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Controlled asystole protocols: a key to more organ donors?

Protocolos de asistolia controlada: ¿una clave para aumentar el número de donantes de órganos?

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Abstract

What do we know about this problem?

Donation after controlled circulatory death (DCD) is organ donation that takes place following diagnosis of death by cardio-respiratory criteria. The growing demand for transplantable organs has led various professional organizations to promote the development of controlled asystole programs. The implementation of these protocols not only increases the number of donors but also reduces the gap between the demand and availability of organs.

What does this study contribute with?

This research aims to establish a solid foundation for future projects that evaluate the feasibility of implementing controlled asystole protocols in our country. The main objective is to significantly increase the number of organ donors, substantially contributing to saving more lives.

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Introduction

Donation after controlled circulatory death (DCD) is organ donation that takes place following diagnosis of death by cardio-respiratory criteria. This diagnosis is certified in patients admitted to the Intensive Care Unit (ICU) following the withdrawal of life-support treatment.

Objective

To describe the main causes of mortality that make the patient a potential donor under a controlled asystole protocol within the ICU of Hospital Pablo Tobón Uribe in Medellín, Colombia.

Methods

This was an observational, descriptive, retrospective study conducted in adult patients who died during the first quarter of 2024 in any of the ICUs at Hospital Pablo Tobón Uribe in Medellín. Data obtained were analyzed using descriptive statistical methods, and all statistical analyses were performed using Jamovi software.

Results

A total of 103 participants were included, 36 women (35%) and 67 men (65%), with a median age of 61 years (44.5–72). The leading cause of death among participants was septic shock. Seventeen potential donors (16.7%) were identified.

Conclusions

There is significant potential to increase the organ donation rate through the implementation of appropriate controlled asystole protocols.

Keywords

Transplantation; Tissue and organ procurement; Donor selection; Brain death; Induced cardiac arrest.

Resumen

Introducción

La donación de órganos en pacientes con muerte circulatoria controlada se realiza después de un diagnóstico de muerte basado en criterios circulatorios. Este diagnóstico se certifica en pacientes ingresados en una Unidad de Cuidados Intensivos (UCI) tras la retirada del tratamiento de soporte vital.

Objetivo

Describir las principales causas de mortalidad que confieren al paciente la potencialidad de ser donante para un protocolo de asistolia controlada, en la UCI del Hospital Pablo Tobón Uribe de la ciudad de Medellín, Colombia.

Métodos

Estudio observacional, descriptivo, retrospectivo. Desarrollado en pacientes adultos fallecidos durante el primer trimestre de 2024 en cualquiera de las UCI del Hospital Pablo Tobón Uribe de Medellín. Se analizaron los datos obtenidos aplicando métodos de estadística descriptiva. Todos los análisis estadísticos se realizaron utilizando el software Jamovi.

Resultados

Se incluyeron 103 participantes, 36 mujeres (35%) y 67 hombres (65%), con una mediana de edad de 61 años (44,5-72). La principal causa de muerte entre los participantes fue el choque séptico. Se identificaron 17 donantes potenciales (16,7%).

Conclusiones

Existe un significativo potencial para aumentar la tasa de donación de órganos mediante la implementación de protocolos adecuados de asistolia controlada.

Palabras clave

Trasplante; Obtención de tejidos y órganos; Selección de donante; Muerte encefálica; Paro cardíaco inducido.

INTRODUCTION

Donation after controlled circulatory death (DCD) is organ donation that takes place following diagnosis of death by cardio-respiratory criteria. This can be either controlled (c-DCD) or uncontrolled (u-DCD). The former takes place in scenarios where life-support treatment is withdrawn following a consensus agreement between the medical team and the family, based on the futility of the treatment and the absence of prognosis, or in the context of treatment refusal. In contrast, u-DCD takes place after an unexpected cardiorespiratory arrest, both intra- and extra-hospital. (1)

Organ donation in c-DCD primarily takes place in a setting of traumatic brain injuries without progression to brain death (BD) and in chronic respiratory or cardiac diseases with a catastrophic prognosis. Another scenario is patients requesting euthanasia, authorized in several countries worldwide, including Colombia; upon

declaring death by circulatory criteria, these patients also become potential c-DCD donors. (2-4)

c-DCD involves significant ethical and logistical challenges, as it requires rapid organ retrieval after death due to the high sensitivity of organs to ischemic periods. This donation modality is common in countries like the United States, United Kingdom, Australia, Netherlands, Canada, and Spain, where specific guidelines for its implementation have been established. The growing demand for transplantable organs has led several organizations to promote the development of c-DCD donation programs. (5-9)

DCD was initially classified according to the Maastricht criteria of 1995. The Modified Maastricht Classification for donors after circulatory death (Madrid 2011) is currently used, among others. However, the Modified Maastricht Classification (Detry, 2012) includes euthanasia (Table 1). Since euthanasia is legal in Colombia,

this classification would be the most appropriate to increase the number of potential donors. (4)

Sudden cardiorespiratory arrest causes numerous deaths worldwide. Although it might seem that u-DCD would be the first option to start a donation program, it is not the most suitable. Programs require precise coordination between emergency services, transplant coordination teams, and surgical teams, demanding experience and speed. The primary challenge lies in the ischemic injury sustained by organs during extended periods of arrest, despite the use of preservation techniques designed to minimize such damage. Post-transplant outcomes are generally less favorable compared to those achieved with controlled donation after circulatory death (c-DCD). The c-DCD process is more readily implemented in the ICU, where donation can be planned following family consent, facilitating better organization and coordination of organ

Table 1. Modified Maastricht Classification for donors after circulatory death (Detry, 2012).

Circulatory Death Donor Uncontrolled	I	Dead in an out-of-hospital setting	1A. Cardiovascular death outside the hospital without witnesses. Completely uncontrolled
			1B. Cardiovascular death outside the hospital with witnesses and rapid resuscitation attempt. Uncontrolled
	II	Failed resuscitation	2A. Unexpected cardiovascular death in the ICU. Uncontrolled
			2B. Unexpected cardiovascular death in the hospital (emergency or hospitalization room), with witnesses and rapid resuscitation attempt. Uncontrolled
Circulatory Death Donor Controlled	III	Awaiting cardiac arrest	3A. Expected cardiovascular death in the ICU. Controlled
			3B. Expected cardiovascular death in the operating room (withdrawal phase > 30 minutes). Controlled
			3C. Expected cardiovascular death in the operating room (withdrawal phase < 30 minutes). Highly controlled
	IV	Cardiac arrest during brain death	4A. Unexpected cardiovascular arrest in a brain-dead donor (in the ICU). Uncontrolled
			4B. Expected cardiovascular arrest in a brain-dead donor (in the operating room or ICU). Highly controlled
	V	Euthanasia	5A. Medically assisted cardiovascular death in the ICU or hospitalization room. Controlled
			5B. Medically assisted cardiovascular death in the operating room. Highly controlled

Source: Authors from Thuong (4).

retrieval and preservation. Consequently, c-DCD represents the most practical and appropriate approach for initiating a donation program in Colombia. (10-12)

In Colombia, organ donation from deceased donors is currently limited to BD cases, since the legal regulations fail to explicitly consider donation following a diagnosis of death based on cardiorespiratory criteria. Law 9 of 1979, which established the National Sanitary Code, regulated the donation of organs, tissues, and fluids exclusively in cases of brain death. Although Decree 2493 of 2004 included a definition of deceased donor encompassing both BD and irreversible cessation of cardiorespiratory functions, it did not explicitly address DCD. (10-12)

Resolution 214 of 2005 from the National Institute of Health (INS) established the Donation and Transplant Network Group, limited to donation after

BD cases. Law 1805 of 2016 also focused exclusively on BD, without addressing DCD. In recent years, the Colombian Association of Organ Transplantation (ACTO), along with the INS and other scientific associations, has promoted the discussion on DCD. Although research projects on this modality have been approved and potential DCDs identified, the lack of a clear legal regulatory framework has prevented its implementation. (10-12) In September 2023, a bill was submitted before the House of Representatives to amend articles 542 of Law 9 of 1979 and articles 8 and 15 of Law 1805 of 2016, intended to consider the possibility of DCD and thus expand the capacity for deceased donor donation in Colombia. (10-12)

This study aims to characterize the primary causes of death associated with the potential for a patient to become a donor under a controlled asystole protocol

in the ICU of Hospital Pablo Tobón Uribe in Medellín, Colombia.

METHODS

An observational, descriptive, and retrospective study was conducted at Hospital Pablo Tobón Uribe (HPTU), a tertiary university center in Medellín, Colombia. Adult patients who died in the Intensive Care Units (ICU) during the first quarter of 2024 were included, excluding those with incomplete medical records lacking relevant data for the research. A convenience sampling approach was used, including only patients who met all eligibility criteria defined by the researchers.

The analyzed variables included sociodemographic (sex and age) and

clinical characteristics such as the cause of ICU admission, cause of death, dates of emergency admission, ICU admission, and death, days of hospital and ICU stay, ventilatory support, vasopressor and inotropic support, use of parenteral nutrition, active infection, antibiotic treatment, renal replacement therapy (RRT), as well as the identification of potential donors, eligible donors, real donors, and total number of donors. Previous comorbidities were also recorded, including cancer, high blood pressure (HBP), chronic kidney disease (CKD), diabetes mellitus (DM), human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), cytomegalovirus (CMV), smoking, illicit drug use, and alcohol abuse.

The following key concepts were defined: potential donor, an individual in whom circulatory and respiratory functions have irreversibly ceased, or in whom such cessation is anticipated within a timeframe that permits organ retrieval; eligible donor, a medically suitable individual who has been declared dead based on the irreversible cessation of circulatory and respiratory functions within a timeframe that permits organ retrieval; A real donor is an authorized, eligible donor in whom a surgical incision was initiated with the intention of retrieving at least one organ for transplantation. A utilized donor is a real donor from whom at least one organ was successfully transplanted into a recipient.

Data were obtained from electronic medical records and systematically recorded in a RedCap database, ensuring the protection of personal data and complying with Colombian legislation. Information will be stored for five years under the custody of the principal investigator and Hospital Pablo Tobón Uribe, with restricted access to researchers and individuals authorized by the hospital committee.

To control biases, all patients meeting the eligibility criteria were included without exception, minimizing selection bias. Patients with incomplete data

were excluded to avoid information bias. Additionally, pilot tests were conducted before data collection, and the registration process was standardized.

Statistical analysis included descriptive statistical methods. Qualitative variables were expressed in absolute and relative frequencies, while quantitative variables were analyzed using the Kolmogorov-Smirnov test corrected according to the Lilliefors test to evaluate their distribution. Results were reported as medians and interquartile ranges (IQR = Q1–Q3). All analyses were performed using Jamovi software.

This study was approved by the Ethics Committee of Hospital Pablo Tobón Uribe, as recorded in minutes 6/2024, issued on April 4, 2024.

RESULTS

During the study period, 103 deceased patients were captured, of whom 36 were women (35%) and 67 men (65%), with a median age of 61 years (44.5–72). The main comorbidities, toxic habits, and infectious backgrounds are detailed in [Table 2](#).

Table 2. Comorbidities, toxic habits, and infectious backgrounds of deceased patients in the first quarter of 2024 at HPTU.

	n = 103	%
Comorbidity		
Hypertension	42	40.8
Chronic kidney disease	31	30.1
Diabetes	29	28.2
Cancer	22	21.4
Toxic habit		
Smoking	30	29.1
Alcohol use	28	27.2
Drug use	12	11.8
History of infections		
Human immunodeficiency virus	26	25.2
Hepatitis B virus	11	10.7
Hepatitis C virus	9	8.7
Cytomegalovirus	6	5.8

Source: Authors.

Table 3. Main cause of ICU admission of deceased patients in the first quarter of 2024 at HPTU.

Cause of admission	n = 103	%
Sepsis	31	30.1
Respiratory failure	23	22.3
Hemorrhagic stroke	9	8.7
Heart failure	8	7.7
Head trauma	8	7.7
Non-neurosurgical postoperative	7	6.8
Post-arrest	6	5.8
Oncological cause	5	4.8
Multiple trauma	3	2.9
Postoperative brain tumor resection	2	1.9
Gunshot wound	1	0.9

Source: Authors.

Table 4. Cause of death of deceased patients in the first quarter of 2024 at HPTU.

Cause of death	n = 103	%
Septic shock	33	32
Multiple organ failure	24	23.3
Respiratory failure	17	16.5
Cerebral edema	14	13.6
Cardiogenic shock	6	5.8
Severe head trauma	4	3.9
Cerebral hemorrhage	3	2.9
Hemorrhagic shock	2	1.9

Source: Authors.

The main cause of ICU admission was sepsis in 31 patients (30.1%), followed by respiratory failure in 23 patients (22.3%). [Table 3](#) describes the main causes of ICU admission of the patients. Nineteen patients were admitted to the ICU due to neurological causes: nine presented hemorrhagic stroke, eight were admitted for traumatic brain injury, and two for brain tumor.

During the ICU stay, 102 patients (99%) required ventilatory support; 94 (91.3%) required vasopressor support; 78 (76.5%) required inotropic support; 65 (63.1%) required enteral nutrition; 20 (19.4%) required renal replacement therapy, and 7 (7%) required parenteral nutrition.

Among the resuscitation measures administered, 5 patients (4.9%) received only basic CPR, while 7 (6.8%) received advanced CPR. Intubation was performed at different times: one patient (1%) was intubated during prehospital care, 30 (29.1%) in the emergency room, and 57 (55.3%) in the ICU. Six patients (7.2%) required tracheostomy, with times to tracheotomy decision ranging from 9 to 23 days from admission.

Complications reported during the ICU stay included: 71 patients (68.9%) with local infection, 63 (61.8%) with systemic infection, and 65 (63.7%) with sepsis. Regarding microbiological isolation: 25 patients (32.9%) had negative cultures, 32 (42.1%) had positive cultures in bronchoalveolar lavage, and 19 (25%) had positive blood cultures.

In terms of the need for surgical intervention, 16 patients (17.2%) required general surgery, 5 (4.9%) required drainage of cerebral hemorrhage, 2 (1.9%) required brain tumor resection, one (1%) required aneurysm clipping, one (1%) required decompressive craniotomy, and one (1%) required endovascular therapy.

All participants died in the ICU of the institution. The main cause of death was septic shock with 33 cases (32%), followed by multiple organ failure with 24 cases (23.3%) and respiratory failure with 17 cases (16.5%), as shown in [Table 4](#).

The mean time between emergency admission and death was five days (IQR=2-11), and between ICU admission and death was four days ([1-9](#)). Sixteen patients (15.5%) presented clinical signs of BD, and 15 (14.7%) were diagnosed with BD. Forty-one patients (40.2%) had a do-not-resuscitate order, and 29 (28.4%) were evaluated for their neurological prognosis. The decision to limit life support with differential measures was adopted in 36 patients (35.3%): 2 (5.6%) had withdrawal of basic CPR; advanced CPR was withheld in 24 (66.7%); and all interventions, including renal replacement therapy, were discontinued in 10 patients (27.8%).

Of the 15 patients diagnosed with BD, 5 families (4.9%) were interviewed regarding organ donation. The remaining 10 patients were excluded by intensivists due to the following criteria: three had a history of HIV, two had cancer, one had chronic

kidney disease, one was over 70 years old, one had a history of drug use, and one had uncontrolled systemic infection.

Finally, of the patients who died from causes other than brain death (BD), 17 potential donors (16.7%) were identified for the controlled asystole protocol. The analysis of this subgroup of 17 patients showed that the main cause of ICU admission was traumatic brain injury in eight cases (48%), followed by hemorrhagic stroke in seven cases (41.2%), and brain tumor in two cases (11.8%). The primary causes of death in these patients were: cerebral edema in 14 cases (82.4%) with a vegetative state that did not meet BD criteria; cardiogenic shock in one case (5.9%), respiratory failure in one case (5.9%), and multiple organ failure in one case (5.9%).

The mean age of the 17 potential donors was 42.8 years (SD 16.3). Of these, fifteen were men. Two had a history of hypertension, and none had a history of cancer, diabetes, or chronic kidney disease. Two were smokers, none used drugs, one consumed alcohol at risk levels, and none had HIV, HBV, HCV, or CMV. Additionally, none had received renal replacement therapy. All patients were on ventilatory support; six received inotropes, thirteen received vasopressor support, and none had systemic infection.

DISCUSSION

DCD is performed following a diagnosis of death by cardio-respiratory criteria and can be either controlled (c-DCD) or uncontrolled (u-DCD). c-DCD usually takes place in patients with traumatic brain injuries that do not progress to brain death, or in those with chronic respiratory or cardiac diseases with a very poor prognosis. Additionally, in countries where euthanasia is legalized, such as Colombia, patients who opt for this option may also be potential donors after a circulatory death diagnosis. ([1-4](#))

Candidates for c-DCD are patients in whom the decision to limit mechanical

support has been made and are likely to die shortly thereafter. This group includes patients with terminal pulmonary and musculoskeletal diseases, and irreversible brain injuries that do not meet BD criteria. (4) Out of 103 deceased patients, 17 (16.7%) were identified as potential donors under a c-DCD protocol. Among these patients, the main causes of ICU admission were traumatic brain injury and hemorrhagic stroke; according to the literature, these patients experienced irreversible brain injuries but failed to meet BD criteria 1.

Of the fifteen patients with BD, only five families were interviewed regarding organ donation. The other ten patients were excluded, as discussed in the results. This means that only one-third of the patients with BD were considered for donation, representing less than 5% of the deceased in the ICU in a quarter. Additionally, as mentioned by Irving et al., the decision to become a donor is influenced by various factors including relational ties, religious beliefs, cultural influences, family influences, bodily integrity, distrust, and knowledge of the individual's will regarding donation; the end result is that only a few of the potential actually become real donors. This situation highlights the need to implement c-DCD protocols to increase the number of potential donors. (13,14)

Globally, DCD represents up to 20% of the total deceased donors, although the implementation of programs varies from country to country. In the United States, 10% of deceased donors are DCD, while in Japan it exceeds 90%. Most donors globally come from Maastricht groups I and II, but the United States and the Netherlands were pioneers in developing type III protocols. Currently, Canada, Australia, Spain, and several European countries have also implemented DCD protocols in their transplant centers. (8,9,15,16)

In Europe, DCD is practiced in 18 countries: eight have both c-DCD and u-DCD programs, four c-DCD only, and six u-DCD only. All these countries have legally binding or non-binding regulations for the practice of DCD. There are variations in the

interventions before and after death used for the practice of c-DCD. During 2008-2016, the highest DCD activity was recorded in the United Kingdom, Spain, Russia, the Netherlands, Belgium, and France. Data on post-transplant outcomes of DCD donors show better results with grafts obtained from c-DCD donors compared to u-DCD donors. In conclusion, DCD is increasingly accepted and performed in Europe, significantly contributing to the number of available organs and providing acceptable post-transplant outcomes. According to the National Transplant Organization (ONT), following the implementation of DCD protocols in Spain, 45% of organ donors in 2023 were with this method. (17)

c-DCD procedures are performed after the planned withdrawal of life support in the ICU or emergency room. This has increased the number of potential donors, especially in patients who have not progressed to BD. In the United States and the United Kingdom, DCD represents a growing percentage of deceased donors, exceeding 13% and 42%, respectively. This increase reflects both the addition of new donors and changes in treatment and outcomes in neurointensive care, with a trend to withdraw life support in cases of severe traumatic brain injuries or cerebral hemorrhages that fail to respond to additional treatment. (4,7,14,18)

Implementing DCD programs requires a well-organized structure and excellent coordination of all stakeholders. Once death is certified, preservation techniques must be initiated, or rapid organ retrieval must be performed to avoid warm ischemia damage. In addition to increasing the number of deceased donors, organs extracted from circulatory death donors have shown long-term results comparable to grafts from conventional brain death donors, provided that both donors and recipients are properly selected and managed. (18-21)

In Colombia, organ donation from deceased donors is currently limited to BD cases; however, in recent years, ACTO, along with the National Health Institute and other

scientific associations, have promoted the discussion on DCD. Although research projects on this modality have been approved and potential DCDs identified, the absence of a clear regulatory framework has prevented its implementation. In September 2023, a bill was submitted before the House of Representatives to amend articles 542 of Law 9 of 1979 and articles 8 and 15 of Law 1805 of 2016, aiming to include the possibility of DCD and thus expand the capacity for deceased donor donation in Colombia. (10-12)

At HPTU, a high-complexity center and a reference in organ transplantation, 93 effective donors have been recorded in the last five years. Of these, 19 were in 2019, 10 in 2020, 13 in 2021, 19 in 2022, and 32 in 2023; all from BD. This situation highlights the importance of this study. Over one quarter, 17 of the patients who died in the ICU could have been potential donors under the c-DCD protocol and, according to the institution's criteria, 12 of them could have been eligible donors. This suggests that implementing the protocol in Colombia could significantly increase the number of effective donors.

CONCLUSIONS

The identification of potential donors for a c-DCD protocol highlights the possibility of increasing the organ donation rate through the implementation of appropriate protocols, in addition to raising awareness among families and medical staff. Among ICU-admitted patients, the main cause was traumatic brain injury, followed by hemorrhagic stroke. The main causes of mortality were cerebral edema, cardiogenic shock, respiratory failure, and multiple organ failure; all had a severe neurological prognosis but failed to meet the brain death criteria. These results underscore the importance of implementing and following c-DCD protocols to increase the number of donors and reduce the gap between organ demand and availability. Developing a national consensus and a clear regulatory

framework for donation after diagnosing circulatory death in Colombia is essential to fully leverage the donation potential and improve transplant outcomes. Systematic improvements in ICU patient management and the implementation of clear end-of-life and life support therapy adaptation protocols, including organ donation as an integral part of end-of-life care, in consensual protocols for organ donation, can significantly contribute to saving lives through organ transplantation.

ETHICAL DISCLOSURES

Ethics Committee Approval

The study was approved by the Ethics Committee of Hospital Pablo Tobón Uribe, as recorded in minutes 6/2024, issued on April 4, 2024 1.

Protection of People and Animals

The authors declare that no experiments were conducted on humans or animals for this research. The authors declare that the procedures followed were consistent with the ethical standards of the responsible human experimentation committee and in accordance with the World Medical Association and the Declaration of Helsinki 1.

Data Confidentiality

The authors declare that they have followed their workplace protocols regarding the publication of patient data.

Right to Privacy and Informed Consent

The authors declare that no patient data have been disclosed in this article. The authors have obtained informed consent from the patients and/or subjects herein discussed. This document is in the possession of the corresponding author.

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Author contributions

YACV, JIM: Conception of the original project, study planning, data collection, interpretation of the results, and drafting and approval of the final manuscript.

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