as a control group. CD95 (FAS) and P53 were studied by flowcytometry, BCR/ABL gene was studied at the cytogenetic and molecular level by RT PCR and ultrastructural apoptotic changes were studied by EM.
Results: Mean level of P53% was highly increased in the all CML patients compared with controls ($p = 0.04$). Mean level of CD95% expression was higher when measured on the whole cell population in the (accelerated and/or blastic crisis) compared with chronic phase and controls ($p = 0.14$). By selecting CD34+ve cells, lower levels of CD95% expression were found in the (accelerated and/or blastic crisis phase) compared with the levels expressed on the whole cell population in the same phase. Mean level of P53% in the treated cases was higher compared to newly diagnosed cases (before treatment) showing a statistically significant difference ($p>0.01$). Higher mean levels of CD95% on whole cell population, and on CD34+ve selected cells were detected after treatment ($p = 0.30$, $p = 0.83$). The mean levels of P53% and CD95% were higher in BCR/ABL fusion gene positive cases than BCR/ABL fusion gene negative cases but didn't reach significant levels respectively ($p = 0.21$, $p = 0.62$).
Conclusions: P53% and CD95% levels expression in the accelerated and blastic crisis phases of CML patients were higher than those in the chronic phase. Comparative studies for the apoptotic markers with cytogenetic analysis and RT PCR techniques revealed higher levels of P53 and CD95 in BCR/ABL positive cases than BCR/ABL negative cases. Also P53 and CD95 levels were higher in treated cases than newly diagnosed cases.

9247 POSTER

Fatal trichosporon fungemia in patients with hematologic malignancies

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Background: Invasive *Trichosporon* infection is becoming increasingly recognized in patients with hematologic malignancies, whereas most studies have been sporadic case reports and little is yet known about details of this infection. Our study aims to clarify the clinical characteristics and management of this disease.
Materials and Methods: We studied 32 consecutive patients with hematologic malignancies who developed *Trichosporon* fungemia (TF) treated at 7 regional tertiary care hospitals in Japan over a 15 years period (1992 to 2007).
Results: Age ranged 4−85 years (mean, 56). Male predominated (91%). Underlying disease included acute myeloid leukemia (AML) in 30 patients (94%), acute lymphoblastic leukemia in 3, chronic myeloid leukemia in 2, and mature lymphoid neoplasms in 3. Thirty patients (94%) had received intensive chemotherapies, and 5 of them undergone allogeneic hematopoietic stem cell transplantation. Twenty-six patients (81%) had neutropenia at the onset. Breakthrough TF occurred in 29 patients (91%) during the use of antifungals, 18 of whom (62%) were receiving micafungin (MF). Attributable death was seen in 24 patients (75%) and 21 of them (88%) died within 10 days after the onset. Univariate analysis revealed that neutrophil recovery was associated with patient survival ($p < 0.01$), and the presence of pneumonia ($p = 0.04$) and hyperglycemia ($p = 0.01$) were correlated with poor prognosis. Overall survival was longer in patients treated with azole containing regimen than in those without azole (log-rank test, $p < 0.01$). TF tended to occur like an epidemic disease in certain hospitals; however, modification of the antifungal regimen, including limited use of MF, produced satisfactory results.
Conclusion: Since TF is mostly lethal at present unless neutrophil recovery occurs, we should pay attention to the occurrence of this infection in patients with hematologic malignancy, particularly AML. When we encounter TF, we should treat with azole and revise the use of agents lacking anti-*Trichosporon* activity to prevent breakthrough infection. This is the largest study of proven invasive trichosporonosis in patients with hematologic malignancies.

9248 POSTER

Safety of romiplostim for treatment of chemotherapy-induced thrombocytopenia (CIT) in patients with advanced non-small cell lung cancer (NSCLC)

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Background: CIT is a potentially serious side effect of chemotherapy with limited treatment options. Romiplostim is an Fc-peptide fusion protein (peptibody) that increases platelet production by the same mechanism as thrombopoietin.
Methods: This was a phase 2, randomized, double blind, placebo-controlled study with the primary objective to evaluate the safety of romiplostim in NSCLC patients (pts) receiving myelosuppressive chemotherapy. Eligible pts were >18 years old with stage IIIB or IV NSCLC receiving Q21 day gemcitabine and platinum chemotherapy and had experienced a transient platelet count decrease to $<100 \times 10^9$/L in a previous treatment cycle. Pts were randomized 4:1 to romiplostim or placebo and received one s.c. administration of romiplostim at 250, 500, or 750 μg or placebo on day 2 for up to 5 chemotherapy cycles.
Results: Overall, 63 pts were randomized. The table contains safety and efficacy parameters for romiplostim. Romiplostim treated pts showed similar rates of adverse events (AEs) and thrombotic AEs as placebo pts. The rate of serious AEs was numerically higher in romiplostim treated pts than in placebo pts, but there were no dose-dependent trends in any AE category. The most common serious AEs were anemia and thrombocytopenia. No pts tested positive for neutralizing antibodies to romiplostim or eTPO. Two non-treatment related deaths were reported: one in the 500 μg group (sepsis) and one in the 750 μg group (progression of NSCLC). There was no evidence that administration of romiplostim had a beneficial impact on platelet count related efficacy endpoints.
Conclusion: Romiplostim appeared to be a well-tolerated treatment in NSCLC pts with CIT. Sample size was limited and additional studies are necessary to define the optimal dose and schedule of romiplostim in this setting.

Overall pt incidence of AEs and first on-study treatment cycle findings

	Placebo	Romiplostim*		
	(N = 12)	250 μg (N = 16)	500 μg (N = 18)	750 μg (N = 16)
Overall AEs				
Any AE, n (%)	12 (100)	16 (100)	18 (100)	14(88)
Serious AEs n (%)	1(8)	7 (44)	5 (28)	5 (31)
Thrombotic AEs, n (%)	0	1(6)	1(6)	1(6)
First on-study treatment cycle				
Grade 3 or 4 thrombocytopenia, n (%)	5 (42)	7 (47)	7 (39)	7 (44)
Duration of grade 3 or 4 thrombocytopenia, days	2	4	3	2
Platelet transfusions, n (%)	1(8)	4 (27)	1(6)	1(6)
Chemotherapy dose reduction, day 8, n (%)	2 (17)	4 (27)	4 (22)	5 (31)

*a pt in the 750 mcg cohort was not dosed and a pt in the 250 mcg cohort did not complete the first cycle so they were not included in the safety and/or efficacy analysis sets.

ClinicalTrials.gov Identifier NCT00413283. Trial status: complete. Trial sponsor: Amgen Inc.

9249 POSTER

Single vs double dose palonosetron for the prevention of acute and delayed nausea and vomiting in patients undergoing high dose chemotherapy and autologous stem cell transplantation

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Objectives: The vast majority of patients (pts) undergoing high dose chemotherapy (HDT) and autologous stem cell transplantation (ASCT) still experience major acute and delayed chemotherapy-induced nausea and vomiting (CINV), showing how emesis control in the ASCT setting remains sub-optimal. Palonosetron (PALO), a new 5-hydroxytryptamine receptor antagonist with long half-life and high receptor binding affinity, achieves