

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 1<sup>st</sup> 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.

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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 to 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.

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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 study (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 treatment 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 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).

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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 conduct 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 ( $\pm$ paclitaxel) in stage  $\geq$  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  $\geq$  IC  $n=4$ . The event free survival at 5 years for patients with stage IA grade 1 and 2 tumors were respectively