Electromagnetic Interference in Implantable Defibrillators in Single-Engine Fixed-Wing Aircraft

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BACKGROUND: Little is known about the possible electromagnetic interferences (EMI) in the single-engine fixed-wing aircraft environment with implantable cardio-defibrillators (ICDs). Our hypothesis is that EMI in the cockpit of a single-engine fixed-wing aircraft does not result in erroneous detection of arrhythmias and the subsequent delivery of an inappropriate device therapy.

METHODS: ICD devices of four different manufacturers, incorporated in a thorax phantom, were transported in a Piper Dakota Aircraft with ICAO type designator P28B during several flights. The devices under test were programmed to the most sensitive settings for detection of electromagnetic signals from their environment. After the final flight the devices under test were interrogated with the dedicated programmers in order to analyze the number of tachycardias detected.

RESULTS: Cumulative registration time of the devices under test was 11,392 min, with a mean of 2848 min per device. The registration from each one of the devices did not show any detectable "tachycardia" or subsequent inappropriate device therapy. This indicates that no external signals, which could be originating from electromagnetic fields from the aircraft's avionics, were detected by the devices under test.

CONCLUSION: During transport in the cockpit of a single-engine fixed-wing aircraft, the tested ICDs did not show any signs of being affected by electromagnetic fields originating from the avionics of the aircraft. This current study indicates that EMI is not a potential safety issue for transportation of passengers with an ICD implanted in a single-engine fixed-wing aircraft.

KEYWORDS: cardiology, pacemaker, aviation.

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The outcome of out-of-hospital cardiac arrest has been improved by the introduction of automated external defibrillators and implantable cardioverter defibrillators (ICD).[2] With the development of ICDs and a risk stratification based on large population studies, implantable defibrillator therapy became accessible for that part of the population having an increased risk for sudden cardiac death.[8,11] Primarily, ICDs were indicated as secondary prevention for survivors of sudden cardiac death. However, current guidelines indicate this therapy for primary prevention in a specific patient population as well.[5,8,11] Thus the number of ICD-bearing patients has greatly increased over the last decade.

The ICD delivers electrical therapy, including high voltage shocks, after detecting a potentially lethal cardiac arrhythmia. To ensure the ICD detects these potentially lethal arrhythmias, the device is set to be as sensitive and accurate as possible to thoroughly monitor cardiac electrical activity. Consequently, due to these electrical sensing capabilities, ICDs are, by their nature, susceptible to electromagnetic interference (EMI). This implies that nonlethal electromagnetic signals from the heart, as well as noncardiac signals either from within the body or from external electrical devices, might mimic rhythm disturbances, resulting in inappropriate device therapy.[6] Hence, the effect of interference on the one hand might be withholding of pacing therapy and, on the other hand, it might result in delivery of an unnecessary high voltage shock, a so-called inappropriate shock.[7,10]

The requirements for the safe operation of commercial airplanes in controlled airspace have been extended with the mandatory use of a pressure-altitude reporting transponder.[3] In addition to this so-called Mode-S transponder, an airplane

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certified for operations in instrument meteorological conditions has to be equipped with communication and navigation radios as well as distance measuring equipment. Consequently, the magnitude of electromagnetic radiation in the cockpit of a general aviation aircraft is higher and of a different nature than experienced in daily life.[1] Passengers on commercial aircraft, however, are considered to be seated far enough away from these potential electromagnetic interference sources to not be at risk from EMI, although this has, until now, not been specifically investigated.

Nevertheless, in a single-engine fixed-wing aircraft, where passenger seats are located directly in the cockpit, it remains unknown whether the magnitude of electromagnetic radiation might lead to EMI with the ICDs of passengers equipped with these devices. Consequently, it remains uncertain whether or not the pilot in command has to refuse passengers with an ICD. Since the ICD devices are implanted more and more for preventive reasons, it is important not to reduce the quality of life of their bearers unnecessarily. For these patients, quality of life might also mean making a flight in a single-engine fixed-wing aircraft. On the other hand, one has to realize that an inappropriate shock in the small cockpit of a single-engine fixed-wing aircraft will have serious impact on the safety of all on board. Interestingly, it has recently been demonstrated that modern pacemakers are not susceptible to EMI in the cockpit environment of single-engine fixed-wing aircrafts.[1] The current study evaluates the possible interaction between electromagnetic fields experienced in a single-engine fixed-wing aircraft and implantable defibrillators during actual flights in both visual and instrument meteorological conditions.

METHODS

Equipment

ICDs of different manufacturers were used to evaluate the potential EMI in a single-engine fixed-wing aircraft. The devices used were a Consulta D234TRK from Medtronic (Minneapolis, MN) (ICD1), a Paradym RF from Sorin group (Milano, Italy) (ICD2), a Promote RF 3213-36 from Saint Jude Medical (Sylmar, CA) (ICD3), and a Lumax 540 HF-T from Biotronik (Berlin, Germany) (ICD4). Except for the Sorin Group device, all devices were ICD and cardiac resynchronization therapy devices. The Paradym model from Sorin Group had just an ICD function and no resynchronization therapy function. Our set-up used for the in vitro testing consisted of a homogeneous phantom based on Irnich's model for testing interference of pacemakers by mobile phones.[4] It consisted of a watertight case made of Fiberglass reinforced ABS resin (Otter Products, LLC, Fort Collins, CO) filled with a 0.9 $g \cdot L^{-1}$ saline solution. The box was lined with foam to fixate the implantable device and the leads under test in position. Torso models like this have been agreed on and frequently used in research environments to test the influence of EMI on active implantable medical devices.[9] The device under test (DUT) was transported in different locations in the cockpit of a Piper Dakota, ICAO designator: P28B. One device was tested at a time during subsequent flights.

Procedure

With each of their designated programmer systems, the ICD devices were set to their most sensitive settings to maximally detect electromagnetic signals. Thus the sensitivity for cardiac signals was set to a maximum, the blanking period was set to a minimum, and the detection threshold for ventricular tachycardia or ventricular fibrillation was set to the lowest possible heart rate. However, it is important to mention is that this ultra-sensitive combination of settings would never be used in normal daily practice.

The date of installation and the date of removal of the DUT from the aircraft were registered in the flight log. Consequently, from this flight log the flights performed with each DUT could be reviewed. Furthermore, the total time of the DUT under EMI exposure was calculated. After a certain amount of flights, the cumulative memory of the ICDs was read out, again with the dedicated programmer. Before the read-out of the ICD's databases, the programmer verified the ICD software to rule out any possible software failure. In the cumulative ICD memory, arrhythmias are registered in case they reached a certain amount of heart beats per minute. The minimum amount of heart beats which is needed to qualify as an arrhythmia varies per device.

Additionally, the number of R- and P-wave detections was registered and read out. In the current study we assumed that these R- and P-waves were signals that could only have originated from electromagnetic interference since the phantom used had no heartbeat of its own. Nevertheless, we state that electromagnetic interference is only relevant in case it results in a potential delivery of (shock) therapy. Consequently, we concluded that in case no tachyarrhythmia was detected and no ICD shock was delivered, no relevant interference had occurred.

RESULTS

The settings of each device are demonstrated in **Table I**. The rate of each device is set on the lowest possible to get the broadest window of opportunity. The mode is set on nominal, or diagnostic in case of ICD1. The minimal amount of beats needed to register a (non)-sustained tachycardia is not given in the manuals, but is assumed to be persistent for clinical relevance.

In total, 181 flights, with a cumulative exposure time of 11,392 min, were made with the devices under test on board. The mean exposure time was 64 min per flight, varying from 23 to 174 min per flight. The number of flights and the total exposure time of each device are presented in **Table II**. After the final flight with the device under test on board, the device was read out with the dedicated programmer. The programmer detected no failure in any of the ICDs. Subsequently, the database of the four different devices under test for electromagnetic interference in a Piper Dakota did not contain any

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Table I. Device Settings.

	MODEL			
	MEDTRONIC CONSULTA D234TRK (ICD1)	**SORIN PRADYM RF DR (ICD2)**	**ST. JUDE PROMOTE RF 3213-36 (ICD3)**	**BIOTRONIK LUMAX 540 HF-T (ICD4)**
Noise detection above	not published	> 16 Hz	> 100 Hz	not published
Episode triggers	Persistence	Persistence	All high	Persistence
Mode	ODO	SafeR	DDD	DDD
Basic Rate	N/A	40	40	30
AV-delay at lower rate	N/A	155	160	150
Sensitivity	0.15 mV (± 75%)	0.4 mV	Auto (≥ 0.2 mV)	0.8 mV
Definition sensitivity	40 ms sine square	CENELEC	CENELEC	CENELEC
		EN45502-2-2	EN45502-2-2	EN45502-2-2
VT-1 criterion 100-130/min	16	30 cycles	24 cycles	26
VT-2 criterion 120-180/min	16	30 cycles	18 cycles	16
VF criterion 150-230/min	16	20 cycles	12 cycles	9
Common Mode Rejection Ratio V-channel				
16.6 Hz	not published	≥ 69 dB	not published	≥ 64 dB
50 Hz	not published	≥ 69 dB	not published	≥ 67 dB
60 Hz	not published	≥ 69 dB	not published	≥ 66 dB

tachycardia or signs of delivery of device therapy. Besides, no R- and P-waves were detected by any of the devices, which indicates that no electromagnetic signals originating from the usual onboard radios were detected by the devices under test.

DISCUSSION

During multiple test flights in a Piper Dakota with various implantable cardio-defibrillators embedded in an artificial thorax, no tachycardias and no R- or P-waves were detected in any of the ICDs of four different manufacturers. This implies that no relevant electromagnetic interference with the radios on board the aircraft occurred during the consecutive test flights.

It is widely known that modern communication technologies employ more and more of the electromagnetic spectrum and thus are an increasing potential source of electromagnetic interference.[7] In addition, previous literature has demonstrated that the source of electromagnetic interference can be diverse, varying from exposure to external electromagnetic fields originating from modern technologies with communication purposes to unintended EMI effects of other electrical technologies.[6] A previous publication regarding EMI with pacemakers in aviation demonstrated that the aircraft radios in a single-engine fixed-wing aircraft did not influence chip-based pacemakers.[1] The amount of interference in chip-based pacemakers of several manufacturers was extensively evaluated. Those results demonstrated the absence of electromagnetic interference in comparable circumstances. Since no electromagnetic interference was detected at all, the origin of potential electromagnetic interference sources was not evaluated. Disruption of function attributed to cosmic radiation have been observed in implantable cardiac defibrillators. This rare phenomenon has increased likelihood in higher altitudes, but was not part of this study.

The effect of EMI on ICDs is dependent of several factors, including distance between the device and the source of the electromagnetic field.[7] Therefore, the artificial thorax employed in the current study was positioned in different locations in the cockpit. Since passengers in the cockpit of a single-engine fixed wing aircraft are at a certain distance from the cockpit radios, the possibility of EMI in this study was, however, expected to be small. Our results indeed confirmed this.

One should realize that besides electromagnetic interference, which could influence the performance of the ICD, the emotional and physical experience of making a flight in a single-engine fixed-wing aircraft might also have influence on the ICD. In the current study we did not address this issue.

Although only four devices were tested in only one single-engine fixed-wing aircraft in the current study, it is suggested that the results obtained in this study apply to other types of ICDs and in other single-engine fixed-wing aircrafts as well, although there is no evidence that results can be extrapolated to other ICD devices and other aircrafts. But since the cockpit layout, as well as the number and type of navigation and communication radios, are similar in both single and multiengine aircraft, we assume that our results can be extrapolated to

Table II. Exposure Time of Devices Under Test.

			EXPOSURE TIME				
MANUFACTURER	**TYPE**	**CRT-D/ICD**	**NO. FLIGHTS**	**MINIMAL**	**MAXIMAL**	**MEAN**	**TOTAL**
Medtronic	Consulta D234TRK	CRT-D	37	20	166	61	2247
Sorin Group	Paradym RF	ICD	9	30	118	65	588
Saint Jude Medical	Promote RF 3213-36	CRT-D	88	24	174	58	5101
Biotronik	Lumax 540 HF-T	CRT-D	47	23	167	74	3456

CRT-D: cardiac resynchronization therapy - defibrillator; ICD: implantable cardioverter defibrillator; the minimal, maximal, mean, and total exposure time is represented in minutes.

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multi-engine aircraft as well. Moreover, since the proximity of the engine in a single-engine aircraft is much closer to the cockpit, the possible electromagnetic influence of the engine would be greater in our test situation compared to a multi-engine environment. However, as stated above, no influence could be detected by any of the devices under study, thus ruling out the possible adverse effect of any electromagnetic source in the cockpit on ICDs. On the other hand, to the best of our knowledge, no articles have been published regarding impaired safety of ICD patients on board general aviation aircraft. Moreover, in everyday life the actual EMI in ICDs appears to be minimal. Thus we can conclude that, with regard to EMI, it is safe for ICD-bearing patients to be transported in a single-engine fixed-wing aircraft.

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