

Effectiveness of the organ donation process

Efetividade do processo de doação de órgãos para transplantes

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Abstract

Objective: to verify the effectiveness of the organ donation process in the State of Paraná.

Methods: Cross-sectional study carried out with data provided by the Department of Transplantation of the State of Paraná referred to the organ donation process, from 2011 to 2016. Of the 3,872 notifications of potential donors with brain death, 2,600 were included in this study since they were eligible organ donors. The outcome of the protocols and variables related to eligible donors, notifying centers and notifications were evaluated. Data were analyzed descriptively by absolute and relative frequencies, and odds ratio was calculated through the Wald Chi-square test, with $p < 0.05$ considered as statistically significant.

Results: Out of the 2,600 eligible donors, 1,267 (48.7%) became effective organ donors. The main obstacles of the process were cardiopulmonary arrest, sepsis and family refusal. The odds of donation were significantly higher in the individuals younger than 60 years old ($p < 0.001$), male ($p = 0.001$) and in the East and West Macro-regions of the State ($p < 0.001$). The percentage of organ donations increased from 38.8% to 66.5% in the period studied.

Conclusion: The state of Parana presented a significant increase in the number of notifications and organ donations in the last six years. The weaknesses identified in the process refer to clinical and cultural issues, which indicate the need for interventions to train health professionals in the identification and maintenance of the potential donor, as well as in raising awareness of the importance of the consent to donation.

Resumo

Objetivo: Verificar a efetividade do processo de doação de órgãos para transplantes no Estado do Paraná.

Métodos: Estudo transversal realizado com dados disponibilizados pelo Sistema Estadual de Transplantes do Paraná referentes ao processo de doação de órgãos, no período de 2011 a 2016. Das 3.872 notificações de potenciais doadores em morte encefálica, 2.600 foram incluídas neste estudo por se constituírem em doadores elegíveis de órgãos. Avaliou-se os desfechos dos protocolos e variáveis relacionadas aos doadores elegíveis, aos centros notificantes e às notificações. Os dados foram analisados descritivamente por frequências absolutas e relativas, e calculou-se *odds ratio* verificando-se a associação pelo teste de Qui-Quadrado de *Wald*, em que considerou-se $p < 0,05$ como significância estatística.

Resultados: Entre os 2.600 doadores elegíveis, 1.267 (48,7%) tornaram-se doadores efetivos de órgãos. Como principais obstáculos do processo destacaram-se a parada cardiorrespiratória, a sepse e a recusa familiar. As chances de efetivação da doação foram significativamente maiores nos indivíduos com menos de 60 anos ($p < 0,001$), do sexo masculino ($p = 0,001$) e notificados pelas Macrorregionais Leste e Oeste do Estado ($p < 0,001$). O percentual de doações de órgãos aumentou de 38,8% para 66,5% no período estudado.

Conclusão: O Paraná apresentou crescimento expressivo no número de notificações e doações de órgãos nos últimos seis anos. As fragilidades identificadas no processo se referiram às questões clínicas e culturais, que indicam a necessidade de intervenções gerenciais de capacitação dos profissionais de saúde na identificação e manutenção do potencial doador, bem como na sensibilização da sociedade quanto a importância do consentimento à doação.

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Introduction

Transplantation is a therapeutic option for several chronic and disabling conditions that endanger the lives of thousands of people. In addition to rehabilitation, it can promote improvement in the quality of life and a return to personal and work activities.^(1,2) For the transplant to happen, healthy organs have to be obtained, usually from deceased donors.⁽³⁾

Several professionals participate in the donation process, especially those working in Intensive Care Units (ICUs) and emergency departments, who are responsible for identifying potential organ and tissue donors, diagnosing brain-death (BD), notifying the responsible institutions and communicating the diagnosis to family members.⁽⁴⁾

In Brazil, current legislation determines that the family is responsible for the decision of organ donation after death. Thus, once the diagnosis of BD has been concluded and the contraindications for donation are discarded, the family is requested to confirm the diagnosis and the Intra-Hospital Organ and Tissue Donation for Transplant Commission (CIHDOTT) offers the possibility of the donation.^(2,5)

Giving this information with objectivity, clarity and simplicity can help the donor's family to make an autonomous decision.⁽⁶⁾ In this perspective, the family is considered as the main element of this process and must be informed and clarified about the situation of their loved one, so that, at the time of the decision, they can do it independently. All of these phases demonstrate the complexity of the organ donation process.

Brazil stands out in the world context, but still faces difficulties for obtaining organs. In 2016, the country did not reach the effective donor target, which was 15.1 per million population (pmp), reaching the rate of 14.6 pmp. Besides, the notification rate of potential donors with BD grows slowly. Thus, the year ended with 34,542 active patients on the waiting list for transplant, of which 2,534 were in the State of Paraná.⁽⁷⁾

Therefore, it is important to evaluate the results obtained in order to identify the phases of the process that are efficient and those that need improvement. Few studies have verified the factors that are essential to support managers and health professionals in planning actions to improve organ donation and reduce transplant lists. In this sense, the ability to make a patient with BD into an effective organ donor is currently an indicator of the quality of this process.⁽⁸⁻¹⁰⁾

Thus, this study aimed to verify the effectiveness of the organ donation process in the State of Paraná.

Methods

Cross-sectional study with data from death reports from the Department of Transplantation of the State of Parana (SET-PR). The SET-PR consists of four Organ Procurement Organizations (OPO), one in each Macro-region: East, based in Curitiba; North, based in Londrina; West, based in the city of Cascavel; and North-west, based in Maringa.

There were 3,872 notifications of potential donors with BD in the SET-PR between 2011 and 2016. The inclusion criterion was death notifications from eligible donors, that is, those without clinical contraindication and with the BD diagnosis concluded. Thus, the sample of this study consisted of 2,600 eligible organ donors with BD.

The effectiveness of the donation was considered a dependent variable of the study. The independent variables were those related to the eligible donors, which included age (<60 years and >61 years) and gender (male and female); and characteristics related to the institution that made the notification and the notification itself: level of care (outpatient, medium complexity and high complexity), type of hospital (general hospital, specialized hospital and outpatient care), type of management (city, state and both), quarter of the notification (1st, 2nd, 3rd and 4th), year of notification (2011, 2012, 2013, 2014,

Results

2015 and 2016) and Macro-regional Health Department (North, Northwest, East and West).

Data were analyzed in the Statistical Package for Social Science (SPSS), version 20.0. Absolute and relative frequencies were used to describe the quantitative variables. The odds ratio was calculated and association was verified by the Wald chi-square test, with $p < 0.05$ adopted as statistical significance.

The development of the study complied with national and international ethics standards for research involving human beings, under the number of the Certificate of Presentation for Ethical Consideration (CAAE): 51707215.8.0000.5231.

The organ donation process is outlined in figure 1. Of the 2,600 eligible donors, 1267 became effective donors (48.7%).

The chance of effective donation was significantly higher among individuals under the age of 60, male, whose deaths occurred in the Eastern and Western Macro-regions. There was a significant increase in the number of potential donors and effective donations as the years progressed: a 320.7% increase in absolute numbers and a 71.4% increase in the proportion of effectiveness, comparing exclusively the years 2011 and 2016 (Table 1).

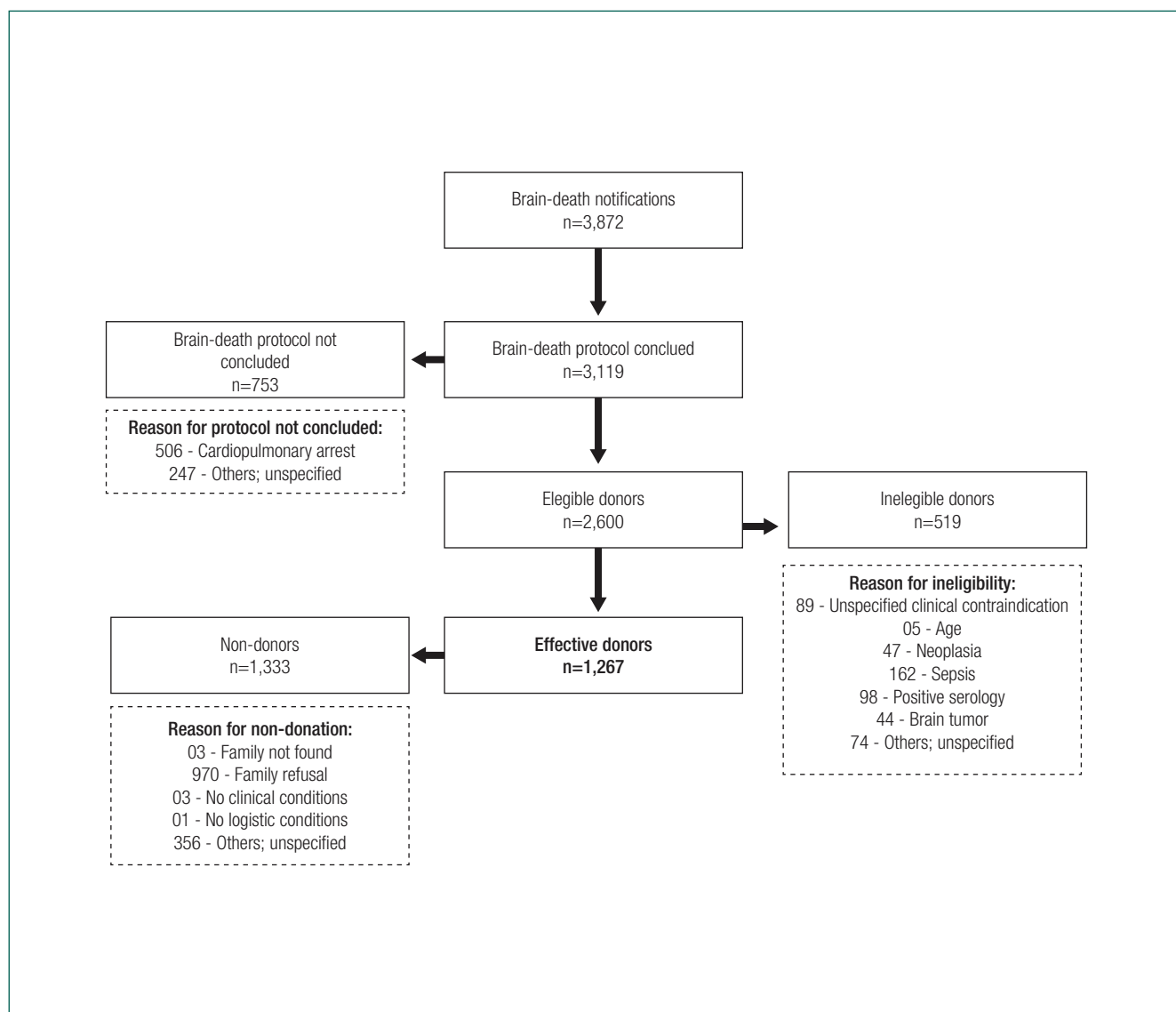


Figure 1. Flow chart of the organ donation process

Table 1. Variables related to the organ donation process

Variables	Effective Donor		p-value	Odds Ratio (95% Confidence Interval)
	Yes n(%)	No n(%)		
Age of eligible donor				
≤60 years	1052(42.6)	1420(57.4)		1
≥61 years	215(33.2)	432(66.8)	<0.001	0.672(0.560-0.806)
Gender of eligible donor				
Female	478(45.5)	572(54.5)		1
Male	788(50.9)	761(49.1)	0.001	1.273(1.100-1.473)
Level of care				
Outpatient care	10(58.8)	7(41.2)		1
Medium complexity	191(48.8)	200(51.2)	0.269	0.243(0.572-1.483)
High complexity	1066(48.7)	1125(51.3)	0.137	0.698(0.813-1.050)
Type of hospital				
General Hospital	1254(48.7)	1323(51.3)		1
Specialized Hospital	3(60.0)	2(40.0)	0.293	1.624(0.658-4.008)
Ambulatory Care	10(58.8)	7(41.2)	0.137	3.333(0.682-6.295)
Type of management				
City	471(50.1)	470(49.9)		1
State	275(48.8)	289(51.2)	0.217	0.903(0.768-1.062)
Both	521(47.6)	573(52.4)	0.751	0.970(0.803-1.171)
Quarter of the notification				
Q1	253(44.6)	314(55.4)		1
Q2	319(49.0)	332(51.0)	0.220	1.140(0.927-1.405)
Q3	364(51.6)	342(48.4)	0.862	1.001(0.805-1.199)
Q4	331(49.0)	345(51.0)	0.205	1.109(0.898-1.370)
Year of the notification				
2011	116(38.8)	183(61.2)		1
2012	151(40.8)	219(59.2)	0.010	1.419(1.086-1.855)
2013	195(41.0)	281(59.0)	0.001	1.513(1.188-1.927)
2014	172(41.1)	246(58.9)	0.010	1.344(1.072-1.684)
2015	261(54.6)	217(45.4)	0.018	1.328(1.049-1.681)
2016	372(66.5)	187(33.5)	0.019	1.149(1.030-1.418)
Macro-regional health department				
East	591(53.4)	516(46.6)		1
West	256(52.0)	236(48.0)	<0.001	0.531(0.436-0.645)
Northwest	210(45.0)	257(55.0)	<0.001	0.543(0.434-0.688)
North	210(39.3)	324(60.7)	0.009	0.731(0.577-0.926)

Among the effective donors, the causes of death were traumatic brain injury (n=439, 34.6%), followed by hemorrhagic stroke (n=342, 27.0%), ischemic stroke (n=109, 8.6%), brain tumors (n=6, 0.5%) and the other causes were not identified (n=371, 29.3%). Regarding blood type, the type O was predominant (n=573, 45.2%), followed by A (n=459, 36.2%), B (n=144, 11.4%), AB (n=47, 3.7%) and the remainder was not indicated (n=44, 3.5%)

Discussion

The cause of death and the ABO blood type were only identified in the reports of the effective donors, which made it impossible to associate these variables with effective donation among eligible donors. Also, limitations of the study include the absence of specific motives in some of the BD protocols not concluded, the uncompleted donations and lack of identification of the reasons for family refusal.

This study verified the strengths and weaknesses of the donation process in the State of Paraná and analyzed the effectiveness of organ donation. These findings can support management in the formulation of public policies and actions to improve the organ donation process and thus reduce waiting lists for transplants.

Cardiopulmonary arrest (CPA) makes the donation of solid organs unviable and was indicated in this study as the main cause for the non-conclusion of BD protocols (13.1%). It is estimated that 10% to 20% of potential donors will evolve to CPA

before the removal of their organs,⁽¹¹⁾ corroborating the rate obtained in this investigation.

However, the literature indicates that BD protocols that last more than 30 hours usually present a higher percentage of cardiac arrest.⁽¹²⁾ It is fundamental to optimize this time and implement actions to maintain the patient's physiological stability, thereby increasing the number of organ donors and the viability of potentially transplantable organs.⁽¹³⁾ In some countries, the eligible donor is kept in cardiopulmonary bypass, which preserves the organs after CPA and guarantees rates of donation of up to 100%. However, this practice is not widely disseminated due to the controversial ethical question and the absence of guidelines and legislation for these cases.^(14,15)

Regarding the causes for ineligibility to donate organs in the Parana State, the main reason found was sepsis (5.2%). As it is known, a clinical and laboratory evaluation of the potential organ donor is essential to avoid the transmission of pathologies and to guarantee quality grafts.⁽¹⁶⁾ However, there are similar physiological processes in sepsis and in BD, which may lead to misdiagnosis.⁽¹⁷⁾ In addition, if the individual is hemodynamically stable and uses antimicrobial, sepsis does not make donation unviable. Cohort studies with patients who received a transplant from donors with sepsis have identified that transmission did not occur among those who received adequate antibiotic therapy for at least seven days.⁽¹⁸⁻²⁰⁾ For this reason, the OPOs in Parana carefully analyze the clinical outcomes of the patients along with CIH-DOTT professionals in order to verify the viability of the donation for these cases.⁽¹⁶⁾

Regarding the reasons for not donating organs among the eligible donors, family refusal ranked first with 37.3%. Family refusal is the main reason why an organ is not donated in Brazil and abroad, with rates ranging from 5.7 to 41.4% in European countries, and 27.5 to 48.9% in Latin American countries,⁽²¹⁾ with a 43% rate in Brazil in the end of 2016.⁽¹⁶⁾

There are many reasons that motivate families to refuse donation, such as fear of mutilation of the body and insecurity about the BD diagnosis, that is, the family has difficulty understanding that a body with a heartbeat, a breath (with the help of applianc-

es) and with normal temperature is dead.^(22,23) Therefore, family care is important during the diagnostic process in order to clarify all possible doubts, so that the family feels safe to make their decision with knowledge and autonomy. Another common reason is that the donor expressed opposition to donating organs during their life or the family does not know the donor wishes about donation,^(22,23) which highlights the importance of dialogue within the family on the subject of organ donation, since if the wish of the donor is known, decision making is easier.

Thus, the weaknesses of the process regarding the inadequate maintenance of the potential donor, the adequate establishment of contraindications and family consent demonstrate the relevance of a permanent education for the professionals involved, since when the professionals are trained and understand the process and the factors that influence the outcome, they are able to intervene appropriately in order to favor organ donation.

Effective donations were greater in males and younger donors, results similar to other Brazilian studies.^(24,25) This predominance may be justified by the probable changes in the profile of potential donors, since external causes (accidents and violence) stand out and occur predominantly among men, with emphasis on BI as the origin of BD.^(17,23,25)

In Paraná the chances of effective donations increased significantly each year analyzed, with an overall increase of 320.7% in absolute numbers and 71.4% in the proportion of effectiveness. In 2016, the State presented a rate of effective donors of 30.9 pmp, while the Brazilian rate was 14.6 pmp. This puts Parana in a prominent position in the national scenario, with a value similar to the countries with the best rates in the world.⁽⁷⁾

This high rate may be related to the SET-PR, which stimulates and invests on the continuous training of professionals working in the state donation process, considering this as the key to achieving a better performance.⁽²⁶⁾ When the professional who works in this process is more trained, the chances of donation effectiveness increase, since lack of knowledge and lack of preparation for assisting the potential donor has already been indicated as an important obstacle in the process.⁽²⁷⁾

Although it did not present a significant difference, the third quarter had a greater percentage of donors in comparison to the others. This fact may be related to the National Organ and Tissue Donation Day, on September 27, and the campaigns to clarify organ donation that occur in that month. Studies have indicated that social marketing is an essential strategy to raise awareness about organ donation, as it allows reflection on its importance, promotes family dialogue about the finitude of life and favors the consent of the donation.^(28,29)

Among the Macro-regions of the State, the West and the East macro-regions presented better results regarding effective donations. This finding may be related to the number of CIHDOTT accredited, because of the 90 institutions, 43 are in the East and West Macro-regions. It may also be because they are the most populous and have more hospitals with good infrastructure, which is an essential factor in the donation process.⁽³⁰⁾ It should be noted that, although SET-PR encourages the professional training of teams, the local coordinators of the OPOs have the autonomy to define how the training works, the frequency and the topics chosen.⁽¹⁶⁾ Thus, the non-homogeneity of actions may have favored the development of some regions in opposition to others.

Conclusion

During the period analyzed, effective organ donations were possible for part of the eligible donors with BD. The most relevant weaknesses of the process were cardiopulmonary arrest before the conclusion of the BD protocol, sepsis as the main reason for ineligibility and family refusal among those without clinical contraindications. The odds of effective donation were significantly higher among those aged less than 60 years old, male, whose BD reports occurred in the East and West Macro-regions of the State. It should be noted that Parana has presented a significant increase in the number of notifications and organ donations in the last six years.

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Collaborations

Gois RSS, Haddad MCFL and Galdino MJQ contributed with the project design, data analysis and interpretation, article writing, critical review of intellectual content and final approval of the version to be published. Pissinati PSC, Pimentel RRS and Carvalho MDB contributed in the interpretation of the data, critical review of the intellectual content and final approval of the version to be published.

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