Pablo Alberto Cuartas BA1, Heitor Tavares Santos MD2, Benjamin M Levy BS1, Michelle Ng Gong MD3, Tia Powell MD4 and Elizabeth Chuang MD, MPH5

1Albert Einstein College of Medicine, Bronx, NY, USA; 2Division of Internal Medicine, Department of Medicine, Albert Einstein College of Medicine, Jacobi Medical Center, Bronx, NY, USA; 3Division of Critical Care Medicine, Division of Pulmonary Medicine, Department of Medicine, Albert Einstein College of Medicine, Montefiore Medical Center, Bronx, NY, USA; 4Montefiore Einstein Center for Bioethics and 5Department of Family and Social Medicine, Albert Einstein College of Medicine, Montefiore Medical Center, Bronx, NY, USA

Abstract

Objective: To model performance of the Sequential Organ Failure Assessment (SOFA) score-based ventilator allocation guidelines during the COVID-19 pandemic.

Methods: A retrospective cohort study design was used. Study sites included 3 New York City hospitals in a single academic medical center. We included a random sample (205) of adult patients who were intubated (1002) from March 25, 2020, till April 29, 2020. Protocol criteria adapted from the New York State’s 2015 guidelines were applied to determine which patients would have had mechanical ventilation withheld or withdrawn.

Results: 117 (57%) patients would have been identified for ventilator withdrawal or withholding based on the triage guidelines. Of those 117 patients, 28 (24%) survived hospitalization. Overall, 65 (32%) patients survived to discharge.

Conclusion: Triage protocols aim to maximize survival by redirecting ventilators to those most likely to survive. Over 50% of this sample would have been identified as candidates for ventilator exclusion. Clinical judgment would therefore still be needed in ventilator reallocation, thus reintroducing bias and moral distress. This data suggests limited utility for SOFA score-based ventilator rationing. It raises the question of whether there is sufficient ethical justification to impose a life-ending decision based on a SOFA scoring method on some patients in order to offer potential benefit to a modest number of others.

Introduction

COVID-19 (2019 novel coronavirus) activity continues to cause a high disease burden and hospitals around the world remain vulnerable to ventilator scarcity.1,2 Crisis based Standards of Care guidelines aim to maximize the number of lives saved by reallocating resources from those who will not benefit to those who will, and reducing potential bias and clinician moral distress resulting from ad hoc bedside rationing.3 In the United States, 26 states have allocation guidelines and 15 use the Sequential Organ Failure Assessment (SOFA) score to triage patients.4 SOFA scores predict mortality in hospitalized patients,5 and provide objective data to reduce the need for clinician judgment that may be prone to bias. It is unknown how efficiently they ration resources to patients who are most likely to survive. We use data from the peak of the spring 2020 surge of COVID-19 in New York City (the period with the highest disease burden) to model performance of a protocol adapted from New York State’s 2015 guidelines.6 The protocol, as adapted from the 2015 guidelines, was not implemented and ventilators were not rationed at the study sites during the study period. This report estimates how well the adapted protocol would have predicted outcomes, had the protocol been implemented. The authors are unaware of other published literature that has modeled a ventilator rationing protocol using similar data.

Methods

This protocol was reviewed and approved by the Montefiore/Einstein Institutional Review Board (IRB# 2020-11324). This is a chart review of a representative random sample (205) of 20.5% of all intubated adult patients (1002) in 3 NYC hospitals between March 25, 2020, and April 29, 2020, regardless of etiology of respiratory failure. All 1002 patients were assigned an ordinal numerical value. A simple randomization program was used to obtain the study
Table 1. Characteristics of study population

| Variables | Survived to Discharge | Expired | RR mortality for meeting exclusion criteria |
|-----------|-----------------------|---------|------------------------------------------|
| Mean Age (years) | 63 (23-97) | Mean BMI (kg/m/m) | 31 (14-55) |
| % | % | 1.31 (0.95 CI: 1.07-1.61; P = 0.009; NNT = 5.52) |
| N | 65 | 31.71% | 140 | 68.29% |
| Male | 28 | 43.08% | 89 | 63.57% |
| Female | 37 | 56.92% | 51 | 36.43% |
| ≥ 1 Comorbidity | 61 | 93.85% | 134 | 95.71% |
| No Comorbidity | 4 | 6.15% | 6 | 4.29% |
| COVID (+) | 52 | 80.00% | 109 | 77.86% |
| COVID (-) | 13 | 20.00% | 31 | 22.14% |
| Blue at T0, T48, or T120 | 28 | 43.08% | 89 | 63.57% |
| Not Blue at T0, T48, or T120 | 37 | 56.92% | 51 | 36.43% |
| Mean Ventilator Days | 18.91 SD 23.27 (1-100) | 9.86 SD 11.08 (0 - 58) |

Approximately 20% of the sample was COVID-19 negative. Of 205 patients, 65 (32%, 95% CI 25-39%) survived to discharge. About 117 patients (57%, 95% CI 50-64%) were categorized as blue at 1 or more points in time and would have been candidates for exclusion from ventilation. Out of the 117 patients who were categorized as blue points, 28 (24%, 95% CI 17-33%) ultimately survived hospitalization. Patients who had ever been in the blue category had a higher mortality rate (76%) if compared with those who were never categorized blue (58%, P < 0.01). Of the 140 patients who died, 89 (63%) were categorized as blue during at least one time point (Table 1). The Figure does not only illustrate fluctuations in patient categorization over time, but also how SOFA at T120 discriminated better than at T48. All 16 blue-category patients at T0 had SOFA scores ≥ 11. Of the 95 blue-category patients at T48, 35 had SOFA scores ≥ 11 and 60 were categorized as blue due to lack of sufficient improvement in SOFA score. Out of 49 blue-category patients at T120, 29 had SOFA scores ≥ 11 and 20 were categorized as blue due to lack of sufficient improvement in SOFA score.

Limitations

The primary limitation of this study is that it is a retrospective descriptive single center study which limits generalizability. Another limitation was missing data for some SOFA scores. However, this limitation represents a real-world challenge which clinicians would face in implementation of an organ dysfunction score-based triage protocol during a public health crisis. Thus, these data reflect the conservative approach to managing such circumstances in practice. The sample size of 205 limits generalizability as well. The lack of detailed outcome analysis, such as the discharge dispositions for patients who were extubated, is another limitation.

Discussion

Ventilator triage protocols aim to maximize survival by redirecting ventilators from those who will die with or without them to patients who are more likely to survive with ventilator support. In this sample, more than 50% of the patients (57%) would have
been categorized as blue and identified as candidates for ventilator removal over the first 120 hours following triage. Mortality was similar in red and yellow categories. However, more lives can be saved only if a ventilator is reallocated from a patient who will die despite ventilation to another patient who will survive with ventilation. The 28 patients who survived were assigned to blue category (43% of survivors) and would have likely died if ventilation was withdrawn. If all 117 ventilators from patients in the blue category were re-directed to prioritized patients with similar survival rate (41%), an estimated 48 patients would have survived compared to the 28 patients in the blue category. Real-life gains in survival would depend on the actual shortfall of ventilators, staff availability, and the rate at which new patients with respiratory failure presented. Improvements in the management of COVID-19 since the initial surge have also improved mortality. Thus, these data may not reflect what would happen in a different institution if there was a need for triage later in the pandemic. Though mortality was higher in this cohort than in other studies from similar geographic areas and time points, this investigation included only patients who required mechanical ventilation.

During the study period, the 3 NYC hospitals were able to avoid rationing by implementing resource augmentation measures such as alternative ventilator support and staffing strategies. The impact of these changes in care delivery processes on mortality is unknown. These data are consistent with other studies which have found poor SOFA score discriminant accuracy up to the time of intubation. However, these data also demonstrate limited SOFA score discriminant accuracy in mechanically ventilated patients at multiple assessment intervals during hospitalization.

Since over 50% of all patients were categorized as blue during at least 1 assessment interval, clinical judgment may still be needed in reallocating ventilators and deciding which patients in the blue category to extubate first. This may re-introduce bias and exacerbate moral distress, both being issues that an effective ventilator triage protocol ought to address. Adjustments to improve score discrimination may include assessing priority at a much later time in order to reflect the prolonged respiratory failure of patients with COVID-19. The difference in outcome prediction accuracy between T48 and T120, as depicted in Figure 1, highlights this. More specific scoring systems such as the 4C mortality score may improve performance compared with the SOFA score. Alternative triage strategies such as the first-come first-served, randomization, clinician judgement, and use of triage committees, all lack empirical efficacy data and have well described ethical shortcomings which would need to be creatively addressed.

Our findings differ from a recent large retrospective cohort study which found that few patients were categorized in the New York State guideline blue category among more than 40000 ICU admissions in a national sample. Our sample more
closely reflects the acuity of pandemic conditions. However, both sets of findings demonstrate that existing guidelines poorly identify those who will not benefit from mechanical ventilation.

**Conclusion**

Currently, apart from excluding patients with overwhelming short-term likelihood of death, no known triage system has empiric evidence that it predicts mortality with sufficient accuracy to substantially increase population survival. The data from this preliminary study suggest that the SOFA score has a limited utility in triage, thus raising questions as to whether there is sufficient ethical justification to impose a life-ending decision on a subset of patients to offer potential benefit to a modest number of others.

**Conflict(s) of interest.** The authors have no conflicts of interest to disclose.

**Funding statement.** Elizabeth Chuang PhD received funding from the National Center for Advancing Translational Sciences Institutional Career Development Core KL2TR002558-03, through the Einstein-Montefiore Institute for Clinical and Translational Mentored Clinical/Translational Research Career Development Award.

**References**

1. Burke RM, Midgley CM, Dratch A, et al. Active monitoring of persons exposed to patients with confirmed COVID-19 - United States, January-February 2020. MMWR 2020;69(9):245-246. Published 2020 Mar 6. doi: 10.15585/mmwr.mm6909e1.
2. Ranney ML, Griffith V, Jha AK. Critical supply shortages - the need for ventilators and personal protective equipment during the Covid-19 pandemic. N Engl J Med. 2020;382(18):e41. doi: 10.1056/NEJMp2006141
3. Committee on Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations; Institute of Medicine. Crisis standards of care: A systems framework for catastrophic disaster response. Washington (DC): National Academies Press (US); March 21, 2012. doi: 10.17226/13351.
4. Piscitello GM, Kapania EM, Miller WD, et al. Variation in ventilator allocation guidelines by US State during the Coronavirus Disease 2019 Pandemic: A Systematic Review. JAMA Netw Open. 2020;3(6):e2012606. doi: 10.1001/jamanetworkopen.2020.12606
5. deGrooth HJ, Geenen IL, Girbes AR, et al. SOFA and mortality endpoints in randomized controlled trials: a systematic review and meta-regression analysis. Crit Care. 2017;21(1):38. doi: 10.1186/s13054-017-1609-1.
6. New York State Task Force on Life and the Law, New York State Department of Health. Ventilator allocation guidelines. Published November 2015. Accessed September 1, 2020. https://www.health.ny.gov/regulations/task_force/reports_publications/docs/ventilator_guide lines.pdf
7. Vincent JL, Moreno R, Takala J, et al. The SOFA (Sepsis-related Organ Failure Assessment) score to describe organ dysfunction/failure. On behalf of the Working Group on Sepsis-Related Problems of the European Society of Intensive Care Medicine. Intensive Care Med. 1996;22(7):707-710. doi: 10.1007/BF01709751.
8. Lambden S, Laterre PF, Levy MM, Francois B. The SOFA score-development, utility and challenges of accurate assessment in clinical trials. Crit Care. 2019;23(1):374. Published 2019 Nov 27. doi: 10.1186/s13054-019-2663-7.
9. Filardo TD, Khan MR, Krawczyk N, et al. Comorbidity and clinical factors associated with COVID-19 critical illness and mortality at a large public hospital in New York City in the early phase of the pandemic (March-April 2020). PLoS One. 2020;15(11):e0242760. doi: 10.1371/journal.pone.0242760.
10. Keene AB, Shiloh AL, Eisen L, et al. Critical Care Surge during the COVID-19 pandemic: implementation and feedback from frontline providers. J Intensive Care Med. 2021 Feb;36(2):233-240. doi: 10.1177/0885066620973175.
11. Raschke RA, Agarwal S, Rangan P, Heise CW, Curry SC. Discriminant accuracy of the SOFA score for determining the probable mortality of patients with COVID-19 pneumonia requiring mechanical ventilation. JAMA. 2021;325(14):1469-1470. doi: 10.1001/jama.2021.1545.
12. Knight SR, Ho A, Pius R, et al. Risk stratification of patients admitted to hospital with covid-19 using the ISARIC WHO Clinical Characterization Protocol: development and validation of the 4C Mortality Score [published correction appears in BMJ. 2020 Nov 13;371:m3334]. BMJ. 2020;370:m3339. doi: 10.1136/bmj.m3339.
13. Wunsch H, Hill AD, Bosch N, et al. Comparison of 2 triage scoring guidelines for allocation of mechanical ventilators [published correction appears in JAMA Netw Open. 2021 Feb 1;4(2):e212183]. JAMA Netw Open. 2020;3(12):e2029250. doi: 10.1001/jamanetworkopen.2020.29250.