ABSTRACT

Do Media Players Cause Interference with Pacemakers?

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Background: Electrical devices generate electromagnetic fields that may interfere with pacemakers. Media players cause telemetry interference with pacemakers, but it is not known whether they cause direct interference with pacemakers. The purpose of this study was to examine the interaction between pacemakers and 3 different media players.

Methods: In this prospective, randomized study, 54 patients with dual chamber pacemakers who were in sinus rhythm underwent baseline observation, followed by observation under telemetry communication. These patients were then randomly evaluated with 3 media players (iPod 3G, iPod Photo, and iPod Touch Apple, Cupertino, CA) with and without telemetry communication for 1 minute each. Patients were monitored for pacemaker malfunction using a single-channel ECG during exposure to media players. The pacemaker was interrogated after each exposure and an interrogation report was printed for evaluation. Pacemaker interference was categorized as type I, II, or III. Types I and II interference described telemetry interference and type III interference was defined as any direct interference with pacemaker function or programmed parameters.

Results: A total of 54 patients (29 men and 25 women; mean age 77.2 \pm 9.3 y) were evaluated. In total, of the 162 tests (for telemetry interference) 36.4% were positive (Type I and II). Type III interference was also evaluated in 162 tests and none showed any evidence of direct interference.

Conclusion: Media players cause telemetry interference with pacemakers, but they do not directly interfere with pacemaker function.

Introduction

A pacemaker is usually implanted subcutaneously in the infraclavicular region. Most handheld, personal-use electronic devices operate at a distance from the patient and therefore, during normal use, may not come close enough to an implanted pacemaker to cause electromagnetic interference (EMI). However, a media player (MP) is commonly carried in a shirt pocket and therefore may come close enough to the pacemaker to cause interference.

Media players have been shown to cause telemetry interference with pacemakers.^{1,2} These studies described interference in the presence of telemetry communication between the programmer and the pacemaker using the inductive wand.^{1,2} Telemetry interference in pacemakers. even if it occurs only with wanded telemetry communication, may have clinical significance because: (1) a wand is used by patients to establish a link with a base station at home for some home monitoring systems; (2) clinically significant telemetry interference has been shown to occur with implantable loop recorders which require telemetry communication with an activator to capture

a patient triggered ECG³; (3) communication between the programmer and the pacemaker or implantable loop recorder occurs at the same carrier frequency; and (4) media players have been shown to emit electromagnetic radiation in the carrier-frequency range.³

Whether pacemaker interference from an MP is limited to telemetry interference is not known because the potential for interference in the absence of telemetry communication (wand) has not been studied. If MPs cause interference directly with pacemakers in the absence of telemetry communication, it may imply that there is a potential for greater clinically significant interference in patients using MPs because both pacemakers and media players are ubiquitous. The purpose of this randomized study was to examine the interaction between pacemakers and 3 different MPs in the presence and absence of telemetry communication.

Methods

This prospective, randomized study was performed in an outpatient pacemaker clinic or on hospitalized patients. The study was approved by the institutional review board and

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followed good clinical practice guidelines, including the use of standard operating procedures.⁴ Written and verbal informed consent was obtained from all patients.

Three types of media players were tested (iPod, Apple, Inc Cupertino, CA.): Third Generation (3G), Photo, and Touch. We chose iPod 3G and Photo because we used these devices in our previous study and iPod Touch because it is the newest, most advanced, flash memory-based device.³

Patient Selection

Only patients with dual-chamber pacemakers manufactured by Boston Scientific Inc. (St. Paul, MN) were selected for this study because our previous study showed more interference in these devices.² Patients were excluded if they were in atrial fibrillation or had atrial or ventricular ectopy during ECG monitoring for 5 minutes.

Study Design

Patients in the hospital were tested in a 30-degree supine position while patients in the pacemaker clinic were tested sitting upright in a chair. Patients were attached to an ECG monitor as well as the ECG on the programmer. The telemetry communication wand was placed over the pacemaker and a telemetry link was established. All pacemaker parameters were downloaded and the histograms were cleared. The patient was observed for 1 minute without the telemetry wand or communication on the ECG monitor and then the pacemaker was reinterrogated and the histograms were printed. The wand was then left over the pacemaker for 1 minute and the pacemaker was interrogated again and the rate histograms were reprinted. In a random fashion, the patients were exposed to the 3 iPods: 3G, Photo, and Touch for 1 minute each, in the presence of the telemetry wand and without the wand. At the end of each exposure, the pacemaker was reinterrogated

and the rate histograms were printed for evaluation. Thus, each patient was tested for telemetry interference 3 times (wand with each of the 3 iPods) and for interference in the absence of the wand 3 times (each iPod).

Definition of Interference

Consistent with our previous report, telemetry interference events were classified as Type I or Type II; both of these occurred in presence of the wand. Type I interference was defined as spurious atrial or ventricular sensing seen on the pacemaker programmer's marker channel during exposure to the iPod and evidence of this being detected in the pacemaker by high atrial or ventricular rates on rate histograms (Figure 1). Type II interference was defined as any interference on the monitor screen, which did not affect pacemaker function and was not detectable by pacemaker interrogation (Figure 2). In addition to these, we added Type III interference, defined as any interference with pacemaker function (failure to pace or sense) or programmed parameters on the pacemaker interrogation report, while the media player was applied directly over the pacemaker without the telemetry wand.

Data Collection and Statistical Analysis:

Standardized data collection forms were used to collect information on demographics, implantation details, pacemaker lead(s) and generator, pacemaker programmed parameters, and test results. All data was maintained in an Excel database and were analyzed using SPSS statistical software (SPSS Inc, Chicago, IL). Data are presented as mean ± 1 standard deviation. Event rates were compared using the χ^2 test. A P value of ≤ 0.05 was considered significant.

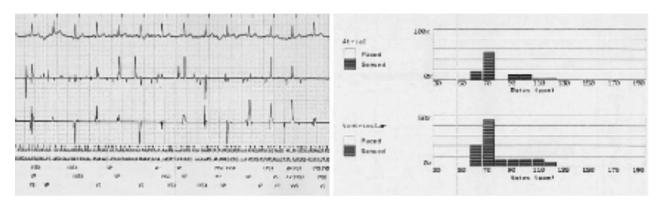


Figure 1. Left panel shows an example of interference induced by an iPod 3G during pacemaker telemetry monitoring. The top channel is the ECG, followed by atrial electrogram, ventricular electrogram, and the marker channel. While the iPod is over the pacemaker and the wand, marked artifacts are seen in the atrial, ventricular, and marker channels. The underlying rhythm is sinus rhythm at a rate of about 75 beats/minute. The marker channel shows high frequency of annotations "AS" and "VS" denoting atrial sensed and ventricular sensed events. The corresponding rate histograms show high atrial and ventricular sensed rates (hatched bars). This was classified as Type I telemetry interference.

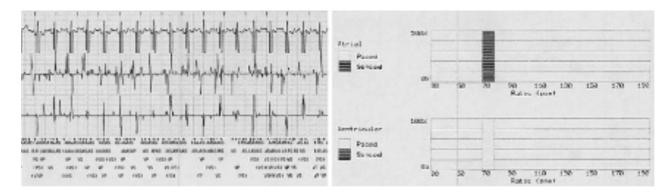


Figure 2. Left panel shows telemetry interference in a patient who has an atrial sensed and ventricular paced rhythm (DDD) at a rate of 70 beats/minute. During iPod application, interference is seen in the atrial channel, ventricular channel, and the marker channel (bottom), but pacemaker interrogation afterward showed atrial-sensed events at 70/min (hatched bar) and ventricular paced events at 70/min (clear bar). Since artifact on the programmer (left panel) was not accompanied by false changes in rate histograms this event was classified as Type II interference.

Results

A total of 54 patients (29 men and 25 women; mean age $77.2\pm9.3\,\mathrm{y}$) with dual chamber pacemakers and in sinus rhythm at the time of the study were evaluated. Demographic data and baseline pacemaker data are shown in Table 1. Indication for pacemaker implantation was sick sinus syndrome in 30 patients, bradycardia in 9 patients, syncope in 6 patients, and complete heart block in 9 patients. These patients had the following pacemakers: Discovery, 1 patient; Insignia 1294, 3 patients; Pulsar Max 1280, 6 patients; Insignia 1297, 7 patients; Pulsar Max 1270, 7 patients; Insignia 1298, 30 patients.

All patients were tested in the programmed pacing configuration (DDD or DDDR) and lead polarities (unipolar or bipolar); no changes were made to the P wave or R wave sensing thresholds prior to testing.

Type I and II interferences are telemetry interference and occur during interrogation with the wand. Each patient underwent evaluation with each of the 3 media players in presence of and without the wand resulting in 162 evaluations under either condition. Type I interference was seen in 6.2% of patients and Type II interference was seen in 30.2%. None of the patients demonstrated any direct interference in terms of pacing malfunction or reprogramming of pacemaker parameters (Type III).

Discussion

The main findings of this study are: (1) media players cause telemetry interference with pacemakers and (2) there is no evidence of direct interference with pacemaker function. Telemetry interference has been described before and these observations are consistent with previous reports.^{1,2}

While telemetry interference in implantable loop recorders has been shown to be clinically significant, telemetry

Table 1. Demographic Data

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Age	77.2 \pm 9.3 years
Sex	29 M; 25 F
Pacemaker Indication	
Asystole	1
Complete heart block	8
Sick sinus syndrome	30
Sinus arrest	1
Symptomatic bradycardia	9
Syncope	5
Pacemaker Sensing Parameters	
P wave	$\rm 2.69 \pm 1.34~mV$
R wave	$\rm 10.37 \pm 4.89~mV$
P wave sensitivity	$\rm o.65 \pm o.55~mV$
R wave sensitivity	$\rm 2.35\pm0.66~mV$

interference in pacemakers may have limited clinical significance, especially if the interference only occurs during wanded telemetry as described previously and in this report.^{1–3} Wanded telemetry is used for checking pacemakers in the clinic and for establishing a link with a base station for some home monitoring systems.^{5–8} Therefore, interference with this process can be deleterious. Wanded telemetry has a range of a few centimeters; while radiofrequency (RF) remote telemetry has a range of a few meters.⁹ Telemetry interference may be more important in pacemakers if it occurs with longer range RF communication because this is fast becoming the new standard for follow-up of implantable

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Table 2. Interference Observations in 54 Patients

	Baseline	Wand Only	Wand +3G	Wand +Photo	Wand +Touch	3G Only	Photo Only	Touch Only	
Type I: wand $+$ iPod	0	0	3	3	4				
Type II: wand $+$ iPod	0	0	34	9	6				
Type III: iPod only	0	0				0	0	0	
Type II interference: 3G vs Photo $P < 0.001$; Photo vs Touch $P = 0.6$.									

pacemakers and defibrillators. However, to our knowledge, this has not been studied. Telemetry interference with RF communication in implantable cardiac defibrillators should also be studied.

All pacemakers studied in this report (Boston Scientific Inc., St. Paul, MN) communicate with the pacemaker programmer at a carrier frequency of 69 to 100 kHz with a bandwidth of ± 100 kHz. We have previously shown that iPods emit electromagnetic radiation in this frequency range and Bassen has measured these emissions to be in the range of 0.2 μ Tesla. This likely accounts for Type I and II interference.

A few characteristics of iPods are responsible for causing telemetry interference. We have compared the low frequency (LF) magnetic field strength in the proximity of 3G and Photo iPods to the field strength employed for wand interrogation and pacemaker communication. From our testing (unpublished data), it is apparent that unintentional magnetic field emissions from both of these iPods occur in the LF band employed for inductive telemetry. Furthermore, the magnitude of the emissions from the iPods are lower than those employed by the interrogating wand, but are in the same order of magnitude as those from the pacemaker. Other investigators have shown that up to 100 kHz emissions from the iPods generate a localized, less than 2 µTesla (<1.6 amperes/meter), magnetic field that is strongest within 1 cm of their internal hard drives. 10 These emissions are too weak to significantly couple to the lead electrodes or to the header end of the pacemaker because a pacemaker's signal detection and processing circuitry is protected by low pass filters at the header and extremely low pass filters further downstream. Thus, significant direct EMI is prevented. As iPod emissions are in the working range of the telemetry wand, they can still generate telemetry interference without altering the pacemaker's pacing-sensing functions.

Short-range and long-range wireless communication is becoming indispensable in both the domestic and the industrial arenas, such as radiofrequency identification used for tracking equipment in hospitals, books in libraries, and so forth. Radiofrequency identification readers have been shown to cause clinically significant interference in pacemakers and implantable cardiac defibrillators as well

as potentially hazardous EMI with medical equipment in an intensive care unit. 11-13 Recently, Halperin et al described short range cyber attacks using an inexpensive software radio to intercept and alter data from an implantable cardiac defibrillator, raising concerns about privacy and safety issues related to wireless RF communication in implantable heart rhythm devices. 14 Security and interference with wireless heart rhythm devices is foreseen as a major upcoming challenge.

Telemetry interference has, hitherto, been considered clinically inconsequential. As we move into an era of wireless RF communication and as the number of these devices increase, we must be wary of the potential for EMI and issues related to electromagnetic compatibility, especially in the medical environment.

Limitations

We studied some of the newest pacemakers, but only a limited number of models from only 1 manufacturer (Boston Scientific Inc.). We studied only 3 models of iPod media players; these are some of the most popular models, but numerous others are also in use. Our findings may not apply to other pacemaker models or manufacturers, implantable defibrillators, other media players, or headphones. Generalization to other pacemaker manufacturers (models) and media players should be exercised with caution. This study examined interference with only telemetry wand communication. While this is an important issue, in the era of home monitoring, interference with longer-range radiofrequency telemetry also needs to be examined.

Conclusions

Media players cause telemetry interference with pacemakers. Telemetry interference can be clinically significant with some heart rhythm devices, but pacemaker patients can be reassured that these media players do not cause any direct interference with pacemaker function.

References

 Webster G, Ligia J, Martuscello M, et al. Digital music players cause interference with interrogation telemetry for pacemakers and implantable cardioverter-defibrillators without affecting device function. *Heart Rhythm*. 2008;5:545–550.

- Thaker JP, Patel MB, Jongnarangsin K, Liepa VV, Thakur RK. Electromagnetic interference with pacemakers caused by portable media players. *Heart Rhythm*. 2008;5:538–544.
- Thaker JP, Patel MB, Liepa VV, Jongnarangsin J, Thakur RK. Media players cause interference in implantable loop recorders. Heart Rhythm. 2008;S278.
- Applications for FDA approval to market a new drug or an antibiotic drug. 21 CFR 314.126 1992.
- Medtronic, Inc., http://wwwp.medtronic.com/Newsroom/ NewsReleaseDetails.do?itemId=1165849256153&lang=en_US.
- St Jude, Inc., http://www.medicalnewstoday.com/articles/107312. php.
- 7. Boston Scientific, Inc., http://www.aboutlatitude.com/how-latitude-works/index.html.
- 8. Biotronik, Inc., http://www.biotronik.com/en/us/5153.
- Savci H, Sula A, Wang Z, Dogan NS. MICS transceivers: regulatory standards and applications (Medical Implant Communications Service). Proc IEEE Southeast Con.; 2005; 179–182.

- Bassen H. Low frequency magnetic emissions and resulting induced voltage in a pacemaker by iPod portable media players. BioMedical Engineering OnLine. 2008;7:7. http://www.biomedicalengineering-online.com/content/7/1/7.
- Seidman SJ, Rugggera PS, Brockman RG, Lewis B, Shein MJ. Electromagnetic compatibility of pacemakers and implantable cardiac defibrillators exposed to RFID readers. *IJRFITA*. 2007;1: 237–246
- van der Togt R, van Lieshout EJ, Hensbrock R, Beinat E, Binnekade JM, Bakker PJM. Electromagnetic interference from radio frequency identification inducing potentially hazardous incidents in critical care medical equipment. *JAMA*. 2008;299(24): 2884–2890
- Berwick DM. Taming the technology beast. *JAMA*. 2008;299(24): 2898–2899.
- Halperin D, Clark SS, Fu K, et al. Pacemakers and implantable cardiac defibrillators: software radio attacks and zero-power defense. *Proceedings of IEEE Symposium on Security and Privacy*, May 2008 DOI: 10.1109/sp.2008.31.