LBA56 - Maintenance chemotherapy versus follow-up after carboplatin and weekly paclitaxel doublet chemotherapy in elderly patients with advanced non-small cell lung cancer (NSCLC): IFCT-1201 MODEL randomised phase 3 trial

Presentation Number: LBA56
Lecture Time: 10:30 - 10:45
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Abstract

Background

The benefit of maintenance chemotherapy with pemetrexed has been demonstrated in fit patients with metastatic lung adenocarcinoma and to a lesser extent in squamous cell carcinoma (SCC) using gemcitabine. Only few elderly patients were included in these trials. The IFCT-1201 trial is the first dedicated study to elderly patients evaluating switch maintenance chemotherapy.

Methods

We conducted a randomised trial in patients with non irradiable stage III or stage IV NSCLC (with no EGFR mutation or ALK rearrangement), aged 70-89 years, not progressing after 4 cycles of induction therapy with monthly carboplatin (AUC 6; d1, 29) and weekly paclitaxel (90 mg/m², d1,8,15, 29) comparing maintenance therapy with either pemetrexed (500 mg/m² d1, 22) in patients with non-SCC or gemcitabine (1150 mg/m² d1,8, 22) in SCC to follow-up. Second-line therapy using erlotinib was recommended in both arms. Patients were required to have a PS 0-2, a Mini Mental Score >23, and MDRD creatinine clearance >= 45 mL/min. The primary endpoint was overall survival (OS).

Results

From May 2013 to Oct. 2016, 632 patients were enrolled: median age 76.4 (70-89), male 76%, PS 0-1 85%. After induction therapy, 328 patients were randomized (119 pemetrexed and 43 gemcitabine). Median maintenance cycles were 4 (1-38). The safety profile was as expected. Median OS (all patients from inclusion) was 11.0 months (95%CI: 9.9-12). Median OS from randomisation was 14.1 months (95%CI: 12-17) in the follow-up arm and 14 months (95%CI: 10.9-16.9) in the maintenance arm, HRa=0.91 [0.71-1.16] ; p=0.45. Progression-Free survival (PFS) was significantly longer in the maintenance arm (5.7 months (95%CI: 4.8-7.1) vs 2.7 months (95%CI: 2.6-3.1) in the follow-up arm, HRa=0.51 (95%CI: 0.4-0.64), p <0.001). Second-line therapy was administered to 103 patients (63.6%) in the maintenance arm versus 133 patients (81.1%) in the follow-up arm.

Conclusions

Although there was a PFS gain with the maintenance chemotherapy, this did not translate to an overall survival benefit. Switch maintenance chemotherapy should not be recommended in elderly patients with advanced NSCLC.

Clinical trial identification: NCT01850303

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