

Time for Determining the Diagnosis of Brain Death and its Relation to Organ Donation

ORIGINAL

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Abstract

This study aimed to identify the time needed for confirmation of brain death and its relation to organ donation. Quantitative, descriptive and retrospective study with 175 patients who had diagnosis of brain death completed between January and December 2013. The time from 11 to 20 hours (38.9%) prevailed, with average of 17.91 hours (SD 17.53). There was significant association between the finding of brain death diagnosis in less than 20 hours and the number of donated livers ($P = 0.041$). We stress the importance of speeding up the diagnosis of brain death as an important step of the donation process, in order to contribute to realization of transplants.

Keywords

Brain Death; Time; Directed Tissue Donation; Nursing.

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Introduction

Brazil has a world reference public program of transplants that covers around 95% of the procedures relating to this treatment. These include preoperative tests, hospitalizations, surgeries, provision of high cost medicines and multiprofessional assistance for both the donor and the receiver [1].

It is noted that the increase of the effectiveness of transplants in the country is directly related to the contribution of deceased donors. Until the end of 2013, 80.3% of the 7,649 organ transplants occurred with this type of donors [2]. The completion of organ transplants involving deceased donors is a result of technological, scientific and legal

advancement related to brain death (BD) diagnosis, which is defined as the irreversible cessation of all brain functions [3].

In Brazil, BD diagnosis is performed by two doctors, one of them mandatorily specialist in neurology or neurosurgery. In this respect, the Brazilian legislation diverges from other countries [3-6].

The Brazilian registry of transplants (BRT) reported that in the country in 2014, 9,351 notifications of potential donors (PD) were published, and 2,713 of these became effective donors (ED) corresponding to 14.2 effective donors per million in the population (pmp) [7]. In 2015, the ED rate was equal to 14.1 pmp. The decrease from 2014 to the next year is attributed to the decrease in PD notification rate [8].

A total of 2,393 PD were present in the first quarter of 2016, and 669 of these became ED. The rate of effective donations in 2016 was 28% and was 4.8% smaller than 2015 (29.2%). Among the PD reported in 2016, 72% had brain death (BD) diagnosis confirmed and became eligible donors, of which 38% became ED [9].

A few years ago, the difficulty to confirm the BD diagnosis represented a challenge to realization of transplants across the country. However, nowadays, the biggest obstacle is obtaining the family consent. This may contribute to the increased mortality from diseases that could be prevented by transplants [9].

Transplanting with deceased donors should be preceded by the identification of patients with clinical criteria for the diagnosis of BD, that is, ap-perceptive and non-reactive coma according to the Glasgow coma scale. A score of 3 on this scale corresponds to absence of eye opening and verbal/motor response. As soon as this status is confirmed, the physician on duty shall inform the family about the severity of the patient's state and the need for confirmatory tests for diagnosis of BD [2, 3].

Furthermore, the possibilities of electrolyte or serious acid-basic disturbances as well as hypothermia and the use of depressants of the central nervous

system (CNS) should be excluded before carrying out confirmatory tests of BD. The evaluation of these parameters is important to confer reliability to the results of clinical tests; these changes may lead to false results of the patient's neurological response [5].

Neurological clinical trials aim to demonstrate the absence of cortical brain activity, as well as the lack of activity of the brain stem, through the following findings: ap-perceptive coma, absence of reflexes and apnea before hypercapnia. The minimum interval between a clinical examination and the other is 6 hours considering the age of potential donors over 2 years [3].

The time for diagnosis of BD should be as short as possible due to the imminent risk of cardiac arrest and other physiological complications caused by paralysis of brain activities. Therefore, it is important that within 12 to 24 hours, care with PD be intensified, as well as care to correct organ dysfunction and capture organs for transplantation as soon as possible [10, 11].

In the context of care to PD of organs and tissues, the intensive care unit represents the ideal place for maintenance because this site has appropriate infrastructure, materials, technological resources, as well as specialized multidisciplinary teams. Interaction and teamwork are key elements for proper maintenance of PD in order to contribute to realization of donations and successful transplants [12, 13].

Based on the above, and on the negative impact on public health resulting from the loss of PD, the realization the present study is very timely. It is expected that the results of this research may contribute to the planning of actions to minimize the time of BD diagnosis, and also stimulate the provision of essential care to the diagnosis and maintenance of PD, aimed at saving lives.

This study aimed to identify the time needed for confirmation of brain death and its relation to organ donation.

Methods

Descriptive and retrospective study with quantitative approach, performed in a notification, procurement and distribution center of organs (CNCDO) in northeastern Brazil. Data were collected in January 2014 and the population consisted of 177 subjects who had opened protocol of BD for the period from January 1 to December 31, 2013.

The sample consisted of 175 patients who completed the BD protocol during the study period, according to the following inclusion criteria: patients aged at or older than two years, patients who had BD protocol completed. Two patients were excluded because they were younger than 2 years due to the recommendation that the time between the first and second clinical examination exceed six hours in order to standardize data with respect to the variable time.

The data collection instrument was developed by the authors based on the Resolution 1,480/97 of the federal council of medicine (FCM). This consisted in a script sheet composed of two parts. The first part of the instrument was aimed at socio-demographic characterization of potential donors (PD) such as: gender (male/female), age (years) and ethnicity (brown/white/black). The second deals with data on the BD protocol, such as cause of coma, date and time of the clinical examination, type of further examination, date and time of its completion, organ and tissue donations, family member responsible for consent.

Ethical and legal principles governing research involving human subjects according to the National Council of Health nº 466/2012 were respected, and the approval from the Ethics and Research Committee of the Federal University of Rio Grande do Norte (CEP-UFRN) 414/10 was obtained [14].

Data were organized in spreadsheets in the *Microsoft-Excel XP software* and presented in tables with absolute and relative frequencies. The analysis was developed using descriptive and inferential statistics, processed in the program Statistical Package

for Social Sciences (SPSS) version 15.0. Data analysis was performed using descriptive statistics, Wilcoxon test for comparison of means. A significance level of $P < 0.05$ was considered in the analyses.

Results

In the year 2013, 177 BD protocols were opened, but two were excluded because they do not meet the selection criteria. Thus, the study population consisted of 175 patients who had completed protocols during the study.

The most common time interval for determining BD diagnosis was between 11 and 20 hours (38.9%). The time of BD corresponds to the time elapsed between the opening and closing of the protocol, including the completion of two clinical tests and one confirmatory test. There was a time variation from 6 hours (minimum) to 195 hours (maximum), with average of 17.91 hours (SD 17.53).

(Table 1).

Table 1. Distribution of patients with BD protocol according to sex, age, ethnicity, cause of coma, and time of diagnosis. Natal/RN, Brazil, 2013.

Variables	Gender				Total	
	Male		Female		n	%
	n	%	n	%		
Age						
< 20	15	8.57	5	2.86	20	11.43
20 to 40	43	24.57	15	8.57	58	33.14
41 or older	56	32.00	41	23.43	97	55.43
Ethnic group						
Light brown	22	12.57	13	7.43	35	20.00
White	81	46.29	45	25.71	126	72.00
Black	11	6.29	3	1.71	14	8.00
Cause of Coma						
TBI	52	29.71	7	4.00	59	33.71
CVAH	38	21.71	35	20.00	73	41.71
CVAI	6	3.43	12	6.86	18	10.29
Anoxic encephalopathy	9	5.14	3	1.71	12	6.86
Other	9	5.14	4	2.29	13	7.43

Variables	Gender				Total	
	Male		Female			
	n	%	n	%	n	%
Time of BD diagnosis						
≤10h	41	23.43	23	13.14	64	36.57
11-20h	49	28.00	19	10.86	68	38.86
21-30h	17	9.71	11	6.29	28	16.00
≥31h	7	4.00	8	4.57	15	8.57
Total	114	65.14	61	34.86	175	100.00

Source: Research Data, 2013.

It was also noted in **Table 2** that the number of hearts and kidney donors was higher among patients who completed the protocol of brain death within 20 hours. However, comparisons of patients who completed BD diagnosis within 20 hours and after 20 hours were not significant.

Table 2. Distribution of patients according to the time elapsed between the opening and closing of BD protocol and effective organ donation. Natal/RN, Brazil, 2013.

Organs	Donation	Up to 20 hours		> 20 hours		Total		P value*
		N	%	N	%	N	%	
Heart	Yes	22	12.6	11	6.3	33	18.9	0.194
	No	110	62.9	32	18.3	142	81.1	
Liver	Yes	26	14.9	15	8.6	41	23.4	0.041
	No	106	60.6	28	16.0	134	76.6	
Kidney	Yes	27	15.4	12	6.9	39	22.3	0.308
	No	105	60	31	17.7	136	77.7	

*: Wilcoxon test, P-value < 0.05

Discussion

In the sample studied, the age group ages ranged from 2 to 95 years, with average of 44.79 and 20.17 years of SD. With regard to gender, studies on BD [15-17] have shown that the highest percentages correspond to males, with 60% and 66.3% of respondents, respectively. These findings are similar to results obtained in this study, in which males accounted for 65.14%. On the other hand, the study

conducted by Freire et al. [18] reported that the majority of patients diagnosed with BD were females, with 51.9% of the cases.

Regarding ethnicity, individuals classified as white (72%) prevailed. Similar results were found in Brazilian studies [19, 20] with predominance of white people, with percentages of 55.34% and 72.2%, respectively. In turn, brown skinned people were the majority (47%) in a study conducted in northeastern Brazil [17].

A study in Latin America found that CVA (49%) was the most prevalent cause of BD in 2004 and, specifically in Brazil, the second cause of BD was TBI (38%) [21]. Another study conducted in 2009, in Brazil, also found similar results; stroke was the main cause of BD, with 49.51% of cases, followed by TBI (36.89%) [19]. These findings corroborate the results of the present study in which CVA predominated as the main cause of BD, with 52% cases; of these, 41.71% were of the hemorrhagic type and 10.29% of the ischemic type, followed by TBI, with 33.71% cases.

Data on age and cause of BD point to a change in organ donor profile. Traumatic causes are being overcome by CVA and the age range of donors has increased over the years. The authors [22] suggest that these changes are credited to increased longevity and the population aging process itself.

In the present study, the period of time elapsed between opening and closing the BD protocol was at least 6 hours, and at most 195 hours, and the mean was 17.91 hours (SD 17.53). A research conducted in a teaching hospital in Brazil investigating the time involved in the confirmation of BD in 103 medical records of patients who progressed to this diagnosis showed a mean of 32.20 hours (SD 27.08) and a median of 24.6 hours. The minimum time was 06.42 hours and the maximum was 175.25 hours [19].

In relation to the minimum and maximum time, the findings were similar to those identified in this study. However, the mean and median were diver-

gent, with lower results in the sample: 17.91 and 15 hours, respectively.

Researchers [23] analyzed 645 medical records of patients; there was suspicion of BD in 219 records. The time between the first record and removal of organs was greater than 30 hours in 75% of donors. Another aspect identified in relation to time is a delay between the suspected BD and the opening of the protocol, which was more than 17 hours. In addition, only 10% of potential donors had an interval of 6 hours between the first and second tests, as recommended by Brazilian law.

The authors also observed that among patients who had BD protocol completed, the time between the second clinical examination and the additional examination was over 15 hours in 50% of patients. And the total time from suspicion to the capture of organs among those surveyed was 37.5 hours [23].

It should be noted that the process of organ donation is complex and the development of stages requires the involvement of specialized professionals, who have, in addition to scientific knowledge, sensitivity and empathy to interact with the people involved. Despite knowing that the reduction of time spent on the steps of BD protocol is related with viability and preservation of organs and tissues, these professionals need to respect the necessary time for families to experience suffering and mourning [10, 11].

Conclusion

Individuals who had the BD protocol concluded were predominantly male (65.1%), caucasians (72%) and older than 41 years (55.4%) with a mean age of 44 years (SD 20.17). The main causes of coma in patients who developed BD were CVA and TBI, respectively, with 52% and 33.7% cases.

The most frequent time interval for determining the diagnosis of BD was between 11 and 20 hours (38.9%), with average of 17.91 hours (SD 17.53) and variation of 6-195 hours. As for the time elapsed

between diagnosis of BD and effective donation of solid organs, significant difference were found between the number of livers donated in patients who completed the process within 20 hours ($P = 0.041$).

It was also observed that the number of donated hearts and kidneys was higher among patients who completed the protocol of brain death within 20 hours, although the comparison between patients who completed within 20 and after 20 hours did not show significant difference.

It is noteworthy that the number of donated organs in our country is insufficient to meet the growing demand of people registered on waiting lists for transplants. Thus, the loss of PD due to impending cardiac arrest, exclusion by clinical and laboratory criteria, maintenance of deficient PD and family refusals, represents a challenge to the whole society. Hence the importance of conducting awareness campaigns in mass media, to stimulate family dialogue about BD and organ donation.

The identification of few studies discussing the time for confirming BD restricted the discussion and comparison of data obtained in the present study, which represents a limitation of the study. Thus, it is expected that further studies be done on this issue and may contribute to dissemination of the importance of time involved in the donation process for the realization of organ transplants.

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