be difficult for patients with co-morbidities. To reduce these toxicities, we conducted a phase II study to evaluate the efficacy and toxicity of weekly cisplatin and docetaxel in advanced NSCLC.

**Methods:** Eligibility included patients with advanced or recurrent NSCLC, ECOG PS of 0-1, and no prior chemotherapy for metastatic disease. This Cancer Institute of New Jersey network, single stage phase II clinical trial was designed to give 3 weekly doses of cisplatin at 25 mg/m² and docetaxel at 35 mg/m², followed by 1 week of rest, for a total of 6 cycles of therapy. Toxicity was monitored weekly, and disease evaluation was performed every 2 cycles. The primary endpoint was response rate (RR); secondary endpoints included time to progression (TTP), median and 1-year survival.

**Results:** From 12/03 to 03/07, 38 patients were enrolled so far. The median age of patients is 63 (range 47-78), the majority is white (n=35), 31 have stage IV disease, and almost half (n=18) are women. Fifteen have an ECOG PS=0 and 23 with PS=1. Histologic subtypes are: adenocarcinoma (n=26), NSCLC NOS (n=7), squamous (n=5).

Fourteen patients received cisplatin and docetaxel cycles delivered is 2.4. Reasons for treatment discontinuation include completion of therapy (n=7), progression of disease (n=17), adverse events (n=8), and patient preference (n=4). Two patients continue on therapy at this time. No complete responses were yet observed; 8 patients (21%) achieved a partial response; 10 patients had stable disease, 10 patients progressed, 8 came off study before first disease evaluation, and 2 have not yet had disease evaluation. Median TTP was 3.8 months (mo) (95% CI 2.0, 4.7), median survival is 8.7 mo (95% CI 5.6,16.2) and 1-year survival is 40.2% (95% CI 20.9, 58.8). Most toxicities were mild but also included neutropenia (grade 3, n=1; grade 4, n=1), neutropenic fever (n=1), renal toxicity (grade 3, n=2), nausea (grade 3, n=1), fatigue (grade 3, n=3), diarrhea (grade 3, n=4) and metabolic abnormalities (grade 3, n=3).

**Conclusion:** Weekly cisplatin and docetaxel is well tolerated with a low incidence of toxicity and demonstrates activity similar to every 3-week treatment in patients with advanced NSCLC.

**Methods:** Data were collected retrospectively from the records of patients (pts) enrolled in centers participating in the Portuguese Lung Cancer Study Group (GECP). The pts had locally advanced or metastatic NSCLC and failed first-line chemotherapy. They received P (500 mg/m² on a three-weekly schedule with vitamin supplementation).

Objective response (OR; complete [CR] or partial [PR] response) was evaluated using RECIST and safety assessed using serious or non-serious adverse events (SAEs/AEs).

**Results:** By December 2006, 19 GECP centers had enrolled 244 pts who had received P for ≥1 cycle, and were considered evaluable for both objective response and safety. Demography: male/female, 175/69; median age, 57.0 years (range 20-81); smoking status, y/ex/n, 116/57/71 adenocarcinoma/squamous-cell carcinoma/other histology, 141/72/31; prior chemotherapy, platinum plus gemcitabine/paclitaxel/vinorelbine/docetaxel, 152/37/30/19; mean number of cycles in 1st line, 4.8 (range 1-8); disease control (OR + stable disease [SD]) was observed in 170 (61.0%) pts: 7 CR, 79 PR and 84 SD; mean time to progression (TTP) 8.07 months. P mean number of cycles in 2nd line, 4.1 (range 1-15); disease control in 209 evaluable pts was observed in 116 (55.5%): 2 CR, 45 PR and 69 SD; mean TTP 4.70 months. The majority of AEs were grade 3 anemia (15 pts) and neutropenia (18 pts).

The mean overall survival was 17.27 months.

**Conclusions:** Our retrospective analysis has observed a similar disease control rate with P in 2nd line (55.5%), and TTP (4.7 months) in our current unselected population to that published in the literature. P is an option for second-line NSCLC with a good tolerability.

---

**P2-226**

**NSCLC: Cytotoxic Chemotherapy Posters, Tue, Sept 4**

**A prospective study between docetaxel and pemetrexed for second line treatment of non-small cell lung cancer in a single institution**

Araujo, António M.; Rego, Sónia; Azevedo, Isabel; Soares, Marta
Portuguese Institute of Oncology - Porto Centre, Porto, Portugal

**Background:** Docetaxel (D) and Pemetrexed (P) are two options for the second-line treatment of non small-cell lung cancer (NSCLC), with similar response rates and overall survivals but different toxicity (Hanna N et al, J Clin Oncol 2004;22:1589-1597). P was introduced in Portugal in October 2004. The authors carried out a retrospective study of patients (pts) diagnosed with NSCLC treated in 2nd line with D or P at Portuguese Institute of Oncology - Porto Centre (IPO-Porto), Portugal.

**Methods:** We made a retrospective review of the pt clinical files with NSCLC treated in second-line with D or P between December 2003 and December 2006 at IPO-Porto. The primary objective was the evaluation of safety assessed using serious or non-serious adverse events. Secondary objectives were to assess time to progression (TTP) and overall survival (OS) between the two drugs on that unselected population.

**Results:** Of 96 evaluated pts who received 2nd line chemotherapy (CT), 78% were male. Median age at diagnosis was 63 years (range: 29-81); 38% were adenocarcinomas, 58% squamous cell carcinoma and 4% were large cell carcinomas; 99% had a performance status ECOG 0. At diagnosis, 50% had metastasis in at least one site. All pts received platinum first line based CT. At 2nd line treatment, 77 (80%) received D and 19 (20%) P. Mean number of cycles received was 5.6 for D and 4.3 for P. The sum of grade III toxicities were observed on 27 pts on D and 7 on P, and grade IV toxicities were observed on 10 pts on D and none on P. Incidence of grade III anaemia was 12% on D and 11% on P.