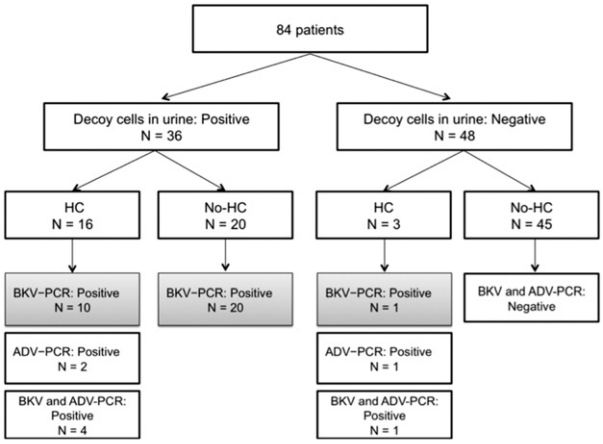
(p=1.00), conditioning (p=0.71), donor source (p=0.43) and acute GVHD (p=0.71). Only BKV subtype III had a statistically significant correlation with HC (OR: 10.8, 95%CI: 1.64-70.93, p=0.013).

Conclusion: BKV is ubiquitous among humans, infecting children asymptomatically and then persisting in renal tissue. Subtype Ic is most prevalent (>90%), followed by subtype IV, while subtype III are rarely found in Japan. Our data suggested the importance of BKV subtype III in the development of BKV-HC. Further studies focused on the viral genomic variation in the pathogenesis of BKV-HC are warranted.



Logistic Regression Analysis

Characteristics		Odds Ratio (95%CI)	*P* value
BKV subtype	III versus Ic	9.0 (1.27 - 63.89)	0.028
	III versus Others	10.8 (1.64 - 70.93)	0.013

Figure 1.

21

Clofarabine and High-Dose Melphalan as Reduced Intensity Conditioning in Adults with High-Risk Leukemia/MDS Undergoing Allogeneic Hematopoietic Cell Transplantation

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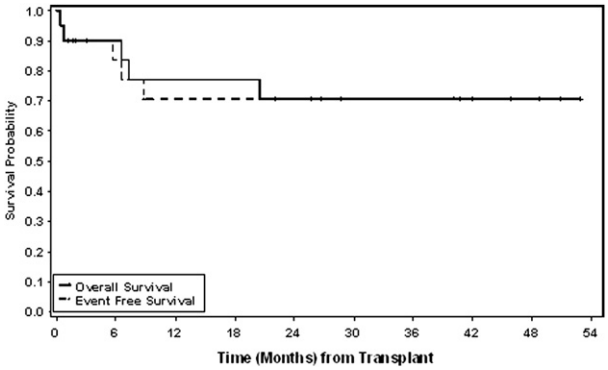
Background: Allogeneic hematopoietic cell transplantation (alloHCT) is the only option for cure for many patients with hematological malignancies such as leukemia and MDS; however many patients, especially the older population, cannot tolerate full-intensity ablative conditioning regimens. Fludarabine and melphalan has been efficacious as a reduced intensity conditioning regimen for alloHCT for multiple malignancies, but the relapse rate for this regimen remains high. We have replaced fludarabine with clofarabine, a rationally designed second-generation purine nucleoside analog. Clofarabine has increased immunosuppressive and anti-leukemic activity compared to fludarabine *in vitro*, and we have found in a phase I study that the clofarabine/melphalan conditioning regimen for alloHCT in patients with acute leukemia or MDS is safe and tolerable. We hypothesized that analysis of outcomes for patients treated using this regimen would demonstrate favorable relapse rates while maintaining a low-toxicity profile.

Patients & Methods: Twenty patients with high-risk leukemia or MDS, with a median age of 63 years, underwent alloHCT from November 2007 until June of 2012. Patients were treated at one of three dose levels of a clofarabine (day -9 to day -5) and melphalan (on day -4) conditioning regimen: 3 patients received 30 mg/m^2 clofarabine and 100 mg/m^2 melphalan (dose level 1), 12 patients received 40 mg/ m^2 clofarabine and 100 mg/ m^2 melphalan (dose level 2), and 5 patients received 40 mg/m^2 clofarabine and 140 mg/ m^2 melphalan (dose level 3). The first 16 patients were included in a phase 1 prospective study and 4 additional patients were treated at dose level 3 off protocol. Graft-versus-host-disease (GVHD) prophylaxis began on day -3 with the combination of tacrolimus and sirolimus.

Results: The median follow-up for surviving patients was 28.7 months (1.1 - 52.9). Overall survival at 1 year and 2 years was 77% and 70 % respectively. Event-free survival at 1 and 2 years was the same, at 70.7% (95% CI: 52.1 - 83.2). Fifty percent of patients experienced acute GVHD (grades I and II only), and 69% of evaluable patients experienced chronic GVHD. The majority of toxicities were related to the gastrointestinal system including elevated liver enzymes with one patient experiencing grade 4 hepatic toxicity. Other adverse events included renal insufficiency (5 patients), CNS toxicity (2 patients), and cardiac toxicity (1 patient).

Conclusion: The combination of clofarabine and high dose melphalan is a well tolerated conditioning regimen that provides a durable remission and event-free survival of 70.7% in patients with high-risk disease. We are planning to initiate a phase 2 trial to examine the anti-leukemic activity of dose level 3 for this clofarabine/melphalan reduced-intensity alloHCT regimen in patients with high-risk acute myelogenous leukemia.



Overall Survival and Event Free Survival Patients treated with Clo/Mel at 30/100 (n=3), 40/100 (n=12), 40/140 (n=5) Transplant Date Range: 11/28/2007-06/28/2012.

22

Platelet Engraftment Failure Leads to Poor Overall Survival Even After Neutrophil Engraftment without Relapse

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