Original

Primary and secondary prevention of sudden cardiac death in a hospital of the social security system in Costa Rica: report from the registry of patients with implantable cardioverter-defibrillators, 2007-2011

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Abstract

Background: Several studies have demonstrated the efficacy of implantable cardioverter-defibrillators in the prevention of sudden cardiac death. The validation of this evidence has to be assessed through various registries. The objective of this study was to describe the main epidemiological and clinical characteristics of patients who were referred to a tertiary hospital in Costa Rica to be treated with a cardioverter-defibrillators implantable; as well as the associated problems and complications.

Methods: A retrospective observational cohort study, which included all patients who were treated with a cardioverter-defibrillator implantable in the "Dr. Rafael A. Calderón Guardia" hospital between 2007 and 2011.

Results: Twenty three patients were included. The mean age was 55 ± 18 years. Ischemic heart disease was the most frequent etiology (10 patients). Twenty patients had functional class I or II and the mean ejection fraction was 0.38 ± 0.17. In 18 patients, the cardioverter-defibrillator was implanted for secondary prevention. Five patients had an early complication; all of them had dual-chamber devices: 2 minor hematomas, 1 coronary sinus dissection, 1 right atrial lead displacement, and 1 cardio embolic stroke. From a total of 101 therapies (in 8 patients), 94 were appropriate (in 5 patients) and 7 were inappropriate (in 3 patients); 2 of the latter 3 patients had a history of atrial fibrillation episodes.

Conclusion: This registry shows that the majority of implantable cardioverter-defibrillators implantations are performed as a secondary prevention, with a high rate of adequate therapies and a low rate of inadequate ones. The registry allowed an assessment of the indications and complications of this device therapy.

Key words: Implantable defibrillators, sudden death, arrhythmias.

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Abbreviatons: ICD, Implantable Cardiac Defibrillator; AF, atrial fibrillation; EF, Left Ventricle Ejection Fraction; VF, ventricular fibrillation; SCD, Sudden Cardiac Death; NIDCM, non ischemic dilated cardiomyopathy.
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Sudden Cardiac Death (SCD) is the leading cause of death in patients with structural heart disease and in channelopathy carriers, such as long QT syndrome or Brugada syndrome, both considered as high risk, or who have not responded to traditional therapies.[1-5] The risk of death from someone who has had an aborted SCD is nearly 95%; half the survivors will be readmitted within one year and 40% will die within the next 2 years.[2-4] SCD risk increases exponentially when the ejection fraction (EF) is less than 0,3.[3] Functional class also proved to be an independent risk predictor for SCD,[4,5] especially in patients with functional class IV, but it only represents one third of such deaths, since the remaining two thirds occur in patients with compensated heart failure symptoms and a functional class II.[6, 7] Identification of populations at risk for SCD had little effect in reducing the cumulative incidence, as it mostly occurs in people without identifiable risk factors, namely "healthy" population.

Several randomized controlled trials have demonstrated the effectiveness of automatic implantable cardiac defibrillators (ICDs), reducing mortality for SCD in primary and secondary prevention for these patients,[8-10] and its superiority against drug treatment. Secondary prevention is defined as those measures applied after an episode of aborted SCD or an episode of sustained ventricular tachycardia (VT), with or without hemodynamic involvement. Primary prevention regards to those measures taken without occurring any such events. International consensus management guidelines have been established [9] and consequently, there has been an increase in the overall number of implants, therefore the evidence applied to the particular situation in each population center must be evaluated. The only way to achieve this is by conducting surveys and records to compare results with other centers and meet the populations who receive ICD´s.[10-14] The aim of this study was to describe the main epidemiological and clinical characteristics at the time of implantation, as well as knowing the immediate and late complications of the population with an ICD, both for primary and secondary prevention, at a third level hospital in Costa Rica.

Methods

An observational, cohort, restrospective study was made at the "Dr. Rafael Ángel Calderón Guardia" Hospital, in San José, Costa Rica. The first ICD implanted at the Cardiology Service was made in 1999, but the implant rate was very low until 2 years ago, when an Electrophysiology program was started. The study was authorized by the Hospital´s Ethics-Scientific Committee, and was not sponsored nor was included in any other study.

Data collection

The total number of patients who received an ICD was taken from the database of registered procedures in the hospital´s Haemodynamics Laboratory, -established in 2002 -, from the records of device providing companies and from clinical records requested to the Archive and Microfilm Service. Data was analyzed regarding demographic characteristics, cardiovascular history, history of supraventricular and ventricular arrhythmias, implant characteristics and programming devices, intraoperative and long-term complications as well as the occurrence of events and therapies provided by the devices. Demographic data and dates of birth and death were corroborated with the Civil Registry of Costa Rica´s database. Death records were last revised on January 6, 2012. Information regarding the events stored in the device´s memory was based primarily on records made by the suppliers, which includes a monitoring report after each appointment.

ICD´s provide three types of therapy: rapid pacemaker stimulation at a higher frequency than VT, R wave-synchronized shock (cardioversion) and unsynchronized shock (defibrillation) to reverse ventricular fibrillation (VF), Figure 1. Therapy was considered appropriate when the device detected properly an episode of ventricular arrhythmia and administered one programmed therapy, while inappropriate therapy was that which made an inadequate discrimination of an episode of supraventricular arrhythmia, or over-sensing extracardiac signals as myopotentials, or electromagnetic interference. "Electrical storm", defined as the occurrence of three or more episodes of sustained VT or VF, within a 24 hour period, each separated from the previous one, at least 5 minutes of ventricular arrhythmia-free interval. Early complication was defined as that which occurred in the first 30 days of device implantation, and late complications were those which occurred after that period. A minor complication was that one which did not require a new intervention, hospitalization, or imply a risk to the patient's life.

Information was recorded on a data collection sheet based on the formula used by the Implantable Cardio-Defibrillator Registry of the Spanish Cardiology Society (available at http://www.secardiologia.es/images/stories/file/arrhythmias/national-record-dai2010.pdf).

Studied Patients

The study included all patients who had an ICD were registered in the database until 2011. Inclusion criteria were: age over 18 years, without excluding gender, ethnicity, country of origin or nationality, and who had undergone implantation of an ICD for primary or secondary prevention of SCD. We excluded patients who haven´t had at least one follow-up appointment in the Cardiology Department.
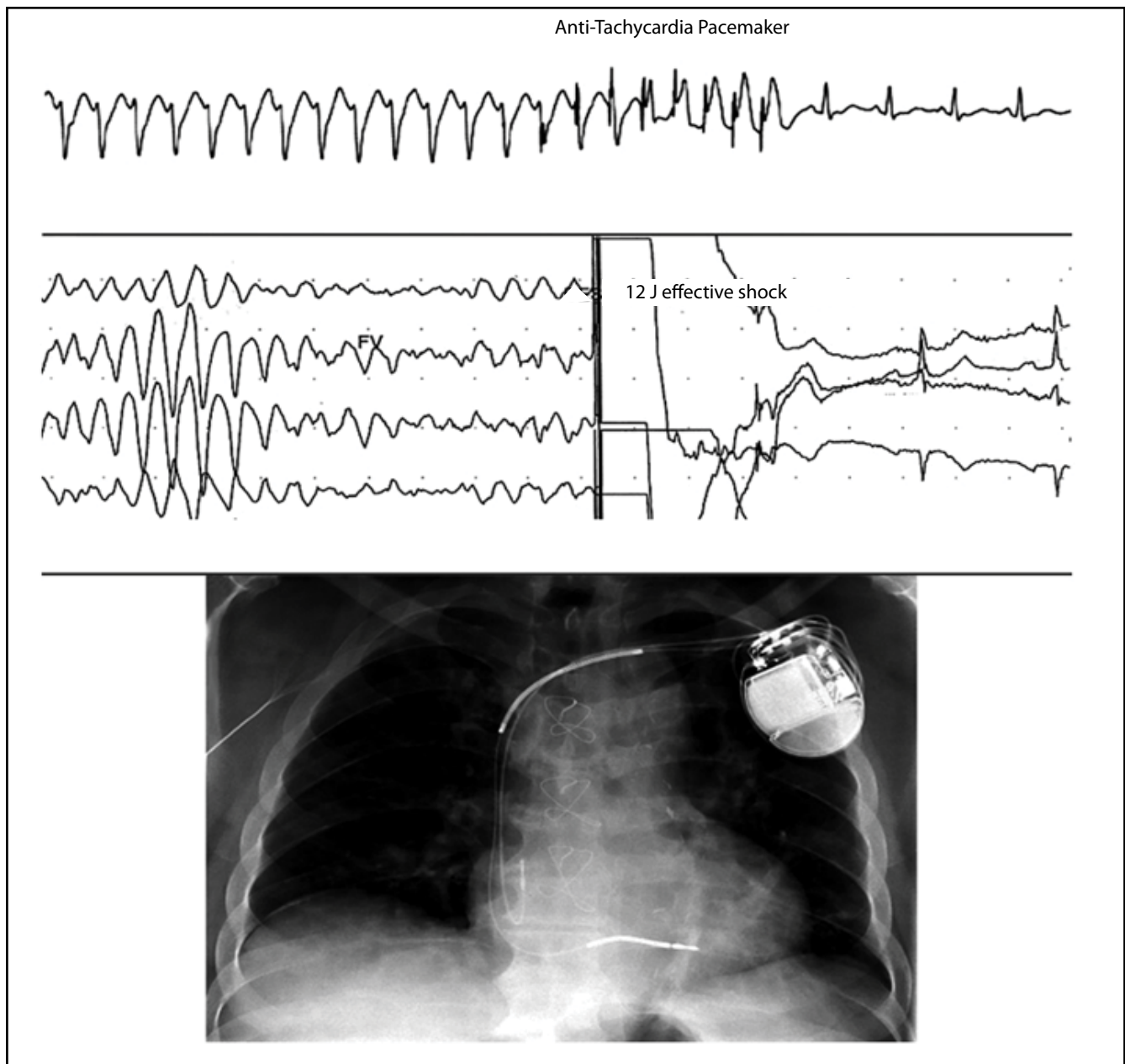
Figure 1. Up: Anti-tachycardia stimulation. During Ventricular Tachycardia (a rapid, regular, rhythm with wide QRS complexes), pacemaker stimulation is administered at a frequency higher than the tachycardia, which reverts it. Center: Defibrillation. When the patient has faster and disorganized rhythms like VF, the ICD gives an intracavitary shock, 12 J in this case, returning to sinus rhythm. Down: Postero-anterior chest X-Ray from a patient with non-ischemic dilated cardiomyopathy and previous myocardial revascularization (bypass). 2 electrodes are seen, one J-like atrial and ventricular; containing 2 coils, one in the superior vena cava and other in the right ventricle (more radiopaque zones), which along with the ICD´s box (in the left pectoral "pocket"), conform the dipole where direct current is administered for cardioversion or defibrillation.

Statistical Analysis

Numerical results were expressed as means and standard deviations. Being a small population of patients, nonparametric statistics were used and expected event frequencies were compared using the chi-square test. T h e Kaplan-Meier method, cumulative survival tables and the Mantel-Cox test, were used to perform comparisons over time, until the occurrence of events in the groups of primary or secondary prevention. A value of $P < 0.05$ was considered significant. Statistical analysis was performed with SPSS, version 17.0.

Results

During the study period, a total of 25 devices were implanted. Information was available only for 23 patients. In 2 cases, the clinical record was lost and there was no possibility of tracking and knowing the clinical variables. Between 2007 and 2009 only 5 devices were implanted, while between 2010 and 2011, 18 ($p < 0.05$ between both periods). The mean age of the 23 patients was 55 ± 18 years.

Table 1. Sociodemographic and health conditions in patients who received an ICD.					
Clinical parameters (n = 23)		Medication		Device	
Age (years)	55 ± 18	Beta-blocker	19	Unicameral	2
Male	16	Aspirin	17	Bicameral	19
Dyslipidemia	15	ACEI/ARB*	17	With resynchronizer	2
High Blood Pressure	11	Amiodarone	16		
Ischemic Heart Disease	10	Statin	15		
Heart Failure	10	Spironolactone	8		
Previous Atrial Fibrillation	9	Furosemide	7		
Smoking History	8	Warfarin	6		
Diabetes	7	Clopidogrel	2		
Renal Failure	6				
Functional Class III o IV	3				
Familiar Sudden Death	2				
Stroke	1				

*ACEI/ARB: Angiotensin Converting Enzyme Inhibitor/Angiotensin AT2 Receptor Blocker.

Although implants were more frequent in male persons (16 men), the difference was not significant (Table 1).

Underlying cardiopathy, ejection fraction, functional class and basal rhythms.

Ischemic heart disease was the most common etiology (10 patients), followed by 8 patients with non-ischemic dilated cardiomyopathy (NIDCM), 2 with hypertrophic cardiomyopathy and 3 with channelopathies (2 Brugada syndrome and 1 with long QT syndrome, Figure 2). Most patients were in functional class I or II at the time of implantation (20 patients). Only 2 patients were in functional class III and one was in class IV. Most of the population had moderate or severe impairment of the FE, with a mean of 0.38 ± 0.17, and in about one third of the population was <0.25. At the time of implantation, 17 patients were in sinus rhythm and five in atrial fibrillation (AF). Nine patients had a previous event of FA. Five patients had left bundle branch block bundle, 3 right bundle branch, 2 had a first-degree atrioventricular block and 1 had Sick Sinus Node Syndrome.

Indications and clinical arrhytmias

Out of 23 patients analyzed, 5 received an ICD for primary prevention and 18 for secondary prevention. The criteria for implantation in primary prevention were: severe ventricular dysfunction in 4 patients with NIDCM (1 with acute low cardiac output) and one with hypertrophic cardiomyopathy, the latter two had nonsustained VT. The criteria for implantation in secondary prevention patients were: symptomatic VT or VF in 16 patients and syncope or symptoms of low cardiac output due to VT or VF induced during an electrophysiology study in 2 patients (Figure 2).
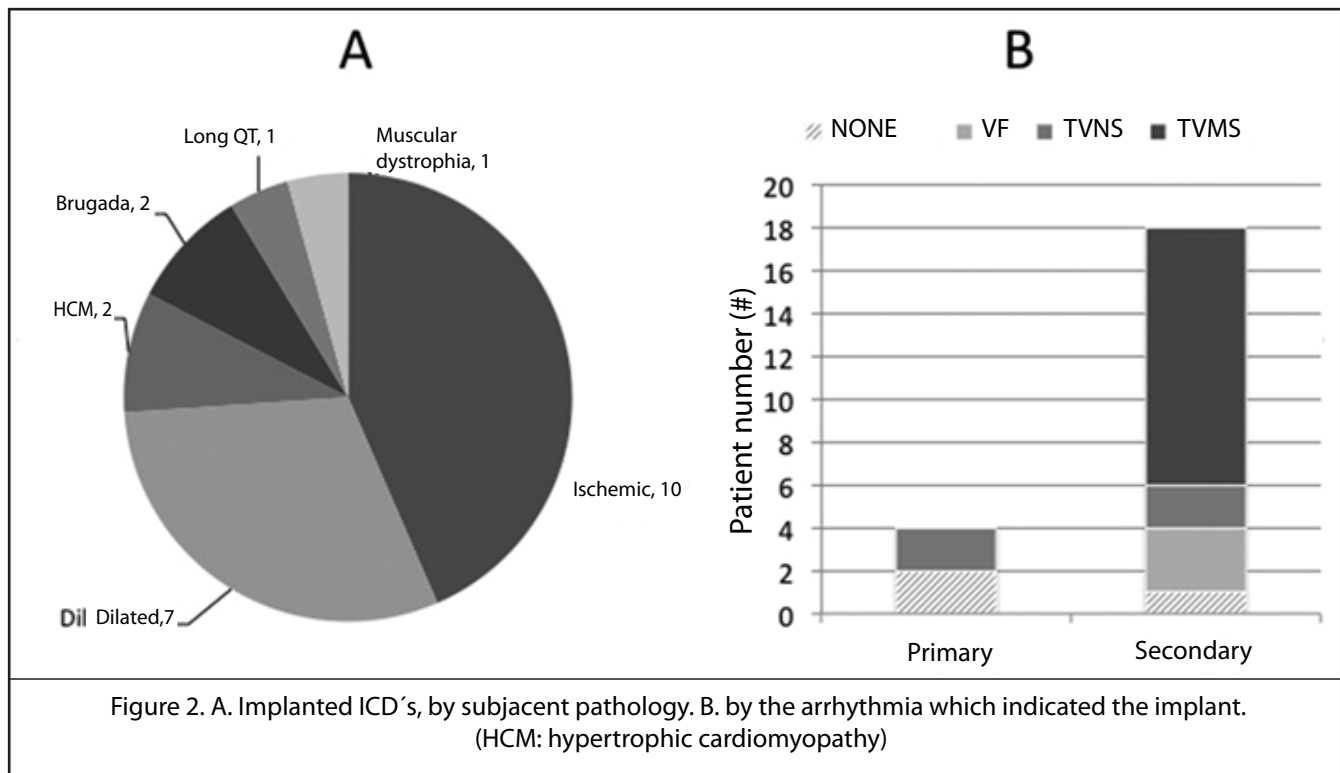
Concomitant medication

According to the type of population to whom the device is implanted, most of them take beta blockers, aspirin, angiotensin antagonists and statins (Table 1). Fifteen secondary prevention patients were medicated with amiodarone, while only one primary prevention patient used it.

First implant and replacement

A total of 18 devices were first implants, while 5 were generator replacements. The cause for the replacement was the depletion of the battery in all cases. The average time until replacement was 5.83 ± 2.55 years, with a minimum of 342 days, in a patient with an accessory pathway and incessant ventricular tachyarrhythmiasm, triggered by paroxysmal AF, and a maximum of 7.42 years (implanted in 2000), in a patient with non-revascularizable ischemic heart disease and spontaneous sustained VT, which never repeated nor registered other events. One patient who previously underwent battery replacement, and after having checked that the electrode worked improperly, had a new ventricular electrode placed, and the dysfunctional ventricular electrode was left in the same position. In the other four cases, the previous electrodes were used, after checking they were in good condition.

Threshold tests, device type and initial programming

Defibrillation threshold test was performed in 15 patients. The main reason why it was not performed was the lack of an available anesthesiologist. The effective mean threshold was 24.2 ± 5.7 Joules and an average of 1.5 ± 0.5 shocks per patient was applied. All devices were implanted in the haemodynamics laboratory by an electrophysiologist cardiologist, and placed in position by subcutaneous subclavian venipuncture. Unicameral devices were used in 2

Figure 2. A. Implanted ICD´s, by subjacent pathology. B. by the arrhythmia which indicated the implant.
(HCM: hypertrophic cardiomyopathy)

patients, dual-chamber devices in 19 patients and cardiac resynchronization devices in 2 patients. The anti-bradycardia pacing mode in 15 patients was DDD, DDDR in 2, VVIR in 5 and VVI in one patient. Prevention algorithms right ventricular stimulation burned in 7 patients. Antitachycardia pacing therapy is scheduled in at least one area of stimulation, in 16 patients.

Primary or secondary prevention

When comparing the demographic and clinical data of patients who received an ICD for primary versus secondary prevention, no significant differences were found regarding age, gender prevalence, EF, functional class, medical history or medication use. The only significant differences between groups were greater use of amiodarone in patients in secondary prevention (already mentioned), and QRS interval duration in the secondary prevention group (p <0.05, Table 2).

Early complications

Out of the 23 patients who received an ICD, 5 had early complications, 3 of which were minor. Everyone had dual-chamber devices, a patient with NIDCM for primary prevention presented coronary sinus dissection and mild pericardial effusion, why not implanted coronary sinus electrode. Two patients developed a hematoma at the site of implantation of the device, both were managed conservatively. One of them took aspirin and clopidogrel in the days prior to the implant, the other one was anticoagulated with warfarin, had an International Normalized Ratio of 1 at the time of implantation, and resumed warfarin 48 hours later, but developed a hematoma 5 days after. It was solved with temporary discontinuation of anticoagulant drugs and local

compression. One patient suffered a right atrial electrode displacement, with phrenic stimulation 19 days after implantation. The electrode was repositioned in the right atrium appendage. The most serious complication occurred in a functional class III NIDCM patient, with EF = 0.35, chronic AF and non-sustained VT, to whom an ICD was implanted for primary prevention. "After the defibrillation threshold test, sinus rhythm was recovered." Despite being optimal anticoagulation before and during implantation, the patient suffered a cardioembolic stroke two days later, compromising the territory of the left middle cerebral artery, and causing motor and language sequelae (Table 3).

Follow up and event description

The mean follow-up of enrolled patients was 367 ± 359 days. Of all primary prevention patients, only 1 had an

Table 2. Comparison of the basal characteristics for patients with ICD, for primary and secondary prevention

Prevention objective	Primary	Secondary	p
Male	3	13	
Left Ventricle Ejection Fraction	$0,30 \pm 0,18$	$0,40 \pm 0,16$	
LBBB	1	4	
Sinus Rhythm	2	15	
QRS duration (ms)	106 ± 11	113 ± 26	p<0,05
Amiodarone use	1	15	p<0,05
Follow up time (days)	392 ± 487	360 ± 333	
*LBBB: Left Bundle Branch			

Table 3. Early and late complications	
Early	
None	18
Hematoma	2
Coronary sinus dissection	1
Electrode displacement	1
Stroke	1
Late	
Electrode damage	2
Capture lost in the right atrium	1

arrhythmic event and therapy provided by the device was appropriate. In the secondary prevention group, 8 patients had events, 5 received appropriate therapies and 3 received an inappropriate therapy. There were no significant differences between groups. The mean time until the first event in the primary prevention group was 774 ± 222 days, while in the secondary prevention group it was 684 ± 148 days. There were no statistically significant differences between groups (Figure 3).

In total, 101 therapies were administered, 49 of them were appropriate antitachycardia pacing therapies, 45 were appropriate shocks and 7 were inappropriate shocks. The patient who received more therapies had a total of 25, while two patients had 2 therapies and 15 patients didn´t receive any. Appropriate therapies were applied for 32 episodes of VF and 62 VT episodes. The 7 inappropriate therapies occurred because of 5 episodes of AF and 2 other supraventricular tachycardias. These occurred in 3 patients, 2 of whom had previous episodes of AF before device implantation and were in the secondary prevention group (Figure 4). Five patients had an "electrical storm"; they were four secondary prevention patients: 3 with ischemic heart disease and 1 with NIDCM. These 4 patients haven´t recurred, after receiving adjustment of antiarrhythmic medication and reprogramming therapy zones with an antitachycardia pacemaker. The last storm case was a man with NIDCM, functional class IV and FE = 0.15, to whom an ICD with resynchronization therapy was implanted, as a rescue option for his advanced disease. He developed recurrent VT and VF, and received appropriate ICD therapies; however, he died three days later because of terminal heart failure and electromechanical dissociation.

Discussion

There was a low number of annual implants in this center; however, there has been a significant increase in the last two years, similar to the global trend towards a linear
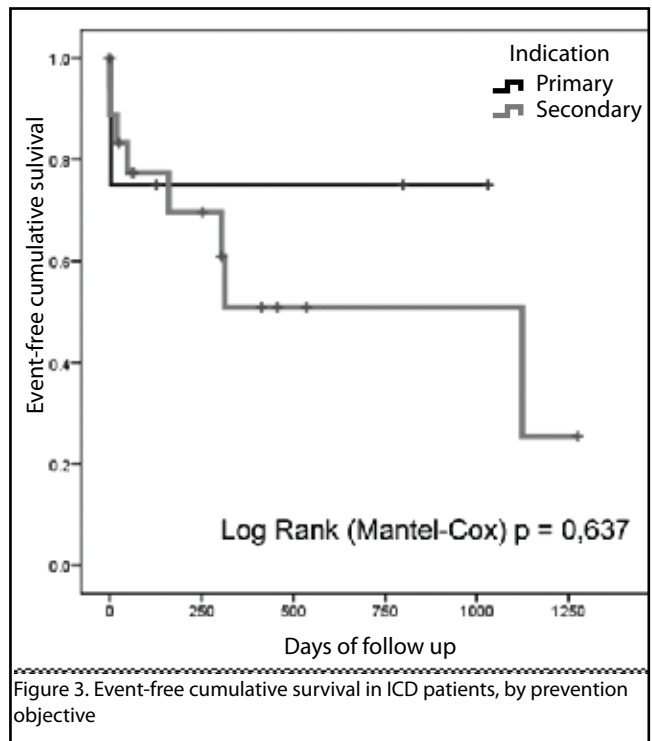

Figure 3. Event-free cumulative survival in ICD patients, by prevention objective

increase in the number of implanted devices. Given its high costs,it must be considered that the number of ICDs implanted in each country depends on GDP and health expenditure, as well as the number of medical facilities that implant the devices. Therefore, inadequate budgets and the ability to provide health services in Costa Rica, could directly affect the availability and implantation of new devices, such as has occurred in other countries.[11] Although the average age appears to be lower in this study compared to other reports, its variation was in the previously reported ranges.[12, 13] Underlying heart disease was also distributed
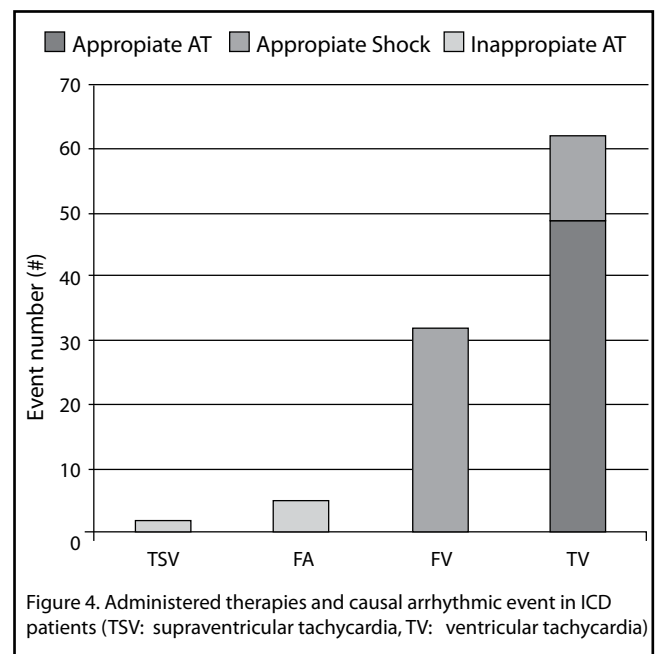

Figure 4. Administered therapies and causal arrhythmic event in ICD patients (TSV: supraventricular tachycardia, TV: ventricular tachycardia)

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similarly, and ischemic heart disease was the most common, followed by NIDCM. [14] Despite the high frequency of chagasic myocarditis in Latin America, [15] there were no cases in this series.

Since in this center implantation of an ICD is considered after patients have optimal medical therapy, a high proportion of patients took all necessary medicines to control their heart failure and low EF. Also, all patients met any class I or II-A recommendations from international guidelines for ICD implantation in primary prevention or secondary prevention.[16] Only two patients underwent electrophysiological studies for induction of ventricular arrhythmias; this allows upgrading to class I recommendation in selected patients. The average EF in this study is similar to that published in secondary prevention studies, there was a lower EF in the primary prevention group, as expected, due to the different indications for implantation, although this wasn´t a significant difference compared to the secondary prevention group.[17] Usefulness of amiodarone in secondary prevention patients has been described, as a measure to prevent and reduce the number of therapies provided by the device, or to make them more tolerable by decreasing VT frequency and allowing the antitachycardia algorithms to function. In this series, this drug was also more frequently used in this subgroup; a primary prevention patient taking the drug, even when it has been shown that it doesn´t provide greater benefit in this group, compared with the ICD.[18]

The high prevalence of AF found in the group is consistent with other reports, in which it is associated with aging and diseased populations, with low EF and heart failure symptoms. Permanent AF increases the risk of a ventricular arrhythmia and receiving appropriate therapy, whereas paroxysmal and persistent forms increase the risk of receiving inappropriate therapies, compared with the group without AF. [19] In this series, 2 out of 3 patients who received inappropriate therapies, had FA.

Being a small study group, the series has an expected number of complications. [20] They all occurred in patients with dual-chamber devices. Only one patient had a clear indication for an anti-bradycardia pacemaker because of Sick Sinus Syndrome. Another 5 patients with left bundle branch block would have been candidates for tricameral device implantation. The majority of patients included in the ICD efficacy studies received an unicameral device, subsequent reports have shown a trend towards the introduction of dual-chamber devices, but the theoretical advantage of such models hasn´t shown a clear superiority over unicameral models; [21] besides, the placement of an additional number of electrodes significantly increases the complication rate.[22] It should be noted that the group of patients receiving a dual chamber ICD had a higher proportion of morbidities and may include some patients that had unsuccessful attempts to put a left ventricular lead. Tricameral ICD implantation increases the risk of complications such as hematomas, electrode displacement, coronary sinus dissection and cardiovascular death, [23] especially if they are taking anticoagulants or antiplatelet therapy concomitantly. Of course, any complication increases stay and hence hospitalization costs.[24]

Between 15 and 31% of all shocks were inappropriate [25-27] and affect up to 15% of patients who received an ICD, [26-27] which coincides with the number of inappropriate events in this study. Most had previous episodes of AF and the shock was triggered by a misdiagnosed supra-ventricular tachycardia. Receiving inappropriate shocks lead to higher recurrence and mortality rates, so the use of more advanced algorithms and improved programming should reduce them, [25] multicenter randomized studies are being made for that purpose. "Electrical storm" has an incidence between 7, 10 and up to 25% per year, [26] as applicable to populations with tri, uni-or bicameral, devices respectively, but also influenced by the different populations that receive uni or bicameral ICD´s. These are mainly in patients with sustained ventricular arrhythmias or high risk of SCD, compared to those in which a cardiac resynchronization capable ICD is implanted, in which heart failure prevails. The series showed, agreeing with previous studies, increased risk of electrical storm in secondary prevention patients; however, most of these patients had an ischemic background, in contrast with the fact that NIDCM patients have a greater risk according to other reports.[27] Most of these patients were managed optimizing medical treatment and reprogramming therapy modalities; the combined use of beta-blockers and amiodarone has shown to significantly reduce the risk of shocks.[28]

The main limitation of this study was the small population size from a single center, which does not represent the reality of the rest of Costa Rica; this also was a retrospective analysis. Most ICD´s came from a single brand; in the future there will be more information about other brands and their clinical results, as the use of ICDs in primary prevention will become larger.

This is the first study to show the clinical characteristics and criteria under which the devices have been implanted in a tertiary care center in Costa Rica. Such a record provides valuable information for term standardization prior to ICD implantation, as well as standardizing the indications for which it should be placed in both primary and secondary prevention; besides, it improves the panorama for future decisions about using the most appropriate device, depending on the patient´s characteristics, and allow monitoring the trend of ICD implants, as well as the frequency of complications, and reevaluating if routine use of dual chamber ICDs is indicated in patients without a clear indication for a pacemaker or resynchronization therapy.

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