Y-90 Microsphere Therapy: Nuclear Medicine Perspective

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Learning Objectives

• Role of Nuclear Medicine in patient selection
• Technical Issues of dose drawing, preparation and delivery system setup
• Radiation safety issues
• Regulatory compliance issues
Human Use of Radiopharmaceuticals

Group 1  In diagnostic studies involving measurement and uptake, dilution, or excretion but not involving imaging.

Group 2  In diagnostic studies involving imaging and localization.

Group 3  and or generators, and reagent kits for preparation of radiopharmaceuticals.

Group 4  In a pharmaceutical for internal therapy that usually does not require hospitalization.

Group 5  In a pharmaceutical for internal therapy that usually requires hospitalization for purposes of radiation safety.

Group 6  Of sealed or solid sources of radioactive material for brachytherapy or ophthalmic treatment.
<table>
<thead>
<tr>
<th>Group</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 7</td>
<td>Sealed or solid sources of radioactive material in devices for certain diagnostic studies involving transmission and excitation.</td>
</tr>
<tr>
<td>Group 8</td>
<td>Sealed or solid sources of radioactive material for teletherapy of cancer.</td>
</tr>
<tr>
<td>Group 9</td>
<td>Sealed or solid sources of radioactive material as marker and calibration sources, depleted uranium for accelerator shielding, survey meter calibration sources, in-vitro or animal studies.</td>
</tr>
<tr>
<td>Group 10</td>
<td>Physician-sponsored nonroutine medical uses of radioactive materials.</td>
</tr>
<tr>
<td>Group 11</td>
<td>Manufacturer-sponsored nonroutine medical uses of radioactive materials.</td>
</tr>
<tr>
<td>Group 12</td>
<td>Sealed or solid source of radioactive material in pacemaker devices.</td>
</tr>
</tbody>
</table>
The Challenges in External Beam Radiation Therapy of Liver Tumors

- Dose to kill adenocarcinomas ~ 100 Gy
- Dose to kill normal liver, lung, bowel ~ 25–30 Gy
- In order to kill most mets and HCCs, considerable radiation damage to surrounding nontarget tissues
Microspheres with Yttrium-90

- **Microsphere**
  - 35 ± 2.5 micron diameter
- **Yttrium-90 beta particle emission**
  - Max energy 2.27MeV (mean 0.93MeV)
  - Maximum range in tissue 11 mm (mean 2.5 mm)
  - Half life 64.1 hours
## Properties of Resin and Glass Y-90 Microspheres

<table>
<thead>
<tr>
<th></th>
<th>Y-90 Microspheres</th>
<th>SIR-Spheres</th>
<th>TheraSphere</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company</td>
<td>Sirtex Medical, Sydney, Australia</td>
<td>BTG Interventional</td>
<td></td>
</tr>
<tr>
<td>Material</td>
<td>Resin-based</td>
<td>Glass-based</td>
<td></td>
</tr>
<tr>
<td>Diameter</td>
<td>20-60 μm</td>
<td>20-30 μm</td>
<td></td>
</tr>
<tr>
<td>Activity per particle</td>
<td>50 Bq</td>
<td>2500 Bq</td>
<td></td>
</tr>
<tr>
<td>Number of microspheres per 3-GBq vial</td>
<td>$40-80 \times 10^6$</td>
<td>$1.2 \times 10^6$</td>
<td></td>
</tr>
<tr>
<td>Specific gravity</td>
<td>1.6 g/mL</td>
<td>3.2 g/mL</td>
<td></td>
</tr>
<tr>
<td>Maximal prescribed dose (GBq)</td>
<td>3</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Relative embolic potential</td>
<td>High</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>Relative pressure for infusion</td>
<td>Low</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td>Contrast injection during infusion</td>
<td>Possible</td>
<td>Not possible</td>
<td></td>
</tr>
</tbody>
</table>

Modified from Ahmadzadehfar et al, Semin Nucl Med 2010; 40:105-121
Resin Microspheres

- 32μ diameter
- Yttrium\(^{90}\)
- Beta 0.93MeV
- 64.1hrs half life
- Penetration
  - 2.5mm mean
  - 11mm max
Cancer Angioarchitecture

Sarcoma
Liver tumor vasculature

To lungs

Metastatic tumor

shunt

Normal liver (portal vein)

Hepatic artery

aorta
SIR-Sphere: Indications

- Unresectable metastatic liver tumors
- < 20% shunting to the lungs
- Able to remove/ligate/block collateral vessels to other organs
Contraindications

- Prior external beam radiation Tx to liver
- Ascites or clinical liver failure
- Markedly abnormal LFTs
- >20% lung shunting
- Significant blood reflux to other organs
- Disseminated extrahepatic disease
- Capecitabine (Xeloda®) therapy < 2months
- Portal vein thrombosis
## Recommended Patient Dose

<table>
<thead>
<tr>
<th>Percent involvement by tumor in the liver</th>
<th>Recommended Y-90 dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;50</td>
<td>3.0 GBq (81 mCi)</td>
</tr>
<tr>
<td>25-50</td>
<td>2.5 GBq (68 mCi)</td>
</tr>
<tr>
<td>&lt;25</td>
<td>2.0 GBq (54 mCi)</td>
</tr>
</tbody>
</table>
Dosage Determination

\[ \%_{\text{tumor\_involvement}} = \frac{\text{volume\_of\_tumor}}{\text{volume\_of\_tumor} + \text{liver}} \times 100 \]

\[ \text{GBq} = (\text{BSA} - 0.2) + \left( \frac{\%_{\text{tumor\_involvement}}}{100} \right) \]
Contraindications (TheraSpheres)

- Prior external beam radiation Tx to liver
- Severe liver dysfunction or pulmonary insufficiency
- Lung shunting > 16.5 mCi to lungs
- Significant blood reflux to other organs
- Complete occlusion of the main portal vein
TheraSphere Dosage Determination

Recommended dose to liver: 80 to 150 Gy

Activity Required (Gbq) = \[ \frac{[\text{Desired Dose (Gy)}][\text{Liver Mass (kg)}]}{50} \]
TheraSphere Dose Ordering

\[
Dose (Gy) = \frac{50 \times \text{Injected Activity (GBq)} \times (1 - F)}{\text{LiverMass (kg)}}
\]

\( F = \text{fraction localizing in lungs} \)

\( \text{Dose to lungs} = F \times \text{Activity, Max} < 0.61 \text{ GBq} \)
Intra-hepatic 99mTc-MAA Scan

- Fraction of particles that will pass through the liver
- 4 mCi
- Any large FOV gamma camera
- ANT and POST images of thorax and liver (same time duration for all)
- ROI over whole liver and whole lungs for geometric mean
Intra-hepatic 99mTc-MAA Scan

All within liver
Intra-hepatic 99mTc-MAA Scan

Gut Uptake
Intra-hepatic 99mTc-MAA Scan

Shunt 29%
Calculating Lung Shunt

\[ \% Shunt = \frac{\text{lung counts}}{\text{lung counts} + \text{liver counts}} \times 100 \]
### SIR-Spheres Dose Reduction Factors for Lung Shunting

<table>
<thead>
<tr>
<th>Percent lung shunting</th>
<th>Reduction Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 10</td>
<td>No reduction</td>
</tr>
<tr>
<td>10 ( \leq ) 15</td>
<td>20 % reduction</td>
</tr>
<tr>
<td>15 ( \leq ) 20</td>
<td>40 % reduction</td>
</tr>
<tr>
<td>&gt; 20</td>
<td>No treatment</td>
</tr>
</tbody>
</table>
Dose limit to lungs with TheraSpheres

- Per treatment limit = 30 Gy
- Cumulative Dose limit to the lungs 50 Gy
TheraSphere® Y-90 Glass Microsphere Treatment Window Illustrator

Patient Name: [Blacked Out]
Patient ID: [Blacked Out]
Target Tissue: left lobe

Target Volume (cc): 468.0
Desired Dose (Gy): 160
Time Zone Variance (h): 3 (see Time Zones tab for details)
Lung Shunt Fraction (% LSF): 5.00%
Anticipated Residual Waste (%): 2.00%
Previous Dose to the Lungs (Gy): 0

Required Activity at Administration (GBq): 1.66
This value is corrected for LSF and Residual Waste if values are entered above.

Places in this Time Zone: Vancouver BC Los Angeles California

Calculated Dose to Lungs (Gy): 4.06
Dose Limit to the Lungs per treatment (Gy): 30

Cumulative Dose to Lungs (Gy): 4.06
Cumulative Dose Limit to the Lungs (Gy): 50

Use the following tables to select a dose size where the Desired Dose (above) is at a suitable treatment time.

Dose Size Selected (GBq): 5 GBq
Date & Time for Administration: 10/20/2016@08:00

Tables below show the dose to perfused target tissue, accounting for target mass, time zone variance, lung shunt fraction and residual waste.

<table>
<thead>
<tr>
<th>Dose Delivered (Gy) for:</th>
<th></th>
<th></th>
<th></th>
<th></th>
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<tbody>
<tr>
<td>3 GBq dose size</td>
<td></td>
<td></td>
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<tr>
<td>Time</td>
<td>Sunday</td>
<td>Monday</td>
<td>Tuesday</td>
<td>Wednesday</td>
<td>Thursday</td>
<td>Friday</td>
<td>Saturday</td>
<td>Sunday</td>
<td>Monday</td>
<td>Tuesday</td>
</tr>
<tr>
<td>8:00 AM</td>
<td>226</td>
<td>174</td>
<td>134</td>
<td>104</td>
<td>80</td>
<td>62</td>
<td>48</td>
<td>37</td>
<td>28</td>
<td>17</td>
</tr>
<tr>
<td>12:00 PM</td>
<td>216</td>
<td>167</td>
<td>129</td>
<td>99</td>
<td>77</td>
<td>59</td>
<td>46</td>
<td>35</td>
<td>27</td>
<td>21</td>
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<tr>
<td>4:00 PM</td>
<td>207</td>
<td>160</td>
<td>123</td>
<td>95</td>
<td>73</td>
<td>57</td>
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<td>25</td>
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<table>
<thead>
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<td>Time</td>
<td>Sunday</td>
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<td>103</td>
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<td>99</td>
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<td>205</td>
<td>159</td>
<td>122</td>
<td>94</td>
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<td>117</td>
<td>90</td>
<td>70</td>
<td>54</td>
<td>41</td>
<td>32</td>
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<table>
<thead>
<tr>
<th>Dose Delivered (Gy) for:</th>
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<tbody>
<tr>
<td>7 GBq dose size</td>
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</tr>
<tr>
<td>Time</td>
<td>Sunday</td>
<td>Monday</td>
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<td>Thursday</td>
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<td>144</td>
<td>111</td>
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<td>61</td>
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<tr>
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<td>389</td>
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<td>232</td>
<td>179</td>
<td>138</td>
<td>106</td>
<td>82</td>
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<td>49</td>
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<tr>
<td>4:00 PM</td>
<td>483</td>
<td>373</td>
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<td>222</td>
<td>171</td>
<td>132</td>
<td>102</td>
<td>79</td>
<td>61</td>
<td>47</td>
</tr>
<tr>
<td>8:00 PM</td>
<td>463</td>
<td>357</td>
<td>276</td>
<td>213</td>
<td>164</td>
<td>126</td>
<td>98</td>
<td>75</td>
<td>58</td>
<td>45</td>
</tr>
</tbody>
</table>
Drawing up the “Prescribed Dose”

~3 GBq (81 mCi)

Dose Calibrator
Use Calibration Factor

Shipping vial
Lower limit

Shipping vial
Upper limit

Rx dose +10%

Rx dose -10%
Reference marker for septum puncture
Nuc Med Puncture Sites
IR Puncture Sites
Measuring Original Patient Dose
Brehmsstrahlung Radiation
SIR-Spheres Delivery System
SIR-Sphere Dose Delivery System

to patient catheter

Flush
Dose

contrast

water

B

C

D

water 3-5 ml

1 cm
TheraSpheres Delivery System
TheraSphere Administration Set

- saline
- 20 ml vented overpressure vial
- dose vial
- injector assembly
- 20 ml syringe
- catheter in patient
- Need > 20cc/min during administration
- 20 ml vented overpressure vial
Question #1

Which of the following is the only correct statement?

a. Y-90 glass microspheres have less radioactivity per particle than the resin microspheres

b. Y-90 glass microspheres have more embolic properties than the resin microspheres

c. Y-90 resin microspheres are delivered to the patient with a saline flush solution

d. Y-90 resin microspheres requires more technologist time for drawing the proper dose
CASE #1
Metastatic Colon Cancer to the Liver
SUV = 7 - 8
Brehmsstrahlung Images
3 months after 1 GBq SIR-sphere
Case #2

• 53 y.o. woman with metastatic carcinoid with flushing symptoms
Shunt = 8.3%
Dose Calculation 1st Tx

- Target left lobe
- Assumptions
  - Left lobe is 30% of whole liver
  - This lobe is 40% occupied by tumor
- Dose calculation
  - 0.72 GBq (19.53 mCi)
Dose Calculation 2\textsuperscript{nd} Tx (1 month later)

- Target right liver lobe
- Assumptions
  - Right lobe is 70\% of whole liver
  - This is 5\% occupied by tumor
- Dose Calculation
  - 1.44 GBq (38.94 mCi)
40.1 mCi
Case #3

- 51 y.o. woman with multifocal adenocarcinoma, unknown primary
- Progressive disease despite chemotherapy
- S/p right liver lobectomy
Shunt = 4.2%
Dose Calculation Tx

- Target left and only lobe
  - Segment IV
  - Segment II & III

- Assumptions
  - Left lobe is 80% of whole liver
  - This is 10% occupied by tumor

- Dose calculation
  - 1.15 GBq (31.03 mCi)
  - ~16 mCi x 2 split dose
Case #4

- 78 y.o. Man with large (13 cm) HCC right lobe (prior seg IV resected)

- Small residual left lobe (22%)

- T bili = 0.3, Alb = 4.0, AST = 58, ALT = 81, ALK = 61, INR = 1.2, plt = 181, AFP = 74

- Potential candidate for extended right lobectomy, but small functioning reserve
Left Lobe = 22% of Total Liver Volume
Hepatopulmonary Shunt = 18%
Should Mandate 40% Dose Reduction
Y^{90} TARE (Resin Microspheres)  
5/26/2011

2 Transjugular Occlusion Balloons R & M Hepatic Veins

Y^{90} RHA
PET-CT Next Day (Internal Pair Production of Bremsstrahlung)

$Y^{90}$ in Tumor, not Lungs
CT Two Months Later
7/11/2011

Tumor Partially Necrotic, Left Lobe Enlarging
7/20/2011 Extended Right Lobectomy
SPECT/CT

- Energy window: 56 - 99 keV
- Scatter windows: 49.4 - 54.6, 100.7 - 111.3
- Raw projection image matrix: 128 x 128
- Frame duration: 20 seconds
- Angles of rotation: 60
Question #2
Which of the following is the false statement?

a. The pretreatment Tc-MAA scan should be done 2 months prior to the microsphere therapy

b. Depending on the shunt fraction a reduction in the total calculated dose to administer to the liver may be necessary.

c. SPECT imaging and SPECT/CT may help in identification of extrahepatic accumulation of MAA particles

d. Free technetium may confound the interpretation of gastric activity on the Tc-MAA scan
UCSD Microsphere Therapy Dose Verification

Prescribed Activity (mCi): 44.9 ± 20%

Required Measured Activity Range (Prescribed ± 10%)
Must be greater than 40.4 (mCi) and less than 49.4 (mCi)
This section will be computed by Excel sheet
Measured (mCi): 45.1
Notify AU BEFORE use for WD revision if not well within ±10%

Pre-Procedure Dose Vial Ion Chamber Measurements

<table>
<thead>
<tr>
<th>Angle</th>
<th>90° mR/hr</th>
<th>180° mR/hr</th>
<th>270° mR/hr</th>
<th>360° mR/hr</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2.10</td>
<td>2.00</td>
<td>2.10</td>
<td>2.10</td>
</tr>
</tbody>
</table>

Average: 2.08

Post-Procedure Dose Vial Ion Chamber Measurements

<table>
<thead>
<tr>
<th>Angle</th>
<th>90° mR/hr</th>
<th>180° mR/hr</th>
<th>270° mR/hr</th>
<th>360° mR/hr</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.85</td>
<td>0.82</td>
<td>0.84</td>
<td>0.89</td>
</tr>
</tbody>
</table>

Average: 0.85

Fraction of Drawn Activity Delivered [1 - (Avg. Post/Avg. Pre)]: 0.59

Activity Delivered (Drawn Activity X Fraction of Activity Delivered): 26.6 mCi

Percent of Prescribed Activity Delivered [(Activity Delivered/Prescribed Activity) X 100]: 59.3%

Percent delivered within 80% - 120% Yes: X No: If No, see the appropriate box below.

CNMT Name: Mary Hoeger
Date: 10/20/2016

If Dose Delivered falls out of Activity Administration Range complete this section
Administration Terminated Due to Stasis
AU Signature: Carli 02 for Dr. Roe
Date: 10/20/16
Which of the following percent of the total administered dose from the prescribed dose signifies a NRC “medical event”?

- a. 10%
- b. 20%
- c. 30%
- d. 40%
Which of the following is the false statement regarding immediate post SIRT treatment?

a. Y-90 is a pure beta emitter so imaging is not possible
b. Planar “Bremsstrahlung” imaging is possible
c. SPECT or SPECT/CT bremsstrahlung imaging is possible and may show more than a planar image
d. Y-90 “pair production” PET imaging can be performed
Patient Radiation Instructions

- No visitor who are pregnant
- No physical contact > 2hr duration
- Sleep in bed alone
- No special care for body fluids
Clinical Trial Results (SIR-Spheres)

- Randomized, controlled clinical trial

70 patients total

- 34 pts FUDR only
- 36 pts FUDR + SIRspheres
Tumor response by volume

<table>
<thead>
<tr>
<th>Response</th>
<th>CR</th>
<th>PR</th>
<th>NC</th>
<th>PD</th>
<th>Others</th>
</tr>
</thead>
<tbody>
<tr>
<td>FUDR only (N=34)</td>
<td>1</td>
<td>7</td>
<td>12</td>
<td>9</td>
<td>5</td>
</tr>
<tr>
<td>FUDR+SIR-Spheres (N=36)</td>
<td>2</td>
<td>16</td>
<td>10</td>
<td>5</td>
<td>3</td>
</tr>
</tbody>
</table>

(p=0.033)
# Time to First Progressive Disease in the Liver

<table>
<thead>
<tr>
<th></th>
<th>FUDR Only</th>
<th>FUDR + SIR-spheres</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Patients</td>
<td>34</td>
<td>36</td>
</tr>
<tr>
<td>Mean Time (days +/-SD)</td>
<td>312 +/- 330</td>
<td>510 +/- 516</td>
</tr>
<tr>
<td>Median Time (days)</td>
<td>233</td>
<td>366</td>
</tr>
</tbody>
</table>

(p=0.05)
## Adverse Events

<table>
<thead>
<tr>
<th>Event</th>
<th>Grade 1 and 2</th>
<th>Grade 3 and 4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>FUDR</td>
<td>FUDR+ SIRspheres</td>
</tr>
<tr>
<td>Hgb</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>AST (SGOT)</td>
<td>110</td>
<td>109</td>
</tr>
<tr>
<td>Alk Phos</td>
<td>90</td>
<td>188</td>
</tr>
<tr>
<td>Nausea/vomiting</td>
<td>5</td>
<td>13</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>6</td>
<td>3</td>
</tr>
</tbody>
</table>

| Total Events     | 222           | 320            | 23            | 23             |
Adverse Events

- Fever, abdominal pain, N&V, diarrhea
- Acute pancreatitis, abdominal pain
- Radiation pneumonitis
- Acute gastritis
- Radiation hepatitis
- Acute cholecystitis
Safety & Efficacy Study

Unresectable hepatic colorectal mets

72 pts

< 25% liver

120 Gy

Hepatic progression 15.4 months
Overall survival 14.5 months

61% Fatigue
21% Nausea
25% Abd pain
13% Bilirubin

Median survival 18.7 months

> 25% liver

120 Gy

Median survival 5.2 months

CT, PET

Safety & Survival

Advanced HCC

108 pts

CT → 120 Gy → CT

Hepatic progression 10 months
Overall survival 16.4 months

Fatigue = 61%
Vague abd pain = 56%
Lung or visceral toxicity = 0%

CR 3%
PR 77%
Stable 53%
Prog 6%

Meta-analysis Microsphere Tx

Response

Colorectal mets in salvage setting
Y90 + 5FU/LV 79%
Y90 + 5FU/LV/(oxaliplatin or irinotecan) 79%

Colorectal mets in 1st line setting
Y90 + 5FU/LV 91%
Y90 + 5FU/LV(oxaliplatin or irinotecan) 91%

Hepatocellular cancer
resin coated microspheres 89%
glass microspheres 78%
Treatment Coding Summary

Patient Referral **Medical Oncologist**
CPT: 99213

*Interventional Radiology Consult CPT: 99204*

**Diagnostic Radiology**
CT Abdomen CPT: 74170 or MRI Abdomen CPT: 74185

3D post scan processing for liver volume CPT: 76375

continued
Treatment Coding Summary

Interventional Radiology

Celiac and superior mesenteric arteriograms CPT: 75726 x2

Nuclear Medicine

99mTc-MAA Scan CPT: 78202

If Patient is Eligible: Order Product 7-10 days prior to therapy

Nuclear Medicine/Radiation Oncology

Clinical Treatment Planning CPT: 77261

Radiation Dosimetry CPT: 77300

Supervision, Handling, Loading CPT: 77790

continued
Treatment Coding Summary

Interventional Radiology
arteriograms CPT: 75726

Nuclear Medicine
Provision of therapeutic radiopharmaceutical : 79900

Post Procedure Observation
Liver Imaging CPT: 78202
Tumor PET/CT CPT: 78815

Office Visit
Post-treatment follow-up CPT: 99212
CPT codes

• pre-treatment office visit or consultation
  – 99201-99205 initial
  – 99211-99215 subsequent
  – 99241-99245 Office consultation

• Pre-treatment radiation planning
  – 77261-77263, clinical treatment planning

• Pre-treatment radiation planning
  – 77300, Basic radiation dosimetry
CPT codes

• Treatment
  – 77790 Supervision, handling and loading of radiation source

• Treatment
  – 79445 Administration of radiopharmaceutical, intra-arterial
Questions

Spreadsheets available
ckhoh@ucsd.edu
Other Targeted Therapies
Magnetically Targeted Carrier - Doxorubicin

FeRx Inc, San Diego, CA
Magnetically Targeted Carrier - Doxorubicin

FeRx Inc, San Diego, CA
Metastatic Colon Cancer

Pre Treatment: Day 0

Treated left lobe lesion

Untreated right lobe lesion

Post Treatment: Day 21