[Hawkins et al., ASCO, 2006] At the time of that analysis, the objective response rate (ORR) in 25 patients in the highest dose group of nab-paclitaxel (340 mg/m^2) was 28% with median progression-free (PFS) and overall survivals of 4.6 and >7.0 months, respectively. Gr 3/4 neutropenia and sensory neuropathy (SN) were 32/16% and 24/0%, respectively. The aim of the current study was to obtain further clinical experience with nab-paclitaxel 340 mg/m^2 in combination with C6 in 76 additional pts with NSCLC.
Methods: Pts with previously untreated, stage IIIB or IV NSCLC with measurable disease and a life expectancy of over 12 weeks received nab-paclitaxel 340 mg/m^2 followed by carboplatin AUC 6 q3w.
Results: Patients Characteristics: 101 pts (99% Caucasian, 1% Hispanic; 80% male; median age, 59; performance status score: 0 [22%], 1 [78%]; stage IIIB [20%], IV [80%]). The median number of cycles was 6 and the median cumulative nab-paclitaxel dose was 1800 mg/m^2. The primary efficacy endpoints are provided in the table. Gr 3/4 hematologic toxicities were: neutropenia, 30%/20%; thrombocytopenia, 23%/4%; leukopenia, 22%/2%; anemia, 9%/5%. The most common non-hematologic toxicities (any grade) were SN, 87%; alopecia, 50%, fatigue, 38%; myalgia, 45%; arthralgia, 44%; nausea, 40%; and vomiting, 28%. Gr 2/3 SN were 22%/29%. Gr 3 SN improved by at least 1 gr in a median of 21 days.
Conclusions: The combination of nab-paclitaxel 340 mg/m^2 + C6 is very active with an ORR 33% in patients with advanced NSCLC. Preliminary PFS and survival data are encouraging. Hematologic toxicity was comparable to that reported with SB-paclitaxel and C6. The higher incidence of grade 3 SN was consistent with the increased dose of paclitaxel in our study, and was reversible. Mature PFS and survival data will be presented.

	nab-Paclitaxel 340 mg/m^2 + C6
ORR	33%
95% Confidence Interval (CI)	24–42
Disease Control[a]	48%
95% CI	38–57
Median PFS (months)	6.2 (62% of events)
95% CI	4.9–7.7
Median Survival (months)	13.1 (32% of events)
95% CI	11–17

[a]SD $\geqslant$16 weeks or Confirmed Response.

6564 POSTER

Frontline cytotoxic chemotherapy (CTx) for newly diagnosed non-small cell lung cancer (NSCLC) patients presenting with brain metastasis compared to whole brain radiotherapy (WBRT): result of a randomized pilot study

D.H. Lee[1], S.J. Yoon[2], J.Y. Han[2], H.T. Kim[2], J.S. Lee[2], H.R. Pyo[2], K.H. Cho[2], S.H. Shin[2], H. Yoo[2], S.H. Lee[2]. *[1]Asan Medical Center, Internal Medicine, Seoul, Korea; [2]National Cancer Center, Research Inst. & Hospital, Goyang, Korea*

Background: WBRT followed by CTx is commonly used for NSCLC patients (pts) with brain metastasis. However, when neurologic symptoms or signs are absent or controlled by supportive care, CTx could be a choice of treatment. We conducted a randomized trial of frontline CTx compared with WBRT in this clinical setting whether frontline CTx was feasible and its efficacy and toxicity profile as well as quality of life and survival outcome was affected by the time of WBRT.
Materials and Methods: The eligibility criteria are as follows: pathologic confirmed NSCLC, stage IV with brain metastasis at first diagnosis, age 18−75, ECOG PS 0−2, and adequate organ functions. After stratified according to PS (ECOG 0−1 vs 2), the number of intracranial metastases (<3 vs 3$\leqslant$) and presence of extrathoracic extracranial metastasis, eligible pts were randomized to the two arms; Arm A, CTx followed by WBRT; Arm B, WBRT followed by CTx. CTx consisted of gemcitabine 900 mg/m^2 and vinorelbine 25 mg/m^2 on D1 & 8 q 3 wk, up to 6 cycles. WBRT consisted of 30 Gy/10fx/12d. We assessed tumor response, toxicity profile and quality of life according to WHO response criteria, NCICTC and EORTC C-30/LC-13 questionnaire, respectively.
Results: Between 2002 Aug and 2005 Nov, 48 pts were enrolled. All of 25 pts in Arm A received CTx and WBRT, while 4 (17%) of 23 pts in Arm B could not receive CTx due to deterioration of PS or death during or immediately after WBRT. Intracranial tumor responses to CTx in Arm A were closely correlated with extracranial responses (k=0.82). There were no statistically significant differences in overall response rate (28% vs. 43%), time-to-progression (3.6 mo vs 4.4 mo) and survival (9.1 mo vs 9.9 mo). However, grade 3/4 neutropenia occurred more frequently in Arm B (79% vs 40%, p = 0.014). Cognitive function deteriorated during frontline CTx, while it already deteriorated after WBRT but did not further deteriorate during chemotherapy.
Conclusions: Frontline chemotherapy can be an appropriate treatment when neurologic symptoms or signs are absent or controlled by supportive care. The timing and the real need for WBRT should be defined in further trials.

6565 POSTER

Is relapsed small-cell lung cancer (SCLC) under treated?

S. Nicum[1], S. Ashley[2], M. O'Brien[1]. *[1]Royal Marsden Hospital, Medical Oncology, London, United Kingdom; [2]Royal Marsden Hospital, Statistics, London, United Kingdom*

Background: Second line treatment of small cell lung cancer (SCLC) has long been a nihilistic area as patients with a short treatment free interval (TFI) are expected not to derive benefit. However a recent study (O'Brien et al, JCO, December 2006) reported that oral topotecan was associated with a prolongation of median survival and symptomatic benefit compared to best supportive care in patients with relapsed SCLC.
Methods: A retrospective analysis of 49 patients receiving second line chemotherapy between 2001–2006 for SCLC [26 with sensitive (>90 days TFI) and 23 with resistant (<90 days TFI) disease] was performed at the Royal Marsden Hospital, UK. We wished to determine if a subgroup of SCLC patients had significantly better outcomes following re-treatment with chemotherapy.
Results: The median age of patients was 61 (range 40−81 years) and 62 (range 34−85 years) with sensitive and resistant disease respectively. The majority of patients (76%) received carboplatin and etoposide first-line. The median TFI after first-line therapy was 303 days (sensitive disease, 95% CI 273 –365 days) and 49 days (resistant disease, 95% CI 21−77 days). At first disease relapse 33% of our patients had limited and 67% had extensive stage disease and the majority (53%) received an anthracycline-based regimen 2nd line.
Median overall survival was 26 weeks (95% CI 20−32 weeks) and median time to progression after 2nd line chemotherapy was 22 weeks (95% CI 13−30 weeks). Factors such as gender and age of patients or the presence of liver metastases had no significant effect on survival.

Table 1. Factors influencing survival after 2nd line chemotherapy (CT).

Variable	Group	MS (weeks)	95% CI	Significance
Gender	Male	24.7	19.5−30.3	0.733
	Female	36.8	15.6−58.0	
Age	<65 years	26.9	21.2−32.9	0.410
	>65 years	23.4	18.2−29.0	
Sensitivity to 1st line CT	Resistant	26	22.9−29.5	0.238
	Sensitive	23.8	6.9−40.3	
PS	1	45.5	25.6−65.4	**0.019**
	2	24.7	18.2−31.6	
	3	5.2		
Liver metastases	No	26.9	9.1−45.1	0.087
	Yes	25.1	15.6−34.7	

Performance status (PS) at the start of 2nd line chemotherapy had a significant impact on median survival: PS 1 (10.5 months) compared to PS 2 (5.7 months) and PS 3 (1.2) months (p = 0.019). Interestingly median survival was similar in patients with resistant disease (6 months) compared to sensitive (5.5 months) disease (p = 0.238).
Conclusions: These data suggest that contrary to current guidelines even patients with resistant disease can have good median survivals and chemotherapy should be considered in this group, particularly in those of good performance status.