

Abstract 157: Overall survival advantage for pegylated liposomal doxorubicin compared to topotecan in recurrent epithelial ovarian cancer

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Background: A recent phase III study compared the efficacy and safety of pegylated liposomal doxorubicin (Doxil®/Caelyx®) with topotecan in patients with recurrent epithelial ovarian cancer that recurred after or did not respond to first-line, platinum-based chemotherapy (Gordon, et al. J Clin Oncol. 2001;19:3312-3322). Response rates were found to be similar for both treatment groups. Final survival data from this study are now reported. **Material and Methods:** Patients (N = 474) were randomly assigned (1:1 ratio) to treatment with pegylated liposomal doxorubicin 50 mg/m² every 28 days or topotecan 1.5 mg/m²/day for 5 consecutive days every 21 days. Patients were stratified prospectively based on whether they had platinum-sensitive/refractory disease and the presence/absence of bulky disease. Primary efficacy endpoints were progression-free and overall survival.

Results: Overall survival was longer in patients treated with pegylated liposomal doxorubicin compared to those treated with topotecan (median 63 and 60 weeks, respectively; P = 0.05, HR = 0.82 [0.68, 1.00]). In the subset of patients with platinum-sensitive disease (46%), this survival advantage was even more striking for patients treated with pegylated liposomal doxorubicin compared to topotecan (median 112 and 77 weeks, respectively; P = 0.002, HR = 0.63 [0.47, 0.85]). In the subset with platinum-refractory disease, survival was similar in the 2 treatment groups (median 36 and 41 weeks, respectively; HR = 1.01 [0.78, 1.31]). As of December 2002, 29 patients initially treated with pegylated liposomal doxorubicin and 10 topotecan-treated patients remain alive. A more favorable toxicity profile was reported with pegylated liposomal doxorubicin, as patients experienced fewer severe adverse events and required less hematologic support and significantly fewer dose modifications.

Conclusions: Patients treated with pegylated liposomal doxorubicin had longer overall survival compared to topotecan-treated patients. The overall survival advantage was more than 35 weeks in patients with platinum-sensitive disease treated with pegylated liposomal doxorubicin. To date, this is the only head-to-head study demonstrating a survival advantage in recurrent epithelial ovarian cancer.