Employee Training

Y-90 Microspheres
Principles & Radiation Safety

CARDINAL RULE

• DEMAND STRICT ATTENTION TO DETAIL FOR ALL ASPECTS OF THESE PROCEDURES !!!

GENERAL PRINCIPLE

• Selective Internal Radiation Therapy – (SIRT) - to selectively target a very high radiation dose to all tumors within the liver, regardless of their cell of origin, number, size or location. While at the same time, maintaining a low radiation dose to the normal liver tissue.
• Blood supply to the “normal” liver is primarily from the portal vein and a small component is from the hepatic artery.
• Liver tumors however receive most of their blood supply from the hepatic artery
• Therefore it is desired that Y-90 microspheres are “perfused” into malignant hepatic tumors via a micro-catheter (ID>0.5 mm) placed into the hepatic artery using the tumor’s own blood supply.
• Yttrium-90 is a pure beta emitter with a maximum energy of 2.27 MeV and average energy of 0.93 MeV with a range in tissue of 11 mm maximum and a mean range of 2.5 mm. It is therefore an excellent internal therapeutic radiation source.
• Microspheres themselves are biocompatible not biodegradable and localize in the tumor via capillary blockage.

<table>
<thead>
<tr>
<th>Commercial Y-90 Microsphere Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>• SIR-Spheres © (Sirtex Medical)</td>
</tr>
<tr>
<td>• Resin microspheres</td>
</tr>
<tr>
<td>• Y-90 embedded in resin</td>
</tr>
<tr>
<td>• ~5.0 ml sterile water</td>
</tr>
<tr>
<td>• 20-60 µm</td>
</tr>
<tr>
<td>• 40-70 Bq per sphere</td>
</tr>
<tr>
<td>• 3 GBq = 30-60 x 10^6 spheres</td>
</tr>
<tr>
<td>• Density (g/cm³) – 1.6</td>
</tr>
<tr>
<td>• TheraSphere © (MDS Nordion)</td>
</tr>
<tr>
<td>• Glass microspheres</td>
</tr>
<tr>
<td>• Y-90 incorporated into glass</td>
</tr>
<tr>
<td>• 0.6 ml sterile water</td>
</tr>
<tr>
<td>• 20-30 µm</td>
</tr>
<tr>
<td>• 2,400-2,700 Bq per sphere</td>
</tr>
<tr>
<td>• 3 GBq = 1.2 x 10^6 spheres</td>
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<tr>
<td>• Density (g/cm³) – 3.29</td>
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**Y-90 Microsphere Therapy**

**RADIOLOGY WORK-UP**

- CT – to assess liver volume and tumor burden
- Hepatic Angiogram – to evaluate hepatic vasculature
  a. Embolization (coiling) of extrahepatic vessels to prevent gastroduodenal ulceration from errant microsphere deposition
  b. Micro-catheter placement
- Tc-99m – MAA Scan to assess lung shunting

![CT Scan](image)

- Lung shunting limited to <20% or an absorbed dose of 25 – 30 Gy

**RADIATION SAFETY – IR SUITE**

**NO ONE** Leaves the IR Suite Exit – Without Being Surveyed for Contamination !!!

- Acrylic Delivery Box - Shields against bremsstrahlung X-ray radiation
- Absorbent Pads on Floor / Device Tray - “Catch” possible loose contamination
- Sterile Drapes from Device to Patient - “Catch” possible loose contamination
- Lead Aprons / Glass and Distance - Shields for Fluoroscopy Use
- “in-Line” RADOS Radiation Monitor of Activity Delivery - TheraSpheres Only
- Door Postings / NMT Entrance Monitor / Gatekeeper - Traffic / Contamination Control
- GM meters – Live contamination surveys of Hands Bottom of Feet, Ant & Post Body Surfaces - **PRIOR TO ROOM EXIT**
- Spill Kit - Immediate Response
- Waste Containers - Collect / Segregate contaminated Items
- Protective Clothing - Gowns, Double Gloves, Masks, Double Shoe Covers
- Personnel Monitoring Devices
**RADIATION SAFETY - CONTAMINATION POTENTIAL**

- Contamination Potential is EXTREMELY HIGH
- Microspheres are approximately ¼ the diameter of a human hair
- A single TheraSphere contains approximately 2500 Bq (67nCi)
- A single SIRSpheres contains approximately 50 Bq (1.35 nCi)
- Microspheres do **Roll** and can **Bounce**
- Microspheres can become **Airborne** if allowed to dry.
- Survey Procedures are unchanged from other radioactive solutions

**RADIATION SAFETY - CONTAMINATION REMEDIAL ACTIONS**

- Microspheres can easily fall into cracks and crevices
- Strategic placement of plastic backed absorbent pads and surgical towels is mandatory
- Masking or Duct Tape can be employed to “pick up” microspheres
- Dampened paper towels can be used
- The following “household cleaning” items should be considered:
  - “Scrubbing Bubbles” to “lift” contamination and / or "Swiffer Wet Jet" with removable moistened pad.
Y-90 Microsphere Therapy

Y-90 MICROSPHERE - NRC ISSUES

- Specifically licensed under 10 CFR 35.1000 – Written Directive Required
- No Leak Test Required
- Licensing Guidance – TheraSphere and SIR-Spheres Y-90 Microspheres (June 2012)
  a. Training and Experience Requirements for Authorized Users (AU’s)
  b. License Commitments for Written Directives, Inventories, Patient Release, Labeling and Medical Event Reporting

Y-90 MICROSPHERES – WRITTEN DIRECTIVE

- Properly ID the patient prior to Tc-99m MAA or Y-90 Microsphere administration
- Signed and Dated by an AU PRIOR to administration – noting either total dose (rad or Gy) or prescribed activity (mCi or GBq) which is preferred
- Written Directive SHALL record the administered activity (or dose) delivered to the primary treatment site and to other specified site(s).
- Written Directive SHOULD specify the maximum activity (or dose) that would be acceptable to the specified site(s) outside the primary treatment site due to shunting (e.g. lung and gastrointestinal tract).
- If appropriate for the type of microsphere used, the statement “or dose / activity delivered at stasis.” Is to be noted as the dose / activity administered when stasis occurred.
- A notation of stasis must include the name of the individual who made the “stasis” assessment, the date and the signature of the AU.
- A Medical Event has NOT occurred if stasis is documented as a treatment endpoint in the written directive

Y-90 MICROSPHERE – SEALED SOURCE INVENTORY AND WASTE

- Semiannual sealed source inventory is required and must include
  a. Radionuclide and physical form
  b. Unique identification of each vial
  c. Total activity contained in each vial(s)
  d. Location of vials
- A separate form for waste storage and disposal is required.
ACTIVITY DELIVERED - ASSURANCE WRITTEN DIRECTIVE FOLLOWED

- Follow manufacturer’s instructions for Pre-administration assay / monitoring

- Follow manufacturer’s instructions for Post-Administration assay / monitoring to confirm agreement with written directive prescribed activity
**Y-90 MICROSPHERE - PATIENT RELEASE**

- The patients’ own tissues will provide sufficient attenuation of the beta emissions such that patients can be immediately released in accordance with NRC criteria under 10 CFR 35.75.
- This release criteria limits total effective dose to others to 500 mrem at one(1) meter. It has been estimated that an administration of 38.5 Ci of Y-90 would be required to exceed this limit.

**Y-90 MICROSPHERE - PATIENT INSTRUCTIONS**

- Written Discharge Instruction May Include:
  
  a. No travel on public transport, including air travel lasting more than two(2) hours for one(1) week
  b. Avoid crowded public places for one(1) week
  c. Do not sleep in the same bed as your partner for one(1) week
  d. No contact with children or pregnant individuals for one(1) week
  e. Adult visitors should stay more than six(6) feet away for one(1) week (if for a prolonged period of time).
  f. There is no need to make special arrangements for bodily fluids (urine, stool, blood, vomit).

**POST – ADMINISTRATION NURSING CARE**

- The patient is moved from the IR suite to a recovery room
- The following guidelines are suggested:
  
  a. Non-pregnant nursing staff only
  b. Pregnant visitors or children should not visit
  c. Nursing care should be delivered from the LEFT side of the patient
  d. Collection of bed linen, rubbish or clothing NOT necessary
  e. Universal Precautions should be stressed

**Y-90 MICROSPHERE – POST ADMINISTRATION PATIENT DEATH**

- The following residual activity limits are suggested for handling deceased patients administered Y-90 microspheres
  
  a. Necropsy 150 MBq (4.05 mCi)
  b. Cremation / Burial 1 GBq (27 mCi)
  c. Embalming 150 MBq (4.05 mCi)
I have read and reviewed the enclosed Y-90 Microsphere workbook with regards to general principles and radiation safety instruction. All questions and concerns have been answered in accordance with my duties and responsibilities for this procedure:

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Radiation Safety Officer

Management

Date: ________________

Date: ________________