

Calculating Patient Specific Dose from Fluoroscopy

Benefit Risk Assessment : Identifying the At-Risk Patient

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Charles E. Chambers, MD, FSCAI, FACC, NCRP
Professor of Medicine and Radiology
Pennsylvania State University College of Medicine
Director, Cardiac Catheterization Laboratories
Hershey Medical Center, Hershey, PA

Introduction

- **Mortality has steadily decreased for CV disease.** Fluoroscopic imaging has contributed specifically in the areas of acute myocardial infarction, sudden cardiac arrest, and heart failure.
- As technique and equipment advance, **“untreatable” pt is treated.** Complex anatomy, elderly, critically ill, morbid obesity, and repeat procedures are more the norm than the exception.
- The **high risk patient** for a catheter based intervention is similarly the **high risk patient for radiation injury.**
- **Regular interactions between physicist and physician/staff are required.**



Heart Disease and Stroke,

2011 American Heart Association Update

In 2007, 2,200 Pts DIED Daily From CVD

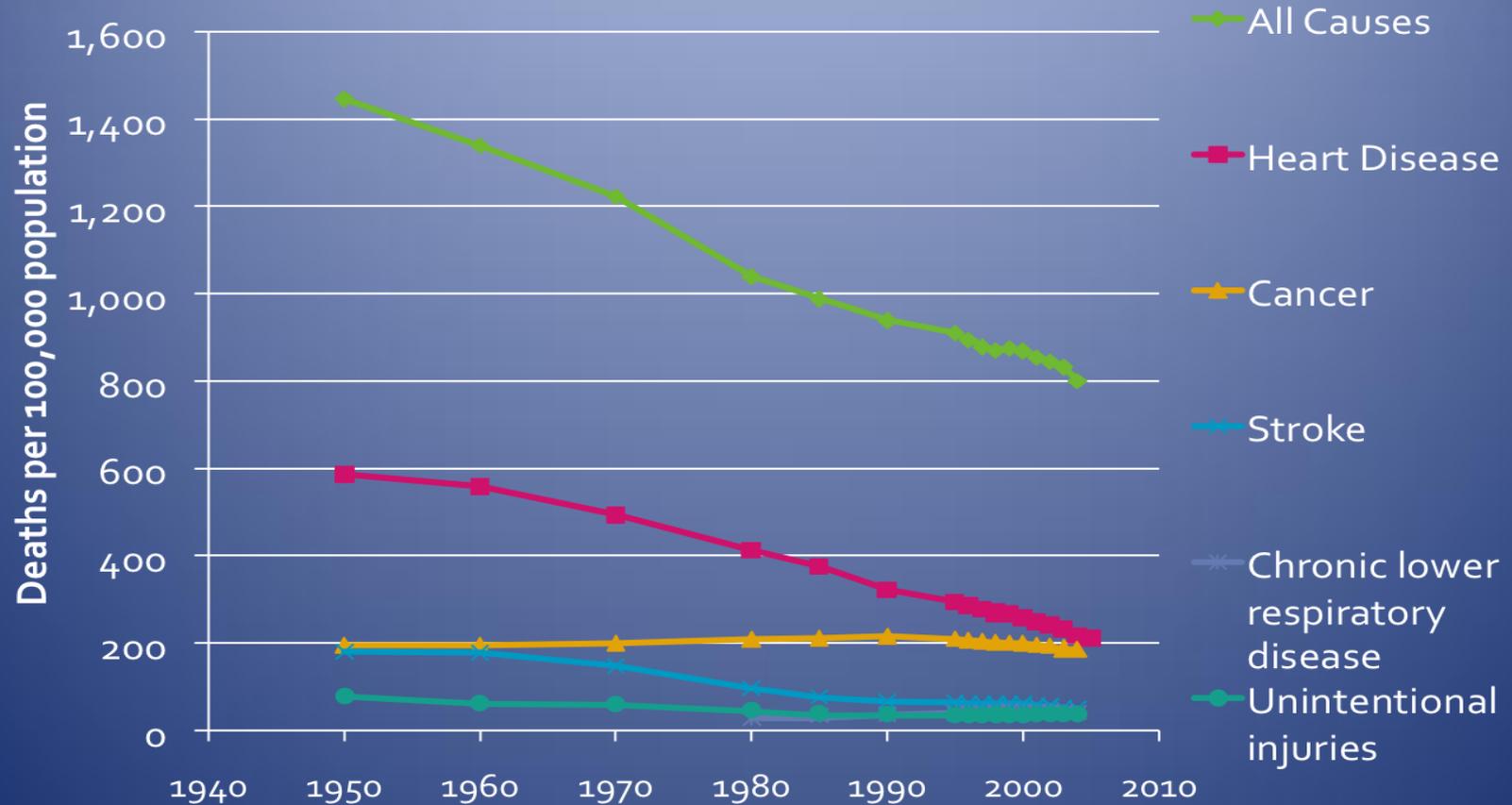
- 1/39 sec; 150,000 <65 yo in 2007
- 785,000 MI's; 470,000 recurrent
- MI every 25 sec; 1 death/min
- (1/6 deaths from CAD)

Risk Factor **NON** Modification

- HTN: 33% > age 20, (76,400,000)
- SMOKE: 23% men, 18% women,
19 % high school students
- LIPIDS: 15% >age 20, have a total
chol of > 240, (33,600,600)
- DIABETES: 8% (18,300,000), 36% pre-DM
- OBESE: 33% of Americans, (BMI>30)

The Benefits from Improving CV Care

Decreasing cardiac death rate

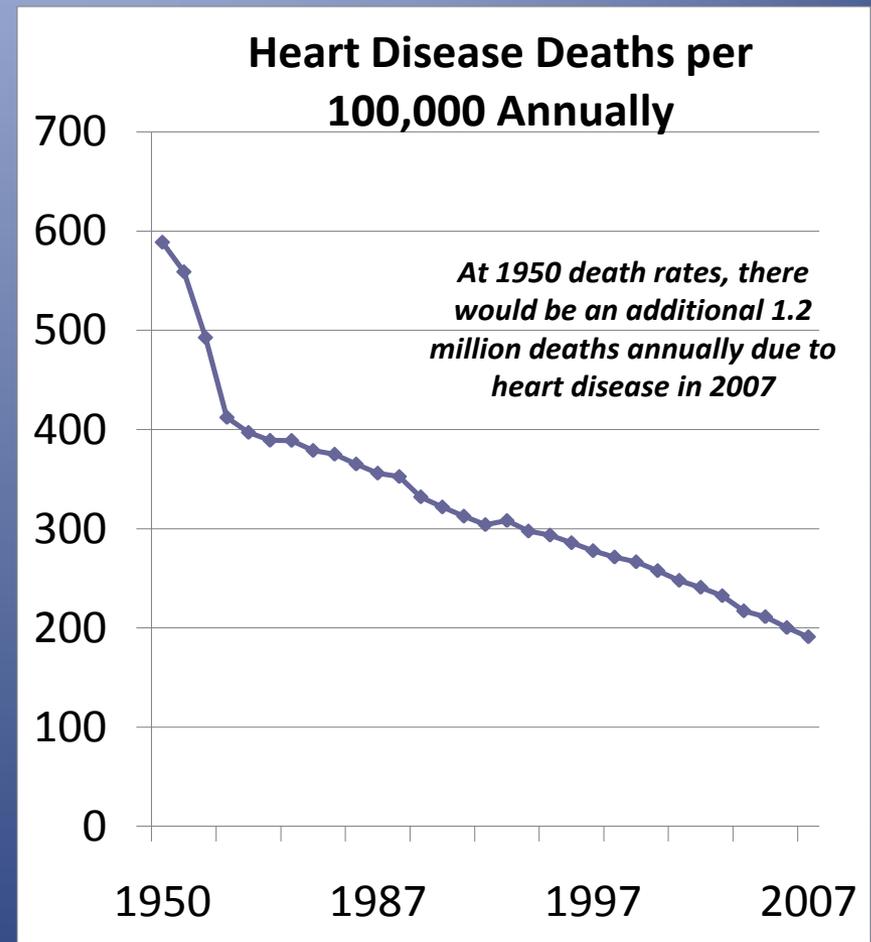


Sources: Thomas GS et al. Am Heart Hosp J. 2010;8(1):44-46 & Health, United States, 2007 . Pg. 55 <http://www.cdc.gov/nchs/data/hus/hus07.pdf>

Advances in Cardiovascular Disease Diagnosis and Therapy

CV Mortality Correction: 1950 to 2007

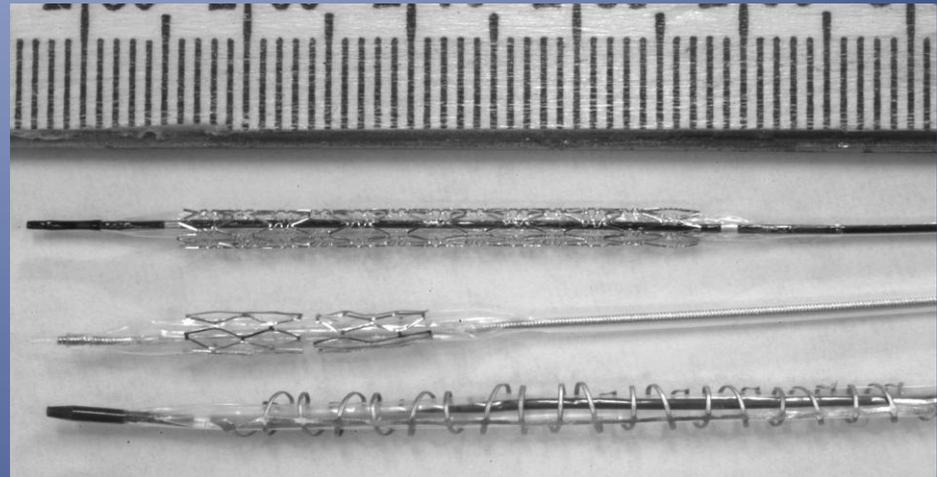
- There has been a dramatic reduction in CV disease death rates over the past 57 years
- 586 CV deaths per 100,000 in 1950
- 188 CV deaths per 100,000 in 2007
- **Considering the current US population of 300 million, 1.2 million fewer CV deaths/yr than if it were 1950**
- The number of lives saved annually is greater than all American deaths in all our wars combined



The Benefits in CV Care ...

Effective Uses of Radiation in Cardiovascular Disease

- Diagnostic Imaging
 - Identification of Disease
 - Risk Stratification
- Therapeutic
 - Atherosclerotic CVD
 - Structural Heart Disease
 - PVD/Carotid
 - Sudden Cardiac Arrest/CHF/Ablation



Acute MI Therapy- Primary PCI

- **Primary PCI for Acute MI**

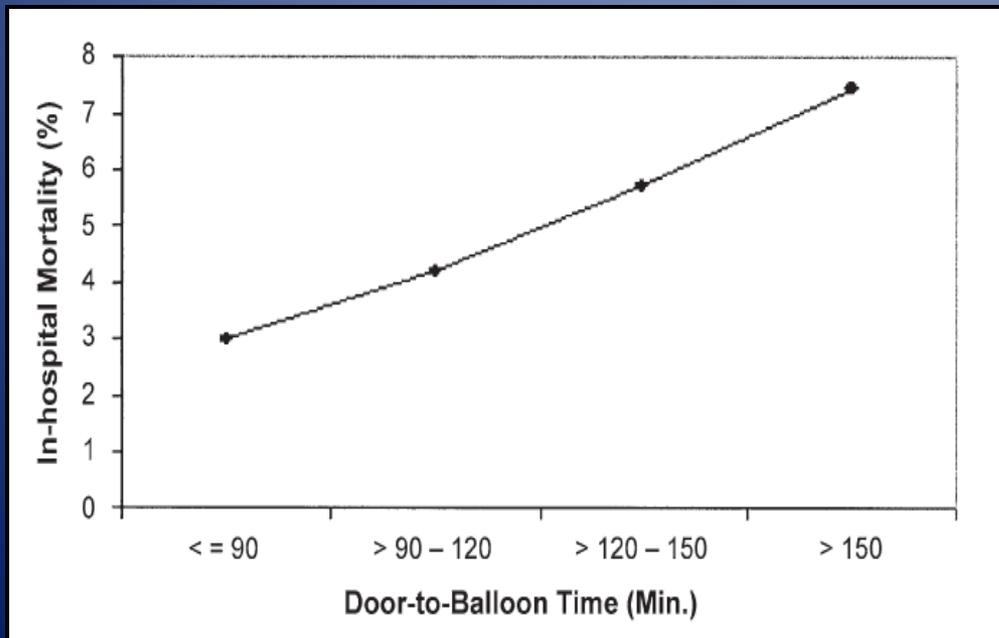
- Improved prognosis over thrombolytic therapy
- Salvage post “lytics”
- Cardiogenic shock

Incidence of Myocardial Infarction (2007)
-785,000 MI's; 470,000 recurrent
-MI every 25 sec; 1 death/min

- **Class I Recommendation**

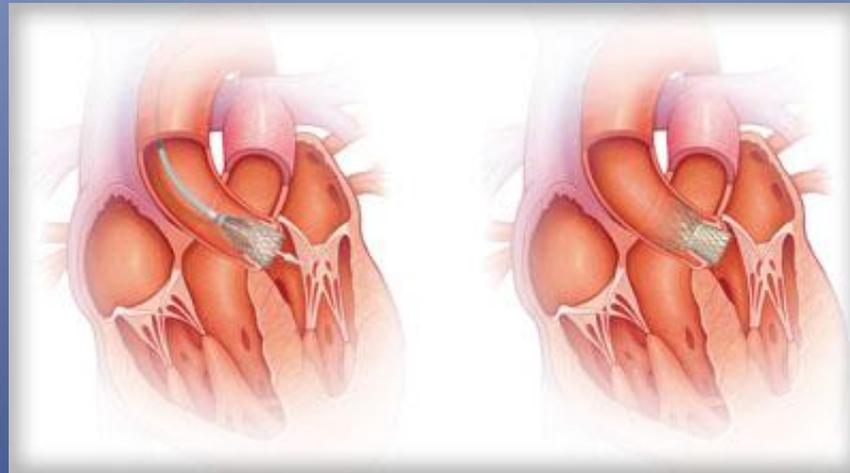
STEMI patients presenting to a facility with interventional capabilities should undergo primary PCI within 90 minutes .

(Level of Evidence: A)



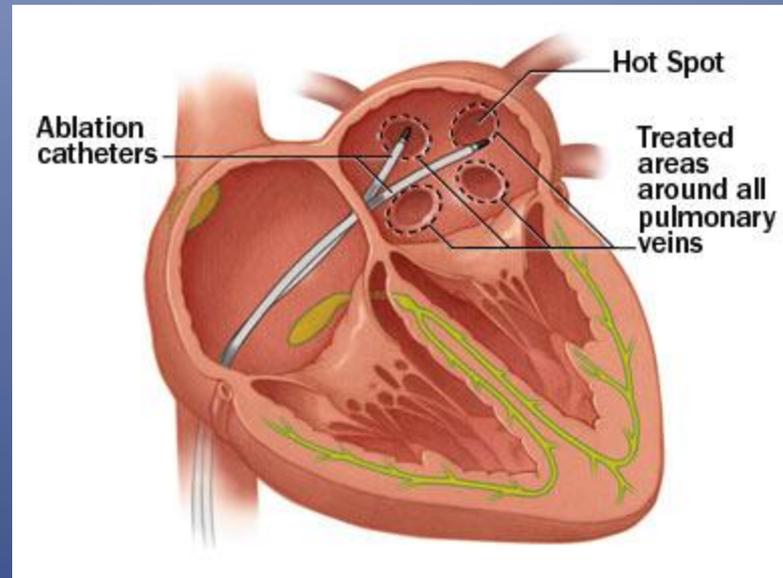
Structural Heart Disease

Percutaneous Valve replacement



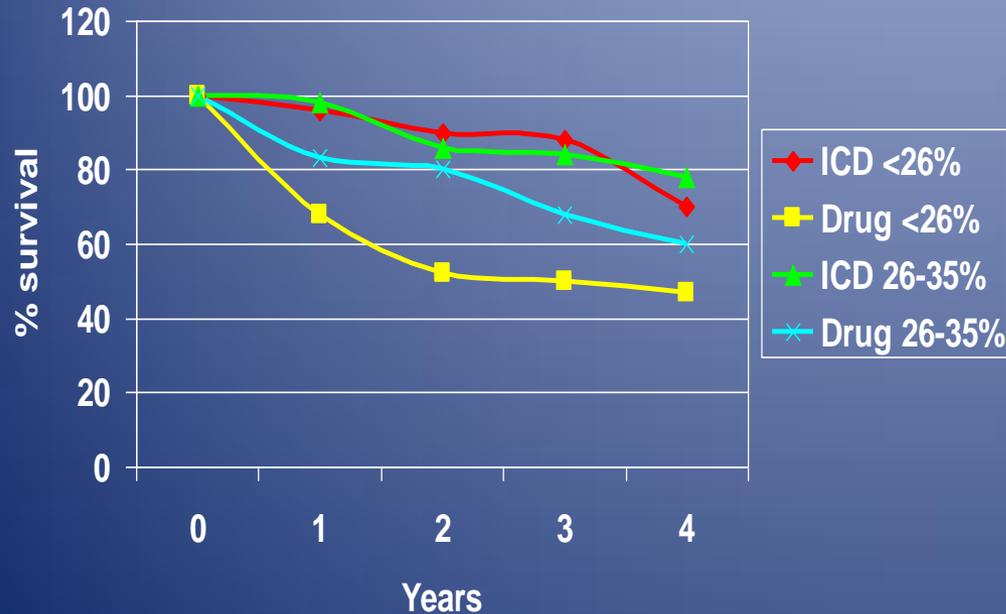
Electrophysiology

Ablation



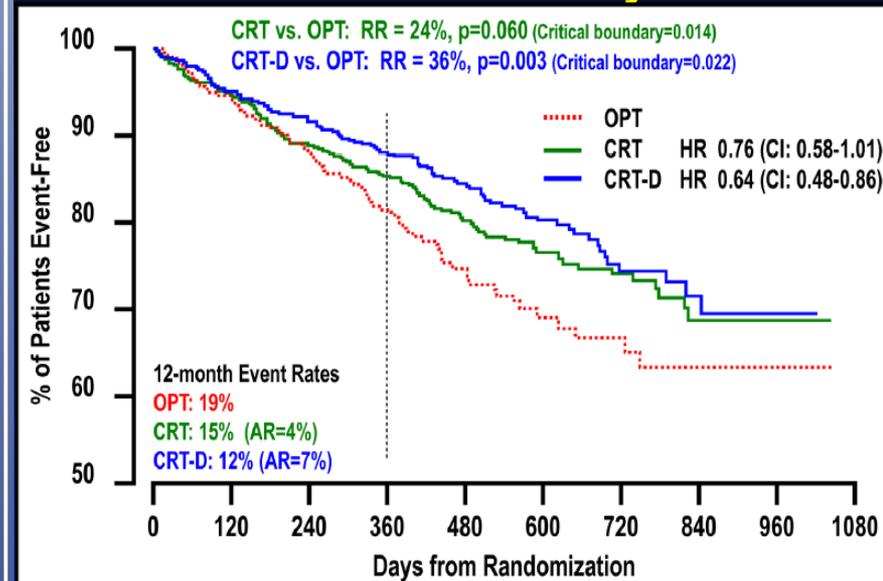
Benefits of Device Placement

MADIT-I Survival By LVEF



Cardiac Re-synchronous Therapy for CHF Patients

COMPANION: Secondary Endpoint of All-Cause Mortality



Risks

**Radiation Risk Must be
Considered, but...**

**What are the Risks of Not
Diagnosing and Treating?**

Life is full of risks

What are the Real Risks?

“Radiation Dose in Diagnostic Cardiac Imaging”

- **Limitations** in Dose Estimation
- Comparison of Doses Determined Using ICRP **Versus** Manufacture’s Dose Coefficients
- **Estimating** Dose in Practice
- Dose and Biological Risk
 - Life-time attributable risk **estimates**

Einstein AJ, et al.

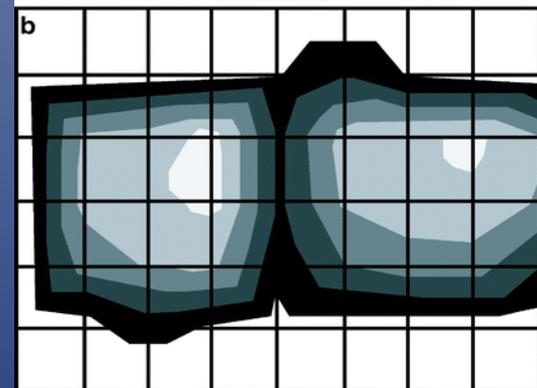
Radiation Dose to Patients from Cardiac Diagnostic Imaging.

Circ 2007; 116;1209-1305

Identifying the At-Risk Patient

Determinants of Patient X-ray Dose

- **Equipment**
 - Current
- **Procedure/Patient**
 - Patient Factors
 - Complex/long case
- **Operator**
 - Equipment use
 - Procedure technique
 - Dose awareness



Imaging Equipment

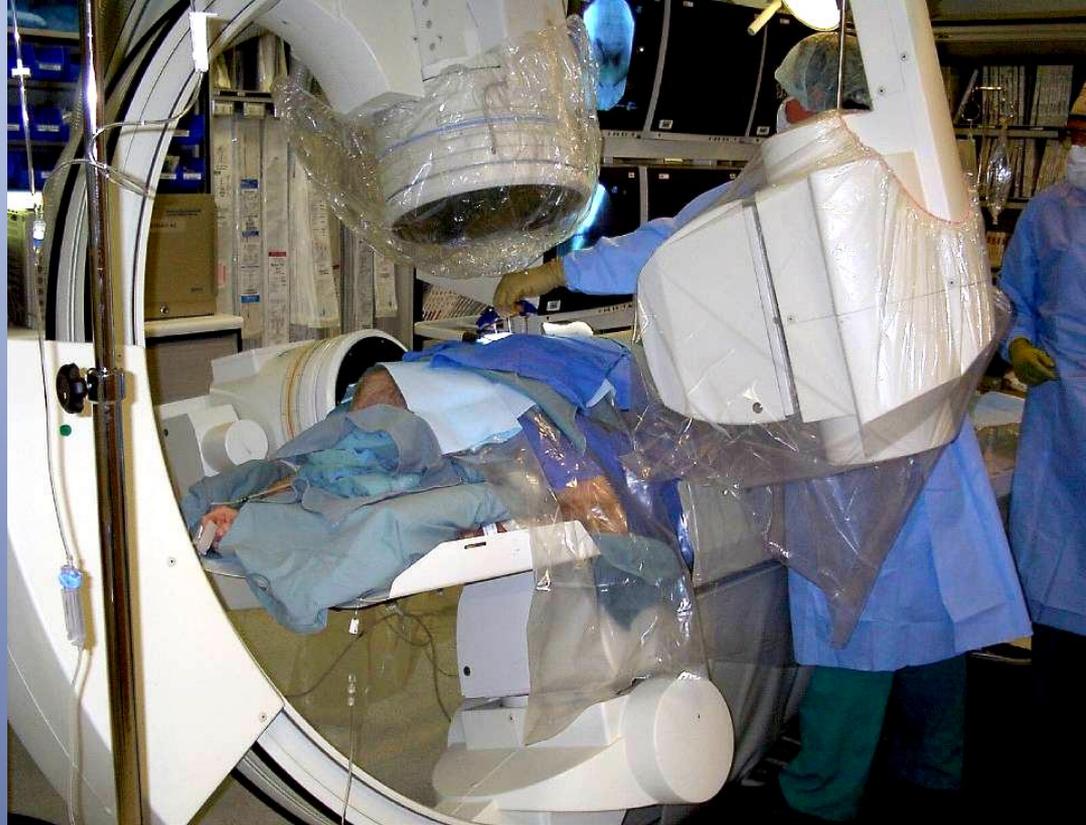
- **Purchase** X-ray units with sophisticated dose-reduction and monitoring features.
- **Maintain** X-ray equipment in good repair and calibration.
- ***The Medical Physicist*** can manage the equipment while the **Physician** can assess the patient and the procedure. **Both** are needed for best results.

The Procedure/Patient

- **As patient size increases...**
 - Image quality deteriorates
 - Input dose of radiation increases exponentially
 - Scatter radiation increases
- **As the complexity increases...**
 - Increasing fluoro/cine time
 - Steeper angles/single port
 - Repeat procedures (30-60 days)

Complex Procedures

- **Coronary**
 - CTO
 - MVD
- **Electrophysiology**
 - Ablation
 - CRT
- **Peripheral/Cerebral Vascular**
 - CTO
 - Lower extremity revascularization
- **Non –Vascular Interventions**
 - TIPS (Transjugular Intrahepatic Portosystemic Shunt)



Radiobiology of Radiation Injuries

- **Interventional procedures (PCI)**
 - one to a few procedures over days to months depending on underlying disease and procedural factors
 - may /may not irradiate same portion of the patient's skin
- **The interval between procedures dictates**
 - repair of the DNA of viable cells within day(s)
 - repopulation with new cells requires months
- For most patients, clinically important skin and hair reactions occur only when the skin dose is >5 Gy.
- Residual effects from previous procedures influence the response of skin to subsequent procedures.

Biologic Factors for Skin Reaction

- **Patient-related factors**

- smoking, poor nutritional status, compromised skin integrity, obesity, overlapping skin folds, and skin location

- **Ethnic differences**

- individuals with light-colored hair/ skin are most sensitive

- **Defects in DNA repair genes**

- predispose individuals to increased radiation sensitivity
- autosomal recessive *ATM* gene, 1% of the population
- patients with serious and unanticipated radiation injuries may be heterozygous for the *ATM* gene, or harbor some other *ATM* abnormality

Biologic Factors for Skin Reaction

- **Diseases with increased radiation sensitivity**
 - hyperthyroidism and diabetes mellitus
 - Autoimmune and connective tissue disorders such as scleroderma, systemic lupus erythematosus, and possibly rheumatoid arthritis
- **Medications may increase radiation sensitivity**
 - actinomycin D, doxorubicin, bleomycin, 5-fluorouracil, and methotrexate mitoxantrone, 5-fluorouracil, cyclophosphamide, paclitaxel, docetaxel, and possibly tamoxifen
- ***Radiation Recall is an inflammatory skin reaction***
 - occurs in previously irradiated body part occurring minutes to days after drug exposure and weeks to years after radiation exposure
 - associated drugs include chemotherapeutic agents (e.g., doxorubicin, etoposide, paclitaxel, bleomycin, epirubicin, and gemcitabine), antibiotics (cefotetan), statins (simvastatin), and herbal preparations (hypericin, otherwise known as St John's wort)

Staged and Repeat Procedures

- **Animal Studies**

- In pig, a single 28 Gy dose caused moist desquamation 50% of the time.
- When radiation delivered in two equal fractions separated by 24 hours, a total dose of 36 Gy (two times 18 Gy) achieves the same effect.

- **Know information from previous case(s) and current case**

- If no entrance beam port overlap, each session is considered separately.
- If re-irradiate of exposed skin, increase time between stages.
- Examine patient's skin before starting next case.
- Previously irradiated skin often looks normal, but reacts abnormally when re-exposed with skin doses above 3–5 Gy.
 - After skin doses of > 10 Gy, tissue will never return to normal.
 - Erythematous reactions is reduced in previously irradiated skin.
- Increased risk of developing skin complications from the effects of external factors such as minor trauma or topical agents.

Risk Management of Skin Effects in Interventional Procedures

- Individualized management by an **experienced radiation wound care team** should be provided for wounds related to high dose radiation.
- For any patient exposed to **significant high dose, > 10 Gy**, not only is medical follow-up essential, full investigation of the entire case is desirable to minimize the likelihood of such an event being repeated.



Provide “Best Patient Care”

Physicians' Responsibility

- **Justification**
 - **Appropriateness**
 - **Guidelines**
 - **Education/Training**
- Avoid any unnecessary study; utilizing ionizing radiation by justification of exposure is one of the basic principles of radiation protection.
 - Exposure to radiation should produce sufficient benefit to the exposed individual to offset the radiation risk it causes.

Operator Training

- **Certain states require training** in fluoroscopy; not universal.
 - High dose operators vs. low dose operators based on 2 Gy procedure
- For board certification, **interventional cardiologists examination includes physics** and radiation safety.
- **All support staff** should receive training commensurate to their responsibilities.
- Physicians should **never supervise procedures for which they do not have** both clinical and fluoroscopic **privileges**.
- **Documentation** of current and appropriate knowledge of radiation safety should be required for institutional privileging.
- A radiation safety **education program** to include:
 - initial training or verification of prior staff training
 - annual updates
 - hands on training for new operators and current operators on newly purchased equipment



A Unified Approach Provides the Best Patient Care

- The Physician/Staff
- The Medical Physicist
- Equipment Manufactures
- Professional Societies
- Legislative Bodies
 - be involved in the process

Protecting the patient will protect the staff and visa, versa