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%),

18 breast (35%), 5 digestive (9%) and 1 bone cancer. Histological findings were of adenocarcinoma in most cases (71%) and 79% had bilateral NPL. Karnofsky performance scale ranged from 10 to 90% (median: 60%); 52% patients had other comorbidities (Charlson index ranged from 6−10; median 7); 48% were previous smokers (2–198 pack-years); hemoglobin levels ranged from 4.9 to 16.7 g/dL (median: 12); body mass index varied from 16.3 to 41 kg/m^2 (median: 24). We also evaluated 34 patients with echocardiography, and 38% of them had signs of associated pulmonary hypertension; ejection fraction ranged from 46 to 83% (median: 69%); diastolic dysfunction was present in 22 and pericardial effusion in 10 patients. Median SpO2 was 91% (range 80−98%); 45% of patients had hypoxemia. Half of the patients had associated stress symptoms (depression or anxiety). At accrual, median QoL scores were of: 34.7 (range: 9.2−83.9) for SF-36 (scale with 0 worst) and 64.8 (range: 0−93.9) for SGRQ (scale with 100 worst). Treatment is shown in table 1 – 50% had SF-36 improvement with 1 month of palliative and supportive treatment. Median survival was of 81 days (range: 0.2−44.5+ months); at 3 months it was of 48%, and 33% of the patients had an unusual longer survival of more than 6 months, still showing good QoL scores.

Table 1. Palliative pulmonary lymphangitis treatment

Corticotherapy	
Systemic	76.9%
Inhaled	13.5%
Opioids	
Weak	63.5%
Strong	53.8%
Oxygen	61.5%
Diuretics	61.5%
Inhaled therapy	
Ipratropium bromide	61.5%
Beta2-agonists	57.7%
Systemic oncological treatment	
Chemotherapy	59.6%
Hormone therapy	5.8%
Physical therapy	53.9%
Benzodiazepines	48.1%
Active palliative sedation	40.4%
Thoracocentesis	38.5%
Antidepressants	36.5%
Blood transfusion	23.1%
Pericardiocentesis	10%

Conclusions: Despite the fact that QoL is generally poor and survival is short for patients with NPL, some patients may have longer survival time and some improvement is possible with active palliative and supportive care.

1124 POSTER

Feasibility and efficacy of video-assisted home care for cancer patients on chemotherapy (medical care continuity-mcc project). the preliminary italian experience

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Background: Cancer patients on chemotherapy may require frequent administration of supportive medications and/or receive oral formulations of antineoplastic drugs. These treatments could potentially be followed with no hospital admission. We evaluated within an EU granted pilot study, an integrated equipment including computer, video-telephone and a high-definition camera to follow patients receiving chemotherapy during their stay at home.
Methods: The equipment allowed 24 h/day communication to an "intermediate physician" of AXA Assistance call-center with transfer to "Tor Vergata" Clinical Center (TVCC) when needed.Five cancer patients (median age 69) treated at TVCC were enrolled between Nov 2006 and Feb 2007. Patient selection was planned to include both metastatic and non-metastatic patients and based on the willingness to use informatic supports.Frequency of patient/doctor contact was calculated as total number of contacts per patient/total weeks of follow-up. All patients were provided with internationally validated and MCC-oriented questionnaires exploring the patient's general health status and opinions on potential improvement of medical assistance by MCC and on complexity of MCC technology. All questionnaires were to be completed at study entry and at the end of the experimentation.
Results: Patients were on chemotherapy for metastatic disease (2 breast, 1 colon) or with adjuvant intent (1 breast and 1 colon cancer). Median duration of experimentation and frequency of patient/doctor contact were 45 days (31–120) and 2.1 contact/week (1.4−5.6), respectively. Contacts were related to technical support and medical reasons in the 35% and 65% of cases, respectively. Overall, 100% positive opinions on MCC care were reported by all participants at the end of the study with a 35% conversion-rate when opinions before study entry were considered.Medical contacts resulted in 67% of cases in drug dose-adjustments (mainly pain-killers or medications for chemotherapy-side-effects) for metastatic patients and in 32% of cases in management of anxiety and post-surgical complications for patients on adjuvant treatment, thus reducing unnecessary hospital admissions by 15%.
Conclusions: The MCC equipment was well managed by both patients and caregivers, main positive changes being the perception that MCC may substantially improve medical assistance by virtue of a constant access to medical advice and reduction of unnecessary hospital admissions.
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1125 POSTER

Chemotherapy has no impact on acute and late skin toxicity when combined with a hypofractionated regimen of breast irradiation

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Background: Hypofractionated whole breast radiotherapy for early breast cancer has been widely adopted in Canada following the results of the Cancer Care Ontario breast fractionation schedule study. Nonetheless, very few patients received chemotherapy in that study, and the toxicity of hypofractionated radiotherapy in patients receiving chemotherapy was not analyzed. We thus set to evaluate the impact of adjuvant chemotherapy on the incidence of skin toxicity in the setting of hypofractionated radiotherapy. Materials & Methods: We conducted a retrospective review of patients with breast cancer treated with hypofractionated radiotherapy consisting of 42.4 Gray in 16 fractions from 2004 to 2006 at the Jewish General Hospital. Patients undergoing lumpectomy with or without adjuvant chemotherapy followed by hypofractionated radiotherapy were included in this study. All patients were evaluated weekly during treatment and on scheduled follow-up visits by the radiation oncologist using the RTOG/EORTC acute and late skin radiation toxicity scale version 2. Furthermore, the EORTC breast cancer-specific quality of life questionnaire QLQ-BR 23 was mailed to all patients.
Results: 163 patients underwent hypofractionated radiotherapy during the study period, 27% (n = 44) of which received chemotherapy. All patients completed their radiotherapy treatment as scheduled. Radiotherapy boost to the tumor bed was more common in the chemotherapy group (n = 19; 43.2% of patients) compared to the radiotherapy alone group (n = 32; 26.9%). There was no statistically significant difference between the two groups with regards to acute skin toxicity of grade $\geqslant$3 (0% in the chemotherapy group vs. 5.3% in the radiation alone group; p = 0.06) or grade 1−2 (60.5% vs. 51.7%, respectively; p = 0.16). With regards to late skin toxicity, there was, again, no significant difference between the chemotherapy and the radiation alone group for grade $\geqslant$3 (0% vs. 2.63% respectively; p = 0.21) or grade 1−2 toxicity (29.3% vs. 30.3% respectively; p = 0.45). Data regarding quality of life and breast cosmesis is pending.
Conclusions: In our retrospective single institution review, it appears that the addition of chemotherapy to hypofractionated whole breast irradiation has no adverse effect on the incidence of acute and or late skin morbidity. Further investigations such as a multi-centre review are necessary to better elucidate the impact of chemotherapy on skin toxicity in the context of hypofractionated irradiation.