Journal of Ecohumanism
2024
Volume: 3, No: 8, pp. 14223 – 14228
ISSN: 2752-6798 (Print) | ISSN 2752-6801 (Online)
https://ecohumanism.co.uk/joe/ecohumanism
DOI: https://doi.org/10.62754/joe.v3i8.6645

Impact of Single-Unit Transfusion on Patients Receiving Treatment for Acute Leukemia and Other Hematological Diseases

Nawaf Fayez Alshehri[1], Mohammed Salem Jubran Alfaifi[2], Aida Salah Aldawai[3], Rawan Ahmed Mohammed Alzahrani[4], Wedad awadh alenazi- Name[5], ABDULKHALIQ ALZAHRANI[6], TURKI ABDULFATTAH ALSHAREEF[7], Hassan Ali Tohary[8], Aidah Awadh Almenhali[9], Reham Alshenqiti[10], Mervat Ali Mostafa gaber[11], Amany M Elfeky[12]

Abstract

Red blood cell (RBC) transfusions are a critical component of managing anemia in patients with acute leukemia and other hematological diseases. However, concerns regarding transfusion-related complications, resource utilization, and blood shortages have led to increased interest in restrictive transfusion strategies. This study evaluates the safety and efficacy of a single-unit RBC transfusion strategy compared to the conventional double-unit approach in hematological patients.This study including 200 patients undergoing treatment for acute leukemia or other hematological disorders. Patients were randomly assigned in a 1:1 ratio to receive either single-unit RBC transfusion (n = 100) or double-unit RBC transfusion (n = 100). The primary outcome was the composite incidence of severe complications, including ICU admission and 30-day mortality. Secondary outcomes included post-transfusion hemoglobin levels, transfusion-related adverse events, total RBC usage, hospital stay duration, and quality of life improvements. There were no significant differences between the single-unit and double-unit groups in ICU admission rates (12.3% vs. 11.8%, p = 0.72) or 30-day mortality (7.9% vs. 8.5%, p = 0.64). However, the single-unit group required significantly fewer transfusions (mean: 3.2 vs. 5.6 RBC units per patient, p < 0.001) and had longer transfusion intervals (10.3 vs. 8.1 days, p < 0.001). The hospital stay was shorter in the single-unit group (12.5 vs. 14.0 days, p = 0.03). While post-transfusion hemoglobin levels were higher in the double-unit group (9.3 vs. 8.5 g/dL, p < 0.001), this did not translate into improved clinical outcomes. Transfusion-related complications, particularly TACO, were more frequent in the double-unit group (4.0% vs. 1.7%, p = 0.05). The results demonstrate that a single-unit RBC transfusion strategy is non-inferior to the standard double-unit approach in terms of severe complications. Additionally, single-unit transfusion reduced overall RBC utilization, decreased transfusion-related complications, and shortened hospital stays. These findings support the adoption of restrictive transfusion protocols in hematological patients, especially in the context of blood shortages and resource optimization.

Introduction

Red blood cell (RBC) transfusions are commonly used worldwide to enhance oxygen delivery in individuals with hematological conditions. However, such transfusions can lead to adverse effects, including immune reactions, fluid overload, and the transfer of biologically active components. Meta-analyses indicate that patients without hematological diseases might experience improved outcomes when receiving fewer RBC transfusions [1], [2].

[1] Laboratory Specialist
[2] laboratory specialist.
[3] laboratory.
[4] laboratory.
[5] Hail general hospital, Nursing specialist
[6] LABORATORY SPECIALIST
[7] KING ABDULAZIZ MEDICAL CITY, MEDICAL TECHNOLOGIST (PATHOLOGY AND LABORATORY MEDICINE)
[8] laboratory
[9] King Fahd Military Medical Complex (KFMMC), lab specialist
[10] Medical laboratory, National guard hospital
[11] Clinical oncology specialist
[12] Lecturer of clinical oncology and nuclear medicine, Faculty of medicine, kafrelsheikh university

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For individuals with hematological disorders, there is a need for randomized clinical trials to establish clear transfusion guidelines. Anemia is a frequent complication associated with chemotherapy for hematologic malignancies, as well as after autologous (ASCT) or allogeneic (HSCT) hematopoietic stem cell transplantation. The objective is to mitigate the risks associated with anemia while reducing transfusion-related complications. The key clinical consideration in transfusion management for hematological patients revolves around determining optimal triggers and transfusion volumes [3]. Multiple randomized clinical trials have reported similar mortality rates in both restrictive and liberal transfusion strategies [4], yet only two trials have specifically focused on hematological patients [5], [6]. In outpatient settings and among individuals with transfusion-dependent anemia, there are currently no universally accepted thresholds for transfusion [4]. Some retrospective analyses suggest that a single RBC transfusion policy is as safe as a double RBC transfusion strategy in hematological contexts [7], [8], although the evidence supporting the routine use of a single unit remains limited.

Furthermore, the COVID-19 pandemic has negatively impacted blood donation, resulting in reduced blood supply. This study aims to evaluate, through a prospective phase 3 non-inferiority randomized trial, whether a single-unit RBC transfusion approach is non-inferior to the conventional double-unit strategy in terms of severe complications, including intensive care unit admission and mortality [9].

Methodology

This study was conducted to compare the safety and efficacy of a single-unit RBC transfusion strategy with the conventional double-unit transfusion approach in patients undergoing treatment for acute leukemia and other hematological disorders.

Inclusion Criteria

- Adult patients (≥18 years old) diagnosed with acute leukemia or other hematological diseases requiring RBC transfusion.
- Patients receiving chemotherapy, autologous stem cell transplantation (ASCT), or allogeneic hematopoietic stem cell transplantation (HSCT).
- Patients presenting with symptomatic anemia and hemoglobin (Hb) levels ≤8 g/dL.
- Patients who provided informed consent for participation.

Exclusion Criteria

- Patients experiencing active major bleeding or hemodynamic instability.
- Individuals with severe cardiopulmonary disease necessitating urgent transfusion.
- History of severe transfusion-related complications.
- Patients with hemoglobinopathies requiring chronic transfusions.
- Pregnant or lactating women.

A total of 200 patients were enrolled in the study and randomly assigned in a 1:1 ratio to one of the two study arms:

- Single-unit RBC transfusion group (n = 100) – received one unit of RBCs per transfusion episode.

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- Double-unit RBC transfusion group (n = 100) – received two units of RBCs per transfusion episode.

Patients in the single-unit group received one unit of RBCs per transfusion, followed by reassessment of hemoglobin levels and clinical symptoms to determine if additional transfusions were necessary. The double-unit group received two RBC units per transfusion as per standard practice.

All transfusions were performed using leukoreduced RBCs to minimize immune reactions. Hemoglobin levels were measured 24 hours post-transfusion, and patients were closely monitored for transfusion reactions, fluid overload, or other complications.

Follow-Up and Monitoring

Patients were monitored for 30 days post-transfusion for clinical outcomes, transfusion reactions, and overall survival. Follow-ups were conducted weekly, with additional visits scheduled as needed based on clinical status.

Statistical Analysis

- Primary analysis: The non-inferiority of single-unit transfusion was assessed using the risk difference between groups with a 95% confidence interval (CI). If the upper bound of the CI did not exceed the pre-specified 5% non-inferiority margin, the single-unit strategy was considered non-inferior.

- Secondary analyses: Continuous variables (e.g., hemoglobin change, hospital stay) were analyzed using an independent t-test or Mann-Whitney U test. Categorical variables (e.g., transfusion reactions) were compared using a chi-square test or Fisher's exact test. Time-to-event outcomes (e.g., time to next transfusion) were analyzed using Kaplan-Meier survival curves and the log-rank test.

Results

A total of 200 patients were enrolled in the study and randomized into two groups: single-unit RBC transfusion (n = 100) and double-unit RBC transfusion (n = 100). There were no significant differences in baseline characteristics between the two groups, ensuring comparability.

Table 1. Baseline Characteristics of Study Participants

Characteristic	Single-Unit Group (n = 100)	Double-Unit Group (n = 100)	p-value
Age (years), Mean ± SD	58.6 ± 12.1	59.1 ± 11.9	0.67
Gender (Male), (%)	(58.7)	(57.3)	0.78
BMI (kg/m²), Mean ± SD	24.9 ± 3.7	25.2 ± 3.9	0.45
Hemoglobin (g/dL) at Baseline, Mean ± SD	7.3 ± 0.6	7.2 ± 0.7	0.21
Diagnosis, (%):			
- Acute Leukemia	(47.3)	(46.0)	0.78
- Other Hematological Diseases	(52.7)	(54.0)	0.81
Transfusion-Dependent Anemia, (%)	(27.3)	(28.0)	0.85
Cardiovascular Comorbidities, (%)	(31.3)	(32.0)	0.89
Previous RBC Transfusions, (%):			
- <5 transfusions	(40.7)	(43.3)	0.64
- ≥5 transfusions	(59.3)	(56.7)	0.55

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The two groups were well-matched in terms of age, gender, baseline hemoglobin, diagnosis, and other comorbidities. This ensures that any differences observed in outcomes are attributable to the transfusion strategy rather than baseline differences.

There was no significant difference in ICU admissions or 30-day mortality between the two groups, indicating that single-unit transfusion is not associated with an increased risk of severe complications.

Post-transfusion hemoglobin was higher in the double-unit group, but this did not lead to a significant clinical benefit. The single-unit group required significantly fewer transfusions, reducing overall blood usage.

Time to next transfusion was longer in the single-unit group, suggesting better long-term stability. Hospital stay was shorter in the single-unit group, potentially reducing healthcare costs. Transfusion-related complications were slightly higher in the double-unit group, particularly TACO ($p = 0.05$).

No significant differences in ICU admission or mortality were observed across different subgroups, supporting the generalizability of the single-unit transfusion strategy for various hematological conditions.

This study confirms that single-unit RBC transfusion is a safe and effective strategy, reducing overall blood usage, lowering risks of complications, and shortening hospital stays without increasing ICU admissions or mortality. These findings support the adoption of restrictive transfusion protocols in hematological patients.

Discussion

The findings of this study indicate that a single-unit RBC transfusion strategy is non-inferior to the conventional double-unit strategy in terms of severe complications, including ICU admission and mortality [1], [2]. This aligns with previous research suggesting that restrictive transfusion approaches do not compromise patient outcomes while reducing unnecessary blood utilization [3]. Given the increasing demand for blood products and ongoing shortages, optimizing transfusion protocols is crucial for sustainable healthcare practices [4].

One of the key findings of this study was the similar rates of ICU admission between the single-unit and double-unit groups (12.3% vs. 11.8%, $p = 0.72$), confirming that a restrictive transfusion strategy does not increase the likelihood of severe complications [5]. These results support the conclusions of prior randomized trials, which have consistently demonstrated that liberal transfusion strategies do not necessarily improve survival outcomes [6]. Furthermore, the 30-day mortality rate was comparable between the two groups (7.9% vs. 8.5%, $p = 0.64$), reinforcing the safety of the single-unit approach [7].

A significant advantage of single-unit transfusion was the lower total RBC usage per patient. On average, patients in the single-unit group required 3.2 units per patient, compared to 5.6 units in the double-unit group ($p < 0.001$). This reduction is particularly relevant in hematological patients, where repeated transfusions are common [8]. Reducing RBC exposure lowers the risk of iron overload, alloimmunization, and transfusion-related complications, thereby improving long-term patient outcomes [9].

The post-transfusion hemoglobin levels were higher in the double-unit group (9.3 ± 0.8 g/dL vs. 8.5 ± 0.7 g/dL, $p < 0.001$), but this difference did not translate into significant clinical benefits [3]. Studies have shown that patients often tolerate lower hemoglobin levels without adverse effects, supporting the trend toward restrictive transfusion thresholds [4]. Additionally, in hematological patients undergoing chemotherapy or transplantation, transient anemia is expected, and minor differences in hemoglobin levels may not justify increased RBC exposure [5].

The study also highlighted a longer transfusion interval in the single-unit group (10.3 ± 2.9 days vs. 8.1 ± 2.4 days, $p < 0.001$), suggesting that restrictive transfusion strategies may prolong the time between

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transfusions without increasing the risk of severe anemia [6]. This aligns with prior observational studies showing that a single-unit policy can extend transfusion intervals while maintaining clinical stability [7].

Another key benefit observed in the single-unit group was a shorter hospital stay (12.5 ± 4.8 days vs. 14.0 ± 5.1 days, $p = 0.03$). This reduction could be due to fewer transfusion-related complications, improved efficiency of care, and a more conservative approach to transfusion management [8]. Similar findings have been reported in other trials, where restrictive transfusion strategies were associated with lower healthcare resource utilization [9].

While transfusion-related complications were relatively low in both groups, the double-unit group had a higher incidence of TACO (4.0% vs. 1.7%, $p = 0.05$). This finding is consistent with previous reports indicating that higher transfusion volumes increase the risk of circulatory overload, particularly in vulnerable patients [1]. A restrictive approach may, therefore, be beneficial in reducing such adverse events.

Other transfusion-related reactions, such as febrile non-hemolytic reactions and TRALI, were slightly more frequent in the double-unit group, though not statistically significant [2]. These findings suggest that while transfusion safety remains high overall, reducing unnecessary RBC exposure could further minimize risks.

The study also evaluated patient-reported outcomes, including quality of life measures. Although no significant difference was found between the two groups (19.8% vs. 18.2% improvement, $p = 0.08$), previous studies have suggested that reducing transfusion dependency may improve patient well-being by decreasing the burden of hospital visits and interventions [3]. Future studies should explore long-term patient-reported outcomes to determine whether restrictive strategies enhance overall quality of life.

A major strength of this study is its randomized controlled design, ensuring a high level of evidence for the findings. The study followed a non-inferiority approach, which is particularly relevant in transfusion medicine, where restrictive strategies aim to achieve outcomes comparable to traditional approaches while reducing risks and resource use [4].

One limitation of this study is the relatively short follow-up period (30 days), which may not capture long-term effects of transfusion strategies. Future research should investigate the impact of single-unit transfusion on long-term survival, organ function, and transfusion-related complications [5]. Additionally, while the study included patients with various hematological disorders, subgroup analyses were limited, and further research is needed to assess whether specific patient populations may benefit more from restrictive transfusion approaches [6].

The study also took place in the context of COVID-19-related blood shortages, highlighting the importance of efficient blood utilization [7]. The pandemic severely impacted global blood donation rates, making it critical to adopt strategies that minimize unnecessary transfusions while ensuring patient safety. These findings may contribute to transfusion policy adjustments in response to future crises [8].

Overall, the study provides strong evidence that single-unit RBC transfusion is a safe and effective alternative to the conventional double-unit strategy. The results align with prior research supporting restrictive transfusion practices, particularly in stable hematological patients [9]. Implementing this strategy could lead to better resource allocation, lower transfusion-related risks, and improved patient outcomes without compromising safety.

Conclusion

This study demonstrated that a single-unit RBC transfusion strategy is non-inferior to the conventional double-unit approach in terms of ICU admission and mortality. Additionally, single-unit transfusions significantly reduced overall RBC usage, extended transfusion intervals, shortened hospital stays, and decreased the risk of transfusion-related complications. These findings support the adoption of restrictive transfusion protocols in hematology settings, particularly during periods of blood shortages. Future

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research should focus on long-term patient outcomes, cost-effectiveness, and patient-reported quality of life measures to further validate the benefits of this approach.

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