

A Five Years Retrospective Study of Adverse Events of Transfusion in a Tertiary Health Care CentreArchana Patil¹, Vinod Susar², Sheela Chikhalikar³¹Professor, Dept. of Pathology, Dr. Vasanttrao Pawar Medical College, Hospital and Research Centre Adgaon Nashik²Technical Supervisor cum Quality Manager, Blood Bank, Dr. Vasanttrao Pawar Medical College, Hospital and Research Centre Adgaon Nashik³Assistant Professor, Dept. of Pathology, Dr. Vasanttrao Pawar Medical College, Hospital and Research Centre, Adgaon, Nashik

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Abstract:**Background:** Blood transfusion has an important role in the modern practice of medicine and has undoubted benefits but some adverse effects do occur despite all relevant laboratory tests. Access to adequate and safe blood transfusion facilities is an integral part of any basic health care service; they are often lifesaving in critically ill patients. Any unfavorable transfusion-related event occurring in a patient during or after the transfusion of blood and blood components is known as a transfusion reaction (TR).**Objective:** Present study aim to investigate the adverse events of transfusion in a tertiary health care centre.**Material and Methods:** This were a retrospective study which included all transfusion reactions reported to the blood bank from clinical departments within the period of May 2018 to May 2023 at a tertiary care centre. These reactions were investigated and classified using the Institute's protocol.**Result:** In our study, a total 13837 number of blood units were issued and 24 transfusion reactions were reported to the blood bank during the study duration. Febrile non-hemolytic transfusion reactions (FNHTR) were the most common followed by allergic reactions.**Conclusion:** During transfusion patient should be closely monitored and in case of an undesirable event, it should be reported to a blood bank. To minimize the risk of transfusion reaction leucofilters or leucocyte-depleted blood products should be advised, especially in cases of multiple transfusions.**Keyword:** Blood Bank, Blood Transfusion, Adverse Transfusion Reaction, Transfusion Transmitted Diseases.This is an Open Access article that uses a funding model which does not charge readers or their institutions for access and distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>) and the Budapest Open Access Initiative (<http://www.budapestopenaccessinitiative.org/read>), which permit unrestricted use, distribution, and reproduction in any medium, provided original work is properly credited.**Introduction**

Blood transfusion has a vital role in the modern practice of medicine such as cardiac surgery, transplant surgeries & treatment of various hematological disorders. [1] The goal of any transfusion service is to provide blood components that are safe for transfusion and that pose minimal risk of transfusion transmissible infection.

Achieving maximum safety at an acceptable cost requires a multi-layered risk reduction strategy, involving safe blood donors, safe blood components and safe transfusion practices. [2] Access to adequate and safe blood transfusion facilities is integral to any basic healthcare delivery infrastructure; they are often lifesaving in critically ill patients. However, blood transfusion also has risk which ranges from minor to life-threatening. [3] with the discovery of blood group antigens by Karl Landsteiner in 1901, blood transfusion has become relatively safe & has further improved with the

advancement of technology. Testing for transfusion-transmitted disease (TTD) is done on blood units which reduces the incidence of transmission of TTD. Still, unfavorable reactions may occur which can be fatal sometimes. [4] Transfusion of blood and blood components should be used carefully as it can be both life-saving and lethal. [5]

It cannot forecast which patient will have a transfusion reaction. Hence clinicians and blood bank staff involved in the process of blood transfusion should be proficient in the types of reactions and measures to be taken in such cases. [6] Transfusion should be advised only when the advantages exceed probabilities of transfusion-transmitted diseases such as HIV, Hepatitis B & C or other infectious agents through blood components. Each one engrossed in the clinical transfusion procedure should make certain that the right blood goes to the right patient at the right time.

[7] Unfavorable outcomes occurring in a patient during or after transfusion of blood & its components are known as transfusion reaction. About 2-5% of transfusions can result in adverse effects.⁸ Types of transfusion reactions (TRs) are: (1) Hemolytic Transfusion Reactions (2) Non-hemolytic Transfusion Reaction. Hemolytic transfusion reactions are the most severe type of transfusion reactions and are further classified into: (1) Intravascular transfusion reactions and (2) Extravascular transfusion reactions.

In intravascular transfusion reactions, hemolysis of red cells takes place within the circulatory system. These types of reactions are mainly due to IgM antibodies, mediated by rapid activation of complement. Clinical manifestations of intravascular transfusion reactions are immediate, usually within minutes after the start of transfusion. Hence, they are also called Acute Hemolytic Transfusion Reactions (AHTR). AHTR is the most severe and life-threatening reaction. Signs and symptoms of AHTR are: burning sensation at the site of infusion, flushing and fever, chills, pain in the back (lumbar region) and chest, shortness of breath, hypotension/shock, disseminated intravascular coagulation (DIC) and acute renal failure.

Extravascular transfusion reactions are rarely severe and are mainly due to IgG antibodies e.g., Rh, Kell or Duffy system. These antibodies bring about the destruction of red cells by macrophages in the spleen and liver. Clinical evidence of reaction is somewhat slower and, in some cases, may be delayed up to two weeks or more after transfusion thus is also called Delayed Hemolytic Transfusion Reaction (DHTR) which could be due to: (1) Primary alloimmunization and (2) Anamnestic or secondary response. In primary alloimmunization, the patients develop antibodies after a couple of weeks after transfusions which are mostly due to incompatibility of Rh or Kell system. Improved antibody detection

methods have greatly reduced the incidence of delayed hemolytic transfusion reactions. [1]

Material and Methods

Study design: This was a retrospective study which included all transfusion reactions reported to blood banks from clinical departments within the period of May 2018 to May 2023 in Dr Vasantrao Pawar Medical College, Hospital and Research Centre. Appropriate ethical guidelines were followed while performing the study.

Data collection methods: The adverse events related to the transfusion of blood and blood products were reported to the blood bank in a transfusion reaction form. Post-transfusion blood and urine samples were collected from each patient having a transfusion reaction.

Investigations: The following investigations were performed: Regrouping for ABO and Rh, pre- and post-transfusion cross-match, direct and indirect antiglobulin test and post-transfusion urine examination. The data was analyzed and documented for age, sex, symptoms, blood products, type of reaction and volume of blood transfused.

Statistical analysis: Data was analyzed using the Microsoft excel. Quantitative variables are presented in mean and standard deviation and qualitative variables are presented as number and fraction of total.

Result

During this retrospective study from May 2018 to May 2023, a total number of 13837 units of blood and blood components were issued and 24 adverse events related to transfusion were reported.

Out of these 24 patients showing adverse events, 18 (75%) were females and 6 (25%) were males. The female-to-male ratio was 3.16:1 and the gender-wise distribution of cases is shown in Figure 1.

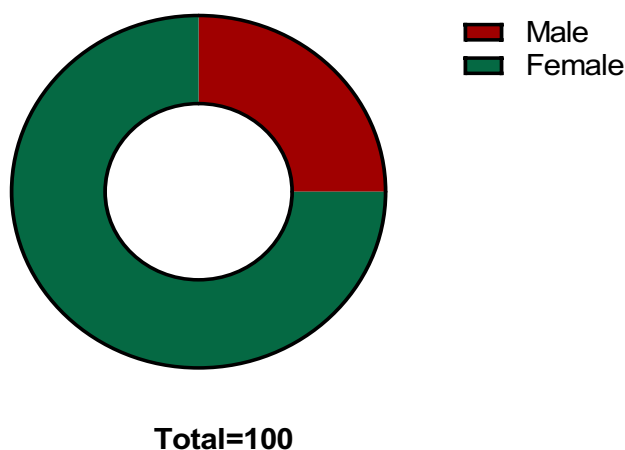


Figure 1: Gender-wise distribution of cases

Reactions were seen in patients ranging from 6 years to 65 years, the youngest patient was 6 years female and the oldest patient was 65 years female shown in Table 1.

Table 1: Distribution of transfusion reaction according to age and gender

Age in years	Male	Female
0-10	-	1
11-20	0	1
21-30	2	9
31-40	2	4
41-50	2	0
51-60	0	2
61-70	-	1
>70	-	-
Total	6	18

Out of all the transfusion reactions reported to the blood bank, 75% of transfusion reactions occurred with packed red cells, 20% with whole blood and 5% with FFPs. No transfusion reaction was reported with platelets transfusion. The distribution of transfusion reaction according to blood and blood components issued were shown in Table 2.

Table 2: Distribution of cases according to blood and blood components

Component Type	Frequency	Percentage
Packed red blood cells	19	75%
Whole blood	4	20%
Fresh frozen plasma (FFP)	1	5%
Platelet concentrate	0	-
Total	24	100%

We found that a maximum number of reactions of 9 (37.5%) were seen in patients with blood group "O" followed by 8 (33.34%) in blood group "B". A detailed description is given in Table 3.

Table 3: Distribution of transfusion reaction according to different blood groups

Blood Group	Frequency	Percentage
O	9	37.5 %
B	8	33.33 %
A	4	16.66 %
AB	3	12.5 %
Total	24	100%

Out of the 24 cases of transfusion reactions, 23 cases (95.83%) were Rh positive and one case (4.2 %) was Rh negative as shown in Table 4.

Table 4: Distribution of transfusion reaction according to Rh type

Rh Type	Frequency	Percentage
Positive	23	95.83%
Negative	1	4.2%
Total	24	100%

Most of the transfusion reactions were observed from obstetrics and gynecology (OBGY) [n=11 (45.83%)] followed by cases from the medicine ward [n=8(33.33%)]. Four patients (16.67%) from the surgery department had transfusion reactions and one case (4.16%) was reported from the orthopaedic department (Figure 2).

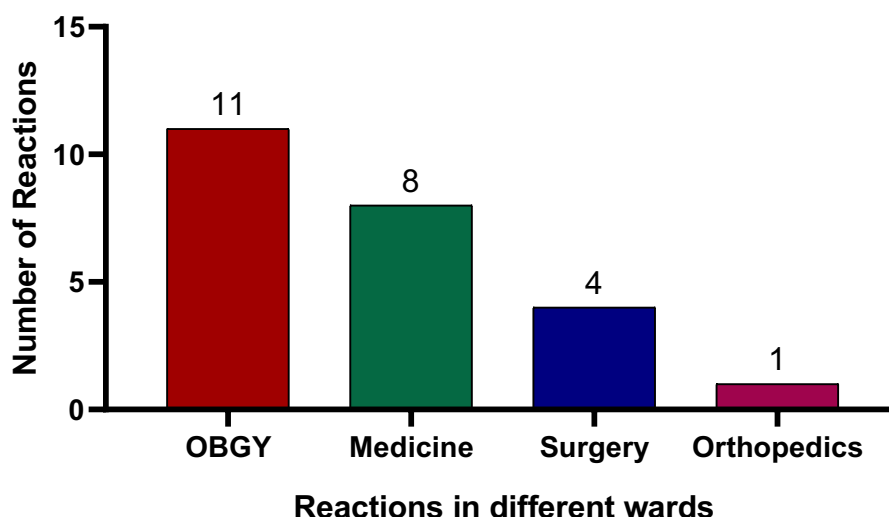


Figure 2: Number of reactions in different wards

In our study, we found different types of reactions. Thirteen cases (54.17%) were of FNHTR which was the most common reaction followed by 8 cases (33.33%) of allergic reaction. Hypotension as the only clinical presentation was observed in two cases (8.33%) and one case (4.17%) showed hematuria. (Table 5)

Table 5: Type of transfusion reactions

Type of Reaction	Frequency	Percentage
FNHTR	13	54.17
Allergic	8	33.33
Hypotension	2	8.33
Hematuria	1	4.17
Total	24	100%

No reaction was reported of anaphylaxis, transfusion-related acute lung injury (TRALI), delayed hemolytic transfusion reaction (DHTR), back pain, and disseminated intravascular coagulation (DIC).

Most of the reactions were observed with transfusion up to 50 ml of (58.33%) blood /blood components while only 20.83% of reactions were observed with 51-100 ml of transfusion. This could be due to the removal of blood bags just after signs and symptoms were noticed. Very few reactions were reported after 150 ml of transfusion. A detailed description of the amount of blood transfused before the transfusion reaction is shown in Table 6.

Table 6: Amount of blood transfused before transfusion reaction

Amount in ML	Frequency	Percentage
<50	14	58.33 %
51-100	5	20.83%
101-150	1	4.1%
151-200	2	8.3%
201-250	0	0
251-300	2	8.3%
Total	24	100 %

In our study, the majority of reactions (15 patients i.e. 62.5 %) were reported with multiple transfusions (Table 7).

Table 7: Transfusion reactions associated with the number of transfusions

Number of transfusions	Frequency	Percentage
Multiple transfusion	15	62.5 %
Single transfusion	9	37.5 %
Total	24	100%

Discussion

The incidence of transfusion reactions in our study was 0.07%. Similar incidence was seen in the study

by Chavan SK et al., (0.34%), Bhattacharya P et al., (0.18%), Kumar P et al., (0.05%) and Gotekar Y R et al., (0.18%). [4,9,10,11] However, in the study

done by Chowdhury FS et al., the incidence of transfusion reactions was high (6.66%) [8].

In the current study female patients were more (75%) commonly associated with transfusion reactions than males (25%) and female to male ratio was 3:1. This gender-based difference was also observed in the study by Sharma DK et al., (59.4%), Chavan SK et al., (71.1%), Gotekar Y R et al., (61.03 %) and Vidya Shree M et al., (52.25%). [3,4,11,12] In the study done by Negi G et al., no significant sex predominance (females 54.4%, Males 49.5%) was observed. [7] In studies done by Bhattacharya P et al., Rahajeng EP et al., and Seirfar N et al., male predilection over females was observed. [9,13,14] According to Rahajeng EP et al., the increased number of transfusion reactions in male as compared to female subjects in their study was probably due to more number of transfusions received in male patients. [13]

In the current study age of patients who had transfusion reactions ranged from 6 years to 65 years with the highest number of transfusion reactions in the age group of 21- 30 years. In the study by Vidya Shree M et al., most transfusion reactions were in the age group of 40-49 years while Chakravarty V et al. noted maximum reactions in the 11-20 years of age group and 21-30 years being the second common age group. [12,15].

In our study transfusion reactions observed were most commonly with packed red blood cells (75%) which is similar to study by Negi G et al., (48.5%), Vidya Shree M et al., (37.25%), Kumar R et al., (73.8%) and Kumar A et al., (135 cases). [6,12,16,17] We observed no reaction with platelet transfusion which was in line with a study done by Sharma DK et al., who observed no reactions with platelet, cryoprecipitate, and cryo-poor plasma transfusions. [3]

In the present study, most of the transfusion reactions were observed in patients having the 'O' blood group (37.5%) followed by the 'B' blood group (33.33%) and 'A' blood group (16.66 %). Similarly, Seirfar N et al., in their study observed more transfusion reactions in patients having an 'O' positive blood group. [14]

Akhter N et al., observed more transfusion reactions in patients having an 'O' positive blood group and 'B' positive blood group (each 'O' positive & 'B' positive blood group 43.47 %). [18] A study by Sharma DK et al. observed more transfusion reactions in patients having an 'A' blood group. [3] In our study, out of 24 cases of transfusion reactions, 23 cases (95.83%) were Rh positive and only one case (4.2 %) was Rh negative. This was in line with Parashar R et al. [19]

In the present study, most reactions were from OBGY (obstetrics and gynaecology) department (11

cases i.e. 45.83%) followed by the medicine department (8 cases i.e. 33.33%). This was similar to observations in the study done by Chavan SK et al., (33.3%). [4] In a study done by Seirfar N et al., predominant reactions were observed from transfusions in patients who underwent surgery. [14] In a study done by Kumar R et al., most of the transfusion reactions were from the emergency ICU (36.8%) followed by the medical ICU (28.5%). [16]

Unexplained rises in temperature of at least 1°C during or shortly after transfusion are febrile non-hemolytic transfusion reactions (FNHTRs). Other causes of fever should be excluded before making a diagnosis of FNHTR. [20] In the current study, the most common i.e. 13 out of 24 (54.17%) transfusion reactions were FNHTR followed by allergic reactions. Similar findings were also reported in the study by Bassi R et al., (73%), Chowdhury FS et al., (62.5%), Bhattacharya P et al., (41 %), Kumar R et al., (60.4%) and Philip J et al., (51.40 %), Rahim R et al., (54.64 %), Pahuja, et al (58.4%). [5,8,9,16,21,22,23] However in a few studies, allergic reactions were more common than FNHTR such as Sharma DK et al., (21%), Chavan SK et al., (55.6%), Vidya Shree M et al., (33.33 %) and Gelaw Y et al., (65 %). [3,4,12,24]

Hypotension as the only presentation was reported in 2 cases (8.3%) in our study. In a study done by Chakravarty V et al., 8% of patients experienced hypotension as a transfusion reaction. They also stated that a variety of transfusion reactions can manifest as hypotension such as acute hemolytic, bacterial contamination, transfusion-related acute lung injury and anaphylaxis. In rare cases, hypotension is the only manifestation. [15]

We found 14 transfusion reactions (58.33%) with transfusion up to 10-50 ml and 2 (8.33%) transfusion reactions up to transfusion of 300-350 ml of blood unit. In a study by Chakravarty V et al., [13] reactions (26%) occurred with transfusion of up to 20 ml of blood and 8 reactions were after transfusion of the whole unit i.e. 350 ml. [15] Sahu et al. stated that most serious adverse reactions or events can occur due to acute transfusion reactions. Awareness of different clinical features of acute transfusion reactions with an ability to assess the serious reactions within time is essential for better management of transfusion reactions. Observation and monitoring are required throughout the transfusion episode, with close monitoring within the first 15 min. [20]

Shivgunde PP et al., in their study, suggested that there is a significant requirement to generate perception and to encourage the documentation of ATR amongst healthcare professionals, which will drive these budding healthcare professionals to actively participate in quality haemovigilance in their future practice. [25] Afroz T et al., concluded

that a sufficient, well-trained, and committed workforce and an encouraging environment for monitoring and documenting adverse events and near-misses in a nurturing, unblemished learning culture is important to have an effective haemovigilance system. [26]

Conclusion

The incidence of transfusion reaction was 0.17%. FNHTR were the most common transfusion reaction followed by allergic reactions. Reactions were more common in patients requiring multiple transfusions. Close monitoring is essential during the transfusion of blood components especially within the first 15 minutes. The low incidence of TRs may be due to under-reporting of the adverse events. To minimize the risk of transfusion reaction leucofilters or leucocyte-depleted blood products should be advised, especially in cases of multiple transfusions. Any undesirable transfusion event must be reported to the blood bank which will avoid underreporting. Standard operating procedures (SOPs) for adverse transfusion reactions must be followed. Blood banks should create awareness among clinicians about transfusion practices and all transfusion reactions must be reported to the haemovigilance system.

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