by histologic type was the following: Leiomyosarcoma (LMS)-33 patients (50.8%); mullerian mixed mesodermal tumor (MMM)—14 patients (21.5%); endometrial sarcoma (ES)—16 patients (24.6%) and other histologies—2 patients (3.1%). Overall survival at 2 and 5 years was 74% and 58%, respectively. Age at presentation, initial symptoms, parity and associated medical conditions were recorded. Overall survival (OS) and disease-free survival (DFS) were analysed by histologic type, hormonal status, tumor extension and treatment. Tumor extension and hormonal status were the most important factors in predicting survival (P < 0.01). No significant difference for prognosis was found for histologic type and medical associated conditions. All patients were treated with surgery (S), radiation therapy (RT), chemotherapy (CT) and hormonal therapy (HT), alone or combined. T1 e T2 patients which underwent postoperative RT did significantly better than those treated with S alone (77% vs 35% 5-year DFS; p < 0.007). The best results were obtained in the subgroup of patients treated with S + RT + CT ((81%) 5-year DFS). There was a significantly lower rate of pelvic recurrence among the women treated with RT (P = 0.01) and a slight tendency to a lower rate of distant failures among those treated with CT (P = 0.07).

1177 POSTER

## PROGNOSTIC VALUE OF HISTOLOGICAL TUMOR REGRESSION AFTER IRRADIATION FOR UTERINE CERVIX CARCINOMA

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Radio-surgical combination is an effective treatment for centro pelvic cervix carcinoma. Using preoperative radiotherapy, 80% of the patients have no residual disease at the time of surgery. The purpose of this study was to determine the prognostic value of the cervix sterilization after initial irradiation.

Patients and methods: Between 1976 and 1993, 200 patients with histologically proven cervix carcinoma (91 patients with clinical stage Ib tumor, 91 with stage IIA, and 18 with stage IIB) have been treated by irradiation followed by radical hysterectomy 6 weeks later. The mean age was 48 years. Median follow up was 86 months. One hundred and five patients underwent an utero-vaginal application of caesium 137. A dose of 60 Gy was delivered in the reference volume followed by radical hysterectomy and lymphadenectomy. Ninety five patients with bulky centro pelvic tumors received an external pelvic irradiation, a brachytherapy and surgery. The mean dose to whole pelvis was 40 Gy (18–50).

Results: Uncorrected five-year overall survival rate was 96% for stage Ib, 61% for stage IIA and 48% for stage IIB.

Sterilization rate after irradiation was 82% for stage Ib, and 61% for stage IIA or IIB. Probability of survival was significantly better in case of tumor sterilization with a 5-year survival rate of 78% versus 65% and 61% for patients with microscopic residual disease and macroscopic persistent tumors, respectively. In univariate analysis, stage and node status according to the lymphography were prognostic factors. A multivariate analysis should be presented.

Conclusion: histological sterilization after irradiation appeared as a favorable prognostic factor.

1178 POSTER

## A PHASE II STUDY OF CPT 11 (IRINOTECAN) IN CHEMOTHERAPY NAIVE PATIENTS WITH ADVANCED CANCER OF THE CERVIX UTERI (C.C.U.)

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Patients with advanced C.C.U. without prior therapy have been treated with the new DNA topoisomerase I inhibitor CPT 11 350 mg/m² q 3 w. Patients were stratified depending on whether all the target lesions were within a field of prior radiation therapy (group B) or not (group A).

Criteria of Inclusion: Age  $\leq 75$ ; WHO PS 0-2; ANC  $> 2 \times 10^9$  platelets  $> 100 \times 10^9$ , creatinine  $\leq 130 \ \mu ml/l$ , bilirubin  $\leq 1.25 \ N$ , Transaminases  $\leq 2 \ N$  (except in case of liver metastases), presence of at least one measurable lesion.

Characteristics: 42 patients have been enrolled to date (median age 48 (30-71); median number of involved organs: 1(1-3) with primary in 46%, lung in 22%, liver and bone in 8% of patients. 27 patients were in group A and 15 in group B.

Efficacy: (Preliminary Results) CR: 1, PR: 4, the five responses have been observed among the 21 evaluable patients of group A (24%).

Safety: The following WHO grade 3-4 toxicities have been reported (% of patients): neutropenia: 27%, (with febrile neutropenia and/or sepsis in 8%), delayed diarrhea: 33%, nausea/vomiting: 30%, alopecia: 32%. One toxic death occurred due to severe diarrhea, neutropenia and sepsis.

Conclusion: The most concerning toxicity is the combination of severe diarrhea and neutropenia. Since these two toxicities are probably favourized by abdominopelvic radiotherapy, a special attention should be paid to patients with extended fields. CPT 11 appears an effective drug in not pretreated C.C.U.

1179 POSTER

## PROGNOSTIC FACTORS AND PATTERNS OF FAILURE IN STAGE I ENDOMETRIAL CARCINOMA TREATED WITH ADJUVANT RADIOTHERAPY

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Institute of oncology and radiology of Serbia, Belgrade, Yugoslavia Purpose: To evaluate the therapeutic outcome of patients with high-risk for recurrence, to describe patterns of failure as well as other important pretreatment and treatment factors which can influence to improve control and lengthen survival. Methods: From 1989 to 1990, 213 patients with endometrial carcinoma with high-risk attributes and disease confined to pelvis were prospectively treated with adjuvant pelvic radiation. The median age was 59.2 years. The Figo/1988/stage distribution was as follows: Ib/G2-G3/ = 61, Ic/G1-G3/ = 83, IIa/G1-G3/ =10, IIb/G1-G3/ = 14, IIIa/G1-G3/ = 6, unknown stage /G1-G3/ = 39. All patients were treated with combined /EBRT/ICBHTR/radiotherapy. The treatment was tailored to the known prognostic factors: grade 1 and greater than 50% myometrial invasion, grade 2 and 3 with less (33%) or greater than 50% myometrial invasion and involvement of the isthmus/cervix. Results were analyzed for specific, and relapse-free survival. Results: Overall 5 year survival was 79%. Five-year specific survival/5 yrs/per stage was 86% in stage Ib, 79% in Ic, 82% in IIa, 72% in IIb and 43% in IIIa. Figo substage in addition to depth by thirds  $|\leq 2/3|$  vs >2/3/grade/1 vs 2 or 3/ age  $|\leq 55$  vs >55/ were predictive for 5 years in univariant analysis. 5-year specific survival decreased with increasing grade and substage from 89% for grade 2 and substage Ib to 70% for grade 3 and substage Ic. p < 0.001 the cervix invasion was more often associated with grade 3 /56% vs 21%/ and deep myoinvasion /64% vs 30%/ than cases without cervix invasion. 5-year relapse-free survival was 78%; 22% relapse, of which 19% distant and 3% local relapse. Multivariant analysis of the above factors revealed Figo stage in addition grade, age and depth by thirds to be independent predictors of outcome. Conclusion: Patients with high risk attributes demonstrated to have disease confined to the pelvis can achieve exellant local-free survival following adjuvant pelvic radiation. However, prospective randomized trials in the same subset of high risk patients, employing adjuvant cytotoxic chemotherapy, hormonal therapy and/or whole abdominal-pelvic radiation should be considered in an attempt to improve survival.

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## A PHASE II STUDY OF GEMCITABINE IN ADVANCED CERVIX CARCINOMA

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In a phase II study in patients with locally advanced (Stage IIIB) and metastatic (Stage IV) histologically proven cervix carcinoma, gemcitabine was given at a dose of 1250 mg/m<sup>2</sup> weekly for 3 weeks (days 1, 8 and 15 followed by 1 week of rest), these 4 weeks constituting 1 cycle of chemotherapy. The patients were chemonaive, had adequate bone marrow reserves, liver and kidney function and bi-dimensionally measurable disease, pelvic disease being measured by means of magnetic resonance imaging. To date, 42 patients have been entered into the study and the data for the first 30 patients is available for analysis. Of these 30 patients, 28 are evaluable for efficacy analysis, having received at least 3 doses of gemcitabine within the first 7 weeks of study participation. 2 patients were not evaluable for efficacy because they did not receive 3 doses of gemcitabine. The average age of the patients was 50 years (29-64 years) and the proportion of stage IIIB and stage IV disease was 53% and 47%, respectively. A partial response has been confirmed in 5 patients giving a response rate of 17.9% (5/28). All 30 patients were evaluated for toxicity. The respective WHO grade 3 and 4 toxicities were: leukopenia 10%