points were similar: median PFS (2.3 v 2.3 months, hazard ratio: 1.004 [0.841-1.199]), response rate (4.4% v 5.5%), stable disease (36.0% v 39.6%), median overall survival (6.7 v 7.2 months, hazard ratio: 0.973 [0.805-1.176]). Clinical benefit was a composite endpoint based on PS, weight, PPI, analgesic consumption, dyspnoea and cough; the primary endpoint of clinical benefit analysis was the rate of clinical benefit responders, defined as those patients who demonstrated improvement in at least one of these parameters, without deterioration in any other parameter, and confirmed once at least three weeks later. No significant difference was observed in the rate of clinical benefit between the vinflunine arm (31 responders, 13.1%, 95% CI 9.1-18.0) and the docetaxel arm (39 responders, 15.5%, 95% CI 11.3-20.6: c^2, p=0.4389).

Conclusion: Vinflunine 320 mg/m^2 every 3 weeks was found to be similar in terms of efficacy to docetaxel 75 mg/m^2 every 3 weeks in patients previously treated with a platinum-containing regimen for advanced NSCLC patients. Clinical benefit was also comparable for the two study treatments. Low, manageable but different toxicity profiles were observed in either arm allowing a good median relative dose intensity > 98%. Therefore, vinflunine offers a new and useful alternative for patients suffering from advanced NSCLC in second line setting.

A3-06 **Cytotoxic Chemotherapy I, Mon, 13:45 - 15:30**

Triplets versus doublets with or without cisplatin in the first-line treatment of stage IIIB-IV non-small cell lung cancer (NSCLC) patients: preliminary results of a multicenter randomized factorial study

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Background: Platinum-based chemotherapy doublets represent the standard first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC), although toxicity is common. Several randomized trials trying to assess whether non-platinum combinations were as effective as platinum-based ones yielded conflicting results. Moreover, another not completely solved question is whether triplet regimens could be more effective than chemotherapy doublets. This 2 x 2 factorial trial aimed at answering both questions: (1) the role of replacing cisplatin (P) with vinorelbine (N), (2) the role of adding a third agent, ifosfamide (I), in a chemotherapy doublet with gemcitabine (G). Primary endpoint was overall survival (OS). Secondary endpoints were response rate (RR), progression-free survival (PFS) and toxicity.

Methods: Patients with stage IIIB or IV NSCLC were randomly assigned to one of four first-line regimens: gemcitabine 1250 mg/m^2 on days 1, 8 plus cisplatin 80 mg/m^2 on day 1 (GP); gemcitabine 1250 mg/m^2 on days 1, 8 plus vinorelbine 25 mg/m^2 on days 1, 8 (GN); gemcitabine 1000 mg/m^2 on days 1, 8 plus ifosfamide 2 g/m^2 on day 1 plus cisplatin 80 mg/m^2 on day 1 (GIP); gemcitabine 1000 mg/m^2 on days 1, 8 plus vinorelbine 25 mg/m^2 on days 1, 8 plus ifosfamide 3 g/m^2 on day 1 (GIN). Treatments were repeated every 3 weeks for a maximum of 6 cycles. Considering the 2 x 2 trial design, two comparisons have been performed: (1) N-containing vs P-containing regimens [GN and GIN vs GP and GIP] and (2) I-triplets vs I-non containing doublets [GIN and GIP vs GN and GP].

Results: From 10/2001 to 07/2006, a total of 433 patients were randomized. The patients characteristics were as follows: 72% males, with median age of 63 years (range of 29-79), 40% adenocarcinomas, 71% stage IV and 53% with ECOG performance status of 0. About the comparison (1), RR was 25.6 vs 36.3% (p = 0.032), PFS 5.0 vs 6.5 months (p = 0.239) and OS 11.1 vs 9.8 months [Hazard Ratio (HR) = 1.04; 95% C.I.: 0.82-1.33; p = 0.719] for N-containing vs P-containing regimens, respectively. About the comparison (2), RR was 29.1 vs 32.8% (p = 0.471), PFS 6.5 vs 5.5 months (p = 0.519) and OS 10.8 vs 9.8 months (HR = 0.95; 95% C.I.: 0.74-1.21; p = 0.705) for I-triplets vs I-non containing doublets, respectively. Grade 3-4 anaemia, leucopenia and thrombocytopenia were significantly more frequent in P-containing regimens; only grade 3-4 leucopenia was more common in I-triplets. Concerning non-haematological toxicity, only grade 3-4 nausea-vomiting was significantly increased in P-containing regimens; no other statistically significant difference in toxicity was observed.

Conclusions: Results of this unplanned preliminary analysis indicate that replacing P with N or the addiction of I to a chemotherapy doublet regimen did not improve OS in the treatment of stage IIIB-IV NSCLC patients. However, P-containing regimens showed a statistically significant advantage in RR over P-free chemotherapy.

A3-07 **Cytotoxic Chemotherapy I, Mon, 13:45 - 15:30**

A prospective randomized multi-center trial of three chemotherapy regimens in Korean patients with advanced non-small cell lung cancer - an interim analysis of Korean Association for The Study of Lung Cancer (KASLC)-0301 trial

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Background: Chemotherapeutic response rate would be different by the ethnic background. This is a randomized prospective trial of three cisplatin-based chemotherapeutic regimens in Korean patients with advanced non-small-cell lung cancer.

Methods: A total of 333 patients with advanced non-small cell lung cancer were randomly assigned to one of the three regimens of 3-weekly cycle: cisplatin of 60 mg/m^2 on day 1 with docetaxel of 75mg/m^2 (DP) or paclitaxel of 130 mg/m^2 (TP) on day 1, or gemcitabine of 1200mg/m^2 on day 1 and 8 (GP). After 2~3 cycles of chemotherapy, non-responding patients were crossly assigned to the second-line monotherapy of either docetaxel or gemcitabine.

Results: There was no significant difference in sex, stage, and performance status (PS) score, number of cycles and delivered dose intensity between the 3 groups. Three fourths of the patients had stage IV disease and one fourth showed ECOG PS score of 2. Mean cycle of the first-line chemotherapy was 3.4, and the relative dose intensity was 97%. The overall response rate was 41.8%, with a median survival of 328 days (95% CI: 271~385) and median progression free survival of 139 days (95% CI: 111~167 days). The response rate and progression free survival did not differ among the 3 groups. The first-line treatment