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Phase II study of pegylated liposomal doxorubicin: inactive in recurrent small-cell lung cancer. A Hellenic Cooperative Oncology Group Study.

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Source

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Abstract

PURPOSE:

Although clinical experience with liposomal doxorubicin is still limited in solid tumours, single agent Caelyx (pegylated liposomal doxorubicin) treatment has shown promising results in AIDS-related Kaposi's sarcoma, metastatic breast and ovarian cancer and anecdotally in other solid tumours. This is the first report of its use in small-cell lung cancer (SCLC). The objective of this multicenter phase II study was to evaluate the safety, tolerance and anti-tumour activity of Caelyx as monotherapy in patients with recurrent SCLC.

PATIENTS AND METHODS:

A total of 14 patients with recurrent SCLC who had not received prior treatment with doxorubicin, were accrued into this phase II study. All patients had progressed or relapsed after first-line chemotherapy. All but one had achieved objective responses to first-line treatment with median duration of five months (range 2-18 months) but half of them had experienced 'refractory' relapses (within 3-4 months). Study treatment consisted of Caelyx 50 mg/m2 (1-hour i.v infusion every 4 weeks for 6 cycles).

RESULTS:

No responses were seen but in three patients disease was stabilised for a median of three months. The median number of cycles was 2 per patient, with 11 of 14 patients not completing 6 cycles of Caelyx treatment. From those, five patients were removed from the study after only one cycle due to rapid disease progression, and one was withdrawn after three cycles due to prolonged toxicity. Overall, treatment was well tolerated with no episodes of grade 4 toxicity and only two episodes of grade 3 toxicities: one of thrombocytopenia and one of prolonged palmar-plantar erythrodysesthesia (PPE).

CONCLUSIONS:

These results demonstrate limited activity of Caelyx in this patient population, which may be related to the poor prognostic features of such patients. Our findings are in agreement with previous observations that doxorubicin-containing combinations are rarely active in platinum/etoposide failures. However, as in other studies the favourable toxicity profile of Caelyx is confirmed.