Conclusions: Given the lack of head-to-head research with active treatments, meta-analyses provide needed comparative information on treatment options in a coherent framework. Evidence for 2nd/3rd line mNSCLC treatment effects on response is stronger than evidence for survival. The exceptions are targeted therapies − this class is likely to be the most promising source for badly needed new therapies.

9082 POSTER

Febrile Neutropenia (FN) in Lung Cancer Patients

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Background: Neutropenia and related complications represent the most common dose limiting toxicity of cancer chemotherapy. Only few data are available about FN in lung cancer patients treated with chemotherapy.
We investigated the incidences and characteristics of febrile neutropenic events in lung cancer patients receiving chemotherapy at our institute.
Material and Methods: All lung cancer patients treated with standard chemotherapy between 01.10.2005 and 30.09.2010 were included in our retrospectiv analysis. Patients with concurrent radiotherapy were excluded. Febrile neutropenia was defined as any febrile episode (38.5ºC once or 38ºC twice) occurring during neutropenia (neutrophil count ⩽500/mm3).
Results: During the analysed period 1757 patients (1425 NSCLC and 332 SCLC) received chemotherapy. Febrile neutropenia were developed in 85 patients. Males were 70.6%, females were 29.4%. Overall incidence of FN was 4.8%: in SCLC was higher, than in NSCLC (13% versus 3%). FN mortality was 8%, 7 patients (6 SCLC, 1 NSCLC) died. In fatal cases absolut neutrophil count was <100/ul. Important factors associated with risk of febrile neutropenia included platinum based and taxan contained chemotherapy, 1< comorbidities (COPD, cardiovascular diseases, diabetes mellitus, alcoholism), low baseline haemoglobin level (<11.5 g/dl), previous chemo/radiotherapy and advanced stadium of disease.
Prophyilactic G-CSF was not given in any of the patients in FN groups. Some of our fatal cases belongs not to the known high risk protocols.
Conclusions: Treatment, patient and cancer-related factors resulted in the FN in lung cancer patients. Frequency and mortality of FN in SCLC was significantly higher than in NSCLC. According to the 2010 EORTC guidelines the risk assessment for FN before each cycle of chemotherapy is clinically relevant. Profilactic use of G-CSF has a clinical benefit in high risk patients.

9083 POSTER

Pemetrexed (PEM) Plus Platinum-based Regimen as First Line Treatment in Unselected Patients Affected With Non-squamous Non-small-cell Lung Cancer (NSCLC): a Retrospective Multicenter Analysis

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Background: PEM plus platinum-based regimen is considered a standard regimen for first-line treatment in non-squamous NSCLC patients. This retrospective multicenter analysis was performed to evaluate the outcomes in an unselected population treated in various oncologic centers.
Methods: Data were obtained by reviewing the clinical chart of pts, affected with advanced non-squamous NSCLC, treated from 2009 to 2010 with first line PEM and platinum-based regimen. One-hundred-twenty three pts were retrieved. Main patient characteristics were: median age 63 years (range 37−79); one-hundred twenty pts were adenocarcinoma, male/female: 67%/33%; ECOG PS 0−1: 94%; weight loss >5%: 21%; current smoker: 31%. Stage IV disease was present in 81% of pts and 79% of pts had ⩾1 site of metastasis. Brain metastasis were present in 14% of pts.
Results: All 123 pts were evaluable for response. The PEM + Cisplatin combination have been used in 81% of pts while 19% of pts received PEM + Carboplatin. Maintenance treatment with P alone was administered to 21% of pts. Objective responses included partial response (PR) in 44 pts (36%) and stable disease in 36 (29%) for an overall disease control rate of 65%. The 1-yr Overall Survival (OS) and the 1-yr Progression-Free Survival (PFS) were 51.4% and 17.4% respectively. At a median follow up of 6.7 months (range 1−22) the median OS was 13 mo (IC95%: 9−16) and the median PFS was 6 mo (IC: 95% 5−8). No differences were seen in PFS and OS according to the type of response (PR or SD), type of platinum-based regimen, smoking status and maintenance treatment (yes vs not). A significant difference in 1-yr OS (63% vs 21%, $p < 0.0001$) and in 1-yr PFS (28.5 vs 6%, $p = 0.007$) was observed for weight loss <5% vs >5%. In the Cox multivariate analysis, the following factors were significant: sex (M vs F, HR 2.1 IC95% 1.17−3.8, $p = 0.01$); PS (0 vs ⩾1, HR 2.12, IC95% 1.24–3.64, $p = 0.006$); sites of disease (1 vs ⩾2, HR 2.38, IC95% 1.07–5.29, $p = 0.03$); type of response (PR vs no response, HR 3.48, IC95% 1.98–6.14, $p < 0.0001$). Regardless to PEM maintenance treatment a trend in improvement in the 1-yr OS was seen (72% vs 55%, $p = 0.07$) whereas not for 1-yr PFS (29% vs 22%, p = ns). Moreover no differences in outcome were seen for patients achieving a PR or SD after the first line treatment and receiving PEM maintenance or in pts with brain metastases. No unexpected toxicity were observed.
Conclusion: This retrospective analysis compares favourably with the data achieved in the registration study and confirms the activity of the PEM + platinum-based regimen also outside clinical studies.

9084 POSTER

A Global Phase 2 Study Including Efficacy, Safety and Patient-reported Outcomes (PROs) With Crizotinib in Patients (Pts) With ALK-positive Non-small Cell Lung Cancer (NSCLC)

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Background: Crizotinib is an ATP-competitive, small molecule ALK inhibitor. We present open-label efficacy, safety and pt-reported outcome (PRO) data from an ongoing multicenter Phase 2 study of crizotinib in pts with advanced *ALK*-positive NSCLC (PROFILE1005, NCT00932451; Pfizer).
Materials and Methods: Pts with *ALK*-rearranged NSCLC (by centralised FISH test) that progressed after ⩾1 chemotherapy regimen for recurrent/advanced/metastatic disease (including treated brain metastases) received oral crizotinib 250 mg BID in continuous 3-week cycles. Disease response was evaluated by RECIST v1.1 every 6 weeks. Adverse events (AEs) and PRO (EORTC QLQ-LC13 v3/QLQ-C30) were assessed every 3 weeks.
Results: On 29 October 2010, 136 pts were evaluable for safety, 109 for PRO and 76 for tumour response. Pts' median age was 52 years, 94% had adenocarcinoma, 68% had never smoked, and 53% were female. Most had ⩾2 prior systemic therapy regimens (93%; range 1−11). Pts received a median 9 weeks' treatment (range 1−13 cycles started) and 88% remain on therapy. Of 76 evaluable pts, most had target lesion shrinkage (63/76 pts [83%]; 41 pts had ⩾30% shrinkage), and seven pts had objective progression. Common treatment-related AEs (nausea [46%], vision disorder [45%], vomiting [39%], and diarrhoea [29%]) were mostly Grade 1/2. Treatment-related Grade 3/4 AEs were reported in 15% of pts (mostly dyspnoea [3%], increased ALT [4%], and neutropaenia [2%]). Two of 9 on-study deaths were considered treatment-related (1 pneumonitis, 1 unknown cause). At cycle 4, most pts (71/136 pts [52%]) had completed 4 PRO assessments; clinically significant (⩾10 point mean change from baseline) improvements in pain, cough, fatigue, insomnia, dyspnoea (by QLQ-C30), and alopecia were reported as early as cycle 2. Of reported increases in constipation, diarrhoea, and nausea/vomiting, only increase in constipation was clinically significant over the course of therapy. Mean quality of life (QoL) did not deteriorate during treatment. Updated data will be presented.
Conclusions: Preliminary Phase 2 data suggest crizotinib in pts with *ALK*-positive advanced NSCLC was safe and well tolerated with antitumour activity and symptom improvement, while QoL was maintained.