Posttreatment Exposure Rates for ^{90}Y-Microsphere Patients: A Comparison of Products

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There has been a significant increase in the use of ^{90}Y-microspheres in treating liver malignancies. This increase could be seen over the last 30 y, and Food and Drug Administration approval of 2 products—Sirtex SIR-Spheres and Boston Scientific TheraSphere—has helped in the proliferation of these treatments. As the increase in use of both products rose at our institution, there was a need to determine whether there should be special considerations for patients who receive one product compared with patients who receive the other product. This determination was made by measuring exposure rates for several regions of the patient before and after implantation. An independent-samples *t* test analysis ($\alpha = 0.05$) was performed for 50 patients (25 TheraSphere and 25 SIR-Spheres) to determine whether the products behaved similarly to the extent that exposure to others was minimized and that as-low-as-reasonably-achievable principles were kept. The results showed that the products exhibited no significant differences in exposure rates, suggesting that no special considerations are needed for the procedure for one product compared with the other.

Key Words: yttrium-90; ^{90}Y; ^{90}Y-microspheres; TheraSphere; SIR-Spheres

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In the treatment of liver tumors, especially hepatocellular carcinoma, ^{90}Y-microspheres have found a useful role. The procedure can be classified as radioembolization, a process that uses both radiation and embolization to block the tumor vascularization, thereby helping to destroy the cancer cells. ^{90}Y radioembolization has been used and studied since the 1960s and has seen improvements in both technique and efficacy since that time (*1*). Today, 2 products are commonly used: SiRTeX SIR Spheres and Boston Scientific TheraSphere.

Although the treatment site is in the liver, some spheres will end up in the lungs because of lung shunting. The percentage of lung shunting is determined by a pretreatment ^{99m}Tc-macroaggregated albumin (*2,3*). This is a critical step, since the cumulative dose cannot exceed 50 Gy or, for a single administration, 30 Gy. To help minimize exposure of others, a patient release criterion is needed. The criterion at our institution is an exposure rate of less than 2 mR h^{-1} at 1 m from the torso.

The program in ^{90}Y-microsphere therapy at our institution began in late 2019. As of December 2021, there had been more than 60 patients who received ^{90}Y-microsphere therapy with either SIR-Spheres or TheraSphere. These products have physical differences, such as in diameter, the material of the sphere, and where the ^{90}Y is located (SIR-Spheres coat the sphere in ^{90}Y; TheraSphere embeds the ^{90}Y into the sphere). The differences have been well documented (*2*). Typical doses prescribed for a ^{90}Y-microsphere treatment are on the order of 50–150 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 whether the physical differences between these 2 products were significant enough to require a new end-to-end procedure for one product compared with the other. Another goal was to ascertain whether a higher prescribed dose would also require a new protocol for this treatment.

MATERIALS AND METHODS

Fifty patients ($n = 25$ for TheraSphere and $n = 25$ for SIR-Spheres) were surveyed before and after the implantation 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 m from the torso was also measured. Once the data were collected, an independent-samples *t* test analysis was performed ($\alpha = 0.05$) for the average readings for each region.

RESULTS

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

DISCUSSION

The measured exposure rates between the 2 products were consistent regardless of region measured. There was a

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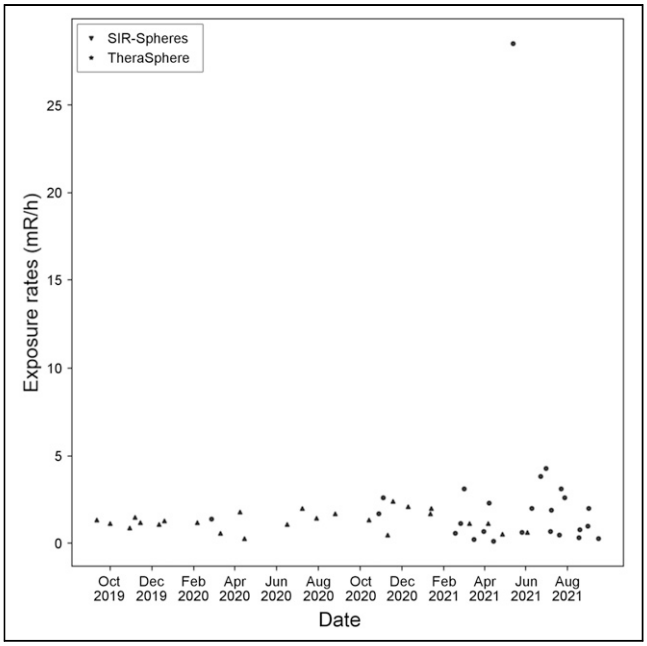

FIGURE 1. Liver exposure rates at surface of patient's body between SIR-Spheres and TheraSphere over time.

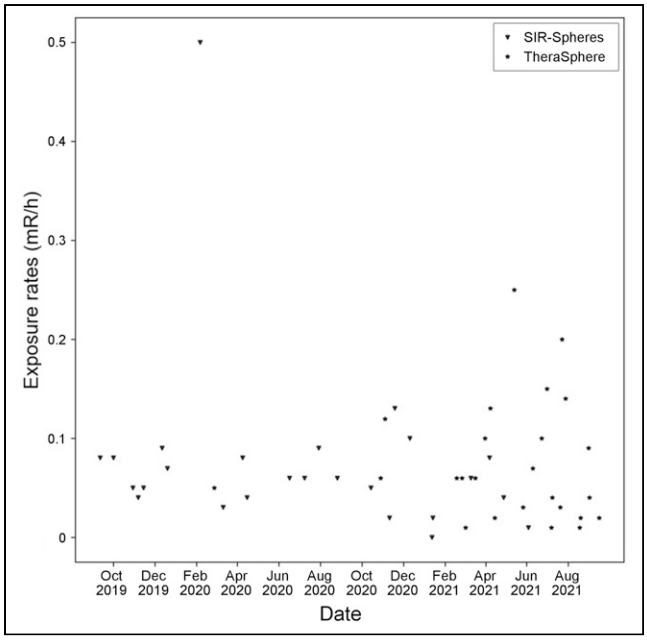

FIGURE 3. Exposure rates at 1 m from torso between SIR-Spheres and TheraSphere over time.

discrepancy between the liver readings for TheraSphere and for SIR-Spheres. With TheraSphere, the assumed activity per sphere was higher than with SIR-Spheres, and the dose was 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 1 patient, the administered activity was a 11.5-GBq TheraSphere vial (first-week calibration), which is the highest activity to date. In addition, it is likely that the perfusion volume was more anterior, which can explain why the maximum exposure rate was 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

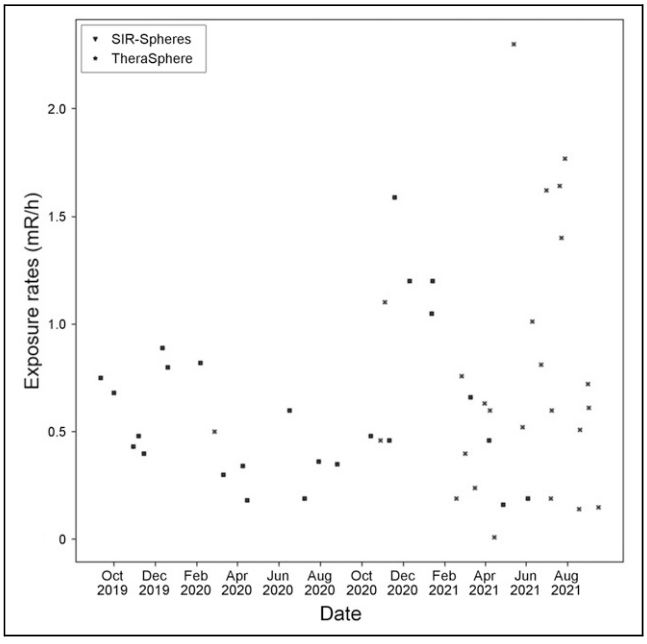

FIGURE 2. Lung exposure rates at surface of patient's body between SIR-Spheres and TheraSphere over time.

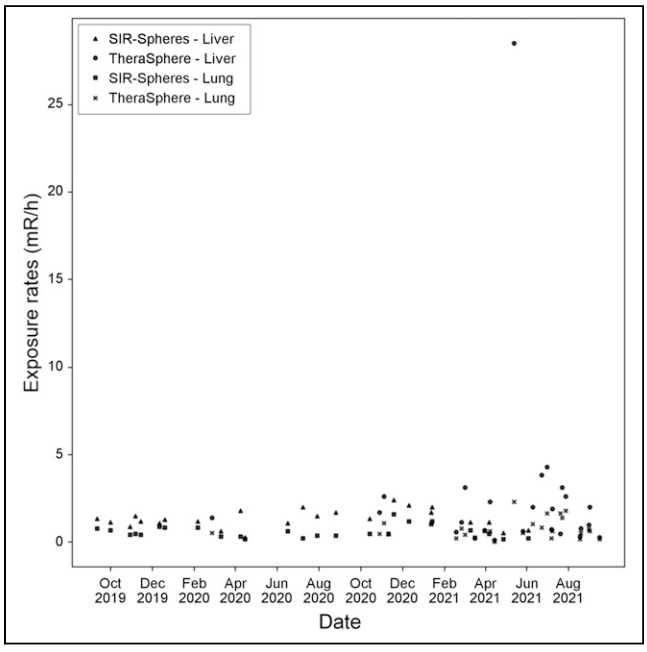

FIGURE 4. Exposure rates at surface for lungs and liver differentiated by either SIR-Spheres or TheraSphere over time.

TABLE 1
Exposure Rates for Regions of Interest for 50 Patients Split by Product Received

	TheraSphere (n = 25)		SIR-Spheres (n = 25)	
Site*	Average reading	Maximum reading	Average reading	Maximum reading
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

*For organs, surface readings were recorded.
Data are mR/h.

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 the surface to get the highest possible reading, which would be as close to the true value (if the survey meter were in direct contact with the structure) as possible. The reading at 1 m from the torso was used as the release criterion. There are no specified values for ^{90}Y therapy according to U.S. Nuclear Regulatory Commission Regulatory Guide 8.39 (*8*). At our institution, the release criterion is 2 mR/h at 1 m. This value corresponds to the release criterion for iodine therapy at our institution, which itself is related to Table 2 of Regulatory Guide 8.39 from the U.S. Nuclear Regulatory Commission (*8*) and was chosen to keep the release criterion consistent among therapies at our institution. To date, no patient has reached this maximum.

A qualitative analysis was performed by visual inspection of the graphs in Figures 1–4. This gave the impression that the exposure rates between the products were 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 2 products are not significantly different ($P < 0.05$).

CONCLUSION

A quantitative analysis was performed between 2 ^{90}Y-microsphere products at 1 institution for patients with hepatocellular carcinoma. The results showed that these products were not significantly different in terms of the exposure rates measured at the surface of the patient's body for the liver and for the lungs or at 1 m from the torso. From a radiation safety point of view, there is no need to use special considerations for one product compared with the other for factors such as release criteria, posttreatment shielding, or even steps in the implantation procedures.

DISCLOSURE

No potential conflict of interest relevant to this article was reported.

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KEY POINTS

QUESTION: Are SIR-Spheres and TheraSphere different enough to require special considerations when one product is used as opposed to the other?

PERTINENT FINDINGS: SIR-Spheres and TheraSphere resulted in non–significantly different posttreatment patient exposure rates for surface readings at the liver and the lungs, as well as at 1 m from the torso.

IMPLICATIONS FOR PATIENT CARE: Since the 2 ^{90}Y products are similar, there is no need to amend a current protocol when using one product or the other.

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