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CONVALESCENT PLASMA THERAPY: A PROMISING APPROACH IN THE TREATMENT OF COVID-19

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ABSTRACT: At present, the whole world fronting a very challenging situation of the pandemic, severe acute respiratory syndrome due to coronavirus (COVID-19). Today, COVID-19 is spreading rapidly in every part of the world; these pandemic affected billions of people. This virus is found as a new human pathogen. However, currently, there is no hasty therapy available, which will provide fruitful results in this regard. As per previously reported data, human convalescent serum (plasma) will be a great choice for the rescue patients from COVID-19 infection, and it will be readily available if there are adequate numbers of people who have recovered and can donate immunoglobulin consisting serum. It includes the administration of antibodies against a given agent to an affected individual for the cause of treating an infectious disease due to the virus. In disparity, active vaccination involves the induction of an immune response that takes time to develop and varies depending on the vaccine recipient. The plasma therapy has a storied history going back and founds as well reported to treat multiple types of viral diseases. In the current review, we tried to explore and systematically discussed how plasma therapy will create a boon for humans to fight against the novel coronavirus disease.

INTRODUCTION: As of late 2019, the whole world is provoking a pandemic in severe acute respiratory syndrome coronavirus 2 (COVID-19). During this writing, COVID-19 covers almost all countries globally, frightening a pandemic that affected billions of people. This virus seems to be a novel human pathogen.

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Presently there are no vaccines, monoclonal antibodies (moAb), or promising drugs available for COVID-19, even though several are in rapid development, and lots of may be existing in a short time.

Present Lookout claims that human serum is a choice for the prevention and treatment of COVID-19 disease that could be quickly available when there are adequate numbers of people who have recovered and can donate immunoglobulin-containing serum [1-4]. Antibody therapy includes the administration of antibodies in contradiction of a given agent of a vulnerable individual for the persistence of preventing or treating an infectious

disease due to that agent. In divergence, active vaccination needs the induction of an immune response that receipts time to progress and varies liable on the vaccine recipient. Consequently, antibody administration is the mere means of providing instant immunity to susceptible persons. Antibody therapy has a great history going back to the 18th century and was the only way of treating definite infectious diseases earlier in the development of antimicrobial therapy on the 19th. [1, 5] Antibody therapy includes the management of antibodies in contrast to a given agent to a susceptible individual for the purpose of preventing or treating an infectious disease due to that agent. Knowledge from previous outbreaks with other coronaviruses, such as SARS-CoV-1, displays that such convalescent sera comprise neutralizing antibodies to the relevant virus [6, 7].

In regards to COVID-19, the anticipated mechanism of action by which antibody therapy would mediate protection is viral neutralization. Nevertheless, other mechanisms may be possible, like antibody-dependent cellular cytotoxicity or phagocytosis. Promising sources of antibody for COVID-19 are human convalescent sera from individuals who have recovered from COVID-19 itself, moAb, or preparations generated in convinced animal hosts, such as genetically engineered cows that give human antibody [5, 8, 9]. Even though many forms of preparations will soon be under development, the mere antibody type that is presently available for immediate use is that it originate in human convalescent sera. As more individual contracts COVID-19 and recover, the number of possible donors will continue to upsurge.

A common principle of antibody therapy is that it is more operative when used for prophylaxis than for treatment of disease. While used for therapy, antibody is of utmost effective when administered shortly subsequently, the onset of symptoms. The motive for temporal variation in efficacy is not well assumed but could reflect that passive antibody works by neutralizing the initial inoculum, which is likely to be much smaller than that of established disease [10-12]. Another clarification is that antibody works by adapting the inflammatory response, which is similarly more effortless accomplished throughout the early immune response, a stage that may be asymptomatic. For example, passive antibody therapy for pneumococcal pneumonia was supreme effective when directed shortly after the onset of symptoms, and there was no use if antibody administration was postponed past the third day of disease [13-16].

History of Convalescent Plasma Therapy: At the beginning of 20th-century, convalescent sera were applied to stem outbreaks of viral infections such as poliomyelitis, measles, mumps, and influenza [17-20]. The analytical study on the use of convalescent sera involving 1703 patients throughout the 1918 H1N1 influenza virus pandemic recommended that those who received serum had lower mortality. In contrast, the efficacy of convalescent sera diverse with the virus, and the study was performed.

There was a compromise at the time that this interference was useful, and it was used in many epidemics. It is remarkable that traditionally, convalescent sera were developed and used in many cases lacking the means to measure antibody titers or knowledge about viral serotypes and in clinical studies that did not encounter modern standards for randomization or blinding [21]. More lately, convalescent serum was applied during viral epidemics. In the year 2009-10, the H1N1 influenza virus pandemic, convalescent serum antibody preparations obtained by apheresis, were applied to treat persons with severe H1N1 2009 contagious demanding rigorous care. Serum-treated person's demonstrated reduced respiratory viral burden, serum cytokine responses, and mortality [22]. Convalescent serum was similarly used in the 2013 West African Ebola epidemic [23, 24].

Sierra Leone was revealed longer existence meaningfully for those treated with convalescent entire blood comparative to those who received standard treatment [24]. There is untrustworthy evidence from the H5N1 [25] and H7N9 [26] avian flu outbreaks that applied of convalescent sera were effective, with all patients surviving. Even though every viral disease and epidemic is different, these knowledge liver significant historical examples that is mutually reassuring and beneficial as humanity now provokes the COVID-19 epidemic [27]. **Fig. 1** represents the schematic representation of the plasma therapy for the prevention of the coronavirus infection.

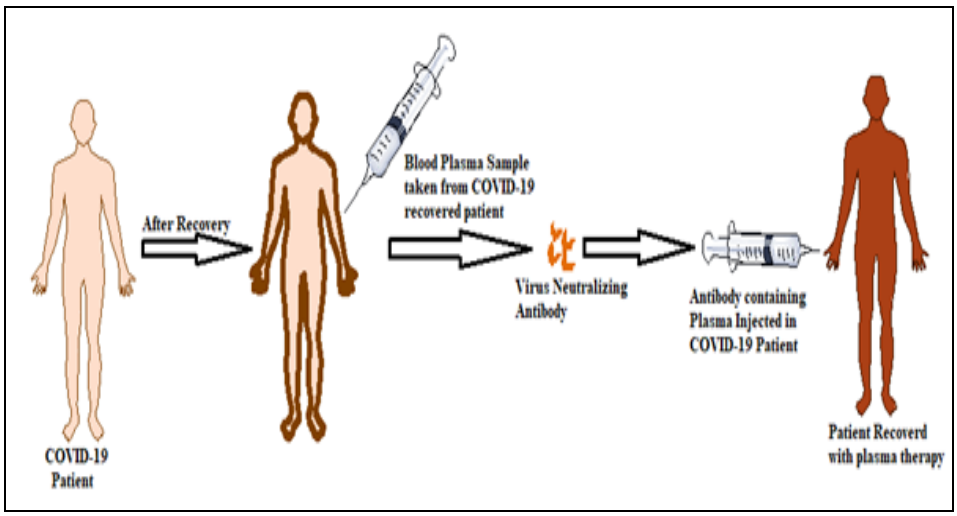

FIG. 1: SCHEMATIC REPRESENTATION OF THE USE OF PLASMA THERAPY IN COVID-19 SUFFERED PATIENT

Reported Results with the Use of MoAb against Covid-19: At the beginning of the 21st century, there have been two other epidemics with coronaviruses that were related to high mortality, Severe Acute respiratory syndrome (SARS1) in 2003 and the Middle East respiratory syndrome (MERS) in 2012. The SARS1 epidemic was controlled, but MERS became endemic in the Middle East and prompted a major secondary outbreak in South Korea. In mutual outbreaks, the high mortality and lack of effective therapies led to the usage of convalescent serum. The major study intricate the treatment of almost 80 patients with SARS in Hong Kong is reported. Patients treated earlier day 14 had enhanced prognosis defined by discharge from hospital before day 22, reliable with the concept that earlier administration is more likely to be active. Additionally, those who were polymerase chain reaction (PCR) positive and seronegative for coronavirus at the time of therapy had enhanced prognosis [28, 29]. There is also some unreliable information on the use of convalescent serum is extremely ill individuals. Three patients with SARS in Taiwan were treated with 500 mL convalescent serum, occasioning in a reduction in serum virus titer, and each lived [28, 30, 31].

TABLE 1: APPROVED IMMUNE GLOBULINS FOR TREATMENT OF DIFFERENT VIRAL DISEASES

S. no.	Common Name	Trade Name	Dose	Symptoms	References
1.	Rabies Immune Globulin (Human) (HRIG)	Rabies-HT Bayrab, IMOGAM	20 IU/kg	Post exposure prophylaxis	41,42
2.	Cytomegalovirus Immune globulin IV (Human)	CytoGam	150 mg/kg I.V.	Prophylaxis of CMV disease associated with organ transplantation	41,43
3.	Immune Globulin (Human)	BayGam	0.02 ml/kg I.M.	Pre-exposure prophylaxis for Hepatitis A and Post-exposure prophylaxis for Hepatitis A	41,44
4.	Varicella Zoster Immune Globulin (Human) (VZIG)	*	125 U/ 10 kg I. m.	High-risk Person exposed to varicella virus	41,45
5.	Hepatitis B Immune Globulin (Human) (HBIG)	BayHep B, Nabt-HB	0.5 ml i. m.	Infants born to HBsAg positive mothers,	41,46
6.	Vaccinta Immune Globulin (Human) (IGIV)	*	0.6 ml/kg I.m.	Therapy of complications with vaccinta vaccination	41
7.	Palivizumab	Synagis	15 mg/kg I. m.	Prevention of serious lower respiratory tract disease caused by RSV	41,47
8.	Respiratory Syncytial virus immune globulin I.V. (Human) (RSV-IGIV)	ResptGam	750 mg/kg I.V.	Prevention of serious lower respiratory tract infection caused by RSV	41,48

*Data not found

Three patients with MERS in South Korea were treated with convalescent serum, but merely two of the recipients had neutralizing antibodies in their serum [32]. The latter study highpoints a challenge in using convalescent sera, specifically that some who improve from the viral disease may not have high titers of neutralizing antibody. Dependable with this point, an analysis of 99 samples of convalescent sera from patients with SARS indicated that 87 had neutralizing antibody, with a

geometric mean titer of 1: 61 [33, 34]. This recommends that antibody regressions with time or that some patients make high titer responses. It is also conceivable that non-neutralizing antibodies are manufactured that donate to protection and recovery, as designated for other viral diseases [35, 36] **Table 1** showing the approved immune globulins for the treatment of different viral diseases in the USA. It is reported that convalescent serum was applied for the therapy of patients with COVID-19 in China during the current outbreak. Even though some details are existing from the epidemic in China and available studies intricate small numbers of patients, the published information advises that convalescent serum administration abridged viral load and was safe [37-40].

Effectiveness of Convalescent Plasma Therapy in Covid-19: According to the recent study, elaborates on the feasibility of convalescent plasma therapy in COVID-19. All enrolled severe COVID-19 patients achieved primary and secondary outcomes. One dose of 200-ml convalescent plasma transfusion was well tolerated, while the clinical symptoms significantly improved with the increase of oxyhemoglobin saturation within 3 d, accompanied by rapid neutralization of viremia. Severe pneumonia caused by human coronavirus was characterized by rapid viral replication, massive inflammatory cell infiltration, and elevated pro-inflammatory cytokines or even cytokine storm in alveoli of lungs, resulting in acute pulmonary injury and acute respiratory distress syndrome (ARDS) [49].

Recent studies on COVID-19 demonstrated that the lymphocyte counts in the peripheral blood were remarkably decreased and the levels of cytokines in the plasma from patients requiring intensive care unit (ICU) support, including IL-6, IL-10, TNF-α, and granulocyte-macrophage colony-stimulating factor, were significantly higher than in those who did not require ICU conditions [50]. Convalescent plasma, obtained from recovered COVID-19 patients who had established humoral immunity against the virus, contains a large quantity of neutralizing antibodies capable of neutralizing SARS-CoV-2 and eradicating the pathogen from blood circulation and pulmonary tissues [51, 52]. In this study, all investigated patients achieved serum SARS-CoV-2 RNA negativity after convalescent plasma transfusion, accompanied by an increase of oxygen saturation and lymphocyte counts and the improvement of liver function. Based on our preliminary results, convalescent plasma therapy can be an easily accessible, promising, and safe rescue option for severe COVID-19 patients. However, the dynamics of the viremia of SARS-CoV-2 was unclear, so the optimal transfusion time point needs to be determined in the future. In the present study, no severe adverse effects were observed [53]. One of the risks of plasma transfusion is the transmission of potential pathogen. Methylene blue photochemistry was applied in this study to inactivate the potential residual virus and to maintain the activity of neutralizing antibodies as much as possible, a method known to be much better than ultraviolet (UV) C light [54].

No specific virus was detected before transfusion. Transfusion-related acute lung injury was reported in an Ebola virus disease woman who received convalescent plasma therapy [55]. Although uncommon in the general population receiving plasma transfusion, this specific adverse reaction is worth noting, especially among critically ill patients experiencing significant pulmonary injury [56]. Another rare risk worth mentioning during convalescent plasma therapy is antibody-dependent infection enhancement, occurring at subneutralizing concentrations, which could suppress innate antiviral systems and thus could allow logarithmic intracellular growth of the virus [57]. The special infection enhancement also could be found in SARS-CoV infection *in-vitro*.

No such pulmonary injury and infection enhancement were observed in our patients, probably owing to high levels of neutralizing antibodies, timely transfusion, and appropriate plasma volume. There were some limitations to the present study. First, except for convalescent plasma transfusion, the patients received other standard care. All patients received antiviral treatment despite the uncertainty of the efficacy of drugs used [58, 59]. As a result, the possibility that these antiviral agents could contribute to the recovery of patients, or synergize with the therapeutic effect of convalescent plasma, could not be ruled out. Furthermore, some patients received glucocorticoid therapy, which might interfere with immune response and delay virus clearance. Second, the

median time from the onset of symptoms to convalescent plasma transfusion was 16.5 d [60]. Although the kinetics of viremia during the natural history remains unclear, the relationship between SARS-CoV-2 RNA reduction and convalescent plasma therapy, as well as the optimal concentration of neutralizing antibodies and treatment schedule, should be further clarified. Third, the dynamic changes of cytokines during treatment were not investigated. Nevertheless, the preliminary results of this trial seem promising, justifying a randomized controlled clinical trial in a larger patient cohort. In conclusion, this pilot study on convalescent plasma therapy shows a potential therapeutic effect and low risk in the treatment of severe COVID-19 patients. One dose of convalescent plasma with a high concentration of neutralizing antibodies can rapidly reduce the viral load and tends to improve clinical outcomes. The optimal dose and treatment time point, as well as the definite clinical benefits of convalescent plasma therapy, need to be further investigated in randomized clinical studies [61, 62].

Threats and Paybacks of the Treatment: COVID-19 convalescent sera can be applied for either prophylaxis of infection or treatment of disease. In a prophylactic mode, the advantage of convalescent serum administration is that it can stop the infection and succeeding disease in those who are at high risk for disease, like susceptible individuals with fundamental medical conditions, health care providers, and those with an introduction to confirmed cases of COVID-19. Antibody administration to stop the disease is previously applied in clinical practice. For example, patients visible to hepatitis B and rabies viruses are treated with hepatitis B immune globulin (HBIG) and human rabies immune globulin (HRIG), correspondingly.

Additionally, the passive antibody is applied for the prevention of severe respiratory syncytial virus (RSV) disease in high-risk infants. While waiting for recently, a polyclonal hyperimmune globulin organized from samples of donors with high serum titers of RSV neutralizing antibody was applied, but these preparations have now been interchanged by Palivizumab, a humanized murine moAb. Applied therapeutically, convalescent serum would be administered to those with clinical disease in an exertion to decrease their symptoms and mortality. The effectiveness of these methods cannot be inferred lacking carrying out a controlled clinical trial. Grounded on the historical knowledge with antibody administration, it can be expected that antibody administration would be more operative in avoiding disease than in the treatment of established disease [1, 63]. Risks of passive administration of convalescent sera fall into two categories, known and theoretical. Known risks are those related to the transfer of blood substances, which comprise unintentional infection with alternative infectious disease agents and reactions to serum constituents, comprising immunological reactions like serum sickness. By means of modern blood banking methods that screen for blood-borne pathogens and match the blood type of donors and recipients, the risks of unintentionally transporting known infectious agents or triggering transfusion reactions are low [64]. Nevertheless, convalescent sera applied in a therapeutic mode would likely be administered to persons with pulmonary disease, in whom plasma infusion transmits some risk for transfusion-associated acute lung injury, and this must be a deliberation in the risk-benefit assessment [65].

The theoretical risk includes the phenomenon of antibody reliant on the enhancement of infection. It can occur in numerous viral diseases and comprises an improvement of disease in the existence of certain antibodies. For coronaviruses, numerous mechanisms for antibody reliant on the enhancement of infection have been defined, and there is the theoretical anxiety that antibodies to one type of coronavirus could improve infection to another viral strain. It may be likely to predict the risk of antibody reliant on enhancement of infection of COVID-19 experimentally, as proposed for MERS [66-68].

Meanwhile, the suggested use of convalescent sera in the COVID-19 epidemic would depend on preparations with high titers of neutralizing antibody in contradiction of the same virus, SARS2-COVID-19, antibody reliant on the enhancement of infection may be unlikely. The obtainable evidence from the use of convalescent sera in patients with SARS1 and MERS and untrustworthy evidence from its use in 245 patients with COVID-19, recommend it is safe [69].

However, in convalescent serum trials, attention, and vigilance to recognize any indication of improved infection will be essential. Alternative theoretical risk is that antibody administration to those showing to SARS-COVID-19 may stop the disease in a manner that weakens the immune response, leaving such persons susceptible to subsequent reinfection. In this regard, passive antibody administration before vaccination with the respiratory syncytial virus was reported to attenuate humoral but not cellular immunity. This concern could be examined as part of a clinical trial by evaluating immune responses in those exposed and treated with convalescent sera to prevent disease. If the risk proved real, these persons could be vaccinated against COVID-19 when a vaccine becomes available [70, 71].

Disposition and proposed use to deploy convalescent serum administration for COVID-19 the following six conditions must be met: (i) availability of a population of donors who have improved from the disease and can donate convalescent serum; (ii) blood banking amenities to process the serum donations; (iii) availability of assays, comprising serological assays, to detect SARS-COVID-19 in serum and virological assays to measure viral neutralization; (iv) virology laboratory support to perform these assays; (v) prophylaxis and therapeutic protocols, which should ideally comprise randomized clinical trials to assess the effectiveness of any intervention and measure immune responses; and (vi) regulatory compliance, counting institutional review board approval, which may vary reliant on location. Preferably, the use of convalescent serum would include multiple centers, follow randomized control protocols, and have a single center as a governing body.

Each of these conditions should be obtainable in established areas affected by COVID-19. At least one pharmaceutical company, Takeda, is gearing up to generate antibody preparations against SARS2 from COVID-19 convalescent sera. Manufacturing highly purified preparations comprising a high titer of neutralizing antibodies against SARS2-COVID-19 is desirable to convalescent sera, given that these are safer and have higher activity [72]. Inappropriately, such preparations will not be obtainable for many months, whereas nearby manufactured convalescent sera could be available much sooner. We anticipate that once the necessary regulatory permissions are in place, persons who convalesce from COVID-19 can be advanced to donate blood for serum preparation or antibody isolation overapheresis. Retrieval from COVID-19 will be measured clinically and such persons must be shown to free of SARS-CoV-2, comprising in their blood by appropriate viral nucleic acid screening. Provided blood products will be screened for infectious agents conferring to current blood banking practices, and individual sera will be studied for specific antibody content and neutralizing activity to SARS-CoV-2.

Depending on the volumes needed and the neutralizing activity of donated convalescent sera, these could be pooled or used individually, and preparations for clinical use would be treated for pathogen attenuation. At this time, we do not know what an effective neutralizing titer would be in a vulnerable individual given antibody therapy for prophylaxis, and responsible this parameter would be part of the study design. Correspondingly, we do not know what doses would be effective therapeutically. We do know that when convalescent serum was applied to prevent measles or mumps the quantities used. In contrast, when convalescent serum was appliedto treat severe disease in soldiers with 1918 influenza, the sums given were in the hundreds of milliliters. These older studies appealed efficacy even however, convalescent serum was given deprived of any knowledge of neutralizing titers [73] that knowledge's recommend that even small amounts of antibody may prevent or treat the infection.

Therefore, we can anticipate that effective prophylactic doses would be much smaller than the therapeutic dose. This makes sense; subsequently, the contaminating inoculum is likely to be much smaller than the viral liability throughout severe disease [74, 75]. COVID-19 convalescent sera could be applied to treat individuals with initial symptoms and prevent disease in those exposed. Nowadays, several physicians, paramedical staff, and first responders showing to known cases of COVID-19, some of whom have established disease, are being quarantined, which threatens to fail the health care system.

It is expected that convalescent serum will prevent COVID-19 infection in those to whom it is administered. If this is recognized, persons who receive convalescent sera may be able to avoid a period of quarantine. This could permit them to maintain their critical function as health care providers.

Convalescent serum could also be used to avoid disease among family members caring for COVID-19 patients at home. Obviously, the application of convalescent serum would be a substitute amount that could be applied in the midst of the current epidemic.

Nevertheless, even the local arrangement will involve substantial coordination between different individuals, such as communicable disease specialists, hematologists, blood banking specialists, and hospital administrators. Therefore, as we are in the midst of a worldwide pandemic, we recommend that organizations consider the emergency use of convalescent sera and starting preparations as soon as possible [75, 76].

CONCLUSION: The necessity to treat the emergent novel coronavirus that created global influence shielding light on developing monoclonal antibody grounded immunotherapy to offer a rapid effect. Nevertheless, there is an important improvement towards the development of monoclonal antibody therapy for coronavirus infection, no monoclonal antibodies have yet been successfully marketed for coronavirus, but recently many countries have started the plasma therapy with the approval of concern authorities.

The growing understanding on MERS and SARS in contemporary years might stimulate the research community to find out important advancement in the COVID-2019 therapy in an augmented time by using the current invention. Further, a detailed understanding of the virus pathogenesis might increase the opportunities for the realistic design of therapeutic agents to treat novel coronavirus. This is the time to use the expertise of all researchers in the world to find out the treatment for the coronavirus with the goal of saving humans and humanity.

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