International Journal of Medical Science and Education

www. ijmse. com

Original Research Article

pISSN- 2348 4438 | eISSN-2349- 3208

RETROSPECTIVE EVALUATION OF ADVERSE TRANSFUSION REACTIONS FOLLOWING BLOOD PRODUCTS TRANSFUSION FROM SMS HOSPITAL, JAIPUR.

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Received: 17/03/2019 ***Revised:20/04/2019*** ***Accepted: 01/05/2019***

ABSTRACT

Background: To improve the quality of blood transfusion and enhancing it's safety, hemovigilance system is established. Reporting of adverse transfusion reactions under hemovigilance system emphasizes on detailed description of adverse event, thus helpful in correctly identifying of adverse transfusion events. Thus taking an appropriate steps can reduce their incidences, and thus helpful for improving the safety of blood transfusion. **Aim:** To evaluate retrospective data on adverse transfusion reaction reported under hemovigilance system in our institute from Sept. 2017 to May 2018. **Materials & Methods:** A retrospective study of data from Sept. 2017 to May 2018 were analyzed at SMS Hospital, Jaipur, RAJ. Continuous variables were evaluated as mean and standard deviation. Nominal/categorical variable were summarized as proportion (percentage) and analyzed by using Chi-Square test/Fisher exact test. p value < 0. 05 was taken to indicate significant difference. **Results:** During the study period total 61069 blood & blood product issued from our blood bank, out of these adverse transfusion reaction reported were 77 (0. 12%) under the hemovigilance system . Most common reaction observed were allergic 45% (n=25) . Not a single case of bacterial contamination was observed. **Conclusions:** Developing institutional guidelines related to correctly identify adverse events and reporting them under hemovigilance system should be implemented for enhancing the quality and safety of blood transfusion.

Keyword: surveillance, blood transfusion, hemovigilance, transfusion reactions.

INTRODUCTION

Transfusion reactions defined as transfusion – related adverse events that occur during or after the transfusion of whole blood or blood components or human – derived plasma products **(1)**. These reactions may vary in severity. To prevent these adverse events, knowledge about various transfusion reactions is essential to correctly identify an adverse event. Reporting these adverse events under hemovigilance system is an important tool for blood safety. It is defined as " a set of surveillance procedures covering the whole transfusion chain from collection of blood and its components to the follow-up off its recipients, intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence and recurrence" **(2)**. The National Blood policy was formulated in 2002 with the action plan on blood safety in 2003. Objectives 5.7 of Action

Plan stated the development of a national programme of haemovigilance **(3)**. Records of transfusion reactions are maintained in blood banks as part of licensing requirements. In 2016 donor vigilance was also added. To improve the quality of blood transfusion and enhancing it' s safety, hemovigilance system is established. Reporting of adverse transfusion reactions under hemovigilance system emphasizes on detailed description of adverse event, thus helpful in correctly identifying of adverse transfusion events. Thus taking an appropriate steps can reduce their incidences and helpful for improving the safety of blood transfusion.

AIM:

To evaluate the retrospective data on adverse transfusion reactions reported under hemovigilance system in our institute.

SUBJECTS & METHODS

The, study was conducted in SMS blood bank of SMS Medical college, Jaipur. Retrospective data were analysed and tabulated from Sept. 2017 to May 2018.

Protocol followed before issue of bag:

As per the standard operating procedures [SOP'S] of our blood bank, the blood sample in EDTA vial along with transfusion requisition form is sent for any requirements of blood components.

The hospital central registration number [CR no.] is unique for the patient, irrespective of name/age/sex. The CR no. should be matched on blood sample and transfusion requisition form by the technician who is receiving the transfusion requisition form and blood sample. The form should be completely filled and signed by the clinician on duty.

The details on the blood sample and the form are checked by the technician at the receiving counter.

Before issuing any of the blood component, the details on the blood bag, cross-match label, and blood transfusion requisition form and CR no. of the patient is tallied, and signed by the technician. Date and time of issue, expiry of bag along with all the others details are documented in blood bank records.

Instructions necessary regarding transfusion are handed over along with the supply of blood component in printed form.

The resident doctor is required to check all the necessary details on the form, blood bag, and the issue label before the start of transfusion.

Protocol followed following adverse event:

All the adverse events are reported on the pro forma as per the SOPs of our blood bank. This includes patient information and transfusion reaction details, transfused product details on behalf of clinician side and post transfusion work up that includes serological workup from blood bank side. After evaluating all sign and symptom and considering serological work up classify the reaction and imputability of reaction is assessed. Transfusion reaction classified as acute and chronic on the basis of duration after blood product transfused. Any reaction occurred within 24 hr. are considered as acute transfusion reaction. In our study all reactions were acute in nature, no delayed reaction was reported.

Analysis of acute transfusion reaction

After occurring an adverse events residual blood bag from which reaction occurred along with BT set and patient's post - transfusion blood sample (both in plain and EDTA vial) and first voided urine sample after reaction along with the duly filled up pro forma is sent to the blood bank for the complete work up. After excluding clerical errors, blood bag along with it's tubing and patient's post-transfusion sample is observed for haemolysis. Repeat blood group of the blood bag, patient's pre and post-transfusion sample and Coombs cross-match is done. Direct Coombs test of patient's post transfusion sample is done. Indirect anti-globulin test of pre-transfusion sample is done. Colour of the urine is noted. If red in colour, then it is centrifuged to distinguish between haematuria and hemoglobinuria. Blood sample from the residual blood bag is sent for sterility testing to microbiology laboratory. Investigation for renal function tests, liver function tests, and complete blood count are sent to the respective laboratory by the clinician in charge.

Criteria for classifying acute transfusion reaction:

The criteria for febrile non haemolytic reactions [FNHTRs] was strictly followed as an increase of body temperature of $\geq 1^{\circ}C$ above $37^{\circ}C$ that can be accompanied by chills, nausea or vomiting, tachycardia, increase in blood pressure and tachypnea for which no other cause is identifiable. Chills and

rigors in absence of fever are also included in FNHTR.**(1)**.

Serious hazards of transfusion [SHOT] guidelines define transfusion-related acute lung injury [TRALI] as acute dyspnoea with hypoxia and bilateral pulmonary infiltrates during or within 6hr. of transfusion, not due to circulatory overload or other likely cause **(5)**. However, in India, due to lack of awareness among the clinicians and financial constraints among the patients, complete investigation are not done in all patient with dyspnoea, thereby unable to differentiate TRALI from TACO. SO, underreporting of these adverse events occur.

RESULTS

Between September 2017 to May 2018 total 61069 blood and blood components issued from our blood bank to various departments of our hospital. The no. different blood components transfused is given in Table no. 1. Total number of transfusion reaction reported to our blood bank during the study period was 77, under the hemovigilance system, of which 46 [59.7]% were in male and 31 [40.2] % were seen in female . Mean age was 38 years [range 15 to 80 yr.]

Mean volume of blood unit transfused, when the reactions were noted was 110ml [range 20-250 ml] for packed red cells . All the reactions in our study were acute transfusion reactions. None of the delayed transfusion reactions were reported to our blood bank during the study. The mean time at which the reaction was reported was 20 min. [range 5-90 min.]

The frequency of transfusion reaction was found to be 0.12% [77 out of 61069]. Average transfusion reaction rate with red cell concentrate (RCC) was 57 [74%] followed by FFP 14[18%] and Platelet concentrate 6 [7%].

Categorisation of transfusion related adverse reactions:

Allergic reactions:

Allergic reactions were the most common type of transfusion reaction found in 35 patients [45% of all reactions of all reactions Figure2]. Clinical sign and symptoms were urticarial, pruritus, skin rash. Components implicated in allergic reaction were packed red cells were 0. 06%, platelet were 0.01%, FFP were 0.08%.

Febrile non haemolytic transfusion reaction:

FNHTR was the 2nd most commonly encountered adverse reaction in this study comprising 29.9% of all the reactions [Figure 1]. Clinical sign and symptoms observed were fever, chills and rigors . FNHTR was seen in 23 patients after component transfusion. Most of the FNHTRs were due to packed red cells 0. 05% followed by platelet concentrate 0. 03%.

Anaphylactic/anaphylactoid reactions:

Anaphylactic/anaphylactoid reactions were seen in 9. 09% cases of all transfusion reactions. . Clinical sign and symptoms in these patients were hypotension, rash, and respiratory distress.

Transfusion related acute lung injury and transfusion associated circulatory overload : due to lack of all the investigations required to meet the criteria to classify transfusion reaction under the above headings, symptoms like severe sudden dyspnoea and cyanosis is noted in TRALI along with post transfusion x- ray showing bilateral pulmonary oedema without cardiomegaly. While TACO present with dyspnoea, cyanosis, jugular venous distension, pedal oedema and increased pulse pressure with wide pulse pressure. This category is considered under transfusion associated dyspnoea, which include respiratory distress without showing any sign of allergic reactions.

Acute haemolytic transfusion reactions:

Not a single case of an acute haemolytic transfusion reaction was reported in our blood bank during study period.

DISCUSSION

Adverse event reporting requires the collaboration between blood bank and the clinicians. It depends chiefly on the knowledge of transfusion procedures, hazards of the use of blood, timely identification of an event related to blood transfusion with its clinical management and further investigations at the blood bank. There are several reports on adverse events including transfusion - associated deaths but the relative risk, based on the number of actual cases divided by the number of blood product unit is relatively low. **(6)**.

The approach to hemovigilance is different between countries. In France, the hemovigilance system is nationwide, with a legal obligation to notify, in written form, every untoward effect in relation to blood transfusion **(7)**.

In the UK, only serious adverse reactions are reported, on a voluntary basis, SHOT. **(8)**. In INDIA, hemovigilance program was launched on December 10, 2012, with NIB as national co-ordinating centre **(9)**. In our institute the transfusion reporting format of INDIA is adopted.

The frequency of transfusion events in our study was 0.12% [77/61069]. This rate is similar to other published results P.Khoyumthem et al 2018 [0.09%] **(8)**, S.Pahuja et al [0. 19%] **(9)** and Chavan k. Surekha et al [0. 3%] **(10)**

Allergic reactions is the most common adverse effect of blood transfusion in our study comprises 45. 4% of all reactions which is similar to other study like S. Pahuja et al41. 4%] **(9)**, P. Khoyumthem [53.57%] **(8)**. In the present study it was 0. 06% with Red cells, 0.01% with platelets, and 0.08% with FFP.

FNHTR is the second most common adverse effect of blood transfusion comprising 29. 8% cases, which is similar to study P. Khoyumthem et.al [35. 7%] **(8)** Rate of FNHTR by Red cells in most studies ranged from 0.1% to 0.5% [8, 9]. In this study, the frequency of FNHTR with use of packed red cells is 0.05%, platelets is 0.03% [Table 4]. The major culprit of FNHTRs are leukocytes. The low frequency in our study is due to use of buffy coat depleted packed red cells.

Anaphylactic reactions were seen in 0.02% with platelet concentrate and 0.03% with FFP. Due to lack of IgE estimation in our setup differentiation of anaphylactic reactions from anaphylactoid were not done.

TRALI is also underdiagnosed due to lack of knowledge in clinician about transfusion reactions, so, further investigations was not meet for defining criteria of TRALI in our set-ups.

No single case of acute haemolytic transfusion reaction was reported in our study.

Transfusion reactions are generally remain under-reported, primarily, due to lack of awareness, and also due to the inadequate feedback system. Developing institutional guidelines and having an appropriate adverse event reporting format and documenting them is crucial. It is important to ensure appropriate use of blood components. Hospital blood transfusion committee has an important role to play.

CONCLUSION

The frequency of transfusion reactions in our study was 0. 12% [77/61069] which is similar to other study [8-10]. Majority of reactions were Allergic 0. 05% [35/61069] closely followed by FNHTRsreactions0. 03% [23/61069].

Developing institutional guidelines, HBTC meetings and adequate, complete hemovigilance reporting should be emphasized. Education of the staff regarding notify adverse events and proper reporting of adverse events and complete follow up is the key step in improving the safety of blood transfusions.

Table 1: detail of blood and blood products transfused during study.

Blood and blood components	**No**.
Whole blood	276
Packed red cells	39720
Platelet concentrate [RDP, SDP, PRP]	8958
Fresh frozen plasma	12060
Cryoprecipitate	41
Total	61069

Table 2: Transfusion –related adverse reactions due to blood and blood products

Blood and blood components	**No.**
Whole blood	0
Packed red cells	57 [74%]
Platelet concentrates[rdp, sdp, prp]	6 [7%]
Fresh frozen plasma	14 [18%]
Cryoprecipitate	0
Total	77

Table 3: Frequency of transfusion related adverse event due to components.

Blood components	Percentage in relation to transfused
Packed red cells	0. 14%[57/39720]
Platelet concentrate[rdp, sdp, prp]	0. 06%[6/8958]
Fresh frozen plasma	0. 11%[14/12060]
Total	

Figure 1 transfusion reactions reported according to gender

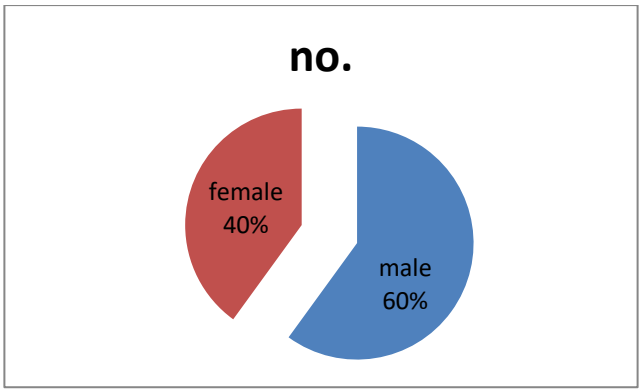

Figure 2: different type of transfusion reaction reported during study period

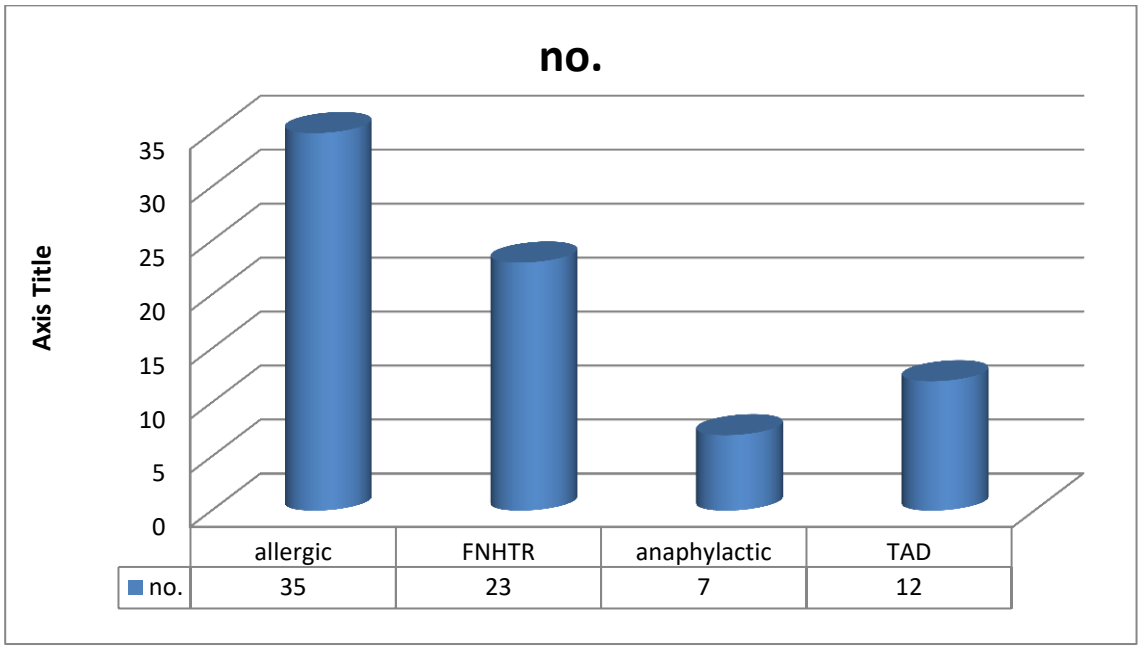

Figure 3 : relation of transfusion reaction according to Rh D positive status

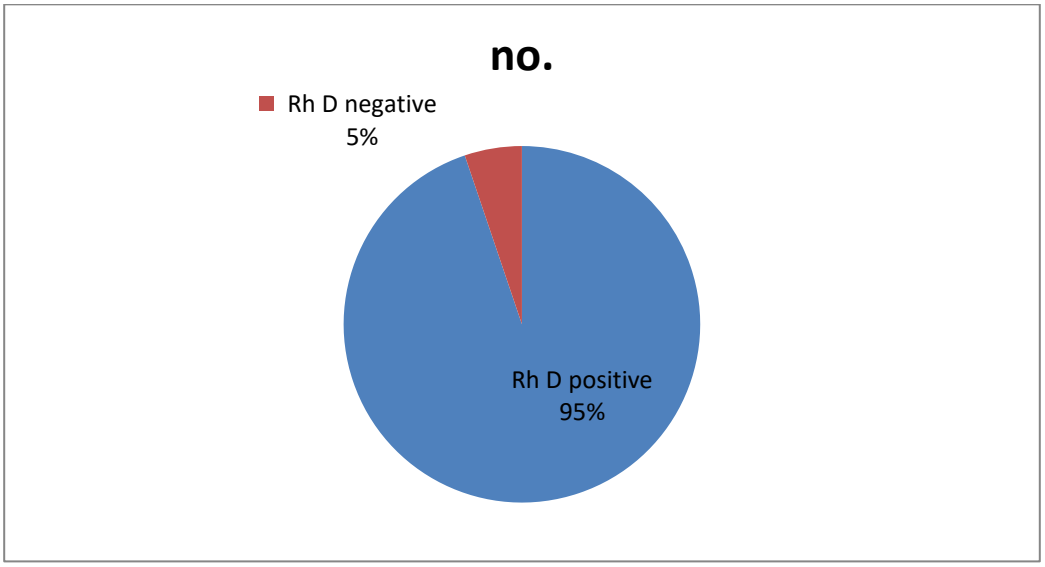

Table 4: Frequency of transfusion events [type of reactions/components]

Type of reaction	Packed red cell	Platelet concentrate	Fresh frozen plasma
Allergic	0. 06%[24/39720]	0. 01%[1/8958]	0. 08%[10/12060]
FNHTRs	0. 05%[20/39720]	0. 03%[3/8958]	-
Anaphylactic	-	0. 02%[2/8958]	0. 03%[4/12060]
TAD	0. 03%[12/39720]	-	-

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How to cite this article: Parashar R., Bundas S., Sharma A., Meena B.S., Pachori P., Sharma S., Retrospective Evaluation Of Adverse Transfusion Reactions Following Blood Product Transfusion From SMS Hospital, Jaipur. Int. J. Med. Sci. Educ 2019; 6(2): 64-69