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Conclusions: This study provides a snap shot of wait times experienced by NSCLC patients undergoing curative-intent surgery and describes how different factors influence timelines based on care interval definitions. In a parallel study we use a subset of these timelines as potential determinants of referral to medical oncology and provision of adjuvant chemotherapy.

6599 POSTER

Comparison of cisplatin-paclitaxel combination versus cisplatinetoposide as first line chemotherapy in SCLC

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Small cell lung cancer is a sensitive tumor to chemotherapy. The initial high response rate is though followed by relapse in nearly 90% of the patients. Cisplatin and Etoposide combination is the standard primary treatment. Other chemotherapy combinations are not often applied. The objectives of the present trial is to compare between two-phase II trials the response rate, time to tumor progression and mainly the median and overall survival. Material and Methods: Seventy-seven patients with small cell lung cancer were enrolled and divided in two arms, 3 patients were not considered evaluable, 37 patients in each of the two arms were balanced to have the different combination chemotherapy. Arm A patients had the combination of Cisplatin 80 mg/m<sup>2</sup> on day 1 and VP-16 (etoposide) 120 mg/m<sup>2</sup> daily on days 1-3 repeated every 3 weeks. Arm B had Cisplatin 80 mg/m² day 1 and Paclitaxel 175 mg/m² day 1 repeated every 3 weeks. The median age of the patients was 65 years (range 46-80). There were 61 male and 13 female. Stage of disease: Arm A: Limited disease 15 patients, advanced 22 patients. Arm B: Limited disease 20 and advanced 17 patients. Patients were planned to have 6 courses. 80% of the patients of each arm had completed their courses. Radiation therapy was given to all the patients of limited disease.

**Results:** Both arms response rates (CR and PR) and survival was similar. In Arm A (with VP-16) it was 65.71% and in Arm B (with Paclitaxel) it was 64.70%. The median survival of Arm A patients was 13 months with range 1–29 and of Arm B the median was 12 and range  $\frac{1}{2}$ –60+ months. Toxicity was also without difference in respect of myelotoxicity, nephrotoxicity and alopecia.

Conclusions: Comparison of Cisplatin and Etoposide combination versus Cisplatin and Paclitaxel showed no difference in response rate, survival and toxicity. The Cisplatin and Paclitaxel combination could be applied in small cell lung cancer patients as an alternative treatment to the standard one.

6600 POSTER

## Risk factors of radiation pneumonitis: a prospective study

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**Background:** To study the clinical, dosimetric, and biological risk factors of radiation pneumonitis (RP) for lung cancer patients(pts) receiving thoracic radiotherapy (RT) in Taiwan

Materials and Methods: From Jul 2003 to Jun 2005, fifty pts were enrolled to study the clinical, dosimetric, and biological risk factors of RP for lung cancer pts receiving thoracic RT in our institute prospectively. Three of them were ineligible for analysis due to incomplete RT or missing data. The remaining pts (n = 47) constitute our study group. Clinical factors including age, gender, history of smoking, history of pulmonary disease, histology, stage, primary site, operation, chemotherapy, pretreatment albumin, hemoglobulin level, and pretreatment quality of life (QoL) were recorded. QoL was measured by EORTC C30 questionaire. V20 (percentage of total lung receiving more than 20 Gray) and mean lung dose (MLD) were recorded as dosimetric factors. Pretreatment plasma cytokine levels (transforming growth factor beta, TGF- $\!\beta$  and interleukin six, IL-6) were recorded as biological factors. Common toxicity criteria v3.0 was used for grading of RP. Uni-variate analysis by Fisher's exact test was used for analysis of risk factors. This study was registered at www.clinicaltrials.gov (NCT00155909).

**Results:** Most of these pts were male (n=39) and aged (median age 63 yrs, range: 36-80) at diagnosis. Most of them had stage III non-small cell lung cancer (NSCLC, n=15) or limited stage small cell lung cancer (SCLC, n=14) and received definitive RT (n=37) and concurrent chemotherapy (n=29). The median RT dose was 54 Gy [range: 36-66,

mostly (n = 3)  $\geqslant$ 50]. The median daily fractional size was 2 Gy [range 1.8–3, mostly (n = 45)  $\leqslant$ 2]. The median (range) V20 and MLD were 27% (2–36) and 15 Gy (2.8–21). The median (range) IL-6 and TGF- $\beta$  levels (pg/ml) were 4.5 (0–71.7) and 1615 (634–3486, missing=14), respectively. At the time of analysis (Mar 2007), the follow-up status were mostly dead (n = 18), followed by lost after disease progression (n = 12), lost with no evidence of disease (NED, n = 1), and regular follow-up with disease (n = 8) and NED (n = 8). Grade II RP was evident in six (13%) pts. The 1 and 3 year overall survival since start of RT for these pts was 59% and 30%. We found gender (female vs male=3/8 vs 3/39, p = 0.05) was the only significant risk factor associated with grade 2 RP.

Conclusions: In this prospective study, no significant risk factor except gender (female) was associated with grade 2 RP.

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## A pilot study of topotecan in patients with irinotecan-refractory small cell lung cancer

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**Background:** Although the efficacy of topotecan as second-line chemotherapy for small cell lung cancer (SCLC) has been consistently demonstrated in clinical trials, the choice of irinotecan as first-line therapy prevented use of the evidence-based option. This pilot study was conducted to determine the activity and safety of topotecan in SCLC patients refractory to first-line therapy with irinotecan/platinum combination.

Materials and Methods: Patients with primary refractory (no response, or progression during or ≤90 days after last chemotherapy) SCLC after treatment with irinotecan/platinum received topotecan 1.5 mg/m² as a 30-min infusion daily for 5 days every 3 weeks. Given a threshold response rate of 10%, at least 18 patients were required to be treated with topotecan in the first stage.

Results: Of 18 eligible patients, 11 patients were previously treated with irinotecan/cisplatin and 7 were treated with irinotecan/carboplatin. The median age was 68 years (range, 44–75) and the median interval from the last chemotherapy was 50 days (range, 21–89). A total of 38 chemotherapy cycles were administered (median, 2; range, 1–5). Causes of therapy discontinuation were disease progression in 11 patients, toxicity in 6 patients, and one patient's refusal. Toxic effects were mainly hematologic (grade ≥3 neutropenia in 67% of patients) and fatigue (grade 3 in 44%). One (6%) patient had a confirmed partial response and 5 patients achieved stable disease. Median progression-free and overall survivals were 1.8 months (95% CI, 1.5–2.1) and 8.3 months (95% CI, 0–18.6), respectively. Palliative radiotherapy and third-line chemotherapy was offered to 4 and 3 patients, respectively, after failure.

Conclusions: The limited antitumor activity of second-line topotecan prompted no further evaluation in patients with irinotecan-refractory SCLC.

6602 POSTER

Induction docetaxel and cisplatin followed by bi-weekly docetaxel with concurrent thoracic radiotherapy for stage III non-small cell lung cancer (NSCLC). A phase II study conducted by the Galician Lung Cancer Group (GLCG)

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**Background:** The most satisfactory treatment for patients with locally advanced NSCLC is combination chemotherapy-radiotherapy (CT-RT). The optimal treatment modalities remain to be determined.

**Methods:** 60 patients (pts) with inoperable stage locally advanced NSCLC, stage IIIAN2/IIIB (no pleural T4), were included in a phase II study with induction chemotherapy consisting of three cycles of Docetaxel 75 mg/m² on D1 and Cisplatin 40 mg/m² D1-2 every 3 weeks and, if no surgery, then received concurrent CT-RT with Docetaxel 30 mg/m² every 2 weeks for four courses, during thoracic conformal radiotherapy (60–66 Gys, 180 cGy/day). The primary objective: overall survival; secondary: progression free survival, response rate (RR) and toxicity. Median follow-up: 9.1 mo. **Results:** The pts characteristics were: mean age 62.9 yrs (43–74); male/female: 56/4; ECOG 0/1 in 17/43 pts; stage IIIAN2: 17 pts (28.3%) and