HISTORICAL VIGNETTE

The Guidant Affair revisited…but this time with good news

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Almost 2 decades ago, an incident known as the Guidant Affair, changed the relationship between the defibrillator industry and clinical electrophysiology practice.[1] Guidant, at one time the second largest manufacturer of implantable cardioverter-defibrillators (ICDs) in the world, promoted and sold a model with insulation flaws capable of short-circuiting (electrical arcing) that could result in an inoperative device that would fail to deliver lifesaving shocks when necessary. The company concealed this problem from clinicians and their patients, while continuing to sell >4000 such defective devices without disclosure, thereby creating potentially adverse medical care for thousands of patients.

That is precisely what happened to Joshua, a 21-year-old college student from Grand Rapids, MN, with high-risk nonobstructive hypertrophic cardiomyopathy (HCM), who was implanted with a primary prevention Guidant ICD (Ventak Prizm 2 DR Model 1861) on October 4, 2001. On a mountain biking trip, 41 months after implantation (March 4, 2005) his ICD failed to terminate ventricular fibrillation when the electrical energy necessary for defibrillation was dissipated and diverted from his heart into the generator, which as a consequence was destroyed functionally. This prevented an appropriate ICD discharge that would have terminated the lethal arrhythmia, instead resulting in avoidable sudden cardiac death.

Public disclosure of this tragic event in May 2005 (and ≥15 other deaths) due to defective ICDs[2,3] generated a massive worldwide recall (largest in device industry history) of >200,000 potentially flawed ICDs, pacemakers, and cardiac resynchronization therapy devices; dramatic loss of market share and ultimately dissolution of the company and termination of the responsible executives; >1000 class action or individual lawsuits; $30 million settlement for Medicare Healthcare fraud; Pulitzer Prize Finalist and George Polk Awards in investigative journalism awards for Barry Meier[3] and the *New York Times*; guilty pleas to 2 federal criminal charges for cover-up; and a $296 million penalty. However, paradoxically, the Guidant Affair ultimately improved regulatory approaches and created greater transparency and more effective ethical communication between the device industry and the practicing cardiology community. Now, so many years later, memories have faded and younger cardiologists have no knowledge of this transformational event in cardiovascular medicine.

Nevertheless, as serendipity would have it, there is still more to learn from the Guidant incident. After Joshua's device implantation in 2001, primary prevention ICDs had also been placed in 2 family members diagnosed with HCM, that is, Joshua's asymptomatic older brother (age 24 years), but also his father (age 49 years) with brief bursts of nonsustained ventricular tachycardia on ambulatory monitoring.

Remarkably, fully 17 years and 4 months after his implant at the age of 66 (June 11, 2019), while in the shower and without prodromal symptoms, the father's ICD (Medtronic #7288) discharged appropriately, delivering a defibrillation shock that threw him to the floor. The interrogated rhythm responsible for device therapy was 18 seconds of monomorphic ventricular tachycardia at a rate of 315/min (Figure 1). There had been no prior device interventions (appropriate or inappropriate), although relatively brief bursts of asymptomatic nonsustained ventricular tachycardia had been identified not infrequently on routine device interrogation.

Echocardiography demonstrated a ventricular septal thickness of 19 mm without left ventricular (LV) outflow obstruction and a LV end-diastolic dimension of 51 mm. LV apical aneurysm was absent, and computed tomography angiogram excluded obstructive atherosclerotic coronary artery disease.

The aborted sudden death event reported here validates the principles of the ICD initiative that represents a paradigm in the management of patients with HCM.[4,5] Furthermore, this observation is consistent with (and expands) our data in large HCM cohorts, showing that it is possible to reliably anticipate the future likelihood of life-threatening arrhythmic events by using a risk stratification algorithm based on ≥ established individual markers.[5]

However, predicting the precise timing of arrhythmic sudden death events in high-risk patients with HCM can be daunting given the unpredictable myocardial substrate with reentry circuits characteristic of this disease, not uncommonly resulting in long periods of ICD dormancy before an initial device intervention.[4,5] Indeed, the 17-year time interval between the implant and the first lifesaving intervention

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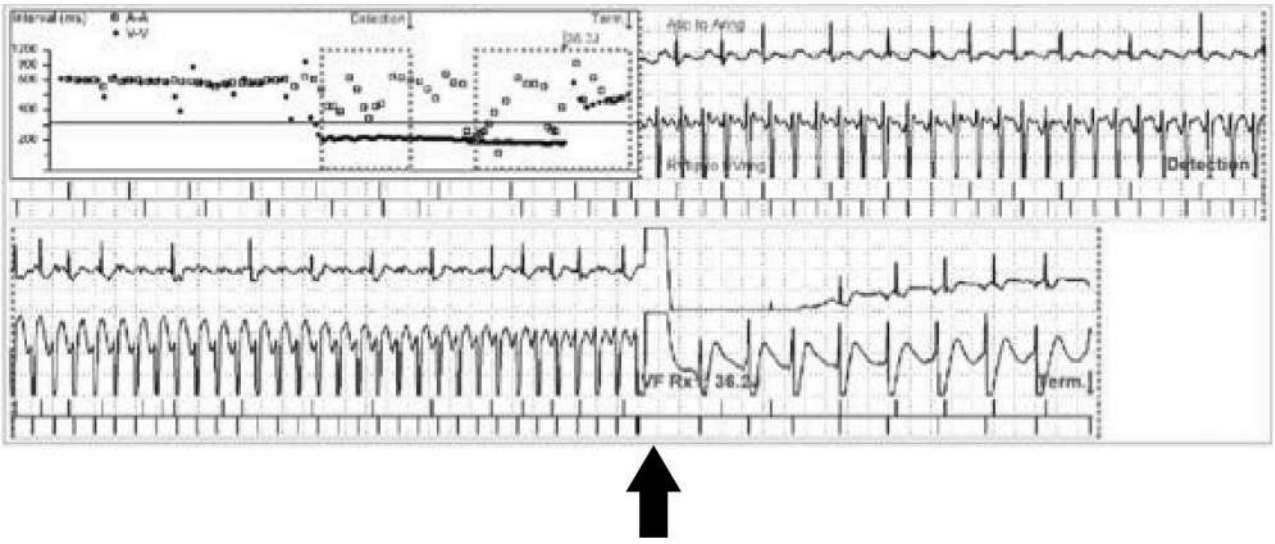

Figure 1 Intracardiac electrogram from a 66-year-old man with nonobstructive hypertrophic cardiomyopathy showing primary prevention implantable cardioverter-defibrillator termination of rapid monomorphic ventricular tachycardia (300/min), with immediate restoration of sinus rhythm (*arrow*).

in the patient reported here is now the longest yet documented in HCM.[5]

Therefore, the story of a defective and malfunctioning defibrillator, associated with industry malfeasance, that tragically resulted in the unnecessary sudden death of the young son with HCM has been transformed ironically into a gratifying event 17 years later in which his father's normally functioning prophylactically implanted ICD effectively aborted a HCM-sudden death event; that is, a life saved for one that was unnecessarily lost.

References

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