	No IFD	Proven or Probable IFD
MBL>1000	79 (84.9%)	14 (15.1%)
MBL<1000	52 (88.1%)	7 (11.9%)

Methods: We conducted an analysis of MBL levels among patients enrolled in a previous prospective cohort study. Serum samples from 152 patients with hematologic malignancies who received chemotherapy and/or HSCT between December 2001 and November 2006 were collected before or early after treatment initiation and stored at -70°C. Quantification of MBL levels was performed by a sandwich-ELISA assay (Viracor-IBT laboratories, Mo). Patients were followed for 6 months and scored as developing proven or probable IFD or not. The relationship between MBL level and developing proven or probable IFD was assessed using chi-square and Mann-Whitney tests. Survival analyses including logistic regression and Cox Proportional Hazards models were used to test the effect of MBL level and IFD status on overall survival and whether MBL level has an effect on IFD-free survival time.

Results: Forty-five of 152 patients (29.6%) developed IFD during the 6 months follow-up period of which 21 (46.7% of IFD cases and 13.8% of patients) were proven or probable IFD. Fifty-nine of 152 patients (38.8%) had MBL levels below 1,000 ng/ml. The rates of proven or probable IFD in patients with MBL levels below and above 1,000 ng/mL were 11.9% and 15.1 % respectively (P=.579). Mean MBL levels were lower in the IFD-free group (2085 vs 2398, p=.429). MBL levels below 1,000 ng/ml were not a predictor of death (P=.233). Mean IFD- free survival times in patients with MBL levels below and above 1,000 ng/ml were 20 weeks and 21 weeks respectively (P=.423). As expected, proven or probable IFD was associated with death (P<.0001).

Conclusions: Our findings indicate that low MBL levels were not associated with an increased risk of developing proven or probable IFD or overall survival in patients with hematologic malignancy.

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Clofarabine-Based Salvage Therapy and Conditioning Regimen in Patients with Relapsed or Refractory AML

Jan Moritz Middeke [1], Stefani Parmentier [1], Nael Alakel [1], Markus Schaich [1], Christian Thiede [1], Uwe Platzbecker [1], Christoph Röllig [1], Mathias Hänel [2], Gernot Stuhler [3], Anke Morgner [2], Ute Eulenstein [4], Gerhard Ehninger [1], Martin Bornhäuser [1], Johannes Schetelig [1]. [1] Medizinische Klinik und Poliklinik I, Universitätsklinikum Carl Gustav Carus der TU Dresden; [2] Klinik für Innere Medizin III, Klinikum Chemnitz gGmbH; [3] Medizinische Klinik und Poliklinik II der Universität Würzburg; [4] Klinikapotheke, Universitätsklinikum Carl Gustav Carus der TU Dresden

Background: In relapsed or refractory AML allogeneic transplantation (HCT) is considered to be the only chance to achieve long-term survival but still only about 40% of younger patients receive allogeneic HCT. Moderate activity of salvage regimens and accumulating toxicity of chemotherapy are reasons that may prevent from transplantation. Our goal was to study the safety and efficacy of a clofarabine salvage therapy prior to allogeneic HCT. Here, we report data from patients of stage I of a two-stage phase II study.

Patients and Methods: Patients above the age of 40 with relapsed or refractory AML who were fit for allogeneic HCT were eligible to participate in this multicenter, single-arm study. All patients received at least one cycle of clofarabine 40 mg/m^2 followed by intermediate dose cytarabine 1 g/m^2 days 1-5 (CLARA). Patients with a donor who exposed at least a reduction of leukemic blasts were scheduled for allogeneic HCT in aplasia after CLARA. The conditioning regimen consisted of clofarabine 30 mg/m^2 on days -6 to -3 and melphalan 140 mg/m^2 on day -2. Cyclosporine in combination with MMF was used for GvHD prophylaxis. In patients with partially matched unrelated donors the administration of ATG was recommended. Primary endpoint was treatment success defined as a complete remission (CR, CR(i)) six weeks after completion of therapy.

Results: Twenty-six patients were enrolled into stage I of this trial. Median age was 60 years. Fifty percent of the patients each had refractory or relapsed AML. At early response assessment on day 15 after CLARA-1 13 patients (50%) had less than 10% marrow blasts. Ten patients (38%) showed a reduction in marrow cellularity or blast percentage. Two patients did not have a significant marrow blast reduction. One patient died after the first cycle CLARA from septic multi-organ failure. Twenty-two patients (85%) received allogeneic HCT within this trial. Donors were HLA-identical siblings in 5 patients (23%), HLA-compatible unrelated donors in 11 patients (50%) and unrelated donors with one mismatch in 6 patients (27%). Liver toxicity was the most frequent adverse event. Seventeen patients (65%) developed grade III liver enzyme elevation while Grade IV was observed in 1 patient. Grad III/IV GvHD occurred in 6 patients (27%). All 26 patients have been evaluated for the primary endpoint. Sixteen patients had a CR (62%) and 6 patients a CRi (23%) at final response evaluation.

With a maximum follow up of 19 months 16 patients have died (7 patients died after relapse). At present 10 patients are alive, 6 of them had refractory disease.

Conclusion: Salvage therapy with CLARA and subsequent conditioning with clofarabine and melphalan prior to allogeneic HCT provides good anti-leukemic activity in patients with relapsed or refractory AML. The CR rate of the first 26 patients was evaluated favorably and the trial is currently recruiting into stage 2.

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Autologous Stem Cell Transplant (ASCT) As an Effective Post-Remission Consolidation Strategy for Good Risk Acute Myeloid Leukemia (AML) Patients

Jan Cerny [1], Muthalagu Ramanathan [2], Andrew Evens [3], William Walsh [4], Alan Rosmarin [5], Rajneesh Nath [6]. [1] Division of Hematology/Oncology, University of Massachusetts, Worcester, MA; [2] UMASS Memorial University Campus, Worcester, MA; [3] Medicine, Umass memorial medical Center, Worcester; [4] University of Massachusetts Memorial Medical Center, Worchester, MA; [5] UMas Memorial; [6] Section BMT, Division of Hematology/Oncology, UMass Memorial Medical Center, Worcester, MA

Background: Good risk AML patients (core binding factor AML; diploid cytogenetics AML without Flt-3 ITD) are frequently consolidated with 3-4 cycles of high dose cytarabine (HIDAC) after induction of remission. About 50% of these patients relapse resulting in long term survival of 40-60% (Marcucci et al. JCO vol. 23 :5705-5717; 2005).

Materials and Methods: We retrospectively analyzed the outcomes of patients with good risk AML who underwent ASCT since 2009.

Results: 17 patients (10 males; 7 females) were identified in the database. Their median age was 60 years (range 29-80). All patients had received HIDAC based induction followed by at least one cycle of HIDAC based consolidation. Mobilizing