Updated survival analysis of JBR.10: A randomized phase III trial of vinorelbine/cisplatin versus observation in completely resected stage IB and II non-small cell lung cancer (NSCLC)

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**Multiple large trials** have been performed to assess for a potential survival benefit for early-stage NSCLC patients treated with cisplatin-based chemotherapeutic regimens after surgery. These include the: Adjuvant Lung Cancer Project Italy (LPI), Adjuvant Navelbine International Trialist Association (ANITA), International Adjuvant Lung Trial (IALT), the Big Lung Trial (BLT) and JBR.10, which was a phase III trial that established adjuvant cisplatin-based chemotherapy as a recommended treatment in early-stage completely resected NSCLC.

The most extensive follow-up data prior to this JBR.10 update came from the International Adjuvant Lung Cancer Trial (IALT), in which 1,867 patients with resected stage I, II, or III NSCLC were randomly assigned to cisplatin-based chemotherapy or to observation. Updated results presented at ASCO 2008 demonstrated a beneficial effect of adjuvant chemotherapy on disease-free survival (p = 0.02), but a difference in overall survival that was not statistically significant. However, there was a significant difference between the results of overall survival before and after 5 years (HR: 0.86; CI: 0.76-0.97, p = 0.01 versus HR: 1.45; CI: 1.02-2.07, p = 0.04). The difference in results between fewer than and more than 5 years of follow-up suggested the need for longer follow-up on other large adjuvant trials.

This report describes the updated survival data for JBR.10 with more than 9 years of median follow up.

This trial had randomized 482 patients with stage IB or II NSCLC to receive observation or chemotherapy with vinorelbine and cisplatin after resection. Median follow up in this update is 9.3 years, with a range of 3.2-13.8 years.

In the updated results, the survival analysis continues to show a benefit for chemotherapy (HR 0.78 CI 0.61 - 0.99, p = 0.04). The benefit appeared at two years follow up and continues over time. The benefit appears to be confined to N1 (stage II) patients when looking at updated survival by stage. In stage II disease, the median overall survival (OS) was 6.8 years in the chemotherapy arm versus 3.6 years in the observation arm (HR 0.68 CI 0.5 - 0.92, p = 0.01).
N0 (stage IB) patients did not appear to benefit: in IB patients, the median OS was 11.0 years in the chemotherapy arm versus 9.8 years in the observation arm (HR 1.03 CI 0.7 - 1.52, p = 0.87). When IB patients were divided into patients with tumors less than or greater than 4 cm, only patients with larger tumors were seen to derive some benefit, although this trend was not statistically significant (HR 0.66, p = 0.14).

Cisplatin-based chemotherapy should be offered to all node positive patients in the adjuvant setting and should be considered for patients that are node negative but have tumors larger than 4 cm, a group in which further study is indicated.

Also see Interpreting a Cancer Research Study