arms B and C pts are reported: toxicity 127 pts (B: 63, C: 64) and response 110 pts (B: 53, C: 57). All groups are well-matched for baseline disease characteristics. Toxicity grade 3−4 by CTC and RTOG criteria was: esophagitis 19.5% (arm B) and 14.2% (arm C); pneumonitis 8.8% (arm B) and 10% (arm C). Neutropenia during I or C therapy: 22% (B) and 6.2% (C). Thrombocytopenia 8% (B) and 3% (C). Neutropenia during concomitant therapy: 6.3% (B) and 6% (C). No thrombocytopenia or severe anemia was found during CT/TRT. The reduction CT rate was superior in consolidation (35%) than in induction (15%) and in arm C during concomitant therapy (22.4% C, 6.5% B). Delay of CT dose was similar in B and C arms during I or C (22% B, 20% C) but superior in arm C during concurrent treatment (19.6% B, 30.6% C). The final response rates were 57% (B) and 56.9% (C). A trend for longer time to progression (TTP) was found (B: 7.6 months [mo] and C: 9.2 mo; $p = 0.12$) but with similar overall survival (B: 14.3 mo and C: 14.7 mo; $p = 0.38$).
Conclusions: Non-platinum CT plus concomitant chemoradiation offer similar response rate and a favorable hematological toxicity profile in unresectable stage III NSCLC pts. No differences in OS but a trend for longer TTP in arm C (I followed by concurrent approach) has been found. Final data are pending in order to select the best sequence for further studies.

6501 ORAL

Global Lung Oncology Branch trial 3 (GLOB 3): Quality of Life (QoL) results of a randomised multinational Phase III trial of oral and i.v. vinorelbine (NVB) plus cisplatin (CDDP) versus docetaxel (DTX) plus CDDP as first-line treatment for advanced non-small cell lung cancer (NSCLC)

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Background: Intravenous weekly NVB (NVBiv) and CDDP represents one of the reference treatments for advanced NSCLC. The oral formulation of NVB (NVBo) has been recently approved in NSCLC with similar efficacy as NVBiv. The aim of this trial was to compare efficacy, tolerance and QoL of a D1 NVBiv and D8 NVBo (NC) versus DTX in a CDDP-based combination (DC). Both regimens were given in 3-week cycles in advanced NSCLC chemonaive patients.
Methods: Patients were randomly assigned to receive CDDP 80 mg/m^2 with NVBiv 30 mg/m^2 on day 1 and NVBo 80 mg/m^2 on day 8, after a 1st cycle at NVBiv 25 mg/m^2 D1 and NVBo 60 mg/m^2 D8 (dose escalated in absence of grade 3/4 neutropenia), or CDDP 75 mg/m^2 and DTX 75 mg/m^2 on day 1, for a maximum of 6 cycles in both arms. The Lung Cancer Symptom Scale (LCSS) questionnaire was filled by the patient at D1 of each cycle before chemotherapy administration and at the end of study treatment.
Results: Between Feb. 2004 and Jan. 2006, 390 patients (NC/DC: 194/196) were randomised and 381 (190/191) treated. Patients characteristics showed no difference between both arms. Mean number of cycles were: NC 4.2±1.8, DC 4.4±1.9. There was no difference in terms of efficacy (ITT): Time to Treatment Failure (TTF)(months) [95% CI]: NC 3.2 [2.9−4.2], DC 4.1 [3.4−4.5]. Objective Response (OR)(RECIST) [95% CI] (after panel review): NC 27.4% [21.2−34.2], DC 27.2% [21.0−34.2]. Median Progression-Free Survival (PFS)(months) [95% CI]: NC 4.9 [4.4−5.9], DC 5.0 [4.3−6.1]. Median Survival (MS)(months) [95% CI]: NC 9.9 [8.6−11.6], DC 9.8 [8.8−11.5]. Tolerance was similar with grade 3/4 neutropenia NC 23.3%; DC 28.2%. Patients evaluability with LCSS questionnaire were 78.4% in NC & 79.6% in DC. The LCSS global score significantly decreased over time ($p < 0.0001$) without significant difference between both treatment arms ($p = 0.56$) as shown in the enclosed table.

Mean change from baseline ± standard error

	3 weeks	6 weeks	9 weeks	12 weeks	15 weeks	18 weeks
NC	−0.16±1.09	0.002±1.30	−0.55±1.57	−0.65±1.86	−4.26±2.30	−6.35±2.82
DC	−0.23±1.19	−0.92±1.39	−1.03±1.67	−3.21±1.72	−4.94±2.06	−5.61±2.35

There was a significant time effect with no treatment effect for the average symptom burden, general quality of life, asthenia, cough, dyspnea, distress & activity scores. For anorexia & haemoptysis, there was neither time effect nor treatment effect. An equal weight & Karnofsky performance status progressive deterioration has been evidenced in both arms.
Conclusions: NVB iv/oral and CDDP achieves similar efficacy as DC in terms of TTF, OR, PFS and MS with similar and acceptable tolerance as front-line chemotherapy for advanced NSCLC patients. QoL was also similar in this first face to face comparison of NC/DC given in 3-week cycles.

6502 ORAL

Pre-operative chemotherapy in patients with resectable non-small cell lung cancer (NSCLC): The MRC LU22/ NVALT 2/EORTC 08012 multi-centre randomised trial

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Background: The 5-year survival rate following surgery for patients with NSCLC is modest, and improvements are urgently required. In 1994 2 small trials showed striking results in favour of the addition of neo-adjuvant chemotherapy, and so the current trial was designed to investigate whether, in patients with operable NSCLC of any stage, neo-adjuvant platinum-based chemotherapy would improve outcomes.
Methods: The primary endpoint was overall survival, and the trial was designed to detect a 15% improvement in 3-year survival (from 40% to 55%) with neo-adjuvant chemotherapy, which required 450 patients and 233 events (deaths). Patients were randomised to receive either surgery alone (S), or 3 cycles of platinum-based chemotherapy prior to surgery (CT-S), clinicians choosing (pre-randomisation) the chemotherapy from 6 standard regimens. Quality of Life was assessed by patients completing the SF-36 questionnaire.
Results: 519 patients were randomised (S: 261, CT-S 258) from 70 centres in the UK, the Netherlands, Germany and Belgium. The median age of the patients was 63 years, 72% were male, 55% were performance status (PS) 0, and 61% had stage I disease. Neo-adjuvant chemotherapy appeared feasible (76% of patients received all 3 cycles of chemotherapy), resulted in a good response rate (4% CR, 45% PR), and appeared to cause down-staging in approximately 13% of patients. However the use of pre-operative chemotherapy did not affect the type of surgery performed (lobectomy: S 61%, CT-S 66%), the post-operative complication rate, or the QL of patients (apart from a reduction in 'role physical' domain in the CT-S group at 6 months). The time to (and sites of) relapse did not differ between the regimens, except that more patients in the CT-S group developed brain metastases (S 16, CT-S 31). A total of 244 patients have died (S 122, CT-S 122), and there is no evidence of a difference in terms of overall survival (HR 1.02, 95% CI 0.80, 1.31). Median, 1, 2 and 5 year survival in the S group were: 54 months, 83%, 69% and 45% respectively, and applying the HR to these figures gives, for the CT-S group: 53 months, 83%, 69% and 44% respectively.
Conclusions: This intergroup trial, which is the largest trial of neo-adjuvant chemotherapy in patients with resectable NSCLC, indicated that the addition of neo-adjuvant platinum-based chemotherapy did not lead to a benefit in overall survival.