TRANSPLANT INTERNATIONAL

Transplant International ISSN 0934-0874

ORIGINAL ARTICLE

Imprecise definitions of starting points in retrospectively reviewing potential organ donors causes confusion: call for a reproducible method like 'imminent brain death'

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Keywords
brain death, donor conversion rate, family refusal, intensive care unit, potential heart-beating organ donor.

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Conflicts of Interest
No conflict of interest.

Received: 2 December 2011
Revision requested: 15 January 2012
Accepted: 3 May 2012
Published online: 30 May 2012

doi:10.1111/j.1432-2277.2012.01505.x

Summary

Low donor supply and the high demand for transplantable organs is an international problem. The efficiency of organ procurement is often expressed by donor conversion rates (DCRs). These rates differ among countries, but a uniform starting point for defining a potential heart-beating donor is lacking. Imprecise definitions cause confusion; therefore, we call for a reproducible method like imminent brain death (IBD), which contains criteria in detail to determine potential heart-beating donors. Medical charts of 4814 patients who died on an ICU in Dutch university hospitals between January 2007 and December 2009 were reviewed for potential heart-beating donors. We compared two starting points: 'Severe Brain Damage' (SBD) (old definition) and IBD (new definition), which differ in the number of absent brainstem reflexes. Of the potential donors defined by IBD 45.6% fulfilled the formal brain death criteria, compared with 33.6% in the larger SBD group. This results in a higher DCR in the IBD group (40% vs. 29.5%). We illustrated important differences in DCRs when using two different definitions, even within one country. To allow comparison among countries and hospitals, one universal definition of a potential heart-beating donor should be used. Therefore, we propose the use of IBD.

Introduction

Measuring the pool of potential organ donors is important for policy making and (inter)national comparison of efficiency of hospitals and countries, especially in an international landscape of low donor supply and a high demand for donor organs for transplantation. The efficiency of organ procurement is often expressed by the number of actual donors divided by the number of potential donors; the donor conversion rate (DCR). Three large studies reviewed the medical records of all deceased patients in the ICU in a group of hospitals in the USA, the UK and four European countries and revealed a DCR of 42%, 45% and 43.2% respectively [1–3]. The Netherlands has lower DCR figures reaching 30% [4,5]. The question, is however, if these rates can be used for a sound comparison among countries. A review published previously in this journal, showed that no uniform definition for a potential organ donor was used in studies from different European countries [6]. The starting points for analysing the pool of potential heart-beating organ donors that were found ranged from patients confirmed with brain death, to severe brain damage with a Glasgow Coma Scale (GCS) of E1, M1, V-intubated without any absent brainstem reflexes [1–3,7–10]. Imprecise definitions of starting points in retrospectively reviewing potential organ donor cause confusion. A methodology to estimate the pool of potential heart-beating donors and

to evaluate the performance in the deceased donation process was recommended by the DOPKI consortium in 2009 [11]. Although this was an important first step in the effort to come to a universal definition, there was no consensus on criteria for the exact starting point like the GCS and the number of absent brainstem reflexes. This same phenomenon is seen in a recent review article in this journal of Dominquez-Gil *et al.*, [12] where a critical pathway for organ donation was introduced. The pathway is very complete, including donation after brain death (DBD) *and* donation after circulatory death (DCD). The definitions of 'eligible', 'actual' and 'utilized' donors (DBD and DCD) are clear. But a valid cornerstone as a starting point for the definition of a 'potential DBD donor' is not formulated. They used as a definition 'a person whose clinical condition is suspected to fulfil brain death criteria', which is not specific enough for retrospective chart analysis. We recommend having a precise and clear definition in detail.

In practice, there are differences in the process of organ donation between countries. The question is at what moment a patient is accounted as a potential heart-beating donor when medical records are reviewed retrospectively. A new definition in detail is necessary which includes cases where the brain death determination was not completed. But then the question is how far can you deviate from the gold standard 'brain death' and still be quite sure that, based on a retrospective review, the deceased patient could have a chance to evolve to brain death. The uncertainty for heart-beating organ donation increases, the further you deviate from the gold standard. In the Netherlands we did not have an answer. Therefore, we organized a number of expert meetings in the Netherlands, with representatives of several areas in the field of organ donation and transplantation. The use of 'imminent brain death' (IBD), as a reasonable probability to become brain dead, was the outcome [13]. A patient who fulfils the IBD definition, in a retrospective medical record review, is admitted to an ICU, mechanically ventilated, has an irreversible catastrophic brain damage of known origin and either a GCS of E1, M1, V-intubated (no eye movement, no motor response, no verbal response) with a progressive absence of at least three of six brainstem reflexes (pupillary reaction, corneal reflex, oculocephalic and oculovestibular responses, gag and cough reflex), or a FOUR Score of E_0, M_0, B_0, R_0 (Eye response, Motor response, Brainstem reflexes, Respiration) [13]. The FOUR Score stands for Full Outline of UnResponsiveness [14,15]. A hierarchy in absent brainstem reflexes was not established, because in clinical practice different sequences of progressive brainstem reflexes failure may occur. Therefore, every deceased patient with some form of cerebral herniation and brainstem failure that could lead to brain death is included. The rationale for three or more absent brainstem reflexes for the definition of IBD is to reflect the severity of brainstem failure [13]. From the universal applicable starting point IBD, restrictive exclusion criteria, like age and absolute contraindications to organ donation, are adjusted in a hierarchical order to obtain the pool of potential heart-beating donors. Subsequently, the DCR and the reasons for non procurement can be analysed from this pool of potential donors. A recent study has shown that the definition of IBD appears to be a more appropriate and practical tool to identify potential heart-beating organ donors by retrospective chart review [16], compared with 'imminent neurological death' as defined by the Organ Procurement Transplantation Network in the USA (see http://optn.transplant.hrsa.gov). This study was conducted in a single university hospital, and did not include the, in the Netherlands, commonly used starting point for heart-beating donation defined by 'Severe Brain Damage' SBD. The definition of SBD is based on a GCS of E1, M1, V-tube and at least one absent brainstem reflex [4,5]. The IBD definition is stricter than the SBD definition and differs in the number of absent brainstem reflexes (minimal one for SBD and minimal three for IBD). In the present study we illustrate the impact of these different starting points in measuring the pool of potential heart-beating organ donors on the DCR on the basis of a retrospective medical record review.

The aim of the study is not to identify potential heart-beating donors as early as possible in clinical practice, because this can only be done in a prospective study where you can follow the progression of catastrophic brain damage during the time of admittance in the hospital. In a retrospective study the medical information of the patient that was recorded just before death is leading to define whether or not the patient could be accounted as a potential heart-beating organ donor or not.

Material and methods

We used data of patients who died on an ICU in seven of the eight university hospitals in the Netherlands during the years 2007 until 2009. These data were collected from the medical records and entered in a web-based application of the Dutch Transplant Foundation by in-house transplant coordinators. One university hospital was excluded from our study because there was incompleteness of data. The last known medical information before death of the patient was leading for reviewing potential heart-beating organ donors. This included the GCS and the number of absent brainstem reflexes, if applicable. When confounding factors for brainstem failure were found (e.g. hypothermia, metabolic disturbances and

sedation), the case was excluded for the potential donor pool. Only medical records of deceased patients until 75 years of age were reviewed, the upper age limit for organ donation during the study period. Therefore, insight in all deceased patients fulfilling the criteria of SBD or IBD (without age limit) is not possible. According to the database of procured organ donors registered by the Dutch Transplant Foundation 0.8% (2/266) of all donors were >75 years. Our selection of records continued with patients who were medically ventilated, and had no restrictive exclusion criteria/'medical contraindication' for organ donation (e.g. unknown cause of death, unknown identity, non treatable sepsis, malignancy except some brain tumours, active viral infections, active tuberculosis and anencephaly). We then retrospectively determined the pool of potential heart-beating organ donors out of the remaining records according to the two different definitions SBD and IBD separately (see box):

Two conditions of heart-beating organ donor potential that were compared:

1. Potential heart-beating organ donors according to 'Severe Brain Damage' (SBD: old definition). A patient in this definition is admitted to an ICU, is mechanically ventilated, suffered severe and irreversible brain damage, as defined by a GCS of E1, M1, V-intubated and has absence of at least one brainstem reflex. These patients have no medical contraindication to organ donation, and are under the age of 76 years [5].

2. Potential heart-beating organ donors according to 'Imminent Brain Death' (IBD: new definition). A patient in this definition is admitted to an ICU, is mechanically ventilated, and suffered irreversible catastrophic brain damage of known origin and has a GCS of E1, M1, V-intubated. Thus far the same condition as SBD, but in addition the absence of at least three of six brainstem reflexes. These patients have no medical contraindication to organ donation, and are under the age of 76 years.

From these defined pools of potential heart-beating organ donors we analysed the admission diagnosis and compared the percentage of donors who were subsequently diagnosed brain death, defined by a GCS of E1, M1, V-tube, absence of all brainstem reflexes, an iso-electric electroencephalogram and a positive apnoea test. We also compared the DCR and the distribution of reasons that were recorded when brain death was not determined. These could be divided in medical reasons (e.g. no fulfilment of all brain death criteria) and social reasons of non procurement (e.g. early family refusal, prior patient refusal).

This study is based on a retrospective review of medical records of deceased patients, therefore, according to Dutch law, no approval of legal representatives or a medical ethical review board was necessary. The board of directors of all centres formally agreed on collecting data of deceased patients from the ICU to identify potential organ donors.

Results

Severe brain damage

In total 4814 patients had died in the study period of whom 3792 were aged 75 years or younger and 3719 were mechanically ventilated as well. After excluding patients who were not suitable for heart-beating organ donation because of restrictive exclusion criteria 559 deceased patients were regarded as potential heart-beating organ donors applying the SBD definition. Table 1 shows the demographics of this group divided over the years 2007–2009. The admission diagnosis was in majority stroke (subarachnoid haemorrhage, intracerebral haemorrhage, cerebral infarction) (57.4%, 321/559) and Traumatic Brain Injury (TBI) (19.3%, 108/559). The admission diagnosis 'other' consists of multiple diagnoses, such as 'intoxication', 'gun shot/stab wound', 'drowning' and 'suicide'. Table 2 shows all absent brainstem reflexes, as recorded in the medical records, divided into the reason of non procurement.

In 188 patients, 33.6% of all 559 potential heart-beating donors according to SBD, formal brain death was determined, leading to 165 actual heart-beating organ donations. The DCR of potential heart-beating donors based on SBD was 29.5% (165/559). In 11 cases families objected to heart-beating but not to non heart-beating donation and organs of all of these donors were procured in a non heart-beating procedure.

Imminent brain death

Of the group of 559 potential heart-beating donors according to the SBD definition, 412 deceased patients met the more strict IBD-GCS criteria and were regarded as potential heart-beating organ donors after applying the IBD definition (Fig. 1). The 147 patients who did not meet the IBD criteria were excluded for additional analysis in the IBD group. The admission diagnosis of these patients was in majority stroke (58.5%, 241/412) and TBI (18%, 74/412). In 45.6% (188/412) of the potential donors according to IBD formal brain death was determined, leading to 165 actual heart-beating donors. The DCR based on IBD-GCS was 40% (165/412). In seven cases families objected to heart-beating donation but not

Table 1. Demographics and admission diagnosis of deceased patients in the group 'severe brain damage' (SBD) and 'imminent brain death' (IBD).

	2007		2008		2009		Total	
	SBD	IBD	SBD	IBD	SBD	IBD	SBD	IBD
Total	192	140	181	135	186	137	559	412
Age, year (±SD)	46.6 (17.2)	46.2 (17.3)	46.5 (17.6)	46.1 (18.5)	47.2 (17.7)	45.9 (17.8)	46.7 (17.5)	46.0 (17.8)
Female gender, % (no.)	46.9 (90)	50.7 (71)	48.4 (90)	42.9 (58)	43.6 (79)	46.7 (64)	46.3 (259)	46.8 (193)
Admission diagnosis								
Stroke	118	88	93	67	110	86	321	241
Traumatic brain injury	33	25	36	24	39	25	108	74
Multi-trauma	21	13	16	12	10	7	47	32
Post anoxic encephalopathy	3	2	15	13	13	9	31	24
Other	17	12	21	19	14	10	52	41

GCS, Glasgow Coma Scale.

Table 2. Number of *absent* brainstem reflexes as written in the medical chart of deceased patients from the ICU's of seven university hospitals.

	1 Reflex absent	2 Reflexes absent	3 Reflexes absent	4 Reflexes absent	5 Reflexes absent
SBD (min. 1 absent BSR, n = 559)	70	77	87	44	281
IBD (min. 3 absent BSR, n = 412)	–	–	87	44	281
Medical reasons of non procurement (n = 111) – SBD	24	26	35	14	12
Social reasons of non procurement					
Family refusal (n = 179) – SBD	23	35	44	23	54
Prior patient refusal (DR) (n = 65) – SBD	21	12	7	5	20
No approval of coroner (n = 6) – SBD	–	1	1	2	2
Not recognized by physicians (n = 2) – SBD	–	1	–	–	1
representatives not present or not reachable (n = 7) – SBD	1	2	–	–	4
HB switched into NHB procedure (n = 1) – SBD	1	–	–	–	–

BSR, brainstem reflex, DR, donor register; HB, heart-beating; IBD, imminent brain death; NHB, non heart-beating; SBD, severe brain damage.

to non heart-beating donation and organs of these donors were procured (data not shown).

Reasons for non procurement before and after brain death

After analysing the reasons for non procurement of the potential donor pool before formal brain death determination, according to the two assessment tools (SBD and IBD), family refusal was the most important reason in both groups (32% and 29.4% respectively) (Fig. 1). Medical reasons of non procurement before formal brain death were: no fulfilment of all formal brain death criteria, circulatory instability, cardiac arrest, and legal incapacity [in total 19.9% (111/559) in the SBD group and 14.8% (61/412) in the IBD-group)].

Reasons for non procurement after formal brain dead were; family refusal (n = 11), eventually medically unsuitable donors (n = 6), patient refusal as registered in the Donor Register (n = 2), sudden cardiac/circulatory arrest (n = 2), refusal by coroner (n = 1) and no medical suitable recipient (n = 1).

Discussion

In this study we illustrated the consequences of applying two different starting points for identifying the pool of potential heart-beating donors by reviewing medical records of deceased patients; SBD and IBD. We analysed data obtained on a national level, in seven Dutch university hospitals, which form an addition to the single centre study where IBD was applied as described earlier [16]. The outcome is revealing: the IBD definition shows a strikingly higher DCR (40%) than the SBD definition (29.5%). When these differences occur within one study, caused by inclusion of two extra brainstem reflexes, what does this imply for DCRs from international data that depend on different definitions for heart-beating potential? The large

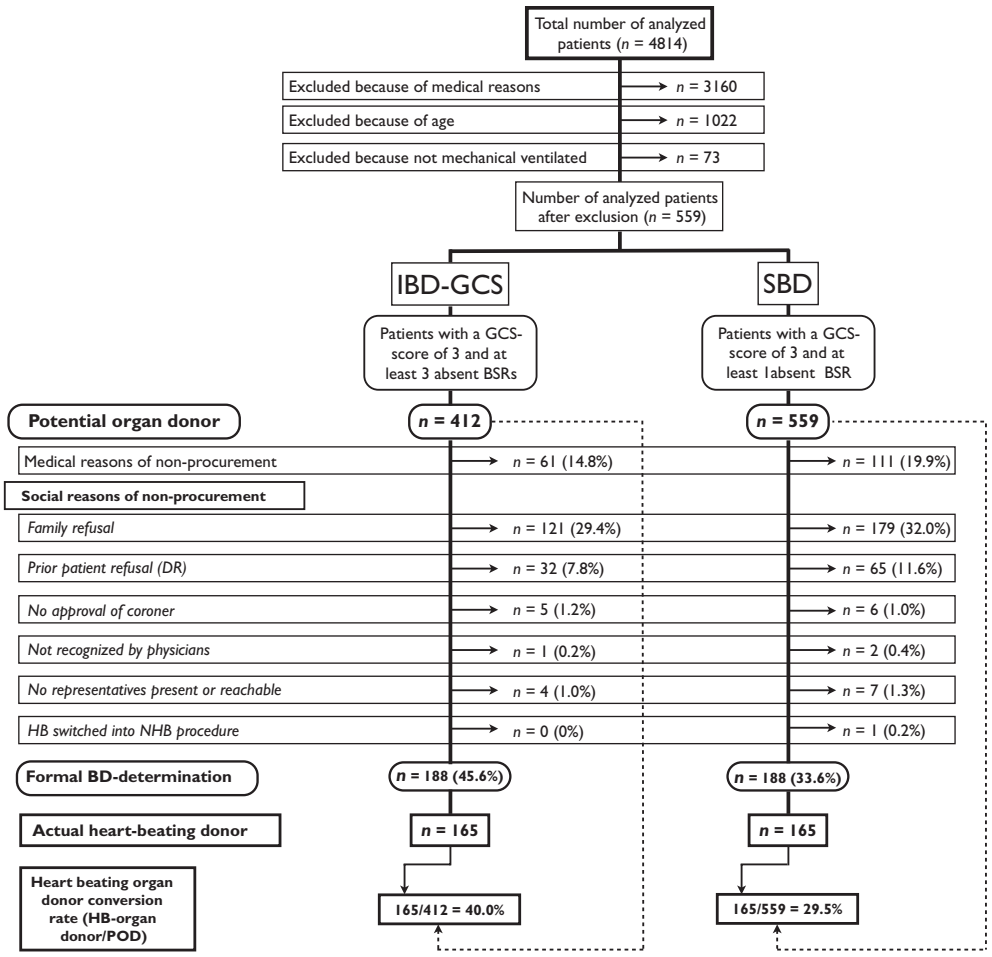

Figure 1 Flowchart of the assessment tools severe brain damage and imminent brain death for identifying potential heart-beating organ donors.

numbers of published articles worldwide on reviews of medical records from ICU deaths indicates the interest in identifying numbers of potential of organ donors [1–3,5,7–10,16–23], but the DCRs' cannot be compared.

Our study showed that a universal starting point, in retrospective data analysis of deceased patients, for defining potential heart-beating donors and to determine the DCR is essential. Bench marking of donation performances is only possible between hospitals or countries when there is one uniform point of departure. Therefore, we call for a reproducible method like IBD. As explained in our article [13] the pool of potential donors can be derived from the total group of patients who meet the criteria of IBD after adjusting restrictive exclusion criteria in a hierarchical order (age and medical contraindication). The observation that in the IBD group 45.6% of the potential heart-beating donors were determined brain death, compared with 33.6% in the SBD group is related to the fact that for the IBD definition more brainstem reflexes must be absent, and therefore reflects more severe brain failure.

The main reason for non procurement was the high proportion of families who refused consent for donation in both the IBD and SBD group. As visible in Fig. 1, a great number of families were requested for organ donation early in clinical course, even when only one brainstem reflex was absent. This has to do with the practice in the Netherlands that in case the medical condition is considered irreversible and no treatment possibilities are left, the prognosis is infaust and further meaningless treatment is prohibited. The relatives are then informed about withdrawal of treatment. In case the patient is medically suitable for organ donation the Donor Register is consulted. If the register is indecisive, the family will then be approached to consent for organ donation. It will be explained that additional tests have to prove if the patient is brain dead. When there is no fulfilment of all formal brain death criteria a non heart-beating procedure is the alternative way to donate organs. In case the family objects to organ donation the brain death determination will not be completed. For retrospective medical chart

review it is impossible to know if this patient could have evolved to brain death and therefore is a true potential heart-beating donor or is a potential non heart-beating donor. As published in a number of articles the high numbers of family refusals is a bottleneck in the donation performance of the Netherlands [4–6]. Thus far, these rates could not be compared to other countries because of differences in the definition of a potential donor. After applying IBD as a universal starting point, the family refusal rate can be determined in an internationally better comparable way, because it also includes potential heart-beating donors who could have evolved to brain death. The possible differences between countries in the moment of approaching families for donation (before or after brain death) can be further assessed. For example, is the family refusal rate lower in countries where brain death is determined and pronounced to the family prior to the request for donation, compared to countries where families are approached in an earlier stage? Furthermore, if in a country the moment of discussing organ donation with relatives changes from after brain death into before brain death, historical data will remain comparable when using IBD.

The stricter IBD definition proved to be a better precursor for heart-beating organ donation than SBD, as used in the Netherlands thus far, and therefore results in a more realistic estimation of the pool of potential heart-beating organ donors. However, using a more stringent definition like IBD has a small risk. It is conceivable that a few potential donors can be missed using this more stringent definition for retrospective chart review. That raises the question what is the best strategy for screening potential heart-beating donors. Taking the chance of losing a few potential donors or including a number of deceased patients to the potential pool that would never had become a heart-beating donor. In our opinion the more realistic the pool of potential heart-beating donors the better data can be used for international comparison.

As mentioned before, potential non heart-beating donors can also occur in the remaining cases where the medical treatment was futile [24]. After withdrawal of life-sustaining treatment and mechanical ventilation, circulatory arrest is expected. When death occurs in a hospital within 2 hours, the kidneys, liver, lungs and pancreas can be donated. These are the so-called Maastricht category III controlled non heart-beating organ donors. During the study period in the seven university hospitals, organs were procured from in total 99 non heart-beating donors (43 of the group of 'medical reasons of non procurement' in case the potential donor did not fulfil all brain death criteria; another 11 non heart-beating donors, of the group of families who objected to heart-beating donation but not to non heart-beating donation. And finally, 45 non heart-beating donors were procured from the group of patients who did not fulfil the SBD criteria). Therefore, a uniform definition for the additional pool of potential non heart-beating should be proposed, which is necessary to evaluate DCR and family refusal for the total group of potential heart-beating and non heart-beating organ donors between hospitals and countries.

Limitations of this study

First, the medical charts of patients in this study were reviewed by 10 in-hospital transplant coordinators. It is conceivable that not everyone assessed the medical information in the exact same way, although data entry into the application was in accordance with one standardized format. There is no information if the GCS and brainstem reflexes were recorded at the same time. This could be a confounder, although only the last medical information before death of the patient is leading for data entry. Furthermore, the medical records did not always give detailed information on the neurological assessment, so the full number of potential heart-beating organ donors could be underestimated.

This study focused on the ICU to identify potential heart-beating donors. To identify all potential donors other departments should be included, for example the accident and emergency department [25].

The FOUR Score, as an alternative to determine IBD [13], is not (yet) used (on a large scale) in ICUs in the Netherlands, so we only reviewed the data on IBD based on the GCS.

We considered analysing differences in the number of potential donors among the seven Dutch university hospitals, because of the small numbers per centre this appeared to be not useful. Furthermore, in the Netherlands a national policy for organ donation is used, this eliminates possible differences in practise between the centres.

Conclusion

This study shows that it is necessary and effective to use a uniform starting point for reviewing medical records of patients who died on an intensive care unit for analysing the potential of heart-beating organ donors. The initiatives taken so far are not enough to allow international comparison of DCRs between countries [11,12]. The results of our study suggest that Imminent Brain Death (IBD) reduces the uncertainty of the probability to become brain dead compared with the Severe Brain Damage (SBD) definition used in the Netherlands so far. We would like to encourage other countries to use IBD, which is according to our opinion, an internationally well

deployable tool to identify the potential heart-beating donor pool. Only with one universally used definition of a potential organ donor, comparison between hospitals and countries is meaningful. Therefore, additional work is needed to test IBD in different settings in various countries with the ultimate goal to achieve comparable DCRs.

Authorship

NEJ: designed and performed the research, analysed the data and wrote the manuscript. YJG: participated in the research design and in the writing of the paper. HAL: participated in the research design, in the data analysis, and in the writing of the paper. BJJMH-K: participated in the research design, and revised the manuscript. EJOK: participated in the research design and revised the paper. AH: participated in research design and in the writing of the paper.

Funding

No funding.

Acknowledgements

We would like to thank the in-house transplant coordinators of the seven university hospitals, who collected all data of deceased patients in the intensive care units. We are also grateful to Hester Lingsma, Erasmus MC Rotterdam, for her critical comments on the manuscript.

Transparency declarations

None to declare.

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