Risks of Infection with SARS-CoV-2 via Transfusion - Findings from Post-Donation Information-Based Studies -

In the post-donation information-based studies conducted by the JRCS, no transfusion-transmitted infection was confirmed in any of the patients who received blood products that tested PCR-positive for SARS-CoV-2.
These studies have recently been published in the Journal of Transfusion,[1] and we would like to report a summary of the results in this document.

Tested donations

Between 15 January 2020 and 31 December 2021, approximately 9,900,000 individuals donated blood in Japan, and 1,983 cases of post-donation information concerning COVID-19 were reported. Among these, there were 513 cases in which the donors were diagnosed with COVID-19 or tested positive for SARS-CoV-2 within 2 weeks after blood donation, and 496 cases in which testing was possible using simultaneously manufactured plasma products or stored samples were ultimately included in the studies.

Country	Japan	France (reference data)
Study period	15 January 2020 - 31 December 2021	18 February 2020 - 18 January 2021
Number of tested donations	496 donations	1,092 donations
Number of donations in which SARS-CoV-2 RNA was detected	23 donations (4.6%)	37 donations (3.4%)
Number of patients who received blood components in which SARS-CoV-2 RNA was detected	3 patients	20 patients*1

*1: Among these, 1 patient who received red blood cell components had COVID-19 before the transfusion.

Japanese case reports of patients who received blood components in which SARS-CoV-2 RNA was detected

Cases		Case 1	Case 2	Case 3
Age/sex		Male in his 60s	Male in his 60s	Female in her 80s
Type of blood component transfused		Red blood cells	Platelets	Red blood cells
Estimated viral load in blood component		< 1,608 IU	1.0 x 10^5 IU	< 1,608 IU
Results of SARS-CoV-2 RNA test on patient blood	Before transfusion/ blood collection date	(-)/immediately before transfusion	(-)/7 days before transfusion	(-)*4/immediately before transfusion
	After transfusion/ blood collection date	(-)/3 days after transfusion	(-)/17 days after transfusion	(-)/28 days after transfusion
Results of IgG-N*2 antibody test for SARS-CoV-2 in patient blood	Before transfusion/ blood collection date	NT*3	(-)/7 days before transfusion	(-)/immediately before transfusion
	After transfusion/ blood collection date	NT*3	(-)/17 days after transfusion	(-)/28 days after transfusion
Symptoms associated with COVID-19		None	None	None

*2: IgG antibody against N (nucleocapsid) protein of SARS-CoV-2. The test results are negative when there is no history of SARS-CoV-2 infection.
*3: Not Tested (Test was not performed.)
*4: Due to insufficient sample volume, the test was performed using a sample diluted 2-fold with PBS.

Results

SARS-CoV-2 RNA was detected in 23 (4.6%) out of 496 donations, and the viral RNA concentration was below the limit of quantitation in most samples. Retrospective studies revealed that 3 patients received red blood cell or platelet components which were positive for the viral RNA. After transfusion, these 3 patients had no symptoms associated with COVID-19, and no viral RNA was detected in the tests on the patients' blood before and after transfusion. For Case 2 and Case 3, IgG-N antibody tests for SARS-CoV-2 also yielded negative results.

For reference: In France, 20 patients received blood products (red blood cells or pooled platelets*5) containing viral RNA-positive plasma, but no patients had symptoms associated with COVID-19 after transfusion.[2]

*5: In France, a pathogen inactivation process is performed on platelet components, which is considered to be effective against SARS-CoV-2.

Conclusion

Although the number of cases was limited, no patients experienced transfusion-transmitted infection after receiving SARS-CoV-2 RNA-positive blood products. Based on the evidence observed to date, the risk of transfusion-transmitted infection is considered to be extremely low.

[References]
1) Shinohara N, et al. Risk of transfusion-transmitted infection with severe acute respiratory syndrome coronavirus 2 from blood donors in Japan. Transfusion. 2024;64(1):116-123.
2) Cappy P, et al. SARS-CoV-2 and post-donation information: a one-year experience of the French haemovigilance network. Blood Transfus. 2022;20(5):362–373.

Safety measures of the JRCS for COVID-19 (For reference)

Response actions based on post-donation information regarding COVID-19

[Target donors]

- Within 2 weeks after donation:
  (1) A donor was diagnosed with or suspected of having COVID-19 and subsequently tested positive on a PCR or antigen test.
  (2) A donor presented with symptoms suggesting COVID-19 including fever and respiratory symptoms such as cough and dyspnea.
- A donor lives with family members who were infected with COVID-19 or were exhibiting suggestive symptoms up to the day after blood donation.
- A donor who had experienced symptoms suggestive of COVID-19, donated blood within 2 weeks after symptom onset or within 3 days after symptom improvement.

[Response actions]

- The inventory status of the products from the above donors should be checked. If the products are before the supply, the delivery should be halted. If the products are within the expiration date and have already been supplied to medical institutions, the information should be provided immediately, and the usage status of the products should be confirmed promptly (if the products have not been used, they should be recalled).

Note: Since December 2023, SARS-CoV-2 PCR tests on products identified based on post-donation information have been abolished.

Course of the major safety measures of the JRCS for COVID-19

<table>
<tr><th colspan="2"></th><th>Donor eligibility criteria, etc.</th><th>Donors requiring actions by the JRCS based on post-donation information</th></tr>
<tr><td rowspan="2">2020</td><td></td><td colspan="2">COVID-19 occurred in Japan.</td></tr>
<tr><td>January</td><td>● Thorough implementation of interviews on COVID-19
● Deferral of donors*6
A donor who has had close contact with a person with (or was suspected of having) COVID-19 within 3 weeks before blood donation</td><td>A donor diagnosed with (or suspected of having) COVID-19 within 3 weeks after blood donation</td></tr>
<tr><td rowspan="2">2020</td><td>February</td><td>● Deferral of donors*6
(1) A donor who has had close contact with a person with (or suspected of having) COVID-19 within 4 weeks before blood donation
(2) A donor diagnosed with (or suspected of having) COVID-19</td><td rowspan="2">A donor diagnosed with (or suspected of having) COVID-19 within 4 weeks after blood donation</td></tr>
<tr><td>2021</td><td>May</td><td>● Individuals who received a vaccine (an mRNA vaccine) became eligible to donate blood.*6</td></tr>
<tr><td>2021</td><td>September</td><td>● The restriction on the acceptance of blood donations implemented based on the donors' disclosure of SARS-CoV-2 infection (including suspected cases) was lifted, and the acceptance of blood donations from individuals who have contracted COVID-19 was started.
● Deferral of donors*6
(1) A donor who has had close contact with a person with COVID-19 within 2 weeks before blood donation
(2) Within 4 weeks after the resolution of COVID-19 symptoms</td><td rowspan="4">A donor diagnosed with (or suspected of having) COVID-19 within 2 weeks after blood donation</td></tr>
<tr><td rowspan="2">2022</td><td>April</td><td>● Individuals who received a vaccine (a viral vector vaccine) became eligible to donate blood.*6</td></tr>
<tr><td>November</td><td>● Individuals who received a vaccine (an inactivated vaccine/recombinant protein vaccine) became eligible to donate blood.*6</td></tr>
<tr><td rowspan="2">2023</td><td>May</td><td>COVID-19 was reclassified as a Category V infectious disease.</td></tr>
<tr><td>December</td><td>● Deferral of donors*6
A donor who was diagnosed with COVID-19 or tested positive for the virus is within 2 weeks after symptom improvement.</td></tr>
</table>

*6: If the blood donation is found to be outside of the donor eligibility criteria, it should be handled based on post-donation information.

If any post-donation information concerning COVID-19 is obtained, we will continue to check the usage status of the blood products. We appreciate your continued cooperation.

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