9098 POSTER

First-Line Modified Schedule of Gemcitabine With a Lower Dose Than Standard in Elderly or PS 2 Patients With Advanced Non-Small Cell Lung Cancer

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Background: Monochemotherapy with gemcitabine (Gem) is often the treatment of choice in elderly or poor performance status (PS) patients with advanced non-small cell lung cancer (NSCLC). Our study was aimed to assess the efficacy and tolerability of a modified schedule of Gem using a lower dose than standard.
Patients and Methods: From May 2009 through December 2010, fifty patients (43 males and 7 females with a median age of 76 years ranging from 64 to 85) with advanced NSCLC (stage IIIB 34.0% and IV 66.0%) were enrolled. Histology was: squamous 39.6%, adenocarcinoma 31.2%, large cell 6.2%, undifferentiated 4.2%, undetermined 18.8%. Only eight patients (16.0%) had a WHO PS 0 whereas nineteen (38.0%) were PS 1 and eleven (46.0%) PS 2. All patients received first-line chemotherapy with 6 cycles of Gem 1000 mg/sq on days 1 and 8 every 4 weeks.
Results: At the time of analysis 35 patients were evaluable for response. Partial response (PR) was achieved in 7 patients (20.0%), stable disease >12 weeks (SD) in 16 (45.7%) whereas 12 had progressive disease (34.3%). Importantly, the clinical benefit rate (PR + SD) was 65.7%. Tumour markers (CEA and NSE) were high in 28 patients with a reduction in their values observed in 11 of them (39.3%). Both pain and PS improved in 6 patients (17.1%) whereas 19 (54.2%) had an improvement in pain with no worsening of PS. We observed only grade 2 WHO haematological toxicities including anemia, leucopenia, neutropenia and trombocytopenia. Not-neutropenic fever occurred in 4 patients (11.4%). Overall, we did not observe any not-haematological treatment-related event.
Conclusions: Our data show that a modified schedule of Gem with a lower dose intensity than standard may be beneficial in terms of both disease control and tolerability when employed in elderly or PS 2 patients with advanced NSCLC.

9099 POSTER

Biweekly Docetaxel-Cisplatin in Chemonaive Patients With Advanced Epidermoid Carcinoma of the Lung − a Phase II Study of Galician Lung Cancer Group

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Background: Non-small cell lung cancer (NSCLC) represents a 80% all lung cancer. A third of the patients have metastatic disease when they are diagnosed. Standar treatment in patients with good performance status is a combination of two drugs, one of them containing platinum. We conducted a multicenter study in advanced stage squamous NSCLC to evaluate the efficacy of first-line biweekly docetaxel-cisplatin.
Materials and Methods: Patients with advanced NSCLC and epidermoid histology received biweekly docetaxel (50 mg/m^2 days 1, 14) and cisplatin (50 mg/m^2 days 1, 14) every 28 days (DC) with restaging after 3 and 4 cycles. The primary end point was to evaluate the overall response rate and the secondary were the progression-free survival and median overall survival.
Results: Forty-five patients were accrued from six centers across Galicia. Overall response rates were 45.9%, all them had a partial response. Median overall survival was 12.6 months (95% confidence interval, 10 to 15.2); progression-free survival was 4.7 months (95% confidence interval, 3.9 to 5.5). The treatment was well tolerated, with the most common treatment-related side effects being grade 1 anemia (48.8%), asthenia (32.5%), nausea (30.2%) and anorexia (27.91%). Grade 3 and/or 4 toxic reactions were neutropenia (20.9%, 11.6% with fever), diarrhea (4.6%), mucositis and neuropathy (2.3% both).
Conclusions: Biweekly docetaxel-cisplatin show favorable toxicity profiles and activity in patients with advanced stage squamous NSCLC.

9100 POSTER

Erlotinib in Previously Treated NSCLC − a Critical Appraisal Based on Monoinstitutional Experience

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Background: Erlotinib is a potent inhibitor of epidermal growth factor receptor tyrosin-kinanase activity approved in the EU and in the USA for the treatment of non small-cell lung cancer (NSCLC) in patients with stage IIIB or IV who had received one or more prior chemotherapy regimens. The registration study BR.21 (NEJM 2005, 14, 353, 123) showed to prolong significantly overall survival (OS) and progression free survival (PFS) in Erlotinib arm. In 2005 AIFA (Italian Agency on Drugs) has activated a web-based national registry of oncology drugs (RFOM) as an appraisal on new drugs introduced into the Italian market. Oncologists are required to subscribe all patients in treatment completing patient's data and recording in follow-up toxicity, variations in dosage and final outcomes. The analysis of polled records achieved in this way may be used for effectiveness estimates.
OS and Time to Progression (TTP) may be achieved from clinical practice as a valuable indicator of effectiveness through retrospective observational analysis. The aim of the study is to assess Median OS and TTP in clinical practice compared to outcome values obtained from the registration study of Erlotinib in NSCLC.
Materials and Methods: An independent Drug Evaluation Unit of the Istituto Oncologico Veneto collected data from the registers and the patient's charts to establish the real clinical impact of the drug. The follow up duration was 39 months, from December 2006 to February 2011. Every patient was checked for *length of treatment, toxicity and outcomes*. The data of EGFR mutation and EGFR FISH positive had not been done for all patients because they are not mandatory for RFOM. For the efficacy/effectiveness comparison assessment we used registration RCT outcome measures: OS, PFS with Kaplan–Meier estimates. The multivariate regression analysis was performed to detect potential associations between the baseline characteristics of the patients and the effect of Erlotinib.
Results: A total of 131 patients treated with Erlotinib were reviewed (median age = 69 years, M = 79, F = 52). More than 50% of patients had received two or more prior chemotherapy regimens. Median TTP and OS were 2 and 3.6 months, respectively compared to Erlotinib arm of the BR.21 study with PFS 2.2 months and OS 6.7 months. There was no significant difference in OS based on age groups ($\geqslant$70 and <70). The disease control rate was 18% (RP = 4, SD = 20) and the median duration of the response was 7.6 months. Only one patient discontinued the treatment due to toxic effects.
Conclusions: The results of our retrospective observational study have showed that for patients with two or more prior chemotherapy regimens and with no selection for EGRF mutation/amplification, it is not recommended the use of Erlotinib for the treatment of NSCLC.

9101 POSTER

Pre-planned Subgroup Analyses From the Phase III, Randomised, Placebo-controlled, Parallel-group Study of Gefitinib (G) as Maintenance Therapy in Patients (pts) With Locally Advanced or Metastatic Non-small-cell Lung Cancer (NSCLC) (INFORM; C-TONG 0804)

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Background: The phase III, randomised, placebo (P)-controlled, parallel-group INFORM study (NCT00770588) investigated the efficacy, safety and tolerability of G *v* P as maintenance therapy in pts with locally advanced/metastatic NSCLC following standard first-line platinum-based chemotherapy (CT).