April 22, 2024

Vartanian Medical PLLC (d/b/a Precision IR) Medical Event Summary
RAML#21-35697-01
Date of event: 4/9/2024
NRC report #57069
Report prepared by: Jonathan Olsen, MD - RSO

84-year-old male with hepatocellular carcinoma previously treated with open ablation presented with recurrent enhancement in the previous ablation cavity, as well as a new enhancing mass adjacent to the cavity, both with imaging characteristics consistent with hepatocellular carcinoma. The new mass is supplied by branches of the right hepatic artery, while the region of recurrent enhancement of the prior ablation cavity was supplied by a small extra-hepatic branch of the right adrenal artery.

The region of recurrent enhancement in the ablation cavity measured 25cc in total without perfusion of normal liver parenchyma. Assuming a 3 GBq dose of TheraSphere Yttrium-90 was ordered with a calibration date and time of 4/7/2024 12:00pm, the target region would receive 1.805 GBq (3014 Gy) during the delivery at 11:00 am 4/9/2024. An extended shelf dose with calibration date of 3/30/2024 was not utilized for concern of stasis due to excessive number of embolic spheres in the small perfusion volume.

During the delivery procedure, a 2.4F Terumo Progreat microcatheter was selected, instead of the larger 2.8F Progreat microcatheter due to concerns of stasis due to catheter induced vasospasm or occlusion. The 2.4F catheter was positioned in the desired location, confirmed with digital subtraction angiography and C-arm CT. The vessel was patent without reflux during imaging. Reflux was achieved with more aggressive flushing, confirming absence of vasospasm and/or catheter induced vessel occlusion.

Infusion of the dose began at 12:40pm. There was expected increased resistance to flushing of the catheter due to the smaller inner diameter of the 2.4F catheter, compared to the larger 2.8F catheter. No leaks were present within the acrylic delivery box or at the connection of the delivery tubing with the microcatheter. 3 complete flushes of the 20cc syringe were performed.

The microcatheter was removed without incident at the completion of the administration. There was no evidence of contamination within the delivery box, at the vascular access site, on the floor near the angiography table, or on the operator's apparel.

Utilizing the post-treatment template measurements on the waste container, it was calculated that 72.9% of the prescribed dose was delivered to the patient. The measurements were repeated, confirming the initial calculation. 72.9% of the prescribed

1.805GBq (3014 Gy to the target volume) results in 1.315GBq (2196.7 Gy to the target volume).

Discussion with the operator after the case revealed that while the syringe was more difficult to flush compared to the standard microcatheter size, at no point did it feel occluded, and it continued to flush forward. It is felt the delivery was below 80% of the prescribed dose is due to the combination of the smaller microcatheter, small perfusion volume, and small feeding artery with slow flow.

The dose delivered was still therapeutic and is expected to achieve the intended results. There was no leak of the TheraSphere during infusion or harm delivered to the patient.

These findings, including the delivery of Y90 under 80% necessitating the medical event report, were discussed with the patient's referring provider, Jeffrey Margolis, MD. It was decided that there was no harm to the patient and the intended therapeutic result was still achieved. Therefore, the patient was not notified of this event.

Please see the attached written directive for reference. If there is any other information that my office can provide, please do not hesitate to ask.

Sincerely,

S. Andrew Vartanian MD
Medical Director, Radiation Safety Officer
Vartanian Medical PLLC d/b/a PrecisionIR

# TheraSphere® Y-90 Glass Microspheres Written Directive

| Patient Name | | | Patient ID / MRN | |
|---|---|---|---|---|
| **Pre-Treatment Planning** | *This section must be approved by the Authorized User.* | | | |
| Target Tissue (Treatment site) | Right Lobe | | Lung Shunt Fraction (%LSF) | 14.00% |
| Target Volume (cc) | 25 | | Cumulative Previous Dose to the Lungs (Gy) | 0.00 |
| Mass (kg) | 0.026 | Package insert states therapeutic range is 80 - 150 Gy. | Contract Manufacturer: Nordion | Device: Y-90 TheraSphere |
| Desired Dose to Target Volume (Gy) | 3014 | | | |
| Treatment date and time | Tue, Apr 09, 2024 11:00 AM | | Required Total Activity at time of Treatment (GBq) | 1.805 |
| Time zone of Hospital | Eastern Standard Time (EST) | | Number of vials to be administered to Target Tissue | 1 |
| | | Dose Vial A: | | |
| Ordered/Received Dose Size (GBq) | | 3.0 | | |
| Calibration Date | | Sunday, April 7, 2024 | | |
| Hours from Calibration to Treatment (hrs) | | 47.0 | | |
| Nominal Activity in Vial at time of Treatment (GBq) | | 1.805 | | |
| Sum of Nominal Activity in Vial(s) at time of Treatment (GBq) | | | 1.805 | |
| Calculated dose to lungs at Treatment time, assuming 1kg lungs (Gy) | | 12.6 | Cumulative dose to lungs (Gy) | 12.63 |
| Dose to Target Volume at Treatment, accounting for lung shunt (Gy) | | 3014 | Authorized User signature & date | |

| **Pre-treatment Dose Calibrator (DC) Measurement** | *Measure the received dose vial(s) in a dose calibrator using TheraSphere setting and correction factor* | | |
|---|---|---|---|
| | Dose Vial A: 3 GBq | | |
| Manufacturer's Lot Number and Vial Number | 2499166 #8 | | |
| Date and Time of DC measurement | Sun, Apr 07, 2024 12:00 PM | | |
| DC Measured Activity, with correction factor (GBq) | 3.050 | | |
| Hours from Calibration to DC Measurement (hrs) | 0.00 | | |
| DC Measured Activity referenced to Calibration time (GBq) | 3.05 | | |
| OPTIONAL: Manufacturer's Activity at Calibration (GBq) | | | |
| Value to be used in Delivery calculations below: | | Measured by (initials): | |

| **Pre-treatment Template Measurement** | *Measure the dose vial (no lead pot) @ 30 cm with ion chamber meter on Template* | | |
|---|---|---|---|
| | Dose Vial A: 3 GBq | | |
| Date and Time of Template measurement | Tue, Apr 09, 2024 10:40 AM | | |
| Measurement of Dose vial on Template (mR/h) | 8.000 | | |
| Background Measurement (mR/h) | 0.020 | | |
| Net dose rate of Dose vial on Template (mR/h) | 7.980 | | |
| | | Measured by (initials): | |

| **Treatment / Administration** | Treatment proceeded as planned | | |
|---|---|---|---|
| Methods used to confirm Patient Identity (select two) | [X] NAME | [X] Birth Date | |
| | Dose Vial A: 3 GBq | | |
| Confirm Lot number and Vial number (on label) matches Line 23 above | ☑ Check if Lot # & Vial # match | ☐ Check if Lot # & Vial # match | ☐ Check if Lot # & Vial # match |
| Administration Start Date & Time | Tue, Apr 09, 2024 12:40 PM | | |
| Patient dose rate, maximum on contact (mR/h) | 4 | Measured by (initials): | |
| Patient dose rate, maximum at 1 meter (mR/h) | 0.5 | | |
| AU / ADMINISTERING PHYSICIAN comments (sign & date): ☐ None | Extremely small artery supplying a small volume with slow flow with a small catheter. There is no spill. | | |

| **Post-treatment Template measurements** | *Measure the waste jar in beta shield @ 30 cm with ion chamber meter on Template* | | |
|---|---|---|---|
| | Waste Jar - Vial A | | |
| Date and Time of Template measurement | Tue, Apr 09, 2024 1:45 PM | | |
| Waste Container Measurement in Beta shield (mR/h), 4 Cylinder Orientations on Template — Background Measurement (mR/h) | 0.010 | | |
| 0° | 2.200 | | |
| 90° | 2.800 | | |
| 180° | 1.700 | | |
| 270° | 1.300 | | |
| Average of 4 Orientations minus Background (mR/h) | 1.990 | | |
| Hours between Pre- and Post- Treatment Measures (hrs) | 3.1 | | |
| Pre-Treatment Net Rate decayed to Post- Treat time (mR/h) | 7.716 | | |
| Percent delivery per Vial (%) | 74.2% | | |
| Hours between Calibration and Treatment (hrs) | 48.7 | | |
| Activity Administered per Vial at time of Treatment (GBq) | 1.315 | | |
| Ratio: Actual Radiation Dose to Target Tissue vs. Desired Dose | 72.9% | Measured by (initials): | |

| **Final Calculations** | *Calculated values below use formulas from the TheraSphere package insert. The AU must confirm accuracy* | | |
|---|---|---|---|
| Total Activity Delivered to Patient at time of Treatment (GBq) | 1.315 | Lung shunt fraction (%) | 14.0% |
| (mCi) | 35.5 | Activity to Lungs (GBq) | 0.184 |
| Activity Delivered to Perfused Liver Tissue (GBq) | 1.13 | (mCi) | 4.97 |
| (mCi) | 30.5 | Radiation to Lungs (Gy) | 9.21 |
| Radiation dose to Perfused Liver Tissue (Gy) | 2198.7 | Cumulative radiation to Lungs (Gy) | 9.21 |
| Physicist/RSO/CNMT signature & date | 4/9/24 | Authorized User signature & date | 4/8/24 |