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

Lauren M. Evans

Agenda

- Background
- Case study
- Trial design
- Purpose of research
- Summary
- References
- Acknowledgements

Background

- Ageing UK 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 (radiotherapy tolerance doses) 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- Pacemaker policies in UK radiotherapy departments are based on evidence that is 16 years old on superceded pacemaker technology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:

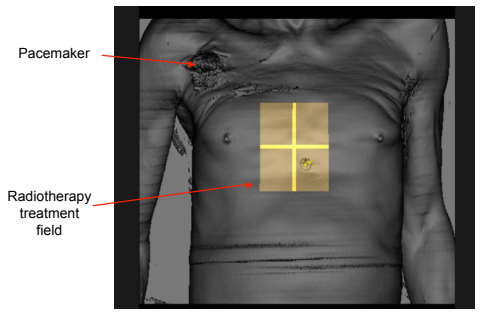
- **Pacemaker make / model** – St. Jude Medical - Zephyer – Dual Chamber
- **Pacemaker leads make / model** – Medtronic
- **Causation –** Complete heart block
- **Pacemaker dependant –** Yes
- **Position of pacemaker –** RT sub-clavicular
- **Measurement of pacemaker from RT field –** SUP corner = 6cm (measuring diagonally)

  * Pacemaker leads in RT treatment field *

- **Physics dose calculation –** Lead dose = 70% = 14Gy

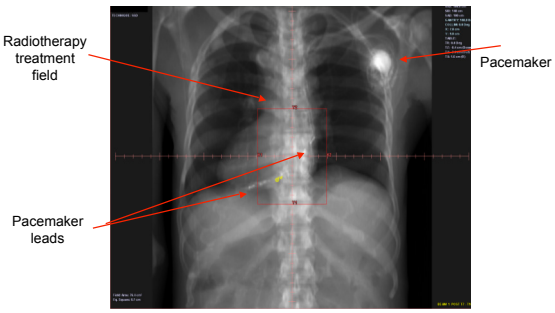
Patient 1

Skin rendering image – Radiotherapy treatment site



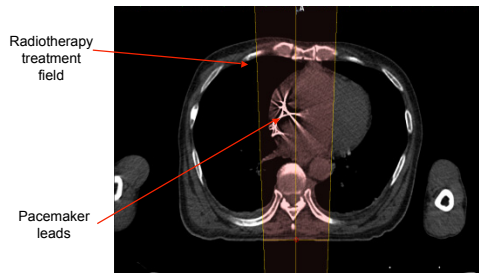
Patient 1

Radiotherapy treatment site (Gantry – 180)



Patient 1

CT Slice – Pacemaker leads in radiotherapy treatment site



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 / vomitting

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

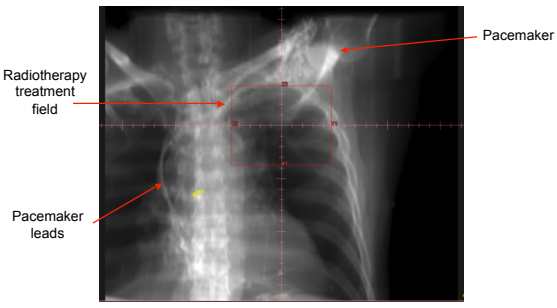
PMH – COPD, permanent cardiac device in situ, ischemic heart disease, hypertension and type 2 diabetes. WHO performance status = 2

Treatment – Palliative radiotherapy (39Gy/13#)

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

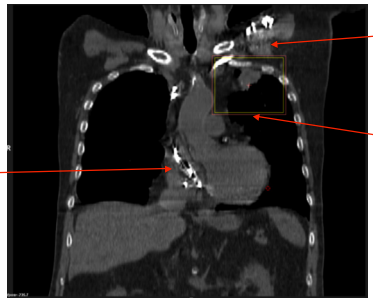
Patient 2

Radiotherapy treatment site (Gantry – 0)



Patient 2

CT Slice – Pacemaker in relation to radiotherapy treatment site



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 Design

Device Testing:

- Pacemakers irradiated total dose of 50Gy in 25 fractions
- 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)

Completion of Phase One Research

- To investigate the safe levels of radiotherapy administered to patients who have an implanted cardiac device
- To extend and develop knowledge in this field
- Publication of national guidelines, clinical protocols and radiotherapy tolerance doses
- Collaborate with the pacemaker manufacturers to modify / develop devices that will be less sensitive to ionising radiation

Summary

This research will guide a phase 2 study specifically focusing on common clinical scenarios relating to radiotherapy treatment in patients with pacemakers

This will allow international contemporary evidence-based clinical guidelines on pacemaker radiotherapy tolerance to be developed

References

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