Gemcitabine and pegylated liposomal doxorubicin alternating with cisplatin plus cyclophosphamide in platinum refractory/resistant, paclitaxel-pretreated, ovarian carcinoma.

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Source

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Abstract

OBJECTIVES:

This phase II study conducted to investigate the efficacy and toxicity of the combination of gemcitabine (GEM) and pegylated liposomal doxorubicin (LDOX) alternating with cisplatin (CDDP) and cyclophosphamide (CTX) in platinum-resistant/refractory, paclitaxel pretreated epithelial ovarian cancer (EOC).

PATIENTS AND METHODS:

Forty-eight patients with CDDP-resistant/refractory and paclitaxel pretreated patients were treated with 8 cycles of GEM 800 mg/m2 days 1 and 8 and LDOX 30 mg/m2 day 1, alternating with CDDP 60 mg/m2 and CTX 600 mg/m2 every 3 weeks.

RESULTS:

Objective responses were observed in 37.5% of patients (4 complete and 11 partial responses) with measurable disease (n=40). CA125 response occurred in 30 (71.4%) of patients with elevated CA125 (n=42). After a median follow-up of 23 months, the median progression-free survival (PFS) was 6.9 months (95% confidence interval, CI: 5.2-8.5), while the median overall survival (OS) was 18.2 months (95% CI: 12.7-23.6). A progression-free interval (PFI) of 0-3 months was associated with lower objective responses (10% versus 46.6%, p=0.06). Chemotherapy was well tolerated. The most frequent toxicities were myelosuppression, neurotoxicity, nephrotoxicity, nausea/vomiting, fatigue and palmar-plantar erythrodysesthesia (PPE). Overall 31 (65%) patients received G-CSF and 13 (27%) antibiotics because of neutropenia and/or febrile neutropenia.

CONCLUSION:

This alternating combination chemotherapy is feasible for patients with platinum-resistant EOC and is associated with encouraging outcomes and a favorable toxicity profile.