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Prevalence Of Adverse Events Related To Blood Transfusion At Tertiary Care Center Of Central India.

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Abstract
Background: *Although blood transfusion is an essential part of medical treatment but it is also associated with significant clinical risks due to blood components' allogenic origin. In recent testing facilities have lowered the incidence of transfusion-transmitted Infections (TTIs) to minimum; however, the incidence of adverse events due to human errors, ABO incompatibility, alloimmunization, bacterial contamination, and immunomodulation phenomena remain a matter of concern.*
Aim of study: *Present study was aimed to determine the frequency and types of NIATRs occurring in hospitalized patients at a tertiary care hospital in central India and its comparison with related study from India and abroad.*
Place of duration of study: *A 10 years retrospective cross sectional study was carried out at the Blood Bank, Gajra Raja Medical College, Gwalior, Madhya Pradesh, India from 1st January 2007 t0 31st December 2016.*
Methodology: *All data relating to blood donors, blood units, transfusion of blood/components and adverse events of transfusion were assessed, calculated, compiled, tabulated and was discussed in the study. Data has been compared statistically by frequency distribution and percentage proportion. Chi square (X2) test was applied to know the significant (p value) ratio of difference statistically.*
Results: *Prevalence of NIATRs in the study was 3.4% (n= 6213/181106). Most commonly Prevalent transfusion reaction was AR 1.56% followed by FNHTR 0.92 %, DHT, 0.46, TACO 0.45%, BS 0.02%, AI 0.005%, AHTR 0.004%, and others 0.003%. Amongst the all transfusion reactions, most frequent transfusion reaction was AR 45.45% followed by FNHTR 26.83 %, DHTR 13.52%, TACO 13.06% , BS 0.74%, AI 0.16%, AHTR 0.13% , and others 0.096% Distribution is statistically significant (p=.000002).*
Conclusion: *We concluded that prevalence of NIATRs at our institute was 3.4%. Clinical features of adverse events are range from mild to severe. Rational use of blood components and Proper implementation of hemovigilance programme at national level is need of the hour to prevent / or minimize the adverse events related to blood transfusion.*

Keywords: *Blood Transfusion, non-infectious adverse transfusion reactions (NIATRs), Hemovigilance, Rational use of blood, Blood components.*

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I. Introduction

Although blood transfusion is an essential and effective therapy, it is associated with significant clinical risks due to blood components' allogenic origin [1]. An adverse reaction or event is an undesirable response or effect in a patient, temporally associated with the administration of blood or blood component [2]. As infectious complications from blood transfusion decrease due to improved donor questionnaires and sophisticated infectious disease blood screening [1]. The recent testing facilities have lowered the incidence of transfusion-transmitted Infections (TTIs) to minimum; however, the incidence of adverse events due to human errors, ABO incompatibility, alloimmunization, bacterial contamination, and immunomodulation phenomena remain a matter of concern. Now-a-days, even in developed countries, the greatest risk to the patient lies in non-infectious complications of transfusions that account for significant morbidity and mortality [3]. The non-infectious adverse events related to blood transfusions are defined as non-infectious adverse transfusion reactions

(NIATRs). The American Association of Blood Banks technical manual provides guidance for the recognition, diagnosis, investigation and classification of non-infectious transfusion reactions, [4]. The acute and delayed NIATRs are classified on time of occurrence and further divided by presumed aetiology into immune-mediated and non-immune mediated subtypes. An overview of NIATRs are summarized in table No. 1 [4]

Acute (Immediate)	Delayed
Immune	
Acute hemolytic transfusion reaction (AHTR) Febrile non-hemolytic transfusion reaction (FNHTR) Allergic reaction Anaphylaxis Transfusion-related acute lung injury (TRALI)	Delayed hemolytic transfusion reaction (DHTR) Alloimmunization Post-transfusion purpura (PTP) Transfusion-associated graft versus host disease (TA-GVHD)
Non-Immune	
Bacterial contamination Transfusion-associated circulatory overload (TACO) Physical or chemical RBC damage Depletion or dilution of coagulation factors and platelets	Iron overload Air embolism

Acute hemolytic transfusion reaction occurs during or immediately after transfusion and is usually the result of an error. The incidence of red-cell products transfused to the wrong patient is estimated to range from 1/12,000 to 1/19,000 transfusions [5, 6]. Mortality from an acute hemolytic transfusion reaction is estimated to occur in approximately 1:800,000 transfusions [7]. Febrile non-hemolytic transfusion reaction is one of the more common transfusion reactions. In the clinical setting of universal leukoreduction of the blood supply, the frequency of febrile non-hemolytic transfusion reaction is 0.15% to 0.19% for red cells and 0.11% to 0.15% for platelets. Where non-leukoreduced products are routinely administered, the frequency is higher, at 0.33% to 0.37% for red cells and 0.45% to 2.18% for platelets. [8, 9, 10]. Allergic reactions are common, with an overall incidence of 0.4% to 3% of transfusions [12]. Most reactions involve urticaria alone. Anaphylactic reactions occur rarely (1/20,000 to 1/50,000 transfusions) [12, 13]. Although difficult to determine precisely, the incidence of delayed hemolytic transfusion reaction is estimated to be approximately 1/2500 transfusions [6, 14]. Transfusion-associated graft-versus-host disease is rarely observed, and is largely confined to patients with immuno-suppression [4]. Post-transfusion purpura occurs relatively uncommonly, with approximately 200 cases reported and is observed in a female-to-male ratio of at least 5 to 1 [4]. Transfusion-related acute lung injury (TRALI) incidence is estimated to be between 0.04% and 0.1% of all transfusions [15, 16]. It is the leading cause of transfusion-related mortality in the US, with an estimated mortality rate of 5% to 8% of transfusion-related deaths [17, 18]. The true incidence of these reactions in India is difficult to determine because of lack of proper hemovigilance system throughout the country [19]. Often, prevailing disease condition in the transfusion recipient makes the definite diagnosis of NIATRs even more difficult [20]. About 0.5-3% of all transfusion results in some adverse events, but most are minor without any significant consequence. [21, 22]. Here the present study was done with the primary objective to determine the frequency and types of NIATRs occurring in hospitalized patients who required blood product transfusion at a tertiary care hospital in central India and its comparison with related study from India and abroad.

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Inclusion Criteria

All the transfusion reactions reported to blood bank are included in the study.

II. Material Methods

A 10 years retrospective cross sectional study was carried out at the Blood Bank, Gajra Raja Medical College, Gwalior, Madhya Pradesh, India from 1st January 2007 t0 31st December 2016. Blood units were collected from the screened donors and tested for transfusion transmitted infections (TTIs) as per standard protocol of Food and Drug Administration, Government of India. Blood was collected in 450 ml triple; quadruple plain, quadruple SAGM and top &bottom SAGM bags. Blood units were processed for components

preparation in close system. In the study, supplied Blood components were grouped as; RBC components [whole blood (WB), Whole Blood Modified (WBM), Whole Blood Reconstituted (WBR), Packed Red Blood Cells (PRBCs), Saline Wash Red Blood Cells (SW RBCs), SAGM Red Blood Cells (SAGM RBCs)], Platelet Components [Platelets Concentrate (PC), Buffy Coat Platelets (BP) and Platelet Rich Plasma (PRP)], Fresh Frozen Plasma (FFP) , Cryoprecipitate (Cry ppt) and Aphaeresis Platelets (AP). First Log Universal leukoreduction (ULR) i.e. removal of buffy Coat was done during preparation of components from the year 2010 [23].

After collection of blood units, ABO and Rh grouping was done by conventional tube method and by gel technology. Along with cross match card, properly labelled ABO & Rh identical or compatible Blood/ blood components units were issued to the patients after proper cross matching. Cross matching was done by saline / ICT (Indirect coomb's test) method. Detection of irregular antibodies was done in multi-transfused patients and multi-para women as per requirement.

When there is any adverse event / blood transfusion reaction happened in the ward remaining blood unit, post transfusion blood and urine sample of the patients along with properly filled transfusion reaction form returned back to blood bank for investigation. Type of reaction was identified by clinical sign & symptoms and supportive investigations on pre and post transfusion blood sample along with urine sample of patients. NIATRs occurring during or after transfusion were evaluated. On the basis of reporting by the treating physician of signs and symptoms accompanied by the blood bank workup, the reactions were classified in accordance with the standards and recognized definitions defined by American association of blood banks (AABB) [4]. Any transfusion-related adverse events occurring within 24 hrs were considered as acute NIATRs while those occurring after, were considered as delayed reactions. Febrile non-hemolytic transfusion reaction (FNHTR) was defined as "a body temperature rise of >1°C occurring in association with transfusion and without any other explanation". Rigors and other symptoms in the absence of fever were also included as FNHTR [4]. Allergic reactions comprised of urticaria or erythematous itchy or non-itchy lesions, not accompanied by fever or other adverse findings. Anaphylactic reactions were categorized as those having systemic symptoms including hypotension and/or loss of consciousness and/or shock [4]. Transfusion related acute lung injury (TRALI) was considered as reaction with acute respiratory insufficiency and/or X-ray findings consistent with bilateral pulmonary edema but with no other evidence of cardiac failure or a cause for respiratory failure. Diagnosis of Hemolytic reactions was based on the clinical and/or laboratory evidence of hemolysis and Direct Coomb's Test (DAT) testing. Bacterial contamination was defined by a positive culture of the blood product transfused. Volume overload referred to respiratory distress leading to pulmonary edema on chest X-ray [4].

All data relating to blood donors, blood units, transfusion of blood/components, and adverse event of transfusion were compiled, calculated, tabulated and was discussed. Data has been compared statistically by frequency distribution and percentage proportion. Chi square (X2) test was applied to know the significant *(p value)* ratio of difference statistically.

III. Result

During the study period, 145227 blood donors donated blood at our center where male: female ratio was 95% (n=137854) and 5% (n=7373), voluntary versus relative donors were 85% (n=122926) and 15% (n=22301) and prevalence of TTIs positive cases among blood donors was 3.58% (n=5204/ 145227) Figure No. 1 Above data are statistically significant (p=.000001) and its yearly distribution is shown in table No.1.

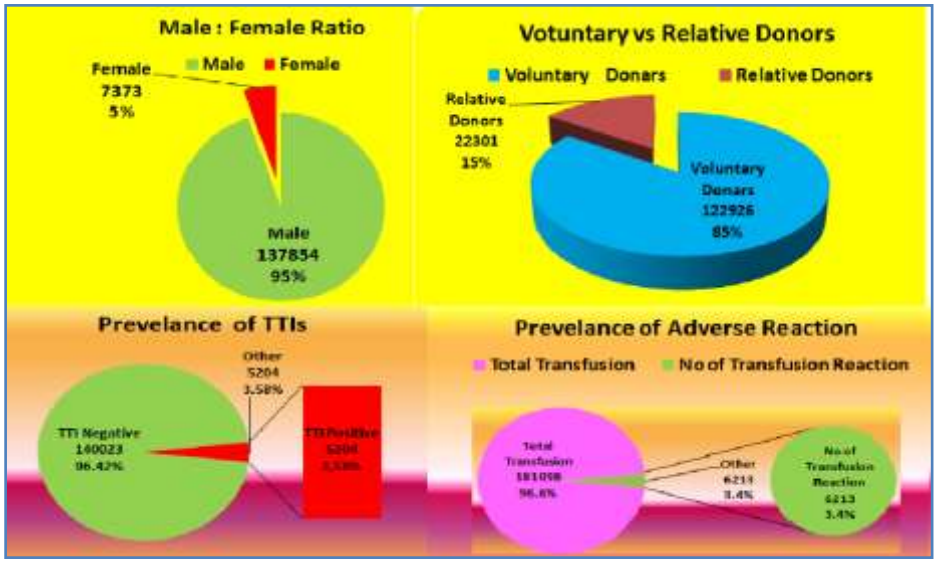

Figure No 1: Prevalence of Male/ Female, Voluntary / Relative Donor, TTIs, and Transfusion reaction in the Study

Table No. 1: Yearly prevalence of TTIs, Male/ Female and Voluntary / Relative Donor in the Study

Year	Total Donation	TTI + units	Total Male	Total Female	Total Voluntary	Total Relative
2007	14461	279 (*p*=.000001)	14001 (*P*=.000001)	460	5580 (*P*=.000001)	8881
2008	12946	325 (*p*=.000001)	12515 (*P*=.000001)	431	7878 (*P*=.000001)	5068
2009	12914	605 (*p*=.000001)	12434 (*P*=.000001)	480	11788 (*P*=.000001)	1126
2010	12638	545 (*p*=.000001)	12175 (*P*=.000001)	463	11449 (*P*=.000001)	1189
2011	13106	510 (*p*=.000001)	12586 (*P*=.000001)	520	11886 (*P*=.000001)	1220
2012	14001	575 (*p*=.000001)	13360 (*P*=.000001)	641	12573 (*P*=.000001)	1428
2013	14473	526 (*p*=.000001)	13821 (*P*=.000001)	652	13613 (*P*=.000001)	860
2014	15761	511 (*p*=.000001)	15101 (*P*=.000001)	660	14979 (*P*=.000001)	782
2015	16630	613 (*p*=.000001)	15072 (*P*=.000001)	1558	15799 (*P*=.000001)	831
2016	18297	715 (*p*=.000001)	16789 (*P*=.000001)	1508	17381 (*P*=.000001)	916
2007-16	145227	5204 (3.58 %) (*p*=.000001)	137854 (*P*=.000001)	7373	122926 (*P*=.000001)	22301

Abbreviations: TTI (Transfusion Transmitted Infections)

During study period from 140023 Fit units (TTIs negative), 181106 blood components were generated and issued to the patients. These Components were RBC Components [Packed RBC (PRBC), Whole blood reconstituted (WBR), Saline wash RBC (SRBC), neocytes concentrate, etc.) 139036 units, FFP (Fresh Frozen Plasma) 21294 units, PRP (Platelet Rich Plasma) 18888 units, Cry ppt (Cryoprecipitate) 869 units and Apheresis Platelet 1019 units. Data distribution of components were statistically significant (*p*=.000001). Yearly distribution of different component is shown in table No. 2.

Table No. 2: Yearly distribution of components transfused in the study

Years	Total Fit units	Total units/component issued	Details of component issued					P value
			RRC/WB/WBR/ SWRBC	FFP	PRP	Cryo ppt	Apheresis platelets	
2007	14182	15000	14102	524	364	10	0	P=.000002
2008	12621	13528	12530	575	393	30	0	P=.000002
2009	12309	15271	12280	1265	1688	38	0	P=.000002
2010	12093	15928	12002	2294	1592	40	0	P=.000002
2011	12596	15883	12519	1400	1764	123	77	P=.000002
2012	13426	17482	13405	2294	1590	91	102	P=.000001
2013	13947	19871	13736	2867	2875	148	245	P=.000001
2014	15250	21016	15182	2784	2803	124	123	P=.000001
2015	16017	22877	16000	3684	2801	161	231	P=.000001
2016	17582	24250	17280	3607	3018	104	241	P=.000001
Total	140023	181106	139036	21294	18888	869	1019	P=.000001

Abbreviations: WB (Whole Blood), WBR (Whole Blood Reconstituted), SWRBC (Saline Wash RBC), FFP (Fresh Frozen Plasma), PRP (Platelet Rich Plasma), Cryo ppt (cryo precipitate)

Prevalence of NIATRs in the study was 3.4% (n= 6213/181106) figure No.1. Most commonly Prevalent transfusion reaction was allergic reaction (AR) 1.56% (n=2824) followed by Febrile Non Hemolytic Transfusion Reaction (FNHTR) 0.92 % (n=1667), Delayed Hemolytic Transfusion Reaction (DHTR), 0.46% (n=840), Transfusion Associated Cardiac Overload (TACO) 0.45% (n=812), Bacterial Sepsis (BS) 0.02% (n=46), Alloimmunization (AI) 0.005% (n=10) , Acute Hemolytic Transfusion Reaction (AHTR) 0.004% (n=8), and others 0.003% (n=6). Others group was constituted of 6 cases of NIATRs (4 belongs to RBC and 2 to PRP

units) and distribution of NIATRs was, two hemolysed RBC units were transfused (hemolysis was due to thermal /mechanical trauma), one each RBC unit was reported TRALI and hypocalcaemia (in Neonate) and rest two PRP units were reported fungal infection. Transfusion reactions like, Immunomodulation, Post Transfusion Purpura (PTP), Anaphylactoid reaction and Graft Versus Host Disease (GvHD) was not observed in the present study.

Amongst the all transfusion reactions, most frequent transfusion reaction was allergic reaction (AR) 45.45% (n=2824/ 6213) followed by Febrile Non Hemolytic Transfusion Reaction (FNHTR) 26.83 % (n=1667/ 6213), Delayed Hemolytic Transfusion Reaction (DHTR) 13.52% (n=840/ 6213), Transfusion Associated Cardiac Overload (TACO) 13.06% (n=812/ 6213)), Bacterial Sepsis (BS) 0.74% (n=46 / 6213), Alloimmunization (AI) 0.16% (n=10/ 6213), Acute Hemolytic Transfusion Reaction (AHTR) 0.13% (n=8/ 6213), and others 0.096% (n=6/ 6213) Table No.3 Figure No.2. Distribution is statistically significant (p=.000002). Components wise frequency of transfusion reactions is shown in table no 3 and figure no.3.

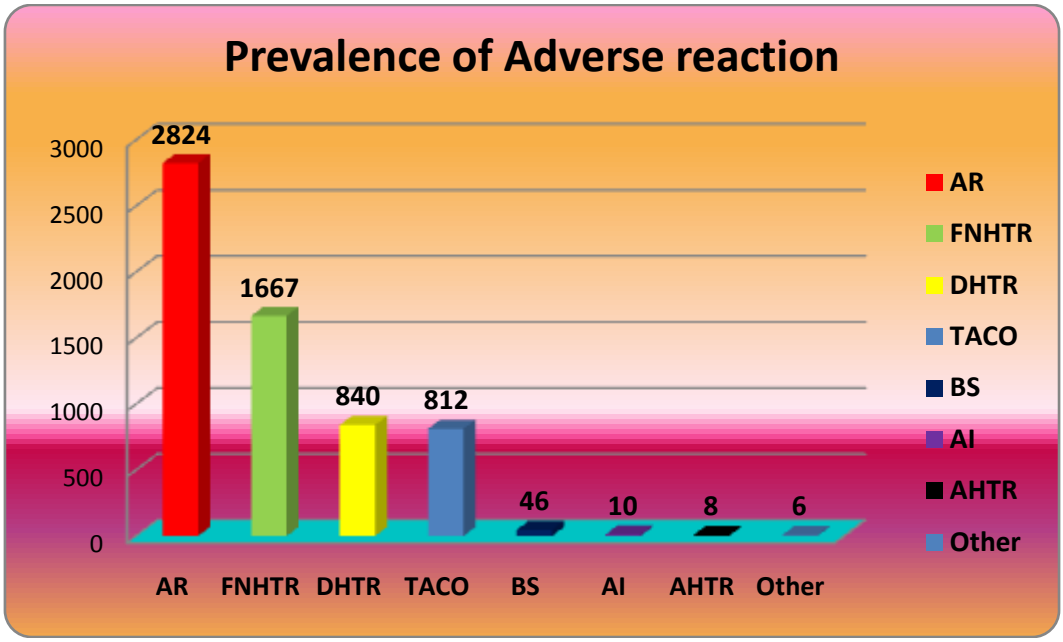

Figure No. 2. Prevalence of Transfusion Reaction

Abbreviations: AR (Allergic Reactions), FNHTR (Febrile Non-Hemolytic Transfusion Reaction), DHTR (Delayed Hemolytic Transfusion Reaction), TACO (Transfusion Associate Cardiac Overload), BS (Bacterial Sepsis), AI (Allo-immunization) , AHTR (Acute Hemolytic Transfusion Reaction)

Table No. 3: Component wise distribution of adverse reaction in the study

Components	No. of Transfusion	Allergic Reaction	FNHTR	DHTR	TACO	Bacterial Sepsis	alloimmuniz ation	AHTR	Other	Total	P value
RBC	139036	2408	1607	840	810	08	10	8	04	5695	P=.000001
FFP	21294	200	20	00	02	00	00	00	00	222	P=.000002
PRP	18888	204	40	00	00	38	00	00	02	284	P=.000002
Cry ppt	869	08	00	00	00	00	00	00	00	8	P=.000002
Apheresis	1019	04	00	00	00	00	00	00	00	4	P=.000002
Total	181106 P=.000001	2824 P=.000002	1667 P=.000002	840 P=.000002	812 P=.000002	46 (P=.000002	10 P=.000003	8 P=.000 003	6 P=.000 001	6213 (P= .000002	P=.000001

Abbreviations: AR (Allergic Reactions), FNHTR (Febrile Non-Hemolytic Transfusion Reaction), DHTR (Delayed Hemolytic Transfusion Reaction), TACO (Transfusion Associate Cardiac Overload), BS (Bacterial Sepsis), AI (Allo-immunization), AHTR (Acute Hemolytic Transfusion Reaction

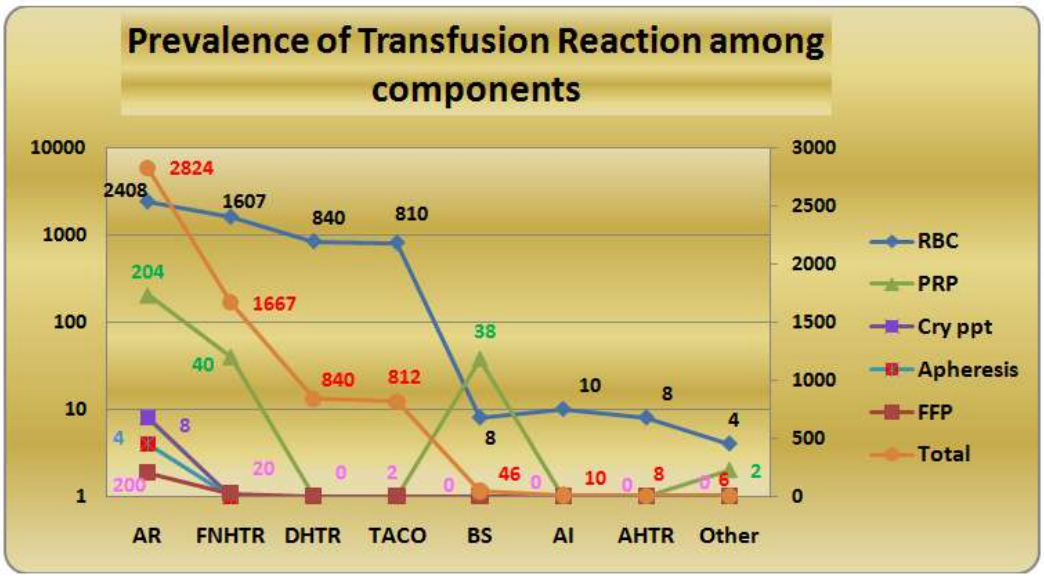

Figure No. 3. Prevalence of Transfusion Reaction among different components

Abbreviations: AR (Allergic Reactions), FNHTR (Febrile Non-Hemolytic Transfusion Reaction), DHTR (Delayed Hemolytic Transfusion Reaction), TACO (Transfusion Associate Cardiac Overload), BS (Bacterial Sepsis), AI (Allo-immunization) , AHTR (Acute Hemolytic Transfusion Reaction), PRP (Platelet Rich Plasma), Cry ppt (cryo precipitate) and FFP (Fresh Frozen Plasma)

IV. Discussion

During the study period, male domination among blood donors (95% male), voluntary donation 85% and prevalence of TTIs positive cases among blood donors 3.58% was reported which further supports the data of our previous studies [24, 25]. In the present study, prevalence of NIATRs was 3.4%. Variable prevalence of NIATRs was reported from different parts of India and abroad. Low prevalence (0.16%) was reported by Vartak U C *et al*. [26] from Mumbai, Bhattacharya et al. [27] (0.18%) in PGI Chandigarh , India over a period of 1-year, Kumar *et al*. [19] found the frequency of transfusion reaction to be 0.05% and Negi G *et al*. [28] from Dehradun, India (0.2%) while higher prevalence was reported by Arewa *et al*.[29] in Nigeria 8.7% , Lubart et al. [30] in elderly patients in a geriatric hospital over a period of 1-year was reported higher incidence in their study as 11% and Williamson *et al*. [31] performed a short analysis and found 52% cases were associated with incorrect blood transfusion, acute lung injury was seen in 8% cases and 15% patients suffered an acute transfusion reaction.

In the Present study, order of prevalence of NIATRs from most to least was allergic reaction 1.56% (n=2824) followed by FNHTR 0.92 % (n=1667), DHTR 0.46% (n=840), TACO 0.45% (n=812), Bacterial Sepsis 0.02% (n=46), Alloimmunization 0.005% (n=10), AHTR 0.004% (n=8), and others 0.003% (n=6). Among the all NIATRs, percentage of distribution was allergic reaction 45.45% followed by FNHTR 26.83 %, DHTR 13.52%, TACO 13.06%, Bacterial Contamination 0.74%, Alloimmunization 0.16% AHTR 0.13%, and others 0.09%. In the study of Bhattacharya P *et al*. [27] most common transfusion reaction was FNHTR 41% (*n* = 43) followed by allergic reactions 34% (*n* = 36) AHTR 8.56% (*n* = 9). anaphylactoid reactions (*n* = 4), bacterial sepsis (*n* = 4), hypervolemia (*n* = 2), hypocalcemia (*n* = 2), TRALI (*n* = 1), DHTR (*n* = 1), and TAGvHD (*n* = 1) and in the study of Mafirakureva N *et el.* [32] from Zimbabwe FNHTR (58.5%), minor allergies (31.6%), haemolytic reactions (5.2%), severe allergic reactions (2.4%), anaphylaxis (1.4%) and hypotension (0.9%). In our study, frequency of FNHTR 26% was much less as reported by Bhattacharya P *et al* [27]41% and Mafirakureva N *et al.* [32] 58.5% because, since 2010 we are doing 1st Log ULR and resulted in comparatively higher percentage of allergic reaction 45.32% in the study. In the comparison to other similar study higher frequency of DHTR 13.52% in our study was reported. It was encountered mainly in multi-transfused patients and multi-Para women.

Next common NIATR was TACO 13.06%. It was due to panic transfusions in emergencies and unawareness of transfusion strategies. The risk of TACO increases with age and the number of units transfused, especially in patients with congestive heart failure, chronic pulmonary disease, anemia, or those receiving plasma products.[33] Bacterial Contamination 0.61% was mainly with the Platelet transfusion because of its storage conditions. Bacterial growth in platelet units continues to be possible despite the implementation of various detection methods in the last 10 years [34]. Prevalence of AHTR in the present study was 0.004% (n=8) and its frequency among NIATRs 0.13% and it was happened mainly due to the clerical mistake and wrong

sampling. Higher prevalence of AHTR 5.2% and 8.5 % was reported by Mafirakureva N *et al*. [32] and Bhattacharya P *et al.* [27] in their respective studies. A suspected AHTR is confirmed by a change in plasma color and a positive result on DAT for IgG, complement, or both [35].

In the present study uneven distribution of NIATRs among different blood components was observed. In apheresis Platelets and Cryo ppt units only allergic reaction 0.39% (n=4/1019) and 0.92% (n=8/869) was reported respectively and it is because of the allergenic nature of plasma proteins. In FFP units, allergic reaction 0.93% (n=200/21294), FNHTR 0.093 % (n=20/21294) and two cases of TACO was reported. FNHTR was due to leukocyte and platelets contents. In PRP Transfusions, allergic reactions 1.08% (n=204/18888), FNHTR 0.21% (n=40 /18888), bacterial sepsis 0.20% (n=38/18888) and two cases of fungal infection was reported. Bacterial sepsis was mainly due to introduction of infection from outside in to the blood during collection, component preparation and transfusion. Fungal infection was reported in blood collection bags and after confirmation by culture report that lot was rejected. In RBC components, allergic reactions (n=2408/139036), FNHTR (n=1607/139036), DHTR (n=840/139036), TACO (n=810/139036), bacterial sepsis (n=8/139036), alloimmunization (n=10/139036), AHTR (n=8/139036) and in four other cases two belongs to transfusion of hemolysed blood and one each of TRALI and hypocalcemia was reported. TRALI is most often caused by antibodies to human leukocyte antigens (HLAs) or human neutrophil antigens (HNAs) in the transfused blood product given to a patient whose leukocytes express the cognate antigen.[36].We have not reported FNHTR and allergic reaction in neocytes concentrates and saline wash RBCs. After 1st log leukoreduction Of RBC components there is substantial reduction in FNHTRs in our institute [23]. The entire adverse events were simply manageable by symptomatic treatment except AHTR, TRALI and transfusion of hemolysed blood where patients require intensive care treatment.

V. Conclusion

Here, we concluded that prevalence of NIATRs at our institute was 3.4%. Clinical features of adverse events were range from mild to severe. Proper monitoring and careful watch at the level of blood bank is helpful in prevention of adverse events and an ability to assess /or early detection of the adverse events related to transfusion can helpful in prevention and better management of the transfusion reaction. Rational use of blood components is also helpful in minimizing the adverse event of transfusion. Proper implementation and documentation of hemovigilance programme at national level is need of the hour to prevent / or minimize the adverse events related to blood transfusion.

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