



THERASPHERE™ Y-90 Glass Microspheres | OCHSNER TUMOR DOSE ANALYSIS

New TheraSphere™ analysis: Durable, reproducible outcomes demonstrated with high dose and high radiation per microsphere (RPM).¹

Single-center data builds on previously published radiation segmentectomy studies (LEGACY² and RASER³) to demonstrate consistent outcomes with days 3-9 post-calibration.

Sandow T, Gimenez J, Nunez K, Tramel R, Gilbert P, Oliver B, Cline M, Fowers K, Cohen A, Thevenot P. Using Voxel-based Dosimetry to evaluate sphere concentration and tumor dose in Hepatocellular Carcinoma treated with Y-90 Radiation Segmentectomy with glass microspheres, Journal of Vascular and Interventional Radiology (2024), doi: <https://doi.org/10.1016/j.jvir.2024.05.020>.

OVERVIEW

Retrospective, single-center analysis of solitary HCC patients (n=56) treated with TheraSphere Y-90 Glass Microspheres.

OBJECTIVE

Explore the relationship between microsphere deposition and distribution and various outcomes following radiation segmentectomy; validate current literature regarding efficacy, pathologic outcomes and adverse events.

ANALYSIS DESIGN/METHODS

Post-treatment voxel-based dosimetry was evaluated using Simplicit90Y™ software and utilized to calculate sphere concentration to tumor. Time to progression (TTP), treatment response, pathologic response, and adverse events were studied.

RESULTS: STRONG RADIOLOGIC AND PATHOLOGIC OUTCOMES ACHIEVED IN RADIATION SEGMENTECTOMY WITH ABLATIVE DOSING AND HIGH RADIATION PER MICROSPHERE

474 Gy

(177-1,290)

Median targeted dose to perfused volume

732 Gy

(252-1,776)

Median Tumor Absorbed Dose

1,446 Bq

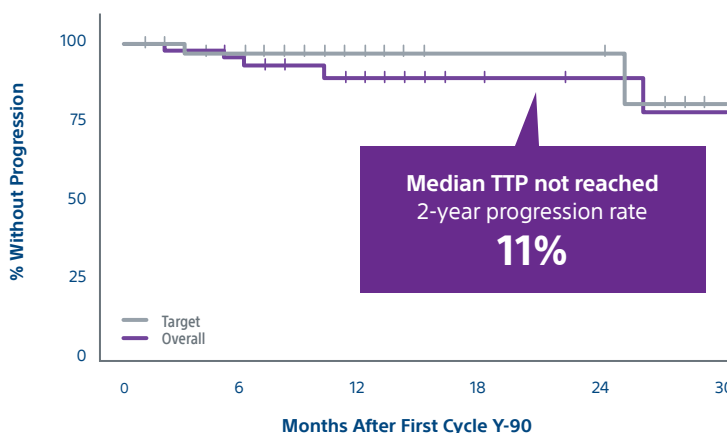
Day 4 post-calibration

(217-2,621)

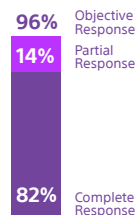
Median RPM and Treatment Day

Duration of Response and Response Rates in line with LEGACY² and RASER³ TheraSphere Radiation Segmentectomy Data

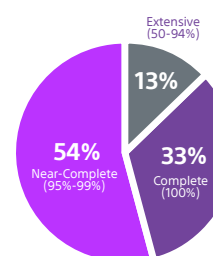
97% DURABLE RESPONSE AT 2 YEARS



STRONG ORR RESULTS n=51 (Targeted mRECIST)



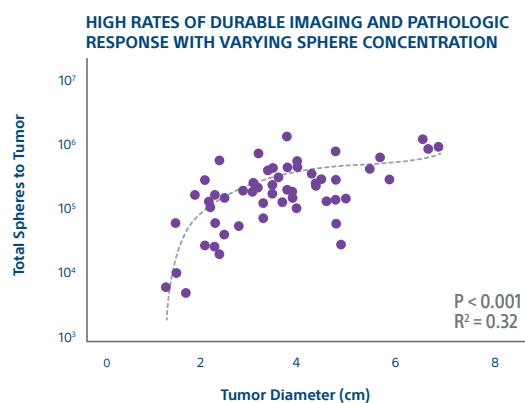
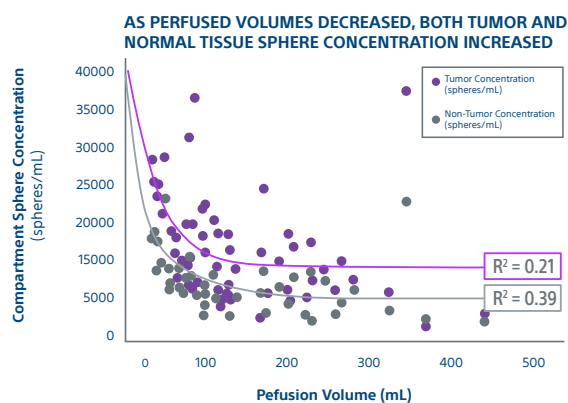
HIGH DEGREE OF NECROSIS ACHIEVED



99%

Median Target Tumor Necrosis in the 15 patients that received liver transplant

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83%
of patients
had a tumor
sphere
concentration
< 20,000
spheres/mL

Despite tumor heterogeneity, high RPM (day 9 post-calibration or earlier) can achieve:

- Reproducible high rates of complete radiologic response
- Durable tumor control
- Pathologic necrosis

ADVERSE EVENTS

Ablative radiation segmentectomy with high radiation per microsphere is well-tolerated with limited AEs in patients with preserved liver function.

0

Grade ≥ 3 AEs at 60 day follow up

2

Grade ≥ 3 AEs* at 180 day follow up

*Platelet count decrease

PATIENT CHARACTERISTICS

All patients in this analysis recieved radiation segmentectomies.

PATIENT DEMOGRAPHICS AND BASELINE CHARACTERISTICS			
GENERAL DEMOGRAPHICS		n=56	
Age at HCC Diagnosis (years), median (range)		66 (42-73)	
Sex, total male (%)		44 (79)	
Race, total (%)			
Caucasian/White		39 (70)	
African American/Black		13 (23)	
Other		4 (7)	
HCC BASELINE		CIRRHOSIS BACKGROUND	
Surgical Track, total (%)		Etiology, total (%)	
Transplant Track		HCV	
HCC BURDEN, total (%)		32 (57)	
Solitary		NASH	
Index HCC Diameter (cm), median (range)		10 (18)	
TRANSPLANT CRITERIA AT DIAGNOSIS, total (%)		HCV + ALD	
Milan		7 (13)	
UNOS-DS		ALD	
AFP (ng/mL), median (IQR)		4 (7)	
		Other	
		3 (5)	
		CHILD PUGH, total (%)	
		A5	
		22 (39)	
		A6	
		14 (25)	
		B7	
		11 (20)	
		B8-B9	
		9 (16)	
		ALBI GRADE	
		Grade 1	
		16 (29)	
		Grade 2	
		36 (64)	
		Grade 3	
		4 (7)	
		MELD COMPONENT and MELD, median (IQR)	
		MELD-Na	
		9 (7-12)	
		MELD 3.0	
		10 (7-13)	

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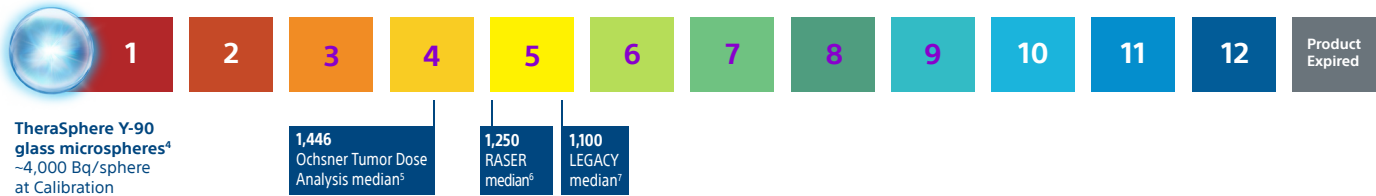
CONCLUSION

Ablative dosing for radiation segmentectomy with high RPM yields durable radiologic and pathologic outcomes with limited adverse events. The study further supports contemporary radiation segmentectomy techniques by targeting doses greater than 400 Gy to the perfused volume and treating within recommended treatment timeframe days 3-9 post-calibration. This approach optimizes radiation per microsphere and allows more critical hits in the “coldest” areas of the tumor, maximizing tumor dose coverage.

Analysis further supports results from previously published landmark trials by following Dosimetry Steering Committee Guidelines

Days post-calibration*

Dosimetry Steering Committee recommended treatment days⁸



*Days post-calibration refers to the number of days a TheraSphere vial has decayed since calibration (Sunday or Thursday).

	LEGACY (n=162)	RASER (n=29)	OCHSNER (n=56)
PATIENT/TUMOR CHARACTERISTICS			
BCLC	A (60.5%), C (39.5%)	A (100%)	O/A (100%)
CHILD PUGH	A5 (66.7%), A6 (33.3%)	A5 (48%), A6 (41%), B7 (10%)	A5 (39%), A6 (25%), B7 (20%), B8-B9 (16%)
MEDIAN PERFUSED VOLUME	155.0 mL (19 - 1,363)	153.6 mL (Mean)	141.0 mL (43 - 325)
MEDIAN TUMOR SIZE	2.7 cm (1.0 - 8.1)	2.1 cm (Mean)	3.4 cm (1.2 - 6.8)
MEDIAN DOSE TO PERFUSED VOLUME	410.1 Gy (70 – 2980)	584 Gy (181 – 3340)	474 Gy (177 – 1290)
OUTCOMES			
MEDIAN TIME TO PROGRESSION	NR (2 years)	NR (2 years)	NR (2 years)
OBJECTIVE RESPONSE RATE	88.3% (84% CR) Localized mRECIST	100% (90% CR) mRECIST	96% (82% CR) Localized mRECIST
DURATION OF REPONSE	76.1% (≥ 6 months)	635 Days (Median)	97% (2 years)

1. Radiation per microsphere (RPM) is a number that refers to the specific activity (SA) of a microsphere (Bq/Sphere). 2. Salem R, Johnson GE, Kim E, Riaz A, Bishay V, Boucher E, Fowers K, Lewandowski R, Padia SA. Yttrium-90 Radioembolization for the Treatment of Solitary, Unresectable Hepatocellular Carcinoma: The LEGACY Study. *Hepatology*. 2021 Mar 19; doi: 10.1002/hep.31819. 3. Kim E, Sher A, Abboud G, et al. Radiation segmentectomy for curative intent of unresectable very early to early stage hepatocellular carcinoma (RASER): a single-centre, single-arm study [published online ahead of print, 2022 May 23]. *Lancet Gastroenterol Hepatol*. 2022;S2468-1253(22)00091-7. doi:10.1016/S2468-1253(22)00091-7. 4. Radiation per microsphere (RPM) is a number that refers to the specific activity (SA) of a microsphere (Bq/Sphere). The RPM for TheraSphere is calculated based on targeted values and process means. Actual RPM can vary between microspheres. All numbers as of Noon Eastern Time. Ref Technical Report 9/124387. 5. Sandoz T, Gimenez J, Nunez K, Tarnel R, Gilbert P, Oliver B, Cline M, Fowers K, Cohen A, Therasen P. Using Voxel-based Dosimetry to evaluate sphere concentration and tumor dose in Hepatocellular Carcinoma treated with Y-90 Radiation Segmentectomy with glass microspheres. *Journal of Vascular and Interventional Radiology* (2024). doi: https://doi.org/10.1016/j.jvir.2024.05.020. 6. TheraSphere™ Y-90 Glass Microspheres RASER Study. Data on file. 7. TheraSphere™ Y-90 Glass Microspheres LEGACY Study. Data on file. 8. Salem, R., Padia, S.A., Lam, M. et al. Clinical, dosimetric, and reporting considerations for Y-90 glass microspheres in hepatocellular carcinoma: updated 2022 recommendations from an international multidisciplinary working group. *Eur J Nucl Med Mol Imaging* 50, 328–343 (2023). https://doi.org/10.1007/s00259-022-05956-w

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