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Cardiocentro ERNESTO CHE GUEVARA SANTA CLARA CUBA

Implantation of the cardioverter-defibrillator: Cuban Registry (2017)

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Acronym
ICD: implantable cardioverter-defibrillator

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ABSTRACT

Introduction: The implantable cardioverter-defibrillator (ICD) has proven useful in the primary and secondary prevention of sudden cardiac death. The increase of its use motivates interest on its effectiveness outside the clinical trials. The first registration of an ICD implantation in Cuba is performed.

Objective: To know the current situation of an ICD implantation in Cuba, regarding clinical data, indication, type of implant, device and complications of the procedure.

Method: The registration's data were obtained through the collection form, which was completed voluntarily by each implantation team during or after the implant.

Results: The total number of implants was 121, and the rate of 10.76 per million inhabitants. The procedure was performed in 5 medical institutions in the country, and 69.4% of the devices were implanted at the *«Instituto de Cardiología y Cirugía Cardiovascular»*. The mean age was 58.05 ± 14.83, with a predominance of men (71.1%). The 52.1% were primo-implantation, dual-chamber devices represented 43.8% and triple-chamber 16.5%. In the primoimplants predominated patients with ejection fraction ≤35% (42.9%), in sinus rhythm (92.1%), with functional class III-IV (49.2%) and ischemic heart disease (41.3%). The 79.4% of the first implants were secondary prevention, and sudden death (42.9%), the most common clinical presentation. Complications were infrequent (4.1%) and the hematoma predominated.

Conclusions: The implantation rate of the ICD per million inhabitants is comparable with that of Latin American countries. The implants of triple-chamber systems and in primary prevention are still modest.

Keywords: Implantable cardioverter-defibrillator, Cardiac arrhythmias, Registry, Health statistics, Cuba

Implante del cardiodesfibrilador automático: Registro en Cuba (2017)

RESUMEN

Introducción: El cardiodesfibrilador automático implantable (CDAI) ha demostrado utilidad en la prevención primaria y secundaria de la muerte súbita cardíaca. El incremento de su utilización motiva interés sobre su eficacia fuera de los ensayos clínicos. Se realiza el primer registro del implante de CDAI en Cuba.

Objetivo: Conocer la situación actual del implante de CDAI en Cuba, respecto a datos clínicos, indicación, tipo de implante, de dispositivo y complicaciones del procedimiento.

Método: Los datos del registro se obtuvieron a través de la planilla de recolección, que fue cumplimentada de forma voluntaria por cada equipo implantador durante o después del implante.

Resultados: El número de implantes fue 121 y la tasa de 10,76 por millón de habitantes. El procedimiento se realizó en 5 instituciones médicas del país, y en el Instituto de Cardiología y Cirugía Cardiovascular se implantó el 69,4% de los dispositivos. La media de la edad fue de 58,05±14,83, con predominio de hombres (71,1%). El 52,1% fue primoimplante, los dispositivos bicamerales representaron el 43,8% y los tricamerales el 16,5%. En los primoimplantes predominaron los pacientes con fracción de eyección ≤35% (42,9%), en ritmo sinusal (92,1%), con clase funcional III-IV (49,2%) y cardiopatía isquémica (41,3%). El 79,4% de los primoimplantes fue prevención secundaria, y la muerte súbita (42,9%), la forma clínica de presentación más común. Las complicaciones fueron infrecuentes (4,1%) y predominó el hematoma.

Conclusiones: La tasa de implante del CDAI por millón de habitantes es comparable con los países de américa latina. Los implantes de sistemas tricamerales y en prevención primaria son aún modestos.

Palabras clave: Cardiodesfibrilador automático implantable, Arritmias cardíacas, Registro, Estadísticas de salud, Cuba

INTRODUCTION

Validated by the results of several clinical trials the implantable cardioverter-defibrillator (ICD) has proven useful in the primary and secondary prevention of sudden arrhythmic death[1-5]. Over the last decades, indications for ICD implantation have substantially increased as well as the number of patients who have received these devices[6].

Health records on ICD implantations are of particular interest as there is scarce information available in the medical literature on the application of clinical guidelines to unselected patient populations.

The present registry collects data on implantations performed in Cuba in the year 2017 and is the first investigation of its kind in the country. Our objective is to describe the current situation in terms of clinical data, indication, implantation and device type.

METHOD

A descriptive study to collect data from ICD implantations in Cuba in 2017 was conducted in five health centers, located in the provinces of Havana, Villa Clara and Holguín. Each team voluntarily completed the collection form during or after the implantation, which recorded the demographic, clinical, device and procedure variables.

The information collected was stored in a database using Microsoft Excel 2010 and was processed with the SPSS statistical program, version 20. The implantation rate per million inhabitants was estimated with the use of data from the Cuban population census in 2012. When more than one form of presentation or clinical arrhythmia was collected in the same patient, we selected the most serious for the analysis. Complications were evaluated at a 30-day follow-up.

The quantitative variables are expressed as mean ± standard deviation or median (interquartile range), according to the variable distribution. Summary measures were used for the qualitative variables (percentages) and were calculated based on the number of first implantations or replacements, as appropriate.

RESULTS

A total of 121 ICDs were implanted, with a rate of 10.76 devices per million inhabitants. The mean age was 58.05±14.83 and male sex predominated (71.1%). The number of primo-implantations (52.1%) slightly exceeded replacements (47.9%). Of the latter, 94.8% were due to battery depletion and the remaining 5.2% to system sepsis (**Table 1**).

Dual-chamber ICDs predominated in the primo-implantations (47.6%) while single-chamber devices did on replacements (41.4%). The first 8 VDD-ICD implantations were performed in the country. Dual-chamber systems predominated (43.8%) and triple-chamber systems only represented 16.5% (**Table 2**). We only found minor complications (4.9%), pocket hematoma (4 patients), system sepsis (1 patient) and no coronary sinus cannulation (1 patient).

As shown in **table 3**, ICD implantation was performed in 5 medical institutions in the country and the *Instituto de Cardiología y Cirugía Cardiovascular* (Havana, Cuba) was the main implantation center (69.4%). The 100% of the procedures were performed by electrophysiologists and cardiologists formerly

Table 1. Distribution of patients according to demographic characteristics.

Type of implantation	Mean	SD	Sex				Total	
			Male		Female			
			Nº	%	Nº	%	Nº	%
Primo-implantation	58.9	14.46	47	74.6	16	25.4	63	52.1
Replacement	57.1	15.29	39	67.2	19	32.8	58	47.9
Total	58.05	14.83	86	71.1	35	28.9	121	100

SD, standard deviation

Table 2. ICDs distribution according to type of device.

Type of device	Primo-implantation		Replacement		Total	
	Nº	%	Nº	%	Nº	%
Single-chamber ICD	16	25.4	24	41.4	40	33.1
Single-lead VDD-ICD	8	12.7	0	0.00	8	6.6
Dual-chamber ICD	30	47.6	23	39.6	53	43.8
Triple-chamber ICD	9	14.3	11	19.0	20	16.5

Table 3. ICDs distribution according to the implantation center.

Hospital	Nº	%
Instituto Cardiología y Cirugía Cardiovascular	84	69.4
Cardiocentro Ernesto Che Guevara	20	16.5
Hospital Hermanos Ameijeiras	9	7.5
Hospital Vladimir I Lenin	7	5.8
Cardiocentro William Soler	1	0.8
Total	121	100

trained in cardiac pacing systems implantation.

In the first implantations (**Table 4**), the most frequent heart condition was ischemic heart disease (41.3%), followed by nonischemic dilated cardiomyopathy (28.5%) and primary electrical heart diseases (11.1%). NYHA functional class III-IV patients predominated, with LVEF ≤ 35% (42.9%) and sinus rhythm (92.1%). Sudden death was the most common clinical presentation (42.9%) and ventricular fibrillation was the most common arrhythmia (41,3%).

Secondary prevention was the cause of 79.4% of primo-implantations. Sudden death predominated as a form of presentation in ischemic heart disease and nonischemic dilated cardiomyopathy, 34.4% and 44.5%, respectively (**Table 5**).

Table 4. Primo-implantation distribution according to clinical characteristics.

Characteristics	Nº	%
Underlying heart disease		
Ischemic heart disease	26	41.3
Nonischemic dilated cardiomyopathy	18	28.5
Hypertrophic cardiomyopathy	2	3.2
Channelopathies	7	11.1
Heart valve disease	1	1.6
With no heart disease	9	14.3
Functional class		
I	18	28.6
II	14	22.2
III-IV	31	49.2
Left ventricular ejection fraction		
≥ 50%	20	31.7
36-49 %	16	25.4
≤ 35%	27	42.9
Basic rhythm		
Sinus	58	92.1
Chronic atrial arrhythmia	3	4.7
Pacemaker	2	3.2
Clinical form of presentation		
Sudden death	27	42.9
Syncope	18	28.6
Other	9	14.3
Asymptomatic	9	14.3
Clinical arrhythmia		
Ventricular fibrillation	26	41.3
Sustained monomorphic VT	24	38.1
No arrhythmia	13	20.6

VT, ventricular tachycardia

DISCUSSION

This registry is the first of its kind conducted in our country and shows data from 100% of the implantations performed. It gives relevant information regarding the clinical characteristics of the patients, indication, type of implantation, device and early complications.

The implantation rate was much lower than that of the developed countries; for example, the 2016 Eucomed registry (implantations in Europe) publishes 320 per million inhabitants[7]. However, our results are compared with those of countries in the region[8,9].

The demographic data is similar to that of other investigations. Age close to 60 years and male gender predominated[10,11]. Sudden cardiac death shows a peak incidence between 45 and 75 years of age, in relation to a higher prevalence of ischemic heart disease. Before age 65, the incidence of sudden cardiac death is 4 to 7 times higher in men than in women[10,11].

The most frequent underlying heart condition was ischemic heart disease. Followed by nonischemic dilated cardiomyopathy. In the Spanish ICD registry, 48.6% of the implantations were performed in patients with ischemic heart disease and 29.5% in the context of nonischemic dilated cardiomyopathy[6]. The ICD-LABOR (Latin American bioelectronic ongoing registry) collects the history of coronary disease in 40% of the sample[8].

Despite ICD implantation is performed in 5 hospi-

Table 5. Primo-implantation distribution according to the type of heart disease, clinical arrhythmia and form of presentation.

Heart disease	Nº	%
Ischemic heart disease (n=26)		
Sudden death	9	34.6
Syncopal sustained monomorphic VT	8	30.7
Non-syncopal sustained monomorphic VT	7	26.9
Primary prevention	2	7.7
Nonischemic dilated cardiomyopathy (n= 18)		
Sudden death	8	44.5
Syncopal sustained monomorphic VT	2	11.1
Non-syncopal sustained monomorphic VT	1	5.5
Primary prevention	7	38.9
Hypertrophic cardiomyopathy (n=2)		
Secondary prevention	1	50.0
Primary prevention	1	50.0
Channelopathies (n=7)		
Secondary prevention	4	57.1
Primary prevention	3	42.9

VT, ventricular tachycardia

tals, about 70% of the procedures were performed in the Department of Arrhythmia, Electrophysiology and Cardiac Pacing of the *Instituto de Cardiología y Cirugía Cardiovascular*, the only one of its kind in the country and national reference center. All this, in addition to the fact that every implantation was performed by highly trained electrophysiologists and cardiologists, justifies the low incidence of complications. Previous investigations show a relationship between the volume of implantations and the number of complications as they decrease in proportion to a greater amount of implantations per center[12].

Dual-chamber systems predominated in the first implantations and in the total number of implantations. The current trend is to implant less single-chamber devices and increase dual-chamber and biventricular ones. The dual-chamber ICD guarantees synchronous atrio-ventricular pacing, provides atrial stimulation if a drug-induced bradycardia occurs and improves tachycardia discrimination, thus reducing inappropriate therapies. However, dual-chamber systems implantation has decreased with the use of triple-chamber pacing therapy. Evidence from clinical trials in patients with heart failure clearly justifies this behavior[13,14].

Triple-chamber devices implantation was very modest as compared with developed countries where the proportion of triple-chamber ICD with respect to total implantations ranges by 40%[6]. Latin American registries report the implantation of triple-chamber systems in 22.3% of the study population[8,9].

The first single-lead VDD-ICD systems implantations were made, allowing to consistently detect tachycardias by atrial sensing. They are particularly useful in patients with concomitant atrial arrhythmias who do not require atrial stimulation.

Patients with severe ventricular dysfunction and marked functional class impairment predominated, similar to other registries[1,2,6,8]. The highest percent of ICD indication was as secondary prevention, which explains why ventricular fibrillation and sustained monomorphic ventricular tachycardia were the most common arrhythmias that led to its implantation, while aborted sudden death and syncope were the most common clinical forms of pres-entation.

MADIT II[5], COMPANION[15] and SCD-HFT[4] trials established the current criteria for ICD implantation and cardiac resynchronization therapy in primary prevention. They also set off a progressive increase in the number of implantations. Approximately one in five ICDs were indicated in primary prevention, unlike developed countries registries, which report between 58-80% of implantations in this type of prevention[6]. In a Latin American registry, 37.3% of the devices were implanted in primary prevention[8].

Although ICDs have proven to be beneficial in the reduction of sudden arrhythmic death, patient selection criteria must be objective and their indication must be individualized. It should be based on access to therapy, safety and cost-effectiveness. Underdeveloped countries must implement it at a reasonable cost to society.

In our country, free health services meet the indications for secondary prevention of the guidelines of the American College of Cardiology, the American

Heart Association and the Heart Rhythm Society[16,17]. Implantations for primary prevention are evaluated individually and, are basically a backup indication in cardiac resynchronization therapy.

CONCLUSIONS

The Cuban ICD Registry in 2017 shows that the implantation rate per million inhabitants is much lower than that of the first world countries, but comparable to those of Latin America. The implantations of triple-chamber systems and in primary prevention are still modest.

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