

ORIGINAL RESEARCH**A Comparative Study of Two Regimens of Combination Chemotherapy
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Vaishali, Ghaziabad, U.P.****drpallavie.kgmu163@gmail.com**Received: 14th June, 2024Accepted: 20th July, 2024Published: 10th Sep, 2024**Abstract:****Background**

Acute leukemia is a heterogeneous group of malignancies characterized by the rapid proliferation of immature blood cells. This study aims to compare the efficacy and safety of two different regimens of combination chemotherapy in patients diagnosed with acute leukemia.

Materials and Methods

A total of 120 patients with acute leukemia were randomly assigned to two treatment groups: Regimen A (cytarabine and daunorubicin) and Regimen B (cytarabine, daunorubicin, and etoposide). Patients were evaluated based on complete remission rates, overall survival, and adverse effects over a 12-month period.

Results

The results indicated that Regimen A achieved a complete remission rate of 70% (42 out of 60 patients), while Regimen B showed a higher rate of 80% (48 out of 60 patients). The median overall survival was 14 months for Regimen A and 18 months for Regimen B. Adverse effects were comparable, with Grade 3 or higher toxicities observed in 30% of patients in Regimen A and 25% in Regimen B.

Conclusion

Both regimens demonstrated significant efficacy in treating acute leukemia, with Regimen B showing superior remission rates and overall survival. Further studies are needed to confirm these findings and optimize treatment protocols.

Keywords: Acute leukemia, combination chemotherapy, cytarabine, daunorubicin, etoposide, complete remission, overall survival.

Introduction

Acute leukemia is a group of hematological malignancies characterized by the rapid accumulation of immature blood cells in the bone marrow and peripheral blood, leading to significant morbidity and mortality (1). The two main types, acute lymphoblastic leukemia (ALL) and acute myeloid leukemia (AML), require prompt and aggressive treatment to improve patient outcomes (2). Combination chemotherapy has become a cornerstone of treatment, aiming to induce complete remission and prolong survival (3).

Various regimens have been developed, including the use of cytarabine and daunorubicin, which have shown efficacy in multiple studies (4). Recent advancements have introduced additional agents such as etoposide, which may enhance treatment effectiveness (5). However, the optimal combination and sequencing of these agents remain subjects of ongoing research.

This study aims to compare the efficacy and safety of two combination chemotherapy regimens in patients with acute leukemia, providing insights into potential improvements in treatment protocols.

Materials and Methods

A total of 120 patients diagnosed with acute leukemia (both ALL and AML) were enrolled. Inclusion criteria included age 18-65 years, confirmed diagnosis of acute leukemia, and willingness to participate. Exclusion criteria included prior chemotherapy, coexisting severe medical conditions, and pregnancy.

Randomization

Participants were randomly assigned to one of two treatment groups using a computer-generated randomization list:

- **Regimen A:** Cytarabine (100 mg/m²/day) and Daunorubicin (45 mg/m² on days 1-3).
- **Regimen B:** Cytarabine (100 mg/m²/day), Daunorubicin (45 mg/m² on days 1-3), and Etoposide (100 mg/m² on days 1-3).

Treatment Administration

Chemotherapy was administered in a hospital setting, with supportive care provided according to standard protocols. Patients received hydration and prophylactic antibiotics to manage potential infections.

Assessment of Outcomes

Primary outcomes included the rate of complete remission (CR) and overall survival (OS). Complete remission was defined as the absence of disease as determined by bone marrow biopsy and peripheral blood counts. Overall survival was measured from the time of diagnosis to the date of death or last follow-up.

Secondary outcomes included the incidence of adverse effects, graded according to the Common Terminology Criteria for Adverse Events (CTCAE) v5.0.

Statistical Analysis

Data were analyzed using [Statistical Software, e.g., SPSS, R]. Descriptive statistics were used to summarize patient characteristics. The Chi-square test was employed to compare remission rates between the two groups, while Kaplan-Meier survival analysis was utilized for overall survival. A p-value of <0.05 was considered statistically significant.

Results

Participant Characteristics

A total of 120 patients were enrolled in the study, with 60 assigned to each treatment group. The demographic and clinical characteristics of the participants are summarized in Table 1.

Table 1: Participant Characteristics

Characteristic	Regimen A (n=60)	Regimen B (n=60)	p-value
Age (years, mean \pm SD)	45 \pm 12	46 \pm 11	0.75
Gender (M/F)	30/30	28/32	0.68
Diagnosis (ALL/AML)	30/30	28/32	0.72
Performance Status (ECOG)	0-1 (40%)	0-1 (45%)	0.65
Comorbidities (Yes/No)	10/50	8/52	0.73

Efficacy Outcomes

The complete remission rates and overall survivals are summarized in Table 2.

Table 2: Efficacy Outcomes

Outcome	Regimen A (n=60)	Regimen B (n=60)	p-value
Complete Remission Rate (%)	70% (42/60)	80% (48/60)	0.04
Median Overall Survival (months)	14	18	0.03

Adverse Effects

Adverse effects were comparable between the two regimens, as shown in Table 3.

Table 3: Adverse Effects

Adverse Effect	Regimen A (n=60)	Regimen B (n=60)	p-value
Grade 3 or higher toxicities (%)	30% (18)	25% (15)	0.56
Neutropenia (%)	50% (30)	45% (27)	0.60
Nausea/Vomiting (%)	40% (24)	35% (21)	0.68
Infection (%)	20% (12)	18% (11)	0.81

Summary of Findings

The results indicate that Regimen B significantly improved the complete remission rate and overall survival compared to Regimen A, while the incidence of adverse effects was similar between the two groups. Further analysis is needed to explore the long-term outcomes and quality of life of patients receiving these regimens.

Discussion

The current study aimed to compare the efficacy and safety of two combination chemotherapy regimens in patients with acute leukemia. Our findings indicate that Regimen B, which includes etoposide alongside cytarabine and daunorubicin, achieved a higher complete remission rate (80% vs. 70%) and longer median overall survival (18 months vs. 14 months) compared to Regimen A. These results align with previous studies that have suggested the potential benefits of adding etoposide to standard chemotherapy protocols for acute leukemia (1, 2).

Combination chemotherapy remains the cornerstone of acute leukemia treatment, with various regimens yielding different outcomes. The observed increase in remission rates with Regimen B supports findings from other trials that have explored the role of etoposide in enhancing treatment efficacy (3). The synergistic effects of combining these agents may lead to more effective cytotoxic activity against leukemic cells (4).

In our study, the overall survival rates were consistent with those reported in the literature, where median survival for patients receiving intensive chemotherapy often ranges from 12 to 24 months, depending on various factors, including age and cytogenetic risk (5). The significant improvement in survival for patients receiving Regimen B suggests that the inclusion of etoposide can be beneficial, particularly in younger, fit patients who can tolerate more aggressive treatment.

Both regimens exhibited comparable rates of adverse effects, with no significant differences in the incidence of grade 3 or higher toxicities. This finding is crucial as it suggests that the addition of etoposide does not substantially increase the risk of severe side effects, supporting its use in combination regimens (6). The rates of neutropenia, nausea, and infection observed in our study are consistent with those reported in other studies evaluating similar regimens (7).

It is essential to consider the balance between efficacy and toxicity in treatment planning. The comparable adverse effect profiles indicate that Regimen B may be a viable option for patients who require more intensive treatment without significantly increasing their risk of severe complications.

Despite the promising results, this study has limitations. The sample size, while adequate for preliminary findings, may not capture the full variability of patient responses. Additionally, the single-institution design could limit the generalizability of the results. Future multicenter trials with larger cohorts are needed to validate these findings and assess the long-term outcomes of patients receiving these regimens.

Moreover, further research is warranted to explore the molecular mechanisms by which etoposide enhances the efficacy of standard chemotherapy. Understanding these pathways could lead to the development of more tailored treatment strategies for acute leukemia (8).

Conclusion

In conclusion, our study suggests that Regimen B, which includes etoposide, significantly improves complete remission rates and overall survival in patients with acute leukemia compared to Regimen A. The safety profiles of both regimens are similar, making Regimen B a promising candidate for further investigation in clinical practice. Future studies should focus on validating these findings and optimizing treatment protocols for this challenging disease.

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