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Original article

Overall survival of patients with acute myeloblastics leukaemia receiving low-dose cytarabine in AML treatment in low-income countries

Survie globale des patients atteints de leucémies aiguës myéloblastiques sous Cytarabine à faible dose dans la PEC de la LAM dans les pays à faible revenu

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Résumé

Introduction : La leucémie myéloïde aiguë (LAM) est une urgence tant diagnostique que thérapeutique limitée dans notre contexte par la précarité du plateau technique. L'objectif était d'évaluer la survie globale des patients atteints de LAM traités par cytarabine à faible dose au service d'hématologie du CHU Ignace Deen.

Méthodologie : Il s'agit d'une étude observationnelle menée sur une période de cinq ans au sein du service d'hématologie du CHU Ignace Deen. Tous les patients hospitalisés pour une LAM ont été répartis en 3 groupes : G1 : patients ayant reçu un support transfusionnel ; G2 : patients ayant reçu 10 mg de cytarabine par jour pendant 10 jours ; G3 : patients ayant reçu 30 mg/m2 de cytarabine une fois par semaine.

Résultats : Nous avons eu 65 patients répartis en trois groupes thérapeutiques : G1 = 4,6 %, G2= 49,2 % et G3 = 46,2 %. L'âge moyen des patients était de 43,5 ans. Les hommes prédominaient, avec un rapport de 1,2. Toutes les catégories professionnelles étaient représentées. Les facteurs de risque identifiés comprenaient l'exposition aux pesticides domestiques (13,8 %) et aux herbicides (10,8 %). Le tableau clinique était dominé par des signes d'insuffisance médullaire (100 %), suivis du syndrome tumoral (73,38 %). Une altération de l'état général a été systématiquement observée, 83,1% des patients étant classés dans les stades 3-4 de l'indice de performance physique. Les cytopénies étaient les résultats les plus fréquents (pancytopénie 41,5 %, bicytopénie 32,3 %), suivies par l'hyperleucocytose (20 %). Le taux de mortalité était de 33,8 %.

Conclusion : La LAM connaît une croissance rapide dans notre contexte et nécessite une prise en charge

d'urgence. La cytarabine à faible dose est une alternative adaptée dans notre contexte permettant d'améliorer la survie et la qualité de vie des patients. L'étude nous montre que nous pouvons sortir de notre inertie de désarmement face à ces situations par des soins mieux tolérés et moins toxique.

Mots-clés : Survie, leucémie aiguë, hématologie, CHU Ignace Deen, Conakry (Guinée).

Abstract

Introduction: Acute myeloid leukaemia (AML) is both a diagnostic and therapeutic emergency, limited in our context by the precarious nature of the technical facilities. The objective was to evaluate the overall survival of AML patients treated with low-dose cytarabine in the haematology department of Ignace Deen University Hospital.

Methodology: This is an observational study conducted over a five-year period in the haematology department of Ignace Deen University Hospital. All patients hospitalised for AML were divided into three groups: G1: patients who received transfusion support; G2: patients who received 10 mg of cytarabine per day for 10 days; G3: patients who received 30 mg/m² of cytarabine once a week.

Results: We had 65 patients divided into three treatment groups: G1 = 4.6%, G2 = 49.2% and G3 = 46.2%. The average age of the patients was 43.5 years. Men predominated, with a ratio of 1.2. All occupational categories were represented. Identified risk factors included exposure to domestic pesticides (13.8%) and herbicides (10.8%). The clinical presentation was dominated by signs of bone marrow failure (100%), followed by tumour syndrome (73.38%). A deterioration in general health was systematically observed, with 83.1% of patients classified as stage 3-4 on the physical performance index. Cytopenias were the most common findings (pancytopenia 41.5%, bicytopenia 32.3%), followed by hyperleukocytosis (20%). The mortality rate was 33.8%.

Conclusion: AML is growing rapidly in our context and requires urgent treatment. Low-dose cytarabine is a suitable alternative in our context, improving patient survival and quality of life. The study shows us that we can overcome our inertia in dealing with these situations by using treatments that are better tolerated and less toxic.

Keywords: Survival, acute leukaemia, haematology, Ignace Deen University Hospital, Conakry (Guinea).

Introduction

Acute myeloblastic leukaemias (AML) constitute a heterogeneous group of malignant haematological disorders characterised by the clonal proliferation of immature cells of the myeloid lineage with a blast percentage ≥ 20% [1]. They represent 80% of acute leukaemias in adults, with a standardised incidence rate in the world population of less than 6/100,000 inhabitants/year [2].

Standard treatment is intensive chemotherapy (induction) according to the "7+3" protocol (7 days of cytarabine and 3 days of daunorubicin) with consolidation and possibly therapeutic intensification by allografting [3]. Administered subcutaneously, low-dose cytarabine has been used as a low-intensity treatment for AML for more than 25 years, with a complete remission (CR) rate between 15% and 25%, with improved haematological parameters [4]. The regimen is generally well tolerated and can often be administered on an outpatient basis [5].

In the United States, the American Cancer Society in 2020 estimated a prevalence of approximately 20,000 new cases of AML and 11,500 deaths over 2 years [5].

In Africa, studies on AML are rare and limited.

In Central Africa, Packo et al. in 2021 reported a prevalence of 2.6% of leukaemia among 1,005 patients, of which 48.4% were AML [7].

In Côte d'Ivoire, N'dhatz D et al. in 2012 reported a prevalence of 1.94% of acute leukaemia, of which 33.6% were AML, with an overall incidence of 11.36 new cases per year [8].

In Guinea, Kanté AS et al. in 2021 reported a prevalence of 60% of AML among acute leukaemias in their study on the hospital prevalence of malignant

haematological disorders at the haematology-oncology department of Donka National Hospital [9]. In Burkina Faso, Traoré C et al. in 2023, in their multicentre study, found 43% of AML over 4.5 years, with a median survival of 3 months and an overall survival of 30% at 6 months and 0% at 12 months [6]. The therapeutic aspect of AML is hardly addressed due to insufficient technical facilities [6].

The increasing incidence of the disease and the absence of structures and possibilities for haematological resuscitation conducive to induction treatments in our context require us to evaluate therapeutic options for their contribution to overall patient survival. Low-dose cytarabine, used elsewhere as palliative supportive treatment, attracted our attention for this option. Hence the realisation of this study, the overall objective of which was to evaluate the overall survival of AML patients receiving low-dose cytarabine in the Haematology Department of Ignace Deen University Hospital.

Methodology

- *Study Type*

This was an observational cohort study conducted over a period of 5 years in the haematology department of Ignace Deen University Hospital in Conakry.

- *Study Population and Period*

All patients diagnosed with AML based on bone marrow examination with or without blast immunophenotyping, aged at least 10 years, during the period from 1 January 2020 to 31 December 2024.

- *Sampling*

Double-blind study with 3 patient groups:

- Group 1: patients who received only transfusion support
- Group 2: patients who received cytarabine at 10 mg subcutaneously for 10 days, combined with transfusion support, to be repeated every 28 days (D1=D28) until haematological remission or progression.
- Group 3: patients who received cytarabine 30 mg/m² subcutaneously weekly, combined with continuous transfusion support until haematological remission or progression.

- *Data Collection*

Data collection was carried out according to the following modalities:

- A consultation followed by an interview with the physician;
- Random inclusion in one of the patient groups;
- A complete blood count was systematically performed on request or before each treatment cycle;
- An evaluation bone marrow examination was performed at W6, M3, M6 and M12;
- A pre-established survey form was completed;
- Protocols and product administration methods;
- Data were collected throughout treatment and follow-up.

- *Data Management and Analysis*

Data were collected using the Kobocollect application and analysed with SPSS version 26 software.

Data entry and presentations were performed using Word, Excel and Power Point software from Office 2021.

For qualitative data analysis, we used a 95% confidence interval (CI) and a P-value threshold < 0.05. We determined overall survival through the Kaplan-Meier curve.

- *Ethical Considerations*

The data collected were used for scientific purposes only and with respect for anonymity, with written informed consent from our patients.

Results

In this study, we included 65 patients, with a male predominance of 38 men and 27 women, distributed into 3 groups with a median age of 43.5 years. The disease exposure factors were, for the most part, the use of insecticides in 13.8%. (See Table I)

Regarding clinical data, the majority of our patients had consulted within an average delay of 15 days and mostly had altered general condition. According to the ECOG Performance Status (EPS), we noted stage

2 (11 patients, 17.18%), stage 3 (51 patients, 78.46%) and stage 4 (3 patients, 4.61%). The complete blood count revealed cytopenias with or without hyperleukocytosis, and AML was secondary in 8 cases (12%) with a predominance of myeloproliferative neoplasms (see Table II).

On the therapeutic level, patients received at least 8 cycles of cytarabine with satisfactory responses. No patient had complete remission, with 23 death cases: G1=33.33%, G2=34.4%, G3=36.7%. Side effects were dominated by digestive manifestations, which were well tolerated.

The survival curve showed a median survival of 23 months. At 24 months, the probability of survival was 59%. (See Figure 1)

In our study, we noted a decrease in patient survival probability throughout follow-up. Thus, patient probabilities at 12, 24, 36, and 48 months were 75.00%, 63.00%, 47% respectively until the end of the observation period. The median survival was 23 months. The maximum survival without treatment was 6 months.

Table I: Distribution of patients according to sociodemographic characteristics and comorbidities

Characteristics	Number	Percentage (%)
Sex		
Male	38	58
Female	27	42
Occupation		
Student	11	16.9
Formal sector	10	15.4
Informal sector	25	38.5
Comorbidities		
Diabetes	4	6.2
Hypertension	12	18.5
HIV/AIDS	2	3.1
CKD	4	6.2
HBV	3	3.1
None	40	61.5

Table II: Distribution according to complete blood count and bone marrow examination parameters

Complete Blood Count	Number	%
Bicytopenia	27	41.5
Pancytopenia	21	32.3
Hyperleukocytosis	13	20.0
Total	65	100.0
Types of haematological disorders causing AML		
MDS*	2	3.1
CMPN*	6	9.2
De novo AML*	57	87.7
Total	65	100

*MDS: Myelodysplastic Syndrome

*CMPN: Chronic Myeloproliferative Neoplasm

*De novo AML: De novo Acute Myeloid Leukaemia

Table III: Distribution of patients according to treatment efficacy and tolerance

Response	**GROUP 2 (%)**	**GROUP 3 (%)**
Very good	8 (25.0)	9 (30.0)
Good	13 (40.6)	10 (33.3)
Poor	11 (34.4)	11 (36.7)
Total	32 (100)	30 (100)
Side effects	**GROUP 2**	**GROUP 3**
Nausea	04	03
Vomiting	04	04
Diarrhoea	02	05
Headache	02	03
Oral aphthae	00	00
None	20	15
Total	32	30

Discussion

We conducted an observational cohort study over a 5-year period, which had the following limitations and difficulties: the non-existence of a platform for performing immunophenotyping, cytogenetics and molecular biology, and the non-evaluation of bone marrow response.

In this study, the frequency of AML found (77.4%) is similar to those of Packo et al. (48.4%) and Traoré C et al. (43.5%), but different from that of N'Dhatz et al. (33.6%); this difference can be explained by the number of specialists who are increasingly equipped to make the diagnosis. The average age of our patients was young, with a peak in the 20-49 age group; our results are similar to those of Packo DSS et al. [7] who found an average age of 29.1, but different from the data reported by Lebon et al. who found an average age of around 60 years. This difference can be explained by the youth of the African population. Moreover, AMLs are essentially the domain of young adults and the elderly.

The predominant sex was male, which is consistent with the literature data (Lebon et al.) on AML showing a male predominance with a sex ratio of 1. The male predominance would be explained by the fact that men are more exposed to disease risk factors. In our study, all socio-professional strata were affected, which determines that AML is not the appearance of a particular socio-professionall stratum and that everyone can develop this pathology. The long diagnostic delay is at the origin of the altered general condition of patients, as we found in this study where the majority of our patients had EPS 3-4.

The anaemic and infectious syndromes were the most represented, followed by the tumour syndrome (hepatomegaly, splenomegaly and adenopathies) and the haemorrhagic syndrome, as described by Traoré C et al. [6]. This is explained not only by bone marrow infiltration by blasts but also by secondary invasion of haematopoietic organs. Cytopenias and/or hyperleukocytosis were the most frequent modes of presentation.

Subject to cytogenetics and molecular biology, patient prognosis was intermediate. Resuscitation measures were basic for all patients, and these measures included transfusion of packed red blood cells, fresh frozen plasma, platelet concentrates, antibiotics, antifungals, and antiparasitics. A better response was observed in group 2. The death rate was proportional in the 2 groups. The most dominant side effects were digestive, combining nausea, vomiting, diarrhoea, and oral aphthae; these data are consistent with the literature showing that the side effects of cytarabine are on the mucous membranes.

The overall survival of all patients combined was 75% at 12 months, 59% at 24 months and 47% at 48 months. These results are superior to those of Traoré C et al. [6] in Burkina who reported a survival of 0% at 12 months. This difference could be explained by the therapeutic protocols which are not the same. The low survival rate in sub-Saharan Africa is due to several factors including delayed consultation, absence of appropriate technical platforms, unavailability and financial inaccessibility of chemotherapy drugs, and insufficient supply of labile blood products

for adequate transfusion support. According to the different patient groups, overall survival at 6 months was respectively null for group 1, 90% for group 2 and 75% for group 3; at 12 months, overall survival was respectively 80% for group 2 and 35% for group 3; and at 24 months, overall survival was respectively 75% for group 2 and 35% for group 3.

Conclusion

AML is growing rapidly in our context and requires urgent management. In the absence of a technical platform conducive to induction, low-dose cytarabine has shown its efficacy and good tolerance with improved patient survival. It presents itself as a suitable alternative in our context, improving patient survival and quality of life, with overall survival varying between 75% and 35% at 24 months for patients who are supposed to die within a few weeks without treatment. The study shows us that we can overcome our inertia in the face of these situations through better tolerated and less toxic care. Both dosages are now included in our local patient management protocols.

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