

moderate. Grade 1 to 3 stomatitis occurred in 26%, 23% and 10%, respectively. Grade 1 to 4 palmarplantar erythrodysesthesia was recorded in 23%, 13% 3% and 3%, respectively. Grade 3 or 4 neutropenia occurred in 23% and 3% of patients while anemia and thrombocytopenia were rare (grade 3 in 3% and 10%, respectively). No patient stopped therapy due to toxicity. Quality of life (QoL) evaluations (EORTC QLQ-C30) revealed a median stabilization of physical functioning over the treatment period of 6 months in 86% of patients. Symptom QoL scores regarding fatigue were reduced over time reflecting disease progression. The combination of L-DXR and GEM is an effective and well tolerated option in platinum-resistant and refractory ovarian cancer.

## 927

## POSTER

### Capecitabine (X) chemoradiation as first-line treatment in patients (pts) with stage IIB-IIIb squamous cervical carcinoma: a Mexican radio-oncology study group trial

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**Background:** Chemoradiation with cisplatin is a standard first-line treatment for locally advanced cervical cancer. Thymidine phosphorylase, the key enzyme responsible for intratumoral conversion of X, is highly concentrated in cervical cancer tissue and upregulated by radiotherapy. As an oral therapy, X simplifies chemoradiation by avoiding problems associated with cisplatin, such as the need for hospitalisation, i.v. infusion, gastrointestinal and bone marrow toxicities. A phase I trial defined the MTD for X chemoradiation for use in this phase II trial. The main objective was safety and secondary objectives were efficacy and quality of life.

**Materials and methods:** Pts received X 825 mg/m<sup>2</sup> orally twice daily (Monday to Friday) during 5 weeks of external radiotherapy, with weekend interruption of treatment. External 4-field radiotherapy (45–50 Gy) was delivered in a 1.8 Gy daily dose 5 days/week followed by brachytherapy 30 Gy 2 weeks after external therapy.

**Results:** Baseline characteristics of the 114 chemo-naïve pts were: median age 50.3 years; ECOG performance status 0/1/2 (56%/38%/6%); median tumour dimension 16 cm<sup>2</sup> (range 2.5–100 cm<sup>2</sup>); stage II/III (62%/38%). Adverse events are shown in table 1.

Table 1

% of pts	All grades	Grade 3/4
Hand-foot syndrome	9	1
Stomatitis	15	0
Diarrhoea	58	2
Vomiting	26	0
Proctitis	28	0
Cystitis	26	0
Radiodermatitis	35	2
Infection	18	1
Anaemia	53	1
Platelets	9	0
Neutropenia	52	0
ALT	16	0
AST	19	0

Global health status improved by 25% vs. the baseline score. An impairment in physical function of 3% was detected after external RT end and was 7% at the end of brachytherapy, but recovered to 100% after 4 weeks. Emotional function improved progressively by 11% after chemoradiation, 17% after brachytherapy and 22% 8 weeks after completing treatment (p=0.011). Cognitive and social function remained constant. Fatigue and nausea/vomiting increased by 50% and 16% respectively during the first 2 weeks but returned to baseline levels at the end of chemoradiation. Pain perception increased at the end of brachytherapy but improved by 50% vs. baseline level 8 weeks after completing treatment. Loss of appetite and diarrhoea were evident at weeks 2 and 4 of treatment, but disappeared before brachytherapy. 44 pts have so far completed therapy: CR 91%, PR 9%. One pt progressed during chemoradiation. Median follow-up for this group is 7.5 months (1.5–20 months) and only 3 pts had tumour recurrence (at 2.5, 6 and 7 months). Median time to recurrence has not yet been reached.

**Conclusions:** X chemoradiation is well tolerated, improves most QoL domains and appears to be highly effective in patients with stage II/III cervical cancer.

## 928

## POSTER

### A multi-center phase II study of gemcitabine and oxaliplatin in platinum-refractory and platinum-resistant ovarian cancer: An Australian and New Zealand Gynaecological Oncology Group Study

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**Background:** Treatment options for patients with recurrent ovarian cancer are limited and never curative. Gemcitabine and oxaliplatin have shown single agent activity in relapsed ovarian cancer patients, and also synergistic interaction in vitro. This combination was used to determine the efficacy, progression-free survival, and toxicity in patients with recurrent ovarian cancer.

**Material and methods:** Patients with relapsed or progressive ovarian cancer and prior primary platinum-based chemotherapy who had measurable lesions and/or elevated CA 125 levels were categorized into 2 groups: Group A platinum-resistant patients (those who relapsed within 6 months of platinum-based regimen), and Group B potentially platinum-sensitive patients (those who relapsed after 6 months of platinum-based regimen). Patients received gemcitabine 1000 mg/m<sup>2</sup> on days 1 and 8 and oxaliplatin 130 mg/m<sup>2</sup> on day 8 every 21 days for up to 8 cycles.

**Results:** Between April 2001 and June 2003, a total 75 patients (21 in Group A and 54 in Group B) were enrolled. The median age was 58 years (range, 37–78); 37/38 patients had stage III/IV disease. By intention to treat analysis, 14 patients achieved partial response for an overall response rate of 18.7%, with 9.5% [2/21] in Group A and 22.2% [12/54] in Group B. Thirty-one patients (41.3%) in the ITT population progressed (11 [52.4%] in Group A and 20 [37.0%] in Group B). The 8-month progression-free survival rate was 47.5% (29.5% in Group A and 53.5% in Group B). Forty eight patients (64.0%) experienced grade 3/4 myelosuppression with neutropenia seen in 61.3%, and thrombocytopenia in 10.7% patients. Seventeen (22.7%) patients required transfusion with 15 receiving packed red blood cells and 2 patients requiring platelet transfusion. Non-hematological grade 3/4 toxicities were nausea (16.0%) and vomiting (24.0%).

**Conclusions:** Single agent chemotherapy with carboplatin, paclitaxel, or liposomal doxorubicin, each produce response rates comparable to those seen in this study, but with considerably less toxicity. Recent studies also suggest a survival advantage for treatment with combinations such as carboplatin and paclitaxel in platinum-sensitive ovarian cancer patients, but again with less toxicity. The relatively high toxicity and suboptimal response rates seen in this study suggest that the combination of gemcitabine and oxaliplatin as employed in this study is unlikely to become a mainstream therapy for relapsed ovarian cancer.

## 929

## POSTER

### Pre-operative selection criteria for operability in recurrent ovarian cancer. A study of the AGO Organkommission Ovar and the AGO Ovarian Cancer Study Group (AGO-OVAR)

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**Background:** The role of cytoreductive surgery (CS) in recurrent ovarian cancer (ROC) has not yet been clearly defined. Patient selection for OP remains arbitrarily and does not depend on established selection criteria but on center's preference.

**Methods:** The AGO performed a retrospective study evaluating criteria for CS in ROC. 25 institutions documented their pts with CS of invasive epithelial ROC performed 2000–2003.

**Results:** 267 pts were included, mean age was 59.5 years (23–83), interval from initial diagnosis was 35 months (3–174) with 108 pts (40.4%) with a treatment-free-interval of 12 months or less. 146 pts (55%) received platinum-based chemotherapy after surgery. Complete tumor resection was achieved in 133 pts (50%). Complete resection was associated with