Gefitinib versus chemotherapy as first-line treatment in elderly patients with advanced non-small-cell lung cancer

Zhang, Xiao-Tong; Li, Long-Yun; Wang, Men-Zhao; Zhang, Li; Zhong, Wei
Peking Union Medical College Hospital & Chinese Academy of Medical Sciences, Beijing, China

**Background:** Elderly patients with non-small cell lung cancer (NSCLC) have been habitually underrepresented in clinical trails. Retrospective analysis has shown similar therapeutic outcome of platinum-based combined chemotherapy for fit elderly, albeit more toxicity compared with younger counterparts. Gefitinib, an oral EGFR-TKI was generally well tolerated with clinically meaningful anti-tumor activity in previously treated patients as well as chemo-naïve patients. The aim of the study was to retrospectively evaluate the toxicity, efficacy and survival of gefitinib versus platinum-based combined chemotherapy as first-line treatment for a series of Chinese patients aged 70 and over with advanced NSCLC.

**Methods:** From January 2002 to December 2005, 38 patients received chemotherapy (17 of Novelbine, 8 of Gemitabine, 7 of taxol and 7 of taxotere, all of which combined with cisplatin or carboplatin) and 17 patients received gefitinib 250mg once daily as first line treatment.

**Results:** Of the 38 patients who received chemotherapy, the median age was 73.3 years old (70-80) with 68.4% male, 73.7% adenocarcinoma and 78.9% patients were in stage 4. The PS of all patients was 0-1. Of the 17 patients who received gefitinib, the median age was 76.9 years old (70-80) with 58.8% male, 64.7% adenocarcinoma and 82.4% patients were in stage 4. The PS of 6 patients was over 2. The most frequently reported adverse events for chemotherapy group were neutropenia (92.1%) and thrombocytopenia(73.7%). Grade 3/4 neutropenia was 21.1% and four patients had neutropenia febril. Grade 3/4 thrombocytopenia was 10.5% and 2 patients needed blood transfusion. Other grade 3/4 adverse effects included 3 cases of vomiting and one case of cardiac arrhythmia. 4 patients withdrew the chemotherapy due to side effects. The most frequently reported adverse events for gefitinib group were skin disorders (70.6%) and diarrhea (35.3%). The majority of these events were mild with grade 1 to grade 2. One patient was hospitalized due to grade 3 diarrhea and recovered without drug administration disruption. Other adverse events included 2 cases of nausea, 1 case of oral ulcer and 1 case of elevation in hepatic enzymes. No patient withdrew due to adverse effect. The partial response and disease control rate were 21.1% and 78.9% for chemotherapy group versus 17.6% and 68.8% for gefitinib group. The median progress free survival and overall survival time were 4.93 ± 0.747 months (95% CI: 3.465, 7.395) and 13.882 ± 0.718 months (95% CI: 12.892, 20.708) for chemotherapy group versus 6.4 ± 1.852 months (95% CI: 2.770, 10.030) and 15.882 ± 2.029 months (95% CI: 13.654, 20.505). The one-year survival was 52.6% in chemotherapy group versus 47.1% in gefitinib group. There is no statistical significance between the two groups for efficacy, progress free survival time and overall survival time.

**Conclusion:** Platinum-based combined chemotherapy was well tolerated and provides significant anti-tumor activity in elderly patients. Gefitinib as first-line treatment provides similar clinical benefit with less toxicity for the elderly NSCLC patients.

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A phase II trial of pemetrexed(p) in patients (pts) with performance status (PS) 2 and 3 as 1st- and 2nd- line treatment for advanced non-small-cell lung cancer (NSCLC)

Zimmer, Ralph G; Fossella, Frank V; Kies, Merrill; Herbst, Roy S; Lu, Charles; Johnson, Faye; Cleeland, Justina; Wang, Shirley; UT MD Anderson Cancer Center, Houston, TX, USA

P (Alimta) is approved as 2nd-line therapy in pts with advanced NSCLC. In a phase III trial comparing P with docetaxel (D), median survival was 8.3 mos (P) vs 7.9 mos (D); P had a more favorable safety profile than D (Hanna, 2004). There are few data on pts with PS 3, and ASCO 2003 guidelines recommend that chemotherapy be reserved for pts with PS 0, 1 and possibly 2. Since P is well tolerated, PS3 pts may tolerate and benefit from it. In this trial, we treated 20 pts with stage IIIb/IV NSCLC and PS 2 or 3, who were chemo-naive or had received 1 prior regimen. Pts received P 500mg/m2 IV D1 Q 3 wks. All pts received folinic acid, vitamin B12 and dexamethasone prophylaxis. Serial blood samples were obtained to monitor inflammatory cytokines, and symptoms were monitored using the validated MDASI instrument. All pts were assessable for toxicity-symptoms, and 17 pts were evaluable for response (assessed after 1st cycle). Pt characteristics: 8 pts were PS 3 (4/8 1st line) and 12 pts were PS 2 (6/12 1st line). Median age was 69 for PS3 and 68 for PS2. 5/8 PS3 pts and 6/12 PS2 pts were men. 2/8 PS3 pts and 4/12 PS2 pts had stage IIIb. 4/8 PS3 pts and 6/12 PS2 pts were chemo-naive. Grade 3-4 toxicities for PS3/PS2 cohorts were: neutropenia 0/1 pt, anemia 1/2, fatigue 2/0, pneumonia 1/1, hypotension 1/1, neutropenic fever 0/1, atrial fibrillation 1/1. Response rates (RR) in PS3 pts were minor response (MR) 1/8, stable disease (SD) 5/8, progressive disease (PD) 2/8; RR in PS2 pts were partial response (PR) 1/12, MR 2/12, SD 3/12, PD 3/12, and 12/12, and 3/12, and 3/12, and 3/12. RR by line of therapy: 1st line 6/10 SD, 2/10 PD, 1/10 PR, 12/10 MR, 3/10 SD, 3/10 PD, and 1/10 inadequate. Reasons for PS3 pts coming off study were progression (4/8), constitutional toxicity (3/8), fatal pulmonary emboli (1/8); PS2 pts came off study due to progression (5/12), constitutional toxicity (2/12), and pneumonia (1/12). 4/12 PS2 pts are still on study. These preliminary data suggest that single-agent P is well-tolerated and has promising RR in poor PS pts. Total planned accrual is 30 PS3 and 45 PS2 pts. Survival, symptoms, and cytokine data will be presented.

**NSCLC: Radiation**

Utility of SPECT for metabolic and functional lung imaging in radiation therapy treatment planning for lung cancer

Agrawal, Sushma; Kheruka, Subhash; Das, Maria; Raj, Karthik; Lal, Punita; Gambhir, Sanjay
Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, India

**Background:** Conformal radiotherapy of lung tumors relies on anatomic imaging with CT scan to define both targets and critical structures, but has its drawbacks in differentiating atelectasis from tumor. Also, it may not represent the metabolic tumor volume and functional lung volume. We attempted to evaluate the utility of SPECT to gain information...