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Original Research Article Convalescent plasma extraction: Our recent experience

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ABSTRACT

Covid-19 is currently a big threat to global health. As many drugs are tried but currently there is no approved treatment for covid-19. The management plan is supportive care with supplemental oxygen and mechanical ventilation. Directorate General of Health Services (DGHS), Government of India has approved convalescent plasma from patients recovered from Covid-19 for treatment of moderate to severe COVID-19 infection cases. Plasma bank of Odisha blood bank, MKCG MCH was involved in the convalescent plasma extraction for treatment of covid-19 patients. Prospective study was undertaken from 5^{th} August 2020 to 5^{th} December, 2020 to evaluate the plasma donors with respect to age wise distribution and common blood group affected. A total 340 donors donated convalescent plasma which commonly were in the age group 31-40 years followed by 21-30 years. Most common donors were from the O+ve blood group and no donors from AB-ve group. Female donors constituted only 1.7 % of total donors. It might be worthwhile to test the safety and efficacy of convalescent plasma transfusion in SARS-CoV-2 infected patients. CP therapy might be a promising treatment option for COVID-19 rescue. Convalescent plasma has been considered a potential modality of treatment for COVID-19 infection.

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1. Introduction

Coronavirus disease 2019 (Covid-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-Cov-2) has been reported in almost all countries globally. From December 2019, COVID-19 has spread worldwide from Wuhan, China.^{1–3} The epidemic spread rapidly worldwide within 3 months and was characterised as pandemic by WHO on March 11, 2020. Convalescent plasma therapy, a classic adaptive immunotherapy, has been applied to the prevention and treatment of many infectious diseases for more than one century. Over the past two decades, CP therapy was successfully used in the treatment of SARS, MERS and 2009 H1N1 pandemic with satisfactory efficacy

and safety.^{4–7} Currently there is no approved treatment for covid 19. Convalescent plasma has been considered a potential modality for COVID-19 infection.

Convalescent plasma therapy has been approved to be used as an OFF-LABEL treatment which may improve the clinical outcome in the patient with covid-19 infection.

MKCG Medical College and Hospital in the state of Odisha has operated one plasma bank at Transfusion Medicine Department since 5^{th} August, 2020 for convalescent plasma therapy.^{8,9}

2. Material and Methods

The present study was carried out for a period of 4 months from 5^{th} August 2020 to 5^{th} December 2020 in Department of Transfusion Medicine and Odisha Blood

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bank at MKCG Medical College, Berhampur, Odisha. It is a prospective study. For plasma donation donors contacted telephonically and explained in detail about the need of plasma and procedures. Inclusion criteria for plasma donation were viz., age between 18-60 years, weight 55 kg or above, prior diagnosis of COVID-19 documented by laboratory test (RT PCR) with complete resolution of symptoms before 28 days prior to donation. Donor eligibility criteria for whole blood donation as per the departmental SOP were followed in accordance with the Drugs and Cosmetics Act, 1940 and Rule 1945 therein. The deferral criteria for donation were women, who have ever been pregnant. Those who have uncontrolled diabetes or on insulin therapy, uncontrolled hypertension, with chronic kidney, heart, lung or liver disease and cancer survivors were excluded from donation. When plasma donors visited the blood bank they screened, consent is sought before donating CP, followed by brief physical examinations. Two EDTA samples (5ml each) and one plain sample (5ml) were drawn for the pre-donation tests as required before donation of plasma. A series of tests performed as required for convalescent plasma donation like- Blood group and antibody screening (Antibody screen positive donors were deferred). Complete blood count including Haemoglobin, Haematocrit (Hct), platelet count, total and differential leucocyte count. Donors with Hb more than 12.5 g/dl, platelet count > 1.5 lacs/cmm and TLC, Hct within normal limits were accepted.

Screening for HIV-I,II, HBV, HCV done by rapid kit followed by TTI screening of HIV, HBV, HCV repeated with ELISA and NAT testing for further confirmation.

Screening for Syphilis and Malaria done by serology. Negative donors were included.

Total serum protein > 6gm/dl were accepted (As per Drugs and cosmetics Rules, 2020)

Presence of IgG antibodies of CoviD-19 to be confirmed. Donors negative and low titre were deferred.

For titration of anti-COVID-19 antibodies (desired titer for IgG antibodies 1:640) samples were sent to Regional Medical Research Centre, Bhubaneswar and titration was done. If not done at the time of plasma collection the donor samples were stored in aliquots at $<-80^{\circ}$ C to be tested at a later date.

Among the consenting and accepted donors, a schedule was prepared for collection of plasma in the blood bank.

On the day of donation, donors were explained about the procedure and adverse events associated with the process and consent taken for the procedure.

Plasma collection was done by centrifugal separation using apheresis equipment. At our institute apheresis was performed using the Trima Accel Cell Separator (Terumo Penpol).

At our centre convalescent plasma was collected from 340 donors over a period of 4 months. During the procedure

400 ml convalescent plasma collected from each donor and divided into two units, stored as 200 ml aliquots at <-40^oC with unique donor identification number as per SOP. After receiving the request for convalescent plasma from the clinician, an ABO compatible plasma bag was cross matched. One unit approximately 200 ml were issued, maintaining all blood bank records after thawing at 37^{o} C. The first plasma transfusion may be followed by one or two additional doses of 200 ml at 24 hours interval according to disease severity and tolerance of infusion. Second plasma units were issued preferably from different donors depending on availability of another ABO-Compatible plasma unit.

3. Results

Table 1:	Age wise	distribution	of plasma	donors
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S. No.	Age	Total Donors
1	18-20	4
2	21-30	138
3	31-40	141
4	41-50	38
5	51-60	19

Table 2: Blood group wise donor distribution			
Blood Group	No of Donors		
A+ve	47		
A-ve	3		
B+ve	115		
B-ve	5		
AB+ve	24		
AB-ve	0		
O+ve	143		
O-ve	3		

Most common age group of plasma donors 31-40 years (Table 1) contributing 141 of total donations, followed by 21-30 years. Least donation among 18-20 years i.e. 4 in number. Most common donors were O+ve blood group i.e. 143 in number (Table 2) followed by B+ve (115 in number) then A+ve (47 in numbers), AB+ve (24 in number), B-ve (5 in number). A-ve and O-ve (3 number in each), however, no AB-ve donors were reported. Almost all are male donors out of 340 donations; female donors were six in number and constituted only 1.7%. The reason behind low rate of female donors as they did not meet the required criteria for convalescent plasma donation.

4. Discussion

An outbreak of novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2 injection first appeared in Wuhan, China and rapidly spread to 171 countries. Numerous therapeutics have been explored or developed during the outbreak. Immunotherapy with virus specific antibodies in convalescent plasma had been used as a last resort to improve survival rate of patients with serious infection diseases, such as severe acute respiratory syndrome. Previous reports have shown treatment with convalescent plasma recovered patients could reduce the hospital stay and mortality of patients. One possible explanation for the efficacy of convalescent plasma might suppress viraemia. Viraemia peaks in the first week of infection in most viral illness. The patient usually develops a primary immune response by days 10-14 which is followed by virus clearance. Theoretically, it should be more effective to administer the convalescent plasma at the early stage of disease.¹⁰ However, other treatments might have an effect on the relationship between convalescent plasma and antibody level including antiviral drugs, steroids, and intravenous immunoglobulin.

Convalescent plasma should be given to patients with Covid-19 at the right phase or severity of illness and at the right time point. The plasma collected from Covid-19 patients contains neutralising antibodies which show potential benefits in reducing viral load and accelerating viral clearance with negative reverse transcriptase polymerase chain reaction (RT-PCR) test reports. The concentration of neutralising antibodies also increases post CP therapy. Improvement of clinical symptoms like fever, cough, dyspnoea, chest pain etc., also reported. There are also improvements in radiological features like reduction of pulmonary lesions on chest CT scan and laboratory parameters after CP therapy.

No adverse events during plasma infusion were recorded in the present study. However, adverse transfusion reactions like anaphylaxis, circulatory overload and especially dangerous one like transfusion related acute lung injury (TRALI) should never be ruled out as a disadvantage along with risk of transmitting the pathogens during convalescent plasma transfusion.¹¹

5. Conclusion

As of now we don't have drugs or vaccines that specifically targets this deadly virus, so convalescent plasma therapy is a potential therapeutic option which has been explored all over the world. Patients receiving convalescent plasma therapy have been studied and shown (early discharge from hospital) lessened oxygen requirements in addition to lower mortality rate. Our study showed most common plasma donors were in the 31-40-year age group followed by the 21-30-year age group. Most common plasma donors are 0+ve blood group followed by B+ve blood group. Female donors are lower in number. According to WHO,¹² management of covid has mainly focused on infection prevention, case detection, monitoring and supportive care. However, no specific anti SARS-CoV-2 treatment is recommended

because of the absence of evidence. New evidence shows that convalescent plasma from patients who have recovered from viral infections can be used as a treatment without the occurrence of severe adverse events. Therefore, it might be worthwhile to test the safety and efficacy of convalescent plasma transfusion in SARS-CoV-2 infected patients. CP therapy might be a promising treatment option for COVID-19 rescue.

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7. Conflicts of Interest

No conflicts of interest.

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