2 courses of consolidation chemotherapy were 81.1/41.3%, 41.4/29.7% and 59.7/50.0%, respectively. Major toxicities were as follows; G4 neutropenia in MVP, IC, PC were 76.9, 13.1, 4.2% (p<0.001), and G3-4 non-hematological toxicities (decrease in PS, and febrile neutropenia) were 13.3, 6.2, 4.2% (p=0.01), and 29.4, 6.9, 4.9% (p<0.001), respectively. The overall response rates were 65.7% (95%CI 57.9-73.5), 58.6% (95%CI 50.5-66.1) and 62.9% (95%CI 55.0-70.8), in MVP, IC and PC, respectively. Complete analysis will be fixed in Oct 2008.

**Conclusions:** Weekly PC with TRT appears good compliance with high achievement rate and MVP appears poor compliance with severe hematological and non-hematological toxicities.

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**C3-04 Combined Modality Therapy in NSCLC II, Wed, 10:30 - 12:15**

**Phase III study comparing a preoperative (PRE) and a perioperative (PERI) chemotherapy (CT) with two different CT regimens in resectable stage I-II non-small cell lung cancer (NSCLC): the IFCT 0002 protocol**

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**Background:** The association of surgery and chemotherapy is now a standard in stages IA-III. The primary objective of this trial was to define the best timing of CT (all before surgery versus perioperative). Another objective was to compare two regimens, gemcitabine-cisplatin (GP) and paclitaxel-carboplatin (TC) (GP: Gemcitabine 1250 mg/m2 d1, 8 and cisplatin 75 mg/m2 d1 q3 wk; TC: Paclitaxel 200 mg/m2/d1 and carboplatin AUC 6, q3 wk).

**Methods:** 528 stage I-II resectable NSCLC were randomized to 4 parallel arms: A: 2 GP in responders, 2 GP, then surgery, B: 2 GP + surgery in responders, 2 GP, C: 2 TC cycles + in responders, 2 TC then surgery, D: 2 TC + surgery + in responders, 2 TC. Quality of life was evaluated with the EORTC QLQ C30 - LC13 questionnaire at days 1, 42 and 147. Results were analyzed two by two: PRE (A+C) versus PERI (B+D) and GP (A+B) versus TC (C+D).

**Results:** 1) The addition of 2 additional preoperative CT cycles in responders did not influence tumor volume, intratumoral necrosis, pleural, venous or intrapulmonary lymphatic invasions. Pathological complete response rates were not statistically different (PRE: 6.3%, PERI: 7.6%, GP: 8.2%, TC: 5.6%). Objective responses were similar (PRE: 50.6%, PERI: 50.9%, GP: 52.2%, TC: 49.2%) 2) 30-day postoperative mortality were identical whether the patient received 2 or 4 cycles before surgery. Similarly, iatrogenic mortality at 6 months did not differ with the number of preoperative CT cycles (PRE:3%, PERI:3.21%). The main toxicities differs between GP and TC only for G ≥2 neutropathy at 6 months (GP: 6.5%, TC: 24.4%, p=10^-3) and G ≥2 nausea (GP: 22.17%, TC: 4.22%, p=10^-3). 3) Proportions of pts receiving cycles 3 and 4 were higher when they were given before surgery than after surgery (PRE: 90.4%, PERI:75.2 %, p=.0011). Percentages of non operated pts after CT were identical in both groups (PRE: 4.5%, PERI: 4.3%). 4) There was no difference in Quality of Life between the 4 groups. At 6 months, decrease of health status, different functioning and symptoms did not differ between the 4 arms in responding pts (except for alopecia).

**Conclusions:** 1) GP and TC were both effective and safe, although with different toxicity profiles. 2) Results of pathological response suggested that 2 preoperative cycles might be as effective as 4 cycles. 3) Dose intensity was higher when all chemotherapy was given before surgery compared to both before and after surgery. 4) Quality of life decrease in the same proportions in each group within the 6 months after randomization.

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**C3-05 Combined Modality Therapy in NSCLC II, Wed, 10:30 - 12:15**

**Chemotherapy (CT) in addition to surgery or surgery plus radiotherapy (RT) in non-small cell lung cancer (NSCLC): Two meta-analyses using individual patient data (IPD) from randomised controlled trials (RCTs)**

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**Background:** A previous IPD meta-analysis (BMJ 1995;311:899) that suggested cisplatin-based CT may have a role in the treatment of NSCLC has been updated. This includes RCTs, regimens and outcomes that were not available in 1995. The meta-analysis examines the role of CT in 7 treatment comparisons. Here we report on Comparison 1: surgery + CT versus surgery alone and Comparison 3: surgery + RT versus surgery + RT.

**Methods:** RCTs were identified by comprehensive search strategies. Updated IPD were collected, checked and re-analysed. Results from RCTs were combined using the stratified (by trial) logrank test to calculate individual and pooled hazard ratios (HRs).

**Results:** Comparison 1

IPD were obtained from 30 RCTs and 8147 patients, representing 95% of all known randomised patients, adding 18 RCTs and 5835 patients to the 1995 analyses. Median follow-up is 6.3 years. 10 RCTs used sequential radio-chemotherapy, 8 RCTs used Tegafur/UFT without cisplatin and 7 RCTs used Tegafur/UFT and cisplatin. There is a significant benefit of CT on survival (HR=0.86, 95% CI 0.81-0.93, p<.0001), with an absolute benefit of 4% (from 60% to 64%) at 5 years. Results were similar for recurrence-free survival (HR=0.83, 95% CI 0.81-0.93, p<0.0001), with an absolute benefit of 5% (from 29% to 34%) at 5 years. Results were similar for recurrence-free survival (HR=0.84, 0.77-0.93, p=.0006, 12 RCTs).

Comparison 3

IPD were obtained from 11 RCTs and 2,626 patients (12% with incomplete resection), representing 86% of all known randomised patients, adding 5 RCTs and 1956 patients to the 1995 analysis. Median follow-up is 6.3 years. 10 RCTs used sequential radio-chemotherapy, 8 RCTs used cisplatin + vinca alkaloid/etoposide, 1 used cisplatin + Tegafur and 2 used other cisplatin regimens. There is a significant benefit of CT on overall survival (HR=0.88, 95% CI 0.80-0.96, p=0.0062), with an absolute benefit of 5% (from 29% to 34%) at 5 years. Results were similar for recurrence-free survival (HR=0.84, 0.77-0.93, p=.0006, 12 RCTs).