treatment cycles was 15 (range, 1-16) and 159 pts (49%) received 16 cycles. A total of 61 pts (19%) discontinued treatment due to adverse events. Thirty-five pts (11%) are known to have died; 31 deaths occurred after disease progression. One death occurred within 30 days of last dose and was considered disease-related.

Conclusions: Based upon a planned interim safety and futility analysis, the IDMC recommended that the AETHERA trial continue per protocol.

149

Characterizing Melphalan Efficacy and Toxicity in Multiple Myeloma Patients with Renal Insufficiency

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High Dose melphalan (200 mg/m2, Mel200) is the standard conditioning for autologous stem-cell transplant (ASCT) in multiple myeloma (MM) patients. Forty percent of MM patients experience some degree of renal insufficiency. Although common practice, there is no standard for dose reduction in melphalan due to renal impairment. In addition, there is no clear correlation between melphalan pharmacokinetics in renal failure and outcome in these patients. Here we report the impact of renal impairment on response and toxicity outcomes in patients receiving Mel200 as part of ASCT.

We identified 111 patients who received Mel200 and ASCT between 2001 and 2012 at the University of Illinois. Overall, the majority of patients were African American (60%). Patients were stratified by renal function (n=35 CrCl <60 ml/min and n=76 CrCl $\geq$ 60 ml/min). Baseline characteristics were equal between the 2 groups aside from age (63.2 years $\pm$ 8.8 vs. 56.8 $\pm$ 8.8. P=.0004). Patients with renal failure experienced a significantly longer time to engraftment (12.2 days $\pm$ 3.51 vs. 10.6 days $\pm$ 1.7, P=.0025) and duration of diarrhea (6.6 days $\pm$ 6.3 vs. 4 days $\pm$ 3.7. P=.007). Length of hospital stay was similar between the two groups (17.6 days $\pm$ 4.5 vs. 16.25 days $\pm$ 5.2. P=.21). Patients with renal failure spent an average of 10.6 days on total parenteral nutrition, compared to 7.27 days in patients with normal renal function (P=ns). There were no deaths related to transplant related mortality in either group. . There was no difference in response rates between the 2 groups in terms of complete response (50% in CrCl<60ml/min vs. 40% in Cr Cl > 60ml/min,P=ns) or overall response rate at day +90 (75% in CrCl<60ml/min vs. 100% in Cr Cl > 60ml/min,P=ns).

This data demonstrates an increase in drug-related toxicities of diarrhea, and time on TPN in patients with renal impairment conditioned with HD Mel. We hypothesize that this is due to reduced renal drug clearance. In addition, longer time to engraftment in the renal failure group may be a result of greater overall melphalan exposure. In light of the large numbers of patients impacted by this data, we suggest that this would be an ideal patient group for the development of pharmacokinetic based strategies for individual patient dosing.

150

Routine Prophylaxis of Pneumocystis Jirovecii Pneumonia in Recipients of Autologous Hematopoietic Stem Cell Transplantation

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Background: Pneumocystis jirovecii pneumonia (PJP) is a potentially life-threatening disease in immunocompromised patients. The at-risk population includes patients with HIV infection and low CD4 counts, hematological malignancies, hematopoietic stem cell (HSC) and solid organ transplant recipients, and patients receiving glucocorticoids or other immunomodulatory agents. The highest-risk group of immunocompromised patients tends to be those with HIV (human immunodeficiency virus) infection, where PJ follows an indolent course. However, in non-HIV immunocompromised patients, such as HSC transplant recipients, the infection tends to present with respiratory failure. The incidence of PJP in autologous BMT (bone marrow transplant) has not been clearly determined, and the indication for prophylaxis in this setting remains unclear. In this study we evaluate the incidence of PJP over a 10-year period in recipients of autologous transplants.

Methods: A retrospective analysis of 1191 consecutive autologous HSC transplants (1-75 years) performed between 1/1/2000 and 6/30/2011 at the University of Michigan BMT Program. The data was obtained from BMT Program Database at The University of Michigan Comprehensive Cancer Center. The diagnosis of PJP was established by bronchoscopy with brochoaveolar lavage (BAL) with polymerase chain reaction (PCR). We analyzed the following risk factors for the development of PJP: diabetes, glucocorticoids, infections, cutaneous T-cell lymphoma, hypertension, and seizure disorder.

Results: A total number of 5 PJ infections were diagnosed during study period, resulting in a cumulative incidence of 0.42% (95%CI [0.136449%–0.976969%]) over 10 year period. All cases occurred between 2001 and 2006, and 3 months or later following transplantation. Most patients (n=4) were older than 50 years old, and all of them were on steroids. Diagnoses included non-Hodgkin's lymphoma (n=3), Hodgkin's lymphoma (n=1) and multiple myeloma (n=1). Conditioning regimen was BEAM (BCNU, etoposide, cytarabine, melphalan, n=4) and high dose melphalan (n=1). Only 2/5 patients were neutropenic at the time of the pneumonia, and this did not correlate with the CD34+ cell infused, which was $\geq$2.2x10E6/kg for all patients. Four patients were on corticosteroids for relapsed lymphoma (n=2), ITP (n=1), BCNU pneumonitis (n=1). The remainder patient was on florinef and was coinfected with candida and herpes virus. There were no particular comorbidities associated with the diagnosis of PJ pneumonia. One patient died of PJ, the remainder were treated successfully.

Conclusions: Our retrospective analysis of a large cohort of autologous transplant recipients reveals an extremely low

incidence of PJP, suggesting that PJP prophylaxis is not routinely warranted in this patient population. Patients who require systemic corticosteroids post–HSC may be considered for PJ prophylaxis.

151

Long Term Outcomes of Autologous Hematopoietic Cell Transplant (AHCT) Following Thiotepa-Based High-Dose Therapy (HDT) in Patients with Non-Hodgkin Lymphoma (NHL)

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There is little consensus regarding the optimal conditioning regimen for AHCT for NHL. Thiotepa is an alkylating agent with anti-lymphoma properties, but it has limited data as a conditioning agent for AHCT in adult NHL. We report here long-term results of our institutional experience in NHL receiving AHCT following HDT with etoposide, cyclophosphamide and thiotepa (VP-16/CY/TT). Patients received etoposide 1800mg/m2 IV x 1 dose, cyclophosphamide (50mg/kg/dose IV x 3-4 doses), and thiotepa (250mg/m2/dose – 300mg/m2/dose x 3 doses). Forty-three patients were consented and enrolled from November 1997 to June 2009.

Table 1
Baseline Demographics

Characteristics	N=43
Median age, years (range)	55 (27-69)
Male gender, n (%)	22 (51%)
Diagnosis (%)	
Diffuse Large B-cell Lymphoma (DLBCL)	23 (54%)
Follicular Lymphoma	7 (16%)
Transformed follicular lymphoma	2 (5%)
Mantle Cell Lymphoma	4 (9%)
T-cell NHL	7 (16%)
Bone Marrow Involvement	10 (23%)
CNS Involvement	2 (5%)
Stage	
Early Stage (1&2)	14 (32%)
Advanced Stage (3&4)	27 (63%)
Missing	2 (5%)
IPI	
Low (0-1)	17 (40%)
Intermediate (2-3)	23 (54%)
High (4-5)	2 (5%)
Unknown	1 (2%)
Prior therapies, median (range)	2 (1-4)
Remission status before transplant	
Complete Remission 1	8 (19%)
Complete Remission 2	17 (40%)
Complete Remission 3	2 (5%)
Partial Remission	16 (37%)
Autologous stem cell source (%)	
Peripheral Blood	35 (81%)
Bone Marrow	4 (9%)
Both	4 (9%)
Karnofsky Performance Status, median (range)	90 (80-100)
Median CD34 cell dose infused (10^6 cells/kg recipient), (range)	5.3 (1.8-10.5)

Disease characteristics are described in Table 1. Peripheral blood stem cell mobilization utilized cyclophosphamide and filgrastim. All patients received antibacterial, antiviral (acyclovir), and antifungal (fluconazole) prophylaxis along with filgrastim support after stem cell infusion. Median follow up for surviving patients was 4.7 years (range 0.26 years to 15.85 years). Median time to neutrophil and platelet engraftment was 13 and 21 days, respectively. Significant regimen-related toxicities included mucositis (51%), neutropenic fever (72%), diarrhea (26%), and pneumonia (9%). No CNS failures were reported. Secondary malignancies occurred in 3 patients (7%) – two of which were soft tissue sarcomas and one MDS/AML. Progression free survival (PFS) and overall survival (OS) at 5 years was 53% (39% - 71%) and 73% (60% - 89%), respectively. Relapse rates at day +100 and 5 years were 9.4% (95% CI: 2.9% – 20.4%) and 40.1% (95% CI: 24.7% - 55.1%), respectively. Cumulative incidence of non-relapse mortality at day +100 and 5 years was 4.7% (95% CI: 0.8% - 14.0%) and 7% (95% CI: 1.8% - 17.4%), respectively. VP-16/Cy/TT is a well-tolerated conditioning regimen for patients with NHL, with promising long term progression-free and overall survival rates.

152

A Higher Number of CD34+ Cells Collected during Mobilization Is Independently Associated with Successful Engraftment in Autologous Stem Cell Transplant Patients

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We performed a retrospective analysis on patients who underwent PBSC collection and subsequent ASCT at our institution to assess whether efficiency of PBSC mobilization is predictive of engraftment failure.
Methods: We identified 369 patients who underwent PBSC collection between 01/01/2006-8/31/2012 for a first ASCT. We collected data on age, sex, use of lenalidomide or thalidomide ("Imid") prior to mobilization, mobilization regimen, # of collections for final cell dose, # of CD34+ cells infused, and the presence of a positive blood culture within 30 days of ASCT. Quintiles were created for the # of CD34+ cells collected. The primary outcome was engraftment failure defined as not achieving an absolute neutrophil count (ANC) >1000/mL or a platelet count >50,000/mL (no platelet transfusion in </= 7 days) by day 30 post-ASCT. Secondary outcomes were time to ANC and platelet engraftment. We performed a multivariate logistic regression analysis to assess the association of collected CD34+ cells and engraftment failure while adjusting for the other variables. For time to event analyses we used Cox proportional hazard models.
Results: Median patient age was 58 and 56% were male. Patient-reported race was: Black (38%), White (17%), and "Other" (45%). Indications for ASCT were Multiple Myeloma (45%), Non-Hodgkin Lymphoma (41%), Acute Leukemia (9%), Hodgkin Lymphoma (3%), Amyloidosis (1%), and Germ Cell Tumors (1%). The median # of CD34+ cells collected was 7.7x10 ^6/kg (range 2.26-120 x10 ^6/kg) and median # of CD34+ cells infused was 5.3x10 ^6/kg (2.3-45x10 ^6/kg). Median # of collections for transplant dose was 2 (range 1-8). CD34 cells collected were divided into quintiles (cut points: 6.04, 7.57, 9.86 and 17.7x10 ^6/kg). We found that a higher # of collected CD34+ cells during mobilization was associated with less engraftment failure (p=.0067): every increase in