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Safety and interaction of patients with implantable cardiac defibrillators driving a hybrid vehicle

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ABSTRACT

Background: Electromagnetic interference (EMI) can affect the function of implantable cardioverter defibrillators (ICD). Hybrid electric vehicles (HEV) have increased popularity and are a potential source of EMI. Little is known about the *in vivo* effects of EMI generated by HEV on ICD.
Objective: This study evaluated the *in vivo* interaction between EMI generated by HEV with ICD.
Methods and results: Thirty patients (73 ± 9 y/o; 80% male) with stable ICD function were exposed to EMI generated by a Toyota Prius Hybrid®. The vehicle was lifted above the ground, allowing safe changes in engine rotation and consequent variations in electromagnetic emission. EMI was measured (NARDA STS® model EHP-50C) and expressed in A/m (magnetic), Volts/m (electrical), and Hertz (frequency). Six positions were evaluated: driver, front passenger, right and left back seats, outside, at the back and front of the car. Each position was evaluated at idle, 30 mph, 60 mph and variable speeds (acceleration-deceleration-brake). All ICD devices were continuously monitored during the study.
The levels of EMI generated were low (highest mean levels: 2.09 A/m at right back seat at 30 mph; and 3.5 V/m at driver seat at variable speeds). No episode of oversensing or inadvertent change in ICD programming was observed.
Conclusion: It is safe for patients with ICD to interact with HEV. This is the first study to address this issue using an *in vivo* model. Further studies are necessary to evaluate the interaction of different models of HEV or electric engine with ICD or unipolar pacemakers.

1. Introduction

The indication for (ICD) has expanded in the recent past, and the number of devices implanted has risen significantly. It is well known that electromagnetic interference (EMI) can affect the function of cardiac implantable electronic devices (CIED), such as permanent pacemaker (PPM) and ICD, with potential serious clinical consequences [2–4].

EMI is a disturbance that affects an electrical circuit due to either electromagnetic conduction or electromagnetic radiation emitted from an external source. The disturbance may interrupt, obstruct, degrade or limit the effective performance of a circuit [4]. The use of metal cases, incorporation of bandpass filters, interference rejection circuits and bipolar sensing have made contemporary PPM and ICD less susceptible to EMI. However, EMI sources are ubiquitous in homes and workplaces (*e.g.*, wireless telephones, house appliances) [5].

Hybrid electric vehicles (HEV) have gained increasing popularity in the past years. Their engine combines two power sources: gasoline (combustion) and electric. Therefore, HEV engines can potentially generate higher levels of EMI, especially during periods of high current flow, which typically happen at the start of engine, and during variation in acceleration or deceleration.

Despite the increasing number of HEV in the streets, little is known about the interaction between these electrical engines and cardiac implantable devices with regards to EMI.

The aim of this study was to evaluate quantitative and qualitatively the *in vivo* interaction between EMI generated by HEV with implantable devices.

Abbreviations: ICD, implantable cardioverter defibrillators; CIED, cardiac implantable electronic device; PPM, permanent pacemaker; HEV, hybrid electric vehicle; RPM, rotations per minute.

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2. Methods

This study was approved by Mayo Clinic Institutional Review Boards after all requirements for approval of research (21CFR56.111 and 45CFR46.111) were met.

A total of 30 patients with implanted ICD were enrolled in the study (Table 1). They were recruited from the cardiac device clinic at Mayo Clinic Arizona. Devices from three major US manufacturers (Boston Scientific, Medtronic and St. Jude Medical) were included in the study, with similar distribution (Table 2).

Patients were eligible for the study if they fulfilled the following criteria: 1) Age ≥ than 18 years, able to provide informed consent, with an ICD at least in the 6th month post implantation; 2) No ICD therapies or shocks in the last 3 months; 3) Normal ICD function; 4) No change in medication that could lead to variations in pacing or defibrillation threshold (such as initiation of antiarrhythmic drugs); and 5) Absence of noise or EMI noted upon ICD interrogation at the time of inclusion in the study.

The following conditions were considered as exclusion criteria: a history of routine exposure to a HEV, either as a driver or passenger; pacemaker-dependent patients; evidence for any device or lead malfunction or recent ICD therapy or shock (< 3 months).

2.1. Device programming and patient monitoring

All procedures were supervised by a Cardiac Electrophysiologist, and certified cardiac device specialist or device nurse. After signing an informed consent, patients underwent baseline device interrogation. Anti-tachycardia therapies (anti-tachycardia pacing and shock therapy) were temporarily turned off in order to avoid inappropriate shock in case of noise related to EMI. The detection/monitor mode was maintained active. An external defibrillator was available, and so was the device programmer, which would allow quick restoration of ICD therapy, if needed. The patient remained under continuous telemetry monitoring through the device programmer, allowing continuous observation of intracardiac electrograms and detection of any arrhythmic event in real time, either a true event or an artifact induced by EMI. The programmed sensitivity of the device was kept unchanged from the original programming in order to better reproduce the actual clinical scenario.

2.2. Simulation of driving conditions

The HEV chosen for this study was a Toyota Prius® 2012. This particular make and model was chosen because it is the most sold HEV in the United States. For consistency, the same vehicle was used during the entire study.

The vehicle was lifted in a parking position using a car-lift. The four wheels were kept at 15 cm above the ground during the protocol, allowing the safe use of the engine at different levels of rotations per minute (RPM), without generating movement of the vehicle (Fig. 1).

Table 1
Baseline characteristics.

Age	72.5 ± 8.7 years
Male sex	24 (80%)
Race	
Caucasian	27 (90%)
African-American	1 (3.3%)
Asian	1 (3.3%)
Hispanic	1 (3.3%)
Height (cm)	174.8 ± 12.3 (150.0–200.5)
Weight (kg)	94.0 ± 23.8 (41.0–147.6)
BMI (kg/m^2)	30.6 ± 6.6 (18.2–49.4)
EF (echo) %	41.3 ± 15% (20–70%)
Time since device implant	2.7 ± 1.9 years (5.1mo – 6.7 years)

BMI = body mass index; EF = ejection fraction.

Table 2
Implanted devices.

Device type	
Single chamber ICD	5 (16.7%)
Dual chamber ICD	18 (60%)
Biventricular/ICD	7 (23.3%)
Indication	
Primary prevention	16 (53.4%)
Secondary prevention	12 (40%)
Syncope. NICM and NSVT	1 (3.3%)
Syncope. NICM and bradycardia	1 (3.3%)
Manufacturer	
Boston Scientific	9 (30%)
Guidant	5 (16.7%)
Medtronic	11 (36.6%)
St. Jude Medical	5 (16.7%)
RV lead:	
Boston Scientific 0184	2 (6.6%)
Guidant (0125–0185)	6 (20%)
Guidant Endotak Reliance	3 (10%)
Medtronic (6944–47)	6 (20%)
Medtronic 6949 (Fidelis)	5 (16.7%)
St. Jude Medical Durata	5 (16.7%)
St. Jude Medical Riata	3 (10%)

NICM = non-ischemic cardiomyopathy; NSVT = non-sustained ventricular tachycardia.

The area surrounding the vehicle was isolated for safety purposes. The volunteers then entered the vehicle and proceeded with the protocol.

One of the main features of a hybrid engine is the capability to switch from gas to electric, depending on the driving conditions. The vehicle is able to start the engine and initiate movement up to 15 mph without using the gas engine. After reaching the speed of approximately 40 mph, the combustion engine becomes the main power source. In other words, the electric engine is activated at lower speeds, while the gas is the predominant power source utilized at higher speed. Most HEV are also able to generate and store energy, reducing the need for periodic charging. The energy is stored in a large battery located at the left back of the vehicle, while the electric motor is located at the front. The activation and deactivation of the electric engine are expected to generate the highest levels of EMI. In order to evaluate the correlation between electric motor usage and the level of EMI, we simulated the following four driving conditions: idle, acceleration at low speed (30 mph), acceleration at higher speed (60 mph) and variable speed (repeated acceleration-deceleration-braking).

2.3. Measurement of EMI

The main sources of EMI in this vehicle are: a high voltage battery located at the back of the vehicle, close to the left rear seat; and an electric motor located at the front, closer to the driver's seat. Based on this particular feature, we raised the hypothesis that different levels of EMI could be detected in different locations around this model of HEV. Therefore, to test this hypothesis, we repeated the different driving conditions in the following six locations: driver's seat, front passenger, left and right back seats, and outside the car, 2 ft away from the front and back bumpers.

A total of 24 sets of measurements were obtained per patient, based on the combination of 4 different driving conditions with the 6 locations described above. EMI was measured using a standard isotropic magnetic field probe used for the magnetic field measurements (NARDA electric and magnetic field analyzer, EHP-50C®). The magnetic and electrical fields generated by electric engines are typically of low frequency (<450 MHz). In our study, we determined:

1) The peak magnetic field strength (H) in Ampere/m (A/m), with determination of its respective frequency in Hertz (Hz). Measurements were obtained in a scale from 10^{-2} to 100 A/m for magnetic field strength, and 0 to 1000 Hz for the frequency

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