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Haemovigilance in pregnancy: A prospective observational study in a secondary care hospital

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Abstract
Background: Blood transfusion is one of the essential element to treat obstetrics emergencies, to reduce maternal mortality and morbidity rate. Therefore, to make blood transfusions safer, haemovigilance finds its hook, so as to prevent, identify reports and treat transfusion reactions. This study aims to evaluate the incidence of transfusion reactions in pregnant woman in a secondary care hospital.
Methodology: This is a prospective observational study conducted in 19 pregnant women who underwent blood transfusions in their antenatal period and have been incurred with blood transfusion reactions in Government Kamaraj Hospital, Chidambaram, from June 2021 to May 2022.
Results: It was observed that occurrence of transfusion reactions were reported predominantly in the age group of 21 to 25 years and in A positive blood group. The most common transfusion reaction reported was rashes contributing to 39% of reported transfusion reaction. There was no mortality noted in our study.
Conclusion: This study has evaluated the incidence of transfusion reactions in pregnant women and also our study signifies the importance of haemovigilance in delivering the blood products for transfusion safety.

Keywords: Haemovigilance, blood transfusion, antenatal, transfusion reaction

Introduction
Blood transfusions are a relatively common medical procedure, although safe, there are multiple complications that are need to be recognized, treated and reported [1]. The transfusion reaction (TR) can be defined as an unintended response in a patient to the transfusion of blood components which prolongs hospitalization, is disabling or incapacitating and increases morbidity or causes mortality [2]. The occurrence of acute blood transfusion reactions has been estimated to be between 0.2% and 10% with fatal outcome of approximately one in 250,000 transfusions [3]
Haemovigilance is defined as a set of surveillance procedures covering whole transfusion chain from the collection of blood and its components to the follow up of its recipients, intended to collect and access information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence and recurrence [4]. Therefore, the aim of a haemovigilance system is to improve the safety of blood transfusion [5].
Blood transfusion in pregnancy can be a frightening scenario and the transfusion reactions in pregnancy remains a nightmare when it proceeds to life threatening emergencies. Several studies were conducted in non-pregnant subjects but pregnancy poses a special challenge as immune response in pregnancy is different and this may possibly affect the nature or onset of complications, as pregnancy is known to cause formation of red cells allo antibodies. Although advances in transfusion medicine, coupled with availability of blood products substitutes had helped in reducing transfusion rates in the western world but such cannot be said to be true in a developing nation like India. Therefore the objective of our study is to evaluate the incidence of transfusion reactions during blood transfusion in pregnant women.

Methodology
Study Design: The present study was a prospective, observational study.

Study Setting
Informed consent was procured from all the subjects prior to their enrolment in the study. The study was carried out in Government Kamaraj Hospital, Chidambaram, a secondary care hospital.

Study Period: Study was carried out from June 2021 to May 2022

Study participants: 19 pregnant women who underwent blood transfusion in Government Kamaraj hospital, Chidambaram, from June 2021 to May 2022 were included in the study.

Data Sources: Data relating to age, parity, indication for transfusion, numbers of the units transfused, adverse reactions and laboratory analysis result following an adverse reaction were collected from department of obstetrics and blood bank of Government Kamaraj Hospital, Chidambaram.

Statistical Analysis: Data collected were entered in MS Excel and analysed

Results

1. Age wise distribution

Vide table 1, among the 19 antenatal mothers, 18 was the least age of reaction and 39 was the highest age in our period of study.

Table 1: Age wise distribution

Age	No of Antenatal mothers
18-20	1
21-25	11
26-30	4
31-35	2
36-40	2

2. Blood group wise distribution

From table 2, 9 were A+, 8 were B+ ve, 1 was B-ve and 2 were O+ve among the antenatal mothers with adverse reaction.

Table 2: Blood group wise distribution

Blood group	No of Antenatal mothers
A+ve	9
B+ve	8
B-ve	1
O+ve	2

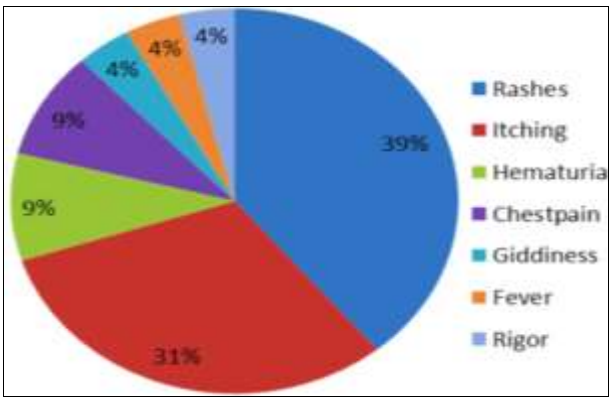

Fig 1: Adverse drug reaction in antenatal mothers

3. Adverse drug reaction

Vide fig 1, 39% of mothers had rashes, 31% with itching, 9% experienced chestpain and 9% hematuria, 4% had giddiness, 4% with fever and 4% with rigor during blood transfusion in their antenatal period.

Discussion

Transfusion of blood and its products is a safe and effective way of correcting haematological defects even during pregnancy where the physiological status is altered. Still, adverse effects do occur during or after transfusion. They may be acute or delayed.

Transfusion therapy in pregnancy has become a standard practice nowadays, particularly in India, where up to 75% of pregnant women are anaemic, paving way for obstetric haemorrhage that has become a common complication [6]. Many a times the increment in the transfusion is not similar to what is expected, it could be do to a number of pre-existing conditions, co-morbidities and confounding factors.

Vide table 1, we observed that, the pregnant mothers in the age of 21-25 had an increased incidence of blood transfusion reactions which is similar to study conducted by Tharn *et al*. [7]. This can be explained by the fact that mothers in this age group are in the active reproductive group in a developing country like India and the most common reason of blood transfusion being nutritional anaemia.

The incidence of blood transfusion reactions was noted among the A positive blood group, from table 2. This may be due to the fact that this blood group type is prevelant in this population. However the blood group does not reflect the incidence of transfusion reactions and ABO compatibility is the most important factor to be noted during blood transfusions.

In our study, the most common transfusion reaction encountered during transfusion was rashes that contributes to 39% of incidence, which is similar to study conducted by Awolker *et al*. [3] In his study the incidence of rashes was 23%. Although this is a non-serious adverse reaction, reporting of transfusion reaction is mandatory. The occurrence of rashes during blood transfusion is due to reaction of Recipient's IgE with donor plasma protein leading to release of mast cell mediators [8].

Transfusion reactions identification and management remains the important aspects of blood safety. The spectrum of transfusion reactions ranges from a mild allergy to life-threatening emergencies, such as anaphylactic shock, that is possibly fatal. The recognition, reporting, and monitoring of transfusion reactions are the key objectives of haemovigilance. The prime aim of haemovigilance is to improve transfusion practice through data-driven evidence-based improvements, with the aim of improving transfusion safety [2].

In order to have a well-organized haemovigilance system in developing countries like India, a comprehensive approach is required. A streamlined mechanism for data collection using standardized tools at hospital level and good coordination at the national level can bring up effective haemovigilance system in a country. A functional hospital transfusion committee acts as backbone for this, by developing policies for transfusion practices, appropriate documentation, reporting and investigation of transfusion reaction. The data from a well-functioning haemovigilance system can be used as quality indicator for monitoring the

blood transfusion safety, and also contribute significantly to evidence-based transfusion medicine. Regulation of blood novelties is guided by Good Manufacturing Practice and Good Clinical Practice thereby a vigilant system may build for the safety of the patients.

The strength of our study is that all age groups and blood groups were included in the study and the limitations are the period of study could have been extended to look for fatal complications and it could have been a multicentric study.

Conclusion

Therefore, our study has validated the incidence of transfusion reactions in pregnancy and significance of haemovigilance.

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Conflict of interest

The authors declare no conflicts of interest.

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