OBJECTIVES: to determine the effect of weekly administration of cisplatin as first line chemotherapy for advanced ovarian cancer patients

METHODS: Patients with advanced epithelial ovarian cancer were randomly assigned (by a computer system) to the experimental dose-dense first line chemotherapeutic arm (Pw, cisplatin 50 mg/mq weekly x 6 cycles) or to the standard arm (Pst, cisplatin 75 mg/mq every three weeks x 6 cycles). Planned cumulative dose of cisplatin was 450 mg/m2 in both groups, while dose intensity was doubled in the Pw arm (50 mg/m2/week versus 25 mg/m2/week). The primary objective of the study was to compare the progression free survival (PFS) in the two arms. Secondary objectives were the overall response to chemotherapy and toxicity. RESULTS: between November 1988 and February 1992 285 patients were randomized in the two treatment arms. The two regimens resulted equally feasible. Planned dose intensity was achieved in both treatment groups (median 45 and 23 mg/m2/week). Toxicity was similar in the two groups, with the exception of grade 3-4 leukopenia which was more frequent in the experimental arm (9% vs 3%, p:0.02). Median follow up was 16.8 years. There were no differences between the two treatment arms in terms of PFS (17 months in the Pw arm, 18 in the Pst arm, p:0.57) and in terms of OS (35 months in the Pw arm, 32 in the Pst arm, p:0.97). CONCLUSION: dose-dense cisplatin is well...
tolerated, but does not seem to bring advantages, in terms of PFS and OS, compared to standard chemotherapy.