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Follow-up of the patient with automatic implantable cardioverter-defibrillator

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ARTICLE INFORMATION

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The authors declare no competing interests.

Abbreviations
AICD: automatic implantable cardioverter-defibrillator
SCD: sudden cardiac death

ABSTRACT

Introduction: Implantable cardioverter-defibrillators improve the survival of patients at risk of sudden cardiac death. There is relatively little data in our country about their follow-up effectiveness.

Objectives: To describe the outcome of patients with primo-implantation of an automatic cardioverter-defibrillator during follow-up.

Methods: An ambispective longitudinal cohort study was conducted in 47 patients with primo-implantation of a cardioverter-defibrillator in the period September 2007 to December 2016, ending on December 31, 2017. The cumulative probability of survival was estimated through the Kaplan-Meier curves.

Results: Mean age was 57 ± 14.6 years, with male predominance (74.5%) and indication in secondary prevention (83%). Adequate therapies were found in 57.4% of patients, inadequate therapies in 23.4%, implantable cardioverter-defibrillator proarrhythmia in 14.9% and arrhythmic storm in 12.8% of patients. Adequate therapies were related to an ejection fraction ≤ 35% (p=0.022) and age (p=0.031). Cumulative free survival from the first event at four years was 34,7%. Cardiovascular mortality was related to: existence of structural heart disease (p=0.044), ejection fraction ≤ 35% (p<0.001), functional class III-IV (p=0.046), adequate therapies (p=0.014) and arrhythmic storm (p=0.002). Cumulative free survival of cardiovascular mortality was 70.7% at the fourth year.

Conclusions: The survival of patients with implantable cardioverter-defibrillator is satisfactory. Mortality is associated with further deterioration of cardiovascular status and with device therapies.

Keywords: Implantable cardioverter-defibrillator, Sudden cardiac death, Sudden arrhythmic death, Proarrhythmia

Seguimiento del paciente con cardiodesfibrilador automático Implantable

RESUMEN

Introducción: Los cardiodesfibriladores mejoran la supervivencia de los pacientes con riesgo de muerte súbita cardíaca. Existen escasos datos en nuestro país acerca de su eficacia en el seguimiento.

Objetivo: Describir la evolución en el seguimiento de los pacientes con primoimplante de un cardiodesfibrilador automático.

Método: Estudio ambispectivo, longitudinal, en 47 pacientes con primoimplante de un cardiodesfibrilador en el período septiembre de 2007 a diciembre de 2016,

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AMB and TOTB: Data analysis and interpretation and helping in the manuscript writing.
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con cierre el 31 de diciembre de 2017. La probabilidad acumulada de supervivencia se estimó a través de las curvas de Kaplan-Meier.
Resultados: La edad media fue de 57 ± 14,6 años, con predominio del sexo masculino (74,5%) y la indicación en prevención secundaria (83%). Presentaron terapias apropiadas el 57,4% de los pacientes, terapias inapropiadas un 23,4%, proarritmia del cardiodesfibrilador un 14,9% y tormenta arrítmica el 12,8% de los pacientes. Las terapias apropiadas se relacionaron con la fracción de eyección ≤ 35% (p=0,022) y la edad (p=0,031). La supervivencia acumulada libre del primer evento a los cuatro años fue 34,7%. La mortalidad cardiovascular se relacionó con: existencia de cardiopatía estructural (p=0,044), fracción de eyección ≤ 35% (p<0,001), clase funcional III-IV (p=0,046), terapias apropiadas (p=0,014) y tormenta arrítmica (p=0,002). La supervivencia acumulada libre de mortalidad cardiovascular fue de 70,7% al cuarto año.
Conclusiones: La supervivencia de los pacientes con cardiodesfibrilador es buena. La mortalidad se asocia a un mayor deterioro del estado cardiovascular y a las terapias del dispositivo.
Palabras clave: Cardiodesfibrilador automático implantable, Muerte súbita cardíaca, Muerte súbita arrítmica, Proarritmia

INTRODUCTION

Sudden cardiac death (SCD) is a major challenge to modern cardiology, because of its incidence, form of presentation and socioeconomic implications. It represents 90% of all sudden deaths and 10-30% of all natural deaths[1]. It is the beginning of the underlying disease in about 30-50% of patients, and in 30% of those recovered, the arrhythmic event recurs[2]. Approximately 80% of the events take place in the context of the coronary heart disease and malignant ventricular arrhythmias are responsible for most of these[3].

The automatic implantable cardioverter-defibrillator (AICD) has shown, in different trials in primary and secondary prevention, a reduction in arrhythmic SCD. This justifies the fact that, in recent decades, its indications have become more widespread, with an increasing number of patients using this device[4-9].

Patients' selection must be individualized, considering the cost-effectiveness analysis, access to therapy and safety. Out of the clinical trials, there is little data on the prolonged follow-up of patients with AICD, about the efficacy, survival and useful life of the device, which is the reason why this research was carried out, with the aim of describing the evolution of patients with an AICD primo-implantation during the follow-up.

METHOD

A unicenter, observational, longitudinal, ambispective study was carried out in patients with a primo-implantation and follow-up of a AICD in the Department of Arrhythmia and Pacemaker of the *Hospital Hermanos Ameijeiras*, in the period from September 2007 to December 2016, with follow-up closing on December 31, 2017. In case of death, the date of death was taken as the follow-up closing. The sample consisted of 47 patients.

During the primo-implantation, an outpatient medical record was made and filed for each patient, containing the clinical and procedural data.

Implantation protocol, programming and follow-up of the AICD

The criteria for the implantation of the AICD were based on the international management guidelines adapted to our country.

The implantation of the system was transvenous, via left subclavian or its tributary veins, and the generator was located in the pectoral region. Antibiotic prophylaxis with cefazolin was carried out, administrating one gram during the procedure, to be continued every eight hours for 48 hours. Stimulation threshold, R-wave amplitude and impedance measurements were taken during the intraoperative period.

The programming of the AICD was preformed taking into account: underlying heart disease, clinical conditions, type of prevention, characteristics of the arrhythmia and pharmacological therapy. A detection area of ventricular fibrillation (188 to 210 beats per minute) was programmed, with antitachycardia therapy during the loading, and a detection area of

ventricular tachycardia ten beats per minute lower than clinical tachycardia, with antitachycardia therapy (three to six repetitions) and shock in case the previous one failed. Algorithms were activated to discriminate supraventricular tachycardia.

Clinical and device controls were performed at the fourth week from the implantation and then, every three to six months, or according to the patient's clinical condition. During each follow-up, the AICD was checked, and the stored events were recorded, which were analyzed and classified, independently, by two electrophysiologists. The outpatient medical record was updated during each follow-up.

Variables of interest were obtained through reviewing the individual medical record stored in the department.

Statistical analysis

Variables with a regular distribution were summarized as mean and standard deviation, and those with non-parametric distribution were expressed in mean and interquartile range. Nominal variables were expressed in frequencies and percentages.

The association between quantitative and qualitative variables was determined using the Student´s t-test, and in absence of a parametric distribution, the Mann-Whitney U test was applied. The relationship between qualitative variables was obtained using the Chi square test (χ^2). The estimation of free survival of adequate therapies and cardiovascular mortality was determined using the Kaplan-Meier method. A significance level of 0.05 was set for all hypothesis tests. The statistical processing was performed using the SPSS program (Chicago Illinois, USA), version 20.

The research was approved by the Institutional Committee of Ethics, and during its whole development, the ethical procedures regarding the information sources' management were met.

RESULTS

The mean age at the moment of the device implantation was 57±14.6 years old, prevailing males (74.5%). The most frequent underlying heart disease was the ischemic one (31.9%). A 46.8% of patients had left ventricular ejection fraction (LVEF) ≤ 35% and 74.5% were in NYHA (New York Heart Association) functional class II-III. Sustained monomorphic ventricular tachycardia (38.3%) was the most common arrhythmia, and only 17% of the patients were indicated for AICD in primary prevention. A 48.9% of the implanted devices were dual-chamber pacemakers (**Table 1**).

Table 1. General characteristics (n=47).

Variables	Nº	%
Age (mean ± SD)	57 ± 14.6	
Sex		
Male	35	74.5
Female	12	25.5
Underlying heart disease		
Ischemic heart disease	15	31.9
NIDCM	12	25.5
Hypertrophic cardiomyopathy	3	6.4
Heart valve disease	3	6.4
Channelopathies	2	4.3
Other cardiomyopathy	2	4.3
Idiopathic ventricular fibrillation	10	21.3
Functional Class		
I	11	23.4
II	18	38.3
III	17	36.2
IV	1	2.1
LVEF		
≤ 35 %	22	46.8
36-49 %	5	10.6
≤ 50 %	20	42.6
Motive for AICD implantation		
Primary Prevention	8	17.0
VF/PVT	17	36.2
SMMVT	18	38.3
Syncope and induction of VF/PVT/SMVT in EPS	4	8.5
Type of AICD		
Single-chamber	21	44.7
Dual-chamber	23	48.9
Triple-chamber	3	6.4

AICD, automatic implantable cardioverter-defibrillator; EPS, electrophysiological study; LVEF, left ventricle ejection fraction; NIDCM, non-ischemic dilated cardiomyopathy; PVT, polymorphic ventricular tachycardia; SMVT, sustained monomorphic ventricular tachycardia; SD, standard deviation; VF, ventricular fibrillation.

A 14.9% of cases presented complications during

Table 2. Distribution of patients according to the follow-up variables (n=47).

Variables	Nº	%
Late complications		
Related to the electrodes	4	8.5
Deep venous thrombosis	1	2.1
Increase of defibrillation threshold	1	2.1
Aseptic necrosis of the generator pocket site	1	2.1
Total	7	14.9
Use of antiarrhythmic drugs		
Amiodarone	28	59.6
Quinidine	3	6.4
Total	31	66.0
First generator replacement	10	21.3
Second generator replacement	3	6.3
Cardiovascular mortality	11	23.4

Table 3. Distribution of patients according to the occurrence of AICD therapies (n=47).

Variables	Nº	%
Adequate therapies	27	57.4
Inadequate therapies		
Supraventricular tachycardia	5	10.6
Detection failure	5	10.6
Non-sustained VT	1	2.1
Total	11	23.4
Arrhythmic storm	6	12.8
AICD proarrhythmia	7	14.9
Ventricular arrhythmias without intervention of the AICD	6	12.8

AICD, automatic implantable cardioverter-defibrillator; VT, ventricular tachycardia.

the follow-up and those related to the electrodes were the most common ones (8.5%). In 66% antiarrhythmic drugs were used simultaneously with the device, and amiodarone was the most indicated one (59.6%). In a 21.3%, a first generator replacement was performed, and a second one in the 6.3%. Cardiovascular mortality was 23.4% (**Table 2**).

Adequate therapies took place in 57.4% of patients. Inadequate therapies were registered in 23.4%; supraventricular arrhythmias (10.6%) and detection failures (10.6%) were the most common causes (**Table 3**). A 12.8% presented at least one arrhythmic storm event, AICD proarrhythmia (14.9%) and ventricular arrhythmias without intervention of the device (12.8%) were also noted.

Mean age was significantly higher in patients with adequate therapies (p=0.031), and LVEF ≤ 35% was statistically associated (p=0.022) with a higher frequency of adequate therapies (**Table 4**).

In the univariate analysis (**Table 5**), cardiovascular mortality was related to the presence of structural heart disease (p= 0.044), LVEF ≤ 35% (p< 0.001), functional class III-IV (p=0.046), adequate therapies (p=0.014) and arrhythmic storm (p=0.002).

Table 4. Relationship between the AICD adequate therapies and the variables at the moment of the implantation.

Clinical variables	Adequate therapies		p
	Yes (n=27) Nº (%)	No (n=20) Nº (%)	
Functional Class III-IV	13 (48.1%)	5 (25.0%)	0.190[a]
LVEF ≤ 35%	17 (63.0 %)	5 (25.0 %)	0.022[a]
Atrial arrhythmias	14 (51.9%)	6 (30.0%)	0.230[a]
Structural heart disease	23 (85.2%)	12 (60.0%)	0.105[a]
Secondary prevention	24 (88.9%)	15 (75.0%)	0.258[b]
Age (mean ± standard deviation)	61.00 ± 12.49	51.50 ± 15.89	0.031[c]

[a] Chi square test (χ^2) with correction
[b] Mann-Whitney U test
[c] LVEF, left ventricle ejection fraction

In 100% of the patients with adequate therapies, these took place in the first four years after implantation, with a greater density of arrhythmic events in the first year (**Figure 1**). Free survival of adequate therapy was 65.6%, 56.1%, and 34.7% at the first, second, and fourth year after the implantation, respectively.

All deaths took place in the first four years of follow-up (**Figure 2**). Free survival of cardiovascular mortality was 91.4%, 81.7%, and 70.7% at the first, third and fourth year, respectively.

Table 5. Relationship between cardiovascular mortality and follow-up and clinical variables.

Variables	Cardiovascular mortality		p
	Yes (n=11)	No (n=36)	
	Nº (%)	Nº (%)	
Males	8 (72.7%)	27 (75.0%)	1.000[a]
Structural heart disease	11 (100.0%)	24 (66.7%)	0.044[a]
Functional Class III-IV	11 (100.0%)	25 (69.4%)	0.046[a]
Left ventricle ejection fraction ≤ 35%	11 (100.0%)	11 (30.6%)	<0.001[b]
Indication in secondary prevention	10 (90.9%)	29 (80.6%)	0.659[a]
Complications	4 (36.4%)	10 (27.8%)	0.710[a]
Adequate therapies	10 (90.9%)	17 (47.2%)	0.014[a]
Inadequate therapies	1 (9.1%)	10 (27.8%)	0.416[a]
Arrhythmic storm	5 (45.5%)	1 (2.8%)	0.002[a]
Age (mean age ± standard deviation)	63.8 ± 13.2	54.9 ± 14.6	0.097[c]

[a] Fisher's exact test
[b] Chi square test (χ) with correction
[c] Mann-Whitney U test

DISCUSSION

The research's outcomes provide information of interest to our field, since studies on this subject are scarce in the country. Although the sample size is modest, a prolonged follow-up, with a maximum of 10.4 years, compensates this fact. The demographic behavior has similarities with previous studies, with a predominance of ages close to 60 years old and males[10,11].

Acute ischemia and its consequences, the characteristics of the necrotic eschar and ventricular dysfunction create a vulnerable myocardium for SCD, which justifies that approximately 80% of SCD take place in this context. In the Spanish Implantable Cardioverter-Defibrillator Registry from 2015[10], the

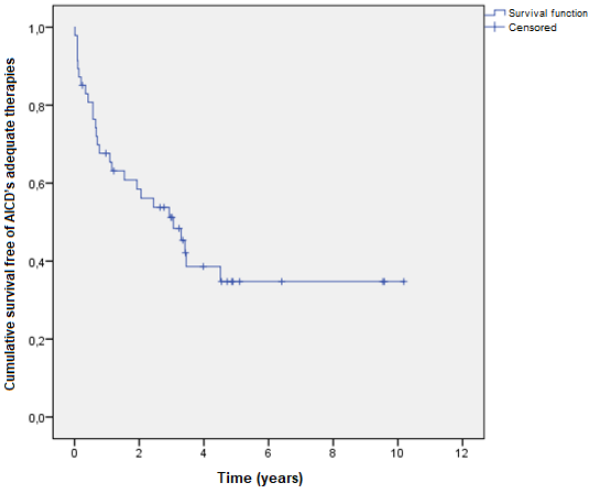

Figure 1. Kaplan-Meier curve of cumulative survival free of AICD's adequate therapies.

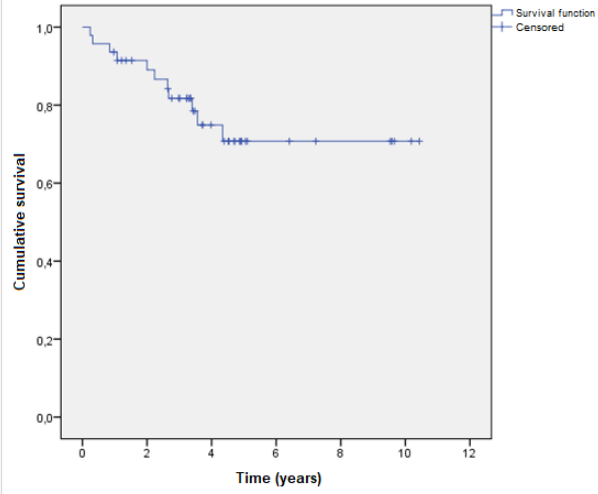

Figure 2. Kaplan-Meier curve of cumulative survival free of cardiovascular mortality.

most frequent underlying heart disease was the ischemic one (52.6%), and in the ICD-LABOR Registry, the history of ischemic heart disease is found in 40% of the sample[11].

Almost half of the patients had a severe systolic dysfunction of the left ventricle, similar to the Spanish Implantable Cardioverter-Defibrillator Registry, which reports a LVEF of less than 30% in 53% of the primo-implantation[10]. In the studies on secondary prevention, AVID[4], CIDS[5], CAHS[6] and ICD-LABOR[11], the mean LVEF was 32%, 34%, 46% and 38%, respectively.

Approximately one out of every five AICDs was indicated in secondary prevention, a result that differs from those registries of United States of America and Spain, where 80% and 58% respectively, are indicated in secondary prevention[10,11]. In contrast, it is similar to Latin American studies, where seven out of every ten devices are implanted in secondary prevention[13]. The fact that health care services in our country are free of charge solves the Class I indications of the current management guidelines, while the indication in primary prevention is individualized and, in most of cases, it is support of cardiac resynchronization therapy.

In our research, there was a discrete superiority of dual-chamber systems. Despite the fact that the clinical trials were mainly performed with single-chamber devices, the introduction of dual-chamber systems guarantees synchronic atrial-ventricular stimulation, solves atrial stimulation in sinus bradycardia by drugs, and improves the discrimination of tachycardia with reduction of inadequate therapies[4].

The implantation of triple-chamber AICDs was very modest in comparison with developed countries, which report 40% of biventricular systems[10,12], but similar to Latin American studies, where these represent 9.5%[13].

Complications were rare, and in concordance with the global rate of complications described in the bibliography, approximately 10%[14-16]. The absence of infectious complications is remarkable, which is attributed to the reduced number of operators, the use of antibiotic prophylaxis protocol and the conditions of the operating room.

Antiarrhythmic drugs were used in 66% of patients, with predominance of amiodarone, given its greater safety in the presence of structural heart disease. Other series report the use of antiarrhythmic drugs in 40-70% of patients[17-19]. The association among AICD and antiarrhythmic drugs is sometimes essential, but it can be problematic as well. Mixed therapy is necessary for the treatment of frequent ventricular tachycardia, supraventricular tachycardia, and for the greatest efficacy of antitachycardia stimulation. Unfortunately, the modification of the arrhythmogenic substrate is difficult to control and sometimes, the drugs have proarrhythmic effects[19].

The incidence of adequate therapies was high (57.4%) and these took place early in the follow-up; findings that we interpret as positive. The decision to implant an AICD in these patients was right, since if not performing it, in many cases the result would have been fatal. Studies on secondary prevention report an incidence of adequate therapies of approximately 54%[20].

Cumulative probability of presenting an adequate therapy was of 65.3% at the fourth year. The highest frequency of a first therapy took place in the first four years, and after this period this probability did not increase. Borleffs *et al*[21] report a cumulative incidence of any form of AICD therapy of 52% and 61% at the fifth and tenth years, respectively.

Mean age was significantly higher in the subgroup with adequate therapies. Schaer *et al*[22] report age as a predictor of adequate therapies (RR 1.02 [per year], 95% 1,01-1,04; p=0,001). Severe left ventricular systolic dysfunction was related with a higher frequency of adequate therapies, a result similar to other studies[22-24]. In turn, the frequency of inadequate therapies was higher than expected for a study with predominance of indication in secondary prevention (23.4% of cases). According to Dichtl and Wolber[20], these therapies take place in 15% of patients with indication in secondary prevention and in 25% in primary prevention.

The incidence of inadequate therapies due to detection problems is remarkable, which were found on equal proportion to those produced by supraventricular arrhythmias. Supraventricular tachycardia is described as the main cause of inadequate therapies, while detection failures correspond to only the 20%. The fracture of the ventricular electrode, found in four patients, may justify the high incidence of inadequate therapies due to detection failures.

The incidence of electrical storm is close to the lower limit found in different studies[25-27]. The rate of patients with ventricular arrhythmias without AICD intervention was high (12.6%) and in all cases it was due to the programming of a cut-off frequency lower than that of the current clinical arrhythmia. The slowing down of the initial tachycardia due to the use of antiarrhythmic drugs and the deterioration of

the cardiac function could be the cause of this behavior.

The frequency of AICD-induced proarrhythmia was representative. In five of the seven patients, the antitachycardia therapy accelerated the previous ventricular tachycardia or degenerated it into ventricular fibrillation. According to other studies, the incidence of this phenomenon is 20% and it is related to severe ventricular dysfunction, and to a cycle length of the tachycardia being less than 300-320 ms[28]. In the remaining two patients, the proarrhythmia was generated by the shock; the reported rate of this phenomenon is less than 5%[29].

In ten of the 47 patients, a first generator replacement was performed, and in three a second one, all of them due to the battery depletion. If we analyze that the maximum follow-up period was of 10.4 years, the longevity of the devices is within what is recognized in the bibliography, with an average durability of five years[30].

Cardiovascular mortality was 23.4% and all deaths took place in the first four years after the primo-implantation. These results are similar to the observational studies and to the AICD treatment branch of the clinical trials[4-9,11,13,31,32].

An *et al*[33], in a study on primary prevention, describe a mortality of 5%, 15% and 20% at the first, second and third year, respectively. Furthermore, Nambordo *et al*[13], in a research with predominance of indication in secondary prevention, found a cumulative probability of survival at five years of 80%.

The presence of structural heart disease, LVEF ≤ 35%, functional Class (FC) III-IV, adequate therapy and arrhythmic storm were related with cardiovascular mortality. The ICD-LABOR study identified four variables associated to mortality in patients with AICD: LVEF less than 30%, FC III-IV, age over 70 years old and males[11]; and Lelakowski *et al*[24] found, as mortality predictors, the LVEF ≤ 30% (RR 3,0; CI 95%: 1,51- 5,98; p=0,0017) and functional class III-IV (RR 3,1; CI 95%: 1,48-6,61; p=0,003).

Multiple AICD therapies generate depression of the ventricular function, injury and myocardial ischemia, cerebral hypoperfusion, proarrhythmia, electromechanical dissociation, early battery exhaustion and sometimes, it can lead to death. Alba and *et al*[34] report a strong association between mortality and the occurrence of adequate or inadequate shocks during the follow-up (RR 2.34; CI 95%: 1.59-3.44). Similarly, Powell *et al*[35] describe an increased risk of death (RR 2.77, 95% CI 1.7-4.51) in patients with shock due to ventricular tachycardia. In a recent meta-analysis, the presence of arrhythmic storm was associated with a relative risk of mortality of 2.51 (CI 95% 1.38-4.58)[36].

CONCLUSIONS

Adequate AICD therapies are common, they take place in the early years of the follow-up, and they are associated with severe left ventricle systolic dysfunction, as well as with the increase of age. The survival of patients with AICD is satisfactory. Death takes place mainly in the first few years after implantation, and it is related to further deterioration of the cardiovascular system and device therapies.

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