Clinical paper

Uncontrolled donation programs after out-of-hospital cardiac arrest. An estimation of potential donors

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A B S T R A C T

Objective: To determine the number of potential deceased organ donors from out-of-hospital cardiac arrest cases (OHCA) attended by public physician-led emergency medical services in Spain, based on data recorded in the nationwide Spanish OHCA Registry (OHSCAR).

Material and methods: We analysed OHSCAR data on deceased OHCA patients in Spain during 13 months (1/10/2013 to 31/10/2014). Variables included age, sex, estimated OHCA time, cardiopulmonary resuscitation (CPR) start time and outcome. Inclusion criteria were: age 16–60 years, witnessed OHCA, no return of spontaneous circulation (ROSC) and time interval <15 min between OHCA occurrence and CPR initiation.

Results: Of a total 8789 cases, 3290 met the age criteria; of these, CPR was not witnessed in 745 cases. Among the remaining 2545 patients, 141 were included in uncontrolled donation after cardiac death (uDCD) programs, 902 arrived at the hospital with ROSC, 64 arrived with ongoing CPR and 15 cases were lost to follow-up. Of the remaining 1423 without ROSC, CPR initiation time was not recorded in 454 cases and 398 did not meet the time criteria <15 min between OHCA and CPR initiation.

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Finally, 571 met all the criteria and could have been potential donors. There were significant differences in the actual donors percentage from potential donors percentage between provinces with and without donor programs (141/322 = 43.8% versus 0/390 = 0%), but there were no differences in ROSC between the two types of provinces (418/1320 = 31.7% versus 652/1970 = 33.4%).

Conclusions: Many potential donors are missed in current clinical practice. uDCD programs are few and underused even in a country with high rates of organ transplantation.

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Introduction

Uncontrolled donation after cardiac death (uDCD) has become an emerging source of organ donation in recent years. The decline in traffic accidents and improvements in the care of patients with cerebrovascular and cardiovascular diseases has radically changed the organ donor patient profile [1,2]. In 2015, there were 1851 donors in Spain and 314 of these were DCD donors [3]. Of these, 95 (30%) were considered uDCD (type lla in the modified Madrid classification) [4].

uDCD represents a growing opportunity for organ procurement. As the number of brain death donors decreases, other ways have to be found so that the number of transplants does not decrease. The two ways currently being used are: live donor transplantation and uDCD [5,6]. The number of uDCD programs in Spain has increased and many provinces without such programs are considering establishing them.

The data show how uDCD programs in Spain generate multiple organs for recipient benefit [7]. However, uDCD figures have stagnated since 2012 when a record number of 134 donors was achieved. Interestingly, the number of uDCD programs has increased in recent years. From the time the first such program was launched in Spain in 1989 [8] until the year 2013, there have been seven autonomous regions with emergency medical services (EMS) participating in uDCD programs [2]. These programs have proven to be feasible in cities with widely varying numbers of inhabitants, which opens a door to the generalization of this strategy. In 2012, the National Transplant Organization (NTO) of Spain published a National Consensus Document [9] to standardize and promote the development of these programs, which was reinforced through a later agreement with the Spanish Society of Emergency Medicine [10]. The document set out inclusion and exclusion criteria for this type of donor. However, their final application depends on protocols between the receiving hospitals and the emergency medical services (EMS) that work with them, in accordance with their experience and each particular case. For these reasons, the criteria vary slightly between different communities.

In 2013, the Out of Hospital Spanish Cardiac Arrest Registry (OHSCAR) project was launched with the participation of public EMS from the 17 autonomous regions of Spain and two large municipal emergency services. The main objective of this project is to determine survival rates and neurological sequelae of EMS-treated patients suffering out-of-hospital cardiac arrest (OHCA) in our country. OHSCAR also provides data about patients who die in the field.

The objective of the present study was to evaluate the number of potential donors after cardiac death in regions with and without uDCD programs.

Material and methods

OHSCAR is a prospective registry of consecutive cases of OHCA treated by public EMS in Spain. Its methodology has been previously described [11]. Briefly, the registry continuously receives data from different EMS in the 17 autonomous regions of Spain and the municipal EMS in two large cities, Madrid and Zaragoza, which together represent all the out-of-hospital public services in Spain. They provide emergency medical coverage for more than 40 million inhabitants and all mobile resources have physicians on board. OHSCAR includes all cases of OHCA where the EMS performed cardiopulmonary resuscitation (CPR) or post-resuscitation care after intervention by a first responder. Among others, the variables included in the registry are gender, age in years, estimated time of CA, CPR, time advanced CPR and resuscitation is initiated in situ, spontaneous recovery of circulation (ROSC), ongoing resuscitation during transfer to hospital and maintenance of resuscitation performed for possible inclusion in a uDCD program. Also recorded are variables such as the fact that the attending EMS participates in a uDCD program, the name of the receiving hospital and province. OHSCAR does not collect patient medical history variables.

The present study covered the period 1 October 2013–30 October 2014 (13 months).

The criteria for inclusion as uDCD were: age between 16 and 60 years old, the CA event was not recorded as “NOT witnessed”, the time of CA and the start time of advanced CPR were known, and the time window between these times was not greater than 15 min. Exclusion criteria were: the presence of ROSC, ongoing CPR to try and achieve ROSC, during transfer to hospital, and the absence of a record describing the patient’s final outcome. We cannot collect other exclusion criteria such as judicial issues or patient comorbidities which may prevent the inclusion of a case in a uDCD program.

We described and compared the number and percentage of eligible cases in provinces with and without uDCD.

Statistical analysis

We performed a descriptive analysis of quantitative variables using measures of central tendency and dispersion. For qualitative variables, the distribution of absolute and relative frequencies was used. Quantitative variables were compared using Student’s t-test after verifying the normality of variable distribution with the Kolmogorov-Smirnov test. For categorical variables, we used contingency tables and chi2 tests, as appropriate. Differences with a p value of less than 0.05 were considered statistically significant. All statistical analyses were performed using SPSS version 15.0.

Results

This 13-month study included a total of 8789 patients with CA, median (IQR) age 66 (53–77) years, 72.1% men.

Of the total, 3290 (37.4%) patients met the age criterion; of these, CPR was not witnessed in 745 cases. Of the remaining 2545 patients, 902 (35.7%) arrived at the hospital with ROSC, 64 (2.5%) arrived with ongoing CPR during the transfer, 141 (5.6%) cases were included in uDCD programs and 15 cases were lost to follow-up. A total of 1423 (56.2%) patients were declared dead at the scene. Of these, we excluded 454 (31.9%) cases because of failure to record the time of the CA event and/or the time of initiating CPR, and 398 (28.0%) patients who did not meet the time-window criterion (interval <15 min between the OHCA event and initiation of advanced CPR).
Finally, 571 patients (40.1%) fulfilled all the inclusion criteria as potential uDCD.

The results, according to whether the different provinces had an uDCD program or not, are shown in Table 1. There were significant differences between the two populations. This was not the case of the ROSC rate but rather with other inclusion criteria such as date completion times, ongoing CPR and patients declared dead at the scene.

In the provinces with a uDCD program, there were 1320 patients who met the age criteria but the CA event was not witnessed in 358 cases. Of the remaining 962 cases, 455 (47.3%) were declared dead at the scene. Of this group, the time of the CA event or the time of CPR initiation was unknown in 154 cases, and the CA-CPR time interval was exceeded in 120 cases. Finally, 181 patients met all the inclusion criteria to be included in a uDCD protocol (Fig. 1).

In the provinces without a uDCD program, there were 1970 patients who met the age criteria but the CA event was not witnessed in 387 cases. Of this group, the time of the CA event or the time of CPR initiation was unknown in 300 cases, and the CA-
CPR time interval was exceeded in 278 cases. Finally, 390 patients met all the inclusion criteria for inclusion in the uDCD protocol (Fig. 1).

Discussion

Our review provides an overview of deceased organ donors from an EMS perspective. In a recent article, Cheetham et al. [12], explored the possibility of obtaining donors from a tertiary hospital perspective and potential donations from patients admitted after ROSC who finally die. In our study, donors are obtained after resuscitation failure [13] which focuses the efforts at the first stage, the pre-hospital setting.

The number of potential uDCD donors was 571, which represents one in every 2.5 OHCA patients who are declared dead at the scene aged between 16 and 60 years and whose CA event was witnessed. This quadruples the number of patients included in uDCD programs (141). Most of these potential donors suffered fatal OHCA in provinces without established donation programs; however, a significant number of cases occurred in areas with active uDCD programs (Table 2).

The comparison between provinces with and without uDCD programs presents some differences that seem logical. Fundamentally there is no difference in the percentage of patients who achieve ROSC. There is a significant difference in declared dead at the scene cases, as well as in the proportion of ongoing CPR, probably due to a higher habit of maintaining ALS during relocation as required by uDCD programs. Differences in time recording are difficult to pinpoint, although we think they may be related to the recording systems of each EMS itself.

Upon analysing the results obtained in provinces that do have a uDCD program, we observed that the number of actual donors was 141, while the number of potential donors who were not included in uDCD programs was 181. The number of potential donors is the absolute maximum that could have been achieved. If we add them to the real donors, there are 322 in provinces that have a uDCD program.

These potential donors met the basic age and time criteria, but we know nothing about other criteria such as biological aspects (bleeding lesions, having a malignant neoplastic disease, suspected infectious contagious disease etc.), logistics, refusal by the family, or simply that the EMS team attending a victim of OHCA did not consider the possibility of inclusion in a donation program. These uDCD programs start in the pre-hospital setting, so their success depends on the motivation of the EMS to improve the inclusion of eligible candidates. It is necessary to know the thoughts and attitudes of EMS professionals in approaching uDCD [14]. We have to work on all the ethics concerns that professionals can feel as problems when making immediate decisions in the field as to the inclusion of a patient in such a program. We have to give them tools and skills to facilitate subsequent family decisions [15,16]. Pre-hospital emergency teams should be instructed to minimize the loss of potential donors.

In those provinces where no such program exists, the number of potential donors was significantly higher. There were 390 cases declared dead at the scene, aged between 16 and 60 years, and the time window between CA and CPR initiation was less than 15 min.

But in these theoretical calculations, we only included cases with known CA and CPR times. A large number of cases were lost because one or both of those times were not known. In the provinces with a uDCD program, 181 of 301 cases (60.1%) met the CA-CPR time window of less than 15 min. Upon extrapolating the data, it could be assumed that of the 154 cases with unknown CA or CPR time, the time window <15 min would be met in approximately 92 cases. If the same percentage is applied in this group (23.7%), we can estimate 22 potential donors missed.

If this calculation is made for the provinces without a uDCD program, the previously mentioned 390 cases should be added to those excluded due to unknown CA-CPR times. If out of 668 cases, the CA-CPR time was known to be less than 15 min in 390 cases (58.4%), there would be about 175 cases falling within the 15 min time limit.

### Table 1

Distribution of patients meeting age criteria by province with and without uncontrolled donation following cardiac death programs.

<table>
<thead>
<tr>
<th></th>
<th>TOTAL</th>
<th>Provinces with uDCD program</th>
<th>Provinces without uDCD program</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>3250</td>
<td>1320</td>
<td>1970</td>
<td></td>
</tr>
<tr>
<td>Male sex (%)</td>
<td>2541 (77.3%)</td>
<td>1038 (78.8%)</td>
<td>1503 (76.4%)</td>
<td>0.059</td>
</tr>
<tr>
<td>Witnessed OHCA (%)</td>
<td>2345</td>
<td>915 (69.3%)</td>
<td>1430 (72.6%)</td>
<td></td>
</tr>
<tr>
<td>ROSC</td>
<td>1070 (32.7%)</td>
<td>418 (31.7%)</td>
<td>652 (33.4%)</td>
<td>0.170</td>
</tr>
<tr>
<td>Ongoing CPR</td>
<td>79 (2.4%)</td>
<td>46 (3.5%)</td>
<td>33 (1.7%)</td>
<td>0.001</td>
</tr>
<tr>
<td>Declared dead at scene</td>
<td>1984 (60.6%)</td>
<td>714 (54.1%)</td>
<td>1270 (65.0%)</td>
<td></td>
</tr>
<tr>
<td>Donors</td>
<td>141 (4.3%)</td>
<td>141 (10.7%)</td>
<td>0 (0.0%)</td>
<td>0.000</td>
</tr>
<tr>
<td>Times registered (both): Collapse and start ALS</td>
<td>2046 (62.2%)</td>
<td>770 (58.3%)</td>
<td>1270 (62.2%)</td>
<td></td>
</tr>
<tr>
<td>Collapse- start ALS interval &lt;15 min</td>
<td>1055 (57.7%)</td>
<td>415 (61.1%)</td>
<td>640 (55.7%)</td>
<td>0.013</td>
</tr>
</tbody>
</table>


### Table 2

Emergency services, provinces and hospitals participating in an uncontrolled donation after cardiac death program.

<table>
<thead>
<tr>
<th>Autonomous Community</th>
<th>Emergency service</th>
<th>Province</th>
<th>Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Andalucía</td>
<td>EPES-061</td>
<td>Granada</td>
<td>Virgen de las Nieves</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sevilla</td>
<td>Virgen del Rocio</td>
</tr>
<tr>
<td>Cantabria</td>
<td>061 Cantabria</td>
<td>Cantabria</td>
<td>Marqués de Valdecilla</td>
</tr>
<tr>
<td>Cataluña</td>
<td>SEM Cat</td>
<td>Barcelona</td>
<td>Clinic Hospital</td>
</tr>
<tr>
<td>Valencian Community</td>
<td>SAMU</td>
<td>Alicante</td>
<td>San Joan Alicante</td>
</tr>
<tr>
<td>Galicia</td>
<td>061</td>
<td>A Coruña</td>
<td>A Coruña</td>
</tr>
<tr>
<td>Autonomous Community of Madrid</td>
<td>SUMMA 112</td>
<td>Madrid</td>
<td>Clínico San Carlos</td>
</tr>
<tr>
<td>Madrid (City)</td>
<td>SAMUR-PC</td>
<td>Madrid</td>
<td>Clínico San Carlos</td>
</tr>
<tr>
<td>Basque Country</td>
<td>Emergencias Osakidetza</td>
<td>San Sebastián</td>
<td>Complejo Hospitalario Donosti</td>
</tr>
</tbody>
</table>

EPES: Empresa Pública de Emergencias sanitarias; SEM Cat: Sistema d’Emergences Mèdiques de Cataluña; SAMU: Servicio de Ayuda Médica Urgente; SUMMA 112 Servicio de Urgencias Médicas.
after extrapolating these results to the 300 cases where one of the times is unknown. If 23.7% were candidate donors, another 41 potential donors would be lost.

Limitations of the study

This was a retrospective study based on a nationwide registry in which not only were there the typical limitations of a registry, but also unknown patient medical histories. Certain data in the medical history may disqualify a candidate for organ donation, despite meeting the inclusion criteria. The registry does not record other possible specific circumstances of cases not included in active donation programs, such as judicial issues or patient comorbidities, which could be reasons for exclusion. There is another important limitation, which is the proportion of cases excluded due to a failure to record the time of the CA event and/or initiation of resuscitation. This is a limitation to be taken into account when using records as quality tools. In addition, these cases fulfilled all the other inclusion criteria such as age and witnessed CA, and it is likely that some were attended within 15 min of the event. These are extrapolated data and can influence any final estimation. On the other hand, it may also suggest that the theoretical calculations made, although important, probably underestimate the real potential of these uDCD programs. The balance is certainly not clear.

Thus, 141 donors were obtained out of a total of 8789 OHCA patients. However, the maximum number of potential donors with the calculations done could have been close to 9% of the patients attended; in other words, almost 800 possible donors.

There is increasing interest in how EMSs approach resuscitation of patients with no real possibilities of survival [17]. Following this concern, the present study highlights that uDCD programs are underused even in a country with such high figures in organ transplantation. It is another multifactorial approach [18] to reducing the number of patients on waiting lists for organ transplantation.

Conflict of interest statement

On behalf of all the authors of the mentioned manuscript, Dr Navalpotro-Pascual declared nothing to disclose.

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