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Editorial

Gimmick or Godsend? The Wearable Cardioverter Defibrillator (WCD)

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See article by Salehi et al., pages xxx-xxx of this issue.

As a practicing clinical cardiac electrophysiologist, I commonly see patients referred for an opinion on how to manage their newly diagnosed nonischemic dilated cardiomyopathy (NICM). Specifically, the question usually is, "Should this patient be offered an implantable cardioverter defibrillator (ICD) implant for the primary prevention of sudden death?"

Fortunately, we have an abundance of literature and clinical practice guidelines[1-3] to assist in decision making. Patients with NICM should generally have their modifiable and reversible causes addressed (eg, tachycardiomyopathy, alcohol-induced, cytotoxic drugs, takotsubo cardiomyopathy, etc) and receive best medical therapy for at least 3 months before committing to an ICD. Indeed, a substantial proportion may recover to a sufficient degree to allow them to safely forego the ICD implant.

This "watch and wait" approach—hoping for improvement—is sensible, measured, and well supported by the literature. But I must confess to a nagging sense of unease every time I dutifully follow the guidelines and send these patients away on their beta blockers and angiotensin receptor blockers to wait for improvement in their left ventricular ejection fraction. For the patients destined not to improve, we are presumably exposing them to an unprotected risk of sudden death for several months. And even for those destined to improve, the risk of sudden death cannot be zero.

The other thing, of course, is that the real world is always very different from the world that is manufactured by the typical rigorous clinical trial. Many patients present themselves to us in different ways than those enrolled in trials. Consider the patient on low doses of the usual "cocktail" of drugs, for example, and an ejection fraction of 25% with no modifiable risk factors. Do we increase the doses further even though the patient reports feeling fatigued on the drugs? Does the clock start ticking only when maximum tolerated doses are achieved? What if the patient has numerous premature ventricular complexes, or reports waves of dizziness? What if they report a 2-year history of dyspnea, raising the possibility that the NICM has been present for a longer period of time? What about the patients with coronary disease whose left ventricular (LV) dysfunction is "out of proportion" to the degree of coronary disease but for whom some of the LV dysfunction may be related to ischemic damage?

These are real-life situations that we, together with our patients, face every day. When the consequences are life and death, watchful waiting can be a very anxiety-inducing exercise for both clinicians and patients. Those of us in this area of clinical practice have all seen sudden deaths during this "watch and wait" period. Fortunately, they are not common, but they do happen.

In this issue of the *Canadian Journal of Cardiology*, Salehi et al.[4] provide not only additional insights into what happens to some patients while they are in this waiting period, but also some insights into the potential role of the wearable cardioverter defibrillator (WCD). The WCD is essentially a vest that patients can wear that monitors for and treats ventricular arrhythmias with shocks. Patients have the option to manually abort impeding shocks if they are conscious and feeling well during an identified episode.

The authors' series examined 127 patients with self-identified heavy alcohol use who had been diagnosed with alcoholic cardiomyopathy (ACM). Although this is not a truly representative group of the unselected patients with NICM we would see consecutively in clinical practice, ACM may represent up to 40% of the total population of NICM in our society.[5] Of the 127 patients, 11 had suffered ventricular tachycardia (VT) or ventricular fibrillation (VF) and thus were essentially a "secondary prevention" population. The remainder (116) would be best classified as potential primary prevention candidates for an ICD.

These patients were then offered a WCD while treatment for the ACM (pharmacological treatment plus encouragement to abstain from alcohol) was instituted. The patients wore the device for a median of 51 days (range 1-743 days) for a median of 18 hours a day. Seven (5.5%) had 9 appropriate shocks while wearing the device with a median time to first

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shock of 30 days. Importantly, 6 of these shocks were for polymorphic VT or VF—rhythms far more likely to have been fatal than monomorphic VT. Four of the 7 who received shock(s) were the primary prevention patients.

Inappropriate shocks—those delivered for either supraventricular tachycardias or because of T-wave oversensing or artefact—were delivered 18 times to 13 patients. Inappropriate shocks are the Achilles' heel of any automatic defibrillator technology and are to be minimized as much as possible because they cause considerable physical pain as well as psychological distress.[6]

Other investigators, through small trials and registries, have evaluated the safety and efficacy of the WCD[7-12] in patients for whom the risk of sudden death is felt to be elevated but for whom there is some reasonable expectation that improvement in myocardial function will occur in the short or medium terms. Some key learnings have emerged: (1) the appropriate shock rate over short periods of time is nontrivial; (2) the WCD is effective in identifying and successfully treating these potentially lethal rhythms; and (3) recovery of LV function in patients with NIDM occurs in a significant minority of patients.

The biggest unresolved question, of course, is whether the systematic application of WCD technology in these patients can be shown to reduce mortality in a population. After all, the sole purpose of any defibrillator technology, surely, is to reduce the risk of overall mortality or at least mortality secondary to ventricular arrhythmias. Although the available data on appropriate shocks delivered to patients wearing WCDs are compelling, history has taught us that this correlates poorly with overall mortality reduction. In other words, an appropriate shock does not always equate to a life saved.

It is also instructive to recall that in the landmark secondary prevention[13-15] and primary prevention trials[16-18] that established ICDs as the standard of care for patients who have survived cardiac arrest or who are at high risk for sudden death secondary to ventricular arrhythmias, the time frame of evaluation was much longer than that seen in the WCD trials and registries. Given the relatively modest relative and absolute risk reductions in the secondary and primary prevention trials, one speculates that the numbers needed to enrol to show a mortality benefit for WCDs would be very high. Is such a trial feasible?

When we were working on the development of wait time benchmarks for primary prevention ICDs approximately 10 years ago, we set the benchmark at 8 weeks.[19] The rationale was that we did not want patients waiting for an ICD to be subjected to any higher wait list-related mortality than patients awaiting cardiac surgery did. At that time, the Cardiac Care Network in Ontario had developed a sophisticated province-wide wait list management system for cardiac surgery that is considered among the best in the world. Their benchmark wait times for cardiac surgery at that time correlated with a 0.5% wait list mortality. By using MADIT II data, and presuming that mortality rates were linear over time, we calculated that 1 in 200 (0.5%) patients awaiting ICD placement for primary prevention would die every 8 weeks because and only because they do not have an ICD in situ.

Accepting the many limitations of this model (including the fact that the MADIT II population is different from those who are nominally eligible for WCD therapy), it is nevertheless helpful to consider the magnitude of these numbers when considering the potential incremental benefit of the short-term use of the WCD.

Is the WCD a gimmick or a godsend? Although it is a bit finicky and uncomfortable to wear for some, it is noninvasive, seems to be highly effective in correctly identifying and treating ventricular arrhythmias, and has great intuitive appeal as a "safety net" or temporizing measure while waiting for either improvement in the clinical condition or for the implant of an ICD. On the other hand, definitive evidence as to its clinically meaningful efficacy (ie, mortality reduction) is lacking and may never come, and the potential downsides (inappropriate shocks; possible psychological morbidity) are not trivial. The future likely lies in the identification of high-risk populations. Salehi et al. have provided for us some important new information on ACM that suggests that these patients may be at higher risk than those with NICM in general. More work to identify high-risk patients would undoubtedly help us to find the proper place for WCDs in clinical practice.

Disclosures

The author has no conflicts of interest to disclose.

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