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Original article

Post-donation information and haemovigilance reporting for COVID-19 in Greece: Information supporting the absence of SARS-CoV-2 possible transmission through blood components

C. Politis[a,*], M. Papadaki[b], L. Politi[c], G. Kourti[d], C. Richardson[e], M. Asariotou[a], A. Tsakris[c], A. Mentis[f]

[a] *Coordinating Centre for Haemovigilance and Surveillance of Transfusion, Hellenic National Public Health Organization,, Athens, Greece*
[b] *Blood transfusion service, Sotiria thoracic diseases hospital of Athens, Athens, Greece*
[c] *Laboratory of microbiology, medical school, National and Kapodistrian University of Athens, Athens, Greece*
[d] *Haematology department, Sotiria thoracic diseases hospital of Athens, Athens, Greece*
[e] *Panteion university of social and political sciences, Athens, Greece*
[f] *Public health laboratories, Hellenic Pasteur Institute, Athens, Greece*

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ABSTRACT

Background. – Although the SARS-CoV-2 virus is transmitted mainly through the respiratory tract, possible transmission by transfusion from asymptomatic carriers should be explored. As yet there are no reports of transfusion transmission of COVID-19. Haemovigilance findings within a three-month surveillance period during the new coronavirus pandemic are presented.
Materials and methods. – Due to great demand and shortage, blood sessions in outpatient facilities were organized during the high prevalence period of COVID-19, alongside a national plan to monitor the evolving public health situation by random molecular screening of high-risk groups of the population. Haemovigilance protocols were implemented as well as surveillance for any COVID-19 case reported post-transfusion. A 14-day quarantine and follow-up molecular and antibody testing of any COVID-19 positive case was obligatory.
Results. – Post-donation, post-transfusion information and molecular testing of swab samples collected from three asymptomatic donors at risk for COVID-19, revealed the case of an immunosupressed patient who had been transfused with whole blood derived platelets from a donor subsequently diagnosed with COVID-19. The recipient exhibited no symptoms of the disease. Molecular and antibody testing results were negative.
Conclusion. – Haemovigilance provided information supporting the absence of transfusion transmission of COVID-19, thus strengthening the hypothesis that, even if it cannot yet be definitively ruled out, COVID-19 is not transmitted through blood transfusion. As of early June 2020, a perfect test does not exist, therefore haemovigilance along with the implementation of strict proactive measures is crucial to identify eluding asymptomatic individuals and ensure blood safety during the pandemic.

1. Introduction

The recent outbreak of the novel coronavirus disease 2019 (COVID-19) was officially reported in December 2019 in China and spread quickly around the globe, resulting in its declaration as a pandemic by the World Health Organization [1–7]. As with all respiratory viruses, the COVID-19 virus is primarily transmitted by the respiratory route [8–12]. Because respiratory viruses have never been reported to be transmitted through blood or blood components, any potential risk of transmission by transfusion of blood collected from asymptomatic individuals remains theoretical [13]. According to the case report described for the first time by Cho et al., the transfusion of apheresis platelets to a patient diagnosed with severe aplastic anaemia from a donor who was subsequently diagnosed with COVID-19 did not result in the transmission of the disease [14]. Any reports indicating possible transmission through transfusion of blood components have not received confirmation and therefore have been discounted. Due to the urgent require-

* Corresponding author.
E-mail address: cpolitis11@yahoo.gr (C. Politis).

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ment for blood, it remains critically important to know whether the COVID-19 virus can be transmitted by blood transfusion, because asymptomatic carriers may donate blood and therefore blood donation could be an unidentified route of transmission. The pandemic has the potential to reduce the supply of blood and blood components by affecting blood system activities, which has led to the publication by authorities worldwide of a variety of statements, precautionary measures, interim guidelines and risk assessments concerning blood safety and sustainability [15–22].

Following the first confirmed COVID-19 case in Greece in late February [23], the authorities promptly took all necessary proactive measures and thus interrupted effectively its spread in the country, with a limited number of cases and fatalities. However, the coronavirus crisis took a toll on blood donations, resulting in shortage of blood supply. As a result, the Coordinating Centre for Haemovigilance and Surveillance of Transfusion (SKAEM) of the Hellenic National Public Health Organization (formerly Hellenic Center for Disease Control & Prevention) issued in March 2020 a detailed guidance protocol for blood safety measures and haemovigilance guidelines during the pandemic, and joined action with the National Blood Centre and other authorities in order to address the problem by organizing voluntary blood donations in several Greek cities in safe outpatient facilities.

In our study we describe the haemovigilance data over a surveillance period of three months (March to May 2020) when prevalence of the virus was high, focusing on post-donation and post-transfusion information regarding the transfusion to an immunocompromised patient of whole blood derived platelets from a donor who was subsequently diagnosed with COVID-19.

2. Materials and methods

2.1. Haemovigilance measures

In Greece, a system for monitoring, reporting, investigating and analyzing any adverse events related to donations, processing and transfusion of blood, is constantly in use; however, during the high prevalence period of the disease in Greece the alertness level was even more elevated. This system includes actions to prevent recurrence of such events and therefore the provision of post-donation and post-transfusion information is essential. In the absence of a commercial kit for routine blood screening for the presence of SARS-CoV-2, measures for blood safety include deferral of certain donors. All donors with active viral infection or recovering from the disease are deferred for at least 28 days after the resolution of clinical signs and symptoms of infection. Possible exposure to the virus through contact with a suspected or confirmed COVID-19 case results in precautionary deferral for at least 28 days after the exposure. Potential donors who travelled to countries with documented active ongoing COVID-19 transmission are also deferred for at least 28 days after return.

2.2. The blood session

On 8th April 2020, a blood session for police officers was organized as part of the actions taken to address the blood shortage. All potential donors were interviewed before donation and information was collected on their medical status and history, travel history and possible contact with suspected or confirmed COVID-19 cases. All were perceived to be healthy and had no fever or respiratory symptoms. The blood session environment and procedures complied with official instructions from SKAEM. These included hand hygiene conditions and disinfection measures, at least 2 m distance between donation armchairs, usage of protective masks throughout the procedure, distancing between donors while waiting, and use of gloves and antiseptics.

2.3. Proactive measures and random screening of high-risk groups for COVID-19

During the period of high incidence of COVID-19 in Greece, the General Secretariat for Civil Protection implemented proactive measures for the effective disruption of the spread of the disease, including random screening of all personnel at high-risk of infection. On April 10th, random screening for the presence of SARS-CoV-2 took place among personnel and police officers stationed at Athens International Airport, with the collection of posterior-pharyngeal (throat) swabs. Among those tested were police officers who had donated in the blood session on April 8th.

Molecular testing of the swab samples was performed according to the manufacturers' recommendations [24] at the Microbiology Department of the Medical School of the National and Kapodistrian University of Athens, using the Maxwell® 16 Viral Total Nucleic Acid purification kit on the automated Maxwell® 16 Instrument (Promega Corporation) for the isolation of the viral nucleic acid and the genesig Real-Time PCR COVID-19 CE-IVD kit (Primer Design) on the AriaMx Real-Time PCR system (Agilent Technologies) for the detection of the novel coronavirus RNA. The results were communicated to the General Secretariat for Civil Protection and to the National Public Health Organization, and the positive patients were informed in order to receive specific counselling and instructions regarding the actions they would need to take during the following 14 days, and for their contacts to be traced, in order to take all the necessary measures for the prevention of spread. Follow-up testing of all positive patients was requested at the end of the 14-day isolation period.

Antibody testing was performed using the SARS-CoV-2 Elisa test systems (Euroimmun, Perkin-Elmer), according to the manufacturer's recommendations [25].

3. Results

3.1. Donor profile

The random screening identified one COVID-19-positive donor; a 27-year-old female police officer stationed mainly at Athens International Airport. She had no history of contact with people showing respiratory tract infection symptoms, nor with suspected or confirmed COVID-19 cases. On the day of the donation, she mentioned no travelling history. Molecular testing showed very low viral load, possibly indicative either of a mild infection or a prolonged remission period. Further investigation showed that she had returned from an 11-day trip to Bali 33 days before blood donation, travelling via Singapore. She did not report contact with suspected or confirmed COVID-19 cases during her trip. After diagnosis, she stayed indoors in self-isolation for 14 days. She remained asymptomatic during quarantine. All her close contacts were tested for COVID-19 and self-isolated as a precautionary measure. Moreover, her colleagues who donated blood in the same session were subjected to molecular testing and 14 days' quarantine. All contacts and colleagues tested negative for COVID-19.

3.2. Post-donation information and traceability findings

The blood establishment where the blood session was performed on April 8th was informed on April 12th of a confirmed COVID-19 case among the donors. Haemovigilance protocols were triggered and information about the confirmed COVID-19 case was requested. Investigations showed that the whole blood derived platelet unit from this donation had been transfused

into an immunocompromised male diagnosed with acute myeloid leukemia. Red cells and plasma processed from the same blood unit had not been used, and were discarded, according to blood safety protocols.

3.3. Recipient profile

The 54-year-old male was diagnosed with acute myeloid leukemia in January 2020, based on bone marrow biopsy and immunophenotype. Cytogenetic analysis and molecular testing established an intermediate prognosis. Consequently, it was planned that he should undergo chemotherapy in order to achieve full remission and be referred subsequently for allogeneic haemopoietic stem cell transplantation (HSCT). He received induction therapy "3 + 7" (idarubicin days 1–3 and cytarabine days 1–7) in the same month. Due to residual disease, a second cycle of intensive treatment with IDA-FLAG (idarubicin, fludarabine, cytarabine and G-CSF) followed in February, after which the bone marrow immunophenotype showed MRD (minimal residual disease) negative. A final third cycle of treatment with IDA-FLAG followed at the end of March. On day +13 of the third cycle (April 12th), the patient was transfused with five units of whole blood derived platelets (corresponding to an adult therapeutic dose) due to severe thrombocytopenia (in the context of severe pancytopenia). No adverse reactions were observed during or after transfusion. During this period of time the patient was without fever, and was treated with piperacillin/tazobactam (10th day), colistimethate sodium (9th day) and vancomycin (1st day – due to diarrhoea with imaging findings of colitis in computed tomography). On day +55 of the third cycle of treatment and while the patient remained without fever, the white blood cells had recovered, but he was still suffering from severe thrombocytopenia and required daily support with platelet transfusions. Moreover, his haematocrit was low, requiring RBC transfusions approximately every five days. He was scheduled for allogeneic HSCT after the full haematological recovery.

3.4. Follow-up

After the donor's diagnosis, re-examination by molecular testing of a posterior-pharyngeal swab sample for COVID-19 was requested. This second sample was collected on April 25th and molecular testing showed the absence of viral RNA. On May 13th (34 days after the original detection of SARS-CoV-2), the donor gave a blood sample which was referred to the Diagnostic Services Laboratory of the Hellenic Pasteur Institute. The examination gave negative IgG and IgA results.

Following the notification of the donor's diagnosis, the recipient's health was closely monitored. The patient showed no symptoms of infection, and there was no evidence of pneumonia on chest computed tomography. Nasopharyngeal swab sampling for molecular testing was not performed immediately by the treating physician for fear of a potential haemorrhagic incident but took place on May 7th, 26 days after the transfusion. Molecular testing was performed according to the manufacturer's recommendations in the Diagnostic Services Laboratory of the Hellenic Pasteur Institute by the Taqman one-step Real-Time RT-PCR, targeting the region of the E gene of the novel coronavirus. The patient was reluctant to give a blood sample at that time but agreed to be screened for antibodies 45 days after the initial transfusion. This blood sample was also referred to the Diagnostic Services Laboratory of the Hellenic Pasteur Institute for antibody testing as above. The examination was negative for IgG and IgA.

3.5. Haemovigilance data

Overall, surveillance data during the high prevalence period of the disease in Greece show that 119,159 blood units were collected nationwide (President of the National Blood Centre, personal communication) and about 183,514 blood components were issued for transfusion during the surveillance period of three months (March to May 2020). There was no report of transfusion transmitted COVID-19. Likewise, surveillance of the population of multi-transfused thalassaemic patients (~2800 patients) revealed no transfusion transmission of COVID-19. During the surveillance period, SKAEM received post-donation information about two donors with possible exposure to the virus through contact with confirmed COVID-19 cases. One donor reported being in the same room as a subsequently confirmed COVID-19 case for ten minutes the day before the blood donation. She was advised to remain self-isolated as a precautionary measure and monitor her health closely. The donated whole blood unit was discarded. The result of her molecular testing for COVID-19 was negative. The second donor reported close contact with a subsequently confirmed COVID-19 person, twelve days before blood donation. Haemovigilance protocols revealed that the processed RBCs had already been transfused into an elderly patient admitted to the ICU due to a herpetic encephalitis infection. This donor was also advised to self-isolate and monitor his health closely. Donor and recipient both tested negative for COVID-19.

4. Discussion

Transfusion of platelet rich plasma obtained from an asymptomatic infected individual did not result in disease transmission, even though the platelet recipient was diagnosed with myeloid leukaemia and was taking immunosuppressive drugs. This is the second report described globally, supporting the absence of transfusion transmission of the disease. Haemovigilance protocols succeeded in tracing the whole blood derived units and retrieve information about the donor and recipient, although there was a delay in communicating results. This experience provides essential information regarding route of transmission and necessity for blood safety measures, while it also raises concerns to be addressed.

Originally, the donor failed to inform the blood facility immediately about her positive COVID-19 molecular testing result, and thus the platelets deriving from the whole blood unit had already been transfused by the time this information reached the blood transfusion service. As the recipient was reluctant to be tested for COVID-19 immediately after the donor's diagnosis, a potential positive result eluding surveillance could be hypothesised; nevertheless, the recipient's health was closely monitored and, despite being immunocompromised, he never exhibited any symptoms. Moreover, the recipient's negative molecular and serological testing results support the absence of transfusion transmission of COVID-19.

The implicated donor had been in a country with ongoing COVID-19 transmission 34 days before donation. As the existing precautionary exclusion measures stipulate 28 days after such travel, the donor was in fact clear for donation. As she was – and remained – asymptomatic, accurate definition of the day of exposure was impossible, especially given her low viral load at the time of the molecular testing and the range of incubation periods among asymptomatic individuals. Therefore, possible exposure to the virus during the final days of her travel could not be ruled out. As a result, we should perhaps consider an extension of the 28 days' exclusion period following travel to a country with ongoing COVID-19 transmission. Even if the donor's exposure to the virus did not take place during travel, her profession and place of work should

have been enough to categorize her among individuals at high-risk of infection. This parameter should perhaps be added to the precautionary exclusion measures implemented for blood safety.

A possible solution for the timely discovery of infected donors could be the application of point-of-care test cassettes for serological screening of COVID-19. In our case, screening of the donor revealed the absence of antibodies circulating in her blood. Asymptomatic COVID-19 individuals display lower viral loads than those requiring hospitalisation and may generate lower levels and different patterns of antibodies [26–30]. In general, the sicker one becomes due to an infection, the more robust is the immune response that is triggered, and consequently more robust immunity is acquired. Serological screening of the donor was performed approximately 4–8 weeks after the assumed date of exposure to the virus and the result was negative. That the donor remained asymptomatic throughout suggests that either she failed to produce antibodies, or antibody secretion was below the detection limit, or she had not yet seroconverted at the time of sampling. There are as yet no data regarding the extent and duration of immunity to the virus and it might be a long time before such information becomes available. We should accept the fact that at that time a perfect test did not exist [28–32], and therefore consider the addition of more stringent criteria to the existing ones to avoid the potential transmission of this infection by blood transfusion, such as precautionary deferral from blood donation based on the profession and place of work of candidate donors, as well as the extension of exclusion periods after travelling.

5. Conclusion

Asymptomatic transmission of SARS-CoV-2 remains the Achilles' heel of public health strategies for COVID-19 pandemic control. Symptom-based screening is useful, but epidemiological evaluation of COVID-19 data strongly demonstrates that COVID-19 transmission from asymptomatic individuals may play a critical role in this pandemic status.

In order to ensure blood safety, most blood transfusion services implement precautionary measures during an outbreak, which involve:

- body temperature and symptom screening of all donors;
- wider screening questionnaire regarding donors' contacts with suspected or confirmed COVID-19 cases and travel to areas with local transmission of SARS-CoV-2 within a certain time period;
- educating donors to inform blood transfusion services of any symptoms and physical condition after the donation;
- recalling untransfused blood products from infected donors, and;
- deferral of currently or recently infected donors.

Additional measures, such as excluding donors at high-risk of infection, the application of point-of-care test cassettes for serological screening (once a test with high sensitivity and specificity is developed), and the extension of the exclusion period after travel to areas with local transmission of SARS-CoV-2 should be considered.

In such circumstances of great demand and shortage, along with all the limitations and "lists of unknowns" in serological and molecular testing, the fact remains that haemovigilance is the essential tool for blood safety. In our study (referring to the period from March to May 2020), haemovigilance suggested the absence of transmission of COVID-19 through blood components, thus supporting the hypothesis that, even if it cannot yet be definitively ruled out, COVID-19 is not transmitted through blood transfusion.

Authorship contributions

CP designed and coordinated the study, edited the manuscript and provided critical revision. MP and GK collected and analyzed data. AT and AM edited and reviewed the manuscript. LP analyzed data, prepared and edited the manuscript. CR edited and reviewed the manuscript. MA provided technical support and submitted the manuscript for publication.

Disclosure of interest

The authors declare that they have no competing interest.

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