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ORIGINAL ARTICLE

The ethics of extracorporeal membrane oxygenation in brain-dead potential organ donors

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SUMMARY

Organ-preserving extracorporeal membrane oxygenation (OP-ECMO) is defined as the use of extracorporeal support for the primary purpose of preserving organs for transplantation, rather than to save the patient's life. This paper discusses the ethics of using OP-ECMO in donation after brain determination of death (DBDD) to avoid the loss of organs for transplantation. We review case reports in the literature and analyze the ethical issues raised. We conclude that there is little additional ethical concern in continuing OP-ECMO in patients already on ECMO if they become brain dead. The implementation of OP-ECMO in hemodynamically unstable brain-dead patients is ethically permissible in certain clinical situations but requires specific consent from relatives if the patient's wish to donate is not clear. If no evidence of a patient's wish to donate is available, OP-ECMO is not recommended. In countries with presumed consent legislation, failure to opt out should be considered as a positive wish to donate. If a patient is not-yet brain-dead or is undergoing testing for brain death, OP-ECMO is not recommended. Further research on OP-ECMO is needed to better understand the attitudes of professionals, families, and lay people to ensure agreement on key ethical issues.

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Key words
brain death, ethics, extracorporeal membrane oxygenator, organ preservation, transplantation

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Introduction

Transplantation medicine faces an ongoing organ shortage. One of the strategies developed to increase the organ pool is better management of brain-dead patients, who remain the primary source of vital organs for transplant.

Progression toward brain death and brain death itself are conditions characterized by hemodynamic instability, with a non-negligible risk of cardiovascular collapse and hence of lost organ donors [1,2]. A policy of aggressive organ donor management [3], focusing on optimal fluid resuscitation, optimal use of vasopressors and hormonal infusion, has been implemented in several intensive care centers in order to decrease the number of organ donors lost due to hemodynamic collapse, with some success [4]. However, even with optimal organ donor management, some consented organ donors are lost due to hemodynamic instability (up to 15% in the UK) [5].

We define 'organ-preserving extracorporeal membrane oxygenation (OP-ECMO)' as the use of extracorporeal support not to save the patients' life, but to preserve their organs for transplantation; in a similar manner to 'organ-preserving cardiopulmonary resuscitation or OP-CPR', which we defined in a previous article

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[6]. Although OP-ECMO can be used in the context of Donation after Circulatory Determination of Death (DCDD) programs, we choose in this study to focus on the use of OP-ECMO in the context of Donation after Brain Determination of Death (DBDD). We feel this is an area of practice that is under-explored in the literature, yet with the growing availability of ECMO, the potential for OP-ECMO also grows. This raises new and important ethical dilemmas for clinicians. Our goal was to help the medical community to decide whether OP-ECMO in the context of DBDD is ethically acceptable, and if so, under which conditions. In this paper, we review case reports on OP-ECMO in DBDD and related papers on transplantation, ECMO, and bioethics. We then analyze the ethical issues raised by the use of OP-ECMO in DBDD and make several recommendations.

Concepts and definitions (Table 1)

Extracorporeal membrane oxygenation is an extracorporeal circuit which oxygenates the blood and removes carbon dioxide. Through a cannula inserted in a major blood vessel of the body, blood is directed by a mechanical pump toward an extracorporeal circuit, where it can be oxygenated and decarbonated. Then, the blood is returned to the patient's body through the same cannula (venovenous), or through another cannula placed also in the venous system (venovenous) or in the arterial system, for example, the femoral artery or ascending aorta (venoarterial) [7,8].

Extracorporeal membrane oxygenation is used in different contexts in the intensive care unit (ICU) to support severely compromised cardiac or respiratory functions. It is used in respiratory failure, such as acute respiratory distress syndrome (ARDS) [8], in refractory cardiogenic shock and cardiac arrest [9,10], and as a bridge for heart or lung transplant. While venovenous ECMO is usually used for respiratory failure, venoarterial ECMO is more often used for cardiac failure. Complications secondary to the use of ECMO are numerous and often serious [11]: local hemorrhages around the cannula insertion point, tamponade (if atrial cannula), thromboembolism (cerebral embolism, intracardiac thrombosis, pulmonary embolism, distal embolism with limb ischemia), infectious complications, cerebral hemorrhages, and brain death [7,12].

Extracorporeal membrane oxygenation can be used in the context of organ donation, where organ preservation rather than saving the patient's life is its primary role, which we call OP-ECMO. OP-ECMO can be used in the context of DCDD or DBDD programs.

In some DCDD programs, OP-ECMO is used after death [13,14], provided the brain, and in nearly all programs also the heart, is isolated from the ECMO circulation within the body. This is an area in development, with the potential to improve the quality and number of donated organs, but is beyond the scope of this study.

In DBDD programs, there are two main scenarios where OP-ECMO may be used. In the more common scenario, a patient is already on ECMO, when she/he suffers a catastrophic brain injury that results in brain death. Usually, this is as a result of brain hemorrhage, a recognized complication of the anticoagulation required in ECMO. In this circumstance, after the confirmation of brain death, if DBDD is contemplated, the ongoing use of ECMO is for its organ-preserving role. In the second scenario, a brain-dead potential organ donor

Table 1. Definitions.

Organ-preserving ECMO (OP-ECMO)	Use of ECMO in order to preserve organs for transplantation purposes and not to salvage the patient's own life. Concerns the context of DBDD or DCDD programs
A brain-dead patient	A patient who is confirmed brain death after formal brain death testing
A not-yet tested brain-dead patient	A patient for whom there is a clinical belief of an irreversible loss of brain function, without the initiation or completion of formal brain death testing
A not-yet brain-dead patient	A patient who has some degree of cerebral function remaining, but for whom there is a clinical belief that irreversible loss of brain function will occur in time
An organ donor	A patient who has donated organs
A consent-verified organ donor:	A person who was either registered as an organ donor (organ donation registry, driving license, organ donation cards, advanced directive, proxy) or for whom the family has given an informed consent to organ donation. In countries with presumed consent legislation, failure to opt out is considered consent to organ donation unless the family veto.
A potential organ donor	A patient who is considered by health professionals to be a candidate for organ donation, without knowing yet his/her wish to donate.

becomes hemodynamically unstable; this may damage the organs or lead to cardiac arrest, making donation and transplantation not possible. OP-ECMO is one method that may reduce this damage and preserve the chance for donation to occur. The ethics of these two different scenarios are discussed separately below, following a section that summarizes the published literature.

Guidelines and case reports

We could find no published guidelines concerning the implementation of OP-ECMO in hemodynamically unstable brain-dead potential organ donors or concerning the ongoing use of ECMO in patients who develop brain death.

After a PubMed and Google Scholar search using key words including ECMO, extracorporeal support, brain dead and brain death, we were able to find only 11 case reports or case series [15–25]. It was often unclear whether ECMO was implemented before, during or after brain death testing, making interpretation difficult.

Carpenter *et al.*, [15] in Phoenix, reported the case of a woman on ECMO for a cardiogenic shock after an acute myocardial infarct, who developed brain death after a cerebral hemorrhagic complication. Two kidneys and the liver were successfully transplanted into three recipients. Smilevitch *et al.*, [16] in Toulouse, reported a similar case of a woman who developed brain death under ECMO previously implemented for a cardiogenic shock; however, the family declined organ donation. Goswami *et al.*, [17] in New York, reported two cases, where brain death was diagnosed under ECMO, previously implemented for refractory cardiac arrest. In one patient, organ donation proceeded, but the organs were not considered suitable for transplantation.

A retrospective study in Philadelphia between 1995 and 2012 identified 41 organ donors (29 DBDD and 12 DCDD), previously supported by ECMO for therapeutic intent; kidney graft function was comparable with non-ECMO organ donors, but a 'higher discard rate' occurred for livers [18].

In a center in Italy, the use of OP-ECMO is reported in one patient who became hemodynamically unstable between the first and the second brain death testing [19]. The second brain death testing was therefore performed under ECMO. It is not clear from this case report whether ECMO was initiated before or after the family gave consent to donate, or indeed whether a specific consent for the use of ECMO was sought. In 2015, the same center reported the implementation of OP-ECMO to allow brain death testing in a patient with severe polytrauma and constant bleeding, who had developed hemodynamic instability. Successful donation occurred of both kidneys and liver [20].

In another center in Italy, the use of OP-ECMO is reported in one patient who became hemodynamically unstable after brain death determination, permitting transplantation of liver and both kidneys [21]. Information regarding consent is not available. Likewise, one case report from the United States describes the use of OP-ECMO on a brain-dead organ donor, who became hemodynamically unstable after the declaration of brain death. In this case, the family gave prior consent for both organ donation and ECMO [22]. Both kidneys were retrieved with good function in the recipient.

In Taiwan, two centers report the use of OP-ECMO in a total of 11 brain-dead potential organ donors [23,24]. OP-ECMO was implemented before, during or after brain death testing. OP-ECMO was generally implemented after the family gave consent for organ donation, but in two patients from one center, OP-ECMO was commenced before the family gave consent to donate [24]. In both centers, it is not clear whether specific informed consent for OP-ECMO was sought. Hearts, livers, and kidneys were retrieved, with good function in recipients. The same center in Taiwan, which reported a retrospective medical chart review of OP-ECMO in brain-dead organ donors from 2001 to 2010 [23], reported a similar review from 2010 to 2013 [25]. OP-ECMO was implemented for hemodynamically unstable potential organ donors, before brain death tests, 'as a bridge to brain-death declaration' [25].

Our literature review shows that there is very little evidence concerning recipient survival and graft function outcomes when organ donors were hemodynamically sustained by ECMO. However, the aforementioned case reports regarding use of OP-ECMO provide encouraging results [23,24]. Good graft outcomes in recipients are also reported when donors were under therapeutic ECMO before brain death [18]. Furthermore, the use of ECMO in DCDD shows promising results [13,14]. However, any transposition of these results to OP-ECMO in DBDD should be cautious because the patients' medical conditions differ.

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Ethical analysis of OP-ECMO

Patients on ECMO, who develop brain death

Extracorporeal membrane oxygenation in these situations will have been implemented as a therapeutic tool on a patient with severe respiratory or cardiac dysfunction. If brain death were to occur, likely as a complication of ECMO, continuation of ECMO would be for its organ-preserving role. We see this as analogous to continuing the mechanical ventilator after brain death is established, which similarly will then have only an organ-preserving role. It is therefore our opinion that there is little *additional* ethical concern in using OP-ECMO in this circumstance.

Instead, the main area of consideration appears to be the technical challenge of diagnosing brain death in patients on ECMO. Goswami *et al.* [17] highlighted that 'conventional apnea testing is not feasible because oxygenation and carbon dioxide elimination are accomplished by ECMO'. No guidelines exist and existing protocols differ [16,17,23,24]. The need for the development of national and international guidance for clinicians in this area is clear.

An alternative to OP-ECMO for hemodynamically unstable brain-dead potential organ donors

When brain-dead potential organ donors become hemodynamically unstable, an alternative to OP-ECMO is 'crash' organ removal from the organ donors following rapid transfer to the operating room. This is dependent on whether the surgical retrieval team is immediately available, which is itself dependent on how far the organ donation process has advanced. In a brain-dead patient, this might result in a Maastricht Category IV DCDD. We have not directly compared the ethical considerations of 'crash' organ removal to OP-ECMO in this study, but accept that the treating clinician should consider such an option if severe hemodynamic instability occurs. The role for the initiation of cardiopulmonary resuscitation in such circumstances is complex, and we have explored this in another publication [6].

OP-ECMO implemented for hemodynamically unstable brain-dead potential organ donors

The ethical analysis that follows focuses on the implementation of OP-ECMO for hemodynamically unstable brain-dead potential organ donors. To decide whether OP-ECMO in DBDD is an ethical procedure, we analyze the ethical issues raised by OP-ECMO in different clinical scenarios, starting with a confirmed brain-dead potential organ donor.

OP-ECMO in the brain-dead patient

As in the whole process of organ donation, OP-ECMO carries both potential benefits and risks of harm for patients, families, and health professionals. There are a number of issues a clinician will need to consider to balance these competing demands.

Extracorporeal membrane oxygenation is invasive, with catheter insertion and recirculation of the whole blood in an external machine. It can damage the body and physical integrity of a brain-dead patient. Although pain and suffering are not possible in a brain-dead patient, invasive procedures damaging the body could still be a potential reason for objection, depending on the personal values of the patient, particularly with regard to the meaning of the body after death. However, this damage must be put in the perspective of the whole process of organ donation, which includes surgical retrieval of organs. Organ retrieval is a very invasive procedure, but it has been approved by society, professionals and consented organ donors. Even if invasive, OP-ECMO will clearly cause less damage to the body than organ retrieval.

In addition, OP-ECMO might risk psychological harm to family members and health professionals for several reasons: (i) it is an invasive procedure; it might be perceived as instrumentalizing death, and (ii) it can induce confusion, as ECMO is normally used as a life-saving therapy, in a context where brain death is often a misunderstood diagnosis.

OP-ECMO in the not-yet brain-dead patient

The use of OP-ECMO before the declaration of brain death, as described in some case reports [23,24], is problematic. First, ECMO increases the potential risks of intracranial bleeding [7,12] and therefore could, in a not-yet brain-dead patient, hasten death. Second, in a severely brain-injured patient, the evolution toward brain death is difficult to predict and often remains uncertain. Implementing OP-ECMO before brain death (even after futility of ongoing treatment to save the life of the patient has been established) runs the risk of OP-ECMO being without benefit, if brain death never occurs. On the other hand, failing to use ECMO could lead to organ donation being impossible. Third, as the

patient still has some brain activity the possibility of suffering cannot be excluded.

Because of major risks of harm, we do not recommend the implementation of OP-ECMO before brain death has been established.

OP-ECMO in the not-yet tested brain-dead patient

For a not-yet tested presumed brain-dead patient, there is less medical uncertainty regarding brain death, because in this circumstance the treating clinicians believe that death has occurred, but the formal testing has not yet been carried out to confirm (or refute) that belief. While there is less uncertainty, residual cerebral functions still cannot be excluded until formal testing and there therefore remains the potential for the patient to feel some suffering. Because of this uncertainty and related legal issues, it seems reasonable to consider the not-yet tested brain-dead patient in the same category as the not-yet brain-dead patient. Because of the above-described risks of harm, we do not recommend OP-ECMO before confirmation of brain death has occurred.

We can see that there may be an argument that ECMO could be used to stabilize a hemodynamically unstable patient to allow brain death testing to occur [19,20]. It is imperative in the not-yet brain-dead patient and the not-yet tested brain-dead patient that ECMO only be used for the direct clinical benefit of the patient and not for any organ-preserving properties the ECMO might confer. Clinicians should only implement ECMO in this situation if the therapeutic goal is to allow a diagnosis of brain death to be made not simply as a means of organ preservation.

Consent

In cases of hemodynamically unstable brain-dead potential organ donors, ECMO should be considered only once brain death has been confirmed by standard brain death tests and once consent to organ donation has been documented or confirmed.

Indeed, if it is unknown whether a brain-dead patient wanted to be an organ donor, there is a risk that OP-ECMO could be contrary to the patient's wishes. It would also impose on the patient an invasive and potentially harmful procedure. Thus, when the wish of the patient to be an organ donor is unknown and the family cannot be contacted to make a decision regarding organ donation, we conclude that OP-ECMO should not be initiated.

In contrast, if the patient's consent to donation has been verified (registration on a national organ donor register or donor card, or family expression to the treating clinical team of the patient's previous expressed wish to donate), it would be ethically problematic if the opportunity for organ donation was lost due to hemodynamic instability. The patient's wish to perform a highly beneficial act at the end of life would be thwarted and the potential legacy for a family that had agreed to organ donation would be lost. The chance for a recipient to receive a lifesaving transplant and for others to receive organs that will improve their quality of life would also be lost. For these reasons, we believe there is a strong argument that OP-ECMO should be considered in all such potential DBDD, where ECMO is available and there is verified consent for donation.

In countries where presumed consent legislation has been enacted, we accept that failure to opt out should be considered as verified consent to donate. However, in all circumstances where the family is required to provide consent to organ donation, we would recommend that the family should also be asked to consent to OP-ECMO. Where family consent is not required for organ donation, we would still strongly advise that families are informed regarding the option of OP-ECMO, but formal consent for OP-ECMO should not be required.

Economic impact of OP-ECMO

Extracorporeal membrane oxygenation is an expensive procedure [26]. There is therefore an economic impact of introducing OP-ECMO, and this raises issues concerning opportunity cost and the allocation of

Table 2. Recommended consent requirements for ECMO.

	Consented organ donor	Donor wish unknown
Brain-dead patient	Consent not required for OP-ECMO but strongly preferred; family can overrule	OP-ECMO not recommended
Not-yet brain-dead patient	OP-ECMO not recommended	OP-ECMO not recommended
Not-yet tested brain-dead patient	OP-ECMO not recommended	OP-ECMO not recommended

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resources. OP-ECMO consumes human and infrastructure resources including professionals' time, ICU beds, and ECMO equipment. If OP-ECMO is used, one has to ensure that it will not deprive saveable patients from the use of therapeutic ECMO. It might be necessary to include OP-ECMO into the reimbursed fees proposed by insurance companies. Particular attention should be given to avoid the costs of OP-ECMO being at the charge of the donors' relatives.

The cost-effectiveness of OP-ECMO needs to be carefully weighed. However, compared to the costs of the whole organ donation process, the additional costs generated by the use of OP-ECMO for several hours are probably not really significant, particularly compared to the expected benefits of organ donation.

Potential benefits and risks of harm of OP-ECMO to society

Organ-preserving extracorporeal membrane oxygenation can benefit society by fulfilling the wishes of those who wish to donate, by making more organs available for transplantation and by saving the lives of patients in need of organs. However, OP-ECMO is an additional invasive procedure which might be considered as instrumentalizing death. This risks a loss of public confidence, particularly if OP-ECMO is implemented, without having previously obtained a specific informed consent. Public mistrust in transplantation might increase, which could in turn decrease the organ donation consent rate.

When evaluating the implementability of OP-ECMO, the medical community has to seriously consider risks of societal repercussions.

We would warn against a challenging ethical issue that could arise in countries where access to health care is not financially possible for every citizen. In such countries, the possibility exists that ECMO might be more commonly seen to be used as OP-ECMO in hospitals servicing more socioeconomically disadvantaged and vulnerable populations, while therapeutic ECMO remains more restricted and only available to those with better health packages. In this sense, there risks the development of, or at least the perception of, a type of 'ECMO apartheid'. This would be a severely unethical development and undermine public trust in organ donation and transplantation.

Conclusion

We believe that where available, OP-ECMO should be considered for any hemodynamic unstable brain-dead potential organ donors, as a means of saving organs that would otherwise be lost. However, certain criteria must be met (see Table 2 for summary).

If the patient has been formally declared brain-dead and is known to be a consented organ donor (however that is defined in any individual country), OP-ECMO can be performed unless specific objections are raised by the family. We strongly advise discussing OP-ECMO with the family before its implementation. If the patient has been declared brain-dead and is not known to be a consented organ donor, OP-ECMO is not recommended, unless the family consents to both organ donation and OP-ECMO. If the patient has not yet been declared brain dead, OP-ECMO is not recommended.

Authorship

DAAL: research, idea, analysis and writing. DMS: analysis, ethical input and minor writing. DG: analysis, ethical input and writing.

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Conflicts of interest

Dr. Gardiner is deputy national clinical lead for organ donation in the UK for NHS Blood and Transplant.

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