87 POSTER

## EFFECTS OF PROPHYLACTIC CRANIAL IRRADIATION (PCI) IN SMALL CELL LUNG CANCER (SCLC); RESULTS OF UKCCCR/EORTC RANDOMISED TRIAL

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This multicentre randomised trial was designed to assess the effect of PCI on survival, appearance of cranial metastasis and cognitive function in patients with limited disease and complete response (CR) to induction treatment. At the time of the abstract submission 299 of the planned 300 patients have been randomised. Ninety-seven patients undergone prospective neuropsychometric assessment. All patients received initial chemotherapy and 84% also had thoracic irradiation. Median age at the time of randomisation was 60 (range 28–79) and 64% were male. The current median survival from randomisation is 10 months (95% confidence interval 9–12 months) with estimated survival 43% at one year, 23% at 2 years and 18% at three years from randomisation. Sixty-four patients have been reported as having cranial relapse, KM estimates being 29% at one year, 37% at 2 years and 42% at 3 years from randomisation. The analysis presented at the meeting will include comparisons of rates of survival, cranial metastases and cognitive function between the randomised PCI or no PCI groups at a time when the trial will have been closed for 6 months and 90% of patients will be more than 1 year from randomisation.

88 POSTER

## MVP (MITOMYCIN-C, VINBLASTINE AND CISPLATIN) CHEMOTHERAPY IN SMALL CELL LUNG CANCER (SCLC)

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Combination chemotherapies in SCLC produce response rates of 70% + but toxicity may be severe and the overall relapse-free survival rate is just 10–20%. MVP chemotherapy (Mitomycin-C 8 mg/m$^2$, courses 1, 2, 4 and 6, Vinblastine 6 mg/m$^2$, Cisplatin 50 mg/m$^2$) is an active low toxicity regimen in non-SCLC (Ellis *et al.* 1995). We now report the results of our phase II trial of MVP in 50 chemo-naive patients (pts) with SCLC. There were 33 men and 17 women with median age 66 years (range 46–83 years); 18 pts had limited disease (LD) and 32 extensive disease (ED). WHO PS was as follows: 3 pts PS 0, 33 pts PS 1, 10 pts PS 2, 4 pts PS 3. A maximum of 6 cycles were given in responding patients. On completion of chemotherapy pts with LD obtaining CR/good PR received thoracic irradiation and those obtaining CR were offered entry into the ongoing MRC PCI trial. The overall response was 79% with 17% CR and 62% PR. For LD pts there were 38% CR and in ED only 1 pt achieved CR. Median response duration for LD pts was 8 months and for ED pts 5 months. Median survival was 10 months for LD pts and 6 months for ED pts. There was complete resolution of symptoms in 24%, partial improvement in 68%, no change in 2% and progressive symptoms in 6%. Toxicity: 24% developed WHO grade 3/4 neutropenia, 16% grade 3/4 thrombocytopenia, and 6% significant hair loss. Two pts died during the first week of treatment with neutropenic infection. Quality of life using the EORTC questionnaire (QLC-C30) with lung cancer module, demonstrated significant improvements from baseline levels in emotional and cognitive functioning, global QOL, of pain, dyspnoea and cough. MVP, an effective palliative regimen for non-SCLC, is also active against SCLC with low toxicity and merits comparison with more toxic conventional schedules.

89 POSTER

## SURGERY AND ADJUVANT THERAPY OF SMALL CELL LUNG CANCER

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In the course of 1957–1993, 1245 patients were treated surgically. In 87 cases undifferentiated carcinoma-small cell carcinoma, anaplastic was confirmed. Forty-five patients received adjuvant therapy: chemotherapy, radiotherapy. In the past three years two courses of chemotherapy were given before surgery. The operation is performed after 50% favourable response. In the cases when the diagnosis of small cell lung carcinoma was confirmed after the operation, the patients were treated with 4 courses of polychemotherapy. The patients with positive lymph nodes (N1 and N2) after chemotherapy receive radiotherapy. We have a control group of patients who did not received any adjuvant therapy (refuse of patients, surgical complications). The follow-up results were better in the group, which had received combined treatment. The best results were observed in the patients, undergoing lobectomy and receiving combined treatment: median survival was 30.3, months, control patients—18.2. In our experience, surgery can be used only in the cases of limited tumor (T1, 2N0 M0). After surgery chemotherapy must be used in all cases (both in negative and positive lymph nodes).

90 POSTER

## HIGH-DOSE SEQUENTIAL CHEMOTHERAPY (ICE) UNDER CIRCULATING PROGENITOR CELLS (CPC) PROTECTION IN PATIENTS WITH SMALL CELL LUNG CARCINOMA (SCLC). PRELIMINARY REPORT ON A MULTICENTRIC STUDY

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Starting in February 1994, 20 patients (pt) with a median age of 50 years (range 41–63) from 7 European centers have been included. Complete data were obtained in 16 patients so far. CPC were mobilized with chemo (Epirubicine 75 mg/m$^2$/d, D1 + D2) followed by G-CSF 5 μg/kg/d for 14 days. HD chemo consisted in 3 sequential courses of ICE regimen (Ifos. 10 g/m$^2$, Carbo. 1200 mg/m$^2$ and Etop. 1200 mg/m$^2$) under CPC protection and G-CSF 5 μg/kg/d. Out of the 16 pt, 12 completed full program (3 cycles). One pt died of septic shock before receiving any ICE course. One pt died during the first ICE of renal insufficiency. Two pt had only 2 courses because of toxicity. Among the 16 pt, response rate (RR) was: 7 CR, 6 PR, 1 PD; 3 pt are not evaluable due to early withdrawal (overall RR: 13/16 = 81%). Thirty-nine cycles of HD chemo were given with a median hematological recovery of 9 days (range 7–12) until neutro. counts > 1.0 × 10$^9$/l and 9 days (range 7–17) until thrombo. > 20 × 10$^9$/l. No cumulative, hematological toxicity was seen. Accrual of patients is still ongoing and updated results will be presented.

91 POSTER

## DELIVERED DOSE INTENSITY WITH AN INDUCTION CHEMOTHERAPY (CT) BY IFOSFAMIDE, ETOPOSIDE AND ANTHRACYCLIN FOR PATIENTS (PTS) WITH SMALL CELL LUNG CANCER (SCLC): A REPORT BY THE EUROPEAN LUNG CANCER WORKING PARTY

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We conducted a randomized trial comparing a maintenance CT versus a simple follow-up in SCLC pts having achieved a complete response after 6 induction CT courses, given at theoretical 3 week intervals, with ifosfamide (IFO) (1.5 mg/m$^2$ d1–3, iv), etoposide (VP) (80 mg/m$^2$ d1–3, iv) and, with a random allocation, epirubicin (EPI) (60 mg/m$^2$ d1) -IVE- versus adriamycin (ADR) (45 mg/m$^2$ dl) -IVA- in a first set of pts or epirubicin (60 mg/m$^2$ dl) -IVE60- versus epirubicin (90 mg/m$^2$) -IVE90- in a second set of pts. The mean absolute delivered dose intensities (ADI) of the anthracyclin in mg/m$^2$/week were as following:

| | First set | | Second set | |
|---|---|---|---|---|
| | IVE | IVA | IVE60 | IVE90 |
| At 3 courses | n = 47 | n = 47 | n = 55 | n = 54 |
| | 18.1 | 13.1 | 16.4 | 23.1 |
| At 6 courses | n = 40 | n = 37 | n = 41 | n = 38 |
| | 17.6 | 13.0 | 16.1 | 23.3 |

Each theoretical schedule was feasible as by Mann-Whitney tests, the distributions of the relative intensities were not statistically different. Comparisons of response rates at 3 courses and of overall survival curves by treatment arm were not statistically different in the 2 series of pts and remained not significant when stratified by relative global dose intensity. However, in responders to the induction CT, using a Cox model, administration of a maintenance CT as well as an increased ADI of the anthracyclin drug -with the equivalence of 60 mg epirubicin to 45 mg