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Post-treatment Exposure Rates for 90Y Microsphere Patients: A Comparison of Products

Steven Blum[1], Eugenio Silvestrini[2,3], Jonathan Weinstein[4], Craig Greben[4]

1 Hofstra University, Hempstead, NY, USA

2 Department of Radiology, Radiation Safety, Northwell Health, Manhasset, NY, USA

3 Department of Physics and Astronomy, Hofstra University, Hempstead, NY, USA

4 Northwell Health, Donald and Barbara Zucker School of Medicine, Hofstra University, Hempstead, NY, USA

Abstract

There has been a significant increase in the use of yttrium-90 microspheres in treating liver malignancies. This increase can be seen over the last 30 years, and FDA approval of two products- SiRTeX SIR-Spheres and Boston Scientific TheraSpheres- has helped in the proliferation of these treatments. As the increase in use of both products rose- which is true at our institution- there was a need to determine if there should be special considerations for patients who receive one product compared to patients who receive the other product. This was investigated by measuring exposure rates for several regions of the patient before and after implantation. An independent samples t-test analysis (α=0.05) was performed for a total of 50 patients (25 TheraSphere and 25 SIR-Spheres) to determine if the products behaved similarly to the extent that exposure to others is minimized and ALARA principles were kept. The results showed that the products exhibit no significant differences in terms of exposure rates, which suggests that there is no need for unique aspects of one procedure for one product compared to the other.

Key Words: Yttrium-90, 90Y, 90Y microspheres, TheraSphere, SIR-Spheres

Introduction

Yttrium-90 (90Y) microspheres have found a useful role in therapeutic treatments of liver tumors, especially hepatocellular carcinoma (HCC). The procedure can be classified as radioembolization in which both radiation and embolization, by blocking the tumor vascularization, help to destroy the cancer cells. 90Y radioembolization has been used and studied since the 1960s and has only seen improvements in both technique and efficacy since (*1*). Today, two products are commonly used: SiRTeX SIR Spheres and Boston Scientific TheraSpheres.

While the treatment site is in the liver, some spheres will end up in the lungs, due to lung shunting. The percent lung shunting is determined by a pre-treatment 99mTc macroaggregated albumin (*2*, *3*). This is a critical step of the treatment since the cumulative dose cannot exceed 50 Gy, or for a single administration, 30 Gy. To aid in ensuring the minimization of exposure to others, a patient release criterion is needed. For our institution, we use the exposure rate at 1 meter from the torso, which must be less than 2 mR h^{-1}.

The program in 90Y microsphere therapy at our institution began in late 2019. As of December 2021, there have been more than 60 patients who have received 90Y microsphere therapy, with either SIR-Spheres or TheraSpheres. These products have physical differences, such as diameter, material of sphere, and where the 90Y is (SIR-Spheres coat the sphere in 90Y, TheraSphere embeds the 90Y into the sphere). The differences have been well documented (*2*). Typical doses prescribed for a 90Y microsphere treatment are on the order of 50 to 150 Gy, but some studies have investigated the use of higher doses, reaching 3,000 Gy (*4*, *5*). The goal of this

investigation was to determine if the physical differences between these two products were significant to the extent where there would be a need to implement a new end-to-end procedure for one product compared to the other, and to ascertain whether a higher prescribed dose would also necessitate a new protocol for this treatment.

Methods and Materials

Patients were surveyed before and after the implant using a calibrated Fluke 451B survey meter, with the window opened (calibration date: September 20, 2021). The regions measured were the liver and lungs at the surface of the patient, and the reading at 1 meter from the torso was also measured. The readings for 50 patients are reported in this study (n=25 for TheraSphere and n=25 for SIR-Spheres). Once data was collected, an independent samples t-test analysis was performed ($\alpha=0.05$) for the average readings for each of the aforementioned regions.

Results

Figures 1, 2 and 3 show how the exposure rates changed over time and between the two products for the liver surface readings, the lung surface readings, and the readings at 1 meter from the torso, respectively. Figure 4 shows the exposure rates for both liver and lungs at surface for both SIR-Spheres and for TheraSphere. Table 1 displays the numerical values for the average and maximum exposure rates for these regions.

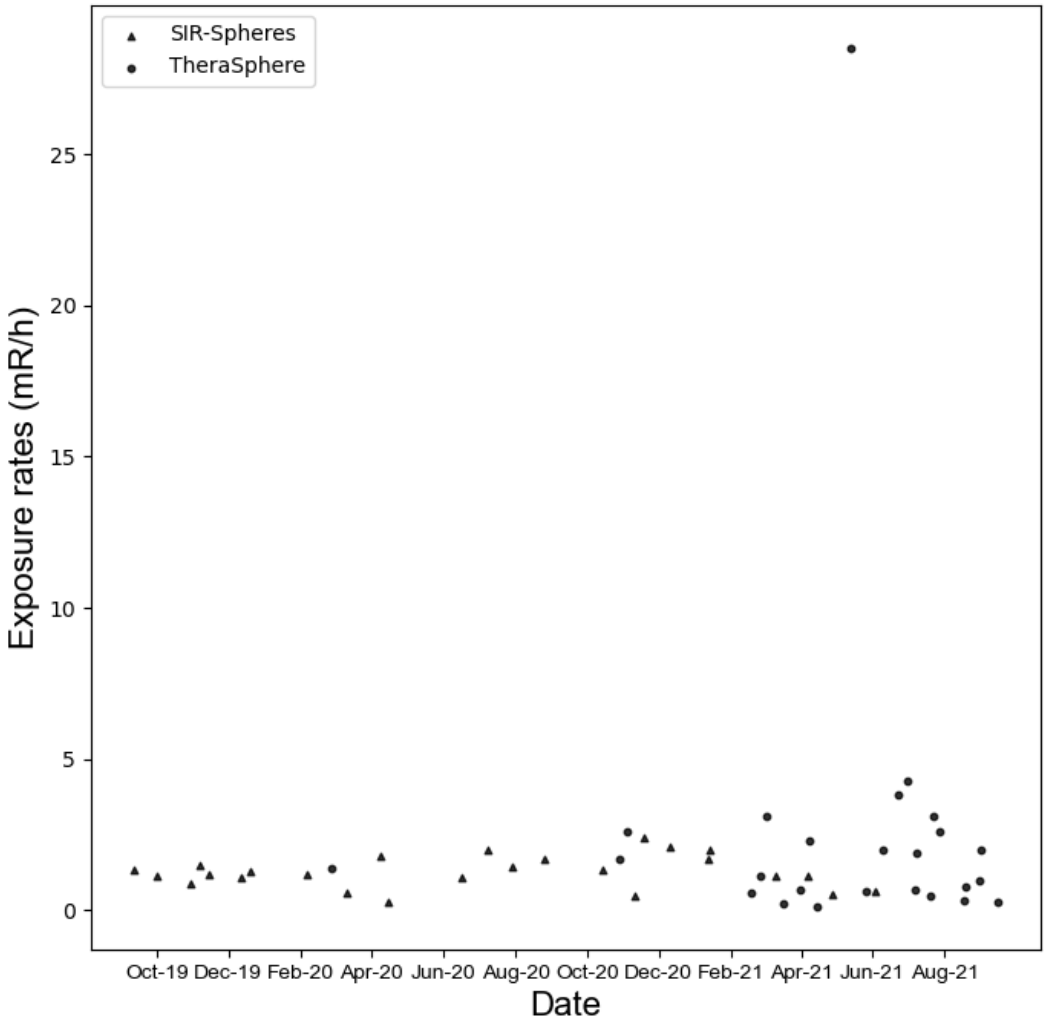

Fig. 1. Liver exposure rates at the surface of the patient's body between SIR-Spheres and TheraSphere over time.

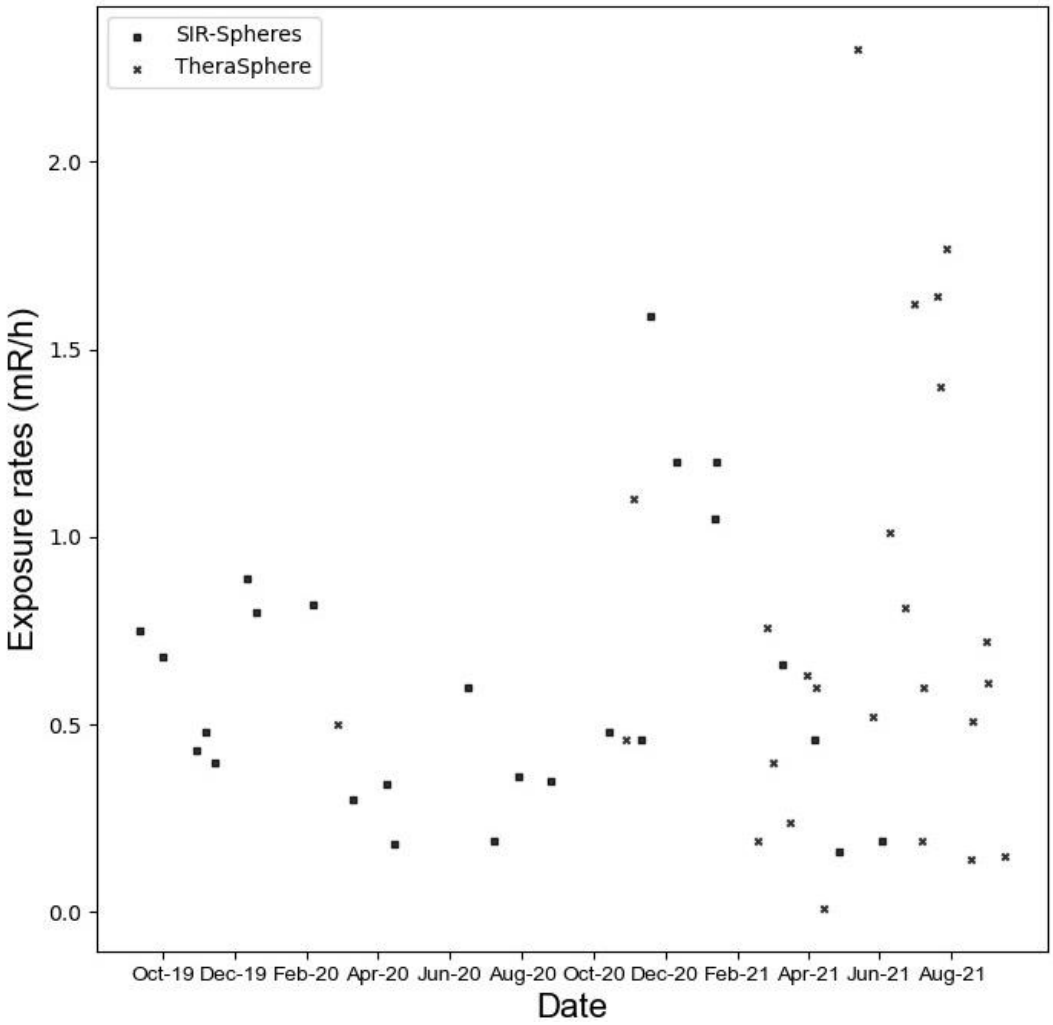

Fig. 2. Lung exposure rates at the surface of the patient's body between SIR-Spheres and TheraSphere over time.

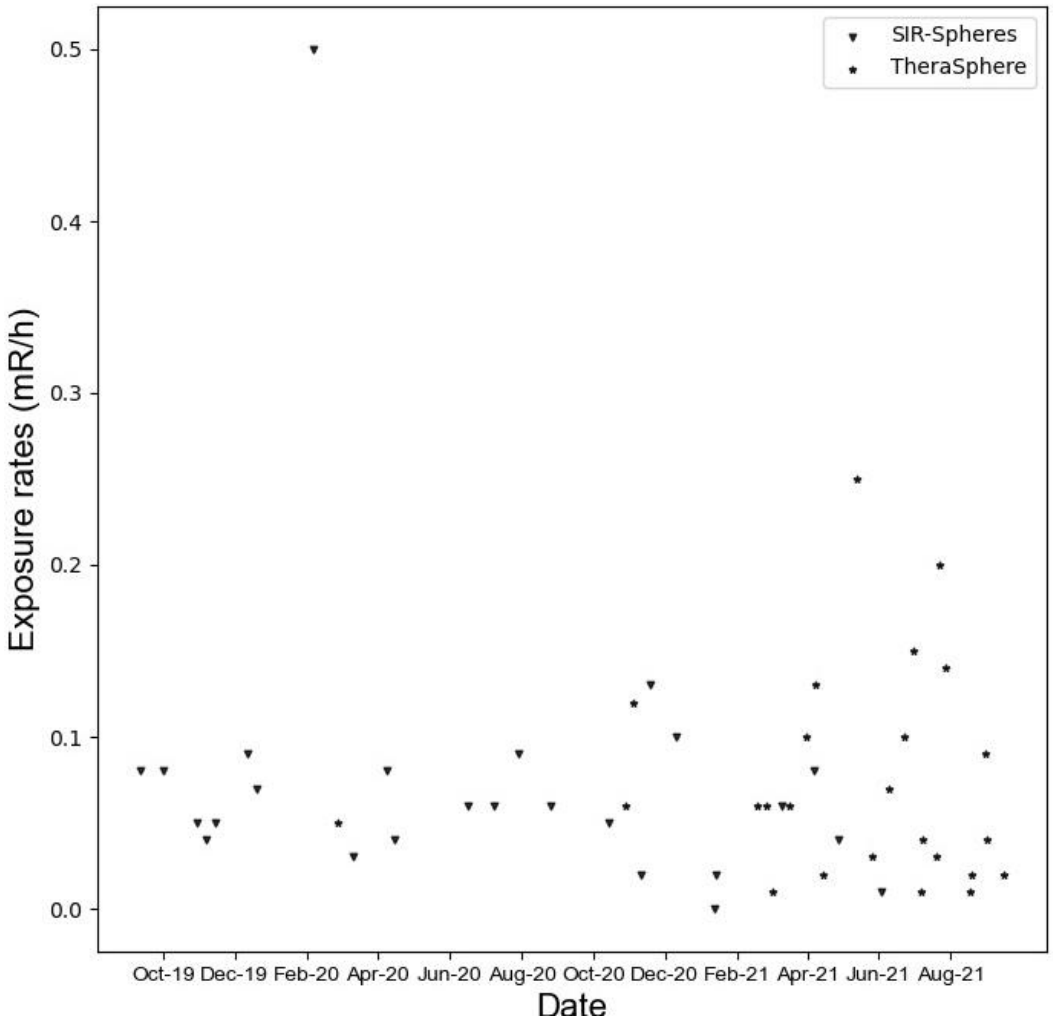

Fig. 3. Exposure rates at 1 meter from torso between SIR-Spheres and TheraSphere over time.

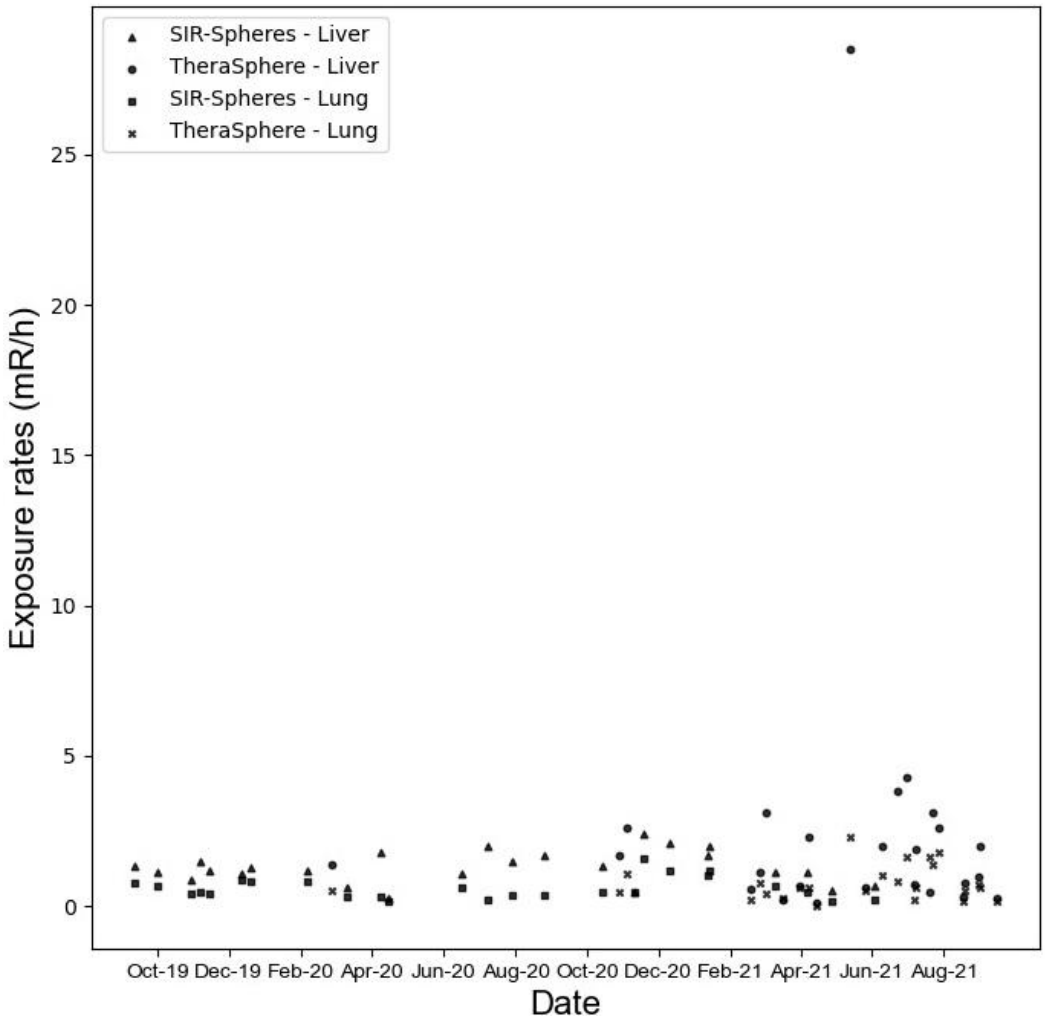

Fig. 4. Exposure rates at surface for lungs and liver differentiated by either SIR-Spheres or TheraSpheres over time.

Table 1. Exposure rates for regions of interest for 50 patients split by product received.

Device	TheraSphere (n=25)		SIR-Spheres (n=25)	
Site (for organs, surface readings were recorded)	Average Reading (mR/h)	Maximum Reading (mR/h)	Average Reading (mR/h)	Maximum Reading (mR/h)
Liver	2.65	28.50	1.23	2.39
Lungs	0.76	2.30	0.56	1.59
1 m from torso	0.07	0.20	0.07	0.50

Discussion

The measured exposure rates between the two products were consistent regardless of region measured. One aspect to note is the discrepancy between the liver readings for TheraSphere and for SIR-Spheres. With TheraSphere, the assumed activity per sphere is higher than in SIR-Spheres, and the dose is delivered in single compartment dosing (*6*, *7*). This means that a higher tumor dose can be delivered via TheraSphere than SIR-Spheres using the same number of spheres. As a result, there should be a higher maximum exposure rate and the average exposure rate would also increase. In addition, a higher dose administered will also increase the maximum exposure rate and average exposure rate. At our institution, these higher doses are typically delivered via TheraSphere. For one patient, the administered activity was 11.5 GBq TheraSphere vial (first week calibration), which is the highest activity to date. In addition, it is likely that the perfuse volume was more anterior, which can explain why the maximum exposure rate is much higher than that for SIR-Spheres.

The regions reported in Table 1 were chosen for their importance in the procedure. The liver and lungs were chosen since these are critical structures in this process, and the liver is also the organ containing our target volume. These regions were read at surface to get the highest possible reading which would be as close to the true value (if the survey meter was in direct contact with the structure). The reading at 1 meter from torso is used as the release criteria. There are no specified values for 90Y therapy according to US Nuclear Regulatory Commission Regulatory Guide 8.39 (*8*). At our institution, the release criteria is 2 mR/h at 1 meter. This value corresponds to the release criteria for iodine therapy at our institution, which itself is related to Table 2 of Regulatory Guide 8.39 from the NRC (*8*) and was chosen to keep the release criteria consistent among therapies at our institution. To this date, no patient has reached this maximum.

A qualitative analysis was performed by visual inspection of the graphs in Figures 1, 2, 3, and 4. This gave the impression that the exposure rates between the products was very similar by trending the readings over time. However, a more concrete analysis was conducted by an independent samples t-test. The results confirmed that the two products are not statistically different ($p<0.05$).

Conclusion

A quantitative analysis was performed between two 90Y microsphere products at one institution for patients with HCC. The results showed that these products were not statistically different in terms of the exposure rates measured at the surface of the patient's body for the liver and for the lungs, as well as at 1 meter from the torso. From

a radiation safety point of view, it was found that there is no need for special considerations for one product compared to the other for factors such as release criteria, post-treatment shielding, or even steps in the implant procedures. Therefore, this research has shown that these two 90Y products are similar and no special considerations is needed for patients using either product.

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Key Points

- As higher doses are being delivered via 90Y microspheres, are the two 90Y microsphere products similar or different enough where special considerations are needed when using one product as compared to the other?
- This study found that both SIR-Spheres and TheraSpheres result in post-treatment patient exposure rates for surface readings at the liver and at the lungs as well as exposure rates at 1 meter from the torso which are not statistically different from one another.
- Since the two 90Y products are similar, there is no need to amend a current protocol when using one product or the other.

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