Right heart catheterization for pulmonary hypertension during the coronavirus disease 2019 pandemic

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Abstract
Right heart catheterization is an essential diagnostic modality in the evaluation of pulmonary hypertension. The coronavirus disease 2019 pandemic has resulted in deferral of elective procedures including right heart catheterization. The benefits of proceeding with right heart catheterization, such as further characterization of hemodynamic subtype and severity of pulmonary hypertension, initiation of targeted pulmonary arterial hypertension therapy, as well as further hemodynamic testing, need to be carefully balanced with the risk of potentially exposing both patients and health care personnel to coronavirus disease 2019 infection. This review article aims to provide best clinical practices for safely performing right heart catheterization in pulmonary hypertension patients during the coronavirus disease 2019 pandemic.

Keywords
coronavirus, COVID-19, infection prevention, pulmonary hypertension, right heart catheterization

Introduction
Coronavirus disease 2019 (COVID-19), caused by the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has resulted in a global pandemic and placed an unprecedented strain on health care resources.1,2 This highly contagious illness can manifest with a spectrum of severity ranging from asymptomatic carrier state or mild upper respiratory tract symptoms, to severe pneumonia, fulminant sepsis, multi-organ failure, and death.3,4 The true proportion of asymptomatic carriers is not currently known, but it has been estimated to be between 17.9% (95% credible interval: 15.5–20.2%) and 30.8% (95% confidence interval (CI): 7.7–53.8%) based on data derived from the Diamond Princess cruise ship and Japanese citizen evacuation from Wuhan, respectively.4,5 Older age and patient comorbidities such as hypertension (odds ratio (OR) 2.85, 95% CI: 1.35–6.05), diabetes (OR 3.05, 95% CI: 1.57–5.92), and coronary artery disease (OR: 21.4; 95% CI: 4.6–98.8) have been associated with higher mortality.6 According to the Centers for Disease Control and Prevention (CDC), there have been 2.3 million reported cases and ~121,000 deaths in the U.S. at the time this article was written.7 Many medical societies have come up with regulations and guidelines for management of diagnostic procedures during these challenging times.

Expert recommendations from the sixth World Symposium on pulmonary hypertension (PH) characterize PH by a mean pulmonary artery pressure (mPAP) >20 mmHg that can be caused by a variety of conditions and is associated with worse outcomes.8 Pulmonary arterial hypertension is a form a pre-capillary PH that tends to progress to right heart failure (RHF),9 with a five-year survival of 61.2–65.4%, despite the availability of many specific therapies.10 In spite of continuous progress in non-invasive diagnostic modalities, right heart catheterization (RHC) remains the gold standard for diagnosis.11 It allows for accurate determination of hemodynamic parameters (such as right atrial pressure, mPAP, pulmonary capillary wedge pressure, and others) and can provide important information for patient management.

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pressure, cardiac output, and mixed venous oxygen saturation), which helps diagnose PH, determine the hemodynamic subtype (pre-capillary and/or post-capillary PH), and assess severity of the disease.\textsuperscript{11,12} Established complementary evaluations during RHC include vasoreactivity testing, exercise, and rapid fluid infusion challenges. In addition, other promising hemodynamic challenges include passive leg raising, intrathoracic pressure estimation, temporary exclusion of arteriovenous dialysis accesses, and dobutamine infusion.\textsuperscript{11-13} Exercise hemodynamics during RHC (with or without ventilatory gas exchange measurements) are becoming an important component of the full hemodynamic evaluation of patients with PH, since it can aid in the characterization of early or unspecified forms of PH, helping better differentiate pre- from post-capillary PH.\textsuperscript{11,14}

Limited information is available about COVID-19 in PH patients at this time. Patients with PH are known to have lower levels of angiotensin-converting enzyme 2 (ACE2), which has a protective role in acute lung injury.\textsuperscript{15,16} ACE2 has been implicated as the functional receptor for coronavirus cell entry and it remains unknown whether a lower level in patients with PH might be a protective factor.\textsuperscript{15} Conversely, others have postulated that the ACE2 down-regulation caused by SARS-CoV-2 in patients with underlying ACE2 deficiency might further exacerbate the inflammatory response and subsequent lung injury.\textsuperscript{17} Interestingly, a recent study in patients with systemic hypertension suggested that ACE inhibitors and angiotensin receptor blockers do not play a role in COVID-19 infection or affect mortality in those infected with the virus.\textsuperscript{18}

Patients with underlying cardiovascular diseases infected with COVID-19 have worse outcomes.\textsuperscript{6} There is evidence to suggest that COVID-19 infection increases the risk of RHF through several mechanisms including increased pulmonary vascular resistance secondary to acute respiratory distress syndrome (ARDS) and pulmonary embolism, direct myocyte injury and negative inotropy secondary to the cytokine storm.\textsuperscript{17} In fact, right ventricular strain in patients with COVID-19 may be able to predict mortality.\textsuperscript{19} Furthermore, striking molecular similarities have been observed between lung damage related to SARS-CoV-2 infection and pulmonary vascular disease, including endothelial dysfunction, vasculitis, and pulmonary microthrombi.\textsuperscript{20} There is concern that severe SARS-CoV-2 infection in susceptible individuals might result in permanent damage to the pulmonary vasculature and parenchyma, facilitating the development of PH and pulmonary fibrosis as a long-term sequela.\textsuperscript{17,20}

The first case report detailing the course of COVID-19 infection in a patient with well-controlled PAH reported a relatively mild course with full recovery.\textsuperscript{21} An electronic survey of Pulmonary Hypertension Association Centers, with 86 responses by PH health care providers reported that 16 patients with PAH/chronic thromboembolic PH patients had tested positive for COVID-19 infection till 6 May 2020.\textsuperscript{22,23} Of these, 58% (n = 11) required hospitalization, meanwhile 55% (n = 6) of those hospitalized required intubation, with an overall mortality of 19% (n = 3).\textsuperscript{23} This survey had several limitations including response bias, potential underreporting of mildly symptomatic cases, and limited PCR testing during the time of the survey.\textsuperscript{22-24} Authors speculated that preventative measures along with potential protective effects of PAH-targeted therapies (phosphodiesterase type 5 inhibitors, endothelin receptor antagonists, inhaled nitric oxide, and prostacyclin) might have contributed to lower rates and attenuated the clinical course of the disease.\textsuperscript{22,23} However, a rebuttal letter, comparing these data against the rate of infection of COVID-19 in the general population, revealed a graver clinical course in PH.\textsuperscript{24} In any case, given poor outcomes in ARDS patients with severe PH,\textsuperscript{25} worsening pulmonary pressures in COVID-19 patients,\textsuperscript{26} and the potential for acute on chronic RHF in PH patients with sepsis, it seems reasonable to be very cautious and speculate that if PH patients are infected with COVID-19 the mortality might be higher than the general population.\textsuperscript{27}

Consequently, Ryan et al.\textsuperscript{27} recommend deferring elective RHC during the COVID-19 pandemic in stable patients with PH, where it is unlikely that the hemodynamic evaluation would change the short-term management of the disease. Instead, considerations should be made on a case by case basis, balancing the benefits of RHC with the risk of COVID-19 exposure to both patients and health care workers. Scenarios where the scales are likely to be tipped in favor of proceeding with RHC include patients in whom results of the RHC would alter management, such as newly diagnosed, or patients that remain on the intermediate or severe risk strata.\textsuperscript{27,28} However, it is prudent to consider that the deferral of testing including RHC, as well as reduction of outpatient visits and hospital transfers, that has invariably occurred as a consequence of the COVID-19 pandemic, may have far reaching implications for PH patients, resulting in suboptimal medical care that could manifest over time.\textsuperscript{29,26} As we learn to live with COVID-19, RHC done for other reasons, such as hemodynamic characterization of PH, risk stratification or assessment of treatment response will resume. There is growing concern that RHC is and will continue to be underutilized for the near future, potentially leading to delays in PH diagnosis and treatment. This apprehension stems from the alarming 38% decrease in STEMI catheterization lab activations during the early phase of the pandemic (95% CI 26–49%; p < 0.001) at large centers in the U.S.\textsuperscript{29} Possible reasons for this decline were speculated to be deferral of medical care by patients due to the pandemic, STEMI misdiagnosis, and increased use of fibrinolysis.\textsuperscript{29}

Recommendations from the American College of Cardiology Interventional Council and the Society for Cardiovascular Angiography and Interventions regarding left heart catheterization include deferral of elective cardiac catheterization and careful assessment of risks and benefits of the procedure in more urgent cases.\textsuperscript{2} Primary
percutaneous coronary intervention (PCI) remains the standard of care for STEMI patients during the pandemic; however, fibrinolysis should be considered when PCI cannot be performed safely (in the absence of appropriate staffing, personal protective equipment (PPE), testing, or cardiac catheterization lab decontamination), in non-PCI capable centers and selected stable STEMI patients. The COVID-19 status of all patients should be available prior to the procedure whenever possible. For COVID-19 positive patients requiring PCI, personnel should use optimal PPE, with proper donning and doffing technique, along with other protective measures, such as powered air-purifying respirator (PAPR) systems, negative pressure rooms, allocation of COVID-19 positive cases to specific laboratories, or deferral to the last procedure of the day, to give time for a thorough decontamination after the case. European Society of Cardiology recommends that all patients entering the catheterization lab wear surgical masks. To decrease nosocomial spread of infection, procedures such as Swan-Ganz catheter placement, pericardiocentesis, and intravascular balloon pump insertion can be done at bedside, instead of transporting to the catheterization laboratory. Some of these recommendations are applicable to RHC as well.

Factors to consider when performing RHC

In March 2020, the Centers for Medicare and Medicaid Services had announced deferral of all elective medical procedures during the pandemic in order to preserve PPE, ensure staff and patient safety, and expand available hospital capacity during the pandemic. Procedures could be done if there was threat to the patient’s health, risk of permanent dysfunction of an extremity or organ, risk of disease progression, or rapid deterioration if the procedure was not performed. However, as states began to lift restrictions, elective procedures are being resumed across the U.S. However, concern remains among patients about getting infected with COVID-19 in the health care setting, with worrisome data suggesting that patients may delay consultation even in the presence of severe medical conditions. Although, there is always a risk when leaving the safe home environment, hospitals follow strict protocols to minimize exposure to COVID-19. In fact, there are no data supporting that hospitals are of particular risk for acquiring this infection.

COVID-19 screening prior to RHC

In our institution we perform routine COVID-19 screening prior to all cardiac catheterizations, including RHC. This approach reflects an overabundance of caution. There are no data to support a universal screening for COVID-19 before RHC. Procedures performed during RHC have generally low risk of aerosolization, except for exercise challenges including invasive cardiopulmonary exercise testing. It is certainly possible that universal COVID-19 testing will change in the future, based on the COVID-19 prevalence in the community and type of the procedure. The rationale for universally testing all patients presenting for RHC at this time is because asymptomatic infections with COVID-19 are common, with data indicating that more than half of subjects who have a positive PCR test are asymptomatic or pre-symptomatic. These asymptomatic individuals may play an important role in transmission as they can transmit the virus to others for up to 14 days or possibly even longer. Wearing of face mask by pre-symptomatic individuals has been shown to reduce SARS-CoV-2 transmission.

Reverse-transcriptase polymerase chain reaction (RT-PCR) is currently the most widely used test, as serum antigen and antibody detection testing is not validated at this time. The sensitivity and specificity of RT-PCR has been estimated to be 70 and 95%, respectively. Given the high specificity and moderate sensitivity, a negative test result needs to be interpreted in the clinical context of the patient, taking into account the clinical suspicion and pre-test probability. The false negative rate for RT-PCR varies over the course of the disease: it is highest within the first five days of exposure (100% on day 1, 67% on day 4), and lowest on day 8 after exposure (20%). Assuming an incubation period of five days, it means the false negative rate is high in asymptomatic patients and lowest on day 3 of symptoms.

The protocol currently being followed at our institution is as follows:

1. Patient is to stay home with instructions for self-isolation.
2. Re-contact patient at 10 days to assess symptoms of COVID-19.
3. If, at 10 days, patient is asymptomatic, reschedule procedure with a date at least two weeks from the date of the 10-day call.
4. If, at 10 days, patient is symptomatic with COVID-19, re-contact in another 10 days.
5. When patient returns for procedure, screen for COVID-19 symptoms; do not repeat coronavirus testing (given frequent false positives).

- If COVID-19 testing is positive but procedure is deemed essential/urgent, proceed while utilizing appropriate PPE including N95 masks for all involved personnel.
- If COVID-19 status is pending, unknown, or expired, the physician assesses the risks/benefits of performing RHC on a case by case basis. If procedure is performed, treat as person under investigation (PUI) and follow the same protocol as if the patient were COVID-19 positive, particularly if risk of aerosolization exists (e.g. exercise testing).
- Rapid COVID-19 testing (results available in 2 h) can be utilized if procedure is needed on urgent basis, according to institution specific guidelines and availability.

Since in our center all patients who undergo routine RHC are negative for COVID-19, we perform Fick cardiac output when indicated (low or high cardiac output by thermodilution or in patients in whom the determination by thermodilution is normal but inconsistent with the clinical presentation (e.g. presyncope/syncope), echocardiographic findings (e.g. severe RV dysfunction), or low mixed venous oxygen values). In patients who undergo RHC on an urgent basis or when results of COVID-19 PCR are not available, we carefully consider the need to perform direct Fick determinations, given the potential for aerosolization and equipment contamination. If Fick cardiac output determination is needed, we dispose of the flow sensor, mask/head gear and coupler or mouthpiece and adapter. In addition, we thoroughly clean the umbilical cord and the metabolic cart following thorough disinfecting procedures. We perform this test in a separate room, and the personnel involved use regular mask in the case of negative COVID-19 or N95 in the event of unknown or positive COVID-19 status.

**Utilization of PPE and health care personnel (HCP) protection**

Coronavirus is transmitted primarily via close contact, respiratory droplets, and touching infected surfaces, with evidence of airborne transmission as well. Current evidence suggests surgical masks to be >70% effective in preventing person-to-person transmission with widespread use. As such, all patients and HCP should wear surgical face masks at all time while in the hospital. A recent systemic review and meta-analysis confirmed face masks reduced the risk of infection (n = 2647; pooled adjusted OR: 0.15 (95% CI 0.07–0.34), risk difference −14.3% (95% CI 15.9 to −10.7)), with higher protection afforded by N95 (or similar respirators) compared with surgical masks and reusable cotton masks (adjusted OR: 0.04 (95% CI 0.004–0.3) versus 0.33 (95% CI 0.17–0.61)). Furthermore, protective eyewear (n = 3713; adjusted OR: 0.22 (95% CI 0.12–0.39), risk difference −10.6% (95% CI −12.5 to −7.7)), and physical distancing of 1 m or more (n = 10,736, adjusted OR: 0.18 (95% CI 0.09–0.38); risk difference −10.2% (95% CI −11.5 to −7.5)) were also found to reduce infection risk.

The CDC recommends use of a face mask or respirator, disposable gown, surgical gloves, and protective eyewear with face shields for HCP when interacting with suspected or known COVID-19 positive patients. In order for PPE to be maximally effective, it is imperative to utilize the proper donning and doffing techniques, as the outer surfaces of PPE are contaminated after use. HCP should be actively educated on proper donning and doffing techniques per CDC and facility specific guidelines and a “buddy system” can be utilized to allow two-person verification that includes the verbalization of steps and confirmation of proper technique to further reduce the risk of cross-contamination. In case of limited PPE, respirators can be sterilized using ultraviolet light, moist heat, or vaporized hydrogen peroxide. Though no separate guidelines exist, based on prior experience from SARS in 2005, these recommendations can be applied to cardiac catheterization laboratories as well.

With regards to aerosol generating procedures, N95 or higher-level respirators such as PAPR/CAPR should be used. Such procedures during RHC could include intubation, bag valve mask ventilation, CPR, tracheal suctioning, high flow oxygen, or non-invasive ventilation using airway management of intubated patients. It is essential to avoid circuit disconnection in mechanical ventilated patients, and use a high-efficiency particulate air filter when using bag valve mask ventilation, to reduce aerosolization. Attempts should be made to minimize these procedures in the catheterization lab, instead opting for elective pre-procedure intubation and using mechanical chest compression devices when possible.

In order to protect HCP and reduce risk of transmission, the number of people in the catheterization lab should be minimized to essential personnel only. Efforts should be made for social distancing among members of the procedure teams, in order to protect the limited number of HCP capable of performing these procedures.

**Environmental considerations**

The traditional or positive pressure ventilation systems in most catheterization laboratories do not make them ideal for infection isolation. Therefore, procedure delays might result from the subsequent thorough decontamination required after a procedure on a COVID-19 positive patient. This can be mitigated by temporary modifications to the ventilation system to negative pressure, ensuring adequate air exchanges (at least 15 exchanges per hour and ideally 30 exchanges per hour), designating specific procedure rooms
for COVID-19 positive patients and PUIs, and/or deferring procedures on these patients till the end of the day.2

Conclusions

COVID-19 has strained global health care resources and changed the way medicine is being practiced. Though not much is known about PH and COVID-19 specifically at this time, PAH patients are known to have worse outcomes with all-cause hospitalization.48 Therefore, as elective procedures such as RHC are now being resumed, it is essential to take utmost precautions to protect the vulnerable PH population from COVID-19. The need of RHC, while essential for diagnosis and management of PH, needs to be evaluated on a case by case basis, to help mitigate the increased risk of COVID-19 exposure to patients and HCP while providing optimal management to PH patients. In an effort to decrease the spread of COVID-19, we recommend (a) careful selection of patients most likely to benefit from RHC, (b) screening all patients for COVID-19 prior to RHC, (c) deferring RHC in COVID-19 positive patients when able, (d) appropriate PPE with proper donning and doffing technique, (e) thorough decontamination of catheterization labs, and (f) minimizing nonessential HCP during procedures.

Authors’ contributions

Kanza N. Qaiser: Participated in the conception, design, writing, and critical revision of the manuscript for important intellectual content and final approval of the manuscript submitted.

James E Lane: Participated in metabolic determination and writing and critical revision of the manuscript for important intellectual content and final approval of the manuscript submitted.

Adriano R. Tonelli: Participated in the conception, design, writing, and critical revision of the manuscript for important intellectual content and final approval of the manuscript submitted. Tonelli is the guarantor of the paper, taking responsibility for the integrity of the content and final approval of the manuscript submitted.

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