survival (OS) & Progression-Free Survival (PFS)
- Statistic Methods:** Multiple imputation & MAIC

PATIENT SELECTION FLOWCHART & STATISTIC METHODS

Lung cancer patients receiving aumolertinib with ≥ 2 hospitalization records extracted from the Eastern Medical Big Data Center, 2020–2026 (n = 5,696)

Exclude
 • Aumolertinib administered as first-line therapy (n = 2893);
 • No EGFR mutation testing performed, or EGFR-T790M negative result (n = 1572)

Aumolertinib was administered after disease progression on a first- or second-generation EGFR-TKI, with the EGFR T790M mutation verified through genetic testing (n = 1,223)

Exclude
 • Prior exposure to any other third-generation EGFR-TKI (n = 398);
 • Unknown date of aumolertinib initiation (n = 147);
 • Treatment duration < 28 days (n = 11).

Eligible patients with advanced T790M-positive NSCLC included for analysis (N = 667)

346 patients with incomplete baseline information

Multiple imputation applied to address missing baseline characteristics (n = 10 imputed datasets)

10 complete real-world patient cohorts

Matching-Adjusted Indirect Comparison (MAIC) to align Real-World and APOLLO Trial baselines

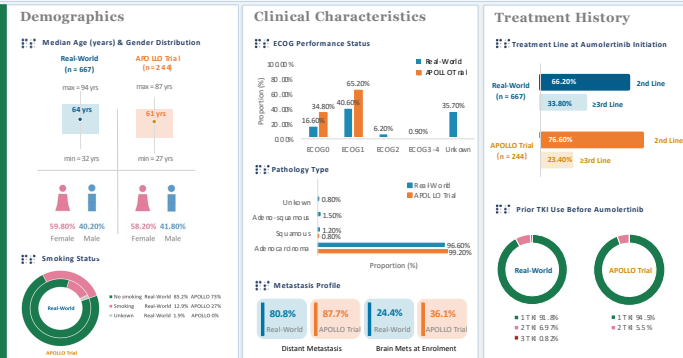
PFS Analysis: Kaplan-Meier, Cox model

OS Analysis: Kaplan-Meier, Cox model

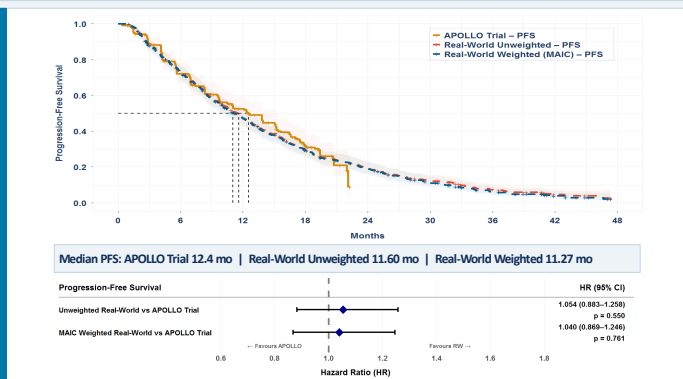
Comparative outcomes between real-world data and the APOLLO Trial

667 Total Patients-Real World | 244 Total Patients-APOLLO Trial | 39.2 mo (38.1-41.9) Median PFS Follow-up | 37.9 mo (36.2-39.7) Median OS Follow-up

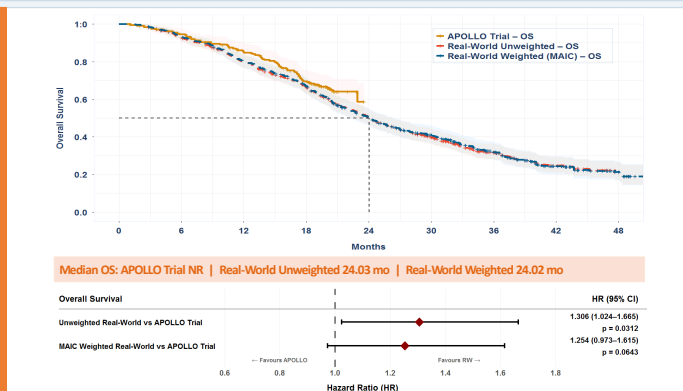
BASELINE PATIENT CHARACTERISTICS



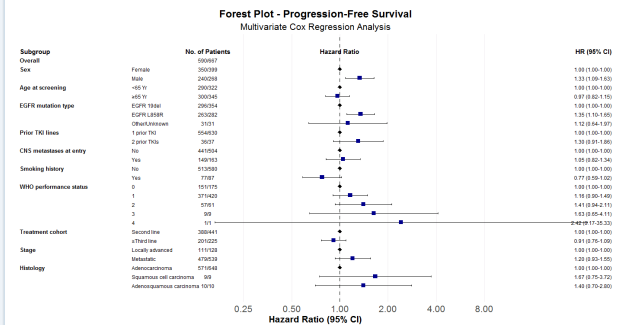
KAPLAN-MEIER CURVES —Progression-Free Survival



KAPLAN-MEIER CURVES —Overall Survival



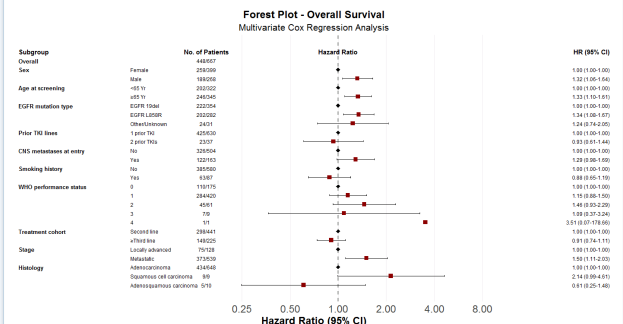
COX REGRESSION—Progression-Free Survival



ADVERSE PROGNOSTIC FACTORS (MULTIVARIATE COX)

Male sex HR 1.33 (1.09-1.63) | L858R co-mutation HR 1.35 (1.10-1.65)

COX REGRESSION & MAIC RESULTS —Overall Survival



ADVERSE PROGNOSTIC FACTORS (MULTIVARIATE COX)

Male sex HR 1.32 (1.06-1.64) | Age ≥ 65 yrs HR 1.33 (1.10-1.61) | L858R co-mutation HR 1.34 (1.08-1.67) | Distant metastasis HR 1.50 (1.11-2.03)

CONCLUSIONS

- Compared with the APOLLO trial, patients in the real-world were older and had poorer ECOG scores.
- Real-World median PFS (11.6 mo) was comparable to APOLLO (12.4 mo; p = 0.55); OS in Real-World patients was significantly lower than the APOLLO Trial, p = 0.0312, HR 1.306 (1.024-1.66).
- After MAIC adjustment, no significant difference in PFS or OS was detected between Real-World and APOLLO Trial.
- Male sex, age ≥65, L858R co-mutation and distant metastasis are independent adverse prognostic factors in real-world settings.
- This study provides robust real-world evidence supporting aumolertinib as an effective treatment for T790M+ advanced NSCLC.

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