

iPad2[®] Use in Patients With Implantable Cardioverter Defibrillators Causes Electromagnetic Interference: The EMIT Study

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Background—Over 140 million iPads[®] have been sold worldwide. The iPad2[®], with magnets embedded in its frame and Smart Cover and 3G cellular data capability, can potentially cause electromagnetic interference in implantable cardioverter defibrillators. This can lead to potentially life-threatening situations in patients. The goal of this study was to determine whether the iPad2[®] can cause electromagnetic interference in patients with implantable cardioverter defibrillators.

Methods and Results—Twenty-seven patients with implantable cardioverter defibrillators were studied. The iPad2[®] was held at reading distance and placed directly over the device with cellular data capability activated and deactivated. The manufacturers/models of devices and the patients' body mass index were noted. The presence of electromagnetic interference was detected by using a programmer supplied by each manufacturer. Magnet mode with suspension of anti-tachycardia therapy was triggered in 9 (33%) patients. All occurred when the iPad2[®] was placed directly over the device. The cellular data status did not cause interference and no noise or oversensing was noted. There was no significant difference between the mean body mass index of the groups with or without interference.

Conclusions—The iPad2[®] can trigger magnet mode in implantable cardioverter defibrillators when laid directly over the device. This is potentially dangerous if patients should develop life-threatening arrhythmias at the same time. As new electronic products that use magnets are produced, the potential risk to patients with implantable defibrillators needs to be addressed. (*J Am Heart Assoc.* 2014;3:e000746 doi: 10.1161/JAHA.113.000746)

Key Words: electromagnetic interference • implantable cardioverter defibrillator • iPad2®

E lectromagnetic interference (EMI) is a transient disruption or alteration in a devices normal function caused by an external signal. In implantable cardiac rhythm devices, the lead creates a loop antenna allowing a magnetic field to induce a current between the lead and the generator. The power of the external force, distance the external force is from the device, and duration and frequency of the signal will determine the degree (if any) of interference.

Implantable cardioverter defibrillators (ICDs) are designed in controlled situations to communicate with specific pro-

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grammers using radiofrequency (RF) signals and are designed to respond to an appropriate static magnetic field by suspending delivery of therapeutic shocks. ICDs incorporate various magnetic sensors that allow programming of the device by applying an external magnet (magnet mode). This suspends all anti-tachycardia therapies without affecting the pacing mode. ICDs are subject to potential EMI disturbances across the entire spectrum of electromagnetic sources. Unplanned static magnetic fields can potentially prevent therapeutic shocks, while induced current from RF signal sources may be incorrectly sensed as an arrhythmia and treated inappropriately.

Currently, research has been conducted for potential EMI interference caused by RF from cell phones, digital music players, and iPods.^{3,4} Additionally, in a study by Lee and colleagues,⁵ EMI from magnets in portable headphones created magnet mode response in 38% of patients with ICDs when placed within 2 cm from the device. With the advancements in shielding, filters, and detection algorithms, EMI of medical devices by emitting RF is relatively uncommon. However, with newer electronic device technology, strong magnets are used to activate features or provide fixation for attachments such as covers. One example is the Apple

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iPad2[®] and later models that incorporate strong magnets along its frame to attach the Smart Cover. The Smart Cover also incorporates magnets to assist fixation and to turn the iPad[®] on and off. iPad[®] devices are often used in close proximity to a person's body, ie, when reading sitting up or laying down. No research to determine EMI in the iPad2[®] or later models was found in the literature and because of their magnets, we theorized that the iPad2[®] could cause EMI in patients with ICDs. The purpose of this study was to determine whether the iPad2[®] would cause EMI in patients with ICDs and, if so, at what distance.

Methods

This study was approved by the Institutional Review Board of Dignity Health System. Prior to patient enrollment, to determine the number of magnets present on an iPad2[®], we utilized magnetic visualization film and placed it over the face of the device without the Smart Cover in place. We then placed the magnetic visualization film over the iPad2® Smart Cover. Additionally, using a magnet detector created by 2 reed switches placed perpendicular to each other, we determined a safe distance between the iPad2® and an ICD utilizing a buzzer and a battery. This magnetic detector system responded to a magnetic field of 0.007 micro-Tesla (7 Gauss), whereas ICDs respond to 0.01 micro-Tesla (10 Gauss).² The reed switches' perpendicular alignment allows them to respond to all magnetic fields that may activate magnet mode in an ICD. This results in an adequate safety margin for detecting any potentially interfering magnetic field.

Patients over 18 years old with ICDs were then enrolled in the study after obtaining informed consent. A baseline interrogation of the ICD was performed to note settings and ensure proper function. A doughnut magnet was placed on each device as a control to make sure the programmer was picking up the magnetic field correctly. The subject then held the iPad2[®] with its Smart Cover attached but open to expose the screen as if he/she was browsing the Internet. The distance that varied between 12 and 18 inches from the implanted device was recorded. A programmer was used to check for EMI and interrogate the device for 1 minute. This was done with both the 3G (cellular data) on and again with 3G off. The subject then reclined and laid the iPad2[®] across his/her chest directly over his/her ICD, as if he/she fell asleep while reading. This was also done with the 3G on and again with it off. The iPad2® was slowly moved around the entire surface of the implanted device only by the investigators to ensure all potential sites for magnet mode trigger were tested. The participant's device was interrogated again before the end of the office visit to ensure proper functioning.

Results

Prior to the start of subject recruitment, we determined there were 6 rectangular hinge magnets on one side of the iPad2[®] frame and 4 magnets on the opposite frame edge for latching the cover in place. The Smart Cover had 6 rectangular hinge magnets that coincided with the hinge magnets on the iPad2[®] frame and 14 on the opposite side that coincided with the frame to latch the cover. There was one circular magnet for the purpose of switching the device on or off.

A total of 27 patients with ICDs were studied. All patients had subcutaneous implantations. Depth of implantation to skin surface was not measured. No noise or oversensing was seen in any devices, but magnet mode was triggered in 9 (33%) of the devices. This occurred in varying models and manufacturers (Figure 1). The magnet mode trigger in the 9 devices only occurred when the iPad2® was laid directly on top of the implanted ICD. Figure 2 shows a printout from a programmer indicating the trigger of magnet response by an iPad2®. Additionally, in 2 of the positive magnet mode triggers of Boston Scientific patients, the ICD was programmed off indefinitely when the iPad2® was placed on the patients' chest over their device. In this case, the ICD did not turn back on when the iPad2® was removed.

We hypothesized that body mass index (BMI) may have been associated with a positive magnet mode response in our patient population. However, on average, the subjects BMI who had a positive magnet mode trigger (M=29.70 kg/m², SE=1.55) compared with those that did not have a magnet mode trigger (M=29.74 kg/m², SE=1.14) did not show a significant difference t(24)=.03, P=0.96.

Results from our magnetic detector determined a magnetic field of <0.007 micro-Tesla (7 Gauss) occurred at 2 cm away from the iPad2[®]. The strongest magnets appear to be on the hinges between the iPad2[®] and the Smart Cover. All positive magnet mode triggers occurred around the areas where the magnets were imbedded in the iPad2[®] and when it was directly on the body and over the device.

Magnet mode response was reproducible in patients that tested positive. In those patients that had a magnet mode trigger, all were in their baseline rhythms and were unaffected.

Discussion

This study showed that the iPad2[®] can cause EMI in patients with ICDs when they are used in close proximity to the device. All positive magnet mode triggers occurred when the iPad2[®] was laid directly on the chest and over the device of the patient. The Smart Cover was attached each time we tested for EMI. There are 10 magnets embedded in the iPad2[®] frame and 20 on the Smart Cover. We determined that RF from the iPad2[®] had no effect on the ICD.

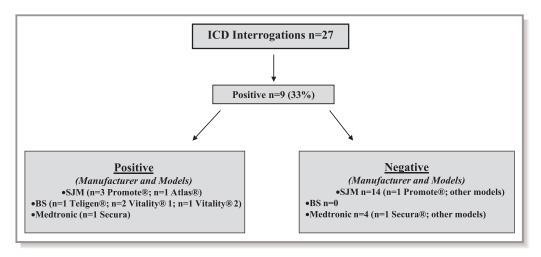


Figure 1. Results of iPad2[®] triggering magnet responses in patients' with ICDs. Results showed triggering of magnet modes in various devices in the study. BS indicates Boston Scientific; ICD, implantable cardioverter defibrillator; SJM, St. Jude Medical.

It is not certain why only some patients had a positive magnet mode trigger; however, it is known that the magnetic field weakens greatly with distance and the magnetic sensor in the ICD is rather small. Because magnet mode was only triggered when the iPad2[®] was placed directly over the device, it was presumed that the magnets in the iPad2[®] were in close proximity to the magnetic sensor in the ICD. The

location of the magnetic sensor varies depending on the manufacturer and model of the ICD. It may be possible that certain locations of the magnetic sensor made the ICD more susceptible to the magnets in the $\mathrm{iPad2}^{\oplus}$. The $\mathrm{iPad2}^{\oplus}$ in patients with a negative response were thoroughly checked; all borders and surface area of the ICD were checked for an extended time to attempt to illicit a positive response.

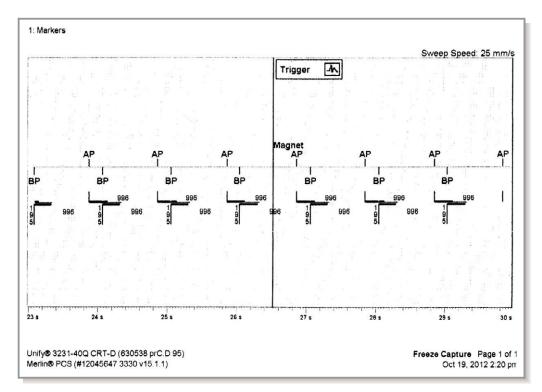


Figure 2. In an implantable cardioverter defibrillator (ICD) manufactured by St. Jude Medical, the ICD was interrogated after an iPad2[®] was applied directly on top. Printout from the programmer showed that magnet mode has been triggered. AP is a marker for atrial pacing and BP a marker for biventricular pacing. CRT-D is cardiac resynchronization therapy with a defibrillator. PCS is the Patient Care System used to interrogate the St. Jude Medical device.

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It was originally hypothesized that a person with a lower BMI would have a higher chance of testing positive. Theoretically a person with a lower BMI has less fat/muscle, and so the distance between his or her ICD and skin might be smaller. However, the difference in BMI in our study between the positive and negative groups was not significant. It may be possible that BMI is not an accurate measurement of the thickness of the tissue over a patient's ICD since fat distribution may differ depending on the patient's body type.

In older Boston Scientific ICD models such as the Prizm 1, Prizm 2, and Vitality 1, the device has a feature called "change tachy mode with magnet" in which the ICD's anti-tachycardia feature will be programmed off when a magnet is applied to the implanted device for at least 30 seconds. This feature will not resume until a magnet is once again reapplied for at least 30 seconds. ^{2,6} This feature was intended for use in operating rooms to prevent inappropriate shocks to patients with ICDs from EMI from surgical equipment. This feature is no longer available in any current ICD models; once a magnet is removed, all programmed features resume. In our study, 2 patients had an older Boston Scientific Vitality 1 ICD. Both patients' devices were programmed off because we analyzed each location with the iPad2® for approximately 1 minute. Therefore, as shown in this study, patients with older devices that develop a magnet mode trigger with an iPad2[®] are at risk for untreated tachyarrhythmias, since their ICDs may remain off for an extended period of time. Newer ICD models with positive magnet mode trigger only turn off their tachy mode while the iPad2[®] is placed directly on the ICD device and will resume programming once the iPad2[®] is removed.

Other tablets were not tested in this study however; the Microsoft Surface also utilizes magnets in the cover and frame. These magnets are stronger than the iPad2® and should be considered a risk to patients with ICDs (David Liang, personal communication, February 4, 2014). Other manufacturers of tablets that utilize magnets in their covers and frames could potentially be a risk factor for magnet mode trigger in patients with implanted ICDs.

Study Limitations

In our study only 3 device manufacturers were used. St. Jude Medical is the company most often used in our area, therefore was the most often studied device. A larger sample size and other companies such as Biotronik and Sorin should be investigated. These device companies have a small market share in the United States and are not utilized in the geographical area where this study was conducted. Though our sample size was small, we feel that this study can still make a conclusion that the iPad2[®] can trigger magnet mode in patients with ICDs when applied directly on top of the device such as in the sleeping position.

Future Research

Future studies could exam larger numbers of patients and other manufacturing device companies for magnet mode triggers in the presence of the iPad2[®]. Currently available only in Europe, there are ICDs compatible with magnetic resonance imaging (MRI).7 Research to determine if magnet interference with these newer ICD devices from small magnets such as those in the iPad2[®] could be important.

In our study we used the iPad2® with its Smart Cover attached. There are also magnets imbedded in the frame of the iPad2[®] and later models; determining if magnet mode could be triggered without the cover may add important safety information.

Additionally, magnet sensor location on the implanted ICD generator may have an association with EMI response and determining location may show beneficial results; in our study there were both positive and negative EMI in patients with identical models however, implantation position was not determined.

Finally, the depth of the implanted device to the skin surface may have a correlation with magnet mode response. Future studies to determine depth of implantation may be warranted.

Conclusion

On the basis of this study, we recommend the following concerning iPad2® or later models and their use in patients with ICDs:

- 1. Patients should avoid placing the iPad2® directly on top of their ICDs.
- 2. For certain Boston Scientific models, such as the Prizm 1, Prizm 2, and the Vitality 1, "change tachy mode with magnet" feature should be disabled for safety. This will prevent the anti-tachycardia feature of the ICD from remaining permanently disabled should magnet mode be activated.
- 3. Upon implanting ICDs, doctors should turn on magnet mode trigger monitoring so that when the patient's device is interrogated, the programmer will be able to tell if the ICD has encountered any magnet mode triggers in the past.

With the aging population, it has been projected that there will be an increase in ICD placement. Among individuals who choose to use electronic devices, the iPad2® and later models with the Smart Cover have become an integral part of their daily lives. As new electronic products that utilize magnets are produced, patients and healthcare providers should be educated regarding the risk of potential ICD malfunction with magnet exposure.

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