

ORIGINAL RESEARCH ARTICLE

Convalescent Plasma Transfusion Practice in Blood Bank For COVID-19 PatientsVaidya Tejas H.¹, Nikita A. Machhi², Gauravi A. Dhruva³¹Senior Resident Doctor, Department of Pathology, GMERS Medical College and Hospital, Junagadh, Gujarat, India.²Assistant Professor, Department of Pathology, GMERS Medical College and Hospital, Junagadh, Gujarat, India.³Professor and Head, Department of Pathology, P.D.U. Government Medical College and Hospital, Rajkot, Gujarat, India.

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Abstract

Background: Plasma contains monoclonal or polyclonal antibodies that is used to spread passive immunity against many diseases via transfusion (through plasmapheresis or from plasma prepared from whole blood). Convalescent means “recovering from sickness or debility”. The aim of this study is to study the characteristic details, analyse frequency rate of donation, analyse donor blood group in eligible COVID-19 convalescent plasma donors. **Material And Methodology:** The present study is undertaken in Blood Bank, Department of Pathology, P.D.U. Government Medical College and Hospital, Rajkot from 1st August, 2020 to 31st July, 2021. After screening, if the donor is suitable for conducting plasmapheresis, Covid Convalescent Plasma is separated from whole blood of donor by apheresis method using apheresis instrument named Fresenius Kabi and Optia and from whole blood by separation method. Separated plasma is stored at (-30)° Celsius or below for 1 year. **Result:** An analysis of 690 Covid Convalescent Plasma donors was done. Age group of donors in 4th decade showed highest number, male donors were more in number as compared to females in the ratio 45: 1. Donors with blood group ‘B positive’ were more in number followed by ‘O Positive’. Plasma was collected with the help of apheresis procedure (462 donations) as well as separation of plasma from whole blood (228 donations) of donors. Total effective plasma units collected were 1100 in number. **Conclusion:** People who recover from the coronavirus have developed antibodies to the virus that remain in the plasma portion of their blood. Transfusing plasma that contains the antibodies into a person still fighting the virus can provide a boost to the patient’s immune system and potentially help them recover.

Key Words: Covid-19, Covid convalescent plasma, donors.

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Introduction

Plasma contains monoclonal or polyclonal antibodies that is used to spread passive immunity against many diseases via transfusion (through plasmapheresis or from plasma prepared from whole blood). **Convalescent means “recovering from sickness or debility”**. For example, **convalescent plasma**, passive antibody transfusion from a previous human

survivor, used to be the only known effective treatment for ebola infection with a high success rate of 7 out of 8 patients surviving.^[1] Behring had pioneered the technique, using guinea pigs to produce plasma.^[2]

Plasma or serum are widely used in diagnostic virology laboratories. The most common use of antiserum in humans is as antitoxin or antivenom to treat envenomation.

Plasma therapy, also known as serotherapy, describes the treatment of infectious disease using the plasma of animals that have been immunized against the specific organisms or their product, to which the disease is supposedly referable.

Coronavirus disease 2019 (COVID-19) is a contagious disease caused by a virus, the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The first known case was identified in Wuhan, China, in December 2019.^[3]

The first confirmed human infections were in Wuhan. A study of the first 41 cases of confirmed COVID-19, published in January 2020 in *The Lancet*, reported the earliest date of onset of symptoms as 1 December 2019.^[4] Official publications from the WHO reported the earliest onset of symptoms as 8 December 2019.^[5] Human-to-human transmission was confirmed by the WHO and Chinese authorities by 20 January 2020.^[6]

Symptoms of COVID-19 are variable, but often include fever,^[7] cough, headache,^[8] fatigue, breathing difficulties, loss of smell, and loss of taste.^{[9][10][11]}

COVID-19 testing methods to detect the virus's nucleic acid include real-time reverse transcription polymerase chain reaction (rRT-PCR),^{[12][13]} transcription-mediated amplification,^{[12][13][14]} and reverse transcription loop-mediated isothermal amplification (RT-LAMP)^{[12][13]} from a nasopharyngeal swab.^[15]

Antibodies in the plasma bind the infectious agent or antigen.^[16] The immune system then recognizes foreign agents bound to antibodies and triggers a more robust immune response. The use of plasma is particularly effective against pathogens which are capable of evading the immune system in their unstimulated state but are not robust enough to evade the stimulated immune system. The existence of antibodies to the agent depends on an initial survivor whose immune system, by chance, discovered a counteragent to the pathogen or a host species which carries the pathogen but does not experience its effects.^[17] Further stocks of plasma can then be produced from the initial donor or from a donor organism that is inoculated with the pathogen and cured by some stock of pre-existing plasma. Diluted snake venom is often used as an antiserum to give passive immunity to snake venom itself.^{[18][19]}

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a new human disease with few effective treatments. Convalescent plasma donated by persons who have recovered from COVID-19, is the acellular component of blood that contains antibodies, including those that specifically recognise SARS-CoV-2. These antibodies, when transfused into patients infected with SARS-CoV-2, are thought to exert an antiviral effect, suppressing virus replication before patients have mounted their own humoral immune response. Intentional collection of plasma should be performed only by apheresis in order to avoid unnecessary red cell loss in the donor and to optimize the volume of plasma that can be generated for investigational use. Convalescent Plasma Therapy has been extensively used across the world and is believed to save the lives of Covid-19 positive patients.

Aims And Objectives

- To study the characteristic details of eligible COVID-19 convalescent plasma donors.
- To analyse frequency rate of donation in eligible COVID-19 convalescent plasma donors.
- To analyse donor blood group in eligible COVID-19 convalescent plasma donors.

Material And Methodology

- The present study is undertaken in Blood Bank, Department of Pathology, P.D.U. Government Medical College and Hospital, Rajkot from 1st August, 2020 to 31st July, 2021.
- After taking consent, eligible donors are screened for Complete blood count, COVID -19 antibody card test (IgG and IgM) and other transfusion transmitted infections.
- After screening, if the donor is suitable for conducting plasmapheresis, Covid Convalescent Plasma is separated from whole blood of donor by apheresis method using apheresis instrument named **Fresenius Kabi and Optia** and from whole blood by separation method.
- Separated plasma is stored at (-30)^o Celsius or below for 1 year.

Criteria For Selection

- Confirmation of previous infection with SARS-CoV-2 by a record of a validated diagnostic test at the time of illness.
- An interval of at least 28 days after full recovery.
- Non reactivity of blood samples for transfusion transmitted infections including HIV, HBV, HCV, syphilis & malaria using approved serological tests, and other required tests for collection of blood components for transfusion.
- Serum Protein test in case of repeat donors, if required.

Donors must meet *all* the required screening criteria for **blood donation** and the additional FDA criteria, as follows:

- Prior diagnosis of COVID-19 documented by a laboratory test or a letter from a hospital or test provider confirming a positive COVID-19 diagnosis.
- A positive diagnostic test at the time of illness OR
- A positive serological test for SARS-CoV-2 antibodies after recovery.

Observation And Results

Present study showed following results of CONVALESCENT PLASMA TRANSFUSION PRACTICE IN BLOOD BANK FOR COVID-19 PATIENTS of 690 donors, which was done in Blood Bank, Department of Pathology, P.D.U. Government Medical College and Hospital, Rajkot from August 2020 to July 2021.

Age wise distribution of Covid Convalescent Plasma donors

Age group of donors in 4th decade showed highest number of donations of plasma.

Table 1: Age wise Distribution of Covid Convalescent Plasma donors

AGE (YEAR)	No. of donors	Percentage
18-20	20	2.90%
21-30	218	31.59%
31-40	251	36.38%
41-50	162	23.48%
51-60	37	5.36%
60-65	2	0.29%
Total	690	100%

Gender wise distribution of Covid Convalescent Plasma donors

There was male predominance with Male to Female Ratio 45:1.



Chart 1: Gender wise distribution of Covid Convalescent Plasma donors

Blood group wise distribution of Covid Convalescent Plasma donors

Covid Convalescent Plasma donors show wide variation in blood group distribution. It shows highest number of B positive donors with 233 donors while least number of AB negative donors with 3 donors.

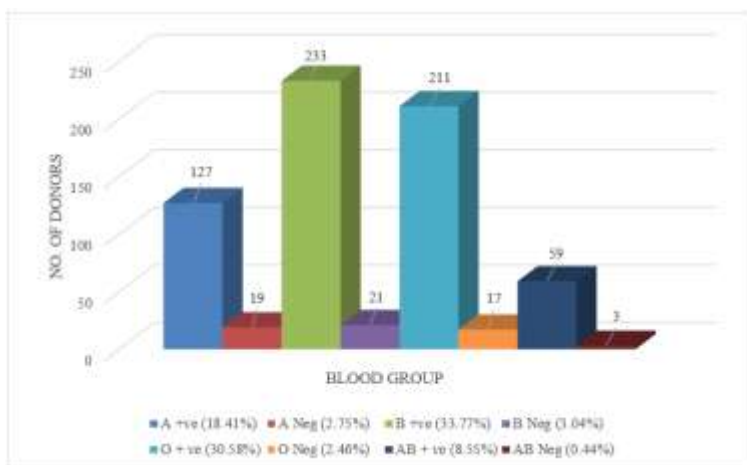


Chart 2: Blood group wise distribution of Covid Convalescent Plasma donors

Procedure wise distribution of Covid Convalescent Plasma donors

Out of 690 donors 462 Plasma collected from Plasmapheresis procedure and 228 Plasma collected from separation of whole blood.

Table 2: Procedure wise distribution of Covid Convalescent Plasma donors

Procedure	No. of donors	Percentage
Plasmapheresis	462	66.96%
Whole blood	228	33.04%
Total	690	100%

Donation frequency of Plasma donors in present study

Out of 690 donors, 552 donors donated once in present study while 138 donors donated repeatedly in blood bank in present study.

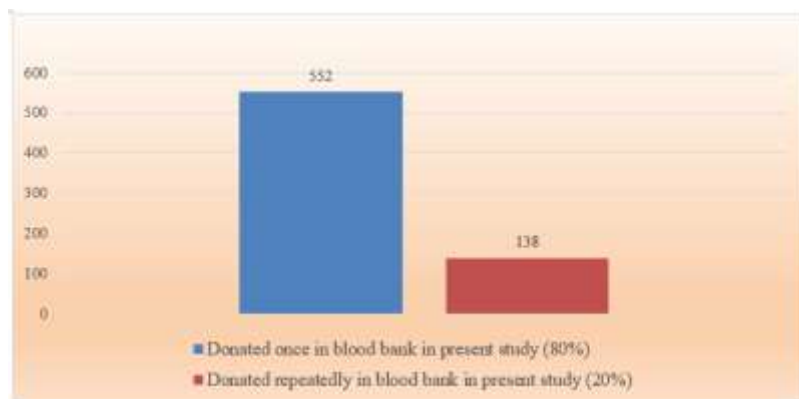


Chart 3: Donation frequency of Plasma donors in present study

Type of Plasma donors wise distribution of Covid Convalescent Plasma donors

Out of 690 Plasma donors, 448 were voluntary donors while 242 were replacement donors.

Table 3: Type of Plasma donors wise distribution of Covid Convalescent Plasma donors

Type of Plasma donors	No. of donors	Percentage
Voluntary Plasma donors	448	64.93%
Replacement Plasma donors	242	35.07%
Total	690	100%

Outcome of Plasmapheresis procedure

Out of 462 Plasmapheresis procedure, 426 procedure were done successfully while 20 were low volume and 16 were failed tap.

Table 4: Outcome of Plasmapheresis procedure

Outcome of procedure	No. of procedure	Percentage
Successful	426	92.21%
Low volume	20	4.33%
Failed tap	16	3.46%
Total	462	100%

Blood group wise distribution of effective Plasma collected

Out of total 1100 effective Covid Convalescent Plasma collected, B positive group showed highest number – 384 (34.91%) while AB negative group showed lowest number – 5 (0.45%).

Table 5: Blood group wise distribution of effective Plasma collected

Blood group	No. of donors	No. of Plasma collected	Percentage
A – Positive	127	195	17.73 %
A – Negative	19	31	2.82 %
B – Positive	233	384	34.91 %
B – Negative	21	33	3.00 %
O – Positive	211	334	30.36 %
O – Negative	17	24	2.18 %
AB – Positive	59	94	8.55 %
AB – Negative	3	5	0.45 %
Total	690	1100	100 %

Discussion

In a time of great uncertainty, and predicted new waves associated with newly emerging SARS-CoV-2 variants, these results will help us to target future convalescent plasma collections.

Thousands of severely symptomatic COVID-19 patients requiring hospital admission arrived contemporaneously at the emergency rooms, quickly overcoming hospitalization capacities. In that dramatic situation, considering the scarce therapeutic resources available at that time, we decided to develop a protocol for the collection and infusion of CCP (Covid Convalescent Plasma) to critically ill COVID-19 patients.

Until effective antiviral treatments and vaccines against the COVID-19 pandemic become available, convalescent plasma therapy is an existing option that can be used against this infection.

CCP was in high demand during the surges of the more aggressive and highly transmissible COVID-19 variants. By better understanding the demographics of donors associated with higher anti-SARS-CoV-2 antibody levels and the rates of decline following infection, donors with higher antibody titers could be selectively recruited in the future.

Comparison according to age group of Covid Convalescent Plasma donors:

There was variation in age with highest number of donors in 4th decade, followed by 3rd decade and 5th decade in the present study of Rajkot (2020-2021). Similarly, in the study of Li L *et al.*, 2020 (China)^[20] 4th decade age group consisted of highest number of donors. In the study of Del Fante C *et al.*, 2020 (Italy)^[21] age group of 6th decade and above 60 year were higher in number. In the study of Schmidt AE *et al.*, 2020 (US)^[22] age from 18 to 40 year showed highest number of donors.

Table 6: Comparison according to age group of Covid Convalescent Plasma donors:

Authors		Age in years						Total
		18-20	21-30	31-40	41-50	51-60	61-65	
Li L <i>et al.</i> , 2020 (China) ^[20]	No.	6		27	11	5		49
	%	12		55	23	10		100
Del Fante C <i>et al.</i> , 2020 (Italy) ^[21]	No.	40		96	138	238		512
	%	7.8		18.8	27.1	46.3		100
Schmidt AE <i>et al.</i> , 2020 (US) ^[22]	No.	30821			21419			52240
	%	59			41			100
Present Study, 2020- 2021 (Rajkot)	No.	20	218	251	162	37	2	690
	%	2.90	31.59	36.38	23.48	5.36	0.29	100

Comparison of gender wise distribution of Covid Convalescent Plasma Donors:

In the present study of Rajkot (2020-2021), male donors were more in number as compared to females. Similarly, in studies of Del Fante C *et al.*, 2020 (Italy)^[21], Li L *et al.* 2020 (China)^[20], Mehew J *et al.*, 2022 (England)^[23], Mitu Dogra *et al.*, 2020 (New Delhi)^[24], Usha Saroj *et al.*, 2020 (Ranchi, Jharkhand)^[25] male donors were more in number as compared to females.

Table 7: Comparison of Gender distribution of Covid Convalescent Plasma donors:

Authors	Male	Female	Total	Male: Female Ratio
Del Fante C <i>et al.</i> , 2020 (Italy) ^[21]	437	75	512	5.83: 1
Li L <i>et al.</i> , 2020 (China) ^[20]	33	16	49	2.06: 1
Mehew J <i>et al.</i> , 2022 (England) ^[23]	23024	6561	29585	3.51: 1
Mitu Dogra <i>et al.</i> , 2020 (New Delhi) ^[24]	727	23	750	31.61: 1
Usha Saroj <i>et al.</i> , 2020 (Ranchi, Jharkhand) ^[25]	206	2	208	103: 1
Present study, 2020-2021(Rajkot)	675	15	690	45: 1

Comparison according to blood group wise distribution of Covid Convalescent Plasma donors:

In the present study of Rajkot (2020-2021), B positive blood group was more common which was same as compared to the study of Usha Saroj *et al.*, 2020 (Ranchi, Jharkhand)^[25]. While in the study of Mitu Dogra *et al.*, 2020 (New Delhi)^[24] according to the available data, combined B positive and B negative donors were more common in comparison to other blood group donors. In contrast, in the study of Jain S *et al.*, 2020 (New York)^[26] O positive donors were more in number.

Table 8: Comparison according to blood group wise distribution of Covid Convalescent Plasma donors:

Authors	Mitu Dogra <i>et al.</i> , 2020 (New Delhi) ^[24]		Usha Saroj <i>et al.</i> , 2020 (Ranchi, Jharkhand) ^[25]		Jain S <i>et al.</i> , 2020 (New York) ^[26]		Present study, 2020-2021 (Rajkot)	
	No.	%	No.	%	No.	%	No.	%
A – Positive	165	22	40	19.23	4193	35.5	127	18.41
A – Negative			00	00		5	19	2.75
B – Positive	331	44.13	85	40.87	1746	14.8	233	33.77
B – Negative			01	0.48			21	3.04
O – Positive	186	24.8	60	28.85	5260	44.6	211	30.58
O – Negative			04	1.92			17	2.46
AB – Positive	68	9.07	17	8.17	595	5.05	59	8.55
AB – Negative			01	0.48			3	0.44
Total	750	100	208	100	11794	100	690	100

Comparison of donation frequency of Covid Convalescent Plasma donors:

In the present study of Rajkot (2020-2021), donors who donated once were more in number as compared to repeated donors. Similarly, in other studies of Del Fante C *et al.*, 2020 (Italy)^[21], Lasky B *et al.*, 2020 (US)^[27], Mitu Dogra *et al.*, 2020 (New Delhi)^[116], donors who donated once were more in number as compared to repeated donors. While in the study of Schmidt AE *et al.*, 2020 (US)^[22], repeated donors were more in number as compared to donors who donated once.

Table 9: Comparison of donation frequency of Covid Convalescent Plasma donors:

Authors	Donated once		Donated repeatedly		Total	
	No.	%	No.	%	No.	%
Schmidt AE <i>et al.</i> , 2020 (US) ^[22]	8399	16	43841	84	52240	100
Del Fante C <i>et al.</i> , 2020 (Italy) ^[21]	427	86	67	14	494	100
Lasky B <i>et al.</i> , 2020 (US) ^[27]	5751	56.2	4480	43.8	10231	100
Mitu Dogra <i>et al.</i> , 2020 (New Delhi) ^[24]	390	52	360	48	750	100
Present study, 2020-2021 (Rajkot)	552	80	138	20	690	100

Comparison according to type of donor (voluntary/replacement) for plasmapheresis procedure of collection of Covid Convalescent Plasma:

In the present study of Rajkot (2020-2021), replacement donors of plasmapheresis were more in number as compared to voluntary donors which was similar to that in the study of Mitu Dogra *et al.*, 2020 (New Delhi)^[24].

Table 10: Comparison according to type of donor (voluntary/replacement) for plasmapheresis procedure of collection of Covid Convalescent Plasma

Authors	Voluntary donor	Replacement donor	Total
Mitu Dogra <i>et al.</i> , 2020 (New Delhi) ^[24]	144	606	750
Present study, 2020-2021 (Rajkot)	230	232	462

Comparison according to outcome of procedure for collection of Covid Convalescent Plasma

In the present study of Rajkot (2020-2021), failed tap was only 3.46 % which was similar with the study of Del Fante C *et al.*, 2020 (Italy)^[21] in which failed tap was only 3.17 %.

Table 11: Comparison according to outcome of plasmapheresis procedure for collection of Covid Convalescent Plasma

Authors	Successful		Failed tap		Total	
	No.	%	No.	%	No.	%
Del Fante C <i>et al.</i> , 2020 (Italy) ^[21]	488	96.83	16	3.17	504	100
Present study, 2020-2021 (Rajkot)	446	96.54	16	3.46	462	100

Conclusion

Several factors may be associated with anti- SARS- CoV- 2 antibody response including donor age and sex. Evaluating these factors during development of future hyperimmune globulin products may help generation of therapies with optimal efficacy.

An analysis of 690 Covid Convalescent Plasma donors was done in the present study.

The parameters included in the study are age, gender, blood group, frequency of donors donating plasma as once or repeated donations, type of procedure for collecting plasma, whether the donors were voluntary or replacement donors of plasma.

In the present study, age group of donors in 4th decade showed highest number of donations of plasma.

Male donors were more in number as compared to females in the ratio 45: 1. Male donor or a nulliparous female donor with a negative history of blood component transfusion was an eligibility criteria for donation. To avoid the risk of Transfusion Related Acute Lung Injury (TRALI) preference should be given to use of plasma from male donors or from female donors who have never been pregnant including abortions. This measure lowers the possibility of presence in the plasma of the antibodies to HLA (Human Leukocyte Antigen) or granulocyte antigens that cause TRALI.

Among all the blood groups, donors with blood group 'B positive' were more in number, followed by 'O positive', 'A positive', 'AB positive' and all negative blood groups out of which least number of donors were of blood group 'AB negative'. This suggests that all blood group type donors were having antibodies against SARS-CoV-2.

In the present study, plasma was collected with the help of apheresis procedure (462 donations) as well as separation of plasma from whole blood (228 donations) of donors. Separation of plasma from whole blood of donors was done when the criteria for doing apheresis procedure was not fulfilled like accessibility of both cubital veins in selected kits like requiring double needles for donation, if donor has less time and is time bound for donating plasma and other factors like donor's willingness for donating whole blood.

The advantage of doing apheresis procedure is that it helps to collect more amount of plasma (2 units of plasma) from a single donor while only one unit of plasma is collected from separation procedure of whole blood of a single plasma donor.

Other advantage of apheresis procedure is that it can be repeated every 15 days in a single donor while plasma from whole blood of a single donor can be collected once in every 3 months.

Voluntary plasma donors (448) were more in comparison to number of replacement plasma donors (242); and out of total donors, first time donors were 80% while repeated donors were 20% which signifies that there was increased awareness regarding donation of plasma in general population that many donors were donating plasma for the first time and were being helpful for management of SARS-CoV-2.

In the plasmapheresis procedure, there was 92.21 % (2 units each from one procedure) complete success rate of collection of plasma, while 4.33 % (1 unit each from one procedure) incomplete success rate of collection of plasma, with only 3.46 % failure rate (failed tap), which signifies the importance of plasmapheresis procedure in collection of Covid Convalescent Plasma for management of COVID-19 patients.

Thus, in the end, 690 Covid Convalescent Plasma donors donated plasma in good faith of helping COVID-19 patients and total effective plasma units collected were 1100 in number.

People who recover from the coronavirus have developed antibodies to the virus that remain in the plasma portion of their blood. Transfusing plasma that contains the antibodies into a person still fighting the virus can provide a boost to the patient's immune system and potentially help them recover.

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