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A Phase I Clinical Trial of Paclitaxel plus Ifosfamide for the Patients with Refractory Ovarian Carcinoma

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In this pilot dose escalation study, the combination of paclitaxel and Ifosfamide was administered to six previous heavily treated patients with advanced refractory ovarian carcinoma. All the patients had stage III suboptimal ( $>2\text{cm}$ ) platinum refractory disease at the initiation of the study. Patients also were required to have adequate renal, hepatic, cardiovascular and bone marrow function and ECOG performance status of less than 3. The study was designed in a manner that two drug doses were escalated one after another with each consecutive course. The starting doses were  $110\text{mg}/\text{m}^2$  of paclitaxel and  $1000\text{mg}/\text{m}^2$  of Ifosfamide. The doses were increased to  $135\text{mg}/\text{m}^2$ ,  $175\text{mg}/\text{m}^2$ ,  $225\text{mg}/\text{m}^2$  for paclitaxel and  $1200\text{mg}/\text{m}^2$ ,  $1500\text{mg}/\text{m}^2$  for Ifosfamide until the toxicities became intolerable. All the patients were premedicated and monitored for hypersensitivity reactions.

The paclitaxel was infused over three hours and then Ifosfamide was administered for 24 hours a day continuously for 5 days with mesna. G-CSF was given for a week following the administration of Ifosfamide. The median number of courses was 5.2. The neurotoxicity was dose limiting and became intolerable at a dose level of  $175\text{mg}/\text{m}^2$  of paclitaxel and  $1500\text{mg}/\text{m}^2$  of Ifosfamide. The partial response was observed in two (33.3%) patients. One minor response and two stable disease were observed with one progressive disease. From these results, it can be stated that the polychemotherapy with paclitaxel and Ifosfamide for suboptimal stage III refractory ovarian cancer is considered not superior to other paclitaxel based regimens. However, future directions should potentiate the study with a large number of patients and recurrent but optimal ovarian cancers also should be included in the study.

I S-44      **Impact on survival rate of combination chemotherapy of carboplatin and cisplatin(JP) in stage III, IV ovarian cancer .**

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**[Purpose]** To evaluate the impact on survival rate of JP in ovarian cancer patients.

**[Patients and Methods]** We treated 35 previously untreated ovarian cancer patients from 1991 with JP. Twenty-three patients were stage III and their age were 26-73 (median 60.5). Twelve patients were stage IV and the age was 31-72 (median 57.5). JP regimen consists of carboplatin  $350\text{mg}/\text{sqm}$  (day 1) and cisplatin  $80\text{mg}/\text{sqm}$  (day 3) intravenously every 4 weeks for 6 courses.

**[Results]** One patient with stage III disease died of HCV hepatitis and 34 patients were assessed for survival. Duration of survival was 4-52 months for stage III patients and 3-48 months for stage IV patients. Survival rate at 42 months was 58.3% for stage III patients and 32.1% for stage IV patients. Major toxicities were thrombocytopenia and leukopenia.

**[Conclusion]** Survival rate at 42 months after JP was much higher than that reported with CAP or CP chemotherapy for stage III, IV patients. This high dose platinum regimen was found to be a efficacious therapy with high response rate and also with higher survival rate at 4 years after therapy.