

OUTCOMES OF A PUBLIC ACCESS DEFIBRILLATION PROGRAM IN GIRONA

A CROSS SECTIONAL STUDY



Universitat de Girona

FINAL DEGREE PROJECT
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INDEX

1.	ABBREVIATION LIST	1
2.	ABSTRACT	2
3.	INTRODUCTION	3
3.1	Epidemiology and regional variations	3
3.2	Etiology of OHCA	4
3.3	Chain of Survival	5
3.4	Automated External Defibrillator development	6
3.5	Public-Access Defibrillation program in Girona	7
4.	JUSTIFICATION.....	9
5.	HYPOTHESIS.....	10
5.1	Main hypothesis	10
5.2	Secondary hypothesis.....	10
6.	OBJECTIVES.....	10
6.1	Main objective.....	10
6.2	Secondary objective	10
7.	METHODOLOGY	11
7.1	Study design	11
7.2	Setting and population	11
7.3	Inclusion and exclusion criteria	11
7.3.1	Inclusion	11
7.3.2	Exclusion.....	11
7.4	Sampling.....	12
7.5	Variables.....	13
7.5.1	Independent variable	13
7.5.2	Dependent variables.....	13
7.5.3	Covariates	14
7.6	Data collection and measure instruments.....	17

8.	STATISTICAL ANALYSIS.....	19
9.	ETHICAL CONSIDERATIONS.....	20
10.	STRENGTHS AND IMPACT.....	22
11.	LIMITATIONS	24
12.	WORK PLAN.....	26
12.1	Initial coordination	26
12.2	Bibliography research.....	26
12.3	Protocol development.....	27
12.4	Data collection.....	27
12.5	Data organization and statistical analyses.....	28
12.6	Final article elaboration and publication of results	28
13.	CRONOGRAM	29
14.	BUDGET	30
15.	BIBLIOGRAPHY.....	32
16.	ANNEXES	36
16.1	Annex 1.....	36
16.2	Annex 2.....	37
16.3	Annex 3.....	38
16.4	Annex 4.....	39
16.5	Annex 5.....	40
16.6	Annex 6.....	42

1. ABBREVIATION LIST

- **OHCA:** Out-of-Hospital Cardiac Arrest
- **EMS:** Emergency Medical Services
- **AED:** Automatic External Defibrillator
- **PAD:** Public Access Defibrillation
- **CPR:** Cardiopulmonary Resuscitation
- **CPC:** Cerebral Performance Category
- **NCE:** Non-Cardiac Etiology
- **ICU:** Intensive Care Unit
- **ECG:** Electrocardiogram
- **CEIC:** *Comitè d'ètica d'Investigació Clínica*
- **ERC:** European Resuscitation Council

2. ABSTRACT

Title: Outcomes of a public-access-defibrillation program in Girona, a descriptive cross-sectional study. **Background:** Out-of Hospital Cardiac Arrest (OHCA) is an important medical issue and a leading cause of mortality all over the world. In Spain there are around 15300 cases of OHCA per year. 82% of them are reported to have a cardiac etiology, with the vast majority suffering from ventricular fibrillation during the early minutes after the collapse. A chain of survival with early defibrillation has shown its effectiveness in recovering these individuals. With the technological improvements in the Automatic External Defibrillators (AED) many Public Access Defibrillation (PAD) programs have been started around the world. A pioneer project of widespread PAD has been started in the province of Girona, north-east of Spain. **Aims:** 1) To analyze the impact of public-access AED use over the survival rate to hospital discharge in patients with OHCA in the province of Girona. 2) To evaluate the one-month neurological outcome in these patients. **Methods:** A total of 673 AEDs have been distributed in the whole province of Girona. Prospective data from all bystander-witnessed OHCA in this province will be gathered from 2015 to 2019. Retrospective data about OHCA cases before PAD program will be recruited from the regional Emergency Medical Services (EMS) database. **Outcome measures:** the main outcome will be survival to hospital discharge in each case. The secondary outcome will be survivor's neurological outcome at one-month, measured by the Cerebral Performance Scale (CPC). **Keywords:** Out-of-hospital cardiac arrest, automated external defibrillator, public-access defibrillation, survival to discharge.

3. INTRODUCTION

Out-of Hospital Cardiac Arrest, defined as a lack of cardiac mechanical activity and undetectable pulse and respiration(1), is an important medical issue and a leading cause of mortality all over the world.

3.1 Epidemiology and regional variations

Epidemiological studies have shown that there is an important regional variation between the reported incidence and survival rates. While there are clear regional variances, it is also observed that the discrepancy is in part related to differences in the definition of the term cardiac arrest and the methodology used between different studies, to regional differences in the emergency systems and hospitalized care(2,3) and finally to differences in the tertiary prevention in patients with established cardiovascular disease(2).

According to the American Emergency service system, over 310,000 patients with OHCA are treated yearly, with an incidence of 55 cases per 100,000 person-year approximately. Global incidence of EMS attended OHCA, calculated by J. Berdowski et al. in a bibliographic review, is of about 95,9 cases per 100,000 person-year, while incidence of EMS treated OHCA is of 62,3 cases per 100,000 person-year(3).

Of all OHCA, 31,4% of these cases receive a bystander CPR, but use of external AED is as low as only in 2,05% of the cases(2,4).

In Europe, with an estimated incidence of 38 cases per 100,000 people per year, over 275000 cases of OHCA per year are estimated according to European population with an estimated survival rate of around 10,7% for all OHCA(5).

According to a study done by Spanish EMS system, the prevalence of OHCA in Spain is of about 1,7%(6). Survival rates reported in Spain are similar to the European series, and a bit superior than the American and Japanese series. Approximately 34 cases per 100,000 person-year, equal to 15300 cases per year, are reported by J. B. López Messa et al.(4) and 10,1% is the survival rate described at the hospital discharge in Spain(4,7,8).

3.2 Etiology of OHCA

Approximately an 82% of the OHCA are reported to have cardiac etiology(9), and hence according to the Utstein recommendations for uniform OHCA data reporting an OHCA is presumed to be of cardiac etiology (primary electrical events, ischemic events or thrombotic events etc.), unless it is known or witnessed to have been caused by trauma, submersion, asphyxia or any other non-cardiac etiology (NCE)(1,9). 85% of the people with an OHCA of primary cardiac cause suffer ventricular tachyarrhythmias during the early minutes after the collapse, ventricular tachycardia that rapidly evolves to a ventricular fibrillation in most of the cases. Otherwise the dysrhythmia can initially start with a ventricular fibrillation or Torsade de Pointes(10).

NCE account for 19,9% - 34,1% of OHCA. Interestingly, cardiac origin seems to be decreasing(9). The most frequent non-cardiac causes are: acute aortic dissection 8,07%, airway obstruction 7,64%, submersion 5,63%, hypoxia due to pneumonia 5,25%, cerebrovascular disorder 4,48%, asthma and acute worsening of chronic obstructive pulmonary disease 2,06% and pulmonary thrombo-embolization 1,46%(9).

3.3 Chain of Survival

Survival rates after OHCA continues to be poor, despite that several measures and techniques have been implemented during the last 30 years to curve the bad prognosis, including cardiopulmonary resuscitation teachings, better EMS actuation times, use of AEDs by EMS personnel and trained first responders (policemen, firefighters etc.)(11,12).

It was not until 1990 that Cummins et al. introduced the concept of “Chain of Survival” (see [Figure 1](#)) trying to give evidence based solutions in order to increase the survival rate in OHCA(10). The chain included a sequence of different links:

- 1) Recognition of early warning signs
- 2) Activation of the emergency medical system
- 3) Basic cardiopulmonary resuscitation
- 4) Defibrillation
- 5) Intubation
- 6) Intravenous administration of medications.



Figure 1: Chain of Survival illustration (4)

The goal of their work was to create some recommendations in each of these links so that all the communities could follow them to strengthen their own Chain of survival(10).

Since then this chain has been the base for worldwide resuscitation programs in different countries, and has evolved along with the evolution of new technologies, like AEDs(11).

One of the most important link in the chain of survival is the earlier defibrillation, as the vast majority of OHCA are accompanied by shock-reversible rhythms(12–14). It is well known that survival rate and neurological outcome decrease drastically in each minute without defibrillation(11,14,15).

3.4 Automated External Defibrillator development

The AEDs were first developed in 1970 and later in 1979 introduced for clinical use(11). Early defibrillation was soon performed by non-medical personnel such as trained EMS technicians(16), police agents(17) etc. Later AED was implemented at the airports and aircrafts(11,12), casinos(12) and also at high-schools(18).

At present, one of the most advocated programs is the spreading of AED everywhere with first time responders, known as public-access defibrillation (PAD) programs(15,19–25). Over the past two decades the AEDs have evolved in such a way that the actual reliability, for rhythm analyses and shock delivery, and ease of use allow us to implement widespread PAD programs. The weight, cost and size have been reduced notoriously to make feasible this type of projects, logistically and economically(11).

The actual AEDs have shown high sensitivity and specificity levels while detecting ventricular fibrillation(26). The simplified usage with adhesive electrode pads, the included voice-prompts, the complete automation of these devices to detect shockable rhythm, and discharge, and the impossibility to give an unnecessary shock, the most important feature, make these devices fully recommendable to take the early defibrillation to the public level, so that even lay persons without any training can use these AEDs(11). In this way the defibrillation times can be reduced and the prognostic can be increased considerably.

3.5 Public-Access Defibrillation program in Girona

Taking in account all the above mentioned considerations a widespread PAD program called *Girona Territori Cardioprotegit* was implemented in the whole province of Girona, north-east of Spain, with a total population of 761,632 persons as by 2013(27). Over 250 OHCA cases per year are estimated by the EMS in this area.

Legal initiatives had to be taken in order to implement this project in Spain, as the use



Figure 2: Fixed position AED tower (from <http://www.dipsalut.cat/premsa.html?id=42>)

of AEDs by non-trained personnel was not legal. With the creation of the decree 151/2012, 20th November, the out-of-hospital AED installation and use by non-trained personnel was legalized. Since its approval, in case of OHCA with absence of a trained person to use the AEDs, anyone can apply the AEDs with therapeutic reasons(28).

A total number of 673 AEDs were deployed over 221 towns included in the province of Girona. The number of AEDs per town was determined proportional to the population of each town. 503 AEDs are placed fixed at the most concurred places and/or with high probability of OHCA accidents (main squares and streets, sports centers, railway stations, schools

etc.)(12). 170 mobile units were distributed between trained first-responders (policemen).

The fixed AEDs are covered with a plastic shield and included in a tower, always connected to the EMS system (see [Figure 2](#)). Any layperson can open the shield and take away the AED to the collapse location. Once an AED is taken from this tower, an automatic signal is sent to the EMS, so that the alarm can be activated (if it is not already activated by laypersons) and an ambulance unit can be mobilized.

On the other hand, the mobile AED units are used by policemen, already trained, when they can provide a lower time to shock-delivery than EMS arrival.

All the AEDs used in this program are Powerheart AED G3 plus, automatic model 9300 (see [Figure 3](#))(29).

This PAD program is accompanied with training course camps at different special events in the main towns and the capital of the province. Various outreach programs are distributed at these events with simple guidelines for AED usage (see



Figure 3: AED used in this Project (24)

[Annex 1](#)). High-school students are also being prepared with resuscitation techniques and AED use(30). A smartphone APP that indicates location of all the fixed AEDs is also being developed in order to facilitate the PAD usage.

4. JUSTIFICATION

Our research is an evaluative project of this PAD program in the province of Girona, in which we will observe the changes in the survival after AEDs implementation. The early defibrillation has shown to be the most important link in the chain of survival in order to increase the survival rate and also the favorable neurological outcome (11,14,15). Other PAD programs in different places over all the world have already shown their effectiveness when the AEDs are well located and there is sufficient number of witnessed OHCA cases in the area (15,19–23).

No such study has been done over a widespread PAD project in Spain, so there is no local data published. This would be a pioneer work in this field with Spanish population. If an important increase in survival rate is seen with this project, more PAD projects can be started in other areas of Spain, furthermore these results can be extrapolated to some populations of other similar provinces.

5. HYPOTHESIS

5.1 Main hypothesis

The use of a public-access AED program increases the survival in patients with OHCA who are witnessed by laypersons. Based on our bibliographic research the use of external AED before EMS services arrival has demonstrated its effectiveness in different studies.

5.2 Secondary hypothesis

The use of public-access defibrillation improves the neurological outcome respective to the cases without AED usage, as earlier defibrillation is associated with favorable neurological outcome.

6. OBJECTIVES

6.1 Main objective

To analyze the impact of public-access AED use over the survival rate to the hospital discharge in patients with witnessed OHCA in the province of Girona.

6.2 Secondary objective

To evaluate the neurological outcome one-month after the OHCA survival in these patients.

7. METHODOLOGY

7.1 Study design

It will be a descriptive cross-sectional study, in which we will measure the difference between the survival rate in patients suffering an OHCA before the public access AED implementation, and after.

7.2 Setting and population

This research will be done in the province of Girona where the public-access AEDs, a total of 673, have been installed in each village and town. The number of AEDs per village is proportional to its population. The AEDs are implemented in public places like in front of sports centers, public schools, in the most concurred streets and squares etc.

The population of this study will be all the people from the province of Girona. According to the Spanish *National Institute of Statistics* it is measured in approximately 761,632 persons (382,685 Men; 378,947 Women). This project will last 5 years approximately.

7.3 Inclusion and exclusion criteria

7.3.1 Inclusion

- All cases of OHCA in the province of Girona, regardless the village or town where they take place, that are bystander witnessed.

7.3.2 Exclusion

- Cases of OHCA that occur in presence of EMS personnel, and hence there is no bystander use of public-access AED, neither bystander cardiopulmonary

resuscitation. For instance, patient with thoracic pain that suffers an OHCA already being attended by EMS personnel.

- Cases where a clear NCE etiology has been witnessed: trauma, submersion, asphyxia, cerebrovascular disorder etc.

7.4 Sampling

The sample for this study will be the part of the population of Girona that suffers an OHCA. According to our survival rate variation expectative, the principal dependent variable of our study, we calculated the needed sample with the help of free online software from Regicor called GranMo.

In a bilateral contrast accepting an α -risk of 0.05, a β -risk lesser than 0,2, and assuming to detect increases in survival rate superior than almost 5% (from 10,1%, as mentioned in the bibliography, up to 15%), with a ratio of 1 between both groups, the sample needed for this study will have to be composed of 749 persons with OHCA before AED implementation in the province of Girona (group 1), and 749 cases of OHCA after the public-access AED program starts (group 2).

Approximately 15300 cases of OHCA are recorded in Spain per year. Therefore, proportionally to its population, about 258 cases of OHCA per year occur in the province of Girona. As found Capucci et al, approximately 70% of the OHCA cases seem to be witnessed in an area like Girona(19). It gives us approximately 181 cases of witnessed OHCA per year for our sample. So we will have to search for retrospective data for 4 years before public-access AED implementation to get the needed 749 cases, and collect data of OHCA cases during 4 years after the AED implementation.

It will have to be a non-probabilistic consecutive type of sampling, as we cannot control the exposition to the OHCA. The data from victims that accomplish the exclusion criteria, as told above, will not be included in this sampling.

7.5 Variables

In our study the main variables are: the use of AED in patients with OHCA, the survival rate at hospital discharge in these patients, and neurological outcome in one month.

7.5.1 Independent variable

- Use of public-access AED in patients with OHCA

We want to study the impact of this measure to increase the survival rate in patients with a witnessed OHCA. This variable will be measured as a qualitative nominal dichotomous variable. Using the Utstein guidelines for uniform data reporting from an OHCA patient, the EMS personnel will note this information as yes or no, as answer to the question about use or not of the public access AED by bystanders.

We will take in account only the cases where the arrest has been bystander witnessed. Data from the cases where the arrest is not witnessed or witnessed by EMS personnel will not be included in this study. This data will be analyzed as proportions of both groups, the one where AED has been used and the other one without AED use.

7.5.2 Dependent variables

- Survival rate to hospital discharge

This is the main dependent variable of this study, and will be a qualitative nominal dichotomous variable which will be analyzed in proportions. We will measure the survival rate once the patients are discharged from the hospital, and not at the moment

they survive the cardiac arrest, as survival to discharge is the real survival rate. Many of the victims are resuscitated at the moment of the acute episode but later a small percentage survive in the ICU at hospital.

- **Neurological outcome in one month**

This is our secondary dependent variable, which will also be a qualitative dichotomous variable, measured as favorable or not favorable. The CPC scale for neurological evaluation, as recommended by the Utstein Guidelines, will be used to classify the patients into groups of favorable or not. We will consider as favorable patients with score of CPC 1 and CPC 2 from the CPC scale, as they are independent for the daily life activities. The rest of the patients will be classified as unfavorable outcome. This scale is shown as an Annex of this protocol (see [Annex 2](#)).

7.5.3 Covariates

They are other variables that affect our dependent and independent variable, but are not our object of study. We will have to control them in order to increase the internal and external validity of our study, as these variables can act as confounders and alter the study results. This confounding effect of these variables can be minimized later with a multivariate analysis.

- **Sex:** it will be a qualitative nominal dichotomous variable that will classify the sample in Male or Female.
- **Age:** this will be a quantitative discrete variable, measured in years.
- **Smoking:** as a risk factor for the OHCA this variable will be collected in this study by a simple question. It is a qualitative nominal variable, with 3 possibilities:
 - o *Smoker*

- *Non-smoker*
- *Former-smoker*
- **OHCA location:** which is a qualitative nominal variable with six possible values:
 - *Home:* all the victims of an OHCA being at their home.
 - *Public schools:* OHCA's that take place at any of the public schools or nearby in the province of Girona.
 - *Streets:* OHCA's that occur in the streets of the villages and towns in the province of Girona.
 - *Sports centers:* AEDs are also allocated near these facilities, and this include the playgrounds and other sports facilities of each town and village.
 - *Girona city Airport:* where AEDs are also deployed.
 - *Other public places:* which includes public places such as theaters, cinema halls, railways stations, shopping malls etc.

We will calculate the proportions of OHCA in each of these locations.

- **Victim's initial electrocardiographic rhythm:** it is also a qualitative nominal variable, with three possible values:
 - *Ventricular fibrillation*
 - *Asystolia*
 - *Others:* such as Pulseless Ventricular Tachycardia, escape rhythms etc.

This data can be obtained by Electrocardiogram (ECG) recordings recovered from the AED used in each case, as it has internal mechanisms to record the ECG rhythm.

- **Time interval between EMS call-receipt and AED shock delivery:** it will be a quantitative continuous variable measured in minutes. EMS personnel will note down the call reception time and the research team will note the time of shock-delivery, if any, once read the AEDs internal time registration. Then the interval between both timings will be calculated.
- **Bystander Cardiopulmonary resuscitation:** which will be qualitative nominal variable with three possible values:
 - o *Conventional CPR:* which includes chest compressions and rescue breathings done by bystanders.
 - o *Chest compressions only CPR:* which lacks of rescue breathings.
 - o *No CPR:* none of both items are done by bystanders.
- **Type of bystander:** which will be a qualitative nominal dichotomous variable, and will classify the bystanders in Trained for the CPR (including medical professionals or EMS personnel not on service, other people with CPR knowledge) or Not trained for the CPR.
- **Number of electrical discharges given by the AED:** it will be a quantitative discrete variable measured in natural numbers (0,1,2,3,4...).
- **Initial survival:** the survival rate to hospital discharge is our main output, but we will collect the rate of initial survival, once the AED is used and CPR is realized, as a covariate. It will be a qualitative nominal dichotomous variable, measured with two possible values: survival or not at the moment of AED usage and CPR.

7.6 Data collection and measure instruments

To collect all these data a template will be created, according to the Utstein recommendations for uniform reporting of data regarded to the OHCA. It will be called *Cardiac Arrest Registry Form* (see [Annex 3](#)).

EMS personnel attending the OHCA victims will be asked for collaboration to fill this questionnaire, as they will be in contact with the bystanders. Printed copies of this form will be given to the EMS personnel, so that they can easily fill them. After every OHCA occurs, research team will contact the EMS to collect the filled questionnaire and the AED used. If a mobile unit of AED is used, the research team will contact with the local police to collect the AED in order to take out the initial rhythm analyses. If any data of the patient is missing later, research team will contact with the patient, if he signed an informed consent previously, to fill it up itself.

To maintain the anonymity and confidentiality of the data this form will only include an identification number for each patient, no personal data will be shown. The personal data will be collected apart on another form prepared with the same identification number (see [Annex 4](#)). If later contact with the patient is needed, this identification number, OHCA date and location will help us to access EMS databases to search the patient.

If the EMS personnel have no information regarding the victim's initial rhythm or the number of discharges realized, it will be noted on the data collection form by the research team later, analyzing the AED's internal ECG recordings. Also the survival to discharge or not will be filled by the research team.

Medical help will be required a month after the patient's discharge for the neurological outcome evaluation, which is a secondary objective of this study. As said above, CPC validated scale will be used in this case to measure this variable. Two neurologists from the Hospital Dr. Josep Trueta will perform the neurological evaluation and the outcome will be integrated to the same template in order to unify the whole data from the same patient.

During this data collection process, the research team will regularly check the data collection forms already obtained, in order to detect errors or missing data, if any. This process will help us in two ways:

- To identify questionnaires with missing important data (for example, time interval between collapse and AED shock delivery, bystander CPR done or not etc.).
- To detect the difficulties faced by EMS personnel while completing the questionnaires and to solve them.

The same questionnaire will be used for retrospective data collection. Access to the EMS databases will be asked by the research team. We will search for the same data as above (except the use or not of the AED) in already occurred cases before AEDs implementation, until we achieve the needed 749 cases as our sampling process showed.

Once all the data has been collected, using the data collection forms the research team will create a database with all this information classified by variables, for further data analysis. So we will need a computer with database creator software tools. Free software called Openoffice Calc will be used in this case.

8. STATISTICAL ANALYSIS

This study will include three levels of statistical analysis once the data collection process is finished.

- **Descriptive analysis:** The results for all the qualitative variables collected will be expressed in percentages for each group, while the quantitative variables normally distributed will be expressed in means, with their respective standard deviation. If the quantitative variables were not normally distributed, they will be expressed as medians, or percentiles.
- **Bivariate analysis:** This analysis will show us the relation between our independent variable and dependent variables, if any. As both of them are qualitative variables, the statistic method used will be χ^2 test.
- **Multivariate analysis:** Which will give our study more external validity, as the relation between our main study variables will be adjusted according to the confounding effect, if any, of the covariates we measured.

As our dependent variables are qualitative dichotomous type we will use Logistic models for a multivariate analysis.

9. ETHICAL CONSIDERATIONS

Respecting the ethical principal of autonomy this study will be carried on with the data obtained from the patients discharged from the hospital who, once informed, accept to participate and allow the research team to use their data. An information sheet (see [Annex 5](#)) and an informed consent (see [Annex 6](#)) will be prepared and explained to the patient so that he/she can freely decide to participate or not in this project.

Victims of an OHCA cannot sign an informed consent at the moment of the episode, that is why if the patient, once stable, does not want to participate, the data already obtained will be destroyed and no further data (for ex. One month neurological outcome) will be collected.

Also the confidentiality of the personal data will be an important issue for us during this study, and will be guaranteed to the patients of OHCA. The EMS personnel will assign each patient they attend an identification number which will be the one that appears on the data collection form, and the personal data will be collected at the same time on another form, assigned also with the same number as the patient.

In this way the research team will work only with the data collection form. The personal data form will not be used by the research team, with exception of neurological evaluation contact or in case of extreme necessity to contact the patient for further information (for example, in order to obtain important missing information in the data collection form).

Same level of confidentiality is guaranteed for all the retrospective data obtained from the EMS database.

The research team declares to have no conflicts of interest with any party or organ related to this study. The PAD project and this study are carried on with the only aim to improve the outcomes from the OHCA in the population of Girona, and hence benefit the same population.

This study will be carried out in accordance with the ethical principles and guidelines established by The Helsinki Declaration and the Spanish Organic Law 15/1999, December 13th, of personal data protection (*Ley Orgánica 15/1999, de 13 de Diciembre, de Protección de Datos de Carácter Personal*).

Once this protocol is finished, before starting the research, this project will be presented at *Comitè d'Ètica d'Investigació Clínica* (CEIC) Hospital Doctor Josep Trueta, which is the organ in charge for the ethical evaluation of research projects done in the province of Girona.

10. STRENGTHS AND IMPACT

The main impact of this study is the innovation in the field of a widely spread public-access AED usage. This would be the first study done in Spain to evaluate the survival rate in patients with OHCA after public-access AED implementation in a whole province.

Most of the publications in this field are studies done at high-schools, airports, public areas in USA, Canada, Japan(13,15,23). A few studies are done in Europe, such as Capucci et al(19), Hanefeld et al(21), Davies et al(20) etc.

In 2003, Lobatón et al published the results of an early defibrillation program, where AEDs were distributed to previously trained non-medical personnel (EMS technicians), in the autonomous community of Galicia(16).

So this project will be one of the most important in this field, as the AED implementation program in Girona is much more widely spread, covering a major geographical area and population.

Another strength of this study is that its results can be easily extrapolated to other parts of Spain, as the Spanish population will be much more similar to Girona, than to the other studies from USA, Japan, UK, Italy or Germany. The results of this study will provide evidence as to whether public early-defibrillation projects can be of benefit in other parts of Spain.

This research topic in itself is also a strength of this study, as the OHCA is a very important issue for our health system, and a very few work has been done to improve

its management and to conclude precise data over the actual situation. This study will provide more information in this field.

Our research team is also well competitive to carry on this study as most of the participants, except the medical student, have experience in scientific publication and are specialized medical practitioners with clinical experience.

11. LIMITATIONS

The most important limitations to carry out our study are:

- **Lack of local background information:** as this is a pioneer project, during the bibliographical research mostly all the previous work on public access defibrillation (PAD) had been obtained in other countries (such as USA, Japan, other European countries). We have to assume that there might be some differences in demographic factors like density of population, and epidemiological risk factors for cardiovascular diseases. This could lead us to expect erroneous survival rate increase with the public-access defibrillation. But as all these studies were published in well-developed countries, with more or less similar infrastructure to ours. Thus, we assumed to design our research proposal based upon the knowledge obtained from these studies.
- **Difficulties for data collection:** EMS personnel attending the OHCA victims is the in charge for a part of data collection in our project. But we have to accept that sometimes it may be difficult to handle information in an emergency situation. This would be a great limitation for our study, as the analysis would be biased if some data was missing. That is why we included a personal data collection form, so that the research team could later contact with the victims if important data like time from collapse to shock, type of CPR, bystander type etc. are missing. It would be done only if the victim previously signed the informed consent and accepted to give further information if necessary.

- **Retrospective data collection:** our data about the OHCA previous to the AED implementation comes out from a database created by the EMS data collection. This can be a possible limitation for this project, as some of the information in the databases may be missing or not fully reliable. As this is the only way to have retrospective data, we will accept this risk to carry on our research.
- **Type of study:** even though with a descriptive study we can only suggest a relationship between the principle study variables and not demonstrate a temporal relationship, an experimental study, such as clinical trial, would not be ethical for the purpose of our study.

12. WORK PLAN

The research team will be constituted by different specialists. Each of them will have a task assigned during the different phases of this study. There will be a last year medical student, two cardiologists, two neurologists and the territorial EMS director. There are several EMS personnel working in Girona who will collaborate for data collection under the leadership of the territorial director, but will not be part of the research team. A statistician will be contracted for the statistical analysis.

The whole project will last over 5 years approximately, as according to our sampling we will have to collect data during 4 years after AEDs implementation to have enough potency in our study.

12.1 Initial coordination

This will be an all-member meeting to start the project, define the roles of each participant, and to create a chronogram clarifying the different phases of the study. This type of coordination meetings will be repeated during the study to debate if there are any problems and also if any modification needs to be done. The whole research team will keep in contact via e-mail, just in case there is a need for improvisation and an extraordinary meeting is needed to be organized.

12.2 Bibliography research

Our objective and hypotheses are based upon the previous knowledge we obtain from other studies done in this field. So this part will be realized by the whole team, and it

will take us over 4 months to plan our study, trying to avoid the problems other authors may have encountered in similar studies.

Beside this first part, more bibliography will also be consulted during other phases of the study if needed.

12.3 Protocol development

Once the bibliography research is done, the whole protocol for the study will be written with the collaboration of all the research team, as before carrying it out approval from ethical committee (*CEIC*) will be needed. It will take about two months.

12.4 Data collection

If the study is approved to be done, the data collection process will start. The medical student and the cardiologists will ask permission from the EMS to access their database in order to achieve retrospective data about the OHCA episodes during 4 years before the AEDs implementation, a total of 749 cases.

The EMS personnel will collect the prospective data from each OHCA during almost 4 years in order to complete our sample. The territorial director will manage their internal coordination for the data collection. During this period the research team will be in charge of checking out the collected data and of filling the survival to discharge in each case.

The medical student and the cardiologists will be in charge for analyzing the ECG registered by the AEDs used in each OHCA, to achieve the shock-delivery time and the initial ECG rhythm.

The neurologists from Hospital Josep Trueta will be in charge of performing the neurological evaluation with the CPC scale a month after the hospital discharge. This phase of the study will last over 4 years approximately.

12.5 Data organization and statistical analyses

Once the data collection is finished according to our sampling, the whole data will be organized in a database by the research team. Also the necessary descriptive, bivariate and multivariate analyses will be performed by the statistician in this period. This part will last about 3 months approximately.

12.6 Final article elaboration and publication of results

This will be done by the research team once the data has been analyzed and concluded. The final article will be published in different medical journals in order to make a correct diffusion of the results. This part will finally take over 3 more months.

13. CRONOGRAM

	Oct 14	Nov 14	Dec 14	Jan 15	Feb 15	Mar 15	Apr 15- Apr 19	Ma y 19	Jun 19	Jul 19	Aug 19	Nov 19	Dec 19
Coordination meeting													
Bibliography review													
Protocol Development													
Data collection													
Data organization and analyses													
Article elaboration and publication													

14. BUDGET

The research team will be in charge for most of the tasks in this study like the bibliography research, redaction, publication etc. The only extra personnel needed will be the EMS personnel for the data collection and a statistician.

The statistician will be contracted for the data analysis, which is estimated to take about 25 hours of work. For rate of 30€ per hour, it will be of a total cost of 750€.

Various coordination meetings will be needed. We calculate that a total of 8 meetings will take place, but may be some more extraordinary meetings will be necessary. We estimate an approximate cost of 40€ per meeting (includes team members' transport), and hence a total cost of 320€ for the 8 meetings.

Consumable material needed for this project is a computer machine, which will be used for bibliographical research, data collection and project handling. It will cost around 500€.

The redaction and the diffusion of the final article is task of the research team, but the cost of peer reviewing and publication in the scientific journals goes up to 2,000€ right now.

Later this project will be presented at the European Resuscitation Council Congress. This international conference will need a budget of about 3,000€, to fulfil the needs of participation cost, plane tickets, hotel reservation for three of the team members (the medical student and the two cardiologists).

BUDGET	
Coordination meetings	320€
Consumable material	500€
Statistician service	750€
Redaction and publication	2,000€
ERC congress participation	3,000€
TOTAL	6,570€

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16. ANNEXES

Annex 1: Divulagation Pamphlet

Annex 2: CPC Scale for Neurologic evaluation

Annex 3: Cardiac Arrest Registry Form

Annex 4: Personal data collection form

Annex 5: Information sheet

Annex 6. Informed Consent

16.1 Annex 1

Com s'utilitza un desfibril·lador?

Quan menys us ho espereu podeu trobar-vos amb la necessitat d'usar un desfibril·lador. Dipsakut –dins el programa "Girona, territori cardioprotegit"– n'implanta a places, carrers i façanes d'equipaments dels municipis gironins. L'objectiu és facilitar una ràpida intervenció en casos d'aturada cardíaca. Els passos que heu de seguir per auxiliar algú que pot haver patit una aturada cardíaca són:

- 1** **COMPROVEU SI LA VÍCTIMA ESTÀ CONSCIENT, SI RESPIRA I SI TÉ POLS.** Demaneu, si és possible, la col·laboració d'algú.
- 2** **TRUQUEU AL TELÈFON D'EMERGENCIES 112 I CORREU A BUSCAR EL DESFIBRIL·LADOR MÉS PROPER.** Porteu-lo al lloc dels fets.





- 3^a** **OBRIU LA TAPA DEL DESFIBRIL·LADOR I SEGUIU LES INSTRUCCIONS DE VEU QUE DONA.** Ageteu els pegats i enganxeu-los a la víctima: l'un –qualsevol–, a la part dreta, sobre el pit, i l'altre, a la part esquerra, sota el pit, a la zona de les costelles.
- 3^b** **SI L'APARELL DECIDEIX QUE ÉS CONVENIENT PER LA DESCÀRREGA,** us avisarà per tal que no toqueu la víctima mentre la fa.
- 3^c** **SI LA PERSONA ES RECUPERA, EL DESFIBRIL·LADOR DEIXARÀ D'ACTUAR. SI NO, L'APARELL REALITZARÀ MÉS DESCÀRREGUES.** En aquests intervals practiqueu –si en teniu nocions– les manobres de reanimació cardiopulmonar a la víctima.





- 4** **ESPEREU L'ARRIBADA DE L'AMBULÀNCIA.**



Com és la columna dels desfibril·ladors?

Els desfibril·ladors instal·lats a la via pública dels campus de la UdG són dins d'unes columnes com aquesta:



Girona territori cardioprotegit
www.girona.territori.heartprotegit.cat

Cerebral Performance Categories

1. **Good cerebral performance.** Conscious. Alert, able to work and lead a normal life. May have minor psychological or neurological deficits (mild dysphasia, nonincapacitating hemiparesis, or minor cranial nerve abnormalities).
 2. **Moderate cerebral disability.** Conscious. Sufficient cerebral function for part-time work in sheltered environment or independent activities of daily life (dressing, traveling by public transportation, and preparing food). May have hemiplegia, seizures, ataxia, dysarthria, dysphasia or permanent memory or mental changes.
 3. **Severe cerebral disability.** Conscious. Dependent on others for daily support because of impaired brain function (in an institution or at home with exceptional family effort). At least limited cognition. Includes a wide range of cerebral abnormalities from ambulatory with severe memory disturbance or dementia precluding independent existence to paralytic and able to communicate only with eyes, as in the locked-in syndrome.
 4. **Coma, vegetative state.** Not conscious. Unaware of surroundings, no cognition. No verbal or psychological interactions with environment.
 5. **Death.** Certified brain dead or dead by traditional criteria.
-

CPC, Cerebral Performance Categories.

Adapted from Cummins, R. O., Chamberlain, D. A., Abramson, N. S., Allen, M., Baskett, P., Becker, L. Eisenberg, M. (1991). Recommended guidelines for uniform reporting of data from out-of-hospital cardiac arrest: the Utstein Style. Task Force of the American Heart Association, the European Resuscitation Council, the Heart and Stroke Foundation of Canada, and the Australian Re. *Annals of Emergency Medicine*, 20(8), 861–74. Retrieved from http://circ.ahajournals.org/content/84/2/960.full.pdf+html?ijkey=01c2b05251464dc b406947673dbdf84243627b82&keytype2=tf_ipsecsha

16.3 Annex 3

Cardiac Arrest Registry Form

Patient ID: _____

Date of OHCA: _____

Sex: Male Female

Age: ____ years

Smoking: Smoker Non-smoker Former-smoker

1. Use of public-access AED YES NO

2. OHCA location:

- a. Home
- b. Public schools
- c. Streets
- d. Sports centers
- e. Girona city Airport
- f. Others

3. Initial ECG rhythm:

- a. Ventricular fibrillation
- b. Asystolia
- c. Other

4. Time interval between collapse and AED shock delivery:

Call reception at: _____ AM/PM Shock-delivery at: _____ AM/PM

Interval: _____ minutes

5. Bystander cardiopulmonary resuscitation:

- a. Conventional CPR
- b. Chest-compressions only
- c. No CPR

6. Type of bystander:

a. Trained for the CPR

b. Not trained for CPR

7. Number of discharges given: _____ discharges

8. Initial survival: YES

NO

9. Survival to discharge: YES

NO

10. Neurological outcome in 1 month:

a. Favorable

b. Unfavorable

16.4 Annex 4

Personal Data Form

Patient ID: _____

Date of OHCA: _____

Sex: Male Female

Age: ___ years

Name:

Surname:

Address:

Phone number:

Full d'informació al participant

Agraïm la seva col·laboració en aquest projecte. La seva participació contribuirà a la millora del coneixement i maneig que tenim de les aturades cardíques.

Objectiu

L'objectiu principal de l'estudi és descriure la utilitat que tenen els Desfibriladors Automàtics (DEA) distribuïts a la província de Girona per augmentar la supervivència de casos d'aturades cardiorespiratòries fora de l'àmbit hospitalari.

Col·laboració sol·licitada

La participació a l'estudi és totalment voluntària. El que li demanem és que ens doni permís per consultar les dades necessàries per aquest estudi, com l'informe de l'ambulància. La informació serà emmagatzemada a una base de dades anonimitzada que només serà utilitzada per la finalitat d'aquest estudi.

També ens agradaria poder contactar amb vostè en un mes i concertar una visita per fer-li una revisió mèdica, on un metge neuròleg valorarà el seu estat cerebral funcional per revisar les seqüeles de l'aturada. Això contribuirà també a millorar el coneixement que tenim de les aturades cardíques sobtades.

Li garantim que les seves dades seran tractades amb absoluta confidencialitat segons la Llei Orgànica 15/1999, de 13 de desembre de protecció de dades de caràcter personal. També es respectarà la llei d'investigació biomèdica (14/2007) i qualsevol altra que resulti aplicable. Les dades seran utilitzades exclusivament amb finalitats d'aquesta investigació científica.

A més, vostè té el dret a sol·licitar als investigadors de l'estudi, en qualsevol moment i sense necessitat d'especificar el motiu, l'eliminació de les seves dades. Per contactar amb el responsable pot dirigir-se a:

Manjot Singh

Adreça: C/ Agudes, 8-10, 1-1, 17006 Girona

Telf. Contacte 658647788

Correu electrònic: ms281190@gmail.com

D'altra banda deixem constància tan de què vostè no s'exposa mena de risc ni perill físic per aquesta participació, com tampoc rebrà cap mena de retribució dinerària per aquesta participació voluntària.

Per portar a terme el projecte que li hem exposat, i atenent a les disposicions legals vigents, sol·licitem la seva autorització. Abans i després de firmar aquest document, del qual vostè se'n quedarà una còpia, pot preguntar tot allò que cregui convenient als metges o personal sanitari responsable de l'estudi.

Nom i cognoms:.....

Signatura:

Data:/...../.....

Consentiment informat

Declaració del participant

He estat informat per el professional de salut que signa aquest consentiment:

- ✓ De las finalitats i implicacions del present estudi;
- ✓ Sobre el procés d'obtenció, magatzem i procés de les dades personals;
- ✓ Que pot ser necessari consultar la informació relacionada amb aquest estudi del meu historial clínic;
- ✓ Que està garantit el compliment de la llei de protecció de dades (15/1999);
- ✓ Que les dades obtingudes tenen com objectiu la investigació biomèdica i que se'n respectarà la llei a tal efecte (14/2007);
- ✓ Que la participació és voluntària i que en qualsevol moment puc revocar el meu consentiment i sol·licitar l'eliminació de les meves dades personals sense cap repercussió en l'atenció sanitària posterior;
- ✓ A més, he pogut fer les preguntes que he considerat oportunes.

D'altra banda, accepto que personal relacionat amb aquest estudi es posi en contacte amb mi en el futur per conèixer el meu estat de salut.

Nom:.....

Signatura:

Data:/...../.....

Declaració del professional de salut mèdica de que ha informat degudament al participant.

Nom:.....

Firma:

Data:/...../.....

APARTAT PER A LA REVOCACIÓ DEL CONSENTIMENT

Jo,, revoco el consentiment de participació a l'estudi a sobre indicat.

Firma:

Data:/...../.....
