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Adjuvant chemotherapy in stage IB non-small cell lung cancer (NSCLC): Update of Cancer and Leukemia Group B (CALGB) protocol 9633.

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Abstract:

Background: In 2004, preliminary results of CALGB 9633 demonstrated statistically significant evidence that adjuvant chemotherapy with paclitaxel and carboplatin (PC) improved disease-free (DFS) and overall survival (OS) in resected stage IB NSCLC. Indeed, the study was closed early by the DSMB after a planned interim analysis demonstrated a p value for OS less than a prespecified stopping boundary. However, two larger trials, NCIC-JBR10 and ANITA, have shown significant OS advantages with adjuvant chemo, but failed to demonstrate improved survival in the stage IB subset. This report provides more mature data from CALGB 9633.

Methods: In CALGB 9633, stage IB patients (pts) were randomized following resection to paclitaxel 200 mg/m^2 and carboplatin AUC 6 q3wks ×4 cycles or to observation. While initially planned to accrue 500 pts, the accrual rate was <50% of expected. Because slow accrual allowed longer observation times for each pt, the accrual target was reduced to 384 pts. OS is the primary endpoint. The redesigned study had 80% power to detect a hazard ratio (HR) of 0.67 after 150 observed deaths using a 1-tailed logrank test conducted at the 0.05 level of significance.

Results: Between 9/15/96 and 11/26/03, 344 pts were randomized. Median follow-up is 54 mo. Demographics and toxicity has been previously reported (JCO Sup, 22:621a, 2004). The current intent-to-treat analysis shows a significant improvement in DFS favoring adjuvant chemo (HR=0.74; 90% 2-sided CI: 0.57-0.96; p=0.027). There is a trend toward improvement in OS that is not significant (HR=0.80; 90% CI: 0.60-1.07; p=0.10). There is, however, a significant advantage in 3-yr survival (79% vs. 70%; p=0.045). Five-yr survival is not different (60% vs. 57%; p=0.32), although median follow-up is <5 yrs and CIs are wide. Continued follow-up is planned since only 131 of 150 deaths required for final analysis have been observed.

Conclusions: This updated but "preliminary" analysis no longer shows a significant OS advantage for adjuvant chemotherapy in stage IB NSCLC. However, the re-designed study does not have adequate power to detect small differences in OS that may be clinically significant. Advantages in DFS and 3-yr survival support continued consideration of adjuvant PC in stage IB NSCLC.