ORIGINAL ARTICLE

Results of the First SAC Implantable Cardioverter-Defibrillator and Cardiac Resynchronization Therapy Registry (RENCARE)

Resultados del primer registro de implante de cardiodesfibriladores y resincronizadores SAC (RENCARE)

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ABSTRACT

Background: Prevention of sudden death and treatment of heart failure are very important topics. Implantable cardioverter-defibrillator and cardiac resynchronization devices are used to prevent sudden death and improve heart failure symptoms and prognosis.
Objectives: The aim of this study was to evaluate the number, type of implanted devices, clinical characteristics of the patients and acute and follow-up complications.
Methods: An observational, prospective, multicenter study was carried out in healthcare centers with the capacity to implant cardioverter-defibrillator and cardiac resynchronization devices. The study included all patients who underwent implantation of these devices from January 2016 to January 2017, with a 12-month follow-up.
Results: A total of 249 patients (73.9% men) with mean age of 64.8±13.7 years, and 72.1% with ejection fraction <35%, were included in the study. The underlying cardiomyopathy etiology was ischemic in 39.8% of cases, dilated in 26.7% and chagasic in 11.2%. Fifty-eight percent of implants were implantable cardioverter-defibrillators and 39% were cardioverter-defibrillators associated with cardiac resynchronization devices. In 84% of cases, procedures were first implants. The most frequent indication of implantation was for primary prevention of sudden death (67.9%). Minor complication rate was 4.4% and no major complications were reported.
Conclusions: The present registry evidenced a large proportion of cardioverter-defibrillator and cardiac resynchronization implants in patients with ischemic heart disease. The main indication was for primary prevention of sudden death and the complication rate was similar to that reported internationally.

Key words: Defibrillators, Implantable - Cardiac Resynchronization Therapy Devices – Registries – Sudden, Death – Heart Failure

RESUMEN

Introducción: La prevención de la muerte súbita y el tratamiento de la insuficiencia cardíaca son temas de gran importancia. Para prevenir la muerte súbita y mejorar el pronóstico de la insuficiencia cardíaca se utilizan los cardiodesfibriladores y cardiorresincronizadores.
Objetivos: Evaluar la cantidad y tipo de dispositivos implantados en nuestro país, así como las características de los pacientes, las complicaciones agudas y las que se presentan en el seguimiento.
Material y métodos: Se realizó un estudio observacional, prospectivo, multicéntrico en centros de salud con la capacidad de implantar cardiodesfibriladores y cardiorresincronizadores. Se incluyeron pacientes a los que se les realizó implante de estos dispositivos desde enero del 2016 hasta enero de 2017, con un seguimiento de 12 meses.
Resultados: Se incluyeron 249 pacientes (edad promedio de 64,8 ± 13,7 años, 73,9% de sexo masculino, 72,1% con Fey < 35%). La etiología subyacente de la miocardiopatía era isquémica en el 39,8%, dilatada 26,7% y chagásica en el 11,2% de los casos. El 58% de los implantes realizados fueron cardiodesfibriladores y el 39%, cardiodesfibriladores asociados con cardiorresincronizadores. El 84% de los procedimientos fueron primoimplantes. La indicación más frecuente del implante fue por prevención primaria de muerte súbita (67,9%). La tasa de complicaciones menores fue del 4,4% y no se reportaron complicaciones mayores.
Conclusiones: El siguiente registro evidenció una gran proporción de implantes en pacientes con cardiopatía isquémica, la indicación principal fue por prevención primaria de muerte súbita y la tasa de complicaciones fue similar a la reportada internacionalmente.

Palabras clave: Desfibriladores implantables - Dispositivos de terapia de resincronización cardíaca - Sistema de registros - Muerte súbita - Insuficiencia cardíaca

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Abbreviations

ICD	Implantable cardioverter-defibrillators	**HTN**	Hypertension
CRT	Cardiac resynchronization therapy	**VT**	Ventricular tachycardia

INTRODUCTION

Primary and secondary prevention of sudden death and heart failure treatment are currently topics of great health importance. To prevent sudden death and improve symptoms of heart failure, implantable cardioverter defibrillator (ICD) and cardiac resynchronization therapy (CRT) devices are used. (1, 2) However, the indication of these treatments for the prevention of sudden death continues to be a challenge for the medical community. Sudden death accounts for half of cardiovascular deaths and 25% of all adult deaths. Approximately, in half of the cases it may occur in people without known heart disease, as an expression of a first episode. (3) To date, studies including patients with Chagas disease (4) and other heart diseases, (5) but with a limited number of cases, have been developed in Latin America. On the other hand, they almost exclusively have included patients with ICD using only one brand of devices. (5, 6) Over the years, the indication for this type of device has increased exponentially, (7) so it is of interest to know its efficacy (outside the context of clinical trials), type of implanted devices and number of implants, safety and "real life" complications. Due to the lack of information, our aim was to collect data on the number of implant procedures performed in our country, clinical characteristics of the patients who receive these devices, and acute and follow-up complications.

METHODS

An observational, prospective, multicenter study was carried out in public and private healthcare centers with the capacity to implant ICD and CRT devices. All patients who underwent ICD and CRT implantation since January 2016 were included. Epidemiological data of treated patients, in-hospital complications, type and indication of devices used were collected through the form available on the SAC website, and a 12-month follow-up was carried out in a second stage.

Statistical analysis

Qualitative variables are described as percentage and quantitative variables are expressed as mean and standard deviation. Statistical significance was defined with a p value <0.05.

Ethical considerations

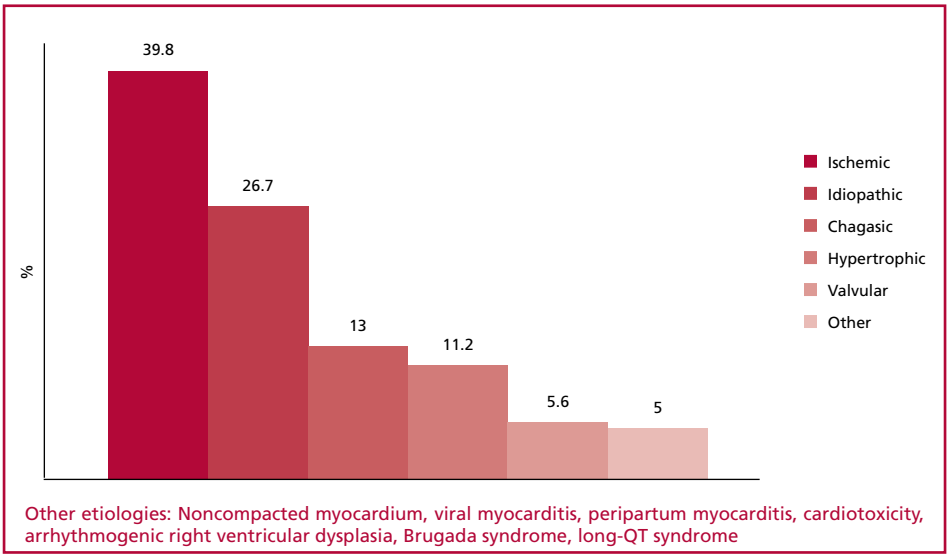
The protocol of this study was approved by the Ethics Committee and the Research Council of the Argentine Society of Cardiology.

RESULTS

A total of 249 patients (73.9% men), with mean age of 64.8±13.7 years were included in the study. The most prevalent cardiovascular risk factor was hypertension (HTN) in 57.1% of cases, followed by dyslipidemia (36%), smoking (32.9%) and diabetes (20.5%). Functional class was I-II in 60% of cases and 12.5% of patients had atrial fibrillation as baseline rhythm. Previous myocardial revascularization surgery was reported in 11.4 % of cases and 72.1% of patients had less than 35% ejection fraction. Other comorbidities were: hypothyroidism in 9.3% of cases, kidney failure in 7%, and chronic obstructive pulmonary disease in 4.3%. In 36.3% of cases, patients had social health insurance, 30.6% had prepaid medical care, 19.7% belonged to PAMI and 13.4% had no health coverage. The underlying cardiomyopathy etiology was ischemic in 39.8% of cases, dilated in 26.7%, chagasic in 11.2%, hypertrophic in 5.2% and valvular in 5% (Figure 1). Patients were treated with beta-blockers in 63.3% of cases, ACEI/ARB II in 60.5%, antialdosterone agents in 53.5%, amiodarone in 19.7%, and furosemide in 39.4%. Fifty-eight percent of patients received ICDs, while 39% were ICD+CRT implants. Dual-chamber ICDs were implanted in 65.5% of cases; 84% were first implants and the rest were generator replacements. Implants were performed in the operating room in 66% of patients and the rest in the electrophysiology lab (54% by a cardiovascular surgeon and 46% by electrophysiologists). The most frequent reason for implantation was primary prevention of sudden death, which was observed in 67.9% of cases (Figure 2). The types of implanted devices are shown in Figure 3. In patients with ICD implantation for secondary prevention, sustained ventricular tachycardia (VT) was the most frequent arrhythmia for this indication (59.5% of cases). Ventricular tachycardia/ventricular fibrillation induction was performed during implants in 7.3% of patients (13.1% in primary prevention and 4.8% in secondary prevention, p=0.25); No relationship was found between induction and the reason for indication of device implantation. In 79.8% of cases, patients who were implanted with an ICD were in FC I-II and 18% in FC III; 53.4% of the patients had a history of hospitalization for heart failure.

Patients with an ICD+CRT were 68.5±11 years old, 77.5% were men and HTN was the most prevalent cardiovascular risk factor (67.6%), followed by dyslipidemia (52.1%), smoking (39.4%) and diabetes 31%. Mean ejection fraction was 24.9±6.7%; 32.4% were in FC II, 56.3% in FC III and 9.9% in FC IV; 87.1% had complete left bundle branch block, 5.7%, complete right bundle branch block and 7.1%, indeterminate intracardiac conduction disorder. Mean QRS width was 164±25.2 ms. A history of hospitalization for heart failure was found in 46.5% of patients and 8.4% presented with kidney failure. The etiol-

Fig. 1. Cardiomyopathy etiology



Other etiologies: Noncompacted myocardium, viral myocarditis, peripartum myocarditis, cardiotoxicity, arrhythmogenic right ventricular dysplasia, Brugada syndrome, long-QT syndrome

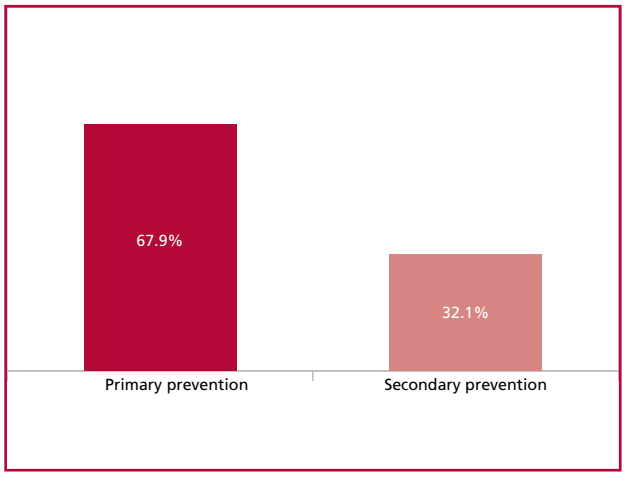


Fig. 2. Type of Indication

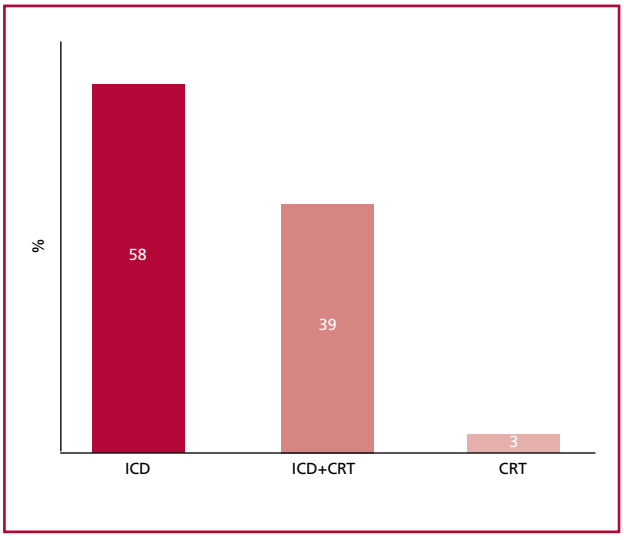
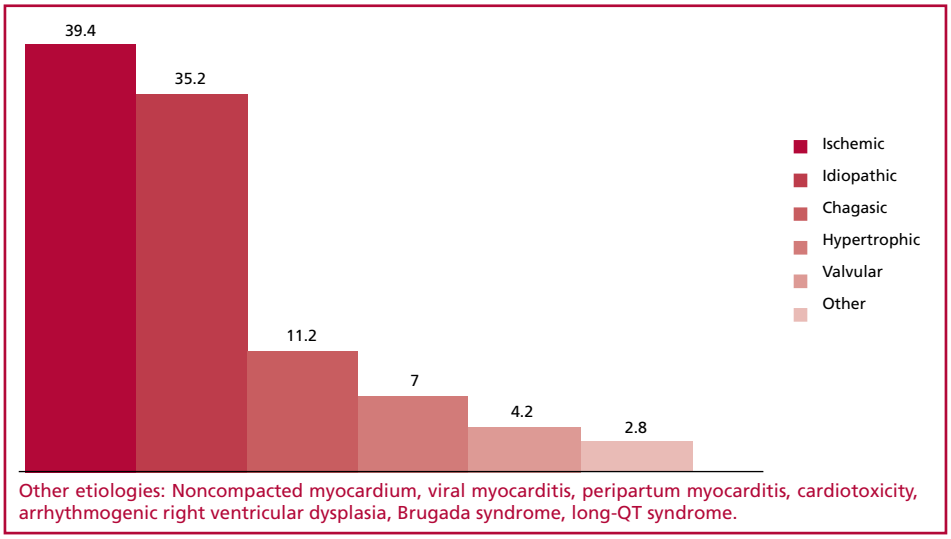


Fig. 3. Type of device implanted

ogy of patients who received ICD+CRT is detailed in Figure 4. An electrophysiologist participated in 87% of ICD+CRT implants. During follow-up 6 patients presented appropriate antitachycardia pacing (ATP) and one patient inappropriate therapy for supraventricular arrhythmia. Two patients presented an electrical storm and in one of them a VT ablation was performed. Three patients died: one as a result of an electrical storm, another due to heart failure and the last one for extracardiac causes. The rate of minor complications (4.4%) was related to the lead: impossibility of placing the resynchronization lead in 4 patients, displacement of the coronary sinus lead in 3 patients and displacement of the right ventricular lead in one patient. A pacemaker pocket infection was reported. No major complications were observed.

DISCUSSION

This is the first registry carried out in Argentina, in which information of ICD implants with and without CRT, including the characteristics of the patients who received them, was obtained. It comprised patients with an indication for implantation of these devices in both primary and secondary prevention, and also patients with cardiomyopathies caused by different etiologies. It should also be noted that patients who received devices from all authorized manufacturers and service providers in our country were included (previous studies in our region included only one brand of devices). (4-6) Most devices were provided by were health insurance and prepaid health coverage, while the state health system was poorly representative. Prevalence of cardiovascular risk factors was led by HTN, followed by dyslipidemia and smoking. Ischemic-necrotic heart disease was the most frequent etiology, followed by idiopathic etiology, which



Other etiologies: Noncompacted myocardium, viral myocarditis, peripartum myocarditis, cardiotoxicity, arrhythmogenic right ventricular dysplasia, Brugada syndrome, long-QT syndrome.

Fig. 4. Percent etiology of patients who received ICD+CRT

is consistent with other international registries. (8) Primary prevention was the main indication for implantation and a higher proportion of indication for this reason than for secondary prevention was observed in this registry in relation to other studies. Unlike other registries, Chagas cardiomyopathy is one of the most frequent causes of indication for ICD in our country. Another difference with other international data is that the participation of electrophysiologists in implant procedures was lower (54% vs. 81.7%). (8-10) The defibrillation test was less frequent than in other registries. It should be noted that this test has been less performed over time and it is only indicated in specific situations. In this registry, the indication for drugs that show improved survival in patients with low ejection fraction and heart failure was low. We should recall that patients who undergo implantation of these devices must be under optimal treatment for heart failure. (11) This cohort of patients provided current information on their characteristics, type of device implanted for primary and secondary prevention of sudden death, their follow-up and complications. The complication rate in this registry was low due to the experience of the participating centers in device implantation and its complications and follow-up. It is therefore important to develop training and certification programs in electrophysiology. (12) The voluntary participation of the different health centers limits national representation. Although it is not yet frequently used in our country, this registry did not include patients who received subcutaneous ICDs nor were their programming parameters discussed in this publication. As a summary of the data obtained, we can highlight the high indication for primary prevention, ischemic and dilated etiologies as the main indication, and the low rate of implant complications.

CONCLUSIONS

This is the first ICD and CRT implant registry made in Argentina. In this study, a high indication rate for primary prevention compared with international registries and a high proportion of indication for ICD-CRT was observed in the population studied compared with the total number of implanted devices. The rate of complications was low and most complications were related to the implantation of the CRT lead for left ventricular resynchronization, the most frequent being the displacement from the coronary sinus. It is important to mention that this study reveals data from our country that were not available up to now.

Conflicts of interest

None declared.
(See authors' conflicts of interest forms on the website/Supplementary material).

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APPENDIX

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Hospital Sor María Ludovica	Jorge Bleiz
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CEMIC	Darío Di Toro
Sanatorio de Los Arcos	Nicolás Maritnenghi
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