Research Square

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Efficacy and Safety of Azacitidine Plus Low-dose Dasatinib Maintenance Therapy for Patients with Intermediate and High-risk Acute Myeloid Leukemia: A Prospective, Randomized, Phase Clinical Trial

Jinli Jian
The First Clinical Medical College of Lanzhou University
Xiao Tang
The First Clinical Medical College of Lanzhou University
Yuancheng Guo
The First Hospital of Lanzhou University
Long Zhao
The First Clinical Medical College of Lanzhou University
Shujuan An
The First Clinical Medical College of Lanzhou University
Bei Liu
liubei@lzu.edu.cn
The First Clinical Medical College of Lanzhou University

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Abstract

Purpose

Acute myeloid leukemia (AML) is a hematological malignancy with a high recurrence rate, particularly in intermediate and high-risk AML patients. Therefore, maintenance therapy is particularly important. Azacitidine (AZA) monotherapy maintenance can significantly improve the prognosis of AML patients. The second-generation tyrosine kinase inhibitors (TKIs) combined with demethylating agents have exhibited a significant synergistic effect in promoting apoptosis and reducing methylation. Therefore, we reported the efficacy and safety of AZA combined with low-dose Dasatinib in the maintenance treatment of AML.

Methods

In this single-center, prospective, randomized phase II trial, newly diagnosed AML patients aged 18 to 76 years with intermediate-high risk were assigned (2:1) to receive either AZA (75 mg/m²/day, d1-d5) or AZA (75 mg/m²/day, d1-d5) plus Dasatinib (20 mg orally, d1-d28) with negative MRD status after induction and consolidation therapy (NCT05042531).

Results

The median overall survival (mOS) was 26 months (95% confidence interval, 18.9–33.1 months) in the AZA group, whereas the mOS was not reached in the AZA + Dasatinib group (p = 0.038). DFS did not differ significantly between the groups (p = 0.25). Hematological adverse events (AEs) occurred in 65% (13/20) of the AZA group versus 90% (9/10) of the AZA + Dasatinib group (p = 0.210). No patient discontinued the treatment due to adverse reactions. AZA in combination with low-dose

Conclusions

Dasatinib as a maintenance treatment exhibits promising efficacy and is well-tolerated in intermediate and high-risk AML patients. This combination may be a novel treatment option for AML patients.

Introduction

Acute myeloid leukemia (AML) is a highly heterogeneous malignant clonal hematopoietic stem cell disease. Following conventional induction chemotherapy, 70% of young patients and 50% of elderly patients achieve complete remission (CR), which is subsequently followed by consolidation therapy to maintain long-term minimal negative residual disease (MRD) status[1, 2]. However, for the intermediate and high-risk patients, the relapse rate can be as high as 60%, with disease-free survival (DFS) of less

than one year[3, 4], indicating a poor prognosis. Preventing relapse presents a significant therapeutic challenge following remission. Allogeneic stem cell transplantation (ASCT) remains a potentially curative therapy during the remission phase; however, due to limited donor availability, age, comorbidities, and performance status, only a small proportion of patients can be cured through transplantation[5, 6]. Consequently, maintenance therapy is particularly crucial for intermediate and high-risk AML patients, new treatment strategies are needed to improve the clinical treatment outcomes for AML patients.

As a demethylating agent, azacitidine (AZA) exerts direct cytotoxic effects while also activating tumor suppressor genes by targeting DNA methylation, thereby promoting myeloid maturation and differentiation[7, 8]. A clinical study on oral azacitidine (CC486) showed that compared with the placebo group, the overall survival (OS) and median relapse-free survival (RFS) in the CC486 group were significantly improved[9]. As early as 1988, Cassileth PA [10]et al. discovered that maintenance therapy for AML could prolong the disease-free survival period (DFS) of patients and delay the recurrence of the disease. All of the above studies have demonstrated that azacitidine maintenance therapy benefits patients with AML.

Dasatinib, a second-generation tyrosine kinase inhibitor (TKI), primarily targets the BCR-ABL fusion protein, c-KIT, FLT3, platelet-derived growth factor receptors (PDGFR) and other Src family kinases (SFKs), thereby inhibiting the tyrosine kinase signaling pathway[11, 12]. Previous studies have demonstrated that TKIs not only suppress the abnormal activation of the tyrosine kinase signaling pathway but also reduce DNA methylation levels. When combined with demethylating agents, TKIs exhibit a synergistic effect in promoting apoptosis and further decreasing methylation levels[13]. A clinical study involving 81 patients initially diagnosed with CBF-AML revealed that, following induction and consolidation therapy, patients receiving Dasatinib maintenance therapy achieved a CR/CRi of 94%, with a cumulative relapse rate of 33.1%, a mortality rate of 6%, and a 4-year OS rate of 74.7%[14]. These results indicate that Dasatinib holds promising application prospects in the treatment of AML. However, there remains a lack of clinical trials regarding the use of AZA combined with Dasatinib for maintenance therapy. Therefore, in this study, we randomly assigned AML patients who achieved CR and were negative MRD after induction and consolidation therapy to receive either AZA monotherapy or AZA combined with Dasatinib as post-remission maintenance treatment. The objective of this study is to evaluate the efficacy of maintenance therapy concerning the primary endpoint (OS) and secondary endpoints (DFS and safety), providing a novel strategy for AML treatment.

Methods

Participants

The inclusion criteria for patients in this study were as follows: (1) patients with AML classified as intermediate or high risk according to the 2022 European Leukemia Net (ELN) risk stratification, aged ≥ 18 years; (2) Patients who achieved CR following induction chemotherapy and consolidation therapy,

with negative MRD by flow cytometry and none of the patients had undergone hematopoietic stem cell transplantation prior to enrollment, due to financial constraints, patient preference, or significant comorbidities that precluded transplantation; (3) Patients were required to have Eastern Cooperative Oncology Group (ECOG) performance-status scores of 0 to 2 and (4) adequate cardiac, pulmonary, hepatic, and renal function, specifically defined as follows: left ventricular ejection fraction greater than 50%, New York Heart Association (NYHA) functional class I or II, absence of cardiac conduction block and arrhythmias; absence of severe restrictive or obstructive pulmonary disease; total bilirubin levels not exceeding two times the upper limit of normal, alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels below 2.5 times the upper limit of normal; and serum creatinine levels not exceeding 1.5 times the upper limit of normal. The exclusion criteria included: patients with concurrent malignancies in other organs, uncontrolled hepatitis B or C virus infections, human immunodeficiency virus infection, and women who were pregnant or lactating.

Study design and treatment

This prospective, randomized controlled phase II study was conducted in the department of Hematology at the First Hospital of Lanzhou University. Patients were randomly assigned, in a 2:1 ratio, to receive either 12 cycles of AZA (75 mg/m², administered subcutaneously on days 1 to 5) or a combination of AZA and Dasatinib (AZA at 75 mg/m², subcutaneously on days 1 to 5; Dasatinib at 20 mg orally from days 1 to 28). Since our research presents preliminary results from a Phase II clinical trial, the dosage requires further verification. Moreover, due to safety concerns regarding the combined medication, the number of participants in the experimental group was reduced. The COVID-19 also affected the study, as many patients needed to take Paxlovid, which has a compatibility contraindication with TKIs. This limitation further restricted the use of the combined treatment regimen, therefore, we used 2:1 ratio to receive AZA and AZA+Dasatinib. Each treatment cycle lasted 28 days. Maintenance therapy could be interrupted or delayed due to grade 3 or 4 toxicity, and the dose of AZA in subsequent cycles could be adjusted to either 50 mg/m² or 37.5 mg/m² per day. Dasatinib remained at a constant dose of 20 mg. Dasatinib 100 mg maintenance therapy has been associated with a significant increase in adverse reactions among AML patients, leading to reduced treatment compliance. Furthermore, lowering the dose of dasatinib does not compromise its efficacy in chronic myeloid leukemia (CML). In addition, comparison with single-agent maintenance therapy suggests that combination therapy may result in increased toxic effects. Therefore, we have decided to reduce the dasatinib dose to 20 mg. Before randomization, all patients received 1–2 cycles of induction therapy and 4–6 cycles of consolidation therapy. The study was approved by the ethics committees of the participating institutions (LDYYLL2020-273) and was conducted according to the Declaration of Helsinki. Written informed consent was obtained from all patients. The study has been registered with the U.S. Clinical Trials Registry (NCT05042531) and the Chinese Clinical Trial Registry (ChiCTR2100042418).

End points

The primary endpoint of this study is to evaluate the OS of AML patients who received maintenance therapy with either AZA monotherapy or a combination of AZA + Dasatinib. OS is defined as the time from the maintenance therapy until the patient's death from any cause or the last follow-up date. Secondary endpoints include DFS, two-year mortality, relapse rate, and the safety profile of the AZA + Dasatinib combination therapy. DFS is defined as the interval from the initiation of maintenance therapy to disease relapse. Relapse is defined as a bone marrow puncture revealing a blast cell proportion exceeding 5% unrelated to hematopoietic recovery, or the occurrence of extramedullary disease. The duration of continuous complete remission is calculated from the date of enrollment to the date of relapse. During treatment, routine blood tests are conducted weekly for the first two cycles. Subsequently, these tests are performed biweekly. Bone marrow aspiration was performed after completion of the first cycle and subsequently at intervals of at least three cycles, or earlier in cases of disease progression, unexplained cytopenia, or leukocytosis.

Statistical analysis

Baseline data were classified into quantitative and qualitative variables. For quantitative variables that followed a normal distribution, t-tests were used for intergroup comparisons. Qualitative changes were analyzed using chi-square tests. Descriptive statistics, including the median, were applied to summarize patient characteristics, with ranges indicating continuous variables and frequencies (%) representing categorical variables. OS and DFS were assessed using the Kaplan-Meier method, and survival distributions were compared using stratified log-rank tests. All statistical analyses were performed using GraphPad Prism version 8. Sample-size calculations were based on a one-sided alpha of 0.025.

Results

Patients

From April 2020 to April 2024, a total of 33 patients were randomly assigned to two groups: the AZA group, which included 22 patients, and the AZA combined with low-dose Dasatinib group, which consisted of 11 patients. Of these, 2 patients in the AZA group and 1 patient in the AZA + Dasatinib group did not receive any treatment due to withdrawal of consent (Fig. 1). Follow-up continued until April 2025, and no patients were lost to follow-up. In the AZA group, two patients (10%) discontinued the trial due to a relapse of AML. Similarly, in the AZA combined with Dasatinib group, two patients (20%) also discontinued the trial for the same reason.

Baseline characteristics were generally balanced between the groups (Table 1). The median age was 42 years (range, 21-60.5) in the AZA group and 49 years (range, 44.3–53) in the AZA + Dasatinib group, with 50% males in both groups. All patients were negative MRD at the time of enrollment. Morphological characteristics in the AZA group were M2 (50%), M4 (15%), and M5 (35%), while in the AZA + Dasatinib group, they were M2 (60%), M4 (20%), and M5 (20%). Both groups received a median of 12 cycles of AZA. The molecular and genetic profiles of the two groups were generally comparable. In the AZA group,

the most frequent mutations were FLT3-ITD (20%), DNMT3A (20%), NPM1 (20%), and CEBPA (30%). In the AZA + Dasatinib group, FLT3-ITD (20%), IDH2 (20%), TET2 (20%), C-KIT (20%), and CEBPA (20%) were more commonly observed. No evident imbalance in the distribution of genetic mutations was identified between the two groups.

Table 1
Patients baseline characteristics

Characteristics	AZA	AZA + Dasatinib	*P* value
n	20	10	
Median age (range)	42 (21–59)	49 (46–52)	0.330
Sex, n (%)			1.000
Female	10 (50%)	5 (50%)	
Male	10 (50%)	5 (50%)	
FAB classification, n (%)			0.766
M2	10 (50%)	6 (60%)	
M4	3 (15%)	2 (20%)	
M5	7 (35%)	2 (20%)	
Gene mutation			
FLT3-ITD	4 (20%)	2 (20%)	1.000
IDH1	2 (10%)	0	0.540
IDH2	1 (5%)	2 (20%)	0.251
TET2	3 (15%)	2 (20%)	1.000
TP53	1 (5%)	0	1.000
DNMT3A	4 (20%)	1 (10%)	0.640
ASXL1	2 (10%)	0	0.540
C-KIT	0	2 (20%)	0.103
NPM1	4 (20%)	0	0.272
CEBPA	6 (30%)	2 (20%)	0.675
AML-ETO	2 (10%)	2 (20%)	0.584
ELN risk stratification, n (%)			1.000
Intermediate	17 (85%)	8 (80%)	
adverse	3 (15%)	2 (20%)	

FAB: French–American–British; ELN: European Leukemia Net

Characteristics	AZA	AZA + Dasatinib	*P* value
The number of AZA cycles (range)	12 (6–14)	12 (7–15)	0.676
Receipt of two or more courses of induction chemotherapy, n (%)			0.700
Yes	9 (45%)	6 (60%)	
No	11 (55%)	4 (40%)	
Prior use of FLT3 inhibitor during induction and/or consolidation treatment, n (%)			0.140
Yes	5 (25%)	0 (0%)	
No	15 (75%)	10 (100%)	
FAB: French–American–British; ELN: European Leukemia Net			

Overall Survival

Regarding the primary endpoint of OS. With a median follow-up of 24.5 months (range, 13.3 to 40 months). In the AZA group, a total of 4 patients (20%) died during the study period. Among these, one patient died of severe pulmonary aspergillosis, two patients died due to disease relapse or progression, and one patient died of neutropenia-associated infection. In the AZA plus Dasatinib group, one patient (10%) died due to severe thrombocytopenia complicated by intracranial hemorrhage. The median overall survival (mOS) in the AZA group was 26 months (95% confidence interval: 18.9–33.1 months), whereas the mOS in the AZA + Dasatinib group was not reached, indicating a statistically significant difference between the two groups (log-rank test, p = 0.038, 95% confidence interval: 0.03–0.96) **(**Fig. 2**)**. The 2-year overall survival rate was 79.5% for the AZA group and 90% for the AZA + Dasatinib group.

Disease-free survival (DFS)

The secondary endpoints included DFS and Adverse Events (AEs). Regarding DFS, in the AZA group, 6 patients (30%) experienced a relapse and in the AZA combined with Dasatinib group, 2 patients (20%) also experienced a relapse, with relapses occurring at 9 and 10 months post-maintenance therapy. The median DFS was 24 months in AZA group while was not reached in combination group.There was no statistically significant difference in the DFS curves between the two groups (p = 0.25, 95% confidence interval: 0.21–11.7) **(**Fig. 3**).** In the AZA group, four of the patients did not receive any treatment after the recurrence, while two patients were treated with the CLAG regimen. In the AZA + dasatinib group, one patient received no treatment, while the other patient was treated with the FLAG regimen. The lack of significant difference in DFS may be related to the small sample size and the short follow-up period.

AEs

There were more AEs of any type in the AZA + Dasatinib group. Specifically, 13 patients (65%) in the AZA group experienced adverse events of any grade, while in the AZA + Dasatinib group, 9 patients (90%) reported such events; however, this difference was not statistically significant (p = 0.210). Furthermore, in hematology-related adverse reactions, neutropenia was the most common. In the AZA group, any grade neutropenia occurred in 55% of patients, with grade 3 or 4 neutropenia accounting for 35%. In the AZA + dasatinib group, any grade neutropenia occurred in 80% of patients, with grade 3 or 4 neutropenia accounting for 60%, all of which were manageable; no patients discontinued treatment because of AEs. Among the AZA + Dasatinib group, the most prevalent non-hematological AEs included liver function impairment (30%), hyperuricemia (20%), and nausea (20%) **(**Table 2**).**

Table 2
Treatment-related adverse events.

AEs	AZA group		AZA + Dasatinib group	
Hematological	Any grade, n (%)	Grade 3 or 4, n (%)	Any grade, n (%)	Grade 3 or 4, n (%)
Neutropenia	11 (55%)	7 (35%)	8 (80%)	6 (60%)
Anemia	4 (20%)	3 (15%)	0 (0%)	0 (0%)
Thrombocytopenia	7 (35%)	4 (20%)	3 (30%)	2 (20%)
Non-hematological				
Liver function impairment	4 (20%)	0 (0%)	3 (30%)	0 (0%)
Nausea	1 (5%)	0 (0%)	2 (20%)	0 (0%)
Infection	1 (5%)	0 (0%)	0 (0%)	0 (0%)
Hyperuricemia	0 (0%)	0 (0%)	2 (20%)	0 (0%)
Abnormal coagulation	0 (0%)	0 (0%)	1 (10%)	0 (0%)

Discussion

This study provided the evidence from a randomized trial evaluating the combination of AZA and Dasatinib as a maintenance therapy for intermediate and high-risk AML patients. The results showed that, among intermediate- and high-risk AML patients who achieved CR with negativity MRD after induction and consolidation therapy, the maintenance therapy combining AZA and Dasatinib significantly improved OS compared to AZA alone. It was also observed that the AZA combination of Dasatinib was ineffective in prolonging DFS. The primary reason for discontinuation of study treatment was disease progression (13%). Additionally, through an analysis of serious adverse events (SAEs). Maintenance

therapy combining AZA with low-dose Dasatinib was generally feasible and well tolerated, with manageable adverse events. No patients discontinued the treatment due to significant hematological toxicity.

Patients who cannot undergo HSCT due to factors such as age, lack of suitable donors, or comorbidities face a high risk of relapse after achieving remission. In recent years, despite implementing various preventive measures, the relapse rate following complete remission has remained high[15]. To tackle this issue, we proposed a novel maintenance treatment regimen specifically designed for patients with intermediate and high-risk AML. A previous study had demonstrated that among patients receiving oral AZA therapy, 21.0% experienced a relapse. The real-world relapse-free survival rate and OS rate at 12 months following the initiation of treatment were 66.9% and 74.5%, respectively[16]. These findings further substantiate the efficacy of AZA as a standard maintenance therapy for AML patients in remission who have not undergone HSCT. These observations form the basis for the current research using azacitidine. Dasatinib is a second-generation TKI. Research has shown that dasatinib can induce apoptosis through the MCL1-dependent pathway, effectively overcoming the resistance to AML associated with BCL2 inhibition[17]. A related Phase II clinical trial is currently in progress, with a focus on recruiting patients. In addition, Dasatinib and Chidamide exhibit synergistic antitumor effects. Studies have demonstrated that the combination of Dasatinib and Chidamide significantly enhances the HDAC inhibitory activity of Chidamide, promotes apoptosis and cell cycle arrest in AML cells, and concurrently strengthens the inhibitory effect on the proliferation of leukemia stem cells[18]. This demonstrates the value of Dasatinib in combination therapy for AML. Marcucci G and colleagues demonstrated that the combination of Dasatinib with chemotherapy significantly enhances the CR, the three-year OS, and the DFS in patients with CBF-AML during consolidation and maintenance therapy. Furthermore, patients harboring KIT mutations exhibited prognoses comparable to those with wild-type KIT[19], indicating that Dasatinib can overcome the adverse prognosis caused by KIT mutations, thereby providing a therapeutic advantage for these patients.

In our study, we found that the mOS for patients treated with AZA alone was 26 months, the mOS for patients treated with Dasatinib in combination with AZA has not yet been reached, indicating a significant survival advantage for the combination therapy. This result suggested that Dasatinib could substantially improve OS for the high-risk AML patients. We discovered that the combination of AZA and Dasatinib does not prolong DFS compared to AZA alone, which differs from the results of Marcucci G's study. This discrepancy may be because Dasatinib was only used as maintenance therapy in our investigation. As a result, further studies with larger sample sizes are needed to explore this issue. This suggests that incorporating Dasatinib into maintenance treatment may provide greater benefits for female patients.

Regarding adverse events, our study indicated that the most prevalent adverse events associated with the combination of AZA and Dasatinib maintenance therapy are hematologic, specifically neutropenia, anemia, and thrombocytopenia. Nonetheless, the incidence of severe hematologic adverse events is low,

and all reactions remain manageable, with no patients discontinuing treatment due to these adverse effects. Consistent with our findings, a French phase II study on CBF-AML reported that Dasatinib, when used as a single-agent maintenance therapy, is safe, exhibiting a severe adverse reaction rate of 19%[20]. In the CALGB 10801 study, six patients experienced pleural effusion after receiving Dasatinib[19], however, pleural effusion was not observed in our study, which may be attributed to differences in Dasatinib dosage. In summary, the combination of AZA and Dasatinib as maintenance therapy is both safe and feasible. Nevertheless, this study has certain limitations, in this study, significant OS benefit was observed without a corresponding significant DFS benefit. We believed the lack of difference in DFS could be attributed to the small sample size and the short follow-up duration. Future clinical studies with larger sample sizes are required to validate these conclusions.

Declarations

The study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of the First Hospital of Lanzhou University (LDYYLL2020-273).

Informed consent

All patients gave written informed consent.

Competing interests

The authors declare no competing interests.

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Author Contribution

The trial was designed by J.L.J., X.T., and B.L. Material preparation and data collection were performed by J.L.J., X.T., Y.C.G., L.Z., and S.J.A. J.L.J. and X.T. performed data analysis. The first draft of the manuscript was written by J.L.J. and X.T., and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Data Availability

The datasets generated and analyzed during this study are available from the corresponding author on reasonable request.

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Figures

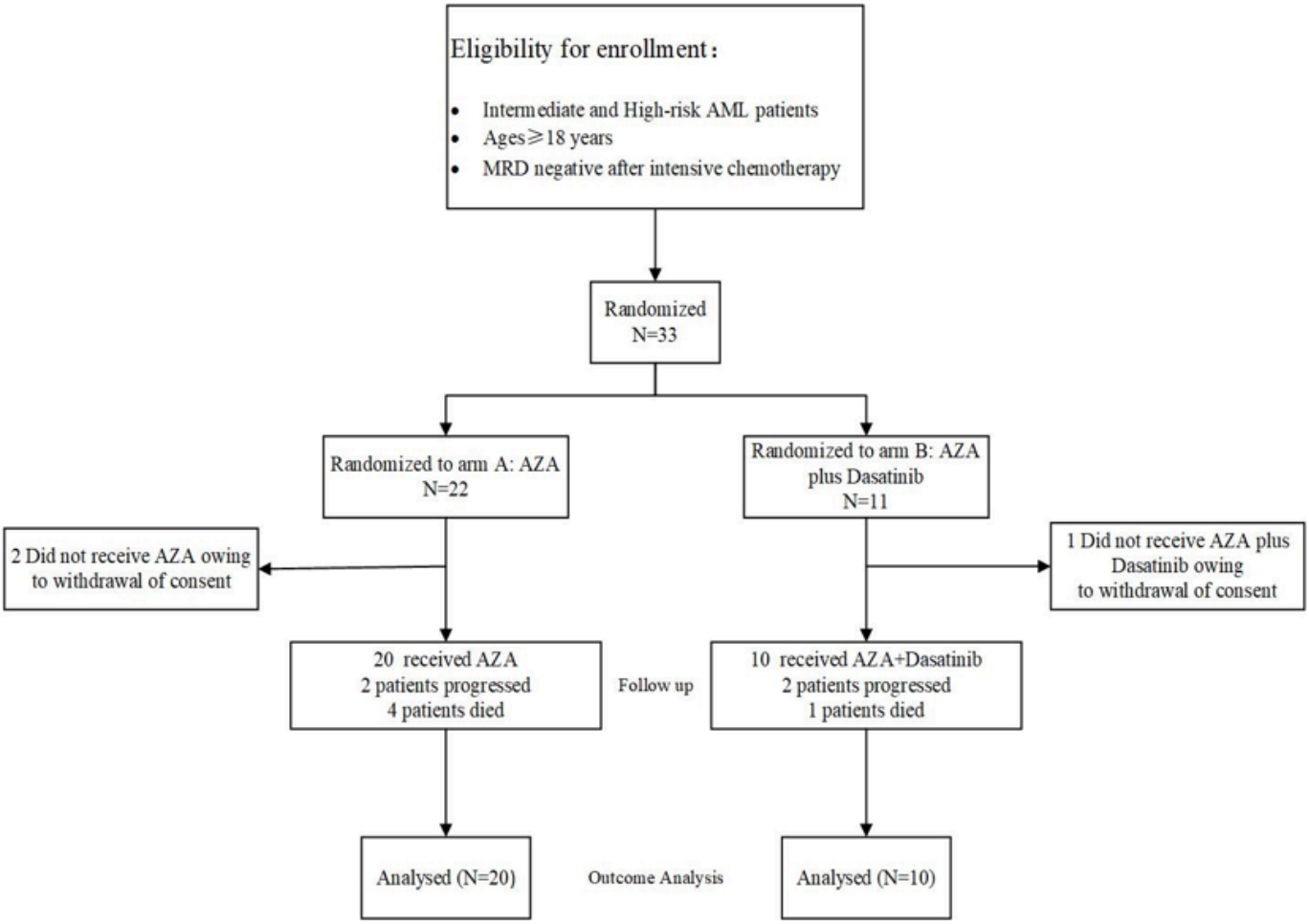


Figure 1

CONSORT study diagram

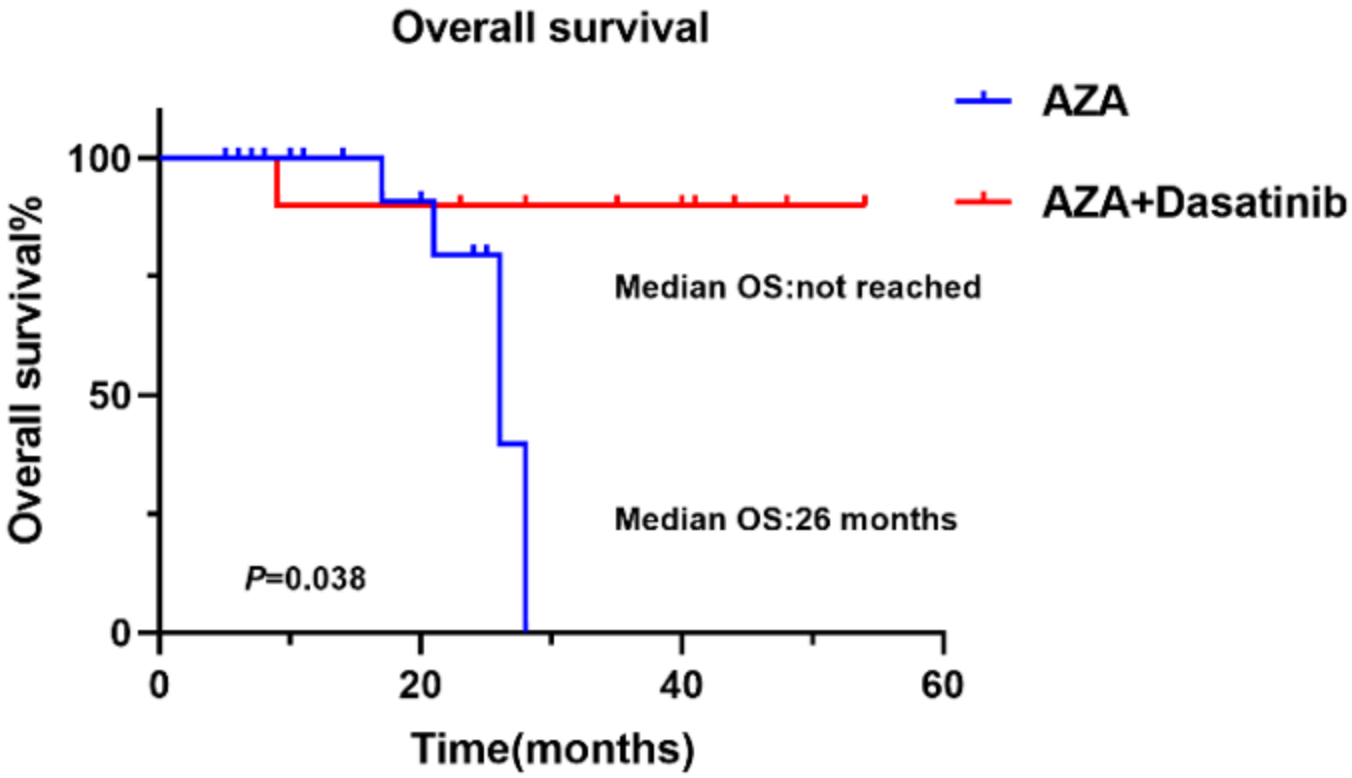


Figure 2

Kaplan Meier curves for overall survival. Red denotes the AZA + Dasatinib arm, and blue denotes the AZA arm

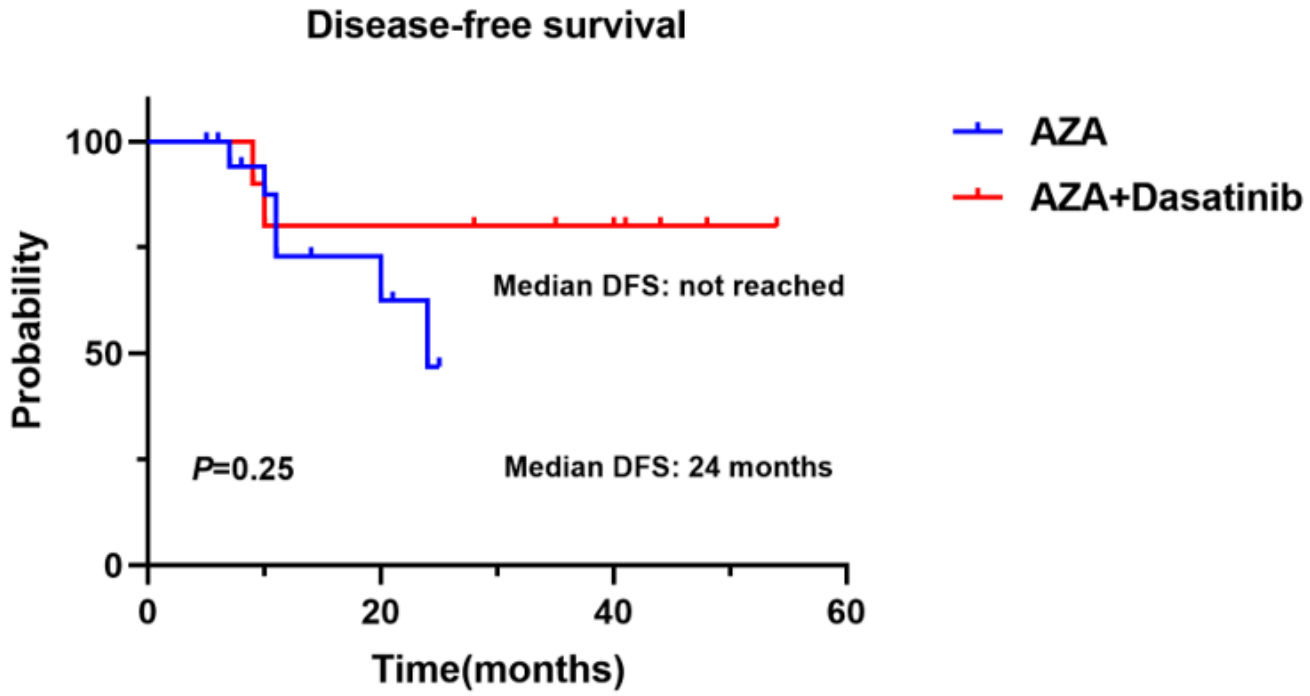


Figure 3

Kaplan-Meier estimates of DFS. DFS of all randomized patients (AZA: n=20, AZA + Dasatinib: n=10)