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A Restrospective Study of Adverse Events during Transfusion at a Teritiary Care Center in Andhra Pradesh

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Abstract

Background: Transfusion of blood products is a double-edged sword and should use judiciously. Improvements in donor screening and transmissible transfusion diseases testing procedures have led to a decrease in the hazards and risks. However, the dangers of non-infectious complications have become more apparent. These non-infectious complications called as adverse transfusion reactions (ATRs) can either be acute in nature or follow a delayed course.

Materials and Methods: A retrospective review of all transfusion reactions reported to the Blood Bank at the tertiary care center between January 2018 and January 2019 was done and analyzed as per Departmental Standard operating procedures.

Results: ATRs during or after blood transfusion reported during the one year were 22 (0.28%) out of 7824 units of blood /blood components transfused. ATRs reported were allergic Reactions 10 (45.45%), febrile non hemolytic transfusion reactions (FNHTR) 9 (40.9%), anaphylactic reactions 2 (9.09%) and Isolated hypotension 1 (4.54%).

Conclusion: The majority of ATRs were Allergic reactions followed by FNHTRs.

Keywords: Adverse transfusion reactions, hemovigilance, whole blood, FNHTR, Allergic Reactions.

Introduction

Transfusion of blood products is a double-edged sword and should be used judiciously. Improvements in donor screening and transmissible transfusion diseases testing procedures have led to a decrease in the hazards and risks that are associated with the transmission of the infectious diseases associated with blood transfusion.

However, the risks of non-infectious complications have become more apparent. These non-infectious complications called as adverse transfusion reactions (ATRs) can either be acute in nature or follow a delayed course.[1]

Knowledge of these ATRs helps not only in their easy identification and management but also it alerts us to prevent its occurrence by taking precautionary and adequate measures. The lack of proper and strict hemovigilance systems throughout the country makes it difficult to assess the exact and actual incidence of these reactions.[2]

The incidence of acute blood transfusion reactions is estimated to be 0.2–10% and is responsible for mortality in 1 per 250,000.[3] hemolytic anaphylactic Nonhemolytic

At times, the prevailing disease condition in the transfusion recipient makes the definite diagnosis of transfusion reactions even more difficult.[4]

Coined the term hemovigilance in France in the early 1990s, has been developed and adopted

internationally and is now an integral part of transfusion practices. It is systemic surveillance of adverse transfusion reaction and events, encompassing the whole transfusion chain and aimed at improving the safety of the transfusion process, from donor to recipient "vein to vein".[5]

The first hemovigilance surveillance system was implemented in France in 1994 as mandatory reporting as required by updated French regulation. Severe hazards of transfusion (SHOT) were in established United Kingdom shortly after 1996 as voluntary reporting.

In the United Kingdom and Ireland, Reported 366 reports of deaths or significant complication of transfusion as a part of the SHOT initiative. The most common adverse event was (52%), giving the wrong blood to the patients.[6] Indian pharmacopoeia commission in collaboration with National Institute of biological has launched a Hemovigilance Programme of India on 10th December 2012.

The main objectives of the programme are to track adverse reactions/events and incidence associated with transfusion of blood and blood product and to help identify trends, recommends best practices and interventions required to improve patient care and safety, while enhancing the overall health care.[7]

Materials and Methods

Setting: Department of Pathology at Maharajah's Institute of Medical Sciences, Vizianagaram

Duration of Study: January 2018 and January 2019.

Study Design: Retrospective analytical Study.

Inclusion Criteria: ATRs occurred in all patients who had received a blood transfusion at our hospital within one year period from January 2018 and January 2019 within 24 hours of Blood or blood components transfused.

Exclusion Criteria: Patients who received blood from outside blood banks.

Data Collection and Procedure: Did the retrospective study after receiving approval from the Institutional Ethical Committee. The predesigned "transfusion adverse reaction reporting form" was filled by the treating physician and reported to the Blood Bank was studied in detail and entered in the excel chart and analysed as per the laboratory investigation form for investigating the transfusion reactions as per standard operating procedures of the Department.

Investigation of transfusion-related adverse event:

1. Patients name, central registration number (C.R. No), red cell ABO and Rh D typing are rechecked on requisition form, pretransfusion sample and transfusion reaction reporting form to rule the possibility of wrong sampling or bedside transposition.
2. Also recorded relevant clinical history of the patient regarding the indication of blood transfusion and similar episodes of adverse reactions in the past during blood transfusion previous history of pregnancy and transfusions.
3. Also recorded clinical features due to clinical features, i.e. fever, chills, rigours, hypotension, pain abdomen, urine color, urticaria, rashes, respiratory discomfort, jaundice and any other sign or symptoms related to transfusion reactions.
4. Implicated blood component had checked for discolouration, clots, foul smell and any leakage.
5. Obtained Post -transfusion blood sample of the patients in EDTA vial for laboratory investigations in transfusion medicine laboratory.
6. After centrifugation plasma is checked for evidence of haemolysis by the presence of pink or red tinge.
7. Serological tests performed on pretransfusion and post transfusion sample are to rule out hemolytic transfusion reactions:
    a. ABO and RhD typing both cell and serum grouping on patients samples.
    b. ABO and RhD typing both cell and serum grouping implicated blood component.
    c. Repeat compatibility testing by the direct spin method and LISS gel Diamed cards.
    d. Antibody screening e. Direct Antiglobulin test
8. Bacterial culture of the blood bag and patients' blood. Blood sepsis had confirmed if the blood culture of the patient and transfused component is the same
9. Other supportive tests like:
    a. Urine for hemoglobinuria
    b. Complete blood counts, peripheral blood smears for schistocytes and spherocytes, reticulocyte count.
    c. Serum bilirubin direct and indirect
    d. Blood urea And Serum creatinine

e. Prothrombin time, Activated partial thromboplastin time.

10. X-ray chest, ECG Etc.

Febrile nonhemolytic transfusion reactions (FNHTR) is defined according to American Association of Blood Bank Technical manual as "A body temperature rise of >1o C or more occurring in association with transfusion and without any other explanation" such reactions are often associated with chills and rigours.[8]

Results

A total of 7824 units of whole blood and components were issued to various departments in the hospital during the 1-year study period (Table 1). These comprised whole blood (3176 [40.59%]), packed red blood cells (3268 [41.76%]), fresh frozen plasma (882 [11.27%]), and platelets (498 [6.36%]). The total number of transfusion reactions reported to Our transfusion service during the study period was 22/7824 (0.28%) of blood transfusions.

There were 17 (77.27%) females and 05 (22.72%) males who had experienced a transfusion reaction (Table 2). The age range of all these ATR spanned between 18 and 52 years.

All the signs and symptoms were reported within 4 h of starting the transfusion. Among the 22 transfusion reactions confirmed by the blood transfusion consultant, there were allergic reactions (n = 10/22 [45.45%]), FNHTR (n = 09/22 [40.9%]), anaphylactic reactions (n = 02/22 [9.09%]), and isolated hypotension (n = 01/22 [4.54%]).

The total number of transfusion reactions reported, in our study, were 22/7824 (0.28%). Acute reactions occurring within four hours of starting transfusion was 21/22 (95.45%). Saw one delayed type of transfusion reaction. The mean volume of blood Transfused when the transfusion reaction occurred was 130 ml.

The most common type of transfusion reaction among all the ATRs was allergic, followed by FNHTRs. Anaphylactic and isolated hypotension. Found not a single case of bacterial contamination or acute haemolytic response in the present study. In this study, there were no transfusion-related deaths.

Out of all blood components transfused, reactions were seen with Whole Blood and Packed RBC, whereas observed no responses with Platelet and Fresh Frozen Plasma transfusion. Saw most of the responses with Whole Blood Transfusion.

Table 1: Type of blood product issued during study period.

Type of product	Whole blood (%)	Packed red cells (%)	Platelets (%)	Fresh frozen plasma (%)
Total (7824)	3176 (40.59)	3268 (41.76)	498 (6.36)	882 (11.27)

Table 2: Sex distribution of all types transfusion reactions.

Sex	Allergic	FNHTR	Anaphylactic	Isolated hypotension	Total
Females	8	7	1	1	17
Males	2	2	1	0	5

FNHTR: Febrile non hemolytic transfusion reaction.

Table 3: Type of transfusion reactions according to a type of component transfused.

Type of components transfused	Allergic	FNHTR	Anaphylactic	Isolated hypotension	Total
Whole blood (WB)	6	7	2	1	18
Packed cell RBC (PRBC)	4	2	0	0	6

Discussion

Adverse reactions are unprecedented risks that are associated with allogenic blood transfusions. This study conducted collected that information regarding the various transfusion reactions from the cases that were referred to the blood bank. Did Evaluation base on clinical examination, laboratory workup, and predefined protocol.

There are a few factors that signify that the number of transfusion reaction that had reported to the blood bank may not be the actual number. Patients receiving multiple transfusions issued unused blood products, blood products. Not returned to the blood bank or discarded may be the causes of underreporting of these transfusion reactions. Underreporting of the actual number of transfusion reactions may also occur.[9]

Transfusion reactions present as adverse signs and symptoms occurring in patients during or after transfusion of blood components. These can be of the following types: (1) Immune reactions, (2) non-immune reactions, (3) immediate Responses, (during or within few hours of transfusion), and (4) delayed reaction (days or weeks after the transfusion). hemolytic anaphylactic, alloimmune.

In this study, the found frequency of transfusion reactions to be 0.28%. In a similar survey done by Bhattacharya Et al.,[10] found the prevalence of transfusion reactions to be 0.18%, whereas Sidhu et al.[11] and Kumar et al.[2] found a rate of 0.28% and 0.05%, respectively. The prevalence rate of our study matched with Sidhu et al.[11] The difference in rates of prevalence is due to factors related to underreporting as reported in a study by Narvios et al.[9]

In our present study, females were more affected than males, similar to the study by Sidhu et al.[11] However, Kumar et al.[2] in their research found males to be more affected than females.

In our study, found the highest incidence of transfusion reactions to be of allergic in nature. Sidhu et al.,[11] Kumar et al.,[2] and Domen and Hoeltge[12] found an incidence of allergic reactions 0.11%, 0.028%, and 0.02%, respectively, in their studies.

Differing from our study, Khalid et al.[13] showed that febrile non-hemolytic reaction (0.03%) was the most frequent transfusion hazard followed by allergic reactions (0.02%). Kumar et al.[2] and Bhattacharya et al.[10] found an incidence of 0.04% and 0.114% of FNHTR, respectively. Can attribute this variation in the frequency of FNHTR among different studies to variations in reporting, therapeutic interventions and at times due to many cases that are not reported to the blood bank.

The overall risk of FNHTR has reduced to 0.12% in non-leukoreduced to versus 0.08% in leukoreduced blood products.[12] Hence, with the broader use of leukoreduced blood products, the incidence of FNHTRs, Cytomegalovirus transmission and platelet refractoriness has decreased.[2] Finally, underreporting by medical staff could have underestimated the number of ATRs in our study.

Found the overall incidence of anaphylactic reactions to be 0.02 in our study. Sidhu et al.,[11] Kumar et al.[2] and Domen et al.[12] found incidence of anaphylactic reactions 0.11%, 0.003% and 0.003% respectively in their studies.

Found the incidence of isolated hypotension to be 0.01% in our study. Khalid et al.[13] had a prevalence of 0.001% of isolated hypotension in their study.

The frequency of transfusion reactions in this study was 0.28% in whole blood transfusions. This reaction rate can be an underestimation of true incidence, because of underreporting, which can be improved by the implementation of the hemovigilance system. This study shows the importance of rational use of blood and its components, improving storage conditions, bedside monitoring of transfusion and documentation of adverse events and implementation of the hemovigilance system, thus helping to improve transfusion safety.

Proper monitoring and knowledge of the signs and symptoms of the ATRs help in the early identification of these reactions and hence timely management and reporting. It is the joint responsibility of the blood transfusion consultant and their clinical counterpart to create awareness about safe transfusion services so that it can achieve proper hemovigilance system to provide patient care. This study is an effort toward this direction.

Conclusion

The majority of ATRs were allergic reactions followed by FNHTRS, a checklist before starting blood transfusion must be made mandatory. Should return it post-transfusion to the blood bank.

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