Rev Port Cardiol. 2019;38(1):43–44

Revista Portuguesa de
Cardiologia
Portuguese Journal of Cardiology
www.revportcardiol.org

EDITORIAL COMMENT

# Implantation of resynchronization and/or defibrillation devices in patients with heart failure: Real-life data from the Síncrone study

## Dados de vida reais sobre a insuficiência cardíaca antes e após a implantação dos dispositivos de ressincronização e/ou de desfibrilhação – o estudo Síncrone

**Victor Sanfins**

*Serviço de Cardiologia, Centro Hospitalar do Alto Ave, Guimarães, Portugal*

Available online 23 January 2019

In 1985 in the USA, a human patient was implanted for the first time with an implantable cardioverter-defibrillator (ICD). At that time the device was only indicated for survivors of sudden cardiac death (SCD) in whom malignant ventricular arrhythmias could still be induced in the electrophysiological study while on antiarrhythmic drugs. The implantation procedure was technically complex (the defibrillator lead was epicardial), ICDs had few of the analytic and decision capabilities available in current devices, and the operative mortality was significant.

The ICD has since become one of the most important therapeutic tools available for reducing mortality in patients with known heart disease and considered, after careful clinical assessment, to be at high risk for SCD.[1] Its efficacy is well documented, both in primary prevention (in patients without known ventricular tachycardia [VT]/ventricular fibrillation [VF] episodes), and in secondary prevention (after documented VT/VF).

Cardiac resynchronization therapy (CRT), which may or may not be associated with an ICD, is indicated for symptomatic patients with congestive heart failure (HF), severely reduced left ventricular function and left bundle branch block despite optimal medical therapy. In appropriately selected patients (i.e. non-responders to medical therapy), CRT has demonstrated clear clinical benefits,[2] including significant reductions in mortality, morbidity and hospitalizations (which account for a large proportion of the costs [1] associated with treatment of HF[3]). CRT has also been shown to halt and even reverse [2] the inexorable worsening of HF. However, the implantation procedure for a CRT device is more complex, given the need for a lead (via a transvenous or epicardial approach) to stimulate the left ventricle.

In Portugal, the first ICD implantation was performed in 1992 at Hospital de Santa Cruz in Lisbon. Making this therapy available to the Portuguese population has not been easy, for various reasons that are beyond the scope of this editorial, although they merit detailed analysis. This difficulty is related not only to questions of cost/benefit, given the significant limitations of funding and human and technical resources in many hospitals, but also – and most importantly – to organizational issues. The result is that Portugal has lower device implantation rates than other European Union countries[4] especially for CRT, meaning that Portuguese patients do not have access to treatments that have been demonstrated, beyond any doubt, to confer significant reductions in morbidity and mortality related to severe HF.[5]

*E-mail address:* vsanfins@hotmail.com

https://doi.org/10.1016/j.repc.2019.01.001

I welcome the initiative of the Portuguese Institute of Cardiac Rhythm (IPRC) to promote this observational prospective multicenter registry,[6] conducted in 16 Portuguese centers, with the aim of documenting clinical practice in Portugal regarding the use and outcomes of electronic cardiac devices for treating patients with HF and left ventricular ejection fraction (LVEF) <35%.

The primary combined endpoint of the study was all-cause mortality and rehospitalization up to one year after the procedure.

Secondary endpoints were mortality and hospitalization due to HF. The study also aimed to determine patients' clinical, electrophysiological and echocardiographic characteristics, to identify predictors of response to CRT, to determine in-hospital and outpatient complications and their predictors, and to assess clinical practice in Portugal regarding implantation of ICDs and CRT devices.

The study included patients of both sexes aged 18 years or over with a diagnosis of HF, LVEF <35% and indication for ICD and/or CRT. Five time points for patient assessment were defined: before device implantation, at hospital discharge, and at three, six and 12 (±1) months after implantation. At each assessment, demographic, clinical, laboratory, therapeutic, radiological, echocardiographic, arrhythmic and electrophysiological data were to be provided.

The study also examined the usefulness of the echocardiogram in the selection of patients for CRT, which at the beginning of the study seemed promising, but was not confirmed in later published studies. The registry initially included 515 patients and data on 419 were analyzed. Mean age was 65±12 years and 77% were male. The main etiologies of HF were ischemic (47%) and idiopathic dilated cardiomyopathy (28%). Of the patients who underwent the initial assessment, half received an ICD and the other half a CRT pacemaker (CRT-P) or CRT defibrillator (CRT-D). Mean LVEF was 28.7±8.5%. Patients with ICDs had less severe disease than those with a CRT-P or CRT-D. Overall one-year mortality, the study's primary outcome, was 3.6%, and all-cause rehospitalization was 11%. Cardiovascular mortality was 1.9% and the main cause for rehospitalization at one year was HF (4.5%), followed by procedure-related complications (2.6%) and arrhythmias (1.4%). Patients with CRT devices presented higher cardiovascular mortality (3.4% vs. 0.5%, p=0.028) and more were rehospitalized (17% vs. 5.6%, p<0.001) than those with ICDs. There was a trend toward higher overall mortality in patients with ischemic etiology (5.4% vs. 1.9%, p=0.05). Implantation-related in-hospital complications were uncommon (4.1%; n=17), occurring mainly in patients with CRT devices, which was related to the greater complexity of the procedure. At one-year follow-up, device-related complications, mainly lead-related, had been recorded in 8.6% of patients. The high rate of appropriate shocks (77%) is noteworthy. Patients undergoing resynchronization presented significant improvements in New York Heart Association (NYHA) functional class (62%), irrespective of previous QRS duration. A complete echocardiographic assessment was obtained in only 82 patients, in whom the presence of intraventricular dyssynchrony was found to be a predictor of improvement in NYHA functional class (relative risk 5.23; 95% confidence interval, 1.13-24.3; p=0.035).

This study, which lasted for several years during which there were various changes in the HF guidelines concerning both devices and pharmacological treatment, paints a useful picture of the situation in Portugal with regard to the use of devices and drugs in the treatment of these patients. A significant percentage of them were prescribed the recommended drugs and class I indications were followed for implantation of appropriate devices in this clinical context, but possible deficiencies in referral were identified, due less to funding constraints than to problems with the organization of HF care. The clinical outcomes recorded in this study are better than those obtained in other similar international registries.

This interesting real-life registry demonstrates the usefulness of implantable cardiac devices in the treatment of HF patients, especially non-responders to medical therapy who can benefit from the significant benefit of CRT over optimal medical therapy. It also identifies echocardiography as a tool that should not be neglected and highlights the need for greater cooperation between different specialties within cardiology in the identification and timely referral of patients indicated for device implantation.

## Conflicts of interest

The author has no conflicts of interest to declare.

## References

1. Colquitt JL, Mendes D, Clegg AJ, et al. Implantable cardioverter defibrillators for the treatment of arrhythmias and cardiac resynchronisation therapy for the treatment of heart failure: systematic review and economic evaluation. Health Technol Assess. 2014;18:1–560.
2. Gold MR, Padhiar A, Mealing S, et al. Economic value and cost-effectiveness of cardiac resynchronization therapy among patients with mild heart failure: projections from the REVERSE long-term follow-up. JACC Heart Fail. 2017;5:204–12.
3. Lin Y-S, Hung SP, Chen PR, et al. Risk factors influencing complications of cardiac implantable electronic device implantation: infection, pneumothorax and heart perforation. A nationwide population-based cohort study. Medicine. 2014;93:1–8.
4. Cavaco D, Morgado F, Bonhorst D, et al. Registo nacional de eletrofisiologia cardíaca (2013/2014). Rev Port Cardiol. 2016;35:407–12.
5. Tomini F, Prinzen F, van Asselt AD, et al. A review of economic evaluation models for cardiac resynchronization therapy with implantable cardioverter defibrillators in patients with heart failure. Eur J Health Econ. 2016;17:1159–72.
6. Bonhorst D, Guerreiro S, Fonseca C, et al. Implantação de dispositivos de ressincronização e/ou desfibrilhação em doentes com insuficiência cardíaca: dados da vida real. Rev Port Cardiol. 2009;38.