

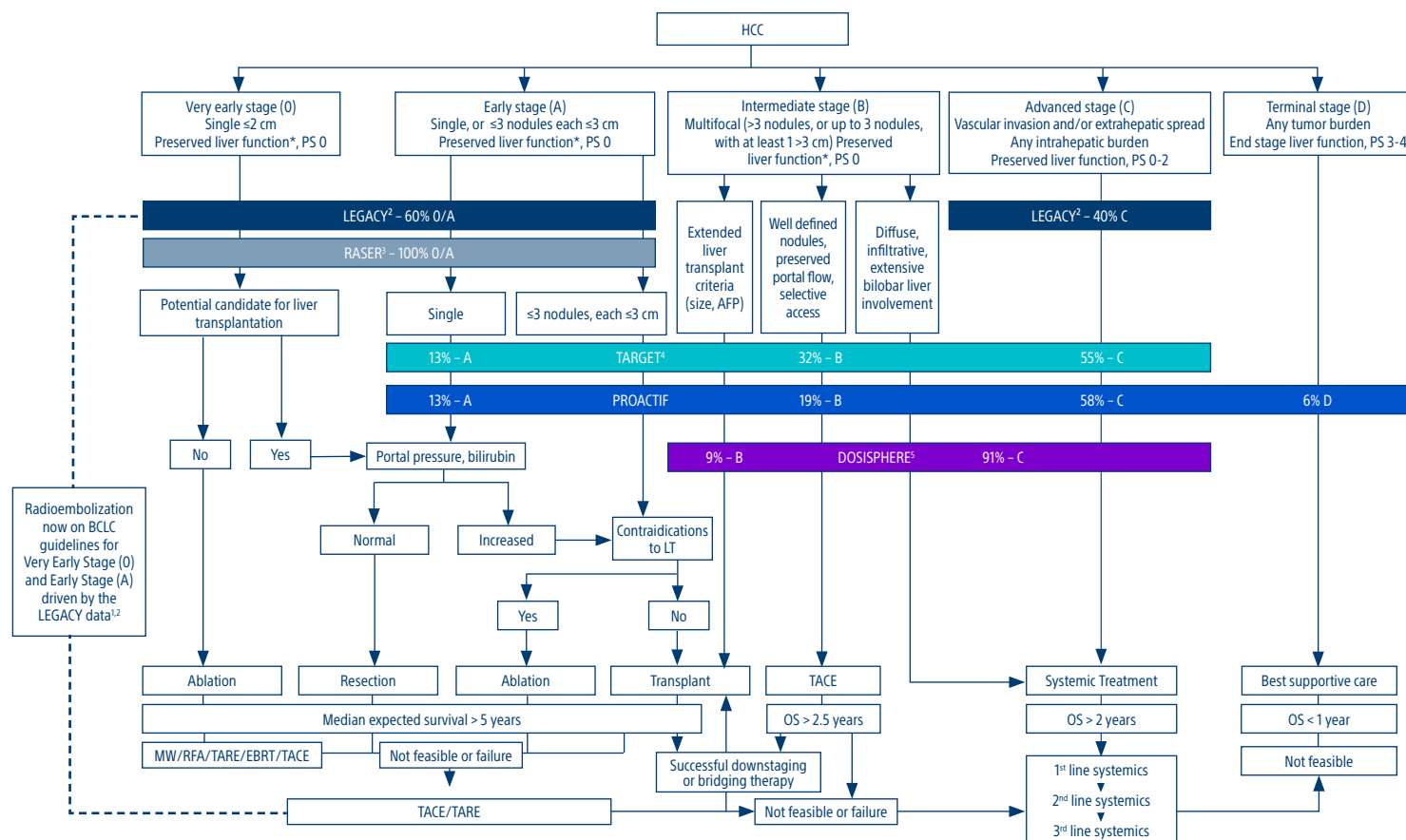


TheraSphere™ Y-90 Glass Microspheres | Key Notable Trials

TheraSphere is a proven minimally invasive transarterial radiation therapy that delivers high-dose radiation directly to the tumor. TheraSphere yields strong local tumor control and prolongs survival without limiting hepatocellular carcinoma (HCC) patient's eligibility for future treatment.

STUDIED ACROSS MULTIPLE BCLC STAGES:

TheraSphere has been studied across a wide range of Barcelona Clinic Liver Cancer (BCLC) stages examining a variety of patients and disease characteristics. BCLC algorithm adapted to show patient population from key notable trials.



*Except for those with tumor burden acceptable for transplant

KEY TRIAL DESIGN AND BASELINE CHARACTERISTICS:

	LEGACY	RASER	DOSISPHERE-01	TARGET	PROACTIF – HCC
Trial Design	Multi-center, U.S.	Single Center, U.S.	Multi-center, France	Multi-center, Global	Multi-center, France
	Retrospective	Prospective, single-arm	Prospective, randomized	Retrospective	Prospective, all-comers
	Single lesion	Single lesion	Single or multifocal [†] disease	Single or multifocal [†] disease	Single or multifocal [†] disease
	N=162	N=29	N=56* (28 PDA, 28 SDA)	N=209	N=989
Baseline Characteristics	BCLC: 0-A, C	BCLC: 0-A	BCLC: B, C	BCLC: A,B,C	BCLC: A,B,C,D
	BCLC C: 39.5%	–	BCLC C: PDA: 89.3%* SDA: 92.9%	BCLC C: 54.5%	BCLC C: 57.9%
	PVT presence [†] : 0%	PVT presence [†] : 0%	PVT presence [†] : PDA: 69.6%* SDA: 75%	PVT presence [†] : 33.0 %	PVT presence [†] : 35.3%
	Lesion size: Median 2.7 cm (range: 1-8)	Lesion size: Median 2.1 cm	Index lesion: Mean±SD PDA: 10.54 cm ±2.43 SDA: 10.92 cm ±2.57	Target lesion ^{**} : ≥ 3 to < 5 cm: 19.6% ≥ 5 to < 8 cm: 34.4% ≥ 8 cm: 45.9% Median 7 cm (range 3.1-17.4)	Lesion size: Median 6.8 cm
	Follow up: Median 29.9 M (by reverse KM)	Follow up: Median 23.0 M	Follow up: Median 65.8 M	Follow up: Median 13.3 M (short term focus based on imaging availability)	Follow up: Median 34.7 M

*Modified Intent-to-Treat (mITT) Population except for those with tumor burden acceptable for transplant

**target lesion with longest diameter using RECIST 1.1

†The safety and efficacy of TheraSphere in treatment of patients with PVT and/or multifocal disease has not been established.

PDA: Personalized dosimetry arm | SDA: Standardized dosimetry arm | TAD: Tumor absorbed dose

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SAFE. TOLERABLE.

TheraSphere demonstrated a consistent safety profile with patients well-tolerating the treatment.

LEGACY	RASER	DOSISPHERE-01	TARGET	PROACTIF
5.6% Low rates of device/ procedure-related SAE's 4.3% Low GI Disorders (abdominal pain, nausea, vomiting) 0% Patients experienced radiation-induced liver disease or failure	Low proportion of high-grade adverse events** (AEs) 14% Grade 3 Leukopenia 7% Grade 3 Thrombocytopenia 7% Grade 3 Non-laboratory- related AEs 0% Patients experienced radiation-induced liver disease	8.6% Low rate of patients experiencing ≥1 AE* (Grade ≥3) of personalized dosimetry approach (vs. 14.3% of standard dosimetry)	4.8% of patients experienced Grade ≥3 hyperbilirubinemia in the absence of disease progression	7.9% of patients had related grade ≥ 3 AEs > 95% of patients had no liver decompensation 12 M after TheraSphere Y-90 Treatment 53.7% received subsequent treatment, including surgery, additional locoregional therapy, and systemic therapy

*Liver AE related to Y-90 **A complete list of adverse events can be found in Table 2 in the publication.

PREDICTABLE HIGH EFFICACY

TheraSphere showed strong local tumor control and a correlation of high absorbed radiation dose-to-survival outcomes.

	LEGACY	RASER	DOSISPHERE-01	TARGET	PROACTIF
ORR in Target Lesion	88.3% best response (mRECIST)	100% (mRECIST)	PDA: 71.4% (EASL at 3 months)* SDA: 35.7% (EASL at 3 months)	70.8% best response (mRECIST)	56.3% best response (mRECIST)
Overall Survival	86.6% OS rate at 3 years (TheraSphere as primary treatment) 92.8% OS rate at 3 years (TheraSphere followed by transplant or resection)	96% Actuarial OS rate at years 1 and 2	PDA: 24.8 M ** SDA: 10.7 M TheraSphere + Resection: Not Reached	Overall Median: 20.3 M TAD Subgroups: >300 Gy: 36.7 M >200 to <300 Gy: 25.1 M <200 Gy: 16.1 M	Overall Median: 21.8 M Intermediate (BCLC B): 27.0 M Advanced (BCLC C): 21.1 Localized PVT (VP1/VP2): 24.8

*target lesion with longest diameter using RECIST 1.1

**Modified Intent-to-Treat (mITT) Population

PDA: Personalized dosimetry arm | SDA: Standardized dosimetry arm | TAD: Tumor absorbed dose

TheraSphere, through its robust clinical trials data across a wide spectrum of HCC patients, demonstrates:

- The role of minimally invasive transarterial radiation therapy that is well-tolerated by the patient.
- Ability to deliver high-dose radiation directly to the tumor yielding a strong local tumor control and prolongs survival.
- Maintenance of patient eligibility for future treatment while providing strong efficacy.

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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, Schwartz M, Facciuto M, Tabrizian P, Knešarek K, Fischman A, Patel R, Nowakowski S, Llovet J, Taouli B, Lookstein R. Radiation segmentectomy for curative intent of unresectable very early to early stage hepatocellular carcinoma (RASER): a single-centre, single-arm study. Lancet Gastroenterol Hepatol. 2022 Sep;7(9):843-850. doi: 10.1016/S2468-1253(22)00091-7. Epub 2022 May 23. PMID: 35617978.

4. Lam, Marnix. A Global Study of Advanced Dosimetry in the Treatment of Hepatocellular Carcinoma with Yttrium-90 Glass Microspheres: Analyses from the TARGET Study. Presented at SIR. March 25, 2021.

5. Garin E, Tselikas L, Guiu B et al. Personalized versus standard dosimetry approach of selective internal radiation therapy inpatients with locally advanced hepatocellular carcinoma (DOSISPHERE-01): a randomised, multicentre, open-label phase 2 trial. Lancet Gastroenterol Hepatol. 2021; 6: 17-29. DOSISPHERE 5-Year: Vilgrain V, Pereira H, Assenat E, et al. Long-term outcomes of personalized vs standard dosimetry in yttrium-90 radioembolization for hepatocellular carcinoma (DOSISPHERE-01): 5-year follow-up of a randomized clinical trial. Eur J Nucl Med Mol Imaging. 2024. doi:10.1007/s00259-024-06624-4

6. Guiu B, Bailly C, Vibert E, et al. Effectiveness and safety of selective internal radiation therapy using yttrium-90 glass microspheres for hepatocellular carcinoma: real-world results from the multi-center prospective PROACTIF cohort of 989 patients. eClinicalMedicine. 2026;95:103195.



TheraSphere™ Y-90 Glass Microspheres
Indications, Safety, and Warnings
<https://www.bostonscientific.com/therasphere-indications>

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