



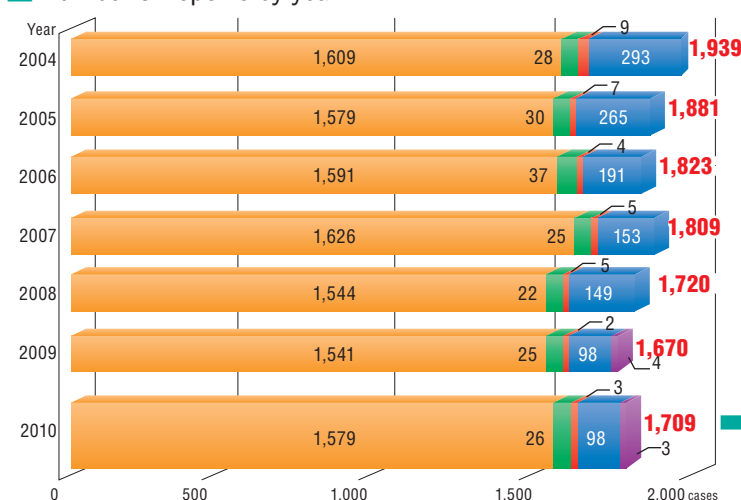
Non-hemolytic Adverse Transfusion Reactions Reported to JRC Blood Centers (2010)

Transfusion-associated adverse reaction and/or suspected transfusion transmitted infectious cases were reported by medical institutions to JRC blood centers. This issue of Transfusion Information shows the result of analysis for non-hemolytic adverse reaction cases in 2010, the most frequently reported cases.

The Number of Reports of Suspected Adverse Reactions* and/or Infections Associated with Transfusion (reports from medical institutions; cases later evaluated to be unrelated to transfusion included)

* Adverse reactions to plasma derivatives are excluded

Number of reports by year



Details of reports[§] (2010)

- In 2010, reported non-hemolytic adverse transfusion reactions totaled 1,579 cases; this accounted for 92% of the total number of reports of adverse transfusion reactions and suspected transfusion transmitted infections, namely, 1,709 cases.
- In 679 (43.0%) of the 1,579 cases, the symptoms of the non-hemolytic adverse reactions were evaluated to be severe.
- The number of patients with any non-hemolytic adverse transfusion reactions was 861 males and 718 females. The median age was 68 years (range: 0 to 98 years).

§ Some cases were counted in multiple appropriate categories.

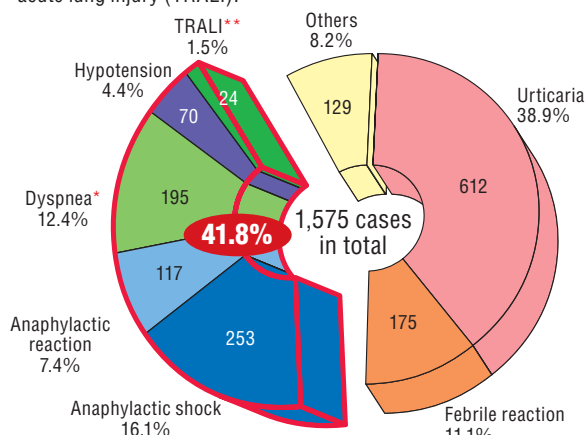
The suspected Transfusion Associated (TA)-GVHD cases all tested negative for chimerism on microsatellite DNA analysis.

■ Non-hemolytic adverse reactions ■ Hemolytic adverse reactions ■ Suspected TA-GVHD ■ Suspected infections ■ Case reports in journals

Non-hemolytic Adverse Transfusion Reactions (2010)

Breakdown of cases by symptoms

The numbers and percentages of non-hemolytic adverse reaction cases categorized by symptoms are shown below. Severe cases were predominant for the following symptoms, and the number of these cases accounted for 41.8% of the total number: Anaphylactic shock, anaphylactic reaction, dyspnea, hypotension, and transfusion related acute lung injury (TRALI).



* Cases of suspected cardiogenic pulmonary edema included

** Cases of possible TRALI included

Notes

[Anaphylactic reaction]

A condition characterized by generalized flushing, urticaria, angioedema (e.g., face edema and laryngeal edema), dyspnea, and other similar systemic symptoms.

[Anaphylactic shock]

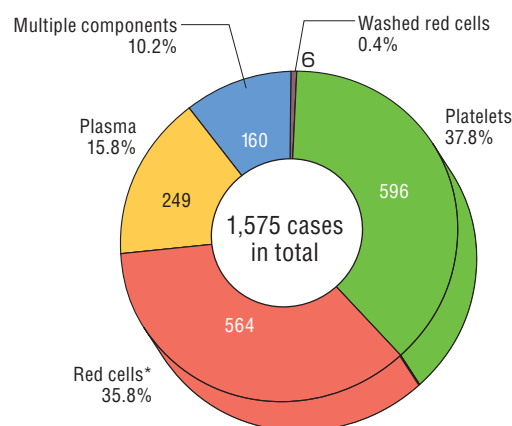
Anaphylactic reaction accompanied with hypotension.

[Hypotension]

Hypotension with no other clinical signs such as skin symptoms or dyspnea.

Transfused blood components

Most of the non-hemolytic adverse reactions were caused by platelets or red cells.



*Excluded frozen-thawed red cells and blood for exchange transfusion.

Note that the blood components mentioned above all include components irradiated before issue, and components irradiated at medical institutions.

* A total of 1,579 cases were reported for non-hemolytic adverse transfusion reactions; however, 4 cases that were evaluated by the reporting physician as being "unrelated to transfusion" were excluded from the analysis.

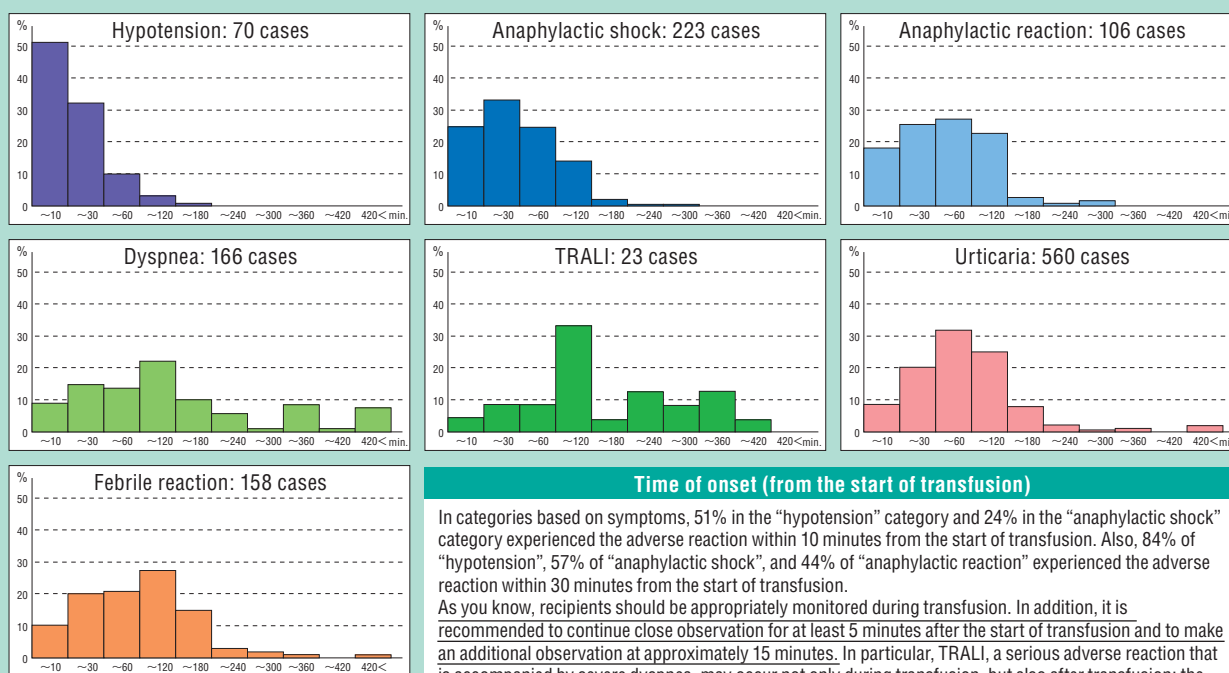
Number of reported cases and frequency by component and symptom (2010)

Component	Platelets	Red cells*	Plasma
Number of bags issued	792,796	3,434,375	969,854
Urticaria	272 cases (1/ 2,900)	156 cases (1/ 22,000)	119 cases (1/ 8,200)
Anaphylactic reaction	76 cases (1/ 10,000)	17 cases (1/200,000)	20 cases (1/ 48,000)
Anaphylactic shock	111 cases (1/ 7,100)	42 cases (1/ 82,000)	60 cases (1/ 16,000)
Febrile reaction	45 cases (1/ 18,000)	105 cases (1/ 33,000)	17 cases (1/ 57,000)
Dyspnea	55 cases (1/ 14,000)	91 cases (1/ 38,000)	13 cases (1/ 75,000)
Hypotension	13 cases (1/ 61,000)	46 cases (1/ 75,000)	10 cases (1/ 97,000)
TRALI	4 cases (1/200,000)	12 cases (1/290,000)	2 cases (1/480,000)
Others	20 cases (1/ 40,000)	95 cases (1/ 36,000)	8 cases (1/120,000)
Total	596 cases (1/ 1,300)	564 cases (1/ 6,100)	249 cases (1/ 3,900)

(Parentheses represent the frequency based on the total number of bags issued) * Excluded washed red cells, frozen-thawed red cells, and blood for exchange transfusion.
The blood components in the table all include components irradiated before issue and components irradiated at medical institutions. Cases given two or more types of blood components in combination were excluded.

Regarding the type of blood component, the frequency of adverse reactions based on the total number of bags issued was the highest with platelets, one case per approximately 1,300 bags.
 Taking symptoms into account, the category with the highest frequency was urticaria, which was caused by platelets, and the frequency was one event per approximately 2,900 bags.

Time of onset (cases with unknown time of onset excluded) (2010)

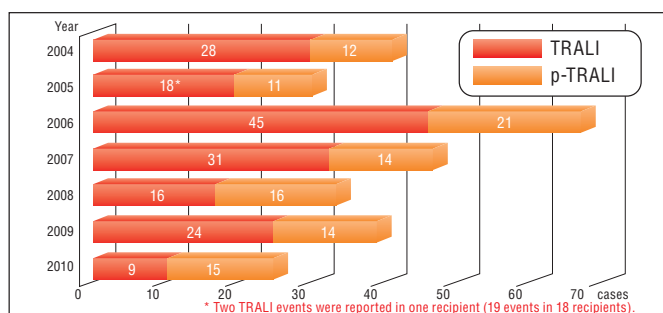


Time of onset (from the start of transfusion)

In categories based on symptoms, 51% in the "hypotension" category and 24% in the "anaphylactic shock" category experienced the adverse reaction within 10 minutes from the start of transfusion. Also, 84% of "hypotension", 57% of "anaphylactic shock", and 44% of "anaphylactic reaction" experienced the adverse reaction within 30 minutes from the start of transfusion.
 As you know, recipients should be appropriately monitored during transfusion. In addition, it is recommended to continue close observation for at least 5 minutes after the start of transfusion and to make an additional observation at approximately 15 minutes. In particular, TRALI, a serious adverse reaction that is accompanied by severe dyspnea, may occur not only during transfusion, but also after transfusion; the time of onset ranged up to 6 hours from the end of transfusion. Thus, recipients should be appropriately monitored, even after the end of transfusion.

The number of TRALI and p-TRALI cases by year

This chart describes the number of TRALI and possible TRALI (p-TRALI) cases reported by medical institutions that were evaluated to meet the relevant diagnostic criteria. In 2010, 9 TRALI cases and 15 p-TRALI cases were confirmed. During the seven years (2004 to 2010), 17 cases were considered to be fatal TRALI.



In case any of adverse reactions and/or infections related to transfusion of blood components or administration of plasma derivatives, please notify the medical representatives of your local JRC blood center immediately. Please provide the residual products, the recipient's pre- and post-transfusion samples, and any other related materials; it is helpful to investigate and/or identify the cause. For storage of residual products and the recipient's samples, refer to the "Guidelines for lookback studies of blood products."

Online Haemovigilance Information for Healthcare Professionals

URL <http://www.jrc.or.jp/mr/english/>

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* For more information, please contact the medical representatives of your local JRC blood center.