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Outcomes of Acute Myeloid Leukemia Patients Presenting in a Tertiary Care Hospital: A Developing Country Experience

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Abstract

Objective: This study evaluates survival outcomes of adult AML patients managed at a tertiary care center in Pakistan.
Methodology: This observational study included newly diagnosed AML patients ≥18 years presenting to the Armed Forces Bone Marrow Transplant Centre, Rawalpindi, between January 2018 and December 2024. Patients with prior AML therapy, acute promyelocytic leukemia, or those lost to follow-up immediately after diagnosis were excluded. Diagnosis and risk stratification followed WHO 2022, FAB, and ELN 2022 criteria. Survival outcomes were analyzed using the Kaplan–Meier method.
Results: Of 229 AML patients, 180 patients were included in survival analysis. The male-to-female ratio was 1.5:1, and most patients were aged 31–50 years. Fever and weakness were common presenting symptoms while pallor being the most common clinical sign. AML with maturation was the predominant subtype, and 76.7% had intermediate risk AML as per ELN 2022. Cytogenetic abnormalities noticed in 30.6% of cases. Treatment with curative-intent was given to 149 patients, while 31 received palliative treatment. Complete remission (CR) following Intensive induction was 50.9% among non-transplant patients. Ninety-four patients underwent hematopoietic stem cell transplantation (HSCT). Common complications included febrile neutropenia (50.2%), mucositis (78.7%), and CMV reactivation (31.9%).
At a median follow-up of 727 days, overall survival was 49.1%, and disease-free survival was 37.7%. Favorable-risk AML patients had better outcomes than intermediate- and adverse-risk groups.
Conclusion: Despite recent advancements in AML therapy, significant challenges remain, particularly in resource limited settings. Diagnostic access and early treatment are essential to improve outcomes.
Keywords: AML, outcomes, low- and middle-income countries, survival analysis.

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Introduction

Acute myeloid leukemia (AML) is a heterogenous hematological malignancy characterized by clonal proliferation of myeloid precursor leading to bone marrow failure. [1,2] Bone marrow failure occurs due to expansion of blasts and disrupting normal erythropoiesis and megakaryopoiesis [3] AML primarily affects older individuals, with a median age at diagnosis of approximately 68 years. The 5-year overall survival (OS) rate is around 32%, however, outcomes vary with age i.e. up to 50% in younger patients while less than 10% in those over 60 years of age. [4] The incidence is higher in males than in females, with an observed male-to-female ratio of approximately 5:3. [3]

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According to the 2022 ELN guidelines, the disease is stratified into favorable, intermediate, or adverse risk categories based on specific diagnostic criteria.[5] This risk stratification influences treatment outcomes in AML. Additionally, outcomes also depend on patient's response to induction chemotherapy followed by consolidative strategies, including chemotherapy or transplant, as per specific cytogenetic and molecular alterations identified at diagnosis. [6]

The standard intensive chemotherapy for AML, combining cytarabine with an anthracycline (daunorubicin or idarubicin) remains the backbone of current induction therapy in younger patients. Clinical outcomes have improved with addition of consolidation using high- or intermediate-dose cytarabine or allogeneic stem cell transplantation (Allo-SCT) in first complete remission (CR1). [7] Recent integration of oral targeted therapies into standard AML treatment has improved outcomes. Common agents include midostaurin (FLT3), ivosidenib (IDH1), and enasidenib (IDH2). Venetoclax, a BCL-2 inhibitor, regardless of mutation status, is

approved with azacitidine or low-dose cytarabine for patients unfit for intensive chemotherapy (VIALE-A and VIALE-C trial result). [8]

Treatment consideration for elderly patients with AML requires careful evaluation due to heterogeneity in disease biology, comorbidities and performance status.[8] The standard regimen is a combination of a hypomethylating agent (azacitidine or decitabine) with the BCL-2 inhibitor (venetoclax). Patients deemed unfit may receive best supportive care. This therapy may be continued indefinitely in patients achieving complete remission. However, ongoing treatment should be guided by a risk–benefit assessment involving the patient, family, and healthcare team. [3]

The healthcare system in low and middle-income countries (LMICs) such as Pakistan faces significant challenges. Delays in the referral system, early diagnosis, and timely management hinder effective treatment. Most clinical centers in Pakistan do not manage AML due to financial limitations, as well as the high morbidity and mortality associated with both the disease and its treatment.[6]

This study aims to evaluate treatment outcomes of adult patients diagnosed with AML presenting to a tertiary care hospital in Pakistan.

Methodology

This observational study was conducted at the Armed forces bone marrow transplant center (AFBMTC), Rawalpindi Pakistan. Written ethical approval from the Institutional Review Board and informed consent of the patients were obtained. All consecutive patients of acute myeloid leukemia (AML) reporting at our center from January 2018 to December 2024 were included in the study.

Newly diagnosed AML patients ≥ 18 years of both genders were included in the study. Patients who received treatment of AML elsewhere previously, those with acute promyelocytic leukemia (APML) and those who were lost to follow-up after initial diagnosis were excluded.

A detailed medical history was obtained and a thorough clinical examination was conducted at the time of presentation. Diagnosis of AML was confirmed by the findings of peripheral blood film, bone marrow morphology and flow cytometric immunophenotyping while risk classification was done by cytogenetic analysis, PCR based molecular testing and myeloid gene panel. The findings from diagnostic investigations facilitated the classification of patients according to the French American-British (FAB) Cooperative Group criteria, 2022 World Health Organization (WHO) diagnostic criteria for AML and the 2022 European Leukemia Net (ELN) guidelines.

The baseline demographic and clinical data was collected on an Excel sheet and then transferred to SPSS software at the time of analysis. Survival endpoints, including overall survival (OS), disease free survival (DFS) were defined in accordance with the revised recommendations of the International Working Group. OS was measured from the date of diagnosis to date of death from any cause or last follow-up. DFS was determined from the date of first remission to either relapse (hematological or extramedullary) or non-relapsed mortality from any cause in complete remission state (BM blast <5% and no persistent extramedullary disease). [9]

The chi-square test or Fisher's exact test was used to analyze categorical variables. For continuous variables, comparisons were made using either the two-sample t-test or the Wilcoxon rank-sum test. The Kaplan-Meier method was utilized to estimate the distribution of OS and DFS.

Results

The study included 229 AML patients, male to female ratio was 1.5:1 with common age group between 31-50 years (n= 80, 44.4%). Forty-nine patients (APML and lost to follow-up) were excluded from final analysis. Table I present the demographic characteristics of overall cohort of AML patients.

Out of 180, depending on age and performance status, curative treatment was given to 149 (82.7%) while palliative to 31(17.2%). Daunorubicin-Cytarabine (D3A7) was the most commonly used induction for patients treated with curative intent (Table II).

Out of 94 patients, 71 (75.5%) patients had MSD allogenic, 15 (16%) had haplo-identical and 8 (8.5%) patients had autologous HSCT. For 86 allo- HSCT, 51

Table I: Demographic characteristics of AML patients. (n=180)			
Factor	Level	n	%
Gender	Male Female	115 65	63.9 36.1
Age groups	18-30 years 31-50 years More than 50 years	63 80 37	35 44.4 20.6
Comorbid	No Yes*	134 46	74.4 25.6
Presenting complaints	Fever, weakness Bleeding, bruising Fever, bleeding, bruising, exertional dyspnea Non healing ulcers and wound	111 14 53 2	61.7 7.8 29.4 1.1
Signs	Pallor	Yes = 97 No = 83	53.9 46.1
	Liver	Not palpable = 142 palpable = 38	78.9 21.1
	Spleen	Not palpable = 154 palpable = 26	85.6 14.4
	Lymph node	Not palpable = 156 palpable = 24	86.7 13.3
CNS disease	No Yes	179 01	99.4 0.6
Presenting counts	WBC (x 10^3 /ul)	7.75 (IQR: 3.10- 32.0)	
	Hemoglobin (g/dL)	8.96 ± 2.3 (Min-Max: 2.8 – 15)	
	Platelets (x 10^9 /ul)	57.0 (IQR: 29.2-122)	
	Bone marrow blasts (%)	70 (IQR:52-80)	
AML FAB classification	minimal differentiation without maturation with maturation myelomonocytic monocytic erythroid leukemia myelodysplastic related changes relapse, refractory, Fanconi anemia, post cytotoxic therapy, myeloid sarcoma, MDS	12 17 87 22 15 2 16 9	6.7 9.4 48.3 12.2 8.3 1.1 8.9 5.0
ELN 2022 classification	Favorable risk	14	7.8
	Intermediate risk	138	76.7
	Adverse risk	28	15.6
Cytogenetics	Normal	120	66.6
	Abnormal**	55	30.6
	Culture failed	5	2.8
*Note: *comorbid commonly seen were diabetes, hypertension and latent T.B* ***commonly seen abnormal cytogenetics were Del 9p,7q, monosomy 7, trisomy 8 , t (9;22), t (15;17), and t (8;21)*			

(54.2 %) donors were brothers, 33 (35.1 %) were sisters, 1 (1.1%) donor was father and 1 (1.1%) was mother. 59

(62.8%) cases had no ABO mismatch, 10 (10.6%) had major, 14 (14.9%) had minor, and 3 (3.2%) had bidirectional ABO mismatch. 89 (94.7%) patients were CMV IgG positive before going for transplant. For GVHD prophylaxis, CSA+MTX were used in 70 (74.5%) patients, CSA+MMF+PTCy in 15 (16%) while 34 (36.2%) cases received ATG. All patients received myeloablative conditioning regimen as part of the preparative process. For allogenic HSCT, bone marrow harvest (BMH) was stem cell source in 56 (59.6 %) patients, while BMH+PBSC was used in 14 (14.9 %) and PBSC alone in 16 (17 %) cases. For autologous HSCT, PBSC was stem cell source in 8 (8.5 %) patients. In Allo-HSCT, median CD34 dose was 3.22x 10^6 /kg (IQR: 2.67 – 4.71) and median TNC dose was 3.97 x 10^8 /kg (IQR: 3.08-4.96). In Haplo-identical HSCT, median CD34 dose was 6.80 x 10^6 /kg (IQR: 4.61 – 8.77) and median TNC dose was 7.79 x 10^8 /kg (IQR: 5.36 - 10.15). In autologous HSCT, median CD34 dose was 5.26 x 10^6 /kg and median MNC dose

Table II: Treatment Pathways and Outcomes of Patients				
Category		n	%	Details / Outcomes
Curative treatment (n=149)				
Non transplant patients (n = 55)				
Complete remission (MRD-negative)		28	50.9	Consolidated per risk category
Less than complete remission		12	21.80	Required re-induction
Re-induction therapies (n = 12)				Outcomes included death or HSCT
	• D3A7	1	8.30	Followed by HiDAC consolidation; did not survive
	• Decita-Venetoclax	3	25	No donor available; 1 received IDAC consolidation, 2 died
	•FLAG-Dauno	8	66.70	4 (50%) died; 4 (50%) proceeded to allo-HSCT
Consolidation regimens (n = 28)	• IDAC	18	64.30	Given to intermediate/low-risk patients
	• HiDAC	10	35.70	Given to high-risk patients
Transplanted patients (n = 94)				
Status at transplant	• CR1	70	74.50	D3A7, IDAC/HiDAC (bridge to transplant)
	• CR2	21	22.30	Salvage chemotherapy (FLAG-Dauno/FLA)
	• CR3	3	3.20	
Palliative treatment (n=31)				
Achieved remission *		18	58.1	Responded to HMA–Venetoclax
Did not achieve hematological remission*		13	41.9	Non responders
Note: *All patients were consolidated with four cycles of HMA–Venetoclax				

was 4.07 x 10^8 /kg.A median day to achieve neutrophilic and platelet engraftment were +13 and +17 respectively.

Febrile neutropenia was most common complications in transplanted patients (n=47,50.2%), followed by gut toxicity in 28 (29.8 %) and mucositis in 74 (78.7 %). About 44 (46.8 %) patients had Grade I-II mucositis and 29 (30.8%) had Grade III-IV mucositis. Two patients (2.1%) had neurological complications i.e seizures, 38 (40.4%) patients have hepatotoxicity, 15 (16%) have renal toxicity and 2 (2.1%) have TA-TMA.30 (31.9 %) patients had acute graft vs host disease (aGVHD). Most common aGVHD was skin (n= 23, 24.5%) followed by gut (n=9, 9.6%) and hepatic (n=2, 2.1%) respectively. There was significant association of BMH with aGVHD (p = 0.03). CMV reactivation occurred in 30 (31.9 %) cases. Median day of CMV reactivation was +26. There was significant association of ATG with CMV reactivation (p= 0.05).

Out of 175 AML patients with available data, the OS was 49.1% at a median follow up of 727 Days, DFS was 37.7% at a median follow-up of 274 days (Figure I). Across ELN 2022 risk groups, the OS was 71.4% with favorable-risk patients, followed by intermediate-risk (48.9%) and adverse-risk categories (39.3%) (p=0.08). The DFS was 50% with favorable-risk patients, followed by intermediate-risk (37.6%) and adverse-risk categories (32.1%) (p=0.14).

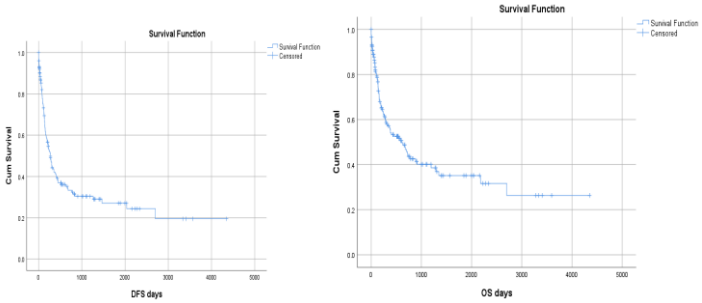

Figure I. Kaplan–Meier curves showing OS (49.1%) and DFS (37.7%) in studied population (n=175).

Discussion

Among hematological malignancies, AML remains most prevalent worldwide.[10] It presents significant challenges to public health, prompting continued discussion regarding its growing global burden. [11,12] According to the study by Yeming, et al., the incidence of AML increased markedly from 79,372 cases in 1990 to 144,645 cases in 2021, with particularly high prevalence in high socio-demographic index (SDI) regions such as North America, Western Europe, and Australasia. [13] This rise is largely related to population growth, aging, and advancements in diagnostic technologies. [14] Although AML-related deaths increased globally, however, the age-standardized death rate (ASDR) and age-standardized DALYs declined, reflecting improvements in medical treatment and patient management. [13]

In this study, we share our center's seven-year experience with AML care and discuss several treatment

challenges that are particularly relevant to LMIC healthcare systems. In our cohort, the male-to-female ratio was 1.5:1 and with more presenting in middle age group. This trend is reported by studies across other LMICs. [15-17] This differs from western data where median age at presentation is over 60 years.[4] Such distribution seems related to gender-based differences and limited health care access by elderly population in LMICs. The common presenting features were fever and generalized weakness while pallor followed by hepatomegaly and splenomegaly were common clinical signs. [15, 16, 18]

Across the cohort, AML with maturation was the common morphological subtype at presentation. This has also been observed in different studies.[18, 19] Based on ELN-2022 risk stratification, majority of our patients were classified in intermediate risk AML. These results are consistent with study of Mihee, et al.[20] However, it differs from other studies were favorable risk AML was common at time of initial diagnosis.[21, 22] Cytogenetics abnormalities were seen in 30.6% of patients (Table II). The common cytogenetics abnormalities observed are complex karyotype, -5 or del 5q, -7 or del 7q, t (9; 22), t [15,17,23, 24] These helps in predicting remission and relapse rates. Around 14.8% newly diagnosed AML patients lost to follow-up due to financial constraints-a challenge consistently reported in LMIC setting influencing survival outcomes. [25]

The achievement of complete remission (CR) following induction intensive chemotherapy (IC) and less IC were 50.9% and 58.1% respectively. These results are comparable to those reported in high-income countries (HIC) where CR rates with 3 + 7 regimen range from 50% to 80%, and with HMA-venetoclax is 50%.[26,27] Induction mortality of our cohort following IC and less IC were 27.3% and 54.8% respectively. These results are substantially higher than those reported in HIC, ranging from 6.1% (with IC) to 20.2% (with less IC). [28]

However, our results are comparable to data across other LMICs, like India, were induction mortality ranges from 15.6 to 24.7%.[29] Several factors are related to these high mortality rates like age, performance status, leukemic burden, induction failures and infections.[26]

Patients transplanted in CR1 have improved OS (60.9%) which is consistent with data across world supporting early HSCT in transplant eligible patients.[30,31] Likewise, significant association of CMV reactivation with the use of ATG in conditioning regimen aligns with the findings of HaiTao, et al. [32]

The OS of our cohort was 49.1% (median follow up of 2 years) while DFS was 37.7% (median follow up around 1 year). These results are consistent with study of Khadega et al. which reported 2-year OS (15.8%-45.3%) and DFS (11.7%- 47.7%).[33] When comparing OS among ELN-2022 risk categories, patients having favorable risk AML had superior outcomes than intermediate and adverse risk AML. Our results were consistent with studies. [22,34]

Our study had several limitations. Firstly, as it was conducted in a LMIC, a considerable number of patients were lost to follow-up after the initial diagnosis, primarily due to financial constraints. Secondly, limited access to resources and targeted therapies may have negatively impacted treatment outcomes. Furthermore, the lack of comprehensive mutational profiling at the time of diagnosis hindered accurate risk stratification, which could have influenced prognosis and guided more appropriate treatment planning.

Conclusion

In conclusion, despite recent advancements in AML therapy, significant challenges remain, particularly in resource limited settings.

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