A PROSPECTIVE CROSS SECTIONAL STUDY TO EVALUATE THE INCIDENCE OF ACUTE TRANSFUSION REACTION AND ITS ASSOCIATED RISK FACTORS IN ATERITIARY CARE CENTER IN ETHIOPIA

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A RESEARCH THESIS SUBMITTED TO HEMATOLOGY UNIT,DEPARTMENT OF INTERNAL MEDICINE, COLLEGE OF HEALTH SCIENCES, IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE SUB SPECIALITY CERTIFICATE IN ADULT CLINICAL HEMATOLOGY.

FEBRUARY 2023

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ACKNOWLEDGEMENT

I would like to thank AAU, college of health sciences, department of internal medicine hematology unit for the opportunity to conduct the research project.

I extend my gratitude to my advisor Dr.Fissehatsion Tadesse for his unreserved support & encouragement to conduct the research.

My deepest appreciation also goes to the medical residents, interns, medical students &hematology unit outpatient transfusion department nurses for their support in collecting the research data.

List of Abrreviations & Accronyms

AAU - Adissababa University

AHTR – Acute Hemolytic transfusion reaction

ATR -Acute Transfusion reaction

BTS - Blood Transfusion Services

CHF - Congestive Heart Failure

COPD -Chronic Pulmonary disease

FFP- Fresh frozen plasma

FNHTR –Febrile Non hemolytic transfusion reaction

ICU -Intensive care unit

RBC - Red Blood Cell

SHOT - Serious hazard of blood transfusion

TACO -Transfusion associated cerculatory overload

TRALI -Transfusion related acute lung injury

UK -United Kingdom

U.S - United states of America

WHO - World Health Organization

ABSTRACT

Background

Transfusion reactions are adverse events associated with the transfusion of whole blood or one of its components. There is no institutional or national data in Ethiopia regarding the incidence of ATR & their risk factors. Theaim of this study is to measure the incidence of ATRs, frequency& time of occurrence of each ATR & evaluate their association with risk factors there by contributing to the institutional & national hem vigilance system.

Objective: The main objective of the study is to measure the incidence of ATR & determine their association with different clinical variables.

Methods: Prospective cross sectional study design is used to study in patient & outpatient adult transfusion recipients at the department of internal medicine, data was collected with a structured check list, analyzed with IBM SPSS version 24 software.

Result: A total of 210 study participants with the age of 13 & above were included in the study from September 1, 2022 – November 30 2022. 50.5 % of study participants are male & 49.5% are females ,the most common age group are between the age of 18 -40,the commonest blood group was O positive.Acute myelogenous leukemia is the commonest underlying diagnosis of the study participants; PRBC is transfused for the majority of patients given for 74.8% of cases. ATR incidence is found to be 10%,ATR was reported in 19.6%of platelet transfused patients as compared to 7% of PRBC, and none of FFP transfused patients develop ATR. FNHTR & urticaria are the commonest ATR observed. Significant association is seen between ATR & female gender, autoimmune disease & ABO incompatible platelettransfusion.

Conclusion: The incidence of ATR is higher than reported from previous studies indicating the need to improve institutional transfusion services particularly in high risk patients.

Key words: blood transfusion, ATR, hemovigilance

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1. INTRODUCTION

1.1BACKGROUND OF THE STUDY

A blood transfusion is an acute intervention, implemented to solve life and health-threatening conditions on a short-term basis by infusion of donated whole blood or blood components like RBCs, platelets, white cells & the different coagulation proteins.[1] Blood transfusion remains a common practice in the management of life threatening clinical situations like trauma, surgical blood loss, severe anemia & different bleeding disorders to replace missing clotting factors and immune system elements.[2,3]Although Blood transfusion is a back bone for the management of a variety of medical & surgical patients, it is not without risks & complications.

Approximately 20%of all transfusions may lead to some type of adverse reactions. Complications associated with blood transfusion therapy may be classified based on time of onset as acute and late transfusion reactions or based on etiology as immunological and non-immunological.

Early onset transfusion reactions are usually acute reactions that occur during transfusion or anytime within 24 hours following transfusion of the blood or blood components, while late reactions occur from 24 hours to 2 weeks following the transfusion [4]

ATRs include acute hemolytic transfusion reaction (AHTR), allergic reactions, febrile non-hemolytic transfusion reaction (FNHTR), transfusion associated circulatory overload (TACO), and transfusion related acute lung injury (TRALI) and anaphylactic reactions.[5]

The type and severity of transfusion reactions vary with the transfused blood product, the clinical condition of the recipient, past medical history and age of the recipient. [6]

Thus, it is important for health professionals to monitor patients during and after transfusion & it is essential to establish a system for monitoring, recording and reporting adverse reactions caused by blood transfusion in each hospital, thereby contributing to the national hemovigilance System.[7]

1.2STATEMENT OF THE PROBLEM

Transfusion reactions are adverse events associated with the transfusion of whole blood or one of its components. Despite the increasing public awareness on the risks and complications of blood transfusion that has resulted in a more stringent approach to donation, testing, and preparation of blood and its components, blood transfusion still is not without complications.

Reports of blood component transfusion reactions are variable across the globe depending on the quality of the blood transfusion service at the center. The frequency of the complications is however inversely related with the care exercised in the preparation for and supervision of the transfusion.[8]In the developing countries blood transfusion services are fragmented, nonuniform, with different levels of care depending on the institution which will increase risk of ATRs. Reported incidences of ATR differ significantly while incidence of 0.2% and 0.34% are reported in Europe and South America, the incidence of acute immune-mediated transfusion reactions is reported to be 11.8% in North East Nigeria. [9]

Learning from transfusion complications can drive the introduction of measures to enhance the quality, safety, efficacy and cost-effectiveness of blood and blood products as well as of the donation and transfusion processes. [10]The risk factors for common ATRs are reported only in few research papers & reviews performed before.

1.3 SIGNIFICANCE OF THE STUDY

In Ethiopia the incidence of ATRs & their associated risk factors is not known & there is no organized institutional hemovigiliance system which record &report ATRs to the national blood bank.

The aim of this study is to measure the incidence of patients who developed ATRs, frequency& time of occurrence of each ATR& evaluate their association with risk factors from patients transfused with blood components at Medical wards, ICU & out patient hematology unit transfusion department of Tikuranbessa specialized hospital during the study period there by contributing to the safe blood transfusion practice & improving the blood transfusion surveillance system in the hospital.

2.LITREATURE RIVIEW

Despite the increasing public awareness on the risks and complications of blood transfusion that has resulted in a more stringent approach to donation, testing, and preparation of blood and its components, blood transfusion is still associated with significant complications. The frequency of the complications, however, varies inversely with the care exercised in the preparation for and supervision of the transfusion. [8]

The most clinically important adverse effects of transfusion are infectious or immunological phenomena.

ATRs are mainly immune related transfusion reactions that occur during the transfusion procedure or shortly after it; these include acute hemolytic transfusion reaction (AHTR), Febrile non-hemolytic transfusion reactions (FNHTR), allergic (urticarial) reactions, anaphylactic reactions & transfusion related acute lung injury. Transfusion associated circulatory overload is also considered as ATRs although it's not an immune mediated complication. [11]

A total of 3,214cases were reported in the serious hazard of blood transfusion (SHOT) report in the year 2020 in United Kingdom. Of the total SHOT cases, 81.6% errors resulted from mistakes or human factors. The number of cases with major morbidity was139 and the total deaths reported were 39.The reported major morbidities were hemolytic transfusion reactions, transfusion associated circulatory overload (TACO), and transfusion-transmitted infection, transfusion related acute lung injury (TRALI), ABO incompatible transfusion, and transfusion of incorrect blood product. Non-infectious complications, particularly delays in transfusion and TACO were the most common causes of transfusion-related deaths in the United Kingdom in 2020. [12]

In U.S 2019 hemovigiliance report there were an estimated 293.7 blood transfusion-associated adverse reactions in the United States that required any diagnostic or therapeutic intervention per 100,000 components transfused, among the ATRs febrile non-hemolytic transfusion reaction is the commonest accounting for 119.1 per 1000 blood component transfusions. [11]

In study by Rohitetal ATRs were documented in 0.2% of the hospitalizations (TACO 0.08%, TRALI 0.06%, FNHTR 0.09%, others 0.003%) among hospitalized patients in United States of America .[13]

In Africa especially sub-Saharan Africa reports of transfusion reaction are limited as the hemovigilance system is not well developed; only few studies are available reporting about the rate of ATRs. In a study done in Namibia only 0.2 % of transfusion reactions were reported to the survelliance system.[14].In study done in Nigeria by Baffa et al the incidence of ATRs was reported to be 3.6%, out of which 3.3% were FNHTR and 0.3% were acute allergic reaction.[8]

In Ethiopia the study done by Yemataw et al ,which is the only study so far , the reported incidence of ATRs were found to be 5.2%.[15]

Frequencies of ATRs differ according to the types of blood components, numbers of transfusions, and patient's condition. In a study reported in Japan byYuki Hatayama et al adverse reactions were reported in 5.7% platelet concentrate ,1.6% of red blood cell component and 2.2%fresh frozen plasma transfusions(FFP) from total of 18,745 transfusions over a period of 3 years. Allergic signs and symptoms accounted for 70% of all adverse events & severe signs and symptoms were observed in 7.1% of patients.[16]

In a study by Chao-Yuan Yao which reported associated factors with ATRs, 3.5% of patients from reported events are associated with ATR. In this study pre transfusion Leukopenia, Increased Diastolic pressure & elevated temperature have significant association with ATRs.[17].

Rohit et al reported that CHF and COPD are the common clinical condition associated with ATRs

Yematawetal reported that multiple transfusion, previous transfusion history, abortion history & longer blood storage time are associated with occurrence of ATRs.[15]

The distribution of the types ATRs is known to vary depending on the types of blood components, the number of transfusions, and the patient's condition.[18]

FNHTR is more common in children than adults, usually seen in plasma products than RBC or platelet transfusion, It is also less common in prestorageleuko reduced blood product.[19]

AHTRs are most commonly seen in the setting of ABO blood group incompatibility due to procedural error during blood group type &crossmatch.[20]

The risk of TACO is increased in setting of multiple transfusions, larger amount of plasma transfusion and faster blood product infusion rate. It is also seen commonly in patients with chronic pulmonary disease.[21]

The clinical conditions associated with TRALI are Liver transplantation surgery, Chronic alcohol abuse, Shock, higher peak airway pressure while being mechanically ventilated, current smoking,& Positive fluid balance according to multicenter prospective cohort study based on active surveillance .[22]
The time of occurrence of ATRs is variable depending on the type & severity of complications, there are no much studies reported evaluating the time of occurrence of the ATRs,

In study done by Yuki etal more severe ATRs tend to occur early than the non-severe ones with the median time of occurrence being 20 minutes & 100 minutes respectively.[18]

In Ethiopia studies about the transfusion related complications are limited. So far only one study is reported on the proportion of patients developing ATRs & associated clinical conditions.

3. OBJECTIVES

3.1 General Objective

- Measure the incidence of ATRs & Evaluate their association with risk factors among patients transfused with different types of blood components.

3.2 Specific Objectives

- Measure the incidence of ATRs
- Determine the association between each ATR & its risk factor
- Measure the time of occurrence of ATRs

4 METHODS & MATERIALS

4.1 Study design

A Cross-sectional prospective study was conducted from patients who was transfused with Blood components at Medical wards, ICU & out patient transfusion department of Tikuranbessa specialized hospital during the study period.

4.2 Study period

The study was conducted from September 1, 2022 to November 30, 2022

4.3 Study area

The study was conducted at TASH which is located in Addis Ababa, the capital city of Ethiopia. It is the biggest referral hospital in the country with 700inpatient beds and providing service to an estimated 500,000 patients annually. It also serves as a teaching hospital for undergraduate & post graduate medical & other health science students under the administration of adissababa university College of health sciences.

4.4 Study population

All Patients who were transfused with different Blood components at Medical wards, ICU & out patient transfusion department of TASH during the study period.

4.4.1 Inclusion criteria

- Age ≥13 years
- Patients who were transfused with blood products at Internal medicine department wards & Medical ICU
- Patients who received blood component transfusion at outpatient hematology unit transfusion department.

4.4.2 Exclusion criteria

- PatientsAge <13 years
- Patients who received transfusion at hospital units other than Internal medicine wards, medical ICU & outpatient hematology unit.

4.5 Study variables

4.5.1 Dependent variables

- Identified acute transfusion reactions

4.5.2 Independent variables

Socio demographic variables

- Age
- Sex

Clinical variables

- Diagnosis of the patient
- Indication for transfusion
- Blood Group & Rh of the patient
- WBC Count, Hemoglobin & platelet count of the patient at time of transfusion
- Type of Blood component transfused

Transfusion related variables

- Risk factor for identified acute transfusion reaction
- Previous history of transfusion
- Number of blood components transfused
- Time of development of acute transfusion reactions after initiation of transfusion

4.6 Operational definitions

1. Acute Transfusion reactions – Any signs & symptoms of transfusion reactions that occur during the transfusion episode or within 24 hours of completion of transfusion.

2. Acute Hemolytic transfusion reactions – development of fever, chills & bleeding from IV site during the transfusion or 24 hours post transfusion plus identification of ABO incompatible blood transfusion.

3. Allergic (urticarial) transfusion reaction –the development of Itching, urticarial or localized angioedema during the transfusion episode or within six hours post transfusion.

4. Anaphylactic transfusion reaction – the development of hypotension, angioedema, respiratory distress and/or wheezing within few minutes of initiation of transfusion & rapid correction of signs & symptoms to epinephrine therapy.

5. Febrile Non Hemolytic transfusion reaction – the development of Fever >38ºC temperature elevation or more than $1^{o}C$ from the baseline& chills without other systemic symptoms or bleeding from any site during the transfusion episode or within six hours post transfusion.

6. Hypotensive Transfusion episode – a drop in systolic blood pressure by 30mmHg from pre transfusion blood pressure excluding other causes of hypotension.

7. Transfusion associated circulatory overload - New development or worsening of pulmonary or peripheral edema diagnosed clinically or radiologically during the transfusion episode or 12 hours post transfusion.

8. TRALI – the development or worsening of fever, chills& respiratory distress during the transfusion episode or 24 hours post transfusion.

4.7 Sample size

The sample size was determined based on single population formula with the following assumption:

$$\mathbf{N= (z\alpha/2)^2 p\ (1-p)/w2}$$

N=minimum sample size, w=estimated error will be half of the incidence in previous study that is 5.2/2 = 2.6% i.e. w= 0.026 because of the small incidence reported; P=population proportion in problem = 0.052, taken from a similar study done in bahirdar on proportion of acute transfusion & associated factors among transfused patients reporting5.2 % proportion of ATRs,[15] $Z\alpha/2$ = degree of confidence =1.645.

$N= (1.645)^2 X0.052\ (1-0.052)/ (0.026)^2$

The minimum sample size, N= 191, by adding 10% nonresponse rate the final Sample size of the study will be 191 + 19 = 210.

4.8 Sampling technique

All patients receiving blood component transfusion at Internal medicine wards, medical ICU & adult outpatient hematology unit transfusion department were included in the study, only their single transfusion episode during the study period was included in the study.

4.9 Data collection procedure

A structured questioner was used to collect data on the dependent & independent variables.

4.10 Data quality assurance

The data was collected by trained nurses, Interns, residents& medical students working in the transfusion department, Internal medicine wards& medical ICU. Before the data collection, the data collectors were trained on how to administer the questioner by the principal investigator. There was also a regular supervision to data collectors by the principal investigator to maintain the data quality.

4.11 Data analysis and interpretation

The data was analyzed using SPSS version 24

4.12 Ethical considerations

Ethical clearance was obtained from Adissababa University College of health sciences institutional review board prior to data collection.

4.13 Dissemination of the study

The result of the study will be submitted to the hematology unit of the department of internal medicine. It will also be submitted to appropriate journal forpublication.

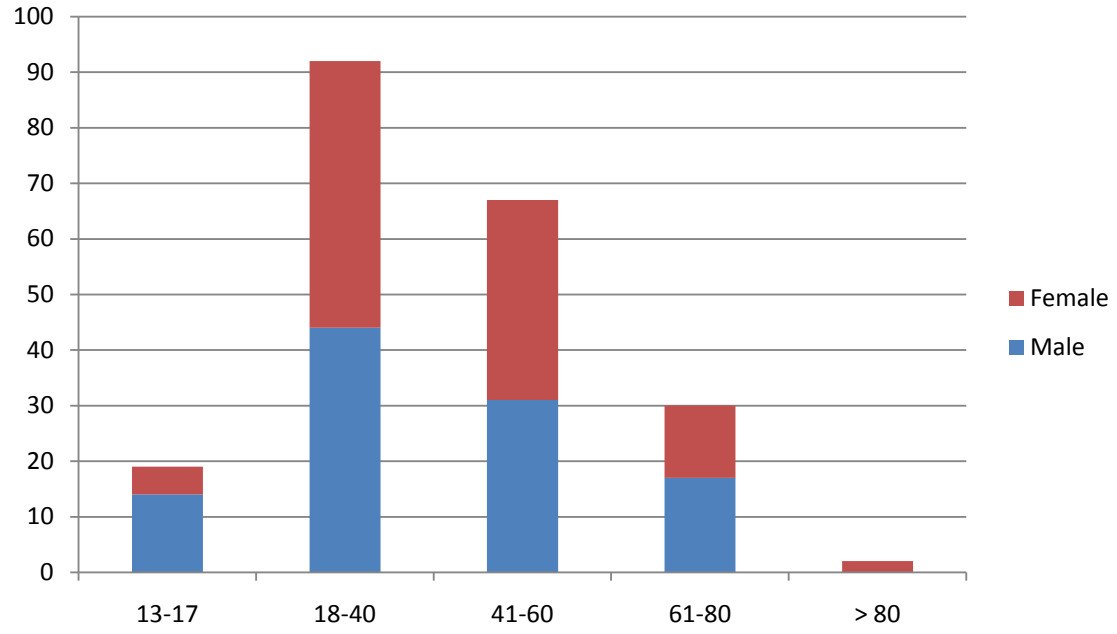
5. **RESULT**

5.1 Socio demographic characteristics of the study participants

From September 1 to November 30, 2022, atotal of 210 patients who were transfused withdifferent blood component during the study period were included in the study.

106 (50.5 %) of patients are males & 104 (49.5%) are females .The study patients were categorized with the age group & the most common age group included in the study were between age group 18- 40 accounting for 92 (43.8%) of patients.

Figure 1- Age& sex distribution of study participants

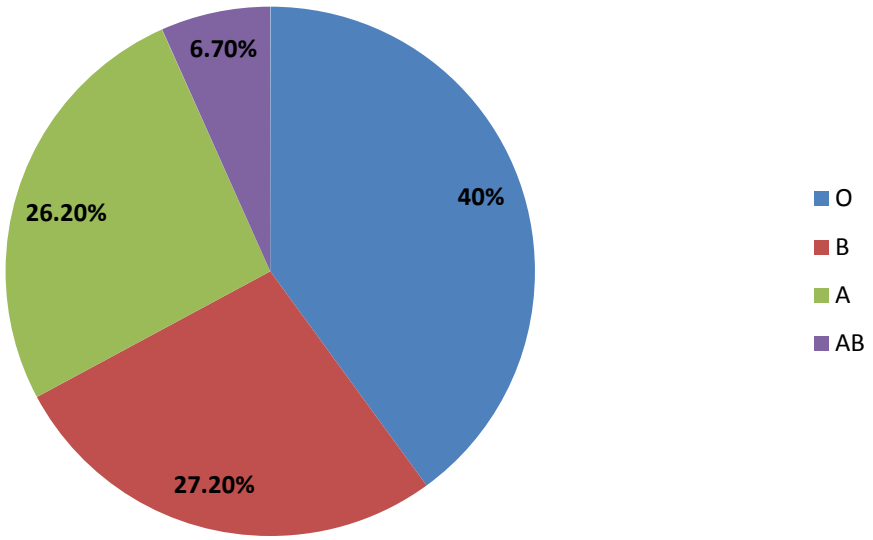


5.2 Blood Group & diagnosis of study participants

The most common blood group identified among the study participants was O blood group which account for 40 % of the study population, others include blood group B(27.2%), A (26.2%) & AB (6.7%) of patients. The RH status of the study also studied & showed 198 (94.3%) were RH positive & 12 (5.7%) were RH negative. Considering both the blood group & Rh status of the patients Otve is the commonest blood group seen in 79 (37.6%) of patients.

The three most common medical problems identified among the study participants were Acute myelogenous leukemia ,Aplastic anemia & Chronic myelogenous leukemia which are observed in 62 (29.5%),32 (15.2%) & 24 (11.4%) patients respectively.

Figure 2 – Blood group of study participants



5.3 Type of blood components transfused

Blood components transfused for the study population were Packed RBC, Platelets& FFP which were given for 157 (74.8%), 51(24.3%), 2 (1 %) patients respectively.

5.4 Proportion of Acute Transfusion reaction

From the total of 210 transfused patients with different blood component products 21 (10%) patients develop acute transfusion reaction during the study period; 11 of which are seen among patients transfused with PRBC,10 patients develop ATR after platelet transfusion.Based on patients subjective report of ATR 32 (15.2%) of patients developed at least one episode of ATR previously.

5.5. Type of ATR

FNHTR & urticaria are the only acute complications of transfusion identified during the study period which were seen in 12 (5.7%) & 9 (4.3 %)patients respectively.

When ATR were analyzed according to blood components, ATR was seen in 11 (7%) patients transfused with packed RBC &10 (19.6%) patients transfused with platelets, no patients transfused with FFP developed ATR.

5.6Time of occurrence of ATR

The time of occurrence of ATR was variable among study subjects.The majority of patients (52.4%) with ATR develop with in a period of one to six hours.

Table 1 - Time of occurrence of ATR

Time of occurrence of ATR	Frequency	Percent
< 30 minutes	**3**	**14.3 %**
30 minutes - 1 hour	**7**	**33.3%**
1 hour – 6 hours	**11**	**52.4%**

5.7 Association of ATR with different clinical variables

5.7.1 ATR &Gender

From patients who developed ATR 15 (71.6%) were females& 6(28.6%) were males. There is significant association between the patients' gender & the development of ATR with two sided significance **P value of 0.04**by Pearson chi-square& Fischer's exact test.

5.7.2 ATR &Age

ATR developed most commonly in age group 18 - 40 years accounting for 47.6 % of ATR cases but there was no significant association between age group differences in the development of ATR with Pearson chi square test **P value of 0.21**.

5.7.2ATR & Blood group

There was no significant association between the blood group of the study subjects & the development of ATR with Pearson chi square test **p value of 0.09**.

5.7.3 ATR & blood component transfused

Among 157 patients transfused with Packed RBC only 7% of patients developed ATR but 19.6 % of patients among 51 platelet transfused patients developed ATR. Large number of patients who are transfused with platelets developed ATR than those transfused with PRBC & FFP & there is a significant association between type of blood component transfused & the development of ATR with a Pearson chi square **P value of 0.03**.

5.7.4 ATR & Previous history of transfusion

Out of the 32 patients with previous history of transfusion 8 patients developed ATR &there is no significant association observed between current ATR & previous history of transfusion with **2 sided significance level of 0.06 (P >0.05)** by Pearson chi square test.

Table 2 – Distribution of ATR by previous transfusion

Acute transfusion reaction	**Previous transfusion**		**Total**
	Yes	**No**	
Yes	8	13	21
NO	24	165	189

P = 0.06 (Fisher exact) Chi-square = 9.438df = 1

5.7.5ATR &Autoimmune disease

11 patients (5.7 %) of the total study population were found to have autoimmune diseases. From those who developed ATR 4 (19%) patients has autoimmune disease documented & the association between ATR & the presence of autoimmune disease is observed with Pearson chi square **P value of 0.011**.

5.7.6 ATR & ABO incompatibility

ABO incompatible transfusion was seen in 6 (2.9%) of the study patients & all were observed during platelet transfusion. ABO mismatch transfusion is seen in 60 % of platelet transfused patients who developed ATR.

Significant association observed between the presence of ABO incompatibility &ATR with Chi square lambda correlational analysis **P value of 0.013**.

6.**DISCUSSION**

A total of 210 blood recipients participated in this study, out of which 106 (50.5 %) of patients are males & 104 (49.5%) are females with M;F ratio of 1.1 : 1 & the commonest age group reported to receive blood component transfusion during the study period are the age group between 18- 40.

The commonest diagnosis reported among transfusion recipients is acute myelogenous leukemia which accounts for 29.5% of the study subjects which is different from the study reported in Nigeria by Baffa A. etal which reported the commonest diagnosis among the blood recipients was HIV/AIDS accounting for 16.1% cases while malignancies in general accounted for 15.6% cases;[8] this may be due to the difference in the baseline characteristics of the study population ,our study is performed in adult medical patients in a tertiary care hospital where majority of transfused patients have the diagnosis of hematologic malignancies.

ATR is seen in 10 % of our study population which is higher than the studies done at U.S which reported ATR incidence rate of 0.2% in the study reported by Rohietal,it is also higher than the studies reported in Namibia,Nigeria which reported incidence rate of 0.2%,3.6% & also higher than the study done in other area of Ethiopia which reported ATR rate of 5.2% (20 patients out of 364 blood recipients).[8-14]

In our study the ATRs identified are only FNHTR &urticaria (acute allergic reactions) which are also the most common ATRs reported from different centers; FNHTR is seen in 57.1 % &urticaria in 42.9% among patients who developed ATR which is similar to the study by Pahuja et al which reported the frequency of FNHTR &urticaria as 54.7% & 41.4% respectively, [24]but it is different from the study by Yematawetal which reported allergic reactions in 65% while FNHTR in 30% of ATRs.[15]

Frequency of ATR is variable depending on the type of blood components transfused, in our study proportion of ATR is higher among platelet transfused patients which is seen in 19.6 % of 51 platelet transfused patients but only 7% of RBC transfused patients developed ATR .This finding is higher than the study

done in japan by Yuki Hatayama et al which reported ATR rate in 5.7% of platelet concentrate ,1.6% of red blood cell component and 2.2% FFP .

In study done in India by NigaetalATR were seen mostly with whole blood(43.5%) and PRBCs (48.5%) ,ATR to platelets was seen in 6/101 (5.9%) cases.[18, 23]

We evaluated the time from initiation of transfusion to the occurrence of signs and symptoms of ATR, the majority of ATR (52.4%) developed during the period of one to six hours after the initiation of transfusion & there was no significant difference between the time of occurrence of ATR, blood component transfused & type of ATR which is similar to the result in the study done in Japan byYuki Hatayama et al. This indicates that patients need close follow-up during the first six hours after transfusion initiation. [18]

In this study, a statistically significant relationship was obtained between ATR and the gender of the transfused patients, type of blood component transfused & the presence of autoimmune diseasein which female, ABO mismatched platelet transfused & those with autoimmune diseases are associated with the development of ATRs ; this findings are different from studies performed in Nigeria which reported a significant relation between ATR with previous transfusion &the age of stored blood components[8];it is also different from the study by Yemataetal which reported ATR was associated with transfusion history ,abortion history, storage time and transfusion of 3 or more of units of blood/blood components .[15]

ABO & RH incompatible platelet transfusion service is given by many centers due to inventory constraints when single donor apheresis platelets are not available; clinically significant transfusion reactions, thoughuncommon,are seen with ABO mismatched platelet transfusions. [25]

In our study all (6 out of 45 platelet transfusions) of ABO mismatched platelet transfusions are associated with ATR particularly acute allergic reactions (urticaria).

In our study there is no significant association seen between ATR &the age, blood group, previous transfusion &previous ATR history of the study participants.

7. CONCLUSION

The incidence of ATR is 10 % of the studied population which is higher than the reports from other studies .FNHTR is the commonest ATR seen in 5.7 % & urticaria was seen in 4.3 % of the study subjects. ATR is seen commonly in platelet transfused patients as compared to PRBC or FFP recipients. Significant association is seen between ATR & female gender, the presence of auto immune disease & ABO incompatible platelet transfusion unlike other studies in which significant association of ATR was seen with previous transfusion history, previous abortion history & baseline leukopenia & storage time of the blood product .

The commonest time of occurrence of ATR is the first six hours after initiation of the transfusion.

It is recommended from this study that Blood transfusion is not without risks, transfused patients need due attention& close follow-up particularly during the first six hours of transfusion. Female patients especially those with autoimmune disease need especial attention due to the strong association with the development of ATR.

Platelet transfused patients need to be followed carefully for the development of ATR & ABO mismatched platelet transfusion need to be avoided as much as possible by advocating single donor platelet transfusion practice.

8. **STRENGTHS AND LIMITATIONS OF THE STUDY**

This study is one of the few studies performed on transfusion medicine & the 2nd of its kind reporting the incidence of ATR & associated factors in the country so far.

It is a prospective crossectional study which tries to assess the incidence of ATR, associated factors & their occurrence time in a setup where there is no strong transfusion reaction reporting system which will help to contribute data to the development of institutional & national hemovigilance system.

Small sample size, short study period & the limited group of patients studied are the limitations of the study which will make the generalization of the results to the wider transfusion recipient population difficult; therefore it is recommended to study wider population over a longer period of observation in the future so that the incidence of ATRs including those that are not identified in our study will be determined.

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10.ANNEXES

This is a study to evaluate the incidence of acute transfusion reaction and its associated risk factors in a tertiary care center in Ethiopia.

It is being conducted by Dr.Temesgen Assefa, final year Adult Clinical hematology fellow at Adissababa University College of health sciences,

The aim of the study is to assess the development of acute transfusion reactions & identify their association with the possible risk factors & determine the commonest time of occurrence of the acute transfusion reactions; this will help to improve the transfusion service in the hospital.

I appreciate your participation in the study and thank you for your cooperation.

I. English version of the questionnaire

Part I: Sociodemographic data

S.No	Characteristics	Findings
1	I care number	
2	Age in years	
3	Sex	1. Male 2. Female
4	Marital status	1. Single 2. Married 3. Divorced 4. Widowed
5	Address by region	1. Adissababa 2. Oromia 3. Amhara

		4. Tigray **5. Sidama** **6. Afar** **7. Somali** **8. Harari** **9. SNNP** **10. South western** **11. Diredawa** **12. Benishangul** **13. Gambella**

Part II: <u>Clinical Data</u>

No	**Characteristics**	**Findings**
1	**Blood Group of the patient**	**1. A 2.B 3.AB 4. O**
2	**Rh status of the patient**	**1.Rh positive 2.Rh Negative**
3	**Diagnosis of the patient**	
4	**Indication for transfusion**	**1Anemia 2.Bleeding 3.thrombocytopenia 4.DIC 5.Other**
5	**Type of Blood component transfused**	**1.Packed RBC 2.Platelet** **3.FFP 4.Cryoprecipitate**
6	**CBC profile of the patient at time of Transfusion**	**1.WBC count_____** **2.Hemoglobin_____** **3.Platelet count_____**

Part III: <u>Acute transfusion reaction data</u>

No	**Characteristics**	**Response**
1	**Acute transfusion reaction developed**	**1. Yes 2. NO**
2	**Type of Acute transfusion reaction**	**1.FNHTR** **2.Urticaria** **3.Anaphylaxis** **4.AHTR** **5.TRALI** **6.TACO**
3	**Time of ATR development after the start of transfusion**	**1.< 30minutes** **2.30 minutes -1 hour** **3.1 hour – 6 hours** **4.6 hour -12 hour** **5. 12 hour -24 hour**
4	**Risk factor identified for ATR**	
	1. Parity (Female transfusion recipient)	**1.Nulliparous** **2.Multiparous**
	2.Previous history of Blood Transfusion	**1. Yes 2.NO**
	3.Underlying Cardiac disease	**1.Yes,Specify_____**

		2.No
	4.Underlying Chronic Pulmonary disease	**1.Yes,Specify** **2.No_____**
	5.Underlying Malignancy	**1.Yes,Specify_____** **2.No**
	6.Underlying Autoimmune disease	**1.Yes,Specify** **2.No_____**
	7.ABO incompatibility	**1. Yes** **2.No**
	8.Other identified risk factor	**1.** **2.** **3.** **4.**

II. Declaration

I, the under signed, declared that this is my original work &has never been presented in this university before, and that all the resources and materials used for the research, have been fully acknowledged.

Principal Investigator:

Name: **Dr Temesgen Assefa (Adult clinical hematology fellow)**

Signature: ----------

Date: ----------

Advisor:

Name: **Dr**. Fissehatsion Tadesse **(Internist/Hematologist, Associate Professor)**

Signature: ----------

Date: ----------