

The Wearable Cardioverter-Defibrillator in Non-Ischemic Cardiomyopathy Patients

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Received: April 02, 2019; **Published:** April 29, 2019

Abstract

Purpose of Review: The Wearable Cardioverter-Defibrillator (WCD) has been shown to be a safe and effective tool for monitoring for dangerous arrhythmias until a decision for an Implantable Cardioverter-Defibrillator (ICD) is reached. While there is more data to support its use in ischemic cardiomyopathy, indications for its use in non-ischemic cardiomyopathy are less clear.

Recent Findings: Multiple clinical studies have shown good compliance and a low rate of inappropriate shock therapy with the WCD. The burden of dangerous tachyarrhythmias in patients with non-ischemic cardiomyopathy has been less well characterized.

Summary: In this focused review, we will summarize the indications for the WCD, review recent clinical trials on the arrhythmia burden in non-ischemic cardiomyopathy patients, and propose an alternate paradigm for evaluating the utility of the WCD.

Keywords: *Wearable Cardioverter-Defibrillator (WCD); Implantable Cardioverter-Defibrillator (ICD)*

Introduction

Sudden cardiac death (SCD) secondary to ventricular tachyarrhythmias is a catastrophic consequence of cardiomyopathy with an estimated annual burden of around 350,000 events in the United States [1]. The availability of prompt defibrillation therapy is imperative to maximize survival and informs the current guidelines for primary prophylaxis with an implantable cardioverter-defibrillator (ICD) in high-risk patients. However, ICD implantation is not recommended during the early phase of ischemic or non-ischemic cardiomyopathy, and during this phase, a wearable cardioverter defibrillator (WCD) has been shown to be safe and effective to provide continuous monitoring and treatment of life-threatening ventricular arrhythmias potentially leading to SCD. In addition, while there is convincing evidence that ICD placement in ischemic cardiomyopathy (ICM) confers a mortality benefit, the data in non-ischemic cardiomyopathy (NICM) is less robust. Here we discuss the role of defibrillation therapy, with a focus on the role of the wearable cardioverter defibrillator in patients with NICM.

Primary prevention of sudden cardiac death in non-ischemic cardiomyopathy

Approximately 20% of patients with SCD have non-ischemic cardiac disease from factors such as genetic causes, prior viral infections, amyloidosis, sarcoid disease, persistent tachycardia, alcohol abuse, or Takatsubo's cardiomyopathy [2]. A few previous randomized controlled trials investigated the role of the ICD for primary prevention in NICM. The CAT (Cardiomyopathy Trial), AMIOVIRT (Amiodarone Versus Implantable Cardioverter Defibrillator Trial), DEFINITE (Defibrillators in Non-Ischemic Cardiomyopathy Treatment Evaluation Trial), and SCD-HeFT (Sudden Cardiac Death in Heart Failure Trial) trials had controversial findings on reducing all-cause mortality

when comparing ICD to medical therapy alone. However, criticisms of these trials included being underpowered, low overall event rates, and poor optimization of medical therapy [3]. A subsequent meta-analysis of five primary prevention trials revealed a 31% decrease in all-cause mortality for ICD when compared to medical therapy [4]. A recent systematic review further showed that an ICD in addition to medical therapy in people with NICM decreased all-cause mortality and SCD [5]. The most recent study looking at the life-saving benefit of the ICD in NICM was the DANISH ICD clinical trial. However, this study found no difference in all-cause mortality, but a significant 50% relative risk reduction in SCD (~4% absolute risk reduction) with an ICD compared to OMT in patients with left ventricular ejection fraction (LVEF < 35%) and New York Heart Association (NYHA) class II-III symptoms [6].

Current guidelines recommend that an ICD be considered for primary prevention in NICM with severely reduced LVEF < 35% and NYHA II/III symptoms (Class I recommendation) or NYHA I symptoms (Class IIB recommendations) despite optimal guideline based medical therapy [1]. The WCD can be used as a ‘bridging therapy’ in patients with a newly diagnosed NICM and severely reduced LVEF who are temporarily at an increased risk for SCD during the time of therapy optimization. At the end of this time period of therapy optimization, they either have a definitive indication for an ICD placement or they could potentially improve their clinical status.

The wearable cardioverter defibrillator in non-ischemic cardiomyopathy

The WCD is an innovative technology consisting of a chest garment with monitoring electrodes capable of detecting shockable rhythms and delivering shock therapy unless aborted by the WCD user. Current AHA/ACC/HRS guidelines feature a Class IIa recommendation for WCD in patients with increased risk of SCD but not eligible for an ICD, including those with newly diagnosed NICM [1], during the time of therapy optimization. The cost of the WCD is approximately \$3300 per month. Efficacy data were initially obtained from the WEARIT and BIROAD trials although there was no deliberate analysis of patients with NICM in this clinical study [7].

The burden of sustained ventricular tachyarrhythmias in at-risk NICM was evident in the WEARIT-II observational registry revealing a 1% incidence at 3 months, suggesting the usefulness of the WCD in NICM patients prior to ICD implantation, although the event rate was relatively low [8]. Analysis of a US Database of 127 patients with NICM secondary to alcohol abuse, who were prescribed WCD supported the high incidence of arrhythmias in NICM with the WCD providing appropriate therapy in 5.5% of patients, again affirming its utility [9]. Another observational study from Germany of 105 NICM and ICM patients showed that 4.8% of patients received appropriate shocks, of which 2 were NICM and 3 were ICM patients, resulting in ICD implantation in half of the patients [10]. In addition, the PROLONG study proposed that a significant proportion of patients with newly diagnosed heart failure show LVEF improvement beyond 3 months after initiation of therapy optimization, suggesting that WCD use could be prolonged, especially in NICM in whom life-ventricular tachyarrhythmia events were also present beyond 3 months use [11-13]. Conversely, a retrospective study of 254 patients at a single center by Singh, *et al.* found that there were no significant ventricular tachyarrhythmia events in patients with NICM [14], questioning the utility of the WCD. Summary of these studies is shown in table 1.

Study/Authors	Year Published	Total number of patients	Number of patients with NICM	Compliance (days/ hours worn)	Appropriate therapy rate	Inappropriate therapy rate	LVEF Improvement Rate in NICM
Kutyifa, <i>et al.</i> WEARIT II [11]	2015	2000	927	90 days/22.5 hours	54% (NICM+ICM)	0.5% (NICM +ICM)	42%
Singh, <i>et al.</i> [14]	2015	639	254	61 days/22 hours	0% (NICM)	1.2% (NICM)	39%
Salehi, <i>et al.</i> [9]	2016	127	127	51 days/18 hours	5.5% (NICM)	10.2% (NICM)	33%
Duncker, <i>et al.</i> PROLONG [13]	2017	156	117	101 days/21.4 hours	7% (NICM)	0%(NICM)	Not reported
Roger, <i>et al.</i> [10]	2018	105	41	68.8 days/21.5 hours	4.8% (NICM+ICM)	0.95% (NICM + ICM)	51.2%

Table 1: Characteristics of WCD studies in NICM patients.

Safety and complications of the wearable cardioverter defibrillator

In the WEARIT/BIROAD study, up to 22.5% of patients discontinued WCD use due to discomfort, skin irritation or lifestyle interference [9]. Results from the BIROAD, WEARIT, and WEARIT-II studies revealed a low incidence of inappropriate shock therapy; 0.67%

inappropriate shock per month in WEARIT/BIROAD [7] and 0.5% of all participants in WEARIT-II [8]. The median wear-time was 22.5 hours per day in WEARIT-II [8]. According to a systemic review of clinical studies published on the WCD, the median wear time was noted to be longer for patients with NICM, and specifically for those with peripartum cardiomyopathy. One proposed reason for this difference was the higher rate of improvement in ejection fraction in NICM patients during the time of therapy optimization [15]. These findings suggest that the WCD is a safe and effective option for management of temporary high risk for SCD in at-risk NICM patients.

Future Directions

Ultimately, current data behind the safety of the use of WCD in NICM during therapy optimization are equivocal. However, the absolute utility of the WCD to better risk-stratify NICM patients who are at an increased risk for arrhythmic events has been less studied, and there were no randomized trials with the WCD in this subset. Nevertheless, it is difficult to ascertain the value of the WCD just by looking at the incidence of shocks. Management of newly diagnosed NICM should focus on optimizing guideline directed medical therapy and addressing modifiable risk factors, and during this time period, the WCD has been proven to be safe and effective to monitor and treat life-threatening ventricular arrhythmias until improvement or decision for an ICD is reached.

Conclusion

The WCD can be invaluable in the period of time where the patient is at high risk for SCD but before ICD implantation. More large-scale studies are needed looking specifically at patients with NICM to better evaluate whether the WCD also confers a mortality benefit. However, the arrhythmia burden in the trials described in this review do not reflect the true utility of the WCD; which is to provide a safe tool while medical management of heart failure is optimized.

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Volume 6 Issue 5 May 2019

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