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Associated Factors With Acute Transfusion Reaction From Hospital Online Reporting Events: A Retrospective Cohort Study

Chao-Yuan Yao, MD,*† Ju-Huei Chien, PhD,‡§ Hsun-Yang Chuang, MS,|| and Tsing-Fen Ho, PhD‡

Objectives: In our hospital's hemovigilance system, a Wi-Fi–based vital signs monitor that automatically transmits data to ensure patient safety has been implemented. We derived the potential clinical characteristics for subsequent association of acute transfusion reactions (ATRs) using the hospital information system database.

Methods: We retrospectively analyzed multiple factors to identify the possible associations between clinical factors and developing ATRs. The following data were collected: recipient's pretransfusion and posttransfusion vital signs, clinical and laboratory characteristics, and presence of ATRs.

Results: In all, 44,691 events were analyzed. Of these, ATR events occurred in 1586 (3.5%). Logistic regression analysis revealed that leukopenia ($<5 \times 10^3/\mu\text{L}$) before transfusion was shown a statistically associated with developing mild ATRs (odds ratio [OR] = 2.38, 95% confidence interval [CI] = 1.68–3.35, $P < 0.001$). The association between elevated body temperature (forehead temperature $> 37.5^\circ\text{C}$) and moderate ATRs was significant (OR = 1.55, 95% CI = 1.22–1.98, $P < 0.001$). In addition, the association between high diastolic pressure (>90 mm Hg) and severe ATRs was significant (OR = 1.78, 95% CI = 1.06–2.99, $P = 0.03$). Therefore, evaluated patient's status such as vital signs before transfusion is very important. In addition, every hospital should established a complete hemovigilance program focus on effectively reporting and real-time monitoring ATRs to improve transfusion patient safety.

Conclusions: Vital signs monitoring and leukocyte counts before transfusion were significantly associated with the subsequent risk of ATRs. When patients with elevated body temperature, leukopenia, and high diastolic pressure who are scheduled to receive transfusion, clinicians should be aware of increasing the risk of ATRs in these patients.

Key Words: hemovigilance, Wi-Fi, vital sign, acute transfusion reactions
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Blood transfusion can be lifesaving, but it can also be life-threatening because of adverse transfusion reactions.¹

From the *Department of Hematology and Oncology, Taichung Tzu-Chi Hospital, Buddhist Tzu-Chi Medical Foundation, Taichung; †School of Medicine, Tzu-Chi University, Hualien; ‡Department of Medical Laboratory Science and Biotechnology, Central Taiwan University of Science and Technology, Taichung; §Department of Laboratory Medicine, Taichung Tzu-Chi Hospital, Buddhist Tzu-Chi Medical Foundation, Taichung; and ||Department of Research, Taichung Tzu-Chi Hospital, Buddhist Tzu-Chi Medical Foundation, Taichung, Taiwan.

Correspondence: Tsing-Fen Ho, PhD, Department of Medical Laboratory Science and Biotechnology, Central Taiwan University of Science and Technology, 666 Buzih Road, Beitun District, Taichung 40601, Taiwan (e-mail: tfho@ctust.edu.tw).

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Hemovigilance is defined as a set of surveillance procedures that cover the whole transfusion chain—from the collection of blood and its components to follow-up of transfusion recipients.^{2,3} Hospital hemovigilance systems aim to increase patient safety and blood transfusion efficacy by collecting and assessing information on unexpected or undesirable effects of the therapeutic use of labile blood products; such systems also aim to prevent the occurrence and recurrence of these effects.⁴

Reporting the adverse events of transfusion is an essential component of a hemovigilance system.⁵ A standard operating procedure for documenting, reporting, evaluating, and following up all adverse reactions was established and integrated into our hospital's information system.⁶ Routine monitoring of patients' clinical status during transfusion may permit patients to receive early appropriate treatment. However, the formerly used paper-based reporting procedure is time-consuming and labor-intensive.⁷ By contrast, online reporting procedures are more effective and can reduce human error in the evaluation of blood transfusion reactions.^{5,8}

Patients' clinical status should be closely monitored during transfusion and recorded in a health care database. Vital signs are measurements of the body's most basic functions that help medical professionals evaluate patient health status.^{9,10} The guidelines of the British Committee for Standards in Hematology recommend that when any of the associated signs and symptoms of transfusion reactions occur, the initial treatment should be based on such signs and symptoms rather than on classification.⁴ Awareness of the clinical features of acute transfusion reactions (ATRs) and their timely assessment can considerably improve their management. Our hospital's information system comprises both institutional policies and a hemovigilance system for blood transfusion. Specifically, a Wi-Fi–based vital signs monitoring system automatically records and transmits blood pressure, pulse rate, and body temperature to hospital information system (HIS) database.

In this study, we retrospectively compared patients' vital signs and other laboratory data before and after blood transfusion and analyzed the data to identify potential clinical characteristics associated with the developing of ATRs.

METHODS

Study Population

This retrospective study collected data on transfusions conducted during 2011–2015 using the computerized HIS of Taichung Tzu-Chi Hospital (499 beds). A flowchart of the enrollment process of this study cohort is shown in Figure 1. This study was approved by the Research Ethics Committee of Taichung Tzu-Chi Hospital (REC 103-42).

Hospital Hemovigilance Online Reporting System

To improve the quality of clinical transfusion care, a patient-focused online reporting system was created and implemented in our HIS in 1997 for monitoring transfusion practices (Fig. 2A).

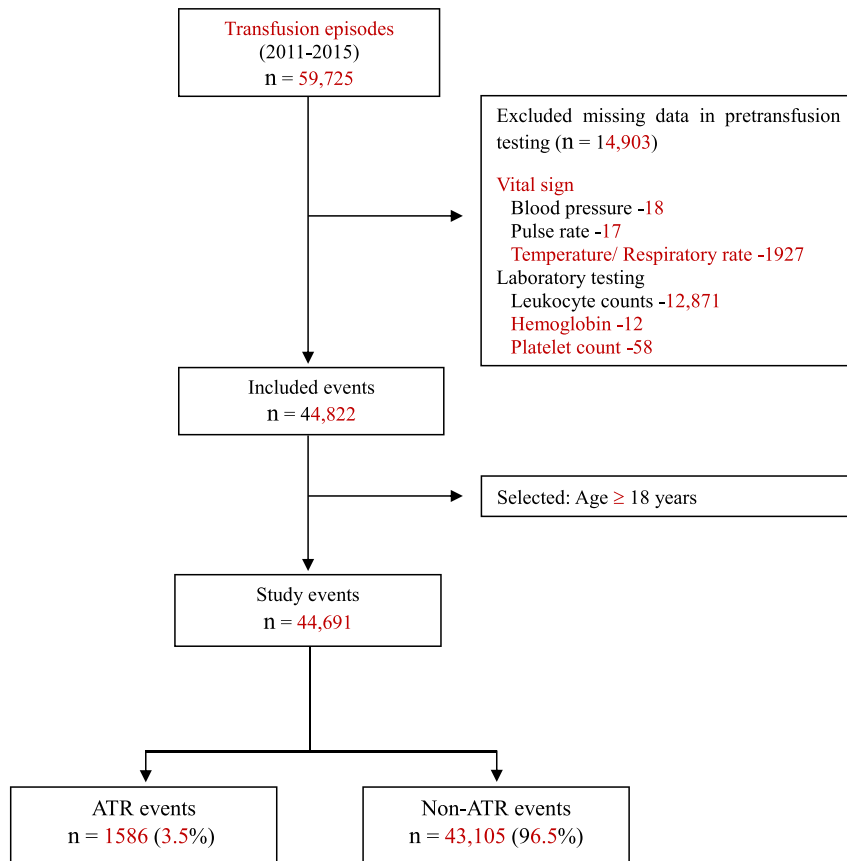


FIGURE 1. Flowchart of study events included in this retrospective study.

Since 2010, a wireless vital signs monitoring system (Dinamap ProCare 300 Vital Signs Monitor; GE Inc, Milwaukee, Wis) has been integrated into the transfusion management system. The English version of the transfusion reaction reporting web page is shown in Fig. 2B. The web page comprises the following four main components: (1) patient information, including medical record number, sex, age, blood type, doctor's name, diagnosis, and laboratory data; (2) cloud-based electronic vital signs data, including body temperature, pulse rate, respiratory rate (using the temperature-pulse-respiration reporting system), and blood pressure; (3) use of blood components: indication for transfusion, volume transfused, and start and end times of transfusion; and (4) adverse transfusion reactions: symptoms or signs that occurred during transfusion or within the subsequent 24 hours. All blood components for transfusion were prescribed by a medical practitioner. To use our reporting system, nurses simply click on the appropriate icon and enter the reporting procedure information throughout the transfusion process. Patients' vital signs are automatically recorded at three time points: before transfusion, 15 minutes after transfusion initiation, and after transfusion of each blood component unit. In addition, patients are asked whether they experience any symptoms during the blood transfusion. The vital signs and symptoms are monitored every 8 hours up to 24 hours after transfusion, and the reporting system automatically connects the nursing record system to the blood bank physician system. In our online reporting system, patients receiving transfusions without any signs and symptoms are identified as "no transfusion reaction." If one or more signs or symptoms occur, they are documented in the electronic medical records. If any ATRs occur, a notification is automatically sent to a doctor for confirmation. Hospital hemovigilance online reports are

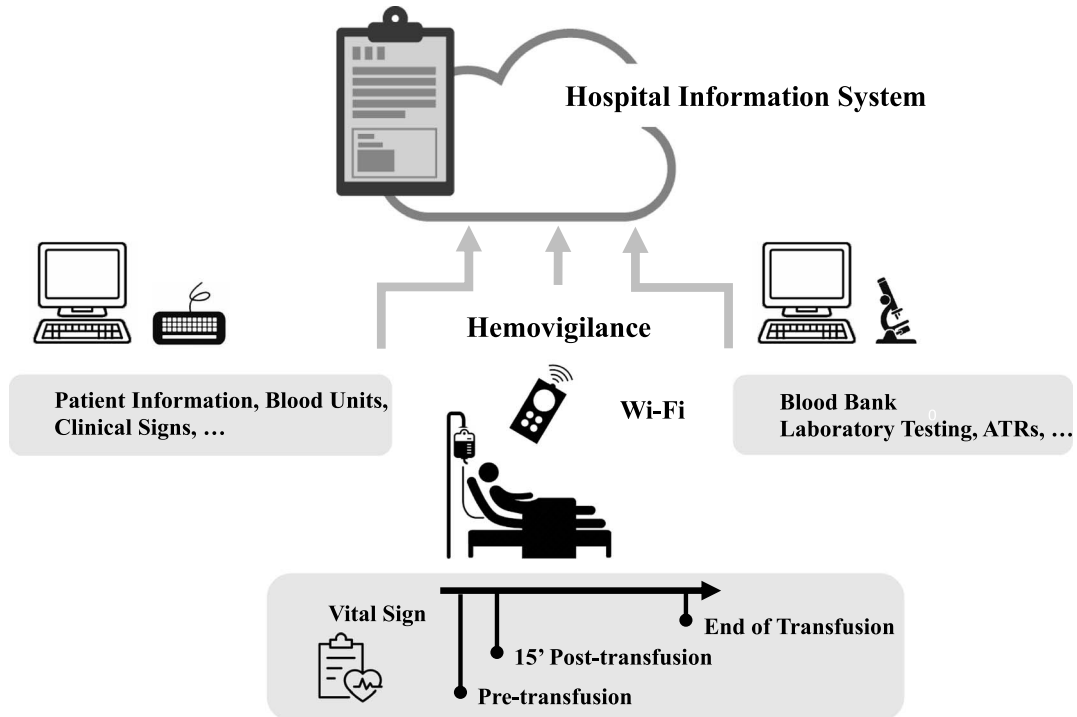
recorded for each blood unit transfused, and each unit is considered a single transfusion event.

Vital Signs Checking and Laboratory testing

There are four primary vital signs: body temperature, blood pressure, pulse rate, and breathing rate. The forehead thermometer is a fast and easy way to measure body temperature. Blood pressure and pulse rate were evaluated using an electronic device (Dinamap ProCare 300 Vital Signs Monitor; GE Inc, Milwaukee, Wis). Clinical blood samples from patient were evaluated for complete blood cell counts and white blood cell with differential analysis using the Sysmex XE-5000 hematology analyzer (Sysmex Co, Kobe, Japan).

Classification of ATRs by Severity

In this study, ATRs were categorized by severity (i.e., mild, moderate, and severe/life-threatening or grades 1–3, respectively), which were adapted from the blood transfusion safety handbook of the World Health Organization.^{4,11} Mild ATRs were defined as those with one of the following signs: itching, urticaria, or nausea/vomiting. Moderate ATRs were defined as those with any two mild ATR signs lasting longer than 30 minutes or one of the following signs: chills, fever (forehead temperature > 37.5°C),¹² headache, blush, or body temperature increase of 1°C to 2°C during transfusion. Severe ATRs were defined as those with purpura, shock, bleeding, delirium, chest/abdominal pain, back pain, dyspnea, consciousness disturbance, fainting, hemoglobinuria, hemoglobin drop, or body temperature increase of greater than 2°C. In our online reporting system (Fig. 2B), patients receiving



A

Medical Record Number		Sex		Age		Blood Type		Doctor		
Diagnosis									Transfusion Reaction	▼
Vital Sign	Temperature	Pulse Rate	Respiratory	Diastolic Pressure	Systolic Pressure	Recorder	Recording Time			
Pre-transfusion	°C	bpm	bpm	mmHg	mmHg		/ / :			
15 min After Blood Transfused	°C	bpm	bpm	mmHg	mmHg		/ / :			
Completion of Transfusion	°C	bpm	bpm	mmHg	mmHg		/ / :			
<input type="checkbox"/> Same Day Surgery <input type="checkbox"/> Fever 1. If Checked "Same Day Surgery" or "Fever", the Online System for "Body Temperature" Switch to Off 2. If Anesthesia, Please Checked "Same Day Surgery"										
<input type="checkbox"/> Special Case: 3. If Checked "Special Case", the Online System for Vital Signs and Transfusion Switch Off										
<input type="checkbox"/> No Transfusion Reaction										
Use of Blood Components										
No.	Blood Components	Bag No.	ABO Type	Rh Type	Transfusion Report	Transfusion Report	Transfusion Report	Transfusion Report		
1					▼	▼	▼	▼		
2					▼	▼	▼	▼		
Symptoms and Clinical Signs of Adverse Transfusion Reactions by Severity										
Grade 1 Mild	<input type="checkbox"/> Itching	<input type="checkbox"/> Urticaria	<input type="checkbox"/> Nausea/Vomiting							
Grade 2 Moderate	<input type="checkbox"/> Chills	<input type="checkbox"/> Fever	<input type="checkbox"/> Headache	<input type="checkbox"/> Blush	<input type="checkbox"/> Grade 1 over Thirty Minutes					
Grade 3 Life-threatening	<input type="checkbox"/> Purpura	<input type="checkbox"/> Shock	<input type="checkbox"/> Bleeding	<input type="checkbox"/> Delirium	<input type="checkbox"/> Chest/abdominal pain	<input type="checkbox"/> Backache				
	<input type="checkbox"/> Jaundice	<input type="checkbox"/> Dyspnea	<input type="checkbox"/> Disturbance	<input type="checkbox"/> Faint	<input type="checkbox"/> Hemoglobinuria	<input type="checkbox"/> Hb Drop				
<input type="checkbox"/> No Transfusion Reaction <input type="checkbox"/> Anesthesia <input type="checkbox"/> Transfer to Another Hospital <input type="checkbox"/> No Reply										

B

FIGURE 2. Online HIS for monitoring ATRs. A, A patient-focused online reporting system at the hospital. B, English version of the online reporting webpage for adverse events of blood component transfusion.

transfusions without any signs and symptoms are identified as "No transfusion reaction." If any ATRs occur, a notification is automatically sent to a doctor for confirmation.

Statistical Analysis

Continuous variables were expressed as means ± standard deviation, and categorical data were expressed as frequencies and

percentages. One-way analysis of variance test was used for continuous variables. Pearson's χ^2 test was used for categorical variables. Independent predictors eligible for inclusion are as follows: sex, forehead temperature (34°C–37.5°C, >37.5°C), pulse rate, respiratory rate, systolic pressure (<90 mm Hg, 90–110 mm Hg, >110 mm Hg), diastolic pressure (<70 mm Hg, 70–90 mm Hg, >90 mm Hg), hemoglobin, platelet counts, leukocyte counts (<5 × 10³/μL, 5–15 × 10³/μL, >15 × 10³/μL). Multivariate logistic

regression models were used to identify associated factors of developing ATRs (mild, moderate, and severe/life-threatening).¹³ The strengths of the relationships were expressed as odds ratios (ORs) with corresponding 95% confidence intervals (CIs). All analyses were conducted using SAS Version 14.0 (SAS Institute Inc, Cary, NC). Statistical significance was set at $P < 0.05$.

RESULTS

Data Collection

The data sources from HIS, including patient information, laboratory data, ATRs, and a detailed bedside database were used. The data were cleaned (purged of inconsistent and/or nonsense values), organized, and merged to create files for the analysis. A transfusion episode was defined as one or more blood component units issued at the same time. As shown in Fig. 1, between 2011 and 2015, there were 59,725 transfusion episodes included in this retrospective study. However, online reports missing data on blood pressure ($n = 18$), pulse rate ($n = 17$), temperature/respiratory rate ($n = 1927$), leukocyte counts ($n = 12,871$), hemoglobin ($n = 12$), and platelet count ($n = 58$) were excluded. The inclusion criteria were 18 years or older. The frequencies of ATRs were calculated by dividing the number of cases of such signs and symptoms by the total number of study events. A total of 44,691 study events were included, of which 1586 (3.5%) were reportable ATR events.

Pattern of Transfusion-Related Signs and Symptoms

There are 1586 ATR reporting events were automatically transmitted to the HIS database system, and 1707 transfusion-related signs and symptoms were observed (Table 1). Elevated body temperature was the most common. Of 1267 reports (74.23% of reportable ATRs), body temperature increase of 1°C to 2°C, body temperature increase of greater than 2°C, and overall body temperature of greater than 38°C occurred in 946 (55.42%), 228 (13.36%), and 93 (5.45%) cases, respectively. The most common clinical signs and symptoms in these cases related to allergic reactions were itching (4.98%, $n = 85$), urticaria (4.80%, $n = 82$), and blush (1.23%, $n = 21$), followed by chills (10.78%, $n = 184$), dyspnea (2.05%, $n = 35$), nausea/vomiting (0.41%, $n = 7$), shock

(0.29%, $n = 5$), headache (0.29%, $n = 5$), chest pain/abdominal pain/backache (0.23%, $n = 4$), hemoglobinuria (0.06%, $n = 1$), and none of the previously mentioned uncomfortable symptom (0.64%, $n = 11$).

Characteristics of the 44,691 Study Events With and Without ATRs

Table 2 summarizes the pretransfusion characteristics of the 44,691 transfusion episodes. The mean \pm SD age was 65.6 ± 15.5 years, and the median (interquartile range) age was 68 (18–105) years. Of the 1586 ATR events, 790 (49.8%) occurred in women and 796 (50.2%) in men. Compared with patients without ATRs, those with ATRs exhibited elevated body temperature (forehead temperature $>37.5^\circ\text{C}$, 5.5% versus 3.8%, $P = 0.001$), abnormal systolic pressure (< 90 mm Hg or > 110 mm Hg, 78.9% versus 75.1%, $P = 0.001$), abnormal diastolic pressure (< 70 mm Hg or > 90 mm Hg, 55.9% versus 59.9%, $P = 0.001$), and abnormal leukocyte count ($< 5 \times 10^3/\mu\text{L}$ or $> 15 \times 10^3/\mu\text{L}$, 40.2% versus 36.5%, $P = 0.003$).

Potential Associated Factors for ATRs

Multivariate logistic regression models were employed to estimate the associations (ORs and 95% CI) between pretransfusion predictors and in developing ATRs. In this study, ATRs were categorized as mild, moderate, and life-threatening. We used multivariable logistic regression models to calculate absolute risk differences while adjusting for possible independent variables, including sex, body temperature, pulse rate, respiratory rate, systolic pressure, diastolic pressure, hemoglobin count, platelet count, and leukocyte count. Transfusion patients with leukocyte counts below the normal range ($5\text{--}15 \times 10^3/\mu\text{L}$) were associated with mild ATRs (OR = 2.38, 95% CI = 1.68–3.35, $P < 0.001$) (Fig. 3A). Multivariate analysis indicated that patients with elevated body temperature (forehead temperature $>37.5^\circ\text{C}$) were associated with moderate ATRs (OR = 1.55, 95% CI = 1.22–1.98, $P < 0.001$) (Fig. 3B). Patients with diastolic pressure above the normal range (> 90 mm Hg) were associated with life-threatening ATRs (OR = 1.78, 95% CI = 1.06–2.99, $P = 0.030$) (Fig. 3C).

DISCUSSION

Blood transfusions are lifesaving, and clinicians and laboratorians endeavor to ensure that blood transfusions are as safe as possible for patients. Each blood product transfusion is associated with some degree of potential risk of an acute or late adverse reaction.¹⁴ Thus, blood transfusion reactions remain unpredictable, and hospitals should establish a hemovigilance system for effectively reporting and real-time awareness of ATRs to improve patient safety during transfusion.¹⁵ To further ensure patient safety during transfusion, clinicians and nurses should be aware of any signs and symptoms exhibited by transfusion recipients before, during, and after blood transfusion. Vital signs monitoring has been a standard blood transfusion assessment for decades. In our hospital's online hemovigilance reporting system, patients' vital signs are monitored at the following three time points: before transfusion, 15 minutes after transfusion initiation, and after transfusion completion. To date, the clinical practice in monitoring patients' body temperature after blood transfusion and documenting vital signs data correctly has been neglected.^{16,17} Thus, our hospital developed and implemented a Wi-Fi-based vital signs monitoring hemovigilance system to enhance user-friendliness and monitor ATRs in real time; this system was integrated into the electronic online reporting system and launched at our hospital in 2010 (Fig. 2).

We identified 1267 reports (74.23% of reportable ATRs) of febrile nonhemolytic transfusion reactions (FNHTRs), including

TABLE 1. Transfusion-Related Signs and Symptoms Recorded on the Online Reporting System

Sign or Symptom	No. Case	%
Body temperature increase of 1–2°C	946	55.42
Fever	228	13.36
Chills	184	10.78
Body temperature increase of 2°C	93	5.45
Itching	85	4.98
Urticaria	82	4.80
Blush	21	1.23
Dyspnea	35	2.05
Nausea/vomiting	7	0.41
Shock	5	0.29
Headache	5	0.29
Chest/abdominal pain/backache	4	0.23
Hemoglobinuria	1	0.06
None of the above mentioned	11	0.64
Total 1586 ATR reporting events	1707	100.00

TABLE 2. Baseline Characteristics of All Included Study Events With and Without ATRs

Characteristic	All Study Events (n = 44,691)	With ATRs (n = 1586)	Without ATRs (n = 43,105)	P
Age, y	65.6 ± 15.5, 68 (18–105)	63.1 ± 16.1, 64 (18–102)	65.7 ± 15.5, 68 (18–105)	<0.001
Sex				
Female	19,903 (44.5%)	790 (49.8%)	19,113 (44.3%)	<0.001
Male	24,788 (55.5%)	796 (50.2%)	23,992 (55.7%)	
Vital sign				
Pulse rate, beat per minute	89.5 ± 19.6	91.0 ± 19.9	89.4 ± 19.5	0.002
Respiratory	19.7 ± 3.9	19.8 ± 4.1	19.7 ± 3.9	0.398
Body temperature				
Normal (34–37.5°C)	42,967 (96.1%)	1499 (94.5%)	41,468 (96.2%)	0.001
Abnormal (>37.5°C)	1724 (3.9%)	87 (5.5%)	1637 (3.8%)	
Systolic pressure				
Normal (90–110 mm Hg)	11,064 (24.8%)	335 (21.1%)	10,729 (24.9%)	0.001
Abnormal	33,627 (75.2%)	1251 (78.9%)	32,376 (75.1%)	
Diastolic pressure				
Normal (70–90 mm Hg)	17,964 (40.2%)	700 (44.1%)	17,264 (40.1%)	0.001
Abnormal	26,727 (59.8%)	886 (55.9%)	25,841 (59.9%)	
Hb, g/dL	9.0 ± 2.5	8.9 ± 2.6	9.0 ± 2.5	0.161
Platelet counts, × 10 ³ /μL	165.8 ± 125.1	175.5 ± 132.6	165.4 ± 124.9	0.002
Leukocyte counts				
Normal (5–15 × 10 ³ /μL)	28,339 (63.4%)	949 (59.8%)	27,390 (63.5%)	0.003
Abnormal	16,352 (36.6%)	637 (40.2%)	15,715 (36.5%)	

Continuous variables were reported as mean ± SD. Categorical variables were reported as counts (%); one-way analysis of variance test was used for continuous variables;

Pearson's χ^2 test was used for categorical variables.

body temperature increase of 1°C to 2°C (55.42%, n = 946), body temperature increase of greater than 2°C (5.45%, n = 93), and fever (13.36%, n = 228) (Table 1). The incidence of FNHTR has been reported to vary from 17% to more than 54%.^{14,18–20} Fever is a crucial and the most common sign of ATRs; it is an early sign that can be used to monitor patients' vital signs during transfusions, and transfusions should be stopped immediately if any change in vital signs or unexpected symptoms occur.^{4,21} According to our blood transfusion reaction definition, a body temperature increase of 1°C to 2°C was a moderate ATR (grade 2); this type of ATR was also considered an FNHTR. We found that a body temperature increase of 1°C to 2°C was the most common sign of transfusion reaction in 55.42% (946/1707) of symptomatic cases. This finding corresponds to that of a previous study, in which FNHTRs were the most common reactions.⁵ The incidence of FNHTRs is different worldwide.²² By contrast, a body temperature increase of greater than 2°C was reported as a systemic symptom (grade 3 ATR) and occurred in 5.45% (93/1707) of cases. The development of a febrile reaction must be conducted promptly because fever may also be the first sign of other more severe reactions, including acute hemolysis and sepsis. Studies have reported that the transfusion of leukoreduced blood components effectively decreases febrile reaction.^{23,24} Leukoreduction may be performed at the prestorage or poststorage filtration stages.²⁴ Studies have also shown that the transfusion of prestorage leukoreduced blood components can prevent leukocyte-associated complications during transfusion.^{23,25–27} The national insurance policy of Taiwan has meant that these types of blood components have been in use in our hospital since 2016.

At our hospital, the incidence of adverse transfusion reactions was 3.5% (1586/44,691) blood units transfused (Table 2). Furthermore,

we reported that vital signs monitoring and leukocyte count before transfusion were significantly associated with the subsequent occurrence of ATRs (Fig. 3). Currently, leukocyte count is not comprehensively performed in pretransfusion assessments.²⁸ We believe that pretransfusion leukocyte count is crucial in assessing patients' clinical status such as infection and sepsis. Clinicians should be more aware of the occurrence of ATRs when patients are leukopenia.

This study has several limitations. First, this was a longitudinal observational study. The data were limited to those files available in the computerized database of the HIS. Second, some online records were incomplete because of transmission errors. However, during the data transmission process, some data may be lost during the Wi-Fi signal loss or device not online (thermometer) and resulted failure of archive data. In addition, some data may be incomplete because of the human error, which nurses forget to measure vital sign before or after transfusion. In particular, respiratory rate was less frequently recorded than other vital signs.^{29,30} The incomplete vital sign data were only 4% (1962/59,725) in our total collected data, which may not cause significantly interference of our statistical analysis. This study used the data that had been entered into the system by medical personnel. Therefore, the accuracy of reporting relies on the recognition and communication of transfusion reactions by medical personnel, availability of relevant patient data, and reporters' proficiency in applying the definition, imputability, and severity criteria. Third, pretransfusion testing such as leukocyte counts, hemoglobin, or platelet counts were not detected for all patients, resulting in missing data (n = 14,903) (Fig. 1). Fourth, delayed transfusion reactions could not be evaluated in the study setting. However, any signs and symptoms occurring within 24 hours of a transfusion are required to be reported for

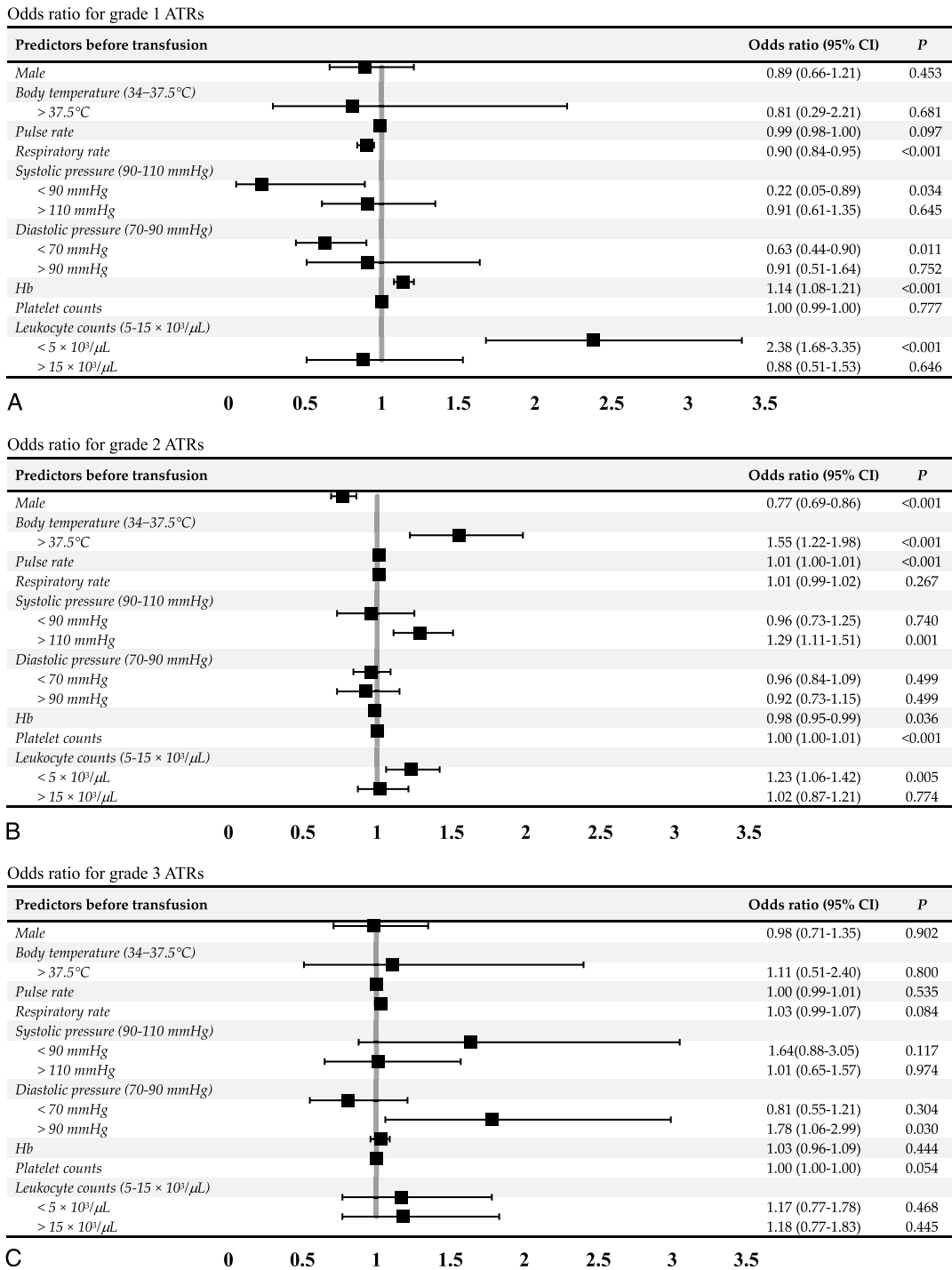


FIGURE 3. Potential risk for ATRs. A, Odds ratio for grade 1 ATRs. B, Odds ratio for grade 2 ATRs. C, Odds ratio for grade 3 ATRs.

all transfusion patients. Hence, ATRs were the focus of this study. Based on the study results, prompt and effective preventive strategies, such as recognizing increased body temperature as an early sign, can be developed for ATRs.

CONCLUSIONS

In summary, we reported on the patient-focused hemovigilance system implemented in our hospital. Establishing a standard

procedure that uses Wi-Fi to transmit patients’ vital signs and collect data correctly during the whole blood transfusion procedure is vital. A well-established hospital hemovigilance system not only reduces possible human errors but also improves the safety of blood transfusion. It is an essential step toward nationwide hemovigilance. Our results indicated that patients with leukopenia, elevated body temperature, and high diastolic blood pressure were associated with ATRs occurrence.

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