A randomized phase II study of carboplatin plus pegylated liposomal doxorubicin versus carboplatin plus paclitaxel in platinum sensitive ovarian cancer patients: a Hellenic Cooperative Oncology Group study.

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Source

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Abstract

BACKGROUND:

Platinum-based combinations are the standard second-line treatment for platinum-sensitive ovarian cancer (OC). This randomized phase II study was undertaken in order to compare the combination of carboplatin and pegylated liposomal doxorubicin (LD) with carboplatin and paclitaxel (CP) in this setting.

METHODS:

Patients with histologically confirmed recurrent OC, at the time of or more than 6 months after platinum-based chemotherapy, were randomized to six cycles of CP (carboplatin AUC5 + paclitaxel 175 mg/m2, d1q21) or CLD (carboplatin AUC5 + pegylated LD 45 mg/m2, d1q28).

RESULTS:

A total of 189 eligible patients (CP 96, CLD 93), with a median age of 63 years, median Performance Status (PS) 0 and a median platinum free interval (PFI) of 16.5 months, entered the study. Discontinuation due to toxicity was higher in the CP patients (13.5% versus 3%, P = 0.016). The overall response rate was similar: CP 58% versus CLD 51%, P = 0.309 (Complete Response; CR 34% versus 23%) and there was no statistical difference in time-to-progression (TTP) or overall survival (OS; TTP 10.8 months CP versus 11.8 CLD, P = 0.904; OS 29.4 months CP versus 24.7 CLD, P = 0.454). No toxic deaths were recorded. Neutropenia was the most commonly seen severe toxicity (CP 30% versus CLD 35%). More frequent in CLD were severe thrombocytopenia (11% versus 2%, P = 0.016), skin toxicity and Palmar-plantar erythrodysesthesia (PPE) grade 1-2 (38% versus 9%, P< 0.001), while grade 3 neurotoxicity and alopecia were higher in CP (7% versus 0%, P = 0.029, 20% versus 5%, P = 0.003). PS and PFI were independent prognostic factors for TTP and OS.

CONCLUSIONS:

The combination of pegylated LD with carboplatin is effective, showing less neurotoxicity and alopecia than paclitaxel-carboplatin. It thus warrants a further phase III evaluation as an alternative treatment option for platinum-sensitive OC patients.