

Maternal and Fetal Outcomes in Pregnant Women with Acute Leukemia

Fangfang Jian¹, Li Chen², Yan Liu¹, Chenmin Yang¹

¹Department of Obstetrics and Gynecology, Ruijin Hospital Affiliated to Shanghai Jiao Tong University School of Medicine, Shanghai, 200025, People's Republic of China; ²Department of Hematology, Ruijin Hospital Affiliated to Shanghai Jiao Tong University School of Medicine, Shanghai, 200025, People's Republic of China

Correspondence: Chenmin Yang, Department of Obstetrics and Gynecology, Ruijin Hospital Affiliated to Shanghai Jiao Tong University School of Medicine, No. 197 Ruijin Er Road, Shanghai, 200025, People's Republic of China, Tel +8621 64370045, Email ycm1185@rjh.com.cn

Aim: Acute leukemia (AL) during pregnancy is a rare condition with limited evidence-based information available on the management. The study aims to analyze the pregnancy and fetal outcomes of pregnant women with acute leukemia diagnosed during pregnancy.

Methods: In this retrospective study, 18 pregnant women who were diagnosed with AL during pregnancy from January 2013 to January 2024 were reviewed.

Results: Of these patients, 6 delivered before chemotherapy while 12 received chemotherapy after induced abortion. Six fetus were born through spontaneous delivery or cesarean section, and one died 3 days after birth. Fourteen patients (77.8%) were found to have decreased platelets by full blood count test. The delivery group had a longer gestational age, longer time from pregnancy termination to chemotherapy compared to the abortion group. The median age of the rest 5 newborns was 32 months. Five newborns were healthy without any deformities or developmental issues. With a median follow-up of 3 years, the overall survival (OS) rates for 18 patients with acute leukemia were estimated at 88.2%. Patients in the delivery group had a significantly lower OS rate compared to those in abortion group. Overall, starting chemotherapy as soon as possible can improve OS rates for pregnant women with AL.

Conclusion: Collectively, we suggest that for pregnant patients diagnosed in early or late stages of pregnancy (after 30 weeks), opting for termination of pregnancy before starting chemotherapy could lead to better outcomes for the mothers.

Keywords: acute leukemia, pregnancy, maternal outcomes, fetal outcomes

Background

The incidence and types of cancer in pregnant women are comparable to those in non-pregnant women of the same age.¹ Solid tumors account for the majority of pregnancy-associated cancers, while hematologic malignancies represent around 25% of cases.² Leukemia during pregnancy is estimated to occur in 1 in 75,000 to 100,000 pregnancies, with acute myeloid leukemia (AML) being the most common type. Acute leukemia (AL) is more frequently diagnosed in the second and third trimesters, with a lower incidence in the first trimester.³⁻⁵ Managing acute leukemia in pregnancy necessitates a nuanced, multidisciplinary approach tailored to maternal health, and fetal viability.

Due to the rarity of AL during pregnancy, there is a lack of prospective clinical trials, and most data came from retrospective studies and case reports. Consequently, there is insufficient evidence to establish a definitive association between pregnancy and AL.

Recent advancements in AL treatment have significantly improved long-term survival of patients, with increasing attention to individualized therapy during pregnancy.^{1,6} The management of AL during pregnancy typically depends on several factors, including the gestational age at diagnosis, disease characteristics, and potential toxicity treatment options.⁷⁻⁹ In this study, we summarized 18 cases of AL diagnosed and treated at our institution during pregnancy, aiming to provide valuable insights into the clinical management of AL in pregnant patients.

Methods

Patients

Data was collected from patients diagnosed with AL (de novo, secondary, or relapse AML and acute lymphoblastic leukemia (ALL)) during pregnancy at our center between January 2013 and August 2024. The diagnosis and classification of all AL cases adhered to the WHO (2016) guidelines.^{10,11} Bone marrow aspiration performed under local anesthesia is safe during pregnancy and poses no harm to the fetus. This study was approved by the Ethics Committee of Ruijin Hospital, affiliated to Shanghai Jiao Tong University, in accordance with the Declaration of Helsinki (no. 2025–343).

The cohort included heterogeneous subtypes of acute leukemia—AML, acute promyelocytic leukemia (APL), and Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL). Given the rarity of AL in pregnancy and the very small number of cases for each subtype, these diseases were analyzed as a combined cohort to allow a meaningful description of overall maternal and fetal outcomes, while subtype-specific clinical characteristics were documented separately where relevant.

Treatment Strategy

Pregnant women with AL were closely monitored by experienced obstetricians specializing in complicated pregnancies. Treatment plans were individualized based on each patient's condition. For women diagnosed with AL in the first trimester, induced abortion was typically recommended prior to initiating leukemia treatment. For those diagnosed in the second or third trimester, initiating leukemia treatment before considering pregnancy termination was an option. Treatment regimens were selected according to leukemia subtype. All patients with APL received induction based on an all-trans retinoic acid- (ATRA-) and arsenic trioxide- (ATO-) containing regimen combined with chemotherapy, tailored according to gestational age. All patients with Ph+ ALL were treated with tyrosine kinase inhibitor (TKI)-based protocols combined with multi-agent chemotherapy and steroids. Among patients with non-APL AML, nine received standard anthracycline-plus-cytarabine (3+7) induction, whereas one patient was treated with decitabine plus cytarabine, aclacinomycin, and G-CSF (CAG) due to clinical considerations. All four ALL patients underwent allogeneic hematopoietic stem cell transplantation (allo-HSCT) in first complete remission, and five AML patients proceeded to allo-HSCT either in remission or after relapse.

Clinical Definition

The efficacy of AL treatment was evaluated based on complete remission (CR) and overall survival (OS). OS was defined as the time from AL diagnosis to death or the last follow-up. The AML patients were classified into favorable, intermediate, or adverse-risk levels, respectively, according to European LeukemiaNet (ELN) 2022 risk stratification criteria.¹² The Sanz risk score is used to classify patients with an APL diagnosis into three risk categories: low, intermediate, and high risk.

Statistics

Continuous variables were compared using independent samples t-tests or the Mann–Whitney *U*-test. If the variables were normally distributed, they were expressed as the mean $\pm$ standard deviation. If they were non-normally distributed, they were expressed as medians. GraphPad Prism 10 was used to estimate OS curves, and the Log rank test was used to compare survival curves. *P* values less than 0.05 were deemed statistically significant.

Results

Clinical Characteristics of AL Patients

This study included 18 pregnant women diagnosed with AL, with a median age of 28 years (range: 22–42 years). Among these, 22% (4/18) were aged over 30 years. Of the patients, 56% (10/18) were primiparous, and 44% (8/18) were multiparous. The onset of leukemia presented in various ways: 8 patients had no obvious symptoms, with abnormalities detected in routine pregnancy blood tests; 10 patients presented with symptomatic onset, including 5 with bleeding, 4

with infection, and 1 who sought medical attention due to an acute ovarian torsion. The median gestational age at diagnosis was 22.3 weeks (range: 5.7–33.0 weeks). Specifically, 6 patients were diagnosed in the early pregnancy phase (0–12 weeks), 7 in the mid-pregnancy phase (13–27 weeks), and 5 in the late pregnancy phase (28 weeks and beyond).

There were 17 cases of newly diagnosed AL and 1 case of relapse. Of these, 16 were de novo and 2 were secondary AL: 1 from chronic myelogenous leukemia (CML) to ALL, and the other from chronic myelomonocytic leukemia (CMML) to AML. As for the leukemia subtypes, 10 patients had non-acute promyelocytic leukemia (non-APL) AML (short as AML), 4 had APL, and 4 had Philadelphia chromosome-positive ALL (ph+ ALL). In the 10 AML patients, genetic testing revealed CEBPA bZIP mutations in 3, AML1:ETO in 2, NPM1 mutation in 2, and KMT2A rearrangements in 3. Of the 9 de novo AML patients, 6 (67%) were classified as favorable risk, 1 (11%) as intermediate risk, and 2 (22%) as adverse-risk according to European LeukemiaNet (ELN) 2022.¹³ The 4 APL patients were classified as 3 Sanz intermediate risk, 1 high risk. The 4 ph+ ALL patients were classified as 3 standard risk and 1 high risk.

At the time of diagnosis, the median levels of white blood cells, hemoglobin, platelets, and bone marrow blasts were $12.51 (1.38–232.8) \times 10^9/L$, 96 g/L (52–111 g/L), $42 (8–244) \times 10^9/L$, and 75.5% (16.5–96%), respectively. The main clinical features at onset are summarized in Table 1.

Treatment Regimen

Seventeen patients were diagnosed with leukemia during pregnancy, and in 1 case, pregnancy was discovered after leukemia diagnosis. Four APL patients received induction therapy first, followed by abortion or delivery. The remaining 14 patients began leukemia treatment after termination of pregnancy. Among them, the median time from delivery to the start of leukemia treatment was 20 days (range: 10–30 days) in 5 patients. In the rest 9 cases, the median time from abortion to chemotherapy was 7 days (range: 4–11 days). The giving birth group had longer time from pregnancy termination to chemotherapy ($P = 0.0012$) (Table 2), compared to the abortion group.

Induction therapy regimens were as follows: for AML, 9 patients received idarubicin plus cytarabine (3+7), and 1 received decitabine plus CAG. Among APL patients, 1 received chemotherapy, 1 received ATRA plus daunorubicin, and 2 received ATRA, ATO and idarubicin. All ph+ ALL patients received tyrosine kinase inhibitor (TKI)-based therapy with steroids: 2 received flumatinib plus prednisone (pred), 1 dasatinib plus pred, and 1 imatinib plus vincristine and pred. One AML patient died during induction therapy from septic shock caused by lung infection and cellulitis. While the patients achieved CR and proceeded to consolidation therapy. All 4 ALL patients and 5 AML patients underwent allogeneic hematopoietic stem cell transplantation (HSCT). One AML patient undergoing HSCT after relapse, while the others underwent HSCT in CR.

Pregnant Outcomes

All the eighteen patients decided to receive induction therapy after giving birth or abortion. Six patients gave birth, 1 by vaginal and other 5 by cesarean section. Twelve patients received induced abortion. All 6 patients in the first trimester underwent abortion to terminate the pregnancy. In the second trimester, one baby (1/7, 14.29%) was born. There were 5 babies born during the third trimester. The characteristics of delivery group or abortion group are listed in Table 2. The giving birth group had a longer gestational age (median, 32 weeks vs 16 weeks, $P = 0.003$), compared to the abortion group. The other characteristics were similar in both groups.

Maternal Outcomes

As of August 30, 2024, the median follow-up was 31.3 months (range: 1.1–134.6 months). Three AML patients relapsed: 1 relapsed 4.7 months after CR and has remained in remission post-HSCT; another relapsed 3.7 months after CR, joined a CAR-T trial due to lack of a donor. The third relapsed 10.5 months after CR and died 1 month later from uncontrolled leukemia.

The overall 10-year estimated overall survival (OS) for all patients was 88.2% (Figure 1A). There were significant differences in OS between the giving birth group and abortion group (OS: 66.67% VS 100%, 95% CI 1.062 to 379.9, HR 20.1, $P = 0.046$) (Figure 1B). Subgroup analysis showed that the 4-year OS for ALL and APL patients was 100%, while it was 77.14% for AML patients ($p = 0.16$) (Figure 1C). Median follow-up time was 39 months for all the patients.

Table 1 Characteristics of Pregnant Patients with Acute Leukemia

Patient No.	Monter's Age	Pregnancy	Weeks of Pregnancy at Diagnose	Months of Follow-Up	Pregnant Outcomes	Interval Between Delivery or Abortion and Chemotherapy (Day)	Blast Cell in Bone Marrow	WBC Count×10 ⁹ /L	Hgb (g/L)	Plt Count×10 ⁹ /L	AL Type	ELN/Sanz Risk	Symptom	Current Status	H SCT
1	27	G1P0	32	37.3	Delivery	30	55.60%	28	110	90	AML-M5	Adverse	Whole blood cell decrease	Alive	Yes
2	28	G2P0	32	11.6	Delivery	20	76.90%	23.08	79	46	AML-M5	Favorable	Platelet decrease intensively since 16 gestational weeks	Dead	No
3	30	G2P0	29	22.7	Delivery	10	58.50%	24.01	102	121	AML-M4	Favorable	Cough with WBC increasing dramatically	Alive	Yes
4	25	G1P0	33	22.7	Delivery	12	27.30%	41	71	24	AML-M4	Favorable	Platelet decrease since 32 gestational weeks	Alive	Yes
5	25	G2P1	33	134.6	Delivery	During pregnancy	87.60%	3.92	59	32	AML-M3	Intermediate	Petechia in thigh	Alive	Yes
6	28	G3P1	27	1.1	Delivery	24	53.76%	49.9	77	14	AML-M0	Favorable	Nausea and vomit with oral ulcer	Dead	No
7	29	G2P1	5	121.5	Abortion	During pregnancy	85.00%	1.2	92	35	AML-M3	Intermediate	Poor appetite, petechia, vaginal bleeding	Alive	No
8	34	G2P0	26	53.7	Abortion	8	0.26%	232.8	97	14	ALL ph+	Standard	Limb petechia	Alive	Yes
9	29	G3P1	25	51.2	Abortion	5	44.50%	1.52	52	16	AML-M0	Favorable	Abnormal chromosome in NIPT	Alive	No
10	30	G3P1	21	48.2	Abortion	8	90.80%	9.22	99	37	ALL-L2 ph+	Standard	Limb petechia since 19 gestational weeks	Alive	Yes
11	38	G7P2	8	33.2	Abortion	7	90.70%	1.4	94	13	AML-M3	Intermediate	WBC and platelet decreased in regular prenatal check	Alive	No
12	39	G3P2	6	29.4	Abortion	During pregnancy	90.00%	4.2	62	62	AML-M4	Favorable	Decreased platelet with fever	Alive	No
13	22	G2P0	6	16.8	Abortion	4	71.00%	107.36	117	73	CML->ALL	High	Decreased platelet	Alive	Yes
14	28	G1P0	20	14.3	Abortion	9	79.50%	25.24	94	204	ALL ph+	Standard	Abnormal chromosome in NIPT	Alive	Yes
15	42	G2P1	12	116.4	Abortion	11	6.80%	11.1	98	46	CMML->AML	Favorable	Decreased platelet	Alive	Yes
16	28	G1P0	23	6.8	Abortion	7	93.50%	59	99	133	AML-M4	Adverse	Sore throat	Alive	Yes
17	25	G2P0	8	7.9	Abortion	4	88.30%	13.3	101	65	AML	Favorable	Decreased platelet	Alive	No
18	25	G1P0	21	59.7	Abortion	During pregnancy	90.30%	9.31	125	13	AML-M3	High	Gums and nose bleeds for half a month, skin petechiae, with headache	Alive	No

Notes: Data were shown in median value. Threshold for cytopenias <100×10⁹.

Abbreviations: G, gravidity; P, parity.

Table 2 The Characteristic Differences Between Pregnant Patients with Acute Leukemia in the Delivery and Abortion Groups

Characteristics	Delivery (n = 6)	Abortion (n = 12)	P
Maternal age (years)	27.50	29.00	0.19
First trimester	0	5	
Second and third trimester	6	7	
Weeks of pregnancy at diagnose	32	16	0.0003
WBC	26.01	10.21	0.69
Hgb	78.00	93.00	0.28
Plt	39.00	41.50	0.86
BM blast (%)	59.94	69.22	0.55
ALL	0	4	
AML	5	5	
APL	1	3	
Medium time to Chemo(day)	20	7	0.0012
HSCT	3	6	

Fetal Outcomes

Out of the 18 singleton pregnancies, 6 live newborns were delivered. The characteristics and outcomes of these neonates born to mothers with acute leukemia are detailed in Table 3. The median gestational age at birth was 32 weeks (range:

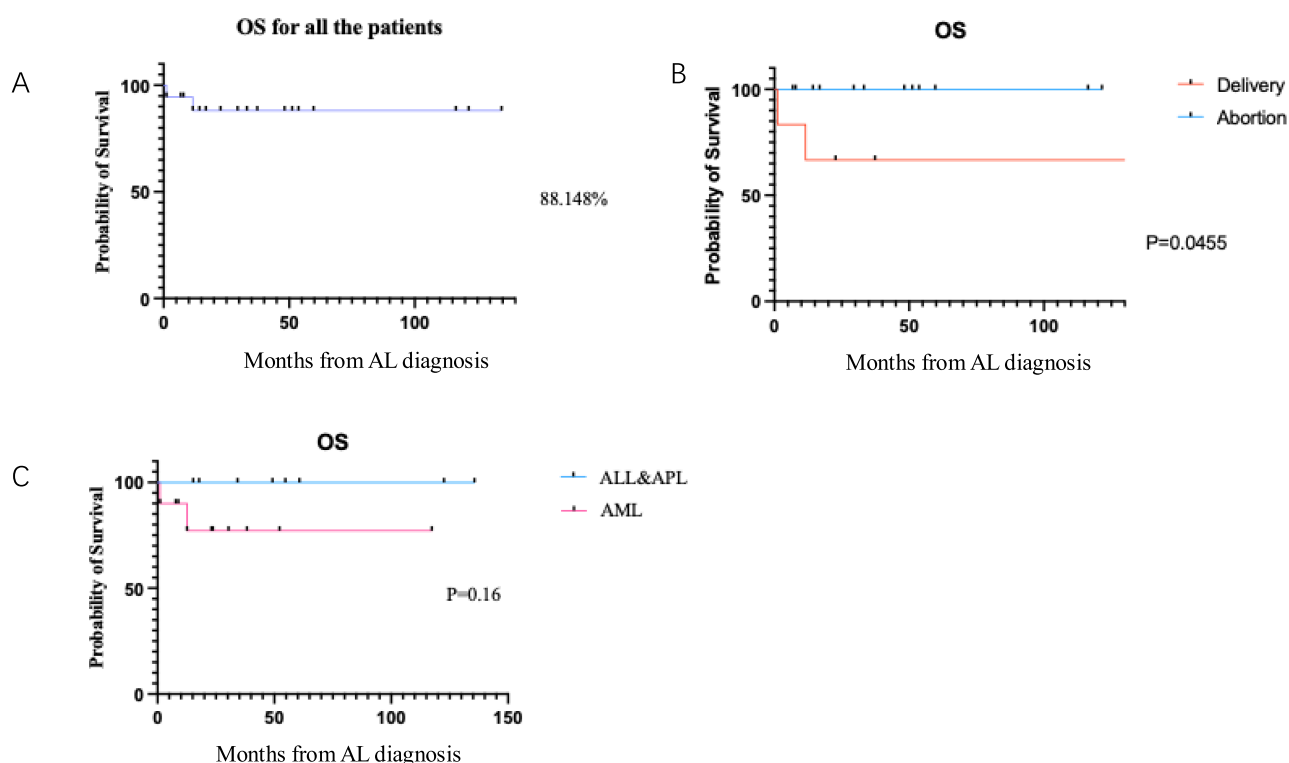


Figure 1 Survival outcome for the 18 AL patients. **(A)** Kaplan–Meier estimate of OS in the 18 patients. **(B)** Kaplan–Meier plots of OS in the delivery and abortion groups. **(C)** Kaplan–Meier plots of OS in the ALL&APL patients and AML patients.

Table 3 Current Status of Newborn

Case No.	Subtype of Mother	Delivery Mode	Gestational Weeks at Birth	Newborn Weight (g)	Gender	Apgar Score	Outcomes
1	AML-M5	Caesarian section	32	1990	Male	10	Alive
2	AML-M5	Caesarian section	32	2010	Female	10	Alive
3	AML-M4	Caesarian section	29	1210	Male	8	Alive
4	AML-M4	Caesarian section	33	2040	Female	10	Alive
5	AML-M3	Vaginal delivery	33	1900	Female	10	Alive
6	AML-M0	Caesarian section	27	950	Male	1	Died 3 days after birth

27 weeks to 33 weeks) and the median birth weight was 1945 g (range: 950 to 2040 g). All of the newborns were preterm. There was one (16.7%) infant with ultralow birth weight and five with low birth weight (83.3%). One newborn died three days after birth. At the last follow-up, the median age of the rest 5 newborns was 32 months (range: 1 to 136 months). Five newborns were alive and free from deformities, hematological malignancies, and developmental or intellectual disabilities. However, these fetal and neonatal findings should be interpreted with caution due to the limited cohort size and the significant prematurity bias.

Discussion

Hematologic malignancies such as AML were ranked as the third most prevalent type of cancer in pregnant women, following breast and cervical cancer. AML accounted for two-thirds of all cases of acute leukemia during pregnancy.^{6,14} In this retrospective study, we examined the data of 18 pregnant women who were diagnosed with AL during pregnancy. Our findings indicate that the majority of cases (72.22%) were identified in the final two trimesters, with AML being the most common type. Detection or diagnosis during first trimester of pregnancy may be associated with adverse pregnancy outcomes. The presentation of AL during pregnancy closely resembles that in non-pregnant women, with diagnostic criteria outlined in the WHO classification of hematologic neoplasms.¹⁵ Similar to the reports before, the majority of patients were AML (77.78%), four patients were ALL (22.22%) in this series.

However, due to the aggressive nature of the disease, it is crucial to promptly treat acute leukemia diagnosed during pregnancy and prevent rapid morbidity and mortality. Unfortunately, the use of cytotoxic agents for treatment can pose risks to fetus due to placental transfer, potentially leading to complications, including birth defects. Drugs like cytarabine and anthracyclines are known to cause fetal abnormalities.^{16–18} Cytarabine is highly teratogenic and has been linked to limb malformations.¹⁹ Managing AL in pregnant patients presents a complex challenge due to the numerous factors that must be considered. Therefore, the guideline in 2015 for AML in pregnancy suggested to deliver the baby before starting chemotherapy if the diagnosis was made after 30–32 weeks of gestation.⁵ This approach aimed to reduce the fetus's exposure to chemotherapy while maintaining a high neonatal survival rate. In this study, 3 patients diagnosed with AML after 30 weeks of gestation received caesarean section before chemotherapy. One patient with APL got chemotherapy during second trimester and gave preterm birth by spontaneous vaginal delivery. Another patient diagnosed at 29 weeks of gestation chose to deliver her baby before chemotherapy. One patient diagnosed with AL at 27 weeks of gestation was forced to receive caesarean section in emergency because of severe pulmonary infection. About 83.33% newborn were alive, except one died 3 days after birth.

APL, as a distinct AML subtype with a high risk of early death from severe coagulopathy, its management during pregnancy is uniquely challenging. ATRA and ATO, the two cornerstone targeted agents, achieve remission by inducing differentiation rather than cytotoxicity. ATRA should be avoided during the first trimester due to teratogenicity but can be safely used in the second and third trimesters until CR. Conversely, ATO is highly embryotoxic and contraindicated during pregnancy.²⁰ Our center has extensive experience in APL management and pioneered ATRA+ATO-based regimens as early as 2011, achieving long-term DFS rates of approximately 80%.^{21–23} In this series, one patient treated with ATRA during the second trimester delivered a healthy infant, whereas three stabilized after targeted therapy plus

chemotherapy and elected pregnancy termination. All four remain in sustained molecular remission, highlighting that modern APL therapy can be highly effective even with the complexities of pregnancy.

In contrast, treatment of non-APL AML followed contemporary standards. The ten non-APL AML cases occurred between 2014 and 2024, during which the “3+7” regimen remained the recommended induction approach for younger patients. Consistent with guidelines, nine patients received idarubicin plus cytarabine, and one received decitabine plus CAG. Post-remission management was guided by ELN 2022 stratification and response: post-CR allogeneic HSCT was performed in five patients, including some with favorable-risk genetics, reflecting real-world decision-making in the context of pregnancy.

Several studies have shown that pregnant patients with AML experience poorer outcomes than non-pregnant female patients of the same age with AML. It was reported that non-pregnant women with AML, 5-year relative survival estimates of 21.4% for all ages combined, 62.2% for ages 25–34, and 60.6% for ages 35–44.²⁴ A meta-analysis of 138 pregnant females with AML revealed a 30% lower overall survival rate in this group compared to non-pregnant women.⁹ Our series showed that the survival rate of mother was 88% at the end of the follow-up. We included 4 APL and 4 ALL patients in the series. HSCT was done in all the patients with ALL and 50% percent of patients with AML, including 3 low risk cases. allo-HSCT is the most effective anti-leukemic therapy for patients with intermediate- and high-risk AML.²⁵ It may improve the prognosis of the patients in our research.

Studies on the pharmacokinetics of drugs during pregnancy showed that the changes in the body, such as increased plasma volume and renal clearance, altered liver function, changes in protein binding, and increased amniotic fluid,^{19,26,27} would result in lower maternal exposure to chemotherapeutic drugs.^{28,29} Recent research reported that the drugs for chemotherapy during pregnancy, including doxorubicin, were in lower levels of blood compared to non-pregnant women. It is recommended to consider the actual body weight rather than reducing the dosage.³⁰ Insufficient dosage of chemotherapeutic agent could contribute to lower overall survival rates.³¹ In this study, 14 patients received chemo after abortion or giving birth except 4 cases of APL. Therefore, their treatment was not affected by the physiological changes of pregnancy, which may have contributed to an improved survival rate.

However, comparison of survival times in patients who gave birth versus who chose abortion before chemotherapy, abortion group got significantly higher OS. Days from delivery to chemo were significantly longer than that from abortion. The delay in administering chemotherapy in order to let the patients recover from cesarean section may contribute to the lower OS of these patients. Greenlund reported that patients who opted to postpone treatment had a significantly higher mortality rate compared to those who did not delay treatment.³² Several researchers found that any delays in diagnosis or initiation of treatment of leukemia might negatively impact on both patient and their fetus.^{17,33} Our research supports these studies and further suggests that adjusting treatment to prioritize the health of the baby may have a negative impact on the mother’s prognosis. Thus, finding a balance between the well-being of the mother and the fetus is a complex challenge.

Although pregnancy imposes constraints—including teratogenicity concerns, altered drug pharmacokinetics, and obstetric emergencies—it does not alter the intrinsic biological risk of acute leukemia, nor does it mitigate the need for timely, effective therapy. Instead, the challenge lies in balancing maternal prognosis with fetal considerations while acknowledging that maternal survival remains the overriding priority in life-threatening hematologic malignancy.

Finally, several limitations warrant consideration: small sample size, single-center design, heterogeneity across leukemia subtypes and treatment eras, incomplete long-term neurodevelopmental follow-up for newborns, and inability to fully adjust for confounding by indication, such as the possibility that patients requiring early delivery had more severe disease or obstetric complications. Nonetheless, the study provides clinically meaningful insights into real-world decision pathways, highlighting the interplay between disease biology, treatment timing, fetal maturity, and the growing role of targeted therapies.

Conclusion

In this rare population, maternal outcomes are shaped primarily by leukemia biology and the timely initiation of effective therapy. Targeted agents such as ATRA, ATO, and TKIs have substantially improved prognosis for specific subtypes, while delays in chemotherapy—even brief—may adversely affect survival. Because treatment safety and feasibility vary across trimesters, management must be individualized, balancing maternal urgency with fetal considerations. Our findings highlight the need for multidisciplinary, trimester-specific strategies to optimize both maternal and neonatal outcomes.

Data Sharing Statement

All the authors declare that data and materials supporting the results reported in the manuscript are available from the corresponding author at reasonable request.

Ethics Approval and Consent to Participate

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This study was approved by the Ethics Committee of Shanghai-Jiaotong University School of Medicine. Informed consent was obtained from all individual participants included in the study.

Consent for Publication

Not applicable as the manuscript does not involve any person's data.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors declare that there are no competing interests in this work.

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