32), IVA (n = 8) and IVB (n = 4). Pelvic lymph nodes were present in 24 pts. Squamous cell carcinoma were: grade 1 (40%), 2 (19%) and 3 (41%). Pelvic external beam therapy (EBT) was performed in 99 pts (median total dose = 50 Gy (9–50)) and low dose rate brachytherapy (BT) in 86 pts. BT was delivered in one time (n = 72), 2 times (n = 13) or 3 times (n = 1). Intracavitary irradiation using personalized mould was associated with iridium implants in 32 applications. The median number of sources used for one application was 3 (1–6) with a median total radioactive length of 115 mm. Surgery and chemotherapy were performed in 7 and 5 pts.

Results: Late toxicities were (Franco-Italian Glossary): rectum: grade 1 (n = 8), 2 (n = 8), 2 (n = 0), 3 (n = 1), sigmoid: grade 1 (n = 6), 2 (n = 4), 3 (n = 1), bladder: grade 1 (n = 17), 2 (n = 5), 3 (n = 1), and ureter: grade 1 (n = 2), 2 (n = 1), 3 (n = 1). Response rates after EBT evaluated at the time of BT were: complete response (20%), partial response (57%) and stability (23%). Three months after treatment, complete response rates were 90% for stage I, 90% for stage II, 68% for stage III and 25% for stage TV. The 5-year overall survival rates were: 65% for stage I, 62% for stage II, 35% for stage III and 15% for stage IV. The pattern of failure (first event) were: in the pelvis only (61%), metastatic only (23%) and combined (16%). In a univariate analysis, the age of pts, the stage of tumours, the response to EBT and the duration of treatment were significantly associated with the survival ($p \leq 0.05$).

Conclusion: EBT combined with BT is an effective treatment for pts with PVSCC, particularly Stage I and II. The incidence and severity of late toxicity were relatively low with the use of a customized vaginal mould. The low local control rates in Stage III and IV, and the recent data concerning the treatment of cervix carcinoma suggest the interest of a concomitant radio-chemotherapy in the treatment of PVSCC.

1220 POSTER

Evaluation of morbidity after external radiotherapy and intracavitary brachytherapy in patients with carcinoma of the uterine cervix or endometrium

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Early and late radiation morbidity were evaluated according to the RTOG criteria in 771 cervical or endometrial cancer patients who were treated with external radiotherapy (ERT) and intracavitary brachytherapy.

Daily ERT dose was 1.8 Gy.Midline shielding was performed at 50.4 Gy.Total ERT dose was 54 Gy in operated patients and 59.4 Gy in inoperable patients.One fraction of 9.25 Gy was applied to 5-7 mm from the vaginal surface in operated patients and two fractions of 8.5 Gy at weekly intervals were applied to point A in inoperable patients via microSelectron-HDR machine.Four-hundred-seven patients had endometrial cancer and 364 patients had cervical cancer. Two hundred-ten cases with cervical carcinoma had been operated.In patients with endometrial carcinoma total doses at vagina, bladder and rectum were 60.36 Gy, 56.2 Gy and 55.6 Gy respectively. BED for the same points were 79.35, 68.63 and 67.37 respectively for early effects and 123.67, 97.65 and 94.85 for late effects. Acute morbidity rate was 41.5%.Ninety-two patients had grade I,42 had grade II,1 had grade III bladder morbidity;25 had grade I,4 had grade II and 1 had grade III rectal morbidity. Late morbidity rate was 20.9%.Five patients had grade I,11 had grade II,1 had grade III bladder morbidity;2 had grade I,8 had grade II and 2 had grade III rectal morbidity;24 had grade I, 28 had grade II and 4 had Grade III vaginal morbidity.Total doses at vagina,bladder and rectum in operated patients with cervical cancer were 60.51 Gy, 56.53 Gy and 55.67 Gy respectively.BED for the same points were 79.77, 69.36 and 67.52 for early effects; 124.74, 99.3 and 95.17 for late effects. Early morbidity rate was 38.1%.Forty patients had grade I,26 had grade II bladder morbidity;4 had grade I,5 had grade II rectal morbidity and 5 had grade I vaginal morbidity.Late morbidity rate was 30.9%.Five patients had grade I,8 had grade II,2 had grade 3 bladder morbidity;2 had grade I,4 had grade II and 2 had grade III rectal morbidity;19 had grade I,17 had grade II and 6 had grade III vaginal morbidity.Total doses at vagina, bladder and rectum in inoperable patients were 70.92 Gy, 66.71 Gy and 62.38 Gy respectively.BED for these points were 97.43, 89.64 and 81.63 respectively for early effects and 159.3, 143.16 and 126.56 for late effects.Acute morbidity rate was 39% being mostly (95%) grade I or II bladder morbidity.Late morbidity rate was 61.7% being mostly (94%) grade I-III vaginal morbidity.

1221 POSTER

The significance of DNA ploidy, proliferative activity, status of mutant p53 and human papillomavirus type 16 and 18in cervical carcinoma treated by irradiation

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Purpose: To investigate mutual correlation among DNA ploidy, S-phase fraction (SPF), mutant P53, human papillomavirus (HPV) type 16 and 18 and their impact on complete remission (CR), 2 year relapse free (RFS) and 5 year overall survival (OS) rates.

Methods: Archival specimous from 75 irradiated only patients with cervical carcinoma were collected. All patients had a minimum follow-up period of 5 years. Polymerase chain reaction (PCR) and flow cytometry were used to identify the status of HPV 16, 18 and DNA ploidy as well as proliferative activity (SPF with a cut-off value of 10). The semi-quantitative approach was used to identify the presence of mutant P53. The immunohistochemical staining reaction of formalin-fixed, paraffin-embedded specimen was evaluated by assessments of the overall staining intensity and by the fraction of stained cells in percentage categories.

Results: Correlation between potential biologic markers and clinicopathologic factors and treatment outcome revealed that aneuplovd pattern related significantly to a high value of SPF 10 (p = 0.001) which in tern related to a high proportion of positive HPV 18 (p = 0.037) but a relatively low CR rate (p = 0.047). The presence of mutant P53 had no direct impact on pathology, (0.729), stage (p = 0.570), DNA ploidy (p = 0.723), SPF 10 (p = 0.724), HPV 16 (p = 0.113), HPV 18 (p = 0.528) and 5 year OS (p = 0.374). Both of positive HPV 16 and 18 relate to more advanced clinical stage (p = 0.007 and 0.005) while only positive HPV 18 showed a higher proportion of patients with poorly differentiated squamous cell carcinoma & decreased 5 years OS rate comparing to HPV 18 (-) patients (p = 0.0372).

Conclusion: None o f mutant P53, DNA ploidy and HPV 16 showed significant correlation to clinical CR rate, 2 year RFS and 5 year OS. Both of HPV 18 and SPF affect treatment response while only a low SPF predict independently a high CR rate.

1222 POSTER

Phase II study of capecitabine (C) in patients with metastatic squamous cell carcinoma of the cervix (SCCC)

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Aim: The efficacy of C correlates with the level of thymidine phosphorylase activity (key enzime of C's metabolism). The highest thymidine phosphorylase activity is registered in SCCC tissue.

Patients and methods: Pts with histological verified metastatic SCCC; measurable disease outside irradiated fields; WHO PS < 2; radiotherapy allowed if finished > 3 months, no more than 2 lines of palliative chemotherapy (CT); adequate liver, renal, hematological functions.

Treatment: Therapy consisted of C 2 500 mg/m2/day, d1- d14, q 3 weeks (1- 8 cycles). Total number of cycles: 72. Median duration of treatment: 7 weeks (min - 3, max - 28).

Results: 25 pts have been accrued; results on 24 pts are available. Pts characteristics: median age 44.6 (25-70); median WHO PS - 1.

Previous treatment: none - 2 pts, radiotherapy - 11 pts, surgery+radiotherapy - 12 pts, CT - 15 pts, CT-naive - 10 pts.

Overall RR - 4/24 pts (17%) (CR-2, PR-2), NC -10/24 pts, PD -10/24 pts. Duration (in months) of CR: 2+ and 7+, of PR: 4+ and 5+; median duration of NC: 2.5. Three of all responsive pts were CT-naive.

All pts were evaluable for toxicity exept 1 (lost for follow-up after 1 cycle). Toxicity included: hand-foot syndrom: G3 - 1/24 pts (1.5% of cycles); G 1-2 - 11/24 pts (43% of cycles); G 1-2 diarrhea: 5/24 pts(7% of cycles); G 1 stomatitis: 4/24 pts(6% of cycles); G 1-2 nausea: 10/24 pts (25% of cycles); G 1-2 asthenia: 12/24 (29% of cycles); G1 dermatitis: 1/24pts (3% of cycles).

Conclusions: C is well tolerated and clinically active cytostatic agent in CT-naive pts with metastatic SCCC.