

and 96 standard. For HLA, there were 45 HLA 10/10, 14 HLA 9/10, 1 HLA 8/10 and for UCB 14 HLA 4/6 and 3 HLA 5/6. After a median follow-up of 25 months (0.2–234), the median OS was 78 months (51–133) for transplanted patients with SD (3years OS: 68%), it was 33 months (27–47) for transplanted patients with UD (3years OS:44%), 21 months (15–37) for not transplanted patients with available SD or UD (3years OS:34%) and it was 31 months (23–221) for patients with ND (3years OS:45%). Median EFS for the same groups was 38 months (23–133), 24 months (17–36), 15 months (11–24) and 23 months (14–48) respectively. In multivariate analysis, 3 significant factors affected OS: disease status (< CR) HR = 2.8 [1.5–5.3]  $p < 0.001$ ; long interval diagnosis-registration HR = 2 [1.2–3.6]  $p = 0.001$  and conditioning (standard) HR = 0.27 [0.1–0.8]  $p = 0.02$ . The interval diagnosis-registration appeared as major factor affecting survival in UD allo-HSCT settings.

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#### LONG TERM OUTCOMES OF ALLOGENEIC TRANSPLANT USING NON-RADIATION BASED PREPARATIVE REGIMENS FOR ACUTE LYMPHOBLASTIC LEUKEMIA

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The role of total body irradiation (TBI) in the preparative regimen before allogeneic stem cell transplantation has been debated. It is associated with higher rates of toxicity. Herein, we report the long term outcomes of 26 consecutive pediatric and adult patients transplanted for acute lymphoblastic leukemia (ALL) in our center with non-TBI based preparative regimens from February 1996 to June 2010. All records were retrospectively reviewed. The median age was 15 years (y); range 4–31, with 18 males and 8 females. Thirteen were in first complete remission (CR1), 12 in CR2 and 1 patient with progressive disease at the time of transplant. All preparative regimens comprised of busulfan combined with melphalan in 3, cyclophosphamide in 14 and fludarabine in 9 patients. The source of the graft was bone marrow in 14 and peripherally collected stem cells in 12 patients. The median follow up was 54 and 83 months (mos) for all and alive patients respectively. During the study follow up, there were 9 relapses and 9 deaths (8 relapse related). The median overall survival (OS) was 18 mos (95% confidence interval [CI]: 4–21) with 5-y probability of 63% (95% CI: 40–79%). The median disease free survival (DFS) was 10.4 mos (95% CI: 5–19) with 5-y probability of 61% (95% CI: 39–78%). The 5-y cumulative incidence of relapse was 39% (95% CI: 19–58%) for all group, 13% (95% CI: 0.5–44%) for patients aged upto 12 y and 53% (95% CI: 25–75%) for patients over 12 y of age. Thirty-three percent of patients (95% CI: 13–54%) had acute graft versus host disease (aGVHD) grade 2 while none had grade 3–4. Nineteen percent (95% CI: 1–37%) had extensive chronic GVHD while only one had limited cGVHD. In the multivariable Cox model of OS using age (continuous variable) and disease status at transplant (CR2 versus CR1), both factors were statistically significant. The hazard ratio (HR) of age and disease status were 1.18 (95% CI: 1.03–1.35) and 10.90 (95% CI: 1.05–112.30) respectively. In conclusion, non-TBI based preparative regimen in children with ALL is a reasonable alternative with excellent results. The age and disease status at transplantation have major impact on survival of those patients. Further larger study is needed to validate these results.

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#### HIGH RATES OF NON-RELAPSE MORTALITY AND GRAFT-VERSUS-HOST DISEASE IN PATIENT UNDERGOING ALLOGENEIC STEM CELL TRANSPLANTATION (ASCT) FOLLOWING NON-MYELOABLATIVE (NMA) CONDITIONING WITH TLI/ATG

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NMA conditioning with TLI/ATG (TA) has shown remarkably low rates of acute graft-versus-host disease (GVHD) and non-relapse mortality (NRM). Randomized comparisons of TA with

more intense conditioning regimens have not been performed. We report here a retrospective comparison of transplant outcome following NMA with TA or reduced “toxicity” conditioning with fludarabine, busulfan and ATG (FBA), in cohort of patients deemed not suitable for conventional myeloablative conditioning regimens.

The study group consists of 48 consecutive patients who underwent ASCT after conditioning with FBA (n = 37) or TA (n = 11) because of advanced age or presence of co-morbidities. FBA regimen consisted of fludarabine 40mg/m<sup>2</sup>/day and busulfan 130mg/m<sup>2</sup>/day intravenously x4 doses starting day -6 and ATG 2mg/kg/day for 3 days, starting day -3. TA group received ATG 1.5mg/kg/day for 5 days and TLI dose of 800 cGy starting day -11.

Baseline characteristics are in table 1.

**Table 1. Patient Characteristics**

Variables	FBA (n=37)	TA (n=11)	p - value
<b>Sex : n (%)</b>			0.74
Men	21 (57)	7 (64)	
Women	16 (43)	4 (36)	
<b>Age: median (range)</b>	53 (17-65)	58 (38-70)	0.20
<b>Diagnosis: n (%)</b>			0.01
Acute Leukemia/MDS	24 (65)	2 (18)	
Non-Hodgkin Lymphoma	8 (22)	8 (73)	
Chronic Leukemia	3 (8)	1 (9)	
Plasma Cell Disorder	2 (5)	0 (0)	
<b>Remission Status: n (%)</b>			0.09
Chemo-sensitive	28 (76)	11 (100)	
Chemo-refractory	9 (24)	0 (0)	
<b>Risk group: n (%)</b>			0.25
Standard risk	12 (32)	1 (9)	
High risk	25 (68)	10 (91)	
<b>Prior autologous transplant: n (%)</b>	5 (13)	1 (9)	1.00
<b>Donor type: n (%)</b>			0.26
Sibling	9 (24)	5 (45)	
Unrelated	28 (76)	6 (55)	
<b>HLA mismatch: n (%)</b>	7 (19)	1 (9)	0.66
<b>CD 34+ dose: median (range) [x 10<sup>6</sup>/Kg body weight]</b>	7.2 (4-12.8)	5.1 (2.6-9)	0.03

The median follow up of surviving patients is 1 year. The rate of grade II-IV acute GVHD in the FBA and TA groups was 45.9% (n = 17) and 36.3% (n = 4) respectively (p = 0.73). Rate of Grade III-IV acute GVHD in the two groups was 8% (n = 3) and 36.3% (n = 4) respectively (p = 0.02). The rate of chronic GVHD in similar order was 37.8% and 36.8% (p = 1.0). Post transplant rates of proven bacterial, fungal and BK virus infections and CMV reactivation were similar between the two groups (p > 0.05). The cumulative incidence of disease relapse at 2years for FBA and TA groups was 46% and 10% respectively (p = 0.1). non-relapse mortality (NRM) for the FBA and TA cohorts at day 100 (2% vs.0%) and 2 years (31% vs.30%) was not significantly different (p = 0.3). Compared to FBA group, TA groups showed trends towards improved 2 year OS (40% vs.60%; p = 0.07) and significantly better 2year progression free survival (36% vs.60%; p = 0.036).

Acknowledging the limitation of our study (including small sample size, retrospective nature, higher proportion of chemosensitive/low-risk patients in TA group), it is worth noting that NRM rates with TA are surprisingly identical to an ablative FBA conditioning. Rates of grade III-IV acute GVHD are also significantly higher despite small patient numbers. The difference in PFS is likely due to low relapse rates in a standard-risk patient population. Our data highlight the need for prospective studies to define optimal conditioning regimens.

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#### PREDICTIVE FACTORS FOR HOSPITALIZATION AFTER OUTPATIENT REDUCED-INTENSITY CONDITIONING (RIC) ALLOGENEIC HEMATOPOIETIC PROGENITOR CELL TRANSPLANTATION (AHPCT)

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