

Comparison of Acute Myeloid Leukaemia Transplant Outcomes in Lower and Middle Income Countries with European Society for Blood and Marrow Transplantation (EBMT) Scoring System

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Abstract

Objective To evaluate the European Society for Blood and Marrow Transplantation's (EBMT) risk scoring system's prognostic ability for transplant outcomes for AML patients undergoing HSCT in low- and middle-income nations.

Methodology: A retrospective observational single centre study of 46 AML patients who received allogeneic HSCT at AFBMT, Rawalpindi during December 2013 to August 2022. Data were collected retrospectively from the AFBMT patient registry however the cut-off date for statistical analysis was February 15, 2024. Patient information such as demographics, transplant parameters (donor type, stem cell source, EBMT score), Disease features (AML ELN risk stratification, cytogenetics), and post-transplant outcomes (engraftment, GVHD, CMV reactivation, mucositis, disease relapse, survival) were gathered. Kaplan-Meier survival analysis was used to estimate OS and DFS and was compared with EBMT risk scores using log-rank test while chi-square test was used to analyse the association of EBMT risk score with incidence of other post-transplant complications and relapse.

Results: Out of the 46 patients who underwent allogeneic HSCT for AML with mean age of 24.59 ± 11.3 years, 27 (58.7%) were males and 19 (41.3%) were females. ELN risk stratification was available for 40 patients among which 15 (37.5%) had favorable risk category, 23 (57.5%) intermediate and 2 (5%) were high risk category. While as per the EBMT score 19(41.3%) were in low risk 25(54.3%) in intermediate risk and only 2(4.3%) in high risk group. The disease free survival (DFS) of the cohort was 39% (median 13.4 months), and overall survival (OS) was 50% (median 16.8 months). The transplant complications included: 26% experiences disease relapse, 39.1% had a GVHD, 41% CMV reactivation, and 15.2% NRM. The EBMT score was correlated significantly with both OS ($p=0.05$) and DFS ($p=0.000$) but not with any of the transplant complications. The median OS for low risk was 48.7 months, intermediate risk patients was 24.1 months and was 9 days for high risk patient. Similarly, in the median DFS was 11.3 months for low risk, intermediate risk patients were 13.6 months and 0 days for high risk patients.

Conclusion: Outcomes of hematopoietic stem cell transplantation (HSCT) in a young AML cohort from a resource-constrained environment are highlighted in this study. The results emphasize the influence of donor selection, stem cell source, and post-transplant complications on outcomes, and they confirm the predictive utility of the EBMT risk score. The EBMT score continues to have predictive relevance in LMICs however the high infection complications, TRM (15.2%), and disease relapse (26%) highlights unique challenges faced by countries with limited resources. According to these results, in order to maximize transplant outcomes, modified risk stratification techniques that take into consideration LMIC-specific challenges such as delayed diagnosis, insufficient MRD monitoring, and increased infection risks.

Keywords: Acute myeloid leukemia (AML); Hematopoietic stem cell transplantation (HSCT); EBMT risk score; Lower-middle income countries; Transplant outcomes; Survival analysis

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Introduction

Acute myeloid leukemia, or AML, is a diverse hematologic cancer with varying prognosis based on clinical, genetic

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variables and socioeconomic condition. Predicting post-transplant survival and complications requires the use of risk stratification tools, such as the European Society for Blood and Marrow Transplantation (EBMT) scoring system. Disparities in healthcare access, treatment practices, and supportive care may affect outcomes in lower- and middle-income countries (LMICs), but the majority of research confirming these models has been

carried out in high-income countries (HICs). Although recent classifications like the WHO's 5th edition and the International Consensus Classification (ICC) have improved AML diagnosis, little is known about their prognostic consequences in settings with low resources.¹⁻⁴

⁵ The EBMT score predicts survival following allogeneic hematopoietic stem cell transplantation (HSCT) by taking into account variables like age, disease stage and donor type. Although it works well in HICs, further research is needed to determine its applicability in LMICs, where delayed diagnosis, advanced disease at presentation, and a lack of adequate transplant infrastructure are widespread. Research on Myelodysplastic syndromes (MDS) and Myelofibrosis has shown that treatment accessibility and disease-related risk factors have a major influence on outcomes in various healthcare settings.³⁻⁴ The prognostic efficacy of the EBMT score in LMICs may also be impacted by differences in AML management, such as the accessibility of targeted treatments and post-transplant care. Obstacles such as donor availability, infection management, and budgetary limitations also affect HSCT results in LMICs. Studies on sickle cell disease (SCD) and other non-malignant conditions demonstrate how the lack of resources in LMICs contributes to a higher transplant-related mortality rate.⁵⁻⁶

Given the increased risks of infection and graft-versus-host disease (GVHD) associated with haploidentical transplants, which are frequently utilized in LMICs due to limited availability of fully matched donors, these obstacles may also have an impact on AML patients.⁷ To take these region-specific difficulties into consideration, the EBMT score might need to be modified. New treatments, such as gene editing, recent targeted therapies and innovative conditioning techniques, present encouraging substitutes but are still mostly unavailable in LMICs.⁸ Furthermore, in settings with low resources, genomic profiling—which is increasingly being utilized to guide transplant timing in MDS—is frequently unavailable.⁹⁻¹⁰ This discrepancy begs the question of whether the EBMT score, which was created in settings with ample resources, can reliably stratify risk in groups of people who have less access to cutting-edge treatments and diagnostics. This research attempts to evaluate the validity of the EBMT scoring system and explore possible adaptations for low-resource settings by comparing AML results in LMICs and HICs. In order to increase prognostic accuracy and transplant success rates in LMICs, this research aims to inform

customized risk-assessment algorithms by examining available data on HSCT outcomes, disease biology, and healthcare infrastructure. To achieve equitable global AML care and optimize transplantation procedures globally, it is imperative to comprehend these discrepancies.

Methodology

This cross-sectional study was conducted at the Armed Forces Bone Marrow Transplant Center (AFBMTTC) after ethical approval from the institutional review board. All patients diagnosed with acute myeloid leukemia (AML), regardless of age and gender, who underwent Allo HSCT during December 2013 to August 2022 were included through a convenient, non-probability sampling method. Data were collected retrospectively from the AFBMTTC patient registry however the cut-off date for statistical analysis was February 15, 2024. Written informed consent was obtained from all patients or their legal guardians for both the transplant procedure and the use of their data for research purposes. The study was conducted in accordance with the Declaration of Helsinki and all relevant local guidelines. Patients who did not proceed to Allogeneic HSCT for any reason or those who had Auto HSCT for AML or incomplete data in the registry, were excluded from the analysis.

As per the transplant protocol at AFBMTTC; EBMT risk score was calculated at the time of admission for HSCT and all patients underwent myeloablative conditioning regimens followed by bone marrow harvest as the main source of graft, along with peripheral blood stem cells (PBSCs) if dose was not sufficient. Donors were matched related siblings in all cases. Post-transplant follow-up included routine monitoring for early complications such as mucositis, infections, and engraftment delays. CMV reactivation was screened fortnightly using quantitative PCR from Day 14 post HSCT, and patients with reactivation were treated with antiviral therapy. Acute and chronic GVHD was monitored and categorized based on clinical and laboratory parameters. Early treatment related mortality (TRM) was defined as non-relapsed mortality during the first 100 days after transplant. Primary graft failure was defined as no signs of engraftment till day 21 of HSCT.

All data was analyzed using SPSS version 23. Qualitative variables, such as the occurrence of mucositis, GVHD, and

CMV reactivation, were presented as frequencies and percentages. Quantitative variables, including CD34+ cell dose, TNC count, time to neutrophil engraftment, and time to platelet engraftment, were summarized as medians with interquartile ranges (IQR) or means with standard deviations (SD), depending on the distribution of the data. In univariate analysis, chi-square test was used to analyse the association of EBMT risk score with incidence of mucositis, CMV reactivation, primary graft failure, TRM, acute and chronic GVHD. Overall Survival (OS) was calculated as time from HSCT to death from any cause or last follow-up. And Disease-Free Survival (DFS) as time from HSCT to relapse or death from AML or last follow up. Kaplan-Meier survival analysis was used to estimate overall survival (OS) and disease free survival (DFS). Survival curves were generated and compared with EBMT risk score using the log-rank test. Statistical significance was set at $p < 0.05$. Cox proportional hazards models were used for multivariate analysis

Results

A total of 46 patients underwent HSCT during the defined study duration. There were 27 (58.7%) males and 19 (41.3%) females. The mean age of the patients was 24.59 ± 11.3 years. 43 patients (93.4%) were diagnosed with de novo AML while 2 (4.3%) progressed from MDS, and 1 (2.2%) had therapy-related AML. As per ELN risk stratification was available for 40 patients in which 15 (32.6%) had showed favorable risk category, 23 (50%) intermediate and 2 (4.3%) were high risk category. The demographics of the patients included in the study are given in table I.

Patient falling in either of the risk stratification category received induction chemotherapy at different institutes and remission assessment was done. Being intermediate or high-risk disease at onset or poor response (Primary refractory disease) remained the base line to take the patient for HSCT. The main indication for HSCT among the patient underwent transplant during study duration, was being in intermediate risk category i.e. 19 (17.4%) or relapsed disease 15 (32.6%). Remission assessment along with minimal residual disease (MRD) was done in a few patients only. Among all patient who underwent HSCT, only 2 had high EBMT high risk score (4.3%), 39 (84.8%) patients had a matched sibling donor (MSD) and 7 (15.2%) had haplo matched donor available. The Stem cell source was bone marrow harvest in 30 patients

(65.2%) while 6 (13.0%) received peripheral blood stem cells and 10 patients (21.7%) had both BMH and PBSC as source of stem cell transplant. Parameters assessed regarding HSCT are shown in the table II.

Table I: Demographics of the patients with Acute Myeloid leukemia undergoing HSCT.

	Frequency	Percentage
Gender of the Patients		
Male	27	58.7
Female	19	41.3
Primary Diagnosis of the Patients		
AML-Mo	2	4.3
AML-M1	6	13.0
AML-M2	23	50
AML-M3	2	4.3
AML-M4	4	8.7
AML-M5	4	8.7
AML-M6	2	4.3
AML-MRC	2	4.3
t-AML	1	2.2
Risk Stratification of the Patients as per ELN classification		
Favorable	15	37.5
Intermediate	23	57.5
Adverse	2	5
NPM1 Status of the Patients		
Positive	5	10.9
Negative	38	82.6
Not available	3	6.5
FLT3 Status of the Patients		
Positive	1	2.2
Negative	41	89.1
Not available	4	8.7
BCR-ABL1 Status of the Patients		
Positive	0	0
Negative	5	10.9
Not available	41	89.1
Genetic Mutations Detected		
TP53	1	2.2
CBFB/MYH11	1	2.2
DEK-NUP214	1	2.2
D835 Mutation	1	2.2
Negative/None	42	91.3

For GVHD prophylaxis all patients receive cyclosporine with methotrexate. Median CD34 dose was 3.39×10^6 cells/kg (IQR: 2.90 to 4.35106 cells/kg) and TNC was 4.19×10^8 cells/Kg (IQR: 3.50 to 5.40). The mean days for neutrophil and platelet engraftment were 11.09 ± 5.1 days and 20.42 ± 6 days respectively. Primary graft failure was observed in 5(10.9%) patients. Regarding early

complications of Allo-HSCT, Mucositis was one of the commonest complication, a total of 37 (80.4%) patients developed mucositis post HSCT out of which majority had grade I or II. CMV reactivation was demonstrated in 19 (41%) patients while among 27 (59.9%) patients no CMV reactivation was recorded. 18 patients out of 46 developed Acute GVHD, out of which majority had limited skin GVHD of Grade I. Four patient needed hospitalization for grade IV GVHD. When the data was further analyzed 11 (23.9%) patients developed chronic GVHD out of which 7 (15.2%) had limited disease and 4 (8.7%) had extensive GVHD. By the end of the study 12 (26%) patients relapsed, those who relapsed 4 (8.7%) patients received DLI after re-induction chemotherapy.

Table II: Parameter assessed prior to Hematopoietic Stem Cell Transplant.		
EBMT risk score groups	N	%
Low Risk	19	41.3
Intermediate Risk	25	54.3
High Risk	2	4.3
Indication of HSCT		
Primary Refractory Disease	8	17.4
Relapse Disease	15	32.6
Intermediate Risk Disease	19	41.3
High Risk Disease	1	2.2
Not Available	3	6.5
Disease remission status prior to HSCT		
MRD Positive, Morphologically Complete Remission	3	6.5
MRD Negative, Morphologically Complete Remission	1	2.2
MRD Not available, Morphologically Complete Remission	42	90.1
Type of HSCT		
Matched Sibling Donor HSCT	39	84.8
Haplo-identical HSCT	7	15.2
Source of Stem Cell collection		
Bone Marrow Harvest (BMH)	30	65.2
Peripheral Blood Stem Cell collection (PBSC)	6	13.0
BMH + PBSC	10	21.7

Out of 46 patients the overall survival rate was 50% with median survival of 16.8 months (95% CI, 0.00-57.2) months (Figure 1). Among which 6 (15.2%) patients experienced non relapsed TRM. Out of 46 patients the disease-free survival rate was 39 % with median survival of 13.4months (95% CI, 8.7-18) (Figure 2). By using log rank test, EBMT score had significant association with OS (P=0.05) and DFS (P=0.000) .In low risk patients the median OS was 48.7 months (95% CI, 0.0 -98.3), while median OS of intermediate risk patients was 24.1months

(95% CI, 7.3-41) and of high risk patients was 9days only as shown in figure 3 Similarly In low risk patients the median DFS was 11.3 months (95% CI, 0.0 -19.4), while median DFS of intermediate risk patients was 13.6 months (95% CI, 6.9-20.3) and of high risk patients was 0 days as shown in figure 4. Where as in univariate analysis no significant association of ebmt risk score was found Table III.

Table II: Transplant Outcomes vs EBMT score					
Transplant Outcomes		EBMT Risk Score Groups			p value
		Low Risk	Intermediate Risk	High Risk	
Mucositis	Yes (37)	18(48.6%)	18(48.6%)	1(2%)	0.092
	No (9)	1(11%)	7(77%)	1(11%)	
CMV reactivation	Yes (19)	8(42%)	11(57%)	0	.771
	No(25)	10(40%)	13(52%)	2(8%)	
	NA(2)	1	1	0	
Acute GVHD	Yes(18)	9(50%)	9(50%)	0	.381
	No(28)	10(35%)	16(57%)	2(7%)	
Chronic GVHD	Yes(11)	5(45%)	6(54%)	0	.709
	No(35)	15(41%)	18(52%)	2(5%)	
Primary Graft Failure	Yes(5)	1(20%)	3(60%)	1(20%)	.149
	No(41)	18(43%)	22(53%)	1(2%)	
TRM	Yes(7)	1(41%)	5(71%)	1(41%)	.151
	No(39)	18(46%)	20(51%)	1(2%)	
Post HSCT relapse	Yes(12)	4(33%)	7(58%)	1(8%)	.641
	No(34)	15(44%)	18(52%)	1(2%)	

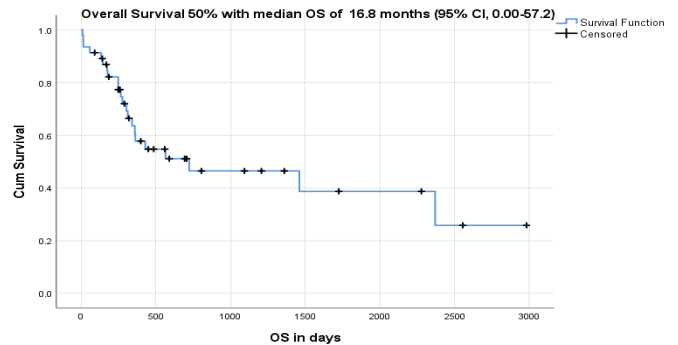


Figure 1: Overall Survival

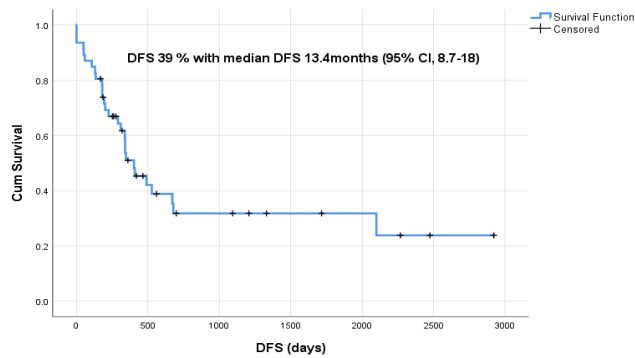


Figure 2: Disease free survival

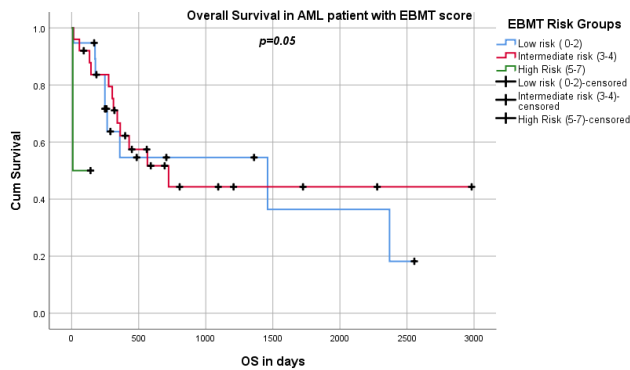


Figure 3: Overall Survival vs EBMT score

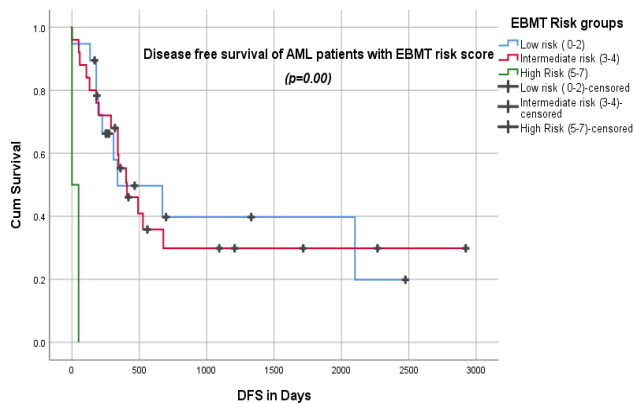


Figure 4: Disease free survival VS EBMT score

Discussion

Comparing the current study of 46 AML patients undergoing HSCT with recent studies, a number of noteworthy findings were found. In contrast to Western research, where median ages usually range from 40 to 60 years, the cohort was relatively young (mean age 24.6

years) and male (58.7%).¹ While secondary AML (4.3% MDS-progressed, 2.2% therapy-related) was less common than studies from tertiary centers (20–30%), the majority of patients (93.4%) had de novo AML.³ In contrast to registry data, which indicates that adverse-risk patients often make up 15–25% of transplants, ELN risk classification revealed 50% intermediate-risk, 32.6% favorable-risk, and only 4.3% adverse-risk individuals.¹¹

This disparity can be the result of regional differences in the accessibility of genetic testing or selection bias in referral patterns. Transplant characteristics revealed that bone marrow accounted for 65.2% of stem cell sources, whereas 84.8% used matched sibling donors (MSD) and 15.2% used haploidentical donors. According to¹¹, this is in contrast to current trends that favor peripheral blood stem cells (PBSC) in 70–80% of cases worldwide. Although it was below the ideal targets ($>4 \times 10^6/\text{kg}$) linked to greater engraftment, the median CD34+ dosage ($3.39 \times 10^6/\text{kg}$) was sufficient.³ Significantly less than the 30–50% rates in trials focusing on MRD-guided transplantation, only 6.5% had proven MRD-negative remission prior to HSCT¹⁰. This probably had a part in the 26% relapse rate, which was higher than the 15–20% observed in cohorts under MRD monitoring.⁹ GVHD occurred in 39.1% (acute) and 23.9% (chronic) cases, 41% experienced CMV reactivation, and 80.4% developed mucositis (mainly grade I–II) as post-transplant sequelae. These rates are greater than those reported by centers that use advanced prophylaxis³, but they are comparable to previous LMIC studies.² It is possible that inadequate conditioning or stem cell dosages contributed to the 10.9% primary graft failure rate, which was higher than the 5–8% average.⁷ In environments with inadequate resources, where infections predominate in post-HSCT death, non-relapse mortality (15.2%) reflected this.⁴ In comparison to recent trials (OS 60–70%), survival outcomes (OS 50%, DFS 39%, median survival 16.8 months) underperformed.¹¹

This was probably caused by inadequate donor selection, high recurrence rates, and poor MRD assessment. Although adding molecular data may improve the EBMT score's predictive potential, its substantial correlation with OS ($p=0.05$) and DFS ($p=0.000$) confirms its prognostic value¹⁰. The median OS of low and intermediate ebmt risk groups were comparable to previous studies but the OS of high ebmt risk score group was lower. In comparison

the DFS of all EBMT risk groups were low in contrast to bigger research, univariate analysis lacks significance, maybe because variable interactions are obscured by small sample sizes.^{9,16} Despite haploidentical choices, these results point to three important deficiencies in LMIC HSCT programs: (1) insufficient MRD monitoring, (2) an excessive dependence on sibling donors, and (3) the requirement for optimal conditioning/engraftment techniques. To enhance patient selection, future initiatives could investigate cost-effective MRD monitoring and incorporate genetic profiling⁸. Adapted methods that balance efficacy and resource constraints are crucial as HSCT availability grows internationally¹⁵, especially for young AML populations that stand to gain the most from curative intent therapy.

Conclusion

Results of the present study highlight the influence of donor selection, stem cell source, and post-transplant complications on outcomes, and they confirm the predictive utility of the EBMT risk score, even if survival rates (OS 50%, DFS 39%) were lower than those documented in high-income nations.

The need for better disease monitoring before transplantation is highlighted by the significant relapse rate (26%) and the poor MRD assessment.

Furthermore, deficiencies in conditioning techniques and supportive treatment are reflected in the high rates of non-relapse mortality (15.2%) and graft failure (10.9%).

As recommended by recent guidelines¹¹⁻¹⁰, including genetic profiling and risk-adapted techniques should improve post-transplant treatment and patient selection even more.

Ultimately, increasing outcomes for AML patients having HSCT in settings with limited resources will depend on tackling these issues through cooperative research and protocol modifications.

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