EGFR-FISH-	25 (31)	13 (52)	0.1682	2.3	0.1412
Any positive	56 (69)	20 (36)		4.0	

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An economic analysis of the National Cancer Institute of Canada Clinical Trials Group (NCIC CTG) BR.21, a randomized trial of erlotinib versus best supportive care after cisplatin based chemotherapy in advanced non-small-cell lung cancer (NSCLC)

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Background: NCIC CTG BR.21 is a landmark trial, establishing the epidermal growth factor receptor inhibitor erlotinib, as a second or third line treatment option for advanced NSCLC after failure of cisplatin based chemotherapy. Overall survival and quality of life outcomes were superior in the erlotinib arm compared to best supportive care, with an overall survival of 6.7 vs. 4.7 months (p<0.001). In view of this clinical benefit, the cost effectiveness of erlotinib was investigated.

Methods: Direct medical resource utilization data were collected from the BR.21 trial database. The analysis was performed based on Canadian Public Healthcare System perspective, using costs (CAD$ 2006) from provincial sources. Direct medical costs include: drug, hospitalizations; toxicity, procedures, transfusions and radiation therapy. Non-medical and indirect costs were not included. Average costs per treatment arm are calculated.

Results: Utilization data were collected on 731 patients (100%), of which 488 patients were assigned to the erlotinib arm. Preliminary results show, an overall mean cost of erlotinib alone, per patient, is $10,584 and $11,642 with additional mark up fees.

Conclusion: The predominant cost in the erlotinib arm is related to drug cost, but this may be within an acceptable level of health care expenditure. Cost effectiveness and costing in patient subgroups will be presented.

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IFCT0401 trial: Phase II study of gefitinib administered as first-line treatment in non-resectable adenocarcinoma with bronchioloalveolar carcinoma features (ADC-BAC) - Does disease control on gefitinib affect progression free survival and overall survival in ADC-BAC?

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Background: ADC-BACs are distinguished from other ADCs by epidemiological, clinical and CT scan presentations as well as molecular biology, leading to some responses to EGF-TKI. We therefore conducted a prospective, multicentric, phase II trial to evaluate gefitinib (250 mg/d) as first-line treatment in non-resectable ADC-BAC.

Methods: Inclusion criteria were previously untreated, non-resectable cyto/pathologically proven ADC-BAC. Primary objective was disease control rate (DCR) at 3 months. Secondary exploratory objectives were progression free survival (PFS), overall survival (OS), and identification of factors associated with PFS and OS using multivariate cox model analyses.

Results: From 04/04 to 06/05, 88/90 enrolled patients were eligible. All were caucasians with stage IV disease, PS <2 in 81.8%, age >70 yrs in 36.4%, females in 54.4% and non-smokers in 43.2%. DC was achieved in 25/85 evaluable patients (DCR=29.3%, CI=[20-39]). Median PFS was 2.9 months (CI=[2.4-3.2]) and median survival 13.3 months (CI=[10.1-21.8]), with a 1-year survival of 55.7% (CI=[44.4-65.5]). DC was independently associated with age >70 yrs (OR=4.9, p=.047); never-smoking (OR=8.1, p=.015); Respiratory Symptoms Scale (RSS) <9 (OR=18.7, p=.002); non-mucinous BAC (OR=15.1, p=.006) and rash (OR=2.1, p=.02). When DC at 3 months was not included as factor in the cox model, reduced risk of progression was independently associated with RSS <9 (HR=0.512, p=.03); non-mucinous BAC (HR=0.316, p=.01) and presence of rash (HR=0.440, p=.004). However, when DC was included in the model, reduced risk of progression was strongly associated with DCR (HR=0.025, p<.0001) with independent effect of non-mucinous BAC histology (HR=0.380, p=.04). When DC was not included as factor in the cox model, decreased risk for death was independently associated with initial stage I-IIIa (HR=0.213, p=.01); absence of bronchorrhea and oxygen support (HR=0.056, p=.01 and HR=0.349, p=.007); RSS <9 (HR=0.363, p=.003); and presence of rash (HR=0.338, p=.0007). However, DC at 3 months did not affect the risk for OS when included in the Cox model.

Conclusions: Gefitinib seems active as first-line treatment of non-resectable ADC-BAC especially, in older patients, never-smokers, patients with fewer pulmonary symptoms and with non-mucinous BAC subtype. While DC by gefitinib at 3 months strongly predicted PFS, it did not independently influenced survival in the IFCT0401 population. This suggested that ADC-BAC has been controlled by second-line chemotherapy given after progression under gefitinib in some patients of the IFCT0401 cohort.

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Concordance of the determination of EGFR and K-ras mutations in a tumor bank obtained by 15 centers in france: a pilot study of the ERMETIC project.

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Background: Epidermal Growth Factor - Tyrosine Kinase Inhibitors (EGFR-TKIs) and especially erlotinib, are authorized in Europe for the treatment of metastatic non-small cell lung cancer (NSCLC) after failure of, at least one, prior chemotherapy. Although, it has been suggested that biological markers (EGFR over-expression, EGFR gene polysomy/amplification and EGFR and K-ras mutations) are predictive of efficacy of EGFR-TKIs, they are not used in clinical practice. In order to help implementation of these biomarkers in France, the French