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Cost-effectiveness of lazertinib as first-line treatment in patients with *EGFR*-mutated advanced lung cancer

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Abstract

Background: Lazertinib demonstrates efficacy similar to that of osimertinib in the first-line treatment of epidermal growth factor receptor (*EGFR*)-mutated advanced lung cancer. However, its cost-effectiveness has not yet been evaluated.

Objective: To study the cost-effectiveness of lazertinib as a first-line treatment for patients with *EGFR*-mutated advanced lung cancer.

Design: A partitioned survival model-based cost-effectiveness analysis.

Methods: We conducted the economic analysis from the perspective of the healthcare sector with a lifetime horizon. Simulated patients were entered into the models upon the diagnosis of *EGFR*-mutated advanced lung cancer. Lazertinib was compared with gefitinib. The model inputs were derived from the trials (survival outcomes, incidence of adverse events (AEs), and subsequent therapies), National Health Insurance payments (costs of drugs and AEs), and hospital cohorts (utility values). Deterministic and probabilistic analyses were also conducted.

Results: Applying the same daily price of osimertinib (US$110) to that of lazertinib, the incremental cost-effectiveness ratio of lazertinib versus gefitinib was US$93,792 per quality-adjusted life year (QALY). The cost of lazertinib was a major determinant. If the daily price of lazertinib could be reduced to US$75, lazertinib would become cost-effective at a willingness-to-pay (WTP) threshold of US$70,000 per QALY. Given the WTP threshold, the probability that lazertinib would be cost-effective was 0.7%.

Conclusion: Lazertinib is not a cost-effective first-line treatment for *EGFR*-mutated advanced lung cancer. Lowering prices enables cost-effectiveness.

Keywords: cost-effectiveness, *EGFR* mutation, lazertinib, lung cancer

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Introduction

Lung cancer is the leading cause of cancer-related death worldwide. Most lung cancers are diagnosed at an advanced stage.[1] For a subset of advanced-stage patients with actionable gene alterations, targeted therapies substantially improve survival and ameliorate adverse events (AEs).[2] Epidermal growth factor receptor (*EGFR*) mutations are the most common targetable gene alterations in lung cancer, which confer a good treatment response to tyrosine kinase inhibitors (TKIs). Approximately 40%–55% of Asian patients with non-small-cell lung cancer and 5%–15% of patients in Western countries harbor *EGFR* mutations.[3] Osimertinib is the first developed third-generation *EGFR*-TKI and has become the preferred first-line therapy in treating patients with *EGFR*-mutated advanced lung cancer. Another third-generation *EGFR*-TKI, lazertinib, was recently developed and has demonstrated favorable efficacy compared with first-generation gefitinib.[4]

According to the FLAURA trial, the hazard ratio for disease progression of osimertinib versus gefitinib/erlotinib was 0.46 (95% confidence interval

(CI): 0.37–0.57), whereas the hazard ratio for death was 0.80 (95% CI: 0.64–1.00).[5,6] The hazard ratios for disease progression and death of lazertinib versus gefitinib were 0.45 (95% CI: 0.34–0.58) and 0.74 (95% CI: 0.51–1.08), respectively, in the LASER301 trial.[4] Given the comparable efficacy results, lazertinib might be a first-line alternative for patients with *EGFR*-mutated advanced lung cancer. To date, several studies have investigated the cost-effectiveness of first-line osimertinib therapy. Most of them concluded that the high cost of osimertinib prevented it from being considered a cost-effective strategy.[7–18] A price reduction of osimertinib could significantly improve its cost-effectiveness profile.[7–9,11,12,15–18] Nevertheless, the cost-effectiveness of first-line lazertinib in this population has never been evaluated.

By applying the same daily price of osimertinib as that of lazertinib and considering the costs of waste drugs and AEs, we attempted to study the cost-effectiveness of lazertinib as a first-line treatment in patients with *EGFR*-mutated advanced lung cancer.

Methods

Model overview

We created partitioned survival models to simulate treatment-naïve patients with *EGFR*-mutated advanced lung cancer who received lazertinib or gefitinib as first-line therapy. Simulated patients were entered into the model upon detecting exon 19 deletions or exon 21 L858R mutation by tissue biopsy. After disease progression, the patients received third-generation TKI (osimertinib or lazertinib), cytotoxic chemotherapy, or first-/second-generation TKI. Pemetrexed plus carboplatin was selected for the subsequent cytotoxic chemotherapy. We considered maintenance therapy with pemetrexed after 12 weeks of pemetrexed plus carboplatin. Erlotinib was selected as the subsequent first-/second-generation TKI. The probabilities of subsequent therapies after lazertinib and gefitinib were directly derived from the LASER301 trial.[4] A model length of 3 weeks was chosen as subsequent cytotoxic chemotherapy was administered every 3 weeks. The time horizon was lifelong, and we applied an annual discount rate of 3% for future costs and life years. This cost-effectiveness study followed the Consolidated Health Economic Evaluation Reporting Standards reporting guideline,[19] shown in Supplemental Table 1.

Survival estimates

A web-based software (WebPlotDigitizer; https://automeris.io/WebPlotDigitizer/) was used to extract the progression-free survival (PFS) and overall survival (OS) curves of lazertinib and gefitinib from the LASER301 trial.[4] We translated the PFS and OS data into patient-level information using the function "*digitise()*" in R software.[20,21] Parametric (exponential, Weibull, log-logistic, lognormal, gamma, and generalized gamma) models were fitted to the data; the one with the most appropriate fit based on the Bayes information criterion (BIC) or Akaike information criterion (AIC) was selected. Using the parametric models selected according to BIC or AIC, PFS and OS were extrapolated to lifetime. Hence, the proportions of patients with progressive disease or death at each cycle in the lazertinib and gefitinib groups were derived. The modeled PFS and OS curves of lazertinib and gefitinib were compared with the LASER301 trial results.[4]

Cost and health utility inputs

We considered the drug costs per cycle and fee for intravenous drug administration (Table 1). All costs for gefitinib, osimertinib, carboplatin, pemetrexed, and erlotinib were based on payments from the National Health Insurance (NHI). We applied the same daily price of osimertinib (110 USD) to that of lazertinib because the NHI had not reimbursed the latter. Body weight of 70 kg, body surface area of 1.84 m^2, and glomerular filtration rate of 73 ml/min (i.e., a 65-year-old man with a serum creatinine level of 1 mg/ml) were used to estimate the doses of the intravenous agents. We rounded up the partially used vials while calculating the costs of intravenous drugs, shown in Supplemental Table 2. In addition, the costs of AEs were multiplied by the incidence rates of AEs[4,6] for each therapy to estimate the costs attributable to AEs, shown in Supplemental Table 3. All costs were equivalent to 2023 USD.

Based on a prior study using Taiwanese tariffs,[22] a health utility value of 0.84 was applied for patients receiving TKIs in the progression-free state. For patients with progressive disease treated with TKI, we assigned a health utility value of 0.80. However, patients with progressive disease

Table 1. Model parameters.[a]

Parameter	Value	Range	Distribution	Source
Proportion of patients in each state, lazertinib	Time-variant	–	–	LASER301 trial's PFS/OS curves[4]
Proportion of patients in each state, gefitinib	Time-variant	–	–	LASER301 trial's PFS/OS curves[4]
Subsequent therapy, lazertinib				
Third-generation TKI: osimertinib	8.7%	–	Dirichlet (4, 24, 18)	LASER301 trial[4]
Cytotoxic chemotherapy	52.2%	–		LASER301 trial[4]
First-/second-generation TKI	39.1%	–		LASER301 trial[4]
Subsequent therapy, gefitinib				
Third-generation TKI: lazertinib	44.3%	–	Dirichlet (47, 17, 23, 19)	LASER301 trial[4]
Third-generation TKI: osimertinib	16.0%	–		LASER301 trial[4]
Cytotoxic chemotherapy	21.7%	–		LASER301 trial[4]
First-/second-generation TKI	17.9%	–		LASER301 trial[4]
IV drug administration, USD	72	57–86	Gamma (100, 0.72)	NHI payment
Drug cost per 3 weeks, USD				
Lazertinib	2315	1852–2779	Gamma (100, 23.15)	NHI payment of osimertinib
Gefitinib	398	319–478	Gamma (100, 3.98)	NHI payment
Osimertinib	2315	1852–2779	Gamma (100, 23.15)	NHI payment
Carboplatin	187	149–224	Gamma (100, 1.87)	NHI payment
Pemetrexed	1825	1460–2190	Gamma (100, 18.25)	NHI payment
Erlotinib	519	415–623	Gamma (100, 5.19)	NHI payment
Health utility				
Progression free under TKI	0.84	0.76–0.92	Beta (15.2, 2.9)	EQ-5D[22]
Progressive disease using TKI	0.80	0.72–0.88	Beta (19.0, 4.7)	EQ-5D[22]
Progressive disease using cytotoxic chemotherapy	0.72	0.65–0.79	Beta (27.3, 10.6)	EQ-5D[22]

[a]Supplemental Table 3 for parameters of AEs.
EQ-5D, European Quality of Life-Five Dimensions; IV, intravenous; NHI, National Health Insurance; OS, overall survival; PFS, progression-free survival; TKI, tyrosine kinase inhibitor; USD, US dollars.

Table 2. Base-case results.

Strategy	Costs (USD)	Life years	QALYs	Incremental cost per life year (USD)	Incremental cost per QALY (USD)
Gefitinib	Total cost: 66,909 Drug cost: 57,916 Cost for AEs: 8993	2.77	2.24	–	–
Lazertinib	Total cost: 134,842 Drug cost: 122,216 Cost for AEs: 12,626	3.69	2.97	73,623	93,792

AE, adverse event; QALY, quality-adjusted life year; USD, US dollars.

who received cytotoxic chemotherapy had a health utility value of 0.72.

Base-case analysis

We analyzed it from the perspective of the health-care sector. The incremental cost-effectiveness ratio (ICER), in terms of the incremental cost divided by the quality-adjusted life year (QALY), was estimated. We acknowledge that the willingness-to-pay (WTP) threshold of 1 per capita gross domestic product (GDP) per QALY in Taiwan might be too low to encourage pharmaceutical companies to develop cancer drugs. Therefore, we selected a WTP threshold of 70,000 USD per QALY, which is approximately 2 GDP per capita in 2023. Each strategy was ranked based on cost. A strongly dominant strategy was the one that had a higher cost and fewer QALY than the next costliest strategy.

Deterministic and probabilistic analyses

We performed one-way deterministic analyses by varying the fee for intravenous drug administration, drug costs, health utilities, incidence rates of AEs, and costs for AEs within plausible ranges and generated tornado diagrams. Probabilistic analysis using a Monte Carlo simulation with 1000 iterations was also conducted to address the effects of parameter uncertainties (Table 1 and Supplemental Table 3). We generated a cost-effectiveness scatterplot and acceptability curves. *R* version 4.4.1. (R Foundation for Statistical Computing, Vienna, Austria) was used to conduct all the analyses.

Ethics statement

This model-based economic analysis received consent exemption from the Institutional Review Board at the National Cheng Kung University Hospital (B-ER-113-274).

Results

Base-case analysis

The modeled PFS and OS curves of lazertinib and gefitinib were similar to those demonstrated in the LASER301 trial,[4] indicating a good fit of the selected parametric models, shown in Supplemental Figure 1.

The lazertinib group incurred an additional 67,933 USD and affected 0.73 QALYs (0.92 life years) as compared with the gefitinib group, leading to an ICER of 93,792 USD per QALY (73,623 USD per life year; Table 2). The main component of the total cost was drug cost, which also constituted the main cost difference between the two treatment strategies. Nevertheless, the cost of AEs played only a minor role in the total cost and cost difference.

Deterministic and probabilistic analyses

The tornado diagram of lazertinib versus gefitinib shows that the cost of lazertinib, health utilities for patients receiving TKIs in a progression-free state, and the cost of pemetrexed were the major determinants of the ICER (Figure 1). Specifically, if the daily cost of lazertinib could be further lowered to 75 USD, lazertinib would be cost-effective, given a WTP threshold of 70,000 USD per QALY. The higher the health utilities for patients receiving TKIs in the progression-free state or the lower the 3-week cost of pemetrexed, the lower the ICER values.

The cost-effectiveness scatter plot (Figure 2(a)) shows that the 95% confidence eclipse of lazertinib did not overlap with that of gefitinib. Lazertinib had 0.7% and 78.2% probabilities of being cost-effective at WTP thresholds of 70,000

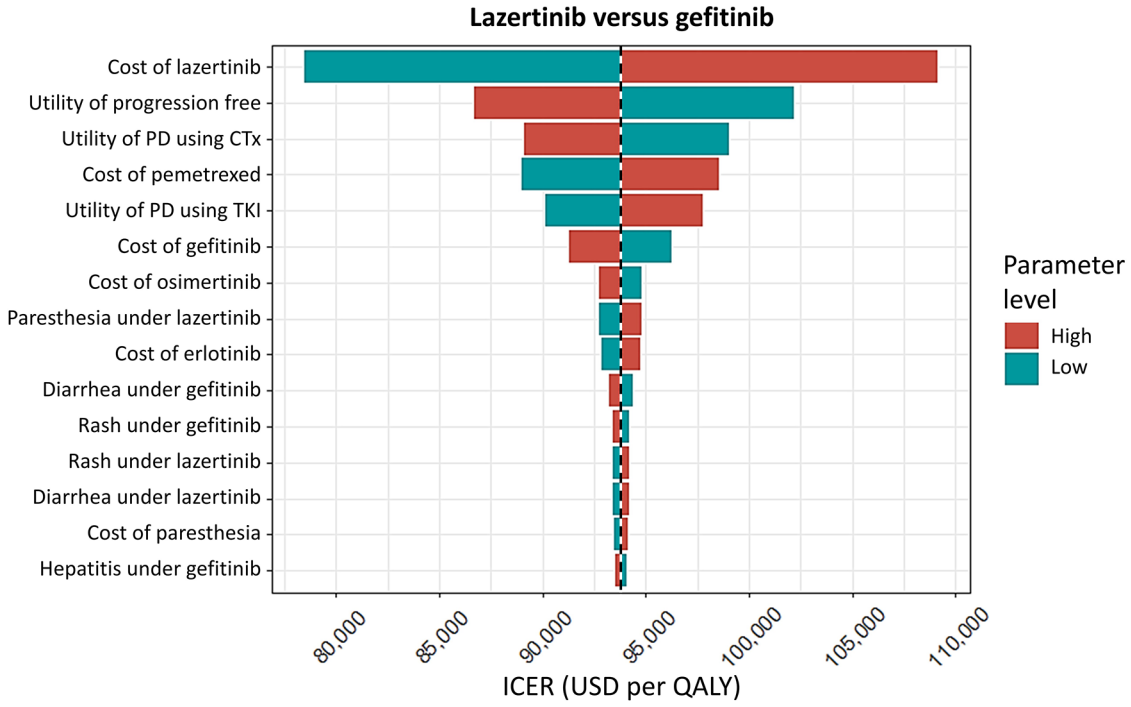

Figure 1. Tornado diagram of lazertinib versus gefitinib. The dashed line represents the base-case ICER.
CTx, chemotherapy; ICER, incremental cost-effectiveness ratio; PD, progressive disease; QALY, quality-adjusted life year; TKI, tyrosine kinase inhibitor; USD, US dollars.

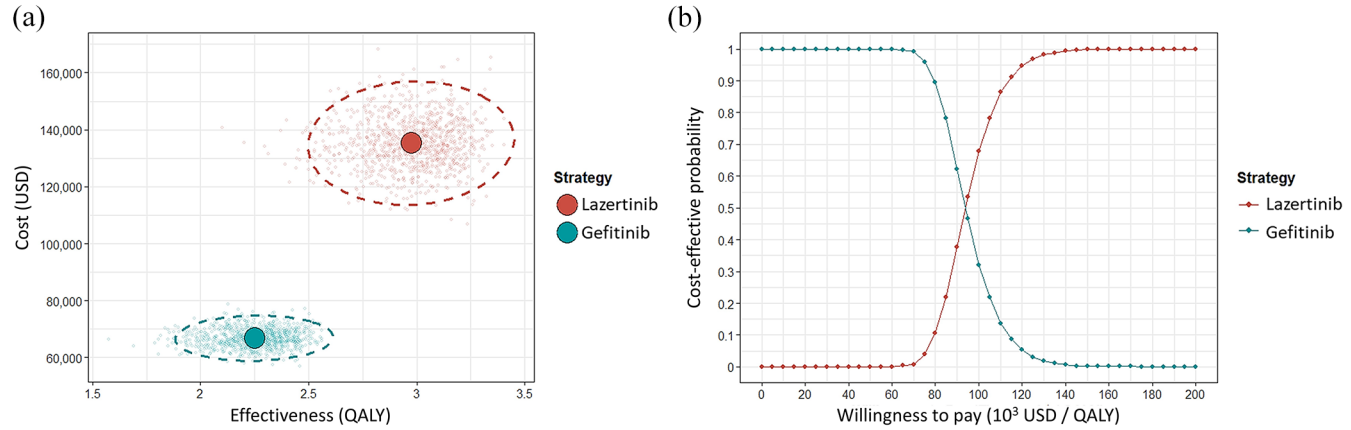

Figure 2. Cost-effectiveness (a) scatter plot and (b) acceptability curves for lazertinib and gefitinib. The dashed circles in (a) indicate 95% confidence eclipses.
QALY, quality-adjusted life year; USD, US dollars.

USD (two per capita GDP) and 105,000 USD (three per capita GDP) per QALY, respectively (Figure 2(b)).

Discussion

Following the success of osimertinib, lazertinib is the second third-generation *EGFR*-TKI demonstrating efficacy in the treatment of *EGFR*-mutated advanced lung cancer. The hazard ratios for disease progression and death with lazertinib versus gefitinib[4] are similar to those with osimertinib versus gefitinib/erlotinib.[5,6] The effectiveness of lazertinib and osimertinib is assumed to be similar. This study is the first to evaluate the cost-effectiveness of lazertinib as a first-line treatment

for *EGFR*-mutated advanced lung cancer. We used regional health utility tariffs[22] and considered waste drug costs and costs for AEs, shown in Supplemental Tables 2 and 3. Applying the same daily price of osimertinib to lazertinib, lazertinib was not cost-effective compared with gefitinib at a WTP threshold of 70,000 USD (2 per capita GDP in Taiwan) per QALY (Table 2).

Drug costs constituted the main cost difference among the different treatment strategies. Gefitinib had become a generic drug in Taiwan and cost only 398 USD per 3 weeks, whereas the 3-week costs of branded lazertinib were nearly six times those of gefitinib (Table 1). Consequently, the difference in drug costs between the lazertinib and gefitinib strategies could reach 64,300 USD though 60.4% of the gefitinib group received third-generation TKI as subsequent therapy after disease progression. In addition, more patients in the lazertinib group underwent cytotoxic chemotherapy than those in the gefitinib group, which, to a certain degree, increased the difference in drug cost.

The cost of lazertinib was the major determinant of ICER when we compared lazertinib with gefitinib (Figure 1). This study has an implication for drug reimbursement. For example, if the NHI prefers to reimburse a cancer drug with an ICER of less than 70,000 USD per QALY, the daily price of lazertinib must be reduced to 75 USD.

Given the WTP thresholds of 35,000 USD (1 per capita GDP) and 70,000 USD (2 per capita GDP) per QALY, lazertinib was not likely to be a cost-effective strategy (Figure 2). Nevertheless, the probability that lazertinib would be cost-effective at a WTP threshold of 105,000 USD (3 per capita GDP) per QALY approached 80%. Health policymakers may judge the current budget constraints to determine the reimbursement for this medication.

We applied the gefitinib group in the LASER301 trial[4] as the reference group to evaluate the cost-effectiveness of lazertinib. However, osimertinib has become the standard first-line therapy for patients with *EGFR*-mutated advanced lung cancer, particularly in the United States and European Union (EU) countries. The reason why we did not use osimertinib for the comparison was that there is no head-to-head trial directly comparing lazertinib with osimertinib in the first-line setting. To study the cost-effectiveness of lazertinib versus osimertinib, investigators need to make an indirect comparison, which relies on plenty of assumptions such as similar characteristics of the trials and patients.

Our study had several limitations. First, the longest follow-up period for the LASER301 trial was 30 months. The median OS of the lazertinib and gefitinib arms had not been reached.[4] Although our modeled OS curves fit well during the trial period, the results of survival extrapolation should be interpreted cautiously. Cost-effectiveness analyses with longer follow-up periods merit further research. Second, we did not consider treatment interruption or dose reduction, leading to an overestimation of targeted therapy drug costs. This phenomenon is particularly noted in the lazertinib group, as the drug could be interrupted or administered in a reduced dose in cases of grade 3 or higher AEs such as paresthesia.[4] Third, we simply selected pemetrexed plus carboplatin as the subsequent cytotoxic chemotherapy and erlotinib as the subsequent first-/second-generation TKI. Other alternatives were not considered. Although thoracic oncologists have their preferences for selecting subsequent drugs, pemetrexed plus carboplatin and erlotinib may be the most popular choices in the respective drug categories. Finally, although the benefits of lazertinib over gefitinib were observed across the exon 19 deletion and exon 21 L858R mutation subgroups, we did not perform subgroup analyses. To date, only PFS estimates in Asian patients by *EGFR* mutation subgroups have been revealed.[23] However, subgroup OS data are lacking. For the same reason, we did not conduct a subset analysis of patients with central nervous system metastases.[24]

Conclusion

In conclusion, lazertinib is not a cost-effective first-line treatment for patients with *EGFR*-mutated advanced lung cancer at the same daily price as osimertinib. If the daily price of lazertinib was less than 75 USD, it would be cost-effective in Taiwan. Health policymakers may consider the study results in reimbursing this novel third-generation *EGFR*-TKI.

Declarations

Ethics approval and consent to participate

The Institutional Review Board of National Cheng Kung University Hospital approved this

study before commencement (B-ER-113-274). Informed consent was waived as data were obtained from published literature reviews and de-identified information.

Consent for publication

Not applicable.

Author contributions

Li-Jung Elizabeth Ku: Conceptualization; Data curation; Resources; Supervision; Validation; Writing – original draft; Writing – review & editing.

Jui-Hung Tsai: Conceptualization; Data curation; Validation; Writing – review & editing.

Li-Jun Chen: Investigation; Project administration; Visualization; Writing – review & editing.

Szu-Chun Yang: Conceptualization; Data curation; Formal analysis; Funding acquisition; Methodology; Project administration; Resources; Visualization; Writing – original draft; Writing – review & editing.

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Competing interests

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Availability of data and materials

The data and material underlying this article have been included as Supplemental Material. Codes are available upon reasonable request to the corresponding author.

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Supplemental material

Supplemental material for this article is available online.

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