1061 POSTER

Randomized trial of platin (MVP) vs. non-platin-chemotherapy (MACC) in non-small cell lung cancer (NSCLC): A negative report from the cuneo lung cancer study group

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Purpose: Combination chemotherapy with cisplatin is the usual treatment for patients with advanced NSCLC, good performance status, and no major clinical contraindications. However, convincing evidence that cisplatin containing programs are superior to older non-platinum combination is scarce (Bucchen. Lung Cancer 1994; 11: 115–117).

Methods: 156 patients with advanced NSCLC were assigned at random to 2 treatment arms. MACC and MVP regimens were given as originally described and continued until progression of disease, unacceptable toxicity, or refusal.

Results: Actual median dose intensities of MVP and MACC were, respectively, 95% and 100% of the intended (p = 0.0132). In all, 16 partial responses in patients allocated to MVP (10 after MACC) were observed. Median progression-free times were 21 and 20 weeks for MVP and MACC, respectively (p = NS). Median survival after MVP was 34 weeks (31 after MACC, p = NS). In multivariate analysis, the chemotherapy assigned was again not significant. Toxicity was moderate in both arms. Subjective rating of physical and psychological well-being were similar in the 2 arms.

Conclusion: In NSCLC, MVP is little more active than MACC. However, we have failed to substantiate any survival benefit from the use of this platinum-based combination.

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MVP versus (vs) MVP plus chemo-radiotherapy in stage III NSCLC: Preliminary results

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70 patients with histological proof of NSCLC, stage 3A and B have been included in a randomized study according to stage 3A vs 3B, and weight loss, comparing two cycles of MVP (arm A) or two cycles of MVP plus concomitant chemo-radiotherapy (5 FU-CDDP-40 Grays) (CCR) arm B before evaluation and surgery.

60 are actually evaluable (1 lost, 1 metastatic, 8 on treatment) with a median follow-up of 3 years. Among 36 stages 3A, 16 in arm A, 20 in arm B, we noted 22 objective responses (OR) after 2 MVP (arm A + B), 15 after CCR. 8 of 16 vs 13 of 20 have been fully resected in arm A and B, with MDS of 11 vs 23 m for entire groups and non-reached for resected patients (70% a live at 4 y).

For selected stage 3B (N3, pleural effusion excluded), 10 in arm A, 14 in arm B, we noted 12 OR after MVP (arm A + B), 9 after MVP and CCR (arm B).

3/10 in arm A vs 7/14 have been secondary resected. MDS of entire groups are 9 m. Survival of resected patients are 4.5–, 16.5+, 31.5– in arm A vs 6–, 10.5–, 15+, 25.5– 41+, 60+ in arm B.

Despite 2 toxic deaths after MVP, 3 ARDS post-operatively, toxicities are manageable.

Inclusions are ongoing but these preliminary results suggest that MVP + CCR could be superior to MVP alone as preoperative approach.

1063 POSTER

Second line chemotherapy (CT) in advanced non small cell lung cancer (NSCLC)

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Since CT has been recognized as a standard treatment for advanced NSCLC, there is a need for an evaluation of 2nd line treatments.

Patients & Methods: A retrospective analysis was performed in 97 pts who received CT alone as 2nd line treatment between 1980 and 94. Eligible pts had first been treated with only CT within a published trial. Second line CT was chosen among internal protocols. Standard inclusion criteria were used for 2nd line CT except for PS (≤4).

Results: Pt characteristics were: median age 60 yrs (28–75), men 93%, squamous cell 61%, stage IV at the time of 2nd line CT 71%.

Regimens:

	1st line:	2nd line:
Single-agent vinorelbine	1st line: 28 pts	2nd line. 4 pts
Vinorelbine-based combination (without cisplatin)	21 pts	0 pts
Cisplatin or carboplatin-based combination	32 pts	65 pts
Single-agent CPT 11 or pepleomycin	16 pts	0 pts
Alkylating-agent-based combination	0 pts	28 pts
	Response rates to 2nd line CT (95% CI)	
All patients	15.2% (9–24)	
According to response to 1st line. Y/N	17 5% (9–25)/15% (8–22)	
Cisplatin-based: 1st line/2nd line	9.3% (0–19)/18.4% (9–28)	

Median survival, calculated from the date of 2nd line first cycle was 5 months. When calculated from the date of 1st CT, median survival was 11 mths for pts who received cisplatin within 1st line CT, 9 mths when cisplatin was given within 2nd line CT.

Conclusion: A response rate of 15% emphasizes the interest of 2nd line CT in NSCLC.

1064 POSTER

Weekly treatment of non-small-cell lung (NSCLC) cancer patients with paclitaxel (P) and carboplatin (C)

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P has demonstrated marked antineoplastic efficacy both as single agent as well as in combination with C in NSCLC. There are preliminary data that weekly chemotherapy with P leeds to promising response rates even with less pronounced side effects compared to the conventional used 3-week treatment. In a phase I clinical trial the maximum tolerated dose of weekly applied P combined with C in patients with stage IIIB/IV NSCLC was determined by Ukena et al. The MTD was reached at 150 mg/m^2 P + C AUC (according to Calvert formula). For the subsequent phase-II-study a dose of 100 mg/m^2 P plus C AUC 2 was chosen preventing cumulative neurotoxicity of P which occurred at weekly doses >100 mg/m^2 P. The patients received 2 blocks of a weekly chemotherapy for 6 weeks separated by a 2 week interval. To date 18 patients completed therapy. Performance status was ≥70. Response data were as follows: partial remission n = 8; no change n = 5; progressive disease n = 5. Transient neutropenia (WHO grade 2), myalgia/arthralgia (WHO grade 2) as well as peripheral neuropathy (WHO grade 2) occurred in all patients. The preliminary results suggest that the weekly chemotherapy leeds to equal or even better response rates compared with conventional applied chemotherapy but to less pronounced side effects. Updated results will be presented. A subsequent randomized phase-III trial comparing weekly vs. q21d standard therapy is planned.

1065 POSTER

Combined preoperative radiochemotherapy for non-small cell lung cancer (NSCLC) stage III UICC

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Purpose: Various clinical phase II-trials have shown advantages for patients with locally advanced NSCLC with combined modality treatment. The role of preoperative radiochemotherapy will be evaluated.

Methods: The therapy consisted of initial chemotherapy (Cisplatin/Etoposid) followed by simultaneous radiochemotherapy with hyperfractionated-accelerated irradiation until 45 Gy and Carboplatin/Vindesin. After restaging we performed surgery, in case of inoperability/incomplete resection followed by a second course of irradiation with 24 Gy. In October 1995 we started a randomized trial, evaluating this treatment against post-operative irradiation with 54/68 Gy in conventional fractionation following initial chemotherapy.

Results: In the phase II trial we treated 54 patients and with tolerable toxicity showed overall survival rates of 68.5/40.2% for the first/second year and a median survival of 20.4 months without significant differences in stage IIIA vs. IIIB. In the active phase III trial 84 patients have been randomized.

Conclusion: Combined modality treatment seems to offer improvement in survival of patients with Stage III NSCLC. Our Phase III trial will show the influence of preoperative radiochemotherapy. Until now, the results are promising.