What is the real benefit of adjuvant chemotherapy in the Adjuvant Navelbine International Trialist Association trial?

We read with great interest the article by Douillard et al. [1]. In their excellent paper the authors demonstrated that adjuvant vinorelbine and cisplatin extends survival in patients with completely resected non-small-cell lung cancer, mainly in those with stage II and III. One of the important issues for a phase III trial is the external validity of the study. This criterion allows one to understand the generalizability of the results, and relates to whether the study patients may be similar to those evaluated in one’s own practice. To better understand the results reported by Douillard et al. [1], the readers should first know further details of the recruitment process. The first question is as follows: overall, how many patients have been evaluated from December 1994 to December 2004 among the 101 centers in 14 countries? In particular among patients meeting the inclusion criteria, what is the eligibility fraction (patients meeting eligibility criteria/patients meeting inclusion criteria)? These data may be important for critical patients such as lung cancer patients. The eligibility fraction gives important data and details of the overall population we see in clinical practice, and allows one to understand the fraction of patients who really can receive and potentially benefit from chemotherapy. A recent revision of the Consolidated Standards of Reporting Trials guidelines suggests that authors should include the number of the potentially eligible patients assessed for eligibility [2]. Patients enrolled in clinical trials may not represent those we see in the daily practice. Lung cancer patients may have several comorbidities, post-operative complications, and all these factors may be a severe barrier to administer chemotherapy. Knowing these details may help to understand the percentage of patients who may actually receive (with the same inclusion criteria) or not receive (with exclusion criteria) adjuvant chemotherapy. The question is as follows: how useful and applicable are the results of such a study in a more typical population?

The second important point is to know the enrollment fraction for lung cancer patients: the ratio between patients enrolled and randomly assigned/patients meeting eligibility criteria.

While we applaud the effort and the great contribution by Douillard et al. [1], we think that knowing these details may contribute to understand the real benefit of adjuvant chemotherapy for patients with lung cancer we see in the clinical practice.

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