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Cardiac Imaging

Safety of Computed Tomography in Patients With Cardiac Rhythm Management Devices

Assessment of the U.S. Food and Drug Administration Advisory in Clinical Practice

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Objectives To assess the safety of computed tomography (CT) imaging in patients with cardiac rhythm management (CRM) devices, which was subject to an advisory from the U.S. Food and Drug Administration (FDA) in 2008.

Background The FDA warned about potential interference of CT imaging with CRM devices and made recommendations for clinical practice despite only limited evidence.

Methods All 516 CT scans that involved direct radiation exposure of CRM devices (332 defibrillators, 184 pacemakers) at 2 large-volume centers between July 2000 and May 2010 were included. The primary outcome was a composite endpoint of death, bradycardia or tachycardia requiring termination of the scan or an immediate intervention, unplanned hospital admission, reprogramming of the device, inappropriate defibrillator shocks, or device replacement/revision thought to be due to CT imaging. Significant changes in device parameters were sought as a secondary outcome (control group 4:1 ratio).

Results The main finding was that none of the CTs were associated with the primary outcome. With serial device interrogations, there were no differences in changes in battery voltage or lead parameters between devices exposed to radiation and their controls. Potentially significant changes in device parameters were observed in a small group of devices (both the CT group and control group), but no definitive link to CT was confirmed, and there were no associated clinical consequences.

Conclusions The findings suggest that the presence of CRM devices should not delay or result in cancellation of clinically indicated CT imaging procedures, and provide evidence that would be helpful when the FDA advisory is re-evaluated. (J Am Coll Cardiol 2014;63:1769–75) © 2014 by the American College of Cardiology Foundation

Computed tomography (CT) imaging has been traditionally considered to be safe in patients with cardiac rhythm management (CRM) devices such as permanent pacemakers (PPMs) or implantable cardioverter-defibrillators (ICDs). It has been suggested in few experimental studies with anthropomorphic phantoms and very limited in vivo data that CT irradiation might affect the functioning of CRM devices (1–4). Subsequently, on the basis of these observations and a few individual reports, the U.S. Food and Drug Administration (FDA) released, on July 14, 2008, a public health notification warning that exposure to x-ray radiation during CT scanning may interfere with the proper functioning of some electronic devices, including PPMs and ICDs (2).

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In the original FDA report, potential problems from CT imaging included unintended shocks, transient changes in pacemaker output pulse rate, generation of spurious signals (including cardiac defibrillation pulses), misinterpretation of signals produced by the x-rays as actual biological signals, missed detection of actual biological signals, and resetting or reprogramming of device settings (2). Although on the basis of only limited peer-reviewed evidence, specific recommendations made by the FDA included having a physician ready to take emergency measures to manage adverse events should they occur, as well

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Abbreviations and Acronyms

AAPM = American Association of Physicists in Medicine

CRM = cardiac rhythm management

CT = computed tomography

FDA = U.S. Food and Drug Administration

ICD = implantable cardioverter-defibrillator

PPM = permanent pacemaker

having the device checked after CT imaging to ensure proper function. To date, this represents the only advisory from a regulatory agency worldwide to have addressed such interference.

The 2008 FDA report and recommendations raised concerns in the medical community due to a lack of significant peer-reviewed evidence, the potential to affect quality of care by avoiding medically necessary CT scans, as well as the potential to divert health care costs by implementing safety policies and procedures that have not been demonstrated to be appropriate or necessary (5).

No published data currently exist regarding the significance of CT interference with CRM devices in clinical practice. Specifically, no data exist regarding the occurrence in clinical practice of inappropriate shocks from ICDs, reprogramming of device settings, or other clinically significant events. This study sought to assess the occurrence of CT-related device interactions mentioned in the 2008 FDA advisory.

Methods

The study was performed at the University of Maryland Medical Center (Baltimore, Maryland) and the Baltimore Veterans Administration Medical Center (Baltimore, Maryland) and was approved by the institutional review boards at both institutions. All CRM devices directly exposed to radiation beams from CT imaging between July 2000 and May 2010 were included. The CT scans were performed using the Philips 4, 16, and 64-slice multidetector (Philips, Best, the Netherlands) at the University of Maryland Medical Center and the SOMATOM Sensation 16 and 64 (Siemens, Erlangen, Germany) at the Baltimore Veterans Administration Medical Center.

Primary outcome: adverse clinical events. The primary outcome of interest was a composite endpoint of death, bradycardia or tachycardia requiring termination of the scan or an immediate intervention, unplanned hospital admissions, inappropriate ICD shocks, resetting or reprogramming of device settings, or device replacement/revision thought to be secondary to radiation exposure from CT imaging. A careful review of medical records was conducted to identify adverse device-related clinical events that may have happened as a consequence of exposure to radiation from CT imaging. This was achieved by reviewing all clinical documentation before and up to the time of device interrogation in the outpatient clinic after CT exposure. This included review of outpatient and inpatient clinical notes, CT scan reports, and hospital discharge summaries. In patients who had device interrogation performed within 2 months after CT exposure, additional review of records was performed up to the time of the second post-CT visit to the device clinic.

Secondary outcome: changes in device parameters. The secondary endpoint of interest was the occurrence of significant changes in device parameters that could have potential clinical significance. These changes were defined a priori as any of the following: 1) unexpected decrease in battery power; 2) lead failure to pace or sense; 3) increase or decrease in lead impedance by 50% or more; 4) decrease of R-wave sensing by 50% or a final sensitivity <2 mV (potentially compromising detection of life-threatening arrhythmia by ICDs); and 5) doubling of threshold amplitude to a voltage >2 V, tripling of pulse width with a follow-up value >0.4 ms (potentially leading to inability to pace assuming minimally programmed pacing parameters of 2 V at 0.4 ms), or change by 50% or more in threshold product (defined as threshold amplitude [V] multiplied by pulse width [ms] to account for pre-/post-CT interrogations using alternating voltage and pulse width decreases).

For every CT scan performed, device lead and function parameters were obtained from 2 consecutive device interrogations conducted prior to and after CT scanning. When multiple CT scans were performed between consecutive interrogations, the CTs were counted as a single entry into the serial assessment of device parameters. Given that small changes in device parameters could occur over time under normal circumstances, a control group was also studied to better assess the secondary endpoint. For every four devices exposed to direct radiation beams from CT scans, one control device with no exposure to CT imaging was included for comparison (closest time-match of pre-CT interrogation for every fourth device). Control subjects had to have 2 consecutive interrogations available to allow analysis of changes in device parameters. With analysis of parameters from consecutive device interrogation sessions, changes in battery voltage, lead impedance, thresholds, or sensitivities were determined, and patients with potentially significant changes were subsequently identified. All patients who underwent device revisions after CT scanning but before the follow-up interrogation were also identified, and the indications for device revisions were carefully reviewed, with a focus on differentiating planned from unplanned revisions.

Statistical analysis. All statistical analyses were performed using JMP Pro version 10.0 (SAS Institute Inc., Cary, North Carolina). Numbers are presented as mean $\pm$ SD or median (interquartile range [IQR]), as appropriate. Serial changes in device parameters are reported as absolute values and as percent changes from baseline. The chi-square test and Student t test were employed for comparison of proportions or means, respectively, between 2 groups. For non-normally distributed variables, a nonparametric test (Wilcoxon rank sum test) was employed. A 2-sided p value <0.05 was considered statistically significant.

Results

Between July 2000 and May 2010, all 516 CT scans that involved exposure of CRM devices (332 ICDs, 184 PPMs) to direct radiation beams from CT imaging were included. The indications for which the CTs were performed are summarized in the Online Table. These CT scans were performed in 386 patients (241 with ICDs, 145 with PPMs) and most (292 patients [75.6%]) underwent only one CT scan (71 patients had 2 scans, 15 had 3, 4 had 4, 3 had 5, and 1 had 6 scans between July 2000 and May 2010). The mean age was 63.7 ± 16.4 years, and 81.1% of the patients were men. Comorbid conditions included coronary artery disease (69.2%), systemic hypertension (53.1%), and diabetes mellitus (29.3%). In 94 patients who underwent more than one CT, the scans were 14 months apart (IQR: 10 to 39 months), and 29 had 2 or more scans between consecutive device interrogations (23 had 2, 5 had 3, and 1 had 4). The baseline characteristics of the devices exposed to CT imaging are summarized in Table 1. The control group, which was included for assessment of the secondary endpoint, consisted of 129 devices (83 ICDs, 46 PPMs) in 129 patients who did not undergo CT imaging.

Of 332 ICDs exposed to radiation, the device manufacturers were Medtronic, Inc. (Minneapolis, Minnesota) (45.8%), Guidant/Boston Scientific (Natick, Massachusetts) (38.3%), St. Jude Medical, Inc. (St. Paul, Minnesota) (13.9%), and other manufacturers (2.1%) (vs. 59.0%, 34.9%, 4.8%, and 1.2%, respectively, in control group; p = 0.04). Of the ICDs exposed to CT, 56.6% were single-chamber devices, 26.8% were dual-chamber devices, and 16.6% were biventricular (vs. 56.6%, 27.7%, and 15.7% in control group; p = 0.97). Of 184 PPMs exposed to radiation, the device manufacturers were Medtronic, Inc. (57.1%), Guidant/Boston Scientific (21.2%), St. Jude Medical, Inc. (20.7%), and other manufacturers (1.1%) (vs. 52.2%, 23.9%, 21.7%, and 2.2% in control group; p = 0.90). Of the PPMs exposed to CT, 14.7% were single-chamber devices and 85.3% were dual-chamber devices (vs. 21.7% and 78.3% in control group; p = 0.26).

Table 1 Baseline Characteristics of CRM Devices Exposed to Direct Radiation Beams From CT

	ICD (n = 332)	PPM (n = 184)
Manufacturer		
Medtronic	45.8	57.1
Guidant/Boston Scientific	38.3	21.2
St. Jude	13.9	20.7
Other	2.1	1.1
Chambers		
Single	56.6	14.7
Dual	26.8	85.3
Biventricular	16.6	0.0
Indication for implantation		
Primary prevention	55.4	—
Secondary prevention	36.5	—
Atrioventricular block	—	42.9
Symptomatic sinus bradycardia	—	21.2
Sick sinus/atrial fibrillation	—	2.7
Unknown	8.1	24.5
Other	0.0	8.7

Values are % of devices.

CRM = cardiac rhythm management; CT = computed tomography; ICD = implantable cardioverter-defibrillator; PPM = permanent pacemaker.

Baseline device interrogation results were available for all devices. All but 6 devices in the CT group had available follow-up interrogations (3 deaths with heart failure [none with a biventricular device], 2 deaths with overwhelming sepsis, and 1 loss to follow-up in the device clinic but had followed up with the primary care physician). An extensive review of the medical records of death cases did not suggest any device dysfunction or a direct or indirect link of fatality to CT scanning.

Primary outcome: adverse clinical events. The primary outcome was not observed in any of the patients who underwent CTs that involved direct radiation exposure of CRM devices. Specifically, there were no deaths, bradycardia or tachycardia requiring termination of the scan or an immediate intervention, unplanned hospital admissions, inappropriate ICD shocks, or device replacement/revision thought to be secondary to radiation exposure during CT imaging. No clinically evident device malfunction during CT imaging was documented. Three patients in the CT group were PPM dependent, but no adverse events were noted. Further review of medical records showed that none of the patients had received a perfusion or interventional CT imaging that could have exposed the device to radiation beams for longer than a few seconds. Arrhythmic events such as atrial fibrillation (mode switching), ventricular tachycardia, or ICD therapy were recorded on 32.0% of post-CT interrogations (vs. 33.1% of pre-CT interrogations; p = 0.69). The time stamps of these arrhythmic events were compared with CT timing, and there was no temporal association or new arrhythmias. No spontaneous resetting or reprogramming of device settings was observed.

Secondary outcome: changes in device parameters. Serial device interrogations were reviewed to assess changes in device settings. In the group of ICDs exposed to CT, the median (IQR) time interval between initial and follow-up interrogations was 119 (91 to 194) days (vs. 98 [91 to 128] days in control group; p = 0.02). The follow-up interrogations in this group occurred 72 (56 to 83) days after CT exposure. In the group of PPMs exposed to CT, follow-up interrogations occurred 186 (164 to 229) days after the initial visits (vs. 182 [122 to 207] days in control group; p = 0.29) and 92 (72 to 105) days after CT scans. The baseline and changes from baseline in parameters of ICDs and PPMs exposed to CT and their controls are summarized in Table 2. Overall, there were no significant differences in

Table 2 Changes in Parameters of CRM Devices Exposed to Direct Radiation Beams From CT

	ICD			PPM		
	CT (n = 332)	Control (n = 83)	p Value	CT (n = 184)	Control (n = 46)	p Value
Battery power						
Baseline, V	3.0 ± 0.2	3.0 ± 0.2	0.80	2.8 ± 0.1	2.8 ± 0.1	0.11
Absolute change, V	−0.05 ± 0.07	−0.02 ± 0.04	0.02	−0.05 ± 0.3	−0.00 ± 0.02	0.18
Absolute change per month, V	−0.01 ± 0.03	−0.01 ± 0.02	0.13	−0.01 ± 0.03	−0.00 ± 0.01	0.12
% Change	−1.5 ± 2.5	−0.8 ± 1.4	0.02	−1.9 ± 11.0	−0.1 ± 0.6	0.18
% Change per month	−0.32 ± 0.81	−0.16 ± 0.49	0.12	−0.2 ± 1.2	−0.00 ± 0.2	0.12
RV lead						
Impedance						
Baseline, Ω	558.6 ± 206.4	510.9 ± 142.4	0.05	627.6 ± 213.7	621.5 ± 260.5	0.89
Absolute change, Ω	−11.3 ± 98.3	+5.2 ± 49.7	0.11	−4.7 ± 65.1	−8.7 ± 106.8	0.82
% Change	−0.4 ± 13.3	+1.4 ± 8.0	0.23	−1.6 ± 9.7	−3.1 ± 12.9	0.58
Sensitivity						
Baseline, mV	11.7 ± 5.2	11.7 ± 5.2	1.00	10.2 ± 4.4	10.7 ± 4.6	0.66
Absolute change, mV	+0.2 ± 3.6	−0.4 ± 2.9	0.26	+0.3 ± 4.6	−0.5 ± 3.0	0.34
% Change	+29.8 ± 239.1	−0.4 ± 29.0	0.18	11.8 ± 50.3	−0.6 ± 23.4	0.13
Threshold product						
Baseline, Vms	0.25 (0.15 to 0.40)	0.40 (0.23 to 0.50)	0.005	0.28 (0.20 to 0.40)	0.30 (0.20 to 0.40)	0.58
Absolute change, Vms	0.02 ± 0.60	+0.01 ± 0.24	0.82	−0.00 ± 0.18	−0.06 ± 0.49	0.45
% Change	+84.4 ± 327.6	+15.7 ± 84.2	0.03	18.6 ± 83.3	+2.5 ± 44.0	0.14
RA lead						
Impedance						
Baseline, Ω	488.1 ± 101.8	509.2 ± 90.9	0.30	558.8 ± 225.6	547.1 ± 175.5	0.76
Absolute change, Ω	+36.3 ± 280.7	−14.7 ± 44.8	0.18	+22.6 ± 179.9	−9.4 ± 49.4	0.13
% Change	+10.6 ± 79.2	−2.7 ± 8.3	0.21	+5.9 ± 46.7	−1.6 ± 7.9	0.15
Sensitivity						
Baseline, mV	3.6 ± 1.7	3.4 ± 1.5	0.60	3.1 ± 1.6	3.7 ± 1.7	0.12
Absolute change, mV	−0.2 ± 1.3	+0.1 ± 1.0	0.27	+0.01 ± 1.2	−0.5 ± 1.1	0.04
% Change	2.6 ± 41.3	+11.9 ± 33.7	0.30	+10.0 ± 57.6	−11.2 ± 28.4	0.02
Threshold product						
Baseline, Vms	0.25 (0.15 to 0.40)	0.30 (0.20 to 0.40)	0.40	0.30 (0.20 to 0.40)	0.20 (0.15 to 0.30)	0.003
Absolute change, Vms	−0.04 ± 0.29	+0.03 ± 0.20	0.22	−0.02 ± 0.38	−0.01 ± 0.12	0.78
% Change	+25.8 ± 122.2	+18.4 ± 59.8	0.74	+28.4 ± 115.1	+7.0 ± 48.4	0.19
CS lead						
Impedance						
Baseline, Ω	464 (368 to 538)	472 (368 to 511)	0.90	—	—	—
Absolute change, Ω	−8 (−36 to +6)	+8 (−29 to +24.3)	0.20	—	—	—
% Change	−1.8 (−6.9 to +1.4)	+1.9 (−6.3 to +1.9)	0.20	—	—	—
Sensitivity						
Baseline, mV	16.7 (6.4 to 24.1)	16.9 (6.6 to 25.2)	0.70	—	—	—
Absolute change, mV	−0.5 (−1.8 to +1.3)	−1.3 (−2.0 to +0.7)	0.60	—	—	—
% Change	−2.1 (−29.7 to +13.9)	−5.0 (−30.1 to +8.2)	0.60	—	—	—
Threshold product						
Baseline, Vms	0.19 (0.11 to 0.26)	0.18 (0.15 to 0.30)	0.90	—	—	—
Absolute change, Vms	−0.08 ± 0.31	+0.01 ± 0.08	0.32	—	—	—
% Change	+10.6 ± 79.6	+1.2 ± 29.8	0.68	—	—	—

Values are mean ± SD or median (interquartile range).
CS = coronary sinus; RA = right atrial; RV = right ventricular; Vms = volts × milliseconds; other abbreviations as in Table 1.

changes from baseline between devices exposed to radiation from CT scans and their controls.

With analyses of serial changes in device parameters, *clinically significant* changes in device parameters or device compromise were sought. These included unexpected decrease in battery power and large changes in lead impedance, threshold, or sensitivity, as previously defined in Methods section.

Among the devices exposed to CT, there was 1 unplanned system extraction and 2 unplanned lead revisions. One PPM and its leads were extracted because of endocarditis and evidence of vegetation on the atrial lead.

The first lead revision was of a right ventricular lead which had migrated through the right ventricular apex prior to CT. The second case involved failure of an epicardial lead to capture or sense following an open heart aortic valve surgery with 2 perioperative CTs performed. The lead was found to have been detached and was reattached, with subsequent normal functioning.

Three leads were found to have doubling or halving of impedance values among devices exposed to radiation (1 atrial, 2 ventricular, vs. none in the control group). Further review showed that doubling of impedance of the atrial lead was related to a lead fracture that occurred prior to CT. The 2 ventricular leads with significant changes in lead impedance were fresh implants with initial impedance values of 1,598 and 879 Ω and post-CT impedance values of 662 and 424 Ω, respectively. Subsequent interrogation showed stable impedances and normal functioning of the leads.

Among the devices exposed to CT, 10 leads (1.9%) were found to have significant changes in threshold values (vs. 8 leads in the control group [6.2%]), but none of these resulted in any clinical consequences. Finally, 1 ICD lead had a decrease in sensing by more than 50%, with a final value <2 mV (1.5 mV, decreased from 3.1 mV), which was discovered 118 days after CT exposure but was found to be in its original range on subsequent interrogations.

Discussion

To our knowledge, this study is the first to assess in a large cohort possible adverse clinical events that could have resulted from exposure of CRM devices to radiation beams during CT imaging. Despite an FDA advisory that warned about possible interactions and made specific recommendations for acute and follow-up management, no prior studies have addressed this issue in a large-scale population, and no data exist regarding the clinical significance of such interaction.

The most important finding was that the direct exposure of a large number of devices to direct radiation beams from CT imaging was not associated with clinically significant adverse events. Specifically, there were no deaths, bradycardia or tachycardia requiring termination of the scan or an immediate intervention, unplanned hospital admissions, reprogramming of the device, inappropriate ICD shocks, or device replacement/revision thought to be secondary to radiation exposure during CT imaging. Importantly, these findings were observed in a 10-year experience of 2 large-volume tertiary care centers. Additionally, radiation exposure of ICDs or PPMs did not appear to have been associated with clinically significant changes in device battery voltage or lead parameters. Potentially significant changes in device parameters were observed in a small group of devices, but no definitive link to CT was confirmed. Accordingly, similar changes were also observed in a group of devices that were not exposed to CT. Importantly, these changes did not result in any clinical events.

The original 2008 FDA advisory warned about possible interference of CT imaging with the proper functioning of some electronic devices, including the possibility of unintended defibrillator shocks and reprogramming of ICD or PPM settings (2). The FDA report made specific recommendations that included having a physician ready to take emergency measures to manage potential adverse events, as well having the device checked after CT imaging to ensure proper functioning. In clinical practice, however, CT imaging is performed without special considerations for CRM devices, and routine device interrogations after CT imaging are not currently the standard of care. Nonetheless, incorporating these recommendations into clinical practice would be logistically challenging and would require a significant amount of resources given the exponential growth of CT use in the past two decades.

In fact, the number of CT services billed to Medicare has grown exponentially, and millions of CT procedures are performed every year in the United States alone (6). Importantly, the number of CTs that may involve direct exposure of CRM devices to radiation beams has significantly increased (6,7), with evidence that CTs of the chest are consistently in the top 10 most frequently billed advanced imaging procedures (6), and of all advanced cardiac imaging procedures, cardiac CT use has grown the most (7).

In clinical practice, CT imaging in patients with CRM devices is frequently considered for a wide variety of clinical indications and is often used as an alternative to magnetic resonance imaging due to safety concerns (8–10). The use of CT imaging was considered safe in such patients until the 2008 FDA advisory. In the published data, multiple studies have evaluated the effect of radiation therapy (11) and electromagnetic interference on the functioning of CRM devices (12–20), but there exists much less published peer-reviewed data about potential interference from CT imaging (1,4,21,22), which raised concerns in the medical community about the 2008 FDA recommendations. Only 2 small studies with limited in vivo data had led to the original FDA advisory and recommendations (1,4). The first study (4) reported transient ventricular oversensing by PPMs in two phantom models and in 6 of 11 patients exposed to CT imaging; this finding was not associated with any significant clinical events or resetting of device programming. Importantly, device malfunction lasted for less than 4 s and was limited to the period of direct exposure of the pulse generator to CT radiation beams (4). The second study (1) exposed 13 PPMs and 8 ICDs, in an anthropomorphic model, to standard and maximal possible radiation CT scans (up to 90 mGy). The standard protocols included those performed for coronary CT angiography (up to 66 mGy), coronary artery calcium scoring (up to 15 mGy), detection of pulmonary embolism (up to 20 mGy), and routine chest CTs (up to 16 mGy). Ventricular oversensing with pacing inhibition was detected in 20 and 17 devices with exposures

to maximal and clinical dose CTs, respectively. However, device dysfunction lasted less than 4 s in most cases, and no programming alterations occurred.

In response to the original 2008 FDA advisory, the American Association of Physicists in Medicine (AAPM) (5) expressed concerns that included, among others, a lack of significant peer-reviewed evidence to support the FDA recommendations. The AAPM suggested that the advisory overstates the potential risk relative to published data and makes recommendations that may decrease the quality of patient care by avoiding otherwise medically necessary CT examinations, by decreasing the quality of medically necessary examinations, and by potentially increasing patients' anxiety, which may interfere with their care. The recommendations by the FDA were considered by the AAPM to possibly divert health care resources or increase costs by implementing safety policies and procedures that have not been demonstrated to be appropriate or necessary. Additional criticism was related to the fact that only 11 patients were included in the peer-reviewed publications and that interference was not observed in all of them. The AAPM argued that most clinically indicated CTs do not involve direct radiation of CRM devices for longer than 2 s and that oversensing in the published reports was transient, without any resetting of device programming, suggesting no long-term effects.

Following the release of the original 2008 FDA advisory report, 2 experimental studies addressed the interference of CT imaging with the proper functioning of CRM devices (21,22). These studies reproduced findings from the original reports (21,22) and suggested that this interference might be even less likely with clinical CT radiation doses (21). Although irradiation at very high doses, such as in patients receiving radiation therapy, interferes with PPMs by producing electrical currents within the PPM semiconductor circuit (23), diagnostic-level radiation is generally below the threshold at which such interference would occur (24). With CT irradiation at typical clinical doses, interference is limited to transient oversensing, permanent changes have not been demonstrated, and therapies from devices with antitachycardia features are unlikely to occur given that the dwell time of the radiation over the electronics module in the pulse generator would be <1 s in a typical CT study. Although CT interference with cardiac devices is more likely to be seen with diagnostic scans with higher dose-length product (e.g., cardiovascular scans) compared with the predominantly noncardiovascular scans in the current report, the published data show that such interference is very limited. Electrocardiogram gating is typically associated with higher radiation doses, but the FDA advisory made no distinction between routine chest scans and electrocardiogram-gated studies. Extrapolation from the previous FDA concerns would suggest that patients undergoing cardiac studies would be at increased risk. However, no primary clinical outcomes were noted in our study, regardless of the type of CT, supporting that these studies are not associated with higher clinical risk. Advances in CT scanner technology have also further mitigated the radiation effects of CT studies. Greater patient coverage in z-axis is possible with newer-generation scanners with an increased number of detectors and wider detector panels. With the additional detectors, fewer rotations of the gantry are necessary to image the entire heart, shortening image acquisition time. Current studies demonstrate dose profiles on par with or less than those of many conventional CT studies (25). There is, therefore, increasing evidence to suggest that CT interference with cardiac devices is even less likely to be seen with modern scanners and protocols.

In March 2013, an updated FDA advisory report did not emphasize routine device checks and specified that a staff physician should be available when the CT involves scanning over the device continuously for more than a few seconds (2). However, despite the original and updated advisory reports, no published peer-reviewed data exist on the significance of this interference in standard clinical practice. The current study provides the first clinical evidence that performing clinically indicated CT imaging is relatively safe in patients with CRM devices. The findings support the recent updates to the FDA advisory and suggest that the possibility of device reprogramming and inappropriate shocks, which are still highlighted in the current version of the advisory, are not commonly observed with routine clinically indicated CTs. However, a prudent approach would be required in PPM-dependent patients when CT scanning would involve continuous radiation of the device for longer than a few seconds. The findings also suggest that routine post-CT device checks, in the absence of any suspicion of device dysfunction, are not necessary. Importantly, the study reports on the magnitude of the risks of exposing CRM devices to CT imaging in clinical practice, including many device models from various manufacturers, as well as a variety of protocols and radiation doses from routine clinical settings and spanning the course of a decade.

Study limitations. This study represents the largest report to date on CT interference with CRM devices in vivo. However, the study could have missed clinically significant events that would occur at very low incidence rates (e.g., <1 of 500). However, it would require large national databases to significantly surpass the number of CTs included in this study, and funding/execution of such a study is unlikely. Additionally, the retrospective design of the study may have missed transient interference (including transient ventricular oversensing with pacing inhibition) that may have happened at the time of CT imaging. However, if present, those did not result in any clinically significant events at the time of CT. Given the small number of devices that were exposed to multiple scans between consecutive interrogations, the study could not assess the relationship between the number of scans and changes in device parameters. However, none of the scans performed between consecutive device interrogations were associated

with the primary outcome of interest. Finally, no measurements of radiation doses were available, and it is possible that higher radiation doses may have resulted in clinically significant effects. However, the vast majority of the scans included in this report, similar to routine diagnostic CTs in clinical practice, would have exposed the CRM device to direct radiation beams for only a few seconds and did not result in any adverse clinical events. The interference is more likely to happen with higher dose-length product scans, but given that this is transient and limited to oversensing for a few seconds with diagnostic scans, adverse clinical events are very unlikely to occur. Furthermore, the findings in the current report represent a wide array of CT protocols that are most employed in clinical settings, and, as previously discussed, radiation doses have dropped significantly with modern protocols and scanners.

Conclusions

The exposure of a large number of CRM devices to direct radiation beams from CT imaging was not associated with clinically significant adverse events or alterations in programmed device settings or lead and generator parameters. The findings suggest that the presence of CRM devices should not delay or result in cancellation of clinically indicated CT imaging procedures. Importantly, the study provides the first evidence from clinical practice assessing such interference and would be helpful when the FDA advisory is re-evaluated.

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Key Words: computed tomography ■ FDA advisory ■ implantable cardioverter-defibrillator ■ pacemakers.

APPENDIX

For a supplemental table, please see the online version of this article.