Management of RT patients with implanted cardiac devices: From recommendation to implementation

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Outline

- CIED relocation. An option?
- CIED malfunction and clinical significance
- Pacing dependency
- ICD therapy. On or off?
- Patient management
  - The patients perspective
  - Prior to treatment
  - During/after treatment
CIED relocation. An option?

CIED implantation risks:
1-2% of patients serious complications (0.3% mortality) requiring acute thoracic surgery (Wilkoff et al., Heart Rhythm 2009;6:1085-1104).

CIED re-implantation on other side risks:
infection (0.4% – 4.0%) which necessitates removal of the device
pneumothorax (0.8%-1.7%) (de Bie et al., Heart Rhythm 2012;9:494-498).

Elective replacement of a CIED:
5.8% serious complications (Gould et al. JAMA 2006;295:1907-1911)
Types of failure in relation to clinical significance

### Pacing pulse

- All amplitude deviations of more than 25%.
- Complete loss of signal (POF).
- All pulse duration changes of more than 25%.

The pulse energy has to be sufficiently high to stimulate the heart. Usually, the pulse energy (pulse amplitude times pulse duration) is programmed at an approximately 50% higher value than the lower threshold value to stimulate the heart of an individual patient. An energy drop of 25% will therefore probably not be noticed by the patient. However, it might indicate that the pacemaker has been damaged.

Hurkmans et al., Radiother Oncol 2005;76:93-98
Types of failure in relation to clinical significance

Pacing frequency
- All frequency changes of more than 10% before or after irradiation (POF).
- Inhibition during irradiation only shorter than 5 s.
- Inhibition during irradiation only longer than 5 s.
- More than a single inhibition before or after irradiation (POF).

If the pacing frequency becomes too high, ventricular tachycardia may occur which can lead to a life threatening decrease of blood pressure (Zweng et al., Angiology 2009;60:509-512.).

Inhibitions during irradiation might be due to the direct irradiation of the pacemaker and might not be seen if the pacemaker is placed outside the field. Frequency changes or inhibitions before or after irradiation indicate that the pacemaker is damaged. A pacemaker technician should inspect the pacemaker.

Hurkmans et al., Radiother Oncol 2005;76:93-98
Types of failure in relation to clinical significance

Sensing threshold changes larger than 25%.

Telemetry
- Temporary loss of telemetry.
- Permanent loss of telemetry (POF).

Miscellaneous
- Battery problems
- Lead impedance changes
- Soft errors / Reset to factory settings
- Erroneous VT/VF detection

Hurkmans et al., Radiother Oncol 2005;76:93-98
Types of failure in relation to clinical significance

Soft errors - Single event upsets caused by neutrons

<table>
<thead>
<tr>
<th>Error type</th>
<th>Feature</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hard error</td>
<td>Damage to hardware of device</td>
<td>Permanent stopping in generating pulses or loss of control with computer</td>
</tr>
<tr>
<td>Soft error</td>
<td>Accidental overwriting of protected memories in RAM (essential for setup)</td>
<td>Beep: on; Mode: changes to safety back-up (e.g., VVI 65 bpm) Correction by computer: needed</td>
</tr>
<tr>
<td>Moderate reset</td>
<td>Interference with protected memories in RAM</td>
<td>Beep: on; Mode: no change; Correction by computer: unnecessary No change in parameters of the device</td>
</tr>
<tr>
<td>Minor error</td>
<td>Slight memory change cannot be detected by the computer directly</td>
<td></td>
</tr>
</tbody>
</table>

18 MV neutron dose 14-20 times higher than for 10 MV beam!

Hashii et al., IJROBP 2012 in press
Types of failure in relation to clinical significance

Table 1: Type, description, and total number of ICD errors caused by the secondary neutron from 107 Gy proton beam irradiation for each of four ICDs (Marquis DR 7274, Medtronic, Minneapolis, MN).

<table>
<thead>
<tr>
<th>Type of error</th>
<th>Explanation</th>
<th>Change in frequency and pulse width</th>
<th>Alarm sounded</th>
<th>ICD reprogramming</th>
<th>Number of sessions detected by the programmer</th>
<th>Number of errors revealed by analysis of the ICD data logs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hard error</td>
<td>The ICDs stop generating pulses permanently.</td>
<td>Yes</td>
<td>No</td>
<td>Impossible</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Soft error</td>
<td>Power-on reset</td>
<td>Yes</td>
<td>Yes</td>
<td>Necessary</td>
<td>13</td>
<td>29</td>
</tr>
<tr>
<td></td>
<td>Partial electrical reset</td>
<td>No</td>
<td>Yes</td>
<td>Unnecessary</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>Minor error</td>
<td>No</td>
<td>No</td>
<td>Unnecessary</td>
<td>5</td>
<td>7</td>
</tr>
</tbody>
</table>

 neutron dose 1-9 mSv/Gy

Hasimoto et al, Radiat Oncol 2012, 7:10
It is obvious that a complete loss of pacing ability will have major implications for pacing dependent patients. If the underlying heart rhythm is not sufficient, the patient will require cardiopulmonary resuscitation. Often, this is followed by external pacing through intravenously placed leads or external electrodes connected to a temporary external pacemaker.
Pacing dependency

A commonly used definition of pacing-dependency is:


The incidence of pacing-dependency in a mixed CIED population is around 10%.
### Tachycardia therapy: ICD therapy off?

In a study of Borleffs et al., approximately 50% of all ICD patients had ICD therapy at least once in a study with 8 years follow-up (Borleffs *Eur Heart J* 2009;30:1621-1626.). The moment of therapy is unpredictable, however, assuming the chance of this therapy is constant, ICD therapy occurring at least once during a 6 week course of radiation treatment can be calculated at approximately 0.7%.

Deactivation of the ICD shock function **during the entire radiation therapy period** would lead to a similar chance of withholding a potentially lifesaving shock.
Tachycardia therapy: ICD therapy on?

In the ICD population, approximately 10-20% of patients experience an unnecessary shock within a 5 year follow-up period. It has been reported that these patients have a loss in their quality of life and may develop psychological complaints as a result (Bostwick and Sola., Heart Fail Clin 2011;7:101-108)

Delivery of an unnecessary shock during RT is highly undesirable.
Tachycardia therapy: ICD therapy on or off?

Off: 0.7% chance on withholding lifesaving shock
On: Chance due to RT on unnecessary shock

Dutch guideline: Off during each fraction (0.005% chance on withholding lifesaving shock)
Patient management


In addition to these recommendations, based on our experience, we suggest the following:

- Be aware of potential sources of device interference in the RT suite, other than ionizing radiation;
- PPMs and ICDs should be interrogated routinely during RT. This is particularly important in pacemaker-dependent patients, when it should be conducted after each session;
- Heart monitoring capabilities should be made available for high-risk patients undergoing RT;
- We reinforce the importance of keeping the implanted devices out of the radiation field, as recommended.
Patient management


Table 4
Precautionary measures for radiation therapy planning and treatment delivery with implanted cardiac pacemakers

<table>
<thead>
<tr>
<th>Pre-radiotherapy</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Take a detailed cardiac history.</td>
<td></td>
</tr>
<tr>
<td>Consult a cardiologist for recording baseline cardiac and pacemaker function (full device interrogation and electrocardiography).</td>
<td></td>
</tr>
<tr>
<td>Liaise with a cardiologist and a pacemaker centre to know dependency rates, the need to reprogramme pacemakers and threshold doses.</td>
<td></td>
</tr>
<tr>
<td>Estimate the absorbed dose to the pacemaker and keep &lt;10 Gy using asymmetric jaws, blocks, multileaf collimators and wedges wherever appropriate.</td>
<td></td>
</tr>
<tr>
<td>Reposition the pacemaker if a safe dose cannot be achieved or if pacemaker is located within 3 cm of proposed radiotherapy portal to avoid inaccuracies in dose calculation.</td>
<td></td>
</tr>
<tr>
<td>Notify department personnel involved in direct patient care.</td>
<td></td>
</tr>
<tr>
<td>Avoid using magnetic resonance imaging or positron emission tomography in radiotherapy planning as these are potential sources of electromagnetic interference.</td>
<td></td>
</tr>
<tr>
<td>Always contour the pacemaker body, electrode and lead separately as an organ at risk.</td>
<td></td>
</tr>
<tr>
<td>Treatment on a linear accelerator has a higher chance of electromagnetic interference than a cobalt unit, may be considered in select high-risk patients.</td>
<td></td>
</tr>
<tr>
<td>Always opt for another non-radiotherapy treatment modality if it will be safer and equally valid. Consider using brachytherapy in appropriate cases.</td>
<td></td>
</tr>
</tbody>
</table>

During radiotherapy

Continuous electrocardiography monitoring with beam-on on the first day in the presence of the treating physician, especially for class I–II patients.

Daily recording of vitals before and after treatment for all patients (by therapist or nurse).

Inform patient and personnel to report any transient and prolonged cardiac symptoms or signs.

Keep a back-up pacemaker system to tackle an emergency on stand by.

Inform the on-call expert cardiac arrest team for class I pacemaker-dependent patients and in cases where the estimated dose to the pacemaker is >10 Gy. In vivo TID or diode measurement to record cumulative dose to the pacemaker.

Regular (weekly) device interrogation and electrocardiography as advised by the cardiologist.

Use a lead apron on a pulse generator as per manufacturer guidelines.

Call pacemaker personnel (at least weekly) to review the electrophysiological functioning of the pacemaker.

Do not put a cardiac monitor within the treatment room, use long leads to place it outside the linear accelerator.

Do not make injudicious use of electronic portal imaging and gating devices.

Post-radiotherapy

Consult a cardiologist to recording any cardiac and pacemaker malfunctions at the conclusion of radiotherapy.

Assess the need to reprogramme or replace the pacemaker.

Ensure appropriate follow-up checks with the cardiologist for several weeks to detect late failure.

Table 3
Classes of Pacemaker dependency

<table>
<thead>
<tr>
<th>Class I</th>
<th>Class II</th>
<th>Class III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptoms</td>
<td>Right-sided</td>
<td>Asymptomatic</td>
</tr>
<tr>
<td>Ventricular rate</td>
<td>No intrinsic activity</td>
<td>Ventricular rate &lt;30 beats per minute</td>
</tr>
<tr>
<td>Fatality</td>
<td>Expected</td>
<td>Not fatal</td>
</tr>
<tr>
<td>Abrupt cessation of pacing</td>
<td>Intense and active, before, during and after radiotherapy: cardiac arrest team on call</td>
<td></td>
</tr>
<tr>
<td>Emergent/urgent situation</td>
<td>Usually present</td>
<td>Routinely</td>
</tr>
<tr>
<td>Level of cardiac monitoring</td>
<td>Pacemaker dependency</td>
<td>Pacemaker dependency</td>
</tr>
<tr>
<td>Previous untoward cardiac history</td>
<td>Highly dependent</td>
<td>Not present</td>
</tr>
<tr>
<td>Pacemaker dependency</td>
<td>Intermediately dependent</td>
<td>Not present</td>
</tr>
</tbody>
</table>

Extra items:

- pacing dependency definition
## Patient management


<table>
<thead>
<tr>
<th>Pacemaker dependant patients</th>
<th>Non-pacemaker dependant patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Cardiac monitoring (ECG) is essential during every treatment session by appropriately trained personnel (with ability to respond to any arrhythmic event).</td>
<td>1 Treatment may be undertaken as per dept protocol.</td>
</tr>
<tr>
<td>2 Device checks are advised after every session.</td>
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</tr>
<tr>
<td>3 If an extreme bradycardia occurs, staff should be prepared to resuscitate the patient using external pacing as required (as a bridge to transvenous pacing and device replacement).</td>
<td>3 TLDs performed day 1 to check dose received by the pacemaker.</td>
</tr>
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<td>4 Cardiac monitoring (ECG) is essential during every treatment session by appropriately trained personnel (with ability to respond to any arrhythmic event). Monitoring must start as soon as the antitachycardia therapy is switched off and continue until the antitachycardia therapy is switched back on after the treatment session.</td>
</tr>
<tr>
<td><strong>Pacemaker and defibrillator patients</strong></td>
<td><strong>ICD patients</strong></td>
</tr>
<tr>
<td><strong>Extra items:</strong></td>
<td></td>
</tr>
<tr>
<td>• Pacemaker vs ICD</td>
<td></td>
</tr>
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<td>1 Use the defibrillator programmer to disable antitachycardia therapy during treatment.</td>
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<td>5 TLDs performed day 1 to check dose received by the ICD.</td>
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Extra “item”: the patients’ perspective

Dutch patient focus group:

- CIED management problems related to radiation therapy of low interest. They are dealing with much more serious health care related problems.

- Some appreciated receiving detailed information while others did not wish to be informed.

- The treating radiation oncologist and cardiologist should together decide and present the best course of individualised treatment to them.
patient management: patient oriented risk categories

- The patient’s risk is not equal to the risk of a CIED defect
- The chance on CIED malfunction mainly increase with dose and are **not** accurately known
- A practical guideline will be easier to implement

<table>
<thead>
<tr>
<th></th>
<th>&lt; 2 Gy</th>
<th>2-10 Gy</th>
<th>&gt; 10 Gy</th>
</tr>
</thead>
<tbody>
<tr>
<td>pacing-independent</td>
<td>Low risk</td>
<td>Medium risk</td>
<td>High risk</td>
</tr>
<tr>
<td>pacing dependent</td>
<td>Medium risk</td>
<td>Medium risk</td>
<td>High risk</td>
</tr>
</tbody>
</table>
Prior to treatment

An estimation of the CIED dose should be made by the responsible clinical physicist, which may be supported by a measurement or calculation.

The accuracy needs to be high enough to reliably determine the patient risk category.
Prior to treatment

No heterogeneity correction for the density of the CIED should be made, as this has not been done in the vast majority of articles published about CIED dose in relation to CIED defects.

Fig from: Gossman MS et al, J OF APPL. CLIN. MED. PHYS.11 (1), 2010
During and after treatment

- ICD might be left on after first fraction if intra-cardiac electrogram during first session is made.
- Medium/high risk: personnel trained in reanimation and a pacemaker technologist and/or cardiologist must be able to reach the patient within 10 minutes of a request in case of an emergency.

Extra item:
- personnel training
acknowledgements

- AAPM annual meeting scientific committee
- AAPM TG 203 members
- Dutch TG on management of CIED patients
- Academic fund Catharina Hospital RT department