Vascular Brachytherapy Safety

Stephen Balter, Ph.D.

New York, NY

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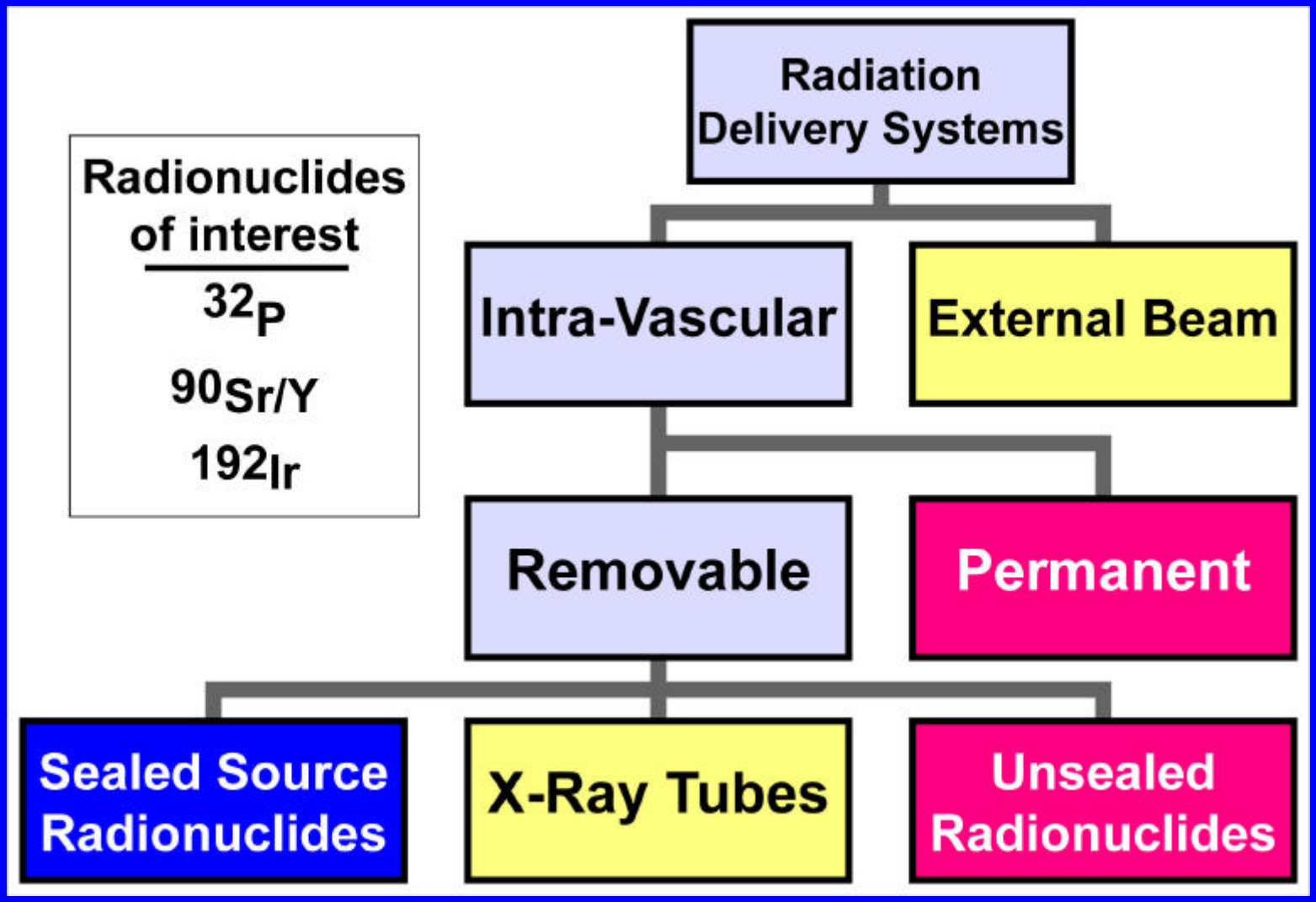
Basic Technology



Removable Sealed Sources

- Wide variety of radionuclides, physical forms, and delivery systems
- Dwell times (3 – 30 minutes)
- All removable sources are HDR in terms of patient safety

Dose Rate Considerations

- Little to no biological repair during treatment with any removable source.
- Shorter Rx Times = Higher Dose Rates
  - ✓ Decreased catheter time
  - –Increased transit dose delivered to other tissues
  - – Less time to react to a technical problem or emergency

Beta - Gamma: Relative Activity

For a 2 mm prescription point:

1 GBq of Sr/Y-90 (Beta)

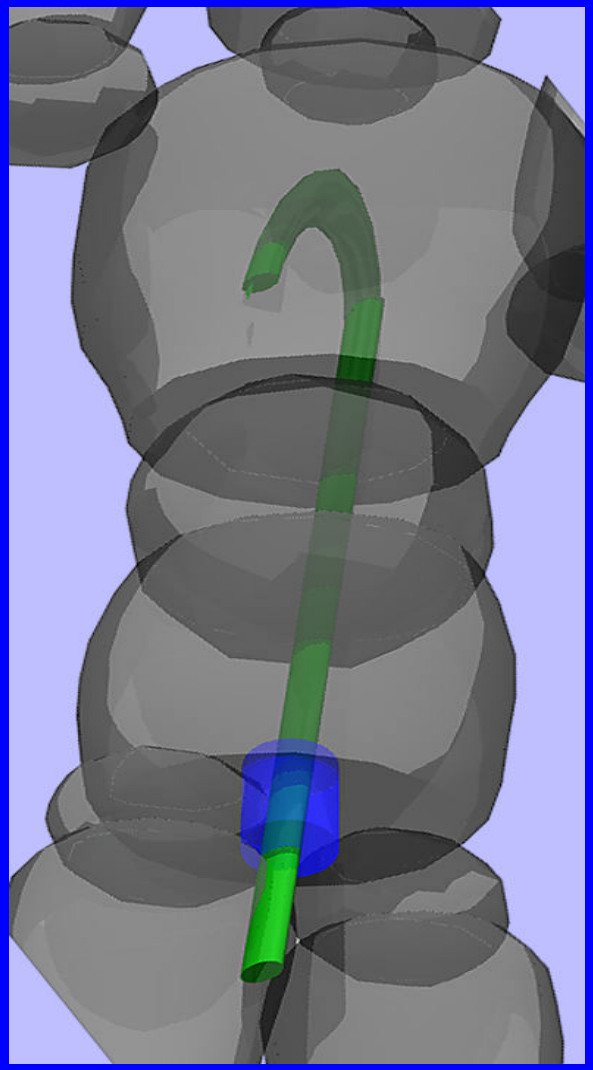
delivers » 50 times the dose rate of 1 GBq of Ir-192 (Gamma).

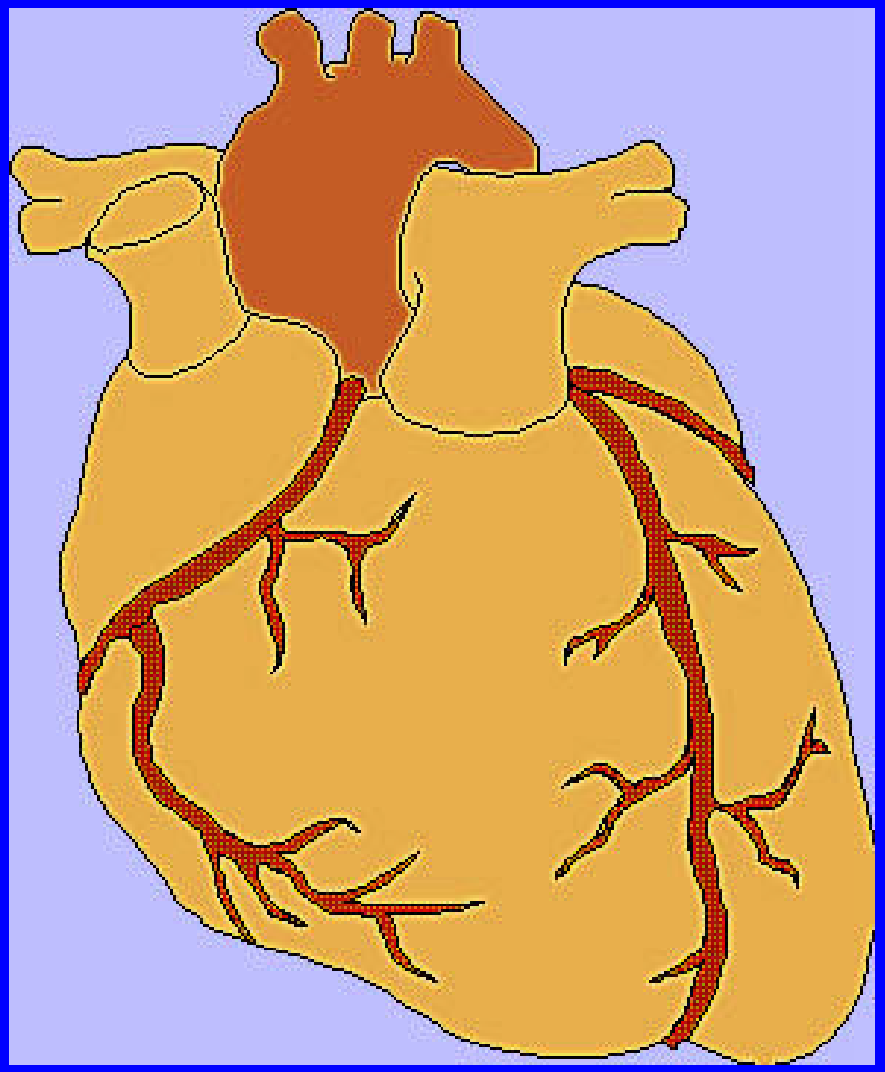
Typical » 30 mm source-train*:

Beta: 1 GBq @ 3 minutes
Gamma: 5 GBq @ 20 minutes

*** Rx Also Differs**

Coronary Artery Access



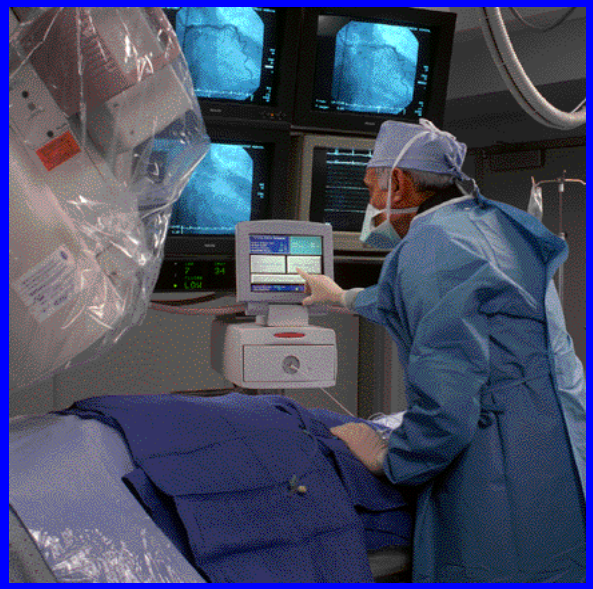


FDA Approved Systems

Cordis (^{192}Ir)

Novoste (^{90}Sr/Y)

Some IDE Systems



Radiance (^{32}P) **Guidant (^{32}P)** **Nucletron (^{192}Ir)**

Patient Safety

1. Reliable source delivery and retrieval
   - Normal, medical and technical emergency
2. Minimize mechanical complications of treatment
3. Avoid ‘toxic’ doses
4. Produce therapeutic effect
5. Minimize remote radiation effects
   - Along delivery path
   - Cancer

Emergency Plans

- **Emergency plans must be developed for several contingencies: *These should be discussed and rehearsed.***
- **Source are usually retrieved normally in case of a medical emergency.**
- **Do not spend time solving a clinical or source transport problem: *Remove the source immediately.***
- **Backup: Source and catheter is pulled as a unit and dumped into bail-out box.**

Typical ^{192}Ir Procedure

plus concepts applicable to all systems

Shielded Storage and Work Area

Treatment Cart with Emergency Equipment

Treatment Setup

Therapy Shields

Usually needed ‘only’ to meet ALARA requirement

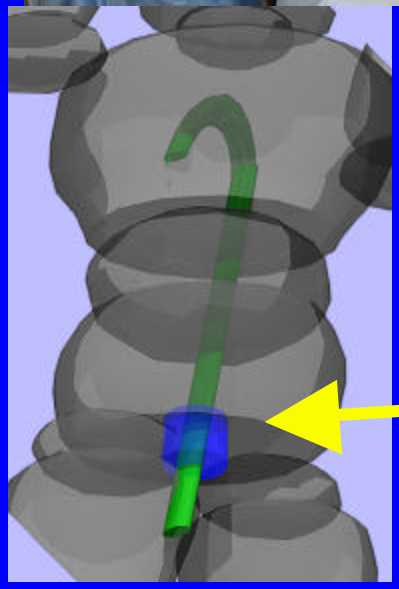
Bail Out Boxes

Beta

Gamma

HDR Gamma

Dummy Run and Access Port



- Standard of practice in HDR is to test using dummy wire immediately before placing the live source.
- The oncologist gets a feel for source placement by testing with the dummy.
- Catheter access port must be wide open to avoid ‘hang-ups’

Source Loading

HDR Physical Presence

During all patient treatments, both the authorized user and either the medical physicist or radiation safety officer must be physically present.
(NRC 93-01)

After Radiation Treatment

- Source removal verified with a sensitive detector.
  - ? Radionuclide study
- Post Treatment
  - calibration
  - or other physical inventory

Staff Safety

- Radiological
  - Avoid deterministic injuries.
  - Minimize staff collective dose while maximizing clinical result.
  - Out of lab radiation safety
- Biological
  - Contamination of the patient by the radiation team's staff and equipment.
  - Blood born contamination of the radiation team's staff and equipment.
- Mechanical
  - Devices are heavy and can have dangerous edges.
  - Mechanical QA is needed.

Radiation Concerns

- **Both b and g sources are extremely dangerous when touched or when the source is exposed in the lab.**
- **Lead aprons offer no real protection for high energy gamma sources.**
- **Radioactive contamination of devices, equipment, and the lab itself.**
  (Not a substantial problem for sealed sources)
- **Misplaced sources.**

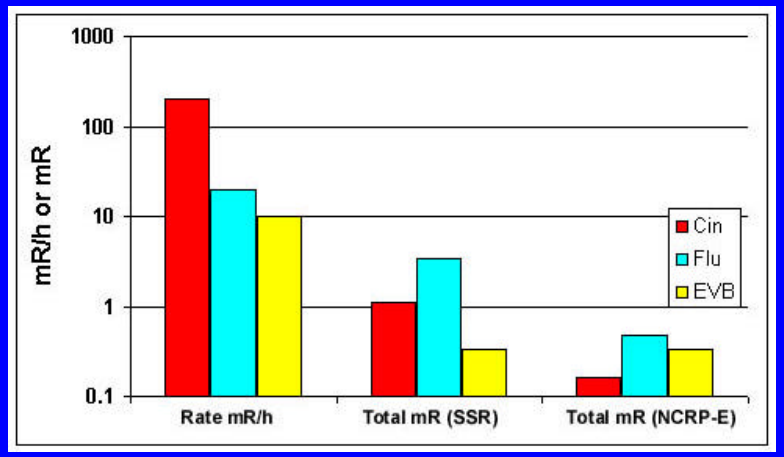
Sources in Air

- The high energy beta particles used for VBT have a range of several meters in air.
- Relative staff dose rates (for any radionuclide) increases as dwell time decreases.
- Staff dose distributions differ for different radionuclides.

Staff Dose per Procedure

- **Angioplasty X-Rays**
  - **Cine (highest instantaneous rate)**
  - **Fluoro (greatest contribution)**
- **VBT**
  - b **Bremsstralung & unshielded sources (Staff in room for entire procedure)**
  - g **Time in room with source out of shield**

‘Typical times’
Cine = 1 minute
Fluoro = 30 minutes
VBT = 2 minutes



Radiation Risk Estimate

- **Interventionalist:**
  - **Fluoro / Cine : 1,000 – 5,000 µSv/y**
  - **Most likely 1,000 – 2,000 µSV/y for busy operators taking adequate precautions**
  - **Significantly less for others involved in the procedure.**
- **EVBT: Collective Dose**

  1 b EVBT << 1 extra Angioplasty

  1 g EVBT » 1 extra Angioplasty

Biological Risk - Patient

- Few RT devices are sterile.
- Sterile barriers are used to isolate devices from the patient.
- Radiation team needs to prep devices for use in a sterile field.
- Post treatment inspection for evidence of a breach of the sterile barriers is important.

Biological Risk - Staff

- Interventional labs are bloody places.
- Universal Precautions assumes that all blood is contaminated with one or more pathogens.
- AVOID biological contamination of:
  - RT equipment
  - Clothing and shoes
  - Staff members bodies

Mechanical Hazards

- Pulling the catheter out of position by inadvertently moving a treatment device.
- Dropping a piece of equipment on the patient or on a staff member.
- Moving heavy equipment (such as gamma shields) into position.

Better mechanical QA of equipment will minimize hazard.

Administrative Safety

- **FDA labeling has formal restrictions.**
  - **Off Label: Physician's discretion and risk.**
  - **No administrative penalty per se.**
- **NRC* licenses are very prescriptive.**
  - **Off License: Administrative penalty for violation of license conditions**
  - **Practice of medicine issues need to be resolved**

- *** NRC = Relevant nuclear authority**

Is Vascular Brachytherapy Safe? Justification and Optimization

Radiation risk can be justified provided that the use of a particular nuclide produces an improved clinical outcome relative to other nuclides or alternative technologies.

Continuing optimization is expected to further reduce risk.