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RESEARCH ARTICLE

Institutional Study of Acute Lymphoblastic Leukemia in Children at BSMMU a Tertiary Level Hospital in Bangladesh

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Abstract

Introduction: Acute lymphoblastic leukemia (ALL) is the most common malignancy among children worldwide. Due to advancements in diagnostic technology and improved treatment, the survival rate in high-income countries is above 90%. However, the survival rate in low and middle-income countries ranges from 22% to 79%.

Methods: A retrospective study was done on demographic, biological, and clinical parameters of children under 18 years of age with newly diagnosed ALL presenting between 2021-2023 in pediatric hematology and oncology centers of BSMMU in Bangladesh.

Results: ALL 220 patients were analyzed. Among them, 80% ALL B-cell (176) and 20% ALL T-cell (n= 44). The median age was 5.5 years (IQR 7.29). At diagnosis, 76% of patients were categorized as standard risk and 34% as high risk, and they received the UK ALL-2019 interim guideline. MRD was done in 92% of patients. Central nervous system (CNS) involvement was evaluated at diagnosis. CNS-1 was 95% (n=195), CNS-2 was 4.4% (n=14), CNS-3 was 0.7% (n=11), and 1.9% (n=8) had cranial nerve palsy. Chemotherapy delays >2 weeks were reported in 82.0% (n=180) of patients. Delays were due to infection in 53.2% (n=161), drug-related toxicities in 26.8% (n=59), and resource constraints in 20%(n=44).

Conclusion: This work reveals a data analysis of ALL and how to improve survival rates, including severe infections, treatment interruptions, drug modification, and how to serve as the new standard of care for pediatric ALL patients.

Keywords: ALL- Acute Lymphoblastic Leukemia, LMIC-Low-and Middle-Income Countries, LIC-Low-Income Countries, CNS-Central Nervous System, MRD-Minimal Residual Disease.

1. Introduction

Acute lymphoblastic Leukemia (ALL) is the most common childhood malignancy. The survival rate for ALL in high-income countries (HIC) is above 90% [1–3], but the survival rate in low-middle-income countries (LMIC) varies from 22-79% [4]. The incidence of childhood cancer is increasing day by day [5-6]. This survival disparity is a consequence of relative differences in tumor biology, pharmacogenomics, and comorbidities, and also due to socioeconomic backgrounds, poor access to standard diagnostic tests, and essential medications, causing delayed diagnosis and therapy initiation [7-9]. This paper describes the results from a retrospective study of demographic, biological, and clinical parameters of children under 18 years of age with newly diagnosed ALL presenting between 2021- 2023 in the pediatric

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hematology and oncology department of BSMMU in Bangladesh. The analyses helped to develop an evidence-based, consensus-derived, adapted treatment guideline.

2. Materials and Methods

A total of 220 patients were analyzed. The study only required existing medical records. This retrospective cohort study analyzed medical records maintained by participants. Participants included children 18 years old with newly diagnosed B- or T-cell ALL between January 1, 2021, and December 31, 2023. Immunophenotype was determined by flow cytometry.

2.1 Data Collection

Demographic and clinical data were collected using questionnaires. Demographic information included age and gender. Clinical information included the date of diagnosis, immunophenotype, risk stratification, treatment, laboratory tests, and follow-up. Local investigators designated a data collection team. Data collection started in January 2021 and was planned to end in December 2023.

2.3 Statistical Analysis

Patient characteristics were summarized using descriptive statistics. Continuous data were summarized using means and standard deviations (SD) or medians and interquartile range (IQR), and percentages were used to summarize categorical data. Induction failure was defined as the presence of ≥25% leukemic blasts in the bone marrow after remission induction treatment. Induction death was defined as death before achieving complete remission (CR, <5% leukemic blasts in the marrow at the end of induction. Treatment abandonment was considered an event. Abandonment was defined as a period of >4 weeks without curative treatment, not due to toxicity or other medical causes. Substantial change to therapy was defined as the elimination or substitution of a drug for more than half of the dose of a treatment phase.

3. Results

3.1 Demographics and Clinical Characteristics

During the 2-year study period, 220 children with ALL were diagnosed.

Table 1. *Characteristics of included patients.*

Treatment center BSMMU	N=220
Male	45.6% (100)
Female	54.4% (120)
Age (years)	
Median, IQR	5.52 (7.29)
Mediastinal Mass	3.9% (18)
Testicular involvement	1.2% (3)
Immunophenotype	
B-cell	91.1% (200)
T-cell	8.9% (20)
Risk group at the start of treatment	
Standard	61.9%. (136)
High	38.1% (84)
CNS status at diagnosis	
CNS 1 (0 blasts)	94.8% (208)
CNS 2 (>1 blasts, <5 leukocytes/HPF)	0.5% (2)
CNS 3 (>1 blasts, >5 leukocytes/HPF)	2.8% (6)
Cranial Nerve Palsy	1.9% (4)
Risk group at the end of induction	
Standard	72.27% (159)
High	27.73% (61)

The demographics and clinical characteristics are summarized in Table 1. A total of 54.4% (n=120) were female, and 45.6% (100) were male, with a median age of 5.5 years (IQR 7.29). B-cell ALL was diagnosed in 91.1% (n=200) of patients and 8.9%. % (n=20) with T-cell ALL. A mediastinal mass was noted in 3.9% (n=18) of patients at presentation, with 1.2% (n=3) reported to have testicular involvement.

Patients with Down syndrome comprised 1.8% (n=13) of ALL cases.

3.2 Diagnostic Assessment

Central nervous system involvement was evaluated at diagnosis in all patients. 94.8% (n=208) patients were CNS-1, 0.5%% (n=2) were CNS-2, 2.8 % (n=6) were CNS-3, and 1.9% (n=4) were cranial nerve palsy. The median time from diagnosis to the start of treatment was 15 days. At the beginning of therapy 27.73% (n=61) of patients were categorized as high-risk, and 72.27% (n=159) were standard risk based on age.

3.3 Treatment Regimens

Patients were treated based on the UKALL- 2019 guideline. During induction, standard-risk patients received a three-drug induction with steroids, vincristine, and L-asparaginase, and high-risk patients received 4 four-drug regimen of steroids, vincristine, L-asparaginase, and daunorubicin. For CNS-directed therapy, patients received a median of 5 doses (IQR 4 doses) of IT chemotherapy during induction.

3.4 Chemotherapy Response

Minimal residual diseases were used to determine treatment response in 95%(n=209). During the end of induction of remission (Day 29), 85% (n=187) of patients had an M1 marrow by morphology, 11.8% (n=26) had an M2 marrow, and 3.2% (n=7) had M3 marrow, Minimal residual disease (MRD) was evaluated in 95% (n=209) at Day 29, 85% (n=189) were MRD negative (<0.005%), MRD intermediate risk (>0.005%) 11.8%(n=26), MRD high risk (>5%)3.2%(n=5). The resulting final risk group composition included Standard Risk (SR), 72.27% (n=159), Sand's High Risk (HR), and 27.73% (n=71).

Table 2. *MRD monitoring for B-cell ALL*

Characteristics	Value (%)
Evaluation of MRD D29, n (%)	
Yes	209 (95%)
No (Due to financial constraints)	11 (5%)
MRD low risk <0.005%	189(85%)
MRD intermediate risk >0.005%	26 (11.8%.)
MRD high risk > 5%	05 (3.2%)

3.5 Treatment-Related Mortality

During the study period, 19.5% (n=43) of patients died, with early deaths represented by an induction death rate of 8.44% (n=19) and a remission death rate of 4.8% (n=11). Infection was the most common cause of death during induction, 89.6% (n=43). Of remission deaths, 20 occurred while the patients were still on therapy; of these 80% (n=16) were due to toxicity, and 9 occurred off therapy. Nine deaths were recorded following treatment abandonment or transfer to an alternate treatment center.

4. Discussion

Treatment-related morbidity and mortality can be decreased by intensifying treatment according to risk stratification. [10-13] This study has provided insight into biological variations. Further work is needed to comprehensively evaluate prognostic features and measure the impact of risk-adapted treatment on survival. This study also showed capacity-based difficulties or modifiable factors. These factors include scarcity of essential cancer medicines at the national level, supportive care and laboratory facilities at the hospital level, and socioeconomic problems, which cause very high rates of abandonment (15%) and treatment interruption in patients. Treatment-related toxicity is widespread, which includes a high frequency of infections. These infections are an important cause of treatment delays and contribute to further resource strain in institutions. [14-17] For example, providers indicated that 17 patients had treatment held due to a lack of bed availability. There is an urgent need to address the infrastructure for essential medicines like PEG-asparaginase. This rationale can be extended to targeted treatments like TKI and bi-specific antibodies, which may have a more significant benefit for populations suffering from difficult-to-treat leukemia. The disproportionately low proportion of patients with CNS involvement also highlights potential diagnostic challenges contributing to misdiagnosis. CNS 2 requires significant laboratory expertise, which may cause the underdiagnosis of CNS involvement. Limitations of advanced diagnostic techniques are barriers to pinpointing risk stratification and treatment necessary to improve cures. [18-19] precisely, lacking complete biological and genetic data about these patients limits the ability to find relevant risk factors. This problem is not limited to patients of Bangladesh only but extends to patients of shared backgrounds worldwide.

4.1 Limitations

It is a single-center study, and treatment guidelines are continuing.

5. Conclusion

This study showed the importance of improving Bangladesh's laboratory capacity, drug access, and supportive care. It addresses the necessity of collaborative study in this region to evaluate the factors affecting cancer survivors. Further evaluation will be needed after the completion of treatment.

Conflict of Interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest

6. References

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