

Concurrent Chemoradiation (CChRT) for stage III Non-Small Cell Lung Cancer (NSCLC): a phase II study from the Galician Lung Cancer Group.

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Background

Combined cytotoxic chemotherapy and radiation therapy is established as the standard treatment for patients with medically inoperable or technically unresectable stage III NSCLC. Multiple randomized studies and meta-analyses demonstrate that CChRT results improved survival compared with sequential chemo-radiotherapy or radiotherapy alone. The aim of our study was to evaluate the effectiveness and toxicities of CChRT with bi-weekly Docetaxel (D) and Cisplatin (C) and thoracic radiotherapy, after one cycle D-C induction chemotherapy.

Methods

Between May 2009 and November 2012, 53 chemo-naive p with histologically confirmed inoperable locally advanced NSCLC, stage IIIAN2/IIIB (no pleural T4), PS 0-1 and adequate lung function (FEV1 > 1.1, V20 < 25%) were included: one cycle of D 75 mg/m² on day 1 and C 40 mg/m² days 1-2 followed at 21 days by CChRT with bi-weekly D 40 mg/m² and C 40 mg/m² for four courses, during conformal thoracic radiotherapy (66 Gys, 180 cGy/day). The primary objective was overall survival (OS); secondary objectives were progression free survival (PFS), response rate (RR) and toxicity. Median follow-up: 17.8 months.

Results

The p characteristics were: mean age 59.4 years (34-75); male/female 47/6; ECOG PS 0/1 in 17/36 p; squamous/adeno/large cell carcinoma: 53%/34%/13%; stage IIIAN2 15 p (28.3%) and stage IIIB 38 p (71.7%). All p were evaluable for response and toxicity. RR: 6 CR, 37 PR (RR 81.8%; 95% CI: 71-92), 4 SD (7.6%) and 6 PD (11.3%). The median PFS was 14 months (95% CI: 11-17) and median OS was 21 months (95% CI: 9-32). The PFS at 1/2 years were 55%/32% and the OS at 1/3 years were 82%/50%. A total of 53 cycles of D-C induction chemotherapy were given; main toxicities (NCI-CTC 3.0) per p Grade (g) 1-2/3-4 (%) were as follows: neutropenia 1.8/15; anemia 11.3/0; nausea/vomiting 26.4/1.8; diarrhea 22.6/3.7; fatigue 35.8/0; there were three episodes of hospitalization: febrile neutropenia 2 p and g3 diarrhea 1p. Main toxicities per p in CChRT (D-C doses: 203, 3.8 per p; mean doses RT: 64,6 Gys) were g1-2/3 (%): neutropenia 28.3/5.6; anemia 62.2/0; esophagitis 50.9/3.7 and pneumonitis 32/0; nausea/vomiting 20.7/0; fatigue 37.7/3.7; there were four episodes of hospitalization: febrile neutropenia, 2 p and g3 esophagitis, 2 p.

Conclusion

CChRT with bi-weekly Docetaxel and Cisplatin and thoracic radiotherapy is a feasible treatment option for inoperable locally advanced stage III NSCLC, showing good clinical efficacy and tolerability with acceptable long-term survival.