marrow status (P= 0.054). The median distant disease free survival was 78 months (73 82, 95% CI) in patients with negative, and 72 months (61 82) in patients with positive bone marrow status (P= 0.051). Multivariate analysis revealed the presence of ITC as significant, independent risk factor for the subsequent development of distant metastases (relative risk 3.6, P= 0.046).

Despite the locoregional predominance of cervical cancer at the time of primary diagnosis, the presence of ITC in the bone marrow is frequent and indicates an increased risk for the development of distant metastases. This information may prove useful to stratify patients for systemic treatment.

161 POSTER

Radical pelvic radiation for uterine cervix cancer in the elderly

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Radical radiation treatment in the elderly remains a controversial issue. A sufficient number of recent references confirms comorbidity but not age itself as a limiting factor of both radio and chemotherapy. Upon the analysis of our historical group of patients with uterine cervix cancer we have tried to examine whether radical pelvic radiation in elderly patients could be advocated, whether it had the same effect and whether it did not compromise the patient status. 2 272 patients with uterine cervix cancer have been treated at the Institute of Radiation Oncology, Prague, Czech republic in the period 1972-1990. Median age was 56 years (18-89) (s=13,6). 1033 of them were eligible for a retrospective analysis i.e. there was a continuous evidence of their status within 5 years after their treatment. This group consisted of 111 pts. more (elderly) and 922 less (younger) than 70 years old at the time of treatment onset. There was a good correlation of disease stage between these subgroups (χ^2 = 5,47) (In the elderly: stage IA 1 pt., IB 18 pts., IIA 9 pts., IIB 38 pts., IIIA 5 pts., IIIB 30 pts., IV 11 pts.). All patients have been radically treated by a combined radiation therapy (40-48 Gy, Linac, Co and 30-35 Gy brachytherapy), predominantly by less sophisticated techniques than current patients (including 2 opposed fields technique). The retrospective data were not sufficient to provide reproducible information on late effects of therapy. However there are reliable data on mortality related to cancer.

The cause of mortality within 5 years after treatment - related vers. not related to cancer - was not significantly influenced by the age (p=0,141). Moreover the probability of death within 5 years related to cancer was very similar in both subgroups (0,32 younger vers. 0,39 elderly, p=0,58). There were no severe or lethal complications of radiotherapy. There was no significant difference between younger and elderly in survival time of those, who died for either reason within 5 years (20 vers. 18 months, p=0,805). The 5 year survival rate was 62% and 48% for younger and elderly patients respectively. These results confirm the age itself does not influence the natural history of the disease and the effects of pelvic radiation. Therefore radical radiation therapy should be administered in elderly patients except cases with a substantial comorbidity.

162 POSTER

Significant impact of integrin beta-3 expression in cervical cancer treated with radiotherapy +/- chemotherapy

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Objective: To investigate the prognostic role of integrin beta-3 (b3) expression in patients with cervical cancer (cCa) treated with radiotherapy ± chemotherapy.

Patients and Methods: Eighty-two biopsy specimen from locally advanced cCa patients (median age: 63yrs) could be evaluated in regard to integrin beta-3 expression by immunohistochemistry (- / + / ++). All patients were treated with radiotherapy (median total dose: 69Gy), in 27 patients combined with cisplatin ± 5-FU. Mean follow-up was 41 months.

Results: Thirty-two out of 82 (39%) primary tumors were 'negative', 50 (61%) were 'positive' ('+': n=31; '++': n=19) for beta-3-expression. The actuarial 5-yrs-local-progression-free-survival difference was statistically significant (p=0.002) with 85% for 'negative' patients and 51% for 'positive' patients ('+': 46%; '++': 56%). The corresponding values are 85% vs 57% ('+': 67%; '++': 50%) for distant-metastasis-free-survival (p=0.037) and 78% vs 41% ('+': 44%; '++': 39%) for cause-specific-survival (p=0.013).

Conclusion: For the first time we could demonstrate that integrin-beta-3-expression offers the possibility to stratify between different risk profiles in patients with cervical cancer.

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Capecitabine chemoradiation for stage II B- III B cervical cancer: preliminary phase I results, Mexican Oncology Study Group.

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Background: cisplatin (DDP) and radiotherapy for advanced locoregional cervical cancer has been adopted in many centers as standard first line treatment. However, toxicity and the need for weekly inpatient iv infusion makes DDP an inconvenient and intermittent radiosensitiser. Capecitabine (X) is an oral fluoropyrimidine which mimics continuous 5-FU infusion through twice-daily administration. Final conversion of X depends on thymidine phosphorylase (TP). Levels of TP are 5 times higher in cervical tumor cells compared with normal tissue and radiotherapy upregulates TP activity in tumor but not in healthy tissue. X dose with pelvic radiotherapy has been defined in phase I trials for rectal cancer, but fields, dose and local tissue toxicity differ in cervical cancer thus we performed a phase I trial.

Materials and methods: we escalated X to determine the maximum tolerated dose with simultaneous standard pelvic radiotherapy (1.8 Gy/day x 5/week total 4-field external dose 45 Gy followed by brachytherapy). X was administered twice daily, 5 days a week.

Results: to date, 21 patients with squamous cell cervical cancer, stage IIB 15, IIIB 6, median age 51 years (range 39-66) have been treated at: 2x250 mg/m^2 (n=4), 2x375 mg/m^2 (n=4), 2x500 mg/m^2 (n=4), 2x650 mg/m^2 (n=3), 2x825 mg/m^2 (n=6). Mild toxicity was: diarrhea 15 pts, stomatitis 2 pts, hand-foot syndrome 1 pt, vomiting 2 pts, external skin and vulvar dermatitis 3 pts, cystitis 3 pts, neutropenia 1 pt, thrombocytopenia 1 pt, liver ALT/AST rise 3 pts. The only dose-limiting toxicities (one patient with grade 3 ALT rise and one patient with bilirubin grade 2 rise for more than 1 week) were reached at a dose level of 2x825 mg/m^2. Three more patients are still under treatment for this dose level 2x825 mg/m^2. Twelve pts are currently evaluable for response: 10 CR with a median DFS of 5.5 months; one PR and one progression.

Conclusions: X can be safely administered concurrently with radiotherapy in cervical cancer with encouraging early efficacy results. X is a particularly convenient option for chemoradiaition and the final safe dose will be tested in a phase II study by MOSG.

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Primary therapy of ovarian cancer with Paclitaxel/Carboplatin/Gemcitabine (TCG): a Phase II Study (Ovar-8 protocol)

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Introduction: The addition of a third, non-cross-resistant substance to Paclitaxel (T) and Carboplatin (C) might be considered as a method to improve the primary therapy of ovarian cancer. In preparation of a phase III study (*Ovar-9*), the addition of Gemcitabine (G) was tested under a multicenter, non-randomized 2-cohort study.

Methods: In the period from October 2000 until July 2002, the study included 55 female patients with a median age of 54 years (range 25-73). After the first operation of a primary ovarian cancer (FIGO Ic- IVa), they were treated with a combination of T (175 mg/m^2 3 h IV on day 1), C (AUC 5 IV on day 1) and G (800 mg/m^2 IV on days 1+8), q 3 weeks. G wasn't applied in the first cohort with ANC <1000/µl and in the second cohort with WBC <1500/µl on day 8 (dosage level -1). A prophylactic dose of G-CSF wasn't required in the protocol. The toxicity was recorded according to NCI-CTC and response was assessed per the RECIST (response evaluation criteria in solid tumors) criteria.

Results: The toxicity data of 52 female patients (261 cycles) were assessable. 40 women were assigned to the cohort 1 and 15 to cohort 2. As haematological toxicities of grade 3/4 in % of cycles occurred: anaemia 3.8/0, thrombocytopenia 11.8/1.5, leucopoenia 31.4/ 3.4 and febrile neutropenia 0.4/0. As non-haematological toxicities grade 3/4 were