Factors Predictive of Success in Uncontrolled Donation After Circulatory Death in the Community of Madrid: An Analysis of Data From the Regional Registry of Donation and Transplantation (CORE Registry)

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ABSTRACT

Unfortunately, organ donation remains a challenge today. In Spain, uncontrolled Donation after Circulatory Death was introduced in cardiorespiratory arrests witnessed by out-of-hospital emergency services (OHES) to increase the number of donors. However, the selection of donor patients remains a challenge today.

Aim. to identify the variables that influence the number of organs for donation obtained from patients attended OHES. To use these variables to create a predictive model of transplant success.

Method. A retrospective, descriptive, analytical, cross-sectional study based on data from the Regional Registry of Donation and Transplantation (CORE registry) of the Community of Madrid from 2007 to 2017. Descriptive bivariate analysis was performed relating the organ donor (yes/no) variable with each of the study variables. Logistic regression models were performed with the variables and showed statistical significance using as principal variable the organ donor (yes/no) variable.

Results. A total of 550 patients were included. Mean age was 46.2 years (SD: 8.7), 86.4% (n = 473) male. Bivariate analysis found a relationship between the variable organ donor (yes/no) and age, weight, and body mass index (BMI) with $P < .05$. The predictive model showed the highest number of donors in the 45 to 55 years age group and BMI 25 to 30. Those aged over 60 with a BMI of 30 and above had a probability of organ donation of 40% or less.

Conclusions. In uncontrolled Donation after Coronary Death involving OHES there is a relationship between organ donation and age and BMI. Patients aged 45 to 55 with a BMI of 25 to 30 more frequently donate organs.

INTRODUCTION

SPAIN achieved a high level of organ donation and transplant activity based mainly on donors after brain death by 2012 [1,2]. In 2012, the numbers of transplants were expected to be very high in light of the historic record number of transplants carried out in 2011 [3] (4218 transplants). By that time, it was generally agreed that alternative donation sources were deemed necessary, with special attention to Donation after Circulatory Death (DCD), as described in the 2011 modified Maastricht classification [4]. Based on this classification, categories 1 and 2 correspond to uncontrolled donation, both in cases when cardiopulmonary resuscitation manoeuvres have not been initiated previously (category 1) and in cases when they have been

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Table 1. uDCD or Code Zero Protocol of the Community of Madrid Pre- and Post-COVID-19 Pandemic

<table>
<tr><th>uDCD or Code Zero Prepandemic (Before May 1, 2020)</th><th>uDCD or Code Zero Postpandemic (From June 1, 2022)</th></tr>
<tr><td colspan="2">Patient in witnessed CRA</td></tr>
<tr><td colspan="2">ECG trace of asystole</td></tr>
<tr><td colspan="2">ALS onset time <15 min</td></tr>
<tr><td colspan="2">ALS attendance time ≥20 min</td></tr>
<tr><td colspan="2">Arrival time from CRA to hospital <120 min</td></tr>
<tr><td colspan="2">Absence of exsanguinating chest injuries</td></tr>
<tr><td colspan="2">Absence of suspicion of risk category*</td></tr>
<tr><td colspan="2">Chest circumference compatible with the use of OH cardiocompressor.</td></tr>
<tr><td>Age between 18 and 60 y</td><td>Age between 18 and 50 y</td></tr>
<tr><td>Hospital Doce de Octubre Hospital & Hospital Clínico</td><td>Hospital Doce de Octubre ONLY</td></tr>
<tr><td>24-h availability</td><td>Availability 14.00-2.00hras</td></tr>
<tr><td></td><td>Screening for SARS-CoV-2 infection will be carried out</td></tr>
</table>

ALS, advanced life support; CRA, cardiorespiratory arrest; ECG, Electrocardiogram; OHES, out-of-hospital emergency services; uDCD, uncontrolled Donation after Circulatory Death.

*Former injecting drug addicts and/or known infectious diseases.

initiated without success (category 2). Additionally, category 2 has two subcategories based on where the cardiorespiratory arrest (CRA) takes place: subcategory 2(a) refers to out-of-hospital cardiac arrest (where the time to carry out the donation-transplant process is much more restricted); and subcategory 2 (b) refers to in-hospital cardiac arrest.

Despite the medical, financial, legal, and ethical challenges, uncontrolled Donation after Circulatory Death (uDCD) is a viable option that has expanded the pool of organ donors to include patients in CRA following failed resuscitation by out-of-hospital emergency services (OHES). In the period 2007 to 2017, the number of CRAs attended by the OHES of the Community of Madrid (CoM) was 16,088, of which 679 met the criteria to be considered uDCD.

The CoM has adopted the *Code Zero* or uDCD [5] protocol for OHES. That protocol describes the infrastructure and equipment required, the hospitals involved, and the inclusion criteria for potential donors (see Table 1).

The COVID-19 pandemic made it necessary to suspend the uDCD protocol from March 2020 due to the inability to determine the infection status of the potential donor *in situ* and the very high overall pressure on the healthcare system. Consequently, an annual reduction of 82% in the number of donors was observed in the CoM, from 34 in 2019 to 6 in 2020 [1]. And in 2021, no donations were even recorded. In June 2022, the uDCD procedure known as the *Code Zero postpandemic* [5] (see Table 1) was adopted, although with a more narrowly defined inclusion criteria. Therefore, in order to optimize the selection of potential donors, it is important to determine the moment at which donors are selected and to be able to predict the availability of organs on the basis of key variables. From June 1, 2022, onwards, only 7 uDCD with ages between 41 and 52 years have been registered, with a total of 3 viable organs procured.

The aim of this study is to determine the variables that may affect the recovery of viable organs from patients treated out of hospital and to create a predictive model of transplant success that could be extrapolated to other OHES within Spain and in other countries.

To the best of our knowledge, there is no extant scientific literature that has analyzed, in the case of Spain, organ viability by type of donor or assessed which donor characteristics might impact transplant success. The only organ donation registry in Spain is the CORE registry [6], ie, the National Integrated Registry of Information on Donation and Transplants of Spain, owned by the National Transplant Organization, which only includes donors from the CoM. Unfortunately, the number of CRAs and deaths is not recorded in this registry.

With the information from the CORE registry, we analyze the relation between the viability of recovered organs with a number of variables accessible in the out-of-hospital setting for patients meeting uDCD criteria, namely age, weight, height, time of assistance (CRA—arrival of mobile ICU/advanced life support (ALS) time, ALS-hospital time and ALS-pump time), and duration of CPR (mechanical cardiocompressor or manual). As one of the most prominent results, we observe that the body mass index (BMI) is negatively correlated with the rate of organ recovery, while the use of mechanical cardiocompressors increases the rate of organ recovery [6]. Based on these results, we conclude by recommending the construction of a predictive model to optimize the number of viable organs recovered and thus reduce the transplant waiting list (which was last reported to stand at 4746 patients) [7].

METHOD

Type of Study

We conducted a retrospective, descriptive, analytical, and cross-sectional study based on data from the Integrated Registry of Donation and Transplantation Information (CORE) for the period 2007 to 2017.

Study Population and Data Collection

CORE is a National Integrated Registry of Information on Donation and Transplants. The platform—owned by the National Transplant Organization—is used for the management and registration of all donors throughout Spain, although, currently, it only contains data from the CoM region, where the uncontrolled asystole donor protocol has been in place since 2007. See Cardenete-Reyes et al [6] for a detailed description of CORE. The registry contains information on donors, while the number of CRAs or the number of deaths are not included. The data for this study were provided by the National Transplant Organization in accordance with the Declaration of Helsinki.

For the study, only donors on the platform who met the *Code Zero* or *uDCD* criteria described in Table 1 were selected. These donors follow prepandemic (pre-2020) zero-code criteria since the CORE registry only contains data from 2007 to 2017 and therefore it is pending postpandemic update.

All staff involved in data collection has received training provided by the National Transplant Organization and the OHES [8−10].

Study Variables

CORE records 62 variables, of which 10 were selected for this study based on their accessibility in the out-of-hospital setting (see Table 2).

Some values had not been collected and were therefore missing. Those data are unrecoverable and given the failure of the authors to reach a consensus on how to impute the missing values, they have been treated as lost data.

The *suspected etiology-OHES* variable is defined as the OHES team's suspected diagnosis. The *confirmed etiology-hospital* variable is defined as the final diagnosis made in hospital following assessment.

BMI was calculated using the weight and height of each patient according to the criteria of the World Health Organization [7,11].

Table 2. Selection of Variables From the CORE Registry for the Study

Age (y)
Height (cm)
Weight (kg)
Suspected etiology-OHES:
—Anoxic encephalopathy
—Other
Confirmed etiology-hospital:
—Cardiac origin
—Noncardiac origin
Response times (min)
—CRA-ALS time: from PCR to arrival of ALS.
—ALS time-hospital: arrival of ALS at hospital.
—ALS time-pump: assistance of the potential donor by the ALS until attachment of pump for organ removal.
Organ viability (yes/no)
Type of cardiocompression
—Manual
—Mechanical
BMI (according to WHO criteria [7])
—Normal weight: <25 kg/m^2
—Overweight: 25-29 kg/m^2
—Obesity: ≥30 kg/m^2

ALS, advanced life support/mobile ICU; BMI, body mass index; cm, centimeters; CRA, cardiorespiratory arrest; kg, kilograms; kg/m^2, kilogram/m^2; OHES, out-of-hospital emergency services; WHO, World Health Organization.

Statistical Analysis

The study has both a descriptive and an analytical aspect.

Initially, a descriptive analysis of the sample was carried out using both quantitative variables (mean and standard deviation) and qualitative variables (absolute value and percentage).

Next, a bivariate analysis was performed relating the organ donor (yes/no) as response variable to each one of the regressors, with $P < .05$ as the threshold for statistical significance.

Since the independent variables to be analyzed in relation to organ donation did not follow a normal distribution, we used nonparametric Levene tests to measure equality of variance and the Wilcoxon−Mann−Whitney test to contrast the null hypothesis.

We then select the regressors that showed statistical significance (age and BMI) and those that approached statistical significance in the bivariate analysis (CRP time and out-of-hospital cardiocompression) and construct two logistic regressions using organ donor (yes/no) as the response variable. In the first regression, all regressors were used and in the second regression, only age and BMI were selected as predictor variables. For both models, in both models, the estimated coefficients for each variable, odds ratio, 95% confidence interval, and statistical significance are shown.

The statistical software used was R Project version 4.3.0 (2023).

RESULTS

Of the 16,088 CRAs attended by the OHES of the CoM, 679 were recorded in CORE [6]. Of those, 129 were excluded due to incomplete data, inconsistencies in the data, or because they were minors. As a result, the final sample includes 550 patients (see Fig 1. Study patient flow chart).

The final sample was 370 patients who met organ viability criteria and the family signed the legal consent form authorizing the donation.

Table 3 shows the results of the descriptive analysis of our sample. The mean age of donors is 46.2 years (SD: 8.7); the mean weight is 82.4 kg; 48.7% (n = 268) of donors are overweight; and 86.4% (n = 473) are men.

In the *suspected etiology-OHES* variable, there are few donors who did suffer from anoxic encephalopathy, so they were grouped under "other." As for the *confirmed etiology-hospital* variable, 94% of deaths were of cardiac origin and the remaining 6% was included in other categories (noncardiac origin).

The mean time from onset of CRA to arrival of ALS was 10.9 (SD: 6.1) minutes and from CRA to arrival at hospital was 73.5 (SD: 17.0) minutes.

For the cardiocompression variable, 70.1% (n = 152) used mechanical cardiocompressors.

The results of the bivariate analysis are shown in Table 4. A statistically significant relationship was found between the dependent variable organ donor (yes/no) and age, weight, and BMI. The variable CRA-ALS time is only significant at 10% (P = .08).

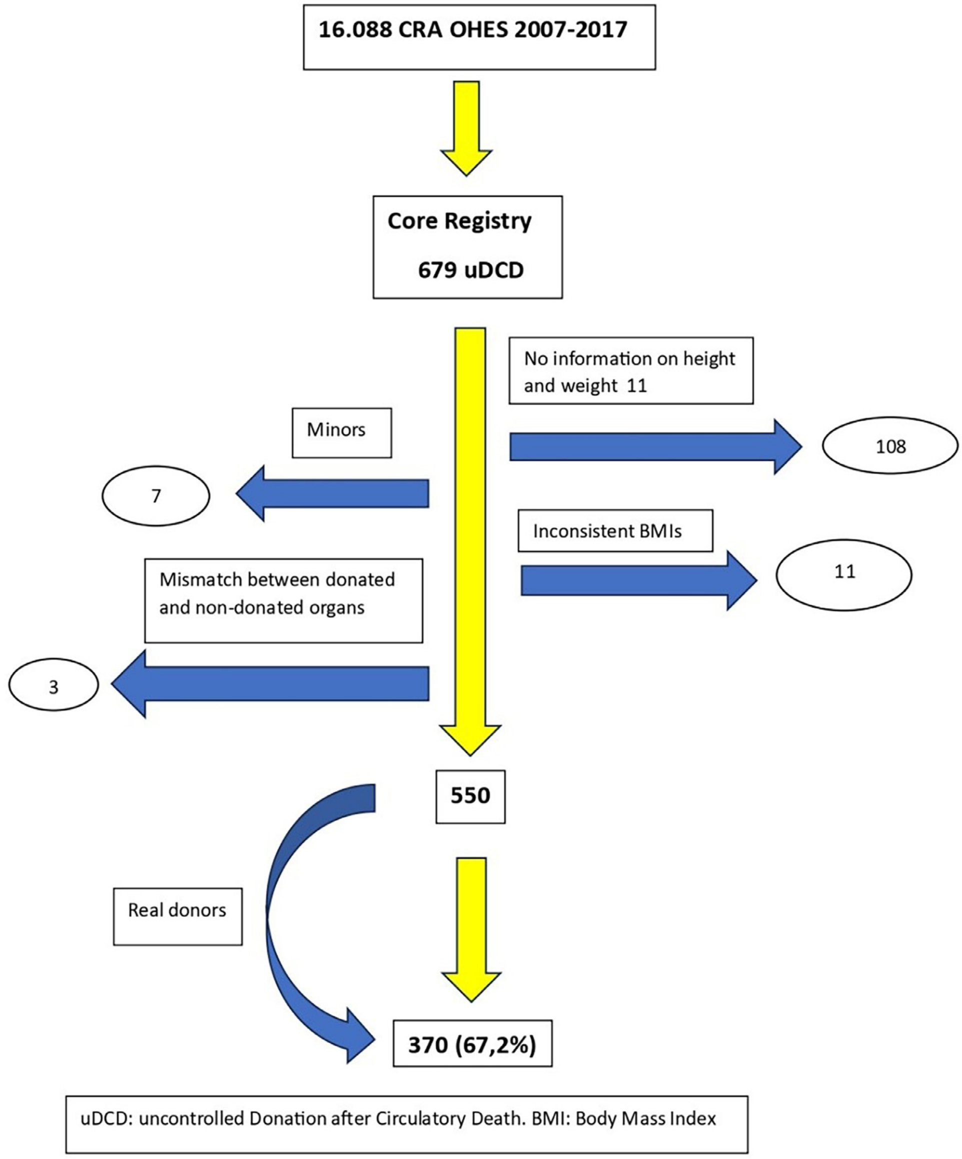

Fig 1. Study patient flow chart. BMI, body mass index; CRA, cardiorespiratory arrest; OHES, out-of-hospital emergency services; uDCD, uncontrolled Donation after Circulatory Death.

The results of the two logistic regression models are shown in Table 5. In the second (multivariate regression) model, the association of age and BMI shows a coefficient value of −0.089, with $P < .05$ and an R^2 of 67%.

In a similar fashion as the two preceding models, we build a total of six new logistic regression models using the same (independent) variables in order to predict when a person does donate, which organ they donate (using dummy variables for donate kidney, donate lung and donate liver) and the probability of such donation.

When these six models are carried out, it shows that the probability of donating a liver is 15.1%, the probability of donating at least one kidney is 95.4% and the probability of donating at least one lung is 10.3% with $P \leq .05$.

In Fig 2 predictive model of organ donation with the variables age and BMI, we plot the predictions from Model 2. Since this model contains two explanatory variables, we represent separate hyperplanes showing the two categories (organ donor: yes, no) in function of age and BMI. That allows us to compare the relationship between the values of those variables and the model's predictions. The red line delimits two regions, representing donors (above the line) and nondonors (below the line).

In addition, the actual number of organ donors/nondonors has been added to the graph, with black dots for those who do not donate and orange dots for those who do, so as to identify patients for whom the prediction model is incorrect.

Table 3. Descriptive Analysis of Study Variables

Study Variable		N (%)
		N: 550 (100%)
Age (y) [mean (SD)]		46.2 (8.7)
Weight (kg) [mean (SD)]		82.4 (13.6)
Height (cm) [mean (SD)]		174.1 (8.0)
BMI[5] (kg/m^2) [mean (SD)]		
Normal weight <25		180 (32.5)
Overweight 25-29		268 (48,7)
Obesity ≥30		102 (18.06)
Sex male		473 (86.5)
Suspected etiology-OHES:		
Anoxic encephalopathy		25 (4.5%)
No anoxic encephalopathy		525 (95.5%)
Confirmed etiology-hospital		N: 437 (100%)
Cardiac origin		411 (94%)
Noncardiac origin		26 (6%)
Response times (min) [mean (SD)]		
CRA-ALS time		10,9 (6,1)
ALS-hospital time		73,5 (17,0)
ALS-pump time		118.8 (16,0)
Cardiocompression		N: 217 (100%)
Mechanical		152 (70.1%)
Manual		65 (29.9%)
Organ donation	Yes	350 (67.3%)
	No	180 (32,7%)
Type of organ donated		
• Liver	Yes	56 (15.1%)
• Kidney	Right	25 (6.8%)
	Left	31 (8.4%)
	Both	297 (80.3%)
	No	17 (4.6%)
• Lung	Right	7 (1.9%)
	Left	3 (0.8%)
	Both	28 (7.6%)
	No	332 (89.7%)

ALS time-pump, time from the arrival of ALS to the cannulation of the line for the extracorporeal system; ALS, advanced life support/mobile ICU; ALS-hospital time, time from arrival of ALS to arrival at the hospital; BMI, body mass index; CRA, cardiorespiratory arrest; CRA-ALS time, time from CRA to the arrival of mobile ICU/advanced life support (ALS); OHES, out-of-hospital emergency services; SD, standard deviation.

Of the 550 possible donors, the model predicts that 530 (96.36%) will donate and that 20 (3.64%) will not donate. The highest number of donors is found in the 45 to 55 age group, with a BMI of 25 to 30.

Finally, two more lines (orange and blue) were added to the graph to show the probability of donation, according to the model. Below the orange line, we plot individuals who have an 80% probability of becoming donors, with the most likely donors being 35-year-old individuals with a BMI of 20 to 25. Above the blue line, we plot potential donors with a probability below 40%, which includes the group over 60 years of age with a BMI above 30. The model had a sensitivity of 95.0% and a specificity of 8.0%.

DISCUSSION

This study shows that the uDCD process is an important source of organs for transplantation [7,12]. In our sample of 550 potential donors, 370 (67.3%) were finally viable donors, with a mean age of 46.2 years, which would lead us to consider lowering the age threshold as inclusion criterion in the current protocols. Indeed, this reduction was already implemented when the *Code Zero postpandemic* reduced the upper age limit from 60 to 50 years [5]. However, the results of the predictive model in this study show that six patients of 60 years of age could be organ donors. Although the model has high sensitivity and low specificity, it raises the question of whether the age limit in current protocols should again be raised to optimize the number of valid donors.

In the postpandemia protocol, in order to optimize potential donors, the age (as an inclusion criterion) was lowered from 60 to 50 years for logistical reasons, since the number of hospitals that implemented organ transplants was reduced to one and the schedule to 12 hours instead of 24 hours. However, our study shows optimal results up to the age of 60 years.

In reference to BMI, 48.7% of donors were overweight, consistent with recent studies that have concluded that overweight patients have higher mortality due to the direct relationship between BMI and cardiometabolic risk factors [11,13−15]. However, the fact that most donors are overweight does not mean that overweight individuals are better donors, given that the likelihood of organ donation is higher in individuals with average weight than with overweight [6,15].

The majority of donors were men (86.5%), consistent with mortality figures published in Spain in 2018 [1,12,16], showing that of a total of 427,721 deaths, 50.60% were men. Indeed, mortality in men was higher than in women in each year of the study. Additionally, cardiovascular disease was the leading cause of death in men, whereas women are relatively protected against this type of affection due to the protection conferred by certain female hormones related to menopause[16]. These data are also similar to mortality studies carried out in America and the Netherlands [14,16−18].

Time is a determining factor in transplantation. Its value should not exceed 120 minutes. In our sample, the donors met this inclusion criterion. Additionally, although it is considered that the time from CRA to the start of AVS maneuvers should not exceed 15 minutes, we have some cases with a time of more than 18 minutes with good outcomes. This result is encouraging and highlights the importance to conduct more studies with larger samples to analyze the impact of time on transplant outcomes.

The *time* variable, which represents the period of time from the onset of cardio-respiratory arrest until arrival at the hospital, is considered a limiting factor as an inclusion criterion for *uDCD*. However, there are no statistical differences in relation to the outcome of the donation. Actually, records show that there may be cases with even lower time values in nondonation cases than in donation. Regarding the results of the logistic regressions conducted in this article, they show a statistically significant association between organ donation and the age and BMI variables. Specifically, the higher the age and the BMI, the lower the probability of organ donation. Thus, the study shows that age and BMI are good predictors for donation and that patients aged 45 to 55 years and with a BMI between 25 and 30

Table 4. Results of the Bivariate Analysis of the Study Variables

Variable	Organ Donation	Average	*Z*	*P*-Value	*N*	%
Age (y)	No	48.22	4.13	<.01		
	Yes	45.19				
Weight (kg)	No	85.11	2.93	.003		
	Yes	81.45				
Height (m^2)	No	174.01	0.11	.91		
	Yes	174.09				
BMI (kg/m^2)	No	28.05	3.76	<.01		
	Yes	26.7				
CRA-ALS time (min)	No	10.18	−1.73	.08		
	Yes	11.36				
ALS-Hospital time (min)	No	73.71	0.32	.74		
	Yes	73.34				
ALS-pump time (min)	No	119.47	0.23	.81		
	Yes	118.44				
Sex:						
Male	YES			1.0	318	86.4
Female	YES				50	13.6
Suspected etiology-OHES:						
Anoxic encephalopathy	Yes			.20	20	5.4
Other	Yes				350	94.6
Death of cardiac origin						
No	Yes			.52	19	6.6
Yes	Yes				268	93.4
OHES Cardiocompression:						
Mechanical	Yes			.17	99	73.3
Manual	YES				36	26.7

ALS, advanced life support/mobile ICU; ALS-Hospital time, time from the arrival of ALS to arrival at the hospital; ALS-pump time, time from the arrival of ALS to cannulation of the line for the extracorporeal system; BMI, body mass index; CRA, cardiorespiratory arrest; CRA-ALS time, time from CRA to the arrival of ALS; OHES, out-of-hospital emergency services.

are the group with higher probability to donate organs. To the best of our knowledge, there is no study in the literature that provides comparative results using these type of data, although, in a related matter, several publications point to the usefulness of uDCD and the need to improve potential donor selection [13,19].

Studies carried out in other international OHES [14,17,20,21] show the existence of distinct guidelines with important differences and major limitations. Some countries have such strict criteria for uDCD that no donors are captured in their studies [14,20], while others have such legal and cultural specificities in their healthcare system, or do not have doctors on staff, that uDCD donors cannot be included in the sample [17,18]. Furthermore, some countries do not recognize uDCD for ethical reasons [16,18,22,23]. Although OHES medicine has developed rapidly in recent years, with improved care and modernized protocols, there is still much work to be done in terms of donation protocols, not only in Spain but also internationally.

It should be noted from a legal perspective that, in uDCD, informed consent is given by families to the transplant coordinator after arrival at hospital. If the family does not wish to proceed with donation once the candidate donor is at the hospital,

Table 5. Results of the Logistic Regression Models

Model 1	**Dependent Variable Organ Donation**					
	Coeff.	Range	*P*-Value	OR	U.L.	L.L.
Age (y)	−0.036	(−0.077, 0.004)	<.1	0.96	0.92	1.0
BMI (kg/m^2)	0.002	(−0.084, 0.087)	>.05	1.00	0.91	1.09
CRA time-ALS (min)	0.035	(−0.016, −0.087)	>.05	1.03	0.98	1.09
OH cardiocompression	−0.305	(−1.180, −0.202)	>.05	0.73	0.37	1.47
Constant	1.923	(−0.813, 4.397)	>.05			
Model 2	**Dependent variable organ donation**					
Age (y)	−0.038	(−0.064, −0.013)	<.01	0.96	0.93	0.98
BMI (kg/m^2)	−0.089	(−0.146, −0.033)	<.01	0.91	0.86	0.96
Constant	4.965	(3.137, 6.792)	<.01			

P-value >.05: It is not statistically significant. *P*-value <.05: It is statistically significant.

BMI, body mass index; Coeff., coefficient; CRA-ALS time, time from CRA to the arrival of ALS; L.L., lower limit; OH cardiocompression, out-of-hospital cardiocompression; OR, odds ratio; U.L., upper limit.

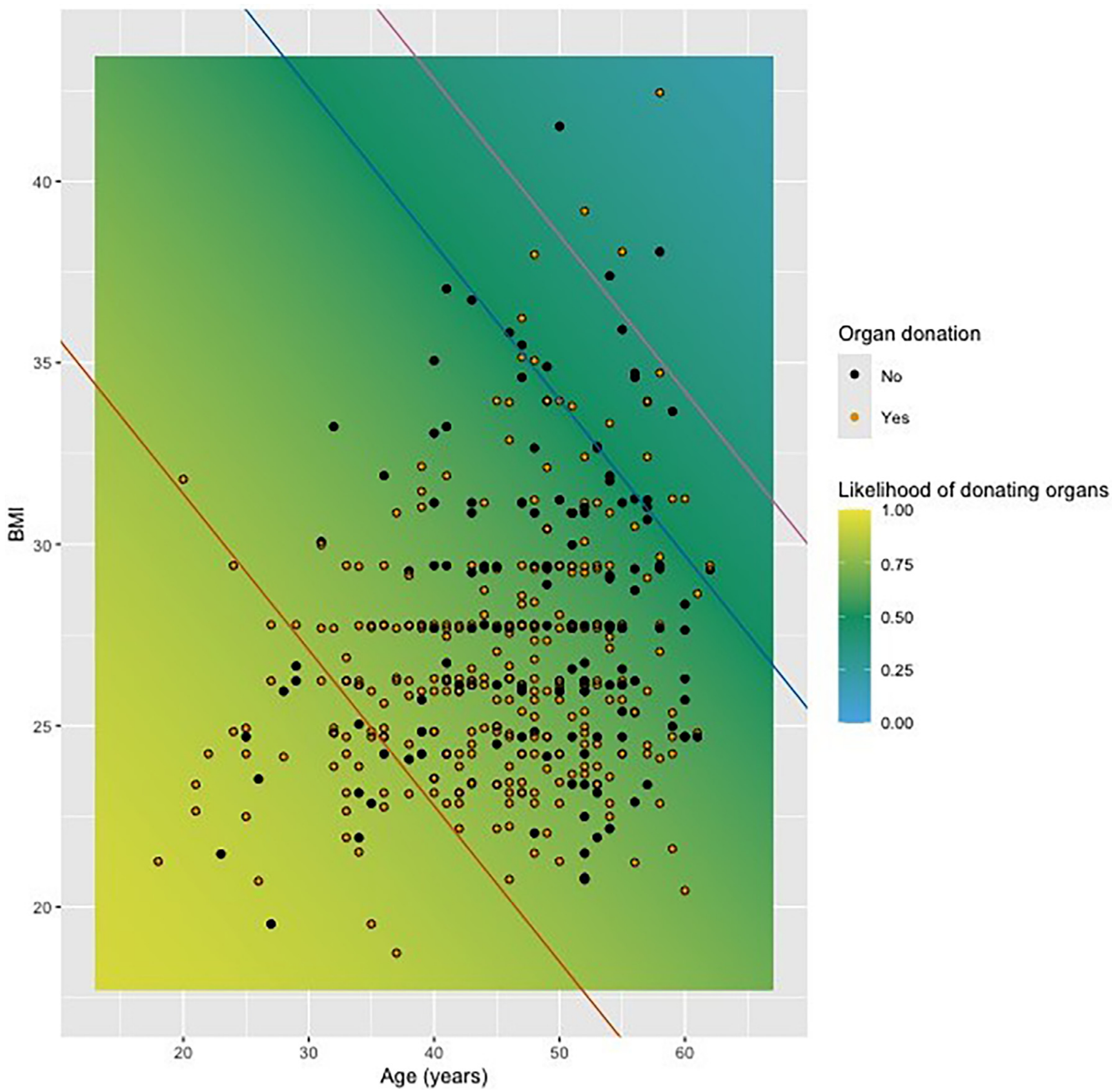

Fig 2. Predictive model of organ donation with the variables age and body mass index (BMI).

the donation process stops, unless an anticipated expression of wishes by the donor is present. That would be the only legally binding document.

The percentage of refusals by families to proceed with donation is low. In 2018, there were 55 refusals recorded in the CoM, representing a 2% annual increase and a refusal rate of around 20%, 5% points above the national average [24].

The experience shows that the main factor limiting donations is the lack of donors and organs, hence the significance of this study.

We should also point out some caveats of our study. The first one relates to the limitation of logistic regression model, which it is not highly accurate since despite its high sensitivity, it has low specificity. Although our model is sufficient to validate the association between donations and their main explanatory factors, it could be improved as a predictive model through the analysis of the impact of additional variables. For instance, it would be of interest for a future line of research to explore the inclusion of more detailed variables of organ donation to create a predictive scale for organ donation in OHES in order to support a more targeted selection of candidate donors and optimize the outcomes of organ donation. The recent study by Rubio-Chacón et al [14] concludes that optimal donor capnometry levels are associated with increased kidney donation. That variable, which is accessible in out-of-hospital settings, is just one that could be added to the predictive model in order to develop such a scale but could not be used because it was not included in the CORE registry used to develop the predictive model for this study.

Other limitations include the late use of mechanical cardiocompressors, which did not begin until 2012, inducing missing values in our sample for variables such as CRA-ALS time.

Although it was expected that the model would generate statistically significant results for as many variables as possible, the association between organ donation and BMI and age has been corroborated. Our intention is to improve and reinforce our results including additional variables, such as capnometry. This way, we intent to signpost future lines of research to standardize protocols for uDCD and create a scale to predict donation in OHES.

We want to underscore that population aging and increasing BMI in Europe will have a negative impact on uDCD donation. However, organ donation is developing rapidly, and adding alternative and well-directed sources of organ donors is critical to improving this problem.

Finally, introducing predictive models into the donation process, in this case including the variables age and BMI, allows the suitability of organs to be assessed. It would not increase the number of valid organs but would allow deciding which is the most efficient donor in a process such as uDCD. In this way, it would help the professional who receives the future donor to be more objective and would improve the decision to accept or not.

In conclusion, this study points to a relationship between organ donation and age and BMI in OHES uDCD. Patients aged 45 to 55 and with a BMI of 25 to 30 are more likely to donate organs. There is a low likelihood of organ donation in patients aged over 60 and BMI greater than 30. The creation of a predictive scale for OHES that incorporates BMI and age might optimize potential donor selection.

The study attempted to create a prognostic model for uDCD donors; however, statistical results were only found for age and weight, which means that the model needs to be improved with a larger number of donors and more explanatory variables.

However, we consider this study shows innovative and relevant results for future research, especially given the lack of references in the research literature on uDCD and the existing gap in related publications from experts of out-of-hospital Emergency Departments.

DECLARATION OF COMPETING INTEREST

The researchers declare that they have no conflict of interest that could affect their proposed ideas or the undertaking of the present research study.

ETHICS APPROVAL

The study was conducted in accordance with the Declaration of Helsinki and Istambul. It was approved by the Ethics Committee of the Francisco de Vitoria University in February 2019 and the Autónoma of Madrid University in February 2023. Because the study used encrypted, anonymized data obtained from a registry, informed consent was not required from patients' legal representatives.

CONSENT TO PARTICIPATE

Informed consent was not required based on national regulations (article 5.1 of the General Data Protection Regulation). As we worked with a database where the data is encrypted, informed consent was not required from the patients.

AVAILABILITY OF DATA AND MATERIALS

The datasets generated and/or analyzed during the present study are not publicly available due to their ownership by the Spanish National Transplant Organization but are available from the corresponding author upon reasonable request.

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CREDIT AUTHORSHIP CONTRIBUTION STATEMENT

All authors have collaborated in the conception and design of the study, data acquisition, data analysis, and interpretation. They have also written or revised the article with their final approval of the version to be presented.

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