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PHASE II TRIAL OF MITOMYCIN C(Mit) PLUS 5-FU IN REFRACTORY OVARIAN CANCER(ROC). ***Peláez I, López R, Palacio I, Fernández Y, Estrada E, Esteban E, Buesa JM and Lacave. Medical Oncology. Hospital General de Asturias. 33006. Oviedo. Spain.***

A combination of Mit plus 5-FU showed a 40% remission rate in patients (pts) with ROC (Semin. Oncol, 15,S 4; 22; 1988). This prompted us to start an intramural phase II study to confirm these results. From Oct. 1990 to Dec. 1992, 18 pts all refractory to cisplatin combination were treated with Mit 10 mgr/m2 i.v. d 1 q 6 wks and 5-FU 500 mgr/m2 i.v. d 1-3 q 3 wks. From 18 pts entered, 15 were fully evaluable, 2 for response (only 1/2 course because rapid progression and death) and 1 for toxicity (only 1/2 course due to important gastrointestinal toxicity). Pts characteristics were : median age 59.5 years (range 49-69); 9 serous , 2 mucinous, 2 clear cell, 2 endometrioid and 3 undifferentiated; PS (WHO) grade 1 (0-2); previous chemotherapy regimens 1 (1-4). Evaluation of response was made by CT scan in 8, physical examination in 8 and by tumor marker (CA-125) in 1. Over 17 pts, there were no objective responses, with 2 NC and 15 PD. Time to progression was 10 wks (3-37) and survival time was 29 (3-118+). Number of cycles were 2 (1/2-11). Grade 3-4 (WHO) maximum toxicity (% of pts): leucopenia 12%, stomatitis 12%, diarrhea 12%, nausea/ vomiting 6% and alopecia in 6%. No toxic death occurred. **In conclusion**, the combination of Mit plus 5-FU given with the same schedule reported by Alberts et al. showed no activity and a moderate toxicity in pts with ROC.

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30 YEARS' EXPERIENCE ON POST OPERATIVE ABDOMINAL AU 198 TREATMENT OF OVARIUM TUMOURS

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Since the 60s about 150 patients suffering ovarian tumour were treated with abdominally adminitered Au 198 colloid so as to avoid peritoneal progression. Most of the patients has already had ascites, or the rupture of the ovarian cyst has been detected before the treatment. Greatest part of the primary tumours were of T_1-T_2 size.

Method: 100-120 mCi /3,7-4,44 GBq/ Au 198 colloid solved in 300 mls of antibiotics containing saline was administered intraperitoneally.

Very good therapeutic effect was observed in comparison with the side effects occured in some cases.

Disadvantages of the treatment, the relatively high exposure of the staff and the rigorous isolation of the patient for about three weeks required.

Beside of the generally accepted treatment of ovarian ca, the intraperitoneal radionuclid therapy has also an important role.

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STAGE III OVARIAN CARCINOMA: TREATMENT RESULTS AND COMPLICATIONS AFTER SALVAGE THERAPY WITH HYPER-FRACTIONATED WHOLE-ABDOMEN IRRADIATION.

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Patients with persistent disease after laparotomy after platinum-based chemotherapy for Stage III ovarian carcinoma have a remote chance of cure with second-line chemotherapy or conventional radiotherapy. To decrease relapse rates and improve tolerance, we have used twice-daily radiotherapy in 28 such patients. All patients received 80 cGy per fraction, twice daily, to a mean total dose of 3020 cGy to the whole abdomen; 21 patients had additional treatment of the pelvis (mean dose, 1454 cGy). With a 2-year minimum follow-up, survival rates at 1, 2, and 5 years were as follows: absolute survival, 79%, 50%, 21%; relapse-free survival, 52%, 36%, 19%. For 11 patients with no evidence of gross residual disease after the second-look laparotomy, absolute survival rates of 100%, 73% and 27% compared favorably with rates of 65%, 34%, and 18% for the 17 patients who had gross residual disease. Only 2 patients required treatment breaks. Four patients had surgical intervention for small bowel obstruction, which in two cases revealed recurrent disease. Two patients died of treatment-related complications. Twenty-one of 22 failures occurred in the abdomen or pelvis. In conclusion, although most patients eventually relapse, a small percentage have a prolonged disease-free interval. Because treatment was well tolerated, escalation of the dose of hyperfractionated whole-abdomen irradiation is being investigated.

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DISTANT METASTAZES IN OVARIAN CARCINOMA

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Of the 421 primary ovarian ca. patients (pts) referred to our institution 79 (19%) developed distant metastazes (mets). Distribution rate of the mets among pts with dissemination was as follows liver 56%, pleura 23%, lung parenchyma 18%, distant lymph node 13%, umblicus 5%, brain 4%, dermis 4%, pancreas 1%, spleen 4%, and bone 3%. 22% (17/79) of the pts had more than one organ involvement at the time of analyses. Involvement rate of the specific sites in the whole series was as follows: liver 11% (44 pts), pleura 4% (18 pts), lung 3% (14 pts), distant lymph node 2% (10 pts), umblicus 1% (4 pts), brain 1% (3 pts), dermis 1% (3 pts), pancreas 1 pt, spleen 1% (3 pts) and bone 1% (2 pts). In pts with distant mets, median survival time in months after the initial diagnosis and after the diagnosis of dissemination, respectively, was as follows: liver mets 12 and 6, pleura 10 and 7, lung 14 and 7, lymph node 14 and 6, umblicus 16 and 7, brain 29 and 9, pancreas (mets at initial diagnosis) 18, spleen 12 and 12, bone 17 and 14.

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HIGH DOSE CHEMOTHERAPY IN OVARIAN CARCINOMA

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From april 1990 to septembrer 1991, 80 patients suffering from stage IIIc or IV ovarian carcinoma with bulky residual disease after the first surgery have been included in a feasibility study of intensive chemotherapy by Cyclophosphamide (300 mg/sqm), Cisplatine (100 mg/sqm) and Carboplatine (300 mg/sqm) every 4 weeks. The toxicity was severe but manageable, with thrombopenia grade IV, neurological toxicity and ototoxicity as most severe side effects. 63 patients underwent second look laparotomy. Pathological complete response rate is 25 %. The survival data will be updated in september 1993. We now conduct a randomized trial comparing this protocol with a standard treatment by cisplatin and cyclophosphamide (60 patients included).