

Potential effects of low-dose average CT on cardiac implantable electronic devices

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Received Dec 5, 2017; accepted Dec 29, 2017

doi:10.1007/s12350-018-1186-y

Background. Average CT has been shown to be more accurate than conventional helical CT in quantitation of the PET data. The risk of CT irradiation of a cardiac implantable electronic device (CIED) causing an adverse event is low and is generally outweighed by the clinical benefit of a medically indicated examination. However, irradiation of CIED over one breath cycle in cine CT scan for average CT could impose risks on a patient who is pacing dependent. The purpose of this study was to demonstrate that low-dose average CT can be safe for CIED.

Methods. A Medtronic CIED of model Protecta VR was submerged in a saline bath for a series of 4-s cine CT scans on a GE CT scanner programmed to deliver a 2-cm-wide radiation at a dose rate of 0.9 to 41.2 mGy/s to the CIED. The number of over-sensings was recorded as the interference of radiation to the CIED.

Results. Dose rates ≥ 1.9 mGy/s caused over-sensing. The higher the dose rate, the more over-sensings there were. The lowest dose rate of 0.9 mGy/s did not cause any over-sensing.

Conclusions. Low-dose average CT at 0.9 mGy/s can be safe for a CIED patient who is pacing dependent. (J Nucl Cardiol 2019;26:1161–5.)

Key Words: PET/CT imaging • computed tomography (CT) • myocardial perfusion imaging: PET

Abbreviations

CIED	Cardiac implantable electronic device
CT	Computed tomography
PET	Positron emission tomography
4DCT	Four-dimensional CT

FDA	Food and Drug Administration
bpm	Beats per minute

See related editorial, pp. 1166–1168

INTRODUCTION

Average computed tomography (CT) from low-dose cine CT has been shown to be more accurate than conventional helical CT for quantitation of the positron emission tomography (PET) data.¹ Average CT is similar to the attenuation map derived from the standalone PET with rotational rod sources in temporal resolution. It can reduce the likelihood of misregistration between the CT and PET data, critical for quantitation of the PET data.^{2,3} Conventional helical CT can generate CT of distorted anatomy that is difficult to register with the PET data because its temporal resolution is typically

Electronic supplementary material The online version of this article (<https://doi.org/10.1007/s12350-018-1186-y>) contains supplementary material, which is available to authorized users.

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Reprint requests: Tinsu Pan, PhD, Department of Imaging Physics, The University of Texas MD Anderson Cancer Center, 1515 Holcombe Blvd., Unit 1352, Houston, TX 70030-4009; tpan@mdanderson.org J Nucl Cardiol 2019;26:1161–5.

1071-3581/\$34.00

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less than 1 second, whereas that of PET is one breath cycle of several seconds.² In contrast, average CT and PET both have a temporal resolution of one breath cycle.

According to the US Food and Drug Administration (FDA), CT irradiation of the generator or circuitry of certain CIEDs can cause electronic interference or over-sensing and affect CIED function and operation. Over-sensing occurs when the CIED inappropriately recognizes radiation-induced electrical signals as native cardiac activity and inhibits pacing. The interference can be avoided if the CIED is outside the primary x-ray beam of the CT scan; in addition, reducing the dose rate lowered the probability of interference. The risk of CT irradiation of a CIED causing an adverse event is low and is generally outweighed by the clinical benefit of a medically indicated CT examination.⁴ However, over-sensing of over a breath cycle in average CT could impose risks on a CIED patient who is pacing dependent, and has not been reported.

Here is a patient example prompting our investigation in the subject. An 88-year-old thyroid cancer patient had a single-chamber, left-sided pacemaker (Medtronic Sensia; ventricle paced; ventricle sensed; pacing inhibited; rate adaptive; lower rate = 75 beats per minute (bpm); max rate = 135 bpm) that had been placed to treat atrial fibrillation and bradycardia. The patient underwent 4D treatment planning simulation with cine CT on a GE LightSpeed RT 16-slice CT scanner with the scan parameters: 120 kVp; 315 mA; gantry rotation cycle, 0.5 seconds; cine duration, 5.05 seconds; x-ray beam width, 2 cm; radiation dose, 117 mGy; and radiation dose rate, 23.2 mGy/s. His next examination 2 weeks after revealed a history of underlying atrial fibrillation (50-70 bpm) and a 5.05-second ventricular high-rate episode (Figure 1), which caused noise reversion pacing (cycle length 795 ms [75 bpm] at 1-2, 5-6, 7-8) and pacing delay (6-7, 8-9). The duration of the ventricular high-rate episode corresponded to the duration of radiation in the cine CT. Although there was no adverse event experienced by the patient, a procedure was put in place to avoid radiation of CIED during 4-dimensional CT (4DCT) simulation as a result of this incident.

A CT examination is typically performed with helical CT in which the patient is irradiated while the table moves at a constant speed that is determined by the pitch factor equal to the ratio of the patient table advancement per gantry rotation to the x-ray beam width. Owing to more tissue attenuation in the posterior-anterior direction, the CIED receives more radiation if the radiation exposure is in the anterior-posterior direction than if the exposure is in the posterior-anterior direction. For a typical protocol with x-ray collimation of 2 and 4 cm at a pitch factor of 1 and a gantry rotation

time of 0.5 seconds, the table moves at the speed of 4 and 8 cm per second for the 16- and 64-slice CT scanners, respectively. The radiation dose is about 10-20 mGy at a dose rate of 20-40 mGy/s, and the CIED is irradiated for less than 0.5 and 0.25 seconds for 16- and 64-slice CT scanners, respectively.

Yamaji et al. reported over-sensing during CT scan with a radiation dose of 17.5 mGy at a dose rate of 35 mGy/s and an exposure time of 1 second on a Siemens Somatom 4-slice CT scanner, which could be prevented by lead shielding.^{5,6} McCollough et al., using a wide range of clinical CT parameters, found over-sensing in 20 of 21 CIEDs placed at the center of the CT gantry without any additional attenuating material in the x-ray beam at a radiation dose of 46.8-92.3 mGy and in 17 of 20 CIEDs placed on the upper left anterior chest of anthropomorphic phantom at the dose of 9.2-65.8 mGy.⁷ CT scans induced over-sensing in most CIEDs.

Two other CT scan modes are axial and cine scan modes. The cine CT scan mode irradiates the anatomy at the same table position for more than 1 gantry rotation, whereas the axial CT scan mode irradiates the anatomy at the same table position for only 1 gantry rotation. The cine CT scan mode has been used in perfusion CT to evaluate blood flow through an organ,⁸ and during interventional procedures to track the biopsy needle position,⁹ as well as in 4DCT to evaluate tumor motion due to respiration.¹⁰ The same cine CT scan parameters are used in average CT and 4DCT; however, 4DCT uses a higher radiation dose rate than average CT does,² and requires respiratory gating to sort cine CT images into multiple phases of 4DCT images.

A cine CT scan protocol (x-ray collimation, 2 cm; gantry rotation time, 0.5 seconds; x-ray tube current, 100-240 mA; scan duration, 6 seconds) can deliver a radiation dose of 50-120 mGy at a dose rate of 8.3-20 mGy/s with an exposure time of 6 seconds, whereas a typical helical CT scan can deliver 10-20 mGy at a dose rate of 20-40 mGy/s with an exposure time of less than 0.5 seconds. Thus, owing to its longer exposure time and moderate to high dose rate, the cine CT scan used in 4DCT will have a larger impact on the function and operation of a CIED than the helical CT scan does.

The purpose of this study was to demonstrate that average CT at the low dose rate of 0.9 mGy/s can be safe for CIEDs in the application of average CT for quantitation of the PET data, whereas several studies have demonstrated that typical CT scans induce over-sensing on CIED.^{5,7}

METHODS

A Medtronic CIED of model Protecta VR implantable cardioverter defibrillator was used in this experiment to test the

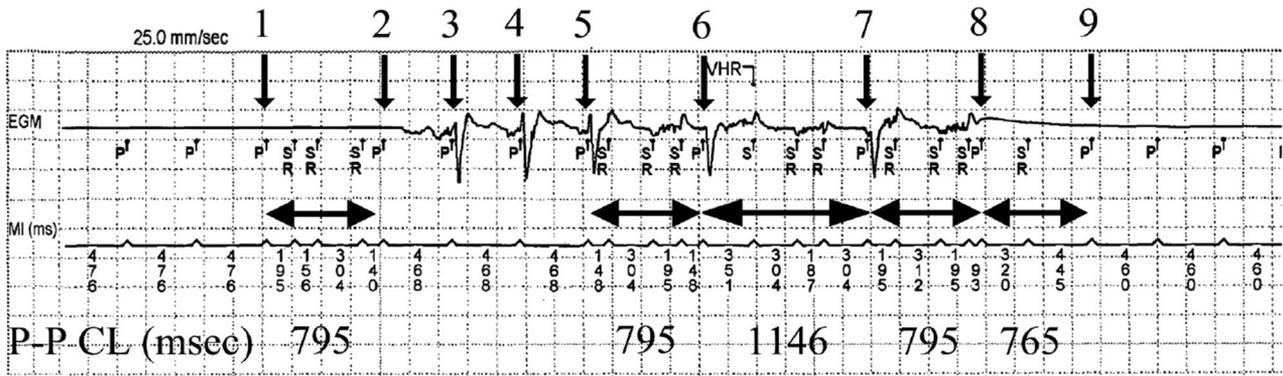


Figure 1. Over-sensing in a cine CT patient scan (radiation dose, 117 mGy; dose rate, 23.2 mGy/s). The durations of cine CT and the ventricular high rate episode were identical (5.05 seconds), suggesting a strong correlation between over-sensing and the high radiation dose rate in this patient scan.

interference of radiation to the CIED device. We submerged the CIED in a saline bath (Figure 2) for a series of 4-second cine CT scans on a GE LightSpeed QXi multislice CT scanner because CIEDs can function outside the body if they are placed in a saline solution. We programmed the scanner to deliver a 2-cm-wide radiation beam to cover the CIED's generator where the computer/control center of the CIED is located. This arrangement was similar to the maximum dose rate configuration.⁷ The radiation dose, dose rate, and scan techniques are shown in Table 1. The highest dose of 164.8 mGy at a dose rate of 41.2 mGy/s was derived from 120 kVp and 440 mA. The lowest dose of 3.4 mGy at a dose rate of 0.9 mGy/s was from 120 kVp and 10 mA. The mAs settings in the experiment were 440, 220, 110, 50, 40, 30, 20, and 10. The 10-mAs scan was repeated 8 times to ensure consistent results for the lowest dose rate, currently used in cardiac PET/CT imaging, whereas the other mAs scans were repeated 3 times. The average number of over-sensings for the three scans was recorded to represent the interference to the CIED by the irradiation.

RESULTS

Figure 3 shows the average number of over-sensings for the range of dose rates in Table 1. The higher the dose rate, the more the over-sensings were except the dose rates of 3.7 and 4.7 mGy/s, which had the same number of over-sensings. Dose rate equal to or greater than 1.9 mGy/s caused over-sensing on the generator. The lowest dose rate of 0.9 mGy/s did not cause any over-sensing in any of the 8 testing acquisitions. Figure 4 shows the three trials of the highest dose rate of 41.2 mGy/s and the first three trials of the lowest dose rate of 0.9 mGy/s. There were 15, 15, and 17 over-sensings in the three trials of the highest dose rate. There was no over-sensing in any of the 8 trials of the lowest dose rate of 0.9 mGy/s, confirming that the use of the lowest dose rate can be safe for the pacemaker-dependent CIED patients in low-dose average CT for quantitation of the cardiac PET data.

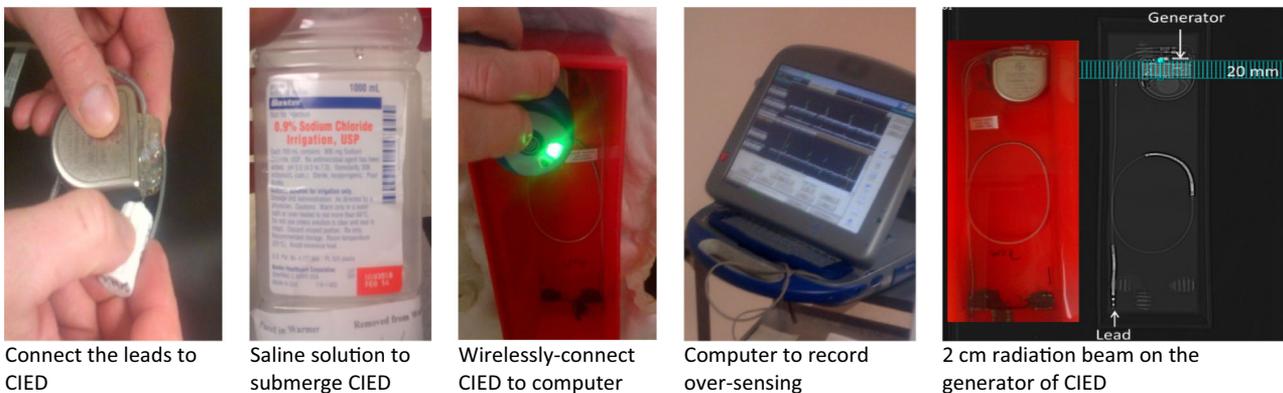


Figure 2. The steps of setting up a CIED for cine CT scan at the dose rates of 0.9 to 41.2 mGy/s in 8 steps of 10, 20, 30, 40, 50, 110, 220, and 440 mAs.

Table 1. Scan techniques and associated radiation dose and dose rates

# Trials	kV	mA	Duration (seconds)	mGy	mGy/s
3	120	440	4	164.8	41.2
3	120	220	4	82.4	20.6
3	120	110	4	41.2	10.3
3	120	50	4	18.7	4.7
3	120	40	4	15.0	3.7
3	120	30	4	11.2	2.8
3	120	20	4	7.5	1.9
8	120	10	4	3.7	0.9

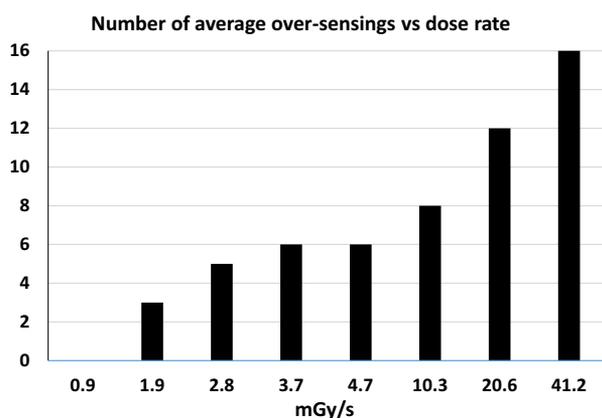


Figure 3. Number of over-sensings in the range of dose rates of 0.9 to 41.2 mGy/s.

DISCUSSION AND CONCLUSIONS

We demonstrated a patient study of cine CT with the duration of over-sensing identical to the duration of the cine CT scan at the high dose rate of 23.2 mGy/s.

The example might be the first reported patient case of over-sensing on a CIED induced by 4DCT. A CIED patient may want to have his/her device checked for over-sensing after a high-dose rate CT scan such as 4DCT and coronary artery CT, although most of the effects will be predominately transient and benign,⁷ and the probability that the interference can cause clinically significant adverse events is extremely low.⁴ We also demonstrated that in an *ex vivo* maximum dose configuration without soft tissue attenuation correction, all dose rates except the lowest dose rate of 0.9 mGy/s induced over-sensing. The lowest dose rate of 0.9 mGy/s is currently used in low-dose average CT for quantitation of the cardiac PET data. There have been no adverse effects from average CT on over 10,000 patient scans of cardiac PET since 2006.¹

If the same accumulated dose is irradiated to the patient in a shorter duration of scan time, the likelihood of over-sensing would increase. In our study, the dose rate of 0.94 mGy/s over 4 seconds not to cause over-sensing would become 1.87 mGy/s over 2 seconds to cause over-sensing. It is the dose rate (in unit of mGy/s)

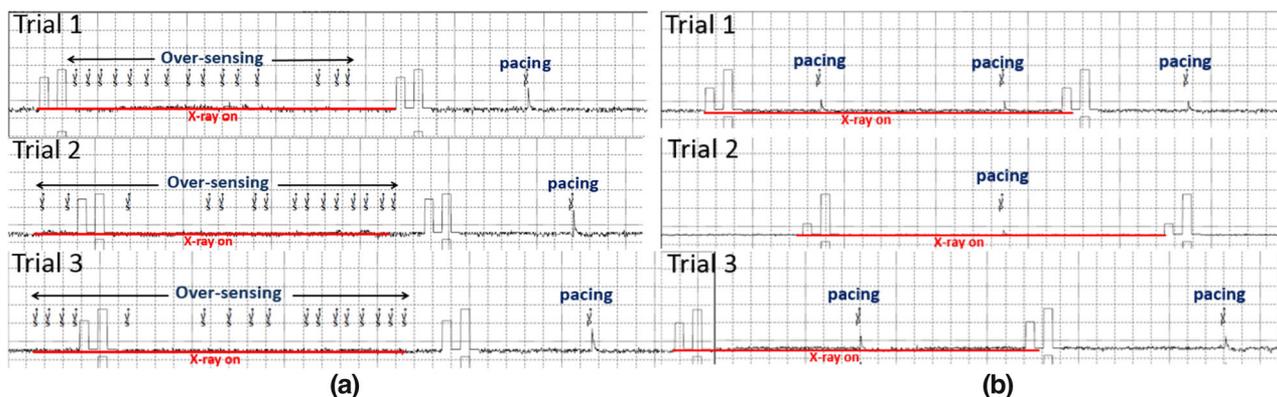


Figure 4. (a) Three trials of the highest radiation dose rate of 41.2 mGy/s for 4 seconds. There were 15, 15 and 17 over-sensings for trials 1, 2 and 3, respectively. (b) First three trials of lowest radiation dose rate of 0.9 mGy/s for 4 seconds. There was no over-sensing in any of the three trials.

rather than accumulated dose (in mGy) that determines interference with the function of CIED. This was in the FDA warning that the probability of x-ray electromagnetic interference is lower when radiation dose and particularly the radiation dose rate are reduced. Using 64-slice CT with a 4-cm detector would improve dose efficiency over 16-slice CT with a 2-cm detector by 8% to 15% on the GE CT scanner depending on imaging with either the small or large X-ray tube focal spot. As a result of higher dose efficiency on 64-slice than 16-slice, no over-sensing on 16-slice CT would lead to no over-sensing on 64-slice CT with the same mAs (tube current x time) setting, not the other way around.

One limitation of this study was that there was one CIED device reported in a patient study for high-dose rate cine CT, and one CIED device tested in a range of dose rates including the lowest dose rate of 0.9 mGy/s. There were 6 out of 11 patients experiencing over-sensing in Yamaji et al.⁵ and 20 out of 21 devices at maximum dose configuration with over-sensing in McCollough et al.⁷ FDA cited both studies in their publication of current patient risk assessment with CIED.⁴ The number of over-sensing cases might be fewer in the study by Yamaji et al. due to their use of helical CT scan, which had a short contact time of only 1 second and which might not directly irradiate CIED in the anterior-posterior direction without soft tissue attenuation. The study by McCollough et al. reported that almost all devices were impacted by over-sensing from irradiation at the clinical dose level with a majority of scans from helical CT. Our *ex vivo* study was similar to the latter study but was with the cine CT scan at maximum dose configuration on the generator, the most sensitive part of the CIED to radiation. Our results could be applicable to other CIEDs.

NEW KNOWLEDGE GAINED

The risk of CT irradiation of a CIED causing an adverse event is low and is generally outweighed by the clinical benefit of a medically indicated CT examination. Low-dose average CT of over a breath cycle at 0.9 mGy/s can be safe for a CIED patient who is pacing dependent.

Acknowledgements

The authors thank late Dr Marc A. Rozner for his guidance in this project and Joseph A. Munch for his assistance in scientific editing of the manuscript. This work was supported in part by the Cancer Prevention Research Institute of Texas Grant RP110562-P2.

Disclosure

There is no conflict of interest in the data and writing of this manuscript, and the manuscript is original and has not been submitted to other journals.

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