ORIGINAL ARTICLE

Cost-effectiveness of a semi-automatic external defibrillation program in Galicia

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None

Objective: To assess the cost-effectiveness of semiautomatic external defibrillator use in a program started in 2001 by the emergency service of the public health service in Galicia, Spain (the FPUS-061 service).
Methods: We calculated the survival rate after cardiorespiratory arrest before and after starting use of semiautomatic external defibrillators; pre-program data for 1999-2000 were compared with data for 2006, when the program was in full operation. All costs related to the program were identified, classified, and recorded; increases were then calculated. Percentages of improvement between the baseline (100%) and second measurement periods were assessed for 3 measures of effectiveness: attempted resuscitations after cardiorespiratory arrest, recovery of vital constants, and survival on hospital discharge. The cost-effectiveness ratio for all cardiorespiratory arrests was compared with the ratio for arrests treated with a semiautomatic external defibrillator.
Results: Attempted resuscitations increased by 72% over baseline, recovery of vital constants increased by 107%, and survival increased by 221%. Total costs related to implementing the use of semiautomatic external defibrillators rose by €122 974.57. The cost per survivor discharged after a cardiorespiratory arrest that was treated with a semiautomatic external defibrillator was €8783.90.
Conclusions: The FPUS-061 program for using semiautomatic external defibrillators is clearly effective in terms of the number of cardiorespiratory arrests attended, recovery of vital constants, and survival at hospital discharge. Survival increased more than 200% over the baseline situation. This study reveals that the cost-effectiveness ratio is very high. [Emergencias 2011;23:8-14]

Key words: Semiautomatic external defibrillator. Ventricular fibrillation. Costs and cost analysis. Emergency health care.

Introduction

Currently the most frequent cause of adult mortality in industrialized countries is cardiopulmonary arrest (CPA) caused by coronary heart disease[1]. In Spain, CPA is estimated to account for approximately 16,000 deaths a year[2], with 70-80% due to ventricular fibrillation (VF)[3].

Acute myocardial infarction (AMI) affects 63,000 people a year in Spain, and one third of these die before reaching hospital. A quarter of AMI mortality occurs in the first hour, 40% in the first two hours and 60% in the first six hours[4]. The younger the victim, the higher the rate of out-of-hospital death. Thus, in AMI victims aged less than 55 years, 94% of mortality occurs outside the hospital.

The time interval from unconsciousness to defibrillation is the major determinant of survival in CPA[5].

Cardiovascular disease (CVD) in all its forms is the main health problem facing the European Union (EU). A recent study by the University of Oxford6 indicates that CVD in the 25-member EU generated costs of 169,000 million euros in 2003. One in every 100 EU citizens (4.4 million) was affected by the disease.

Although any economic approach to health problems is liable to controversy, and should not be the main consideration in a public-access defibrillation program, the cost-effectiveness of implementing such a program must be evaluated and made known. Nichol et al, in a meta-analysis of studies on cardiopulmonary resuscitation (CPR) performed by emergency medical services (EMS), found that the reduction in time to defibrillation not only improved survival but was also beneficial in economic terms[7]. In the OPALS II study, the cost

per life saved of the early defibrillation program was €42,000 in setting up the program and €1,800 in maintenance[8].

The aim of this study was to evaluate the relationship between cost and effectiveness of the SAED program. This involved analyzing the program results and associated economic costs. The concept of effectiveness refers to the impact resulting from an action carried out under routine conditions. Thus it refers to the benefit for an individual or group derived from the application of a pharmacological or practical medical procedure[9]. Cost-effectiveness analysis is a form of full economic evaluation that examines both the costs and consequences of the programs or medical treatment[2]. This kind of economic analysis establishes some kind of relationship between inputs and outputs of an activity, ie, the costs and consequences or results. It is used to establish criteria for deciding between the different possible uses of scarce resources. This study therefore aimed to measure the effectiveness of the program or, in other words, to determine whether there is a positive relationship between the inputs required and outputs obtained, and whether this ratio is more favorable than that prevailing in the previous situation before the implementation of the program, by calculating costs and assessing whether they are acceptable and justified.

Methods

In the first stage of the study, in order to assess improved survival rates of SCA patients with rapid access to early defibrillation, we obtained:

– Data from the pre-SAED period, from April 1999 to December 2000. This covered the previous situation in the Autonomous Community of Galicia regarding out-of-hospital PCA patients attended by the emergency service FPUs-061, an agency of the Galician Health Service responsible for coordination and emergency health care throughout the region of Galicia.

– Data on PCA patients attended by basic life support (BLS) and advanced life support (ALS) ambulance teams in 2006. The BLS ambulances are staffed by two health transport technicians (HTT) specially in SAED use. Each time a SAED is used, a specific data sheet must be completed to cover the event and the data are recorded on a chip, which is handed to the physician responsible for each ALS. There are periodic meetings to discuss cases, reduce errors and identify areas for improvement in the program. All BLS (101) have a SAED type 2 Fore Runner by Philiphs. The ALS (9 land vehicles and 2 helicopters) are staffed by two HTT (except helicopters), a physician and a registered nurse. The ALS vehicles are equipped with manual Life Pack 12 defibrillators.

For data analysis we used:

– Computerized data sheets of the ALS services.

– Register of CPA diagnosed by the ALS services.

– Record Sheet of SAED use by BLS HTT and the computerized SAED form from the central coordination service of health emergencies-061 (CCUSA-061).

To access and process all the data, we received written permission from the management the FPUs-061, and all data were handled in accordance with the law, with patient identities unknown to the researchers.

The data were collected following the Utstein style recommendations[11]. However, some modifications were made depending on the data available and those needed to conduct the study (Figure 1). The year 2006 was chosen since that was when the SAED program became fully operational.

In the second stage, in order to calculate costs, we identified, categorized and quantified the cost structure of the SAED program, as follows:

– Variable costs: costs directly linked to carrying out the activity.

– Fixed costs: structural costs that exist regardless of whether or not the activity is carried out and to what extent.

– Direct costs: costs specifically attributable to a service/product.

– Semidirect costs: those in which one knows the activity that caused the cost, but some cost sharing must be considered since completion of the activity may be common to several services/products.

– Indirect costs: general overheads not directly attributable to a service/product.

Hospital costs are not included in any calculation of the study since we wished to focus on out-of-hospital costs.

In the second stage of the study we needed to evaluate the effectiveness of the SAED program. This was done using three indices, each reflecting the expected improvement from implementing the program, expressed as percentages, in the second period as compared to the first (baseline 100%). The criteria were based on the following criteria:

- Criterion-1: Number of patients treated (resuscitations attempted).
- Criterion-2: Recovery of vital constants.
- Criterion-3: Survival to hospital discharge.

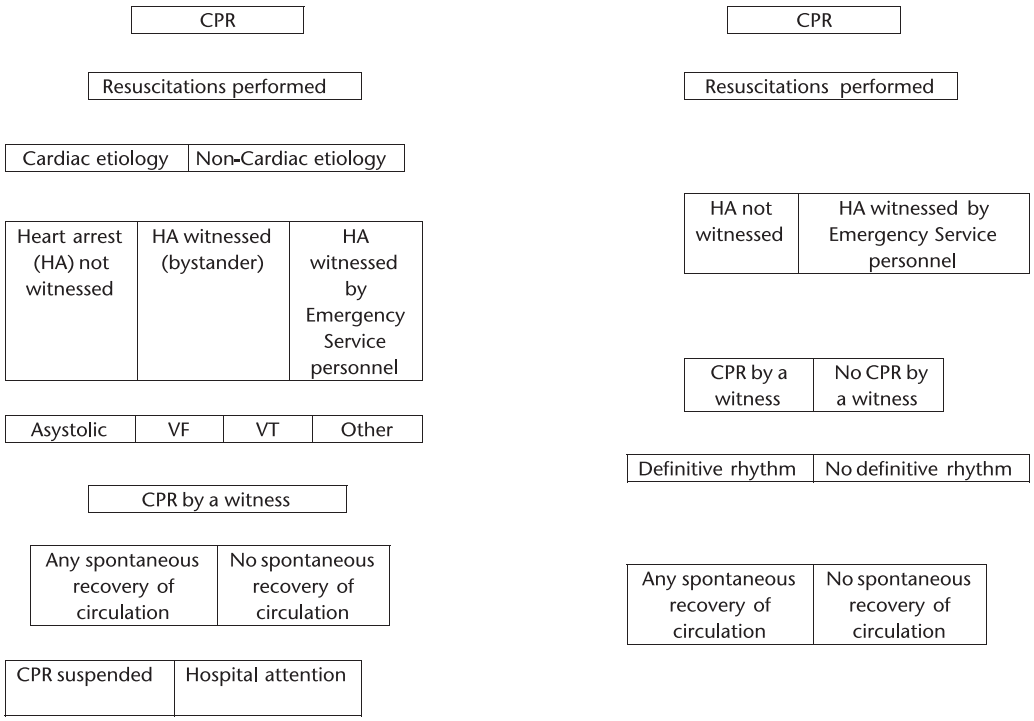

Figure 1. Esquema del estilo Utstein de recogida de datos (izquierda) y sistema modificado empleado en el presente estudio.

The indices (IC-1 IC-2 and IC-3) were calculated according to the following formula:

Index = [Performance using the SAED program/Performance without the SAED program] x 100.

Thus, for each of the criteria we used the results obtained before and after SAED program implementation, expressed as a percentage.

The third and last stage of the study was to estimate the relationship between the cost and effectiveness of the SAED program. In this study, we performed an incremental analysis, ie, we compared the additional costs arising from implementing the SAED program with the effects, benefits or additional utility that the program generated.

To assess the cost-effectiveness of the SAED program, we calculated the cost-effect ratio, taking survival as the the effect, i.e. lives saved after implementing the SAED program.

The cost-effectivness (CE) indices were defined as follows:

TOTAL CPA CE = incremental cost of the program/(number of survivors to hospital discharge in 2006 – number of survivors at discharge in the initial period).

SAED CPA EC = incremental cost of the program SAED/(number of survivors at discharge in 2006 treated with SAED).

We calculated both indices, although we attach more weight to the second index, since the former includes those who survive after being treated by ALS teams. The first index is of interest but it really should include the incremental cost of ALS treatment in the period 1999-2006.

For all the above calculations, we used data from the initial period (21 months) extrapolated to 12 months so that they would be comparable with the SAED period of 12 months. Quantitative variables were expressed as mean and standard deviation and were compared using Student t test, while qualititative variables are expressed as absolute values and percentages, and compared using the chi square test. A *p* value of less than 0.05 was considered statistically significant.

Results

Table 1 shows the total cost of the SAED program and the distribution of costs by categories. Table 2 summarizes the main data of the CPA patients attended by ALS units of the FPUs-061 in the two study periods, with significant differences in terms of the number of CPA patients attended, CPR initiated by bystanders and initial ECG before defibrillation, which was higher in the SAED period, as was response time. Table 3 includes all cases of CPA attended and treated with SAED during the year 2006, by both BLS and ALS units, as well as all cases of CPA attended by the emergency service FPUs-061 in the same period, in absolute numbers and percentages.

Table 4 shows the main comparative CPA data from the pre- and post-SAED periods, with pre-SAED data extrapolated to 12 months. It shows the increases in IC-1 IC-2 and IC-3 defined previously (program effectiveness). These data show that the incidence of CPA attended per 100,000 people per year has increased from 16.50 before the introduction of SAED to 28.46, an increase of 11.96 CPA attended per 100,000 people per year. Likewise, attended cases of CPA increased from an average 37.61 per month before SAED implementation to 64.88 per month after implantation. The percentage of change in the indices with respect to the initial period was +72%, +107% and +221%.

Regarding the cost-effectiveness of implementing the SAED program, total incremental cost was €122,974.57 in 2006 (a cost which obviously did not exist before the SAED program was implemented). The cost per CPA patient treated by 061 and discharged from hospital in the year 2006 was €1,983.46. The cost per CPA patient treated by RTSU-SAED and discharged from hospital in the year 2006 was €8,783.90.

Discussion

The system established in Galicia to attend CPA patients using RTSU BLS units, with the support of the CCUS-061 ALS units, has optimized resources needed for implementing such a program, reduced costs[12,13] and reduced implementation times with HTT involvement[14,15].

The economic cost of this project, and the possibility of extending it to a public-access defribillation (PAD) program[16] for places of general assembly where the probability of CPA events is high[17,18], have long been debated in our community since its inception and when the first results of lives saved became known. However, in the case in Galicia, most CPA events occur at home. The problem in rural areas remains the same; the economic cost of installing defibrillators in these places is enormous, with no cost-effectiveness[19,20]. In this respect there is much controversy about whether PAD programs are cost-effective or not[21]. We believe that for a community like Galicia, it would not be cost effective[22] as compared with RTSU ambulance servives, which have proved their worth and, in our view, constitute the right system for use in Galicia due to its characteristics[23]. This does not mean that we should not follow the recommendations of ERC[24] on PAD programs, but in Galicia this would mean installing a limited number of SAED.

Table 1. Distribution of costs in the SAED program, in euros

Cost type	Euros
Total relevant saed program costs	**122,974.57**
1. Direct and semi-direct costs	54,931.89
A. Variable costs	24,212.19
Expendables:	24,212.19
– Patches	13,786.00
– Batteries	9,168.89
– Compress	465.30
– Shavers	792.00
B. Fixed costs	30,719.70
– Defibrillators	30,719.70
2. Indirect costs (all fixed)	68,042.68
Study of needs, SAED program set up and execution in BLS units	2,515.17
SAED training	57,471.18
– Technical Course on SAED	18,460.00
– Refresher SAED course	39,011.18
Elaboration of Training Books:	4,419.30
– Student Guide	1,262.66
– Teacher's Guide	1,262.66
– Set of Slides	1,262.66
– Implementation Plan	631.33
Book publishing training plan:	1,738.00
– Student Guide	568.00
– Teacher's Guide	140.00
– Set of Slides	180.00
– Implementation Plan	850.00
14 SAED training simulators. With remote control and programming Kit	1,426.10
2 basic CPR dummy models with ventilation and massage options	472.94

BLS: Basic Life Support; CPR: Cardiopulmonary resuscitation.

The PAD study[24] and subsequent AHA recommendations[25] on PAD programs indicate that for one of these programs to be cost-effective, automated defibrillators should be placed in locations with a probability of at least one episode of sudden cardiac arrest every two years. The PAD study

Table 2. Summary of CPA attended by ALS units in the two study periods

	PRE-SAED Period (21 months) (N = 790)	SAED Period (12 months) (N = 455)	*P* value
Evolution (n, %)			0.41
– Recovery vital constants	233 (29.5)	147 (32.3)	
– Continued CPR	61 (7.8)	28 (6.2)	
– Death	495 (62.7)	280 (61.5)	
CPA attended (n, %)	179 (22.7)	142 (31.2)	< 0.001
Bystander CPR (n, %)	266 (33.7)	214 (47.0)	< 0.001
Initial rhythm (n, %)			< 0.05
– Defibrillation possible	258 (32.6)	175 (38.5)	
– Defibrillation not possible	532 (67.4)	280 (61.5)	
Location (n, %)			0.54
– Home	427 (54.0)	237 (52.1)	
– Other	363 (45.0)	218 (47,9)	
Response time (minutes) (mean ± SD)	13.9 ± 3.0	17.1 ± 3.2	< 0.001
Survival to hospital discharge (n, %)	92 (11.6)	48 (10.5)	0.61

CPR: Cardiopulmonary resuscitation; SD: Standard deviation.

Table 3. Results of CPA attention in 2006

	n (%)
CPA patients attended by BLS units with SAED in 2006	
Patients receiving SAED treatment	321
Patients defibrillated	69 (21.5)
On-site recovery of spontaneous circulation	38 (11.8)
Survival to hospital discharge without sequelae	14 (4.4)
Total CPA treated in the year 2006 (BLS + ALSU)	
Patients	776
Patients defibrillated	244 (31.4)
On-site recovery of spontaneous circulation	141 (18.2)
Survival to hospital discharge without sequelae	90 (11.6)

BLS: Basic Life Support; SAED: Semiautomatic external defibrillation; ALS: Advanced Life Support.

included sites with assemblies of at least 250 people over 50 years of age in the area during daylight hours (approximately 16 hours).

The incidence of attended CPA per 100,000 people per year has increased from 16.50 before the introduction of the SAED to 28.46 after it. This is almost double the number of CPA cases attended each year in Galicia, either by medicalized ambulances or RTSU units equipped with a SAED. The number of out-of-hospital CPA cases in Galicia has increased from 37.61 per month in the pre-SAED period to 64.88 per month after SAED implantation. This represents a 72.50% increase for the three years after implantation.

We found a high incidence of CPA, although this series relates primarily to cities, with only a few cases from non-urban areas. Even so, this higher incidence was to the large number of inhabitants and not to the influence of the rural area in our study.

Asessment of the proposed criteria showed very positive results. There was an increase of almost 75% in the number of resuscitations attempted (776-451). This index shows that with virtually the same resources (although there has been a small increase), we treated a large number of CPA cases with a defibrillator that were not adequately treated before. Two factors may help to explain this finding: firstly, there is greater public knowledge of the emergency service number 061 for attention of such emergencies, and secondly, increased health education and public awareness have enabled more of the general population to recognize the symptoms of a heart attack and those of CPA.

The second criterion is closely related to the first. The number of treated patients has increased, as has the number of victims who recover vital constants at the point of care (141-68). However, this increase is not linear. Increased recovery of vital constants is not only due to higher numbers being treated. The index shows a more than a two-fold increase after SAED implementation, so there must be other intervening factors.The decisive factor is the acquired expertise of the attending professionals, including their training and skills development, due to a specifically designed training program which has resulted in greatly improved learning, retention and acquisition of knowledge.

The third criterion indicates that survival rate of treated CPA patients has increased by over 300% (90-28). This is clearly the most important factor, since it is of little use to achieve recovery of vital constants in a victim who is later left with irreversible neurological sequelae. The important thing is undoubtedly high survival without sequelae, which is what this index measures.

From this study we were able to draw various conclusions, but above all we stress the fact that more CPA patients were treated in an appropriate manner, were resuscitated and were able to return to normal life. Considering that most were middle-aged patients, often with a reasonable work future, they not only recovered but also gained years of life with some quality. In this regard, it would be interesting to conduct a cost-utility study, assessing years of life gained adjusted for Quality of Life, which we believe could be quite high.

This type of study would also benefit from the inclusion of one-year survival data, but these are very difficult for the emergency service SEM to obtain. In any case, survival to discharge is a very good parameter to assess the effectiveness of a technique used during resuscitation.

Table 4. Comparison of outcomes of CPA care PRE and POST-SAED

	Total PRE-SAED (21 months, April 99-Dec 00)	PRE-SAED Extrapolation (12 months)	Total POST-SAED (12 months, Jan 06-Dec-06)	POST/ PRE-SAED ratio (%)	Percentage of change
Patients	790	451	776	172*	+72*
Patients defibrillated	259	148	244	165	+65
On-site recovery of spontaneous circulation	119	68	141	207**	+107**
Survival to hospital discharge without sequelae	48	28	90	321***	+221***
Percentage of survivors with respect to all patiens	6.1	6.2	11.6	187	+87

SAED: Semiautomatic external defibrillation. *Value of IC-1. **Value of IC-2. ***Value of IC-3.

Table 5. Estimated cost per life saved using SAED, in USA dollars

Defibrillation site	Estimated cost per life saved, in USA dollars
Galicia SAED Program 2006	**12,353.91**
Public area, by police officers (27)	27,000
Public area, by bystanders	44,000
Aircraft (28)	< 50,000
Large aircraft >200 passengers (29)	35,300
Nursing Homes (30)	87,837

The cost per patient discharged from hospital could not be assessed because it would have required prior assessment of the incremental costs of CPA care by ALS units. This cost has changed since the pre-SAED period (1999-2000). In view of the great difference in cost of patients discharged after receiving RTSU-SAED treatment, we consider that this study should be expanded to assess these costs and actually calculate the cost of conventional treatment by ALS physicians and nurses. We also believe this should be done, given the percentage of patients surviving to hospital discharge.

Regarding the primary endpoint, we found that in 2006 the incremental cost of each CPA patient treated with SAED and surviving at discharge was €8,730.90. Comparing this cost with those reported in other studies listed in Table 5, we found that the Galician SAED program occupied the top position in terms of lower cost per life saved.

Table 5 shows the comparison of cost in dollars per life saved of the major studies with that obtained in our autonomous community of Galicia in 2006 (exchange rate 1€ = 1.4195 USD). As can be seen, we are situated in the lower half of lower costs of those included in the program.

We conclude that the SAED program launched by FPUs-061 is clearly effective, with an increase in the number of treated CPA, vital constants recovery and survival to hospital discharge (IC-3). These data, together with the costs analyzed, show that the program is highly cost-effective.

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Estudio coste-efectividad de la implantación de un programa de desfibrilación externa semiautomática en Galicia

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Objetivo: Evaluar la relación coste-efectividad (C-E) del programa de desfibrilación externa semiautomática (DESA) puesto en marcha en el año 2001 por la Fundación Pública Urxencias Sanitarias de Galicia-061 (FPUS-061).
Método: Se valora la tasa de supervivencia de las paradas cardiorrespiratorias (PCR), antes y después de la implantación del programa DESA. Se utilizan los años 1999-2000 (pre-DESA) y 2006 (programa DESA implantado en su totalidad). Se calculó el coste incremental del programa mediante la identificación, clasificación y cuantificación de la estructura de costes del mismo. Se definieron tres índices para valorar la efectividad del programa, que estimaban el porcentaje de mejora clínica obtenida en el segundo periodo respecto al primero (valor basal 100%) en relación a tres criterios: resucitaciones intentadas (IC-1), recuperación de constantes (IC-2) y supervivencia al alta hospitalaria (IC-3). Se calculó también el C-E de la PCR en total y en la PCR tratada con DESA.
Resultados: Respecto a la efectividad del programa DESA, se obtuvo un IC-1 de + 72%, un IC-2 de + 107% y un IC-3 de + 221% como porcentaje de cambio relativo respecto al periodo inicial. Respecto al C-E de la implantación del programa DESA, el coste incremental total del programa DESA en el año 2006 fue de 122.974,57 €. El coste por paciente dado de alta hospitalaria que ha sufrido una PCR y ha sido tratado con un DESA en 2006 fue de 8.783,90 €.
Conclusiones: El programa DESA puesto en marcha por la FPUS-061 es claramente efectivo, con incremento en el número de PCR atendidas (IC-1), de recuperación de constantes (IC-2) y de altas hospitalarias (IC-3). La supervivencia se incrementó en un 200% respecto al periodo anterior a su implantación, y la relación C-E del programa DESA es muy elevada. [Emergencias 2011;23:8-14]

Palabras clave: Desfibrilador externo semiautomático. Fibrilación ventricular. Costes de salud. Servicios de emergencias médicas.