

Original Article

Survival Analysis and Prognostic Factors in Acute Myeloid Leukemia: Real-world Data from a Single-center Retrospective Cohort in the Trakya Region

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ABSTRACT

Aim: Acute myeloid leukemia (AML) is an aggressive hematologic malignancy predominantly affecting older adults, with prognosis influenced by cytogenetic and molecular risk profiles, age, performance status, and comorbidities. This study evaluated the clinical and genetic characteristics, treatment-related complications, and prognostic factors that affect survival among patients diagnosed with AML at the Hematology Clinic of Trakya University Health Practice and Research Hospital.

Methods: This retrospective study included 111 patients aged ≥ 18 years diagnosed with AML between 2017 and 2021, selected from 185 cases based on data completeness. The diagnosis was established according to the World Health Organization 2016 and 2022 classifications, while risk stratification followed the updated European LeukemiaNet (ELN) 2022 guidelines. Continuous variables were compared using the Mann-Whitney U or Kruskal-Wallis test, and categorical variables were compared using the chi-square test. Correlations were assessed with Spearman's rank correlation coefficient. Survival was analyzed using the Kaplan-Meier method with log-rank test, and prognostic factors were evaluated using univariate and multivariate Cox regression analyses. Statistical analyses were performed using SPSS version 26, with a two-tailed $p < 0.05$ considered statistically significant.

Results: Of the cohort, 57.7% were male, with a median age of 66 years; 59.5% were ≥ 60 years old. According to ELN 2022 risk stratification, 31.5% were classified as favorable risk, 37.0% as intermediate risk, and 31.5% as adverse risk. Induction therapies included the 3+7 regimen (cytarabine 100-200 mg/m²/day on days 1-7 plus daunorubicin 60-90 mg/m²/day or idarubicin 12 mg/m²/day on days 1-3) in 54.1; azacitidine + venetoclax in 18.0; azacitidine monotherapy in 25.2; and 3+7+ all-trans retinoic acid for acute promyelocytic leukemia in 2.7%. The most common complications were febrile neutropenia (84.7%), sepsis (34.2%), invasive fungal infections (23.4%), and typhlitis (22.5%). The median follow-up was 9 months (maximum 96 months), and the overall mortality rate was 63.1%, with sepsis as the leading cause of death. The median overall survival was approximately 34 months and significantly longer in the favorable-risk ELN group. In multivariate Cox regression analysis, the Charlson Comorbidity Index [hazard ratio (HR) 1.319 per unit increase] and sepsis (HR: 1.967) emerged as independent predictors of poor prognosis.

Conclusion: Real-world data from the Trakya Region demonstrate that advanced age, high comorbidity burden, adverse genetic risk, and sepsis significantly worsen AML survival. While the 7+3 regimen remains superior in patients fit for intensive chemotherapy, azacitidine + venetoclax offers a valuable alternative for unfit patients. These findings underscore the importance of individualized treatment strategies and provide region-specific data to inform future studies.

Keywords: Acute myeloid leukemia, survival analysis, prognosis, comorbidity, venetoclax

Introduction

Acute myeloid leukemia (AML) is an aggressive hematologic malignancy characterized by the clonal proliferation of myeloid progenitor cells and impaired differentiation. The

disease typically peaks in older age, and its prognosis varies significantly depending on cytogenetic and molecular genetic abnormalities, age, performance status, comorbidity burden, and treatment response [1-3]. The World Health Organization (WHO) 2016/2022 classification and the

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European LeukemiaNet (ELN) 2022 risk stratification provide prognostic categorization based on cytogenetic and molecular markers, reflecting the heterogeneous nature of AML [1,4]. Nevertheless, in real-world settings, the lack of comprehensive molecular profiling in every patient—particularly in regions with limited resources—continues to restrict diagnostic and therapeutic approaches.

In the management of AML, induction regimens are individualized according to patient fitness; however, treatment-related complications substantially influence mortality rates [5,6]. Complication rates are particularly elevated in older and unfit patients with high comorbidity burden, which in turn shortens survival [7]. Although international randomized trials have demonstrated that the combination of hypomethylating agents plus venetoclax improves response rates and survival in unfit populations, outcomes in real-world cohorts remain variable due to patient heterogeneity, dose modifications, and resource limitations [2,8].

In Türkiye, national registry studies on the epidemiology and prognosis of AML are limited, and regional differences—such as age distribution, comorbidity profiles, and access to healthcare—have not been sufficiently elucidated [9-11]. Data specific to the Trakya Region are even more scarce; in a previous study from our center, we examined demographic characteristics and induction treatment response rates [12]. This retrospective cohort study aims to provide a detailed evaluation of clinical and laboratory findings, genetic features, treatment-related complications, and survival outcomes within the same patient population; to determine the independent effects of prognostic factors; and to contribute region-specific data to the literature. These findings are expected to support the optimization of individualized treatment strategies and serve as a foundation for future multicenter research.

Methods

This study was a retrospective cohort analysis of adult patients diagnosed with AML at the Hematology Clinic, Department of Hematology, Division of Internal Medicine, Trakya University Faculty of Medicine, between January 2017 and December 2021. The study was approved by the Trakya University Faculty of Medicine Scientific Research Ethics Committee (approval no: 15/01, date: 14.09.2020). In our previous study, the demographic characteristics and induction treatment response rates of the same cohort were evaluated in detail. This article focuses on clinical and laboratory findings, available genetic and cytogenetic features, treatment-related complications, and survival outcomes.

All patients aged ≥ 18 years who were diagnosed with AML according to the WHO 2016/2022 diagnostic criteria at our clinic during the specified period were potentially eligible for inclusion [4,13]. The diagnosis of AML was confirmed by the presence of $\geq 20\%$ blasts in the bone marrow (with revised thresholds applied in the presence of defining genetic abnormalities) and by immunophenotyping via flow cytometry.

Risk stratification was performed according to the ELN 2022 guidelines using available cytogenetic and molecular data. Of the 185 patients, 111 (60%) who had complete clinical and laboratory data and partial genetic data were included in the final analysis. Exclusion criteria were defined as incomplete data (absence of critical parameters in the electronic medical record system), a history of another hematologic malignancy before AML diagnosis, age in the pediatric range, and insufficient follow-up data. The patient selection process is illustrated in Figure 1 as a flow diagram.

Statistical Analysis

All data were collected retrospectively and anonymously from the hospital's patient management information system. The collected parameters were limited to clinical features, laboratory findings, genetic and cytogenetic characteristics, treatment regimens, treatment-related complications, survival data, follow-up duration, and the date of the last patient visit or death. Continuous variables were expressed as mean $\pm$ standard deviation or median [interquartile range (IQR)], depending on the distribution, while categorical variables were presented as numbers (percentages). The normality of continuous variables was assessed using the Shapiro-Wilk test. Comparisons between groups were performed using the chi-square test, Mann-Whitney U test, or Kruskal-Wallis test, as appropriate. Correlations between continuous variables were evaluated using Spearman's rank correlation coefficient, and the strength of correlation was interpreted as weak ($|r| < 0.3$), moderate ($0.3 \leq |r| < 0.6$), or strong ($|r| \geq 0.6$). Survival analyses were performed using the Kaplan-Meier method, and differences between groups were assessed using the log-rank test. The independent effects of prognostic factors were examined using univariate and multivariate Cox proportional hazards models. A two-tailed p value < 0.05 was considered statistically significant.

Results

The clinical and laboratory characteristics, genetic and cytogenetic profiles, treatment-related complications, and

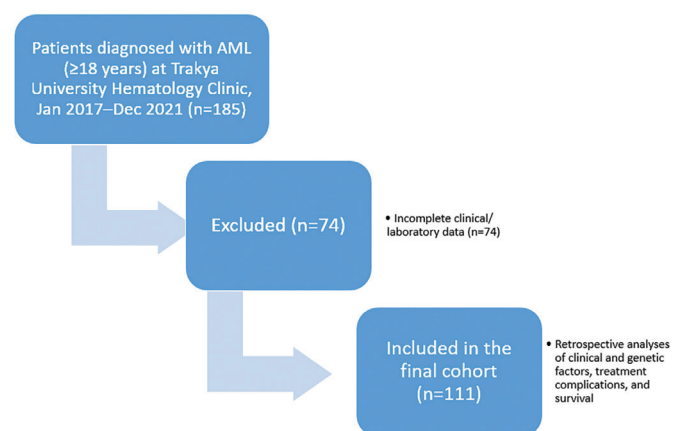


Figure 1. Patient selection flowchart
AML: Acute myeloid leukemia

survival outcomes of 111 patients with AML are presented. Demographic features and induction treatment response rates were evaluated in detail in our previous study, and are therefore not repeated here.

At the time of diagnosis, the median hemoglobin level was 8.62 g/dL, the median platelet count was 59,000/mm³, and the median leukocyte count was 8,700/mm³. Anemia was present in 96.4% of the patients, thrombocytopenia in 71.2%, neutropenia in 55.0%, leukopenia in 34.2%, and leukocytosis in 48.6%. In the ≥60-year age group, platelet and creatinine levels were significantly higher, where as albumin levels were significantly lower than in younger patients. Positive correlations were observed between age and the Charlson Comorbidity Index, creatinine, and platelet count; a negative correlation was observed between age and albumin level. The relationships among laboratory parameters and continuous variables, such as age, Charlson Comorbidity Index, and blast percentage, were evaluated using correlation analyses and summarized in Table 1.

When cytogenetic and molecular genetic data were assessed, 68 results were available: 63.2% (n=43) were from male patients and 36.8% (n=25) were from female patients. The prevalence of cytogenetic abnormalities was 30.2% in males and 24.0% in females, with no statistically significant difference between genders ($\chi^2=0.305$, $p=0.581$). The median age was 55 years (IQR: 43-63) in patients with cytogenetic abnormalities and 68 years (IQR: 55-75) in those without abnormalities; patients with cytogenetic abnormalities were significantly younger ($U=0.279$, $p=0.011$). The rate of cytogenetic abnormalities was 15.8% in patients aged 60 years and older, compared with 43.3% in those under 60 years ($\chi^2=6.317$, $p=0.012$). The associations among Eastern Cooperative Oncology Group (ECOG) performance status, the Charlson Comorbidity Index, and cytogenetic abnormalities appeared to be limited to the effect of age; partial correlation analysis revealed no significant independent relationships (ECOG $r=-0.219$, $p=0.075$; Charlson $r=-0.06$, $p=0.619$). According to molecular genetic results, the adverse prognostic anomaly group had significantly higher

Table 1. Correlation analysis between continuous numerical variables

		Ch. I.	Alb	LDH	CRP	GGT	ALP	Cre	Neu	Plt	Hct	Hgb	Wbc	BMB
Age	r	0.878	-0.372	0.100	0.096	-0.122	0.160	0.425	0.150	0.199	-0.110	-0.164	0.092	-0.161
	p	0.001	0.001	0.297	0.314	0.201	0.093	0.001	0.115	0.037	0.252	0.085	0.336	0.092
BMB	r	-0.064	-0.097	0.177	0.155	0.066	-0.019	-0.019	0.064	-0.041	0.044	0.036	0.271	
	p	0.512	0.324	0.069	0.112	0.500	0.847	0.844	0.513	0.679	0.651	0.715	0.005	
Wbc	r	0.144	-0.070	0.750	0.259	0.337	0.175	0.375	0.777	-0.157	0.155	0.110		
	p	0.130	0.466	0.001	0.006	0.001	0.066	0.001	0.001	0.100	0.104	0.248		
Hgb	r	-0.110	0.203	0.042	-0.010	0.181	0.017	0.076	0.120	0.202	0.968			
	p	0.252	0.033	0.665	0.916	0.058	0.860	0.429	0.211	0.033	0.001			
Hct	r	-0.049	0.180	0.077	0.017	0.170	0.021	0.140	0.150	0.248				
	p	0.609	0.059	0.423	0.861	0.075	0.830	0.144	0.115	0.009				
Plt	r	0.206	-0.106	-0.241	-0.084	0.030	0.067	0.009	-0.054					
	p	0.030	0.268	0.011	0.280	0.758	0.486	0.922	0.570					
Neu	r	0.176	-0.041	0.546	0.218	0.368	0.262	0.407						
	p	0.064	0.672	0.001	0.021	0.001	0.006	0.001						
Cre	r	0.467	0.023	0.274	0.182	0.210	0.225							
	p	0.001	0.808	0.004	0.055	0.027	0.017							
ALP	r	0.208	-0.132	0.197	0.290	0.500								
	p	0.029	0.166	0.039	0.002	0.001								
GGT	r	-0.060	-0.174	0.318	0.380									
	p	0.534	0.068	0.001	0.001									
CRP	r	0.104	-0.357	0.239										
	p	0.275	0.001	0.012										
LDH	r	0.179	-0.096											
	p	0.060	0.318											
Alb	r	-0.276												
	p	0.003												

Spearman's rank correlation coefficient was used; r values and p values are presented. Statistically significant correlations ($p<0.05$) are shown in bold
BMB: Bone marrow blast percentage, Wbc: White blood cell count, Hgb: Hemoglobin, Hct: Hematocrit, Plt: Platelet count, Neu: Neutrophil count, Cre: Creatinine, ALP: Alkaline phosphatase, GGT: Gamma-glutamyl transferase, CRP: C-reactive protein, LDH: Lactate dehydrogenase, Alb: Albumin, Ch. I.: Charlson Comorbidity Index, r: Spearman correlation coefficient

proportions of female patients and of patients aged over 60 years, a higher median age, a higher Charlson Comorbidity Index, and a higher proportion of patients with elevated ECOG scores. These findings are presented in Table 2.

The distribution of induction treatment regimens was as follows: 3+7 induction regimen (cytarabine 100-200 mg/m²/day as continuous intravenous infusion for 7 days plus daunorubicin 60-90 mg/m²/day or idarubicin 12 mg/m²/day for the first 3 days) in 54.1% (n=60), azacitidine + venetoclax in 18.0% (n=20), azacitidine monotherapy in 25.2% (n=28), and “3+7+all-trans retinoic acid” for acute promyelocytic leukemia in 2.7% (n=3). The most frequent treatment-related complications were febrile neutropenia (84.7%, n=94), sepsis (34.2%, n=38), invasive fungal infections (23.4%, n=26), typhlitis (22.5%, n=25), and mucositis (4.5%, n=5); these are illustrated in Figure 2. Febrile neutropenia was more common in patients with an ECOG score of 0, whereas typhlitis was significantly more frequent in the ≥60-year age group (p<0.05). The incidence of typhlitis was significantly higher in the “3+7” regimen group compared with the other treatment groups.

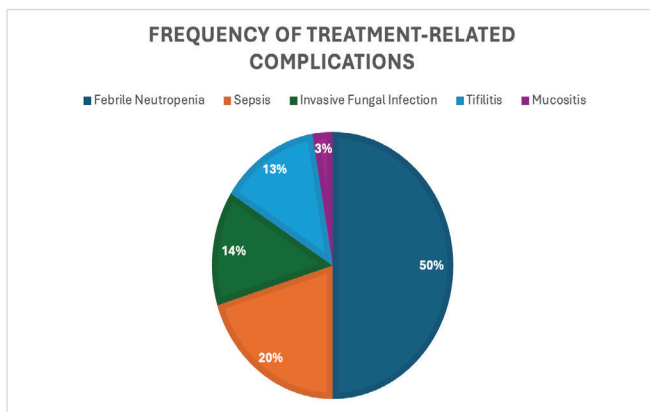


Figure 2. Frequency of treatment-related complications

The median follow-up was 9 months (IQR: 3-30 months; maximum 96 months). The overall mortality rate was 63.1% (n=70 deaths), with sepsis being the most common cause. The median overall survival (OS) for the entire cohort was approximately 34 months. By age group, median OS was ~18 months in patients <60 years and ~7 months in those ≥60 years; the difference was statistically significant (log-rank p<0.001; presented in Figure 3). When stratified by ELN 2022 risk groups, median OS was ~56 months in the favorable-risk group, ~26 months in the intermediate-risk group, and ~27 months in the adverse-risk group. The favorable-risk group demonstrated significantly better survival than the other groups (p<0.05; Figure 4). Across treatment regimens, median OS was ~36 months in the “3+7” group, ~9 months in the azacitidine + venetoclax group, and ~5 months in the azacitidine monotherapy group; the differences between groups were statistically significant (p<0.001; Figure 5).

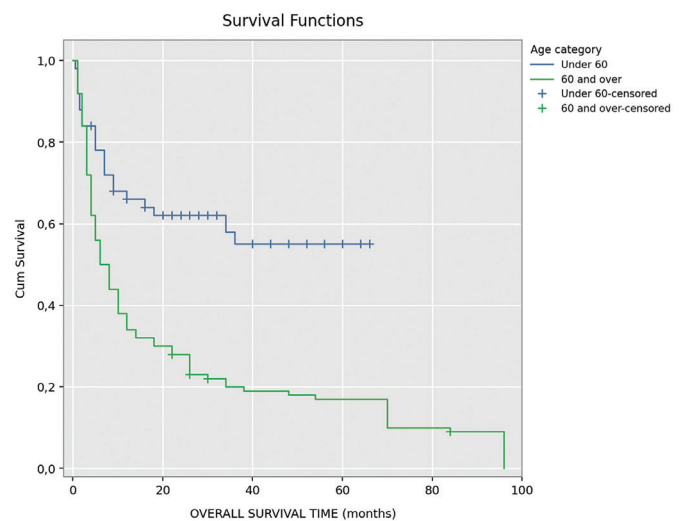


Figure 3. Survival curve according to age groups

Table 2. Distribution of molecular genetic results according to various parameters

Parameters		Adverse prognostic anomaly absent (n=38) n (%)	Adverse prognostic anomaly present (n=33) n (%)	p
Gender	Male	29 (76.3%)	14 (42.4%)	0.004
	Female	9 (23.7%)	19 (57.6%)	
Age*		57.0 (44.0-71.5)	68.0 (63.5-75.5)	0.003
Age groups	<60 years	22 (57.9%)	6 (18.2%)	0.001
	≥60 years	16 (42.1%)	27 (81.8%)	
ECOG	0	28 (73.7%)	13 (39.4%)	0.001
	1	9 (23.7%)	12 (36.4%)	
	2	0	7 (21.2%)	
	3	1 (2.6%)	1 (3.0%)	
Charlson Index*		3.0 (2.0-5.0)	5.0 (4.0-7.0)	0.001
Bone marrow blast percentage*		60 (32.5-79.0)	70.0 (34.5-85.0)	0.353

*: Median (25th-75th percentile). Chi-square test was used for categorical variables; Mann-Whitney U test was used for continuous variables [presented as median (25th-75th percentile)]

ECOG: Eastern Cooperative Oncology Group

In univariate analysis, factors adversely affecting OS included advanced age, a high Charlson Comorbidity Index, elevated creatinine level, low hemoglobin and low albumin levels, high ECOG performance status, an adverse ELN risk group, refractory disease, and sepsis ($p < 0.05$; Table 3). In the multivariate Cox regression analysis, only the Charlson Comorbidity Index [[hazard ratio (HR): 1.319; 95% confidence interval (CI): 1.169-1.488; $p < 0.001$] and the development of sepsis (HR: 1.967; 95% CI: 1.109-3.486; $p = 0.021$) emerged as independent poor prognostic factors.

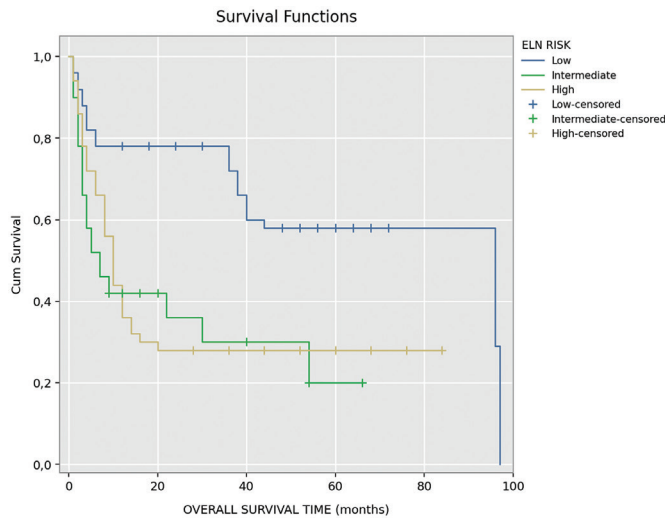


Figure 4. Overall survival curves according to ELN 2022 risk stratification
ELN: European LeukemiaNet

Discussion

Real-world data from the Trakya Region were used to evaluate the clinical and laboratory profiles, genetic characteristics, treatment-related complications, and survival outcomes of patients with AML. Laboratory findings at diagnosis were largely consistent with the literature [1,9]. In the older age group, thrombocytopenia, elevated creatinine levels, and decreased albumin levels were more pronounced. The correlation of these parameters with the Charlson Comorbidity

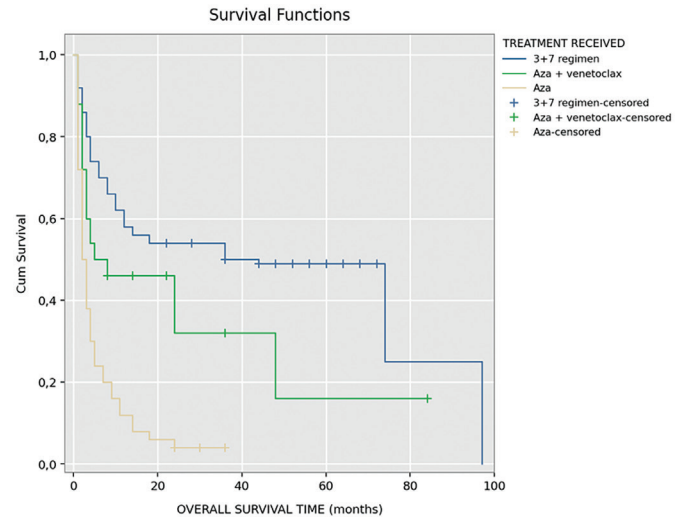


Figure 5. Overall survival curves according to treatment groups

Table 3. Distribution of numerical parameters in survivors and non-survivors

Parameter	Survivors	Non-survivors	p value
Age (years)	55.5 (42.25-67.50)	68.0 (57.75-75.25)	<0.001
Charlson Comorbidity Index	3.0 (2.0-4.0)*	5.0 (3.75-7.0)*	<0.001
Bone marrow blast percentage (%)	60.0 (32.8-80.0)	60.0 (30.0-80.0)	0.694
White blood cell count (/mm ³)	6850 (1950-27100)	12800 (2075-52775)	0.209
Hemoglobin (g/dL)	9.16±2.06	8.23±1.87	0.035
Hematocrit (%)	26.1 (23.30-30.38)	23.55 (21.28-27.35)	0.034
Platelet count (/mm ³)	50000 (27250-106750)	59500 (25750-102750)	0.730
Neutrophil count (/mm ³)	750 (125-3500)	1500 (300-5075)	0.172
Creatinine (mg/dL)	0.8 (0.70-0.87)	0.9 (0.70-1.10)	0.020
ALP (U/L)	69.5 (48.75-96.50)	75.0 (57.50-93.50)	0.658
GGT (U/L)	30.5 (16.0-64.75)	31.5 (22.0-48.25)	0.788
CRP (mg/L)	2.6 (0.52-8.1)	4.75 (1.46-13.92)	0.085
LDH (U/L)	370.0 (276.75-549.25)	493.0 (314.0-872.0)	0.059
Albumin (g/dL)	3.81±0.55*	3.50±0.57*	0.006

*: Mean ± standard deviation (SD); Ort (25th-75th percentile): median (25th-75th percentile), continuous variables with normal distribution were compared using the independent samples t-test (presented as mean ± SD); non-normally distributed continuous variables were compared using the Mann-Whitney U test [presented as median (IQR)]

ALP: Alkaline phosphatase, GGT: Gamma-glutamyl transferase, CRP: C-reactive protein, LDH: Lactate dehydrogenase

Index and age underscores the systemic effects of the disease and the prognostic importance of comorbidity burden.

Cytogenetic abnormalities were significantly more frequent among younger patients ($p=0.011$), whereas adverse molecular anomalies were associated with advanced age, a higher Charlson Comorbidity Index, and a higher ECOG performance status. This finding, using region-specific data, supports the prognostic value of the ELN 2022 risk classification based on molecular markers suggests that cytogenetic abnormalities in younger patients may indicate more aggressive disease subtypes.

Although our cohort was diagnosed between 2017 and 2021—a period during which both the ELN 2017 and ELN 2022 classifications were in clinical use—risk stratification in this analysis was performed retrospectively according to the updated ELN 2022 criteria. This decision was based on three considerations: first, the ELN 2022 update represents the current international standard for prognostic categorization in AML [1]; second, applying a uniform classification system across the entire cohort eliminates the heterogeneity that would arise from mixing two different risk frameworks; and third, the ELN 2022 criteria allow direct comparison of our findings with contemporary real-world data, including the recent nationwide Turkish AML registry analysis by Pinar et al. [11]. The principal differences between ELN 2017 and ELN 2022 that affected our cohort include: (i) the feline McDonough sarcoma-like tyrosine kinase 3-internal tandem duplication (FLT3-ITD) allelic ratio is no longer considered in risk classification, and all FLT3-ITD-mutated cases are assigned to the intermediate-risk group regardless of nucleophosmin 1 (NPM1) status; (ii) AML with NPM1 mutation accompanied by adverse-risk cytogenetic abnormalities is now reclassified as adverse risk; and (iii) only in-frame mutations affecting the basic leucine zipper region of CEBPA are categorized as favorable risk. These refinements provide a more accurate prognostic stratification that better reflects the current molecular understanding of AML.

Among treatment complications, febrile neutropenia (84.7%), sepsis (34.2%), and invasive fungal infections (23.4%) were the most common, with 63.1% of all deaths attributed to sepsis. In the study by Härmäläinen et al. [14]. Involving 84 patients, sepsis was observed in 35 cases, and 9 patients (25%) died due to this complication. Malik et al. [15] in a large cohort of 5,501 patients, sepsis was reported in 16% of cases, with a 30% mortality rate among those who developed sepsis. The sepsis rate was 34.2%, and the sepsis-related mortality rate was 39%. This relatively high rate may be explained by antibiotic consumption in Türkiye exceeding the European Union average [16] and by socioeconomic factors that complicate infection control. The higher incidence of typhlitis in the “3+7” regimen reflects the toxicity of intensive chemotherapy, while the lower complication profile observed with azacitidine ± venetoclax regimens is consistent with the literature [2].

Survival outcomes clearly demonstrated the decisive role of age and comorbidity burden. While the median OS for the entire cohort was approximately 34 months, it decreased to ~7 months in patients aged ≥ 60 years ($p<0.001$). In the meta-

analysis by Walter et al. [17], which included 6,283 patients from ECOG, Southwest Oncology Group, and MD Anderson Cancer Center studies, the 3-year OS rate was 10%, and the 5-year OS rate was 4.9% in patients over 60 years, compared with 28.3% and 22.9%, respectively, in those under 60 years. The relationship between lower ECOG performance status and improved survival (log-rank $p=0.001$) has also been reported in the literature [18]; this association is attributed to better tolerance of the administered treatment and fewer complications in patients with lower ECOG scores, who generally have less comorbidity. According to the ELN 2022 risk stratification, the median OS was ~56 months in the favorable-risk group, while the “3+7” regimen provided the best survival (~36 months) among fit patients. In the multivariate analysis, the Charlson Comorbidity Index (HR: 1.319; 95% CI: 1.169–1.488; $p<0.001$) and the development of sepsis (HR: 1.967; 95% CI: 1.109–3.486; $p=0.021$) were identified as independent poor prognostic factors. The addition of approximately 4 months to survival with the azacitidine + venetoclax combination supports the value of targeted therapies in unfit patients and is consistent with international randomized trials [2].

Study Limitations

The main limitations of this study include its retrospective design, single-center experience, and the availability of genetic/molecular data for only 60–65% of patients. This resulted in incomplete evaluation of certain adverse molecular markers, particularly myelodysplasia-related mutations. Nevertheless, the strengths of the study lie in providing real-world data from the underrepresented Trakya Region, in the detailed examination of the relationship between treatment complications and survival, and in its representation as a regional reference center.

Conclusion

Our regional data confirm the impact of age and comorbidity burden reported in international studies. The results support the preference for low-intensity regimens in older patients and those with a high comorbidity burden, while emphasizing the clinical importance of an individualized treatment approach. Our data represent the first comprehensive survival analysis specific to the Trakya Region and serve as a foundation for future prospective and multicenter studies.

Ethics

Ethics Committee Approval: The study was approved by the Trakya University Faculty of Medicine Scientific Research Ethics Committee (approval no: 15/01, date: 14.09.2020).

Informed Consent: Retrospective study.

Footnotes

Authorship Contributions

Concept: A.M.D., Design: A.M.D., Data Collection or Processing: F.Y., Analysis or Interpretation: F.Y., A.M.D., Literature Search: F.Y., Writing: F.Y.

Conflict of Interest: No conflict of interest was declared by the authors.

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