were mucosal (G3, 5 pts; G4, 1 pt), asthenia (G3, 2 pts), hand-foot syndrome (G3, 9 pts). GS=1 neutropenia occurred in only 6 pts (14%) (G2, 4 pts; G4, 1 pt). 8 pts required dose reductions. Enzymatic analysis in 12 pts to date suggests ratio of TP/tumor-normal tissue; TP/DPD in tumor and nuclear TS may be useful markers of response. Final data will be presented at the meeting. In summary, the combination of capcibacilnine and low dose docetaxel is well tolerated. PFS appears similar to every 3 weeks docetaxel, although RR appears higher and encourages evaluation of this regimen as a 1st line regimen in NSCLC.

Background: Platinum-based chemotherapy remains the standard of care in treatment of advanced NSCLC although CDDP-related toxicity is a constant concern. A conventional means of minimizing CDDP side effects is to split the dose, which is not expected to alter efficacy.

**Patients and Methods:** From February 2000 to April 2002, fifty patients with advanced NSCLC were treated with CDDP 330 mg/m² and VNR 30 mg/m² on days 1 and 8 of a three-week cycle for up to 8 cycles. Ondansetron and Dexamethasone were prescribed routinely. HRQL was assessed at baseline, prior to each cycle, and in initial follow-up using the EORTC core questionnaire,QLQ-C30, and lung cancer module, QLQLC13.

**Results:** Patient characteristics were average age 63 years (median, range 37-79), male 23 (46%), ECOG 0-1 31 (62%), stage IV or recurrent disease 39 (78%), and adenocarcinoma 21 (42%). The median number of cycles completed was 4 (range 1-6). Median survival was 266 days, with one-year survival 39%. CTC version 2 grade 3/4 toxicities included neutropenia 23 (46%), anemia 7 (14%), and thrombocytopenia 1 (2%). Four patients (8%) had febrile neutropenic episodes, 11 (22%) received blood transfusions, and 2 (2%) received platelet transfusion. There were no grade 3/4 renal dysfunction although grade 1/2 elevations in serum creatinine occurred in 11 patients (22%). Compliance with HRQL assessments at each time point ranged from 78-100%. Rated as ‘quite a bit’ or ‘very much’ were nausea in 18/44 (41%), vomiting in 6/44 (18%), and tingling in the hands or feet in 8/44 (19%). By the end of the last cycle, 21/39 patients (54%) demonstrated a clinically significant greater than 10 point decline in global health status score compared to baseline, while 14/39 (36%) had stable or improved scores. Further analyses of HRQL outcomes will be presented.

**Conclusions:** Survival and toxicity with this schedule of CDDP and VNR are comparable to other established platinum-based regimens used in treatment of NSCLC. HRQL is also similar to results from recent randomized trials. Establishing that split-dose CDDP is associated with low CDDP-related toxicity and improves HRQL requires further study.

**Phase II trial exploring gemcitabine and cisplatin as treatment of patients with non-small cell lung cancer (NSCLC) and inoperable brain metastases**

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**Background:** Brain metastases are frequent in NSCLC, either at diagnosis or during follow-up. Patients with inoperable metastases are treated with whole brain radiotherapy (WBRT) and have a poor prognosis, with median survival shorter than 6 months. Despite the availability of platinum-based chemotherapy, patients with brain metastases are often excluded from clinical trials, because it is considered that the blood-brain-barrier does not allow chemotherapy drugs to enter in the central nervous system (CNS). Yet, this has been refuted by some investigators. Therefore, the purpose of this study was to evaluate the efficacy of gemcitabine and cisplatin in the treatment of NSCLC patients with inoperable brain metastases.

**Patients and methods:** Patients with NSCLC and inoperable brain metastases enrolled in this study. All patients signed informed consent. Treatment consisted of gemcitabine 1000 mg/m² and cisplatin 50 mg/m², both delivered on days 1 and 8, every three to four weeks.

**Results:** Consecutive patients were enrolled in our institution. 22 had synchronous brain metastases and were chemotherapy-naive. 4 patients were enrolled after brain relapse following previous chemotherapy (disease free interval: mean: 13.2 months, range: 9-26). Two patients were not evaluable because of early death, after 6 and 8 weeks, respectively. After 2 cycles, the documented CT scan response rate (RR) in brain metastases was 71% in 24 evaluable patients. After 4 cycles the RR was 73% in 15 evaluable patients. With 7 complete responses and 8 partial responses, the overall RR was 62%. One patient had stable disease. All but three of the responding patients had a response on their primary lung tumor lesion. The mean duration of response was 6.8 months and the overall mean survival is 5.4 months overall and 7.2 months in responding patients. Toxicity: no infection, no bleeding, no non hematotoxicity. 2 patients experienced complete CNS toxicity post radiotherapy was noticed (42% of the patients received WBRT).

**Conclusions:** This chemotherapy regimen shows encouraging activity in NSCLC patients with CNS metastases. Further trials in patients with NSCLC and CNS metastases are warranted.