moderate. Grade 1 to 3 stomatitis occurred in 26%, 23% and 10%, respectively. Grade 1 to 4 palmoplantar 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^2 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^2(range 2.5–100 cm^2); 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^2 on days 1 and 8 and oxaliplatin 130 mg/m^2 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

significantly longer survival compared to any residual disease (median 45.2 vs 19.7 months; HR 3.71 (95% CI 2.27–6.05); p < 0.0001). Variables associated with a higher probability for complete resection in multivariate analysis were good performance status (ECOG 0 vs >0; OR 2.56; p < 0.001), no ascites (< vs >500 ml; OR 4.26; p < 0.003), no residuals after 1st surgery (0 vs >0; OR 2.09; p = 0.009) and no evidence for peritoneal carcinosis in pre-OP diagnostics (yes vs no; OR 2.67; p = 0.005). Complete resection was possible in 81% if these 4 variables were present. Prognostic factors in multivariate analysis for survival after a secondary cytoreductive surgery were complete surgical resection at recurrence (0 vs >0; OR 2.86; p < 0.001), post-OP platinum chemotherapy (yes vs no; OR 1.83; p = 0.009) and no ascites (< vs >500 ml; OR 2.09; p = 0.012).
Conclusions: Only patients with complete resection seem to benefit from CS in ROC. The presence of the 4 variables as shown above helped to predict surgical outcome. Based on these data the AGO will evaluate this new panel of selection criteria in a prospective multi-institutional study.

930 POSTER

Adjuvant radiotherapy improves outcome in pathologic stage III endometrial cancer confined to the pelvis

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Purpose: Patients with pathologic stage III endometrial cancer confined to the pelvis are often treated with pelvic radiotherapy (RT). However, data regarding predictors of outcomes is limited. This retrospective study assesses prognostic factors and patterns of recurrence in these patients.
Methods: Between 1990 and 2003, 121 patients with pathologic FIGO stage III endometrial adenocarcinoma confined to the pelvis were treated at a single institution. Adjuvant RT was delivered to 76 patients (62.8%). The influence on outcome of age, histologic subtype and grade, lymphovascular invasion, depth of myometrial invasion, involvement of the lower uterine segment, cervix, uterine serosa, adnexa, and nodes, number of extrauterine sites involved, resection margin status, and adjuvant RT, chemotherapy, and hormonal therapy were evaluated.
Results: Median follow-up was 38.7 months. Five-year actuarial overall survival is significantly improved in patients treated with adjuvant RT (68.0%) compared those with resection alone (50.3%; p = 0.029). Five-year disease-free survival in patients treated with or without adjuvant RT was 66.5% and 36.9%, respectively (p = 0.004). Age, histologic grade, uterine serosal invasion, adnexal involvement, number of extrauterine sites, and treatment with adjuvant RT predicted for improved survival in univariate analysis. Cox regression multivariate analysis revealed that only histologic grade, uterine serosal invasion, and treatment with adjuvant RT were independent predictors of survival. Five-year actuarial local control improved significantly with the delivery of adjuvant RT (73.7% versus 49.1%; p = 0.011). Predictors of local control included depth of myometrial invasion, uterine serosal invasion, adnexal involvement, resection margin status, and treatment with adjuvant RT in univariate analysis. Depth of myometrial invasion and treatment with adjuvant RT were independent predictors of local control in multivariate analysis. The overall 5-year actuarial distant control was 65.2%. In univariate analysis, histologic subtype and grade, and uterine serosal invasion were significant predictors of distant control. However, only histologic subtype and uterine serosal invasion were independent predictors of distant control in multivariate analysis. Acute and late grade 3 or higher toxicity was observed in four patients (5.3%) and two patients (2.9%), respectively, treated with adjuvant RT. No treatment-related deaths were observed.
Conclusions: The use of RT in the treatment of pathologic stage III endometrial cancer confined to the pelvis is well tolerated and appears to improve survival. Pelvic RT should always be considered in management of these patients.

931 POSTER

Chemotherapy directed by the ATP-based tumor chemosensitivity assay versus physician's choice in platinum-resistant ovarian carcinoma: a multicenter prospective randomized controlled trial of the TCA Ovarian Cancer Trial Group

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Background: Recurrent ovarian cancers (ROC) are characterized by a broad heterogeneity in their response to chemotherapy (Ctx). Based on results from a previous case-control strudy (Kurbacher et al., ACD 1998), this multicenter prospective randomized controlled trial was initiated in order to evaluate whether the ATP-based tumor chemosensitivity assay could aid the choice of Ctx and improve outcome.
Patients and methods: The primary endpoint of this trial was to determine the objective response rate (ORR) and progression-free survival (PFS) in patients (pts) with platinum-resistant ROC treated according to the ATP-TCA (arm A), or by physician's choice (arm B). Pts progressing on or within 6 months after cessation of primary platinum-based Ctx were eligible as were those showing primary progression on or early relapse after platinum-based re-induction for suspected platinum-sensitive ROC. In each case, solid tumor or ascites was sent for assay from the 10 treament centers to one of the two central laboratories (UK or Germany). In arm B, the assay results were blinded but pts were allowed to cross-over to assay-directed Ctx upon failure of physician's choice. The study was designed to accrue a total of 180 pts to detect a 20% difference in outcome with 80% power and 99% confidence.
Results: 94 pts were randomized to arm A, and 86 to arm B. Both groups were well balanced. Median follow-up at analysis was 18 months. In arm A, combination Ctx was used in 89% of pts vs 64% in arm B, with increasing use in the latter during the the course of the trial. The novel combinations treosulfan+gemcitabine and mitoxantrone+paclitaxel were the most frequently used regimens in both arms. Both hematological and non-hematological toxicities did not differ significantly between both arms. Response was assessable in 147 pts with an ORR of 40.5% in arm A (CR: 8%) and 31.5% in arm B (CR 7%). ITT analysis showed a median PFS of 104 days in arm A and 93 days in arm B (p = 0.14). The ORR of pts crossed-over to assay-directed Ctx after failure of physician's choice was 41%. There was no difference in overall survival between both arms.
Conclusions: This study showed a trend towards improved ORR and PFS for ATP-TCA-directed Ctx without reaching statistical significance. This may partly be attributable to the unexpectedly good results in arm B related to both a learning effect and a particularly successful post-study treatment in pts crossed over to assay-directed Ctx. Although this trial was technically negative, the use of the ATP-TCA may thus be a reasonable approach to individualize Ctx in platinum-refractory ROC pts. Other than classical phase III designs may be more suitable to evaluate predictive techniques in clinical oncology (J. Sargent, JCO 2005).

932 POSTER

Conservative treatment in epithelial ovarian cancer: results of a french multicenter study

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Background: Conservative management of epithelial ovarian cancer (EOC) remains controversial in the literature. The aim of this study is to assess and evaluate the clinical outcomes and fertility following fertility sparing surgical management in a retrospective multicenter study.
Material and methods: A multicenter retrospective study was performed among members of 2 French groups in order to collect cases of conservative treatment of EOC. An Institutional Review Board authorization was obtained before to conduce this study. Six inclusion criteria were defined: 1. Epithelial ovarian tumor with histologic review of the initial ovarian tumor by the same pathologist; 2. Patient's age <40 years); 3. Conservative management (preservation of the uterus and at least a part of 1 ovary) after 1 or 2 step(s) surgical procedures (restaging surgery); 4. Complete peritoneal staging (including at least: peritoneal cytology and omentectomy and peritoneal biopsies); 5. Delivery of a platinum based chemotherapy (±paclitaxel) in stage ⩾ IC and 6. A follow-up >1 year after the end of the treatment.
Results: Data of 59 patients (pts) were reviewed. Thirty-four fulfilled all inclusion criteria and were treated in 1 step (n = 2) or 3 steps surgical procedures (n = 32). Histologic subtypes were: mucinous (n = 21); endometrioid (n = 5); serous (n = 3); clear cells (n = 2) and mixed (n = 3). Tumor grade (G) were: 16 G1; 14 G2 and 4 G3. Thirty had stage IA disease (G1 n = 13; G2 n = 14 and G3 n = 3); 3 stage IC and 1 stage II. Ten pts received postoperative platinum-based chemotherapy. The median time of follow-up was 47 (range, 12–224) months. Eleven patients recurred (8 at least on the remaining ovary) with a median free interval of 14 (range, 2–51) months. Ten patients had recurrent invasive disease and 1 pt had borderline recurrence on the preserved ovary. Among 10 pts with invasive recurrence, initial stage and grade were: stage IA G1 n = 1; stage IA G2 n = 4; stage IA G3 n = 1 and stage ⩾ IC n = 4. The event free survival at 5 years for patients with stage IA grade 1 and 2 tumors were respectively