Technology and Health Care 28 (2020) 1–12
DOI 10.3233/THC-191891
IOS Press

Patients with pacemakers or defibrillators do not need to worry about e-Cars: An observational study

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Received 27 July 2019

Accepted 25 September 2019

Abstract.
BACKGROUND: Electric cars are increasingly used for public and private transportation and represent possible sources of electromagnetic interference (EMI). Potential implications for patients with cardiac implantable electronic devices (CIED) range from unnecessary driving restrictions to life-threatening device malfunction. This prospective, cross-sectional study was designed to assess the EMI risk of electric cars on CIED function.
METHODS: One hundred and eight consecutive patients with CIEDs presenting for routine follow-up between May 2014 and January 2015 were enrolled in the study. The participants were exposed to electromagnetic fields generated by the four most common electric cars (Nissan Leaf, Tesla Model S, BMW i3, VW eUp) while roller-bench test-driving at Institute of Automotive Technology, Department of Mechanical Engineering, Technical University, Munich. The primary endpoint was any abnormalities in CIED function (e.g. oversensing with pacing-inhibition, inappropriate therapy or mode-switching) while driving or charging electric cars as assessed by electrocardiographic recordings and device interrogation.
RESULTS: No change in device function or programming was seen in this cohort which is representative of contemporary CIED devices. The largest electromagnetic field detected was along the charging cable during high current charging (116.5 μT). The field strength in the cabin was lower (2.1–3.6 μT).
CONCLUSIONS: Electric cars produce electromagnetic fields; however, they did not affect CIED function or programming in our cohort. Driving and charging of electric cars is likely safe for patients with CIEDs.

Keywords: Electric cars, electromagnetic interference (EMI), cardiac implantable electronic devices (CIED), pacemaker, defibrillator

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1. Introduction

Cardiac implantable electronic devices (CIEDs) such as permanent pacemakers (PMs), implantable cardioverter-defibrillators (ICDs) and cardiac resynchronization therapy (CRT) devices are standard of care for treatment of certain bradycardias, tachycardias, and heart failure [1–4]. The prevalence of CIEDs is increasing [5–7].

Exposure to electromagnetic fields generated by everyday electrical equipment is ubiquitous; for example, communication and office equipment (e.g. cellular phones), household appliances (e.g. washing machines, dishwashers), power tools and industrial machines (e.g. welding equipment), and security devices (e.g. metal detectors) [8,9]. *In vitro* studies demonstrate the potential for electromagnetic fields generated by electronic devices to be sensed by CIEDs and erroneously attributed to intrinsic intracardiac signals [10,11]. This electromagnetic interference (EMI) can affect CIED function; resulting in pacing inhibition, delivery of inappropriate anti-tachycardia therapy (due to oversensing), or changes to programmed CIED parameters [12,13]. CIED manufacturers are aware of potential risks and, in addition to providing patient education [14,15], they mitigate EMI risk through improved noise-detection algorithms, shielding and filters for problematic frequencies. Adverse events are rare, but still occur [16–20].

Electric cars are a potential, emerging EMI source. The popularity of electric cars has grown and growth is predicted to continue aided by superior fuel efficiency and incentives to operate low-emission vehicles [21–23]. Therefore, increasing numbers of patients will be exposed to EMI via private vehicles and public transport. However, there is no data regarding the safety of electric cars for patients with CIEDs, nor is there evidence whether restrictions on patients with CIEDs are required. Device manufacturers recommend patients with CIEDs maintain a distance of at least 30 cm from engine ignition systems and electric boat motors [14,15]. The engines of modern electric cars have outputs significantly larger than average ignition systems (60–310 kW vs 1–2 kW, respectively) [24–26]; however, there are no specific recommendations for electric car use.

The potential for EMI increases with the strength of electromagnetic field, which is proportional to the power of the electric motor. To assess this potential risk, we conducted *in vivo* evaluation of CIED function during exposure to driving and charging the four most popular electric cars in Europe [27]. The primary results of this study have been previously published as a brief research report in Annals of Internal Medicine, but the methodological details and specific device and leads characteristics are reported here [28].

2. Methods

2.1. Statistics and sample size calculation

At the time of the study, there was no data on potential EMI between CIEDs and electric cars. Therefore, we based our sample size on the number required to detect common events; i.e., 1–10% [29]. Hence, we calculated 100 patients were required to observe at least one EMI event with a probability of 99.4% if the EMI event rate was 5%. With an estimated drop-out rate of 10%, the target sample size was 110 patients. Data are presented as numbers and percentage and mean ± standard deviation (SD).

2.2. Participants

Consecutive patients presenting for routine follow-up of PM, ICD or CRT function at our institution,

Table 1
Patient and device characteristics

Patient	
Total number	108
Men	90 (83%)
Age (years)	58 ± 15
Indication	
Indication for anti-bradycardia therapy (PM)	34 (31%)
Sinus-node dysfunction	16 (15%)
Atrioventricular block[†]	17 (16%)
Carotid sinus syndrome	1 (1%)
Indication for anti-tachycardia therapy (ICD)	74 (69%)
Primary prevention of SCD	40 (37%)
Secondary prevention of SCD	34 (31%)
Pacing mode	
VVI or VVIR	37 (34%)
VVIRV	2 (2%)
DDD or DDDR	48 (44%)
DDD0V or DDDRV	21 (19%)

Values given as number with percentage in parentheses except age. [†]including patients with combined sinus node and atrioventricular node dysfunction. SCD = sudden cardiac death.

between May 2014 and January 2015 were assessed for eligibility. Of 150, 40 declined to participate and two withdrew consent. Hence, we studied 108 patients. This cohort was predominantly male (83%) with a mean age of 58 ± 15 years. Two thirds were ICD-recipients and one third had pacing indications only (Table 1). No patients met our exclusion criteria; suspected lead malfunction, battery life less than three months or intrinsic heart rates $>$ 120/min. Informed consent was obtained.

2.3. *Electric cars*

The four electric cars with the largest market-share in Europe at the time of the study were evaluated: Nissan LEAF, Tesla Model S P85, BMW i3 and VW eUp [27]. All are full electric cars, but with different motor power, torque, battery-size and charging properties (Table 2). Hybrid electric vehicles, combining electric propulsion with conventional powertrain were excluded, because pure electric mode of operation (with associated maximal electromagnetic field) could not be ensured during testing.

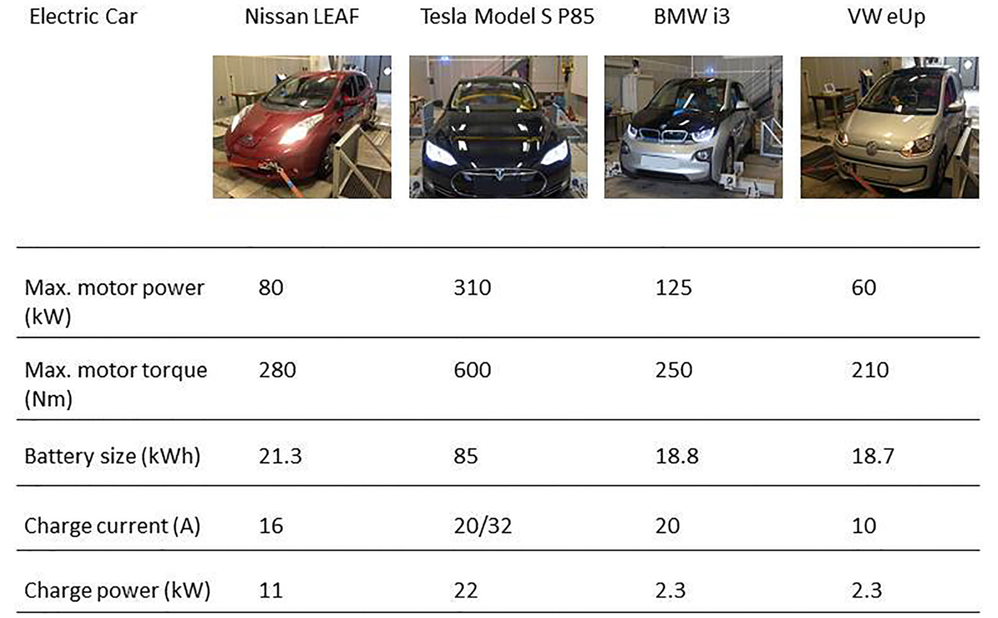
2.4. *Roller dynamometer test-bench*

Driving simulation took place on a roller dynamometer test-bench at the Institute of Automotive Technology, Department of Mechanical Engineering, Technical University of Munich, Germany. The roller test-bench enabled programmed simulation of dynamic driving resistances encountered in real life. Additionally, the roller-bench facilitates safe, standardised and reproducible test cycles with maximal acceleration and deceleration protocols; essential to obtain maximal engine torque and subsequent maximal electromagnetic field generation [32].

2.5. *Measurement of electromagnetic fields*

Magnetic field strength was measured as a surrogate for electromagnetic field strength. There is a direct relationship between magnetic and electromagnetic field strength which permits the use of this

Table 2
Properties of the tested electric cars on the test-bench [24,25,29,30]



Electric Car	Nissan LEAF	Tesla Model S P85	BMW i3	VW eUp
Max. motor power (kW)	80	310	125	60
Max. motor torque (Nm)	280	600	250	210
Battery size (kWh)	21.3	85	18.8	18.7
Charge current (A)	16	20/32	20	10
Charge power (kW)	11	22	2.3	2.3

Table 3
Test protocols

Test drive number	Protocol
1	Maximal acceleration to 30 km/h followed by braking to a full stop
2	Maximal acceleration to 50 km/h followed by braking to a full stop
3	Maximal acceleration to 80 km/h followed by braking to a full stop
4	Maximal acceleration to 120 km/h followed by braking to a full stop

surrogate measurement. The magnetic field meter used was a calibrated ELT 400 (Narda-STS, Pfullingen, Germany) and a B-field probe (three orthogonal coils; total sensing area $= 100$ cm^2; frequency detection range 1 Hz to 400 kHz). We used a probe with a large sensing area in case the fields measured were heterogeneous. The magnetic field tester is compliant with CE standard IEC/EN 62233 and Generic Standard IEC 62311, and limit value tracing conforms with ICNIRP 1998, 2010 and EMF Directive 2013/35/EU. The magnetic field was measured in and around the cars during the roller-bench test. The locations measured were in front and behind the cars, beside both front and back doors, in the front seat, and along the charging cable during re-charging. Further measurements of magnetic field strength were taken inside the cabins of all four cars whilst driving on public roads.

2.6. *Test protocol*

Patients underwent routine device interrogation following our standardized device follow-up protocol including evaluation of battery status, pacing and sensing thresholds, lead impedances and review of CIED event monitors. In all patients, ventricular pacing was ensured by increasing the basic pacing rate or by adjusting the atrio-ventricular delay in dual chamber devices. Pre-programmed sensitivity levels were unchanged. In ICDs, tachyarrhythmia detection algorithms were set to the minimum number of intervals to enhance the probability of inappropriate arrhythmia detection. ICD shocks were disabled

Table 4
CIEDs tested for EMI from electric cars

Manufacturer	Device	Number of device tested	Type of device
Biotronik			
	Cylos	1	PM
	Ecuro	1	PM
	Effecta	1	PM
	Iforia	3	ICD
	Lumax	8	ICD
	Philos	1	PM
	Talos	1	PM
Boston scientific			
	Advantio	1	PM
	Altrua	1	PM
	Cognis	3	ICD
	Dynagen	1	ICD
	Energen	1	ICD
	Incepta	1	ICD
	Ingenio	2	PM
	Inogen	1	ICD
	Punctua	1	ICD
Guidant			
	Altrua	1	PM
	Vitality	2	ICD
Medtronic			
	Adapta	1	PM
	Cardia	1	ICD
	Entrust	2	ICD
	Maximo	2	ICD
	Protecta	5	ICD
	Secura	4	ICD
	Sensia	5	PM
	Viva	2	ICD
Sorin			
	Ovatio	2	ICD
	Paradym	11	ICD
	Reply	3	PM
St. Jude Medical			
	Accent	2	PM
	Current	3	ICD
	Ellipse	3	ICD
	Fortify	11	ICD
	Identity	1	PM
	Promote	2	ICD
	Sustain	2	PM
	Unify	5	ICD
	Verity	2	PM
	Victory	2	PM
	Zephyr	2	PM
Vitatron			
	C 20	1	PM
	C 60	3	PM

ICD = implantable cardioverter defibrillator, PM = pacemaker.

during the study where applicable. This optimized CIED programming for identification of EMI have been established in other EMI-studies [33–35].

Patients sat in the front seat of the cars while on the test-bench and the electromagnetic field strength

Table 5
Leads tested for EMI from electric cars

Manufacturer	Lead	n
Biotronik		
	Corox	4
	Linox	9
	Safio	3
	Selox	1
	Sentus	2
	Setrox	7
	Siello	20
	Solia	4
	Synox	1
	Y-53	1
Boston Scientific		
	Easytrak 3	1
	Endotak Reliance	4
	Flextend	3
	Reliance 4-Front	1
Guidant		
	Easytrak 2	2
	Endotak Endurance	1
	Endotak Reliance	6
LivaNova/Sorin		
	Beflex	2
	Tilda	1
	Vigila	2
	Volta	1
Medtronic		
	4057	3
	4598	1
	Attain	2
	Attain StarFix	1
	CapSureEpi	2
	CapSureFix Novus	12
	CapSure Sense	2
	CapSure SP	3
	CapSure SP Novus	4
	Sprint	1
	Sprint Fidelis	4
	Sprint Quattro	5
	Sprint Quattro Secure	5
St. Jude Medical		
	Durata	26
	IsoFlex	1
	OptiSense	3
	QuickFlex	8
	QuickSite	1
	Riata	6
	Tendril	34
Vitatron		
	IMD49B Excellence+	2
Unknown		
		4

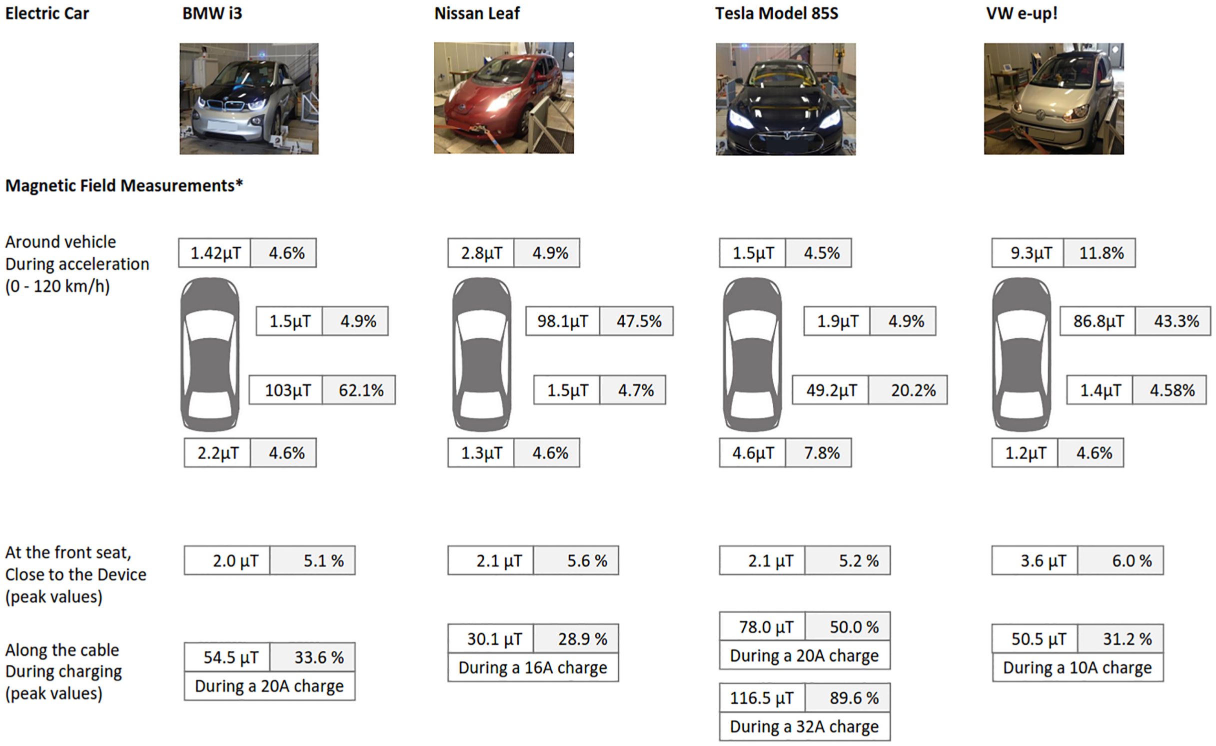


Fig. 1. Magnetic field strength during testing. *Values displayed as maximal field strength and as a percentage (normalized by frequency) of the maximum recommended exposure by ICNIRP [36]. Adapted from Ann Intern Med with permission [28].

within 5 cm of the CIED was recorded. Under continuous 6-lead ECG recording patients were instructed to perform pre-defined maximal accelerations and decelerations (Table 3). Patients then charged the car; this included plugging in, holding and unplugging the charger cable under continuous ECG-monitoring. Each patient performed this protocol with a single car.

All ECGs were analyzed for abnormal CIED function; e.g. inhibition of pacing, loss of capture, tracking to the upper rate limit or inappropriate mode switch. Device event monitors were interrogated for ventricular over-sensing resulting in inappropriate tachyarrhythmia detection. After each test, the device settings were compared with the initial settings to identify spontaneous reprogramming and the CIED subsequently reprogrammed to the settings specific for that patient.

All ECG recordings were independently analyzed by two cardiologists blinded to patient and car.

The study was approved by the ethics committee of Technical University of Munich, Munich, Germany and registered with clinicaltrials.gov (NCT02252575).

3. Results

3.1. Device types

One hundred and eight CIEDs comprising 42 different CIED families from 7 manufacturers were tested (Table 4). Of the 108 CIEDs 46 (42.6%) were dual chamber or CRT-ICDs, 28 (26%) were single chamber ICDs, 31 (28.7%) were dual chamber PMs, and 3 (2.7%) were single chamber PMs. One

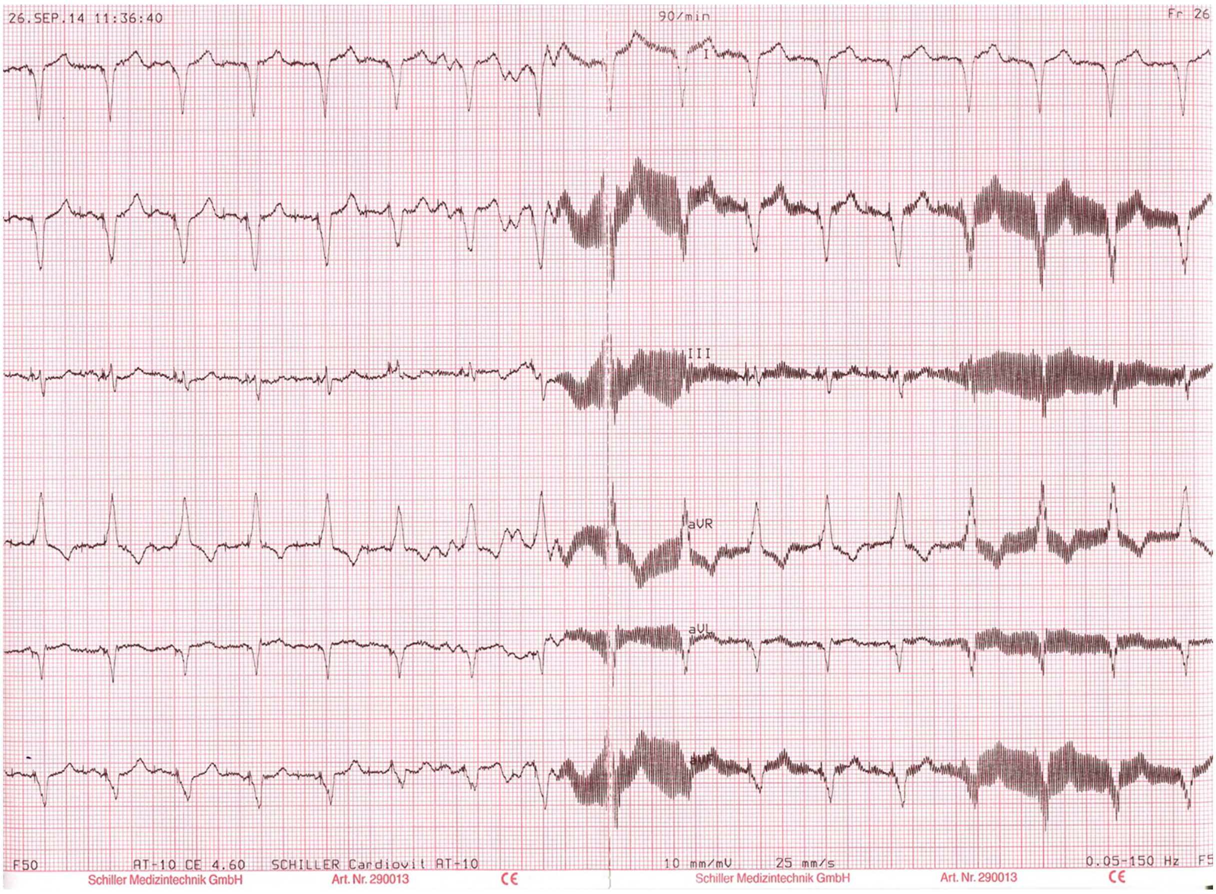


Fig. 2. High frequency, low amplitude EMI seen during testing.

hundred and eighty-three leads (75 atrial and 108 ventricular) comprising 42 lead families from 7 manufacturers were tested (Table 5). The mean sensitivity was 0.43 ± 0.24 mV for the atrial leads and 1.16 ± 1.08 mV for the ventricular leads. The sensing mode was bipolar in 99% (74/75) of atrial and 95% (103/108) of ventricular leads; the remaining leads were programmed to unipolar sensing.

3.2. Magnetic field

The magnetic fields measured in and around the cars while driving on the test-bench and charging are shown in Fig. 1. The International Commission on Non-Ionizing Radiation Protection (ICNIRP) recommended exposure to magnetic fields for the general population varies with the magnetic field frequency and so field strengths are presented as absolute values (inclusive of all frequencies) and as a percentage of recommended exposure normalized for frequency [36]. The largest magnetic field measured was along the cable during charging; 116.5 μT in the Tesla Model 85S in high current (32A) charge mode. The strength of the magnetic field in the cabin of the cars measured 2.1–3.6 μT; there was no difference in the cabin measurements taken on the test-bench versus on-road driving. We found variation in the magnetic field around the cars; the largest values were adjacent to either the front or rear doors (Fig. 2).

The magnetic field of the test-bench measured in stand-by and with full-load torque was 1 μT.

3.3. Functional device interference

We observed no evidence of EMI when driving nor when plugging in and charging. There were no episodes of over- or under-sensing, no inappropriate pacing or inhibition of pacing and no spontaneous device re-programming occurred. Pacing thresholds, sensing and lead impedance remained unchanged on post-test examination.

3.4. Electromagnetic interference with ECG-machine

The only EMI detected was with the ECG-machine. An example of the high-frequency EMI signal is shown in Fig. 2. The underlying pacemaker rhythm was not influenced as demonstrated by the constant, paced R-R intervals (CL 667 ms) and there was no functional effect on the CIED when interrogated.

4. Conclusions

To our knowledge, this is the first study to evaluate the effect of electromagnetic fields and potential EMI produced by fully electric cars on CIEDs. We found no effect on CIED functional or programming during driving or charging.

Though our group have previously published the primary safety outcome of this study here we report the full methodological details and importantly the complete details of devices tested. This demonstrates the wide selection of devices studied and thus the generalisability of our results. Furthermore, it facilitates industry, physicians and patients to assess whether a particular device has been evaluated.

We aimed to maximise observation of detectable EMI by reducing tachyarrhythmia detection to minimal settings and placing patients in several locations in and around the car during maximal engine output and during charging.

Fully electric cars were selected because the electromagnetic field of hybrid vehicles varies due to concurrent internal combustion engine use. Moreover maximal power is usually higher in pure electric than in hybrid vehicle. Our results are consistent with a smaller study that investigated EMI in a single hybrid vehicle [37]. Nevertheless, important differences in our study include the testing of multiple models; all fully electric. This enabled evaluation of more powerful electric motors and their associated electromagnetic fields than is possible in hybrid vehicles. Furthermore, use of a resistive roller-bench rather than a suspended car for test drives allows maximal engine power output to be achieved and thus generation of maximum electromagnetic fields; circumstances impossible with a suspended car.

The magnetic fields within the cabin during road driving matched that during roller-bench testing. It is thus reasonable to assume that our measurements are representative of real-life driving.

Electric cars are designed with electromagnetic shielding to prevent interference with other on-board computer systems. Therefore, it is reasonable to anticipate the shielding also provides protection from EMI to CIEDs inside the car. Indeed, the magnetic field measured inside the cabin (2.1–3.6 μT) was substantially less than outside the cars (up to 103 μT for the BMW).

The main source of the electromagnetic field generated by electric cars is the battery, though there is contribution from the power inverters, wiring, and power steering pumps [32,38]. Differences in location of the battery and of other source components are the likely explanation for the variation of the electromagnetic field around the cars. However, the magnetic field detected around the cars is unlikely to be clinically relevant because it is only produced by moving cars and pedestrians would be exposed for a very short time.

More potentially clinically-relevant exposures occurred during charging; the observed values were consistent with previous studies [32]. A plausible explanation for the higher values is that the charging cable is less shielded. Despite this, no events were detected during charging while standing next to the cable. It should be noted that the recommended exposure limits were designed to prevent adverse health outcomes and pertain to biological systems and not electronic devices. The field strength along the charging cable increased as current increased. This is relevant because of plans to increase charging capability to deliver up to 400A (versus 32A maximum in our study) and thereby produce larger electromagnetic fields [39].

Stunder et al. demonstrated that PM with nominal sensitivity settings encountered EMI in a magnetic field starting from 300 μT; moreover, with sensitivity maximized, EMI was first detected in a 130 μT magnetic field [40]. This raises concerns regarding planned high current chargers, but is reassuring for the low field strength measured in the cabin.

No restrictions were placed on types of lead or device, thus increasing generalizability of our results. We did not study effects at speeds over 120 km/h, but magnetic fields are strongest with maximal acceleration and are unrelated to speed. Our results are not definitive evidence of safety; however, if there is EMI between electric vehicles and CIED, it would be a rare event. Future research should investigate potential EMI produced by super-charging cables and how to shield these cables for patients with CIEDs.

Although our sample size was too small to detect rare events (between 1 in 1,000 and 1 in 10,000) [29], other information supports the conclusion that riding in electric cars is safe for patients with CIEDs. First, magnetic fields can also be generated in gasoline-powered cars if the steel-belted tires are magnetized [41]; average values of $\sim$ 20 μT were reported in the back seat for 12 different models and as high as 97 μT close to the tires [42]. Similar values have been reported in electric trains and trams [43]. These values are comparable to those we measured. Nonetheless, we are unaware of EMI cases associated with cars or trains.

In summary, electromagnetic fields produced by electric cars did not affect function or programming of CIEDs in our cohort. These results suggest current electric cars are safe for patients with CIEDs and no restrictions on travelling in them are required. Nevertheless, vigilance is required to monitor for rare events, especially associated with vehicle charging and proposed super-charger technology.

Acknowledgments

The study was supported by the Karl and Lore Klein Stiftung. The funder had no role in study design, data collection and analysis, or reporting. The grant was used to rent the cars and test-bench and cover personnel costs.

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