RANDOMIZED TRIAL ON ADJUVANT IV CHEMOTHERAPY (CDDP+CPA) VERSUS PO CHEMOTHERAPY (CPA) FOR STAGE IA OVARIAN CANCER BY THE JAPAN GYNECOLOGIC ONCOLOGY AND CHEMOTHERAPY STUDY GROUP. Natake M., Onishi Y., Noda K., Yakushiji M., Ozaki K., Ochiai K., Kuzuya K., Takahashi T., Tateno M., Yoshikawa H., Nishida T (Japan Gynecologic Oncology and Chemotherapy Study Group)

Objective: To evaluate the role of adjuvant i.v. CDDP+CPA chemotherapy for stage Ia ovarian cancer patients comparing to adjuvant p.o.CPA. Methods: Between March 1992 and February 1997, 98 patients postoperatively diagnosed stage Ia epithelial ovarian cancer patients were entered prospectively on the protocol. They were randomized to IV group (3 courses of CDDP 75mg/sqm + CPA 500mg/sqm i.v. every 4 weeks) and PO group (CPA 50mg/sqm p.o. daily for 3 months). Results: Two patients were excluded due to borderline malignancy. 47 patients have been randomized to IV group and 49 to PO group. The background of two groups were not significantly different (age, histology type, operation methods and completion of adjuvant chemotherapy). The side effects were significantly severe in IV group (WBC, RBC, Hb, appetite loss, nausea, vomiting and hair loss). Median follow-up duration was 19.4 (5.3-54.4) months for IV groups and 19.5 (3.4-58.5) months for PO group respectively. One patient of each group was died during the follow-up period. One patient of IV group was 15 y.o. with grade 1 mucinous cystadenocarcinoma died at 11 months. Another patient of PO group was 47 y.o. with clear cell carcinoma died at 6 months. There are no significant difference in survival (log rank test p=0.986, generalized Wilcoxon test p=0.852) and progression free survival (PFS) between two groups. Conclusion: Survival and PFS were not significantly different between two groups and side effects were severe in IV group. From this study, we concluded IV adjuvant chemotherapy for stage Ia ovarian cancer is not useful comparing to PO adjuvant chemotherapy.