



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.

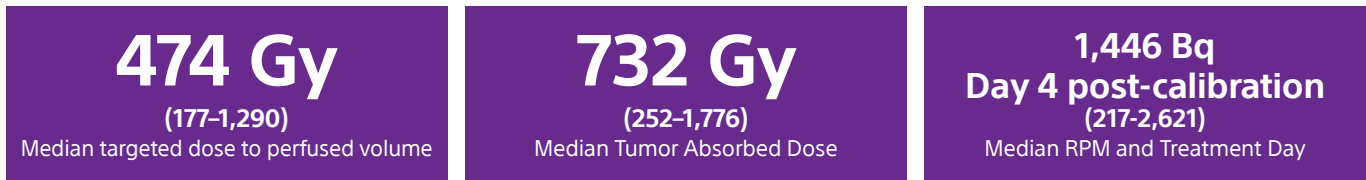
OBJECTIVE

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

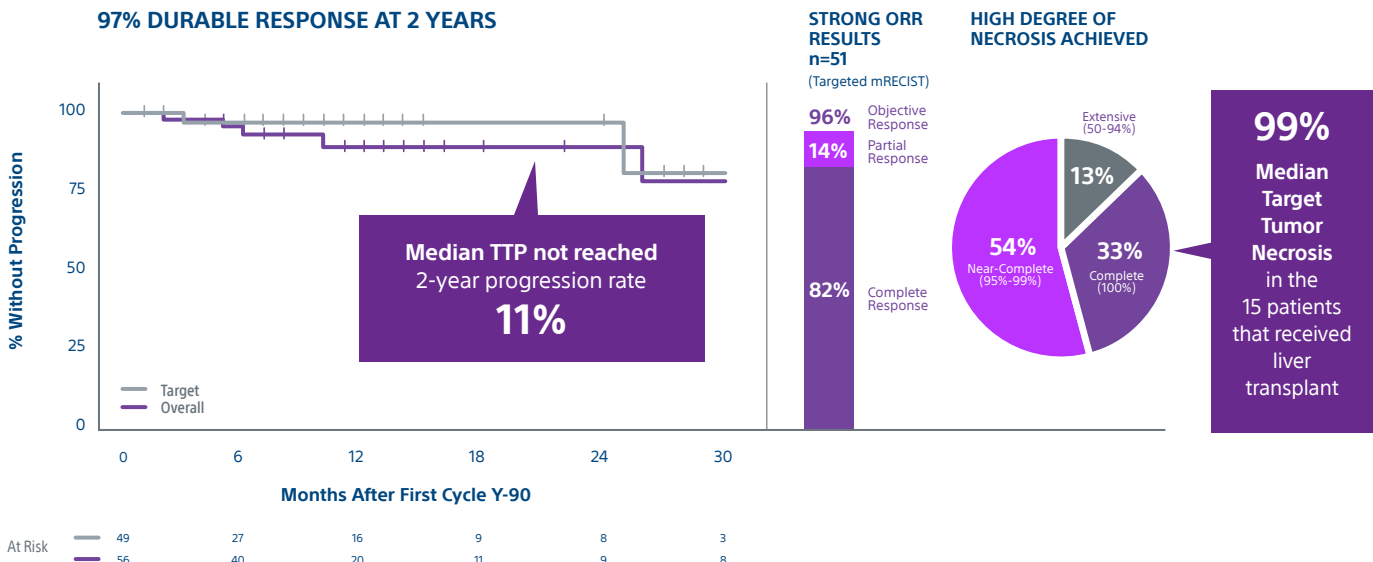
ANALYSIS DESIGN/METHODS

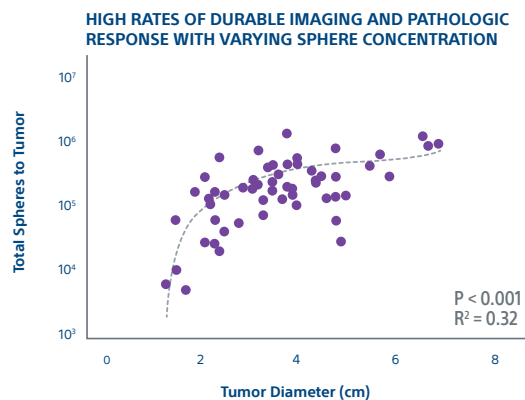
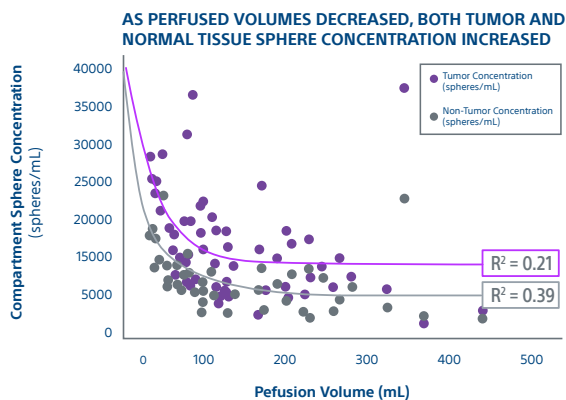
Post-treatment voxel-based dosimetry was evaluated using Simplicit90Y™ software and utilized to calculate sphere concentration to tumor. Time to progression (TTP), treatment response, pathologic response, and adverse events were studied.

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



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





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	CIRRHOSIS BACKGROUND	
Age at HCC Diagnosis (years), median (range)	66 (42-73)	Etiology, total (%)	
Sex, total male (%)	44 (79)	HCV	32 (57)
Race, total (%)		NASH	10 (18)
Caucasian/White	39 (70)	HCV + ALD	7 (13)
African American/Black	13 (23)	ALD	4 (7)
Other	4 (7)	Other	3 (5)
HCC BASELINE		CHILD PUGH, total (%)	
Surgical Track, total (%)		A5	22 (39)
Transplant Track	21 (38)	A6	14 (25)
HCC BURDEN, total (%)		B7	11 (20)
Solitary	56 (100)	B8-B9	9 (16)
Index HCC Diameter (cm), median (range)	3.4 (1.2-6.8)	ALBI GRADE	
TRANSPLANT CRITERIA AT DIAGNOSIS, total (%)		Grade 1	16 (29)
Milan	50 (89)	Grade 2	36 (64)
UNOS-DS	6 (11)	Grade 3	4 (7)
AFP (ng/mL), median (IQR)	5.9 (3.5-40)	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 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%)	0/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 97124387. S. Sandow T, Gimenez J, Nunez K, Tranel 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. 5. 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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