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THERASPHERE™ Y-90 Glass Microspheres | RASER STUDY

Radiation segmentectomy for curative intent of unresectable very early to early stage hepatocellular carcinoma (RASER): a single-center, single-arm study

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

First prospective study to assess outcomes after radiation segmentectomy (RS) in patients with very early or early stage hepatocellular carcinoma which showed 100% initial objective response with TheraSphere Y-90 glass microspheres.

OVERVIEW

The aim of this study was to assess the safety and efficacy of RS in patients with unresectable hepatocellular carcinoma (HCC) deemed unfavorable for ablation. The study provides a strong rationale for new randomized trials comparing RS to ablation and supports inclusion of RS in BCLC guidelines.

OBJECTIVE

Primary endpoint: Target tumor response measured by modified RECIST (mRECIST).
Secondary endpoints: Time to progression (TTP) of the target lesion and overall disease, and adverse events using CTCAE version 5.0.
CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events

STUDY DESIGN/METHODS

The study included adults (>18 years) with solitary HCC with unfavorable location for ablation, without metastasis or macrovascular invasion. Eligibility criteria included measurable disease ≤ 3 cm in diameter, Child-Pugh score A–B7, an ECOG score of 0, and adequate hematological and organ function. Of the 44 individuals assessed for eligibility, 29 patients were included in the study. Patients were followed up with imaging and office visits for up to 24 months.

KEY RESULTS

PARTICIPANT DEMOGRAPHICS

ECOG	0
Sex	Male: 23/29 (79%) Female: 6/29 (21%)
Child-Pugh	A5: 14/29 (48%) A6: 12/29 (41%) B7: 3/29 (10%)
Mean Perfused Liver Volume	153.6 mL (mean SD 99.2)
Median Tumoral Dose Delivered	1004.6 Gy (95% CI [190.8–3730.0])

TARGET LESION RESPONSE; % OF PARTICIPANTS (n=29)

Initial Objective Response	Initial Complete Response	Partial Response	Sustained Complete Response
100% (29)	83% (24)	17% (5)	90% (26) Median Time: 43 days Median Duration: 635 days

TARGET LESION & OVERALL DISEASE PROGRESSION; % OF PARTICIPANTS (n=29)

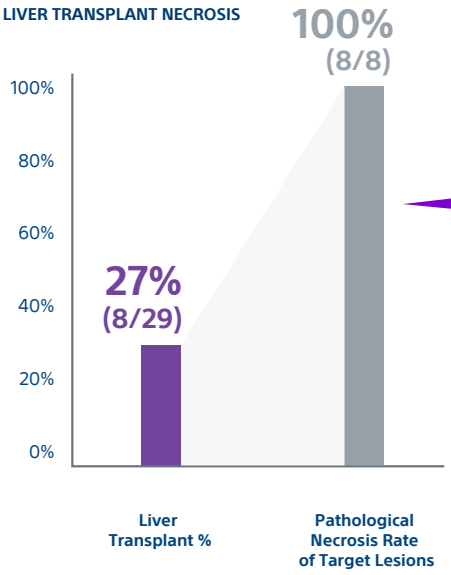
Target Lesion Progression	Cumulative Incidence of Target Lesion Progression	Actuarial Overall Survival	Overall Progression	Cumulative Incidence of Overall Progression
10% (3)	Year 1: 4% Year 2: 12%	Year 1: 96% Year 2: 96%	31% (9)	Year 1: 14% Year 2: 27%

LOW PROPORTION OF HIGH-GRADE ADVERSE EVENTS* (AEs); % OF PARTICIPANTS (n=29)

Grade 3 Leukopenia	14% (4)
Grade 3 Thrombocytopenia	7% (2)
Grade 3 Non-laboratory-related adverse events	7% (2)

*A complete list of adverse events can be found in Table 2 in the publication

LIVER TRANSPLANT NECROSIS



Eight patients received a liver transplant. Pathology results show all eight target lesions had 100% necrosis.

CONCLUSION

In this study, radiation segmentectomy with TheraSphere Y-90 glass microspheres was shown to be effective, with a low proportion of high-grade adverse events in patients with unresectable very early to early-stage hepatocellular carcinoma with suboptimal location for ablation.

Sustained complete response rates and local progression of the target lesion were similar to the previously reported rates after thermal ablation.**

Given complete pathological necrosis of the explanted tumors, larger investigative studies on the curative potential of radiation segmentectomy are warranted.

**References results cited in the publication.

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ThereSphere™ Y-90 Glass Microspheres Indications, Safety, and Warnings

https://www.bostonscientific.com/therasphere-indications

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