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Clinician Ethical Perspectives on Extracorporeal Membrane Oxygenation in Practice

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Abstract

Purpose: Extracorporeal membrane oxygenation (ECMO) is an expensive and scarce life sustaining treatment provided to certain critically ill patients. Little is known about the informed consent process for ECMO or clinician viewpoints on ethical complexities related to ECMO in practice.

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Declaration of Conflicting Interests

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Supplemental Material

Supplemental material for this article is available online.

Methods: We sent a cross-sectional survey to all departments providing ECMO within 7 United States hospitals in January 2021. One clinician from each department completed the 42-item survey representing their department.

Results: Fourteen departments within 7 hospitals responded (response rate 78%, N = 14/18). The mean time spent consenting patients or surrogate decision-makers for ECMO varied, from 7.5 minutes (95% CI 5-10) for unstable patients to 20 minutes (95% CI 15-30) for stable patients (p = 0.0001). Few clinician respondents (29%) report patients or surrogate decision-makers always possess informed consent for ECMO. Most departments (92%) have absolute exclusion criteria for ECMO such as older age (43%, cutoffs ranging from 60-75 years), active malignancy (36%), and elevated body mass index (29%). A significant minority of departments (29%) do not always offer the option to withdraw ECMO to patients or surrogate decision-makers. For patients who cannot be liberated from ECMO and are ineligible for heart or lung transplant, 36% of departments would recommend the patient be removed from ECMO and 64% would continue ECMO support.

Conclusion: Adequate informed consent for ECMO is a major ethical challenge, and the content of these discussions varies. Use of categorical exclusion criteria and withdrawal of ECMO if a patient cannot be liberated from it differ among departments and institutions.

Keywords

extracorporeal membrane oxygenation; informed consent; ethics; withdrawal of life-sustaining treatment

Introduction

Extracorporeal membrane oxygenation (ECMO) is a method of life support provided to adult patients with cardiac or pulmonary failure that can maintain life even when these organs have failed.[1,2] While ECMO can fully replace the function of a failed heart or lung temporarily over days, weeks or sometimes months, approximately half of adult patients receiving ECMO die before hospital discharge.[3,4] Patients who survive liberation from ECMO may have persistent health concerns post-ECMO including anxiety and depression.[5] ECMO is a limited resource with fewer than 6% of hospitals in the United States recognized as Extracorporeal Life Support Organization Centers, and is expensive to maintain with predicted cost per quality of life year of about 30,000 US dollars.[2,6-9]

Many ethical concerns relate to the use of ECMO. These concerns include whether it is ethical to withhold ECMO from certain populations such as those with advanced age or meta-static cancer, whether is it just to continue maintenance of ECMO when a patient is unable to be liberated from it, and how one obtains adequate informed consent.[10,11] Some ethicists have questioned whether it is possible to obtain adequate informed consent for ECMO due to time constraints, the fact that patients considered for ECMO are often critically ill, and also because of the complexity of ECMO therapy.[12]

To date, there has been no cross-sectional study focusing on clinical department viewpoints and practices across institutions for obtaining informed consent for adult patients considered for ECMO, categorically excluding patients from ECMO, or assessing for differences in

practice when caring for patients who cannot be liberated from ECMO. This study aims to assess these practices and viewpoints.

Methods

We designed and conducted a cross-sectional survey at 7 hospitals in January 2021. The primary aim of this study is to describe department practices and attitudes toward obtaining informed consent for adult patients considered for ECMO across institutions. Our secondary aims include describing department attitudes towards continuation of ECMO when a patient cannot recover and describing inter-hospital and inter-departmental differences in practice for patients who receive or are considered for ECMO.

Participants and Recruitment

We sent this survey to clinical departments with the use of Research Electronic Data Capture (REDCap) hosted at Rush University.[13,14] From 7 geographically-diverse academic hospitals in the United States, we identified all departments and divisions potentially involved in obtaining consent from adult patients for ECMO, and identified one clinician to communicate ECMO practices from their department or division. We chose these hospitals they were affiliated with the team conducting this research study. We asked each surveyed clinician to answer questions provid the majority viewpoints of their department on the informed consent process, consideration of withdrawal of ECMO in situations considered medically futile, and criteria that exclude patients from consideration of ECMO. If clinicians did not initially reply to the email, we sent a total of 3 emails encouraging survey completion. The Rush University Institutional Review Board granted study exemption for this project.

Survey Design

We created a 42-item survey including multiple choice and free response questions (e-Appendix). As no previously validated survey existed to measure our intended goals, we created a unique survey following a literature review using survey design best practices.[15] The primary creator of the survey is a palliative medicine physician with the assistance from 2 pulmonary and critical care fellows, a surgery resident, a cardiology fellow, a director of quality and education for ECMO nurse practitioner, and a pulmonary and critical care attending physician. The survey assesses who is involved in the informed consent process for ECMO, how long the informed consent process typically lasts, and whether discussion of a time-limited trial should be included in the consent process. It asked survey respondents to report whether patients or surrogates had full informed consent prior to being placed on ECMO, with the definition of full informed consent left open to interpretation by each respondent. It also assesses viewpoints on how to manage patients who are unable to be liberated from ECMO, departmental exclusion criteria for ECMO, and knowledge of patient preferences and values for medical care. In addition to these questions, we collected demographic information from each survey respondent including the name of their department, whether they are primary involved with venovenous ECMO, venoarterial ECMO or both, and their gender.

Statistical Analysis

Categorical variables are described by frequency of occurrence and continuous variables by mean and standard deviation. Comparisons of continuous variables were analyzed using the two-sided t-test using GraphPad Prism, version 8.0. *P*-values of ≤ 0.05 were determined to be statistically significant.

Results

Of the clinicians sent the survey to complete on behalf of their department, 78% (N = 14/18) responded. The majority of respondents were attending physicians (n = 13, 93%) and male (n = 11, 79%). Departments surveyed included anesthesia (n = 3, 21%), cardiac surgery (n = 3, 21%), cardiology (n = 2, 14%), emergency medicine (n = 1, 7%), and pulmonarycritical care (n = 5, 35%). Most departments surveyed are involved in the care of patients both on venovenous and venoarterial ECMO (e-Table 1).

Informed Consent

In most departments, an attending physician (n = 9, 64%) or fellow physician (n = 3, 21%) is always involved in the informed consent process for patients placed on ECMO. Other participants sometimes or often involved in ECMO consent include advanced practice providers (n = 4, 29%), resident physicians (n = 2, 14%), and social workers (n = 1, 7%). Palliative medicine clinicians were rarely included in informed consent discussions (n = 2, 14%) (e-Figure 1). For patients with expected survival greater than 24 hours, the median time spent discussing informed consent was 20 minutes (95% CI 15-30) compared to 7.5 minutes (95% CI 5-10) if the patient was unstable with expected survival less than one hour (p = 0.0001) (Figure 1). In most departments (71%), the decision to place a patient on ECMO occurs following discussion with other physicians. In some departments, an individual can make the decision without discussion with other physicians or department approval (n = 3, 21%).

Only 29% (n = 4) of respondents report patients or their surrogate decision-maker always have full informed consent prior to the patient being placed on ECMO. A minority of respondents (n = 5, 36%) agree clinicians in their department are always aware of patient preferences and values for care for the patients they care for who are on ECMO (Figure 2). The most common barriers to informed consent include lack of time (n = 7, 50%), lack of patient or surrogate decision-maker understanding of the medical situation (n = 7, 50%) and lack of availability of a decision-maker (n = 6, 43%). An example of one response provided about barriers to informed consent is “Informed consent is a fallacy. This is life and death, the ‘risks’ are very different and weighed very differently. It’s hard to explain anything once ‘they will likely die without this’ enters into the conversation.”

Regarding how long informed consent for ECMO can last, responses varied. In some departments, informed consent lasts until the ECMO cannulation is completed (n = 2, 14%), or for a maximum of 48 hours after talking with the patient or surrogate decision-maker (n = 1, 7%), or throughout the hospital stay (n = 2, 14%), or potentially may have no expiration (n = 1, 7%). Regarding the need for informed consent if a patient decompensates during

surgery, most departments (n = 9, 64%) do not require informed consent for ECMO in this situation and can place the patient on it without prior discussion with the patient or surrogate decision-maker about ECMO.

Recommendations regarding whether discussion of a time limited trial should be included in the informed consent discussion for patients on ECMO varied with the patients' diagnosis. For diagnoses including cardiac arrest (n = 11, 79%), refractory hypoxemia from interstitial lung disease (n = 10, 71%), cardiogenic shock secondary to myocardial infarction (n=9, 64%), and bridge-to-transplant (n = 8, 57%), a majority of respondents agree ECMO informed consent should include discussion of a time limited trial (Figure 3). How long that time limited trial should last varies widely amongst departments and hospitals, ranging from 3 days to indefinite (e-Table 2).

Exclusion Criteria

Most departments (n = 13, 92%) reported having absolute exclusion criteria in consideration of placing patients on ECMO. Exclusion criteria varies among departments, with most departments having exclusion criteria related to medical comorbidities (n = 9, 64%) and some departments excluding patients based on age (n = 6, 43%) (Table 1). Half of the departments surveyed report having unique exclusion criteria when considering placing patients with coronavirus disease 2019 (COVID-19) on ECMO, including a lower age cutoff when compared to non-COVID-19 patients placed on ECMO (n = 6,43%), and decreased duration on mechanical ventilation prior to consideration for ECMO (n = 2, 14%) (e-Table 3).

Withdrawal of ECMO

The majority of departments (n = 8, 57%) always provide patients or their surrogate decision-maker with the option to withdraw ECMO support; however, a significant minority (n = 4, 29%) report they do not always offer this option (Figure 2). For patients on ECMO for significant time periods who cannot be liberated from it and are not eligible for heart or lung transplant, some departments (36%, n = 5) would recommend the patient be removed from ECMO. For departments that would continue ECMO for patients who cannot be liberated from it (64%, n = 9), some would not escalate life support if the patient's condition declined (43%, n = 6), while others would escalate life support (21%, n = 3) (Figure 4).

Ethics Consults

Half of respondents report at least one ethics consult was placed for a patient on ECMO in the past year. Reasons for the consult include inability to wean the patient from ECMO in a patient ineligible for heart or lung transplant (n = 2, 14%), difference in opinions amongst clinicians or families (n = 2, 14%), withdrawal of ECMO for reasons of medical futility (n = 1, 7%) and all patients on ECMO receive an ethics consult (n = 1, 7%).

Discussion

In this multi-center study, we found variability in department practices regarding informed consent, withdrawal of ECMO support and exclusion criteria for adult ECMO patients.

Informed consent for ECMO is approached differently across departments and hospitals in the United States including whether discussion of a time limited trial should be included with the consent and how long this trial should occur. Potential barriers to obtaining adequate informed consent may include lack of time in emergent situations, limited knowledge of patient preferences or values for care, and limited patient or surrogate decision-maker understanding of what ECMO fully entails. Most hospitals surveyed have categorical exclusion criteria which eliminate patients from consideration of ECMO, which are unique to each hospital. Withdrawal of ECMO if a patient cannot be liberated from it is approached differently across the US, with some departments recommending removal of the patient from ECMO and others recommending continuing life support with escalation even if the patient declines.

Our study uncovered significant concerns that informed consent does not occur for many patients placed on ECMO and most clinicians do not always know patient preferences and values for care. Informed consent discussions should respect patient autonomy to make medical decisions concordant with their preferences and are positively associated with patient satisfaction.[16-18] Obtaining the known benefits of informed consent is difficult for patients being considered for ECMO due to multiple factors, including lack of time, lack of patient decision-making capacity, and the complexity of ECMO as a form of life support. As observed by our results, clinicians spend a median of 7.5 minutes obtaining informed consent in an unstable patient, significantly less than the median of 20 minutes if the patient was stable. For many critically ill patients, it is likely impossible for them to fully understand ECMO in this short time frame even if they are awake and alert.[12] Likely also contributing to the low rate of ECMO informed consent is the reported belief that some patients do not require informed consent for ECMO prior to being placed on it, such as patients who decompensate during surgery, as found by this study. Although there are numerous recommendations for how to obtain informed consent to best respect patient values for care, such as allowing patients to speak more during informed consent discussions,[19-24] many of these recommendations cannot be done for patients considered for ECMO due to the significant barriers discussed.

Most departments surveyed have specific exclusion criteria for removing patients from consideration for ECMO. Exclusion criteria were found to be more severe for patients with COVID-19, likely related to increased scarcity of ECMO circuits and clinicians shortages during the pandemic.[25,26] There is substantial variability in categorical exclusion criteria for ECMO among institutions similar to the variability seen in other scarce resource allocation guidelines during the COVID-19 pandemic, as not all departments chose to follow Extracorporeal Life Support Organization’s relative and absolute contraindication guidelines for ECMO during the pandemic, created based on available evidence and expert opinion.[27,28] Variety in exclusion criteria is in part likely related to differences in ethical principles most valued by each department. For example, some institutions likely place higher emphasis on the approach of saving the most patient life-years rather than saving the most lives and thus only consider patients under a certain age. Other departments holistically evaluate each patient regardless of age, which likely promotes saving the most lives rather than the saving the most life-years approach.[29]

Withdrawal of ECMO can be a challenging and ethically complex decision. Our study found significant variability in whether clinicians offer patients or decision-makers the option to withdraw ECMO or whether clinicians recommend withdrawal of ECMO if the patient cannot be liberated from it. This variety in beliefs is similar to the diversity in viewpoints regarding withdrawal of other life sustaining treatment seen among providers and institutions around the world.[30] There is significant literature discussing withdrawal of certain forms of life support, such as mechanical ventilation,[31,32] and ethical and legal support exists for withdrawing life sustaining treatment in settings where the patient would not want it or when scarcity of medical resources occur.[33,34] Even though this support exists, we found 29% of departments report in practice they do not always offer patients or their families the option to withdraw ECMO. This may in part be due to unique difficulties on withdrawing ECMO support from patients,[35] especially when patients who cannot be liberated from ECMO are mentally alert and are requesting to remain on ECMO.[36] Situations like these may put patient autonomy in conflict with the principle of justice and fair allocation of medical care. ECMO is an expensive resource, with one 2019 study finding the average mean hospital charges for ECMO was $731,941 per patient.[37] This significant cost, and the fact that ECMO is often restricted to large academic medical centers, can lead to inequalities in who is provided ECMO. It also contributes to concerns about whether it is equitable to continue to provide ECMO to maintain a person's life for months without hope they can be liberated from ECMO while other patients in the United States do not have access to basic medical care.[38,39] Survival statistics may contribute to medical decisions to continue ECMO rather than withdraw it in certain situations, such as when a patient recently received an organ transplant, as the Centers for Medicare & Medicaid Services require certain survival statistics for transplant center certification.[40] Survival statistics may play less of a role in medical decision for other ECMO patients, in part because survival statistics are not currently a required component of applications sto become aExtracorporeal Life Support Organization Center for Excellence.[41]

Limitations

Despite a high response rate from hospitals and departments across the United States, these findings are representative of 7 hospitals and may not be generalizable to practices and viewpoints at other hospitals in the United States or internationally. There is potential for recall bias as this survey was cross-sectional and required the recollection of past experiences in caring for patients on ECMO. These results may be affected by responder bias as clinicians more interested in ethical concerns regarding ECMO may have been more likely to complete this survey. Each clinician completing the survey was asked to provide responses based on viewpoints and guidelines from their department. Thus there is potential for these responses to differ depending on the respondent selected to complete the survey within each department. This approach also diminishes the ability to evaluate for intradepartmental variability. As this was an anonymous survey, we were unable to follow up with respondents to ask further questions based on their responses, such as whether clinicians involved in the informed consent process had received previous training in leading these conversations, why some departments choose to obtain ethics consults for patients on ECMO, or why some departments choose to escalate life support measures for patients unable to be liberated from ECMO. Further studies are needed to explore these findings, as

well as to explore the ethics of ECMO in practice from the patient and surrogate perspective. Finally, no pilot survey was performed to evaluate survey effectiveness prior to its use in this study; however, this survey was evaluated by multiple clinicians for content and clarity prior to being sent to survey participants.

Conclusions

Adequate informed consent for ECMO is often not obtained for adult patients, and clinicians sometimes do not know the preferences and values of care for patients they care for on ECMO. The content of informed consent discussions, the use of criteria to exclude patients from ECMO, and consideration of withdrawing ECMO for patients who are unable to be liberated from it differ across departments and hospitals, which potentially may contribute to differences in patient outcomes.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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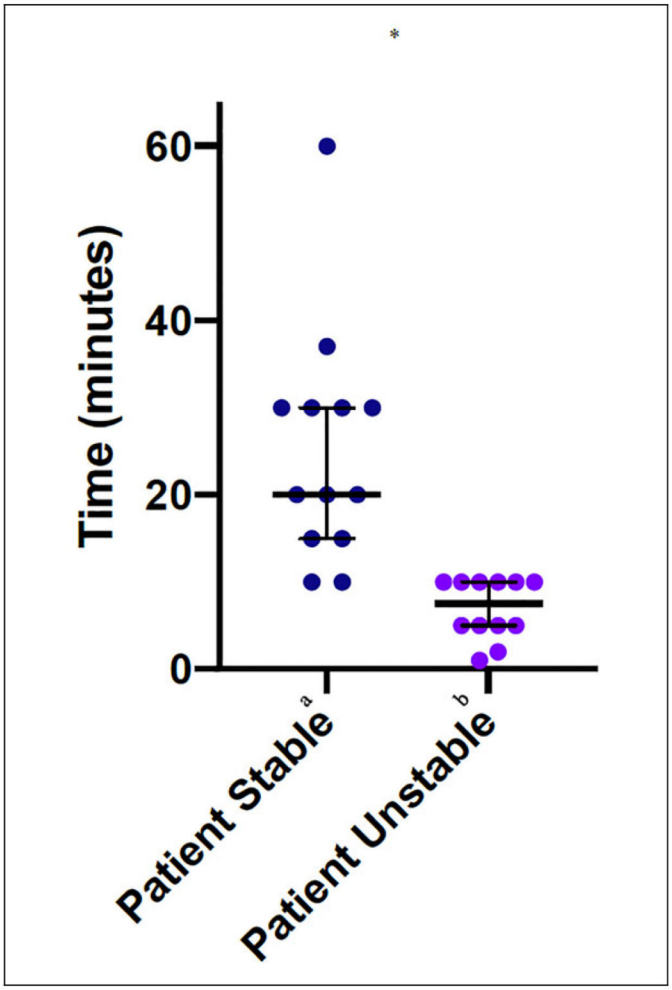

Figure 1.

Time spent acquiring informed consent for ECMO.

[a]Patient expected survival greater than 24 hour.

[b]Patient expected survival less than 1 hour.

*P = 0.0001.

Bars identify median and 95% confidence interval.

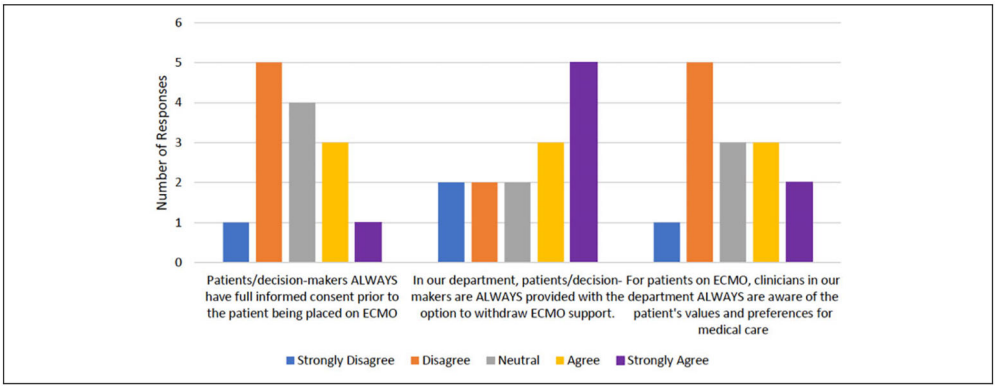

Figure 2.

Patient and decision-maker knowledge and values for care.

ECMO, extracorporeal membrane oxygenation.

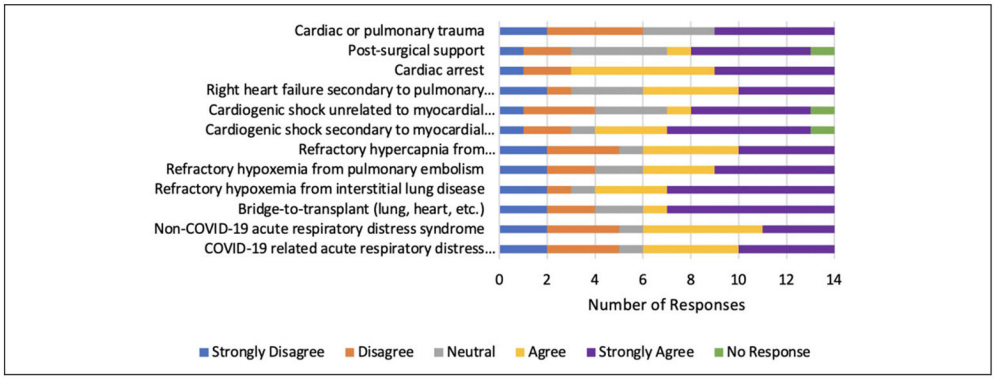

Figure 3.

Discussion of a time limited trial should be included in the informed consent discussion for ECMO.

ECMO, extracorporeal membrane oxygenation; COPD, chronic obstructive pulmonary disease; COVID-19, coronavirus disease 2019.

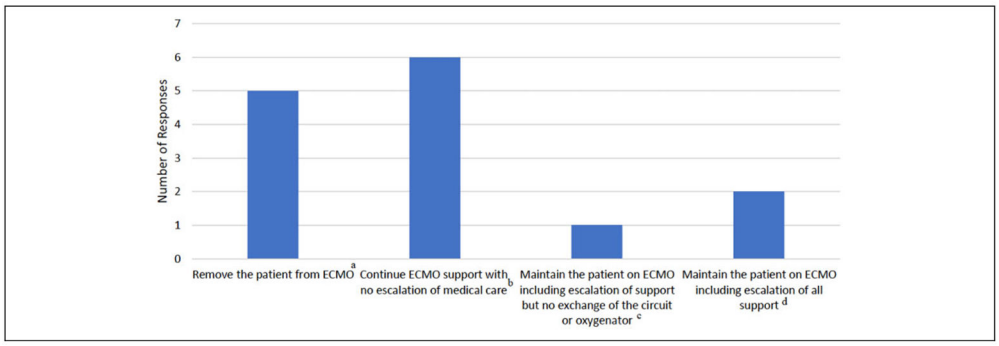

Figure 4.

Recommended care for patients who cannot be liberated from ECMO.

ECMO, extracorporeal membrane oxygenation.

Full question: A 60-year-old patient was placed on venovenous ECMO 6 months ago for hypoxic respiratory failure. Imaging shows significant lung fibrosis. The patient is declared ineligible for lung transplant due to poor social support. The patient is awake and alert and reports his current quality of life is acceptable to him. Multiple attempts have been made to wean the patient from ECMO support without success. You believe the patient will never be successfully weaned from ECMO or eligible for lung transplant. In this situation, which of the following actions should be taken.

[a]Recommend removing the patient from ECMO as the patient's condition will not improve and it is unjust to continue providing ECMO when other patients could benefit from access to medical care.

[b]Inform the patient you will continue ECMO support, but there will be no escalation of medical care (no circuit exchange or addition of pressors, antibiotics etc.).

[c]Maintain the patient on ECMO including escalation of support (increasing sweep, adding pressors, adding antibiotics), but informing the patient if the circuit or oxygenator fails, the device will not be exchanged.

[d]Maintain the patient on ECMO including escalation of support (circuit or component exchanges, increasing sweep, adding pressors, adding antibiotics) if condition declines.

Table 1.

ECMO Exclusion Criteria.

	Departments, N = 14 (%)
Absolute exclusion criteria	
Yes	13 (92)
General exclusion criteria	
Age	6 (43)
>60	1 (7)
>65	1 (7)
>70	2 (14)
>75	1 (7)
Age is an exclusion factor, limit not specified	1 (7)
BMI	4 (29)
>45	2 (14)
>55	1 (7)
BMI is an exclusion factor, limit not specified	1 (7)
Medical comorbidities	9 (64)
Active oncologic or hematologic malignancy	5 (36)
Advanced chronic heart failure and not a transplant candidate	4 (29)
Cannot perform activities of daily living	1 (7)
Cannot receive anticoagulation	2 (14)
Chronic kidney disease	1 (7)
Chronic lung disease and not a transplant candidate	4 (29)
Cirrhosis	2 (14)
End stage malignancy	1 (7)
Life expectancy less than 6 months	1 (7)
Multiorgan failure	3 (21)
Prolonged cardiac arrest	3 (21)
Prolonged time on ventilator greater than 7 to 14 days	3 (21)
Severe nonreversible neurologic disease or injury	5 (36)

Abbreviations: ECMO, extracorporeal membrane oxygenation; BMI, body mass index.