2 cycles of chemotherapy. Common non-hematologic toxicities of all grades during consolidation chemotherapy were anorexia(45%), alopecia(41%), asthenia(35%), and esophagitis(41%). Hematologic toxicities were mild. Although Grade 3-4 neutropenia occurred in 5 cycles out of 65 cycles, there was no treatment-related mortality

Conclusions: These results suggest that CCRT with weekly docetaxel and cisplatin is feasible and consolidation chemotherapy with same agents after CCRT is also well tolerated. Further data will be updated on presentation.

PD4-1-5 **Combined Modality Therapy in NSCLC, Tue, 16:00 - 17:30**

Docetaxel, carboplatin and thoracic radiotherapy in unresectable stage III non-small cell lung cancer (NSCLC): A safety report of the first 100 patients treated with this concurrent chemoradiation as part of a multicenter web-based trial, D0410

Rigas, James R.[1] Rubin, M. S.[2] Waples, J. M.[3] Dragnev, K. H.[1] Zimmerman, D. M.[4] Reimer, R. R.[5] Droder, R.[6] Rathmann, J.[7] Green, N. B.[8] Carey, Mark[1]

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Background: Concurrent chemoradiotherapy (chemoRT) is the preferred treatment for patients with unresectable stage III NSCLC. Limited safety information is available on the use of concurrent docetaxel, carboplatin and thoracic RT. We report the safety information on the initial 100 patients (pts) treated with this chemoRT as part of an ongoing US randomized web-based phase III trial (D0410) evaluating the role of erlotinib/placebo following this concurrent chemoRT treatment. The sample size is 400 pts and the primary endpoint is progression-free survival.

Methods: Pts with unresectable pathologically confirmed stage III NSCLC are randomized to receive either erlotinib 150 mg or placebo orally daily for 2 years following concurrent chemoRT with docetaxel 20 mg/m^2, carboplatin AUC=2 intravenously weekly for 6 wks with thoracic RT of at least 61 Gy in 33 fractions over 6.5 weeks. The planned total lung volume exceeding 20 Gy (V20) was less than 32%. Only the chemoradiation safety information is being reported. This data was reviewed by an independent safety and data monitoring committee.

Results: Pt characteristics; 59% males, median age 69 years (range 38 to 86), 21% adenocarcinoma, 48% squamous cell, 94% ECOG PS0-1, 49% stage IIIA, 15% weight loss ≥ 10%. Of 600 planned chemotherapy treatments, 500 were administered (93 wk 1, 86 wk 2, 83 wk 3, 82 wk 4, 80 wk 5, 76 wk 6). There were 27 chemotherapy dose reductions; most commonly for esophagitis (8), neutropenia (5), renal dysfunction (3), hypersensitivity (2). There were no treatment-related deaths. There were 28 grade 3 and 3 grade 4 treatment-related adverse events. The most common grade 3/4 events were esophagitis (7), fatigue (3), dysphagis (2), odynophagia (2), neutropenia (1), thrombocytopenia (1), dematitis (1).

Conclusions: This concurrent chemoradiation regimen appears to be safe. Enrollment to the phase III trial continues. There is a planned interim efficacy evaluation at 150 events (deaths or disease progression). Funded in part by Sanofi-Aventis, Genentech, and OSI Pharmaceuticals.

PD4-1-6 **Combined Modality Therapy in NSCLC, Tue, 16:00 - 17:30**

Acute esophageal reactions from proton beam therapy and concurrent chemotherapy for non-small cell lung cancer (NSCLC): Reduction in incidence and severity despite higher doses

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The UT M. D. Anderson Cancer Center, Houston, TX, USA

Purpose and Objective(s): To assess the incidence and severity of acute esophageal reactions from concurrent chemotherapy and 3-dimensional proton beam therapy (PBT) in the context of previous results with concurrent chemotherapy and 3-dimensional photon therapy (XT) for NSCLC.

Materials and Methods: Twenty-five consecutive patients with NSCCL (stages IIB [1], IIIA [8], IIIB [8], IV [2], post-operative recurrent [6], underwent PBT and concurrent chemotherapy with curative intent on IRB approved protocols. Chemotherapy was platinum-based in all patients, most frequently carboplatin/paclitaxel (16 patients). There were 16 males/9 females ranging in age from 49 to 81 years (median 67 years). Histopathologic diagnosis was squamous cell carcinoma in 9 and non-squamous in 16 patients. All patients were evaluable for acute (< or = 90 days from first treatment) reactions. Toxicity was based on NCI common toxicity criteria vs. 3.0. XT comparisons were based on published data from our institution (215 patients) (Wei X et al, Int J Radiat Oncol Biol Phys 2006)

Results: Total doses with PBT ranged from 63 cobalt-gray equivalent (CGE) (using RBE of 1.1 vs. cobalt gamma rays) to 74 CGE (60-69.6 Gy with XT) in 33 to 37 fractions (30-58 fractions with XT). The median total dose was 74 CGE vs. 63 Gy for XT. Acute esophageal reactions were observed in 60% of PBT patients (200 of 215/93% with XT). Seven (28%) of patients had grade 2 esophageal reactions (97 of 215/45.1% with XT). Four (16%) of patients had grade 3 esophageal reactions (43 of 215/20.0% with XT). No patient had a grade 4 reaction (1of 215/0.5% with XT).

Conclusions: Proton beam therapy permitted higher total doses (17%+) with concurrent chemotherapy yet were associated with reduced esophageal reactions compared with 3-dimensional conformal photon therapy.

PD4-1-7 **Combined Modality Therapy in NSCLC, Tue, 16:00 - 17:30**

Consolidation chemotherapy with monthly Paclitaxel and Cisplatin (PC) or observation after concurrent chemoradiotherapy for locally advanced non-small cell lung cancer (NSCLC): Randomized phase II study

Kim, Young Seok[1] Choi, Eun Kyung[1] Lee, Jung Shin[2] Suh, Cheolwon[2] Kim, Sang-We[2] Kim, Woo-Sung[3] Park, Seung Il[4] Do, Kyung-Hyun[5] Song, Si Yeol[1] Park, Jae Won[1]

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Purpose: Concurrent chemoradiotherapy has become the standard treatment for unresectable locally advanced non-small cell lung cancer (NSCLC). However, distant metastases remain the major site of failure. Here we report a randomized phase II trial of consolidation chemotherapy with monthly paclitaxel and cisplatin (PC) or observation after concurrent chemoradiotherapy in patients with locally advanced NSCLC to evaluate the feasibility and the role of consolidation chemotherapy.

Methods: Between March 2000 and August 2002, a total of 104 unresectable stage III NSCLC patients who showed at least minimal response (6 complete, 86 partial, and 12 minimal responses) after concurrent chemoradiotherapy were randomized to receive 3 cycles of consolidation chemotherapy (n=50) or to be observed (n=54). Concurrent chemoradiotherapy consisted of weekly paclitaxel 40 mg/m^2 and cisplatin 20 mg/m^2 plus thoracic radiation (total dose of 70.2 Gy). Consolidation chemotherapy with paclitaxel 135 mg/m^2 and cisplatin 60 mg/m^2 started 4 weeks after completion of concurrent chemoradiotherapy and repeated every 4 weeks.

Results: With a median follow-up of 41 months, there were no significant differences in progression-free survival (PFS) and overall survival (OS) between consolidation and observation groups (median PFS, 13 vs. 12 months; median OS, 19 vs. 24 months). During consolidation PC, grade 3 or 4 neutropenia was observed in 29% of the patients. However, there was no episode of febrile neutropenia.

Conclusions: Consolidation chemotherapy with monthly PC after concurrent chemoradiotherapy is feasible and generally tolerable, however, does not show a survival benefit in locally advanced

PD4-1-8 **Combined Modality Therapy in NSCLC, Tue, 16:00 - 17:30**

Prognostic impact of total tumor volume in stage III non-small-cell lung cancer treated with concurrent chemoradiotherapy

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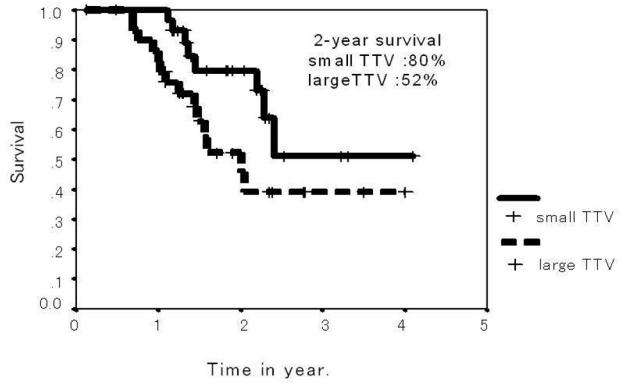
Background: Some papers report that tumor volume is a significant prognostic factor in thoracic radiotherapy for non-small-cell lung cancer (NSCLC) patients. The purpose of this study is to investigate and confirm the impact of total tumor volume(TTV) on survival in patients with stage III NSCLC treated with thoracic radiotherapy and concurrent chemotherapy.

Methods: From prospectively maintained database of our department, sixty patients were identified who underwent thoracic radiotherapy and concurrent chemotherapy in stage III NSCLC patients with an age under 75 year between October 2002 and December 2005. All patients underwent a CT scanning to facilitate treatment planning. TTV were calculated by the three-dimensional radiotherapy planning system. The median follow-up duration was 21 months in surviving patients. The Kaplan-Meier method, the log rank test and the Cox proportional hazard model were used for evaluation of survival. Survival was updated on March 1,2007.

Results: The patients consisted of 47 males and 13 females in gender, 64 year old of median age (range 44-75), 27 IIIA and 33 IIIB in TNM staging, 24 squamous cell carcinoma, 30 adenocarcinoma and 6 others in histology and 39 PS 0, 19 PS1, 2 PS2 in performance status, respectively. TTV was ranged between 11 and 1512 cc (median 78.5 cc). A prescribed dose of radiotherapy was 60 Gy in 30 fractions using 4-,6- or 10-MV X-rays in all patients. Chemotherapy regimens were as follows: 1) weekly paclitaxel (TXL)+ weekly carboplatin(CBDCA) consolidation CBDCA + TXLx2 in 33 patients, 2) mitomycin C + vindesine+ cisplatin x 4 in 12, 3)cisplatin+vinorelbinex4 in 8 and 4)others in 7. The overall 2-year survival rate was 66 %. In patients with larger TTV than median TTV 78.5 cc and with smaller TTV, the overall 2-year survival rates were 52% and 80%, respectively. The median overall survival was 29 months. The median overall survival with smaller TTV is not mature enough to be evaluated. On univariate analysis, stage IIIA was significantly better prognostic factor than IIIB (P=0.042) and the survival with smaller TTV tends to be favorable (P=0.056). PS (P=0.908) and gender (P=0.356) were not significant. On multivariate analysis, there was tendency of favorable survival in smaller TTV (P=0.068) and others (stage, PS, gender) were not significant.

Conclusion: TTV is an independent prognostic factor in stage III NSCLC treated with concurrent chemoradiotherapy.



PD4-2-1 **Cytotoxic Chemotherapy I, Tue, 16:00 - 17:30**

Optimal duration of chemotherapy for advanced non-small cell lung cancer: A systematic review and meta-analysis

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Background: The optimal duration of chemotherapy for advanced non-small cell lung cancer (NSCLC) is unclear. We performed a systematic review and meta-analysis of published randomized controlled trials (RCT) comparing longer versus shorter durations of chemotherapy.

Methods: We searched MEDLINE, EMBASE and CENTRAL for RCTs comparing 1) a defined number of cycles of chemotherapy versus continuing until disease progression, 2) a defined number of cycles versus a higher number of cycles of the same chemotherapy and, 3) a defined number of cycles of initial chemotherapy vs the same initial chemotherapy followed by additional cycles of a different chemotherapy. The primary outcome was overall survival (OS). Secondary outcomes included progression-free survival (PFS), adverse events (AE), and quality of life (QL). Hazard ratios (HR), confidence intervals (CI) and p-values (p) were estimated with fixed effects models using Revman 4.2.8