

number of PIRCHES for potential donors prior to HSCT may allow reducing complications after HLA-mismatched HSCT by avoiding donors that can recognize higher numbers of PIRCHE. The present observations indicate that selection of HLA-mismatched donors with low numbers of PIRCHES may lead to 5-year survival probabilities similar to 10/10 matched unrelated donors. These observations require, however, confirmation in other cohorts. Moreover, the PIRCHES concept may also be valuable in other HSCT settings, such as CB transplantation and HSCT with a 10/10 matched unrelated donor that is mismatched for HLA-DPB1.

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### Outcomes of Double Unit Umbilical Cord Blood Transplantation Using Fludarabine/Busulfan Based Reduced Intensity Conditioning Regimen

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**Background:** Umbilical cord blood (UCB) is increasingly used as a source of unrelated donor hematopoietic cells. Advantages of UCB include immediate graft availability, higher likelihood of acceptable match, and reduced likelihood and severity of graft vs. host disease (GVHD). Incorporation of Busulfan (Bu) with Fludarabine (Flu) in a reduced intensity conditioning (RIC) regimen has the potential advantages of improved disease control and acceptable toxicity.

**Patients:** Eighteen patients (pts), median age 57 years (range 27–70), median weight 83 kg (range 54–127), Karnofsky performance status 80–100%, underwent double unit UCB transplantation for hematologic malignancies (AML 44%; ALL 22%) between January 2012 and February 2013. Early disease was seen in 44%, intermediate 12%, and advanced 44%. Adverse cytogenetics were present in 39%. CMV seropositivity was seen in 16/18 (89%) pts. Hematopoietic cell transplantation comorbidity index (HCT-CI) scores were HCT-CI score 0, 44%; score 1–2, 44%; and score > 3, 12%.

**Methods:** UCB units were 4–6/6 HLA-A, -B antigen, and DRB1 allele matched to the pt, with median  $4.36 \times 10^7$  total nucleated cells(TNC)/kg (range 2.86–6.93) per transplant. RIC regimen included Bu 0.8 mg/kg IV q6h x 8 doses, Flu 35 mg/m<sup>2</sup> IV/day x 5, TBI 300–450cGy total, and ATG 1.5 mg/kg/day x 3. Cyclosporine and mycophenolate mofetil were given for GVHD prophylaxis.

**Results:** Median follow up of surviving pts was 12 months. Day 180 overall survival (OS) was 72%. One yr OS and non-relapse mortality (NRM) were 45% and 49%, respectively. Relapse occurred in 1 pt. Cumulative incidence of myeloid and platelet engraftment was 83% and 72%, median 20 and 47 days (d), respectively. First chimerism evaluation occurred at median 21 d, all evaluable patients had  $\geq 95\%$  donor chimerism. At day 100, 79% of evaluable pts had single UCB unit dominance. Acute GVHD grades II–IV occurred in 39% and grades III–IV in 6% of patients. Chronic GVHD occurred in 17% during the follow up period. CMV reactivation occurred in 9/15 at risk pts, median 41 d post-transplant (range 18–54). A median of 3 CMV reactivations per pt was observed. Two died with CMV disease during first reactivation, while 2

others developed ganciclovir resistance. EBV reactivation occurred in 5/17 pts, 1 pt developed Post Transplant Lymphoproliferative Disorder (PTLD) unresponsive to therapy. One death was due to disseminated mucor.

**Discussion:** Flu/Bu based RIC regimen for double unit UCB transplantation is associated with rapid donor chimerism and possibly reduced disease relapse. Acute GVHD incidence was low. Failure to achieve neutrophil and platelet engraftment and high incidence of viral reactivation led to significant morbidity and high 1 yr NRM. Definitive conclusions based on the data are limited by small patient numbers and short follow up. Further strategies are needed to improve immune function after RIC double unit UCB transplant.

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### Comparative Analysis of T CELL Depleted Matched Vs Mismatched Unrelated DONOR Transplants in Patients with Hematologic Malignancies

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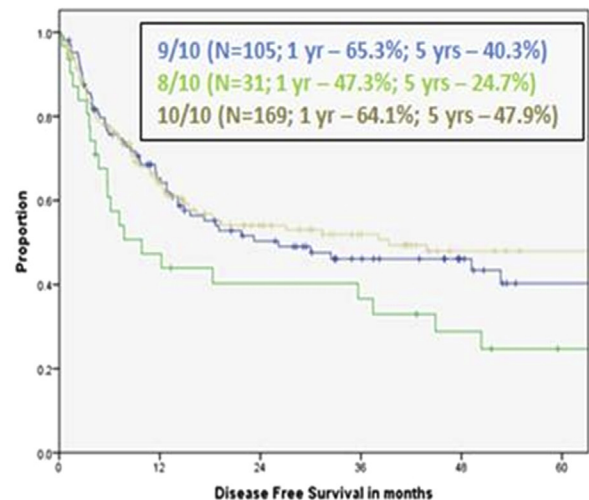
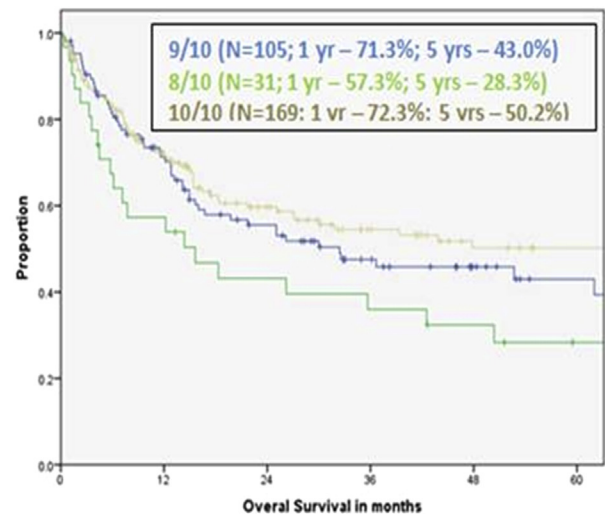


Figure 1. Kaplan Meier Curves for DFS and OS