Results: Median age was 59 years (range 35–78) for cohort 1 and 57 years (range 35–83) for cohort 2. Median ECOG PS was 1 (range 0–3) for cohort 1 and 0 (range 0–1) for cohort 2. The median number of prior chemotherapy regimens was 5 for both cohorts. 60 pts. in cohort 1 and 62 pts. in an interim analysis of cohort 2 were evaluable for response. There were a total of 5 objective partial responses (PRs) (RR = 4%), 2 in cohort 1 and 3 in cohort 2. 7 pts. (6%) had SD with CA-125 reduction of ⩾50% (4 in cohort 1, 3 in cohort 2). An additional 3 pts (2%) had SD for ⩾6 months (all in cohort 1, cohort 2 data still premature). Overall rate of activity = 12%. Overall median time to progression (TTP) was 6.6 weeks (7.0 weeks in cohort 1, 6.6 weeks in cohort 2). Of the 65 tumor biopsies from cohort 1, 31 were evaluable and 8 (26%) were positive for pHER2 by ELISA. TTP for pHER2+ pts. was 20.9 weeks (n = 8), compared to 6.0 weeks for pHER2 – (n = 23), and 9.1 weeks for unknown pHER2 status (n = 29). P was well tolerated with diarrhea in 61% of pts (grade 1–3) (57% in cohort 1, 65% in cohort 2). 5 pts. had a drop in ejection fraction to <50% with 1 confirmed by a central facility.
Conclusions: As a single agent P is well tolerated. Clinical activity was observed in 12% of pts with heavily pretreated OC as demonstrated by PRs, SD ⩾6 months, and SD with CA-125 reductions of ⩾50%. This study suggests P may be active in OC. Preliminary analysis suggests pHER2 status may be important for P activity.

904 ORAL

Adjuvant treatment of early stage cervix cancer: a systematic quantitative review

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Background: Patients with early stages cervix cancer (IA_2-IIA) with postoperative findings of lymph node metastasis, lymphovascular space invasion, depth of invasion more than 10 mm, parametrial invasion, non-squamous histology, or positive surgical margins are at increased risk for subclinical dissemination of the disease. Postoperative radiotherapy has been found to decrease the incidence of local recurrence with little or no effect on overall survival. This review has been undertaken to assess the available evidence for adding chemotherapy to radiotherapy in the adjuvant treatment of those patients.
Material and methods: We have searched the Cochrane Library, CENTRAL, MEDLINE, EMBASE, LILACS, Biological Abstracts, CINAHL, SciSearch and Cancerlit. We have handsearched the congress proceedings of cancer societies. All randomised controlled trials comparing postoperative chemotherapy and radiotherapy (intervention group) with postoperative radiotherapy alone (control group) in the treatment of stages IA_2-IIA cervix cancer were included. Outcome measures were overal survival, progression-free survival, local recurrence, distant recurrence, major treatment toxicities (grades 3 and 4) and quality of life.
Results: We found 10 randomised controlled trials, but only two met the selection criteria, including a total of 314 patients. Overall survival: Patients in the intervention group had a significantly reduced hazard of death in 48 months (HR 0.43, 95% CI 0.25 to 0.76). Progression-free survival: At 48 months the hazard ratio was estimated to be 0.45 (95% CI 0.28 to 0.74). Local recurrence: At 48 months, there was less local recurrence in the intervention group (HR 0.50; 95% CI 0.26 to 0.98). Distant recurrence: There was no difference between the intervention and the control groups in the hazard of distant recurrence at 48 months (HR 0.74; 95% CI 0.36 to 1.52). Major toxicities: The odds for grade 3 and 4 major toxicities was significantly higher in the intervention group (Peto OR 5.19 [95% CI 2.90 to 9.29] and 4.62 [95% CI 1.96 to 10.86], respectively). We were unable to obtain data about quality of life.
Conclusions: In this systematic review, the overall evidence suggests that the addition of chemotherapy in the adjuvant treatment of early stage cervix cancer with risk factors for recurrence provides clinical benefit. However, the evidence is limited because the selected studies were quantitatively and qualitatively limited, with small number of patients and limited time of follow-up. There is a need for further randomised controlled trials to compare adjuvant chemotherapy and radiotherapy with adjuvant radiotherapy alone in the treatment of early stage cervix cancer with risk factors for recurrence. This review is registered in the Cochrane Gynaecological Cancer Group (H011).

905 ORAL

A randomized phase III trial of concurrent chemoradiation in locally advanced cervical cancer: preliminary results

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Background: Concurrent chemoradiation by platinum based is the standard treatment for locally advanced cervical cancer. Carboplatin is platinum analogue which has comparable activity with cisplatin. 5FU is the drug that has synergistic effect with radiation. The therapeutic index of 5FU is improved when given as a continuous intravenous infusion. Tegafur-Uracil (UFT®) is an oral chemotherapy which is recommended to replace the continuous intravenous infusion of 5FU as a radiosensitizer. This study was a preliminary result of a randomized two arms, prospective, open-label phase III trial comparing the activity and safety of the concurrent chemoradiation of UFT & carboplatin or carboplatin alone in locally advanced cervical cancer.
Materials and Methods: The stage IIB-IIIB cervical cancer patients were randomized to have UFT 225 mg/m^2/day orally and carboplatin 100 mg/m^2 IV over 30–60 minutes, weekly on day 1 concurrent with standard radiotherapy (UFT group) or carboplatin alone concurrent with standard radiotherapy (control group). In UFT group, UFT was taken in 3 divided doses daily at the same day of radiotherapy, 5 days a week and stopped on weekend. The tumor response and toxicity were evaluated weekly during treatment, 1 month interval for 3 months and 3–6 months for 5 years.
Results: From July 2001 to December 2003, 469 patients were randomized to UFT group (n = 234) or control group (n = 235). There was no significant imbalance in patient characteristics. The treatment interruption and the dose modification were nearly the same in both groups. The tumor response at 3 months follow up time was no significant difference. The only prognostic factor to improve the complete response rate was the hemoglobin (Hb) level. The patients in UFT group who had Hb < 10 gm/dl had the relative risk to complete response 1.48 compared to that in control group (P = 0.025, 95% CI 1.07, 2.04). The severe toxicity or adverse event had not been reported. The median follow up time for UFT group and control group were 12.6 and 11.8 months, respectively. There was no statistical difference in PFS and OS.
Conclusion: Concurrent chemoradiation by UFT and carboplatin was not difference in tumor response rate or treatment toxicity compared to carboplatin alone. The combination drugs might have benefit in poor prognostic patients such as the baseline Hb < 10 gm/dl.

906 ORAL

A differential gene expression profile reveals RUNX1/AML1 and ERM/ETV5 up-regulation correlating to infiltration stages in endometrioid endometrial carcinoma

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Background: endometrial cancer (EC) is the most common gynaecological cancer in industrialized countries. Among the different subtypes, type I or endometrioid EC (EEC) represents the 80% of its incidence. It is associated with oestrogen exposition and affects mainly peri- and post-menopause young women. Good prognosis is related with early diagnosis and uterus localization. In this context, myometrial affectation as the initial event of tumour invasion and distant dissemination, determines an increase in recurrences after a first surgical treatment, and a decrease in the five years survival. Studies focused on the molecular basis of EC have demonstrated correlations among molecular alterations (PTEN gene silencing, microsatellite instability associated with defects in DNA mismatch repair genes, or mutations in the K-ras gene) and tumour progression, its molecular pathology remaining essentially unknown.
Material and methods: identification of molecular factors responsible of endometrial tumorigenesis by cDNA microarrays. Validation of the candidate genes by Real-Time quantitative PCR and tissue arrays.