toxicities were fatigue; nausea; asthenia, vomiting and arthralgia/ myalgia.

More than forty percent of the patients received 2nd line therapy and, from those, 23% were responsive to the treatment.

Maintenance therapy with gemcitabine in perfusion for 120 minutes versus for 30 minutes both combined with carboplatin, showed similar response rates and safety profiles.

P2-296 **NSCLC: Cytotoxic Chemotherapy Posters, Tue, Sept 4**

Treatment of advanced stage NSCLC with low dose gemcitabine and carboplatin in patients above age of 60 years

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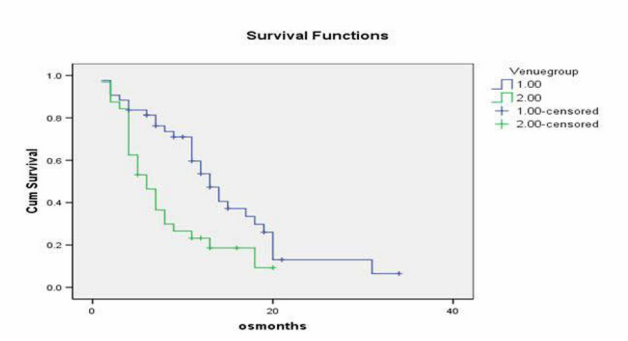
Background: NSCLC is a common malignancy worldwide-including developing countries like India. The standard treatment of advanced stage NSCLC is platinum doublet chemotherapy, one of the most active being Gemcitabine- platinum combination. Gemcitabine requires conversion by deoxycytidine kinase into its active metabolite. This rate limiting step can be circumvented by prolonging infusion duration.

Methods: In the present study we treated 75 elderly patients (age 60 or more) having advanced stage NSCLC with low dose prolonged infusion Gemcitabine (350mg/m^2 over 4 hours, Day 1 and Day 8) and standard dose Carboplatin (AUC-5, Day 1 only) repeated every 3 weeks for maximum 6 cycles.

Results: There were 60 (80%) males and 15 females. Of them 43 were between the age of 60 and 65 yrs, 18 between the age of 65 and 70 whereas 14 patients were above the age of 70 yrs. PS was 1 in 54 and 2 in 24 cases. Stage wise distribution was 40 (53.3 %) with Stage IV and 35 (46.7 %) with Stage IIIB. Histopathology was adenocarcinoma in 46, squamous cell in 14 and not specified in the remaining 15 patients. Of these 75, 30 had significant co-morbidities. Chemotherapy was administered by medical oncologists in 43 patients and others (other oncologists/ non oncologists) in the remaining 32 cases. All 6 cycles were completed in 46 (61.33 %) of patients - 33 completed all 6 cycles without any dose reduction, 13 completed 6 cycles with dose reduction and 29 could be goven less than 6 cycles of CT. Partial response was seen in 19 (25.3 %), stable disease in 36 (48 %) and progressive disease in 20 (26.7 %). There was no treatment related mortality. The median overall survival was 11 months (range 1 - 34 months). There were significant differences among patients treated by medical oncologists (group 1) and by others (group 2). The overall RR was 37.2 % (16/43) in Group 1 and 9.4 % (3/32) in Group 2. The median survival was 13 months in Group 1 and 6 months in Group 2 (p value = 0.004), the overall RR was and the medial OS was 6 months. These differences were statistically significant.

Conclusions: We conclude that low dose prolonged infusion gemcitabine and standard carboplatin combination is an effective treatment for patients above the age of 60 years with advanced stage NSCLC. Dose intensity impacts on RR as well as overall survival and is best optimized when chemotherapy is administered by medical oncologists.

Overall Survival
Rx by medical oncologist vs others



Median OS – Medical Oncologist (13 mths) vs others (6 mths; p value 0.004)

P2-297 **NSCLC: Cytotoxic Chemotherapy Posters, Tue, Sept 4**

Phase II trial of weekly docetaxel and gemcitabine for chemotherapy-naive patients with advanced non-small cell lung cancer

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Background: Docetaxel and gemcitabine combination chemotherapy has been reported to be active against non-small cell lung cancer (NSCLC) and myelosuppression was the most common dose-limiting toxicity. This prospective phase II study was designed to test the hypothesis that better tolerance and increased dose intensity might be achieved if patients are treated with weekly administration schedule.

Methods: Consenting patients with stage IIIB/IV or recurrent NSCLC received first-line chemotherapy with docetaxel 35 mg/m^2 and gemcitabine 600 mg/m^2 on days 1, 8 and 15. Treatment was repeated every 4 weeks, for up to 4 cycles.

Results: Of the 35 patients who started treatment, only 6 patients (17%) completed planned 4 cycles of therapy. Other than the completion of all planned treatment cycles, the main reasons for treatment discontinuation were toxicity (43%) and progressive disease (40%). The most frequently encountered toxic effects were anemia (52% of patients), nausea and vomiting (60%), fatigue (71%) and anorexia (57%). One patient died of bilateral pneumonitis shortly after the administration of first cycle. Disease control (objective response and stable disease) in the ITT population was achieved in 49% of patients and the overall response rate was 29% (95% CI, 14 to 44%). With a median follow-up duration of 9.2 months, the median progression-free survival was 2.8 (95% CI, 0.7 to 4.8) months and the 1-year survival was 53%.

Conclusion: Weekly schedule of docetaxel and gemcitabine has modest activity in advanced NSCLC. This regimen offered no potential advantages over standard treatment approaches.