Study to investigate the safe levels of radiotherapy that can be administered to patients who have an implanted cardiac device.

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Background

- Ageing population - number of patients with cardiac pacemakers presenting for radiotherapy treatment increasing
- Clinical practice there are a variety of different pacemakers in use:
  - Implantable internal pacemakers
  - Implantable cardioverter defibrillators (Marbech et al, 1994)
- Pacemaker manufacturers use CMOS circuits – more sensitive to ionising radiation than bipolar semiconductor circuits used previously (Little, 1996)
- Increased sensitivity can lead to damage to both the hardware and software components of the pacemaker (Last, 1998)
  - Transient damage and / or serious and permanent damage (Mouton et al, 2002)

Background

- Literature states that the maximum radiotherapy dose to the pacemaker should be limited to less than 2 Gy (Marbach et al, 1994)
- Published pacemaker manufacturers guidelines based on anecdotal experience and research carried out in 1994 by the American Association of Physicists in Medicine
- Pacemaker policies in UK radiotherapy departments are based on evidence that is 18 years old on superceded pacemaker technology
- Frizzell (2009) - most up to date review on pacemakers and radiotherapy = 1994 AAPM recommendations are no longer a complete guide and policies need to be updated to reflect advances in pacemaker technology
- Clinical audit
- Consequently - clinical need for research in the UK to determine the behaviour of modern pacemakers when in or close proximity to the radiotherapy treatment field

Case Study – Patient 1

Diagnosis – Gleason 8, adenocarcinoma prostate. Hormone relapsed – metastatic disease
Admitted through A&E with generalised left sided flank pain
PMH – Permanent cardiac device in situ, aortic stenosis and hypertension. WHO performance status = 2 (poor)
Treatment – Cord compression.
CT – soft tissue mass at T8 (Unable to have MRI – pacemaker)
Radiotherapy Treatment – Palliative RT – 20Gy/5#
Pacemaker leads in the radiotherapy treatment site

Case Study – Patient 1

Pacemaker Information:
- Pacemaker make / model – St. Jude Medical - Zephyr – Dual Chamber
- Pacemaker leads make / model – Medtronic
- Causation – Complete heart block
- Pacemaker dependant – Yes
- Position of pacemaker – RT sub-clavicular
- Measurement of pacemaker from RT field – SUP corner = 6cm (measuring diagonally)
  * Pacemaker leads in RT treatment field
- Physics dose calculation – Lead dose = 70% = 14Gy
**Patient 1**

Skin rendering image – Radiotherapy treatment site

- Pacemaker
- Radiotherapy treatment field

**Patient 1**

Radiotherapy treatment site (Gantry – 180)

- Radiotherapy treatment field
- Pacemaker leads

**Patient 1**

CT Slice – Pacemaker leads in radiotherapy treatment site

- Radiotherapy treatment field
- Pacemaker leads

**Case Study – Patient 1**

During radiotherapy treatment:

Patient’s physiological response:

- Rapid heart rate
- Chest pain
- Flushed and sweating
- Light headed / several dizzy spells
- Nausea / vomiting

**Case Study – Patient 2**

Diagnosis – Left apical carcinoma of the lung

4cm mass in the left apex infiltrating the pleura with no pathological mediastinal lymphadenopathy and no disease below the diaphragm

Staging – T2 N0 M0

PMH – COPD, permanent cardiac device in situ, ischemic heart disease, hypertension and type 2 diabetes. WHO performance status = 2

Treatment – Palliative radiotherapy (39Gy/13#)

Radiotherapy treatment field is adjacent to the inferior edge of the pacemaker

**Patient 2**

Radiotherapy treatment site (Gantry – 0)

- Radiotherapy treatment field
- Pacemaker leads
Phase 1 Research

Research Question:
What is the effect of radiotherapy on pacemaker function?

Study aims:
- Publish evidence-based guidelines on the safe use of radiotherapy in patients with implanted cardiac devices.
- Research team is a collaboration between Velindre Oncology, UHW Cardiology and Cardiff University School of Engineering and School of Healthcare Studies.
- Uniquely, this team is working with pacemaker manufacturers to inform future development and manufacture of cardiac devices.

Phase 1 Research

- Research outcomes and subsequent guidelines will be cascaded to all health professionals in both the Oncology and Cardiology field of practice and to all pacemaker manufacturers.
- In accordance with the Strategic Plan published by the Society of Radiographers, this research project and its findings will have a practical application in the clinical setting.
- In liaising and collaborating with a multi-disciplinary healthcare team, pacemaker manufacturers and research and development bodies, the focus will be firmly established on the benefits to the field of radiotherapy, improving patient care and identifying best clinical practice.

Trial Design

- Quantitative methodology, research will adopt an experimental approach to data collection

Device conditions and set-up:
- 15 pacemakers from 3 different manufacturers will be tested
- Varian linear accelerator with 120 MLC and portal imaging with x-ray energy of 6Mv, set at a dose rate of at a rate of 600 MU/min
- Monitoring devices placed directly on the pacemaker which is connected to a simulator
- Pacemaker positioned along the projected central axis of the primary radiation beam in a phantom with tissue equivalent bolus material to replicate the clinical setting

Trial Setup

- Pacemaker Programmer

Device Testing:
- Pacemakers irradiated at 0.5Gy / fraction
- Before, during and after exposure, pacemakers will be subjected to programming and functionality tests
- Manufacturers extensively test and analyse pacemakers exhibiting signs of damage or adverse effects and provide a full service report
- Thereafter, the devices will be returned to the hospital and irradiated to their definite point-of-failure (120Gy)
Testing - Device

Testing - Leads

Completion of Phase One Research

- To investigate the safe levels of radiotherapy on implanted cardiac device
- To extend and develop knowledge in this field
- Publication of national guidelines, clinical protocols and radiotherapy tolerance doses – Society of Radiographers
- Collaborate with the pacemaker manufacturers to modify / develop devices that will be less sensitive to ionising radiation
- Current clinical audit between UHW Cardiology and Velindre Oncology
- National audit - UK radiotherapy department current pacemaker polices

Summary

On completion of the research, guidelines will be published on the use of radiotherapy in patients with implanted cardiac devices. This research will increase knowledge in this field, leading to the publication of both national and international guidelines.

This research will also inform a phase 2 study specifically focusing on common clinical scenarios relating to radiotherapy treatment in patients with implanted cardiac devices.

This will allow international contemporary evidence-based guidelines on the use of radiotherapy in patients with implanted cardiac devices to be developed.

References


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