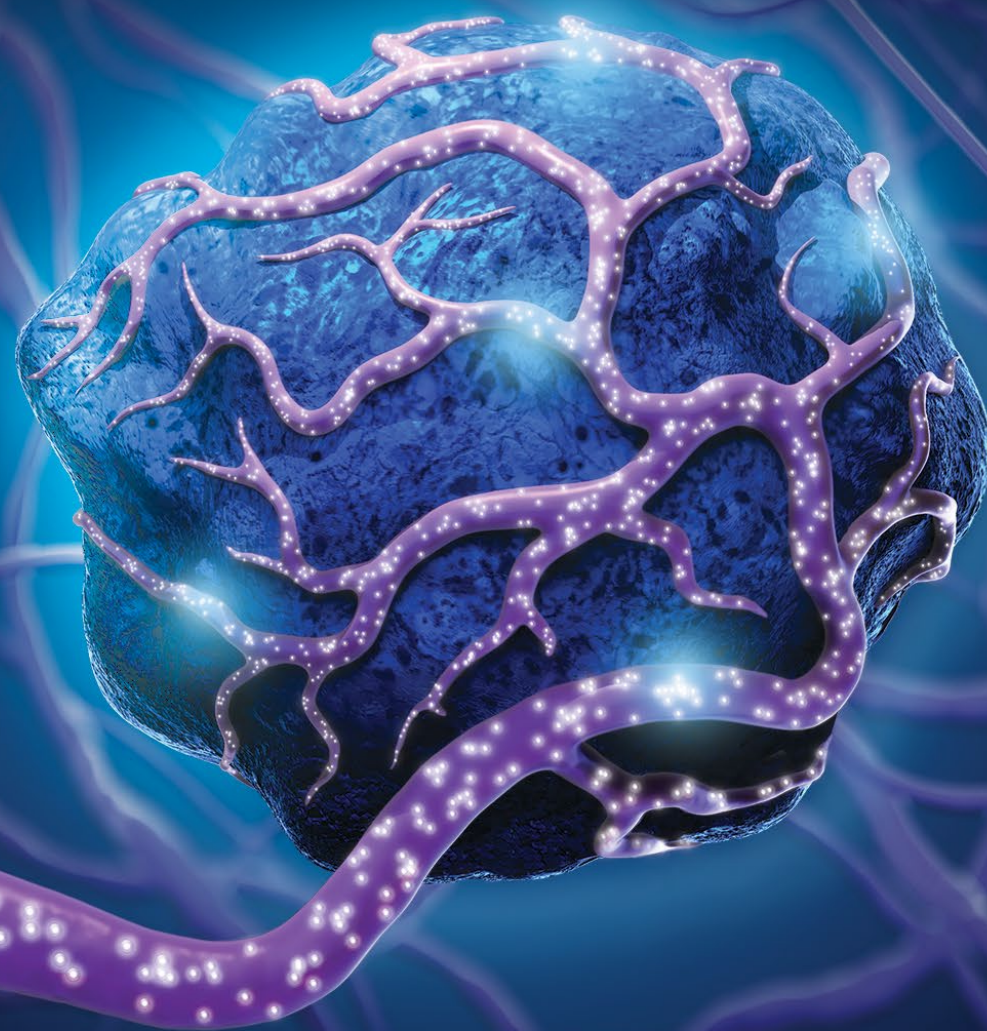


CASE VIGNETTE | PRE- AND POST Y-90 TREATMENT IMAGING REVIEW

Classic case examples utilizing TheraSphere Y-90 Glass Microspheres in hepatocellular carcinoma (HCC) liver cancer



OVERVIEW

RADIATION SEGMENTECTOMY CASE 1

Pre-treatment

Post-treatment

Key Takeaways

RADIATION SEGMENTECTOMY CASE 2

Pre-treatment

Post-treatment

Key Takeaways

RADIATION LOBECTOMY CASE 3

Pre-treatment

Post-treatment

Key Takeaways



RADIATION SEGMENTECTOMY | CASE 1

64 year old Female

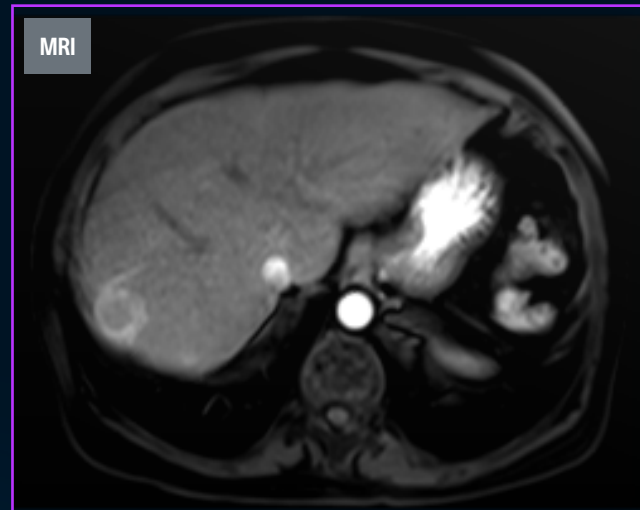
Hepatitis-C, Cirrhotic Liver with a 2.3 cm LI-RADS 5 Single lesion

AFP 2,941 | BCLC A | CP A | ECOG 0

Patient determined not to be a surgical candidate due to comorbidities

Referred to Interventional Radiology for liver directed therapy

Delivered a dose **450Gy** to **Segment 7** to achieve adequate response



Arterial Phase



Delayed Phase

OVERVIEW

RADIATION SEGMENTECTOMY CASE 1

Pre-treatment

Post-treatment

Key Takeaways

RADIATION SEGMENTECTOMY CASE 2

Pre-treatment

Post-treatment

Key Takeaways

RADIATION LOBECTOMY CASE 3

Pre-treatment

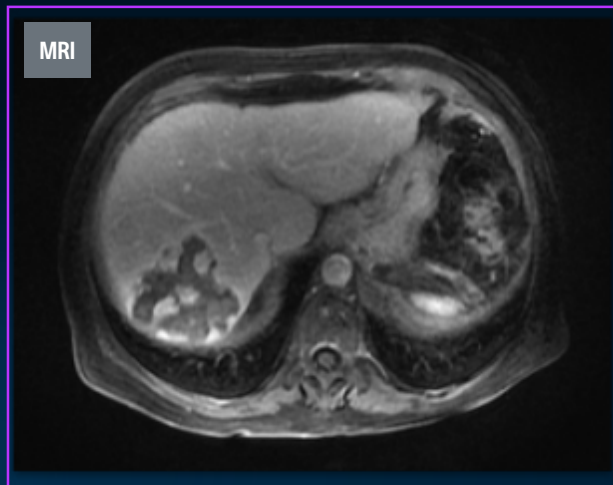
Post-treatment

Key Takeaways

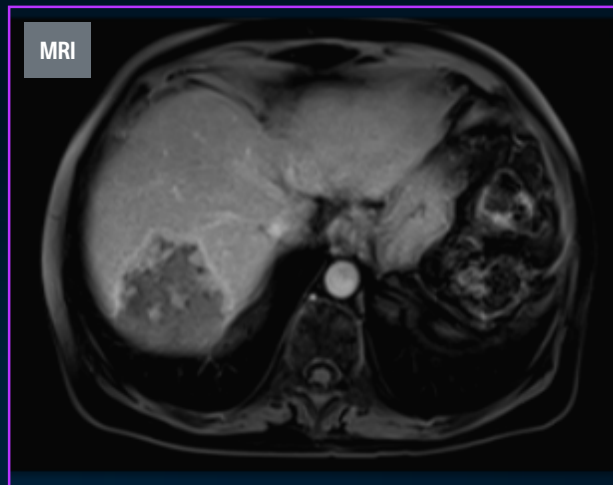


RADIATION SEGMENTECTOMY | CASE 1

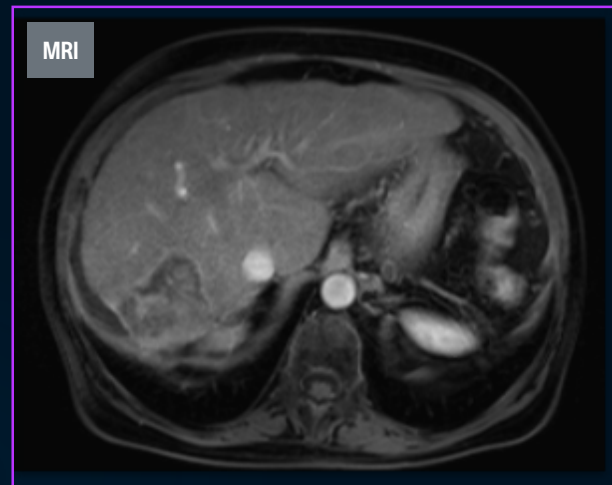
64 year old Female



1 month results post-Y90
Demonstrating necrotic cavity with foci of enhancing nodularity due to granulation tissue



3 month results post-Y90
Showing Complete necrosis of treatment cavity without evidence of viable disease



1 year results post-Y90
Showing treatment cavity with capsular retraction

OVERVIEW

RADIATION SEGMENTECTOMY CASE 1

Pre-treatment

Post-treatment

Key Takeaways

RADIATION SEGMENTECTOMY CASE 2

Pre-treatment

Post-treatment

Key Takeaways

RADIATION LOBECTOMY CASE 3

Pre-treatment

Post-treatment

Key Takeaways





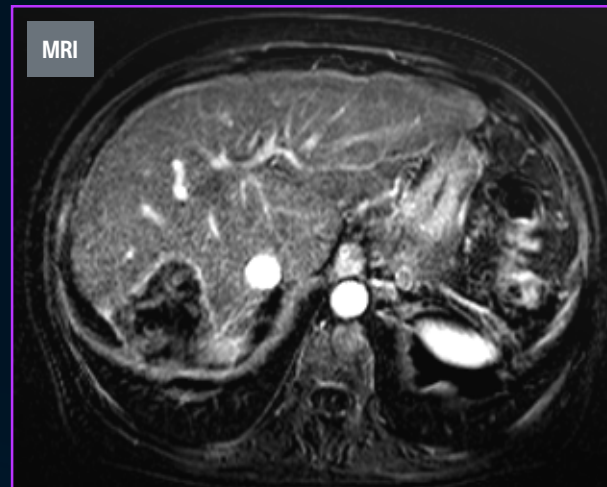
RADIATION SEGMENTECTOMY | CASE 1

64 year old Female

Superselective treatment and deliver a lethal ablative radiation dose and achieve adequate margins within a treatment cavity

Example of:

- Progression of post radiation segmentectomy imaging highlighting heterogeneity at 1 month
- Evolution into unequivocal complete necrosis of tumor by 3 months
- No evidence of residual tumor in treatment cavity with capsular retraction



1 year results post-Y90

OVERVIEW

RADIATION SEGMENTECTOMY CASE 1

Pre-treatment

Post-treatment

Key Takeaways

RADIATION SEGMENTECTOMY CASE 2

Pre-treatment

Post-treatment

Key Takeaways

RADIATION LOBECTOMY CASE 3

Pre-treatment

Post-treatment

Key Takeaways



RADIATION SEGMENTECTOMY | CASE 2

88 year old Male

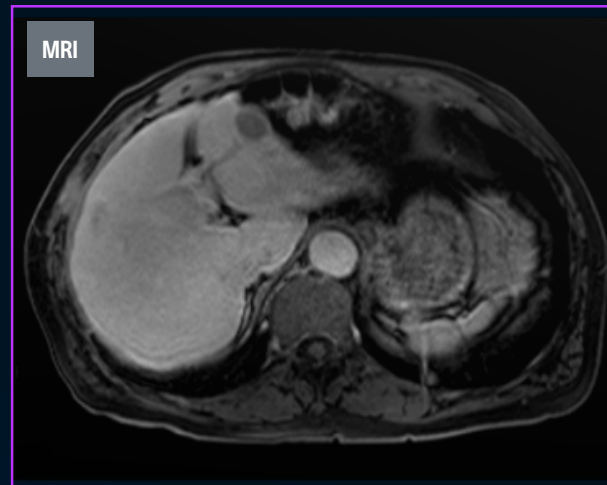
Hepatitis-C, Cirrhotic Liver with a 2.1 cm segment 4/2 LI-RADS 5 lesion

BCLC A | CP A | ECOG 1

Patient determined not to be a surgical candidate due to comorbidities

Referred to Interventional Radiology for liver directed therapy

Delivered a dose **740Gy** to **Segment 4** to achieve adequate response



OVERVIEW

RADIATION SEGMENTECTOMY CASE 1

Pre-treatment

Post-treatment

Key Takeaways

RADIATION SEGMENTECTOMY CASE 2

Pre-treatment

Post-treatment

Key Takeaways

RADIATION LOBECTOMY CASE 3

Pre-treatment

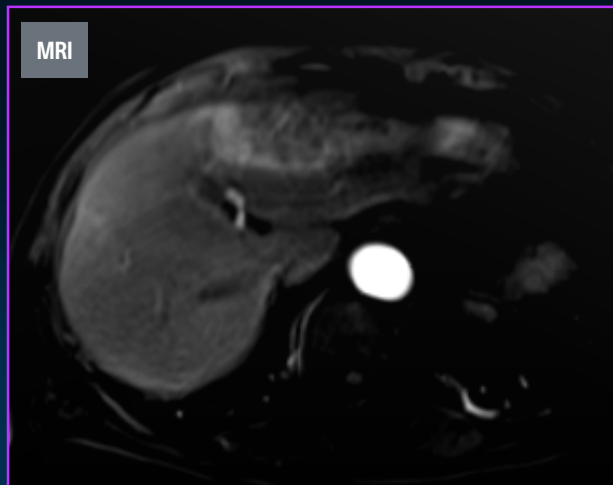
Post-treatment

Key Takeaways

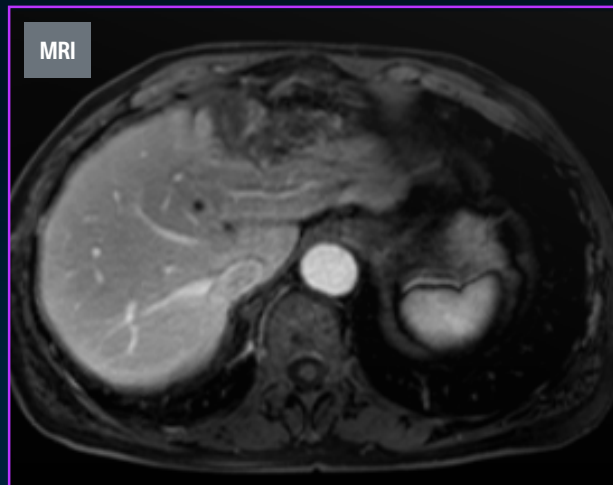


RADIATION SEGMENTECTOMY | CASE 2

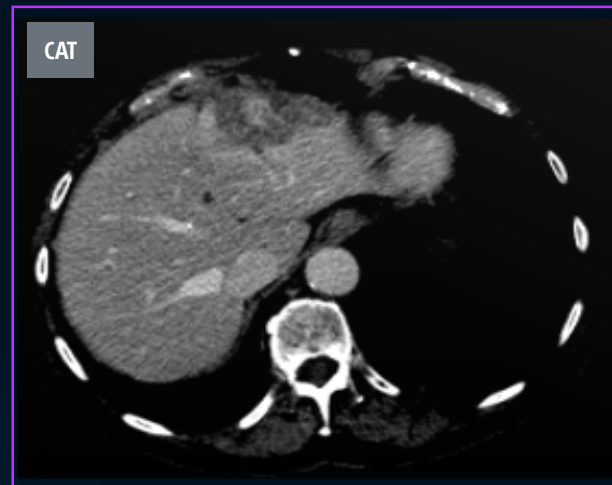
88 year old Male



1 month results post-Y90
Demonstrating necrotic cavity with surrounding radiation necrotic changes



3 month results post-Y90
CAT scan shows tumor cavity with surrounding radiation necrotic changes correlating with MRI scan showing evolving post-Y90 changes



OVERVIEW

RADIATION SEGMENTECTOMY CASE 1

Pre-treatment

Post-treatment

Key Takeaways

RADIATION SEGMENTECTOMY CASE 2

Pre-treatment

Post-treatment

Key Takeaways

RADIATION LOBECTOMY CASE 3

Pre-treatment

Post-treatment

Key Takeaways

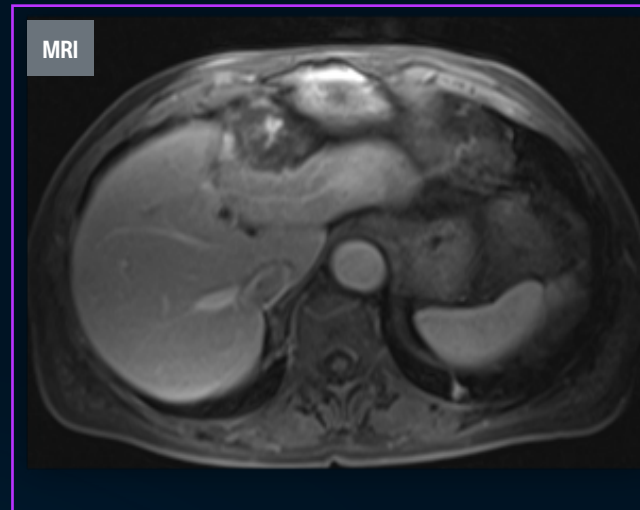


RADIATION SEGMENTECTOMY | CASE 2

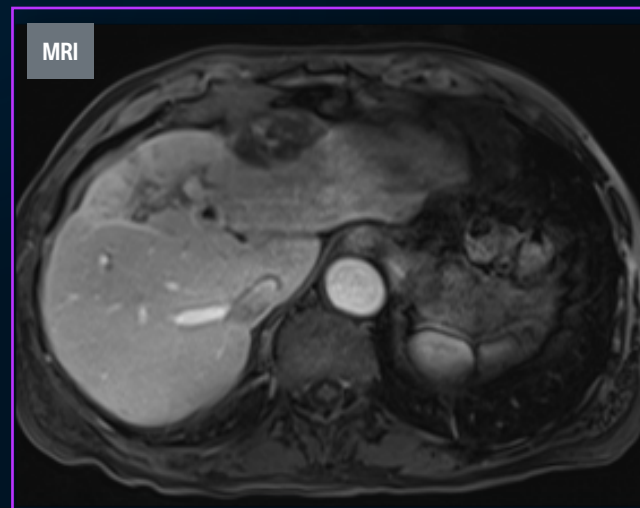
88 year old Male

Example of:

- Progression of post radiation segmentectomy imaging highlighting heterogeneity at 1 month
- Evolution into unequivocal complete necrosis of tumor at 3 months
- Progression to unequivocal tumor necrosis with atrophy of Y90 cavity shown in 1 and 3 scans



1 Year results post-Y90



3 Year results post-Y90

OVERVIEW

RADIATION SEGMENTECTOMY CASE 1

Pre-treatment

Post-treatment

Key Takeaways

RADIATION SEGMENTECTOMY CASE 2

Pre-treatment

Post-treatment

Key Takeaways

RADIATION LOBECTOMY CASE 3

Pre-treatment

Post-treatment

Key Takeaways



RADIATION LOBECTOMY | CASE 3

57 year old Male

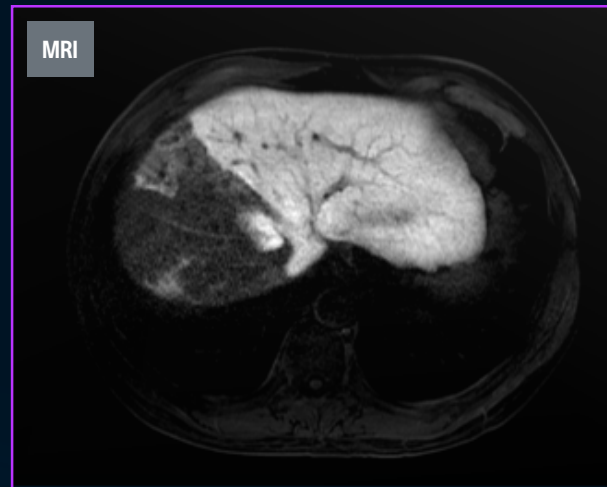
Hepatitis-C, Cirrhotic with a large infiltrating HCC predominantly in segments 7 and 8, involving the entire right lobe

PIVKA-II 2,300 | BCLC C | CP A | ECOG 0

Disease was considered oncobiologically aggressive with high risk of reoccurrence; patient was outside transplant criteria

Referred to Interventional Radiology for liver directed therapy

Delivered a dose **180Gy** to the entire right hepatic lobe to achieve adequate response



OVERVIEW

RADIATION SEGMENTECTOMY CASE 1

Pre-treatment

Post-treatment

Key Takeaways

RADIATION SEGMENTECTOMY CASE 2

Pre-treatment

Post-treatment

Key Takeaways

RADIATION LOBECTOMY CASE 3

Pre-treatment

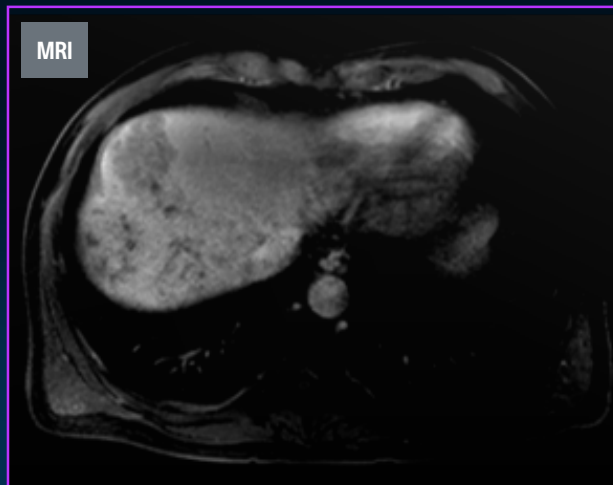
Post-treatment

Key Takeaways

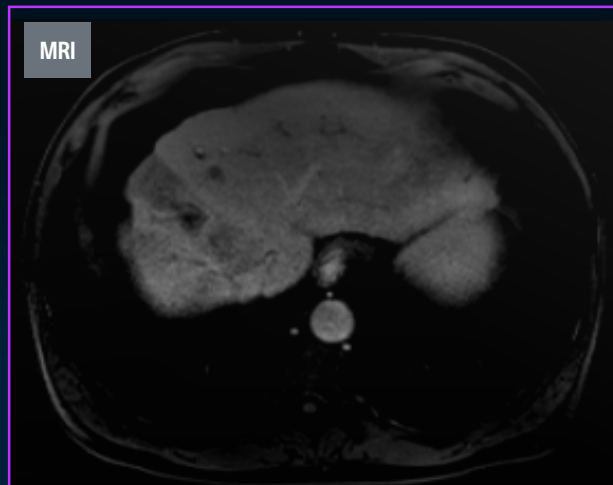


RADIATION LOBECTOMY | CASE 3

57 year old Male



1 month results post-Y90 radiation lobectomy showing radiation treatment change with start of atrophy of the right hepatic lobe



6 month results post-Y90 Evolving post-Y90 treatment changes with continuing atrophy of the right hepatic lobe with contralateral left hepatic lobe hypertrophy. Patient now awaiting transplant.



9 month results post-Y90

OVERVIEW

RADIATION SEGMENTECTOMY CASE 1

Pre-treatment

Post-treatment

Key Takeaways

RADIATION SEGMENTECTOMY CASE 2

Pre-treatment

Post-treatment

Key Takeaways

RADIATION LOBECTOMY CASE 3

Pre-treatment

Post-treatment

Key Takeaways





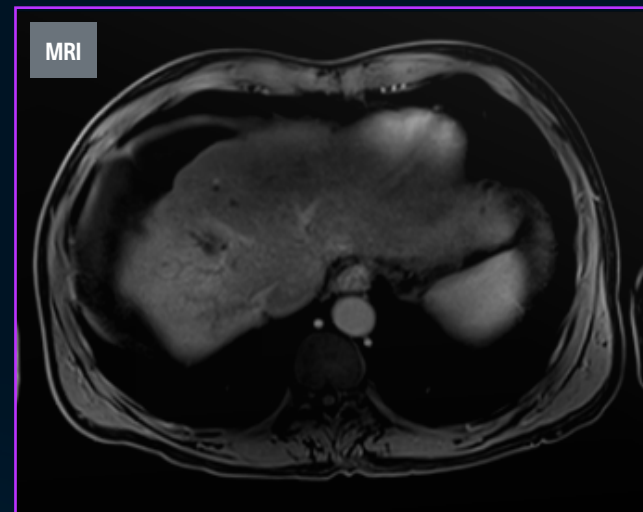
RADIATION LOBECTOMY | CASE 3

57 year old Male

Post radiation lobectomy imaging findings can be drastically different from selective transarterial treatments. It is very common to have residual heterogeneous enhancing patterns, but it is crucial to look for secondary findings indicative of decreasing tumor burden.

Example of:

- Evolving post Y90 treatment changes
- Continued atrophy of treated lobe with contralateral lobe hypertrophy



9 month results post-Y90

OVERVIEW

RADIATION SEGMENTECTOMY CASE 1

Pre-treatment

Post-treatment

Key Takeaways

RADIATION SEGMENTECTOMY CASE 2

Pre-treatment

Post-treatment

Key Takeaways

RADIATION LOBECTOMY CASE 3

Pre-treatment

Post-treatment

Key Takeaways





THERASPHERE™ Y-90 Glass Microspheres

OVERVIEW

RADIATION SEGMENTECTOMY CASE 1

Pre-treatment

Post-treatment

Key Takeaways

RADIATION SEGMENTECTOMY CASE 2

Pre-treatment

Post-treatment

Key Takeaways

RADIATION LOBECTOMY CASE 3

Pre-treatment

Post-treatment

Key Takeaways

TheraSphere™ Yttrium-90 Glass Microspheres

INDICATION FOR USE: TheraSphere is indicated for use as selective internal radiation therapy (SIRT) for local tumor control of solitary tumors (1-8 cm in diameter), in patients with unresectable hepatocellular carcinoma (HCC), Child-Pugh Score A cirrhosis, well-compensated liver function, no macrovascular invasion, and good performance status. **CONTRAINDICATIONS:** TheraSphere is contraindicated in patients: whose Tc-99m macroaggregated albumin (MAA) hepatic arterial perfusion scintigraphy shows any deposition to the gastrointestinal tract that may not be corrected by angiographic techniques • who show shunting of blood to the lungs that could result in delivery of greater than 16.5 mCi (0.61 GBq) of Y-90 to the lungs. Radiation pneumonitis has been seen rarely in patients receiving doses to the lungs greater than 30 Gy in a single treatment. • in whom hepatic artery catheterization is contraindicated, such as patients with vascular abnormalities or bleeding diathesis • who have pulmonary insufficiency (conventionally defined by an arterial oxygen pressure (Pa,O2) of < 60 mmHg, or oxygen saturation (Sa,O2) of < 90%) or severe liver dysfunction, including hepatic encephalopathy, clinically evident ascites or treatment with diuretics for ascites • with portal vein thrombosis (PVT) Type 4 involvement and lack of Tc-99m MAA deposition on the PVT seen on the Tc-99m MAA imaging with >70% tumor replacement in the liver • with comorbidities or poor overall health (e.g., ECOG performance status rating > 2) which may make the patient a poor candidate for locoregional radiation treatment. • who are pregnant. **WARNINGS:** The following pre-treatment, high-risk factors (disease characteristics) have been associated with serious adverse events deemed possibly related to use of the device: infiltrative tumor type • tumor nodules too numerous to count • AST or ALT > 5 times ULN • bilirubin > 2 mg/dL • tumor volume > 50% combined with albumin < 3 g/dL. Keep the TheraSphere dose vial upright and stored in its lead pot before and during patient treatment, except as required for radiation measurement. Do not open the dose vial acrylic shield prior to patient treatment. Post-treatment, waste materials require caution to prevent contamination and beta shielding due to residual glass microspheres. **PRECAUTIONS: GENERAL PRECAUTIONS:** As in any intra-arterial procedure, aseptic technique should be practiced, and care should be taken to ensure minimum patient anesthesia exposure extraneous to therapeutic objective. • Consideration of patient comorbidities should be used when determining the type and volume of fluid to infuse via catheter to avoid electrolyte imbalance, fluid shift, and hyperglycemia. • It is important to avoid any aggressive arterial procedure that may lead to arterial spasm that impairs TheraSphere distribution into the perfused liver target volume which may lead to underdosing or non-target deposition of TheraSphere. **PRECAUTION IN PATIENTS WITH IMPAIRED LIVER FUNCTION:** No efficacy or safety data from the LEGACY study are available to support the use of the device in patients with Child-Pugh score B or C cirrhosis. **PRECAUTION IN VULNERABLE PATIENTS:** No effectiveness or safety data are available to support the use of the device in children or breast-feeding women. **ENDOCRINE DISRUPTION, CARCINOGENICITY, MUTAGENICITY, TOXICITY TO REPRODUCTION:** Ideally the use of this radioactive device in women of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses. **RADIATION SAFETY:** Radioactive products should be used only by healthcare professionals who are qualified by specific training in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides. • As in the use of any radioactive material, ensure minimum radiation exposure to the patient extraneous to the therapeutic objective, and to minimize radiation exposure to workers and others in contact with the patient. **RELEASE AND POST-TREATMENT PRECAUTIONS:** Post treatment patient care: use universal precautions for body fluid contact. Trace Y-90 may be detectable in blood and urine; handle with gloves and dispose as normal body fluids. The radiation field is expected to be less than 1 mrem/h (10 µSv/h) at 3 ft (1 m) from the patient's abdomen. Supplemental shielding and segregation of the patient are not required to maintain exposure to others below regulated limits. • Release instructions: The patient should follow good hygiene (e.g., proper hand washing). Caregivers, family, and others do not require restrictions on patient contact; however, they can minimize their radiation exposure by avoiding prolonged time (>12 hours per day) within 1 ft (0.3 m) of the patient's abdomen for the first week post therapy. Patients should be advised that radiation emitted from the patient may be detectable at security screening (e.g., international travel). • Special precautions post-administration: If the patient requires hospitalization, surgery, medical assessment or treatment regarding any part of their thorax or abdomen within first 2 weeks of treatment, the patient should advise the hospital and treating physician of the Y-90 TheraSphere implant. The physician should consult their radiation safety staff for handling and disposal of liver tissue. • Special liver tissue handling: Special liver tissue handling may be required for post-treatment surgery, explant, or transplant since the glass microspheres remain permanently implanted in the liver tissue. Disclosure of the treatment will be required if cremation is considered. **POTENTIAL ADVERSE EVENTS:** The use of this product leads to irradiation of both tumorous and normal liver tissue. As a result, patients with compromised liver function may be at greater risk of liver function impairment and hence could experience complications. Clinical side effects usually occur within the first 4 to 6 weeks after treatment. Based on clinical trial data, literature reviews and post market surveillance, adverse events potentially associated with treatment using Y-90 microspheres, including TheraSphere, may include the following: Allergic reaction • Altered liver function, acute or chronic • Anorexia • Anxiety • Ascites • Bile Duct injury • Bleeding/hemorrhage • Chills / rigors • Cholecystitis (inflammatory or infectious) • Colitis • Death • Dehydration • Diarrhea • Dizziness • Dyspnea • Edema (any location) • Electrolyte abnormalities • Elevated BUN/creatinine • Fall • Fatigue • Fever • Gastrointestinal bleeding / hemorrhage • Gastrointestinal ulcer or ulceration • Hepatic encephalopathy • Hepatorenal failure • Hiccups • Hypertension • Hypotension • Infection (any location) • Liver failure, acute or chronic • Lymphopenia • Malaise • Mood alteration • Muscle weakness • Nausea • Neutropenia • Pain (any location) • Pancreatitis • Platelet count abnormalities • Pleural effusion • Portal hypertension • Pre-existing chronic liver disease decompensation • Pulmonary edema • Pulmonary fibrosis • Radiation hepatitis • Radiation induced disease, acute • Radio Embolization Induced Liver Disease (REILD) • Sepsis • Supraventricular arrhythmia • Thrombosis (arterial or venous) • Tumor inflammation (including tumor edema) • Tumor-lysis syndrome • Vomiting • Weight loss. Complications related to the administration procedure itself may include: Allergic reaction: Arterial injury including vessel dissection • Aspiration pneumonia • Bruising/bleeding/hematoma at site • Constipation/abdominal distension • Fatigue • Flushing • Infection • Nausea • Nerve damage. **CAUTION:** Federal (USA) law restricts this device to sale by or on order of a physician. PI-992004-AA. **Note:** Dose to the liver does not exceed 150 Gy.

Peripheral Interventions

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www.bostonscientific.com

To order product or for more information
contact customer service at 1.888.272.1001.

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