

performance status 2 was evident in 26.3 %, 26 %, and 5 % respectively. Among all the patients treated the overall response rate (RR) was 53.2%, 95% confidence interval 40.1-66%. Response rates were 52.6% for arm A, 65.2% for arm B, and 40% for arm C.

The median survival times were as follows: Arm A, 9.8 months, arm B, 12 months, arm C, 9.2 months. Survival did not differ among the 3 arms ($p=0.42$). The one year survival rate was 26.3 %, 34.7 % and 25% in groups A, B and C respectively. Survival for two years or more was evident in 10.5%, 17.3%, and 5% in group A, B, and C respectively. The median time to progression was 5 months for arm A, 11 months for arm B and 6.3 months for arm C. The median number of cycles was 4 with range 1-6 cycles.

In general, the 3 regimens were well tolerated: Neutropenia (all grades) was encountered in 31.5 %, 47.7 %, and 15 %, thrombocytopenia was encountered in 5.2 %, 26 % and 5 % and anemia occurred in 31.5 %, 34.8 % and 35 % in groups A, B and C respectively. As for non hematological toxicity, arm A and C had more tendency to neuropathy while arm B had tendency to hepatotoxicity but there were no statistical differences.

Conclusion: Our results showed that paclitaxel/cisplatin, gemcitabine/cisplatin, and paclitaxel/gemcitabine combinations provide no significant difference in response, survival or toxicity. Treatment was well tolerated by the patients in the 3 different groups.

P2-177

NSCLC: Combined Modality Therapy Posters, Tue, Sept 4

A multicenter phase II study of carboplatin plus gemcitabine followed by concomitant chemoradiation in patients with non-resectable stage III non-small-cell-lung cancer: preliminary report of the Cher@Nos trial

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Background: Combined chemoradiotherapy is now considered the standard of care in patients with unresectable stage III NSCLC. Despite the therapeutic advances that have been made during the last decennium, there remains a need for better local and distal control of disease in patients with locally advanced NSCLC. At present it is not clear which combined modality approach provides optimal results (both in terms of survival and toxicity).

In the present study we wanted to evaluate whether by combining a carboplatin-gemcitabine based induction chemotherapy with weekly cisplatin during standard thoracic radiotherapy, it is possible to obtain good efficacy with minimal toxicity

Methods: Patients (PS 0-1) with unresectable stage III NSCLC were treated with 3 cycles of induction chemotherapy followed by chemo-radiotherapy. The induction chemotherapy consisted of carboplatin (AUC 5 on day 1) with gemcitabine (1200 mg/m² on day 1 and 8) every 3 weeks for 3 cycles. The chemo-radiotherapy consisted of cisplatin (30 mg/m² weekly) concomitant with conventional radiotherapy (2.0 Gy/fraction, 5 fractions a week, up to a total dose of 60 Gy). The primary endpoint of this phase II trial was a survival rate at 2 years of >35%.

Results: Between February 2003 and November 2005, 45 patients were enrolled: The demographics were as follows: 34/11 male/female, 14/30 stage IIIA/IIIB, median age 62 y (range 41-81 y), 42% squamous cell and 33% adenocarcinoma. All patients received at least one cycle of induction chemotherapy: 7% only 1 cycle, 7% 2 cycles and 87% all 3 cycles. Chemoradiotherapy was started in 36 patients. Median total radiation dose and duration was 60 Gy and 43 days.

Grade 3/4 toxicities during chemotherapy were: neutropenia (36%), thrombocytopenia (18%), febrile neutropenia (1%), rash (1%), elevation of transaminases (1%) and constipation (1%). The effect of the treatment on the pulmonary function is summarized in the following table:

	Baseline	Post-chemo	Post-chemoradio	Follow-up at 6 months	Follow-up at 12 months
Mean FEV1 (L)	2.26	2.42	2.48	2.33	2.27
Mean FVC (L)	3.19	3.41	3.14	3.32	3.05
Mean DLCO (%)	67.7	60.4	60.7	64.2	65.4

The overall response rate was 31% (2% CR, 29% PR) following induction chemotherapy, and 58% (2% CR, 56% PR) at the end of treatment. With a median follow-up of 14.4 months (range 1-35 months), the median progression-free survival is 10.6 months. The overall 1- and 2-year survivals are 61% and 39%.

Conclusions: The preliminary results from this phase II trial showed that induction chemotherapy with carboplatin and gemcitabine followed by thoracic radiotherapy with concurrent weekly cisplatin is a well tolerated combined modality approach with promising overall survival in patients with unresectable stage III NSCLC.

P2-178

NSCLC: Combined Modality Therapy Posters, Tue, Sept 4

Mediastinal-based treatment decision tree in stage IIIA-N2 non-small cell lung cancer

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Involvement of N2 lymphatic structures, i.e. ipsilateral mediastinal lymph nodes in non-small cell cancer of the lung represents a very inhomogeneous disease, according to size, number, location, extension, and biologic features. Despite recent advances, the therapeutic strategy for stage IIIA subcategory remains unclear, particularly regarding the role of surgical resection. Controversial recent data suggest a potential impact of post-induction surgery specifically limited to patients who respond at the mediastinal level. Others make differences in approaches according to the location of mediastinal N2 involvement. Authors propose a simple decision-making algorithm based upon last advances in imaging, clinical trials, mediastinal status, response after induction, staging and re-staging new techniques, and current burning remaining questions.