Biweekly pegylated liposomal doxorubicin as second-line treatment in patients with relapsed ovarian cancer after failure of platinum and paclitaxel: results from a multi-center phase II study of the NOGGO.

BACKGROUND: Pegylated liposomal doxorubicin (PLD) is one of the most effective cytotoxic agents in recurrent ovarian cancer. Palmar-plantar erythrodysesthesia (PPE) is a typical and commonly noted adverse event and often represents the dose-limiting toxicity. The purpose of this multicenter study was to determine the efficacy of this regimen as second-line therapy for patients with recurrent ovarian cancer. PATIENTS AND METHODS: Patients with recurrent epithelial ovarian cancer after surgery and initial treatment with carboplatin and paclitaxel were enrolled. Eligible patients were required to have an ECOG performance status of ≤2, and sufficient organ function. PLD was administered at a dose of 20 mg/m² every two weeks. RESULTS: Twenty patients were recruited into this trial. Overall, 155 cycles of chemotherapy with a median of six courses (range 4-24) were administered. The median patient age was 64 years (range, 41-77 years). The hematological and non-hematological toxicity profile was favorable. No grade IV toxicity was observed. PPE grade III toxicity was noted in only one patient. Median overall survival was 19.2 months (range 1.8 to 39 months; 95%
confidence interval (CI) 14.2-29.7 months) Progression-free survival was 3.3 months (range 1.38 to 36.4 months; 95% CI 1.84-13.4 months). CONCLUSION: Biweekly PLD is an effective second-line treatment for patients with relapsed ovarian cancer. Toxicity incidence with this treatment schedule does not appear to be associated with the number of previous chemotherapies. Our data supports the need for a randomized study comparing biweekly with conventional monthly administration of 40 mg/m^2 or 50 mg/m^2 PLD to determine the best therapeutic index for PLD.