A Transdisciplinary COVID-19 Early Respiratory Intervention Protocol: An Implementation Story

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My colleague asked, "Do you remember that patient?" I froze because, like most emergency physicians, this phrase haunts me. It was the early days of the COVID-19 epidemic, and the story that followed was upsetting. A patient who looked comfortable when I admitted him was intubated hours later by the rapid response team who was called to the floor. All I could think was, "But he looked so comfortable when I admitted him; he was just on a couple of liters of oxygen. Why was he intubated?"

In the days after COVID-19 arrived in our region, there were many such stories of patients sent to the floor from the Emergency Department who were intubated shortly after admission. Many of those patients subsequently endured prolonged and complicated courses on the ventilator. While we would typically use noninvasive modalities such as high-flow nasal cannula (HFNC) or noninvasive ventilation (NIV) for acute respiratory failure, our quickness to intubate was driven by two factors: (1) early reports that noninvasive modalities posed a high risk of failure and subsequent intubation and (2) fear that HFNC and NIV would aerosolize SARS-CoV-2 and unnecessarily expose the heath care team.[1] We would soon find out that our thinking was flawed on both accounts.

RETHINKING INITIAL ASSUMPTIONS

When we dug into the evidence for early intubation, we realized that these recommendations were based on a 12-patient series in which 5 patients were trialed on NIV but ultimately intubated and placed on invasive mechanical ventilation (IMV). As the pandemic progressed, more case series and small studies were published, revealing a different picture.[2] Sun and colleagues reported a multifaceted intervention of 610 inpatients, of whom 10% were critically ill, that identified at-risk patients and used NIV or HFNC and awake proning. Reportedly, fewer than 1% required IMV.[3] Similarly, a small study found intubation was avoided in 85% of patients with severe acute respiratory failure caused by COVID-19 with use of HFNC and NIV.[4] Early findings from New York University in New York, New York, where only 8.5% of patients undergoing IMV were extubated by the time of outcome reporting, suggest early IMV could lead to poor outcomes.[5]

Still, we had concerns about use of HFNC and NIV because of worries about the health and safety of other patients and particularly that of healthcare workers (HCWs) because they have been disproportionately affected by the disease.[6] Fortunately, we identified emerging data that revealed that HFNC is no more aerosolizing than low-flow nasal cannula or a nonrebreather mask and droplet spread is reduced with a surgical mask.[7,8] In light of these new studies and our own developing experience with the disease, we felt that there was insufficient evidence to continue following the "early intubation" protocol in patients with COVID-19. It was time for a new paradigm.

GATHERING EVIDENCE AND STAKEHOLDERS

In order to effectively and quickly change our respiratory pathway for these patients, we initially sought out protocols from other institutions through social media. These protocols, supported by early data from those sites, informed our process. We considered data from various sources, including emergency medicine, hospital medicine, and critical care. We then assembled stakeholders within our organization from emergency medicine, hospital medicine, critical care, and respiratory therapy because our protocol would need endorsement from all key players within our organization who cared for these patients across the potential spectrum of care. We made sure that all stakeholders understood that the quality of the evidence for treatment of this novel disease was much lower than our typical threshold to change practice, but that we aimed to reflect the best evidence to date. We also were careful to identify pathways that would be amenable to near-immediate implementation.

UNVEILING A NOVEL PROTOCOL

Our group reached consensus within 48 hours and quickly disseminated our first draft of the protocol (Appendix Figure). Dubbed the "Early Intervention Respiratory Protocol," it differed from usual management in several ways. First, we had consistently observed (and confirmed from the literature) a phenotype of patients with "silent hypoxemia"[9] (that is, a subset of patients who presented with profound hypoxemia but minimally increased work of breathing). The protocol encouraged tolerance of lower oxygen saturations than is usually seen

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TABLE. **Facilitators for Rapid Translation of Protocol Into Practice**

Facilitator	Details	Rationale
Flowchart for bedside care	Easy-to-read algorithm for escalation of respiratory support (See Appendix Figure)	Simplified decision-making at the bedside and reduced cognitive overload for the individual.
Multipronged dissemination	Email	Built on the historical expectation that clinicians check work email.
	Text messaging (Whatsapp)	Responded to an increase in use of the clinician text messaging group, which was leveraged to maximize reach.
	Living document for shift (Google Drive)	Allowed protocol to be uploaded to a living document that was updated in real time and designed to be used on shift.
	In-person education	Ensured everyone working a shift (physicians, residents, nurses) were acquainted with the protocol through huddles at the beginning of emergency department shifts.
Unit Reorganization	All COVID-19 patients needing substantial respiratory support grouped into a single unit	Put high-risk patients together for closer monitoring and expedited intervention, if needed. Conserved personal protection equipment.
	Interdisciplinary consultation: Rapid response team and critical care team agreed to round on unit daily and be available as needed for consults	Ensured safety of patients and provided hospitalists with additional support.
Rapid Training	Train-the-trainer sessions	Allowed rapid training and dissemination, created champions of the protocol, and reinforced dissemination efforts.
Institutional support	Supported by multiple departments (Emergency Medicine, Critical Care, Hospital Medicine, Pulmonary Medicine, Respiratory Therapy, and hospital leadership)	Promoted buy-in from clinicians and enabled protocol use throughout the spectrum of care (eg, Emergency Department, hospital floor, Intensive Care Unit)

on inpatient units. This required ensuring all stakeholders were comfortable with a target oxygen saturation of 88%. Second, the protocol leveraged early "awake" proning by patients. Historically, proning is used in mechanically ventilated patients with acute respiratory distress syndrome (ARDS) to improve ventilation-perfusion matching, promote more uniform ventilation, and increase end-expiratory lung volume.[10] Prior literature was limited to the use of awake proning in small case series of ARDS, but given our limitations in terms of ICU capacity, we agreed to trial awake proning in a sizable proportion of our COVID-19 patients outside the ICU.[11,12] Finally, we clarified safe practices regarding the risk of aerosolization with noninvasive modalities. Local infection control determined that HFNC wa not aerosol generating, and use of surgical masks was added for further protection from respiratory droplets. In addition, airborne personal protective equipment was to be worn on the inpatient ward, and we used NIV sparingly and preferentially placed these patients in negative pressure rooms, if available.[13]

Implementation of the protocol involved aggressive dissemination and education (Table). A single-page protocol was designed for ease of use at the bedside that included anticipatory guidance regarding aerosolization and addressed potential resistance to awake proning because of concerns regarding safety and hassle. Departmental leaders disseminated the protocol throughout the institution with tailored education on the rationale and acknowledgment of a reversal in approach. In addition to email, we used text messaging (WhatsApp) and a comprehensive living document (Google Drive) to reach clinicians.

For ease of monitoring and safety, we designated a COVID-19 intermediate care unit. We partnered with the unit medical director, nurse educator, and a focused group of hospitalists, conducting individual train-the-trainer sessions. This training was carried forward, and all nurses, respiratory therapists, and clinicians were trained on the early aggressive respiratory protocol within 12 hours of protocol approval. In addition, the rapid response and critical care teams agreed to round on the COVID-19 intermediate care unit daily.

As a result of these efforts, adoption of the protocol was essentially immediate across the institution. We had shifted the mindset of a diverse group of clinicians regarding how to support the respiratory status of these patients, but also detected reductions in the proportion of patients undergoing IMV and ICU admission (we are planning to report these results separately).

TRANSLATING KNOWLEDGE INTO PRACTICE

The COVID-19 pandemic has highlighted the importance of having cognitive flexibility when the evidence base is rapidly changing and there is a need for rapid dissemination of knowledge. Even in clinical scenarios with an abundance of high-quality evidence, a gap in knowledge translation on the order of a decade often exists. In contrast, a pandemic involving a novel virus highlights an urgent need for adaptive knowledge translation in the present moment rather than a decade later. In the absence of robust evidence regarding SARS-CoV-2, early management of COVID-19 was based on expert recommendations and experience with other disease processes. Even so, we should anticipate that management paradigms may shift, and we should constantly seek out emerging evidence to adjust our mindset (and protocols like this) accordingly. Our original protocol was based on nearly nonexistent

evidence, but we anticipated that, in a pandemic, data would accumulate quickly, so we prioritized rapid translation of new information into practice. In fact, further evidence has emerged regarding the improvement in oxygenation in COVID-19 patients with self-proning.[14]

The final step is evaluating the success of both clinical and implementation outcomes. We are attempting to identify changes in intubation, length of stay, days on ventilator, and days in ICU. In addition, we will measure feasibility and adaptability. We are also attempting, in real time, to identify barriers to its use, including conducting qualitative interviews to understand whether there were unintended consequences to use of the protocol.

This endeavor highlights how the COVID-19 pandemic, for all its tragedy, may represent an important era for implementation science: a time when emerging literature from a variety of sources can be implemented in days rather than years.

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References

1. World Health Organization. Clinical management of severe acute respiratory infection (SARI) when COVID-19 disease is suspected. 2020. https://www.who.int/publications-detail/clinical-management-of-severe-acute-respiratory-infection-when-novel-coronavirus-(ncov)-infection-is-suspected. Accessed March 25, 2020.
2. Zhou F, Yu T, Du R, et al. Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study. *Lancet*. 2020;395(10229):1054-1062. https://doi.org/10.1016/s0140-6736(20)30566-3.
3. Sun Q, Qiu H, Huang M, Yang Y. Lower mortality of COVID-19 by early recognition and intervention: experience from Jiangsu Province. *Ann Intensive Care*. 2020;10(1):33. https://doi.org/10.1186/s13613-020-00650-2.
4. Wang K, Zhao W, Li J, Shu W, Duan J. The experience of high-flow nasal cannula in hospitalized patients with 2019 novel coronavirus-infected pneumonia in two hospitals of Chongqing, China. *Ann Intensive Care*. 2020;10(1):37. https://doi.org/10.1186/s13613-020-00653-z.
5. Petrilli C, Jones SA, Yang J, Rajagopalan H, et al. Factors associated with hospitalization and critical illness among 4,103 patients with Covid-19 disease in New York City [preprint]. *medRxiv*. 2020. https://doi.org/10.1101/2020.04.08.20057794. Accessed April 12, 2020.
6. Wang D, Hu B, Hu C, et al. Clinical characteristics of 138 hospitalized patients with 2019 novel coronavirus–infected pneumonia in Wuhan, China. *JAMA*. 2020;323(11):1061-1069. https://doi.org/10.1001/jama.2020.1585.
7. Leonard S, Volakis L, DeBellis R, Kahlon A, Mayar S. Transmission Assessment Report: High Velocity Nasal Insufflation (HVNI) Therapy Application in Management of COVID-19. March 25, 2020. *Vapotherm Blog*. 2020. https://vapotherm.com/blog/transmission-assessment-report/. Accessed March 25, 2020.
8. Iwashyna TJ, Boehman A, Capecelatro J, Cohn A, JM. C. Variation in aerosol production across oxygen delivery devices in 2 spontaneously breathing human subjects [preprint]. *medRxiv*. 2020. https://doi.org/10.1101/2020.04.15.20066688. Accessed April 20, 2020.
9. Meng L, Qiu H, Wan L, et al. Intubation and ventilation amid the COVID-19 outbreak [online ahead of print]. *Anesthesiology*. 2020. https://doi.org/10.1097/aln.0000000000003296.
10. Munshi L, Del Sorbo L, Adhikari NKJ, et al. Prone position for acute respiratory distress syndrome: a systematic review and meta-analysis. *Ann Am Thorac Soc*. 2017;14(suppl 4):S280-S288. https://doi.org/10.1513/annalsats.201704-343ot.
11. Scaravilli V, Grasselli G, Castagna L, et al. Prone positioning improves oxygenation in spontaneously breathing nonintubated patients with hypoxemic acute respiratory failure: a retrospective study. *J Crit Care*. 2015;30(6):1390-1394. https://doi.org/10.1016/j.jcrc.2015.07.008
12. Ding L, Wang L, Ma W, He H. Efficacy and safety of early prone positioning combined with HFNC or NIV in moderate to severe ARDS: a multi-center prospective cohort study. *Crit Care*. 2020;24(1):28. https://doi.org/10.1186/s13054-020-2738-5.
13. Alhazzani W, Møller MH, Arabi YM, et al. Surviving Sepsis Campaign: guidelines on the management of critically ill adults with coronavirus disease 2019 (COVID-19). *Intensive Care Med*. 2020;1-34. https://doi.org/10.1007/s00134-020-06022-5.
14. Caputo ND, Strayer RJ, Levitan R. Early self-proning in awake, non-intubated patients in the emergency department: a single ED's experience during the COVID-19 pandemic [online ahead of print]. *Acad Emerg Med*. 2020. https://doi.org/10.1111/acem.13994.