Original Article

COVID-19 seropositive donors yield comparable post-lung transplant outcomes

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Background: Recent reports have suggested that coronavirus disease 2019 (COVID-19) infection can cause pneumonitis even in the absence of clinical symptoms and COVID-19 associated pulmonary inflammation can persist resulting in long-term fibrosis. This single-center study utilized standardized immunological testing to determine whether lungs from COVID-19 seropositive donors, indicative of past COVID-19 infection, can be safely used for clinical transplantation.

Methods: The study included 90 consecutive lung transplant procedures incorporating donor serological testing for past COVID-19 infection. Donors were negative for active COVID-19 infection and met institutional criteria to be used for lung transplantation. The outcomes of lung transplant recipients were compared between donors with and without serological evidence of past COVID-19 infection.

Results: No significant difference was found in post-transplant survival rates between recipients of lungs obtained from donors with serological evidence compared to those without. Additionally, there were no significant differences in primary graft dysfunction grade 3 rates or other post-transplant clinical parameters, such as operative time, ischemic time, extracorporeal membrane oxygenation use, intensive care unit stay, and hospital stay.

Conclusions: Our findings suggest that lungs from COVID-19 seropositive donors, but not active COVID-19 infection are safe and feasible for transplantation, yielding comparable post-transplant outcomes to donors who are negative COVID-19 antibodies. This study supports the utilization of lungs from donors with historic COVID-19 infection as long as they meet current transplant criteria, potentially addressing the concerns related to the use of such organs.

Keywords: Coronavirus disease 2019 (COVID-19); lung transplant; primary graft dysfunction (PGD)

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Introduction

With the pandemic causing millions of coronavirus disease 2019 (COVID-19) cases worldwide, concerns have arisen about lung donation after COVID-19 infection. This is of particular concern since COVID-19 can cause pneumonitis without causing overt clinical symptoms which can potentially result in long-term fibrosis (1,2). While solid organ transplants from donors with recent or active COVID-19 have been done, lungs are sometimes excluded due to the unclear impact of COVID-19 on the respiratory system (3-5). Notably, severe consequences have ensued when lungs from a donor with COVID-19 were unknowingly transplanted (3,4). Even cases with mild or no symptoms can manifest noticeable lung damage on radiographs (2,6,7), leading to apprehensions about potential graft dysfunction or increased mortality from using lungs of donors with past COVID-19. Nonetheless, given the extent of COVID-19, outright rejection of donors with a history of the infection would worsen the existing organ deficit. While it's clear that lungs from donors with active COVID-19 infection should be excluded, the safety of lungs from recovered donors hasn't been well defined. Owing to the absence of reported outcomes after transplanting lungs from donors with a prior COVID-19 history, a consensus on their safety is lacking. Anecdotally, we and others have noted successful lung transplants from recovered COVID-19 donors without subsequent primary graft dysfunction (PGD) or early mortality (8-10). Though the long-term outcomes of such transplants remain uncertain, based on these initial successes, we hypothesized that a past COVID-19 infection in donors wouldn't compromise long-term results.

Presently, the Organ Procurement and Transplant Network's donor evaluation and documentation practices don't encompass specific details about COVID-19 infection or exposure, limiting our understanding of the infection's nuances and its impact on post-transplant outcomes. We hypothesized that if donor lungs (I) meet the standard criteria for usage, and (II) test negative for COVID-19 using polymerase chain reaction on lower respiratory tract samples, they would yield comparable long-term results, irrespective of prior COVID-19 strain, timing, or severity of infection. Lacking specific COVID-19 data, we relied on seropositivity status to infer past infection, as described elsewhere (11). To distinguish antibodies from immunization, we tested all donors for both COVID-19 and vaccine-induced antibodies. By adopting these immunological evaluations, our study aims to address the dearth of COVID-19 history in lung donors and offer robust evidence supporting the safety and feasibility of transplants from donors recuperated from COVID-19 and meeting the clinical lung transplant criteria.

Highlight box

Key findings

- Donor lungs from individuals with a serologic evidence of prior coronavirus disease 2019 (COVID-19), provided they currently show no signs of active infection (verified by negative PCR testing of lower respiratory fluids), are potentially viable for transplantation.

What is known and what is new?

- With the pandemic causing millions of COVID-19 cases worldwide, concerns have arisen about lung donation after COVID-19 infection. While solid organ transplants from donors with recent or active COVID-19 have been done, lungs are sometimes excluded due to the unclear impact of COVID-19 on the respiratory system. It is unknown if dearth of COVID-19 history in lung donors are safe and feasible for lung transplant.

What is the implication, and what should change now?

- This study highlights that lungs from COVID-19 seropositive donors, but do not have an active COVID-19 infection could be safe and feasible for lung transplantation, yielding comparable post-transplant outcomes to donors who have negative COVID-19 antibodies.

Methods

Study design

Patient data were collected retrospectively using electronic medical records that were stored in a database at the Northwestern University Medical Center in Chicago, Illinois, USA. Consecutive adult patients who underwent lung transplantation at our institution, between January 2018 and June 2023, were included. Patients who underwent multiorgan transplants were excluded from the study. Data on patient demographics, comorbidities, donor characteristics, preoperative laboratory values, intraoperative, and postoperative outcomes were collected. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The retrospective study was approved, with a waiver of consent, by the Institutional Review Board of Northwestern University (Nos. STU00207250 and STU00213616) prior to any data collection.

Donor assessment

All donors met the standard criteria for lung transplantation and were microbiologically confirmed to be negative for active COVID-19 by at least two polymerase chain reaction (PCR) tests conducted using a nasopharyngeal swab and lower respiratory fluid, as performed as standard of care by the organ procurement organization. Donor blood was collected in the donor facility and was tested for anti-severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) nucleocapsid total antibodies (this test detected total immunoglobulin), anti-SARS-CoV-2 spike protein IgG, and IgM (both tests were performed by the Beckman Access SARS-CoV-2 IgG, IgM method) (the quantification range was between 0.4 and 2,500.0 U/mL; and 0.8 U/mL is used as a cutoff for positivity). History of donor COVID-19 or history of vaccination was found to be unreliable as less than 2% of all donors had a documented history of COVID-19, which is inconsistent with the reported incidence of COVID-19 in the general population.

Definition of complications

PGD

Patients with no evidence of pulmonary edema on chest X-ray (CXR) were considered grade 0. The absence of invasive mechanical ventilation was graded according to the partial pressure of oxygen (PaO_2)/fraction of inspiratory oxygen concentration (FiO_2) ratio using methods similar to those used for mechanical ventilation. If PaO_2 was not available for calculation of the PaO_2/FiO_2 ratio, then an oxygen saturation/FiO_2 ratio was used. Grade 1: PaO_2/FiO_2 ratio >300; grade 2: PaO_2/FiO_2 ratio is 200–300; grade 3: PaO_2/FiO_2 ratio <200. The lowest PaO_2/FiO_2 ratio, within 72 hours of lung transplantation, was used. The use of ECMO for bilateral pulmonary edema on CXR images was classified as grade 3. Continuous use of ECMO without pulmonary edema on CXR imaging was excluded (12).

Acute kidney injury (AKI)

AKI was defined using the risk, failure, loss of kidney function, and the end-stage kidney disease classification (13).

Statistical analysis

Recipient and donor characteristics, preoperative laboratory values, and intra- and post-operative outcomes were compared. Transplant outcomes prior to and after the onset of the COVID-19 pandemic were determined. Additionally, outcomes were compared with the use of donor lungs classified by serological testing, using anti-SARS-CoV-2 nucleocapsid antibodies. The Mann-Whitney *U* test or Student *t*-test was used to compare independent, continuous variables between the groups. The chi-squared test was used to compare categorical variables, which were reported as numbers and percentages. The Kaplan-Meier test was used to estimate survival, while the Wilcoxon signed-rank test was performed to compare survival between the groups. Statistical significance was set at $P<0.05$. EZR software (Saitama Medical Center, Jichi Medical University, Saitama, Japan), and a graphical user interface for R (the R Foundation for Statistical Computing, Vienna, Austria), were used to perform all of the analyses (14).

Results

Serological evidence of past SARS-CoV-2 infection does not impact post-transplant outcomes

This study included 299 patients who underwent lung transplantations during the study period. Of these, 209 patients who were multiorgan transplant recipient or had no serological testing for COVID-19 infection were excluded. Total 90 patients were included in this study. We determined whether seropositivity related to COVID-19 infection would impact post-transplant outcomes. In 90 consecutive lung transplant procedures from April 2022 to June 2023, we performed serological testing for COVID-19 infection (Figure S1). Of these, 75 (83.3%) donors were positive for anti-SARS-CoV-2 nucleocapsid total antibodies. There were no significant differences in donor and recipient characteristics between the anti-SARS-CoV-2 nucleocapsid total antibody-negative and -positive groups except donor cause of death (anoxia is higher in anti-SARS-CoV-2 nucleocapsid total antibody-negative group: 66.7% *vs.* 29.3%, P=0.008) (*Table 1*). In the anti-SARS-CoV-2 nucleocapsid total antibody-positive group, 5 patients (6.6%) were positive for SARS-CoV-2 spike protein IgM, and 64 patients (85.3%) were positive for SARS-CoV-2 spike protein IgG. There was no correlation between documented history of COVID-19 in the donor records with the serological testing highlighting the potential inaccuracies in elucidation of COVID-19 infection in donors.

There was no difference in post-transplant survival between the anti-SARS-CoV-2 nucleocapsid total antibody-positive and -negative groups (P=0.40, *Figure 1*).

Table 1 Characteristics of patients

Variable	Donor COVID nucleocapsid antibody		P value
	Negative (n=15)	Positive (n=75)	
Recipient factors			
Age, years	60.7±11.0	61.5±11.1	0.81
Female	8 (53.3)	45 (60.0)	0.78
BMI, kg/m^2	25.5±3.3	27.0±4.5	0.36
BSA, m^2	1.8±0.2	1.9±0.3	0.37
Smoking history	9 (60.0)	48 (64.0)	0.78
Hypertension	7 (46.7)	43 (57.3)	0.57
Diabetes	2 (13.3)	20 (26.7)	0.34
Dialysis	0	2 (2.7)	>0.99
Pre ECMO use	0	5 (6.7)	0.59
Bilateral	8 (53.3)	46 (61.3)	0.58
LAS	50.3±17.2	51.7±17.9	0.81
CAS	24.3±5.3	25.5±7.6	0.79
On the waiting list days	15 [8–31]	15 [7–34]	0.82
Etiology			
ILD	3 (20.0)	34 (45.3)	0.09
COPD	4 (26.7)	14 (18.7)	0.49
PAH	1 (6.7)	4 (5.3)	>0.99
Others	7 (46.7)	23 (30.7)	0.25
Laboratory			
Hemoglobin, g/dL	12.6±1.6	12.2±2.8	0.57
WBC, 1,000/mm^3	9.0±2.6	9.7±3.7	0.48
Platelets, 1,000/mm^3	245.7±70.3	256.6±77.3	0.62
Sodium, mEq/L	137.9±2.7	139.6±4.1	0.13
BUN, mg/dL	15.1±4.7	16.5±6.2	0.39
Creatinine, mg/dL	0.79±0.24	0.84±0.25	0.53
Total bilirubin, mg/dL	0.7±0.4	0.5±0.3	0.20
INR	1.0±0.1	1.1±0.1	0.09
DSA	0	6 (8.0)	0.58
PRA	3 (20.0)	28 (37.3)	0.25
Arterial blood gas			
pH	7.40±0.06	7.39±0.07	0.60
$PaCO_2$, mmHg	43.5±8.1	48.6±10.2	0.07
PaO_2, mmHg	273.5±94.5	261.7±87.0	0.64

Table 1 (*continued*)

Table 1 (*continued*)

Variable	Donor COVID nucleocapsid antibody		P value
	Negative (n=15)	Positive (n=75)	
Donor			
Age, years	34.3±10.2	33.5±11.8	0.81
Female	10 (66.7)	53 (70.7)	0.76
SARS-CoV-2 spike protein IgM	0	5 (6.7)	0.59
SARS-CoV-2 spike protein IgG	8 (53.3)	57 (76.0)	0.11
Cause of death			
Anoxia	10 (66.7)	22 (29.3)	0.008
Head trauma	3 (20.0)	31 (41.3)	0.15
Other	2 (13.3)	22 (29.3)	0.34

Data are shown as means ± standard deviation, median [interquartile range], or number (percentage). BMI, body mass index; BSA, body surface area; ECMO, extracorporeal membrane oxygenation; LAS, lung allocation score; CAS, composition allocation score; COPD, chronic obstructive pulmonary disease; ILD, interstitial lung disease; COVID, coronavirus disease; PAH, pulmonary arterial hypertension; WBC, white blood cell; BUN, blood urea nitrogen; INR, international normalized ratio; DSA, donor specific antibody; PRA, panel reactive antibody; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; $PaCO_2$, partial pressure of arterial carbon dioxide; PaO_2, partial pressure of oxygen.

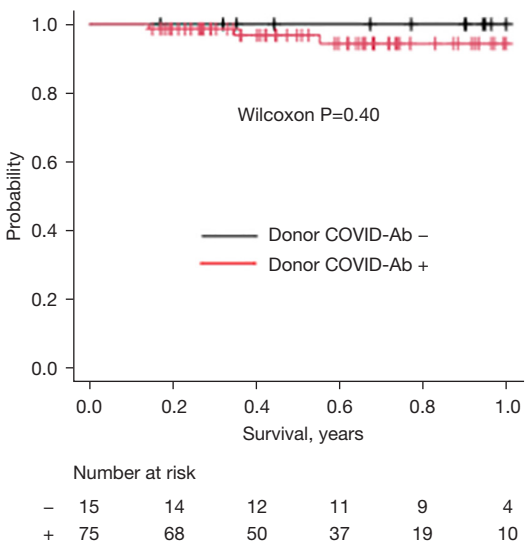

Figure 1 Kaplan-Meier analysis of overall survival after lung transplantation. Comparison of the survival rates between anti-SARS-CoV-2 nucleocapsid total antibody negative *vs.* positive. SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; COVID, coronavirus disease.

Additionally, there was no significant difference in the PGD grade 3 rate in donors that were anti-SARS-CoV-2 nucleocapsid total antibody-negative, compared to those that were positive (6.7% *vs.* 12.0%, P>0.99). There was also no significant difference in operative time, ischemic time, intensive care unit stay (days), and hospital stay (days), but post lung transplant ventilator use (days) was longer in anti-SARS-CoV-2 nucleocapsid total antibody-positive group [1 (interquartile range, 1–2) *vs.* 2 (interquartile range, 1–3), P=0.006, *Table 2*].

Discussion

This single-center study evaluates the outcomes of lung transplants from donors with anti-SARS-CoV-2 nucleocapsid antibodies—a marker of previous infection. Our findings indicate that lungs from donors with resolved COVID-19 infections, when meeting all other transplant suitability criteria, are likely safe for transplantation and yield comparable outcomes to lungs from donors with no COVID-19 history.

We performed a prospective analysis of consecutive donor lungs through well validated serological assays. The data confirmed that lungs from donors with serological evidence of past COVID-19 did not perform inferiorly compared to lungs from donors without evidence of COVID-19 infection even when there was no serological evidence of past COVID-19 vaccination.

The recorded history of COVID-19 among donors

Table 2 Intra- and post-operative outcomes of lung transplant recipients

Variable	Donor COVID nucleocapsid antibody		P value
	Negative (n=15)	Positive (n=75)	
Intra-operative outcomes			
Operative time (hours)	4.9 [3.4–5.6]	5.1 [3.8–5.8]	0.38
Blood transfusion			
pRBC (U)	0 [0–1]	0 [0–2]	0.54
FFP (U)	0 [0–0]	0 [0–0]	0.50
PLT (U)	0 [0–0]	0 [0–0]	0.43
Ischemic time (hours)	4.9 [4.0–5.5]	5.1 [4.3–6.1]	0.31
VA ECMO use	7 (46.7)	49 (65.3)	0.24
VA ECMO time (hours)	0 [0–2.8]	2.2 [0–2.8]	0.57
Post-operative outcomes			
AKI	5 (33.3)	40 (53.3)	0.26
PGD grade 3	1 (6.7)	9 (12.0)	>0.99
PGD grade 1–3	11 (73.3)	55 (73.3)	>0.99
Dialysis	3 (20.0)	7 (9.3)	0.36
ICU stay (days)	5 [4–7]	7 [4–10]	0.39
Post-transplant ventilator (days)	1 [1–2]	2 [1–3]	0.006
Hospital stay (days)	12 [9–22]	17 [12–31]	0.09
Post ECMO use	0	5 (6.7)	0.58
HD after discharge	2 (13.3)	3 (4.0)	0.20

Data are shown as median [interquartile range] or number (percentage). COVID, coronavirus disease; AKI, acute kidney injury; pRBC, packed red blood cells; FFP, fresh frozen plasma; PLT, platelets; VA ECMO, veno-arterial extracorporeal membrane oxygenation; PGD, primary graft dysfunction; ICU, intensive care unit; ECMO, extracorporeal membrane oxygenation; HD, hemodialysis.

was surprisingly sparse; fewer than 2% had documented past infections, much lower than prevalence rates in the broader population (www.cdc.org). One possible reason for the low documented history of COVID-19 among donors could be the prevalence of asymptomatic or mild cases. Many individuals might have contracted the virus without experiencing severe symptoms, leading to undiagnosed or unreported cases. Discussing the challenges of identifying asymptomatic cases and the implications for documentation accuracy would provide valuable context. However, this discrepancy led us to incorporate serological testing to better gauge previous infections. While antibody testing provides a viable means of screening and is advantageous for its accessibility and rapidity, it's not without flaws. The variability in test sensitivity and specificity could lead to misclassification—either excluding donors with past infections due to false negatives or falsely identifying a history of COVID-19 from false positives. Antibody titers can wane, particularly following mild or asymptomatic cases, and cross-reactivity with other coronaviruses can produce false positives. Moreover, evolving viral variants may undermine the reliability of these tests. We also faced the challenge of incomplete vaccination records, precluding a clear understanding of how vaccination might mitigate any risks associated with prior infections. Nevertheless, our findings suggest that, absent active infection and assuming the donor lungs are otherwise healthy, serology or previous infection status may not significantly influence post-transplant success.

This study has several limitations. First, this study was single-center and relatively small in nature. Furthermore, we found that none of the anti-nucleocapsid antibody positive donors had concomitant pulmonary fibrosis on

CT—which would suggest more severe past infection—were approved for transplant. One limitation of this study, though, was we did not assess patients not accepted by our center and we, therefore, could not ascertain whether a previous COVID-19 infection played a role in declining their offer or if they had fibrosis. In this study, even though there was no significant difference in PGD grade 3 rate and post-transplant survival between the anti-SARS-CoV-2 nucleocapsid total antibody-positive and -negative groups, there is no data regarding rejection rate, *de novo* DSA formation, and development of chronic allograft dysfunction due to relatively short period observation.

Lastly, study was performed from 2020, and during this time period there have been several strains of COVID of varying degree of virulence, and we could not analyze if strains of COVID impact the outcomes or not.

Conclusions

In summary, our data suggest that donor lungs from individuals with a serologic evidence of prior COVID-19, provided they currently show no signs of active infection (verified by negative PCR testing of lower respiratory fluids), are potentially viable for transplantation. The outcomes parallel those of lung transplants from donors without any known history of COVID-19, reinforcing the practicality of including these donors in the organ pool. All donors were confirmed negative for active COVID-19 infection through PCR testing of lower respiratory tract fluids, adhering to OPTN policy. Our comprehensive donor assessment protocol extended beyond PCR testing to include computed tomography for signs of pulmonary fibrosis, lung compliance, and gas exchange efficiency (PaO_2/FiO_2 ratio >300)—due to potential permanent damage from COVID-19 (13,14). On-site evaluations at the donor facility further involved manual palpation and compliance testing of the lungs.

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Footnote

Data Sharing Statement: Available at https://jtd.amegroups.com/article/view/10.21037/jtd-24-496/dss

Peer Review File: Available at https://jtd.amegroups.com/article/view/10.21037/jtd-24-496/prf

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://jtd.amegroups.com/article/view/10.21037/jtd-24-496/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The retrospective study was approved, with a waiver of consent, by the Institutional Review Board of Northwestern University (Nos. STU00207250 and STU00213616) prior to any data collection.

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