rates (<10%). Most of these patients develop distant metastases, and this rationalizes the use of induction chemotherapy. There is ongoing discussion about the role of surgical resection (vs. radiotherapy) as local treatment modality after induction therapy. The aim of this retrospective analysis was to evaluate results of surgery and radiotherapy after neoadjuvant chemotherapy in the clinical setting.
Methods: Patients with stage IIIA NSCLC treated with neoadjuvant chemotherapy from 1994 to 2006 were identified from registration databases. During this period all treatment proposals (or trial participation) were discussed by a multidisciplinary thoracic oncology committee. Response to induction therapy, definitive local therapy, recurrence of disease, and overall survival were reviewed.
Results: Ninety-nine patients, 66 men and 33 women, were identified. The mean age was 61 (36−77), 40 tumors were left-sided. Neoadjuvant chemotherapy consisted of platin-based doublets/triplets. Clinical mediastinal downstaging was achieved in 32 patients. Thirty-nine patients underwent surgery: 19 lobectomies, 19 pneumonectomies, and one thoracotomy without resection. Microscopic complete resection was achieved in 26 patients (69%). Thirty-days mortality was 3% (n = 1 after pneumonectomy). Forty-two patients received radiotherapy with radical intent. Radiation doses actually delivered ranged from 51 to 81 Gy, median dose given was 60 Gy. The 2- and 5-year overall survival after surgery was 58% and 29% respectively, survival in lobectomy patients being significantly higher (p = 0.03). The 2- and 5-year overall survival after radiotherapy was 40% and 16%. The cumulative incidence of locoregional recurrence at 2 and 5 years was 27 and 41% for surgically treated patients and 45 and 54% for irradiated patients (p = 0.39). Mortality within 6 months after local treatment was high in patients who underwent pneumonectomy (21%), and much lower in patients who underwent lobectomy or radiotherapy (5%).
Conclusions: Radiotherapy is being regarded as the standard local treatment modality after neoadjuvant chemotherapy for stage IIIA NSCLC. Our retrospective data show that in selected patients complete surgical resection is associated with favorable locoregional control and long-term survival. Due to excess early mortality, pneumonectomy should be avoided.

6576 POSTER

Extent of mediastinal lymph-nodes resection as prognostic factor for survival in stage I−IIIA non-small-cell lung cancer (NSCLC) patients undergone surgery: a retrospective analysis of a mono-institutional series

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Background: The role of mediastinal lymphoadenectomy in patients undergoing lobectomy or pneumonectomy for early stage (I-IIIA) NSCLC as prognostic factor is still under debate. A non significant effect of such approach on both progression-free and overall-survival (PFS/OS) has been reported. Although adjuvant chemotherapy has recently demonstrated to significantly improve survival, different extents of mediastinal surgery across all adjuvant trials are reported; for this reason an update regarding the supposed independent prognostic role of this intervention is required.
Methods: A retrospective database of surgically resected NSCLC patients who referred to the Regina Elena National Cancer Institute was gathered. A panel of known prognostic factors (sex, type of surgery, histology, tumor size, node involvement, grading) plus the number of resected mediastinal nodes (#RMNs) was correlated to clinical outcomes (PFS and OS) by using the Cox regression model (considering #RMNs as quantitative variable; significance cut-off <0.10) as well as classification and regression trees (CART) analysis.
Results: A data-set of 191 stage I-IIIA NSCLC patients undergone surgery was built. Patients with more than 26 removed nodes had better outcome according to the CART analysis; by using this cut-off, #RMNs was considered as categorical variable too. Multivariate analysis is shown in the table.

		HR	95% CI	p
PFS	Nodal involvement	1.90	1.16, 3.12	0.01
	Type of surgery	3.24	1.33, 7.91	0.01
	#RMNs	2.59	1.17, 5.72	0.018
OS	Nodal involvement	1.86	1.00, 3.44	0.048
	Type of surgery	3.21	1.05, 9.75	0.04
	#RMNs	3.05	1.11, 8.38	0.03
	Grading G2−3	1.88	0.99, 3.57	0.053

Conclusions: The presented data suggest that prognosis of stage I-IIIA NSCLC patients can be conditioned by the extent of mediastinal nodes resection. Further prospective trials are needed to confirm this result.

6577 POSTER

Prospective phase II trial of a combination of gemcitabine, cisplatin and UFT as first-line treatment in patients with advanced, unresectable, non-small cell lung carcinoma

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Background: Most patients with advanced non small cell lung cancer (NSCLC) receive either single agents or chemotherapy doublet. Meta-analysis have showed combination chemotherapy consisting of cisplatin plus new agent yielded a substantial survival advantage compared with carboplatin plus new agent in patients with advanced NSCLC. And also combination chemotherapy comprised of oral UFT and cisplatin was shown to be an effective and safe regimen. Therefore a Phase II study was conducted using the combination of gemcitabine, cisplatin and UFT in patients with advanced NSCLC.
Materials and Methods: Eligible patients had histologically or cytologically confirmed stage IIIB or IV NSCLC and good performance status. Patients who had recieved prior cytotoxic treatment were excluded. Gemcitabine (1,250 mg/m^2, 10 mg/kg/min on days 1 and 8) and cisplatin (75 mg/m^2 on day 1) were injected intravenously and UFT (400 mg/day) was administered orally on day 1−14. Treatment was repeated every 3 weeks. Primary end points was overall response rate and secondary end points were overall survival, time to progression and toxicity.
Results: Thirty seven patients with advanced NSCLC were enrolled. The median age of the patients was 60 years (range: 44 to 72). The performance status (WHO) was 0 for 4 (11%), 1 for 30 (81%) and 2 for 3 (8%) patients. Twenty three patients did complete six cycles. The median number of cycles of gemcitabine was 6 (range 1−6). Complete response was achieved in 1 (3%) patient, partial response in 17 (46%) patients, stable disease in 9 (24%) patients. Overall response rate was 49%. Among response available patients (33 patients), response rate was 55%. The mean survival time was 16.0 months (95% CI: 13.2, 18.9) and the 1-year survival rate was 40% and then median time to progression was 3.4 months. Toxicity was moderate and mostly hematologic. Grade 3/4 neutropenia occurred in 37%, 5 patients with febrile neutropenia. Grade 3/4 anemia and thrombocypenia was occurred in 37% and 5%. Nonhematologic toxicity was mild.
Conclusion: The combination therapy comprising gemcitabine, cisplatin and UFT is active and tolerated first line regimen in NSCLC patients.

6578 POSTER

No evidence of an association between EGFR inhibitor treatment and interstitial lung disease in patients with advanced lung cancer

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Background: The EGFR tyrosine kinase inhibitors (TKIs), erlotinib and gefitinib, have been evaluated for the treatment of advanced non-small-cell lung cancer (NSCLC), both as monotherapies and in combination with cytotoxic agents. Interstitial lung disease (ILD) has been reported as a rare and unexpected adverse event of TKI therapy. To investigate if TKIs are associated with ILD, we conducted a meta-analysis to compare the incidence of ILD events in the treatment and placebo arms of randomized trials of TKI treatment. We also investigated the potential dose effect relationship between drug administration and ILD development.
Methods: We searched the MEDLINE database to identify trials randomizing patients with advanced NSCLC to either TKI therapy or placebo. For the dose effect analysis, we identified trials randomizing patients to different doses of TKIs. For both comparisons, trials were considered eligible only if treatment arms differed solely regarding the administration of TKIs. We abstracted data on the incidence of ILD. Fixed effects meta-analysis was performed to estimate a pooled odds ratio (OR) and its confidence interval, with values higher than one indicating that ILD is more common in patients receiving TKIs or in those receiving higher TKI doses (for the dose effect assessment). Continuity correction, propotional to the relative size of the opposite of the study, was used for studies with zero events in one arm. Sensitivity analyses were performed using different correction methods or no correction. Results are presented in accordance with the QUOROM guidelines.