Lung Adjuvant Cisplatin Evaluation (LACE): A pooled analysis of five randomized clinical trials including 4,584 patients.

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Abstract: **Background:** Several recent trials have shown a benefit of adjuvant cisplatin-based chemotherapy on overall survival (OS) in patients with non-small cell lung cancer (NSCLC). The aim of the Lung Adjuvant Cisplatin Evaluation (LACE) is to identify treatment options associated with a higher benefit, or groups of patients benefiting more from adjuvant chemotherapy.

**Methods:** Individual patient data were collected and pooled from the five largest trials (ALPI, ANITA, BLT, IALT and JBR10) of cisplatin-based chemotherapy in completely resected patients, conducted after the NSCLC-meta-analysis (BMJ 1995, update ongoing). The interactions between patient subgroups or treatment types and chemotherapy effect on OS were analysed using hazard ratios (HR) and logrank tests stratified by trial.

**Results:** With a median follow-up of 5.1 years, the overall HR of death was 0.89 (95% confidence interval [CI]: 0.82-0.96; p<0.005) corresponding to a 5-year absolute benefit of 4.2% with chemotherapy. There was no heterogeneity of chemotherapy effect among trials. The benefit varied with stage (test for trend, p=0.046) with the HR for stage I-A 1.41 [95% CI: 0.96-2.09], stage I-B 0.93 [0.78-1.10], stage II 0.83 [0.73-0.95] and stage III 0.83 [0.73-0.95]. The effect of chemotherapy did not vary significantly (test for interaction, p=0.10) with the associated drugs: vinorelbine (HR=0.80 [0.70-0.91]) etoposide/vinca-alcaloide (0.93 [0.80-1.07]) or other (0.98 [0.84-1.14]). There was no interaction between chemotherapy and sex, age, planned radiotherapy or planned total dose of cisplatin.

**Conclusions:** Adjuvant cisplatin-based chemotherapy improves survival in patients with NSCLC. This benefit depends on stage and is greatest in patients with stages II and III. Our analysis suggests that platinum-based adjuvant chemotherapy may not benefit stage I-A patients. Results of disease-free survival will be presented at the meeting. Supported by PHRC and LNLCC