non-small cell lung cancer, early stage

THE EUROPEAN THORACIC ONCOLOGY PLATFORM LUNGSCAPE PROJECT: A WAY TO BRIDGE NON-SPORTIVE CELL LUNG CANCER MOLECULAR CHARACTERISTICS AND CLINICAL DATA

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Background: The Lungscape project aims at building a virtual biobank to facilitate an international high-quality analysis of large numbers of tumors for molecular alterations linked to clinical and biological characteristics captured in the iBiobank.

Methods: Retrospective radically resected stage I-III non-small cell lung cancer cases from 15 ETOP centers, with mandatory comprehensive clinical annotations including at least 2 years of FU have been reviewed and captured.

Results: This first set of 1614 cases was enriched in adenocarcinoma (61.8%), with 28.8% of squamous and 4.9% of large cell histologies. Median age is 65 yrs, 37.6% are women, and respectively 13.9%, 33.5% and 49.6% are never, current and former smokers. Stage distribution is: IA 23.7%, IB 35.4%, IIA 16.4%, IIB 11.6%, IIIA 20.8%, IIIB 1.7%. At last FU, 52.8% of patients were still alive, with a median FU of 5.3 yrs.

PFS No. of patients 5 years (95% C.I.) Median (mos) (95% C.I.)
TOTAL 1614 46 (43.3, 48.6) 49.0 (43.9, 55.2)
Stage
Ia 382 64.5 (59.1, 60.5) NR
Ib 417 55.0 (50.6, 60.5) 78.0
IIa 264 44.8 (38.4, 51.3) 46.9
IIb 187 39.2 (31.6, 46.6) 33.7
IIIa 335 20.0 (15.2, 24.8) 17.5
IIIb 28 11.9 (0.0, 25.3) 10.1
OS
1614 52.0 (49.3, 54.7) 64.2 (57.3, 76.9)
Stage
Ia 382 70.0 (64.9, 75.2) NR
Ib 417 60.6 (55.5, 67.5) NR
IIa 264 44.8 (38.4, 51.3) 46.9
IIb 187 39.2 (31.6, 46.6) 33.7
IIIa 335 20.0 (15.2, 24.8) 17.5
IIIb 28 11.9 (0.0, 25.3) 10.1

Conclusion: This is the first large-scale series based on 7th TNM classification reporting on OS and PFS in the context of European standards of care. These data confirm the discriminative capacity of the 7th TNM with a potentially somewhat inferior outcome. Histologies other than adenocarcinoma are currently actively being captured. Complete data including PFS and TTP - never reported before - as well as OS based on the expected 2400 patients correlated to stage, gender, smoking status, histology and age will be provided. This complete clinical dataset will be invaluable to investigate the impact of molecular characteristics on outcome. It will allow building future hypotheses for prospective evaluation of new treatment strategies and help in the development of a molecularly refined TNM.

Disclosure: All authors have declared no conflicts of interest.
Methods: From September 2007 to Dec 2009, 200 patients with completely resected stage IIA and IIIA (exclude multi-station N2 cases) NSCLC were randomized to receive either oral S-I (40 mg/m² twice per day) for consecutive 2 weeks repeated every 3 weeks for 1 year or cisplatin (60 mg/m² day1) plus oral S-I (40 mg/m² twice per day) for consecutive 2 weeks repeated every 3 weeks for 4 cycles within 8 weeks after surgery. Main inclusion criteria were no prior chemotherapy or radiotherapy; ECOG PS 0-1, an age of less than 75 years, and an adequate organ function. Stratification factors included histology, stage and institutions. Primary endpoint was relapse free survival rate on 2 years and secondary endpoints were overall survival (OS) and toxicity.

Results: Patient demographics were well balanced between the arms in terms of sex, age, histologic type and stage. 52.6% of patients in S-I arm and 76.7% in cisplatin plus S-I arm were completed planned administration. Relapse free survival rate on 2 years was 65.6% (95% confidence interval, 55.3-74.8%) in the S-I arm and 58.1% (95% confidence interval, 47.7-67.2%) in the cisplatin plus S-I arm. OS were not matured in the both arms. Though the rates of leukopenia or neutropenia of grade 3/4, febrile neutropenia, nausea, and vomiting were more frequently in the cisplatin plus S-I arm, there were no treatment related deaths in the both groups.

Conclusion: Both S-I monotherapy and cisplatin plus S-I are feasible as adjuvant chemotherapy for completed resected NSCLC.

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I182P IMMUNOGENICITY AND SAFETY OF THE PRAME CANCER IMMUNOTHERAPEUTIC IN NON-SMALL CELL LUNG CANCER (NSCLC): PHASE I DOSE ESCALATION STUDY

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Introduction: Adjuvant chemotherapy (CT) is the standard treatment for stage II-IIIA NSCLC, but is debated for stage IB. As not all patients (pts) are eligible for CT and many of them relapse, alternative therapies are needed. The PRAME tumor antigen, expressed frequently in NSCLC and at lower levels in few normal cells, offers an attractive target for active immunization. Moreover, while most NSCLC tumors expressing the antigen MAGE-A3 are PRAME positive, 45% of PRAME-expressing NSCLC do not express MAGE-A3. This dose-escalation phase I open study aimed at determining the optimal dose of the PRAME cancer immunotherapeutic (PRAME recombinant protein (recPRAME) with AS15 immunostimulant) by evaluating its safety and immunogenicity in NSCLC pts.

Methods: Pts with PRAME-positive resected stage IB-IIIA NSCLC were enrolled in 3 consecutive cohorts to receive up to 13 injections of recPRAME (20 µg, 100 µg, and 500 µg) with AS15 (fixed dose) over approximately 2 years. Adverse events (AEs), including pre-defined dose-limiting toxicity (DLT), were recorded throughout the study. The anti-PRAME humoral and cellular responses were assessed post-dose 4 by ELISA and flow cytometry (PRAME-specific T-cells producing both IFNγ and TNFα), respectively.

Results: 60 pts were treated in the study (18, 18, 24 pts received 20, 100, 500 µg recPRAME, respectively). AEs were mostly grade 1/2. No grade 3/4 AEs considered by the investigator to be causally related were reported. One grade 2 serious AE causally related to PRAME administration was reported. No DLTs were reported. Immunogenicity results are shown in the table.

Conclusions: The PRAME cancer immunotherapeutic was well-tolerated and elicited similar humoral responses in all 3 cohorts. A trend for an increased cellular response was observed with increasing dose of recPRAME. Thus, the highest dose was selected for further clinical development.

I183P USE OF ADJUVANT CHEMOTHERAPY (CT) AND RADIOTHERAPY (RT) IN INCOMPLETELY RESECTED (R1) EARLY STAGE NON-SMALL CELL LUNG CANCER (NSCLC): A EUROPEAN SURVEY CONDUCTED BY THE EUROPEAN SOCIETY FOR MEDICAL ONCOLOGY (ESMO) YOUNG ONCOLOGISTS COMMITTEE

R. Califano, on behalf of the Young Oncologists Committee of the European Society for Medical Oncology

Background: Stage NSCLC is potentially curable with radical surgery. Cisplatin-based adjuvant CT improves survival and is recommended in the ESMO guidelines for stage II-III completely resected NSCLC. There is limited evidence to guide the use of adjuvant CT and RT in incompletely resected (R1) early stage NSCLC.

Design and objective: A European survey of oncologists treating lung cancer was conducted to evaluate the use of adjuvant CT and RT for R1-resected NSCLC and to identify factors influencing treatment decisions. Demographics were collected and outcomes such as clinical stage, regimens, cycles planned, radiotherapy site, multidisciplinary management and discussion about inconclusive evidence with the patient were analyzed. Logistic regression model was used to detect statistical association and to estimate Odds Ratios. Cochrane-Armitage test was used to detect trend.

Results: 768 surveys were collected from 41 European countries between January to April 2012. 82.9% of participants were medical oncologists; 49.3% ESMO members; 37.1% based in a University Hospital; 32.6% practicing oncology for more than 15 years and 81.4% active in research. 91.4% of participants prescribed adjuvant CT. Prescription according to stage: I/II/IIA/IIB/IIIA = 13.9%/44.8%/83.9%/90.5%/ 94.5%, respectively. Most common CT regimens were: Cisplatin/Vinorelbine (81.2%), Cisplatin/Gemcitabine (42.9%), Carboplatin/Vinorelbine (31.6%), Carboplatin/ Paclitaxel (31%) and Carboplatin/Gemcitabine (26.7%). Number of cycles planned: 3/ 4/6 = 7.5%/78.1%/14.5%, respectively. 85% discussed limited clinical evidence with the patient. 48.3% of patients prescribed adjuvant RT. Among these, RT to the surgical bed and for pN2 disease was prescribed by 85.1% and 84.8%, respectively. Most common RT regimens for surgical bed; 60 Gy in 30 fractions (Fx) (45.6%), 54 Gy in 27-30 Fx (29.6%), 50 Gy in 20 Fx (23.4%) and 52.5 Gy in 20 Fx (3.6%). Most common RT regimens for pN2 disease; 60 Gy in 30 Fx (35.2%), 54 Gy in 27-30 Fx (34.1%), 50 Gy in 20 Fx (24.1%) and 50 Gy in 25 Fx (4.8%).

Conclusions: This European survey indicates that adjuvant CT and RT for incompletely resected (R1) NSCLC are commonly used in clinical practice despite limited evidence. Prospective trials for R1-resected NSCLC are necessary to clarify optimal management.

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Immunogenicity post-dose 4 (ATP population).

Cohort (recPRAME dose) (1 mg µg) (2 mg µg) (3 mg µg)
Humoral responders, n/N* 10/10 11/11 19/19
CD4+ T-cell responders, n/N* (%) 3/9 (33%) 6/10 (60%) 12/15 (80%)
CD8+ T-cell responders, n/N* (%) 0/8 (0%) 0/10 (0%) 0/13 (0%)
N. number of patients enrolled into each group; * number of patients with pre and post-vaccination results; n. number of responders; ATP, according-to-protocol

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**1184P** PROGNOSTIC FACTORS IN EARLY STAGE NON-SMALL CELL LUNG CANCER (NSCLC): THE IMPORTANCE OF NUMBER OF RESECTED LYMPH NODES AND VASCULAR INVASION

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**Introduction:** Despite an appropriate surgical treatment, half of early-stage NSCLC patients will die due to lung cancer. The number of resected lymph nodes and tumor vascular invasion have proved to be a prognostic factor in other solid tumors, as well as breast and colorectal cancer. Here we evaluate their prognostic impact in the largest mono-centric series of resected NSCLC patients.

**Methods:** Clinical and pathological characteristics and prognostic outcomes of 439 consecutive patients undergoing radical surgical resection for NSCLC at our Institution were evaluated.

**Results:** The multivariate analysis showed that number of resected lymph nodes, vascular invasion and sex had a prognostic impact on overall survival. The optimal cut-off of lymph node numbers with the highest specificity and sensitivity for estimating the outcome was set at 10 after Receiver Operating Characteristics (ROC) curve analysis. Removing 10 lymph nodes in our study represents a cut-off with a significant prognostic impact particularly in resected stage II NSCLC.

**Conclusions:** Similarly to other cancer types (i.e. colorectal cancer), our results suggest that an adequate classification of NSCLC should always include an adequate lymph nodes clearance, particularly in stage II NSCLC. Again vascular invasion resulted an independent prognostic factors for overall survival (HR = 0.82, CI 0.68-0.96, p = 0.042). Therefore the number of resected lymph nodes, together with vascular invasion, may also drive the selection of NSCLC patients for adjuvant treatment.

**Disclosure:** All authors have declared no conflicts of interest.

**1185P** PROGNOSTIC ROLE OF ERBB FAMILY RECEPTORS, MYC AND MITOTIC ACTIVATING PROTEIN KINASE (MAPK) IN PATIENTS WITH EARLY-STAGE NON-SMALL-CELL LUNG CANCER

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**Background:** EGFR deregulation has been extensively studied in non small-cell lung cancer (NSCLC), but the expression and the role of other ErbB receptors and their downstream signal transductions remains still unclear. MYC and MAPK are key downstream components of the EGFR pathway and have significant roles in cell survival, proliferation, and growth. This study evaluates the prognostic role of EGFR, ErbB2, ErbB3, ErbB4, MYC and MAPK by immunohistochemistry (IHC) in early stage NSCLC.

**Methods:** One hundred and nine NSCLC patients were evaluated: median age was 67 years (range 40-84); Male/Female: 93/16; squamous (SCC)/adenocarcinoma (ADC)/BAC/other: 52/36/3/18; smoker/never smoker:100/9, and stage I/II/III:67/17/25. IHC results were evaluated by two independent observers and the tumors with BAC/other: 52/36/3/18; smoker/never smoker:100/9, and stage I/II/III:67/17/25. IHC results were evaluated by two independent observers and the tumors with BAC/other: 52/36/3/18; smoker/never smoker:100/9, and stage I/II/III:67/17/25.

**Results:** EGFR was expressed in 55.9%, ErbB2 in 24.7% ErbB3 in 33.9%, ErbB4 in 27.5%, Myc in 23.8% and MAPK in 27.5 % of patients, respectively. EGFR and ErbB3 were associated with SCC (p = 0.001) and p = 0.004, respectively) whereas ErbB2 and adenocarcinoma with distinct poor outcomes.

**Conclusions:** Our results suggest that in early stage NSCLC the co-expression of EGFR, ErbB2 and MAPK was an independent predictor for worse DFS and OS (HR = 5.7, p = 0.004; HR = 8.67, p < 0.001, respectively).

**Disclosure:** All authors have declared no conflicts of interest.

**1186P** GENE AMPLIFICATION OF ACTN4 IN LUNG CANCER: A NOVEL PROGNOSTIC INDICATOR FOR STAGE I ADENOCARCINOMA OF THE LUNG


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**Background:** Even if detected at an early stage, a substantial number of lung cancers relapse after surgery. Patients with such tumors are likely to benefit from adjuvant therapy, but methods for identifying such patients have yet to be established.

**Methods:** We retrospectively analyzed multiple cohorts totaling 1744 patients who underwent resection of lung adenocarcinoma. Expression of actin-4 protein in tumors was evaluated immunohistochmically, and copy numbers of the actin-4 (ACTN4) gene were determined by fluorescence in situ hybridization.

**Results:** Amplification of the ACTN4 gene correlated significantly with smoking history (p = 0.02), pathological stage (p = 0.002), and histological differentiation (P < 0.001, chi-squared test). Overall survival was significantly worse for patients with stage I lung adenocarcinoma harboring ACTN4 gene amplification than for those with tumors showing no such gene amplification (P < 0.001, log-rank test). Multivariate analysis revealed ACTN4 gene amplification in stage I lung adenocarcinoma as an independent factor associated with higher risk of death (hazard ratio, 6.78; 95% confidence interval, 2.59-17.7; P < 0.001, Cox regression analysis). The 5-year survival rate of patients with stage I lung adenocarcinoma showing increased actin-4 protein expression and ACTN4 gene amplification was 58%, compared to 87% for patients with tumors lacking gene amplification and 95% for patients with tumors lacking actin-4 protein expression. The former group showed significantly worse overall survival than either of the latter (P < 0.001).

**Conclusions:** Amplification of the actin-4 gene defines a subset of stage I lung adenocarcinoma with distinctly poor outcomes.

**Disclosure:** All authors have declared no conflicts of interest.

**1187P** THE ROLE OF MUTATIONS OF EGFR, K-RAS, EML4-ALK, AND B-RAF GENES IN RESECTED PATHOLOGICAL STAGE I LUNG ADENOCARCINOMA

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**Background:** The mutations of EGFR, K-ras, EML4-ALK and B-RAF genes are an early event during oncogenesis of NSCLC. This study retrospectively assessed the mutations of these genes and their clinical significance in resected adenocarcinomas.

**Methods:** A total of 256 patients with resected stage I lung adenocarcinoma were retrospectively included in this study. The mutations of EGFR and K-ras were determined using PCR-based fragment analysis and direct sequencing. The EML4-ALK fusion gene was assayed by immunohistochemistry and multiplex RT-PCR. The mutation of B-RAF gene was determined using direct sequencing. The DFS for prognostic value and the OS for predictive value of treatment after recurrence were evaluated.

**Results:** In 256 tumors, the mutations of EGFR, K-ras, EML4-ALK and B-RAF genes were detected in 114 (44.5%), 15 (5.5%), 7 (2.7%), and 3 (1.2%), respectively. One patient with the EML4-ALK fusion gene harbored the mutation of EGFR, and double mutations of EGFR and B-RAF were also observed in one patient. The incidence of EGFR mutations was significantly higher in females than males (41.2% vs. 34.4%, p < 0.05). The incidence of K-ras mutations was higher in males than females and older patients than younger patients (not significant). The EML4-ALK fusion gene was detected in younger patients (42.4 vs. 0%). The DFS and OS of K-ras mutant group were significantly inferior than those of EGFR mutant group, EML4-ALK fusion gene group, and wild-type group. Twenty-four of 41 patients with recurrent analysis adjusting for stage, the co-expression of EGFR, ErbB2 and MAPK was an independent predictor for worse DFS and OS (HR = 5.7, p = 0.004; HR = 8.67, p < 0.001, respectively).

**Conclusion:** Our results suggest that in early stage NSCLC the co-expression of EGFR, ErbB2 and MAPK predicted a worse prognosis. Such features may have important implications for future targeted therapies. We thank Italian Association for Cancer Research (AIRC) for supporting the study.
Background: Histology is a prognostic and predictor of the response factor in advanced non-small cell lung cancer (NSCLC). Adenocarcinoma (ADC) has a better prognosis in advanced NSCLC whereas it is considered that resected patients (pts) with squamous-cell-carcinoma (SqCC) have a better outcome. We have analyzed our experience of resected stage I-II NSCLC pts to determine the impact of ADC vs SqCC histology in this setting.

Methods: From 1996 to 2010, 289 stage I pts and 220 stage II pts were treated by surgery. Chemotherapy (CT) was administered in 19 (6.6%) pts with stage I disease and 94 (42.7%) pts with stage II disease. Overall survival (OS) and cause-specific survival (CSS) curves were estimated by Kaplan-Meier analysis and differences were assessed with the log-rank test or the Peto and Peto modification of the Gehan-Wilcoxon test.

Results: Most pts (92.9%) were men. Median age was 68 years and median follow-up was 37.4 months. Median OS for pts with stage I NSCLC was 68 mo (IC 95: 55-123) for ADC and 55 mo (IC 95: 47-67) for SqCC (p = 0.0604) with an estimated OS at 5 years of 54.1% vs 48%. Median CSS were not achieved in the two histology groups, with an estimated CSS at 5 years of 78.3% for ADC versus 71.5% for SqCC (p = 0.626). For pts in stage II disease, the median OS was 31 mo (IC 95: 21-45) for ADC and 24 mo (IC 95: 18-34) for SqCC (p = 0.515) with an estimated OS at 5 years of 20.5% vs 29.6%. Median CSS were 45 mo (IC 95: 31-NA) for ADC and 93 mo (IC 95: 39-NA) for SqCC (p = 0.462), with an estimated CSS at 5 years of 44.8% vs 54.3%.

Conclusions: A trend for better OS of ADC was observed in stage I compared to SqCC but it disappeared for CSS. Thus, no statistically significant differences in OS nor CSS were observed in resected stage I-II NSCLC patients between ADC vs SqCC histology.

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