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The Impact of Hemovigilance Studies on Transfusion Practices: Single Centre Experience

Hemovijilans Çalışmalarının Transfüzyon Uygulamalarına Etkisi: Tek Merkez Deneyimi

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The Impact of Hemovigilance Studies on Transfusion Practices: Single Centre Experience

ABSTRACT

Objective: Blood product transfusion is one of the most commonly used medical interventions worldwide. However, transfusion-related adverse events (TRAEs) can cause morbidity and rarely even mortality. For this reason, hemovigilance studies have recently gained importance in terms of safe and effective implementation of transfusion.

Material and Method: Transfusion practices issued in the period of 2016-2023 were analyzed retrospectively. All TRAE including adverse reactions (AR) and adverse events (AE) were recorded. The impact of hemovigilance practices on the incidence of TRAE was analyzed by comparing the numbers and types of events between years.

Results: In the 8-year period between 2016 and 2023, a total of 135,506 blood products belonging to 45,571 patients were used. 172 adverse reactions (AR) were reported in 170 patients. The overall AR incidence was found to be 126.8 (/100000). The highest yearly AR rate was reported in 2018 with 168.04 (/100000). Since hemovigilance measures were tightened, a statistically significant decrease was recorded in ARs from the beginning of 2020 to date ($p<0.001$).

Conclusion: The result of the current study demonstrated that a reduction in ARs could be achieved with hemovigilance measures. Although some common TRAEs like allergy seem unlikely to prevent due to the underlying pathophysiological mechanisms, we hope that our study showing that some reactions can be reduced by hemovigilance will encourage clinicians and hemovigilance units. Even though hemovigilance studies are being conducted to improve transfusion safety, the most critical concern is reducing exposure to blood components.

Keywords: Hemovigilance, reaction, transfusion.

ÖZET

Amaç: Kan ürünü transfüzyonu dünya çapında en yaygın kullanılan tıbbi müdahalelerden biridir. Ancak transfüzyonla ilişkili advers olaylar (TRAE'ler), hastalarda morbiditeye ve hatta nadiren mortaliteye neden olabilir. Bu nedenle son yıllarda transfüzyonun güvenli ve etkin uygulanması açısından hemovijilans çalışmaları önem kazanmıştır.

Gereç ve Yöntem: 2016-2023 döneminde yayımlanan transfüzyon uygulamaları geriye dönük olarak incelendi. Olumsuz reaksiyonlar (AR) ve olumsuz olaylar (AE) dahil olmak üzere tüm TRAE kaydedildi. Hemovijilans uygulamalarının TRAE insidansına etkisi, yıllar arasında olay sayısı ve türü karşılaştırılarak analiz edildi.

Bulgular: 2016-2023 yılları arasında toplam 8 yıl boyunca toplam 45571 hasta için 135506 kan ürünü kullanıldı. 170 hastada 172 advers reaksiyon (AR) bildirildi. Genel AR insidansı 126,8 (/100000) olarak bulundu. Yıllık en yüksek AR oranı 168,04 (/100000) ile 2018 yılında bildirildi. Hemovijilans tedbirleri sıkılaştırıldığı için AR'lerde 2020 yılı başından bugüne istatistiksel olarak anlamlı bir düşüş kaydedildi *($p<0.001$)*.

Sonuç: Bu çalışmanın sonucu, hemovijilans önlemleriyle AR'lerde azalmanın sağlanabileceğini gösterdi. Alerji gibi yaygın görülen bazı TRAE'lerin altta yatan patofizyolojik mekanizmalar nedeniyle önlenmesi pek mümkün görünmese de bazı reaksiyonların hemovijilans ile azaltılabileceğini gösteren çalışmamızın klinisyenleri ve hemovijilans birimlerini teşvik edeceğini umuyoruz. Hemovijilans çalışmalarıyla daha güvenli transfüzyon yapılmaya çalışılsa da en önemli konu kan bileşenlerine maruziyetin en aza indirilmesidir.

Anahtar Sözcükler: Hemovijilans, reaksiyon, transfüzyon.

Introduction

Blood product transfusion is one of the most commonly used medical interventions worldwide. However, transfusion-related adverse events (TRAE) can cause morbidity and rarely even mortality. For this reason, hemovigilance studies have recently gained importance in terms of safe and effective implementation of transfusion (1). Hemovigilance strategies and processes begin with donor selection and continue through several phases such as blood component processing, providing the product to the patient, monitoring during and after transfusion at the bedside, and attempting to obtain information regarding adverse events. Based on those data, it must be used for preventing recurrence (1,2).

Due to its importance, the International Haemovigilance Network Database was established, with the participation of 25 countries, to ensure universal information transfer, and the results were published. They determined the rate of adverse reactions to transfusion of blood products was 660 per 100,000 individuals; nearly 3% of these were categorized as severe (1).

Blood transfusion has become a generally safe therapy as blood banking and transfusion medicine techniques have improved over the previous several decades. However, adverse events associated with blood transfusions might occur, thus their avoidance is a top priority in transfusion medicine. It is not clear whether hemovigilance studies prevent undesirable events. Some studies have shown it to be useful in preventing some transfusion reactions (3). However, it is often thought to be effective in reducing errors made during the transfusion process. In our study, we investigated whether hemovigilance studies in our center had an effect on adverse TRAE.

Material and Method

Transfusion practices in our tertiary referral hospital from 2016 to 2023 were analyzed retrospectively. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. This study was approved by the Hitit University Ethics Committee (Date: 03/04/2024 number: 2024-08). The number of blood products used, blood type, and how many patients were transfused were analyzed and recorded according to the years. Transfusion committee records, decisions regarding hemovigilance and subsequent practices were recorded. TRAE was classified and defined as adverse reactions (AR) and adverse events (AE) according to International Society for Blood Transfusion: Proposed standard definitions for surveillance of non-infectious adverse transfusion reactions (4). An AE is an undesirable and unintended occurrence before, during, or after the transfusion of blood or a blood component, which may be related to the administration of the blood or component. It does not necessarily result in a reaction in the recipient (4). An AR is an undesirable response or effect in a patient temporally associated with the administration of blood or a blood component (4). All hemovigilance notification sheets that were properly filled in with reports of ARs confirmed by a hematologist from the transfusion center were included. In our hospital, notification forms filled out by clinicians regarding transfusion reactions and adverse events that occur during or after transfusion are forwarded to the blood center hemovigilance unit. Regulatory and preventive activities are planned after the necessary information about these events and event-specific management practices are made. These forms are then archived. After an assessment is made by the transfusion medicine service, the final diagnosis is entered into the database and communicated to the primary clinical team. TRAEs are classified by physician on the transfusion medicine service. These records were analyzed, and the type and number of transfusion reactions and adverse events were recorded by year. The incidence and severity of transfusion reactions and adverse events were compared between years to determine whether hemovigilance procedures had an impact on them.

Statistical Analysis

Data obtained in the study were analyzed statistically using SPSS vn. 27 software (IBM SPSS Statistics 27). Frequency tables and descriptive statistics were used to interpret the findings. Demographic data were summarized with descriptive statistics. Numerical variables were presented as median (minimum-maximum) values, and categorical variables as

number (n) and percentage (%). Pearson-χ2 cross-tabulations were used to examine the relationships between two qualitative variables. A value of *<0.05* was accepted as statistically significant.

Results

In our center, which serves as a transfusion center in a tertiary care hospital, 135506 blood products were used for a total of 45571 patients for a total of 8 years between 2016 and 2023. The distribution of the products used by years is given in Table I.

Table I The distribution of the products used by years

Blood product type	Number (n)	Patients (n)
Erhtyrocyte suspension	86311	30076
Fresh Frozen Plasma	38924	11830
Pooled platelet	8174	2857
Apheresis platelet	620	408
Cryoprecipitate	1072	86
Whole blood	405	314
Total	135506	45571

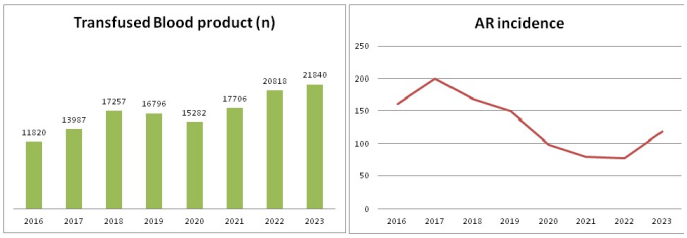

Figure I Distribution of transfused blood product (total number/year) and Adverse Reaction (AR) incidence (n/100000) among years

Hemovigilance studies performed during the 8-year follow-up period are given in Table II. During the follow-up period, 172 adverse reactions (AR) were reported in 170 patients. The total AR incidence was found to be 126.88/100000. The highest yearly AR rate was reported in 2018 with 168.04 (/100000). AR rates by years are given in Table III. It was observed that the most developed AR was allergic reactions (n=102, 59.3%). The number of AR types by year is given in Table IV. As of 2020, it was decided to record not only ARs but also transfer, service and clinician-related undesirable events that cause product destruction and make the necessary notifications. A total of 60 AEs were recorded in 3 years. The distribution of AEs was given in Table V. Since 2020, the number of nurses has been increased, hemovigilance measures have been tightened, and serious training has started to be provided. When AR was compared by years, it was found that the total incidence of AR decreased significantly starting from 2020 (*p<0.001*). ARs without allergic reactions were significantly decreased by the year of 2020 (*p<0.001* for Febrile nonhemolytic transfusion reaction (FNHTR), *p=0.011* for other types). The comparison of total and subtypes of AR by year was given in Table VI and graphical view was shown in Figure I. Since AE was registered after 2020, no comparison was made in this respect.

Table II Details of hemovigilance studies by year

Years	Newly added Hemovigilance Practices
2016	A decision was taken at the transfusion committee meeting and in-service training was provided to doctors and service personnel regarding blood and product applications.
2017	At the transfusion committee meeting, the administration was informed that the transfusion center needed to assign an additional hemovigilance nurse in accordance with the relevant legislation, as the annual requests exceeded 12000.
2018	Committee members were informed about 3-month transfusion reactions. It was decided to emphasize the sensitivity of the issue regarding control nursing to the clinical unit managers.
2019	It has been decided by the hospital management to provide periodic on-site training to all units twice a year. These trainings continue to be given by hemovigilance nurses to this day.
2020	The second hemovigilance nurse started working. Documents such as transfusion forms have begun to be checked more thoroughly. Field checks have also started to be carried out regularly. During the field controls, it was emphasized that a new vascular access should be opened for transfusion, and if there is an old vascular access, it should be used after washing with saline. Hemovigilance Guide has been updated. Emphasis has been placed on sending physician-nurse signatures and stamps to hemovigilance on transfusion follow-up and monitoring forms. In our center, the process of collecting whole blood from donors has been stopped, except in cases of necessity. Products other than whole blood coming from the regional center have begun to be used. From now on, it was decided to record not only undesirable reactions but also transfer, service and clinician-related undesirable events that lead to product destruction and make the necessary notifications.
2021	Information was provided by stating that the most important errors in protecting patient safety are preventable errors caused by improper authentication and incorrect barcoding.
2022	Training was given on confirming the patient's blood group by taking two blood group samples at different time intervals. Emphasis was placed on increasing the level of awareness for safe blood transfusion.
2023	General information is provided to new healthcare personnel in our hospital by providing orientation training on blood and blood products. Training was given to clinical support teams about the importance of safe blood transportation.

Table III Number of transfused blood products and incidence of adverse reactions

Years	Adverse reaction (AR, n)	Transfused Blood product (n)	Transfused Patients (n)	AR incidence (n /100000)
2016	19	11820	4110	160.74
2017	28	13987	4756	200.18
2018	29	17257	5639	168.04
2019	25	16796	5903	148.84
2020	15	15282	5782	98.15
2021	14	17706	6789	78.82
2022	16	20818	6232	76.85
2023	26	21840	6360	119.04
Total	172	135506	45571	126.88

Discussion

Blood transfusion is one of the most frequently used methods in daily practice in hospitals. Approximately 17,000 blood products are used annually in our center, confirming that transfusion is one of the frequently used modalities. It was determined that a total of 172 ARs developed in 8 years and a total of 60 AEs developed in the last 3 years. When compared in general, it was seen at a similar rate to the AR incidence reported in the world (1).

Table IV Types of Adverse Reactions

Years	Allergy	FNHTR	Angioedema	TACO	Hypotension	TRALI	Anaphylaxis
2016	6	10	2	1	0	0	0
2017	17	10	1	0	0	0	0
2018	15	8	0	1	4	1	0
2019	14	8	0	0	2	1	0
2020	11	3	0	0	1	0	0
2021	10	4	0	2	1	0	0
2022	11	2	0	0	0	0	0
2023	18	6	0	1	0	0	1
Total	102	51	3	5	8	2	1

FNHTR: Febrile nonhemolytic transfusion reaction, TACO: transfusion associated circulatory overload
TRALI: transfusion related acute lung injury

While ARs arise from immune or nonimmune causes blood product or recipient, AE events are often undesired events caused by either human or mechanical defects in the processes involved. In our center, AE has started to be recorded in the last 3 years and approximately 20 events are recorded per year. Among these, a situation that may also cause hemolytic AR and result in mortality is transfusion of different groups of blood products to a patient. An undesirable event may suddenly cause a serious undesirable reaction. It has been observed that 1 blood group incompatible erythrocyte suspension (ES) transfusion was performed in the last 3 years, and it did not cause a serious reaction. It was thought that the reason for this was that the patient had a stem cell transplant before. Researchers have documented a reduction in ABO incompatible red cell transfusions over the last 20 years, although bothdocument these 'never events' continue to occur indicating that further action is necessary. The most common AE event is when the clinician gives up transfusion for any reason after the blood product is prepared for the patient, and therefore the product is destroyed as wastage. Other adverse events that have reduced over time from interventions and policy setting prompted by analysis of hemovigilance data include transfusion associated acute lung injury (TRALI), bacterial infections, transfusion-associated graft-versus-host disease (TAGvHD), and post-transfusion purpura (PTP) (5). Similar to recent reports, our study showed that without allergic reactions, especially FNHTR was significantly decreased by hemovigilance studies. Since allergic reactions generally occur due to immune causes, this was an expected result for us.

Table V Distribution and characteristics of Adverse Events

Years	Cross match incompatable transfusion	Destruction due to transfer problems	Second product destruction due to previous reaction	Destruction due to the clinician giving up the transfusion decision	Patient refused
2021	1	1	2	1	0
2022	0	0	6	31	0
2023	0	1	2	14	1
Total	1	2	10	46	1

There has been a significant decrease in AR over the years, especially as of 2020. This is an important

result as it shows how important a role haemovigilance studies play. Hemovigilance practices are very important as a way to prevent all these. However, it is not clear to what extent the effects of hemovigilant applications on AR and AE are present. In general, issues involving transfusion safety have evolved significantly in recent years to now fully encompass the effectiveness of transfusion. New methods to evaluate transfusion safety and effectiveness under the name of hemovigilance studies need to be developed and implemented (6). At this stage, the most important tasks are to detect inappropriate practices, evaluate and analyze undesirable events, and, if possible, prevent their recurrence or take measures to prevent it. Several factors that have been shown to be associated with AR have been reported in some studies. It is conceivable that ARs can be reduced by paying attention to these risk factors. For example, it has been shown that leukopenia may be a risk for mild AR, and high body temperature may be a risk for moderate AR (7). In another study, it was demonstrated that beneficial strategies to avoid TRAE include judicious use of blood components, identification of high-risk patients, adherence to recommended clinical processes and awareness of TRAE pathophysiology (3). Since AE events started to be recorded in our center as of 2020, the effect of hemovigilance studies on them could not be evaluated by year.

Table VI Comparison of Adverse Reactions before and after the year 2020

	Periods (between years)		*p*
	2016-2019 (n=101)	2020-2023 (n=71)	
Incidence of total adverse reactions (n/100000)	168.72	93.85	***<0.001***
Incidence of allergic reactions (n/100000)	86.86	66.09	*0.089*
Incidence of FNHTR (n/100000)	60.14	19.82	***<0.001***
Incidence of other reactions (n/100000)	21.71	7.93	***0.011***

FNHTR: Febrile nonhemolytic transfusion reaction

As can be seen in our study, one of the most common ARs is allergic reactions (59.3%). The total number of allergic reactions was decreased by the year of 2020, but it is not statistically significant. Based on this result, we can consider allergic reactions developed because of immunological reasons so that it is unlikely to reduce or prevent allergy with hemovigilance studies. One of the most common undesirable events we encounter is that if an allergic reaction occurs to any blood product, the clinician gives up on subsequent transfusion and therefore destroys the product. Although it is actually an inappropriate approach in general, there have been recent results showing that this may be correct. The prophylactic approach in patients at risk of allergic reactions is a controversial issue. Pre-transfusion administration of antipyretic or antihistaminemedication could be considered in patients with a medical history of alergic AR. Randomised controlled trials did not find any benefit of premedication on allergic reaction prevention (3). In a single-center study published in 2020, acute reactions were significantly associated with transfusion history and receiving three or more units of blood (8). Similar to these results, meta-analysis still demonstrated that there is no recommendation that blood products should not be used again in patients who have previously developed allergic reactions. In fact, there is not enough evidence to use prophylactic treatment such as antihistamines and steroids in subsequent transfusions in a patient who has previously developed an allergic reaction (9). With all these data, clinicians do not need to give up transfusion decisions when necessary due to fear of previous reactions. What needs to be done is monitoring closely the patients with a history of allergic transfusion reactions when receiving subsequent transfusions.

However, it is a mystery whether the data in our study and in most hemovigilance studies around the world fully reflect what is actually happening. These data may not fully reflect reality; It depends on clinicians paying attention to these events, detecting them, and then keeping a report and informing the blood center and hemovigilance. Hemovigilance systems with voluntary declaration may underestimate TRAE incidence. These data may be less reflective than they should be, due to reasons such as clinicians not being aware of an event even if it occurs or not attributing this event to transfusion. For this reason, in order to reach real data, hemovigilance training should be provided to

clinicians to carefully monitor adverse events and report them to the blood center.

Conclusion

The result of the current study showed that a reduction in ARs could be achieved with hemovigilance measures. Although some common TRAEs like allergy seem unlikely to prevent due to the underlying pathophysiological mechanisms, we hope that our study showing that some reactions can be reduced by hemovigilance will encourage clinicians and hemovigilance units. Based on all these data, all blood banks and transfusion centers need to handle hemovigilance studies more seriously and strictly. Even though safer transfusion is tried to be done with hemovigilance studies, the most important issue is minimizing exposure to blood components.

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