AHOT | Acta Haematologica Oncologica Turcica

Acta Haematol Oncol Turc

Original Article

DOI: 10.4274/ahot.galenos.2026.2026-2-1

Retrospective Evaluation of Patients with Acute Myeloid Leukaemia in the Trakya Region of Türkiye

Faruk Yıldız[1], Ahmet Muzaffer Demir[2]

[1]*Trakya University Faculty of Medicine, Department of Internal Medicine, Edirne, Türkiye*
[2]*Trakya University Faculty of Medicine, Division of Hematology, Edirne, Türkiye*

ABSTRACT

Aim: Acute myeloid leukaemia (AML) is an aggressive haematological malignancy that primarily affects older adults. Its prognosis varies widely depending on cytogenetic and molecular risk profiles, as well as age, performance status, and comorbidities. This study aimed to examine the demographic and clinical characteristics, treatment responses, and prognostic factors of patients diagnosed with AML at the Haematology Clinic of Trakya University Health Application and Research Hospital and to assess their role in treatment decision-making.

Methods: This retrospective cohort study included 111 patients (out of 185 adults aged ≥18 years diagnosed between 2017 and 2021) for whom complete data were available. The diagnosis was established according to the World Health Organization 2016/2022 criteria. Collected data encompassed age, gender, Eastern Cooperative Oncology Group (ECOG) performance status, Charlson comorbidity index, European LeukemiaNet 2022 risk group, induction therapies, and treatment response. Statistical analyses were conducted using SPSS v.26; $p<0.05$ was considered significant.

Results: The median age was 66 years, with 59.5% of patients aged 60 or older. The male-to-female ratio was 1.36. Among the patients, 46% were from outside Trakya (Edirne: 29%; Kırklareli: 17%) and 8% were from abroad. Annual incidence ranged from 5.9 to 7.4 per 100,000. Among the 80 evaluable patients, 66.3% (n=53) achieved complete remission (CR), 2.5% had a partial response, and 31.3% had refractory disease. In the CR group, age and Charlson comorbidity index were significantly lower, while the proportion with ECOG 0 was significantly higher ($p=0.016$). The "3+7" regimen achieved a markedly higher CR rate than hypomethylating agent monotherapy ($p=0.002$); azacitidine + venetoclax showed comparable efficacy to "3+7" ($p=0.431$).

Conclusion: Advanced age and a high comorbidity burden adversely affect treatment response. The "3+7" regimen remains the gold standard for fit patients, while azacitidine + venetoclax emerges as a promising, lower-toxicity alternative for elderly or unfit individuals. This study provides the first comprehensive real-world AML data from our region and may serve as a foundation for prospective research.

Keywords: Acute myeloid leukaemia, cytogenetics, prognosis, Trakya, venetoclax

Introduction

Acute myeloid leukaemia (AML) is a heterogeneous group of aggressive haematological malignancies that typically occur in older adults. It is characterised by the uncontrolled clonal proliferation of leukemic cells in the bone marrow, along with impaired maturation of myeloid progenitor cells, leading to their accumulation there and, less commonly, in extramedullary tissues.

The aetiology involves multiple contributing factors, including genetic abnormalities (such as chromosomal translocations and gene mutations), exposure to ionising radiation, and prior treatment with certain chemotherapeutic agents (especially alkylating agents or topoisomerase II inhibitors).

AML is the common type of acute leukaemia in adults, accounting for roughly 80% of cases in this age group [1,2]. In contrast, it accounts for less than 10% of acute leukaemias in children under 10 years old. Globally, the incidence is reported to be about 3-5 cases per 100,000 population [3-5]. According to global data, the median age at diagnosis among adults is approximately 65 years, with 60% of patients aged 65 or older. However, in Türkiye, the average age is slightly younger,

Address for Correspondence: Faruk Yıldız MD, Trakya University Faculty of Medicine, Department of Internal Medicine, Edirne, Türkiye
E-mail: faruk_yildiz@hotmail.com **ORCID ID:** orcid.org/0009-0008-4530-8558
Received: 03.02.2026 **Accepted:** 10.03.2026 **Epub:** 30.03.2026

Cite this article as: Yıldız F, Demir AM. Retrospective evaluation of patients with acute myeloid leukaemia in the Trakya region of Türkiye. Acta Haematol Oncol Turc. [Epub Ahead of Print]

at around 58 years, and 45.5% of cases occur in people aged 60 and above [6]. The incidence rises sharply with age: it's approximately 2 per 100,000 in those under 65, but increases to around 20 per 100,000 in those over 65 [7]. The male-to-female ratio is approximately 5:3. While AML epidemiology in Türkiye follows similar global patterns, national registry data indicate that the median age at diagnosis is somewhat lower than in many other countries [6].

Mortality increases with age, and about 72% of deaths occur in people aged 65 years and older. The average age at death for AML patients is around 72 years.

Treatment decisions depend on several factors, including the patient's overall performance status, comorbidity burden, and cytogenetic/molecular risk profile. The classic induction regimen "3+7" (cytarabine plus an anthracycline) remains curative in fit patients. For older adults, those with high comorbidities, or frail individuals, lower-toxicity options like hypomethylating agent (HMA) (e.g., azacitidine or decitabine) tend to take priority. In recent years, adding venetoclax to these HMA regimens has yielded promising results, thereby opening a valuable new treatment pathway, particularly for patients who are not candidates for allogeneic stem cell transplantation. When considering intensive chemotherapy for AML, clinicians should assess two key criteria to determine the patient's tolerance to the treatment. The patient's performance status, as measured by the Eastern Cooperative Oncology Group (ECOG) score [8], and the presence of comorbidities that may affect life expectancy, evaluated using the Charlson comorbidity index [9], should always be carefully reviewed.

This retrospective study, drawing on hospital-based data, aims to evaluate the demographic and clinical characteristics and treatment responses of patients diagnosed with AML in the Trakya region over 5 years, thereby contributing to national AML data in Türkiye.

Methods

This retrospective cohort study included 111 of 185 adults aged 18 years and older diagnosed with AML between January 2017 and December 2021, for whom complete clinical and laboratory data were available. TThese patients were seen at the Haematology Clinic, Division of Internal Medicine, Trakya University Faculty of Medicine. Ethical approval for this study was obtained from the Scientific Research Ethics Committee of the Faculty of Medicine, Trakya University, and the study was conducted in accordance with the principles of the Helsinki Declaration (decision no: TÜTF-BAEK 2020/350, date: 14.09.2020). Committee under protocol number 2020/350.

AML diagnosis was established according to the World Health Organisation 2016/2022 classification systems [10, 11]. Bone marrow aspiration and biopsy were performed in patients presenting with laboratory abnormalities such as anaemia (Hb <12 g/dL), thrombocytopenia (<100,000/mm^3), thrombocytosis (>450,000/mm^3), leukopenia (<4,000/mm^3), or leukocytosis (>10,000/mm^3). The diagnosis relied primarily on the presence of blast cells constituting ≥20% of total bone marrow cellularity, along with immunophenotyping results (by flow cytometry) consistent with AML. In cases where defining genetic abnormalities were present (e.g., specific translocations), the blast threshold was evaluated according to the revised criteria [12]. The demographic characteristics of the patients, performance status (ECOG score [8]), comorbidity burden (Charlson comorbidity index [9]), and European LeukemiaNet 2022 risk groups, as well as administered induction therapies, treatment responses, and complications, were retrospectively collected in anonymised form from the electronic medical record system.

Statistical Analysis

Statistical analyses were performed using SPSS version 26; p values <0.05 were considered statistically significant.

Results

Demographic characteristics are summarised in Table 1. Among the patients, 64 (57.7%) were male and 47 (42.3%) were female, yielding a male-to-female ratio of 1.36. The median age of the cohort was 66 years (25th-75th percentiles: 48.0-75.0). When stratified by gender, median ages were 60 years (47-71.8) in males and 68 years (56-76) in females. Patients were dichotomised at 60 years: 45 patients (40.5%) were <60 years old, while 66 patients (59.5%) were ≥60 years old. Among females, 70.2% (n=33) were in the ≥60 years group, compared with 51.6% (n=33) of males; this difference was statistically significant (chi-square test: χ^2=3.910, p=0.048). The distribution of patients by place of residence was as follows: 29% from Edirne, 17% from Kırklareli, 10% from İstanbul, 8% from Tekirdağ, 8% from abroad, 6% from Çanakkale, 2% from Bursa, and the remaining 20% from various other provinces in Türkiye (each contributing <1%). The proportion of patients coming from outside the Trakya region was 46%. The geographic distribution of patients' residences is shown in Figure 1.

As shown in Figure 2, in 2017, of 444,515 patients presenting to our hospital, 9,178 were referred to the haematology clinic and 33 were diagnosed with AML. Among 521,876 hospital admissions in 2018, 9,650 patients were seen in Haematology, of whom 31 received an AML diagnosis. Of 554,764 hospital admissions in 2019, 11,662 were managed in haematology and AML was confirmed in 40 patients. In 2020, of the 367,393 total presentations, 8,685 were evaluated by haematology, which resulted in 26 AML diagnoses. Of 455,409 hospital admissions in 2021, 10,163 patients were referred to haematology and 32 were diagnosed with AML. The crude, age-independent AML incidence rates at our hospital (per 100,000 hospital admissions) were calculated as follows: 7.4 in 2017, 5.9 in 2018, 7.2 in 2019, 7.0 in 2020, and 7.0 in 2021 (Figure 3). The incidence rate was determined using the formula: (incidence rate per 100,000) = (number of new AML cases diagnosed in that year ÷ total number of patients presenting to the hospital in that year) ×100,000.

Among the 80 patients for whom response evaluation was possible, the complete remission (CR) rate was 66.3% (n=53). This group included 29 patients aged <60 years and 24 aged ≥60 years. Partial response (PR) was observed in only 2 patients (2.5%), whereas the non-responsive group comprised 25 patients (31.3%), with 8 in the <60 years group and 17 in the ≥60 years group. Given the small number of partial responders, patients were classified into two groups: CR and non-responders. The distributions of demographic and clinical parameters for the two groups are shown in Table 2. The distribution of administered treatment regimens was as follows: 20 patients (18%) received the azacitidine + venetoclax combination and 28 patients (25.2%) received azacitidine monotherapy. Among cases achieving CR, those on azacitidine ± venetoclax regimens accounted for 22.6% of the group.

When evaluating responses to induction therapy, non-responders were significantly older and had higher Charlson index scores than complete responders. For ECOG scores, the categories "1," "2," and "3" were combined for analysis, and the complete response group had a notably higher proportion of patients with a score of "0" than the non-responsive group (p=0.016). In subgroup analysis by treatment received, the complete response rate in the "3+7" treatment group was significantly higher than that in the azacitidine monotherapy group (p=0.002). No significant difference in response rate was found between the "3+7" group and the azacitidine + venetoclax group (p=0.431). Similarly, there was no significant difference in treatment response rates between the azacitidine monotherapy group and the azacitidine + venetoclax group.

Discussion

AML is an aggressive haematological malignancy that typically occurs in older adults, and its treatment is individualised based on factors such as age, performance status, comorbidities, and cytogenetic and molecular risk profile. The classic

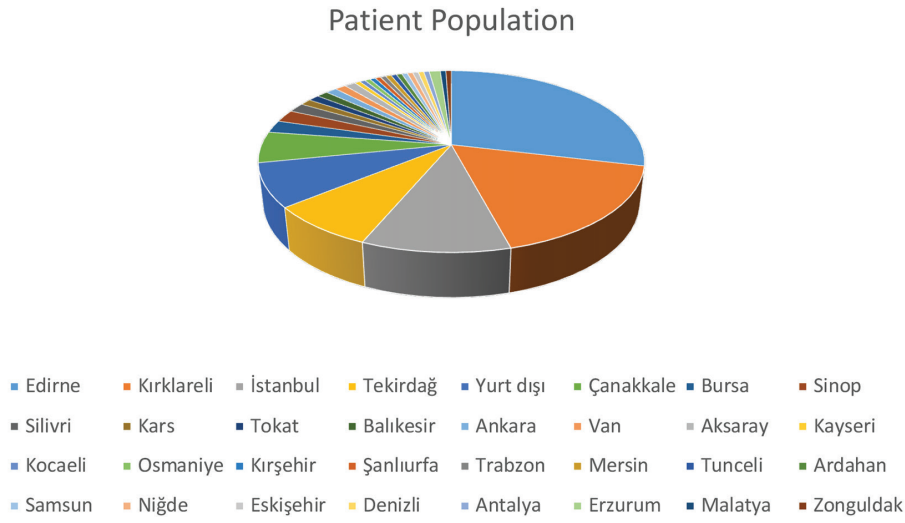

Figure 1. Distribution of patients according to their place of residence

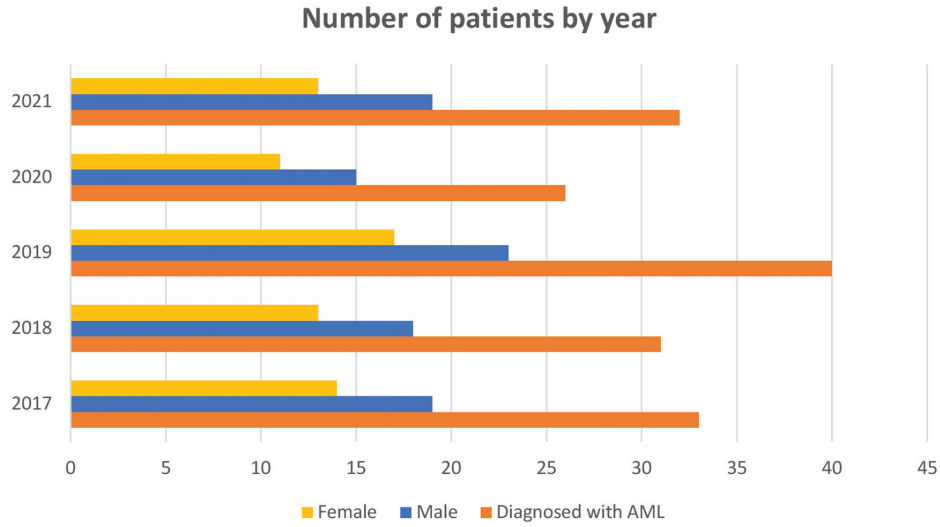

Figure 2. Number of patients by year
AML: Acute myeloid leukaemia

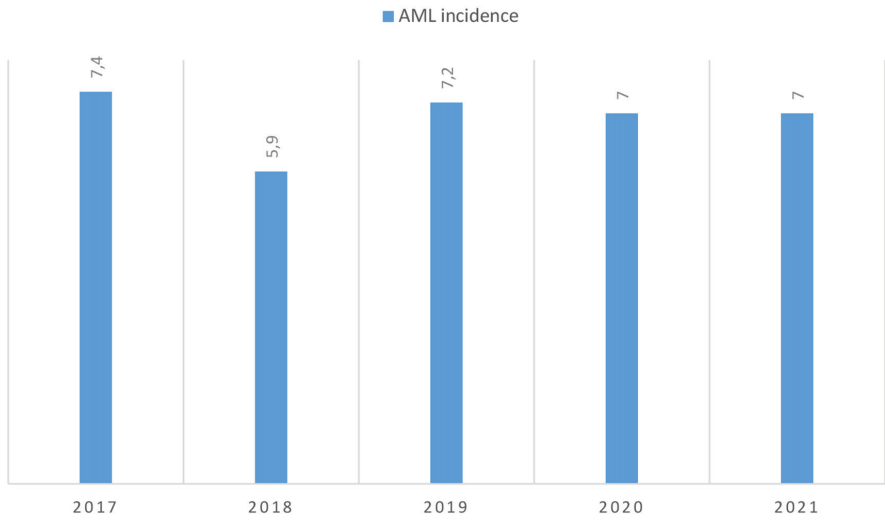

Figure 3. AML incidence by year
AML: Acute myeloid leukaemia

"3+7" induction regimen still holds curative potential in fit patients, whereas in elderly and frail individuals, HMA-based therapies come to the forefront due to their lower toxicity. In recent years, the addition of venetoclax to HMAs has notably improved response rates and survival, particularly among patients ineligible for allogeneic transplantation. This study retrospectively evaluated the demographic, clinical, and therapeutic characteristics of 111 patients with AML diagnosed in the Trakya region, thereby highlighting the role of prognostic factors in treatment response.

Globally, the incidence of AML has been gradually increasing over the past few years. According to the Global Burden of Disease (GBD) 2017 data, the number of new cases increased from approximately 63,840 in 1990 to 119,570 in 2017, representing an 87.3% increase. More recent GBD 2021 analyses indicate a rise from 79,372 cases in 1990 to 144,645 cases in 2021 (an 82% increase). This upward trend is largely attributable to population growth and ageing [13]. Higher case numbers have been reported in Western Europe and South Asia. At the country level, India, China, and the United States (USA) stand out as the countries with the highest absolute numbers of cases. According to the United States National Cancer Institute (NCI) SEER data, the incidence rate during 2012-2016 was 4.3 cases per 100,000 population per year. The most recent SEER data for 2018-2022 show that this rate has remained stable at the same level (4.3 per 100,000) [13,14]. In our study, the hospital-based crude incidence rates ranged from 5.9 to 7.4 per 100,000 admissions. This figure likely reflects the referral pattern to our tertiary referral centre, which receives more advanced-stage cases. 46% of patients came from outside the Trakya Region, and 8% from abroad, highlighting that our centre has become a leading and trusted institution in regional health tourism.

According to an analysis of NCI SEER-21 data, the median age of patients diagnosed with AML was 68 years [15]. In a Turkish study by Medeni et al. [16], a 2015 study including 140 patients reported a median age of 53±15.3 years. Another local study by Cömert et al. [17], published in 2014 and comprising 87 patients, reported a mean age of 52.44 years. In our group of 111 patients, the median age was 66,0 years (25^{th}-75^{th} percentile: 48-75), being 60,0 years (47-71.8) for males and 68,0 years (56-76) for females, as shown in Table 1. The interim results of the Turkish Society of Haematology AML registry study [6], which included 891 patients, reported a median age of 58 years (45.5% aged ≥60 years). The higher age at diagnosis in our Trakya cohort may reflect regional demographic differences, such as an older population and referral patterns to our tertiary centre. According to NCI SEER-21 data, the male-to-female ratio among AML patients is 1.44 [15]. In our study, 64 patients (57.7%) were male and 47 (42.3%) were female, yielding a male-to-female ratio of 1.36, consistent with existing literature. Patients in the studies by Medeni et al. [16] and Cömert et al. [17] were notably younger than those in our series, whereas our median age and gender distribution align more closely with international figures.

Table 1. According to the studies, the median age

	Median age (years)
NCI SEER 21 [15]	68
Medeni et al. [16]	53±15.3
Cömert et al. [17]	52.44
TSD AML Working group [6]	58
Our study	66

NCI: National Cancer Institute, AML: Acute myeloid leukaemia, TSD: Turkish Society of Hematology

Among patients for whom response evaluation was possible, the CR rate was 66.3%, consistent with rates reported in large series. In the study by Chang et al. [18]. Among 379 patients, the CR rate was 59.8%. In our series, PR remained limited (n=2,

2.5%); therefore, the patients were divided into two groups—CR and non-responsive—and the distribution of parameters between these groups is presented in Table 2. Twenty patients (18%) received the azacitidine + venetoclax regimen, and 28 patients (25.2%) received the azacitidine monotherapy. Among the cases achieving CR, these regimens accounted for 22.6% of the total. Response rates by treatment group are also shown in Figure 4.

In recent years, the identification of genetic abnormalities and recognition of the role of hypermethylation in pathophysiology have led to the introduction of new treatment modalities. The incorporation of the two molecules classified as HMAs has been shown to alter the course of myeloproliferative disorders [19]. This observation aligns with findings from randomised trials, such as VIALE-A, supporting the view that the HMA + venetoclax combination represents an effective alternative for low-intensity treatment [12].

Study Limitations

The main limitations of this work are: the limited number of patients in our study, the predominance of the "3+7" protocol among participants, and the absence of subgroup analysis of induction treatment response by cytogenetic risk group. In patients over 60 years of age, treatment with HMA is considered an important option because of its markedly lower complication rate compared to the "3+7" regimen.

Table 2. Patient characteristics according to induction response

Parameters		Grouping based on induction response		p
		Complete response (%)	Non-response (%)	
Gender	**Male**	32 (60.4)	14 (56.0)	0.714
	Female	21 (39.6)	11 (44.0)	
Age		59.0 (43.0-69.0)*	69.0 (53.0-76.5)*	**0.025**
Age groups	**<60 years**	29 (54.7)	8 (32.0)	0.061
	≥60 years	24 (45.3)	17 (68.0)	
ECOG	**0**	40 (75.5)	12 (48.0)	-
	1	10 (18.9)	7 (28.0)	
	2	2 (3.8)	5 (20.0)	
	3	1 (1.9)	1 (4.0)	
Charlson index		3.0 (2.0-4.0)*	4.0 (3.0-6.0)*	**0.037**
Treatmet	**3+7**	39 (73.6)	11 (44.0)	-
	Azacitidine	6 (11.3)	10 (40.0)	
	Azacitidine + venetoclax	6 (11.3)	3 (12.0)	
	3+7+ ATRA**	2 (3.8)	1 (4.0)	

*: Median (25.-75. percentile), **: ATRA: All-trans retinoic acid, ECOG: Eastern Cooperative Oncology Group

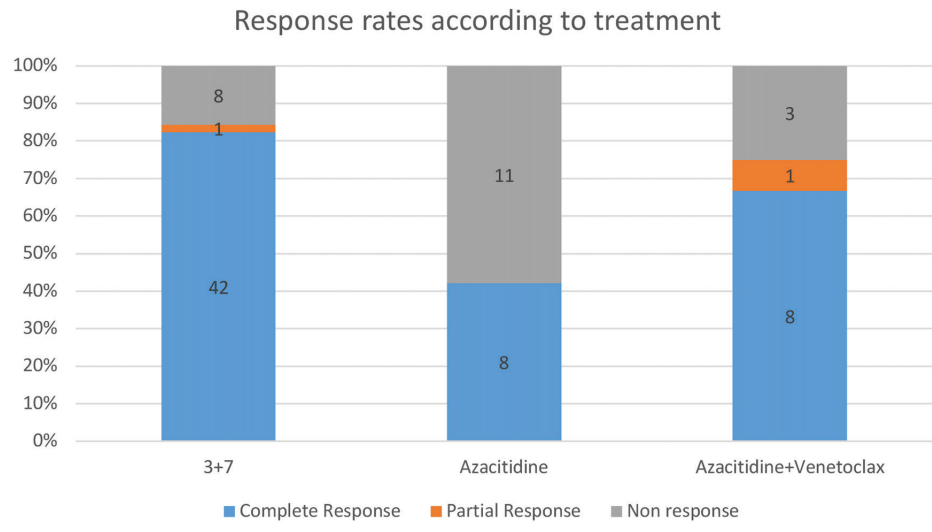

Figure 4. Response rates accordin

Conclusion

In this retrospective study, the demographic distribution, year-by-year incidence, and referral patterns of AML patients diagnosed in the Trakya region were evaluated with respect to age, performance status, comorbidities, and treatment regimens, revealing significant associations with treatment response. The findings confirm that AML is predominantly a disease of advanced age and that the age at diagnosis is significantly higher among female patients. The age and gender ratios observed in our study were consistent with those reported in the national and international literature. Furthermore, the fact that a substantial proportion of AML cases presenting to our hospital originated outside the Trakya region, both indicates that our centre has become a regional referral hub and reflects the trust placed in the healthcare services we provide. The increase in diagnosed cases over the years suggests improvements in both diagnostic capabilities and the capacity of our haematology clinic.

The strong negative associations between age and comorbidity index scores and between age and treatment response, once again, underscore the importance of individualised treatment approaches. The “3+7” regimen remains effective in younger, medically fit patients, whereas the azacitidine + venetoclax combination is a promising alternative for older adults and those with significant comorbidities. These data constitute the first comprehensive dataset of demographic and therapeutic information specific to our region and provide a foundation for future studies.

Ethics

Ethics Committee Approval: Ethical approval for this study was obtained from the Scientific Research Ethics Committee of the Faculty of Medicine, Trakya University, and the study was conducted in accordance with the principles of the Helsinki Declaration (decision no: TÜTF-BAEK 2020/350, 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.

Financial Disclosure: The authors declared that this study received no financial support.

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