Paclitaxel and gemcitabine versus paclitaxel and vinorelbine in patients with advanced non-small-cell lung cancer. A phase III study of the Hellenic Cooperative Oncology Group (HeCOG).

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Source

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Abstract

BACKGROUND:

Paclitaxel (Taxol) and vinorelbine have shown synergism of cytotoxic effects in vitro and clinical activity in phase I and II studies. This combination was compared prospectively with the paclitaxel/gemcitabine regimen in non-operable non-small-cell lung cancer.

PATIENTS AND METHODS:

Chemotherapy-naive patients, stage IIIbwet and IV with performance status (0-1), were randomized to receive paclitaxel 200 mg/m(2) on day 1 plus gemcitabine 1 gm/m(2) (group A) on days 1 and 8 every 3 weeks or paclitaxel 80 mg/m(2) plus vinorelbine 22.5 mg/m(2) (group B) on days 1, 8 and 15 every 4 weeks.

RESULTS:

A total of 398 out of 415 patients were eligible for analysis on intent-to-treat basis (group A: 196, group B: 202). Progression-free survival (PFS) was 5.0 months [95% confidence interval (CI) 4.3-5.6] and 4.4 months (95% CI 3.7-5.2) for groups A and B respectively (P=0.365). Median survival was 11.1 months (95% CI 9.2-13.0) and 8.6 months (95% CI 7.0-10.2) for groups A and B respectively (P = 0.147). Grade 3/4 neutropenia and leukopenia were worse in group B (P<0.001, in both cases). Febrile neutropenia and severe infections were more prominent (P<0.001, P=0.029 respectively) in group B.

CONCLUSION:

Although response rate, PFS and survival were non-different in both groups, toxicity was significantly worse in group B and therefore further investigation of P-Vin is of no value.