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ORIGINAL RESEARCH

A Prospective study of monitoring of Adverse Transfusion Reactions occurring in patients administered Packed Red Blood Cells (PRBC)/Fresh Frozen Plasma (FFP) /Platelets (Random Donor Platelets) in Obstetrics and Gynecology Department

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ABSTRACT

Background: Adverse drug reactions (ADRs) have become one on the leading causes of morbidity and mortality. The present study was conducted to record the immediate and delayed adverse transfusion reactions related to the transfusion of Packed Red Blood Cells/Fresh Frozen Plasma/Platelets (Random Donor Platelets)/combination of 2 or all 3 components in patients admitted in Obstetrics and Gynaecology department of King George's Medical University, Lucknow.

Materials & Methods: The study was conducted in the Department of Pharmacology in collaboration with Department of Obstetrics and Gynecology and Department of Transfusion Medicine, King George's Medical University, Lucknow. Pre-transfusion and post-transfusion vitals were recorded. Post- transfusion vitals were recorded at 1,4 and 24 hrs. Patients were followed up at 10 days and 1 month for occurrence of any delayed transfusion reaction.

Results: Out of the study participants had a mean age of 29.88 years (SD = 7.67), with a median age of 28 years. Ages ranged from 18 to 60 years, indicating a diverse age distribution among the 206participants. The majority of participants (64.1%) fell within the 18-30 years age interval, followed by 24.3% in the 31-40 years range, 10.2% in the 41-50 years range, and a smaller percentage of 1.5% in the 51-60 years range. Among the 206 participants, packed red blood cells (PRBC) were the most commonly transfused product, accounting for 65.05% of the cases. PRBC combined with fresh frozen plasma (FFP) or random donor platelets (RDP) were less frequent, constituting 15.5% and 10.7% of the cases respectively. Maximum incidence of transfusion reactions was seen in the group administered PRBC alone (56.5%) followed by the group administered PRBC and FFP (21.7%) while the group administered a combination of all 3 components, PRBC, RDP and FFP had an incidence of 4.3%.Among the participants, 11.2% experienced transfusion reaction, while the majority, 88.8%, did not encounter any adverse reactions to the blood transfusion.The Imputability assessment regarding the transfusion-related adverse reactions revealed that 26.1% of cases were classified as "possible" while the majority, 73.9%, were categorized as "probable".Febrile non-hemolytic reactions, including both 1-degree and 2-degree temperature rises, accounted for 17.4% of cases. Allergic reactions constituted the largest proportion at 34.8%. Anaphylaxis and hypotensive transfusion reactions were less common, each representing 8.7% of cases. Transfusion-related dyspnea and post- transfusion purpura were observed in 13% of instances each. Notably, no

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occurrences were reported for certain reactions such as immunological hemolysis due to ABO incompatibility or transfusion-related acute lung injury.

Conclusion: This study serves as a crucial prompt for the medical community to deepen its understanding of transfusion reactions through focused research. By uncovering and addressing the complex risk factors associated with blood transfusions, healthcare providers can enhance safety protocols, improve patient outcomes, and drive forward medical innovations in transfusion practices.

Keywords: Adverse drug reactions, Blood, transfusion reactions

INTRODUCTION

Adverse drug reactions (ADRs) have become one on the leading causes of morbidity and mortality.[1] In order to prevent and minimize these adverse drug reactions (ADRs) and to improve public health, there was felt the need for mechanisms to be implemented in place for monitoring and evaluating the safety of medicines in clinical use.[2] This was achieved by placing a well-established and organized pharmacovigilance system.[3] In the 1990s it was defined as "The detection in the community of drug effects, usually adverse. It may be passive (collection of spontaneous reports) or active (patients and prescribers are recruited andsurveyed).[4,5] The specific aims of pharmacovigilance are toimprove patient care and safety in relation to the use of medicines and all medical and paramedical interventions,improve public health and safety in relation to the use of medicines,contribute to the assessment of benefit, harm, and risk of medicines, encouraging their safe and effective use,promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public.[6,7]The present study was conducted to record the immediate and delayed adverse transfusion reactions related to the transfusion of Packed Red Blood Cells/Fresh Frozen Plasma/Platelets (Random Donor Platelets) /combination of 2 or all 3 components in patients admitted in Obstetrics and Gynaecology department of King George's Medical University, Lucknow.

MATERIALS & METHODS

The study was conducted in the Department of Pharmacology in collaboration with Department of Obstetrics and Gynecology and Department of Transfusion Medicine, King George's Medical University, Lucknow. All were informed regarding the study and their written consent was obtained.The total duration of study was 12 months i.e. April 2023 to March 2024. Data such as name, age, gender etc. was recorded. Socio-demographic details of the patients were recorded in the Case Report Form (CRF) at the time of inclusion in the study.Pre-transfusion and post-transfusion vitals were recorded. Patients were also monitored during the transfusion. Post- transfusion vitals were recorded at 1,4 and 24 hrs. Patients were followed up at 10 days and 1 month for occurrence of any delayed transfusion reaction. If discharged, then the follow up was done telephonically. Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean and SD. Qualitative variables were compared using Chi-Square test /Fisher's exact test as appropriate. A p value of <0.05 was considered statistically significant.

RESULTS

Table: I Age distribution of study population

Age intervals	No. of patients (%)	No. of transfusion reactions (%)	% of patients demonstrating transfusion reactions
18-30 years	132 (64.1)	17 (73.9)	12.87%
31-40 years	50 (24.3)	1 (4.3)	2.0%
41-50 years	21 (10.2)	5 (21.7)	23.8%
51-60 years	3 (1.5)	0 (0)	0
Total	206 (100)	23 (100)	

Table I shows that out of the study participants had a mean age of 29.88 years (SD = 7.67), with a median age of 28 years. Ages ranged from 18 to 60 years, indicating a diverse age distribution among the 206participants. The majority of participants (64.1%) fell within the 18-30 years age interval, followed by 24.3% in the 31-40 years range, 10.2% in the 41-50 years range, and a smaller percentage of 1.5% in the 51-60 years range.

Table :II Transfusion of various blood products

Product transfused	No. of patients (%)	No. oftransfusion reactions found (%)	% of transfusion reactions of the products transfused
FFP	3 (1.5)	0 (0)	0
PRBC	135 (65.0)	13 (56.5)	9.6%
PRBC+FFP	31 (15.5)	5 (21.7)	16.12%
PRBC+RDP	22 (10.7)	4 (17.4)	18.18%

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PRBC+RDP+FFP	3 (1.5)	1 (4.3)	33%
RDP	12 (5.8)	0 (0)	0
Total	206 (100)	23 (100)	

Table II shows that among the 206 participants, packed red blood cells (PRBC) were the most commonly transfused product, accounting for 65.05% of the cases. PRBC combined with fresh frozen plasma (FFP) or random donor platelets (RDP) were less frequent, constituting 15.5% and 10.7% of the cases respectively.Maximum incidence of transfusion reactions was seen in the group administered PRBC alone (56.5%) followed by the group administered PRBC and FFP (21.7%) while the group administered a combination of all 3 components, PRBC, RDP and FFP had an incidence of 4.3%.

Table: III Transfusion reactions found in the participants

Transfusion reactions found	No. of patients	%
Yes	23	11.2
No	183	88.8
Total	206	100.0

Among the participants, 11.2% experienced transfusion reaction, while the majority, 88.8%, did not encounter any adverse reactions to the blood transfusion.

Table IV Evaluation of imputability for transfusion reactions

Imputability	No. of patients	%
Certain	0	0
Probable	17	73.9
Possible	6	26.1
Unlikely	0	0
Excluded	0	0
Not assessed	0	0
Total	23	100.0

The Imputability assessment regarding the transfusion-related adverse reactions revealed that 26.1% of cases were classified as "possible" while the majority, 73.9%, were categorized as "probable".

Table :V Nature and categorization of adverse transfusion reactions

Nature/categorization	No	%
Febrile non hemolytic reaction • 1 degree rise intemp • 2 degrees rise intemp	4 3 1	17.4%
Allergic reaction	8	34.8%
Anaphylaxis	2	8.7%
Immunological haemolysis due to ABO incompatibility	0	0
Immunological haemolysis due to Allo-antibodies	0	0
Non immunological hemolysis	0	0
Hypotensive transfusion reaction	2	8.7%
Transfusion related acute lung injury	0	0
Transfusion related dyspnoea	3	13%
Transfusion associated circulatory overload	0	0
Transfusion transmitted bacterial infection	0	0
Transfusion associated parasitic infection	0	0
Post transfusion purpura	3	13%
Transfusion associated graft vs host reaction	0	0
Other reactions	1	4.34%
Total	23	100%

Febrile non-hemolytic reactions, including both 1-degree and 2-degree temperature rises, accounted for 17.4% of cases. Allergic reactions constituted the largest proportion at 34.8%. Anaphylaxis and hypotensivetransfusion reactions were less common, each representing 8.7% of cases. Transfusion-related dyspnea and post- transfusion purpura were observed in 13% of instances each. Notably, no occurrences were reported for certain reactions such as immunological hemolysis due to ABO incompatibility or transfusion-related acute lung injury.

DISCUSSION

Blood transfusion is a critical intervention in some obstetric and gynaecological situations that can save

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lives but comes with the risks of adverse reactions and infection transmission. Therefore, it is essential to use blood and its products appropriately to ensure the safety of patients.[8] This study on monitoring adverse transfusion reactions due to the administration of PRBC, FFP, and RDP in obstetrics and gynaecology underscores the need for vigilant monitoring to enhance patient safety. Differences in reaction rates among blood products suggest that monitoring and prevention strategies should be tailored accordingly. The study highlights the effectiveness of pre-transfusion testing, clinical monitoring, and real-time surveillance in managing transfusion-related risks.[9] Educating healthcare professionals on recognizing and managing transfusion reactions is crucial for improving outcomes. The study advocates for a multidisciplinary approach to transfusion safety, suggesting further research on biomarkers for better prediction and diagnosis of adverse reactions.[10] This research contributes to ongoing efforts to optimize transfusion practices in obstetric and gynaecologic care. The present study was conducted from April 2023 to March 2024 on patients admitted to Obstetrics and Gynaecology department, KGMU who were administered PRBC/FFP/Platelets (Random Donor Platelets)/combination of 2 or all 3 components for any Obstetric or Gynaecological indication.

Out of the study participants had a mean age of 29.88 years (SD = 7.67), with a median age of 28 years. Ages ranged from 18 to 60 years, indicating a diverse age distribution among the 206participants. The majority of participants (64.1%) fell within the 18-30 years age interval, followed by 24.3% in the 31-40 years range, 10.2% in the 41-50 years range, and a smaller percentage of 1.5% in the 51-60 years range.Chawla S et al[11]ascertained and analyzed the indications for transfusion of blood components in obstetric practice at our center.1.3% of all obstetric patients from our center had blood components transfusion during the study period. Postpartum hemorrhage, placental causes and anemia are the commonest causes for need of transfusion in obstetric practice. Among the 206 participants, packed red blood cells (PRBC) were the most commonly transfused product, accounting for 65.05% of the cases. PRBC combined with fresh frozen plasma (FFP) or random donor platelets (RDP) were less frequent, constituting 15.5% and 10.7% of the cases respectively. Maximum incidence of transfusion reactions was seen in the group administered PRBC alone (56.5%) followed by the group administered PRBC and FFP (21.7%) while the group administered a combination of all 3 components, PRBC, RDP and FFP had an incidence of 4.3%.Among the participants, 11.2% experienced transfusion reaction, while the majority, 88.8%, did not encounter any adverse reactions to the blood transfusion.The Imputability assessment regarding the transfusion-related adverse reactions revealed that 26.1% of cases were classified as "possible" while the majority, 73.9%, were categorized as "probable".BorhanyM et al[12] found that maximum 16.20% blood transfusions were given during cesarean section in third trimester in unbooked cases who came with severe anemia in labour. Others were APH (12%) and abortions (13.05%). This shows that anemia is still a major cause of maternal mortality and morbidity in India. In Gynecological cases blood transfusion was more in third parity and above indicating that perimenopausal women were also more susceptible for anemia due to disease of perimenopausal age group like AUB and fibroid.

Febrile non-hemolytic reactions, including both 1-degree and 2-degree temperature rises, accounted for 17.4% of cases. Allergic reactions constituted the largest proportion at 34.8%. Anaphylaxis and hypotensive transfusion reactions were less common, each representing 8.7% of cases. Transfusion-related dyspnea and post- transfusion purpura were observed in 13% of instances each. Notably, no occurrences were reported for certain reactions such as immunological hemolysis due to ABO incompatibility or transfusion-related acute lung injury. Tyagi S et al[13]studied the frequency and type of Acute Transfusion Reactions (ATRs) occurred in patients receiving blood transfusions. ATRs during or after blood transfusion reported during the five years period were 77 (0.21 %) out of 35,593 units of blood /blood components transfused. ATRs reported were febrile non hemolytic transfusion reactions (FNHTR) 46 (59.74%), allergic Reactions 29 (37.66 %), anaphylactic reactions 2 (2.59 %) in order of frequency.

CONCLUSION

This study serves as a crucial prompt for the medical community to deepen its understanding of transfusion reactions through focused research. By uncovering and addressing the complex riskfactors associated with blood transfusions, healthcare providers can enhance safety protocols, improve patient outcomes, and drive forward medical innovations in transfusion practices. Awareness among health professionals for identifying and reporting of adverse reactions as well as the rules of hemovigilance should be spread. This research was essential for evolving and refining the methods used to prevent and manage adverse reactions, ensuring that blood transfusions remain a safe and effective treatmentoption.

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