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Acute Transfusion Reactions in a Tertiary Care Hospital: The Saudi Context

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ABSTRACT

Although blood transfusion is a life-saving procedure, it can be associated with complications in rare cases. An acute transfusion reaction (ATR) is a complication where recipients exhibit an adverse reaction within 24 hours of a blood transfusion. This study aimed to determine the incidence of ATRs. This retrospective study reviewed the ATRs for all patients who received blood products over three years (2018, 2019, 2020). Of 81,498 transfusion episodes investigated, 132 (0.16%) were associated with ATRs. The most frequent adverse reactions were allergic reactions (62.9%, n = 83), followed by febrile non-haemolytic transfusion reactions (FNHTR) (32.6%, n = 43). Among blood products, it was found that allergic reactions were associated with platelet transfusions (40.9%, n = 34) and FNHTR with packed red blood cell transfusions (79.0%, n = 34). Serious complications such as acute haemolytic transfusion reaction and transfusion-related lung injury were not reported. The low percentage of recorded ATRs may indicate an underestimation of the true incidence due to under-reporting. Accurate reporting of ATRs is a crucial element of the haemovigilance system and would improve blood transfusion safety and enhance patient management.

> KEYWORDS FNHTR; allergic reactions; TACO; haemovigilance; urticarial rash

CITATION

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1. Introduction

Blood transfusion remains unquestionably a life-saving procedure. Its direct aid in achieving vital therapeutic outcomes in treating patients outweighs the infrequent, though possible, adverse events that can ensue. These adverse events have been reduced historically through the universal development of enhanced guidelines in blood transfusion services. These range from strict policies in selecting blood donors and screening donated blood for transfusiontransmissible infections to establishing hospital transfusion committees and direct feedback on transfusion adverse reactions to monitoring systems. These monitoring systems are now globally known and designated as haemovigilance, formally defined as the set of surveillance procedures covering the transfusion chain from blood donations to blood transfusions (Jain and Kaur, 2012). This vital concept of monitoring blood transfusion practices and events can help us define and understand the possible adverse events or reactions following a transfusion and aid in developing techniques and procedures that prevent their recurrence (Prakash, Basavaraj, and Kumar, 2017).

Acute transfusion reactions (ATRs) may differ in severity depending on the type and susceptibility of the patient. These reactions are defined as any unfavourable transfusion-related reaction that occurs to a recipient during or after the transfusion of blood or its components. ATRs occur during or within 24 hours of transfusion and are classified as immune- or non-immune-mediated adverse reactions. They include acute haemolytic transfusion reaction (AHTR), transfusion-related acute lung injury (TRALI), transfusionassociated circulatory overload (TACO), febrile non-haemolytic transfusion reaction (FNHTR), anaphylactic reactions and allergic transfusion reactions.

The international haemovigilance system was founded in 2009, and many developed countries have established haemovigilance systems at various levels. In Saudi Arabia (SA), establishing a national haemovigilance system is an important goal of the Saudi Society of Transfusion Medicine and the Ministry of Health (Hindawi, 2020). However, studies have reported that ATRs in Saudi hospitals are very rare, and only a small number of studies were found in the literature (Ali, Ibraham, and Joseph, 2005; Badawi et al., 2021; Hindawi et al., 2016). Measuring adverse transfusion events provides healthcare providers insights into blood transfusion safety and consequently enables them to improve it. This study aims to report and analyse ATR events over three years at a tertiary care hospital in Riyadh, SA.

2. Materials and Methods

This retrospective cross-sectional study was conducted at King Fahad Medical City, a tertiary hospital in Riyadh, SA. The institutional ethics committee approved the study (registration number: H-01-R-012). Reported transfusion reactions documented due to different transfused blood products, namely, leucodepleted packed red blood cells (PRBC), platelets and fresh frozen plasma (FFP), over three years (from January 2018 to December 2020) were analysed. When a transfusion reaction was reported to the blood bank, a transfusion reaction form was provided to medical staff. ATRs were examined using a standard transfusion reaction investigation protocol, which includes: clerical checking; an inspection of a post-transfusion blood sample for any evidence of haemolysis and comparison of the same with a pre-transfusion sample if available; rechecking of the patient's pre- and post-transfusion samples for blood grouping; carrying out direct antiglobulin and auto-control tests for the patient's pre- and post-transfusion samples; examining the patient's pre- and posttransfusion samples with the donor sample to recheck compatibility; repeating the antibody screen with a 3-cell panel and, in the event of a positive result, carrying out an antibody identification test using an 11-cell panel; and performing a bacteriological culture.

In addition to information obtained through the protocol, other data (age, sex, type and number of transfused products, symptoms and the diagnosed adverse reaction) were retrieved from the transfusion reaction reports. Acute reaction reports adequately filled out and confirmed by a haematologist were included. Those reports which did not describe the symptoms and type of the adverse reaction were excluded, as were delayed adverse reaction reports. For statistical analysis, Microsoft Excel 2016 was used for data analysis and to obtain the event percentages.

3. Results

This retrospective study collected data on a total of 81,498 transfused blood components over the study period (from 2018 to 2020). The most transfused blood components were PRBC units (56%), followed by platelets and FFP (both 22%), as seen in Table 1.

Table 1. Number and type of transfused blood components over the study period.

| Issued blood components | Number of units (2018) | Number of units (2019) | Number of units (2020) | Total (%) |
|------------------------------------|---------------------------|---------------------------|---------------------------|-------------|
| PRBC | 14278 | 15270 | 15925 | 45473 (56%) |
| Platelets | 5999 | 6103 | 5790 | 17892 (22%) |
| FFP | 6149 | 6040 | 5944 | 18133 (22%) |
| Total transfused units per year | 26426 | 27413 | 27659 | 81498 |

Patients who developed ATR events ranged widely in age (1 to 94 years); 46.21% were male, and 53.79% were female. Of the total transfused units, 132 adverse events were reported, setting the average rate of transfusion reactions at 0.16%. The rates of allergic reactions and FNHTR were approximately 0.1% and 0.05%, respectively.

As illustrated in Table 2, most of these events were associated with PRBCs (43.2%). The highest reported types of ATRs were allergic reactions (62.9%), followed by FNHTR (32.6%). Most of the allergic reactions were associated with platelets (40.9%), followed by FFP (36.1%), while 79.0% of FNHTR events were associated with PRBCs. Moreover, allergic reactions affected more females than males (59% vs 41%). The opposite was noted with FNHTR, which was observed more in males than females (56% vs 44%). Three cases of anaphylactic reactions were reported, representing 2.3% of all cases. No TRALI or AHTR were reported.

Table 1. Types and percentages of the reported ATRs and their association with specific blood components.

| Type of ATR | Component transfused | | | | Incidence (per 10,000 |
|--------------------|--------------------------|------------|------------|-------------------------|-----------------------|
| Type of ATK | PRBC | Platelets | FFP | Total (n=132) | components) |
| Allergic reactions | 19 | 34 | 30 | 83(62.9% ^B) | 10.2 |
| FNHTR | 34 | 5 | 4 | 43 (32.6%) | 5.3 |
| Anaphylactic | 1 | 0 | 2 | 3 (2.3%) | 0.4 |
| Hypotension | 1 | 0 | 0 | 1 (0.8%) | 0.1 |
| TACO | 1 | 0 | 0 | 1 (0.8%) | 0.1 |
| Others | 1 | 0 | 0 | 1 (0.8%) | 0.1 |
| Total | 57 (43.2% ^A) | 39 (29.5%) | 36 (27.3%) | 132 | 16.2 |

A Percentage of adverse reactions of total adverse transfusion reactions was noted

B Percentage incidence of adverse transfusion reaction after transfusion of the blood component.

ATRs, acute transfusion reactions; FNHTR, febrile non-haemolytic transfusion reaction; TACO, transfusion-associated circulatory overload; PRBC, packed red blood cells; FFP, fresh frozen plasma.

The clinical presentations reported in these events covered a wide range of symptoms; the 12 symptoms reported are illustrated in Figure 1. Urticaria was the most frequent symptom, comprising 21% of the reported symptoms. Rash, fever, chills or flushing were also frequent, with percentages ranging between 12% and 14% of the total reported symptoms. Swelling of the face and pain in the chest or back were the least frequent symptoms experienced by only six and seven patients, respectively. All ATRs were reported following the standard hospital procedure and verified by blood bank haematologists.

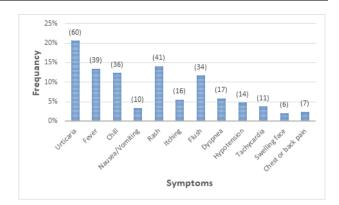


Figure 1. Distribution of ATR symptoms.

4. Discussion

This study provides a retrospective analysis of the ATR incidence resulting from the transfusion of 81,498 blood components over three years. This study's incidence rate of ATRs is 0.16%, comparable to another study from SA, which reported a rate of 0.2% (Hindawi *et al.*, 2016). These percentages are similar to those reported from other countries and range from 0.14% to 1.2% (Borhany *et al.*, 2019; Cho, Choi, Kim, Alghamdi, and Kim, 2016; Saha, Krishna, Prasath, and Sachan, 2020).

Allergic reactions and FNHTR are the most common adverse reactions seen with transfusion (Borhany et al., 2019; Kumar, Thapliyal, Coshic, and Chatterjee, 2013; Saha et al., 2020). Similarly, this study found that the most frequent reactions of 132 reported ATRs were allergic reactions (63%), followed by FNHTR (32%). Urticaria and skin rash were the most common symptoms, correlating with the high rate of allergic reactions (Cho et al., 2016; Pahuja, Puri, Mahajan, Gupta, and Jain, 2017). However, some studies reported a higher percentage of FNHTR than allergic reactions (Grandi, Grell, Areco, and Barbosa, 2018; Prakash et al., 2017). Several factors were associated with FNHTR, such as age, gender and the number and type of transfused components (Menis et al., 2015). The rate of FNHTR was lower than that detected in other studies (Kumar et al., 2013; Pahuja et al., 2017; Prakash et al., 2017), which could be explained by the use of leucodepleted blood (Bianchi et al., 2016). FNHTR can result from patients' leucocyte antibodies reacting with donors' leucocyte antigens, leading to the release of endogenous cytokines or leucocyte cytokines accumulated in the blood products. Consistent with our results, the frequency of FNHTR was higher with red cell transfusions than with platelets (Menis et al., 2015). Moreover, compared with FNHTR, allergic reactions are associated more with platelets and plasma transfusion than red cells (Saha et al., 2020). The severity of these adverse reactions ranged from mild non-systemic to severe and life-threatening systemic reactions. The frequency of severe anaphylactic reactions was low, representing 2% of the total allergic reactions (Grandi et al., 2018). In this study, of the total adverse events, three events (2.3%) presented clinically with hypotension, bradycardia, urticaria and dyspnoea. Two events were ATRs from an FFP transfusion and a PRBC transfusion.

Syndromes of acute respiratory distress, TACO and TRALI, occur during or within six to 12 hours of transfusion (International Society of Blood Transfusion Working Party on Haemovigilance in collaboration with The International Haemovigilance Network and AABB, 2018; Vlaar *et al.*, 2019). TACO was described as one of the leading causes of transfusion-related fatalities (44%) (FDA, 2019). Only one TACO reaction after a PRBC transfusion was observed in this study period. The presenting symptoms were chills, dyspnoea and chest pain. These findings are in contrast to other studies, which

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reported a higher percentage, such as the study by Saha *et al.* (2020), where six TRALI events were detected among 140 ATR events (4.3%). However, no TACO events were seen in other studies (Borhany *et al.*, 2019; Prakash *et al.*, 2017).

Like TACO, TRALI is one of the leading causes of transfusion-related mortality (FDA, 2019). Although TRALI can result from the red blood cell component, most severe cases are related to plasma-rich components (Peters, Stein, and Velar, 2015). In the majority of cases, donors' antibodies were detected, reacting against recipients' human leucocyte antigens (HLA) class I/II and/or human neutrophil antigens (HNA) (Peters et al., 2015). HNA and HLA may develop when the immune system is exposed to foreign HNA or HLA antigens, such as during pregnancy or transfusion. The incidence of TRALI has reduced significantly following the use of plasma-rich components from men and women who have not been pregnant or have tested negative for HLA antibodies (Otrock, Liu, and Grossman, 2017). In SA, the vast majority of donors are men, with women representing only 2% of the total donors (Alsughayyir et al., 2022). These mitigation strategies have played an essential role in reducing the incidence rate of TRALI. No TRALI event was detected in our study, which is consistent with the study conducted in Jeddah, SA, by Hindawi et al. (2016). Moreover, the use of leucodepleted blood components can play a role in reducing the incidence of TRALI (Simancas-Racines et al., 2019). Nevertheless, this adverse effect can occur even when leucodepleted products are used (Maulydia, Airlangga, Imam, Siregar, and Hendriana, 2022).

The fatal risk of blood transfusion from ABO incompatibility transfusion events can cause severe AHTR and has significantly reduced in the last few decades (Storch, Rogerson, and Eder, 2020). In our study, no AHTR was reported in the three-year study period. This may be due to the hospital protocol, which includes verifying patients' ABO type using a second or historical sample. In addition, no bacterial sepsis event was reported, which may indicate the implementation of quality measures at different steps of the blood transfusion chain.

Moreover, only one event of isolated hypotension reaction associated with PRBC transfusion was reported in the study period, in contrast to other studies, which detected a higher incidence rate (Hendrickson *et al.*, 2016; Saha *et al.*, 2020).

As this study is retrospective, adverse events may have been underreported. Compared with international studies, the low incidence of total ATRs and some specific adverse events, such as TACO and isolated hypotension, may indicate the under-reporting of transfusion reaction events. Furthermore, as there are few published national studies, a statistical comparison of the results of this study with other Saudi studies was not possible. However, our data can help evaluate the safety of transfused blood in the country and identify areas for improvement.

In conclusion, our results showed that the most frequent ATRs are allergic reactions and FNHTR. Adequate reporting of ATR events should be emphasised, as this would help improve the haemovigilance system and, consequently, blood safety. This study adds to the published national data to allow benchmarking. Moreover, the upcoming Saudi National Haemovigilance Project could utilise the published data in developing national and local benchmarks for ATRs.

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