

1.2–3.6) were independent prognostic variables for OS. Timing of BM presentation was not significant for OS (RR 1.83, CI 0.8–3.7). Relevant side effects were as follows: corticosteroids toxicity in 3 p, MRI with leukoencephalopathy/radiation necrosis in 11 p, hydrocephalus in 3 p, stroke in 2 p, and neuro-cognitive symptoms (moderate/severe) in 10 p. **Conclusions:** 1. No differences in survival were observed if we consider timing of BM presentation. 2. For the global series low KPS, progression of the primary tumor, and no WBI treatment influenced on survival. 3. For NSCLC patients, MST and prognostic factors were similar.

Publication
Lung cancer

1165 PUBLICATION
Second-line treatment with pemetrexed following platinum based doublet chemotherapy in Malignant Pleural Mesothelioma

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Background: The most widely used first-line chemotherapy regimens in Malignant Pleural Mesothelioma (MPM) are platinum based doublet regimens, with pemetrexed plus cisplatin being the reference treatment. There is however no universally agreed standard for second line treatment following failure to first line treatment. Pemetrexed has previously shown activity as single agent in first-line treatment with a 14% response rate. It was thus the purpose to evaluate the activity of pemetrexed in second-line treatment of MPM pts without prior exposure to this agent.

Material and methods: Pts had MPM and had disease progression after previously first-line treatment with cisplatin plus vinorelbine. They received 0.4 mg folic acid PO q d and 1 mg vitamin B12 IM q 9 weeks, both starting one week before chemotherapy. Pemetrexed 500 mg/m² was administered as a 10 minutes intravenous infusion q 3 weeks. Standard prophylactic antiemetic treatment using prednisolone, 5-HT3 receptor antagonists, and metochlopramide was given for 3 days in each course.

Results: A total of 17 patients were included since March 2004. There were 15 males (88%), histologic subtypes were epithelial in 13 pts (76%), biphasic in 3 (18%), and sarcomatous in 1 (6%). IMIG stages II, III, and IV occurred in 1, 8, and 8 pts, respectively, and median age was 63 yrs (range 30–72 yrs). A total of 82 treatment courses have been delivered, with a median of 5 (range 1–9). CTC grade 3 or 4 toxicity was only observed with respect to leucopenia (2 pts had grade 4) and thrombocytopenia (1 pt had grade 4). There was one case of febrile leucopenia, and with fatal outcome. Three partial responses were observed (response rate 18%), time to progression was in median 17 weeks, and median survival 19+ weeks (range 5–45+ weeks).

Conclusions: Pemetrexed has a noteworthy activity as second-line treatment in pts with MPM and progression following platinum containing first-line treatment. There was one toxic death during febrile neutropenia, but the treatment was in general well tolerated. Pemetrexed may be considered for second-line treatment to MPM patients without prior exposure to this agent.

1166 PUBLICATION
Effect of second-line chemotherapy on survival of patients with advanced non-small cell lung cancer pre-treated with docetaxel-based front-line chemotherapy: a retrospective survival analysis.

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Purpose: The effect of second-line chemotherapy (S-LCh) on the survival of patients with advanced non-small cell lung cancer (NSCLC) was retrospectively evaluated in a cohort of patients enrolled different in prospective clinical trials of the Hellenic Oncology Research Group (HORG).

Patients and Methods: Six hundred and thirty-four patients with inoperable stage IIIB or IV NSCLC enrolled on different first-line chemotherapy trials during the period 1995–2000 were analyzed. S-LCh was administered in the context of different ph II HORG'S trials. Patients who did not received S-LCh were considered as "best supportive" control group. Patients' survival was studied with respect to the administration of S-LCh (S-LCh group) or best supportive care (BSC group). Survival was calculated both from the day of starting first-line chemotherapy (OS1) and from the day of first-line treatment failure or the initiation of S-LCh (OS2) until death.

Results: Two hundred twenty-four patients comprised the S-LCh group and 410 the BSC group, respectively. There were significant differences between S-LCh and BSC groups in terms of age, histology, early discontinuation of first-line chemotherapy and performance status after first-line chemotherapy. Three (1.3%) complete and 25 (11.2%) partial responses to second-line chemotherapy were observed for an overall response rate of 12.5% (95% CI: 8.2%–16.8%). The median OS1 was 13 and 7 months (p<0.001) and the OS2 7 and 3 months (p<0.001) for the S-LCh and BSC groups, respectively. In Multivariate analysis revealed that response to first-line chemotherapy, early termination of first-line chemotherapy, performance status and disease stage after first-line chemotherapy, and administration of S-LCh had an independent significant effect on both OS1 and OS2.

Conclusions: Taken into account the limitations of a retrospective study, the presented data support the hypothesis that second-line chemotherapy in patients with NSCLC is associated with a survival benefit.

1167 PUBLICATION
Adjuvant chemotherapy (CT) and patient compliance in non-small cell lung cancer (NSCLC). A multivariate analysis of 356 consecutively treated patients

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Introduction: After the recent Publication only of the positive results of some large randomized trials, a growing interest was noticed for platinum based adjuvant CT after radical surgery in NSCLC. The patient compliance to CT has been equally noticed as an important issue, in the recent and previous studies, with an average of 50% of patients receiving the intended number of CT cycles.

Patients and methods: We retrospectively evaluated the compliance to adjuvant CT for a series of 356 consecutively treated patients, during 1994–2003. All patients had macroscopic and microscopic radical resection of the primary tumor, with or without mediastinal node dissection or sampling, had received at least one adjuvant CT cycle, with or without post-operative irradiation (RT). The CT was planned to be delivered for 6 cycles. The following schedules were used: cisplatin 60 mg/m², cyclophosphamide 600 mg/m² and epirubicin 50 mg/m² on day 1 (16%), etoposide 120 mg/m² + cisplatin 30 mg/m², both intravenously on days 1–3, every 21 days (68%), other platinum based (16%). A multivariate analysis, for a target of 4 and 6 cycles, was performed in order to evaluate the impact of the following categories: age, sex, extent of surgery, stage, RT, patient residence.

Results: One hundred seventy nine patients (50%) completed all 6 cycles, while 299 (84%) received at least 4 cycles. The medium number of administered cycles was 5.

The multivariate analysis of patient characteristics on treatment compliance is shown in the table below.

Characteristic	Total	4 cycles			6 cycles		
		%	OR (95%CI)	p	%	OR (95%CI)	p
Age ^a			0.99 (0.96–1.02)	0.63		0.97 (0.95–0.99)	0.01
Gender							
M	289	85	0.78 (0.38–1.58)	0.49	52	0.65(0.37–1.14)	0.13
F	67	81			42		
Surgery							
Pneumectomy	129	83	0.83 (0.44–1.58)	0.58	43	0.54 (0.33–0.87)	0.01
Lesser resection	227	85			54		
RT							
Yes	147	86	0.52 (0.31–1.10)	0.10	50	1.04 (0.66–1.63)	0.84
No	209	77			49		
Residence							
Local	164	81	0.67 (0.37–1.20)	0.18	46	0.75 (0.49–1.16)	0.20
Remote	192	86			54		
Stage							
I, II	149	84	0.90 (0.48–1.70)	0.75	51	1.17 (0.73–1.82)	0.51
III	207	83			51		

^aAge used as a continuous variable. OR: odds ratio, CI: confidence interval.

Conclusion: Using the above mentioned combinations, the patient compliance with adjuvant CT was good, with 84% receiving at least 4 and 50% all 6 cycles. The medium number of cycles was 5. For a target of 4 cycles none of the investigated variables had a significant impact. For a longer CT duration, age and extent of surgery were correlated with a lower compliance.