

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.

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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 ≥ 2 g/dl and/or an achievement of Hb value ≥ 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 ± 12 yrs, male 50%, performance status 0 (13%), 1 (46%), ≥ 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.

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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 ≥ 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 ≥ 1 dose 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 ≤ 0.75 g/dL supporting the noninferiority of the DA-EDS arm. The %pts with Hb ≥ 11 g/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 ≥ 11 g/dL – BL to EOS [n]	94 (90, 98) [323]	94 (91, 98) [334]
KM median time to achieve Hb ≥ 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.

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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,