Malfunction of cardiac devices after radiotherapy without direct exposure to ionizing radiation: mechanisms and experimental data

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Aims
Malfunctions of cardiac implantable electronic devices (CIED) have been described after high-energy radiation therapy even in the absence of direct exposure to ionizing radiation, due to diffusion of neutrons (n) causing soft errors in inner circuits. The purpose of the study was to analyse the effect of scattered radiation on different types and models of CIED and the possible sources of malfunctions.

Methods and results
Fifty-nine explanted CIED were placed on an anthropomorphous phantom of tissue-equivalent material, and a high-energy photon (15 MV) radiotherapy course (total dose = 70 Gy) for prostate treatment was performed. All devices were interrogated before and after radiation. Radiation dose, the electromagnetic field, and neutron fluence at the CIED site were measured. Thirty-four pacemakers (PM) and 25 implantable cardioverter-defibrillators (ICD) were analysed. No malfunctions were detected before radiation. After radiation a software malfunction was evident in 13 (52%) ICD and 6 (18%) PM; no significant electromagnetic field or photon radiations were detected in the thoracic region. Neutron capture was demonstrated by the presence of the $^{198}$Au($^{197}$Au + n) or $^{192}$Ir($^{191}$Ir + n) isotope activation; it was significantly greater in ICD than in PM and non-significantly greater in damaged devices. A greater effect in St Jude PM (2/2 damaged), Boston (9/11), and St Jude ICD (3/6) and in older ICD models was observed; the year of production was not relevant in PM.

Conclusion
High-energy radiation can cause different malfunctions on CIED, particularly ICD, even without direct exposure to ionizing radiation due to scattered radiation of neutrons produced by the linear accelerator.

Keywords
CIED malfunction • Radiotherapy • Soft errors • Scattered radiation • Implantable cardioverter-defibrillator • Pacemaker

Introduction
Radiotherapy is a widely used treatment for several malignancies and its rate increased of nearly 200% in the last decade in pacemaker (PM) and implantable cardioverter-defibrillator (ICD) patients. As ionizing radiation can lead to cardiac implantable electronic devices (CIED) malfunctions, every effort is usually made to focus the beam away from the device, according to the document published in 1994 by the American Association of Physicists in Medicine. Nevertheless, a damage is possible even if the target of the therapy is far from the thorax, especially if directed to deep structures (as prostate, bladder, and gut), and X-ray production is achieved by the emission of high-energy electrons from the linear accelerators (LINACs). At photon beam energies > 10 MV, neutrons are produced by a reaction in the head of the LINAC; these neutrons can be captured in CIED mainly by boron and lithium.
What’s new?

- During radiotherapy, the risk of CIED malfunctions is frequently underestimated in the absence of direct exposure to ionizing radiation; nevertheless, to reach deep structures, X-ray production can be achieved by the emission of high-energy electrons from the linear accelerators, with the production of scattered neutrons causing soft errors in inner circuits.
- At devices interrogation, performed after a simulation of radiotherapy treatment for prostatic cancer on an anthropomorphic phantom of tissue-equivalent material, permanent malfunctions were frequently observed.
- Malfunctions were more frequent in ICDs than in PMs and in older ICD (but not PM) compared with more recent models; different effects were observed among manufacturers.
- No significant electromagnetic field or photon radiations were detected in the thoracic region during radiotherapy.
- Neutron capture was demonstrated by the presence of the \( ^{198}\text{Au}(^{197}\text{Au} + \text{n}) \) or \( ^{192}\text{Ir}(^{191}\text{Ir} + \text{n}) \) isotope activation in the devices; it was significantly greater in ICD than in PM and non-significantly greater in damaged devices.

contained in memories and battery (Figure 1) and this can be source of PM and ICD malfunctions due to soft errors. In a population study, a low risk of damages was detected, but a beam energy \( \geq 15 \text{ MV} \), often used for the treatment of sub-diaphragmatic tumours, was the greatest predictor of malfunctions, particularly electrical reset. Very recently, German guidelines developed by the German Society of Radiation Oncology (DEGRO) and the German Society of Cardiology and a detailed review of the literature by Zaremba et al. were published. However, the incidence, precise mechanism, and the variety of effects on different devices are still unknown.

The aim of our experimental study was to assess the risk and the mechanism of malfunctions in several CIED (both PM and ICD) placed on a neutron tissue-equivalent anthropomorphic phantom exposed to high-energy radiation, simulating a course of treatment for prostate cancer.

Methods

All CIEDs explanted for any reason (except malfunction of generator) from 1 July 2013 to 31 August 2014 and never previously exposed to radiations were analysed.

To simulate a radiotherapy course for prostatic cancer, a 15 MV X-ray radiotherapy treatment with a dose of 70 Gy was performed by a LINAC Varian Clinac 2100C (15 MeV).

For the purpose of the study, two anthropomorphic phantoms designed for neutron dosimetry by a group of researchers of the National Institute for Nuclear Physics according to the indications of the International Commission on Radiological Protection were used. Before 24 June 2014, a phantom made up of seven sheets of plexiglass and a central sheet of polyethylene (with a hydrogen composition similar to the human tissue and therefore equivalent with regard to neutron absorption), weighing \( \sim 37 \text{ kg} \) (Jimmy) was used; afterwards, another phantom (Ryan), all made of polyethylene and assembled by employing the size of the average man (71 kg), was used, as Jimmy was no longer available. All devices were positioned, in several sessions, on the phantom, in a site equivalent to the pectoral region, under a polyethylene layer of 3 cm simulating for neutrons the adipose tissue and skin (Figure 2).

Radiation dose and neutron uptake at the CIED site were measured. To quantitatively evaluate the radiation gamma-dose absorbed by the CIED, a dosimetric film GAFCHROMIC-EBT2 was used. Neutron dose was measured with bubble dosimeters for both thermal and fast neutrons and with CR-39 track detectors.

The radiation emitted by the devices before and after radiotherapy was used to assess whether their activation could be associated with the capture of thermal neutrons. For this purpose, we used a High Purity Germanium detector for gamma spectrometry as already indicated by Koivunoro et al.

The presence of any significant electromagnetic field was evaluated by a specific ElectroMagnetic (EM)-field measuring device (PMM 8035A with a EP300 probe).

After radiation, all devices were interrogated again. All the test results were affected by a statistical error of \( \sim 10\% \).
Data were presented as mean and standard deviation or count and percentages, as appropriate. Comparison between groups was made by using the ANOVA test for continuous parameters and $\chi^2$ for discrete variables.

## Results

Fifty-nine devices from several manufacturers (34 PM: 10 Boston Scientific/Guidant/Intermedics, 9 Medtronic/Vitatron, 3 Sorin, and 2 St Jude Medical; 25 ICDs: 11 Boston Scientific/Guidant, 7 Medtronic, and 7 St Jude Medical) were analysed (Table 1). Most devices ($n = 43, 73\%$) were explanted because of nearly depleted battery although still working. Some devices were explanted because of lead malfunction/infection ($n = 6, 10\%$), system upgrading ($n = 2, 3.5\%$), or death ($n = 2, 3.5\%$). In six patients (10%), the reason of explant was not available.

The interval between market release and the analysis was $12 \pm 3$ and $9 \pm 2$ years for PM and ICD, respectively. Medtronic models were the oldest ($15.1 \pm 0.3$ PM, while Boston ($9.5 \pm 1.4$ years) and St Jude ($9.9 \pm 1.5$ years) were the oldest ICD.

At baseline interrogation, performed just before irradiation, all CIED were working and no malfunctions were detected. After radiation delivery, battery depletion was excluded because battery voltage and impedance values were unchanged.

A software malfunction was evident in 13 (52%) ICD and 6 (18%) PM. Different kinds of soft errors were detected, or at least different responses to the interrogation were given by the programmer (Table 2): an electrical reset was present in two PM and one ICD, backup to VVI mode in two PM (all the St Jude models), a ‘failure of the pulse generator’ in seven ICD (in all cases Renewal 3 or 4, Boston Scientific); one PM and three ICD were impossible to interrogate, in one ICD the programming was found to be changed and in one ICD the response to magnet was deactivated.

Among PM, some malfunctions were present in 1 of 9 Medtronic, in 3 of 10 Boston, and in both the St Jude devices. No malfunctions were evident among Biotronik (0/10) and Sorin (0/3) devices (Figure 3A).

Among ICD, malfunctions were more frequently detected in Boston (9/11) and St Jude (3/6) devices, while failures were less frequent among Medtronic ICDs (1/8) (Figure 3B).

The interval between the year of production and irradiation was not statistically different in damaged and not damaged PM ($10.3 \pm 5.0$ and $12.6 \pm 2.4$, respectively; $P = 0.55$) while, among ICD, malfunctioning models were older in comparison with those not damaged ($9.8 \pm 1.3$ vs. $7.4 \pm 2.0$; $P = 0.001$).

Table 1: Cardiac devices evaluated

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Model</th>
<th>$N$</th>
<th>Year of production</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pacemakers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boston Scientific ($n = 10$)</td>
<td>Insignia I Ultra DR 1290</td>
<td>3</td>
<td>2003</td>
</tr>
<tr>
<td></td>
<td>Altrua 60 S606</td>
<td>1</td>
<td>2008</td>
</tr>
<tr>
<td></td>
<td>Intels II 1499</td>
<td>2</td>
<td>1999</td>
</tr>
<tr>
<td></td>
<td>Insignia I Ultra DR 1290</td>
<td>1</td>
<td>2003</td>
</tr>
<tr>
<td></td>
<td>Altrua 60 S601</td>
<td>2</td>
<td>2008</td>
</tr>
<tr>
<td></td>
<td>Insignia I Ultra DR 1291</td>
<td>1</td>
<td>2003</td>
</tr>
<tr>
<td>Medtronic ($n = 9$)</td>
<td>Geo1 SSI VSC 01/9.1</td>
<td>3</td>
<td>1999</td>
</tr>
<tr>
<td></td>
<td>Kappa KDR703</td>
<td>5</td>
<td>1999</td>
</tr>
<tr>
<td></td>
<td>Sigma SS 303</td>
<td>1</td>
<td>1998</td>
</tr>
<tr>
<td>Biotronik ($n = 10$)</td>
<td>Axios D</td>
<td>10</td>
<td>2001</td>
</tr>
<tr>
<td>Sorin ($n = 3$)</td>
<td>Rhapsody D2410 (T3)</td>
<td>3</td>
<td>2003</td>
</tr>
<tr>
<td>St Jude Medical ($n = 2$)</td>
<td>Verity AD × XL SR 5156</td>
<td>1</td>
<td>2003</td>
</tr>
<tr>
<td></td>
<td>Sustain XLDC PM 2134</td>
<td>1</td>
<td>2011</td>
</tr>
<tr>
<td>Defibrillators</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boston Scientific ($n = 11$)</td>
<td>Cognis 100D P107</td>
<td>1</td>
<td>2008</td>
</tr>
<tr>
<td></td>
<td>Contak Renewal 3F H215</td>
<td>2</td>
<td>2005</td>
</tr>
<tr>
<td></td>
<td>Contak Renewal4 H190</td>
<td>2</td>
<td>2003</td>
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<tr>
<td></td>
<td>Contak Renewal4 H195</td>
<td>1</td>
<td>2003</td>
</tr>
<tr>
<td></td>
<td>Vitality 2 DR T 163</td>
<td>2</td>
<td>2004</td>
</tr>
<tr>
<td></td>
<td>Contak Renewal4RF H230</td>
<td>3</td>
<td>2005</td>
</tr>
<tr>
<td>Medtronic ($n = 8$)</td>
<td>Concerto C174 AVK</td>
<td>2</td>
<td>2006</td>
</tr>
<tr>
<td></td>
<td>Maximo II DR D284DRG</td>
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<td>2008</td>
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<tr>
<td></td>
<td>Maximo II CRT-D D284TRK</td>
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<tr>
<td></td>
<td>InSync III Marquis 7279</td>
<td>1</td>
<td>2003</td>
</tr>
<tr>
<td></td>
<td>Protecta CRT-D D364 TRG</td>
<td>1</td>
<td>2010</td>
</tr>
<tr>
<td></td>
<td>Maximo-VR</td>
<td>1</td>
<td>2008</td>
</tr>
<tr>
<td>St Jude Medical ($n = 6$)</td>
<td>Atlas + VR V-193 Merlin PCS</td>
<td>3</td>
<td>2004</td>
</tr>
<tr>
<td></td>
<td>Epic VR V-197 Merlin PCS</td>
<td>1</td>
<td>2002</td>
</tr>
<tr>
<td></td>
<td>Atlas II + HF V-367 Merlin PCS</td>
<td>2</td>
<td>2006</td>
</tr>
</tbody>
</table>

The dosimetric film GAFCHROMIC-EBT2 positioned at the thoracic region for the detection of photonic radiation measured an average dose under 0.2 Gy.
No electromagnetic field was detected with the specific EM-field measuring devices.

The measured neutron dose in the CIED region was 19 ± 4 mSv. Neutron capture was demonstrated by the presence of the isotope $^{198}$Au($^{197}$Au + n) or $^{192}$Ir($^{191}$Ir + n) $\gamma$ lines from the devices. The activation of elements was slightly greater in ICD than in PM (7.5 ± 5.5 × 10$^2$ Bq vs. 6.6 ± 5.0 × 10$^2$ Bq), in damaged vs. not damaged PM (7.4 ± 4.8 × 10$^2$ and 6.4 ± 5.2 × 10$^2$ Bq, respectively), and ICD (8.3 ± 5.4 × 10$^2$ and 6.4 ± 5.5 × 10$^2$ Bq, respectively), although the differences were not statistically significant.

Data about neutron dosage were comparable using the two phantoms.

**Table 2** Damaged devices

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Model</th>
<th>n</th>
<th>Type of malfunction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pacemakers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medtronic</td>
<td>Sigma SS 303</td>
<td>1</td>
<td>Electrical Reset</td>
</tr>
<tr>
<td>Boston Scientific</td>
<td>Intels I 1499</td>
<td>1</td>
<td>Interrogation Impossible</td>
</tr>
<tr>
<td></td>
<td>Insignia I Ultra DR 1291</td>
<td>1</td>
<td>Electrical Reset</td>
</tr>
<tr>
<td></td>
<td>Altrua 60 S601</td>
<td>1</td>
<td>Electrical Reset</td>
</tr>
<tr>
<td>St Jude Medical</td>
<td>Verity AD × XL SR 5156</td>
<td>1</td>
<td>Backup in VVI mode</td>
</tr>
<tr>
<td></td>
<td>Sustain XLDC PM 2134</td>
<td>1</td>
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</tr>
<tr>
<td>Defibrillators</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>St Jude Medical</td>
<td>Epic VR V-197 Merlin PCS</td>
<td>1</td>
<td>Magnet deactivation</td>
</tr>
<tr>
<td></td>
<td>Atlas II + HF V-367 Merlin PCS</td>
<td>1</td>
<td>Interrogation impossible</td>
</tr>
<tr>
<td></td>
<td>Atlas II + HF V-367 Merlin PCS</td>
<td>1</td>
<td>Change of programmation</td>
</tr>
<tr>
<td>Boston Scientific</td>
<td>Contak Renewal4 H190</td>
<td>2</td>
<td>Failure of the pulse generator</td>
</tr>
<tr>
<td></td>
<td>Vitality 2 DR T 165</td>
<td>2</td>
<td>Failure of the pulse generator</td>
</tr>
<tr>
<td></td>
<td>Contak Renewal4RF H230</td>
<td>1</td>
<td>Interrogation impossible</td>
</tr>
<tr>
<td></td>
<td>Contak Renewal4RF H230</td>
<td>2</td>
<td>Failure of the pulse generator</td>
</tr>
<tr>
<td></td>
<td>Contak Renewal3F H215</td>
<td>1</td>
<td>Failure of the pulse generator</td>
</tr>
<tr>
<td></td>
<td>Contak Renewal4 H195</td>
<td>1</td>
<td>Interrogation impossible</td>
</tr>
<tr>
<td>Medtronic</td>
<td>InSync III Marquis 7279</td>
<td>1</td>
<td>Electrical Reset</td>
</tr>
</tbody>
</table>

**Figure 3** Number of damaged and not damaged PM (A) and ICD (B) according to different manufacturers.

No electromagnetic field was detected with the specific EM-field measuring devices.

The measured neutron dose in the CIED region was 19 ± 4 mSv. Neutron capture was demonstrated by the presence of the isotope $^{198}$Au($^{197}$Au + n) or $^{192}$Ir($^{191}$Ir + n) $\gamma$ lines from the devices. The activation of elements was slightly greater in ICD than in PM (7.5 ± 5.5 × 10$^2$ Bq vs. 6.6 ± 5.0 × 10$^2$ Bq), in damaged vs. not damaged PM (7.4 ± 4.8 × 10$^2$ and 6.4 ± 5.2 × 10$^2$ Bq, respectively), and ICD (8.3 ± 5.4 × 10$^2$ and 6.4 ± 5.5 × 10$^2$ Bq, respectively), although the differences were not statistically significant.

Data about neutron dosage were comparable using the two phantoms.

**Discussion**

In radiotherapy, the most commonly used types of radiation are photons, electrons or (less frequently) protons, generated and delivered by a LINAC. Even if not predictable by a threshold value, CIED malfunctions due to ionizing radiations can occur in the presence of a radiation dose exceeding 2 Gy at the CIED site. In order to protect the CIED from electromagnetic interferences, several measures have been suggested: magnet position, device reprogramming, or even CIED relocation in the presence of direct exposure to the radiation beam in high-risk patients, such as those who are PM dependent. A lead cover can be inadequate as it should be too thick to be considered in clinical practice.

Permanent CIED malfunctions may be due either to the destruction of the electrical components, often by direct irradiation, or to negative effects on the random access memory (RAM) by secondary radiations, scattering or electromagnetic interferences. In addition, photons in megavolt range (commonly 6–20 MV) are used to increase the depth of the maximal delivered radiation for more deeply located neoplasms. When photons energy exceeds >10 MV, or in the presence of Proton Beam Therapy, neutrons are produced; these neutrons can be source of PM and ICD malfunctions due to soft errors. The effect of a temporary exposure to radiation can vary from the inability to communicate with the programmer to...
deactivation of shock therapy or inappropriate shocks, reset, loss of
diagnostics, limitations in programmability, or damage to the device
components. However, effects due to direct radiation are different
from those due to scattering radiation or secondary radiation,11
which may locally induce ionization. The ionization leaves the local
electric circuits intact but gives rise to error data; this type of
interaction is called soft error. Soft errors, in semiconductor devices,
are due to three types of reactions: (i) radiation α, (ii) high-
energy neutrons resulting from cosmic radiation, and/or (iii) the
interaction between thermal neutrons and the 10B content in the
devices,12 producing ionizing particles (α) according to this reaction:
\[ n + ^{10}B \rightarrow \alpha + ^{7}Li. \]

The first guidelines for the management of patients with CIED
undergoing radiotherapy were published in 1989 as a Newsletter
from the American Society for Therapeutic Radiology and Oncol-
yogy.13 More formal recommendations were published in 1994 by
the American Association of Physicists in Medicine2 but they did
not include patients with ICD.

The maximum tolerated doses are rather variable; typically a
maximum photon dose of 2 Gy for PM (and possibly 1 Gy for
ICD) is suggested, but other types of radiations are not mentioned
and, in particular, the interaction between the devices and the
neutrons is not entirely clear if not almost unknown among
cardiologists.

Some reports suggest that in clinical practice malfunctions can
happen even in the absence of direct exposure to beams of ioniz-
ng radiation, as in patients undergoing radiation treatments for
prostate or rectal cancer.14 This has been ascribed to the diffusion
of neutrons produced by the LINAC when high energy is delivered,
casting the soft errors in the circuits.12 According to Elders et al.,3
in 5 of 17 radiation treatments (29%) there were 6 ICDs malfunc-
tions (35%), all observed at 10 and 18 MeV beam energies; a direct
comparison of these doses showed that the risk is higher using
18 MeV than 10 MeV.15 According to another in viuo experience
by Zaremba et al. mimicking the treatment of breast cancer with
high-energy (18 MV) and low-energy (6 MV) photon beams, in all
PM from the 18 MV group some malfunctions were detected,
and models is not clear. A more complex electronic circuit or a
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cardiologists.
Limitations of the study

The limited number of CIED evaluated cannot allow definitive conclusions, in particular about the different effect on different models of CIED.

Our data suggest a higher risk of malfunctions than what detected in clinical practice. However, also other in vitro studies showed a high rate of malfunctions. These discrepancies may have several explanations:

- a possible different time dependent, and not only dose dependent, effect of radiations cannot be excluded; despite all efforts to reproduce clinical conditions were made, in our simulation the whole dose (70 Gy) was administered in a single session, a condition not practicable in the real patient.
- Despite mimicking biologic tissue, matter composition of phantoms can have different effects on radiations; our phantoms were built to mimic neutron absorption, but the heterogeneity of biologic tissues is difficult to reply.
- The effect of other device components, as leads, cannot be evaluated during in vitro studies.
- During in vitro studies, the worst possible situations are usually tested: in our laboratory all devices were radiated with high energies (>15 MV) and were placed in the thoracic region from 30 to 60 cm far from isocentre of the radiation beam.
- During in vivo studies, the limited number of patients with comparable CIED and therapy regimens can lead to some inaccuracies and in large population studies an underestimation of malfunctions can be possible, as a comprehensive evaluation of all devices both before and after radiotherapy can be difficult to achieve.

According to our measurements, the presence of significant electromagnetic fields (range 0.15–300 V/m) was excluded, but these data should be considered just indicative, as low frequencies (<100 KHz) were not explored with our instruments. However, significant electromagnetic interferences due to LINACs were never described during radiotherapy and low frequencies in particular, although being a possible source of interference, are very unlikely to cause permanent malfunctions. As an experimental model, other possible malfunctions (modifications of pacing thresholds, inappropriate sensing or shock delivery) could not be excluded, although rarely associated with soft errors. In order to evaluate and estimate all possible malfunctions of the interface CIED patient, a study with the devices connected to a cardiac simulator could be desirable, but this was not the aim of our analysis.

Conclusions

High-energy radiation can determine CIED malfunctions even in the absence of direct exposure to the radiation beam, because of the diffusion of neutrons produced by the LINAC, causing soft errors in the circuits. In our experimental model, we simulated a complete radiotherapy treatment for prostatic cancer on an anthropomorphic phantom designed for neutron dosimetry. Despite the absence of significant phonic radiation and electromagnetic field in the thoracic zone, some malfunctions were detected in 52% of ICD and 13% of PM. The effect was more evident in some ICD and PM models than others; the year of production did not seem to be correlated with the risk of PM damages, while damaged ICD were older than those without malfunctions; finally a slightly, although non-significantly, greater neutron uptake in ICD than in PM and in damaged vs. not damaged PM was observed.

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References