Ann Oncol. 2000 Jul;11(7):799-805.

Paclitaxel (175 mg/m2) plus carboplatin (6 AUC) versus paclitaxel (225 mg/m2) plus carboplatin (6 AUC) in advanced non-small-cell lung cancer (NSCLC): a multicenter randomized trial. Hellenic Cooperative Oncology Group (HeCOG).

Kosmidis P, Mylonakis N, Skarlos D, Samantas E, Dimopoulos M, Papadimitriou C, Kalophonos C, Pavlidis N, Nikolaidis C, Papaconstantinou C, Fountzilas G.

Source

Hygeia Hospital, Athens, Greece. parkosmi@otenet.gr

Abstract

PURPOSE:

The combination of paclitaxel and carboplatin has become a widely used regimen in NSCLC due to phase II reports of moderate toxicity, reasonable activity and easy outpatient administration. Purpose of our present prospective study was to evaluate the dose response relationship of paclitaxel.

PATIENTS AND METHODS:

Since July 1996, 198 patients with non-operable NSCLC and measurable disease without previous chemotherapy entered the trial. Ninety nine patients (group A) were randomized to receive paclitaxel 175 mg/m2 in three-hour infusion plus carboplatin dosed to an area under the concentration-time curve of 6 every 3 weeks and 99 (group B) to receive the same regimen with paclitaxel increased to 225 mg/m2. Eligibility criteria included WHO performance status 0-2, documented inoperable stage IIIA and IIIB, IV, no brain metastasis, no prior chemotherapy and adequate renal and hepatic function. Patients in both groups were well-matched with baseline disease characteristics.

RESULTS:

In group A with 90 evaluable patients, the response rate was 25.6% (6 CR, 17 PR) whereas in group B with 88 evaluable patients, the response rate was 31.8% (3 CR, 25 PR), P = 0.733. Median time to progression favored the high-dose paclitaxel (4.3 vs. 6.4 months, P = 0.044). The median survival was 9.5 months for group A versus 11.4 months for group B (P = 0.16). The one-year survival was 37% for group A and 44% for group B (P = 0.35). The best prognostic factor for one-year survival was the response rate (P < 0.0001). With a relative dose intensity of paclitaxel 0.94 in both groups, neurotoxicity (P = 0.025) and leucopenia (P = 0.038) were more pronounced in group B patients. No toxic death was observed.

CONCLUSIONS:

Higher dose paclitaxel prolongs the median time to progression but causes more neurotoxicity and leucopenia. The better response rate, the longer overall and better one-year survival seen with the higher dose of paclitaxel are not statistically significant.