Recurrent Inappropriate ICD Shocks: Header Bonding Malfunction in Guidant Vitality Device

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ABSTRACT. Inappropriate implantable cardiac defibrillator (ICD) shocks remain a major challenge despite advances in the technology and better discrimination algorithms. One of the important causes of inappropriate ICD shock is lead failure over time. Weakened header bonding causing lead noise and resultant over-sensing that causes inappropriate ICD is rare but has been reported with the Medtronic Elite family of pacemakers and Boston Scientific Cognis/Teligen ICD series. We report the first case of inappropriate ICD shock resulting from weakened header bonding in the Boston Scientific Guidant Vitality series.

KEYWORDS. Defibrillator, ICD shock, ventricular arrhythmia.

Introduction
Implantable cardiac defibrillators (ICDs) are indicated for both primary and secondary prevention of sudden cardiac death. However, inappropriate ICD therapy remains a major challenge and is associated with poor quality of life and increased morbidity and mortality in patients with chronic heart failure. One important cause of inappropriate ICD therapy is related to lead integrity or circuitry failure, myopotential over-sensing, or electromagnetic interference (EMI). We present a case of inappropriate recurrent ICD shocks that resulted from device malfunction due to a header bonding issue in a Boston Scientific Guidant Vitality series (Boston Scientific Corp., Boston, MA).

Case description
A 43-year-old Caucasian male presented with recurrent ICD shocks. He had PMH of Congenital Long QT syndrome and had a dual-chamber ICD implanted prepectorally (Boston Scientific Guidant Vitality HE T 180) in 2007 for secondary prevention. The right ventricular (RV) lead used at implant was a Guidant/CPI 0180 Endotak Reliance SG (Boston Scientific), and the atrial lead was a St. Jude Medical 1688T Tendril SDX (St. Jude Medical, St. Paul, MN). Other pertinent medical history included diabetes mellitus, hypertension, and obstructive sleep apnea. Patient did well and had no ICD discharge or therapy until 2 days prior to the current admission. His device interrogation revealed intermittent increases in RV pacing impedance 3,000 ohms and intermittent decreases in R-wave sensing amplitude 5 mV from a baseline of 10 mV (Figure 1). It further revealed multiple ventricular tachyarrhythmia (Figure 2) detection and therapies. Intracardiac electrogram (EGM) analysis showed noise on the RV lead. A representative EGM is shown in Figure 3. The patient was admitted for further management. Tachycardia detection and therapy were temporarily inactivated. Posterior-anterior and lateral chest X-ray views showed no alteration in lead integrity, and the terminal pins were appropriately inside the header port.

The patient was taken to the hybrid operating room for high-risk RV lead extraction and replacement. During intraoperative pocket exploration, the header spontaneously separated from the rest of the titanium generator casing (shown in Figure 4). The RV lead was then tested through the external pacing system analyzer (PSA). The lead sensing, threshold, and pacing impedance were normal. Similarly, the right atrial lead sensing, threshold, and pacing impedance were within normal range. Cine
fluoroscopy of the leads showed no obvious fractures. This posed a diagnostic dilemma as it was unclear whether the problem was with the header attachment or the rest of the can. A closer review of the EGMs of the tachyarrhythmia revealed noise on the atrial lead and in some of the tachyarrhythmia episodes. This implied that the noise sensing affected both leads and was therefore very unlikely to be related to lead integrity failure in both. This suggested either problems with the ICD pulse generator, myopotentials, or EMI. No history of EMI or exposure to high magnetic fields was noted. In addition, neither would explain the intermittently elevated right ventricular pacing lead impedance. The noises seen on the leads were not reproducible with various arm exercises in the outpatient device clinic when the patient was first seen. The only other explanation would be loose bonding between the header and can giving rise to make-break potentials, which are larger in amplitude and would also explain the markedly elevated pacing impedance.

The leads were connected to a new dual-chamber ICD pulse generator, and defibrillation testing was performed. The pacing and shock coil impedance were

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**Figure 1:** Device interrogation showing serial measurements of atrial lead-sensing amplitude, atrial lead impedance, ventricular lead-sensing amplitude, ventricular lead-pacing impedance, and ventricular lead shock coil impedance from March to August 2014.
Figure 2: Device interrogation showing ventricular arrhythmia encounters including the total number of treated and aborted episodes since the last reset in May 2014.

Figure 3: Device interrogation showing a representative EGM of a ventricular tachyarrhythmia episode with the atrial EGM marker channel, integrated bipolar right ventricular sensing EGM (Tip-coil), shock coil EGM, and EGM markers.
normal, so the procedure to perform RV lead extraction and replacement was cancelled. Subsequent clinical follow-up showed normal functioning of the device, and no incidence of elevated RV pacing impedance was noted.

Discussion

This case highlights the case of inappropriate ICD shocks resulting from bonding failure between the header and titanium casing 7 years after implant. Inappropriate ICD shock remains a major challenge despite advances in ICD technology. One of the important causes of inappropriate ICD therapy is lead integrity failure. Frequently these involve fracture of the lead over time, resulting in noise and over-sensing with resultant interpretation of ventricular tachyarrhythmia by the device and consequent therapy. There have also been reports of connection issues affecting the lead terminal pin in the header port, resulting in increased impedance and noise. These were reported in a case series with Medtronic Marquis family ICD devices by Pickett et al. Weakened header bonding with the titanium casing has been rarely reported. The first case of header separation from the generator casing was described in 2002 by Mellert et al in the Medtronic Pacemaker (Elite 7075). In 2007, Kobza et al reported a loose header as a result of a weakened bond between the header and titanium casing in a Guidant device (VENTAK PRIZM 2). More recently in 2013, Hayat et al reported a case series of three patients who had undergone subpectoral cardiac resynchronization therapy defibrillator (CRT-D) implantation with Guidant Cognis devices and later presented with ICD malfunction. These cases presented with intermittent and then persistent rises in shock coil impedance, associated with non-physiological noise in the shock EGM channels. The issues were resolved after generator replacement. Our case is the first report of header bonding failure with the titanium generator casing in the Boston Scientific Guidant Vitality series. This was confirmed after a thorough search was made of the Manufacturer and User Facility Device Experience (MAUDE) database.

![Figure 4: Intraoperative picture showing spontaneous disconnection of the header from the rest of the titanium generator case.](image-url)
maintained by the United States Food and Drug Administration (FDA). In contrast to the report by Hayat et al, the present patient had intermittent elevated pacing impedance >3,000 ohms but normal shock coil impedance. There was non-physiological noise mostly in the RV pace-sense EGM but also occasionally in the atrial lead EGM channel. The likely mechanism of non-physiological noise in our case was an intermittent make-break phenomenon resulting in high amplitude signals. Similar to Hayat et al, the problem resolved following generator replacement. While the majority of the reported cases of weakened header bonding are subpectorally implanted devices, there has been a report of weakened header bonding with prepectoral implantation\(^9\) similar to our index case. Our case highlights the need to be vigilant for and effectively manage similar device malfunctions resulting from loosened header bondings.

References