

No Electromagnetic Interference Occurred

in a Patient with a HeartMate II Left Ventricular Assist System and a Subcutaneous Implantable Cardioverter-Defibrillator

Ajay Sundara Raman, MBBS
Farshad Raissi Shabari, MD,
MPH
Biswajit Kar, MD
Pranav Loyalka, MD
Ramesh Hariharan, MD,
FHRS

The use of subcutaneous implantable cardioverter-defibrillators is a novel option for preventing arrhythmia-mediated cardiac death in patients who are at risk of endovascular-device infection or in whom venous access is difficult. However, the potential for electromagnetic interference between subcutaneous defibrillators and left ventricular assist devices is largely unknown. We report the case of a 24-year-old man in whom we observed no electromagnetic interference between a subcutaneous implanted cardioverter-defibrillator and a HeartMate II Left Ventricular Assist System, at 3 different pump speeds. To our knowledge, this is the first report of such findings in this circumstance. (Tex Heart Inst J 2016;43(2):183-5)

Key words: Combined modality therapy/instrumentation; defibrillators; implantable/adverse effects; electromagnetic phenomena; equipment design; equipment failure analysis; heart failure/physiopathology/prevention & control/therapy; heart-assist devices/adverse effects; risk assessment; treatment outcome

From: Division of Cardiac Electrophysiology (Drs. Hariharan, Raissi Shabari, and Sundara Raman) and Center for Advanced Heart Failure, Cardiopulmonary Support and Transplantation (Drs. Kar, Loyalka, and Raissi Shabari), University of Texas Health Science Center at Houston, Houston, Texas 77030

Address for reprints: Farshad Raissi Shabari, MD, 6400 Fannin St., Suite 2010, Houston, TX 77030

E-mail: raissif@gmail.com

© 2016 by the Texas Heart[®] Institute, Houston

Many patients who have a left ventricular assist device (LVAD) also have an implantable cardioverter-defibrillator (ICD). The use of subcutaneous ICDs (S-ICDs) to prevent arrhythmia-mediated sudden cardiac death is a novel option, particularly in patients who are at increased risk of bloodstream infection and in whom venous access is difficult. In LVAD-supported patients who have no need for pacing, S-ICDs can be used to treat sustained ventricular arrhythmias. However, the presence and extent of electromagnetic interference (EMI) between LVADs and S-ICDs is largely unknown. We report our findings after we tested the EMI between a patient's S-ICD and LVAD.

Case Report

In 2012, a 24-year-old man who had advanced nonischemic cardiomyopathy and a left ventricular ejection fraction (LVEF) of 0.20 underwent implantation of a HeartMate II[®] Left Ventricular Assist System (Thoratec Corporation, now part of St. Jude Medical, Inc.; St. Paul, Minn) for acute myocarditis. He was discharged from the hospital after a relatively uneventful postprocedural course. In 2014, he had recurrent episodes of sustained, symptomatic atrial tachycardia. After an electrophysiologic study, he underwent radiofrequency ablation of a high right crista terminalis focus of the atrial tachycardia.

While in cardiac rehabilitation, the patient had recurrent salvos of short, nonsustained, asymptomatic ventricular tachycardia (VT). Given his youth, no requirement for pacing, and the higher risk of infection from endovascular devices, we decided to implant an S-ICD with an SQ-RX[®] Pulse Generator, model 1010 (Boston Scientific Corporation; St. Paul, Minn) in February 2014 (Fig. 1).

During the uneventful implantation procedure, we tested for EMI between the HeartMate II and the S-ICD at different LVAD pump speeds, to ascertain device functionality. Surface electrocardiographic (ECG) electrograms were recorded in the primary, secondary, and alternate vectors (Fig. 1) at pump speeds of 6,000, 8,000, and 10,000 rpm (Fig. 2). (For reasons of patient safety, we did no testing at 12,000 rpm.) Adequate sensing was obtained at the different speeds, and no EMI was evident. Defibrillation testing was also performed: a 50-Hz burst was used to induce ventricular fibrillation, which was successfully terminated with a 65-J shock with a charge time of 14.2 s.

The patient was monitored monthly at our LVAD clinic. No adverse event was noted. His LVEF improved from 0.20 to 0.45, and his LVAD was explanted in Janu-

ary 2015. As of January 2016, he was asymptomatic, with no noteworthy findings on physical examination and no arrhythmic episodes recorded by his S-ICD.

Discussion

To our knowledge, this is the first report of a patient who had both a HeartMate II and an S-ICD. Therefore, the EMI analysis in such a patient is also new. Sporadic electromagnetic interactions between continuous-flow LVADs and conventional ICDs have been reported, chiefly involving impaired ICD-programmer telemetry communication in older ICDs.^{1,2} Oswald and colleagues² reported 4 instances of impaired telemetry communication in 39 patients who had an older ICD

and a HeartMate II. Loss of telemetry occurred in 4 of 23 other such patients.³ This was attributed to the similar frequency (7–8 KHz) used by the device programmer (in older St. Jude Medical ICDs and certain SORIN ICDs) and the pulse-width modulator of the HeartMate II. This EMI can sometimes be overcome by various methods of shielding the LVAD and programming wand, thus precluding the need for a device exchange.^{4,5}

In 2011, Mozes and co-authors⁶ described inappropriate shock delivery from a dual-chamber Vitality[®] ICD, model T125 (Boston Scientific), 2 months after the implantation of a HeartWare HVAD[®] (HeartWare Inc.; Framingham, Mass). Noise on the right ventricular ICD lead was directly correlated to the rotational speed of the HeartWare impeller. The LVAD inflow was very close to that lead, which was programmed in an integrated bipolar sensing configuration.⁶

An unusual form of EMI—dissimilar to that in other case reports—has been described in association with the VentrAssist[™] LVAD (Ventricor Ltd.; Chatswood, Australia). The VentrAssist is a 3rd-generation, nonpulsatile centrifugal pump with the magnetic and hydrodynamic levitation of an impeller. This LVAD caused interference with a Boston Scientific ICD, resulting in oversensing of noise on the pace/sense lead and inappropriate shock delivery. This occurred only when the battery pack was plugged into a 240-V alternating-current outlet with sensitivity levels programmed to be most sensitive. However, this EMI did not occur when sensitivity was reprogrammed to the least sensitive value.⁷ The explanation for this observation is unclear.

The frequency of signals generated by a nearby nonpulsatile LVAD can be detected by an S-ICD. Saeed and colleagues⁸ described a case in which a HeartWare HVAD interfered with S-ICD sensing. In that patient,

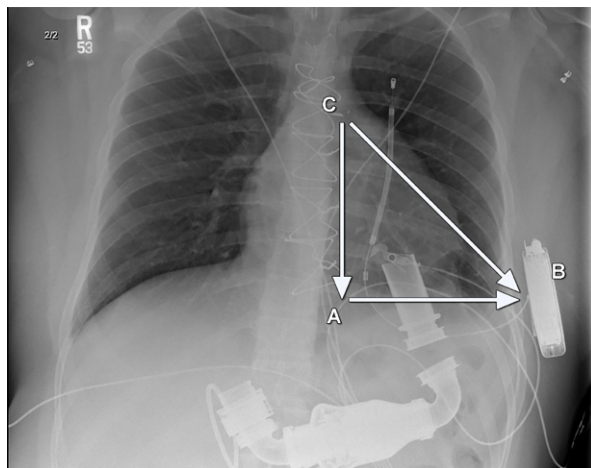


Fig. 1 Chest radiograph shows the HeartMate II inflow cannula and the subcutaneous implantable cardioverter-defibrillator. A to B is the primary vector, C to B is the secondary vector, and C to A is the alternate vector.

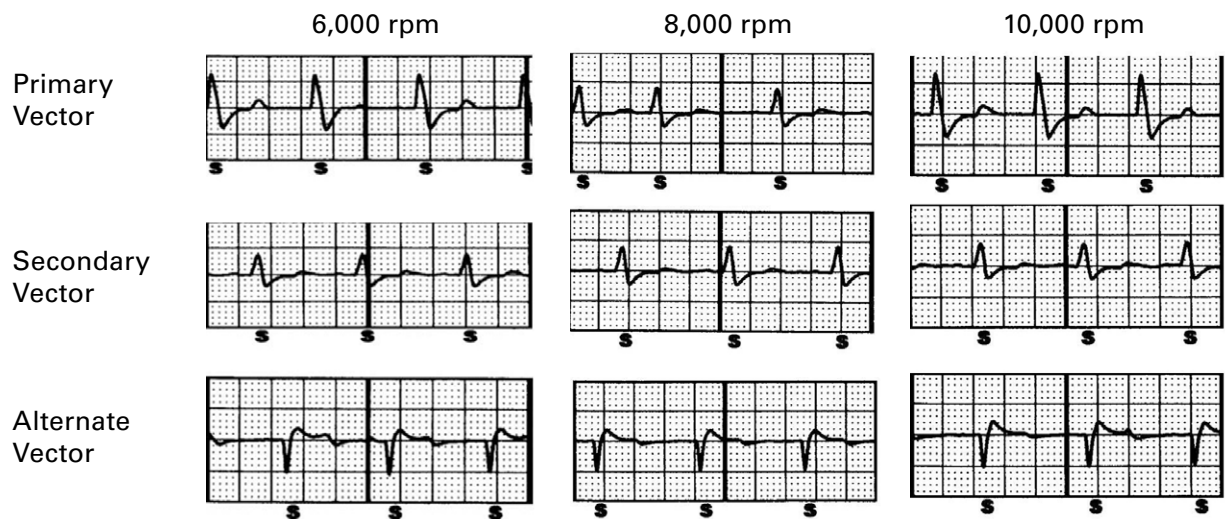


Fig. 2 Surface electrograms are shown in all available vectors at HeartMate II pump speeds of 6,000, 8,000, and 10,000 rpm; no electromagnetic interference is evident.

noise involving the pulse generator was detected during sensing in the primary and secondary vectors. The authors attributed this to the proximity of the S-ICD's pulse generator to the LVAD. Conversely, in another patient who had a HeartWare HVAD, the S-ICD detected no noise.⁸

We found no evident EMI on S-ICD electrograms from our patient's HeartMate II. This nonpulsatile axial-flow rotary pump has a higher rotational speed (range, 6,000–12,000 rpm) than does the HeartWare HVAD (1,800–3,200 rpm). It is likely that the frequency of HeartMate II rotations causes comparatively less EMI with S-ICD signal detection.

The S-ICD's unique sensing function uses a surface ECG electrogram and a novel algorithm that determines the best sensing vector for avoiding double QRS-counting and T-wave oversensing.⁹ In the Subcutaneous versus Transvenous Arrhythmia Recognition Testing (START) trial, S-ICDs exhibited greater specificity in discriminating supraventricular tachycardia from VT than did conventional ICDs.¹⁰ The S-ICD's noise-suppression algorithm rejects nonphysiologic signals by using the double-differentiated detected signal presented to the sensing circuit in the S-ICD's system amplifier. The number of inflection points within an adaptive refractory period is examined to discern whether the signal is physiologic in origin. If the signal within the refractory period exceeds the prespecified number of inflection points, the detected signal is discarded and is not used to calculate heart rate.* The S-ICD programmer emits radiofrequencies at 403.5 MHz and 2.5 GHz. In our patient, we observed no issues with telemetry or EMI at 3 different HeartMate II pump speeds.

Of clinical relevance: in heart-failure patients, S-ICDs currently cannot provide bradycardia pacing, cardiac resynchronization, anti-tachycardia pacing, thoracic impedance measurements, or remote monitoring. Therefore, careful selection of patients is necessary before deciding to implant S-ICDs.

We found that the concomitant use of an S-ICD and a HeartMate II LVAD yielded no evident EMI, specifically in association with the S-ICD's signal detection and noise-suppression algorithm. However, more experience is needed to definitively determine the safety of these devices in simultaneous use. This is particularly important in view of the anticipated increased use of both devices in the future.

*Personal communication: Donald Scheck, BSEE (Cameron Health, Inc.); March 2014.

References

1. Kuhne M, Sakumura M, Reich SS, Sarrazin JF, Wells D, Chalfoun N, et al. Simultaneous use of implantable cardioverter-defibrillators and left ventricular assist devices in patients with severe heart failure. *Am J Cardiol* 2010;105(3):378-82.
2. Oswald H, Klein G, Struber M, Gardiwal A. Implantable defibrillator with left ventricular assist device compatibility. *Interact Cardiovasc Thorac Surg* 2009;8(5):579-80.
3. Boudghene-Stambouli F, Boule S, Goeminne C, Botcherby E, Marquie C, Kouakam C, et al. Clinical implications of left ventricular assist device implantation in patients with an implantable cardioverter-defibrillator. *J Interv Card Electrophysiol* 2013;39(2):177-84.
4. Labedi MR, Alharethi R, Kfoury AG, Budge D, Bruce R, Rasmusson B, Bunch TJ. Electromagnetic interference of automatic implantable cardioverter defibrillator and HeartWare left ventricular assist device. *ASAIO J* 2013;59(2):136-9.
5. Guise KD, Franconame F, Chung EH. Circumventing a left ventricular assist device and implantable cardioverter defibrillator interaction: an alternative method of shielding. *Europace* 2013;15(12):1689.
6. Mozes A, DeNofrio D, Pham DT, Homoud MK. Inappropriate implantable cardioverter-defibrillator therapy due to electromagnetic interference in patient with a HeartWare HVAD left ventricular assist device. *Heart Rhythm* 2011;8(5):778-80.
7. Foo D, Walker BD, Kuchar DL, Thorburn CW, Tay A, Hayward CS, et al. Left ventricular mechanical assist devices and cardiac device interactions: an observational case series. *Pacing Clin Electrophysiol* 2009;32(7):879-87.
8. Saeed D, Albert A, Westefeld R, Maxhera B, Gramsch-Zabel H, O'Connor S, et al. Left ventricular assist device in a patient with a concomitant subcutaneous implantable cardioverter defibrillator. *Circ Arrhythm Electrophysiol* 2013;6(3):e32-3.
9. Aziz S, Leon AR, El-Chami MF. The subcutaneous defibrillator: a review of the literature. *J Am Coll Cardiol* 2014;63(15):1473-9.
10. Gold MR, Theuns DA, Knight BP, Sturdivant JL, Sanghera R, Ellenbogen KA, et al. Head-to-head comparison of arrhythmia discrimination performance of subcutaneous and transvenous ICD arrhythmia detection algorithms: the START study. *J Cardiovasc Electrophysiol* 2012;23(4):359-66.