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To investigate the safe levels of radiotherapy administered to patients who have an implanted cardiac device.

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Summary

With an ageing UK population, the number of patients with cardiac pacemakers presenting for radiotherapy treatment is increasing. Research has shown that in clinical practice there are a variety of different pacemakers in use. Over the past three decades manufacturers have increasingly used a variety of pacemaker components which are subsequently more sensitive to ionising radiation. Therefore, this project aim is to investigate the safe levels of radiotherapy administered to patients who have an implanted cardiac device. While it is accepted that pacemaker manufacturers publish their own guidelines regarding radiotherapy tolerance doses to their cardiac devices, research has also shown that there are no national guidelines and most radiotherapy departments have no formal risk management strategy in place or a cardiac pacemaker policy. The policies that are in place are based on manufacturers’ guidelines and anecdotal experience from the United States of America and were published in 1994. Due to this there is a clinical need for research based in the United Kingdom to determine the behaviour of a given cardiac device when it is in or close to the radiotherapy treatment field.

Description of the project:
Background and Objectives of study

Introduction to study:

With an ageing UK population, the number of patients with cardiac pacemakers presenting for radiotherapy treatment is increasing. Life expectancy of the population has increased by more than 65% in England and Wales over the past century (Office of National Statistics, 2004). One consequence of this increase in longevity is the increase in prevalence of cardiovascular morbidity (Kalache and Keller, 2000). This in turn is leading to an increase in the number of patients with cardiac pacemakers (Last, 1998). The age-standardised incidence of cancer has increased by more than 25% in the past 30 years (Office of National Statistics, 2004). It has been estimated that 50–60% of all patients with cancer will require radiotherapy at some point during the course of their illness (The Royal College of Radiologists, 1998).

Purpose of Research:

Research shows that in clinical practice there are a variety of different pacemakers in use, for example implantable internal pacemakers and implantable cardioverter defibrillators (Marbach et al, 1994). Implantable internal pacemakers, such as bipolar pacemakers, are permanent cardiac devices and they vary in sophistication. Implantable cardioverter defibrillators (ICDs) are more sophisticated devices and they have the ability to automatically defibrillate the heart, by constantly monitoring the heart rate and delivering appropriate electrical therapy. Pacemakers are usually placed in a subcutaneous pocket over the pectoral muscles in the left infraclavicular region. The pacemaker leads that lie in contact with cardiac musculature, deliver electrical impulses to the heart and carry the signals back to the pacemaker generator (Fischer and Ritter, 1998).

Research has shown that over the past three decades manufacturers have increasingly used complementary metal-oxide semi-conductors (CMOS) circuits in their pacemakers, which can be more sensitive to ionising radiation than the bipolar semiconductor devices used previously (Little, 1996). However, this increased sensitivity can lead to damage to both the hardware and software components of the pacemaker (Last, 1998). Mouton et al. (2002) state that such damage could be transient, for example dropped beats, transient inhibition, altered sensitivity, increased or decreased pulse width and frequency or triggering of pacemakers. Nevertheless, consequences could be serious and permanent. For instance, severe circulatory damage could potentially lead to a major catastrophic failure of the cardiac conduction system and ultimately death of the patient (Little, 1996).

It is not possible to predict the exact behaviour of any given pacemaker when it is in, or in close proximity to the radiotherapy treatment field (Solan et al, 2004). The American Association of Physicists in Medicine report by Marbach et al in 1994 recommend that the maximum dose to the pacemaker should be limited to less than 2 Gy. Subsequent retrospective data has resulted in further recommendations being issued by Mouton et al in 2002. In their in vitro study, ninety six patients having thoracic radiotherapy whose pacemakers were adjacent to the radiotherapy treatment field exhibited a range of short and long term side effects. Their results showed that one of the irradiated pacemakers exhibited clinically significant disturbances at a cumulative dose of only 0.15 Gy, two pacemakers exhibited defects at a dose of 1 Gy and nine pacemakers failed at a cumulative dose of 2 Gy. Therefore there is a significant risk when irradiating patients with cardiac pacemakers (Mouton et al, 2002). While it is accepted that pacemaker manufacturers publish their own guidelines regarding radiotherapy tolerance doses to the pacemaker, research has also shown that there are no national guidelines and most radiotherapy departments have no formal risk management strategy in place or a cardiac pacemaker policy (Solan et al, 2004). The policies
11. References:


