Evolving Airway and Ventilatory Care for Suspected or Confirmed COVID-19 Patients

Implications for Patient & Provider Safety

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Introduction

The COVID-19 pandemic has dominated life throughout the world since it's abrupt arrival on the last day of December 2019. As of December 1, 2020 the World Health Organization reports 62,662,181 confirmed cases of COVID-19 resulting in 1,460,223 deaths [1]. Since the beginning of the pandemic only about 5% of cases have required critical care, primarily for patients over the age of 60 and/or with co-morbidities [2]. However, given the pandemic spread of the disease, COVID-19 patients have impacted care providers in all clinical settings, and have in many cases overwhelmed available hospital and intensive care resources. The need for greater numbers of intensive-care capable healthcare providers to staff overwhelmed healthcare facilities has combined with the potential for loss of healthcare providers due to quarantine or disease to create substantial logistical challenges to the delivery of care.

Early published case studies and treatment guidelines for this challenging patient population included some technically challenging and uncommon practices and procedures. In the ten months since these initial reports over 150,000 academic articles have been published chronicling the evolution of care strategies and outcomes across the globe [3]. The combination of rapidly changing care guidelines, highly demanding (and sometimes unusual) intensive care regimens, and logistical challenges related to staffing, facilities, and equipment create a substantial increase in safety risks to patients and providers alike. This paper focuses specifically on potential risks to patients and providers associated with evolving guidelines for improving oxygenation and ventilation for patients with moderate to severe respiratory failure. Published patient/provider safety risks will be described for respiratory standards of care and potential solutions will be proposed to increase safety within this challenging pandemic care environment.

Evolving Understanding of Pathophysiology

Early understanding of COVID-19 suggested that, at least from a pulmonary perspective, it was very similar to the Adult Respiratory Distress Syndrome (ARDS) which, like COVID-19, is characterized by persistent hypoxemia primarily caused by high permeability pulmonary edema [4]. In this condition fluid collects in the interstitial space between the alveoli and pulmonary capillaries impeding gas exchange. In contrast to high pressure (also known as cardiogenic) pulmonary edema, the fluid leaks from the capillary bed because of damage to the capillary walls with none of the pressure associated with right heart failure. Applying this physiology to COVID-19 suggests:

- In early stages ventilation may be nearly normal (good air movement) because the hypoxemia is caused by poor gas exchange and not ineffective ventilation. At this stage, many patients are moving air well and do not need assisted ventilation.
- If hypoxemia is not corrected, the patient's physiologic response is likely to include faster and faster ventilatory rates which may result in airway irritation and big swings in intrapulmonary pressure, both which may cause pressure injury to the lungs which may lead to development of respiratory compromise
- If not carefully managed, intubation and mechanical ventilation can worsen pulmonary pressure injury and result in further deterioration and hypoxia.
- Worsening and sustained hypoxemia increases the risk of vascular abnormalities that may lead to renal dysfunction, multiple organ failure and death.

Greater understanding of this pathology has influenced treatment recommendations related to oxygen therapy and the appropriate roles for non-invasive positive pressure ventilation (NIPPV), intubation, and mechanical ventilation.

Severity of COVID-19 Patients Varies

Early reports out of China described a distribution of severity that has remained relatively consistent throughout the pandemic: 81% mild (can recover at home), 14% severe (require medications and possible hospitalization) and 5% critical (require intensive therapy for management of respiratory failure, septic shock, and multi-organ failure). Mortality was 2.3% (about half of critical patients) [2]. An in-depth study of 52 critically ill patients in a single hospital in Wuhan described the frequency of multiple organ pathologies associated with COVID-19 [5]:

- Acute Respiratory Distress Syndrome (ARDS) 67%
- Hyperglycemia: 35%
- Acute kidney injury: 29%
- Liver dysfunction: 29%
- Cardiac injury: 23%
- Hospital-acquired pneumonia: 11.5%

These pathologies resulted in a broad array of critical care interventions including mechanical ventilation (71%), prone ventilation (11.5%) and extracorporeal membrane oxygenation (ECMO, 11.5%). Twenty-eight-day mortality for these patients was 61.5% [5]. Huang reported similar results for hospitalized patients. Thirty-two percent required ICU care, and 85% of ICU patients were diagnosed with ARDS. Mortality of patients admitted to ICU was 38% [6].

Fortunately, while hospitalization rates have stayed fairly steady, the mortality rate for COVID-19 has significantly decreased since these early reports. Rates of intubation and ventilation have dropped from 70-75% in April to as low as 50% in July, and mortality for patients on mechanical ventilation has decreased from 36% to 32% during the same period [7]. Another study found survival of ICU patients increased from 58% to 79% between March and June, with an increase in survival for all hospitalized patients from 72% to 95% to during the same period [8].

Because COVID-19 mortality (and treatment complexity) is predominantly in the 5% of patients who are critical the remainder of this paper will focus on this group.

Guidelines for Critical Care of COVID-19 Patients

Within weeks of the pandemic outbreak several authors created comprehensive treatment guidelines. The first, submitted on January 29 and published February 6, proposed broad guidelines for evaluation, categorization, and treatment of minor and severe cases at home and in the hospital. Specific recommendations were described for treatment of severe patients, with particular focus on the management of hypoxemic respiratory failure and ARDS [9]. The US Department of Defense issued its Practice Management Guide on March 23rd with a specific section on management of ARDS [10]. At about the same time the Society for Critical Care Medicine issued Surviving Sepsis Campaign: Guidelines on the Management of Critically Ill Adults with Coronavirus Disease 2019, which issued 54 statements that encompassed best practice statements and recommendations. Eighteen of these statements pertained to ventilation [11].

These three guidelines originated in different countries and contexts, but their guidance for airway and ventilator care for the critical COVID-19 patient (most likely with ARDS) were extremely consistent [9-11], and remain as the guiding principles for management of the critical COVID-19 patient. <u>The original guidelines are underlined below; newer insights on the guidelines are in *italics.*</u>

Supplemental Oxygen

<u>Administer supplemental oxygen to maintain SpO2 between 93%-96%. If SpO2 cannot be maintained using conventional oxygen delivery strategies transition to High Flow Nasal Cannula (HFNC).</u>

Delays in treating hypoxia (SpO2 <90%) increase mortality and lead to the need for more invasive therapies which carry their own risks [12, 13].

Non-Invasive Positive Pressure Ventilation (NIPPV)

<u>If HFNC is not available a trial of Non-Invasive Positive Pressure Ventilation (NIPPV) may be attempted, although the clinical efficacy of this treatment is controversial.</u>

Some early authors recommended utilizing NIPPV when HFNC is not available or unsuccessful in maintaining oxygenation [9-11]. There is uniform agreement that HFNC is the optimal therapy if conventional oxygen therapy fails to improve SpO2, but controversy remains on the risk/benefit of NIPPV. It does appear that failure of HFNC is a poor prognostic sign and indicates a need to promptly move to more aggressive strategies such as intubation, mechanical ventilation, *or proning [14, 15]. It should be noted that HFNC use increases the risk of aerosolized virus exposure of staff [16].*

Intubation

If ventilation and oxygenation cannot be effectively managed rapidly using the above strategies perform intubation. Early intubation is preferred over waiting for patient deterioration to occur.

Subsequent studies have demonstrated that there is no apparent benefit from "early intubation" [15, 17]. While sometimes necessary to stabilize patients, endotracheal intubation confers substantial risk to patients and providers. Desaturation during the procedure occurs in up to 73% of intubations—problematic in an already hypoxic patient—and also frequently causes hypotension [18, 19]. Performance of intubation is also stressful for staff who fear COVID-19 exposure and is reported to be associated with development of COVID symptoms in 10% of intubations, and a COVID diagnosis for nearly half of the symptomatic staff [18, 20]. It should be noted that some investigators report NO cases of COVID symptoms or diagnosis in intubating staff [19, 21].

Mechanical Ventilation

Optimal ventilator settings target low tidal volume, low target plateau pressures, and higher than normal PEEP. Use these as targets but establish ventilator settings that achieve SpO2 and ventilation goals.

Prone Ventilation

Utilize prone ventilation (12-16 hours/day) for moderate to severe ARDS and/or the inability to maintain adequate oxygenation and ventilation in the supine position.

These initial recommendations were based on data gathered on non-COVID-19 ARDS patients receiving mechanical ventilation [22-24]. While proning seemed beneficial to all patients, subgroup analyses showed the greatest improvement was in the sickest patients [25]. These results have now been reported in mechanically ventilated COVID-19 patients, in whom 82% had improvement in PaO2 and/or PaO2/FiO2 ratio [26].

The process of transferring the patient between prone and supine positions, which requires a mean of 10 minutes and 4.6 staff members, is associated with multiple complications: airway obstruction (39%), ventilator disconnection (20%), desaturation (12%), and accidental extubation (0.5%) [25]. Other reported complications include unplanned central catheter removal during prone positioning, unplanned extubation, ET tube obstruction, ventilator associated pneumonia, and skin breakdown [10, 24, 27].

Over 40% of proned patients experienced significant complications including facial edema, skin pressure injuries, and airway complications/ETT obstruction.

Over 40% of proned patients experienced significant complications including facial edema, skin pressure injuries, and airway complications/ETT obstruction [26, 28]. These complication rates are comparable to those reported for non-COVID patients [26]. Literature and direct communication with ICU staff suggest that pressure injuries experienced by intubated patients in the prone position may be exacerbated by commercial ETT securement devices [29, 30]. In fact, in the procedure for patient preparation prior to proning, the DoD COVID19 Practice Management Guide specifically states "Do not secure ETT with a commercial securement device (i.e. Hollister)" while also reinforcing the need for frequent changes in tape securing the ETT "... RT needs to change ETT tape at least once a day or more frequently if necessary due to facial swelling." [10]. This creates a conundrum for clinicians. Securing the ETT with a commercial device provides superior protection against unplanned extubation but may increase facial pressure injuries; securement with tape or twill may reduce the incidence of facial pressure injuries but is associated with increased rates of unplanned extubation [31-33] Some clinicians have reported that they remove commercial devices and *utilize tape and twill for securement prior to proning, and then return to commercial devices after proning is completed [29, 30], requiring additional staff time and increasing the risk for ETT movement during the transition.*

Interestingly, it has been reported that proning non-intubated patients who are conscious and able to follow instructions has improved SpO2 and PaO2/FiO2 ratio without impacting pH or PaCO2 [34, 35]; an ED study documented improvement of median SpO2 from 84%- to 94% following 5 minutes of patient "self-proning" with no change in FiO2 [34].

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Neuromuscular Agents

Administer neuromuscular blocking agents when necessary to enable airway control and ventilation, and to facilitate protective lung ventilation. Intermittent bolus administration is preferred but continuous infusion may be required.

Beyond facilitating patient compliance with airway control and mechanical ventilation, paralysis/sedation also serves to protect the lungs from increased pressure related damage caused by patient efforts to "buck" the ventilator [4].

Extra Corporeal Membrane Oxygenation (ECMO)

For continuing deterioration consider use of Extra Corporeal Membrane Oxygenation (ECMO) if expertise and equipment are available.

Logistical ICU Challenges associated with the COVID-19 Pandemic

One of the greatest challenges of the COVID-19 pandemic is matching healthcare delivery capacity with patient needs. The experiences of both China and Italy demonstrate the consequences of having inadequate medical resources to meet patient needs. The Society of Critical Care Medicine has developed a resource estimate for availability of critical care resources [36]. Key findings of the estimate include:

- Hospital and ICU beds The United States is reported to have the most critical care beds per capita of any country in the study (US 34.7/100,000 inhabitants, compared to 12.5 for Italy and 3.6 for China); the number of ICU beds in the US is just under 100,000. Based on estimates from the American Hospital Association that 1.9 million US COVID-19 patients will require ICU admission, each ICU bed would need to be able to care for 19 patients during the pandemic surge.
- Staffing Prior SCCM surveys found that 48% of acute care hospitals have no intensive care specialists. During the pandemic staff levels of intensivists, as well as critical care trained nurses and respiratory therapists, will likely be below current levels due to sickness and quarantine. The SCCM estimates that staffing shortages alone will limit the ability of ICUs to care for any more than 135,000 patients requiring mechanical ventilation—far below the SCCM estimate of 960,000 COVID-19 patients who will require mechanical ventilation.
- Ventilators 2009 estimates of ventilator inventory in hospitals suggests that there are approximately 62,000 ventilators available in US hospitals. An additional 99,000 ventilators of varying age and functionality may also be available as "backup", although some may not meet demanding patient needs or still be serviceable. Assuming that only the "front line" ventilators are available, each ventilator would be needed to care for at least 15 patients during the pandemic surge. The SCCM report suggests that

the ventilator supply may be adequate but will be limited by trained staff availability. As of September 2020, it was reported that the U.S. Strategic National Stockpile (SNS) contained 120,000 functioning ventilators [37]. Each state also has their own individual plans for procurement, stockpile and deployment of state assets and facilities including hospitals and EMS systems should we aware of the process for deployment of these assets in their own state.

"Perfect Storm" for Risks to Patient and Provider Safety

The guidelines that have been issued for the challenging intensive care of severe COVID-19 patients are extraordinarily helpful and offer value in optimizing and standardizing care across the world. However, the combination of high intensity care guidelines with space, staffing and equipment challenges creates predictable and severe safety risks to both patients and providers. Identification of these risks will hopefully increase provider vigilance and adherence to best practices. More important, they must inform establishment of improved care and monitoring processes to mitigate risk and assure safety. Table 1 outlines the safety risks and potential solutions associated with COVID-19 Treatment Guidelines.

Conclusions

The COVID-19 pandemic challenges the healthcare delivery system in historic ways. Assuring competent and safe care to growing volumes of critical patients requires careful attention to emerging care guidelines coupled with deliberate efforts to mitigate challenges created by shortages of hospital and ICU beds, critical care prepared staff, and equipment. This article offers the following suggestions for optimizing safe care:

- Use evidence-based guidelines to clearly identify which procedures are "aerosolizing" and present infectious risk to healthcare providers. Establish procedures and checklists for oxygen delivery and airway management for these patients and follow CDC/WHO guidelines for appropriate PPE. To assure adequate inventory of PPE for these procedures restrict use of N95 (respirators) to aerosolizing procedures and have adequate surgical masks in stock for all other uses.
- Utilize evidence-based strategies to prevent (and recognize when it does occur) unplanned extubation including use of continuous capnography, effective ETT securement, adequate patient sedation, clear unit policies and procedures for monitoring/maintenance of ETT and mechanical ventilator, and adequate and frequent staff training (especially with non-critical care staff).
- Develop and use checklists for moving intubated/ventilated patients into the prone position. Practice the procedure before performing. Utilize best practices for monitoring and maintaining ETT security (described above) before, during and after the move.
- Have clear unit policies and procedures regarding both neuromuscular blockade and sedation. Perform monitoring regularly and assure that adequate staffing and restraint is in place during periods when sedation is reduced.
- Select patients to receive ECMO carefully and ONLY have ECMO performed by experienced staff. Avoid "crash" ECMO by performing before patients are in extremis.

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Table 1

Guideline	Safety Risks	Potential Solutions
High flow nasal cannula, appropriate care for respiratory distress such as bronchodilation, and early intubation [38] in patients who are not adequately oxygenated.	Risk of aerosolized secretions that may expose healthcare providers [39].	This article offers the following suggestions for optimizing safe care: • Utilize optimal intubation processes to reduce the risk of aerosol release during the procedure [18-21, 38, 40]. • Some guidelines recommend placement of a surgical mask on patients being treated with high-flow therapies as a secondary safety measure [41]. • Follow CDC/WHO guidelines for healthcare provider PPE when any of these procedures are being performed. • In facilities/systems in which respiratory supplies (N95) are low, reserve their use for procedures with high aerosolized risk.

Prone positioning of intubated patients receiving mechanical ventilation	This article offers the following suggestions for optimizing safe care:
	• One study reported that 95% of proned patients experienced at least one of the following compli-cations [42]:
	• Unplanned extuba-tion, airway obstruction, transitory de-saturation/ hypotension, dislodgement of lines or tubes **during transfer.**
	• ETT kinking or ob-struction **during prone periods** may occur in 2.4%-25% of patients [26, 27] .
	• Facial edema or skin pressure injuries dur-ing prone periods.
	• Inconsistent or inade-quate blockade and se-dation are associated with unplanned ex-tuba-tion in supine patients [43, 44]. Risk increases during lifting of sedation associated with ICU liberation.
		Utilize (and practice) coordinated teams [18-21] and checklists when transferring patients between supine and prone positions.
		• Evidence and treatment guidelines state that reliable use of checklists reduces complications substantially [10, 27].
		• A key element of successful checklists is the delineation of team roles and responsibilities, which is especially important when working with an unfamiliar or less experienced team.
		Utilize evidence-based strategies for preventing unplanned extubation before, during and after pronation including:
		• Continuous monitoring of oxygenation and ventilation using capnography and oximetry.
		• Adequate sedation and management of agitation [43, 44]
		• Utilization of clear policies related to ETT monitoring, assessment, and weaning [45]
		• Adequate and frequent training. When inexperienced staff must be used assure they are teamed with and under the supervision of trained and experienced critical care colleagues [45].
		• Assure that the ETT is secure.
		    • Commercial ETT securement devices have been proven more secure than tape[24, 31-33]; various devices provide equal protection [25].
		    • Newer securement devices may provider greater resistance to external force [46, 47].
		    • Seek devices with short profiles that reduce/eliminate facial skin pressure.
		    • When possible, avoid REMOVING securement devices in an attempt to reduce facial pressure. Removal increases the risk of ETT malposition or extubation

Table 1 cont.

Guideline	Safety Risks	Potential Solutions
Neuromuscular blocking agents and sedation	Inconsistent or inade-quate blockade and sedation are associated with unplanned extu-ba-tion in supine patients [43, 44]. Risk increases during lifting of sedation associated with ICU liberation.	• Regularly monitor both blockade and sedation and have clear guidelines for "target" sedation. • Assure adequate staffing and physical restraint when sedation is reduced to prevent unplanned extubation and other causes of patient and staff harm.
ECMO	ECMO is infrequently performed in many facilities, and has multiple complications including death.	• ONLY have experienced staff perform ECMO using the procedures and equipment with which they are familiar. • Utilize (and practice) checklists when performing ECMO. • Avoid "crash" ECMO by performing BEFORE the patient is in extremis following the failure of other therapies. In addition, select patients carefully. Because of the high resource requirements ECMO should only be used in selected COVID-19 patients who are expected to improve [11].