CIED DOSE ESTIMATES FOR RADIOTHERAPY PATIENT MANAGEMENT

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Introduction

The efficacy of radiation therapy in the treatment of cancer is beyond question. It is important to reduce the risk of harm to these patients by attempting to minimize radiation dose outside the intended treatment volume. When a cancer patient is first referred for radiation therapy much time is spent planning the radiation therapy course to decrease the risk of potential complications that may result from the therapy. A common issue, with many older patients, arises when a patient has a CIED, for example a pacemaker (PM) or an Implantable Cardioverter Defibrillator (ICD), that might be exposed to potential damaging amounts of radiation during therapy. Research has shown that CIEDs malfunction or even fail when exposed to high enough doses of radiation[2][5]. Patients encounter risks to their health when CIEDs malfunction, yet minimal work has been done to design a detailed system to manage patients with CIEDs based on their treatment.

Creating a better risk management system using dose estimates may lower the risk of complications during therapy and optimize time during treatment planning. Treatment plans can vary significantly from one patient to another, so a preliminary risk analysis utilizing previous research may better streamline individualized treatment plans. Furthermore, oncologists can better recognize patients' risks and develop alternative plans that might mitigate any potential damage.

Technology

CIEDs have evolved since radiation treatments were first utilized. Originally, CIEDs relied on TTL (Transistor-Transistor Logic) technology to function until CMOS (Complementary Metal-

Oxide Semiconductor) technology replaced it in the early 1990's due to its lower power consumption[7]. Unfortunately, CMOS technology is more radiosensitive, thus increasing the likelihood of CIED malfunction due to radiation. Estimated at 100-1000 Gy – an order of magnitude lower than the bipolar transistors – CIEDs have a significantly larger malfunction zone.[2] This rating only estimates the tolerance of the material and not its functionality with other components in the circuitry. Factoring in the sensitivity of the circuitry decreases the overall radiosensitivity of the device. In one study[3], a device was rated at a tolerance of 100 Gy but noticeable malfunctions occurred at 10-20 Gy and even as low as 2 Gy.[5]

CIEDs: PMs and ICDs

Several differences exist between PMs and ICDs – primarily function and design – but the main concern of this work is the difference in their resistance to radiation. Several recent studies have attempted to discover a radiation threshold for these devices but scattered results have led to no conclusions. Even CIED manufacturers have been unable to reach a universal criteria for their devices. One such manufacturer, Guidant, claims that a 2 Gy threshold should be applied to their products[9], however, Medtronic, another CIED manufacturer, claims a tolerance above 5 Gy for PMs and between 1-5 Gy for ICDs.[2] **Table 1** shows several dose studies performed and their results. The scattered results of CIED dose thresholds have left medical physicists uncertain of what doses will cause devices to malfunction in their treatment plans.

Malfunctions

A CIED is constituted as malfunctioning upon its inability to regulate or maintain a patient's cardiac rhythm. CIEDs can incur malfunctions from two types of interference: transient and permanent.

Transient interference causes temporary malfunctions that are reversible upon removal of the interfering source. Such interference can be caused by electromagnetic noise in the heart lead signal and dynamic magnetic fields interfering with the magnetic relays.[5] Permanent interference leads to significant damages that may render devices useless. Such damage can be induced from EM waves reprogramming the CIED or ionizing radiation damaging electrical components. Such issues permanently damage the CIED and require its replacement.[10]

Sources of EM noise can be from motors and transformers in the linear accelerator or the magnetron/klystron.[5] However, EM fields near linear accelerators are weak and no studies show significant effects on CIEDs .[1]

Dose Rate

Few studies have been performed to explore the effects of dose rate on CIED functionality. The only published study found[6] shows that dose rate effects weren't noticed below 0.2 Gy/min and only two devices have shown malfunction below 1 Gy/min. It has been concluded that the dose rate threshold should be held at 0.2 Gy/min, which is rarely exceeded at the site of the CIED during therapy.[2] Therefore, dose rates are of minor concern in affecting CIED function in radiotherapy.

Classification

Currently, risk of device failure for patients must be determined individually during treatment planning by utilizing the treatment planning system (TPS) to approximate the dose to the CIED. However, TPSs utilize algorithms that poorly estimate peripheral doses[8], which is where CIEDs are typically located. Due to TPS's poor estimation ability, experimental values for CIED dose are preferred. This process has rendered itself cumbersome, so establishing precise CIED doses before treatment planning would aid in classifying the patient's risk.

AAPM TG 34 states CIED dose thresholds of 2 Gy, which has been used as the primary guideline in a patient's risk analysis.[5] Using this value, a risk management system for patients has been established.

Patients are labeled as low, medium, or high risk depending upon the expected cumulative dose the CEID receives. They are further categorized based on their dependency on the device. Patients that risk becoming symptomatic upon CIED malfunction are labeled as 'pacing-dependent,' whereas all other patients are labeled as 'pacing-independent.' **Figure 1** shows a typical classification of patients used by clinics.

Low CIED doses (<2 Gy) and pacing independency label a patient as low risk. General measures will be taken so as to ensure patients' safety. Visual observation of the patient is mandatory during treatment and personnel should be prepared for emergency intervention if needed.[2] In addition, routine testing of the devices weekly during the radiation therapy course by a cardiology device technologist is essential.

Medium risk patients have their CIEDs receive doses around 2-10 Gy while being pacing-independent or under 2 Gy while being pacing-dependent. Precautionary measures are required for medium risk patients since there is a greater chance of the CIED malfunctioning. During each fraction of the treatment, necessary equipment must be present to resuscitate the patient immediately if malfunction occurs. This includes an ECG-monitor to monitor the patient's heart as well as a defibrillator for resusicitation.[2] Trained personnel must be present at all times and be prepared to intervene during treatment if necessary. Weekly checks by a technician are also necessary to ensure maintained CIED operation.[2]

High risk patients receive CIED doses over 10 Gy.[2] In cases of high risk to the patient, the first measure should be an attempt to alter the treatment plan or temporarily relocate the device. If these actions are not possible and patients choose to move forward with treatment, measures taken with medium risk patients should be replicated. Immediate monitoring of the patient's CIED should occur for 24 hours after each treatment.

Methods

Eleven different external beam treatment plans from previously treated patients were selected as samples at Indiana University Health Ball Memorial Hospital. All treatments utilized external photon beams as treatment and varied in beam energy, modulation, and treatment site. A anthropomorphic radiation therapy phantom (**Figure 2**) – a simulated human torso with synthetic tissue and bone equivalent material – was used to simulate a patient in each treatment, and a thermoluminescent dosimetry (TLD) was used to collect all dose data (**Figure**

3). The TLDs used were dosimeters purchased from Mirion Technologies that include both photon and neutron sensitivity.

CIEDs are placed above the left pectoral muscle and under the skin—this was simulated with the TLDs (in place of a CIED) by taping each on the phantom with a 1 cm think skin-equivalent bolus on top. An outline was marked on the phantom's exterior in order to reposition the new TLD holder after each treatment. Each TLD measured the dose of one fraction of a patient's treatment. This was repeated ten times for each treatment plan to increase statistical significance.

To quantify the intrinsic source of error of the TLDs, a set was irradiated an equivalent distance from the primary beam. This was done by taping the TLDs to a bucket phantom and placing a High Dose Rate IR-192 (HDR) source at the center (**Figure 4**).

Results

A majority of the treatment plans produced minimal dose to the CIED site. Nine out of the eleven treatment plans had the CIED receiving a dose of less than 3 cGy per treatment. Since cumulative dose to the CIED is of the most concern, an average cumulative dose was estimated to compare against the 2 Gy threshold. **Table 2** shows the treatment sites along with dose per fraction, number of fractions, and cumulative dose. The head and neck VMAT treatment plan resulted in the CIED receiving the greatest cumulative dose – beyond the recommended 2 Gy threshold – of 329 cGy. The next highest dose received was 158 cGy in the Spine 3D treatment – just under the recommended dose threshold.

All other treatments resulted in cumulative CIED doses under 40 cGy – significantly lower than the 2 Gy ceiling.

Conclusion and Analysis

In all cases, the CIED was located at the periphery of the primary beam. Peripheral doses are significantly smaller than the dose incurred in the treatment area since most of the dose received by a CIED is leakage radiation, collimator head scatter, and internal scatter.[8] Cases where any device is included inside the treatment area requires the temporary removal of the device to prevent its malfunction and attenuation of the dose to the tumor.

Although most of the CIED doses are significantly smaller than 2 Gy, this does not eliminate the risk of CIED malfunction. One case study in the literature[4] has shown malfunctions occurring at doses as little as 0.15 Gy. As can be seen from all the studies in Table 1, electronic devices may be temperamental in their radiosensitivity. Patients with devices whom encounter low level doses are still considered at risk albeit low risk and need to be monitored accordingly.

Assuming a patient is pacing independent, most of these treatments would classify the patient as low risk. Only in cases where the patient is pacing dependent is it necessary to have monitoring and resuscitation equipment nearby. In the case where the treatment area is in the spine or head-neck area, more stringent precautions should be taken and the protocol for medium risk patients should be followed or the treatment reconsidered.

Error in the data was determined by using a two-tail 95% confidence interval with the data collected. Each treatment plan was performed ten times to optimize the data. Limits were built after defining the mean and standard deviation for each treatment set as follows:

$$Lower\ Limit = \ \bar{x} - t_{.95}\frac{s}{\sqrt{N}}$$

$$Upper\ Limit = \bar{x} + t_{.95}\frac{s}{\sqrt{N}}$$

Where $\bar{x}$ is the sample mean, $t_{.95}$ is the t-score associated with a 95% confidence interval, s is the sample standard deviation, and N is the number of trials. Since there were ten trials performed, a t-score associated with 9 degrees of freedom was used:

$$t_{.95}(d.o.f. = 9) = 1.833$$

The error bars in **Figure 5** show the confidence intervals for one fraction of each treatment site.

Systematic error can be observed by the last trial set performed in the data. Ten TLDs were placed equidistant using a cylindrical bucket phantom from the primary beam delivering a dose of about .400 cGy. An error (standard deviation) of about .03 cGy was observed on the TLDs, providing little issue in our observations.

In treatments that involve a higher energy beam of 18 MV, a small portion of the dose delivered is contributed by neutrons. Treatments that have partial neutron doses are marked with an asterisk in **Table 2**. It was questioned whether to incorporate the neutron dose directly or by equivalent dose. Since all of the literature describes CIED dose thresholds in units of Gray, it was decided to avoid mixing Sieverts with Grays and directly incorporate the neutron dose

into the calculations. Further study could be performed to provide better insight to neutron dose's effects on CIEDs.

Although a 2 Gy threshold has been provisionally established by manufacturers and the AAPM, it is far from a conclusive measurement. Each patient's treatment requires risk analysis that should not be rushed by the physician or the medical physicist. Treatment plans vary greatly due to individual anatomy variation, fractionation and dose per fraction, which greatly impact the dose a CIED would receive. These measurements offer only estimates of radiation exposure and possible risks. Therefore, results should not be seen as conclusive or exhaustive but as a starting point in risk determination.

The primary goal of this work is to show dose approximations of various treatments to patients' CIEDs to assist in patient management. Treatments to common areas were performed and the dose received on the periphery of the primary beam was measured and analyzed. By following the AAPM's recommended 2 Gy threshold for CIED dose, a basis for patients' risk categorization and proper management was formed. Data can provide quick estimations for medical physicists who encounter patients with CIEDs, which can assist in their treatment planning.

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