

# Treatment of Adult Patients with Acute Promyelocytic Leukemia Using the AIDA Protocol: Survival Analysis at the National Research Oncology Center (NROC)

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## Background

Acute promyelocytic leukemia (APL) is a unique subtype of acute myeloid leukemia associated with the t(15;17) translocation and the formation of the PML::RARA fusion gene. Previously, the disease was characterized by an extremely unfavorable prognosis. However, the introduction of protocols using tretinoin (ATRA) and anthracyclines, in particular AIDA (idarubicin, ATRA), has significantly improved treatment outcomes. Despite the high sensitivity of the tumor to therapy, unresolved issues remain, including early mortality, relapse, and outcomes in high-risk patients, which necessitates an analysis of institutional data.

## Aim

To evaluate overall survival (OS) and relapse-free survival (RFS) in adult patients with APL who received therapy with the AIDA protocol at NROC (2014–2024), as well as to analyze factors influencing treatment effectiveness.

## Materials and Methods

The study included 70 patients with APL confirmed through cytogenetic and molecular testing, treated at NROC from 2014 to 2024. Key patient characteristics are presented in Table 1.

All patients received treatment according to the AIDA protocol, which consists of a combination of ATRA and idarubicin for induction, consolidation with the AIDA regimen, and subsequent maintenance therapy (ATRA ± chemotherapy depending on risk group).

Treatment effectiveness was assessed based on complete remission rate, early mortality, relapse rate, as well as OS and RFS indicators. Additional analysis was conducted on the impact of age, risk group, and leukocyte levels on treatment outcomes.

## Results

Most patients achieved complete remission after the first induction with the AIDA protocol: remission was achieved in 60 patients (85.7%). Early mortality occurred in 10 cases (14.3%), primarily due to infectious and hemorrhagic complications at disease onset.

During the observation period, 9 relapses (12.9%) were observed. A second remission was achieved in 6 patients, while 3 patients died after relapse.

Survival rates confirmed the effectiveness of the AIDA protocol, but remain insufficient for long-term disease control. Five-year OS was 73.7% (Picture 1), while RFS declined to 59.3% (Picture 2).

Prognostic factor analysis showed that patients under 60 years of age had significantly higher OS and RFS compared to older patients ( $p=0.012$ ). High leukocytosis at disease onset was associated with poorer outcomes, including higher relapse rates and mortality ( $p=0.00024$ ). The best survival outcomes were achieved in the low-risk group, while outcomes were significantly worse in the high-risk group ( $p=0.0021$ ).

## Conclusions

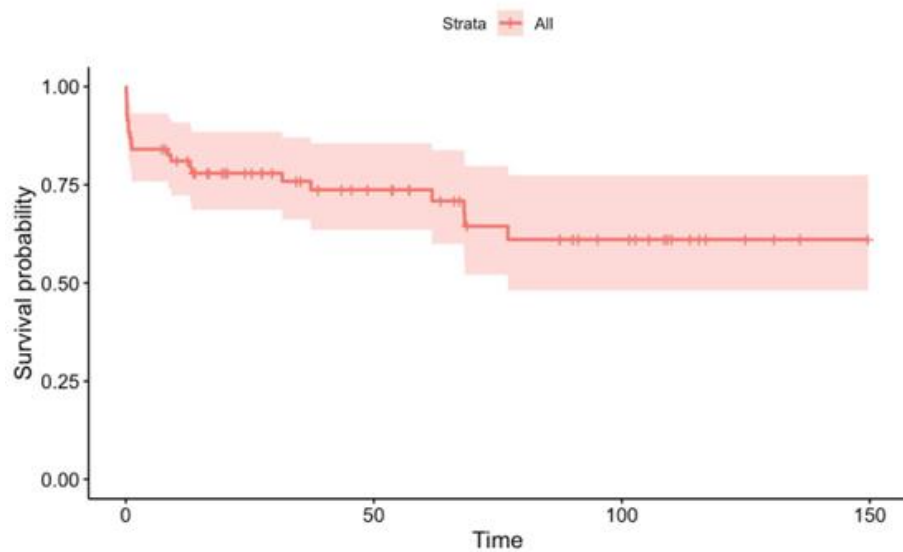
Despite the high rate of complete remission with the AIDA protocol, significant challenges remain: early mortality (14.3%), relapses (12.9%), and suboptimal 5-year survival rates (OS 73.7%, RFS 59.3%).

Adverse outcomes are associated with older age and high leukocytosis at onset, highlighting the need for a more differentiated, risk-adapted approach. An unresolved issue remains optimizing therapy in elderly patients, where less toxic regimens and personalized treatment strategies are required.

**Table 1**

Characteristic	n=70 (100%)
<b>Sex</b>	
Male, n (%)	32 (45,7%)
Female, n (%)	38 (54,3%)
<b>Mean age (years)</b>	42,5 (19–72)
Age <60 y.o, n (%)	55 (78,6%)
Age ≥60 y.o, n (%)	15 (21,4%)
<b>Distribution by risk groups</b>	
low	38 (54,3%)
Intermediate	14 (20,0%)
high	18 (25,7%)
<b>Main treatment-related complications</b>	
Infectious complications (sepsis, pneumonia, febrile neutropenia)	22 (31,4%)
Hemorrhagic syndrome (DIC, intracranial and other hemorrhages)	15 (21,4%)
Differentiation syndrome (ATRA syndrome)	5 (7,1%)
Other complications (thrombosis, skin reactions, gastrointestinal toxicity)	3 (4,3%)
<b>Leukocytes at disease onset</b>	
≤10×10 <sup>9</sup> /L	52 (74,3%)
>10×10 <sup>9</sup> /L	18 (25,7%)
<b>Methods of confirming translocation <i>t(15;17)</i></b>	
FISH — Fluorescence in situ hybridization	66 (94,3%)
PCR (Polymerase Chain Reaction)	68 (97,1%)
Cytogenetics (karyotype)	62 (88,6%)
<b>Clinical treatment outcomes</b>	
Complete remission	60 (85,7%)
Early mortality (≤30 days from therapy initiation)	10 (14,3%)
Disease relapse	9 (12,9%)

Pic 1.



Pic 2.

