Results: 70 patients were randomized. Complete remissions (CR) were observed in 4 of 33 evaluable patients in the IP arm. No CR occurred in the EP arm. Overall response rate was 67% and 59% in the IP and EP arm. Three patients (2 in the IP arm and 1 in the EP arm) were not evaluable for response assessment due to early death. Significant differences in grade 3 and 4 thrombopenia (17% IP vs 48% EP, $p = 0.01$) and neutropenia (26% IP vs 51% PE, $p < 0.01$) were found. Grade 2–4 diarrheoa was more frequent with IP (17%) than with EP (6%) ($p = 0.16$). Median progression-free survival (PFS) was 9 months (95% CI 7.1 – 10.9) in the IP arm and 6 months (95% CI 4.1 – 7.9) in the EP arm ($p = 0.03$).
Conclusion: IP is less toxic and improves PFS. This phase II analysis justifies the extension into phase III to assess the impact on survival. The phase III trial will be performed.

1135 POSTER

Skip mediastinal nodal metastases in the IIIA/N2 non-small cell lung cancer

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Objectives: To study the incidence and characteristics of mediastinal nodal metasteses without N1 nodal metasteses ("skip-N2 metastases") in patients with resected pIII/A/N2 non-small cell lung cancer (NSCLC).
Methods: A total of 322 NSCLC patients who underwnt RO surgical resection with a systemic mediastinal nodal dissection in four years time period (2000–2003) were retrospectively reviewed. The 85 patients (26%) at stage IIIA/N2 (pN2+) were grouped according to their skip metastases status. Patient's data were statistically analyzed.
Results: Skip N2 metastses were found in 21 patients (25%) without N1 nodal involvement. The postoperative survival for skip-N2 desease was almost the same as that for pN2 desease with N1 nodal involvement. The incidence of N2 metastses seemed to be more frequent in adenocarcinoma patients ($p > 0.005$), but skip N2 metastses were significantelly higher ($p > 0.001$) in squamous cell carcinoma patients. Altough skip metastases involved more often upper mediastinal lymph nodes and one station level, the difference was not found statsitically significant ($p > 0.227$). Complications rate showed no difference between anlyzed groups of patients.
Conclusion: Sample mediastinal lymphadenectomy may not be appropriate in surgery for NSCLC, because skip metastases were found in 25% of patients without N1 nodal involvement. Role of intraoperatively sentinel node lymph dissection has yet to be proven.

1136 POSTER

Preoperative concurrent chemotherapy with accelerated hyperfractionated radiotherapy in non-small-cell lung cancer; feasibility, toxicity and long-term results of a phase II study

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Purpose: We carried out a phase II trial to evaluate the feasibility, toxicity and effect on survival of polychemotherapy delivered concurrently with accelerated modified hyperfracctionated radiotherapy (AMHR) in non-small-cell lung cancer stage III patients.
Methods: Thirty eight patients with locally advanced stage III NSCLC received neoadjuvant therapy consisting of two cycles of polychemotherapy using cisplatin 80 ml/m^2 on day 1, ifosfamide 1.5 gr/m^2 on day 1 and VP-16 100 mg/m^2 for 3 days and concurrent with the second cycle of chemotherapy AMHR 40.2 Gy (1.8 Gy+0.88 Gy) in 3 weeks.
Results: From October 1997 to October 2001, 38 patients were entered into the study. There were 37 IIIA and 1 IIIB. All the patient were pathologically staged (mediatinoscopy or node punction). The most frequent cell type was squamous cell carcinoma, 20 (52.6%), and adenocarcinoma 12, (31.6%). PS was 0 in 3 patients (8%), PS 1: 31 (81%) and PS 2: 4 (11%). The prominent grade 3–4 side-effect was leucopenia 22%, trombopenia 13.5% and anemia 11%. Other toxicity grade 3–4 was esophagitis in 3%. There was 1 surgically related death. The response rate was one complete response (3%), 16 PR (42%), 13 (34%) with stable disease and 8 (21%) with progressive disease. Surgical-pathological staging showed downstaging in 20 patients including complete sterilization of the tumor in 14 patients (36.8%). The median survival for all 38 patients was 21.85 months with 71.05%, 49.19% and 21.39% 1 year, 2 and 5-years survivors respectivally. On univariate analysis about overall survival were significant; surgical technique, pneumectomy versus lobectomy and others ($p = 0.0028$), postoperative tumor viability, non versus yes ($p = 0.0005$), and downstaging ($p < 0.0001$). On multivariate analysis were only significative the surgery (no versus yes) ($p < 0.0001$)
Conclusions: This neoadjuvant chemoradiotherapy treatment is a tolerable and survival-enhancing multimodality approach to stage III NSCLC.

1137 POSTER

Phase II study of carboplatin and irinotecan (CPT-11) in patients with limited disease small cell lung cancer (SCLC)

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Background: To evaluate the efficacy and safety of combination chemotherapy containing carboplatin and irinotecan (CPT-11) in the first-line treatment of limited disease small cell lung cancer (VALG classification).
Patients and methods: From December 2002 to May 2004 61 patients (pts) were enrolled. 40 pts (66%) were male, 21 pts (34%) female. Median age was 63 years (range 41–77) and median ECOG performance status was 1. Patients received carboplatin AUC 5 on day 1 and irinotecan (CPT-11) 50 mg/m^2 on days 1, 8 and 15, every 4 weeks, followed by standard irradiation (irradiation of the chest with 56 Gy after complete or partial remission, irradiation of the brain with 30 Gy after complete remission).
Results: A total of 233 chemotherapy cycles were administered. The median number of cycles per patient was 4. The overall response rate (ORR) to chemotherapy was 64% (15 CR (24.6%), 24 PR (39.4%), 13 SD (21.3%), PD (3.3%), 7 not evaluable (11.4%)). The median overall survival was 12.6 months (95% confidence intervall 11.6 months – inf.), the median disease-free survival 10.9 months (95% confidence intervall 7.88 – 11.89 months), and the 1-year survival rate 53.5%. Hematological and non-hematogical toxicity was low (CTC-grade 3 neutropenia 14.8%, grade 3 thrombocytopenia 5.4%, grade 3/4 anemia 5.1%, grade 3 vomiting 5.1%, grade 3 emesis 3.6%, grade 3 diarrhoea 3.6%, grade 3 alopecia 3.6% of pts).
Conclusions: The results suggest that the combination of carboplatin and irinotecan (CPT-11) is active and well tolerable in patients with limited disease small cell lung cancer. We recommend to compare carboplatin and irinotecan (CPT-11) with standard chemotherapy cisplatin and etoposide in a randomized phase III study.

1138 POSTER

How accurate is the RTOG/EORTC scoring schema (RESS) in reflecting the late radiation morbidity in lung cancer patients?

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Introduction/Purpose: The increasing use of dose escalation and altered fractionation regimens in the definitive treatment of lung cancer patients emphasizes the importance to accurate grading of late lung toxicity. RESS, the most frequently used grading tool, combines clinical symptoms and radiological abnormality making it confusing and potentially inaccurate. We compared the late lung toxicity using the RESS to a Symptom Only Scale and report the results.
Materials/Methods: The medical records and chest x-rays (CXR) of patients with NSCLC who received curative radiation with doses of 52.5 Gy/15 fractions or 60 Gy/30 fractions were reviewed. All patients had a minimum follow-up of 12 months with no signs of local relapse. Patients' symptoms and CXR findings between 6–12 months post-radiation were recorded. They were scored as per the RESS and the following Symptom Only Scale: *grade 0*: no increase in lung symptoms, *grade 1*: increase in lung symptoms due to RT but not requiring steroids, *grade 2*: same but steroids are required, *grade 3*: oxygen is needed, *grade 4*: assisted ventilation is required and *grade 5*: death related to radiation.
Results: 50 patients were analyzed. All had radiographic changes (Fig. 1). There were 0, 28, 49, and 23% grade 0, 1, 2 and 3 toxicity respectively according to RESS, mostly on the basis of radiographic abnormalities. Most patients had no or mild symptoms only. According to the Symptom Only Scale they were scored 86, 7, 7 and 0% grade 0, 1, 2 and 3 toxicity