Materials and Methods: Pts (⩾18 years, stage IIIB/IV NSCLC, WHO PS 0−2, completed 4 cycles of first-line platinum-based doublet CT without progression/unacceptable toxicity) were randomised 1:1 to G 250 mg/day or P 3−6 weeks post-CT. Progression-free survival (PFS; primary endpoint; intent-to-treat population) was assessed: Cox proportional hazards adjusted for histology (adenocarcinoma *v* non-adenocarcinoma), smoking status (never-smoker *v* smoker), EGFR mutation status (positive [M+] *v* negative [M-] *v* unknown), best response to first-line CT (complete response [CR]/partial response [PR] *v* stable disease [SD]). PFS subgroup analyses defined by: primary PFS analysis covariates, type of CT (taxane *v* non-taxane), gender, disease stage at screening (IIIB *v* IV). A global treatment by covariate interaction (5% significance level) assessed consistency across subgroups. Secondary endpoints included objective response rate (ORR), disease control rate (DCR), overall survival (OS).
Results: 296 pts (n = 148 G, n = 148 P) were randomised (27 centres in China; 26 September 2008−10 August 2009; PFS data cutoff 24 January 2011). Median duration of follow-up: 16.8 months. Demography was balanced between treatments: 54.1% never-smokers, 70.6% adenocarcinoma, 40.9% female. For PFS G *v* P: HR = 0.42; 95% CI 0.32–0.54; p < 0.0001; median PFS 4.8 *v* 2.6 months. A generally consistent treatment effect was observed across all subgroups (interaction p = 0.4256). ORR and DCR significantly favoured G *v* P; median OS 18.7 *v* 16.9 months.

Subgroup	N		PFS	
	G	P	HR	95% CI
Adenocarcinoma	105	104	0.33	0.24–0.46
Non-adenocarcinoma	43	44	0.72	0.46–1.14
Never smoker	79	81	0.36	0.25–0.51
Smoker	69	67	0.52	0.35–0.75
CR/PR	58	51	0.44	0.29–0.66
SD	90	97	0.40	0.29–0.56
Male	83	92	0.49	0.35–0.69
Female	65	56	0.34	0.22–0.50
Taxane	60	66	0.41	0.28–0.61
Non-taxane	88	82	0.43	0.31–0.61
Stage IIIB	42	32	0.46	0.28–0.77
Stage IV	106	115	0.41	0.30–0.55
EGFR M+	15	17	0.16	0.07–0.40
EGFR M-	32	31	0.64	0.38–1.07
EGFR M unknown	101	100	0.43	0.31–0.58

Conclusions: PFS was significantly longer with G *v* P as maintenance therapy in pts with locally advanced/metastatic NSCLC, with generally consistent benefit observed across all subgroups. ORR and DCR significantly favoured G; there was no significant difference between treatments for OS.

9102 POSTER

A Phase II Study of Biweekly Irinotecan and Cisplatin for Patients With Extensive Stage Disease Small Cell Lung Cancer

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Background: An irinotecan and cisplatin (IP) combination is one of active regimen used in treatment of extensive stage disease (ED) small cell lung cancer (SCLC). However, a 4-week cycle of irinotecan treatment can result in significant myelosuppression and diarrhea. Therefore, the present study was conducted to evaluate the efficacy and safety of biweekly IP in patients with ED SCLC.
Methods: Patients with previously untreated ED SCLC received intravenous irinotecan at a dose of 60 mg/m^2 and cisplatin at a dose of 30 mg/m^2 on days 1 and 15 every 4 weeks.
Results: Thirty-five patients were enrolled in this study. Three complete responses and 23 partial responses were confirmed, giving an overall response rate of 74.3%. After a median follow-up of 15.1 months, the median time to progression and overall survival were 7.7 months and 12.2 months, respectively. Grade 3/4 neutropenia occurred in seven patients and grade 3 febrile neutropenia was observed in one patient. Grade 3 diarrhea occurred in two patients.
Conclusions: The combination chemotherapy of biweekly IP was found to be well tolerated and effective in patients with ED SCLC. Further evaluation of the combination of IP at the dose and schedule in this study is warranted in ED SCLC patients.

9103 POSTER

Phase II Trial of NGR-hTNF and Doxorubicin in Relapsed Small Cell Lung Cancer (SCLC)

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Background: NGR-hTNF is a selective vascular targeting agent, which is able to improve the intratumoral doxorubicin penetration by normalizing tumour vasculature and decreasing interstitial fluid pressure. A phase I trial previously selected NGR-hTNF 0.8 μg/m^2 + doxorubicin 75 mg/m^2 for further testing.
Methods: SCLC patients relapsing after a platinum-based regimen received every 3 weeks NGR-hTNF until progressive disease (PD), while doxorubicin dose was capped at 550 mg/m^2. The trial had 2-stage design with a total of 27 patients to be accrued. Progression-free survival (PFS) was the primary study aim.
Results: Twenty-eight patients (median age: 63 years; M/F: 19/9; PS 0/1−2: 13/15) were recruited. Prior treatment lines ranged from 1 to 3. Median treatment-free interval from last line was 2.8 months (95% CI, 1.0−3.9), with 16 patients being platinum resistant (pl-R; PD ⩽ 3 months) and 12 patients platinum sensitive (pl-S; PD >3 months). Baseline neutrophil-to-lymphocyte ratio (NLR), an index of systemic host immune response to tumour, was ⩽ or > the median value of 4 in 18 and 10 patients, respectively. Overall, 114 cycles were given (median 3; range 1−10) and 13 patients (46%) received ⩾4 cycles. NGR-hTNF did not increase doxorubicin related toxicity. No grade 3−4 toxicities related to NGR-hTNF were noted, while grade 1−2 events were transient chills (61%). The median PFS time was 3.2 months (95% CI 2.6−3.8). Six partial responses (PR; 22%) and 9 stable diseases (SD; 33%) were observed for an overall disease control rate of 55% (95% CI 35−74). Patients who experienced PR or SD had median PFS times of 6.3 and 4.1 months, respectively. With median follow-up of 19.3 months, the 6-month and 1-year overall survival (OS) rates were 49% and 34%, respectively. By subset analyses, response rates were 19% and 27%, median PFS times were 2.7 and 4.1 months, and 1-year OS rates were 27% and 42% for pl-R and pl-S patients, respectively. For patients pretreated with two or more regimens (n = 8), median PFS was 4.1 months and 1-year OS rate was 44%. By univariate Cox analyses, both PFS and OS did not correlate with age, gender, PS and platinum sensitivity, while only NLR was associated with OS (HR = 0.30). The 1-year OS rates in patients with baseline NLR below or above the median value were 48% and 10%, respectively (p = 0.01).
Conclusion: Further development of NGR-hTNF plus doxorubicin in platinum resistant or sensitive SCLC is of interest.

9104 POSTER

Weekly Divided Carboplatin Combined With Irinotecan in Patients With Small Cell Lung Cancer

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Background: Systemic chemotherapy is mainstay of treatment in patients with small cell lung cancer(SCLC). However, adverse effects of chemotherapeutic agents, especially platinum-based, causes neutropenia, infection, sepsis, and even death. Weekly devided platinum-based chemotherapy in concurrent chemo-radiation of non-small cell lung cancer is acceptable regimen. We tested feasibility of devided platinum-based chemotherapy in SCLC without concurrent radiation.
Material and Methods: Patients with chemotherapy-naive SCLC received carboplatin 2 AUC combined with irinotecan (60 mg/m^2) at day 1, 8, and 15 every 4 weeks for 4 cycles at out-patient department. The primary end point was evaluation of over all response rate, and secondary end points were treatment related serious adverse events and discontinuation of chemotherapy due to side effects.
Results: Twenty-one (16 extensive stage and 5 limited stage) patients were enrolled. Complete response, partial response, stable disease, and progressive disease were 2(9.5%), 16(76.2%), 1(4.8%), and 2(9.5%), respectively. Serious adverse events were happened 5 times in 2 patients, 1 patient stopped chemotherapy due to side effects.
Conclusions: Weekly divided carboplatin combined with irinotecan was feasible regimen in never treated SCLC patients.