vival for blacks and whites with localized adenocarcinoma was 52.0% and 60.6%, while survival was 44.5% and 41.5% for blacks and whites with squamous cell carcinoma, respectively. With regard to age group comparisons, there was a significant decrease in 5-year survival with advancing age among those with localized disease.

Conclusions: Differences in relative survival of lung cancer was strongly dependent upon histologic subtype. Indeed, five-year survival for adenocarcinoma of the lung is significantly superior to that of other histologic subtypes. Improved survival in adenocarcinoma appears to be related to a more favorable stage distribution, which facilitates curative therapies

B4-07 **Prevention & Early Detection + Epidemiology, Tue, 13:45 - 15:30**

Sputum Methylation Analysis Detects Patients With Lung Cancer

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Background: Sputum methylation analysis is feasible and by some studies suggested to show an increased risk for lung cancer. The aim of this study was to examine 6 methylation markers in sputum of patients with lung cancer and controls.

Methods: In the Canisius Wilhelmina Hospital Nijmegen sputum has been prospectively collected for several years of patients with lung cancer and controls. From this bank 102 cases with lung cancer and 102 controls, most of them with COPD DNA was retrospectively extracted. Samples were subsequently randomized and blinded (TdB). Coded samples were exchanged between collaborators unaware of its origin. Quantitative MSP was performed for APC, Cytoglobin, MGMT, 3-OST-2, p16, RASSF1A, and TCF21. Follow-up was retrieved independently (MvdD). Pathology diagnosis was based on biopsy or only cytology. After submission of methylation data (to ZF with subsequent information of TdB) statistical analysis was performed (WY,ZF).

Results: The pathology diagnosis was squamous cell carcinoma (n=23), adenocarcinoma (n=23), SCLC (n=16) or NSCLC not further specified. The 77 of the 102 controls had a Gold score for COPD >0. Sputum samples were collected within 6 months of lung cancer diagnosis. Follow-up of COPD cases was minimally 2 years.

Reproducibility of methylation analysis between two labs was poor for MGMT.

RASSF1A showed hypermethylation in 81 % of the SCLC and 69% of the NSCLC lung cancer cases with a specificity of 94 and 74%, respectively. For two markers the sensitivity showed a decrease in sensitivity for SCLC and NSCLC to 50%, and 57%, respectively. The specificity increased for SCLC and NSCLC to 99 and 95%, respectively.

Conclusions: This blinded study shows that hypermethylation in sputum is with two markers detects 50% of the lung cancer patients.

Session B5: NSCLC: New Paradigm in Radiation Therapy
Tuesday, September 4

B5-01 **NSCLC: New Paradigm in Radiation Therapy, Tue, 13:45 - 15:30**

Phase III trial of cisplatin (P) plus etoposide (E) plus concurrent chest radiation (XRT) with or without consolidation docetaxel (D) in patients (pts) with inoperable stage III non-small cell lung cancer (NSCLC): HOG LUN 01-24/USO-023

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Background: Concurrent chemoradiation is standard treatment for pts with inoperable stage III NSCLC. A previously reported single-arm, phase II study by SWOG (Gandara et al JCO 2003) suggested D following EP/XRT further improved survival. We report results from a randomized, prospective phase III trial comparing EP/XRT with or without consolidation D.

Methods: Eligible pts had inoperable, stage IIIA/B NSCLC, PS 0-1 at study entry, FEV-1 > 1 L, and < 5% wt loss in the preceding 3 mos. Pts (n=243) received P 50 mg/m^2 iv d 1,8,29,36 and E 50 mg/m^2 iv d1-5, 29-33 concurrently with chest XRT to 5940 cGy. Non-progressing pts (PS 0-2) were randomized to D 75 mg/m^2 iv every 21 d for 3 cycles vs observation (O). The primary endpoint was to compare OS (Kaplan-Meier analysis). A multivariate parametric accelerated failure time model was performed to identify factors that affected survival. Accrual of 259 pts to randomize 180 was planned to demonstrate a difference in MST of 25 vs 15 mos (5% 2-sided alpha, 80% power). Based upon evidence of futility (predefined as p>0.7271), a DSMB recommended early termination after an analysis of the initial 203 pts.

Results: Median f/u 25.6 mos. Pt characteristics (n=203): 34%/66% F: M; median age 63; 39.4%/60.6% IIIA/B; staged with PET 66.5%; FEV-1 > 2 46.7%; current smoker 41.9%. G3/4 toxicities during EP/XRT included 9.8% febrile neutropenia (FN), 17.2% esophagitis. 147 of 203 pts (72.4%) were randomized to D (n=73) or O (n=74). 82.2% randomized to D received 3 cycles. G3/4 toxicities during D included: 10.9% FN, 8.2% pneumonitis. 28.8% of pts were hospitalized during D (vs 8.1% in O arm) and 5.5% died due to D. Factors predictive for improved survival included age < 70, FEV-1 > 2, and hemoglobin > 12 at baseline. PFS for D was 12.3 vs 12.9 mos for O (p=0.9412). The MST for all pts (n=203) was 21.15 mos; MST for D was 21.6 mos (95% C.I. 17.7-35) vs 24.2 mos for O (95% C.I. 18.1-34.4) (p=0.9402).

Conclusions: The MST with EP/XRT was higher than historical controls; however, consolidation D does not further improve survival, is associated with significant toxicity including an increased rate of hospitalization and premature death.