

The Diagnostic Evolution of the Cardiac Implantable Electronic Device: The Implantable Monitor of Ischemia

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Editorial Comment

The term evolution refers to a process of growth, development, or formation. The foundation of evolution is the accumulation of prior successes or failures that have ultimately directed the process. Fundamental to the practice of electrophysiology has been the technology evolution of the cardiac implantable electronic device.

In 1958, Rune Elmquist developed the first implantable cardiac pacemaker that was implanted by Åke Senning.¹ This device was strictly used for therapy. It delivered an electrical stimulus at a rate of 70–80 beats per minute with a pulse amplitude of 2 V and a width of 1.5 mV. Although the first device failed almost immediately and the second one only lasted approximately 6 weeks, Arne Larson, the first patient to receive them, lived another 43 years and survived to have received over 20 devices of various sizes and technologies.²

The success of the implantable cardiac pacemaker also prompted the need for the technology to evolve. The device accurately and reproducibly delivered a set therapy; but without a means to diagnose and respond to intrinsic cardiac conduction, patients exchanged one set of symptoms for another. The diagnostic evolution of pacemakers remains a contemporary area of research and investigation. Even the simplest of modern devices can sense and respond to intrinsic conduction in the atrium and/or ventricle.

Some devices automatically determine lead thresholds and adjust energy delivery to optimize battery life or alert the patient if a possible failure has occurred. Pacemakers can diagnose, record, and act on tachyarrhythmias in both the atrium and ventricle (Fig. 1A). For example, in Figure 1B a pacemaker diagnosed the period of time per day the patient was in atrial fibrillation (AF). This patient underwent radiofrequency ablation of his AF and had an abrupt decline in the percentage per day in the arrhythmia. The device diagnostics was influential in the identification of the AF, as well as the response to therapy.

A more recent area of diagnostics is that applied to a specific disease state. A natural transition of the technology occurred as the devices were implanted broadly to patients with ischemic and nonischemic left ventricular dysfunction in that they could record and quantify parameters of heart failure. These parameters include heart rate variability, thoracic impedance, and daily activity.^{3,4} Although the device does

not act on these parameters at this time, the values alert the heart failure physician regarding potential upcoming decompensation. Newer device technology, which is currently investigational and in the process of clinical trials, has allowed for the continuous monitoring of right ventricular pulmonary artery pressures, patient activity, as well as other hemodynamic parameters.⁵ This technology can give insight into a disease state such as heart failure or pulmonary hypertension and provide feedback of therapeutic response to target drug therapy.

In regard to disease states, coronary atherosclerosis is the leading cause of morbidity and mortality in the United States. Paramount in the effort to minimize cardiovascular disease-related sequelae are the early diagnosis and treatment of cardiac ischemia. Since the pacemaker is a continuous cardiac monitor, the following intriguing questions arise. First, can the pacemaker readily diagnosis the onset of cardiac ischemia? Second, can the device prompt the patient to receive early evaluation and treatment?

Prior studies have demonstrated the feasibility of using device technology to detect ischemia.^{6–10} Electrograms generated from a temporary lead in the right ventricular apex to a cutaneous patch accurately demonstrated ST segment changes with onset of ischemia.^{6,7,9,10} Recently, these data were replicated with permanently implanted leads in a porcine model.⁸ In this study, the investigators also attempted to determine if the device could diagnose and alert the physician. The device sampled 10 QRST segments every 30 seconds. If three consecutive beats met the threshold for ST segment changes suggestive of ischemia, an alert was activated. The technology worked in all animals regardless of the epicardial vessel occluded.

Patients with ischemic cardiomyopathy and persistent left ventricular dysfunction that have an implantable cardioverter defibrillator (ICD) remain at high risk of morbidity and mortality due to recurrent myocardial infarction. For example, a pathologic analysis of the OPTIMAAL trial (a randomized trial of 5,477 patients with heart failure or evidence of left ventricular dysfunction following acute myocardial infarction to losartan or captopril) concluded that a majority of sudden deaths (57%) were due to recurrent infarction.¹¹ The need for early ischemia detection in these ICD candidates provides the background behind the research by Williams, Mendenhall, and Saba in this issue of the *Journal*.¹² In this carefully conducted study, 10 pigs were implanted with a dual coil lead ICD system. After 1 week of recovery, the pigs underwent cardiac catheterization. Each of the three coronary vessels was cannulated in a random fashion. An angioplasty balloon was inflated for 3–5 minutes to induce ischemia, followed by 30 minutes of reperfusion until another vessel was instrumented. During peak ischemia the R-wave amplitude increased in the left anterior descending artery (LAD) and

J Cardiovasc Electrophysiol, Vol. pp. 1-3.

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doi: 10.1111/j.1540-8167.2007.01061.x

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