

> 39kg/M2. A more objective secondary analysis divided our patients' BMI into quartiles was also used to explore risk threshold.

**Results:** The median BMI for our entire population was 33.9 (15.6-57.6). The 100 day mortality in the myeloma and NHL patients were 4/153 (2.6%) and 2/72 (2.7%), respectively. Using the above literature driven definitions, the data showed a significantly higher mortality with increasing obesity ( $p < 0.0001$ , see Table).

**Table 1. Risk of Mortality by Degree of Obesity**

BMI Group	Alive	Dead	Total
<35kg/m2	114	13	127
35-39 kg/m2	88	0	88
>39 kg/m2	12	5	17
Total	214	18	232

$p < .0001$  (Chi-Square).

In the quartile analysis, there was one death in the lowest quartile, no deaths in the second quartile, three deaths in the third quartile and two deaths in the fourth quartile.

**Conclusion:** Our results mirror what other studies have found; that increasing obesity is especially significant in a range above 30-35 kg/M2 based solely on BMI classification. Our quartile analysis appears to demonstrate a steep slope over our median (33.9kg/M2).

### 139

#### RETROSPECTIVE COMPARISON OF DAY +5 VERSUS DAY +3 INITIATION OF G-CSF IN MULTIPLE MYELOMA PATIENTS RECEIVING AUTOLOGOUS HEMATOPOIETIC STEM CELL TRANSPLANTATION

Koralkar, R., Hundley, B., Donna, S.E., Vaughan, W.P. University of Alabama at Birmingham, Birmingham, AL

**Background:** Filgrastim (G-CSF) administration after autologous hematopoietic stem cell transplant (aHSCT) is routinely used to shorten duration of neutropenia and risk of infection. The optimum post transplant Day for starting G-CSF is not standardized. We have historically used aHSCT Day +3, but others have reported good results using Day +5.

**Methods:** Beginning 15 May 2009, patients with multiple myeloma (MM) transplanted with myeloblastic doses of melphalan and an aHSCT 24 hours later received GCSF (250  $\mu\text{g}/\text{m}^2$ ) subcutaneously daily from Day +5 until absolute granulocyte count (AGC) of 2000/ $\mu\text{L}$ . We performed a validation after 49 patients comparing time to engraftment of platelets and neutrophils compared to the immediately preceding 98 control patients given daily gCSF from Day +3 to the same AGC endpoint. Additional endpoints included stomatitis, transfusion support, incidence of neutropenic fever, length of day, and 30 day mortality.

**Results:** There was no significant difference in number of CD34+ cells infused among the two groups and there was no 30 day mortality in either group. The Day +3 patients achieved neutrophil engraftment a median of one day shorter than the Day +5 patients ( $p < 0.001$ , log-rank). Median time to platelet recovery of more than  $50 \times 10^9/\text{L}$  was two days earlier in Day +3 Group than Day +5 Group ( $p = 0.02$  in log rank test). However, the rate of neutropenic fever rate was significantly higher in Day +3 Group compared to Day +5 Group (62% vs. 42%,  $p = 0.019$ ). The rate of stomatitis was also higher in Day +3 Group compared to Day +5 Group (82.7% vs. 52.1%,  $p = < 0.001$ ).

**Table 1. Characteristics of study population**

	Day +3 group (N=98)	Day +5 group (N=49)	p Value
Age (yrs)	60.2 (36.77)	57.6 (43-74)	0.29†
CD34+ stem cells infused	$3.3 \times 10^6$ ( $2.5 \times 10^6$ )	$3.04 \times 10^6$ ( $2.8 \times 10^6$ )	0.79†
WBC engraftment day	11 (9-15)	12 (10-14)	<0.001*
Platelet engraftment (days)	12 (8-97)	14 (9-63)	0.023*
Neutropenic fever Rate	61 (62.2%)	20 (41.7%)	0.019†
Stomatitis Rate	81 (82.7%)	25 (52.1%)	<0.001†

Median (range),

\*Log-rank test,

†U test

**Conclusion:** Day +3 Administration of G-CSF provides early engraftment but there is increased rates for fever, stomatitis. The apparent illogic of more neutropenic fever with faster white blood cell (WBC) engraftment may be explained by better infectious disease prophylaxis in the more recent group.

### 140

#### IMPACT OF CD34 CELL DOSE ON PLATELET ENGRAFTMENT AND PLATELET TRANSFUSIONS FOLLOWING AUTOLOGOUS HEMATOPOIETIC STEM CELL TRANSPLANTATION

Shariatmadar, S.<sup>1</sup>, Pereira, D.<sup>2</sup>, Smith, R.<sup>2</sup>, Goodman, M.<sup>2</sup> <sup>1</sup>University of Miami Miller School of Medicine/Jackson Memorial Medical Center, Miami, FL; <sup>2</sup>University of Miami Miller School of Medicine/Jackson Memorial Medical Center, Miami, FL

**Introduction:** Maximizing the CD34 cell content of the graft has been reported to lead to faster platelet engraftment and lower requirement for platelet transfusions in patients undergoing autologous stem cell transplantation (A-HSCT). We evaluated the impact of CD34 cell dose on platelet recovery and transfusion requirements in 114 consecutive adults undergoing A-HSCT with a CD34 cell dose of  $> 2 \times 10^6/\text{kg}$  recipient body weight (BW) infused.

**Methods:** From January 2007 to March 2010, 114 adults with NHL (n: 45), multiple myeloma (n: 44), Hodgkin's disease (n: 23) and AML (n: 2) underwent apheresis (range: 1-7) and A-HSCT. Patients were categorized in to 3 groups based on the CD34+ cell dose transplanted [group 1:  $2.0-2.99 \times 10^6$  (n: 55), group 2:  $3.0-5.0 \times 10^6$  (n: 38) and group 3:  $> 5 \times 10^6$  CD34/kg recipient BW (n: 21)]. Neutrophil and Platelet engraftment (platelet count  $> 20,000/\text{ul}$  for 2 consecutive days without platelet support) and transfusion requirements post-transplant were evaluated and correlated with patient's age, diagnosis and number of apheresis.

**Results:** Median neutrophil engraftment following transplantation was 11 days in all groups, while median platelet engraftment was 14 days in group 1 and 13 days in groups 2 and 3. Platelet recovery by days 30 and 60 was 90.7%/96.3% in group 1, 94.7%/100% in group 2, 90.5%/95.2% in group 3. Two patients with NHL in group 1 (3.6%) and one with AML in group 3 (4.8%) were platelet-dependent  $> 60$  days post-transplantation. One patient with NHL in group 1 expired on day 6 from transplant-related complications. Median platelet transfusions were 3 doses of platelets in group 1 and 2 doses in other groups. Patient's age, diagnosis and number of apheresis did not affect 30 and 60 day platelet recovery/transfusions post-transplant. Nine patients (7.9%) received plerixafor-mobilized transplants with median platelet engraftment 14 days post-transplant.

**Conclusion:** CD34 cell dose did not significantly impact platelet recovery and transfusion requirements post-transplantation with rapid platelet recovery achievable with CD34 cell dose  $> 2 \times 10^6/\text{kg}$  rec BW. Other factors including the number of platelet precursors in the transplanted product rather than CD34 cell dose may be a more important indicator of platelet recovery post-transplantation.

### 141

#### EFFICACY AND SAFETY OF HEMATOPOIETIC STEM CELL REMOBILIZATION WITH PLERIXAFOR (MOZOBIL®) + G-CSF IN PATIENTS WITH GERM CELL TUMOR

Schriber, J.<sup>1</sup>, Horwitz, M.<sup>2</sup>, Libby, E.<sup>3</sup>, Huebner, D.<sup>4</sup>, Mody, P.D.<sup>4</sup>, Holman, P.<sup>1</sup> <sup>1</sup>Banner Blood and Marrow Transplant Program, Phoenix, AZ; <sup>2</sup>Duke University Medical Center, Durham, NC; <sup>3</sup>UNM Cancer Center, Albuquerque, NM; <sup>4</sup>Genzyme Corporation, Cambridge, MA

Autologous hematopoietic stem cell transplantation can be curative for patients (pts) with germ cell tumors (GCT). Many such pts are heavily pretreated. Moreover, most protocols call for tandem transplant requiring higher cell yields. This creates a situation where many pts are unable to successfully mobilize adequate cells. Mobilization with plerixafor (P)+ G-CSF (G) is safe and effective for pts with myeloma and lymphoma. Herein we describe the safety

and efficacy of P + G in pts with GCT who had previously failed collection.

This is a retrospective analysis of pts with GCT enrolled in the US plexiafor compassionate use program. In this trial, pts with previous mobilization failure (defined as the inability to collect  $\geq 2 \times 10^6$  CD34+ cells/kg or to achieve an adequate peripheral blood (PB) count), were remobilized with P + G. G (10 $\mu$ g/kg SC) was given every morning for 5 days. P (0.24 mg/kg SC) was given in the evening on Day 4, ~11 hours prior to apheresis the next day. P, G, and apheresis were repeated until pts collected  $\geq 2 \times 10^6$  CD34+ cells/kg.

Records of 21 males with GCT were analyzed. Median age was 35 years. Previous mobilization regimens included growth factor (GF) alone in 14 (67%) and GF + chemotherapy in 7 (33%) pts; 17 (81%) pts failed to collect the minimum transplantable cell dose (median yield: 1.35 (range, 0.33 - 2.1)  $\times 10^6$  CD34+ cells/kg); 4 (19%) pts did not undergo apheresis due to low PB CD34+ cells. Remobilization with P + G resulted in a median yield of  $3.2 \times 10^6$  CD34+ cells/kg. Seventeen (81%) pts collected  $\geq 2 \times 10^6$  and 9 (43%) pts collected  $\geq 4 \times 10^6$  CD34+ cells/kg in a median of 2 (range 1-3) and 3 (range 1-4) days, respectively. Sixteen (76%) pts proceeded to transplant; 8 (38%) pts received tandem transplants. Median times to neutrophil and platelet engraftment were 11 and 21 days, for single transplant and 10.5 and 24 days, for tandem transplants. Drug-related adverse events were observed in 8 (38%) pts; most were mild and commonly included diarrhea (n = 3), nausea (n = 2), injection site reactions (n = 2), chills (n = 2) and bone pain (n = 2). There were no serious adverse events.

The majority of pts with GCT who had failed prior mobilization with GF  $\pm$  chemotherapy could collect an adequate number of HSC with P + G for at least 1 transplant. Using this approach 76% and 38% of pts could undergo a single and tandem transplant respectively. None of these pts would have collected sufficient cells to proceed to transplant without this approach.

**Table 1. Remobilization Outcomes**

No. of Patients	21
Median age (range)	35 (20-51)
Gender, male (%)	21 (100)
Median CD34+ cells/kg $\times 10^6$ Collected (range)	3.2 (0.76 - 15.80)
No. of patients collecting $\geq 2 \times 10^6$ CD34+ cells/kg (%)	17 (81)
No. of patients collecting $\geq 4 \times 10^6$ CD34+ cells/kg (%)	9 (43)
Median days to collect $\geq 2 \times 10^6$ CD34+ cells/kg (range)	2 (1-3)
Median days to collect $\geq 4 \times 10^6$ CD34+ cells/kg (range)	3 (1-4)
No. of patients proceeding to single transplant (%)	16 (76) patients proceeding to single transplant (%)
No. of patients proceeding to tandem transplant (%)	8 (38)
Median days to neutrophil engraftment (range)	11 (9-18)*
Median days to platelet engraftment (range)	20 (12-48)*

\*No significant differences were seen in engraftment times between the first and second transplant

## 142

### BUMELTT (BUSULPHAN, MELPHALAN, AND THIOTEPA) AS A PREPARATIVE REGIMEN PRIOR TO AUTOLOGOUS STEM CELL TRANSPLANTATION IN PATIENTS WITH RELAPSED/REFRACTORY HODGKIN'S DISEASE DOES NOT OFFER ANY ADVANTAGE OVER MORE STANDARD REGIMENS LIKE BEAM OR BEAC

Ganguly, S.<sup>1</sup>, Jain, V.<sup>2</sup>, Divine, C.L.<sup>1</sup>, Ajitawi, O.<sup>1</sup>, Abhyankar, S.<sup>1</sup>, McGuirk, J.P.<sup>1</sup> <sup>1</sup>University of Kansas Center, Kansas City, KS; <sup>2</sup>University of Kansas Medical Center, Kansas City, KS

High-dose chemotherapy with carmustine, etoposide, cytosine arabinoside, and melphalan (BEAM) or cyclophosphamide (BEAC) followed by autologous hematopoietic stem cell transplantation (ASCT) represents a standard therapy for many patients with relapsed Hodgkin's disease (HD). A more intense preparative regimen like BuMelTT (busulphan, melphalan, and thiotepa) has been applied in patients with hematological malignancies with variable success and toxicity.

In an attempt to compare efficacy, outcome, and toxicity of BuMelTT versus more standard BEAM or BEAC in patients with HD undergoing ASCT, we retrospectively evaluated our center's experience between January 2008 and April 2010.

Out of 9 patients in the BuMelTT group (median age 30y; range 19-46y), 8 patients (89%) had active disease and out of 14 patients in the BEAM (n = 11)/ BEAC (n = 3) group (median age 33y; range 20-67y), 10 patients (72%) had active disease at the time of transplantation. The probability of disease-free survival (DFS) (55% in BuMelTT versus 43% in BEAM/BEAC group; p = 0.6) and overall survival (OS) (83% in BuMelTT versus 85% in BEAM/BEAC group; p = 0.4) were comparable in both the groups at one year with a median duration of follow-up of 17 months. Probability of DFS (BuMelTT 43%; BEAM/BEAC 18%; p = 0.5) and OS (BuMelTT 83%; BEAM/BEAC 85%; p = 0.9) at one year when transplanted with active disease were comparable between the two groups as well. No patient died from transplant-related complications. More patients in the BuMelTT group (100%) developed grade 2 or greater mucositis compared to patients in the BEAM/BEAC group (50%). Average length of stay was longer in BuMelTT group (median 21 days; range 18-22) compared to BEAM/BEAC group (median 18 days; range 9-36) (p = 0.016) with more observed inpatient cost with BuMelTT (mean: \$51,650; range \$33,242-166,867 versus \$40,730; range \$22, 661-63,668) (p = 0.03).

In conclusion, BuMelTT as a preparative regimen was not superior compared to more standard BEAM or BEAC in patients with relapsed/refractory HD. BuMelTT chemotherapy is associated with more GI toxicity, longer hospital stay and greater observed cost.

## 143

### MEASUREMENT OF ALDEHYDE DEHYDROGENASE ACTIVITY IN ALLOGENEIC OR AUTOLOGOUS PERIPHERAL STEMCELL GRAFTS MAY SUBSTITUTE TIME CONSUMING CELLS CULTURES

Leitner, G.C.<sup>1</sup>, Bartuschka, A.<sup>1</sup>, Schulenburg, A.<sup>2</sup> <sup>1</sup>Transfusion Medicine, Vienna, Austria; <sup>2</sup>BMT Unit, Vienna, Austria

**Background:** Autologous and allogeneic stem cell (PBSC) transplantations are a curative option in hematologic-oncologic diseases.

In daily routine stem cell harvests are measured on CD34 antigen and vitality. The colony-forming ability (CFU) of the harvested stem cells is predictive for the hematological engraftment but results are not available until 14 days. The metabolic marker aldehyde dehydrogenase (ALDH) was found in hematological vital stem cells. Former investigations described a correlation between ALDH activity of harvested stem cells and CFU. Therefore this assay may be useful for characterizing PBSC graft quality, especially as the results are available simultaneously to the CD34 and vitality data.

In a prospective analysis we investigated the ALDH activity in freshly collected PBSC and in frozen products and correlated the results with the number of CFUs

**Material and Methods:** In the allogeneic setting 16 PBSC harvests from 13 donors, 7 males and 6 females, median age of 45 years (24-60) and in the autologous setting 42 products of 25 patients, 15 males and 10 females, median age 52 years (21-67) were investigated.

Stem cell harvests were measured on CD34+ cells and vitality with 7 AAD by flow cytometry according to the ISHAGE protocol. ALDH activity was also determined by FACS analysis using the Aldefluor@kit (Stemcell Technologies, France) according to the manufacturer's instructions.

Analyses were done in freshly collected PBSCs and in cryopreserved products before transplantation or after 6 months of storage, respectively.

**Results:** The allogeneic stem cell grafts had a CD34 purity of 0.74% (0.47-1.83), an ALDH activity of 0.7% (0.45-2.18) and a CFU content of  $236 \times 10^3$  (28-480).

The autologous grafts showed a CD34 purity of 0.6% (0.11-7.63), an ALDH activity of 0.59% (0.15-8.89) and CFUs of  $139 \times 10^5$  (0-892).

CFUs and ALDH activity showed a higher correlation than CFUs and CD34+ cells in the autologous grafts (R0.73 vs R0.40) No such difference was observed in the allogeneic grafts. Low initial ALDH activity (below 0.20%) was combined with low numbers and low recovery of CFUs after thawing frozen PBSC. No correlation was observed between vitality and CFUs in both settings.

**Conclusion:** Measuring of ALDH activity in PBSCs may alleviate the PBSC harvest management in patients with CD34 yields near the threshold for a successful transplantation.