

First Argentine Registry of Cardioverter-Defibrillator and Cardiac Resynchronization Therapy: An Opportunity to Analyze the Present to Improve the Future

Primer registro argentino de cardiodesfibriladores y resincronizadores: Una oportunidad de analizar el presente para mejorar el futuro

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Implantable cardioverter defibrillators (ICD) and cardiac resynchronization therapy (CRTD) are highly effective therapeutic interventions to prevent sudden cardiac death in patients with low ejection fraction (EF) and heart failure. There are differences between the clinical characteristics of patients evaluated in randomized ICD and CRTD studies and real world patients in everyday clinical practice. Clinical registries are systematic and (precise deleted) rigorous methods for collecting scientific data through observational studies with the intention of evaluating certain population, its clinical characteristics, and its response to a certain therapeutic intervention. (1)

In 2004, the positive results of the SCD-HeFT study published in the United States, (indicating deleted) demonstrating a reduction in the risk of sudden cardiac death in patients with a cardiomyopathy and EF <35%, (gave the signal for deleted) signaled an imminent expansion in the use of defibrillators in patients at risk of sudden cardiac death. (2) This facilitated the creation of a national (cardioverterdefibrillator deleted) ICD registry as a precondition to approve the Medicare and Medicaid health insurance coverage of an expensive therapy such as ICD implantation for primary prevention of sudden cardiac death with potential morbidity and mortality. (3) The National ICD Registry in the United States was based on a complex multidisciplinary organization, with data collection from the available scientific evidence, which facilitated access to information and scientific research centered on registry data. The evolution of this registry provided answers to the clinical questions on who received an ICD, type of devices implanted, who implanted the device, and in-hospital outcomes. (3-5) (Later on deleted) Subsequently, additional information such as data on defibrillation leads was incorporated and the trend of an increase in the implantation of CRT vs. ICD was observed (with respect) as compared to previous

years. Initial data showed that, in the United States, only 79% of ICD recipients had an indication in accordance with clinical guidelines, (that deleted) there was a higher rate of complications Ascension Medical Group St. Vincent. Cardiac Electrophysiology. Lafayette, Indiana. United States of America in women, and that an association had been identified between the type of implanter's training (to insert the device deleted) and the clinical outcome. (4, 6, 7) Furthermore, in patients who received a dual-chamber ICD a higher rate of complications and a very limited clinical indication for pacemaker implantation was observed. (8)

Three Latin American registries were previously published (on deleted) in patients with defibrillators. The ICD Labor registry focused on patients resuscitated from cardiac arrest due to ventricular fibrillation or ventricular tachycardia, 25% of which (had deleted) carried a Chagas cardiomyopathy. Essentially, this was an ICD registry for secondary prevention of sudden cardiac death. (9) The ICD Registry Latin America included 62% of patients for secondary prevention and 37% for primary prevention. (10) Another Latin American registry exclusively evaluated patients with Chagas cardiomyopathy who had received an ICD. (11) Once again, most of the patients were included for secondary prevention of sudden cardiac death (91%) and 82% of these patients presented with sustained ventricular tachycardia.

In this issue of the Argentine Journal of Cardiology, Eidelman et al. published the Results of the First Argentine Registry of Cardioverter-defibrillator and Cardiac Resynchronization Therapy SAC (RENCARE). (12) Unlike studies previously published by Latin American researchers, this ICD and CRTD registry was carried out exclusively in Argentina and included mostly patients with primary prevention implants (67.9%). The most frequent etiology was ischemic cardiomyopathy, in a smaller proportion than other international reg-

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istries, followed by idiopathic dilated cardiomyopathy and to a lesser extent, Chagas cardiomyopathy. In 58% of cases, patients received an ICD and 39% received a CRTD (device deleted) (a small number of patients received a dual-chamber pacemaker). The former had better EF and functional capacity compared with patients with CRTD, indicating that it (is deleted) was a healthier population; however, both groups had a similar history of hospitalization for congestive heart failure.

In this new registry by Eidelman et al., the percentage of patients who received a dual-chamber ICD was higher than in some international registries (65%). (5, 12) Some patients with sinus node disease or intraventricular conduction disorders may be reasonable candidates for a dual-chamber device. However, the National ICD Registry showed that only 40% of patients who receive a dual-chamber ICD have a pacemaker indication as recommended by clinical guidelines. Given the advances in discrimination algorithms in single-chamber ICDs, dual-chamber ICDs provide no advantage in avoiding inappropriate shocks due to supraventricular arrhythmias. (13) In the Madit II study, dual-chamber ICDs were not associated with a lower chance of receiving inappropriate shocks. (14) On the other hand, patients receiving a dual-chamber ICD are exposed to 40% (more deleted) higher risk of perioperative complications and (higher deleted) mortality compared with (a deleted) single-chamber ICD recipients. These arguments suggest that it would be reasonable to promote educational sessions (between deleted) among cardiologists and electrophysiologists to consider the risk/benefit ratio of using dual-chamber ICDs with the aim of reducing the associated morbidity.

The RENCARE study reported a relatively low proportion of patients treated with beta-blockers, angiotensin converting enzyme inhibitors or angiotensin II receptor blockers, and aldosterone antagonists, drugs well known (to deleted) for decreasing mortality in heart failure patients with low EF. These were the real-world patients that this work aimed to study; therefore, it is likely that a campaign promoting more aggressive heart failure drug (treatment deleted) therapy, targeting internal medicine and cardiology specialists, could have a favorable impact on survival among these patients.

In the study by Eidelman et al., it is gratifying to observe greater involvement of electrophysiologists in more complex implants, such as CRTD, but limited involvement in ICD implants. Although the complication rate in this registry was low, the desired percentage of electrophysiologists involved in implants should be close to 100%. The National ICD Registry demonstrated that (adequately deleted) formally trained electrophysiologists have a lower rate of complications than cardiovascular surgeons. (7) Therefore, in Argentina, patients would benefit from the expansion of intensive and supervised training programs in cardiac electrophysiology that include a significant number of

pacemaker, ICD and CRTD implants in the (syllabus deleted) core curriculum.

Although the sample may well be representative of the population of patients receiving ICDs in general, one of the limitations of this registry is the relatively low number of patients included. Given the low incidence of some clinical events, a larger number of patients would be needed to identify differences between the studied subgroups. On the other hand, the population under study is almost entirely limited to the city of Buenos Aires and its metropolitan area, with the exception of La Plata and Bahía Blanca. (So deleted) Therefore, it is reasonable to (ask deleted) wonder whether the studied sample is representative of a country as large and diverse as Argentina. For example, it is expected that in the north of the country there will be a higher incidence of Chagas cardiomyopathy, a specific population poorly studied in (implanted defibrillators deleted) ICD's for primary prevention. It would be (convenient deleted) desirable that the (representativeness of deleted) RENCARE data to be validated with an expansion towards a national registry with the participation of all the hospitals in Buenos Aires and health centers in all the provinces in which implants are performed.

Finally, RENCARE has been a remarkable and promising effort to collect and analyze data on patients with defibrillators. Prospective data collection should continue for some time to increase population data validation (representativeness deleted) and to continue accumulating (regular deleted) clinical information as the use of complex devices expands and the specialty of implanting physicians (to implant defibrillators deleted) changes with the progress of electrophysiology training programs. This will require a significant (multisectoral deleted) multidisciplinary effort including national leaders in cardiac electrophysiology, the support of representatives from the (implantable deleted) device industry, national health authorities, and clinical researchers. The authors of this registry on ICD's and CRTD's have already taken the first step.

Conflicts of interest

None declared.

(See authors' conflicts of interest forms on the website/ Supplementary material)

Ethical considerations

Not applicable.

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