ADDISS ABABA UNIVERSITY
COLLEGE OF HEALTH SCIENCE
DEPARTMENT OF MEDICAL LABORATORY

Assessment of Platelet Count Changes in Adult Acute Leukemia Patients Receiving Platelet Transfusions at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia

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Table of Contents

List of Tables

List of Figure

Abbreviations:

AAU - Addis Ababa University

AL - Acute Leukemia

AML - Acute Myeloid Leukemia

ALL-Acute Lymphoblastic Leukemia

CHS - College of Health Sciences

CCI - Corrected Count Increment

CMV - Cytomegalovirus

DIC - Disseminated Intravascular Coagulation

HIT - Heparin-Induced Thrombocytopenia

HLA - Human Leukocyte Antigen

ITP - Immune Thrombocytopenic Purpura

MDS - Myelodysplastic Syndromes

Ml - Micro Liter

PLADO - Platelet Dose

PRP - Platelet Rich Plasma

PTR - Platelet Transfusion Refractoriness

RH - Rhesus

SPSS - Statistical Package for the Social Sciences

TASH - Tikur Anbessa Specialized Hospital

Abstract

Background: Many cancer patients, especially those with blood cancers like acute Leukemia, face a serious risk of bleeding, which can lead to death. About 52% of these patients have bleeding complications. The extent of optimal platelet transfusion response is not well known, and the predictors of transfusion effectiveness remain poorly understood. Therefore, assessing the factors influencing transfusion outcomes is essential, yet research on this remains limited.

Objective: To assess of Platelet Count Changes in Adult Acute Leukemia Patients Receiving Platelet Transfusions at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia.

Methods: A facility-based cross-sectional study was conducted from December 2024 to May 2025 at Tikur Anbessa Specialized Hospital involving 174 adult acute leukemia patients receiving platelet transfusions. Informed consent was obtained from all participants. Blood samples were collected pre-transfusion, at 1 hour, and 24 hours post-transfusion. Corrected count increment (CCI) was calculated by subtracting pre-transfusion platelet counts from post-transfusion counts, multiplying by the patient's body surface area (m^2), and dividing by the total number of platelets transfused. An optimal response was defined as a CCI $\geq 7.5 \times 10^9$/L at 1 hour and $\geq 4.5\times 10^9$/L at 24 hours. Logistic regression was used to identify predictors of CCI.

Result: Of the 174 patients, the mean age was 31.45 years, and 67.2% were male. Acute lymphoblastic leukemia was more common (59.2%) than acute myeloid leukemia. Overall, 81.7% and 68.6% of transfusions resulted in optimal CCI at 1 hour and 24 hours, respectively. In multivariable analysis, not taking medication was significantly negatively associated with achieving optimal CCI at 1 hour (AOR=0.54, P=0.022). Additionally, new infection (AOR= 0.1248, P=0.003) were negatively associated with optimal 1-hour CCI. An increase in the number of transfused platelet units was significantly associated with decreased odds of achieving an optimal CCI at 24 hours (AOR = 0.027, p = 0.045 as the AOR was less than 1.

Conclusion: Most patients achieved optimal CCI post-transfusion. The unit of transfused platelets was inversely associated with optimal CCI at 24 hours. Infection and not taking medication were inversely associated with optimal 1-hour CCI. Future longitudinal studies using incorporating immunological assessments are recommended to understand predictors of optimal platelet increment change.

Key Words: Platlet Count,Acute Lukemia,Platlet transfusion.

1. Introduction

1.1 Background

Leukemia is a hematologic malignancy characterized by an uncontrolled proliferation of abnormal white blood cells, leading to significant disruptions in normal blood cell production. Among the various types of Leukemia, Acute Myeloid Leukemia (AML) and Acute Lymphoblastic Leukemia (ALL) are the most common forms affecting adults, with notable consequences on platelet production and function due to bone marrow involvement and chemotherapy-induced suppression of hematopoiesis [1,2]. One of the hallmark complications of Leukemia, particularly in advanced stages, is thrombocytopenia, or a low platelet count, which can lead to increased bleeding risks and compromised clotting mechanisms [3].

Platelet transfusion is critical in managing bleeding in patients with hematological malignancies, particularly acute myeloid Leukemia (AML), which predominantly affects adults. Chemotherapy-induced thrombocytopenia often necessitates platelet transfusions to maintain hemostasis and reduce bleeding risk. The standard threshold for prophylactic transfusions in stable adult AML patients is typically set at 10,000/μL, but this may increase to 20,000/μL or higher in cases of fever, infection, or invasive procedures, depending on individual risk factors such as disseminated intravascular coagulation (DIC) and rapid declines in platelet counts [4].

Platelet concentrates for transfusion can be derived from single-donor apheresis or pooled from multiple donors. While both methods provide similar hemostatic benefits, pooled platelet concentrates are more cost-effective for routine use. Single-donor apheresis is preferred for patients with platelet transfusion refractoriness (PTR), which affects 30-70% of patients and is primarily caused by alloimmunization against HLA antigens [5]. Management of PTR includes using HLA-matched or cross-matched platelets and minimizing alloimmunization through leukoreduced, irradiated, and pre-storage filtered platelets [6].

To address the issue of post-transfusion failure in resource-limited settings, it is essential to identify high-risk groups and tailor platelet transfusion practices to individual patient factors such as fever, splenomegaly, infection, and coagulation disorders [7]. These factors can significantly impact post-transfusion platelet recovery. Recent studies have explored innovative strategies, including low-dose platelet transfusion to conserve resources, though the risk of bleeding still requires further research [8,9].

Historically, the concept of platelet transfusion emerged in the mid-20th century, with studies in the 1960s and 1970s demonstrating reduced bleeding risks in Leukemia patients receiving prophylactic infusions [10]. Initial transfusions used whole blood-derived platelets, but advancements in apheresis techniques have since improved safety by reducing alloimmunization risks. Maintaining a platelet count above 10 × 10^9/L has proven effective in minimizing bleeding episodes for chemotherapy patients [11].

The issue of platelet refractoriness, particularly in AML patients, has been managed using histocompatibility platelets for those who develop antibodies against HLA antigens. HLA-matched platelets are recommended but often unavailable in developing countries like Ethiopia [12]. Recent studies stress adherence to transfusion guidelines to avoid unnecessary transfusions, which can lead to complications and increased healthcare costs [13]. Advances in platelet storage techniques, such as cold storage and cryopreservation, are being researched to extend the shelf-life and function of transfused platelets [14].

The situation in Ethiopia mirrors challenges faced in other resource-limited settings. Despite efforts to improve blood transfusion services through awareness and training, there are still significant barriers to the appropriate use of platelet transfusions, necessitating further advancements in practices and policies [15].

1.2 Statement of the problem

Acute Leukemia, including Acute Myeloid Leukemia (AML) and Acute Lymphoblastic Leukemia (ALL), is a rare but serious disease that affects both adults and children. Globally, the annual incidence of acute Leukemia in adults is estimated to be about 3-5 cases per 100,000 people. Acute Myeloid Leukemia (AML) is the more common form of adult Leukemia, accounting for approximately 80-85% of adult acute Leukemia cases. Acute Lymphoblastic Leukemia (ALL), though more common in children, also affects adults, albeit less frequently [16].

Thrombocytopenia is a significant and prevalent complication among acute Leukemia patients, particularly those undergoing intensive chemotherapy. This condition not only increases the risk of bleeding but also poses a major challenge to effective cancer management. Historical data reveal that hemorrhage accounted for 67% of deaths in this population from 1954 to 1959, a figure that decreased to 37% between 1960 and 1963, largely due to the introduction of platelet transfusions [17]. The prevalence of thrombocytopenia among patients with acute Leukemia varies globally. Worldwide, it is observed in nearly 47% of patients with hematologic malignancies like acute Leukemia. This high prevalence is attributed to bone marrow suppression caused by the disease and its treatments, including chemotherapy [18].

In patients with hematological malignancies like acute Leukemia, the prevalence of thrombocytopenia can be particularly high, often necessitating multiple platelet transfusions throughout treatment due to the myelosuppressive effects of chemotherapy and the underlying disease [19]. In acute myeloid Leukemia (AML), chemotherapy-induced stress often enhances the metastatic potential of leukemic cells. This occurs partly because chemotherapeutic agents can foster a supportive tumor microenvironment by promoting inflammatory responses, altering metabolic pathways, and increasing chemoresistance. For example, the upregulation of CD36, a receptor involved in fatty acid metabolism, has been linked to chemoresistance and increased metastatic behavior in AML cells [20].

The prevalence of platelet refractoriness (PTR), defined as inadequate increments in platelet count following transfusion, is another critical issue impacting patient outcomes. This condition is frequently associated with the presence of anti-HLA antibodies, which can elevate mortality rates and complicate transfusion therapies. Women, especially those with a history of pregnancy, are particularly susceptible to

developing HLA immunization, leading to a higher incidence of refractoriness [21]. Additionally, older adults face increased risks, as age-related changes in bone marrow function and comorbidities can affect transfusion efficacy [22].

PTR prevalence among patients requiring platelet transfusions, including those with acute Leukemia, ranges from 5% to 34%. Immune-mediated PTR, primarily due to HLA alloimmunization, occurs in approximately 4-8% of patients receiving transfusions worldwide. These numbers reflect the challenges in managing transfusion support for hematology patients [23]. Moreover, specific treatment protocols, particularly those involving cytotoxic chemotherapy, are associated with a higher incidence of thrombocytopenia and refractoriness [24]. In Ethiopia, the prevalence of refractoriness is exacerbated by limited access to appropriately matched platelet donors, further complicating patient management [25].

The impact of thrombocytopenia on mortality rates is profound. Patients with platelet counts below critical thresholds (e.g., 20,000/μL) face heightened risks for severe bleeding complications, which are often fatal. The lack of standardized transfusion protocols and inadequate healthcare infrastructure in Ethiopia leads to prolonged storage of platelet products, diminishing their effectiveness and increasing the risk of adverse outcomes [26].

As far as our literature review goes, there is currently no consensus on optimal transfusion practices or monitoring strategies for acute Leukemia patients. This lack of clarity may stem from insufficient knowledge regarding predictors of transfusion effectiveness and the characteristics of individuals who are most susceptible to refractoriness [26]. Therefore, this study aims to assess platelet changes in increments of platelet counts and to identify associated factors.

1.3 Significance of the study

This research aims to identify factors that influence platelet change following transfusion will allow for adjustments to the transfusion process, enhancing patient outcomes by reducing the risk of bleeding complications and improving overall quality of life. Hospitals and healthcare providers can use the findings to create evidence-based guidelines for platelet transfusions, ensuring more efficient resource utilization. Insights into when and for whom transfusions are most beneficial can help minimize unnecessary procedures. For researchers, this study may fill gaps in the literature regarding platelet transfusion change and their predictors in Acute Leukemia patients, providing a foundation for future research on the causal effects of these predictors and their impact on long-term outcomes. For policymakers, the findings can inform the development of evidence-based guidelines that improve quality of care and align with health policy goals focused on efficiency and safety.

2. Literature Review

This literature review is organized into three sections. The first section addresses the issue of thrombocytopenia in Acute Leukemia patients. The second section discusses the effectiveness of platelet transfusions in increasing platelet counts, while the third section presents factors that influence the success of these increments.

Magnitude of Thrombocytopenia in Acute Leukemia Patients

Thrombocytopenia is a prevalent and significant complication in acute Leukemia patients, particularly those undergoing intensive chemotherapy. In adult patients with acute Leukemia, the degree of thrombocytopenia can be profound. For example, a study involving 78 patients undergoing induction therapy for acute Leukemia noted that many participants had platelet counts significantly below normal ranges, with thresholds often requiring transfusion interventions to mitigate bleeding risks [19]. Patients in this cohort displayed a mean platelet count that necessitated careful management, highlighting the severe impact of their underlying conditions and treatment regimens. Data from African countries are less abundant, but studies suggest that thrombocytopenia is equally prevalent, if not more so, in this region compared to other parts of the world. A retrospective study at South Africa from October 2015 to April 2016 by Singh A found that 80% of adult acute Leukemia patients had platelet counts below 100×10^9/L at diagnosis [27]. Across sectional study conducted in Nigeria reported that 70% of adult acute Leukemia patients with AML presented with thrombocytopenia, often exacerbated by limited access to timely diagnosis and treatment [28]. Thrombocytopenia in African Leukemia patients is often more severe, attributed in part to delayed presentation, lack of comprehensive healthcare, and higher rates of infections and other comorbidities that complicate the management of acute Leukemia.

Platelet Increments After Transfusion in Acute Leukemia Patients

The difference between optimal and suboptimal percentage platelet increment talks about the effectiveness of Post transfusion platelet increment. But the threshold level may difference among studies. Percentage Platelet Increment (PPI) of$\geq$30% at 1 hour and $\geq$20-30% at 24 hours after transfusion is referred as optimal response. on the other hand, PPI of below the previous threshold are regarded as suboptimal increment

which are caused by underlying clinical factors such as alloimmunization, splenomegaly and infection. The percentage of patients that achieve optimal PPI is varies, based on existing research optimal response rates have been found to range from 50% to 80%, depending on the patient group, transfusion methods, and underlying disease burden [29,30]

A double blind randomized controlled trial conducted among 69 adult patients in Massachusetts platelet increments found that platelet increment varied significantly with different platelet dose levels. The medium-dose group achieved a platelet increment of 33 ± 22 × 10^9/L, while the high-dose group demonstrated a substantial improvement, with an increment of 51 ± 29 × 10^9/L ($p < 0.01$). The very high-dose group showed the highest increments, reaching 62 ± 34 × 10^9/L ($p < 0.01$), indicating that higher doses lead to more substantial increases in platelet counts [31].

A cohort study among 60 adults acute Leukemia patients in India found that the average platelet increment 1-2 hours post-transfusion was 27.3 × 10^9/L. The response was lower in patients with active disease and those who had undergone aggressive chemotherapy [32]. Another study in India reported similar findings, with an average platelet increment of 20-25 × 10^9/L in AML patients compared to 30-35 × 10^9/L in ALL patients [33].

A randomized controlled trial conducted in the United States involving 78 patients undergoing induction therapy for acute Leukemia, the effects of different transfusion thresholds were observed. Patients receiving transfusions at a threshold of 10,000/μL had a mean platelet count of 83,500 ± 10,900, showing a more favorable response compared to those at a threshold of 20,000/μL, who had a mean of 65,800 ± 10,500 [19]. This suggests that patients with lower pre-transfusion counts may experience more significant increments.

Furthermore, a study established clinically significant thresholds for post-transfusion platelet increments, identifying at least 5.0 × 10^9 platelets/L at one hour and 2.4 × 10^9 platelets/L at 24 hours as meaningful indicators of transfusion success [34].

Factors Influencing the Success of Platelet Transfusions in Acute Leukemia Patients

Platelet transfusions are critical in managing thrombocytopenia in acute Leukemia patients, but their effectiveness can vary significantly based on several factors, including sex, age, treatment regimens, the presence of infections, and splenomegaly.

1. Sex

Studies have shown that female patients, particularly those who have had multiple pregnancies, may exhibit decreased increments after transfusions due to the presence of lymphocytotoxic antibodies. This reduction can be as significant as -8.9 × 10^9/L, suggesting that female patients may require closer monitoring and potentially tailored transfusion strategies [35].

2. Age

Age is another critical factor affecting transfusion success. Older adults may experience altered responses to transfusions due to changes in bone marrow function, comorbidities, and the overall physiological decline associated with aging. Younger patients typically respond better to platelet transfusions, making age an essential consideration in treatment planning [36].

4. Treatment Regimens

The type of treatment a patient undergoes can influence the success of platelet transfusions. Chemotherapy often leads to profound thrombocytopenia, complicating transfusion needs. A study showed that approximately 21.8% of patients receiving cytotoxic chemotherapy developed thrombocytopenia, underscoring the need for platelet management during such treatments [37]. Additionally, the effectiveness of transfusions can be impacted by the specific regimens used

5. Infections

Acute Leukemia patients are highly susceptible to infections due to their immunocompromised state. The presence of infections, particularly bacterial or fungal infections, can lead to increased platelet destruction or sequestration in the spleen, affecting the success of platelet transfusion [38].

The presence of infections or febrile episodes can also affect platelet increment post-transfusion. Research indicates that infections may lead to immune-mediated destruction of transfused platelets or increased consumption, resulting in diminished increments [39]. Patients with fever or active infections often experience lower post-transfusion platelet counts.

6. Splenomegaly

An enlarged spleen, often seen in Leukemia patients, can trap transfused platelets, leading to their premature destruction. This condition can significantly impact the efficacy of platelet transfusions in acute Leukemia patients [40].

Prevalence of blood group among acute leukemia patients. In a case control study of 293 patients with acute lymphoblastic leukemia (ALL) in Iran, the distribution of ABO blood groups revealed that blood group O was the most prevalent (43.7%), followed by group A (28.0%), group B (20.1%), and group AB (8.2%). Among male patients (n=184), 45.1% were blood group O, 26.6% group A, 22.3% group B, and 6.0% group AB. Female patients (n=109) exhibited a slightly different pattern, with 41.3% group O, 30.3% group A, 16.5% group B, and 11.9% group AB [41].

In conclusion, thrombocytopenia presents a significant challenge in the management of acute Leukemia patients, particularly those undergoing cytotoxic chemotherapy. Platelet increment following transfusions can vary widely, influenced by factors such as underlying health conditions, infections, and treatment regimens.

Although the relationship between platelet transfusions and bleeding outcomes is well-established, many patients continue to experience refractoriness, particularly in settings with limited resources. Furthermore, factors such as age, sex, and specific treatment protocols have been shown to impact transfusion efficacy, yet localized data remain scarce. Therefore, this study aims to assess the effect of platelet transfusion on platelet change in adult acute Leukemia patients at Black Lion Hospital.

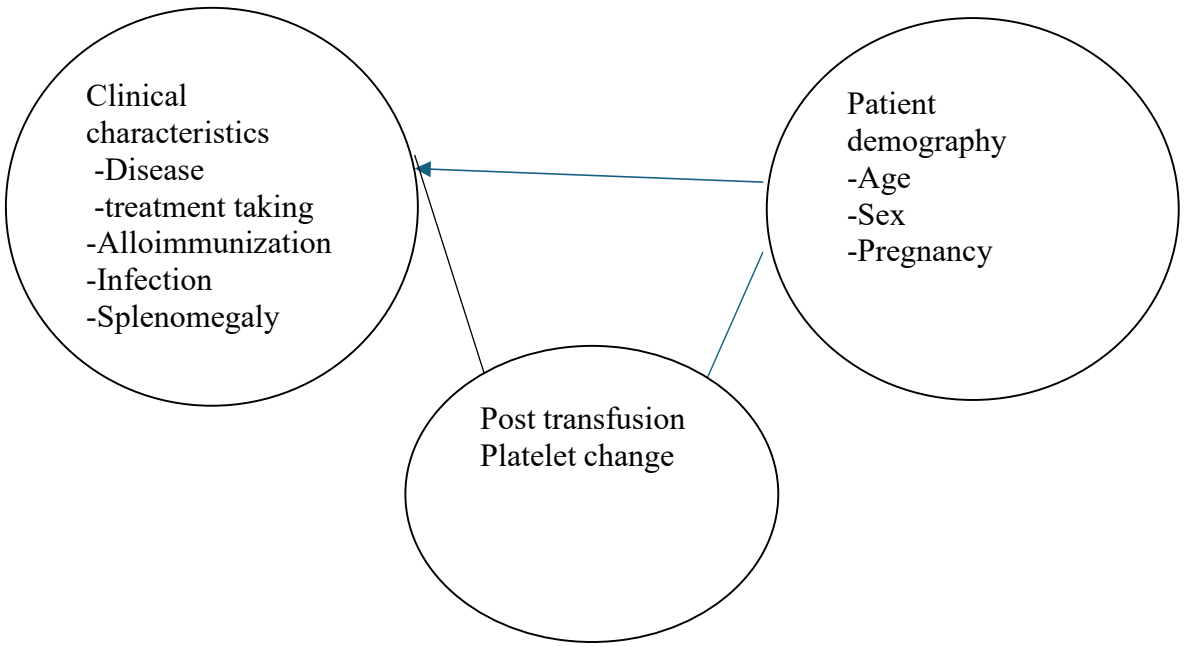

Figure 1: the conceptual framework of post platelet transfusion platelet increment

3.Objective

3.1 General Objective

To determine of Platelet Count Changes in Adult Acute Leukemia Patients Receiving Platelet Transfusions at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia from December 2024 to 2025

3.2 Specific objectives

1. To investigate of Platelet Count Changes in Adult Acute Leukemia Patients Receiving Platelet Transfusions at Tikur Anbessa Specialized Hospital from December 2024 to 2025
2. To determine predictors of platelet, count changes after transfusion in adult Acute Leukaemia patients at Tikur Anbessa Specialized Hospital from December 2024 to 2025

4. Materials and Methods

4.1 Study Area

The study was conducted at Tikur Anbesa Specialized Hospital (TASH) in Addis Ababa, Ethiopia, within the Department of Adult Hematology. TASH is the largest specialized hospital in Ethiopia, with over 700 beds, and serves as a teaching hospital. It has a dedicated team of 200 doctors, 115 health professionals, and 379 nurses, offering a range of specialties including oncology, cardiology, neurology, and orthopedics. TASH also provides emergency, intensive care, and diagnostic services, and functions as Ethiopia's primary referral facility for complex cases. The Adult Hematology unit specializes in the diagnosis and treatment of blood disorders, including anemia, Leukemia, lymphoma, hemophilia, and sickle cell disease, and serves as a training center for hematology and oncology professionals [42].

4.2 Study Design and period

A hospital based cross-sectional study was conducted at Tikur Anbesa Specialized Hospital, from December 2024 to May 2025.

4.3 Population

4.3.1 Source Population: Acute Leukaemia patients in Addis Ababa.

4.3.2 Study Population: Acute Leukemia patients (≥18 years) who receive transfusions and willing to participate during the study period.

4.4 Inclusion and Exclusion Criteria

4.4.1 Inclusion Criteria:

The study will include adult Acute Leukemia patients who receive platelet transfusions. All patients willing to provide blood samples one hour and 24 hours after the transfusion

4.4.2 Exclusion Criteria:

Patients who have experienced severe pain and are unable to communicate.

4.5 Study Variables

4.5.1 Dependent Variables: platelet count change

4.5.2 Independent Variables: Age, gender, previous platelet transfusions, presence of infection, splenomegaly, blood group, treatment received, weight and height.

4.6 Sample Size Calculation and Sampling Method

4.6.1 Sample Size Calculation: The sample size was calculated using a single population proportion formula. The required sample size is 148, determined by the formula:

$n=(Z\alpha/2)\ ^2P(1-P)/d^2$

where n is the sample size, Z corresponds to a 90% confidence level (Z-score of 1.645), P is the estimated proportion of Platlet Transfusion Refractoriness (0.2 in this case) [27] and d is a 5% margin of error. This results in a sample size of approximately 174.

4.6.2 Sampling technique: All Acute Leukemia patients who receive transfusions and met the inclusion criteria during the study period were included by using convenience sampling technique.

4.7 Measurement and Data Collection

4.7.1 Data Collection Process: Data were collected from patients, including demographics (age, sex, diagnosis, treatment history, and previous platelet transfusions). Pre-transfusion and post-transfusion platelet count information were measured to assess platelet increments and the effectiveness of transfusions. Information regarding the type and dose of platelet products transfused was collected. Platelet counts were measured at 1 hour and 24 hours post-transfusion to evaluate short-term responses. Additionally, data was collected using interviewer administer questionnaires to assess patient-related factors that might affect platelet response.

4.8 Data Quality Assurance

All personnel involved in data collection will receive training to ensure research quality. Pre-testing of data collection instruments and procedures were conducted prior to the study. Regarding blood sample, it was collected in a standardized manner to measure platelet counts pre- and post-transfusion. First, a patient identifier was used to prevent mix-ups. Four to five milli liter of blood was collected using aseptic techniques to minimize contamination and avoid hemolysis. For post-transfusion samples, we were draw blood at one hour and 24 hours after the transfusion. The samples were handled and transported to the laboratory within 1-2 hours, with the tubes gently inverted to mix the blood with the anticoagulant. Then, the samples were analyzed using calibrated hematology analyzers. Regular monitoring was established to review data collection practices and identify discrepancies and errors during the study period.

4.9 Laboratory analysis

The analysis process involves multiple stages, including pre-analytical, analytical, and post-analytical phases. Each of these stages is critical for obtaining reliable and accurate results.

4.9.1 Pre-Analytical Analysis

The pre-analytical phase involves all the steps before the laboratory analysis of platelet counts. This phase includes patient preparation, specimen collection, handling, and storage.

Patient Preparation

Clinical Assessment: A thorough clinical evaluation is conducted to assess the patient's status, platelet count before transfusion, and any other relevant factors such as active bleeding, infection, or concurrent medications that may influence platelet function or count.

Timing of Sample Collection: Blood samples were collected at defined intervals:

Before Transfusion (Pre-transfusion): A baseline platelet count is measured immediately before the transfusion to assess the initial platelet level.

Post-transfusion: Subsequent blood samples are drawn at specific time points after platelet transfusion to monitor changes in platelet count at 1 hour and 24 hours post-transfusion.

Specimen Collection

Sample Type: Peripheral blood samples are typically collected using sterile techniques. A 5-10 mL sample of whole blood should be drawn into a sodium citrate tube or an EDTA tube, as these anticoagulants are ideal for platelet count measurement and preserving platelet morphology.

Collection Procedure: Blood collection was done using proper venipuncture techniques to minimize hemolysis and platelet activation, both of which could affect the results.

Specimen Handling and Transport

Transport to Laboratory: Blood samples were transported to the laboratory promptly (ideally within 30 minutes) to avoid any delays in analysis, as platelet counts can drop or undergo changes over time due to clotting or cell degradation.

Sample Storage: If samples cannot be analyzed immediately, they were stored in a refrigerator at 2-8°C. However, platelet counts were measured as soon as possible after sample collection to minimize alterations due to storage.

4.9.2 Analytical Analysis

The analytical phase includes all laboratory procedures used to assess platelet count and evaluate changes before and after platelet transfusion.

Platelet Count Measurement

Calibrated Automated hematology analyzers Beckman Coulter Model 800: The primary method for platelet count analysis is automated blood cell counters. These machines can rapidly count platelets, providing reliable results. Platelet counts are typically reported as the unit of platelets per microliter of blood. Automated analyzers use impedance or optical techniques to detect and count platelets (43-45).

4.9.3 Post-Analytical Analysis

The post-analytical phase involves the interpretation and reporting of results.

Data Reporting

Platelet Count Change: The primary outcome measure is the change in platelet count.

Platelet Count Refractoriness: If there is minimal or no increase in platelet count after transfusion, it may indicate platelet transfusion refractoriness.

Timeliness: Laboratory results were reported promptly.

Record Keeping: Laboratory findings were carefully documented in the data collection form, along with transfusion details (e.g., platelet type, volume, transfusion time).

4.10 Data Analysis

Data were checked for cleanliness before analysis. Statistical analysis was performed using SPSS. Frequency and counts were used to present platelet increments, while clinical and demographic characteristics were summarized using tables, frequencies, graphs, and summary measures such as mean, median, standard deviation, and interquartile range. Bivariate analyses were performed to identify predictors, and variables with p-values <0.2 were included in a multivariable logistic regression model. Variables with p-values <0.05 in the final model was considered significant predictors of platelet increment.

CCI at 1 hour was calculated by subtracting the pre-transfusion platelet count from the 1-hour post-transfusion platelet count, multiplying this difference by the patient's body surface area (in square meters), and then dividing by the total number of platelets transfused. Then it was classified as optimal and sub-optimal. Similarly, CCI at 24 hour was calculated by subtracting the pre-transfusion platelet count from the 24-hour post-transfusion platelet count, multiplying this difference by the patient's body surface area (in square meters), and then dividing by the total number of platelets transfused. Then it was classified as optimal and sub-optimal.

CCI = ((post-transfusion platelet count − Pre-transfusion platelet count) × Body Surface Area in m^2) ÷ Number of platelets transfused

4.11 Operational Definitions

Corrected count increment at 1 hour: An increase of $7.5*10^9$/L and above is considered optimal [34].

Corrected count increment at 1 hour 24 hours: An increase of 4.5* 10^9/L is considered optimal [34].

4.12 Ethical Considerations

Ethical approval was obtained from the department of Medical Laboratory Sciences, College of Health Sciences, Addis Ababa University Research Ethics Committee to conduct the study, following the evaluation of the proposal. Official permission was also be secured from the TASH Adult Hematology Department. Written consent was sought from participants. The nature of the study and the procedures involved were explained to the study participants, with all information collected solely for research purposes. Participants' privacy and confidentiality were rigorously protected by restricting data access exclusively to the principal investigator. No one outside the study team had access to the de-identified data. Although the study did not offer direct benefits to the participants, its findings are expected to contribute to future improvements in patient care and transfusion practices at TASH and similar settings

4.13 Dissemination of Results

This thesis will be submitted and presented to the Department of Medical Laboratory Science upon completion of the research. The findings will also be disseminated through publication in peer-reviewed journals.

5. Results

5.1 Socio demographic and clinical characteristics

A total of 174 patients with acute leukemia were included in the study. The majority were male (67.2%), and the mean age was 31.45 years. The mean weight of participants was 55.43 kg. The means height was 165.82 cm. Regarding leukemia type, ALL was more common, affecting 59.2% of patients. A large majority of patients (92.5%) had a history of previous blood transfusion, while 6.9% reported a history of transfusion reactions. Additionally, 19.5% had a history of splenomegaly, 61.5% had new infections, and 97.1% were undergoing treatment at the time of the study (Table 1).

Table 1: Sociodemographic and clinical characteristics of participants in TASH, 2025

Variable	Category	Frequency (n)	Percent (%)
sex	Female	57	32.8%
	male	117	67.2%
Age	Mean	–	31.45
	Standard deviation	–	11.74
Weight	Mean	–	55.43
	Standard deviation	–	8.25
Height	Mean	–	165.82
	Standard deviation	–	6.99
Type of Leukemia	ALL	103	59.2%
	AML	71	40.8%
Previous Transfusion History	Yes	161	92.5%
	No	13	7.5%
History of Transfusion Reaction	Yes	12	6.9%
	No	162	93.1%
History of Splenomegaly	Yes	34	19.5%
	No	140	80.5%
New Infection	Yes (2.00)	107	61.5%
	No (1.00)	67	38.5%
On Treatment	Yes (2.00)	169	97.1%
	No (1.00)	5	2.9%

5.2 Platelet Count After 1 Hour and 24 Hours Post-Transfusion and Corrected Platelet Count Increment

The pre-transfusion platelet counts among the patients had a mean value of 2.24x10⁹/L. Following transfusion, platelet counts increased, with the 1-hour post-transfusion count showing a mean of 4.11x10⁹/L. At 24 hours post-transfusion, the mean platelet count decreased slightly to 3.5x10⁹/L. The 1-hour CCI had a mean of 15x10⁹/L. The 24-hour CCI had a mean of 11.2x10⁹/L (Table 2).

Table 2: Platelet Count After 1 Hour and 24 Hours Post-Transfusion and Corrected Platelet Count Increment among Acute Leukemia Patients in TASH, 2025

Variable	Mean (10^6 /L)	SD (10^6 /L)	Median (10^6 /L)
Pretransfusion platelet count	2240.11	1390.41	2050
post transfusion platelet counts after1hr	4116.09	2387.07	4000
post transfusion platelet counts after 24 hrs.	3598.28	2733.45	3000
1 hour corrected count increment	15985.51	11476.46	14472.73
24 hour corrected count increment	11219.99	14830	10409.09

As illustrated in the pie charts, out of a total of 174 platelet transfusions, the majority (81.7%, n = 143) resulted in an optimal CCI at 1 hour. At the 24-hour mark, 120 transfusions (68.6%) were associated with an optimal CCI.

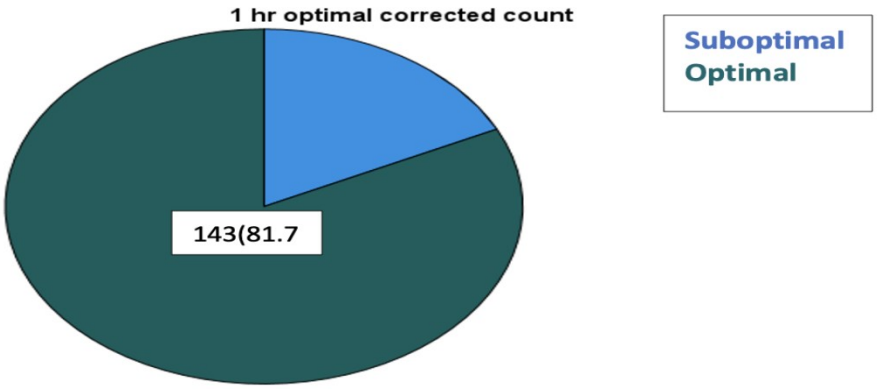

Figure 2: Magnitude of optimal CCI at 1-hour among acute Leukemia patients on platelet transfusion in TASH, 2025

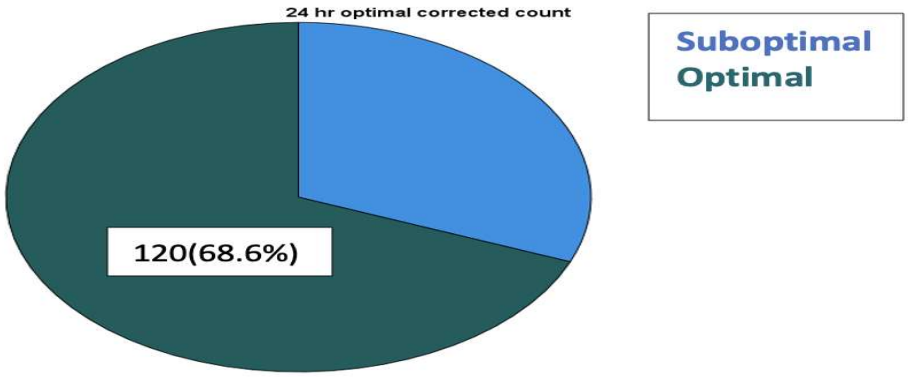

Figure 3: Magnitude of optimal CCI at 24-hour among Acute Leukemia Patients on platelet transfusions in TASH, 2025

5.3 Optimal CCI at 1 hour and associated factors

In this initial analysis (Table 3), four variables showed statistically significant associations with optimal CCI in adult acute leukemia patients at TASH: sex (P = 0.108), height (P = 0.009), Weight (P = 0.142), Unit of Transfused Platelets (P= 0.026), new infection (P=0.002) and Treatment taking status (P = 0.20). These variables were then selected for inclusion in the multivariable logistic regression to assess their independent effects on the outcome (Table 3).

After selecting variables for the final model, we checked multcollinearity and model performance. Multicollinearity was checked using Variance Inflation Factor (VIF) and the values for all predictors were well below the threshold of 10, suggesting no multicollinearity. A binary logistic regression was also performed, treating optimal as a categorical dependent variable (optimal, suboptimal). The intercept-only model had an odds ratio of 10.6, suggesting a higher likelihood of optimal platelet count in the absence of predictors. The model's goodness-of-fit was assessed using the Hosmer and Lemeshow test, which revealed close agreement between observed and expected values. The model correctly classified with an overall classification accuracy of 93.1% (Annex 5).

Table 3: Association between sociodemographic and clinical characteristics with optimal CCI at 1-hour among acute leukaemia patients, TASH,2025

variables	Category	Frequency	Un adjusted OR(95%)	Adjusted OR(95%)	P-value
sex	Female	57	0.890(0.394,2.010)	0.659(0.61,1.659)	0.2
	Male	117			
age			0.997(0.965,1.031)		0.880
weight			1.038(0.988,1.090)	1.039(0.966,1.118)	0.142
height			1.078(1.019,1.141)	1.061(0.988,1.138)	0.104
Blood group of patient			0.543(0.136,2.160)		0.386
Blood group of transfused platlet			0.404(0.068,2.405)		0.319
Type of leukemia	ALL	103	1.243(0.568,2.718)		0.587
	AML	71			
Not taking treatment	Yes	5	0.311(0.050,1.943)	0.54((0.004,0.652)	0.022*
	No	169			
New infection	Yes	107	7.350(2.136,25.287)	0.1248(0.487,0.778)	0.003*
	No	67			
History of transfusion reaction	Yes	12	0.000	0.000	0.999
	No	162			
Previous transfusion reaction	Yes	161	1.208(0.254,5.746)		0.812
	No	13			
History of splenomegaly	Yes	34	0.986(0.369,2.632)		0.977
	No	140			
Number of transfused platlet			0.027(0.001,0.650)	0.066(0.001,4.042)	0.195

In the adjusted multivariable logistic regression model (Table 4), new infection status remained statistically significant. Individuals with a new infection had an 87.62% decrease in the odds of achieving optimal CCI at 1 hour. Not taking medication was also negatively and significantly associated with the outcome (B = -4.051, p = 0.02); those who were taking medication had 0.54 times the odds of achieving optimal CCI at 1 hour compared to those not taking medication. Although age, weight, height, and units of transfused platelets were significant in the bivariate analysis, they were not independently associated with the outcome after adjustment, suggesting that their effects were confounded by other predictors in the modeL.

5.4 Optimal CCI at 24 hour and associated factors

In the bivariate logistic regression, six variables based on their p values and clinical significance were selected for inclusion in the multivariable logistic regression model to determine their independent effects on the outcome (Table 5).

In the multivariable model, each additional unit of transfused platelets was associated with a 97% decrease in the odds of achieving optimal post–24-hour CCI (OR = 0.027, p = 0.045). Although new infection was significantly associated with 1-hour CCI, it was not significantly associated with the 24-hour CCI outcome. History of splenomegaly, history of transfusion, height, and weight were not significantly associated with post–24-hour platelet increment (p > 0.05 for all).

Table 4: Association between sociodemographic and clinical characteristics with

variables	Category	Frequency	Un adjusted OR(95%)	Adjusted OR(95%)	P-value
sex	Female	57	0.788(0.402,1.544)		0.487
	Male	117			
age			1.001(0.974,1.029)		0.938
weight			0.987(0.949,1.026)	0.985(0.931,1.403)	0.511
height			0.982(0.937,1.029)	0.974(0.13,1.038)	0.444
Blood group of patient			1.040(0.319,3.395)		0.948
Blood group of transfused platlet			1.619(0.472,5.550)		0.443
Type of leukemia	ALL	103	0.796(0.411,1.540)		0.498
	AML	71			
Not taking treatment	Yes	5	1.828(0.199,16.748)		0.594
	No	169			
New infection	Yes	107	1.186(0.608,2.313)	0.766(0.332,1.771)	0.617
	No	67			
History of transfusion reaction	Yes	12	0.423(0.089,2.001)		0.278
	No	162			
Previous transfusion reaction	Yes	161	2.624(0.561,12.269)	3.651(0.620,21.5)	0.152
	No	13			
History of splenomegaly	Yes	34	1.079(0.483,2.409)	0.996(0.397,2.500)	0.853
	No	140			
Number of transfused platlet			0.61(0.04,0.951)	0.027(0.001,0.921)	0.045*

Optimal CCI at the 24-hour mark among acute leukaemia patients, TASH,2025

6. Discussion

In this study, 81.7% of platelet transfusions resulted in an optimal CCI at 1 hour, indicating a high level of transfusion efficacy among acute leukemia patients at TASH. The high rate of CCI at 1 hour (81.7%) observed in this cohort of acute leukemia patients at TASH exceeds the 50–80% reported in previous studies [29,30]. However, it goes in line with a study done on leukemia patients receiving cross-matched platelets reported 85.2% optimal response rate at 1 hour [47]. The 81.7% decline to 68.6% optimal CCI at 24 hours. This aligns with earlier studies [29,30]. It also goes in line with a study conducted on 130 acute leukemia patients. The study showed nearly identical 24-hour CCI (68.3% for apheresis platelets, 65.1% for whole-blood-derived platelets), despite higher refractoriness rates (42.95–49.71%) [48]. However, our study contrasts a multicenter ICU study which reported only 22% optimal 24-hour CCI in patients with multiorgan failure, where inflammation accelerated platelet clearance. The 24-hour CCI (68.6%) mirrors outcomes in general leukemia studies but exceeds rates in critically ill patients (30–40%) [49]. Clinical and physiological variations can be the reason for the observed discrepancy between our result and other studies, involving critically patients. This might be due to the fact that systemic inflammation was lower, and blood vessel were in a normal, undamaged state in our study. On the other hand, increased inflammation, endothelial damage, and capillary leak are frequently observed in intensive care unit patients with multiorgan failure. These factors increase immune-mediated platelet clearance and decrease the efficacy of transfusions. Additionally, post-transfusion increments may be reduced if older or non-matched platelet products are used in critical settings.

As expected, the 24-hour response rate was lower than the 1-hour rate, likely reflecting platelet consumption or clearance over time. Several factors may explain the higher proportion of optimal responses at 1 hour in our study, despite the decline at 24 hours. Important clinical variables such as detailed chemotherapy regimens, the severity of thrombocytopenia, and the duration of chemotherapy were not fully explored, though these are known predictors of CCI. Additionally, our study defined response based on CCI thresholds, whereas other studies have used absolute platelet count increases, which may have contributed to differences in reported response rates. The relatively young mean age of our study (31.45 years) may also have supported

better marrow function and platelet recovery. In contrast, studies involving older or critically ill patients, such as those with sepsis or multiple comorbidities, tend to report higher rates of suboptimal responses [30].

We found that new infection significantly and negatively associates with optimal CCI at 1-hour aligns with previous research. Infections, especially bacterial or fungal, can accelerate platelet destruction or sequestration in the spleen, compromising transfusion efficacy [38,39]. These mechanisms likely contribute to the reduced odds of achieving an optimal CCI in infected patients observed in this study. A study of 105 leukemia patients found that infection reduced 1-hour CCI by 30–40% (OR: 0.367; 95% CI: 0.140–0.956), with fever independently lowering platelet increments (OR: 0.382) [50]. Similarly, critically ill sepsis patients exhibited 45–55% optimal 1-hour CCI rates nearly 40% lower than non-infected cohorts due to endotoxin-induced platelet consumption [49]. In sepsis, suboptimal platelet transfusion response (reflected by low corrected count increments) occurs due to heightened platelet consumption or destruction [51]

In addition, not taking medication was significantly and negatively associated with optimal CCI at 1 hour indicating that patients not on any form of treatment had lower odds of achieving an effective response. This contrasts with previous studies that emphasize the adverse effects of chemotherapy on platelet levels. A study showed that 21.8% of patients receiving cytotoxic chemotherapy developed thrombocytopenia [37]. Although chemotherapy is known to suppress bone marrow function, patients under treatment may benefit from more frequent monitoring, supportive care, and intervention [50]. In addition, based on studies, discontinuation of treatment due to disease progression or severe complications can independently impair platelet recovery and reduce transfusion responsiveness. Therefore, the observed lower CCI in patients not on treatment may reflect the underlying severity of their disease rather than the absence of treatment itself [52].

Unit of transfused platelets was found to be strongly and negatively associated with CCI at 24 hours indicating that patients who received higher platelet doses were less likely to achieve an optimal response, with a reported 93% decrease in the odds of optimal CCI. This finding contrasts with earlier research indicating a positive dose-response relationship between transfused platelet volume and post-transfusion

increment levels [31–33]. A study involving adult patients demonstrated that platelet increments increased progressively with higher doses, suggesting a dose-dependent improvement in platelet counts [31]. However, our result aligns with more recent evidence highlighting a threshold effect. A randomized controlled trial in hemato-oncology patients revealed that high-dose single-donor apheresis platelets resulted in significantly lower 24-hour CCI compared to standard doses, despite higher absolute platelet increments. This suggests that beyond a certain threshold, increasing platelet dose may not enhance, and could potentially impair, transfusion efficacy. Beside these, the discrepancies may arise from variations in study populations, transfusion thresholds, or underlying disease severity [19,34].

In this study, several factors including sex, age, splenomegaly, leukemia type, and blood group were not significantly associated with optimal CCI at 1 and 24 hours. While previous studies have linked these variables to platelet transfusion outcomes, such associations were not observed here, possibly due to sample characteristics such as a male-dominant and relatively young participants, high rates of treatment and infection, and limited variation in some variables.

Strength

Unlike other studies, this study aimed to measure optimal platelet increments at both 1 hour and 24 hours post-transfusion. Additionally, it applied a stringent cutoff point to ensure that only clinically significant platelet increments were reported as optimal.

Limitations

The use of a cross-sectional design in this study limits the ability to establish causal relationships between potential predictors and platelet transfusion outcomes. The reliance on convenience sampling from a single tertiary hospital may introduce selection bias and limit the generalizability of the findings to other settings. The study did not assess certain immunological factors, and some potential confounders identified in previous literature were not evaluated or controlled for due to budget constraints. Additionally, important clinical factors such as detailed chemotherapy

regimens, the severity of thrombocytopenia, and the duration of chemotherapy were not fully explored.

Conclusion

This study found that a high proportion (81.7%) of transfusions resulted in an optimal CCI at 1-hour post-transfusion, while 68.6% achieved an optimal CCI at 24 hours indicating a sustained but slightly reduced response over time. New infection and not taking medications were negatively associated with optimal CCI at 1-hour. Additionally, the unit of transfused platelet units was significantly and negatively associated with 24-hour CCI, suggesting that higher transfusion volumes were linked to poorer platelet response.

Recommendations

To establish a clearer cause-effect relationship, we recommend that future researchers conduct longitudinal studies, such as cohort studies. Additionally, to enhance the generalizability of the findings, we recommend that other researchers use probabilistic sampling techniques.

Given that the number of transfused platelet units was significantly and negatively associated with optimal CCI at 24-hour intervals, patients requiring multiple units should be monitored more closely for suboptimal response and possible underlying complications.

Since new infection was negatively associated with optimal CCI at 1-hour, clinical attention should be given to these factors when planning transfusion and evaluating outcomes. The inverse association between not taking medication and 1-hour CCI also underlines the need to consider treatment status as part of transfusion decision-making.

Since clinical variables such as detailed chemotherapy regimens, the severity of thrombocytopenia, and the duration of chemotherapy were not explored in this study, we recommend that future research investigate these factors to better explain platelet transfusion refractoriness.

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8.Annex 1

Standard Operating Procedure (SOP)

for the Analysis of Platelet Change in Adult Leukemia Patients Receiving Platelet Transfusion at Tikur Anbessa Specialized Hospital

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to outline the laboratory procedures and guidelines for analyzing platelet changes in adult Leukemia patients receiving platelet transfusions at Tikur Anbessa Specialized Hospital. This SOP covers the pre-analytical, analytical, and post-analytical phases of platelet analysis, ensuring accurate and consistent results for clinical decision-making.

2. Scope

This SOP applies to all laboratory staff involved in the assessment of platelet changes in adult Leukemia patients receiving platelet transfusion at Tikur Anbessa Specialized Hospital. It covers:

Patient preparation and blood sample collection

Platelet count analysis and quality control

Data interpretation and reporting

3. Responsibility

Laboratory Technicians: Responsible for collecting blood samples, conducting platelet count analysis, and performing quality control tests.

Research Coordinators: Responsible for ensuring that the research protocol is followed, and appropriate data are recorded.

4. Materials and Equipment

Blood collection tubes: Sodium citrate or EDTA tubes (5-10 mL)

Automated Hematology Analyzer: Coulter or Sysmex analyzers for platelet count measurement

Microscope and Hemocytometer: For manual platelet counting, if necessary

Refrigerator: For storing samples if immediate analysis is not possible

5. Procedure

5.1 Pre-Analytical Phase

5.1.1 Patient Preparation

Verify the patient's identity and obtain informed consent for participation in the study.

Conduct a clinical assessment to evaluate the patient's platelet count and bleeding status before transfusion.

Record baseline clinical data, including the type of Leukemia, treatment regimen, and any complications.

5.1.2 Specimen Collection

Collect a baseline blood sample before platelet transfusion using proper venipuncture techniques.

Use a sodium citrate or EDTA tube for blood collection to prevent clotting and maintain platelet integrity.

Draw 5-10 mL of blood.

Label the sample with the patient’s ID, date, and time of collection.

5.1.3 Sample Handling

Transport the samples to the laboratory immediately after collection.

Ensure that the sample is not subjected to extreme temperature variations during transport.

Store samples in a refrigerator (2-8°C) if analysis cannot be performed immediately.

Platelet counts should be performed as soon as possible after collection to minimize changes.

5.2 Analytical Phase

5.2.1 Platelet Count Measurement

Use an automated hematology analyzer (e.g., Coulter or Sysmex) to measure platelet counts in all blood samples.

Ensure that the analyzer is calibrated and maintained according to the manufacturer’s instructions.

Prepare a blood smear, stain it with Wright-Giemsa, and examine under the microscope to check for platelet morphology and aggregation.

5.2.2 Quality Control

Ensure that all instruments are calibrated regularly.

Run control samples alongside patient samples to confirm the accuracy of platelet counts.

In cases of abnormal results or discrepancies, recheck the sample and repeat the analysis to confirm accuracy.

5.3 Post-Analytical Phase

5.3.1 Documentation and Reporting

Record all platelet count results, including pre-transfusion and post-transfusion values, and any abnormalities found during manual counts or platelet function testing.

Prepare a report that includes:

Pre-transfusion platelet count.

Post-transfusion platelet count at the specified time intervals.

Any significant clinical findings (e.g., patient reactions, bleeding events).

6. Safety and Quality Control

Personal Protective Equipment (PPE): All laboratory staff must wear appropriate PPE, including gloves, lab coats, and face shields, to ensure safety during blood collection and analysis.

Waste Disposal: Dispose of all sharps and biological waste in appropriate biohazard containers.

Infection Control: Follow institutional infection control policies, particularly when handling blood products and patient samples.

9 . Annex 2

consent form

As a data collector, you will be responsible for collecting accurate and reliable data from participants in accordance with the study protocol. You must adhere to all ethical guidelines and ensure participant confidentiality throughout the data collection process. This includes protecting all collected data and storing it securely.

You agree to maintain the confidentiality of all information obtained during the study and will not disclose any patient information to unauthorized individuals. Your participation as a data collector is voluntary. If at any time you feel uncomfortable or unable to continue, you are free to withdraw from your role without any consequences. However, we encourage you to notify the principal investigator if you choose to do so.

By signing below, you acknowledge that you have read and understood the contents of this consent form. You agree to fulfill the responsibilities of a data collector, including maintaining confidentiality and adhering to the ethical standards of the study.

Data Collector's Statement:

I understand my role and responsibilities as a data collector.

I agree to collect data as per the study guidelines and ensure its accuracy.

I will maintain the confidentiality of all participants and data.

I will securely handle and store all data as per the hospital's data security protocols.

Signature Section: -

Name of Data Collector _____

Signature _____ Date _____

Name of Principal Investigator Amanuel Genene

Signature _____ Date _____

Email: amanuelbanchi@gmail.com
Telephone: +251925504670

Consent Form

I confirm that I have a clear understanding of the objectives and conditions of the study and that I give my consent to participate. I have been provided with the necessary information about the research and understand that I have the right to withdraw from the study at any time.

Are you willing to participate in this study?

Yes _____

No _____

Signature: _____

10 . Annex 3

Questionnaire

Category	Question/Detail	Response Options
Patient Demographics	Sex	Male / Female
	If applicable, is the patient pregnant?	Yes / No
	Age	[ ] years
	Weight	[ ] Kg
	Height	[ ] cm
Medical History	Duration of illness	[ ] months/years
	Previous transfusion	Yes / No
	Treatment being taken	Specify: _____
	Duration of treatment	Specify: _____
Pre-transfusion Data	Platelet count	[ ] * 10^9
	Date of transfusion	[ ]
Transfusion Details	Number of units	[ ]
	Number of donors	Single / Multiple
	Transfusion reaction	Yes Specify: _____ / No
Post-transfusion Monitoring	Platelet count (1 hr post-transfusion)	[ ] * 10^9
	Platelet count (24 hr post-transfusion)	[ ] * 10^9
	Post-transfusion adverse reaction	Yes Specify: _____ / No
	Did the patient experience any infections?	Yes Specify: _____ / No

Category	Question/Detail	Response Options
Additional Information	Comments	_____

11 . Annex 4

መጠየቂያ ቅፅ

ምድብ	ጥያቄ/ዝርዝር	መልስ አማራጭ
የታካሚ መረጃ	ፆታ	ወንድ / ሴት
	ካለ፣ ታካሚው እርጉዝ ነው?	አዎ / አይደለም
	እድሜ	[ ] ዓመት
	ክብደት	[ ] ኪ.ግ
	ቁመት	[ ] ሴ.ሜ
የሕክምና ታሪክ	የሕመም ቆይታ	[ ] ወር/ዓመት
	ቀደም እንደተሰጠ የነበረ የደም ማስተላለፍ?	አዎ / አይደለም
	የምርመራ መድሀኒት በመውሰድ ላይ ነው?	ዝርዝር ይግለፁ: _____
	የሕክምና ጊዜው	ዝርዝር ይግለፁ: _____
ከመተላለፍ በፊት የተያያዘ መረጃ	የፕሌትሌት ቆጠራ	[ ] * 10^9
	የመተላለፍ ቀን	[ ]
የመተላለፍ ዝርዝር	የተሰጠው ክፍያ	[ ]
	የአቅራቢዎች ብዛት	አንዱ / ብዙ
	የመተላለፍ ምርምር	አዎ ዝርዝር ይግለፁ: _____ / አይደለም
ከመተላለፍ በኋላ እይታ	ከመተላለፍ 1 ሰዓት በኋላ የፕሌትሌት ቆጠራ	[ ] * 10^9
	ከመተላለፍ 24 ሰዓት በኋላ የፕሌትሌት ቆጠራ	[ ] * 10^9
	ከመተላለፍ በኋላ የተነሳ የጤና ችግር	አዎ ዝርዝር ይግለፁ: _____ / አይደለም
	ታካሚው ማንኛውንም እንክብካቤ ያጋጠመው?	አዎ ዝርዝር ይግለፁ: _____ / አይደለም
ተጨማሪ መረጃ	አስተያየት	_____

12 . Annex 5

Declaration

The undersigned declares that this thesis complies with the regulations of the University meets the accepted standards with respect to originality and quality. PI also agrees to accept responsibility for the scientific ethical and conduct of the Research project and for provision of required progress reports.

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