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

92% and 70%. All patients with stage > IA recurred. Ten pregnancies were observed in 9 pts.
Conclusion: Conservative surgery for patients with EOC could be considered in young patient with stage IA grade 1 disease adequately staged. This procedure should be evaluated in patients with stage IA grade 2 disease but should not performed in patients with FIGO stage > IA.

933 POSTER

Immunotherapy in patients with recurrent epithelial ovarian cancer with the anti-idiotypic monoclonal antibody ACA125 (AGO-OVAR, Phase I/II trial)

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Background: Despite first-line chemotherapy with platinum-taxane most patients with advanced ovarian cancer (OC) relapse. Therefore new, promising strategies are needed to prolong survival. An innovative immunotherapy is ACA125, a murine anti-idiotypic antibody of the tumour-associated antigen CA-125, that leads to the generation of anti-anti-idiotypic antibodies (Ab3).
Material and methods: In this multi-centre phase I/II trial 36 pts. with platinum-sensitive recurrent OC were treated after completion of chemotherapy with ACA125 for consolidation. Two vaccination schedules were compared: 9 (group A) vs. 6 injections (group B), 18 pts. in each group. Four s.c. injections at 2.0 mg were administered every two weeks and then monthly for 2 or 5 additional doses. Primary objective of the trial was safety of ACA125, secondary objective was immunological response (induction of Ab3, human-anti-mouse-antibodies (HAMA) and IFN-γ secretion of antigen-specific T-cells after in-vitro stimulation with ACA125/CA125).
Results: Treatment was completed as planned in 44% and 89% of patients in group A and B, respectively. Treatment was stopped premature due to patient's withdrawal or progression. In both groups no treatment limiting toxicities occurred. The most common toxicity related to the vaccine was local injection site reaction (grade 1/ 2). Other toxicities seemed to be related to prior chemotherapy or disease. Induction of Ab3 was found in all pts. except in 2 (group A) and one pts. (group B), who progressed prior to Ab3 evaluation (median titer 6 weeks after last vaccination, group A vs. B: 359.6 μg/ml (range: 98.9–988.7) vs. 209.6 μg/ml (range: 8.6–618.9) ($p = 0.056$). No differences with regard to HAMA-induction (median titer 6 weeks after last vaccination, group A vs. B: 8.1 μg/ml (range: 1.4–184.9) vs. 2.0 μg/ml (range 0.017–13.2) ($p = 0.1$) and IFN-γ secretion was shown for both schedules.
Conclusions: ACA125 vaccination is a safe and well tolerated therapy that induced humoral and cellular immune response. With regard to immunogenicity and toxicity no difference was found in both schedules.

934 POSTER

Phase II study of irinotecan and oral etoposide in patients with platinum/taxane-resistant ovarian carcinoma

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Purpose: To evaluate the efficacy and toxicity of intravenous irinotecan (topoisomerase-I inhibitor) and oral etoposide (topoisomerase-II inhibitor) as combination chemotherapy in patients with platinum/taxane-refractory or -resistant ovarian carcinoma.
Patients and methods: Between October 2002 and September 2004, 28 patients with platinum- and taxane-refractory or resistant ovarian carcinoma were enrolled in this study. The eligible patients had received at least one prior chemotherapy including both platinum and taxane. Irinotecan 70 mg/m^2 was administered intravenously for 90 minutes infusion on days 1 and 15, and etoposide 50 mg/body orally on days 1 to 21 in principle. In consideration of safety of this study, the initial doses were set to CPT-11 60 mg/m^2 and etoposide 50 mg/body for heavy pretreated patients. The treatment courses were repeated every 4 weeks. Subsequent doses were unchanged, reduced, or omitted according to the observed toxicity and protocol guidelines. Patients were evaluated for response using the RECIST or CA-125 criteria and for toxicity using NCI-CTC Version 3.
Results: All of 28 patients were eligible and assessable. There were 10 partial responses (PRs) and one complete response (CR) for an overall response rate of 39.3% (95% confidence interval, 23.6% to 57.6%). The progression-free rate (CR/PR+stable disease rate) was 82.1%. The overall median response and stable disease duration was 7.0+ months and 8.0+ months, respectively. The major toxicity was neutropenia, with 21.4% grade 3 and 39.3% grade 4 reported. Diarrhea was infrequent and mild, and gastrointestinal toxicity was moderate and manageable. Febrile neutropenia of grade 3 or higher occurred in four cases (14.3%). They were improved by the administration of antibiotics. There were no treatment-related deaths.
Conclusions: Irinotecan/oral etoposide showed a favorable response rate to platinum/taxane-resistant ovarian cancer. Furthermore, the progression-free rate exceeded 80% if stable disease was included. It had no increased hematological toxicity when compared to irinotecan single-agent. Or rather, diarrhea was more mitigated than by an irinotecan single-agent. It was shown that irinotecan/oral etoposide was a promising combination therapy as a salvage therapy from the viewpoint of effect and toxicity.

935 POSTER

Prognosis of isolated lymph node relapse (ILNR) of ovarian epithelial carcinoma (OEC). About 27 cases at a single centre.

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Background: Relapses of OEC have a poor prognosis, which depends on initial tumor staging, progression-free survival (PFS) after initial treatment, possibility of complete surgical resection, response to second-line chemotherapy and location of the relapse. ILNR are considered as chemo-resistant and of relatively good prognosis with intensive therapy.
Material and methods: We conducted a retrospective study concerning all patients treated at our centre for OEC between 1986 and 2001. 27 patients experienced an ILNR during this 15-year period.
Results: Isolated lymph node relapses occurred in 4.2% of the cases (27 among 640 OEC patients). At diagnosis, average age was 59 years, tumor stage included stage I (n = 4), II (n = 5), III (n = 15) and IV (n = 3). Most patients were initially treated with optimal surgery and chemotherapy. Half of the patients received consolidation intra-peritoneal chemotherapy. 85% of the cases (23 out of 27) had an elevated CA125 at the time of ILNR. Sites of relapse were retroperitoneum (n = 17), left supraclavicular (4), iliac (4) and inguinal (3). Nodes were at a unique location in 63% of the patients (n = 17) and at multiple locations in 37% (10). Treatment of the relapse was chemotherapy alone (n = 7), chemotherapy combined with radical surgery (n = 5) or with radiotherapy (n = 2), radiotherapy alone (n = 2), surgery alone (n = 2) or surgery followed by radiotherapy (n = 1). Seven patients were not treated due to asymptomatic relapse. Two patients were lost to follow up after 58 and 12 months respectively. The median PFS before nodal relapse was 26 months, and the median overall survival (OS) was 68 months. Median survival after nodalrelapse was 26 months. 13 patients relapsed more than 2 years after the initial diagnosis. 30% of patients had a very long survival (>110 months), independent of their initial staging or time of relapse. There was no difference in 2-year survival after ILNR between the groups of early relapse (before 24 months) and late relapse (after 24 months), 59% and 47% respectively. In the seven non-treated patients, median OS was 107 months and three patients had a spontaneous partial remission or >50% decline in CA125 level.
Conclusions: Our study showed that ILNR is a rare event in OEC and that the time to relapse may not have the same significance than in the other sites of relapse. We were surprised by the documented spontaneous partial remission or slow growing tumors in a significant number of these patients. Based on these results, we therefore recommend that in case of isolated asymptomatic nodal relapse, treatment should not be always initiated at diagnosis of relapse. Genetic and molecular studies are warranted in case of slow growing tumor or spontaneous remission.

936 POSTER

Prognostic impact of the pretherapeutic hemoglobin level for patients with primary ovarian cancer receiving a carboplatin-based chemotherapy

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Background: The standard chemotherapy of primary ovarian cancer is carboplatin-based. Anemia is a frequent side-effect of platinum-containing chemotherapy regimen. Furthermore ovarian cancer is known to be often associated with tumor anemia. It was the aim of this study to evaluate the prognostic relevance of the hemoglobin levels before and during carboplatin-based chemotherapy.
Material and methods: We studied retrospectively n = 64 patients with primary ovarian cancer receiving a carboplatin-based chemotherapy. The majority of the patients (n = 46) was treated with a combined chemotherapy