Pegylated liposomal doxorubicin (CAELYX) in patients with advanced ovarian cancer: results of a German multicenter observational study.

PURPOSE: Pegylated liposomal doxorubicin (PLD, CAELYX) has demonstrated activity in several phase-III trials and has been approved for the therapy of relapsed ovarian cancer after platinum treatment. Aim of this observational study was to analyze the efficacy and toxicity profile of PLD under routine clinical conditions and without the general restrictions of defined inclusion and exclusion criteria of clinical trials.

METHODS: Between 2003 and 2005, a total of 190 patients with relapsed ovarian cancer were enrolled. 183 patients were available for evaluation; dose-intensity, modifications, treatment duration, toxicities and response were systematically analyzed.

RESULTS: The median patient age was 62 years (range 23-86 years). 45.4% of the patients received PLD as second-line therapy and a median of four courses per patient were administered. The median dose of PLD was 40 mg/m\(^2\), most frequently used every 4 weeks (68.8%). Grade 3 Leucopenia (1.6%) and grade 3 and 4 thrombocytopenia (0.5%) were the most frequent hematological toxicities. The most frequent non-hematological toxicities were skin toxicity, pain and nausea, which were observed in 38.8, 41 and 45.9% of the patients, respectively.

Twenty-seven percent of the patients...
showed a response to therapy with 6.9% achieving complete remission and 20.1% achieving partial remission. 37.7% achieved a stable disease. The median duration of response for all patients was 4.8 months (range 0-51.8 months). Median progression-free interval and overall survival were 5.8 months (95% CI 5.1-6.6 months) and 16.6 months (95% CI 13.9-22.6 months), respectively. CONCLUSIONS: PLD is safe and effective in patients with relapsed ovarian cancer, even after numerous previous treatment regimens. A dose of 40 mg/m(2) every 28 days seems to be an effective and well-tolerated therapeutic option in advanced ovarian cancer with a low incidence of hematological toxicities and acceptable non-hematological toxicities.