Incidence and Analysis of 7 Years Adverse Transfusion Reaction: A Retrospective Analysis

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Abstract Safe blood transfusion is the primary need of all the health care delivery system. Though with the advances of transfusion medicine, the incidences of transfusion risk is gradually reduced, but the adverse transfusion reaction (ATR) of non hemolytic type still prevails. The purpose of this study was to estimate the incidence and pattern of transfusion-related adverse events at our centre. The present retrospective observational study was conducted in the Department of Transfusion Medicine from April 2011 to April 2018, at a multi-organ transplant centre in South India. All the Adverse transfusion reactions were investigated in detail in the blood bank for the clerical errors, immunohematology workup and classified according to their nature with imputability assessment. A total of 140 ATR were reported out of 100,569 blood components distributed during the study period. After the analysis and workup of the reported reactions, majority of the reactions were observed in males (71%, $n = 99$). Most common symptom presented was Itching/Rashes in 43.6% ($n = 61$) ATR. Allergic reactions (51.4%, $n = 72$), were the most commonly encountered ATR followed by FNHTR (25.7%, $n = 36$). FFP transfusions (0.2%) contributed to the majority of the reactions followed by Red cell transfusion

(0.15%). ATR were observed maximum in Hepato-biliary disease and liver transplantation patients (62%) followed by oncology patients (15%). The overall incidence of ATR in our study is 0.14% which is comparatively low compared to other studies due to well established hemovigilance systems. Adoption of more equipped methods & sensitive technology in various areas of blood banking will help to bring down the unwanted adverse transfusion reactions.

Keywords Transfusion reaction · Allergic reaction · Hemolytic · Febrile · Hemovigilance · Blood

Introduction

Access to safe blood transfusion practice is an integral part of all the basic healthcare delivery system. Inspite of these, blood transfusions are also embedded with risks ranging from minor to severe life threatening. These risks are being classified into the broad category of immune mediated and non-immune mediated. Over the past few decades, several strategies are being adopted to minimize the rate of adverse transfusion reaction (ATR) rates. The strategies include not only promotion of voluntary non-remunerated blood donors, stringent selection of blood donors and screening of donated blood for transfusion-transmissible infections using sensitive assays, but also regular quality control on blood units, leukoreduction techniques, conduction of hospital transfusion committees and reporting ATRs to hemovigilance. Advances in transfusion medicine, coupled with availability of blood products and their substitutes helped in reducing transfusion reaction rates [1, 2] The purpose of this study was to estimate the incidence and pattern of transfusion-related adverse events in our centre.

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Materials and Methods

Study Set Up

Data from standardized records were collected from Department of Transfusion Medicine (TM), in a multiorgan transplant centre in South India. Records of all the events were reviewed from (April 2011–April 2018) over a period of 7 years and were analyzed.

Study Design

This was a retrospective observational study in which all ATRs were reported to the blood bank. All transfusion reactions during this period were included in this study. As per hospital policy, 100% components were prepared and no whole blood was issued to patients at our centre. All the components were 100% buffycoat reduced and in liver disease patients, only prestorage leukoreduced using labside filters and leukoreduced Single donor platelets (SDP) were transfused.

A clerical check was performed by the assigned staff before transfusing the blood component and patient was monitored from the start of each transfusion till the end for the occurrence of any ATRs. In the event of a transfusion reaction, a filled up transfusion reaction reporting form was sent to the blood bank along with left over blood product bag & post-transfusion patient blood and urine samples. Further workup for confirmation of transfusion reaction was carried out in the TM department.

A repeat ABO/Rh blood grouping & typing, repeat compatibility testing, screening for irregular antibodies was done and was compared with the pretransfusion sample. In case of a suspected hemolytic transfusion reaction—Direct antiglobulin test, Qualitative and Quantitative estimation of plasma Hemoglobin %, Serum Bilirubin and Peripheral blood smear examination for the presence of schistocytes and spherocytes.

The turn-around time of transportation of unit from blood bank to bedside, storage conditions, delayed start of transfusion (> 30 Min) or prolonged transfusion (> 4 h),

any evidence of thermal, oncotic or osmotic injury was checked by checking the unit for hemolysis to rule out pseudo-hemolytic transfusion reactions.

Allergic, Febrile nonhemolytic transfusion reaction (FNHTR), anaphylactoid reactions were diagnosed solely on the basis of clinical features like fever, chills, rashes, where other possible reasons were ruled out. Allergic reaction was differentiated from anaphylactoid reactions by the absence of systemic manifestations such as bronchospasm, hypotension etc.

FNHTR was defined as a body temperature rise of > 1 °C or more, with or without chills and rigor occurring in association with transfusion and without any other explanation.

In suspected cases of bacterial sepsis, remaining bag was sent for blood culture and results were co related with patients culture reports.

TRALI was diagnosed in patients with acute respiratory distress within 6 h with bilateral infiltrates on chest X-ray and was differentiated with Transfusion associated circulatory overload (TACO) on basis of Blood pressure, volume status of patient and response to diuretics.

Hypotensive reaction was defined as isolated fall in systolic or diastolic BP of > 30 mm Hg within one hour of transfusion and systolic BP < 80 mm Hg.

After completion of transfusion reaction workup, categorization of transfusion reaction was done on basis of reported signs and symptoms, workup results and investigation reports as defined in AABB [3] and the data were submitted to the Hemovigilance Programme of India (HvPI) after imputability assessment since 2017.

Results

A total of 100,569 blood components were issued to various wards, OT, adult and pediatric critical care units and transfused during the study period (April 2011–April 2018). The incidence of ATR per thousand components is shown in Table 1. A total of 140 (0.13%) adverse

Table 1 Year Wise frequency of ATRs with respect to total number of units

Year	Total no of units transfused	Frequency of ATR (%)	Incidence of ATR (Per 1000 components)
2011	9305	6 (0.06%)	0.644
2012	12,147	8 (0.06%)	0.658
2013	13,741	18 (0.13%)	1.30
2014	13,207	24 (0.18%)	1.81
2015	13,085	11 (0.08%)	0.84
2016	15,939	29 (0.18%)	1.81
2017	17,570	38 (0.21%)	2.16
2018 ^a	5575	6 (0.1%)	1.07
Total	100,569	140 (0.139%)	1.39

^aIncludes Jan to April month data only

Table 2 Characteristics of Recipients with recognized ATR

Age (years)	Paediatric age median (n = 8)	14.5 (1–18 y)
	Adult age median (n = 132)	50 (20–86 y)
Gender	Male	99 (70.7%)
	Female	41 (29.3%)
Department/ speciality wise	Hepato-biliary diseases & Liver Transplantation	87 (62.14%)
	Intra-operative	4 (4.59%)
	Therapeutic	83 (95.4%)
	Oncology	15 (10.71%)
	General medicine	11 (7.85%)
	Cardiology	9 (6.43%)
	Neurology	5 (3.57%)
	Nephrology	3 (2.14%)
	Orthopaedics	5 (3.57%)
	Urology	3 (2.14%)
	Gastroenterology	2 (1.42%)
	Repeat ATR	15 (10.71%)

transfusion events were reported in the study period in 132 patients. The majority of ATR were noted in adults, the median range being 50 (20–86 years). The majority of adverse events occurred following transfusion of SDP transfusion (0.27%). Table 2 shows speciality wise transfusion reactions that occurred which is maximum in Hepatology department.

Mean volume of blood unit transfused at the time of ATR was 45 ml (20–245 ml). Out of 54 units of packed red cells causing ATR, (24) 44.5% were buffy coat reduced while (30) 55.5% leukofiltered components which were issued to transplant unit on a request basis. Table 3 shows

Fig. 1 Prevalence of types of ATR from 2011 to April 2018

the type of transfusion reactions with respect to the associated component transfused. Allergic reactions were the most commonly encountered ATR (51.4%). Rashes and itching (43.6%) were the most common symptom noticed in ATR followed by Tachycardia (39.3%) and Fever (26.4%).

Allergic Reaction

Allergic reactions were the most commonly encountered ATR in this study comprising 51.4% (72/140) of all ATRs (Fig. 1). FFP was implicated in 0.14% (40/72), followed by RDP in 0.07% (14/72) (Table 3). About 96.7% of Allergic Patients presented with a common symptom of rashes and itching.

Table 3 Type of ATRs with respect to component transfusion

Types of ATR	Components transfused						Total (n = 140)
	^a BC-PRC (n = 17,745)	^b LDPRC (n = 18,566)	FFP (n = 28,775)	SDP (n = 4406)	RDP (n = 19,985)	Cryoprecipitate (n = 11,092)	
Allergic	6	8	40	3	14	1	72 (51.42% ^a)
FNHTR	10	14	7	5	0	0	36 (25.7%)
Hypotension	0	2	3	2	0	2	9 (6.4%)
TACO	2	1	2	1	0	0	6 (4.3%)
TRALI	2	0	2	0	1	0	5 (3.6%)
HTR	3	2	0	0	0	0	5 (3.6%)
Anaphylactoid	0	1	2	1	0	0	4 (2.9%)
Others	1	2	0	0	0	0	3 (2.1%)
TOTAL	24 (^b 0.13%)	30 (0.16%)	56 (0.19%)	12 (0.27%)	15 (0.08%)	3 (0.03%)	140

BC-PRC buffy coat depleted Packed red cells, LDPRC leukodepleted Packed red cells, FNHTR febrile nonhemolytic transfusion reaction, TACO transfusion associated circulatory overload, TRALI transfusion related acute lung injury, HTR hemolytic transfusion reaction

^aPercentage of adverse reaction out of totals adverse transfusion reactions noted

^bPercentage incidence of adverse transfusion reaction after transfusion of blood component

Febrile Non Hemolytic Transfusion Reaction (FNHTR)

FNHTR was the second common type comprising 25.7% (36/140) of ATRs (Fig. 1). FNHTR was seen in 0.07% (14/36) patients after Leukodepleted packed red cells (LDPRC) transfusion followed by 0.05% (10/36) after Buffy coat depleted Packed red cells (BC-PRC) transfusion (Table 3). About 78.4% of FNHTR patients had the most common symptom of Fever and about 66.6% had complaints of chills and rigor.

Anaphylactoid Reaction

Anaphylactoid Reactions were seen in only 2.9% (4/140) (Fig. 1) in which two were due to FFP transfusion and one each due to LDPRC and SDP transfusion (Table 3). 1 out of 4 (0.25%) anaphylactoid reaction was reported intra-operatively where patient developed hypotension and bronchospasm during SDP transfusion, the rest 3 (0.75%) were reported in ICUs. All the patients recovered without any sequelae.

Transfusion Related Acute Lung Injury (TRALI)

TRALI was reported in 3.6% (5/140) ATR cases (Fig. 1). FFP was associated in 2(0.006%) followed by Buffy coat depleted PRC in 2 (0.01%) TRALI cases, whereas pooled RDP was associated in 1 (0.005%) (Table 3). All patients were suffering with liver disease with history of multiple transfusions and presented with dyspnea and respiratory distress was in 4 out of 5 (80%) of TRALI cases. TRALI were confirmed by chest X ray showing bilateral infiltrates.

Transfusion Associated Circulatory Overload (TACO)

TACO comprised 4.3% (6/140) of ATR cases (Fig. 1). TACO was reported in patients on multiple transfusions specially after PRC and FFP transfusion (Table 3). One patient is a case of combined Chronic kidney disease with cardiac dysfunction and the rest are end stage liver disease patients.

Hemolytic Transfusion Reactions (HTR)

Hemolytic reactions contributed to 3.6% (5/140) of ATR rates (Fig. 1). Out of 5, three are males and two were females. 4 cases were observed after BC- PRC and one LDPRC transfusion (Table 3). 2 out of 5 HTR (40%) were reported intraoperatively with features of red colored urine and hypotension during liver transplant surgery. Various possible reasons were checked and a possible diagnosis of

pseudo hemolytic HTR due to improper warming of blood before transfusion was given.

2 (60%) patients, HTR were noticed in the intensive care units due to improper storage of blood in domestic refrigerator and delayed transfusion respectively. One case was a road traffic accident (RTA) with massive bleed and multiple units transfusion and had dark colored urine 2 h post transfusion and possibility of mechanical hemolysis by applying pressure on blood units was kept.

Hypotensive Reactions

We observed 9 (6.4%) hypotensive ATR cases (Fig. 1). 4(0.01%) cases were seen after FFP transfusion (Table 3).

Discussion

Any unfavourable transfusion related event occurring in patient during or after transfusion of blood and blood components is labelled as Adverse Transfusion Reaction (ATR). ATRs are being reported by transfusing centres/hospitals on a voluntary basis to hemovigilance in India. Incidence rates of transfusion reactions are reported by various hemovigilance systems. The hemovigilance network in France reported a rate of 0.25 incidents/100 blood components between 1994 and 1998 [1]. According to 2001 report of a hemovigilance system of the Canadian province of Quebec, the incidence of ATR was 0.35% for labile blood components [2].

Incidence of ATR in our study is 1.39 per 1000 components transfused which is comparable to other study from India by Philip et al. which was 0.73 [4]. Geiger and Howard in their study reported rise of allergic reactions between 0.09 and 21% in patients who received platelet transfusions [5].

Majority of the reactions in our study are allergic type contributing to the plasma (0.14%) and platelet (0.07%) products being transfused. This high incidence of allergic reactions in patients receiving plasma components can be attributed to the allergy to plasma proteins and also because the majority of the cases being liver disease patients with coagulopathy and require multiple transfusions. However, the incidence of allergic reactions were reduced specially after Single donor platelet transfusion due to the implementation of platelet additive solution usage in SDPs with nil ATR due to SDP transfusion since 2017.

Despite the ubiquity of these reactions, their mechanism of action is still under debate and multifactorial involving donor, patient and product factors. Allergic reactions most commonly are mild, involving localized pruritis and/or urticaria to severe reactions involving angioedema, bronchospasm, or hypotension which occur in < 10% of

reactions [6, 7]. In our current study, most common symptom noted was rashes in 43.6% ($n = 61$). Allergens responsible are mainly IgA and haptoglobin (Hp). Although most IgA—related transfusion reactions happen in IgA deficient individuals ($\text{IgA} < 0.5 \text{ mg/l}$) and in those whom there are detectable serum class-specific IgA antibodies, and in patients with normal IgA levels also [8].

Various studies showed that IgA, Hp detection and tryptase levels are available and can be useful in diagnosing Allergic reactions. Other tests like basophil activation test (BAT) is also found promising in examining allergic reactions [9, 10]. Though sensitivity and specificity of these tests are yet to be determined. But due to limitations of availability of resources, in most centres, allergic reactions are being diagnosed mainly on the basis of patient symptoms and their time of onset (immediate or after transfusion).

Estimated risk of Anaphylactoid reactions in our study is 2.9% ($n = 4$) which is mainly with plasma product transfusion. This is relatively more compared to reported incidence which is 62.6 per 100,000 platelet pools [11]. IgG antibodies are usually detected in IgA and Hp mediated anaphylaxis, but IgE antibodies are also detected in several studies by Burks et al., Harper et al. [12, 13]. Anaphylactoid reactions are clinically similar to anaphylactic reactions but mechanisms other than IgE are responsible for their occurrence [5].

Next most common reaction reported in our study is FNHTR ($n = 36$) with incidence 25.7% in 32 patients. Data on the incidence varies from study to study, which might be due to differences in reporting of reaction, recording of symptoms by the nursing staff, use of premedication to the patient and multiple transfusions to the patient. In contrast to all other studies by Philip et al., Kumar et al., Bhat-tacharya et al. we have transfusion reactions similar in both LDPRC group (0.07%) and BC-PRC group (0.05%) [4, 14, 15]. Patients on multiple transfusions had transfusion reaction needs further investigation may be due to HLA alloimmunization which might be the reason for this disparity. Over all incidence of FNHTR in our study (25.4%) is similar to study by Sharma et al. (28.1%) [16] and highest incidence of 73% by Bassi et al. [17] from North India due to usage of non leukoreduced packed red cells for transfusion. Febrile reactions result from interaction of the recipient antibodies with antigens on donor leukocytes and fever is the most common presenting symptom in 78.4% patients in our study.

Incidence of TACO in the present study is 4.3% seen in ($n = 6$) patients transfused with PRC and FFP which is quite high compared to other studies from India [4, 18] and similar to studies from outside India [19] which is a multicentric study with 1–8%. This disparity in incidences can be due to various reasons like different patient populations,

definitions of TACO, and study designs. Blumberg et al. hypothesized that TACO may therefore not be solely explained by volume overload but instead may also have an inflammatory/immunological component [20]. A careful investigation of patient's fluid balance tends to provide a clue to the underlying disease.

In contrast the reported incidence of TRALI/Possible TRALI in our study is high comparatively with 3.6%. TRALI is new acute lung injury (ALI) occurring during or within 6 h of transfusion with a clear temporal relationship to transfusion without or with risk factors to ALI other than transfusion [21]. Possible TRALI is said when patients have other risk factors for ALI such as sepsis, aspiration, near-drowning, disseminated intravascular coagulation, trauma, pneumonia, drug overdose, fracture, burns and cardiopulmonary bypass [22].

TRALI is usually an under reported and under diagnosed reaction due to resource limited setups in India. Our incidence is in par with study by Hendrickson et al. which is 4.9% [19]. All the cases reported had one or the other comorbidity noted (End stage Liver disease/multitransfused RTA case) in our study. TRALI and TACO are often misdiagnosed. They are noted mostly after plasma transfusion in our study and so as the other studies. Multiparous female donors are considered to be highest contributing factor to TRALI though not the common reason in India where majority of donations are from Male donors [23]. Diagnosis of TRALI was confirmed from the development of new bilateral infiltrates in chest X-ray in our cases. We did not observe any TRALI cases due to LDPRC transfusion probably due to reduction of leukocytes. Appropriate use of plasma or replacing plasma with platelet additive solution in the apheresis platelets can be a practical way of reducing the risk of TRALI.

Hemolytic Transfusion reactions (HTR) are defined by an accelerated RBC destruction, either of the transfused RBCs, the recipient's RBCs or both due to incompatible RBCs given to the recipient with regular or irregular antibodies that are directed against the donor RBCs [24]. Incidence of HTR in our study is 3.6% with all categorised under pseudo hemolytic transfusion reaction. No ABO mismatch, crossmatch incompatibility or any irregular antibodies were found to be associated with HTR. Pseudo hemolytic transfusion reactions may occur due to transfusion of hemolysed unit and present as HTR. This may occur when the red cells are damaged in the blood bag by freezing or heating, chemically by adding incompatible drugs or solutions or by exceeding the storage time, temperature [25]. In our case, inappropriate warming of unit, storage in the unmonitored domestic refrigerator in the ward, applying external pressure on the blood product at the time of transfusion of blood product was suspected though it couldn't be confirmed as the reactions were noted

Table 4 Comparative studies of incidence of ATRs

Name of the study	Allergic reaction (%) ^a	Anaphylatoid reaction (%)	FNHTR (%)	HTR (%)	Hypotensive reaction (%)	TACO (%)	TRAL (%)	Others (%)	Incidence (per 1000 components)
Payahdeh et al. [26]	49.2	–	37.2	–	6.8	–	–	6.8	9.45
Mafirakureva et al. [27]	34	1.4	58.5	5.2	0.4	0.25	0.25	–	0.46
Bassi et al. [17]	24	–	73	1	1	–	–	1	3.98
Sharma et al. [16]	65.6	3.12	28.1	–	–	–	–	3.18	9.26
Philip et al. [4]	40.14	0.70	51.40	4.22	–	0.70	–	2.81	0.73
Pahuja et al. [18]	41.4	1.27	54.7	1.27	–	0.955	0.31	–	1.95
Present study (2018)	49.2	1	25.37	3	5.22	4	3	1.49	1.39

^a% denotes percentage out of total adverse reactions noted in given study

“–” denote that the given study did not report the reaction

post transfusion. As a corrective action, nursing staff were trained for bed side transfusion practises.

We observed fifteen repeat transfusion reactions in seven patients, of which 9 reactions happened in 6 patients during TPE which manifested as allergic reactions. Although plasma transfusion is safer today than in the past, zero-risk is not attainable.

Table 4 shows the comparative incidence of ATRs from different parts of India and outside India [4, 16–18, 26, 27]. The incidence of ATR in present study (1.4%) is lower compared to studies from North India and outside India, which had higher incidence (9.5% by Payahdeh et al. [26] from Iran) per 1000 components issued. Most of the Indian studies showed higher incidence of FNHTR [4, 17, 18] in contrast to allergic transfusion reactions reported in our study.

There was no incidence of adverse reactions due to bacterial contamination of blood units which highlighted the adoption of quality measures at various steps of blood collection and processing.

The limitation of the study includes incomplete data on imputability assessment and severity assessment as it was included only after enrollment of centre under HvPI in 2017. IgA or IgE levels were not tested on suspected allergic or anaphylactoid reactions. Therefore, we could not clearly differentiate between anaphylactic and anaphylactoid reactions.

It is important that transfusion of blood components to be monitored carefully and other way is to minimize the number of transfusions given to patients when there is no clearly defined goal. Greater understanding of blood component and risk factors for transfusion reactions will lead to novel treatment and preventive strategies for reducing the risk of transfusion reactions. Blood transfusion

should be started immediately after its issue from the blood bank, ideally within half hour, if not, it should be returned to blood bank for cold chain maintenance. Hence, strict adherence to protocol in blood bank and clinical wards, ICUs, will help in reducing transfusion reactions. With regard to allergic reactions, atopic susceptibility in the recipients well as donor and component characteristics play a huge role and so as the first transfusion itself.

Conclusion

The overall incidence of ATR in our study is comparatively lower compared to other studies which can be contributed to methods of stringent donor selection, advancement in component separation, adoption of leukoreduction techniques and usage of automated methods of antibody screening and identification of all donor and patient samples. However, more emphasis can be laid on the adoption of more equipped methods like BAT for further clear understanding of adverse reactions contributing to blood transfusion or patient related factors.

Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical Approval All procedures were done in accordance of ethical standards. Informed Consent was taken from the patient before blood transfusion.

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