Nereo Zamperetti Rinaldo Bellomo Claudio Ronco Cardiac death or circulatory arrest? Facts and values in organ retrieval after diagnosis of death by cardio-circulatory criteria

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# Introduction

Transplantation is the most effective long-term treatment for end-stage disease of vital organs. Patients who are declared dead by either neurological or cardio-circulatory criteria are the most important source of organs. Donation after cardiac death (DCD) was the first source of cadaveric organs for transplantation. After the definition of brain death (BD) became accepted, and retrieving well-perfused organs from heart-beating brain-dead donors became possible, DCD was all but abandoned. It has now regained ground in the last 15 years because of a severe imbalance between the number of people dying while waiting for transplantation and the number of available organs.

Donation after cardiac death can take place in patients who die after unsuccessful CPR after unexpected cardiac

arrest (*non-controlled* DCD, Maastricht class 1, 2 and 4) or after planned forgoing of artificial life support (*con-trolled* DCD, Maastricht class 3). Because of its particular bioethical aspects, in this paper we will consider only this latter situation and when referring to DCD will mean controlled DCD.

# Cardiac death or circulatory arrest?

The Uniform Determination of Death Act states that "An individual who has sustained either irreversible cessation of circulatory and respiratory functions, or irreversible cessation of all functions of the entire brain, including the brain stem, is dead." [1]. To fit within the DCD protocols, such a standard has to be interpreted. After forgoing of futile or refused (even if indispensable) artificial life support, *cessation of circulatory function* must be intended as loss of *mechanical* rather than *electrical* cardiac function. Furthermore, *irreversible* should be intended as *spontaneously* irreversible, meaning that no effort should be made to restore effective circulation.

Unfortunately, the above construct has been challenged, and support for it from the public and healthcare workers has been called into question [2–5]. Surely, declaring a patient dead on cardiovascular criteria and then proceeding to successful transplantation of the heart can be, in the very least, counterintuitive and, at worst, manipulative and contradictory. Yet, this is what is now both theoretically possible [2] and practically done [6].

Also the timing for the definition of the irreversibility of cessation of cardiac function is critical. The shorter the interval between asystole and incision, the greater the possibility that the irreversible loss of intracranial functions (BD) has not yet occurred. Again, when donors are declared dead in DCD protocols, the absence of perfusion may still be reversible, and, with perfusion, life could be easily restored. In this sense, a risk exists of mistaking prognosis For this reason, viability of the heart and absence of circulation are not necessarily one and the same, and an

In fact, this interval varies in different protocols [2, 7], the usual time interval being 2 min (ranging from 2 to 5). A significantly shorter interval has been recently proposed by Boucek and co-workers, who reported their DCD protocol for transplantation of infant hearts. According to this protocol, three newborns were declared dead 75 s after the loss of an effective circulation, and organ retrieval was immediately performed [8]. The paper is accompanied by three editorials, which challenge the protocol on the basis of the questionable procedure of declaring death on cardiac criteria and moving on to heart transplantation. Veatch stated that "it is impossible to transplant a heart successfully after irreversible stoppage: if a heart is restarted, the person from whom it was taken cannot have been dead according to cardiac criteria. Removing organs from a patient whose heart not only can be restarted, but also has been or will be restarted in another body, is ending a life by organ removal" [9]. Truog and Franklin [10] added: "[The authors'] interpretation creates the paradox that the hearts of patients who have been declared dead on the basis of the irreversible loss of cardiac function have in fact been transplanted and have successfully functioned in the chest of another. [...] although it may be ethical to remove vital organs from these patients, we believe that the reason it is ethical cannot convincingly be that the donors are dead."

We do not know if this protocol has been adopted outside of Denver or even if it is still followed in Denver. Yet, hearts have been retrieved also on 2-min official DCD protocols. So, the above and following considerations apply to the DCD protocols in general.

We believe that part of the problem is semantic. The expression "cardiac death" holds two distinct (even if related) meanings: the death of the heart (the myocardium, or cardiac muscle) and the death of the patient certified on cardio-circulatory criteria. Traditionally, these two facts have coincided. At present, in an intensive care setting, the death of the myocardium does not necessarily coincide with the death of the patient. Maintaining the patient's life is exactly the meaning of basic and advanced life supports even in the case of dissociated cardiac death [11], a condition in which an extracorporeal membrane oxygenation (ECMO) can be an extreme but effective resource [12].

On the other hand, the presence/absence of circulation is distinct from the vital status of the myocardium. After a DNR decision has been made and all artificial life support forgone, a patient usually experiences a decline in myocardial pulsatile function, which usually ends in electromechanical dissociation, followed by ventricular fibrillation or asystole. During these latter phases, the cardiac muscle is still viable but there is no effective circulation. culation are not necessarily one and the same, and an absent circulation can well coexist (at least for some minutes) with a vital (and transplantable) myocardium. Claiming that auto-resuscitation has never been shown to occur after 1 min of absent circulation, irreversible cessation of circulatory and respiratory functions could be certified to have occurred, and patients could be declared dead after 75 s-according to the Boucek protocol. In other words, in the setting of such a protocol, "cardiac death" should be intended as death of the patient certified on cardio-circulatory criteria while the cardiac muscle is still viable (and the brain and the rest of the organism as well). We argue that the correct term would be "donation after circulatory arrest" (DCA) rather than "donation after cardiac death." This term would not imply that the heart has died. The heart could then, like other organs, be transplanted, admitting that heart retrieval is permissible in such a context.

Two core questions, at this point, can be formulated. First, is this logical construct really tenable, or is it just a semantic trick? Second, is it sufficiently clear to lay people, and above all to patients and relatives who might accept donating organs in such a DCA protocols?

We believe that absence of perfusion is easily verifiable. Similarly, the fact that death is the inevitable consequence if resuscitation is forgone is obviously intuitive. Yet, declaring that the patient's death has already taken place is morally questionable and scientifically untenable as long as adequate and effective perfusion of the brain and all other organs can be easily restored.

As a second point, the risk of confusing genuine education and adequate awareness with manipulation of people's opinions has already been addressed, and some authors have reported that "OPOs [organ procurement organizations] today have focused their efforts on convincing members of the public to become organ donors rather than on providing adequate unbiased information and education about organ donation" [5].

Transplantation is important. That's why a widely and publicly acceptable policy of organ retrieval should be openly formulated.

We strongly believe that after 75 s (and perhaps also 2 min) of cessation of effective perfusion, the loss of circulatory and respiratory functions can certainly be called persistent, but hardly permanent. Permanent cessation ('irreversibility' adequate for a diagnosis of death, as the process of dying is completed) will follow in several more minutes and depends on the decision of forgoing CPR. In this sense, it is evident that declaring the patient's death when the heart, the brain and the whole organism are still vital—though no more effectively perfused and bound to undergo irreversible hypoxic damage in a very short time—is a moral rather than a scientific position.

#### **Proposed options**

Yet, do we really need to define death after prolonged absence of circulation in a DNR patient before retrieving vital organs?

Since its very beginning, organ transplantation has been guided by the dead donor rule (DDD), which states that impaired vital organs can be retrieved only from cadavers. This rule had the obvious advantage of removing every moral discussion regarding the ethical nature of organ retrieval, as the donors are dead. In this sense, this approach has contributed greatly to the diffuse acceptance of transplantation medicine.

Yet, such a position has also raised bitter objections, and "some authors have accused the transplant community of drawing the line between life and death wherever it maximizes changes for organ procurement" [3]. Most probably, Boucek's protocol will not lessen these concerns.

In this sense, a "paradigm change to ensure the legitimacy of DCD practice" has been suggested, which should include societal and legal abandonment of the dead donor rule [5]. As seen above, this is also the opinion expressed by Truog in the above-mentioned editorial.

In a different way, Shewmon [13] argued that death could not be a necessary prerequisite for organ retrieval in the DCA protocol if the retrieval process itself does not affect the process of dving. Considering that the core problem is not the patient's vitals status but the influence of retrieval on the patient's death, this author argued that removing all organs except the heart and lungs even before respiratory arrest will neither cause nor hasten a death that will anyway follow in some minutes after forgoing of artificial life support. For the first hours after organ retrieval, absence of kidneys, liver, intestine and pancreas has no significant adverse effect on the body, as death from renal, hepatic or pancreatic insufficiency would require days or weeks to happen. In this sense, for the retrieval of non-cardiopulmonary organs in a DCA protocol, it would then be ethically irrelevant whether the donor is dead.

As for the heart and/or lungs, "it makes no physical or moral difference whether the ventilator is disconnected before or after opening the chest cavity." Therefore, it could be possible to forgo artificial life support, being ready to inject the necessary tissue-preserving fluid into the cardiac and pulmonary circulation "as soon as final asystole [...] can be determined with moral certainty to be truly final." Such an approach would neither cause nor hasten death, as "once circulation has effectively ceased due to the effect of progressive hypoxia on the heart, the dying or decaying process continues just the same regardless whether the non-beating heart and non-functioning lungs remain physically in the circulationless body or not."

As with current DCA protocols, what is really important is the body perfusion (the circulation of blood), not the electric myocardial activity. The difference is that, according to Shewmon, even a possible subsequent beat or two after some seconds of asystole are irrelevant. as they "would not produce an 'effective circulation' that would change in any significant way the process of dying/decaying already set in motion. Thus, it does not really matter exactly when loss of potential for cardiac auto-resuscitation occurs or whether 2 or 5 min or some other duration of asystole suffices to provide certainty that [loss of potential for auto-resuscitation] has already passed. This is because any potential cardiac autoresuscitation would necessarily be very transient, by virtue of the ongoing apnea and severe hypoxemia; moreover, a very brief and weak circulation of anoxic blood would do nothing to counteract the inexorable process of dying/decaying already set in motion" [13]. In other words, once it has been decided to forgo all artificial life support in a consenting patient, even heart and lungs can be retrieved for transplantation after waiting for a sufficient time interval to reasonably (not absolutely) exclude auto-resuscitation, i.e., when the process of dying is sufficiently advanced (but not yet concluded), spontaneously irreversible and unaffected by organ retrieval.

The above position is not completely convincing on theoretical grounds as it seems too complicated and full of sophistry and physiological intricacies. Moreover, it appears to be of difficult application in practice. Retrieval of non-cardiopulmonary organs together with sternotomy, pericardiotomy, dissection and cannulation of great vessels before cardiac arrest demand a level of anesthesia (sedation, analgesia and muscle relaxation), which would surely inhibit any spontaneous breathing, being the direct cause of respiratory arrest once patient is disconnected from the ventilator—a situation that is neither morally nor legally irrelevant.

In truth, the real problems of both abandoning the dead donor rule and accepting Shewmon's position (who indeed argued that organ retrieval could be possible even outside the dead donor rule) is that they both rest in the strict dichotomy between life and death.

### A possible alternative option

These different points of view reflect the difficulty of matching facts and values in such complex situations in which life and death are not two clearly defined dichotomous entities (as they used to be before the advent of intensive care), and where the transition from one to another is complex, slow and ill-defined. Trying to set a clear definition is like "zooming in on the prismatic spectrum midway between green and blue, and demanding that someone not only identify it unequivocally as either 'green' or 'blue' but also have a convincing, logical rationale for doing so" [13].

A possible alternative option consists in critically reevaluating the reality of the donor's condition in a DCD protocol. The clear clinical fact is the absence of effective circulation, which—depending on the moral decision to forgo CPR—rapidly (but not rapidly enough) becomes irreversible in a few minutes, while, in parallel, the adequacy of organs for transplantation decreases.

The most important relevant values are the dignity of the patients who are going to become donors (which means adequate information and previous consent from the patient or from the person responsible), the compassionate treatment of the relatives and the need to preserve vital organs. Also the integrity of the medical, nursing and ancillary professions should be safeguarded: every action done on a patient should be in the interest of that very person. The mere suspicion that other hidden interests guide the management both of end-of-life care and of transplantation would undermine the morality of the patient-clinician relationship (the therapeutic alliance) and the public's confidence in medicine. If these interests are openly expressed, patients can really make informed choices, and there is no risk of abuse, of misunderstanding and of the public's confidence being undermined by suspicion of medical manipulations of the definitions of death.

As we already suggested [14], the essential step is to move away from the above-mentioned strict death-life dichotomy and to recognize that the traditional concepts of life and death are totally inadequate to describe the situation of DCD donors.

As a matter of fact, even if insufficient to assume that the process of dying is completed, prolonged absence of circulation in a DNR patient is a clinically and scientifically useful point of no return in such a process, which can be used to guide moral and social decisions and legal norms. Once that effective circulation has ceased but is still easily reversible and all vital organs are dying but still viable, the patient's vital condition is impossible to determine as an absolute value as it is quite out of our traditional concepts of life and death [4]. Such a condition is something between, a highly unstable state in which the donor is neither alive (as life is normally considered) nor surely yet dead (as death is currently defined). If this is true, a definition cannot be a substitute for knowledge [15], especially if such a definition is scientifically untenable and morally questionable. Furthermore, it is likely that the moment when the patient crosses the line from prognosis of imminent death to the diagnosis of completed death might be too late for the needs of transplantation.

Thus, this is the reality of facts: we cannot identify the moment of established death. What we can identify is a moment in the process of dying of DNR patients in which the process, although not yet completed to established death (as it is still easily reversible), is sufficiently advanced to permit the retrieval of viable and functioning vital organs from consenting patients. Why should we persist pretending that donors in DCD protocols are surely biologically dead (the process of dying is completed)? Would not an open explanation of the reality of such protocols be easier and better? Why do we believe lay people are not clever enough to understand the reality of DCD?

If we speak of "donation after circulatory arrest" (DCA) rather than "donation after cardiac death," neither death of the cardiac muscle (which can be retrieved for transplantation) nor the completion of the patient's dying process are assumed. In a legal process sense, then, it would become relatively simple and reasonable to verify two steps: (1) the agreement to implement a DNR order and (2) the acceptance of cessation of the circulation for a suitably agreed upon realistic time frame as the moment for retrieval of vital organs. This would preserve integrity, self determination, public confidence, legal protection and the public's confidence that the process is being conducted in a transparent way that does not involve medical judgment alone, but also incorporates the patient or his legal representatives and society as well.

#### Conclusion

We believe that DCD/DCA protocols rest on the definition of a moment (a suitably prolonged absence of circulation in a DNR patient) that—even if does not identify the actual death of the patient (the completion of the process of dying)—is a sufficiently advanced stage in such a process that organ retrieval can be allowed, provided that it had been consensually agreed that disconnecting the ventilator is in that patient's interest from a clinical and moral point of view and that adequate information and consent are present. We believe that if we call this protocol "donation after circulatory arrest," the public would easily understand and accept this concept, the law could protect it and regulate it, and the procurement of vital organs (including the heart) would be facilitated and seen to be ethically sound.

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