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 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 (Marbach 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)

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**Case Study**

- **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 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

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**Agenda**

- Background
- Case study
- Trial design
- Purpose of research
- Summary
- References
- Acknowledgements
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/13f)

Radiotherapy treatment field is adjacent to the inferior edge of the pacemaker
Patient 2

CT Slice – Pacemaker in relation to radiotherapy treatment site

Pacemaker

Radiotherapy treatment field

Pacemaker leads

Trial Design

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 500 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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