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What do we know about eligible organ donors? Analysis of data from a local Registry

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Abstract

Background. The imbalance between supply and demand for organ donations remains a hot topic for international debate. Brain-dead organ donors (DBDs) constitute the majority of organ donations in Poland.

Objectives. To identify the factors that guided intensivists in qualifying a brain-dead patient as a potential organ donor, and whether the factors that significantly influenced the decision to qualify constituted an actual contraindication.

Materials and methods. We performed a retrospective study based on data from the Silesian ICU Registry from 2010–2020 and publicly available information from Poltransplant. We compared the demographic and clinical characteristics of patients diagnosed with brain death who were identified as eligible and ineligible organ donors.

Results. Out of 25,465 patients enrolled in the Silesian ICU Registry, brain death was diagnosed in 385 (1.51%) study participants, and 61 of the records were excluded due to data incompleteness. In the remaining group (n = 324), there were 201 men and 123 women. Of them, only 180 study participants were reported as eligible donors (55.5%). Six patients had absolute contraindications to organ donation.

Conclusions. A relatively small number of patients diagnosed with brain death were qualified by intensivists as eligible organ donors, with a limited number of medical factors influencing this decision. This means that other non-medical factors may affect the qualification of DBDs for organ procurement.

Key words: brain death, tissue and organ procurement, tissue donors

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Background

The imbalance between supply and demand for organ donation remains a hot topic for international debate and continues to determine the prognosis of patients with end-stage organ dysfunction.[1] In 2020, 529 deceased organ donor applications were received in the Polish Transplant Coordinating Center (Poltransplant). In 74% of these cases, a successful organ procurement was performed, resulting in 1,183 organ transplantations.[2] Yet, by the end of the year 2021, the total number of patients awaiting transplantation was vastly larger, reaching a total of 5,741 cases. Indeed, Poland ranks 23rd out of 28 European countries in terms of deceased organ donors (per million population).[3]

Brain-dead organ donors (DBDs) make up the majority of organ donations and outnumber cardiac arrest organ donors and living donors.[2,4] The number of donations after cardiovascular death is low, but the retrieval programs seem promising.[5,6] Therefore, the patients eligible for donation after brain death are mainly diagnosed with a traumatic brain injury (TBI) or subarachnoid hemorrhage.[7] Such acute neurological states often require admission to the intensive care unit (ICU), which then becomes the main facility for DBD qualification and brain death management.[8,9] Therefore, based on medical and non-medical conditions, intensivists of brain-dead patients determine who qualifies and should be submitted to donor programs.

In this study, we compared the demographic and clinical characteristics of patients diagnosed with brain death who were and were not submitted by their attending physicians to Poltransplant as eligible organ donors.

Objectives

The purpose of this study was to identify the factors that influenced ICU physicians to not qualify a patient with confirmed brain death as an eligible organ donor, and whether the factors that significantly influenced the qualification decision constituted an actual contraindication for donation. In other words, we aimed to find out whether the process of qualifying a patient with confirmed brain death as an eligible donor is a deliberate process based on structured criteria, or whether it depends on the subjective judgment of the qualifying physician.

Materials and methods

Study design

In this study, we compared the demographic and clinical characteristics of patients diagnosed with brain death who were or were not submitted by their attending physicians to the Poltransplant as eligible organ donors.

Setting

This retrospective cross-sectional study was based on data from the Silesian Registry of Intensive Care Units, Poland, from the years 2010–2020. This Registry is a secured voluntary collection of demographic and medical data regarding over 25,000 adult patients hospitalized between 2010 and 2020 at ICUs in the urban region of southern Poland.[8]

Participants

Patients who were diagnosed with brain death were included in the study. We excluded patients with insufficient data regarding hospitalization or organ donation status (n = 61). After exclusions, the study group consisted of a total of 324 patients.

Variables

Demographic and medical data were retrieved, including sex, age, comorbidities, primary ICU admission cause, patient's condition on admission, and applied treatment and invasive procedures during the ICU stay. In the paper, we used definitions and categories applied a priori in the Registry.[10] Patient submission as an eligible organ donor was defined as the outcome. Submission meant that the patient was reported to the Poltransplant center as an eligible organ donor. An eligible donor is a patient with confirmed brain death in whom there are no known absolute contraindications to becoming a donor.

Data sources/measurement

All data were obtained from the Silesian ICU Registry. All data were analyzed employing units used in the Registry.

Bias

We excluded patients whose stay data were incomplete or unclear upon evaluation. Except for the excluded patients, every patient with a diagnosis of brain death was included. Potential bias was reduced due to the fact that we were working with a Registry in which the structure was standardized. The Registry was not focused on any outcome or purpose, only on collecting data, which may potentially reduce the risk of selection bias.

Study size

The study size was achieved by using all available data from the Registry from all years of its functioning.

Quantitative variables

The only quantitative variables analyzed in our study were age and length of stay. Quantitative variables were expressed as median and interquartile range (IQR).

Statistical analyses

Statistical analysis was performed using MedCalc Statistical Software v. 15.4 (MedCalc Software Ltd., Ostend, Belgium). Qualitative variables were expressed as absolute values and percentages. Between-group differences for quantitative variables were assessed using the Mann–Whitney U test. Their distribution was verified with the Shapiro–Wilk test, while χ^2 or Fisher's exact tests were applied for qualitative variables. A $p < 0.05$ was considered statistically significant.

Results

Of the 25,465 patients included, 385 (1.51%) were diagnosed with brain death. Sixty-one patients with a diagnosis of brain death registered in 2010 (n = 11), 2011 (n = 47) and 2020 (n = 3) were excluded due to incomplete data (Fig. 1).

Taken altogether, 324 (1.27%) of the registered study participants were diagnosed with brain death, and only about half of them (55.5%) were regarded by their attending physicians as eligible organ donors. The median age of brain-dead patients was 54 years (IQR: 43–64), and there were more male patients (n = 237; 61.5%). Considering the patients' chronic diseases, the most common were arterial hypertension (42.3%) and coronary artery disease (24.9%). A more detailed between-group comparison is presented in Table 1.

In most cases, patients were admitted to the ICU from the emergency department (32.2%), and in almost every case (96.4%), it was their first ICU admission. The most common cause of admission was acute respiratory failure (with additional complaints of acute heart failure and an acute altered neurological status, Table 2).

Regarding data at admission, patients who were submitted as eligible organ donors were more likely to be unconscious (95.0% compared to 88.1%) and less likely to need hemodynamic support with catecholamines than non-submitted patients (43.8% compared to 65.3%, Table 3).

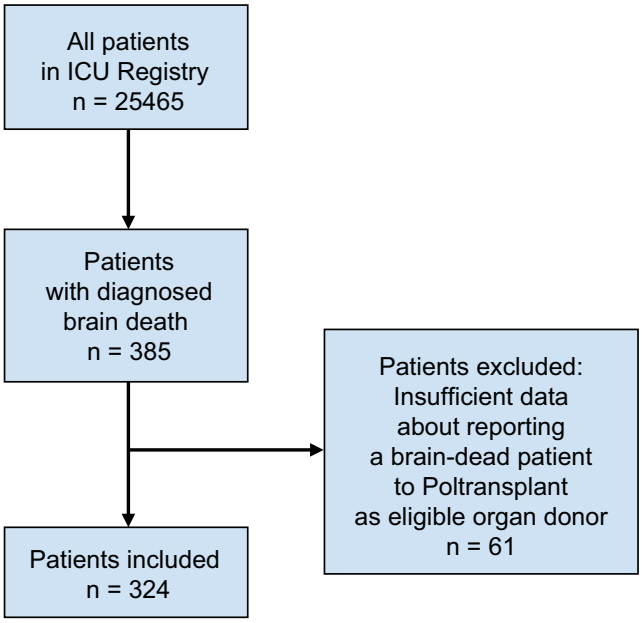

Fig. 1. Flow diagram for the patient selection process

ICU – intensive care unit; Poltransplant – Polish Transplant Coordinating Center.

Table 1. Comparison of demographics and comorbidities between brain-dead study participants who were submitted as eligible and ineligible organ donors

Variable	Patients not submitted as eligible organ donors (n = 144)	Patients submitted as eligible organ donors (n = 180)	Test value	df	p-value and test name
Female	52 (36.1%)	71 (39.4%)	0.249	1	0.617[a]
Age* [years]	60 (IQR 50–69)	51 (IQR 41.5–60)	–	–	<0.001[b]
Coronary artery disease	53 (36.8%)	31 (17.2%)	14.972	1	<0.001[a]
Chronic heart failure	39 (27.1%)	12 (6.6%)	23.627	1	<0.001[a]
Arterial hypertension	63 (43.8%)	79 (43.8%)	0.008	1	0.930[a]
Chronic respiratory failure	16 (11.1%)	2 (1.1%)	13.401	1	<0.001[a]
Alcohol abuse	9 (6.2%)	23 (12.7%)	3.132	1	0.076[a]
Diabetes mellitus	15 (10.4%)	17 (9.4%)	0.011	1	0.917[a]
Chronic renal failure	16 (11.1%)	1 (0.5%)	15.869	1	<0.001[a]
Previous cerebral stroke	13 (9%)	16 (8.8%)	0.023	1	0.878[a]
Chronic neurological disorders	10 (6.9%)	8 (4.4%)	0.536	1	0.464[a]
Malignancies	6 (4.1%)	0 (0%)	5.521	1	0.018[a]
HCV infection	1 (0.6%)	3 (1.6%)	0.079	1	0.778[a]

Continuous variables were expressed using medians and interquartile ranges (IQR). Qualitative variables were expressed as absolute values and percentages. *Normality should be rejected due to result of Shapiro–Wilk test (W-value = 0.9892; p = 0.016); HCV – hepatitis C virus; [a] – χ^2 test; [b] – Mann–Whitney U test; df – degrees of freedom.

Table 2. The primary reason for ICU admission*

Variable	Patients not submitted as eligible organ donors (n = 144)	Patients submitted as eligible organ donors (n = 180)	χ^2	df	p-value
Acute respiratory failure	114 (79.1%)	131 (72.7%)	1.442	1	0.229
Exacerbation of chronic respiratory failure	12 (8.3%)	1 (0.5%)	10.627	1	0.001
Acute heart failure	87 (60.4%)	87 (48.3%)	4.225	1	0.039
Sudden cardiac arrest	48 (33.3%)	30 (16.6%)	11.263	1	<0.001
Shock (any)	30 (20.8%)	12 (6.6%)	13.002	1	<0.001
Multiorgan failure	14 (9.7%)	14 (7.7%)	0.176	1	0.674
Sepsis	4 (2.7%)	1 (0.5%)	1.343	1	0.246
Acute pancreatitis	3 (2%)	0 (0%)	1.855	1	0.173
Post-surgical status	36 (25%)	30 (16.6%)	2.930	1	0.086
Traumatic brain injury with multiorgan failure	6 (4.1%)	12 (6.6%)	0.536	1	0.464
Non-traumatic brain injury	31 (21.5%)	80 (44.4%)	17.651	1	<0.001
Traumatic brain injury	17 (11.8%)	41 (22.7%)	5.828	1	0.015
Poisoning/intoxication	2 (1.3%)	3 (1.6%)	0.063	1	0.801
Severe metabolic disorders	20 (13.9%)	18 (10%)	0.823	1	0.364

*Patients could be classified in several causes of admission, e.g., a patient with respiratory failure may also suffer from circulatory failure, acute neurological or metabolic state, etc. Qualitative variables were expressed as absolute values and percentages. ICU – intensive care unit; df – degrees of freedom.

Table 3. The medical status at ICU admission

Variable	Patients not submitted as eligible organ donors (n = 144)	Patients submitted as eligible organ donors (n = 180)	χ^2	df	p-value
Lack of consciousness	127 (88.1%)	171 (95.0%)	4.140	1	0.041
Endotracheal intubation and mechanical ventilation	125 (86.8%)	148 (82.2%)	0.945	1	0.331
Catecholamine support (any)	94 (65.3%)	79 (43.8%)	13.860	1	<0.001

Qualitative variables were expressed as absolute values and percentages. ICU – intensive care unit; df – degrees of freedom.

Table 4. Medical support required during ICU stay

Variable	Patients not submitted as eligible organ donors (n = 144)	Patients submitted as eligible organ donors (n = 180)	χ^2	df	p-value
Catecholamine support	132 (91.6%)	169 (93.8%)	0.309	1	0.578
Need for tracheostomy	14 (9.7%)	3 (1.6%)	8.885	1	0.002
Need for RRT	15 (10.4%)	2 (1.1%)	12.125	1	<0.001
Antibiotics use	88 (61.1%)	117 (65%)	0.367	1	0.544
Surgery during ICU stay	11 (7.6%)	39 (21.6%)	11.012	1	<0.001

Qualitative variables were expressed as absolute values and percentages. RRT – renal replacement therapy; ICU – intensive care unit; df – degrees of freedom.

During the ICU hospitalization, the submitted patients were less likely to be dependent on ventilatory support with a need for tracheostomy (1.6% compared to 9.7%) and less likely to have qualified for renal replacement therapy (RRT; 1.1% compared to 10.4%) than the non-submitted individuals (Table 4). The median length of ICU stay did not differ between groups (non-submitted: 5 (IQR: 2.5–10) compared to submitted: 5 (IQR: 3–8); p = 0.136).

We selected 10 factors, considering primarily the clinical aspect, that could significantly negatively influence the intensivist's decision on the patient's qualification as an eligible organ donor, and reviewed how many patients had at least one of these factors (regardless of whether the factor was statistically significantly more or less frequent in patients who qualified or were not qualified to be eligible donors). The chosen factors included shock (any type), sepsis and sudden cardiac arrest as the primary cause of admission, comorbidities before admission (diabetes, chronic circulatory failure, chronic renal failure, chronic respiratory failure, and alcohol abuse), and a need

for continuous renal replacement therapy (CRRT) or need for tracheostomy during the ICU stay. Seventy-three of the 180 patients not qualified as eligible organ donors (40.55%) had at least one of these selected factors.

Discussion

The results of this study indicate the possible larger problem of qualifying too few patients as eligible organ donors despite confirmed brain death. The efficiency of the donor qualification for these patients appears to be unsatisfactory, as only half of brain-dead patients were regarded as eligible organ donors by their attending physicians. Only a few medical variables significantly influenced donor eligibility, which may indicate the presence of other factors affecting the organ donation process.[11]

The upper age limit for disqualifying a patient from being a donor is variable, with an increasing trend over the years,[12] and can vary from organ to organ. For example, for kidney donation, the limit is an age >70 in most cases. It is worth noting that for each organ, this is a relative contraindication, which is due to the statistically higher incidence of damage and reduced organ function in the elderly and, thus, reduced transplant survival.[13] However, this should not be applied to every case, as age should only be an auxiliary factor in assessing the suitability of a patient's organs for possible transplantation, not a determining factor. Despite this, the fact that younger patients were statistically more likely to qualify is clear in our study.

Chronic organ failure is not an absolute contraindication to organ donation. Intuitively, it seems obvious that a worse organ condition, as determined with biomarkers, imaging studies or clinical signs of failure, will negatively affect organ function in the prospective recipient. However, there is a lack of strong evidence to support this claim, so chronic organ failure in an eligible donor should not be considered a contraindication to donation in every case, nor should it be a factor that, in isolation, without being linked to the full clinical picture of the patient, influences the failure to qualify a person with a confirmed brain death as an eligible donor.

Both in Poland and internationally, the main cause of brain death is acute neurological conditions, often associated with TBI.[14,15] Thus, it is not surprising that patients admitted for the aforementioned conditions more often qualified as eligible donors. These conditions mostly caused disorders of consciousness, which may indirectly indicate that qualified patients were more often unconscious on ICU admission. It should be noted, however, that unconsciousness is a very broad concept that can result from many causes, not only those directly related to brain damage.

Our study lacks data on the type of procedures performed during the ICU stay. However, it can be assumed that the majority of these were neurosurgical procedures aimed at reducing intracranial pressure (ICP), such as craniotomy. Patients with increased ICP requiring decompression will be the vast majority of patients with severe brain damage, which can lead to brain death and qualify for organ donation. This may explain why they were qualified more often.

Neither the need for a tracheostomy during an ICU stay nor the initiation of RRT are absolute contraindications to organ donation from a donor with confirmed brain death. The fact that in our study, these factors were more common in the group of ineligible patients may be explained by a prolonged ICU stay, which is often associated with performing the above procedures (especially tracheostomy, which is most often performed when prolonged mechanical ventilation is required).[16] The length of ICU stay is indirectly impacted by the severity of the patient's condition, which may translate into the deterioration of organ function, regardless of the reason for the ICU stay, and thus may explain the increased incidence of tracheostomies in patients who were ultimately not reported as eligible donors. The Registry did not provide information on when or why RRT was initiated in a patient, but it should be assumed that in most cases, this information refers to the initiation of RRT prior to the determination of brain death. Although the use of RRT in eligible donors is beneficial in the presence of acute kidney injury (AKI),[17] the need for this procedure prior to the determination of brain death was likely dictated by the severity of the patient's condition and driven by the therapeutic indications specific to the patient, hence the higher number of patients who required RRT in the group that did not qualify as eligible donors is to be expected.

Donation from eligible DBDs is suboptimal, and the multidirectional attempts to improve retrieval rate are insufficient.[18,19] Considering absolute values of the individual variables, it should be noted that there were very few patients with absolute contraindications to organ donation, such as isolated cases of malignancies in our study (6 cases).[20]

Only 40.55% of the patients had at least 1 of 10 factors that, according to the authors, could have significantly influenced the patient's ineligibility as a donor. It should be noted that the selected factors are not absolute contraindications to organ donation. The qualification process is, of course, complex and should not be reduced to an assessment of single factors; however, it appears that a significant proportion of patients are disqualified from being an eligible donor due to other unspecified factors, which is an opportunity for improvement.

It is worth mentioning that, according to Polish law, an absolute contraindication to organ donation from a deceased donor is an objection expressed during life as defined by law.[21] As of December 31, 2020, a total of 37,728 people were registered in the Central Register of Objections.[2] This represents 0.09% of the Polish population. Therefore, this parameter can be considered irrelevant

in the context of this study as well as in the context of patient eligibility for organ donation.

Given the increasing need for organ transplantation, it is important to maximize the number of eligible organ donors. This can be achieved by increasing the qualification rate of confirmed brain-dead patients. To improve donation outcomes, it is crucial to provide thoughtful and critical care management to eligible organ donors, with a focus on meeting donor management goals.[22] This could contribute directly to an increase in the absolute number of transplants performed, thereby reducing mortality and improving the well-being of those waiting for a transplant. The results also suggest the need to ask oneself before deciding not to qualify a patient diagnosed with brain death as an eligible donor – is this patient unable to be a donor, or does he or she have any absolute contraindications to organ donation? It seems reasonable to consider the patient's condition on a case-by-case basis and try to qualify them for organ donation, as this can significantly increase donation rates.[23] Moreover, it has been documented that many declined donor livers have the potential to be evaluated by machine perfusion.[24]

Limitations

This study has several limitations. First, it was a registry-based analysis and therefore retrospective in design and with a limited amount of available data. This paper did not analyze the organ donation process as the Registry was not designed for that purpose. Therefore, certain variables were not included. Some variables were too vague to interpret and determine their impact on the qualification process of a patient diagnosed with brain death as an eligible donor.

Laboratory data, including inflammatory markers or biochemical indices, were not monitored. Additionally, 61 patients were excluded from the analysis due to incomplete data. It is important to note that ward participation in the Registry was voluntary, which may have limited the amount and representativeness of the data inputted. Furthermore, the Registry was run locally, exclusively in the Silesian Province of Poland. Although the study group seems representative, it is important to compare the results obtained with those from institutions across Poland.

Conclusions

In our study, a small number of patients diagnosed with brain death were considered eligible organ donors by their attending physicians. A significant proportion of patients did not have any factors that could have potentially influenced donor eligibility, which may indicate the presence of other factors affecting the whole organ donation process. This implies that the clinician's subjective judgment may play a significant role, which could result in disqualifying a considerable number of eligible donors.

Data availability

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

Consent for publication

Not applicable.

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