randomized, multicenter phase III trial to assess the efficacy and toxicity of weekly chemotherapy with CTR against MVP with CTR via a non-inferiority design.
Materials and Methods: MVP: mitomycin (8 mg/m^2 on days 1, 29), vindesine (3 mg/m^2 on days 1, 8, 29, 36), and cisplatin (80 mg/m^2 on days 1, 29) with CRT (60 Gy). Pts subsequently received 2 courses of consolidation chemotherapy with MVP; IC: weekly irinotecan (20 mg/m^2)/carboplatin (AUC 2) for 6 weeks and CTR (60 Gy) followed by 2 courses of irinotecan (50 mg/m^2)/carboplatin (AUC 5); PC: weekly paclitaxel (40 mg/m^2)/carboplatin (AUC 2) for 6 weeks and CTR (60 Gy) followed by 2 courses of paclitaxel (200 mg/m^2)/carboplatin (AUC 5). The primary endpoint was overall survival (OS), with secondary endpoints of progression free survival (PFS), response, and toxicity.
Results: From Sep 2001 to Sep 2005, 456 pts were randomized. Pretreatment characteristics were well-balanced among the 3 arms. Major toxicities: Gr 3−4 neutropenia in the MVP, IC, and PC arms was 95.9, 72.1, and 46.9% ($p < 0.001$). Gr 3−4 non-hematologic toxicities in terms of fatigue, febrile neutropenia, and gastrointestinal disorder were 13.0, 6.1, and 4.8% ($p < 0.001$), 37.0, 8.8, and 10.2% ($p < 0.001$), and 24.0, 8.2, and 9.5% ($p < 0.001$) in the MVP, IC and PC arms, respectively. The overall response rates were 66.4, 56.5, and 63.3%, in the MVP, IC and PC arms, respectively. The median survival times were 20.5, 19.8 and 22.0 months and the median PFS (MPFS), 8.2, 8.0 and 9.5 months in the MVP, IC and PC arms, respectively. Non-inferiority of the 2 experimental arms compared with MVP was not achieved, although no significant differences in OS and PFS were apparent among the treatment arms. The PC arm displayed the most favorable MST, MPFS, and hematologic/non- hematologic toxicities.
Conclusions: Weekly PC with CTR displayed similar efficacy, more favorable toxicity profiles compared to MVP with CTR. Therefore, weekly PC with CTR warrants use as the reference regimen in future WJOG studies.

9105 POSTER

Phase III study of concurrent chemoradiotherapy followed by surgery (S) vs. chemotherapy (C) followed by S for stage IIIA (pN2) non-small cell lung cancer (NSCLC): results of prematurely terminated trial, WJTOG9903

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Background: To ascertain whether the addition of concurrent preoperative radiotherapy to induction chemotherapy followed by surgery would improve survival outcome for patients (pts) with stage IIIA NSCLC with mediastinal lymph node metastases. Materials and
Methods: NSCLC pts with pathologically proven N2 disease were randomized either to receive induction chemotherapy (docetaxel 60 mg/m^2 and carboplatin AUC 5×2 cycles) plus concurrent radiation therapy (40 Gy) (CRS arm) or only induction chemotherapy (CS arm). Pts subsequently underwent pulmonary resection if the tumor was determined to be resectable. An original sample size of 180 was used to detect a 20% survival difference (alpha = 0.05) with a power of 0.8. The primary endpoint was overall survival.
Results: From Jan 2001 through Dec 2005, 60 pts were randomized. As accrual of the pts was slow, the study was prematurely terminated in Jan. 2006. Two pts assigned to the CRS arm were ineligible due to staging misconducts. Age ranged from 34 to 70 (median 57), and 66% of the pts were male. The two arms were well balanced in terms of age, gender, smoking status, T stage, and operative procedures. The percentage of squamous cell/adenocarcinoma differed slightly between the two arms (28%/55% for CS, 17%/72% for CRS). Induction therapy was well tolerated and there was no treatment-related death in either arm. Neutropenia (grade 3⩽) was presented by 75% and 89% (P = 0.16) and thrombocytopenia (grade 3⩽) by 0% and 7% of the pts in the CS and CRS arms, respectively. The objective response rate was 25% for both arms (CR/PR/SD/PD was 0%/25%/68%/7% for both groups). The period between induction therapy and surgery was short and shrinkage could not be confirmed for many pts, which resulted in a relatively low response rate and a high SD rate. Surgical resection was performed on 86% and 89% of the pts in the CS and CRS arms, respectively. Progression-free and overall survival were 29.9 months and 9.7 months in the CS arm, respectively, and 39.6 months and 12.4 months in the CRS arm, respectively. Hazard ratios for PFS and OS were 0.68 (95% CI: 0.38−1.21) and 0.77 (95% CI: 0.42−1.41) for CS and CRS. The 3-year survival rate was 39.3% and 51.7% in the CS and CRS arms, respectively. Downstaging was achieved for 21% in the CS arm and 40% in the CRS arm. Recurrent disease at either the hilar or mediastinal lymph node was observed in 58% and 20% in the CS and CRS arms, respectively.
Conclusions: Both the CS and CRS were well tolerated and safe. The addition of induction radiotherapy appeared to confer better local control without adding significant adverse events. The favorable local control, however, did not relate to a statistically significant survival difference probably due to the small number of patients.

9106 POSTER

The role of involved field radiotherapy as a salvage treatment for loco-regional recurrence after complete resection of NSCLC (non-small cell lung cancer)

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Background: In patients with local and/or regional recurrence following initial complete resection of NSCLC, radiation therapy would be an option for salvage treatment. This retrospective study investigated the treatment outcome of salvage radiation therapy in this clinical setting.
Material and Methods: Between 1995 and 2007, 67 patients had local and/or regional recurrences without distant metastasis after complete resection of NSCLC. Median time to recurrence from date of surgery was 10 months. Thirty one patients (46%) had local recurrences, 28 patients (42%) had regional recurrences and 8 patients (12%) had both of local and regional recurrence components. Salvage treatment was done with radiation therapy (79%) or concurrent chemo-radiation therapy (21%) at Samsung Medical Center. All patients received megavoltage radiation therapy with two-dimensional or three-dimensional conformal radiation therapy. Only the recurrence sites were included in the target volume. Elective nodal irradiation was not used. Median radiation dose was 70.2 Gy_{10} (Biologically Effective Dose, 40.8−85.8). Actuarial statistics of local control and survival were estimated using the Kaplan-Meier method.
Results: Median follow-up time from the start of radiation therapy was 15 months. More than half of the patients (66%) had radiographic tumor response after salvage treatment. In-field failure free survival (IFFFS) and loco-regional failure free survival (LRFFS) at 2 years were 50.5% and 32.7%, respectively. Distant metastasis free survival (DMFS) at 2 years was 59.5%. The median survival after radiation therapy was 18 months and 2-year overall survival (OS) was 47.5%, respectively. On multivariate analysis, radiographic tumor response to salvage treatment was predominant prognostic factor for IFFFS, LRFFS and OS. And other prognostic factors associated with failures were the time interval of postoperative recurrence, radiation dose, performance status and tumor histology ($p < 0.05$).
Conclusions: The current study showed superior survival to other published studies for salvage radiotherapy. Responders to salvage treatment showed improved survival. The involved field radiotherapy was effective as a salvage treatment for loco-regional recurrence after complete resection of NSCLC.

9107 POSTER

Dose escalation using Three-Dimensional Conformal Radiotherapy (3D-CRT) in concurrent setting with vinorelbine and a platinum compound, preceeded by induction chemotherapy and followed by consolidation chemotherapy in locally advanced Non-small cell Lung Cancer (NSCLC) - a preliminary report of a modified phase I-II study

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Background and Purpose: local and distant control are poor in locally advanced NSCLC. In order to improve them we aimed to evaluate the maximum-tolerated dose (MTD) and efficacy of dose escalation using 3D-CRT in concurrent setting with vinorelbine and a platinum compound, preceeded by induction chemotherapy (ChT) and followed by consolidation ChT with the same drugs, in locally advanced NSCLC.