Conclusion: Weekly schedule of docetaxel and cisplatin in the first-line treatment of NSCLC demonstrated good efficacy and manageable toxicities.

9083 POSTER

Oral vinorelbine in elderly or unfit patients with metastatic NSCLC

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Background: Standard treatment for unfit or elderly patients (PTS) with NSCLC often includes single-agent (not platinum-based) chemotherapy or best supportive care (BSC), rather than a classical chemotherapy doublet. The Elderly Lung Cancer Vinorelbine Italian Study (ELVIS) stated that vinorelbine (VNB) provides both a survival and symptomatic benefit over BSC in elderly pts with NSCLC. The currently available oral formulation of VNB should be handier, with activity and safety profile similar to intravenous formulation.
We aimed to investigate efficacy and safety of oral VNB and its role as the next best in pts with advanced NSCLC not tolerating a classical combination chemotherapy.
Materials and Methods: We enrolled 55 consecutive patients (M/F = 41/14) with median age of 71 years (range 59−84), ECOG PS=1−2, major comorbidities and stage IIIB (n = 23) or IV (n = 32) NSCL (Adenocarcinoma = 51%, Squamous = 31%, NOS = 18%). Patients received oral VNB 60 mg/mq day 1.8 q21 as first-line chemotherapy until progression or unacceptable toxicity, evaluated according to NCI-CTC scale. Time to progression (TTP) was defined as the time between the beginning of treatment and the first evidence of tumor progression. Clinical benefit was evaluated according RECIST score.
Results: The 7% of treated pts had a partial response (RP), 41% stable disease (SD) until the regular treatment suspension and 52% showed a progression disease (PD), with a total clinical benefit of 48%. The median observed TTP was 6 months (range 2−23).
Treatment was well tolerated from the great part of pts and the main toxicities were low-grade (G1-G2). Few pts reported severe (G3-G4) adverse events such as fatigue 4% (n = 2), diarrhea 4% (n = 2), neutropenia 4% (n = 2), vomiting 2% (n = 1), anemia 2% (n = 1).
Conclusions: In our experience, oral VNB represents a safe first line chemotherapy in elderly, unfit pts with metastatic NSCLC not suitable for combination chemotherapy. The oral formulation allows a good compliance to treatment, optimal nausea/vomiting control by oral antiemetics and no required dose adjustment. Furthermore, oral VNB seems to preserve quality of life in the half of treated patients.

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Pemetrexed vs docetaxel as second-line in NSCLC: is there a difference between adenocarcinoma and squamous cell carcinoma? – a retrospective analysis of a single institution

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Background: Emerging data suggest that chemotherapy with pemetrexed is more effective in patients with adenocarcinoma compared to those with squamous histology, with a longer survival. So the tumor histology should be carefully evaluated in second-line chemotherapy for patients with relapsed or metastatic non-small lung cancer. We retrospectively analysed patients with metastatic NSCLC divided in subgroups on the basis of histology, to evaluate the differential efficacy of pemetrexed and docetaxel.
Materials and Methods: From July 2000 to December 2008 we evaluated 368 patients with NSCLC, treated with pemetrexed or docetaxel, of whom 238 with adenocarcinoma and squamous cell carcinoma. One hundred and ninety-nine (83%) pts were evaluable for PFS and OS. Patients with histology not specified were excluded. Patients characteristics were: median age 63 years, F/M 23/77%, ECOG PS 0−1 86%, current/former/never smokers 37/45/13% (unknown 5%). The most part of pts were previously treated with platinum-based chemotherapy. One hundred and twenty-one pts were treated with pemetrexed, of whom 93 with adenocarcinoma and 28 with squamous cell carcinoma; 78 pts were treated with docetaxel, of whom 53 with adenocarcinoma and 25 with squamous cell carcinoma. Docetaxel was administered at 75 mg/sqm every three weeks (median 3 cycles, range 1−6). Pemetrexed was administered at 500 mg/sqm every three weeks (median 3 cycles, range 1−10).
Results: We analysed the two histologic subgroups and the different type of chemotherapy. The median follow-up is 14 months, median PFS and OS were 2.2 and 8.5 months. The median PFS and OS are presented in the tables below:

	Median PFS (mos)		
	Pemetrexed	Docetaxel	
Adenocarcinoma	2.1	2.3	p = 0.877
Squamous cell carcinoma	2.2	2.3	p = 0.627

	Median OS (mos)		
	Pemetrexed	Docetaxel	
Adenocarcinoma	9.4	8.0	p = 0.860
Squamous cell carcinoma	7.2	9.0	p = 0.636

Conclusions: Our retrospective analysis of adenocarcinoma and squamous cell carcinoma treated with pemetrexed or docetaxel, did not show a statistically significant differences in PFS and OS. Further analyses are needed to validate these data.

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A platinum based second line rechallenge chemotherapy improves survival in small cell lung cancer patients

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Background: Patients with SCLC that progress after first-line (FL) chemotherapy have a poor prognosis and the evidence of a benefit of SL is still limited. This retrospective analysis evaluates the clinical outcomes of patients who received SL treatment for SCLC.
Methods: Retrospectively we reviewed 166 consecutive patients who progressed after FL and received a second or third-line treatment, between 1993 and 2008 in 17 institutions. In our analysis we divided patients in four subgroups, according to the type of SL treatment: 1) Platinum-based rechallenge (P), 2) Non platinum-based polichemotherapy (NP), 3) Non topotecan monochemotherapy (NT), and 4) topotecan monochemotherapy (T). Our endpoints were Overall survival (OS), Progression free survival (PFS) and Response Rate (RR). Survival curves were designed with Kaplan-Meier method and Cox proportional hazard model was used for investigating factors which influence survival.
Results: Median age was 63 (range 25−86). Median OS from the SL was 6.2 months and PFS 2.9. 163 patients received a platinum based chemotherapy as FL, among them 67% obtained a response (CR = 14%, PR = 53.7%) and 19% had progressive disease (PD). 30% of the complete responders and 22% with partial response after FL had a response in SL, whilst only 16% of patients with SD/PD after FL had a response with SL (test for trend p = 0.03). No statistical differences among regimens groups were found. However, patients receiving platinum-based rechallenge did better than others if they had a long PFS after FL (p = 0.02).
Conclusions: The clinical benefit of SL therapy for SCLC is poor and strictly dependent on response and on duration of response with FL treatment. Consistently with published data, our retrospective analysis confirms that median OS for patients receiving SL is about 6 months and median PFS is 2.9 months. Rechallenge with platinum could be the best options in patients with a long PFS in FL. Single agent topotecan did not show evidence of superiority against other chemotherapy regimens.

9086 POSTER

Pralatrexate plus vitamin B12 and folic acid supplementation in patients with previously-treated, advanced non-small cell lung cancer: safety and efficacy in a phase 1 trial

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Background: Pralatrexate showed activity in previously treated patients (pts) with advanced non-small cell lung cancer (NSCLC) at doses of