ORIGINAL ARTICLE

Prehospital non-heart-beating donors: 4 years' experience of the SUMMA112 emergency service

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Received:
7-12-2009

Accepted:
22-1-2010

Conflict of interest:
None

Acknowledgements:
The authors wish to thank Mrs. Antonia García Requena for the organization of all the cases of non-heart-beating donors.

Background and objective: The emergency medical service of Madrid (SUMMA112) participates in a program to facilitate organ donation from patients in cardiorespiratory arrest who do not respond to advanced cardiopulmonary resuscitation maneuvers before arriving at the hospital. Patients who meet the criteria for inclusion are transferred to a transplant unit for extraction of organs while resuscitation maneuvers continue. The aim of this study was to determine time intervals under the program, the percentage of donors, the characteristics of donors and nondonors, and the number of organs obtained.
Material and methods: Descriptive, retrospective study of donors and organs obtained through the participation of SUMMA112 in the donation program over a 4-year period (2005-2009), based on review of medical records. The following data were extracted: age, sex, time until arrival of the ambulance, time until arrival at the hospital, number of organs donated, and type of organ donated. We also recorded the reason for not donating: patient refusal, family refusal, pump failure, biologically nonviable state, and other.
Results: A total of 132 cases (85% male) were found. The mean age of patients was 40 years. The mean time until arrival of emergency caregivers at the scene was 14 minutes, 55 seconds. The mean time until arrival at the hospital was 92 minutes. Three hundred fifty-six organs (158 kidneys, 16 livers, 97 corneas, 72 bone tissues, and 13 lungs) were obtained, corresponding to 2.3 organs per patient; 27.3% of the patients were nonviable donors. There were no age or sex differences between viable and nonviable donors. Reasons for not donating were failure of extracorporeal circulation (8.3%), refusal of the family (13.9%) or the patient while alive (2.8%), biologically nonviable state (44.4%), and other (30.6%).
Conclusion: A considerable number of organs are donated through this program, which helps to solve the problem of lengthening transplant wait lists. [Emergencias 2010;22:96-100]

Key words: Emergency medical services. Non-heart-beating donors. Kidney.

Introduction

Non-heart-beating (NHB) donors are patients who meet the general criteria for organ donation[1] and die due to irreversible cessation of heartbeat. In 1995, the Maastricht Conference[2] defined four categories of NHB donors to differentiate viability and legal and ethical support[3]: type I (dead on hospital arrival, including victims of accidents or suicide that are found dead on the scene and did not receive resuscitation, there is little experience reported in the literature on the use of this type of patient as a potential donor), type II: [unsuccessful resuscitation, consisting of those patients who suffer cardiorespiratory arrest (CRA) and in whom resuscitation attempts are unsuccessful: in these patients is easier to control warm ischemia time (WIT), which is the time considered when assessing organ viability], type III (controlled cardiac arrest, consisting of those patients with severe neurological injury that do not meet the criteria for brain death and where life support measures are withdrawn; this is the largest group) and type IV (cardiac arrest during the diagnosis of brain death).

Prehospital NHB donors are those patients who, having suffered cardiac arrest outside the hospital, were transferred with hemodynamic

support measures in order to donate their organs. That is, they correspond to Maastricht types I and II, called uncontrolled donors because warm ischemia time cannot be exactly determined. Although the exclusion criteria include judicial killing, as we shall see further on, in some cases the judge has given permission for the procedure, but these have been exceptional cases. Thus prehospital NHB donors are usually of type II.

For the procedure to be adopted, the emergency mobile unit physician must be legally and ethically empowered to confirm the death of the patient and proceed to activate the protocol. In Spain, this legal process is outlined in the Royal Decree 2070/1999 on donation and transplantation of organs and tissues[4] that establishes a diagnosis of death by CRA with the following requirements: (i) diagnosis of death using cardiorespiratory criteria based on the observation of unequivocal absence of a heartbeat, evidenced by the absence of central pulse or electrocardiographic tracing, and the absence of spontaneous breathing, both during a period of not less than five minutes, (ii) irreversible cessation of cardiorespiratory function must be ascertained after an appropriate period of advanced CPR (this period and the CPR manoeuvres must be adjusted according to age and circumstances leading to the CRA, and at all times must follow the protocols specified for advanced CPR periodically published by relevant scientific societies), and (iii) in cases of body temperature below 32 degrees, the body must be warmed before irreversibility of CRA can be established, and therefore the diagnosis of death.

The SUMMA112 prehospital NHB program was initiated in 2004. The aim of this study is to report on the characteristics of the program, the percentage of valid donors, the number of organs obtained and the main causes of non-donation.

Method

SUMMA112 is the emergency medical service of the Community of Madrid. During 2008, the coordinating center received more than a million emergency calls and mobilized 442,387 accident and emergency resources. The Community of Madrid has a population more than 6 million people with a healthcare network of 32 hospitals of which 11 are third level. Hospitals enrolled in the prehospital NHB program include the University Hospital Universitario Clínico San Carlos and the Hospital Universitario 12 de Octubre.

The criteria for patient inclusion in the prehospital NHB protocol of SUMMA112 are: meeting the general conditions with respect to neoplastic, systemic or transmissible diseases, age between 1 and 55 years, known CRA time, time interval from the occurrence of the CRA until advanced CPR less than 15 minutes, time to arrival at the hospital less than 90 minutes from the CRA, cause of death known or easily diagnosable (discarding aggression), no suspicion of bleeding abdominal or chest lesions and healthy external appearance, and absence of HIV risk. Exclusion criteria are: penetrating wounds of the chest and abdomen, judicial or violent death, and failure to meet the criteria for inclusion, although these criteria are currently under review. The timing and process of activating the Prehospital NHB protocol is shown in Table 1. Currently, the following organs are removed for transplantation: kidneys, lungs, liver, corneas and bone tissue. Potential donors are transferred to intensive care units of receptor hospitals where they are prepared by a multidisciplinary team for extracorporeal pump circulation pending legal requirements for the extraction of organs.

For each NHB case, a hospital report is issued on patients transferred to the transplant units. Contrary to what happens with brain-death donors, the NHB organs are not usually exported; they are transplanted into patient recipients in the hospital or in other centers nearby. The report information is supplemented by more data from the clinical history and computer record, including: age, sex, time to arrival of emergency services, time to arrival at the hospital, total number of organs donated, type of organs donated. Also included is the reason for non-donation when applicable: patient refusal, family refusal, pump failure, biological cause, and other. Patient refusal refers to those cases where the negative attitude was reflected in life. Pump failure refers to failure to cannulate the patient or subject the patient to extracorporeal circulation. Biological cause refers to patients with positive blood test, active cancer or any other medical reason to exclude them as donors. Finally, "other" reasons include judicial refusal (judge's refusal to allow organ extraction), technical problems, times exceeded or inability to place intravenous catheters by the surgeon on call, among others. The rate of functionality is defined as the percentage of organs that do not suffer primary function organ failure in the recipient. A valid donor is defined

Table 1. Time schedule and development of prehospital non-heart-beating (NHB) donation

	Prehospital setting	Hospital setting	Legal Proceedings
0-90 min	NHB Alert Transfer to hospital	Hospital extraction team alert	Application to the judge for cannulation for organ preservation
90-120 min		Extracorporeal circulation	
120-240 min		Inform the family	Application to the judge for organ extraction

The connection between the emergency services and transplant teams is made via the nursing coordination commission included in the coordinating centre of SUMMA112. The alert sent to the hospital extraction team, applications to the judge and information for the family is done by the transplant coordinator present at the hospital on arrival of the potential donor.

as a person donating at least one of their organs.

For this retrospective study of case series we included all cases of prehospital NHB donation from January 2005 to December 2008, based on data collection from medical histories. Statistical analysis was performed with SPSS 16.0© statistical software. Quantitative variables are expressed as means or medians with standard deviation. Qualitative variables are presented as percentages. For hypothesis contrast we used the chi-square test or the Fisher test when necessary.

Results

There were 132 cases of possible NHB donors, with a mean age of 40 years (14-64 years), and most were male (85% of cases). From the emergency call to the scene, emergency vehicles took an average of 14 minutes 52 seconds (14'52''; range 6'40''- 48'00''). From the emergency call to the receiving hospital, average time was 90 minutes 55 seconds (45'19''-150'47''). Of the 132 patients, 96 (72.7%) were valid donors, mean age 40 years, and the great majority (86%) were men. There were no significant differences in sex and age between the valid and non-valid donors (Figure 1).

The 96 valid donors a total of 356 organs were harvested and transplanted, which corresponds to an average of 3.7 organs (SD 2.45) and a median of 4 organs per donor. Organs transplanted were: 158 kidneys, 16 livers, 97 corneas, 72 bone tissues and 13 lungs. Only 14 patients exclusively donated tissues only, which corresponds to 15% of the valid donor population. The reasons for non-donation are given in Table 2. The main reason was positive serology (44.4%) and, in contrast, the least frequent reason was judicial refusal, recorded in only two cases.

The number of donors and donated organs, as well as the average number of organs retrieved per donor varied greatly from year to year (Figure 2), and the best numerical results were obtained in 2008 and the worst in 2007. Finally, that the rate of functionality of these organs in recipients was 91% for kidneys and 75% for the liver[5].

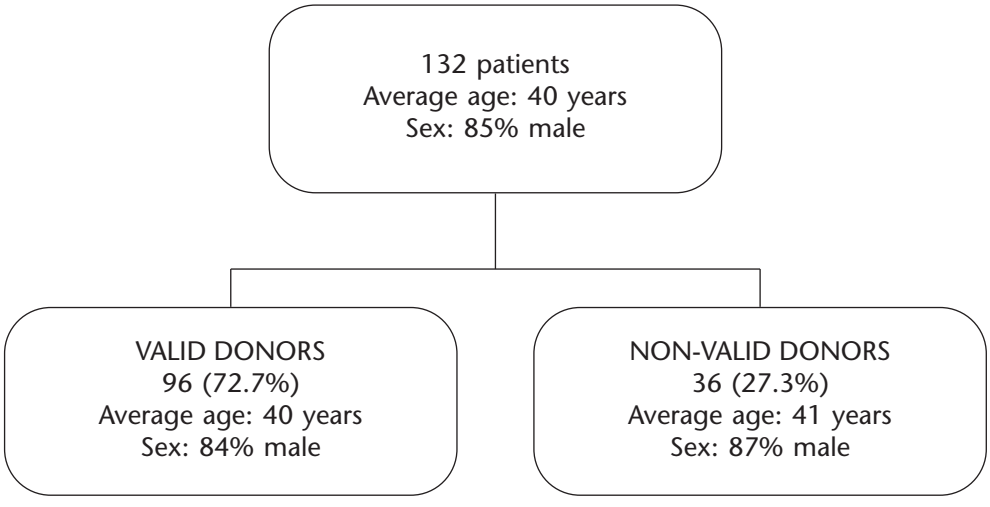

Figure 1. Distribution of cases in the study.

Table 2. Reasons for non-donation in 36 patients in the present study

	N (%)
Seropositive	16 (44.4%)
Family refusal	5 (13.9%)
Pump failure	3 (8.3%)
Patient refusal	1 (2.8%)
Other*	11 (30.6%)

* Corresponding to: 7 cases exceeded inclusion time, 2 problems in cannulation and 2 cases of judicial refusal.

Discussion

Published case series studies on prehospital NHB donation report similar data on age, sex and emergency service times[5,6]. Alvarez et al conducted a study similar to ours and in the same area of Madrid in 2000, before SUMMA112 was integrated into the program[7].

In that study, the donor population was significantly older, aged 60 years on average, but emergency service arrival times to CPR and to the hospital were similar. They reported about 43% of valid donors, with an average of four organs retrieved per valid donor. We found a greater number of valid donors, but the same average number of organs per donor. Similar data were published in 2009 by the French SAMU[8].

Notably, the times found in our study are within the limits established by the inclusion criteria of the protocol. The median time for arrival at the hospital was just 90 minutes (maximum time for arrival) so that 50% of cases of possible prehospital NHB donors arrived later than the recommended times. This fact has led to increasing the inclusion criteria time to 120 minutes, agreed by the transplant teams at both hospitals.

As for the reasons for non-donation, the most frequent was biological causes, i.e. more thorough interrogation of the family or pre-extraction blood test revealed the presence of HBV, HCV, or malignancy. A remarkable finding was the low frequency of family refusal, only 7.6%, while with brain death donors there are series describing rates of 24%[9]. Despite the fact that, by law in Spain, any person is a donor unless there are objective data for exclusion, the family is asked about the existence of a viewpoint on the subject by the deceased or by the family. If this is contrary to donation, the procedure is stopped.

In our donor population the rate of renal nonfunction was 9%, significantly higher than that reported for brain-death donors, which is around 4%. Similarly, we found liver failure in a quarter of the prehospital NHB transplanted livers. Despite these rates of failure in organs retrieved, the achievement of more than 350 organs in four years represents an important increase in the number of organs available for transplant, which helped to reduce the waiting list for organ transplantion: at that time the waiting list was constant because the number of organs available from brain-death donors had reached a maximum.

The joint effort of the prehospital emergency services and transplantation teams is necessary to optimize these programs to achieve a greater number of organs. The current inclusion times are very strict and there is evidence that warm ischemia times can be increased. Also, the Maastricht definition of "uncontrolled" for these patients is debatable and with optimization of advanced CPR and the currently available mechanical devices for cardio-compression, uncontrolled time can be drastically reduced.

The specific criteria for lung transplantation remain to be defined. In the same way that optimal blood flow must be maintained for the other organs, in the case of the lungs that flow is harmful and what is needed is correct ventilation. Therefore, hypothetically, prehospital NHB donors not meeting the criteria for inclusion due to abdominal trauma or rupture of large vessels might in fact be candidates for lung donation.

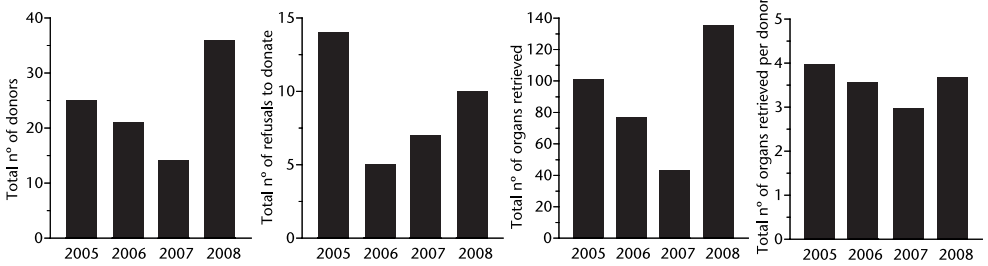

Figure 2. Annual evolution of the prehospital non-beating-heart donation program.

In conclusion it can be said that almost 80% of patients transferred under the prehospital NHB donor program were valid donors. In four years this program achieved a total of 356 donations between organs and tissues, which we consider a large number, thus contributing to better quality of life of many patients on the waiting list. In addition to the technical difficulties involved in any transplantion, we must add the difficulty of ensuring the connection and interaction of health services as separate as the SEM, transplant teams, nephrology and surgery departments etc. The achievement of such a large number of organs is a direct consequence of the effort of our professionals in these services, but the whole program is dependent on the generosity of donor families who, at a critical time when they have just lost a loved one, choose to donate their organs so that another unknown person may continue living.

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Análisis de cuatro años de funcionamiento de un programa de donante a corazón parado extrahospitalario

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Objetivo: El Servicio de Urgencias Médicas de Madrid SUMMA112 está integrado en un programa de donación de órganos de pacientes con una parada cardiorrespiratoria (PCR) extrahospitalaria que no responden a las maniobras de reanimación cardiopulmonar (RCP) avanzada. El objetivo de este estudio es conocer el cumplimiento de los tiempos del programa, la proporción de donantes, las características de los donantes y no donantes y el número de órganos obtenidos.
Métodos: Estudio descriptivo retrospectivo de los donantes y órganos obtenidos durante 4 años (2005-2009) que se basa en la revisión de las historias clínicas. Se recogen los siguientes datos: edad, sexo, tiempo de llegada a la asistencia, tiempo de llegada al hospital, número total de órganos donados, tipo de órgano donado y la no donación si ésta existiera.
Resultados: Se recogieron un total de 132 casos, 85% varones. La edad media fue de 40 años. El tiempo medio de llegada a la escena fue de 14 minutos y 52 segundos y al hospital fue de 91 minutos. Se consiguieron 356 órganos procedentes de 96 donantes válidos (158 riñones, 16 hígados, 97 córneas, 72 tejidos óseos y 13 pulmones; 3,7 órganos por paciente). El 27,3% de los pacientes fueron no válidos. No hay diferencia entre los donantes válidos y no válidos en la edad y el sexo. Las causas para la no donación fueron el fallo en la circulación extracorpórea (8,3%), la negativa familiar (13,9%) o del propio paciente en vida (2,8%), la causa biológica (44,4%) y otros (30,6%).
Conclusión: Un programa de estas características consigue un número de órganos para trasplante muy importante que ayuda a disminuir las listas de espera. [Emergencias 2010;22:96-100]

Palabras clave: Servicios médicos de emergencia. Donante a corazón parado. Riñón.