Actuarial distant failure rate at 2-year was strongly influenced by negative biopsy (43.5% vs. 81.3%, $P < .0001$). In conclusion, 2-year survival after concurrent chemoradiotherapy for stage III NSCLC is favorably influenced by the addition of etoposide to cisplatin and a negative biopsy is highly predictive for long-term survival.

1055 ORAL

FROM THE RESULTS OF THE META-ANALYSIS EVALUATING THE ROLE OF CHEMOTHERAPY IN NON-SMALL CELL LUNG CANCER (NSCLC) TO THE IALT PROJECT

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A recent meta-analysis using individual data from 54 trials included more than 9000 NSCLC patients in three adjuvant settings (surgery ± chemotherapy (CT), surgery + radiotherapy (RT) ± CT, radical RT ± CT) and in the supportive care setting. Of the 14 trials analysing the first adjuvant setting, only 7 including 1062 patients, used a cisplatin-based regimen. Even if the CT protocols would be now considered suboptimal, the results suggested a relative benefit of CT of 13% in terms of death reduction. This is equivalent to an absolute improvement of survival of 5% at 5 years (from 47% to 52%). Chemotherapy after curative resection of NSCLC could therefore improve survival. The main objective of IALT is to evaluate the effect on overall survival of 3 or 4 cycles of cisplatin-based CT at a dose ranging from 80 to 120 mg/m^2 combined with a vinca-alkaloid or etoposide compared with no adjuvant CT in stage I to IIIA completely resected lung cancer. This hypothesis deserves to be tested in a large-scale trial in order to obtain clear evidence on the value of adjuvant CT. With widespread collaboration, it will be possible to include the necessary 3000 patients for randomisation in only a few years.

1056 ORAL

PRE-THROMBOTIC STATE IS A STRONG UNFAVORABLE INDICATOR OF LUNG CANCER (LC) PROGNOSIS: RESULTS FROM A PROSPECTIVE STUDY

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Both experimental and clinical data indicate that coagulation disorders may affect patients with cancer, even though clinical symptoms occur in a very small percentage of subjects. Prothrombin Time (PT), Partial Thromboplastin Time (PPT), Anti-Thrombin III (AT-III), Platelet Count (PC), Fibrinogen (F), and D-Dimer (DD) were prospectively recorded from a series of 287 consecutive patients with a new primary LC. Other variables (in all, 39) included anthropometric, clinical, physical, laboratory, radiological, and pathologic tumour findings, as well as the subsequent clinical course. Spearman rank correlation between coagulation factors were weakly significant, or, more often, nonsignificant (the correlation index between PT and PTT, the best one, was −0.25, P= 0.0000). Univariate survival analyses showed that lower values of PT (P = 0.003), and PTT (P = 0.06), and higher values of F (P = 0.001) and DD (P = 0.00002) were all associated with a poor prognosis. Few, weak correlations between other well-established prognostic variables (stage of disease excluded) and coagulation factors were found. Because of the weakness of this correlation pattern, coagulation factors resulted as important independent survival predictors in any of the Cox' model regression analyses attempted, whatever the number of co-factors was.

1057 ORAL

THE HEALTH ECONOMICS OF LUNG CANCER AND AN ESTIMATE OF THE COST EFFECTIVENESS OF SINGLE AGENT GEMCITABINE IN STAGE IV NSCLC

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Statistics Canada has developed a model for costing lung cancer management and evaluating the cost-effectiveness of new therapeutic interventions, based on Canadian practice. This costing model was used to compare costs of gemcitabine versus best supportive care (BSC) (no chemotherapy) for stage IV NSCLC. Gemcitabine costs are based on chemotherapy preparation time, nursing administration time, cost of all supplies, clinic visits, and nursing and physician assessments for gemcitabine administration assuming a weekly × 3 treatment schedule every 4 weeks. As the price of gemcitabine has yet to be determined, a variety of costs per cycle were used ($Cdn 1,000–1,800). The hospitalization costs for BSC were based on the NCIC BR5 trial of BSC versus chemotherapy. The 1993 cost for the BSC arm (including terminal care) was $Cdn 20,914. The incremental cost per case to manage with gemcitabine was $Cdn 1258 (assuming $Cdn 1000 per cycle). The estimated cost per life year gained varied from $Cdn 3193 to 9529 depending on the cost of drug per treatment cycle. This high cost effectiveness is achieved in part because of the reduction in hospital days for terminal care in treated stage IV patients. The cost effectiveness analysis was repeated assuming lower survival. Cost effectiveness decreased, but even in the worst case scenario ($Cdn 1800/cycle; survival −50%), the cost per life year gained was still only $Cdn 16,230. Based on this model, gemcitabine therapy for advanced NSCLC is cost-effective over a range of costs per cycle even when sensitivity analyses are performed that reduce survival expectations.

1058 POSTER

A PHASE II EVALUATION OF BONE MARROW PROTECTION BY ETHYOL® (AMIFOSTINE)(AM) IN PATIENTS WITH NON-SMALL CELL LUNG CANCER (NSCLC) TREATED WITH CARBOPLATIN(C)

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Amifostine(Am), provided by US Bioscience, is a thiol compound which has been shown to protect normal tissues from alkylating agents without loss of anti-tumour activity. 21 patients (pts) with inoperable NSCLC were entered into a randomised phase II study to determine the extent and duration of bone marrow protection by Am and provide a preliminary indication of whether the given dose intensity of carboplatin(C) with Am (CAm-arm) produces a higher than expected therapeutic benefit. 2 pts had an ECOG = 0, 12 pts had ECOG = 1 and 6 pts had ECOG = 2. Median age for CAm-arm = 64 (Range 45–69), C alone (C-arm) = 61 (Range 41–70). All pts received C 600 mg/m^2 before being randomized to receive either 3 cycles of C or CAm at 28 day intervals. Originally pts received 3 infusions of Am 910 mg/m^2 at each cycle, but this was reduced to 683 mg/m^2 because of toxicities. All pts were evaluable for toxicity and 18 pts were evaluable for response. 21 courses of CA-arm were compared with 25 courses of C-arm. Time to platelet recovery (> 100×10^9/l) (13.5 vs 21 days; P = 0.04) and need for iv antibiotics and hospitalisation were reduced in the CAm-arm (3% vs 23%; P = 0.03). Tumour response rates for CAm-arm (5/9 pts had PRs) and C-arm (2/9 had PRs) were 56% (95% CI = 21–86) and 22% (95% CI = 3–60), respectively. Median survival time for CAm-arm was 14 months and for C-arm was 9 months, suggesting that the combined modality i.e. CAm-arm might enhance the cytotoxic activity of C as has been suggested in mice (Treskes (1994) *Eur. J. Cancer.* 30a, 183–187). Main toxicities of Am are hypotension, flushing, nausea and vomiting, sneezing and dizziness. In conclusion, these results show that Am given with C reduces the duration of thrombocytopenia and may provide protection from severe infection and reduce the duration of hospitalisation. Further studies from this combination are warranted.

1059 POSTER

CISPLATIN, VINDESINE, MITOMYCIN (MVP) *VS* CISPLATIN, IFOSFAMIDE, NAVELBINE (PIN) *VS* CARBOPLATIN, NAVELBINE (CAN) IN ADVANCED NON-SMALL CELL LUNG CANCER (NSCLC)

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FONICAP

In the present randomized phase II trial two novel navelbine-containing programmes were tested along with the standard MVP regimen. 132 chemotherapy-naive pts were randomized: 47 pts had MVP (Cisplatin 100 mg/sqm d1, Vindesine 3 mg/sqm, d1 and d15, Mitomycin-C 6 mg/sqm d1 q 28 d, 46 pts PIN (Cisplatin 80 mg/sqm d1, Ifosfamide 3 g/sqm d1 and Navelbnine 25 mg/sqm d1 and 8 q 21 d) and 39 pts CaN (Carboplatin 350 mg/sqm d1 and Navelbine 25 mg sqm d1 and 8, q 28 d). Pts characteristics in the three arms were: median age 61, 64 and 61 yrs; squamous cell histology 47%, 52% and 46%; stage IIIb 32%, 43%