progression and so we examined the relationship of achieved Hb and outcome.
Materials and Methods: We performed a combined analysis of pt-level data from 6 Amgen-sponsored RCTs of DA to treat CIA in pts with screening Hb⩽11g/dL, nonmyeloid malignancies, ⩾1 prior chemotherapy (CTX) cycle, and additional planned CTX cycles. Adverse events (AEs) were mapped to a common reporting dictionary (MedDRA v.9) to consistently define TE. Deaths or DP were identified based on reasons given for drug or study discontinuation and either a reported fatal AE (death) or end-of-study disease status (DP). An exploratory analysis examined if a Hb event (Hb > 12 or 13 g/dL, or Hb increase >1 g/dL in a 14-day window during study, excluding Hb within 28 days after a transfusion) is associated with an increased risk of death, DP, and TEs. Each Hb event was assessed individually as a time-dependent covariate (based on time to first occurrence) in a Cox proportional hazards model.
Results: The analysis included 901 DA pts who received ⩾1 DA dose (mean[SD] age, 62.3[12.3] yrs; 54.6% women; 48.3% ⩾65 yrs old; 81.9% with stage III or higher/extensive disease). The risk of on-study death was lower if a Hb event occurred, reported as HR (95% CI): 0.41 (0.20−0.83) for Hb > 12 g/dL, 0.60 (0.25−1.45) for Hb > 13 g/dL, and 0.48 (0.26−0.89) for a >1-g/dL increase in 14 days. A similar pattern was seen when deaths were identified during a study's follow-up period. Risks of DP and progression-free survival (PFS; time until death or PD, whichever earlier) were lower when Hb > 12 g/dL (HR: 0.45 to 0.67), Hb > 13 g/dL (HR: 0.63 to 0.84), or a >1-g/dL increase in 14 days (HR: 0.55 to 0.64). Achieving a Hb event was associated with an increase risk of TEs, though CIs include 1: 1.66 (0.90−3.04) for Hb > 12 g/dL, 1.82 (0.86−3.83) for Hb > 13g/dL, and 1.67 (0.96−2.88) for having >1 g/dL increase in Hb in 14 days.
Conclusions: In these DA studies in CIA pts, having Hb >12 or 13 g/dL or a >1 g/dL increase in Hb in 14 days was associated with a decreased risk of death or DP, and an expected increased risk of TEs. Therefore, in these pts, the primary health risk associated with Hb > 12 g/dL (above the current recommended treatment target in the US) or >1 g/dL increase in Hb in 14 days appears to be increased risk of TEs.

1121 POSTER

The effect of methylnaltrexone on global clinical impression of change (GCIC) in the bowel status of cancer patients with opioid-induced constipation

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Cancer patients frequently use opioids and suffer from opioid-induced constipation (OIC) that is refractory to laxative therapy. Previously reported study results demonstrated that methylnaltrexone, a selective peripheral mu-opioid receptor antagonist rapidly induces laxation without affecting analgesia.
The current analysis examines effect of methylnaltrexone on patient and clinician reported Global Clinical Impression of Change (GCIC) in bowel status in a sub-group of cancer patients.
In this randomized, double-blind placebo-controlled trial, advanced illness patients with OIC were treated with placebo or methylnaltrexone (0.15 mg/kg SC QOD dosing) for 2 weeks with the option to double the dose on Day 9 if there had been <3 rescue-free laxations in the first week. Baseline laxatives were continued during the study with rescue laxatives not permitted for 4 hrs before and after each dose. Patients and clinicians reported their assessment of change in bowel status on Day 7 and Day 14 using a 7-point Likert GCIC scale (1 = Much worse, 7 = Much better). Patients assessed constipation distress using a 5-point Likert scale (1 = None, 5 = Very much) at baseline, Day 7 and Day 14. A sub-group of cancer patients (N = 64) was selected and proportion of patients showing improved status (GCIC score >4) as indicated by patient and clinician GCIC scores were compared between methylnaltrexone and placebo using chi-square test. Correlation coefficients were estimated between patient and clinician reported GCIC and change in constipation distress scores.
Significantly higher percentages of methylnaltrexone-treated cancer patients and their clinicians rated patient's bowel status as improved compared to the placebo group on Day 7 (patient: 75% vs 37.5%: $p < 0.05$; clinician: 65.6% vs 37.5%: $p < 0.05$) and Day 14 (patient:75% vs 37.9%: $p < 0.05$; clinician: 68.8% vs 46.7%: $p < 0.05$). A significant positive correlation was found between patient and clinician reported GCIC scores across both groups on day 7 ($r = 0.86$; $p < 0.001$) and day 14 ($r = 0.84$; $p < 0.001$). A significant inverse correlation ($p < 0.001$) was found between the change in constipation distress and GCIC scores in the methylnaltrexone group on Day 7 (patient: $r = -0.79$; clinician: $r = -0.84$) and Day 14 (patient: $r = -0.55$; clinician: $r = -0.49$).
Methylnaltrexone showed a significant positive impact on bowel status in this study of cancer patients with opioid induced constipation as reflected by the patient and clinician reported GCIC scores.

1122 POSTER

Prevention of anemia by early intervention with once weekly epoetin alfa during chemotherapy

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Background: There is good evidence that epoetin alfa (Eprex®, EPO) is effective in treating moderate to severe anemia during cytotoxic cancer treatment. Further research is required to clarify its role in the treatment of mild anemia and the prevention of anemia in this setting.
Materials and Methods: In a randomised, multicentre trial the effects of EPO on hemoglobin (Hb) levels and the need for bloodtransfusions (BT) were assessed in cancer patients (pts) started on chemotherapy (CT). Pts with Hb < 12.1 g/dl and likely to receive CT for at least 12 weeks, were randomised (1:1) to EPO (40.000 U QW) to be started with CT simultaneously (early EPO) or when Hb dropped below 10.1 g/dl (standard EPO).
Results: A final analysis was performed after enrolling 110 pts (55 early EPO versus 55 standard EPO) as planned. Treatment groups were comparable for gender, age, performance score and tumor type. Mean Hb at baseline was 11.2 and 11.3 g/dl, respectively, and EPO was started at an average Hb value of 11.2 and 10.0 g/dl. Hb values in the two treatment groups diverted significantly after week 6, 8/9, 10, 12 and 15/16 ($p < 0.05$, Wilcoxon two sample test). No significant difference was observed in the percentage of pts receiving BT's after early versus standard EPO (27.8% of patients transfused in both groups). The amount of blood transfused, however, was almost twice as high in the standard EPO group versus the early EPO group. EPO treatment was well tolerated in both groups. Adverse events (AE's) were as expected in a population of cancer pts treated with CT. Slightly more thrombovascular events (TVE's) were observed in the early EPO group. There was no significant difference in overall survival between both groups.
Conclusions: EPO treatment for mild CT-induced anemia (Hb < 12.1 g/dl), increases Hb values and results in significantly higher Hb values as compared to EPO therapy initiated when Hb drops below 10.1 g/dl. Percentage of pts receiving BT's after early versus standard EPO was similar, however, the amount of blood transfused was almost twice as high in the standard EPO group. Maintaining Hb values around 12.1 g/dl may have a positive impact on quality of life according to several literature reports on this topic.

1123 POSTER

Neoplastic pulmonary lymphangitis: clinical aspects, symptomatic treatment and quality of life in a prospective palliative care series

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Background: Neoplastic pulmonary lymphangitis (NPL), or lymphangitis carcinomatosa, has a poor prognosis and is a distressing form of lung metastasis. Since measuring quality of life is an important step toward improving management in cancer patients, and breathlessness in pulmonary lymphangitis is a complex syndrome in end-of-life care, we evaluated a cohort of those individuals.
Methods: 52 consecutive patients with NPL were prospectively followed in 3 services, with clinical data gathering, and quality of life (QoL) evaluation also, using Medical Outcomes Study 36-item Short-Form Health Survey (SF-36) and Saint George's Respiratory Questionnaire (SGRQ).
Results: Sixty-five percent of patients were female; age ranged from 37 to 84 years (median: 60.5). Primary tumor sites were: 28 lung (54%),