Study shows convalescent plasma doesn't benefit severely ill patients hospitalized with COVID-19

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Convalescent plasma, widely given to severely ill patients hospitalized with COVID-19 during the pandemic, does not improve their ability to

survive or recover, according to a national clinical trial led by Vanderbilt University Medical Center and published in the journal *CHEST*.

The multicenter blinded, randomized placebo-controlled, Passive Immunity Trial for our Nation (PassITON), looked at the efficacy and safety of COVID-19 convalescent plasma therapy for adults hospitalized with moderate to severe COVID-19 within 14 days of the onset of symptoms.

The rationale for using convalescent plasma for acute viral infections like COVID-19 has been that transfusing the plasma component of blood from a patient who has recently recovered from the same disease to a patient early in the stage of infection might provide the currently infected patient with antibodies against the infecting virus, helping them recover more quickly.

"During this trial, we were fortunate to have tremendous collaboration among thousands of people across the country, including patients, families, clinicians, study personnel at 25 hospitals and a wonderful team at VUMC," said Wesley Self, MD, MPH, associate professor of Emergency Medicine, vice president for Clinical Research Networks and Strategy at VUMC and lead author of the study. "We asked a very specific question in this study: At time of hospital admission when a patient is severely ill with COVID, does the transfusion of convalescent plasma available to clinicians in the U.S. improve the ability to recover and survive? The answer is clearly no."

"Providing passive immunity with convalescent plasma does not appear to benefit patients once their illness has progressed to the point of needing treatment in the hospital. Despite receiving convalescent plasma with a higher titer of neutralizing antibodies, the therapy did not help hospitalized patients," said Todd Rice, MD, MSc, associate professor of Medicine, vice president for Clinical Trial Innovations and Operations at

VUMC, and senior author of the study.

In the study 960 adults hospitalized with COVID-19 were randomized into two groups—those receiving one unit of convalescent therapy and those receiving placebo. The results showed that the two groups had nearly identical clinical outcomes; at 28 days following treatment, 18.5% of patients in the convalescent plasma group and 17.2% of patients in the placebo group had died.

The study was led by the Vanderbilt Institute for Clinical and Translational Research (VICTR). It was funded at the beginning by the Dolly Parton COVID-19 Research Fund, then expanded into a multicenter study in September 2020 with funding from the National Center for Advancing Translational Sciences of the National Institutes of Health.

COVID-19 caused about 450 million people to become ill and 6 million deaths worldwide during the first two years of the pandemic. From the beginning, convalescent plasma was heralded as a potentially promising treatment.

But rather than administering an unproven therapy to patients, the clinical and research enterprise at VUMC decided to take a safe and controlled approach, looking at the evidence behind the idea that convalescent plasma would help.

"We decided instead of jumping on the ship and giving convalescent plasma to all of our COVID-19 patients at Vanderbilt, we were going to do a proper trial," Self said.

"VUMC is a true academic medical center, and conceptualized, coordinated and/or participated in a large number of randomized clinical trials," said Jill Pulley, MBA, research professor of Medicine and

VICTR executive director. "This trial investigated an unproven intervention…it was beautifully executed, and although the results are unfortunate—we wish the therapy did work—they illustrate why trials are always needed," she said.

Self said although the VUMC study is the most well-controlled trial of COVID-19 convalescent plasma in hospitalized patients, other studies have been conducted over the past couple of years showing similar results—that convalescent plasma as a therapy for those hospitalized with COVID-19, at least as currently deployed, doesn't work. "It's solid evidence," he said.

For more than a year VUMC enrolled patients, and with the help of Blood Assurance, a blood donation center, developed its own "pipeline" of convalescent plasma.

Jillian Rhoads, Ph.D., senior scientific project manager at VICTR, said that blood for the convalescent plasma trial was collected at VUMC and shipped across the country to the other 24 hospitals participating in the study.

"So many generous Vanderbilt employees and community members donated plasma and truly kept our study going," she said. "It was amazing that they were able to give enough plasma to enable a nearly 1,000-patient, 25-center trial."

More information: Wesley H. Self et al, Neutralizing COVID-19 Convalescent Plasma in Adults Hospitalized with COVID-19: A Blinded Randomized Placebo-Controlled Trial, *Chest* (2022). DOI: 10.1016/j.chest.2022.06.029

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