Implantable Cardioverter-Defibrillators and Cardiac Resynchronization Therapy in the Treatment of Heart Failure with Reduced Ejection Fraction

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Abstract

It has been long acknowledged that electrical-conduction disturbances may be both a cause of heart failure and a consequence of it.¹,² In fact, many patients with heart failure have an asynchronous contraction pattern of the heart muscle that further reduces the heart ability to pump blood. Electrical disturbances may therefore result in progressive left ventricular dysfunction, due to the added effects of HF-related electrical dyssynchrony. For this reason, device therapy may play a key role in the management of patients with heart failure and reduced ejection fraction (HFrEF). In particular, Implantable Cardioverter-Defibrillators (ICD) and Cardiac Resynchronization Therapy (CRT) may improve ejection fraction by reestablishing mechanical synchrony, possibly reversing symptoms and signs of heart failure, in addition to the more obvious role of ICD in terminating ventricular arrhythmias that threaten sudden death. Recommendations on device therapy from the current guidelines on heart failure management put out by the ESC/HFA in 2016 update our understanding of the evidence base for the use of ICD and CRT in HFrEF. We review these recommendations and the evidence behind them.

Keywords: Heart failure; Guidelines; Devices

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Introduction

It has been long acknowledged that electrical-conduction disturbances may be both a cause of heart failure and a consequence of it.¹,² In fact, many patients with heart failure have an asynchronous contraction pattern of the heart muscle that further reduces the heart ability to pump blood.³ Electrical disturbances may therefore result in progressive left ventricular dysfunction, due to the added effects of HF-related electrical dyssynchrony.⁴ For this reason, device therapy may play a key role in the management of patients with heart failure and reduced ejection fraction (HFrEF). In particular, Implantable Cardioverter-Defibrillators (ICD) and Cardiac Resynchronization Therapy (CRT) may improve ejection fraction by reestablishing mechanical synchrony, possibly reversing symptoms and signs of heart failure, in addition to the more obvious role of ICD in terminating ventricular arrhythmias that threaten sudden death. Recommendations on device therapy from the current guidelines on heart failure management put out by the ESC/HFA in 2016⁵ update our understanding of the evidence base for the use of ICD and CRT in HFrEF.

ICD

ICD’s are pacemaker-like devices, originally developed in the 1970s for the electrical termination of ventricular tachyarrhythmias.⁶ This technology has undergone considerable advances in the procedure of implantation, size and function. Whereas ICD’s initially required invasive procedures for implantation (i.e. thoracotomy), advances in microprocessor technology have made the devices progressively smaller and therefore more easily implantable in the pectoral region with a per-cutaneous procedure. This procedure often lasts about 1 hour under local anesthesia. The ICD is composed of a microprocessor, batteries, capacitors and a “header” that contains a site to attach leads.⁷

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Different types of ICDs exist: single-chamber (one lead is placed in the right ventricle), dual-chamber (one right atrial lead and one right ventricular lead), and CRT ICDs (with also a left ventricular lead that is placed via the coronary sinus or epicardially).

Modern ICD’s or mixed function devices now frequently fulfill multiple life-saving or disease modifying functions including atrial and ventricular defibrillation, anti-tachycardia pacing, backup bradycardia pacing, electrogram storage, and biventricular pacing.

According to the new ESC guidelines, ICD’s may be used in selected patients with HFrEF with the following aims: for primary prevention of sudden cardiac death in symptomatic patients and for secondary prevention of sudden cardiac death in symptomatic patients. Recommendations from the ESC guidelines, combined with a consideration of the ESC/European Heart Rhythm Association guidelines on ventricular tachyarrhythmias and sudden cardiac death are below described.

ICD treatment in asymptomatic low ejection fraction patients
Regardless of symptoms, ICD implantation is recommended to prolong survival in patients expected to live more than 12 months with left ventricular systolic dysfunction (LVEF ≤ 35%) of ischaemic or non-ischaemic origin, provided in the case of recent MI the patient is at least 40 days after the acute myocardial infarction. Studies have demonstrated that ICD reduces mortality rates in these patients.[11,12,4,9] Importantly it has been demonstrated that in the 40 days immediately post-MI ICD implantation does not improve prognosis[9,10] and therefore ICD therapy is not recommended during this 40-day window.

ICD treatment in symptomatic heart failure patients
For primary prevention, ESC guidelines recommend ICD in order to diminish the risk of sudden death and all-cause mortality in symptomatic patients with NYHA class II–III and LVEF ≤ 35% despite at least 3 months of optimal medical therapy, and if there is clinical evidence of the following criteria: a) expectation of survival longer than 1 year with good functional status; b) ischaemic heart disease (unless patient has had a myocardial infarction in the prior 40 days, as above described); c) dilated cardiomyopathy. In fact, it has been found that ICD decreases the rate of sudden death for arrhythmia in patients with HFrEF.[13,14] Notably, mortality rates are associated with the severity of heart failure.[15] Patients with worse heart failure obtain a greater benefit from ICD, in terms of survival. Similarly, patients with ischaemic heart disease receive a greater benefit from ICD as they are at greater risk of sudden death than patients with dilated cardiomyopathy.[14] However, ICD is not recommended in heart failure patients with an extremely short prognosis, ie NYHA class IV and severe symptoms that are pharmacologically resistant and are not candidates for CRT, a ventricular assist device, or cardiac transplantation. In these patients, ICD has been found not to be beneficial.[16–18] ICDs may be also used for secondary prevention. The new guidelines state that ICD is recommended “to reduce the risk of sudden death and all-cause mortality in patients who have recovered from a ventricular arrhythmia causing haemodynamic instability, and who are expected to survive for >1 year with good functional status”. [5] In this case, an ICD should be considered with the aim of prolonging survival. Notably, studies have shown that survival benefit is less clear when LVEF is over 35% and that the presence of comorbidities affects survival within the following year.[19–20] Thus, it is pivotal to carefully assess these
parameters and patient’s quality of life before taking the clinical decision for an ICD.[5] Before replacing the generator, the patient must be re-assessed to monitor the clinical status, his/her needs and possible changes in treatment aims, in order to decide if continue or not ICD therapy.[21–23] Finally, a wearable ICD may be considered for a short period of time or as a bridge to cardiac transplantation in patients at risk of sudden cardiac death.[24]

**CRT**

CRT is a device that may be used to restore synchronization, i.e. the normally coordinated pumping action of the ventricles. Unlike other pacemakers, CRT has a third lead that is positioned in a vein on the outer surface of the left ventricle. Advancements in CRT design and implantation have made the device smaller and more practical (e.g. battery life is longer).[25] Specifically, CRT sends small, undetectable electrical impulses to both lower chambers of the heart to help them beat together, simultaneously stimulating the left and right ventricles.[3] A coordinated pattern may therefore be re-established, improving the heart’s ability to pump blood and oxygen to the body.

The current ESC/HFA guidelines recommend CRT in selected HFrEF patients to improve symptomatic and reduce morbidity and mortality (see Figure 9.1).[5] CRT is recommended to reduce mortality and morbidity in symptomatic patients in sinus rhythm with QRS duration ≥ 150 msec, a LBBB pattern and LVEF ≤ 35% despite optimal medical therapy. The guidelines also indicate that the use of CRT should be considered for patients with the aforementioned characteristics and non-LBBB QRS morphology, despite slightly less evidence in such patients. CRT is also recommended in symptomatic patients with heart failure in sinus rhythm and with a QRS duration of 130–149 msec and a LBBB QRS morphology with LVEF ≤ 35% despite optimal medical therapy in order to improve symptoms and reduce morbidity and mortality. The use of CRT may also be considered for patients with these characteristics and a non-LBBB QRS morphology, but some inconsistencies in available data do not allow us to draw firm conclusions in such patients.[5]

In order to improve symptoms and reduce morbidity and mortality, CRT should be considered for patients with LVEF ≤ 35% in NYHA class III–IV despite optimal medical therapy, if the following conditions are satisfied: a) atrial fibrillation; b) QRS duration ≥130 msec; c) patient expected to return to sinus rhythm (or a bi-ventricular capture strategy has been set). Regardless of NYHA class, CRT (rather than right ventricular pacing) is recommended for patients with HFpEF who are candidates for ventricular pacing for high degree atrio-ventricular block in order to reduce morbidity. This also includes patients with atrial fibrillation.

Although there are some inconsistencies in the available studies, CRT may be considered for patients with HFpEF who have received a conventional pacemaker or an ICD and subsequently develop worsening heart failure (but not if they have stable heart failure) despite optimal medical therapy and if they present a high proportion of right ventricular pacing. Thus, CRT therapy may reduce all-cause mortality, including sudden cardiac death. It may also improve hospitalisations in HFpEF patients.[25] However, a marked heterogeneity of response has been noted in clinical trials on CRT.[7,26]

**Response to treatment and complications**

The response to CRT implantation in heart failure varies considerably according to features such as sex, QRS and LBBB characteristics and the aetiology of the heart failure. Specifically, studies on CRT have found that men are less likely to respond than women, possibly due to a larger body and heart size.[27,28] QRS width and morphology appear to be related to a beneficial response to CRT. In particular, QRS duration has been consistently found to predict the effects of CRT on morbidity and mortality in patients with symptomatic HFpEF who are in sinus rhythm.[29] Whether LBBB morphology per predicts a more favourable response to CRT independent of QRS width is less clear. The importance of QRS duration is evident from the individual patient meta-analysis performed by Cleland and colleagues (see Figure 2).

Patients with an ischaemic aetiology are less responsive, as the myocardial scar tissue is less amenable to effective remodelling.[30] These clinical features should be carefully assessed to understand clinical benefit versus implantation risks. In fact, a number of complications related to implantation and device activation have been described with the use of both devices.[7,31] Major complications include inappropriate shocks, device infection, lead malfunction and complications related to extraction of devices.[25] A harmful effect related to CRT has been found in patients with a QRS duration < 130 msec.[29,32,33] Thus, risk-benefit ratio of device therapy should be considered during clinical assessment and monitoring. Diminishing the implantation risks is a main challenge for upcoming research.

In conclusion, there is consistent evidence supporting the use of ICD and CRT in selected patients with HFpEF, to prolong life and avoid sudden death. With a strict application of the aforementioned recommendations from current guidelines, ICD and CRT treatments form an essential component of the modern management of patients with HFpEF.

**Declaration of Interest**

The author declares no conflicts of interest.

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