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Research Article

Relationships Among Select Comorbidities, Duration of Mechanical Ventilation, Treatment Modalities, and Patient Survival in Patients with COVID-19 who Require Extracorporeal Membrane Oxygenation (ECMO)

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Abstract

Background: Up to 12% of patients with COVID-19 develop multisystem problems and require ICU admission commonly due to ARDS and need for mechanical ventilation. In some cases, the acute hypoxic respiratory failure (AHRF) is refractory to standard therapies and requires initiation of venovenous extracorporeal membrane oxygenation (VV ECMO). Several comorbidities may be associated with poorer outcomes. The purpose of this single site retrospective chart review was to evaluate the relationships among select comorbidities (hypertension, diabetes, obesity, and asthma) in relation to patient outcomes of time on ECMO and survival **Methods**: A retrospective chart review in two adult ICUs of a tertiary academic medical center in the southeast between March 24, 2020 and June 30, 2020 was conducted. Adult patients with refractory AHRF who tested positive for COVID-19 and required VV ECMO were evaluated. **Results**: The ages of the 60 patients ranged from 20 to 65 years. The number of comorbidities ranged from 0 to 4. The most common comorbidity was hypertension. Of the 60 patients, 43 survived their ICU admission. The number of days on ECMO ranged from 2 to 108 (median 14 days). Ventilation days ranged from 1 to 48 days. Significant findings included a shorter period on ECMO in those with higher PaO_2/FiO_2 ratios, which was also associated with a shorter LOS. Anticipated predictors of outcome, such as SOFA score, age, and comorbidities were not found to impact mortality in these patients. **Conclusions**: VV ECMO was found to reduce mortality despite presence of significant pre-COVID illness.

Keywords: COVID-19; Extracorporeal membrane oxygenation; ARDS; Respiratory failure; Intensive care unit

The novel respiratory pathogen, coronavirus SARS-CoV-2 (COVID-19) has a wide clinical spectrum. [1-2] The pathophysiology associated with coronavirus often results in severe or catastrophic illness. Between 5% and 12% of patients develop complex multisystem problems and require Intensive Care Unit (ICU) admission 2 commonly due to Acute Respiratory Distress Syndrome (ARDS) and need for mechanical ventilation. [3] In some cases, the acute hypoxic respiratory failure is refractory to standard therapies (e.g., mechanical ventilation, prone positioning, epoprostenol) and require initiation of venovenous extracorporeal membrane oxygenation (VV ECMO) to give the lungs time to heal. [4-5].

Several comorbidities (e.g., hypertension [6-9], diabetes [10-12], obesity [13-17], and asthma [18-20] may be associated with poorer patient outcomes in patients with COVID-19. Notably, there are fewer data supporting a relationship between risk of infection with COVID-19 or severe disease and asthma. [21] The purpose of this single site retrospective chart review is to evaluate the relationships among the aforementioned comorbidities, age, severity of illness on admission (Sequential Organ Failure Assessment [SOFA] and PaO_2/FiO_2 on admission in relation to patient outcomes of time on ECMO, time on mechanical ventilation, and survival. The study received approval through the university's institutional review board.

Methods

Study Design, Data Source, and Study Population

This retrospective chart review was conducted in two adult ICUs of an academic medical center in the southeast. Data from the electronic medical record were reviewed on patients with polymerase chain reaction (PCR)-confirmed COVID-19 infection refractory acute hypoxic respiratory failure who required VV ECMO who were admitted to one of two ICUs between March 24, 2020, and June 30, 2020. The investigators collected data on presence of specific comorbidities (hypertension, diabetes, asthma, and obesity), SOFA score, and PaO_2/FiO_2 ratio on admission, age, length of time on VV ECMO and mechanical ventilation, and hospital length of stay. The comorbidities were selected based on their associated risk of COVID-19 disease severity (Williamson et al., 2021). Patients included for evaluation were at least 18 years of age, hospitalized in the Acute Respiratory ICU or Cardiovascular ICU, and tested positive for COVID-19 via PCR. Those excluded were under 18 years of age or tested negative for COVID-19 via PCR.

Statistical Analysis

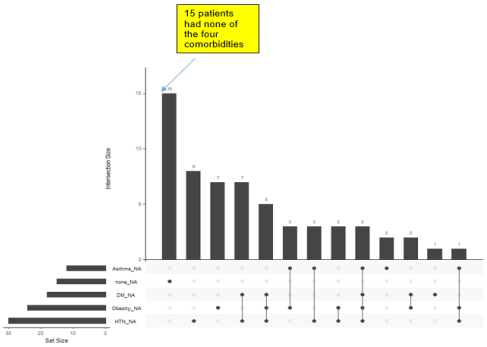
Given a sample size of 60 with an expected survival rate of 60-70% (lower bound estimate based on current data), at 80% power and 5% level of significance, we were able to detect a large cox hazard ratio coefficient of β=0.44-0.50 for the number of comorbidities as a predictor of survival. We were also able to detect a moderate-to-large effect size association between the presence of these four comorbidities and time on VV ECMO. For example, we were powered to detect a difference of 30-40% for the presence of these comorbidities between those who survive and those who did not (Cohen's ω=0.3-0.4 moderate to large effect sizes). Similarly, for a sample size of 60, we were powered to detect a moderate-to-large correlation (r=0.35) between the number of comorbidities and time on ECMO. [Power analyses conducted using PASS 2021, PASS 2021 Power Analysis and Sample Size Software (2021). NCSS, LLC. Kaysville, Utah, USA, ncss.com/software/pass.

Statistical Methods

All data were reviewed for completeness, missing values, outliers as well as possible typographical errors or other unusual or invalid values. No missing data were detected. Descriptive statistics were run for patient demographics, type and number of comorbidities, hospital length of stay, time on VV ECMO, time on mechanical ventilation, and survival. Comparison statistical tests (t-test, Mann Whitney test, Chi-square or Fisher's exact test) were performed to compare results between subjects with and without each comorbidity (hypertension, diabetes, obesity, or asthma) and for those who survived or died. Non-parametric Spearman's rho was computed to assess the association between time to event measures (ventilation days, VV ECMO days or hospital length of stay), number of comorbidities, age, SOFA, and PaO_2/FiO_2 ratio. Kaplan Meier log-rank (Mantel-cox) tests were performed to compare time to event (ventilation days, VV ECMO days or length of stay) adjusting for whether or not the patient died before the end point was observed. Cox proportional hazards regression was performed to assess the association between age, number of comorbidities (or presence or absence of the four comorbidities), SOFA, PaO_2/FiO_2 ratio, and time to event (time on ventilation, ECMO, or hospital stay) with right-censored times for those who did not survive. Logistic regression was run to assess the association between age, number of comorbidities (or presence or absence of the four comorbidities), SOFA, PaO_2/FiO_2 ratio, and survival outcome (survived or died). SPSS v.27 (IBM Corp. Released 2020. IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY: IBM Corp.) statistical analysis software was used for all analyses with 5% level of significance used for all tests.

Results

The ages of the 60 patients ranged from 20 to 65 averaging 43.9 (SD 12.5) years old. The number of comorbidities ranged from 0 to 4; 25% of the patients had none of the pre-determined comorbidities. The highest reported comorbidity was hypertension (50%); the second highest occurring comorbidity was obesity (40%). Thirteen percent of the patients only had hypertension and 11.7% only had obesity. However, 11.7% had the dual-comorbid condition of hypertension and diabetes and 8.3% reported the triple-comorbidity of hypertension, diabetes, and obesity. (Figure 1). Of the 60 patients, 17 (28.3%) died with the remaining patients being discharged to another ICU (upon being deemed COVID-19 negative) or outside hospital ICU of origin (35%), floor (23.3%) or long-term acute care, acute rehabilitation unit, or home (13.4%). The length of stay in the hospital ranged from 2 to 126 days with a median stay of 27 days; days on ECMO ranged from 2 to 108 with a median of 14 days; and days on ventilation ranged from 1 to 48 with a median of 19 days. (Table 1).



DM = diabetes, HTN = hypertension

Figure 1: Patterns of Four Comorbidities or None of These Four.

Measure/Variable	Mean (SD)	Range (min–max)
Age	43.93 (12.48)	20-65
SOFA Score	9.77 (3.6)	2-19
PaO_2/FiO_2 ratio	147.6 (65.8)	35-315
P/F	n (%)	
> 300	1 (1.7%)	
200 – 299	13 (21.7%)	
100 – 199	28 (46.7%)	
< 100	18 (30.0%)	
	Median [IQR]	Range
Ventilation Days	19 [12, 29.8]	1-48
ECMO Days	14 [8.3, 30.5]	2-108
Length of Stay in Hospital	27 [18, 43]	2-126
Number of Comorbidities	1 [0.3, 2]	0-4
Comorbidities (not mutually exclusive)	n (%)	
Hypertension	30 (50.0%)	
Diabetes	18 (30.0%)	
Obesity	24 (40.0%)	
Asthma	12 (20.0%)	
Discharged to	n (%)	
Floor	14 (23.3%)	
Long-term acute care	6 (10.0%)	
Expired	17 (28.3%)	
Other ICU within facility	18 (30.0%)	
Outside hospital of origin	3 (5.0%)	
Home	1 (1.7%)	
Acute rehabilitation	1 (1.7%)	
Top 5 “comorbidity patterns”	n (%)	
No comorbidities	15 (25.0%)	
Hypertension only	8 (13.3%)	
Obesity only	7 (11.7%)	
Hypertension and Diabetes	7 (11.7%)	
Hypertension, Diabetes, and Obesity	5 (8.3%)	

Table 1: Descriptive Statistics (n=60).

Survival

We found no significant differences in age, number of comorbidities, presence or absence of comorbidity, SOFA score, PaO_2/FiO_2 ratio, time on mechanical ventilation, ECMO time, nor hospital length of stay. For time on mechanical ventilation, there were no significant difference between those who died and those who survived; no difference by discharge location; no differences by comorbidities or total number of comorbidities; and no significant association with age, SOFA score, or PaO_2/FiO_2 ratio.

Time on ECMO

Patients discharged to the floor had the shortest time on ECMO (Kruskal-Wallis test p=.011) and had a small-to-moderate association with SOFA score (Spearman's rho=0.255, p=.049). Patients with asthma had shorter times on ECMO than the other pre-determined comorbidities (Kaplan-Meier log-rank test=0.038, Breslow test p=.081). (Figure 2). Older age was associated with longer times on ECMO (age < 43 years versus age > 43 years, log-rank test=0.002, Breslow test p<.001) (Figure 3) and higher PaO_2/FiO_2 ratio was associated with shorter times on ECMO (Kaplan-Meier log-rank test=0.031, Breslow test p=.093 for PaO_2/FiO_2 categories). (Figure 4). Cox proportional hazards regression yielded significant results for age (hazard ratio 0.962, p=.005). That is, patients aged over 43 years had a statistically longer amount of time on ECMO. Patients with a higher PaO_2/FiO_2 on admission were on ECMO for a shorter amount of time (hazard ratio 1.004, p=.038).

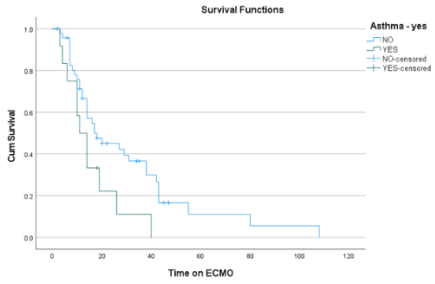


Figure 2: Time on ECMO by Asthma (Patients with asthma had a shorter time on ECMO than those with other comorbidities.)

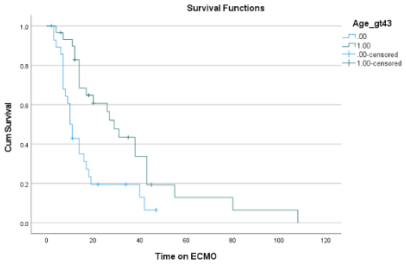


Figure 3: Time on ECMO by Age Categories – older age, longer time on ECMO.

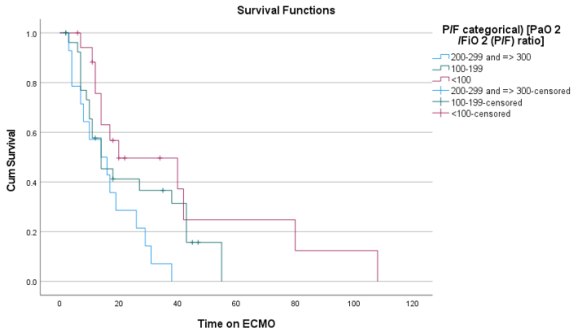


Figure 4: Survival Plots – Time on ECMO by P/F Ratio Categories (Patients with a higher P/F had a shorter time on ECMO.)

Hospital Length of Stay

There was no difference between discharge locations, no differences by comorbidities presence versus absence or total number of comorbidities, and no significant association with SOFA or age. There were significant differences by PaO_2/FiO_2 categories (Kaplan-Meier log-rank test=0.031, Breslow test p=.093). (Figure 5). Cox proportional hazards regression yielded significant results for PaO_2/FiO_2 ratio (hazard ratio 1.007, p=.001). Patients with a higher PaO_2/FiO_2 on admission experienced a shorter HLOS.

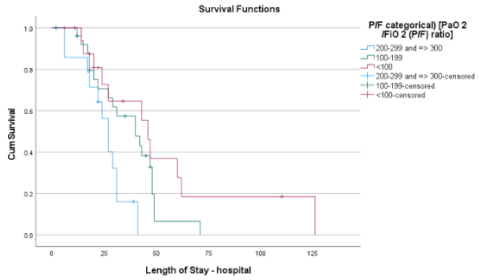


Figure 5: Hospital Length of Stay by P/F Ratio Categories (Patients with higher P/F had a shorter hospital length of stay.)

Discussion

We conducted a single site retrospective analysis of 60 patients with COVID-19-related refractory acute respiratory distress syndrome who required VV ECMO. Data are limited on this patient cohort.

[21] In our study, the survival rate was 71.7%. This survival rate is higher than in previous studies of patients with COVID-19 who received ECMO, ranging from 27% to 60% [22-24] The reason for the lower mortality rate in this patient cohort is unknown but may be related to the additional comfort caring for this acutely ill population and evolving evidence-based treatment modalities. There was no significant difference between survival rate and patient age, number of comorbidities, SOFA score, PaO_2/FiO_2 ratio, time on mechanical ventilation, ECMO time, nor HLOS.

We found no significant relationship between age and mortality. This contrasts with other studies where demographic variables, including age have been implicated in mortality rates. [22,24-26] For example, younger patients with COVID-19-related ARDS who received ECMO are more likely to survive than their older counterparts. [27-28] Our data are inconsistent with these previous reports of the direct correlation between age and mortality. The mean age for our sample was 43.9 years with a range of 20 to 65 years. This age is similar or slightly younger compared to previously reported patient cohorts. [21-24] Our findings could relate to differences in the timing of initiation of these patients for ECMO; earlier imitation of ECMO may be associated with better outcomes. Additionally, therapeutic regimens and strategies for critically ill patients with COVID-19 have evolved rapidly during the period of this review and have been, in part, governed by institutional access to pharmacologic agents from antibodies to anti-inflammatories. Further, no clear therapeutic regimen has emerged as the single gold standard in treating these patients other than the application of dexamethasone and remdesivir. Such large variations in therapeutic approaches may have contributed to such outcome differences.

Our patients were on ECMO a median of 14 days. This time on ECMO is similar [35] or shorter than previous and comparable patient cohorts (20 days) [23].

Obesity has been identified as a risk factor for mortality associated with COVID-19, [29-30] presumably due to impaired coronavirus clearance. [31-32] This remains controversial as others have reported a positive relationship between higher Body Mass Index (BMI) and survival. [26-33] Our findings suggest that obesity was a non-significant determinant of outcome in these patients. As noted previously, this may relate to differences in timing and initiation of ECMO and therapeutic strategies among study groups.

Since asthma is a chronic inflammatory condition associated with an impaired viral immune response, it is somewhat surprising that asthmatic patients were liberated from ECMO sooner, when compared to non-asthmatics. Particularly, since ECMO itself is a proinflammatory process, where exposure of blood to an extracorporeal circuit inevitably activates inflammatory cascades that would exacerbate the cytokine storm seen in these severe cases. However, data are conflicting as to whether asthma is identified as a risk factor in COVID.

Its not be considered a risk factor may be due in part to the heterogeneous immune response observed in asthmatic patients. Our traditional understanding is that T helper cell-led responses to benign allergens trigger an inappropriate and chronic inflammatory response. This culminates in the typical clinical and biochemical picture of variable airway obstruction and hyper-responsivity, associated with elevations in proinflammatory compounds and immune system components (e.g, interleukins, eosinophils). It is this chronic activation inflammation that led to the assumption that asthma places patients at high risk in the setting of COVID. However this has not been borne out in extensive clinical reviews. In a meta-analysis by Morais-Almeida et al, [34] which included over 180,000 patients, the most common comorbidities and risk factors for severe disease included obesity, diabetes, and heart disease and non-asthmatic COPD. Asthma was not found to be an independent risk factor except in 27 of the 28 cohorts analyzed.

It is therefore of great interest that the chronic inflammatory state, thought to place the patient at risk, has been shown to be associated with a down-regulation of ACE2 receptors, thereby reducing viral binding capacity in these patients. When coupled with impaired interferon production by plasmacytoid dendritic cells, further immune modulation may be taking place, which down regulates the overall severity of the cytokine storm that typifies severe COVID infection. In addition, the hyper-eosinophilia of asthma may provide additional protection against the eosinopenia of COVID. These factors may then be synergistic with the typical asthma medications and produce sufficient immune modulation as to “protect” the asthma patient infected with COVID. Inhaled steroids, for example, have been shown to further down regulate ACE2 receptors, suppress proinflammatory mediator production and viral replication. [35-36] Additional allergen immunotherapy or biologic agents may also play a role in improving outcomes. Clearly, ongoing studies are required to distill a clear therapeutic strategy moving forward, which may be translated to both asthmatic and non-asthmatic patients.

Limitations of this study are two-fold. First, it is a single-site study, which limits its external validity. Second, there are other factors that can impact survival of COVID-19 (e.g., C-reactive protein and ferritin levels, immunocompromised condition, leukocytosis, antibiotic days, thrombocytopenia, extra-pulmonary organ dysfunction), [36-37] which were not controlled for in this study.

Conclusion

Despite the presence of comorbidities that place patients at risk for COVID-19, the use of extracorporeal membrane oxygenation

may decrease mortality rates of patients with COVID-19 induced ARDS. Randomized controlled trials will provide stronger support of this relationship and provide further guidance for clinicians to determine who will benefit from this costly yet therapeutic modality.

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