1032 PUBLICATION

Neoadjuvant chemotherapy vs. radiotherapy alone for superior vena cava syndrome (SVCS) due to non-small cell lung cancer (NSCLC): Preliminary results of randomized phase II trial

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Background: Radiotherapy (RT) is the standard approach to SVCS due to NSCLC but promising results of cisplatin-based chemotherapy (CT) warrant their use as adjuncts in the management of such patients. Moreover, mass reduction induced by cytotoxic drugs could favours local-control of bronchogenic carcinoma by RT.

Methods: The trial design was as follows: arm A, RT alone with 60 Gy (stage III) or 45 Gy (stage IV) administered to the primary tumor, ipsilateral hilum, mediastinum, and supraclavicular areas; arm B, neoadjuvant QT (NCT) with up to 3 cycles of cisplatin (30 mg/m^2/d1–d3), epirubicin (90 mg/m^2/d1), and vinblastine (4 mg/m^2/d1 e d8), followed by the same RT plan and up to 3 additional CT cycles to responders. We intend to proceed partial analysis with 50 pts at all (end of first-stage of enrollment) but we antecipated it because of slow acrual.

Results: From 12/95 to 5/98 31 pts were randomized; 14 were assigned to RT and 17 to NCT. Both groups were balanced according to age, sex, Karnofsky performance status, histologic type, and stage. Treatment toxicity was more frequent in CT arm. With a median follow-up time of 16 weeks (range: 0–68), survival in arm A (12.4 wk) and in arm B (10.0 wk) was similar (logrank p = 0.62).

Conclusion: Additional follow-up time and recruitment is advisable but neoadjuvant CT seems not to confer survival advantage to NSCLC pts with SVCS.

1033 PUBLICATION

Docetaxel (D, Taxotere®) with concurrent radiation in locally advanced non-small cell lung cancer (NSCLC)

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Concurrent radiation and chemotherapy play an important role in the treatment of unresectable NSCLC. We performed a phase I/II study of D, 1 h i.v. infusion given at days 1, 8, 22, 29 with concurrent radiotherapy of 2 Gy, 5 days/wk for 5 wks.

Results: 42 patients (pts) entered the study, M/F ratio: 27/15, median age: 59 (41–71), median WHO PS: 1 (0–1), squamous/adeno: 18/21. 12 pts entered the phase I, the MTD was reached at D 40 mg/m^2, oesophagitis was the dose limiting toxicity. 30 pts have been treated in the phase II study with D 30 mg/m^2 as recommended dose. Among the 26 pts evaluable for response, an ORR of 57.7% (95% CI: 38.7–76.7) was observed including 6 Complete Responses and 9 Partial Responses.

	N = 30	95% CI
Median Survival Time (months)	15.9	[7.7–24.8]
1 year survival (%)	51.2	[30.4–71.8]
Median TTP (months)	8.4	[4.7–+]

No hematological toxicity was observed. Non-hematological toxicities: grade 1–2, dysphagia 100% of patients, grade 3–4:1 infection, 1 stomatitis, 1 myocardial infarction (recovered), 1 dyspnea, 1 nausea and 1 neuropathy.

Conclusion: D 30 mg/m^2 weekly for 4 weeks and 50 Gy of concomittant radiotherapy is effective and well tolerated. A randomized comparative trial is warranted.

1034 PUBLICATION

A retrospective survey of anemia in lung cancer (LC) patients receiving cytotoxic chemotherapy (CT)

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For the UK Anaemia Study Group.

Purpose: Anemia frequently occurs in cancer patients (pts) and can produce symptoms (eg, breathlessness, lethargy) that adversely affect the pts' quality of life. As part of an effort to determine the incidence of anemia in LC pts and to examine some factors that influence anemia, quantitative data were obtained on CT, hemoglobin (Hb) levels, transfusion (TF) requirements, and other parameters in LC pts receiving cyclic platinum-containing (PL) or non-platinum-containing (NPL) CT.

Method: Relevant data from the hospital records of 511 pts treated with PL-CT and 321 treated with NPL-CT were reviewed retrospectively. The LC pts were a subgroup in a previously reported survey of 2715 cancer pts with selected tumor types treated at 28 centers in the UK. The study period was from January 1994 to October 1997. Anemia was defined as Hb less than 11 g/dL.

Results: The prevalence of anemia (expressed as the percentage of pt-courses during which anemia was experienced) increased progressively from baseline rates of 14% for the PLC-CT group and 9% for the NPL-CT group to 50% and 49% for the respective groups at the start of cycle 6 of CT. Corresponding mean Hb levels were 12.8 (range, 7.4–18) g/dL and 13.2 (9.3–17.5) g/dL at baseline versus 11.1 (7.9–13.9) g/dL and 11.3 (7.3–15.5) g/dL at the start of cycle 6. The percentages of pts in each cycle who received TFs increased progressively from baseline to cycle 6, ie, from 6% to 29% in the PL-CT group and from 13% to 28% in the NPL-CT group. Anemia and TFs were associated with the duration of CT.

Conclusion: The results of this survey indicated that anemia frequently develops in LC pts receiving PL- or NP-CT and with repeated courses of CT.

1035 PUBLICATION

The value of cytokeratines as preoperative predictors of survival in NSCLC stages I and II

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Lung cancer is the malignancy which causes the highest number of deaths in the world today. Even if the patients are considered operable, less than half of these patients will be cured. The aim of this study was to investigate if preoperative cytokeratin levels in serum of patients could be used as tumormarkers with impact on survival.

Materials and Methods: In this study of 44 patients with NSCLC stage I and II, bloodsamples were collected preoperatively during February 1994 and February 1996. The median age of the patients was 64.2 years (range 39–80 years). The following cytokeratin ELISA tests were used: CK8/1, CK8/2, CK8/3 (three different epitopes of CK8); CK8/18, CK18 and CK19. The cytokeratin levels were included, one by one, in different multivariate analyses together with the clinical parameters gender, smoking habits, performance status, weightloss, histopathology and grade. The cytokeratin levels were considered as continuous variables in these analyses.

Results: During the follow-up time of 30–54 months, 24 patients (54%) died. In the two multivariate analyses in which CK8/18 respective CK18 were included together with the clinical prameters, the cytokeratin tests were the only statistically significant variables, p = 0.033 and p = 0.041, respectively. The other cytokeratin tests were, in this study, not statistically significant associated to survival.

Conclusion: The cytokeratin tests för CK8/18 and CK18 were statistically significant correlated to survival and may therefore be suitable as preoperative markers for identifying high risk patients among operated patients with NSCLC stages I and II.

1036 PUBLICATION

Phase I–II trial of carboplatin (CBDCA) an vinorelbine (VNR) in stage IV non-small cell lung cancer (NSCLC). A pilot study of Spanish Lung Cancer Group

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Aims: Both CBDCA and VNR are active as single agent in advanced NSCLC. Their cytotoxicity is mediated by different mechanism. Subjective toxicity is low and common secondary effect is myelotoxicity. CBDCA-VNR combination may have interest in palliative setting. Best CBDCA dosing is defined using AUC. This association needs to be explored in Phase I–II trial with dose-increasing levels trying to define MTD.

Study Design: Assess toxicity profile and activity. Analysis of VNR dose intensity (DI). Inclusion criteria: Stage IV, chemo-naïvew p, PS 0–1, adequate bone marrow, hepatic and renal functions, informed consent. Symptomatic