An Institutional Experience Managing the Care of Patients with CIEDs

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Outlines

- Discuss functionality and components of pacemakers (ICPs) and defibrillators (ICDs)
- Review potential effects of ionizing radiation on CIEDS
- Review published recommendations
- Discuss University of Michigan study
  - Management of CIED patients from simulation to treatment

JIP 2

Motivation

- Average life expectancy of Americans has increased from 70.1 (1960 – 65) to 78.1 years (2000 – 05).
- Number of CIED patients presenting for RT has steadily increased.
- Current guidelines are conservative and at times conflicting
  - Some vendors recommend no radiation to CIED

JIP 3

Arrhythmia

- Disorder of heart rate or rhythm.
  - Bradycardia (too slowly, < 60 beats per min)
  - Tachycardia (too quickly)
  - Fibrillation (irregular pattern)
- If the arrhythmia is serious or of concern, either an implantable cardiac pacemaker (ICP) or defibrillator (ICD) may be implanted.

http://www.nlm.nih.gov/medlineplus/pacemakersandimplantabledefibrillators.html

JIP 4

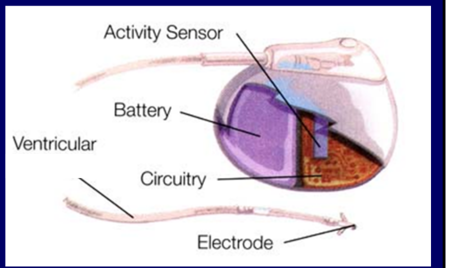
Purpose of ICP

- Sensing – monitors heart rhythms
- Recording
- Therapy
  - Sends electrical signal to the heart to correct for slow (below threshold) or interrupted heart beat - undetectable by patient
  - Coordinates the chambers of the heart

http://www.jointhepacemakers.com/what-is-a-pacemaker/index.htm#.UtEw7vsnokY

ICP Components

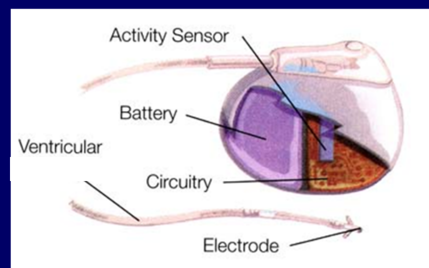
- Battery
  - Powers the generator
- Pulse generator
  - Microprocessor and circuitry - sensing, data capture, storage and control of therapy delivery



http://www.brighamandwomens.org/departments_and_services/medicine/services/cvcenter/patient/pacemaker.aspx
G.H. van Welsenes *et al.*, Neth Heart J, 19 (1), 24 – 30 (2011).

ICP Components

- Leads/electrodes
  - Detects heart's electrical activity and in some cases patient's vitals.
  - Transmits electrical impulses to stimulate heart to beat.



http://www.brighamandwomens.org/departments_and_services/medicine/services/cvcenter/patient/pacemaker.aspx

JIP 7

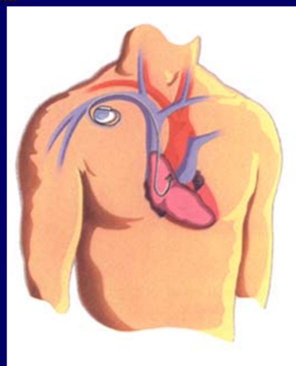
Types of ICPs

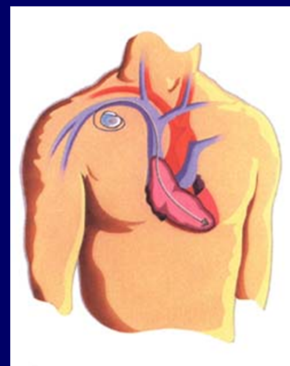
- Single chamber pacemakers
- Dual chamber pacemakers
- Biventricular pacemakers

http://www.med.umich.edu/lrc/coursepages/m1/anatomy2010/html/clinicalcases/pacemaker/pacemaker.html

JIP 8

Single Chamber ICP





Right atrium - Sinus node (natural pacemaker) is not working adequately, but rest of heart functioning normally.

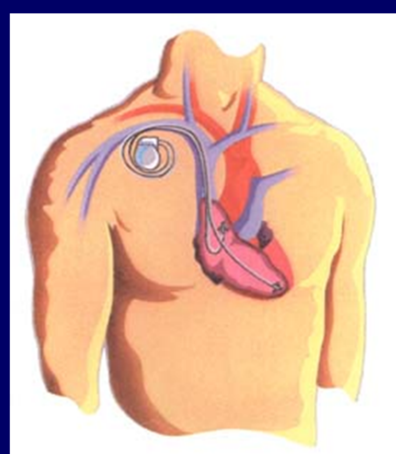
Right ventricle – when the normal impulses from the atria cannot reach the ventricle.

http://www.brighamandwomens.org/departments_and_services/medicine/services/cvcenter/patient/pacemaker.aspx

JIP 9

Dual Chamber ICP

- **One lead is in the right atrium and the other in the right ventricle.**
- **Coordinates atrial and ventricular contraction, by sequentially pacing atria then ventricle to maximize the heart's pumping ability.**
- **Most commonly used pacemakers.**

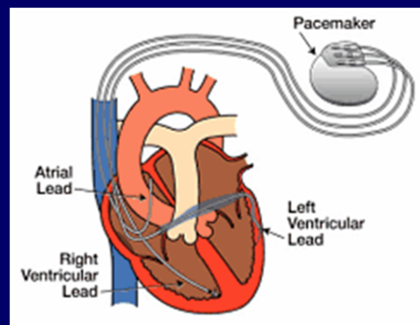


http://www.brighamandwomens.org/departments_and_services/medicine/services/cvcenter/patient/pacemaker.aspx

JIP 10

Biventricular ICP

- Leads are placed in the right and left ventricles, and typically a third lead is added to the right atrium.
- The addition of the lead in the left ventricle works to contract the left and right ventricle simultaneously.



http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm081143.htm

JIP 11

Purpose of ICD

- Sensing – monitors heart rhythms
- Recording
- Therapy
  - Sends electrical signal to the heart to correct for slow (below threshold) or interrupted heart beat
  - Can deliver a high energy pulse to correct dangerous arrhythmias (defibrillation)

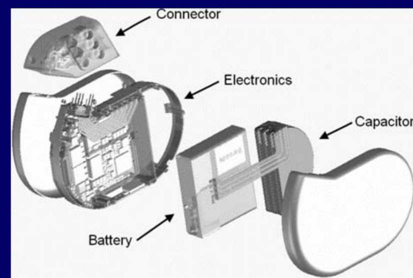
Modern ICDs provide same functionality as ICP plus…

http://www.nlm.nih.gov/medlineplus/pacemakersandimplantabledefibrillators.html

JIP 12

Components of ICD

- Battery
- Pulse generator
  - Microprocessor and integrated circuits
  - Capacitor - store and deliver charges
- Leads used for sensing, pacing and defibrillation



van Welsenes *et al.*, Neth Heart J, 19 (1), 24 – 30 (2011).

JIP 13

Types of ICDs

- Similar to pacemakers, ICDs are available as:
  - Single chamber – lead placed in right ventricle
  - Dual chamber – leads are placed in the right atrium and right ventricle
  - Biventricular – leads are placed in the right and left ventricles, and often a third is placed in the right atrium

http://www.webmd.com/heart-disease/guide/abnormal-rhythms-icd

JIP 14

Traditional Management of ICP Patients

- Based on AAPM Task Group 34 (1994)
- Relevant recommendations:
  - ICP should not be irradiated with primary radiation
  - Dose to the ICP should be estimated prior to RT
  - If total dose to the ICP is expected to be > 2 Gy, ICP should be interrogated prior to RT and weekly during treatment

Marbach *et al.*, Medical Physics, 21(1), 85-90 (1994).

JIP 15

Limitations of TG 34

- Based on older device technology → obsolete
- Guidelines only address pacemakers, not defibrillators
- Delivery equipment and techniques have changes considerably – 20 year old report
  - Introduction of MLCs and dynamic wedges
  - Introduction of IMRT and SBRT

Marbach *et al.*, Medical Physics, 21(1), 85-90 (1994).

JIP 16

What about Vendor Recommendations?

Vendor	Device	Dose Limit (Gy)
Biotronik	ICD	No safe dose
	ICP	< 10 Gy
Boston Scientific	ICD/ICP	No safe dose
Medtronik	ICD	1 – 5 Gy (based on model)
	ICP	5 Gy
St. Jude	ICD/ICP	No safe dose (but tested to 30 Gy, few errors observed at 20 Gy)

Based on company literature on radiation tolerance of their CIEDs.

JIP 17

Effects of Ionizing Radiation on CIEDs

- **Modern CIED circuits use complementary metal oxide semiconductors (CMOS)**
- **Pro - CMOS circuits have led to smaller, more energy efficient and reliable CIEDs**
- **Con - CMOS is known to be susceptible to ionizing and electromagnetic radiation, which may result in transient or permanent device defects**

JIP 18

Effects of Ionizing Radiation on CIEDs

- Ionizing radiation creates excess electron hole pairs in the SiO_2 layer (insulator) of the CMOS
- Holes trapped in valence band form aberrant electrical pathways in the insulator
- May result in minor or significant malfunctions

JIP 19

In Vitro Studies - Effects of Ionizing Radiation on CIEDs

JIP 20

Influence of High E Photon on ICPs

- 96 explanted ICPs (varying ages) were studied
- Devices irradiated in direct beam with 18MV photons
- Devices were irradiated with varying dose rates up to a total dose of 200 Gy or point of failure

Mouton *et al.*, Physics in Medicine and Biology, 47, 2879-93 (2002).

JIP 21

Issues Due to Irradiation

1. Missing pulse at start of irradiation
2. Amplitude modification of pacing pulse ≤ 10 %
3. Slowed down rate
4. Accelerated rate
5. Signal deformation
6. Amplitude changes > 10%
7. Silences > 10 s
8. Permanent silences

Most common event, 66%

Mouton *et al.*, Physics in Medicine and Biology, 47, 2879-93 (2002).

JIP 22

Influence of RT on Modern ICPs

- 19 new ICPs from 4 different manufacturers were studied
- Irradiated with 6X, primary beam
- Irradiated to 120 Gy or point-of-failure

Hurkmans *et al.*, Radiotherapy Oncology, 76, 93-98 (2005).

JIP 23

Issues due to Irradiation

- Change in the amplitude or duration of the pacing pulse, or loss of signal
- Inhibition of pacing frequency – during irradiation
- Change in sensing thresholds
- Temporary or permanent loss of telemetry
- Battery problems
- Change in lead impedance

Most common event

Hurkmans *et al.*, Radiotherapy Oncology, 76, 93-98 (2005).

JIP 24

Influence of RT on ICDs

- 11 ICDs were irradiated with 6MV photons, 4 different models and/or manufacturers
- 3 irradiation scenarios: direct beam, 5 cm outside field, and lead(s) in field
- A total of 20 Gy was delivered in a fractionated manner

Uiterwaal *et al.*, Neth Heart J, 14(10), 330 – 334 (2006).

JIP 25

Issues due to Irradiation

- Pacing interference and/or rapid ventricular pacing was noted when the ICD was in direct beam
  - Interference was not observed when the ICD was outside of the beam aperature
  - No correlation was identified between cumulative dose and interference events

Uiterwaal *et al.*, Neth Heart J, 14(10), 330 – 334 (2006).

JIP 26

What about Neutrons?

- Raitt *et al.*, Chest, 106 (3), 955-7 (1994).
  - Case study: "Runaway pacemaker occurred in a patient undergoing high-energy neutron radiation therapy despite adherence to published safety guidelines."
- Wilkinson *et al.*, IEEE, 5(3), 449 – 51 (2005).
  - Secondary neutrons from linacs were demonstrated to cause "soft errors" in nearby electronics. → Transient changes in memory/logic of device

JIP 27

What about Neutrons?

- Gelblum *et al.*, Int J Rad Onc Biol Phys, 73(5), 1525-31 (2009).
  - One patient (of 33) experienced a default of their device to its initial factory setting.
  - This patient had initially been treated with a 15 MV beam.
- Trigano *et al.*, J Inter Card Electrophysiol, 33(1), 19-25 (2012).
  - 14 devices from 4 manufacturers tested (in vitro). In six cases, an electrical reset was observed at time of interrogation.
  - Electrical reset present after exposure to high [neutron] fluence.

JIP 28

Potential CIED Errors (Heart Rhythm Society)

- Oversensing – inappropriate inhibition of

Most frequently observed with EMI interactions

- Effects influencing rate response algorithm
- Resets – Device returned to initial

Rare but more commonly caused by therapeutic irradiation

- Pulse generator damage or permanent failure
- Damage of the lead tissue interface

Crossley *et al*., HRS, 8(7), 1114 – 54 (2011).

JIP 29

Potential Risk Factors

- Total dose
- Distance
- Time
- Modality
- Energy
- Dose rate (inconclusive)

JIP 30

Recently Published Consensus-Based Recommendations

JIP 31

Heart Rhythm Society

- Consensus statement on perioperative management of patients with CIEDs
  - Included recommendations on diagnostic and therapeutic radiation
- Members – Cardiologists, Anesthesiologists, and Thoracic Surgeons

Crossley *et al.*, HRS, 8(7), 1114 – 54 (2011).

JIP 32

Heart Rhythm Society

- Diagnostic radiation
  - No significant adverse effects on CIEDs
  - Transient oversensing events have been reported
- Therapeutic radiation
  - Avoid direct irradiation of CIED
  - Total dose to device < 5 Gy
  - Reset have been observed due to secondary neutron exposure

Crossley *et al*., HRS, 8(7), 1114 – 54 (2011).

JIP 33

Dutch Society of Radiotherapy and Oncology (2012)

- Management of radiation oncology patients with CIEDs
- Members – Cardiologists, Device Technologists, RO physicians, RO physicists

Hurkmans *et al.*, Radiation Oncology, 7, 198-215 (2012).

JIP 34

Dutch Society of Radiotherapy and Oncology (2012)

- **Recommendations**
  - **Device should not be directly irradiated**
  - **Dose to device should be estimated pre-treatment**
  - **Dose limits:**
    - **Rather than recommending universal dose limits, patient risk categories proposed**

Hurkmans *et al.*, Radiation Oncology, 7, 198-215 (2012).

JIP 35

Dutch Society of Radiotherapy and Oncology (2012)

- **Low risk (< 2 Gy and non-dependent) – no extra measures needed**
- **Medium risk (> 2 Gy < 10 Gy and/or dependent) – emergency equipment present during each txmt, weekly CIED check by pacemaker technician. Personnel trained in resuscitation and CIED tech or cardiologist available.**

Hurkmans *et al.*, Radiation Oncology, 7, 198-215 (2012).

JIP 36

Dutch Society of Radiotherapy and Oncology (2012)

- High risk (> 10 Gy and CIED relocation not possible)
  - Does the benefit of RT outweigh the CIED related risks?
  - If yes, same precautions as medium risk + daily monitoring

Hurkmans *et al.*, Radiation Oncology, 7, 198-215 (2012).

JIP 37

- To minimize likelihood of adverse events, need to identify patients with CIED as early in the process as possible.

JIP 38

University of Michigan Study

- **In 2005, UofM's depts of Radiation Oncology (RO) and Cardiac Electrophysiology (EP) section established a formal communication process.**
- **Effectiveness of this program was assessed by retrospectively reviewing patients with CIEDs who received RT between 2005 and 2011.**

JIP 39

Workflow for Patient's with CIEDs

Initial Consult w RO

↓

Presence of CIED identified

↙ ↘

Simulation

- **Physics on set**
- **Estimate position of device relative to ROI**

EP Consultation

- **Interrogate device**
- **Establish baselines and vitals**
- **Assess dependency**

JIP 40

Assessing Position of CIED

Physical Measurement

Topogram

JIP 41

Why is this important at sim?

- Several studies have suggested a small risk of CIED oversensing during CT irradiation.
  - ICPs - inappropriate inhibition of pacing output
  - ICDs - unneeded tachycardia therapy
- Effects transient, only observed when CIED generator in direct beam.
- Potential concern for patient's scheduled for dynamic CT scan (e.g., 4DCT).

McCollough *et al.*, Radiology, 243(3), 766-74 (2007)
Yamaji *et al.*, Circulation Journal, 70, 190-97 (2006)

JIP 42

Possible Issues Related to MR Imaging

- Image distortion
- Heating at lead tip and tissue interface
- Force and torque on device
- Alteration of programming
- Asynchronous pacing
- Inhibition of pacing
- Electrical reset
- Component damage
- Death

L. Santini *et al.*, Pacing Clin Electrophysiol, 36 (3), 270 – 78 (2013).

JIP 43

MR-Conditional CIEDs

- Must be mindful of protocols and vendor specifications
  - Current devices tested at 0.5 and 1.5T

L. Santini *et al.*, Pacing Clin Electrophysiol, 36 (3), 270 – 78 (2013).

JIP 44

Simulation Checklist

- Patient evaluated or scheduled with EP to verify device dependency
- Verify presence of CIED noted in patient's record
- Estimate distance of device from ROI
  - If it might be in direct beam, contact EP
- Document device make, model and SN

JIP 45

Workflow for Patient's with CIEDs

Initial Consult w RO

Presence of CIED id'ed

Simulation

EP Consultation

Treatment Planning

JIP 46

Treatment Planning Considerations

- Establish treatment planning objectives and priorities to target and OARs (including CIED)
- Departmental Limits:
  - ICPs – 2 Gy
    - Based on TG34 (Marbach *et al.*)
  - ICDs – 1 Gy
    - Based on Solan *et al.* and limits suggested by Medtronic

Marbach *et al.*, Medical Physics, 21(1), 85-90 (1994).
Solan *et al.*, Int J of Rad Onc Biology, Physics 59 (3): 897-904 (2004).

JIP 47

Treatment Planning Considerations

- Techniques to minimize dose to the CIED:
  - Contour device – Avoidance and estimate dose
  - Avoid high E photon beams
  - Avoid physical wedges
  - Use MLC and/or segmental fields to shield device

JIP 48

Peripheral Dose

Internal Scatter + Collimator Scatter + Leakage

- < 10 cm, main contributors internal and collimator scatter, internal dominates
- 10 – 20 cm, contribution of collimator scan increases, internal still dominates
- ~ 30 cm, internal scatter and leakage equivalent
- > 30 cm leakage dominates

M. Stovall *et al.*, *TG. 36*, Medical Physics (1995); 22 (1): 63 - 82.

JIP 49

Accuracy of TPS

- Howell *et al.* investigated accuracy of peripheral dose (PD) calculations for the Eclipse AAA algorithm (v8.6).
- PD were underestimated by an average of 40%.
- Huang *et al.* performed study using Pinnacle v9.0.
- PD for IMRT plans were evaluated and were underestimated by an average of 50%.

Howell *et al.*, Phys Med Biology, 55 (23): 6999 – 7008 (2010).
Huang *et al.*, JACMP, 14 (2): 186 – 197 (2013).

JIP 50

Peripheral Dose Estimates

- TPSs are not commissioned for PD calculations. Their accuracy is known to decrease with increasing distance from the field edge.
- Most clinics estimate PD based on publications.
- Estimates dependent on beam energy, field size, and distance from field edge

JIP 51

Treatment Planning Considerations

- Techniques to minimize dose to the CIED:
  - Contour device
  - Device should not be in the path of primary beam
  - Avoid high energy (>10 MV) photon beams
  - Avoid physical wedges were avoided
  - Use MLC and/or segmental fields to help shield device

JIP 52

Planning Checklist

- Verify that only 6X photons or electrons used and physical wedges avoided
- Estimate distance from device to closest treatment field edge
- Estimate dose/fx and total dose
- Verify device dependency

JIP 53

What if we exceed these limits or cannot avoid direct irradiation?

- Consult with Electrophysiology
  - Is the patient dependent on the device?
  - What is the estimated dose to the device?
  - Should magnets be used? Should the device be turned off or put into a safety mode?
  - Should cardiac monitoring frequency be increased?
  - Should the device be relocated?

JIP 54

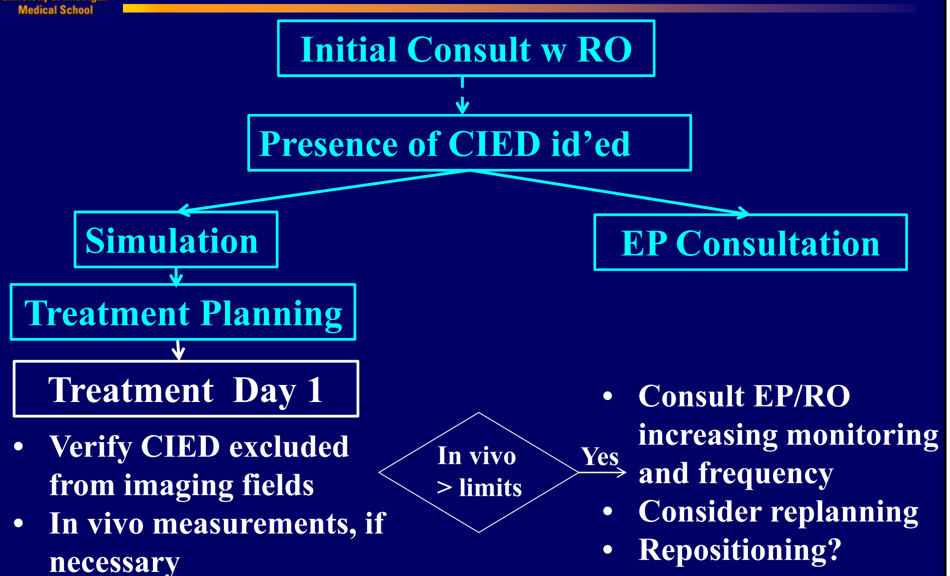
Relocating CIED

- Decision made considering all aspects of the patient's care
  - Co-morbidities
  - Risk associated with re-implantation
    - Infection (0.4 – 4.0%)
    - Pneumothorax (0.8 – 1.7%)

Hurkmans *et al.*, Radiation Oncology, 7, 198 – 208 (2012).

JIP 55

Workflow for Patient's with CIEDs



JIP 56

First Day of Treatment

- Should we perform *in vivo* measurements?
- A distance/dose criteria is used:
  - Yes
    - < 10 cm and estimated dose > 2 Gy (ICP) or > 1 Gy (ICD)
  - No
    - > 10 cm and estimated total dose < ICP and ICD departmental limits

JIP 57

In vivo Dosimeters

- Which dosimeter?
- There are inherent limitations in using *in vivo* dosimeters for PD measurements
  - *In vivo* dosimeters are calibrated in-field whereas measurements are performed out-of-field
  - Energy spectrum out-of-field differs compared to in-field due to the contributions of low energy scattered photons

JIP 58

Diodes

Advantages

- Instantaneous readout

Disadvantages

- Energy, dose rate, angular, and temperature dependence
- Requires wired connection

JIP 59

TLDs

Advantages

- Response independent of dose rate, angle of incidence, and temperature

Disadvantages

- Preparation time (with powders)
- Readout complicated and time intensive
- Fading
- Must be handled carefully to avoid surface contamination
- Thermal annealing time consuming

JIP 60

OSLDs

Advantages

- Response independent of energy(MV photons and electrons), dose rate, angle of incidence, and temperature
- Multiple readouts with minimal loss of signal
- Stable reading (~ 10 - 15 min post irradiation)

Disadvantages

- Accumulate residual signal due to deep energy traps
- Sensitive to light, must be kept in light-tight containers

Reft, Med Phy, 36 (5), 1690 – 99 (2009).
Jursinic, Med Phys, 34(12), 4594 – 4604 (2007).

JIP 61

Day 1 Checklist – Based on Limits

- Place OSLD on CIED under bolus
- Verify imaging fields do not irradiate CIED
- Estimate dose/fx and total dose to device
- Summarize findings
- If estimated dose exceeds departmental limits, notify EP

JIP 62

University of Michigan Study

- **Between 2005 and 2011, we treated 69 patients with CIEDs (50 ICPs and 19 ICDs) in Radiation Oncology**
- **CIEDs were from one of four leading CIED manufacturer (Biotronik, Boston Scientific, Medtronic, or St. Jude)**

Makkar, Prisciandaro *et al.*, Heart Rhythm, 9(12), 1964-68 (2012).

JIP 63

University of Michigan Study

Treatment Site	Number of Plans
Abdomen	8
Breast and thorax	28
Esophagus	6
Extremities	
Lower	4
Upper	6
Head and neck	33
Pelvis (prostate, bladder, gyn)	18
Spine	4

Makkar, Prisciandaro *et al.*, Heart Rhythm, 9(12), 1964-68 (2012).

JIP 64

University of Michigan Study

Treatment Technique	Number of Patients
3D conformal (including at least one wedge)	35
IMRT	13
SBRT (lung)	6
SRS	1

- **36 patients were treated with at least one high energy (16X) photon beam**
- **29 patients were treated with at least one plan in which their CIED ≤ 10 cm from the field edge**

Makkar, Prisciandaro *et al.*, Heart Rhythm, 9(12), 1964-68 (2012).

JIP 65

Results from UofM Study

- **ICPs and ICDs were exposed to doses ranging from 0.9 to 505.7 cGy and 4 to 169 cGy, respectively**
- **However, only two ICD patients experienced a partial reset of their device during their treatment**
  - **One was treated with 6X/16X plan and device was within 2.5 cm of treatment fields**
  - **Second was treated with 16X beams that were far from the ICD**

Makkar, Prisciandaro *et al.*, Heart Rhythm, 9(12), 1964-68 (2012).

JIP 66

Results from UofM Study

- We suspect partial resets were most likely due to the interaction of secondary neutrons with the ICD circuitry
- Re-planned both cases with 6X and no further events noted.

Makkar, Prisciandaro *et al.*, Heart Rhythm, 9(12), 1964-68 (2012).

JIP 67

Future Direction – TG 203

- In 2010, AAPM created a new task group to establish recommendations for the management of patients with CIED
- Multidisciplinary Team – Physicists, Electrophysiologist, and a vendor consultant (Medtronic)

JIP 68

Status of TG 203 Report

- Report is currently being finalized
- Expect to submit report to parent committee in the next few months
- Similar to the Dutch study, recommendations from report will be based on patient risk categories (5 Gy vs 10 Gy)

JIP 69

Summary

- As the average lifespan of Americans increase, the number of patients with CIEDs presenting for RT will continue to increase.
- Degree of patient monitoring should be based on factors such as CIED distance from field, dose to device, and device dependency.
- With the proper precautions and patient monitoring, patients may safely receive RT.
- Key to success is to build a focused, multi-disciplinary team.

JIP 70

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JIP 81