

Results: A total of 28 patients were enrolled on this study from four institutions between 15/7/02 and 11/7/05. Patient characteristics: median age 65 (range 50 - 75). Male 61%. Performance status 0/1:11/17. Histology: squamous/mixed 12, adenocarcinoma 6, large cell/undifferentiated 10. Stage IIA 1, IIIA 16, IIIB 11. All patients received 60Gy. Chemotherapy dose was successfully escalated to level 4 (expanded cohort: 16 patients). No DLT's were observed during the escalation phase. Response (28 patients evaluable): overall response rate 61% on PET scan, 46% on CT; complete response 43% (PET) 21% (CT). Of 16 patients failing, first site of progression was locoregional: 11, distant: 4 and both: 1. At the close-out date 31/10/06 median survival had not been reached and survival at 24 months was 60% (95% CI: 39-82%).

Conclusions: Gefitinib 250mg per day can be safely given with full dose chemoradiation consisting of 60Gy plus carboplatin and paclitaxel. Locoregional progression is the major cause of treatment failure.

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P2-163 NSCLC: Combined Modality Therapy Posters, Tue, Sept 4

Concurrent Chemoradiation for Stage III Non-Small Cell Lung Cancer (NSCLC): A Single Institution Canadian Experience

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Background: Combined modality therapy remains the best chance of cure in the setting of locally advanced NSCLC. The optimal combination of concurrent chemotherapy and radiation (CRT) continues to evolve. In this study we report our single institution experience with tri-modality therapy in patients with Stage III NSCLC.

Methods: 55 patients with Stage III NSCLC and ECOG 0-1 were prospectively studied between September 1995 and March 2004 at CancerCare Manitoba, Winnipeg, Canada. From 1995 through 1997, the standard regimen (PE) consisted of Cisplatin (25 mg/m²) & Etoposide (100 mg/m²) for 3 days every 3 weeks for 2 cycles combined with either radical intent (5000 cGy in 20 fractions) or palliative intent (3000-3500 cGy in 10 fractions) concurrent radiation. In 1998, the standard regimen was switched to TC using Carboplatin (AUC 3) & Paclitaxel (45mg/m²) once weekly for 4-6 weeks combined with 5000 cGy in 20 fractions. After a treatment related death in 1999, the Carboplatin dose was reduced (AUC 2) and radiation was revised to either 4500 cGy in 25 fractions for Stage IIIa or 6000 cGy in 30 fractions for Stage IIIb disease. All patients were assessed for clinical response, toxicity, surgical resection, pathologic response, and survival.

Results: Median age was 62, Stage IIIa 59%, and Adenocarcinoma 43%. Eighty-eight percent of patients received their prescribed dose of PE and 90% received at least four cycles of prescribed TC chemotherapy. Radical radiation therapy was the intended therapy in 95% of cases however only 75% of patients received at least 5000 cGy of radiation. Clinical response to therapy is shown in the table below.

Regimen	N	Complete Response	Partial Response	Stable Disease	Progressive Disease
Cisplatin & Etoposide (PE)	26	0 (0%)	17 (59%)	8 (28%)	4 (14%)
Carboplatin & Paclitaxel (TC)	29	2 (8%)	8 (31%)	8 (31%)	8 (31%)

Grade 3 toxicity occurred in 2 patients on PE and 10 on TC. One patient receiving TC died of treatment related toxicity. Ten patients in

each chemotherapy group went on to surgical resection with partial pathologic response seen in 50% PE and 80% TC. Median survival was 2.05 years for this population with no significant survival difference between treatment groups (PE 2.25 vs. TC 1.98 years, p = 0.39). Dose of radiation (≥ 5000 cGy vs. < 5000 cGy) did not significantly impact survival. Patients who proceeded to surgical resection survived a median of 3.33 years compared to 1.62 years for un-resected patients (p = 0.0006).

Conclusions: In our experience, both combinations of chemotherapy combined with radiation were equally effective in terms of overall survival in Stage III NSCLC. TC based CRT appears to have better clinical and pathologic response compared to PE at the expense of a slight increase in treatment related toxicity. The few patients who proceeded to surgery post CRT had significantly improved survival.

P2-164 NSCLC: Combined Modality Therapy Posters, Tue, Sept 4

Radiotherapy with concurrent low-dose carboplatin for inoperable stage III non-small-cell lung cancer (NSCLC) in elderly or frail patients

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Background: Purpose of this study was to evaluate feasibility of thoracic radiotherapy (TRT) with concurrent daily low-dose carboplatin for inoperable stage III NSCLC in elderly or frail patients in the Central European population.

Methods: Modified Japanese treatment protocol originally published by Atagi et al (Jpn J Clin Oncol, 30, 2, 59-64) was used. TRT 60 Gy (2 Gy fractions, 5 days a week) was administered over a 6-week period. Carboplatin 25 mg/m² as a 30 min infusion was given one hour before TRT, daily, over four weeks, starting on day one. The eligibility criteria for patients included: age 65 years or over with ECOG PS 0 - 2 or younger with ECOG PS 2, histologically and/or cytologically confirmed NSCLC, inoperable stage III disease, satisfactory blood count and standard biochemical parameters. There was no age-limit.

Results: Twenty patients were treated. Patients' characteristics: elderly/non-elderly: 18/2, age - median: 73.5 years (range: 55 - 80), male/female: 18/2, ECOG PS 0/1/2: 0/10/10, squamous cell carcinoma/adenocarcinoma: 18/2. All patients were assessable for treatment response and toxicity. In fourteen was it possible to administer the entire protocol therapy without any disruption. The response by the end of treatment was: complete response: 0, partial response: 12 (60%; 95%CI: 39 - 78%), stable disease: 7 (35%; 95%CI: 18 - 57%), progressive disease: 1 (5%; 95%CI: 1 - 24%). Survival time - median: 19 months (range: 3 - 36+; 95%CI: 10 - 26), 2-year survival rate - 35% (95%CI: 18 - 57%). Main toxicities were as follows: NCI CTC grade 3/4 neutropenia in 25/5%, thrombocytopenia in 15/5%, febrile neutropenia in 5/0%, respiratory infection in 10/0%, and esophagitis in 5/0%. Transfusions and/or erythropoietin were given due to grade 2 anemia in 40% of patients. All toxicities were manageable and there was no treatment related death.

Conclusion: TRT with daily low-dose carboplatin was feasible in our group of patients. Response rates and survival are comparable with those achieved in younger good prognosis patients by more sophisticated combinations of TRT and chemotherapy.