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Original Article

Process Validation and Reporting in Hospital Hemovigilance Services

Hastane Hemovijilans Hizmetlerinde Süreç Validasyonu ve Raporlaması

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ABSTRACT

Objective: Hemovigilance covers the entire transfusion chain, from the collection of the blood product and its components to the monitoring of adverse reactions. The aim of our study was to perform a process validation for the hemovigilance system of our hospital and to evaluate patients who developed blood transfusion reactions.

Method: University of Health Sciences Turkey, Dr. Behçet Uz Child Health and Diseases Training and Research Hospital; among the patients who received blood transfusion between January 2019 and December 2019, 238 patients were identified by systematic sampling method. Blood components used in patients undergoing treatment in different clinics; Examining the physician and nurse observation notes and the data in the hospital information system, whether the transfusion process is appropriate; It was evaluated by hospital hemovigilance coordinator, hemovigilance nurse, pediatric hematologist and pediatric intensive care specialist.

Results: Of the 238 randomly selected patients, 122 (51.3%) were male and 116 (48.7%) were determined as female. The median age was 91 (14-180) months. In the evaluation of the transfusion process; Only 1 patient (0.4%) was observed to exceed the optimal transfusion time. No error was detected in other blood transfusion processes. It was observed that 8 (3.3%) of the patients who underwent transfusion had a transfusion reaction.

Conclusion: In our study, it was found that there is no significant problem in recognizing, applying and reporting transfusion reactions before and during transfusion applications. In our country, there is no previous study on hemovigilance process validation. Prospective process validations are required.

Keywords: Hemovigilance, blood transfusion, process validation, transfusion reactions

ÖZ

Amaç: Hemovijilans, kan ürünü ve bileşenlerinin toplanmasından istenmeyen reaksiyonların izlenmesine kadar tüm transfüzyon zincirini kapsar. Çalışmamızın amacı, hastanemizin hemovijilans sistemine yönelik bir süreç validasyonu yapmak ve kan transfüzyon reaksiyonu gelişen hastaları değerlendirmekti.

Yöntem: Sağlık Bilimleri Üniversitesi, Dr. Behçet Uz Çocuk Sağlığı ve Hastalıkları Eğitim ve Araştırma Hastanesi'nde; Ocak 2019-Aralık 2019 tarihleri arasında kan transfüzyonu yapılmış hastalardan sistematik örnekleme yöntemi ile 238 hasta belirlendi. Farklı kliniklerde tedavisi süren hastalara kullanılan kan bileşenlerini; hekim ve hemşire gözlem notları ve hastane bilgi yönetim sistemindeki veriler incelenerek transfüzyon sürecinin uygun olup olmadığını; hastane hemovijilans koordinatörü, hemovijilans hemşiresi, çocuk hematoloji uzmanı ve çocuk yoğun bakım hekimi tarafından değerlendirildi.

Bulgular: Randomize seçilen 238 hastanın 122'si (%51,3) erkek, 116'sı (%48,7) kız olarak belirlendi. Hastaların yaş ortanca değeri 91 (14-180) ay idi. Transfüzyon sürecinin değerlendirilmesinde; sadece 1 hastada (%0,4) optimal transfüzyon süresinin aştığı görüldü. Diğer yapılan kan transfüzyon süreçlerinde hata saptanmamıştır. Transfüzyon uygulanan hastaların 8'inde (%3,3) bir transfüzyon reaksiyonu kaydı bulunduğu gözlendi.

Sonuç: Çalışmamızda, kan transfüzyonu öncesinde ve transfüzyon uygulamalarında, transfüzyon reaksiyonlarının tanınması, uygulanması ve bildiriminde önemli bir sorun olmadığı saptanmıştır. Ülkemizde daha önce hemovijilans süreç validasyonuna yönelik bir çalışma bulunmamaktadır. Prospektif olarak yapılacak süreç validasyonlarına ihtiyaç vardır.

Anahtar kelimeler: Hemovijilans, kan transfüzyonu, süreç validasyon, transfüzyon reaksiyonu

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INTRODUCTION

Hemovigilance which is defined as a set of surveillance procedures from blood collection to the follow-up of the recipients covers the entire transfusion chain and carries out the collection of data about unexpected or undesirable situations to prevent their recurrences. The term hemovigilance is derived from the Greek word "Haema" (blood) and the Latin word "Vigilance" (on alert). The ultimate goal of hemovigilance is to increase the safety of the blood donors and transfusion recipients by preventing the recurrence of adverse reactions and events [1]. Hemovigilance has varying methodologies due to differences in health infrastructure and regulatory requirements in every country [2-4]. The first attempt for the implementation of this system was established in Japan in 1993 [5]. Following the establishment of a hemovigilance system France in 1994; today it is applied almost all over Europe and is increasingly spreading in countries outside of Europe [6].

When we look at the historical background regarding hemovigilance in our country; following the establishment of transfusion committees in hospitals and the determination of their working principles and duties in 2004, surveillance reports of blood donation and transfusion were made mandatory and standard forms regarding hemovigilance notifications were created between 2007and 2009. With the publication of the first national guide in 2016; a permanent hemovigilance system was implemented in European standards. The guide was last updated in 2020.

Although it is important to carry out with a workflow in accordance with the national guidelines and standards, checking and validating the system is necessary to ensure the transfusion safety.

From this point of view, a process validation study has been planned to go through our hemovigilance system in order to detect malfunctions in the system.

MATERIALS and METHODS

To perform a process validation study for the hemovigilance system in University of Health Sciences Turkey, Dr. Behçet Uz Pediatric Diseases and Surgery Training and Research Hospital in Turkey, 238 patients were selected randomly by a systematic sampling technique at a 95% confidence interval from the patients who received a total of 6986 blood component transfusions between January 2019 and December 2019. For these patients an evaluation form was prepared to determine the patient demographic variables (age, sex, etc), blood transfusion variables (blood component, transfusion time, component volume, etc), follow-up variables (adverse events and effects).

The criteria evaluated for process validation were determined according to the 2020 hemovigilance guide. 180-240 minutes for ERT and 30-60 minutes for fresh frozen plasma and apheresis platelet concentrate were sought as the appropriate transfusion time [15]. Transfusion reactions are divided into two groups as early and late type. Those that developed in the first 24 hours were defined as acute type, and those that occurred from 24 hours to 28 days were defined as late type. They were also grouped among themselves as hemolytic and non-hemolytic. All transfusion reactions (febrile non-hemolytic transfusion reaction (FNHTR), mild allergic transfusion reaction) occurring in patients were recorded.

By examining the pre and post-transfusion patient records remarkable data on vital signs, laboratory findings, discordance between physician orders and notes and nursing observation notes were also registered at enrollment.

Nonconformities in the process were evaluated by the team consists of a hemovigilance coordinator, a hemovigilance nurse, a pediatric hematologist and a pediatric intensivist.

A written informed consent was taken from all parents of the participants.

The ethics committee approval for the study was obtained from the local ethics committee of the University of Health Sciences Turkey, Dr. Behçet Uz Pediatric Diseases and Surgery Training and Research Hospital (approval number: 83, date: 04.06.2020).

Statistical Anaysis

Statistical analysis was done using SPSS 22.0 software. All numerical and categorical data were evaluated using descriptive statistical methods. Mann-Whitney U test was used for numerical data that did not show normal distribution, and the chi-square test was used for the analysis of categorical data, and results with p -values below 0.05 were considered statistically significant.

RESULTS

122 (51.3%) of the blood transfusion patients were male and 116 (48.7%) were female. The median age of the patients was 91 (14-180) months. Although the median

age of the males was higher than females, no statistically significant difference was found between the two groups in terms of median age (p=0.433). The most frequent blood component used in transfusion was RBC with 66% (n=157) and it was followed by fresh frozen plasma with 15.5% (n=35). One hundred thirty-eighth (58%) of patients were transfused in pediatric hematology clinic, whereas 80 (33.6%) were in the pediatric intensive care unit, 17 (17.1%) were in a general pediatric clinic and 3 (1.3%) were in pediatric infection clinic. Looking from the viewpoint of transfusion indications, it was observed that thalassemia (34.5%) and malignancy (20.6%) were prominent in the cases (Table 1). Evaluating the procedures involved in blood transfusion the only finding for evidence of unconformity was prolonged time interval for blood transfusion in a patient (0.4%). The reason for the prolongation up to 5 hours was determined as the stand still of transfusion due to fever (38.5 °C) in the patient which was not considered as an adverse reaction associated with transfusion and attributed to the underlying disease.

Additionally, examination of physician orders and notes and nursing observation notes revealed no essential clinical finding to suggest pretransfusion infection while the laboratory measurements of white blood cell count, C-reactive protein and procalcitonin were normal and no growth detected on blood cultures of the patient. With these findings, the case commented as a FNHTR.

In total, transfusion-associated adverse reactions were detected in 8 cases (3.3%) in which 6 of them were mild allergic reactions and 2 were FNHTRs (Table 2).

Seven of these cases (2.9%) were patients followed in a pediatric hematology clinic and one case (0.4%) was a patient treated in the pediatric intensive care unit. It was also observed that all adverse reactions had been followed in concordance with the national hemovigilance guidelines, no conformity or error on pre- and post-transfusion processes were detected.

DISCUSSION

The main purpose of the hemovigilance system in inpatient treatment facilities is to detect transfusion-related adverse effects and events, including near-miss events, and to take measures to prevent their

Table 1. Blood components used in patients and transfusion indications

Indication	Erythrocyte suspension	Fresh frozen plasma	Apheresis platelet concentrate	Cryoprecipitate	Total
Thalassemia	81 (98.8%)	0 (0.0%)	1 (1.2%)	0 (0.0%)	82 (34.5%)
Malignancy	25 (49.0%)	5 (9.8%)	19 (38.7%)	2 (4.0%)	51 (20.6%)
Cardiac disease	16 (44.4%)	16 (44.4%)	4 (11.1%)	0 (0.0%)	36 (16.0%)
Sepsis	6 (46.2%)	4 (30.8%)	2 (15.3%)	1 (7.6%)	13 (55%)
Acute abdomen	2 (20.0%)	5 (50.0%)	3 (27.3%)	1 (9.0%)	11 (4.6%)
Metabolic disease	7 (63.6%)	1 (9.1%)	3 (27.3%)	0 (0.0%)	11 (4.6%)
Hemophilia A	0 (0.0%)	0 (0.0%)	1 (11.1%)	8 (88.9%)	9 (3.8%)
Renal disease	7 (87.5%)	0 (0.0%)	0 (0.0%)	1 (12.5%)	8 (3.4%)
ROP operation	5 (71.4%)	2 (28.6%)	0 (0.0%)	0 (0.0%)	7 (2.9%)
Burn	3 (60.0%)	2 (40.0%)	0 (0.0%)	0 (0.0%)	5 (2.1%)
ABO blood group incompatibility	3 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (1.3%)
G6PD enzyme deficiency	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.4%)
Hereditary spherocytosis	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.4%)

G6PD: Glucose 6 phosphate dehydrogenase, ROP: Retinopathy of premature

Table 2. Transfusion reactions and blood products administered to patients

Blood products	Febrile non-hemolytic transfusion reaction	Mild allergic transfusion reaction (ATR)	No transfusion reaction
Erythrocyte suspension	6 (2.5%)	0 (0.0%)	151 (63.4%)
Fresh frozen plasma	0 (0.0%)	0 (0.0%)	35 (14.7%)
Apheresis platelet concentrate	0 (0.0%)	2 (0.8%)	31 (13.0%)
Cryoprecipitate	0 (0.0%)	0 (0.0%)	13 (5.4%)

recurrence by performing root-cause analyzes. In this respect, the haemovigilance system, as an important part of the hospital quality management system, is the most important constituent for a safe transfusion by promoting traceability, error event reporting and audits to identify errors, adverse events and reactions associated with blood transfusion. In this point of view, a process validation study for the hemovigilance system of children's hospital was planned to with a retrospective, cross-sectional research method. It was also aimed to determine the demographic and clinical characteristics of patients who underwent blood transfusion and patients with transfusion reactions. One hundred and twenty-two (51.3%) of 238 patients who were randomly selected and included in our study with a systematic sample were male and 116 (48.7%) were female, and the median age of the patients was determined as 91 (14-180) months. Similarly, in a study conducted in Canada, it was found more frequently in males (52%) [2].

In pediatric studies, the median age characteristics vary according to hospital profiles, ranging from 1 month to 8 years [7,8]. In large-scale multi-center cohort studies from different countries, it has been reported that the most commonly transfused blood component is erythrocyte concentrate [2,9,10]. In the United States of America (U.S.A.), National Healthcare Safety Network records showed that blood components used in between 2010 and 2013 were erythrocyte concentrates in 57.1 percent, apheresis thrombocyte concentrates in 18.3 percent, fresh frozen plasmas in 18.7 percent and cryoprecipitates in 5.9 percent [3]. Similarly, in our study, the most commonly used blood component (66%) was determined as erythrocyte concentrate. Given that the majority of patients included in our study had underlying hematological diseases and malignancies it was an expected result. Similiarly, in the 11-year cohort analysis conducted in Canada, 50.7% of the patients who received blood transfusion were determined as hematology patients [2]. Even though it is life-saving in patients, blood transfusions can cause adverse effects ranging from simple reactions to fatal complications [11-13]. In a multicenter study in the U.S.A. transfusion-associated adverse reactions were reported in 5136 (0.23%) of 2,144,723 blood transfusions that were performed in 77 centers. The most common reactions had been observed in the study were allergic reactions (46.8%) and FNHTRs (36.1%) and it was stated that platelet transfusions had associated with adverse reactions more frequently [7]. In another study from Iran, allergic transfusion reactions and FNHTRs were reported in 42.5% and 37.1% of patients, respectively [14].

In our study, transfusion reactions were observed in 8 (3.3%) of the patients whereas 6 were mild allergic reactions and 2 were FNHTRs the most frequent blood component used in patients with transfusion reactions was found to be apheresis thrombocyte concentrate.

Process validation, within the scope of transfusion-related health applications; includes well-defined practices for blood donation and blood component preparation stages [15]. Although the hemovigilance system is a quality assurance system on its own in terms of transfusion services with its monitoring and control steps, validation of this process is also necessary and essential for transfusion safety.

In our study that there is no significant problem observed in the recognition, application and reporting of transfusion reactions before and during transfusion practices in our hospital, the hemovigilance system operates as defined, and work flow charts are applied to monitor and prevent adverse effects and events that may occur.

However, since the study was conducted retrospectively; It should be foreseen that patient findings and nurse observation and physician observation files cannot be evaluated simultaneously, and some problems (absence of physician's stamp and signature, incomplete datasets, time mismatch in records, etc) may have been corrected after the checks of the hemovigilance nurse. Hemovigilance requires regular training and continuous monitoring as well as a good electronic recording system. Although validation studies are carried out for various methods and processes at different levels in blood transfusion services, there is almost no study about process validation for hemovigilance entirely in hospitals [16,17].

Study Limitations

The most important limitation of the study is its retrospective design. Since the data in our study were analyzed retrospectively, transfusion-related errors may have been corrected by the interventions of the hemovigilance team.

CONCLUSION

For the validation of the hemovigilance process, it is necessary to determine the deficiencies through annual analyzes. Our hospital was validated to be safe in terms of the hemovigilance system. However, since some of

the deficiencies of the transfusion process are corrected with the work of the hemovigilance team in the process, the problems seen in the first place may not be detected retrospectively. Evaluating the process prospectively may be an important step to strengthen transfusion safety.

Ethics

Ethics Committee Approval: The ethics committee approval for the study was obtained from the Local Ethics Committee of the University of Health Sciences Turkey, Dr. Behçet Uz Pediatric Diseases and Surgery Training and Research Hospital (approval number: 83, date: 04.06.2020).

Informed Consent: A written informed consent was taken from all parents of the participants.

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Author Contributions

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