Journal of
Cardiology & Cardiovascular Therapy
ISSN: 2474-7580

Juniper Publishers
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Mini Review
Volume 9 Issue 1 – January 2018
DOI: 10.19080/JOCCT.2018.09.555754

J Cardiol & Cardiovasc Ther

The Wearable Cardioverter Defibrillator: Still without a Compelling Indication

Peter Ott*

Associate Professor of Clinical Medicine, Banner University Medical Center, USA

Submission: December 18, 2017; **Published:** January 17, 2018

***Corresponding author:** Peter Ott, MD, Associate Professor of Clinical Medicine, Sarver Heart Center, Banner University Medical Center-Tucson, 1501 N Campbell Avenue, Tucson AZ, 85724, USA, Tel: 520 626 6358; Email: ottp@email.arizona.edu

Introduction

The wearable cardioverter defibrillator (WCD) has recently been introduced as a therapy to reduce mortality in patients presumed to be increased risk for sudden arrhythmic death. Its efficacy appears to be implied by its proven ability to detect and defibrillate VT/VF. However the currently available data on the WCD is non-randomized and comes from several reports of single center experiences, and reviews of post market release, often vendor supported, registry data. In the absence of randomized trials, the effect of the WCD on patient survival cannot be determined. The mere ability to shock terminate VT/VF by the WCD does not suffice to assume survival benefit when used in large patient populations. These severe limitations have been acknowledged in the recent AHA science advisory report [1], providing a "tentative interim framework" resulting in mostly class II b recommendations ("treatment may be considered") with only level C support ("consensus opinion by experts only"). This contrasts sharply with AHA class I recommendations ("treatment should be considered") with level A support ("multiple clinical randomized trials") for the implantable cardioverter defibrillator.

The WCD is being heavily advertised to temporarily "protect" patients presumed at increased risk for arrhythmic death but not eligible for ICD implantation. The largest of such populations meet ICD indications but are temporarily ineligible for device implantation either because of recent MI (40 day waiting period), recent CABG/PCI (90 day waiting period) or newly diagnosed dilated cardiomyopathy (90 day waiting period). These waiting periods are based on the exclusion criteria of clinical trials establishing the benefit for the implantable ICD [2,3], and practically serve to allow for optimizing medical therapy, which often results in improvement of cardiac function with subsequent removal from ICD eligibility. The actual mortality risk, and in particular the risk of sudden arrhythmic death, during these waiting periods is not well established.

The VALIANT trail [4] is often cited in support of the need for defibrillator therapy in patients early after MI. This trial randomized 14,609 patients after MI with reduced LV function and/or clinical heart failure to valsartan, captopril or both. During 2.4 year follow up, 2,800 deaths were observed, of which 1067 were classified as either sudden death (N=903) or resuscitated cardiac arrest (n=104). The median time to event occurrence was 180 days, but 580 events occurred within the first 30 days (event rate 1.4%), suggesting a possible role for defibrillator therapy early after MI. However, autopsy data [5], available on a subset of this patient population with sudden death, revealed a non-arrhythmic mechanism (mostly recurrent MI or cardiac rupture) in 51%, a finding that would be expected to limit the therapeutic benefit of defibrillator therapy.

Consistent with these data are the results of two randomized implantable defibrillator trials [6,7] in a total of 1,572 patients with acute MI, reduced LV function and additional risk markers. While in both trials the arrhythmic mortality was reduced in the ICD group, an increase on non-arrhythmic mortality was seen resulting no benefit in total survival. Information on the WCD in the immediate post MI period is based primarily on a large post market release database review (n=8,453), with, by design, limited clinical information [8]. In the first three months 133 patients (1.6%) were defibrillated by the WCD for ventricular arrhythmias. Despite successful defibrillation, 51 (38%)of those patients died (12 patients did not survive to ER, 3 died within 2 days after admission and 41 died more than 3 days after the shock event). An additional 34 patients died due to bradycardia/asystole. The WEARIT-II registry [9] reporting on 2,000 patients (805 with established ischemic cardiomyopathy, 905 with non-ischemic cardiomyopathy, 286 with congenital heart disease) encountered 120 VT/VF events in 41 patients during a3-month follow. For 90 VT events, the patient withheld WCD therapy due to hemodynamic tolerance. Thus, in this patient population, the effect of the WCD on total mortality remains unknown.

Patients with newly diagnosed dilated cardiomyopathy may be at risk for sudden arrhythmic death. The only randomized trial

comparing ICD with no ICD therapy in patients with recent onset (<9 months) non-ischemic cardiomyopathy on optimal medical therapy was terminated early due to low overall mortality and lack of survival benefit [10]. Likewise, registry data on the WCD use in this patient population has shown a very low incidence of device treated VT/VF: in the initial nationwide registry data [11] only 4 out of 546 patients with newly diagnosed DCMP experienced VT/VF events defibrillated by the WCD during a 2 month follow up. The more recent prospective WEARIT-II registry [9] showed a 1% VT/VF event rate in 922 patients with newly diagnosed DCMP within 3 months of WCD therapy. A single center experience [12] reported no shocks for VT/VF in 271 patients with newly diagnosed non-ischemic cardiomyopathy during a median wear time of 71 days. Reversibility of the cardiomyopathy processes, as well as early improvement in LV function with vigorous pharmacological therapy may explain the low incidence of VT/VF in this patient population, and suggests that the addition of short-term therapy with the WCD may have limited, if any, effect on overall survival.

The lack of clinical randomized trial date on the effect of the WCD on mortality in these particular patient populations is concerning. Given the risk of arrhythmic death in these patients, yet absence of mortality benefit with standard ICD technology, a randomized trial using the non-invasive WCD with relatively short follow-up period of 1-3 months (40-90 day waiting) would be expected to yield results quickly. However, the only randomized trial (VEST, NCT01446985), started enrolling patients with LV ejection fraction <35% early after acute MI in 2008. The goal is to enroll 1,900 patients. The primary outcome is sudden cardiac death at 3 month after MI, and results are not expected until 2017.

Thus, in patients with reduced LV function after recent MI or new onset dilated cardiomyopathy, the data discussed above shows low VT/VF event rates, a substantial proportion of non-arrhythmic sudden death mechanism on autopsy, hemodynamic tolerance of many VT episodes and a significant short-term mortality despite successful VT/VF termination. Thus there is doubt as to whether short-term therapy with the WCD would reduce mortality in these patients. Results of randomized studies of WCD therapy in these patient populations are urgently needed before widespread use of this technology can be recommended.

DOI: 10.19080/JOCCT.2018.09.555754

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How to cite this article: Peter O. The Wearable Cardioverter Defibrillator: Still without a Compelling Indication. J Cardiol & Cardiovasc Ther 2018; 9(1): 555753. DOI: 10.19080/JOCCT.2018.09.555754.