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A qualitative analysis of physician decision making in the use of extracorporeal cardiopulmonary resuscitation for refractory cardiac arrest



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Abstract

Aim of Study: To prepare for the design of future randomized clinical trials of extracorporeal cardioupulmonary resuscitation (ECPR), we sought to understand physician beliefs regarding the use of ECPR and subsequent management, among physicians who already perform ECPR, as these physicians would be likely to be involved in many planned ECPR trials.

Methods: We performed 12 semi-structured interviews of physicians who already perform ECPR across a variety of medical specialties, centers and geographic regions, but all with 10–50+ cases of ECPR experience. We qualitatively analyzed these interview to identify key characteristics of their experience using ECPR, the tensions involved in patient identification, the complications of subsequent management, and their willingness to enroll potential ECPR patients in randomized trials of ECPR.

Results: Physicians who routinely perform ECPR have strong beliefs regarding the use of ECPR, and typically have protocols they follow, though they are willing to break these protocols to cannulate young or healthy patients, or patients with immediate pre-hospital CPR and shockable rhythms. We found that physicians lacked equipoise to randomize these types of patients to continued conventional CPR. Future RCTs might be successful in enrolling older patients, younger patients without immediate pre-hospital care/bystander CPR, or patients with obvious comorbidities.

Conclusions: RCTs for ECPR will need to avoid targeting patients in whom physicians feel strongly compelled to do ECPR or not do ECPR, instead identifying the middle range of patients in whom the physicians consider ECPR reasonable, but not required or contraindicated.

Keywords: Extracorporeal cardiopulmonary resuscitation, Decision making, Clinical Trials, Randomization, Equipoise, Trial design, Qualitative analysis, Mixed methods

Introduction

Extracorporeal cardiopulmonary resuscitation (ECPR) is a complex process with technical, situational, social, and organizational hurdles. *Technically*, ECMO cannulation with ongoing chest compressions is difficult.^{1,2} *Situationally*, ascertaining relevant patient history and physiologic assessments is often delayed. *Organizationally*, as ECPR only supports the body, but does not treat the cause of the arrest, these patients requires additional therapies, which have to happen expeditiously and in coordination.^{3,4} ECPR is also a *socially* complex process, with a team of providers who need to be 'on the same page'.^{2,5,6} Finally, the entire process from arrest to ECMO cannulation needs to happen expeditiously—ideally in <60 minutes—as increasing duration of arrest is inversely associated with survival.^{7,8}

For the individual physician, accepting a patient for ECPR brings significant responsibility to determine the patient's best interests in a short period of time with imperfect information. The need to make high stakes decisions quickly under stress is likely a factor in provider decisions about the acceptability of randomizing in an RCT.

Some of the questions surrounding ECPR—such as for whom this therapy is useful and the best diagnostic and management strategies—could be addressed with properly conducted randomized controlled trials (RCTs). Two RCTs of ECPR have recently been published,^{9,10} but focused on narrow patient groups and were performed in select settings; thus, many further questions still remain. RCTs have the potential to significantly impact care for commonly utilized treatments, as they may demonstrate a lack of efficacy or even reveal harm.¹¹ Requests for RCTs of unproven therapies already in use have been stymied by physicians' unwillingness to

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enroll patients due to a deep belief that the current therapy is superior—making it, in their view, unethical to randomize to placebo.¹² At present, very few RCTs of ECPR exist¹⁰ and much of the current practice patterns are based on expert opinion and institutional knowledge, not on scientific evidence.^{13,14}

Planned RCTs of ECPR are likely to involve physicians who have procedural experience performing ECPR. RCTs for ECPR will provide valuable guides to practice; however, in planning ECPR trials it is important to understand which patients physicians would or would not be willing to randomize in a trial. Some physicians may be unwilling to forgo ECPR if a patient for whom the physician believes ECPR may confer a benefit would be randomized to usual care, even while they recognize that unbiased information is needed to guide patient selection. As physician opinion is a measurably important factor that determines (a) management of cardiac arrest,¹⁵ (b) selection for ECMO,¹⁶ and (c) continuation of life sustaining care,¹⁷ we believe that the ability of prospective RCTs to enroll patients for ECPR trials will depend on physicians' opinions of whether ECPR for refractory cardiac arrest should be performed at all and for which group of patients. In order to prepare for future RCTS in ECPR patients, we undertook this study to understand the perspectives of physicians who would likely be included in clinical trials, around the use of ECPR.

Aim

The goal of this study was to explore the perceptions and experience of physicians who routinely perform ECPR regarding the use of ECPR for adult cardiac arrest in order to inform the feasibility of enrolling patients within a clinicial trial in which the intervention (ECPR) was to be randomized.

Methods

Design

This is a qualitative study using semi-structured interviews with physicians who regularly cared for ECPR patients.

Ethics

This study was approved by the Institutional Review Board at the University of Utah on 11/9/2017 under #106639.

Participants and recruitment

Twelve physicians who had cared for adult patients treated with ECPR were recruited from 4 medical specialties: emergency medicine, critical care, cardiothoracic surgery and cardiology. These specialties were chosen as they provide different expertise and perspectives in the care of ECPR patients. All physicians had been involved in the care of ECPR patients for at least 5 years, had individually performed 10–50+ cases, and worked in the United States, Canada, or Australia. Our consent specified that individual details would not be associated with responses, so we report these participant characteristics in aggregate only.

Interviews

Interviews were performed using a form of Cognitive Task Analysis termed the Critical Decision Method (CDM).¹⁸ CDM is a retrospective interview strategy designed to clarify the cognitive processes of

specific incidences that require expert judgment. Experts are known to have difficulty accessing their knowledge (due to the degree of overlearning). This qualitative method uses cognitive probes aimed at identifying both *explicit* and *implicit* knowledge involved in specific decisions and behaviors for critical incidents. The technique is designed to maximize recall by using 3 waves of review that explore the context of the case, the goals, decision points, information needs, behavioral options, and strategies. Further details are listed in the Supplement.

The overall goal was to explore decision-making, planning and sense-making for a specific incident. CDM is a more effective technique for extracting complex information than what could be obtained in a generalized interview about typical procedures because it elicits both tacit and explicit knowledge.¹⁹ CDM was chosen as it is best for rare events such as ECPR and accommodates heterogenous groups.²⁰

All interviews were done individually, audio recorded, and transcribed. Prior to the interview, participants were asked to identify and review a specific memorable clinical case in which ECPR was used, or one in which it was strongly considered, but not used. At the interview, investigators used a previously developed script that was piloted and tested for clarity with three ICU fellows who had participated in ECPR.

The interviews, as described, were designed to identify and extract explicit and implicit knowledge and decision making around the use of ECPR, in order to inform the feasibility of a RCT among physicians who already routinely perform ECPR. The analysis of the interviews, described below, enabled us to then identify high level themes present across respondents. As such, individual cases and decision making difficulties are not presented beyond the direct quotes (Tables).

Analysis

The semi-structured interviews lasted 20–60 minutes. Interviews were transcribed (TranscribeMe, Oakland, CA) and imported into NVivo (Burlington, MA) for analysis. Analysis was performed using a method adapted from Framework theory beginning with an essentially inductive approach. Three investigators read the text independently, highlighting relevant material associated with the interviewees' beliefs, decision points, information needs, etc. The investigators conducting the review (n = 3 [JET, CW, HTK]) had diverse backgrounds and experience, increasing the reliability of the review. The investigators first inductively created a coding protocol, coded the transcripts and developed themes. Illustrative quotations were selected to illustrate the stated and implicit experiences of the physicians. This process was repeated, consolidating or expanding themes as needed. Further details are listed in the Supplement.

Results/Discussion

Overview

The physician's experience of ECPR is intense and associated with a combination of both uncertainties in the patient's condition and very specific guidelines for implementing ECPR. The ECPR team moves rapidly into motion as a patient in refractory arrest is identified and after a series of multiple decisions the patient is placed onto ECMO. After ECMO is initiated, care of the patient becomes more regular until a resolution is achieved.

The physicians reported throughout their interviews the extraordinary power of ECPR. Physicians making decisions to perform ECPR begin with living in an *Ordinary World* with set protocols and decision trees that outline criteria for ECPR including patient specific selection criteria. However, the patient in front of them may not be that clear cut, but nonetheless presents with a clinical need (cardiac arrest). With the decision to pursue ECPR, the physician answers the *Call to Adventure* with all of the concomitant organizational complexity. Once the patient is cannulated, the physician and patient have *Crossed the Threshold*; they then embark upon their clinical journey, which is full of all of the trials and tribulations associated with the *Ordeal*, as patient's clinical course unfolds. Finally, the *Road Back* encompasses the resolution of the ordeal.

Below, we describe the principal themes that conceptually summarized the respondents' beliefs. Direct quotes are listed in the tables. Theme 1: Normal functioning with guidelines and protocols One of the first shared experiences physicians had of ECPR could be described under the umbrella theme of 'normal functioning and protocols' prior to arrival of a theoretical ECPR patient. There is a wellplanned response that calls the ECMO team into action in anticipation of putting the patient on. Physicians reported that they worked under established clinical criteria and protocols for the initiation of ECPR. Physicians often adhered to these protocols, but not always (Table 1).

In general, criteria for initiating ECPR include the patient's age, duration of time from cardiac arrest to hospital arrival, the initial arrest rhythm, physical body size and laboratory criteria. The following quotes are exemplary of the physicians' experience of living in an ordered system 'Ordinary World--Everything is in place'. (Fig. 1, Panel 'Ordinary World').

Theme 2: The patient in front of you is a 'call to adventure'

In contrast to the perceived ordered and structured world of guidelines, the patient in front of you is much less clear. The arrival of the patient and visual assessment is described as an event that immediately evokes strong emotional responses from physicians. This can be summarized thematically as a 'Call to Adventure' because of its emotional intensity and the need to make a decision to accept or refuse the adventure. (Fig. 1, Panel 'Call to Adventure'). Table 2.



Fig. 1 – Graphic representation of the Hero's Journey Metaphor for ECPR

Table 1 - Theme 1: Normal functioning with guidelines and protocols.

Fig. 1, Panel "Ordinary Exemplary Physician Quotes World"

"So, we have a set criteria for who's eligible. The paramedics call us for out-of-hospital arrest and also, for ED (Emergency Department)-based arrest. And so, we have an inclusion sheet that they have to tick off for the patient that has a patient sticker on it. So, they go through the criteria and see whether the patient meets criteria. If the patient does meet criteria, then they get our unit clerk to initiate our fanout, and that calls two of our perfusionists to come in, as well as interventional cardiologist, and then also the cardiac surgeon, and the trauma team leader. So those are the additional personnel who come in to deal with these cases in addition to the existing emerg(ency) staff who are there."

"So if it's an out-of-hospital cardiac arrest, then- the paramedics who have the exact same inclusion cards that they keep on their phones or in a pocket card—they have a cardiac arrest and they look at the cards and they say, "This person meets criteria." If they do, then they phone the emergency department and talk with the on-duty emerg(ency) physician. And if they agree that the patient meets criteria, then the protocol gets activated..."

Table 2 - Theme 2: The patient in front of you is a "call to adventure".

Fig. 1, Panel "Call toSubtheme: Time is Critical Adventure"	Exemplary Physician Quotes
	"So, trying to get the required information in as quickly and sort of timely manner as possible can be a bit tricky. But yeah, probably I reckon three minutes or thereabouts to make the decision, are they a candidate? And by that point, we've got most of our equipment ready, and then we're prepared to start the process."
	"But we're also cognizant of the fact that, particularly for our out-of-hospital cardiac arrests, we have an issue getting the patients into the emergency department within the 45 minutes from onset of arrest."
	"When you're making these decisions and there's– as you know, there's a lot going on at the same time in a very quick order. And it's full steam ahead to get the patient on ECMO (extracorporeal membrane oxygenation) as the time aspect is so critical. I think we probably would've stopped if we had gotten the ABG (arterial blood gas) result before the patient went on ECMO flows"
	"The information required isn't that complex or difficult based on our current system. But I think what makes it challenging is all of the simultaneous events that are trying to be coordinated - the people, the equipment, the room - whilst also trying to ascertain whether they're truly a candidate or not."
Subtheme: The power of the patient in front of you	"It's interesting how when we talk to paramedics on the phone and we're talking about who's eligible and who's not, it's very easy. They don't meet criteria, we're not going to activate. That's it. But then when you have this patient in front of you and you've started to cannulate and you're ready to put them on ECMO, it's gets incrementally harder and harder to stop at that point."
	"But it's definitely becoming more common, but it's really hard- age is one of those things that it's really hard to say no to."
	"Age is a compelling factor. And so it was that plus– I mean, looking at him from the end of the bed, he was a pretty fit, athletic-looking young man at 38 years old. So I think I made the decision based on the fact that I think he would have probably tolerated the longer period of CPR (cardiopulmonary resuscitation), given his young age."
Subtheme: Compelled to do something	"And it's difficult to say no to a patient that doesn't qualify in terms of contraindication. What is the difference between a 20 % survival versus a 40 % survival when you have a patient that is younger than 50, that has a family? Everybody may want to at least try it."
	"If you're in the gray zone, 40 s and approaching what you would usually say no to. And so, it's one of those patients where you would do everything for. And I don't think we necessarily caused any harm by putting him on— we used a lot of resources, obviously, but that's why we've instituted the program."
	"I struggle every time because I enrolled into the arrest trial, so I'm fully conflicted. So, every time I have a patient who randomizes to the control arm, I have to battle myself. So, I feel the conflicts of that decision now today versus three years ago when we first started talking about this trial."
	"if you're uncertain, then on balance, for the benefit of doubt, you should probably cannulate."

The patient's arrival and/or assessment presents a series of decisions that must be made quickly and under considerable time stress. When the patient receiving CPR arrives in front of the physician, death is imminent without an intervention. Physicians reported a feeling of moral imperative/duty to rescue. The initial patient evaluation is a period of high cognitive load for the physician who must make a rapid decision with incomplete information. Decision making is emotionally intense and there is momentum toward performing ECPR if there is a perception of any possibility for success. This is especially true when the patient is young. Thus, physicians may only be willing to randomize patients in whom they do not feel this momentum to cannulate. The ability to share decision making with other trusted physicians decreases the cognitive load and the stress of decision making. There is an emotional overlay to this experience as physicians are fully aware of the importance of this decision and the ethical implications are very salient: the decision not to cannulate assures the patient's death; the decision to cannulate may simply postpone death at great cost.

Theme 3: ECMO is a commitment/crossing the threshold

The third theme encompassing the shared experiences of physicians caring for ECPR patients could be described as 'ECMO is a commitment.' This can be thematically described as a 'Crossing the Threshold' (Fig. 1, Panel 'Crossing the Threshold'). Table 3.

Once a decision has been made to put a patient on to ECMO, physicians understand that this is a commitment of time and resources. The decision to start may be accompanied by a sense of relief as the intense period of decision making is now over and the team starts the well-known process of putting someone onto ECMO.

Theme 4: Decision making, complications, and the ordeal of waiting

The fourth theme encompasses the collective shared experiences of physicians during ECPR and could be described as 'Decision making, complications and the ordeal of waiting.' This can be thematically described as 'The Ordeal' (Fig. 1, Panel 'The Ordeal') as the process is not linear and every patient presents with unique complexities. Table 4.

Once the patient is successfully placed on ECMO, the ordeal is one of waiting for the patient's heart to resume function, or for the patient to accumulate sufficient complications that survival is not feasible. Other team members are allies in the ordeal as unexpected complications are common and require frequent and often difficult decisions. These decisions can require intensive cognitive effort, which can be lightened by protocols and team discussions. Thus, a RCT of ECPR should have detailed protocols, including around post-cannulation care. Physicians caring for these patients are invested in the patient's outcome, and complications are a source of frustration. The most frustrating aspect of the ordeal is to have the 'perfect' patient that doesn't survive. Not understanding the cause of ECPR failure can make the case linger emotionally. When the outcome is especially 'horrible' and sudden, it is a worse experience.

Theme 5: Patient outcomes and the long road back

The final theme describing the collective shared experiences of physicians caring for ECPR patients can be described as 'Patient outcomes and the long road back.' This can be thematically described as 'The road back' (Fig. 1, Panel 'The Road Back'). Table 5.

As not all patients who receive ECPR survive, physicians appear comforted by the fact that the patient would have died without ECPR, so death—unlike complications—is understandable. Decisions regarding major changes in direction of care are often made in conjunction with the family. If family are available, they have been waiting intently on the sidelines. The conversation can vary by physician in terms of how much the family will contribute to the decision. Physicians often feel that the family understands that ECPR was a heroic attempt. Physicians often report taking solace in memories of the patients who did well and were able to resume their lives without terrible neurologic complications. Future RCTs could address these emotionally charged experiences through a variety of approaches, including studying non-mortality outcomes among patients who receive ECPR.

Discussion

The experience of physicians with ECPR is vivid and nuanced. ECPR requires that physicians make pressured decisions about the possibility of ECPR success for each case, and then mobilize significant resources to get the person cannulated onto ECMO – in other words – to do the extraordinary. As authors and researchers, we propose that their experience can be described thematically as a 'heroic' medical event in which a person who is certain to die is given a chance to survive. This process occurs while under the stresses of ongoing CPR and generally in the absence of guidance from families. Physicians who perform ECPR embark on a journey with few signposts and many ordeals for each person placed on ECMO.

Table 3 – Theme 3: ECMO is a commitment / crossing the threshold.			
Fig. 1, Panel "Crossing the Threshold"	Exemplary Physician Quotes		
	"So, once you put somebody on ECMO, where you're basically saying to the medical world, 'I understand what it is. I'm going to commit to stabilizing them with this machine and give them a chance to wake up and bridge them to something.' And what we're sort of implicitly saying to the family or agreeing with the family is that they are also going to give it that chance."		
	"We're going to give them every shot we can until we feel medically the answer is they're not going to do well, and we're relying on the family to sort of give us that leeway."		
	"But then when you have this patient in front of you and you've started to cannulate and you're ready to put them on ECMO, it's gets incrementally harder and harder to stop at that point."		

Table 4 – The	eme 4: Decision making,	complications, and the ordeal of waiting.
Fig. 1, Panel "The Ordeal"	Subtheme: Complexity and Decision Making	Exemplary Physician Quotes
		"I mean, there are probably 80 % of people follow the protocols and 20 %, for some reason, we have to deviate from thosewhether to withdraw or not and wait even longer than we normally do beyond the one-week time frame before we even start prognosticating."
		"So, we were debating whether we should discontinue care, as would be recommended by our protocol at that point in the emergency room"
		"But it's hard to know when is the right time on a patient who's dwindling. And you obviously don't want to do it too soon, and you definitely don't want to do too late. So, hitting that sweet spot is hard."
		"[It] is a benefit to the programthat we do have multiple providers show up at these activations. And one of the pros and cons of that is that, in some cases, there is a lot of experience among those providers who come: the cardiac surgeon, the cardiac interventionalist, and the trauma team leader, and then the cardiac intensivist. In some cases, these individuals have very little experience, but in most cases, there's at least one or, hopefully, two who has a lot of experience in treating with ECMO patients for which you carmake these decisions."
	Subtheme: Complications and Waiting	"The complications that we see with our ECPR patients, sometimes they're completely unpredictable."
		"The unique thing is she had a very weird and a horrible outcome. I mean, we've had head bleeds, but they've also been very random in VV (veno-veno) ECMOs and other patients that we've put them in. And, all of a sudden, I was like 'Whoa, that was like 3,000 of heparin! How do you get a head bleed from that?' So I think that's what made her unique is that I think her outcome surprised me."
		"They're not really there to help us prognosticate. In the end, the only way they us prognosticate is by telling us that nothing bad happened yet. So you do the head CT (computed tomography)—there is no giant stroke, there is no giant brain bleed. And more often, if it's not one of those things, it'd be cerebral edema. And if you don't see that, you're reassured. You do the neuro-specific enolase and if it's not through the roof, you're reassured. You see the EEG (electroencephalogram) and there's no status epilepticus, you're reassured. But in the end, none of those things tell us that there's going to be a good outcome. It just tells us that we don't yet know what the bad outcome will be, if there is oneIn the end, it comes down to a clinical assessment and putting all those things together to really help the family understand what it is that's going on."
		"His EEG was diffusely slowed but nothing catastrophic, no status epilepticus, or a flat EEG. And he was otherwise improving from a cardiac perspective, so we continued, and then he did eventually wake up a week and a half, or two weeks into it to a point where we could actually extubate and talk to him."
		"He did not do anything neurologic at that point and he was not moving. He had, basically, intact reflexes and that was it even after rewarming him. So we sat and we waited and talked to his family and waited."

Table 5 - Theme 5: Patient outcomes and the long road back.

Fig. 1, Panel "The Road Exemplary Physician Quotes Back"			
	"It's totally a difficult decision. But I think the families realize that their family members are getting sort of beyond the standard of care in terms of interventions."		
	"And at that point, based on the progression of the patient, with cerebral edema and lower extremity ischemia that would require amputation, and the progression to renal failure, we discussed with the family. And we thought the efforts were futile at that point."		
	"So regardless of how well the heart was functioning, this was a neurologic injury and deficit they wouldn't recover from"		
	"So havingpoints where you can review [the clinical situation] and, as a group, consider when to stop and palliate, I think, is important. Otherwise, a lot of resources get thrown at people who really aren't going to survive."		
	"So he lived. That was more than I think most people thought was going to happen."		
	"The second thing is that we have to acknowledge how little we know about these people. And so for all of our criteria, this is a guy who's one of the classic examples that I talked about a lot because for all the criteria we have, we have cases that defy all of them."		

These interview results from physicians provide unique insight into the charged decision-making processes of ECPR and how this decision-making process can challenge those who wish to run RCTs. The personal and ethical issues of randomizing patients to ECPR are revealed through these narratives.

Physicians recognized the need for more RCTs to collect definitive information to guide their decisions on who will most benefit from ECPR; they also acknowledged their willingness to part from guidelines based on the power (i.e. survival potential) of the patient in front of them. These two competing ideas are at the heart of the difficulty of randomizing patients into an RCT. While two recently completed RCTs demonstrate the benefit of ECPR, these studies were performed in highly select patients, within select systems of care.9,10 Many other factors associated with survival, identified in observational research, require prospective validation and RCTs.1,21-35 The constant need for more information is a fundamental tension that emerges from the physician's narrative beginning with the initial decision making and continuing through to the resolution of each case. Most physicians, but not all, expressed the opinion that there are a group of patients who they would be unwilling to randomize as they felt ECPR offered the patient a chance for survival that was not available without ECPR - reflecting the emotional intensity of the decision.

Generally, RCTs are considered acceptable if equipoise exists in the use of a therapy. Equipoise is more than the personal uncertainty of one choice over another, but the collective uncertainty (or variation in practice) across a community of clinicians. Clinical trials can thus test interventions and practices that vary across a community of physicians. Clinical trials can also take into account the clinician's uncertainty at different decision points and different contexts, utilizing this uncertainty as the tested intervention in the trial.³⁶ Specific to ECPR, both of these approaches would enable clinical trials of ECPR management—even among physicians who broadly lack equipoise for withholding ECPR. Given this perspective, our study identifies some of the important decision-making factors associated with ECPR, which inform the design of future RCTs for ECPR.

We found that physicians were most likely to break their protocols in order to cannulate young or healthy patients, or in patients with immediate pre-hospital CPR and shockable rhythms. We found that physicians lacked equipoise to randomize these types of patients to continued conventional CPR. Thus, future RCTs might be successful in enrolling older patients, younger patients without immediate prehospital care/bystander CPR, or patients with obvious comorbidities. This latter group of patients is less likely to survive overall, and physicians may or may not be willing to randomize them. Future work is required to define subgroups of patients that clinicians would endorse as having the correct balance of potential benefit to harm who they would be willing to randomize.

Conclusion

In this qualitative analysis of 12 semi-structured interviews of physicians who cared for patients with cardiac arrest who were treated with ECPR, we identified distinct themes. Physicians had strong feelings about the use or non-use of ECPR; our analysis suggests that RCTs will need to identify the middle range of patients in whom physicians consider ECPR reasonable, but not required or contraindicated.

Appendix A. Supplementary material

Supplementary material to this article can be found online at https://doi.org/10.1016/j.resplu.2022.100278.

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