tologically confirmed NSCLC inoperable were evaluable for analysis. 249 (Group A) were randomized to receive P 200 mg/m^2 in 3 h infusion, day 1 plus C AUC = 6, day 1 and 252 (Group B) to receive P 200 mg/m^2 in 3 h infusion, day 1, plus G 1 gm/m^2 days 1, 8. In both groups the treatment was given every 3 weeks with standard premedication and antiemetics without growth factors Eligibility criteria included WHO performance status 0–2, documented inoperable stage IIIA, IIIB, IV, stable brain metastasis, no prior chemotherapy and adequate renal and hepatic function. Baseline demographics and tumor characteristics were well-matched in both groups. Dose intensity of P was 94% and 89% in groups A and B respectively whereas for G 89%.

Results: Response rate for pts in group A was 28% (2%CR, 26%PR) (95%CI 21–36) whereas in group B 35% (5%CR, 30%PR) (95%CI 29–44) P = 0.12. Median TTP was 6.1 months (95%CI 5.2–7.0) for group A and 5.8 months (95%CI 5.1–6.5) for group B (P = 0.35). The median survival time was 10.3 months (95% CI 8.8–11.8) in group A and 9.8 months (95% CI 8.0–11.7) in group B (P = 0.36). The 1-year survival was 40.5% and 41.5% for groups A and B whereas the 2-year survival was 17.4% and 16.4% respectively The best prognostic factor for response was PS: 0–1 (P = 0.004) whereas for median and 1-year survival: stage (P = 0.001), PS (P < 0.0001) and response (P < 0.0001). No toxic deaths were seen. G 3/4 neutropenia was seen in 15% in both groups, thrombocytopenia G 3/4 2% in group A and 1% in group B and anemia G 3/4 5% and 2% in groups A and B respectively. Neurotoxicity G 3 was noticed in 8% and 6% in groups A and B respectively

Conclusion: These final results indicate that both combinations are effective, equally active with comparable toxicity. At least, in this study, the non-platinum combination is neither more active nor less toxic in NSCLC.

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Fractionated thoracic radiotherapy gives better symptom relief in patients with non-small cell lung cancer

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Aims: To determine whether fractionated thoracic radiotherapy offers better symptom relief, quality of life or survival than single fraction treatment in patients with advanced non-small cell lung cancer.

Methods: Patients were randomised to 30 Gy in 10 daily fractions (F) to the chest or a 10 Gy single fraction (S). The principal endpoint was physician-assessed symptom score for cough, chest pain, dyspnoea, haemoptysis and dysphagia. Subsidiary endpoints were survival and quality of life. Symptom scores were compared using the Wilcoxon signed rank test.

Results: 148 patients were randomised into groups matched for age, gender, histology, performance status and initial total symptom score (TSS). Patients randomised to F had lower TSS at 1 month review (p = 0.014) or at 1 and 3 month review (p = 0.001). This group also had better scores at either review for dyspnoea (p = 0.010), chest pain (p = 0.014) and cough (p = 0.029). Overall, TSS improved following TRT in 28/60 assessable patients with S and 40/57 with F (χ^2 = 6.64, df = 1, p = 0.01). Median survival was 23 weeks with S and 28 weeks with F (p = 0.197). Patients treated with S had higher anxiety scores than patients with F (1 month p = 0.01, 1 or 3 months p = 0.003).

Conclusions: Fractionated TRT offered better symptom relief and reduced anxiety compared to single fraction palliation, but did not increase survival.

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Postoperative oral administration of UFT for completely resected pathologic stage I non-small cell lung cancer: the West Japan study group for lung cancer surgery (WJSG), the 4th study

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[Purpose] To examine the efficacy of UFT, an oral 5-fluorouracil derivative anti-tumor agent, as a postoperative adjuvant therapy for p-stage I non-small cell lung cancer (NSCLC), because previous prospective studies suggested the efficacy for early-stage NSCCL patients. [Patients and Methods] Patients who underwent complete tumor resection with mediastinal dissection for p-stage I, adenocarcinoma (Ad) or squamous cell carcinoma (Sq) were eligible. A total of 332 patients were randomized to the surgery-alone group (control group) and the treatment group (UFT 400mg/m2 for 1 year after surgery, UFT group) after stratified by the histologic types. [Results] For Ad patients, the 5- and 8-year survival of the UFT group (n=120) were 85.2 and 79.5%, respectively, which seemed better than those of the control group (n=121) (79.2 and 64.0%, respectively) although without statistical significance (p=0.081). For p-stage IA Ad patients, the difference reached statistical significance (p=0.011). For Sq patients, there was no difference in the prognosis between the control group (n=48) and the UFT group (n=43). For all p-stage IA NSCLC patients, the 5- and 8-year survival rates of the UFT group were 85.8 and 79.7%, respectively, significantly better than those of the control group (76.7 and 61.6%, respectively, p=0.027). In contrast, UFT proved not to be effective for p-stage IB NSCLC patients. [Conclusions] Postoperative UFT administration proved to be effective for p-stage IA NSCLC patients, especially for p-stage IA, Ad patients.

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A three-arms phase III randomised trial comparing combinations of platinum derivatives, ifosfamide and/or gemcitabine in stage IV non-small cell lung cancer (NSCLC): an european lung cancer working party study

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Purpose: To determine, in stage IV NSCLC, if the combination of gemcitabine -a new active drug - with ifosfamide (IG) or with the cisplatin-carboplatin association (CCG) will improve survival (primary endpoint) in comparison to a first-generation regimen, cisplatin-carboplatin-ifosfamide (CCI).

Patients and methods: A total of 284 patients without prior chemotherapy and with metastatic NSCLC were randomised. Four were ineligible and 16 not assessable for responses. Cisplatin was given at 60 mg/m2 on day 1, carboplatin AUC 3 on day 1, ifosfamide 4.5 g/m2 on day 1 and gemcitabine lg/m2 on days 1,8 and 15. Courses were repeated every 4 weeks. Response was assessed after 3 courses and chemotherapy was continued in case of response until best response. There were 94 eligible patients in the CCI arm, 92 in CCG and 94 in IG.

Results: Objective response rate was, respectively for CCI, CCG, and IG, 23% (95% CI: 15-32), 29% (95% CI: 20-39) and 25% (95% CI: 16-33) (p = 0.61). Median survival time was respectively 24,34 and 30 weeks (p = 0.20); 1-year survival time 23%, 33% and 35% and 2-year survival time was 11%, 14% and 17% respectively. There was a significant survival advantage in disfavour of CCI in the subgroups of women and of patients older than 60 years. Toxicity was tolerable: severe alopecia was less frequent in the CCG arm, IG was significantly associated with more thrombopenia and CCG with more leucopenia.

Conclusion: The regimens including a new drug (gemcitabine) were associated with a better survival (statistically significant in some subgroups) than a classical first-generation cisplatin containing regimen in the treatment of stage IV NSCLC. The non-platinum combination with gemcitabine was as effective as the platinum regimen with gemcitabine.

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Phase II Eastern Cooperative Oncology Group (ECOG) pilot study of paclitaxel (P), carboplatin (C), and trastuzumab (T) in HER-2/neu (+) advanced non-small cell lung cancer (nsclc): early analysis of e2598

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Background: Multiple NSCLC cell lines and 20% to 50% of pathologic specimens express HER-2/neu, the target of trastuzumab (Tsai JNCI 1993;85:897). HER-2/neu expression has also proven to be an independent, unfavorable prognostic factor in resected patients with pulmonary adenocarcinoma (Cancer Res 1990;50:5184-91). Trastuzumab has demonstrated in vitro synergy with carboplatin and additivity with paclitaxel. ECOG therefore launched a phase II study evaluating combination carboplatin, paclitaxel and trastuzumab in patients with incurable, advanced NSCLC.

Methods: Eligibility stipulated measurable tumor; HER-2/neu positivity (1+ to 3+ by IHC, confirmed by central pathology review); ECOG PS 0-1;