Results: In patients for whom treatment was recommended, 54% (263/484) received treatment. In patients for whom immediate treatment was not required, 14% (124/908) were treated with an ESA or transfusion. Among patients for whom treatment was recommended, patients with colorectal cancer (AOR = 0.36, 95% CI=0.17−0.77) and lymphoma (AOR = 0.40, 95% CI=0.17−0.93) were less likely to receive treatment than patients with other cancers, adjusting for age, Hb, prior transfusion, prior chemotherapy, COPD, cardiac disease, fatigue, and cancer duration. Furthermore, in the same multivariate model, patients with lower Hb were more likely to receive treatment (p = 0.004). Among patients for whom immediate treatment was not required, no differences in patient characteristics were found between those who were and were not treated.
Conclusions: Transfusions and ESAs were only administered to 54% of patients where guidelines recommend treatment. Cancer type and lower hemoglobin were associated with receiving a transfusion or ESA among patients for whom CIA treatment was recommended.

1140 POSTER

Epoetin beta therapy in anemic patients with solid tumor or non myeloid hematological malignancies receiving chemotherapy: results of a large prospective cohort study

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Background: Anemia is the most frequent hematological complication of cancer patients (pts) receiving chemotherapy. The efficacy of epoetin beta (E) is well documented in clinical trials in anemic cancer pts. This study was conducted to assess E use, efficacy, safety and impact on quality of life (QOL) in cancer pts, in routine practice.
Methods: This prospective, multicenter, longitudinal, observational French cohort assessed a 4-month follow-up of informed consent cancer pts (including both solid tumors [ST] and non myeloid hematological malignancies [H]) treated with E for chemotherapy-related anemia. Patients were included between January 2005 and March 2006. The response was defined
as an Hb increase of $\geqslant$2 g/dl and/or an achievement of Hb value $\geqslant$12 g/dl without any blood transfusion after E treatment initiation. QOL was assessed by FACT scale.
Results: Among 3256 pts enrolled in 423 centres, 2880 were analysed: 75% of pts had a ST (lung: 30%; breast: 20%) and 25% had a H (non-Hodgkin lymphoma 51%; multiple myeloma 31%). Pts' characteristics were: mean age 63$\pm$12 yrs, male 50%, performance status 0 (13%), 1 (46%), $\geqslant$2 (41%). The median time from diagnosis to inclusion was 5 months. 52% of pts received their first line of chemotherapy and 25% their second one. 44% of pts (56% of ST and 9% of H) received platinum based regimen. 26% of pts received prior radiotherapy. 12% of pts had a past history of EPO administration. At inclusion, Hb levels were distributed as: 19% <9 g/dl, 66% [9−11[g/dl, 15% [11−13[g/dl. Endogenous erythropoietin concentration was controlled in only 2% of pts, ferritin in 17% of pts, transferrin saturation in 12% and reticulocytes in 11%. At initiation, 98% of pts received a median dose of 30000 U/week of E on a once weekly regimen schedule. Iron supplementation was given in 49% (3% IV) of ST and 13% of H pts. 21% of pts (18% of ST and 31% of H) received at least one blood transfusion during the study. Median Hb level at baseline was 10.1 g/dl [95CI 10−10.1] in ST and 9.6 g/dl [95CI 9.4−9.6] in H. Hb RR was 54.8% [95CI 52.6−56.9%], 54.5% in ST and 56.1% in H. In multivariate analysis, gender, PS, number of prior lines of chemotherapy, platinum based regimen and iron supplementation were identified as predictive factors of response. The mean of FACT score improved from 27.5 [95CI 27−28] at initiation to 31.3 [95CI 31−32] at the end of study (p < 0.001). Thromboembolic events were reported for 1.9% of patients.
Conclusion: this large prospective cohort study confirms the efficacy and safety of epoetin beta and its positive impact on QOL in routine practice treatment of anemic cancer patients. The study also shows very few biological tests were done before initiation of E in routine practice.

1141 POSTER

Evaluation of extended dosing intervals versus weekly dosing of darbepoetin alfa (DA): A phase 2 study in cancer patients (pts) with chemotherapy-induced anemia (CIA)

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Background: Being able to treat CIA with erythropoiesis-stimulating agents like DA on the same schedule as chemotherapy (CTX) regimens could benefit pts by reducing clinic visits.
Materials and Methods: This was a phase 2, 25-week (wk), open-label study to evaluate noninferiority of DA in pts with CIA who were randomized 1:1 to either an extended dose schedule (DA-EDS) group (DA 300 mcg Q2W if CTX was QW, Q2W, or Q4W or DA 500mcg Q3W if CTX was Q3W) or a weekly DA (DA-QW) group (150 mcg QW regardless of CTX schedule). Stratification factors were CTX cycle length, screening hemoglobin (Hb) (<10 vs $\geqslant$10 g/dL), and type (lung/gynecological vs other cancers). The primary endpoint was change in Hb from baseline (BL) to wk 13.
Results: The analysis included all randomized pts (374 DA-QW pts; 378 DA-EDS pts) who received $\geqslant$1dose of DA. Demographics were broadly similar, DA-QW vs DA-EDS (median age, 63 vs 64 years; 32% vs 35%, lung/gynecological cancer; 78% vs 75%, disease stage III/IV.) Results are shown (Table). There was no difference between DA-EDS and DA-QW in mean change in Hb (BL to wk 13) (95% CL: −0.3, 0.2), with an upper limit $\leqslant$0.75g/dL supporting the noninferiority of the DA-EDS arm. The %pts with Hb $\geqslant$11g/dL by Kaplan-Meier estimates was also similar (difference [95% CL] = 1 [−3, 6]). Adverse events were similar between the groups, DA-QW vs DA-EDS, 23 (6%) vs 21 (6%) with thromboembolic events, 4 (1%) vs 5 (1%) with myocardial infarction or coronary artery disease, and 39 (10%) pts in each arm died.
Conclusions: In this study, DA, when administered synchronized with CTX schedules, appeared to be efficacious with no unexpected adverse events. This study provides the first prospective data on how the multiple dosing regimens available with DA can be paired with chemotherapy administered across a range of dosing schedules.

Table

	DA-QW n = 374	DA-EDS n = 378
Mean (SD) BL Hb, g/dL	10.1 (0.9)	10.1(0.8)
Mean* (SE) change in Hb, g/dL – BL to wk 13 [n]	0.9 (0.08) [374]	0.9 (0.08) [375]
KM% (95%CL) pts who achieved Hb $\geqslant$ 11 g/dL – BL to EOS [n]	94 (90, 98) [323]	94 (91, 98) [334]
KM median time to achieve Hb $\geqslant$ 11 g/dL – BL to EOS [n]	7.0 (6.0, 8.0) [323]	7.0 (7.0, 9.0) [334]
KM% (95%CL) pts who had TFNs – BL to EOS [n]	29 (24, 34) [374]	26 (21, 30) [378]
Pts who had treatment-related adverse events, n (%)	18(5)	14(4)

*Least squares mean, last value carried forward; SD = standard deviation; BL = baseline; Hb = hemoglobin; CL = confidence limit; KM = Kaplan-Meier; TFN = transfusion.

1142 POSTER

Breakthrough pain in cancer patients: assessment and treatment by four specialities in five European countries

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Background: To gain in-depth understanding of the incidence and treatment of breakthrough pain (BTP) in cancer patients, market research was undertaken in France, Germany, Italy, Spain and UK, among four clinical specialities.
Methodology: A total of 483 oncologists, GPs, palliative care, and pain specialists surveyed on their involvement in cancer patients with BTP and approaches to treatment.
Results: Among cancer patients treated by oncology specialists in the previous year approximately one quarter had died. Of these ~60% were estimated to have experienced chronic pain and 40% as having an average of ~4 episodes of BTP/day for a total of 28 days. In contrast, for cancer patients who had died in the past year seen by GPs and pain specialists,

~75% were estimated to have experienced chronic pain and ~60% as having BTP an average of ~3 episodes/day for 39 days. Morphine is the most frequently used drug for BTP by all specialities. Oncologists are primarily responsible for the initiation of BTP therapy, with palliative care specialists (France and UK) and pain specialists (France and Italy), involved in initial treatment choice. Oncologists and GPs are the specialties responsible for maintaining treatment of BTP, although UK palliative care specialists are perceived to be more involved than oncologists. In France, pain specialists are also involved in maintaining the treatment of BTP. Inadequate control of BTP was defined by all specialities as a patient experiencing ⩾3 BTP episodes per day, and in such cases the chronic pain medication would be changed rather than continue with the therapy for BTP. All specialities in all countries were not totally satisfied with current treatment options for BTP. Complete pain relief, fast onset of action, minimal side effects, and improvement in patients' quality of life were considered primary qualities for effective treatment of cancer BTP.
Conclusions: Although widespread in occurrence, treatment of BTP with oral morphine remains standard and is not considered fully effective. Novel methods providing, rapid, efficacious and easily administered relief are required to ease the suffering of BTP in cancer patients.

	Oncology specialists	GPs/ Pain specialists
Deceased patients seen in previous year (N)	128	12
Chronic pain (mean %)	62	75
BTP (mean %)	41	60
BTP patients given opioids for chronic pain (mean %)	84	86
Days suffering (mean N)		
Chronic pain	69	88
BTP	28	39
Average episodes BTP/day (N)	4	3
Estimated episodes BTP per deceased patient	100	120

1143 POSTER

Oral palonosetron (PALO) is as effective as intravenous (IV) PALO: a phase 3 dose ranging trial in patients (pts) receiving moderately emetogenic chemotherapy (MEC)

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Background: PALO (Aloxi®, Onicit®) is a pharmacologically unique 5-HT3 receptor-antagonist approved as a single IV injection 0.25 mg for prevention of nausea & vomiting (CINV) associated with moderately and highly emetogenic chemotherapy. In 2 previous Phase 3 trials in pts receiving MEC, PALO was superior to ondansetron and dolasetron in preventing acute and delayed emesis; pooled data from those studies indicated PALO significantly reduced interference in pt functioning due to nausea. An oral PALO formulation is being developed as it may be preferred in certain clinical situations or settings of care.
Material and Methods: In this multinational, multicenter, double-blind, double dummy, dose ranging trial, 651 pts were randomly assigned (stratified by gender and history of chemotherapy {naive vs non-naive}) to: oral PALO 0.25 mg, 0.50 mg, 0.75 mg or a single IV dose of PALO 0.25 mg. Pts were also randomized (1:1 balance) to receive dexamethasone (DEX) 8 mg or a matched placebo on day 1. The primary endpoint was complete response (CR; no emesis, no rescue therapy) 24 hours after MEC. The primary hypothesis was that at least 1 dose of oral PALO would be non-inferior to IV PALO.
Results: There were 635 evaluable pts for efficacy. Demographics were similar across the treatment groups: ~73% women, ~59% chemo-naive, mean age ~56 yrs.

CR (% of pts) 95% CI	Oral 0.25 mg (N = 155)	Oral 0.50 mg (N = 160)	Oral 0.75 mg (N = 158)	IV 0.25 mg (N = 162)
Acute (0–24 hr)	73.5 [65.8, 80.2]	76.3 [68.8, 82.5]	74.1 [66.4, 80.5]	70.4 [62.6, 77.1]
Delayed (24–120 hr)	59.4 [51.2, 67.1]	62.5 [54.5, 69.9]	60.1 [52.0, 67.7]	65.4 [57.5, 72.6]
Overall (0–120 hr)	53.5 [45.4, 61.5]	58.8 [50.7, 66.4]	53.2 [45.1, 61.1]	59.3 [51.3, 66.8]

Adverse events were similar in nature and rate for oral PALO vs IV groups and typical for this class of drug (headache/constipation); no dose response relationship was noted in AEs for oral PALO. DEX improved acute CR > 15% for all groups except oral PALO 0.25 mg (~7%).

Conclusion: Oral PALO has a similar efficacy and safety profile as IV PALO 0.25 mg. An oral PALO dose of 0.50 mg appears to be optimal for preventing both acute and delayed CINV in patients receiving MEC.

1144 POSTER

Comparison of two questionnaires assessing fatigue in patients with chemotherapy-induced anaemia treated with darbepoetin alfa every 3 weeks

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Background: Chemotherapy-induced anaemia (CIA) is often associated with fatigue and reduced quality of life (QoL). Darbepoetin alfa (DA) administered every 3 weeks (Q3W) can effectively treat CIA. This study aims to evaluate the effectiveness of DA treatment and to compare psychometric outcomes using the Functional Assessment of Cancer Therapy Fatigue Subscale (FACT-F) and The Fatigue Symptom Inventory (FSI) in CIA patientes (pts) treated with DA Q3W.
Materials and Methods: This was a longitudinal, single-centre prospective study in adult pts with solid tumours undergoing chemotherapy (CT) and with mild to moderate cancer-related fatigue (CRF) (Visual Analogue Scale [VAS] ⩾30 mm). Pts with haemoglobin (Hb) levels <11 g/dL were treated with DA 500 mcg Q3W. Key clinical parameters, FACT-F, and FSI measurements were collected at the beginning and end of the CT treatment period. Psychometric indicators for reliability and validity were calculated.
Results: One hundred pts were included. Mean age was 62.0 years (SD 12.2), 53.7% were women, 92.0% had ECOG status 0−1, 64.0% had IV stage cancer, and 70% had no prior CT. Breast (25%), colon (16%) and lung (15%) were the most common tumour types. Median CT duration was 16.0 weeks (range, 3.3−64.1) and all pts received DA treatment during CT. Mean baseline Hb was 10.15 g/dl (SD 0.68).The median number of DA doses administered was 3 (range, 1−7). Hematopoietic response (defined as Hb ⩾ 12 g/dL or Hb rise from baseline ⩾2 g/dL) was 65.0% (crude rate). Only 7% of pts required blood transfusions from week 5 to end of treatment. FACT-F and FSI scores improved by 3.5 and 13.0 points respectively during CT. This improvement was higher in pts whose Hb level increased by ⩾2 g/dL (improvement in FACT-F = 5.3, FSI = 17.2) or between 1−2 g/dl (improvement in FACT-F = 4.8, FSI = 15.8). Internal consistency (Cronbach alpha coefficient) was good and similar for both questionnaires at the beginning (FACT-F = 0.92; FSI = 0.96) and end (FACT-F = 0.98; FSI = 0.98) of CT treatment period. The intraclass coefficient was also satisfactory (FACT-F = 0.72; FSI = 0.83) for both questionnaires
Conclusions: Treatment of CIA with DA 500mcg Q3W seems to be effective and improves QoL in this clinical practice study. Both the FACT-F and FSI QoL questionnaires measured a change in fatigue during the study with high and similar consistency.

1145 POSTER

Use of percutaneous transhepatic biliary drainage to reduce the jaundice due to biliary obstruction in advanced hepatobiliary, gall bladder & pancreatic cancer: experience from a developing country

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Background: Hepatiobiliary & pancreatic adenocarcinoma account for approximately 7−8% of all malignant neoplasm. Majority of the patients present in late stage with liver metastasis and biliary obstruction. The only treatment option at this stage is to reduce the jaundice by either bypass surgery, ERCP stenting or Percutaneous transhepatic biliary drainage (PTBD). In some of the cases palliative chemotherapy is possible after reduction of jaundice. The aim of our study was to see affectivity and cost effectiveness of Percutaneous Transhepatic Biliary Drainage (PTBD) to reduce jaundice in advanced hepatiobiliary & pancreatic carcinoma.
Material & Methods: During period from January 2004 – December 2006 we selected 300 consecutive cases of advanced hepatiobiliary & pancreatic cancer in the Medical Oncology department of Netaji Subhash Chandra Bose Cancer Research Institute, a tertiary cancer center of Eastern India. The inclusion criteria were performance status more than 50% (Kornofsky) normal renal function (creatinine <2) and absence of ascitis. All patients with failed bypass surgery or ERCP stenting were tried for PTBD silicon tube under ultrasonography guidance. Mean pre-stenting serum bilirubin was 18.6 mg% (Range 6−28 mg%).
Result: PTBD was possible to introduce in 240 patients (80%). They tolerated the procedure well. In 200 patients (66.66%) the serum bilirubin came down to less than 2 mg% in average of 22days (Range 13−35 days). Palliative chemotherapy with Gemcitabine & Cisplatin was possible in those