Personal Protective Equipment for Liver Transplant in SARS-CoV-2 Polymerase Chain Reaction-Positive Convalescing Recipients

Yehuda Raveh[a,b][*], Joshua Livingstone[a,b], Rodrigo Vianna[c], and Ramona Nicolau-Raducu[a,b]

[a]Department of Anesthesia, University of Miami, Jackson Memorial Hospital, Miami, FL, USA; [b]Miami Transplant Institute, University of Miami, Jackson Memorial Hospital, Miami, FL, USA; and [c]Department of Surgery, Miami Transplant Institute, University of Miami, Jackson Memorial Hospital, Miami, FL, USA

ABSTRACT

Personal protective equipment (PPE) comes in several variations, and is the principal safety gear during the COVID-19 pandemic. Unfortunately, the user is severely impacted by its serious non-ergonomic features. What PPE is appropriate for labor-intensive cases, like liver transplant (LT), remains unknown. We describe our experience with 2 types of PPE used during 2 separate LT performed in COVID-19 positive recipients. We conclude that for the safety of both health care workers and patients, hospitals should designate a few PPE kits for labor-intensive surgical procedures. These kits should include powered air-purifying respirators, or a similar loose-fitting powered air hood.

THE early stages of the SARS-CoV-2 pandemic brought forth unprecedented challenges to solid organ transplantation (SOT) across the globe. As the pandemic unfolded in early 2020, the scarcity of scientific knowledge compelled transplant policymakers to impose stringent but presumably safer policies for organs retrieval and SOT [1−3]. The inevitable consequence was a drastic decrease in SOT volume, and an ensuing increase in waitlist time, disease progression, dropout, and mortality [4,5]. The unforeseen magnitude of detrimental consequences of stringency instigated and warranted a change to the a priori restrictive guidelines. Some European countries reported as high as an 80% drop in transplant rates [6]. Moreover, about 60,000 vulnerable European patients lost transplant opportunities, and inexorably suffered disease burden and unquantified excess waitlist mortality [6]. In the United States, however, the heterogeneous impact of SARS-CoV-2 on waitlist mortality varied according to the waited organ and candidate's geography, age, sex, and ethnicity [7,8]. Accumulated medical knowledge regarding the small risk of transmissibility in SARS-CoV-2 polymerase chain reaction (PCR) positive convalescing patients enabled a gradual and cautious leniency in transplantation. Lacking formal guidelines for SOT in candidates with a COVID-19 positive PCR result, transplant centers had to independently balance the risk of waitlist dropout or mortality vs transplantation on a case-by-case basis. This practical approach matches SOT risk tolerance to recipient acuity, and inevitably results in non-uniform local practices. To our best knowledge we reported the first 2 cases of liver transplant (LT) in SARS-CoV-2 PCR-positive convalescing candidates [2]. Case reports and case series for all non-lung abdomino-thoracic SOTs performed in PCR-positive convalescing recipients followed suit from across the globe, and usually with favorable outcomes [9−18]. A survey of several LT programs (Table 1) in the United States showed significant variability in transplant practices in recipients convalescing from COVID-19. In addition, larger series of SOT in SARS-CoV-2 PCR-negative convalescing candidates ascertained the safety of transplantation within days or weeks after COVID-19 infection [19−23]. The ensuing increase in organs recovered from PCR-positive donors or transplanted in PCR-positive recipients underscored the challenge of health care personnel (HCP) protection during these complex procedures. Furthermore, the prolonged pandemic and the ever-changing SARS-CoV-2 virulence, transmissibility, and the vaccine-resistance of the rapidly evolving variants resulted in prevailing professional predictions that SARS-CoV-2 will remain endemic for many years to come [24]. Thus, it is prudent to identify safe and effective means to protect HCP during transplantation.

*Address correspondence to Yehuda Raveh, MD, Department of Anesthesiology, University of Miami, Jackson Memorial Hospital, 1611 N.W. 12th Avenue, Miami, Florida 33136, USA. Tel.: (+1) 305 585 6983, Fax (+1) 305 585-7477. E-mail: yraveh@miami.edu

Table 1. Survey of United States Transplant Program Regarding Liver Transplantation in PCR Positive Recipients

Program	Transplant in PCR+ recipients	PPE	Portion of Procedure Donned	Extra Staff
UCSF	No PCR testing 10-90 d after onset	None	n/a	N/A
MTI	Yes	Full attire	Variable	Yes
Mayo Clinic Florida	Yes	No	N/a	N/A
UCLA	Yes	full attire or PAPR	All	Yes
Ochsner Health	No PCR testing after 28 d	No	N/a	N/A
UPMC	Yes	N-95, goggle /face shield	All	No
Henry-Ford	Yes	Per ID N-95/face shield	Induction, lines	Yes
UW	Yes	Full attire	Induction, lines, transport	Yes
CC	Yes, per CT	Variable	variable	No
UTH	No	N/A	N/A	N/A
UIC	Yes	N-95/face shield	All	No

CC, Cleveland Clinic Foundation; CT, cycle threshold; ID, infectious disease consultant; MTI, Miami Transplant Institute; N/A, not applicable; PAPR, powered air-purifying respirator; PCR, polymerase chain reaction; PPE, personal protective equipment; UCLA, University of California, Los Angeles; UCSF, University of California San Francisco; UIC, University of Illinois, Chicago; UPMC, University of Pittsburgh Medical Center; UTH, University of Texas Houston; UW, University of Washington.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

The Occupational Safety and Health Act (1970) established 2 different—but closely related—government institutions: 1. the Occupational Safety and Health Administration (OSHA), a federal office within the Department of Labor charged with the responsibility to create and enforce safety rules that employers must follow; and 2. the National Institute for Occupational Safety and Health (NIOSH), a research and education federal entity within the Centers for Disease Control and Prevention, and under the jurisdiction of U.S. Department of Health and Human Services [25]. The primary mission of NIOSH's Personal Protective Technology Program is to promote occupational safety and prevent work-related injury, illness, or death. The key components of NIOSH and OSHA mandated HCP exposure control are administrative measures (eg, adequate personnel training and minimizing contact), well-designed engineering infection controls (eg, negative-pressure isolation room for airborne-infection), and the use of Personal Protective Equipment (PPE). Thus, PPE is the principal last line of defense safety gear used during COVID-19 global pandemic [26]

PPE Types

A PPE comes in several variations [26]; its essential components are 1. airborne precautions—N-95 or similar respirators, or a powered air-purifying respirator (PAPR); 2. droplet precautions—eye protection, such as goggles, a face shield or a visor, or a combination thereof; and 3. contact precautions—gloves, and a fluid-resistant gown or coverall. [26,27].

The N-95 masks filter at least 95% of particles <5 μm in diameter; these masks effectively block aerosol (<5 μm) and droplet-size (5-50 μm) particles and are readily available. Their most significant disadvantages include the necessity for size fitting testing, compromised efficacy by an improper fit (eg, facial hair), poor tolerance due to breathing resistance, and heat and moisture build up.

A PAPR is a battery-powered blower that provides positive airflow through a filter, a cartridge, or a canister to a hood or a face piece. The air is drawn through a high-efficiency particulate air (HEPA) filter that eliminates at least 99.97% of particles 0.3 μm in diameter. The use of HEPA filters in PAPRs offers a greater level of respiratory protection than N-95 masks; a PAPR is, therefore, the respirator of choice for infection control airborne precautions. PAPRs also have the advantage of providing head and neck protection, do not require fit testing because of the full-size hood, are approved for use with facial hair, and allow for continuous bedside care of patients. Their disadvantages include higher cost, a need for users training, limited availability, impaired communication due to blower noise and noise induced by the movement of a loose hood, and a need for electricity for operation [28]. Importantly, PAPRs are generally reusable and require special care during doffing, cleaning, and handling.

The Stryker Modified Helmet PPE

The limited access to PAPRs during the COVID-19 pandemic, and the availability of surgical helmet systems used by arthroplasty surgeons instigated the repurposing and retrofitting of the Stryker Flyte helmet (Stryker, Mahwah, NJ, USA) into a functioning PAPR [29]. The most important modification to the Stryker Flyte helmet is the covering of the normally open intake port of the fan with a 3D-printed durable manifold, thus creating 2 sealed air passages each connected to an air filter and anesthesia tubing that opens to room air at the back. Figure 1 presents the retrofitted helmet, hood, and the full PPE attire.

Ergonomic Limitations of PPE

The use of PPE is fraught with undesirable effects on the well-being, comfort, and performance of its user [30,31], and, thus, may compromise the user's and patient's own safety. Hazards include restricted movement, impaired visibility, reduced dexterity and hampered manual performance, heat stress and risk of dehydration, back pain (PAPR suit), and communication impediment due to head cover and the humming noise of the PAPR [31,32]. Several physiological and psychological stressors are

Fig 1. A repurposed Stryker Flyte helmet. **(A)** The fan inlet was sealed with a manifold that was attached to 2 high-efficiency particulate air filters and to anesthesia tubing. **(B, C)** The assembled hood and the full personal protective equipment attire, respectively. **(D)** The anesthesia tubing should be pulled out of the gown at the back to ensure unhindered inflow of room air.

associated with PPE use and include stress resulting from the confining nature of PPE suits, diminished situational awareness secondary to reduced hearing and understanding speech, and overall discomfort and fatigue [30−33]. In addition, facial hair interferes with proper fit of masks while improper PPE use and suit penetration or tears are constant potential hazards [32].

PPE for Use During LT

The significant immune impairment of cirrhosis [34] highlights the need for safe and ergonomic PPE for LT in PCR-positive recipients, since prolonged (70 days) infectious shedding of SARS-CoV-2 has been demonstrated in immunocompromised subjects [35]. The principal mode of COVID-19 transmission is

via airborne particles and droplets; fomite transmission is plausible, but the risk is generally low [36,37]. Anesthesiologists are at increased risk for cross-infection, especially during aerosol generating procedures. PPE, therefore, is donned throughout the period of anesthesia care since disconnection of the ventilatory circuit and suctioning of the airway may be required at any stage of a procedure. The length, complexity, workload, and associated stress of the operative procedure are critical factors in the overall adverse impacts of PPE on its user. What PPE is appropriate for prolonged labor-intensive cases, however, remains unknown. LT is among the most labor-intensive and stressful procedures performed in the operating room. Our survey (Table 1) points out to significant variability between LT programs in assessed risk of SARS-CoV-2 transmissibility of convalescing PCR-positive recipients, and, therefore, inconsistent PPE practices. To our knowledge special PPE considerations for LT were not previously reported. [12,16,38]. To fill this gap we describe our experience with 2 types of PPE used during 2 LT performed in PCR-positive recipients.

PRESENTATION OF LT CASES
LT Case No. 1

The patient was admitted for LT 3 months after a moderately severe COVID-19 pneumonia, with a model for end-stage liver disease (MELD) score of 23, a positive COVID-19 PCR, and a cycle threshold of 40 [39]. Treatment for SARS-CoV-2 was not indicated. An infectious disease consultant cleared the patient for LT and mandated PPE for all care givers. The anesthesia team's PPE included level 4 encapsulated coveralls, N-95 respirators, and face shields or visors. A sterile gown was donned for the placement of 4 vascular access lines. No special training was required for donning and doffing of this standard PPE. Fogging, sweating, and glare severely impaired visibility during these procedures. After 1 hour, heat stress and generalized sweating became unbearable. To minimize the spread of a respiratory aerosol if disconnection of the ventilatory circuit and suctioning of the airway were indicated, the patient's upper body was covered with a clear plastic drape prior to surgical prep. Thereafter, the anesthesia team replaced the coveralls and eye protection with surgical gowns, and goggles. The sequence of donning and doffing of a standard PPE is illustrated in Fig 2. The patient received 500 mg of methylprednisolone intraoperatively; postoperative immunosuppression included methylprednisolone and tacrolimus. Two subsequent SARS-CoV-2 PCR nasopharyngeal swabs were negative, and the patient was discharged home on postoperative day 9. All personnel involved in the intra- or postoperative care remained asymptomatic.

LT Case No. 2

The patient was transferred to our institution for LT secondary to acute hepatic decompensation, and was listed for LT after 2 negative COVID-19 PCR tests. On day 9, his PCR test became
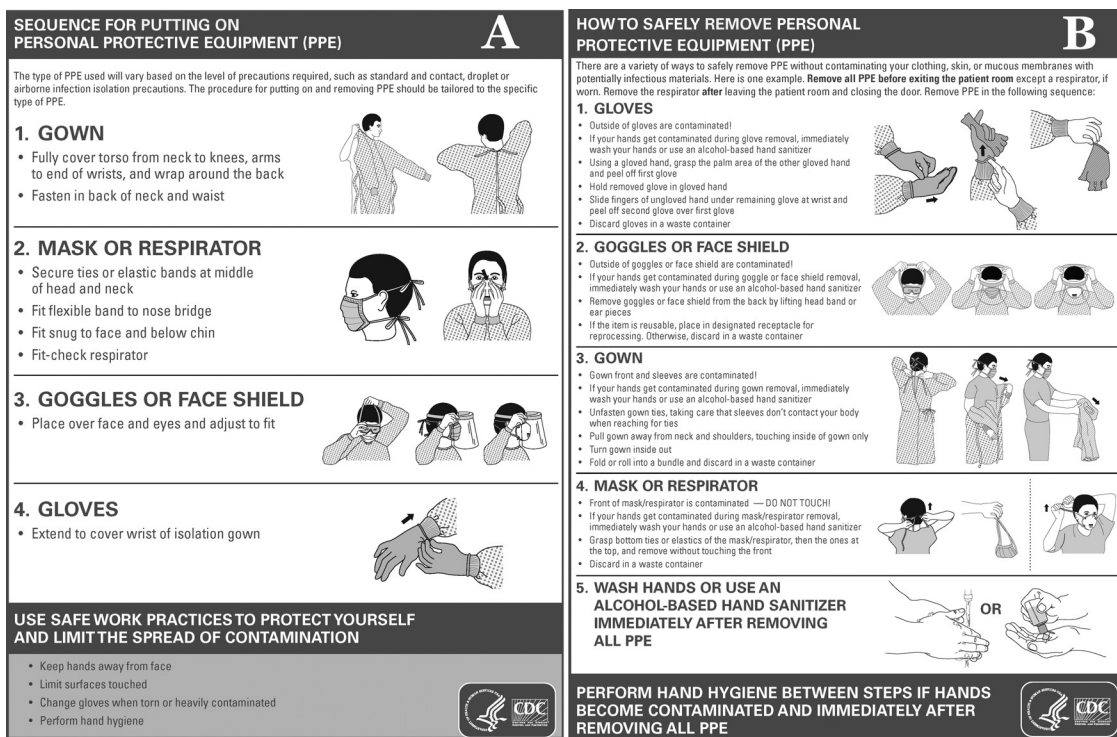

Fig 2. Recommended sequence for donning **(A)** and doffing **(B)** of standard personal protective equipment. Image courtesy of the Centers for Disease Control and Prevention (https://www.cdc.gov/hai/pdfs/ppe/ppe-sequence.pdf).

positive and his listing was put on hold (status 7). Over the following weeks, he developed respiratory distress, hemodynamic instability, and acute renal failure. Despite ongoing positive PCR results and given his critical condition, frailty, MELD of 40, and PCR cycle threshold >24 [39], the patient was cleared by an infectious disease consultant for an ultima ratio combined LT and kidney transplant, after 27 days from his initial positive PCR. PPE was mandated for all care providers. Remdesivir was not given due to patient's severe liver disease. LT took place 53 days after his initial PCR and 6 days after the most recent positive PCR. In view of the severe undesirable impact of standard PPE on performance as experienced in patient 1, the anesthesia team selected a PPE assembly of a surgical gowns, an N-95 respirator, and a retrofitted and repurposed Stryker Flyte helmet [29]. A single training for donning and doffing the special PPE attire was provided and supervised by a trainer experienced with the repurposed Stryker hood. An additional sterile gown was donned during placement of 5 vascular access lines. During the 8-hour procedure, the patient received 57 units of blood product, multiple vasopressor infusions, and renal replacement therapy. The anesthesia team felt well protected, and experienced no visual impairment or fogging. The air flow inside the hood kept the head and face cool. The large diameter of the ballooned hood, however, restricted access to the patient's arm under the surgical drapes. Normal volume communication was limited to a 3 feet range, due to the muffling of voice and the constant humming of the helmet's fan, but was ameliorated with the assistance of a communication runner. Shifting of the hood during tilting of the wearer' neck was a nuisance. The overall experience was very good despite the intensity of the procedure. An experienced team member provided assistance with doffing and storage of the used helmet.

Intraoperatively the patient received 500 mg of methylprednisolone. The kidney was grafted 2 days later. Post-LT immunosuppression included methylprednisolone and tacrolimus; a single dose of anti-thymocyte globulin was added after his kidney transplant. Recipient had an adequate liver function, but a delayed graft function of the kidney. His overall recovery was slow. Two nasopharyngeal PCR taken on postoperative days 9 and 20 were negative, and during his postoperative period, no clinical findings suggestive of an ongoing SARS-CoV-2 infection were found. All personnel involved in the intra-, or postoperative care remained asymptomatic. SARS-CoV-2 immunoglobulin G and total antibody 66 days after initial positive PCR were reactive.

CONCLUSIONS

Our experience strongly suggests that for the safety of both health care workers and patients, hospitals should designate a few distinct PPE kits for LT and similarly labor-intensive surgical procedures. These kits should include a PAPR, or a similar loose-fitting powered air hood. It is highly recommended to have a go-between "runner" to overcome the communication impediment during PAPR use. If unavailable, an enhanced

airborne and droplet precautions PPE may be used, but is likely to compromise the performance due to unsafe ergonomic features.

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