



Research Reporting Standards for Radioembolization of Hepatic Malignancies

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ABBREVIATIONS

CR = complete response, EASL = European Association for the Study of the Liver, HCC = hepatocellular carcinoma, PD = progressive disease, PFS = progression-free-survival, PR = partial response, RECIST = Response Evaluation Criteria in Solid Tumors, SD = stable disease, SPECT = single photon emission computed tomography, TTP = time-to-progression, WHO = World Health Organization

RATIONALE

Radioembolization is a field of interventional oncology that continues to evolve. The number of institutions adopting

this approach is increasing; this trend is paralleled by a greater number of research investigations reported in the peer-reviewed literature. Therefore, developing standardization and reporting criteria therefore becomes of para-

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Table 1. Brief Description of Available Radioembolic Devices

Name	TheraSphere	SIR-Spheres	¹³¹ I-Lipiodol
Radionuclide (symbol)	Yttrium 90 (⁹⁰ Y)	Yttrium 90 (⁹⁰ Y)	Iodine 131 (¹³¹ I)
Half-life (h)	64.2	64.2	192.5
Carrier	Glass microspheres	Resin microspheres	Iodized oil
Carrier size (μm)	20–30	20–60	NA

Note.—HDD = 4-hexadecyl-1,2,9,9-tetramethyl-4,7-diaza-1,10-decanethiol; GMS = glass microspheres.

mount importance in order to facilitate clear communications between investigators. The vehicle of a standards document provides the framework for reporting various aspects of the technique, including classification of methodology, descriptors of toxicities and complications, imaging guidance, and appropriate terminology that require specific attention when reporting clinical studies. It is the standpoint of the group that adherence to the recommendations will facilitate the main objective: improved precision and communication for reporting the various aspects of radioembolization. This approach should translate to more accurate comparison of data across centers and, ultimately, to enhanced research methodology.

INTRODUCTION

Primary Liver Tumors

Hepatocellular carcinoma (HCC) is the most common primary malignancy of the liver; its incidence is increasing worldwide. It ranks as the sixth most common tumor and third most common cause of cancer-related mortality (1,2). Primary liver tumors include HCC and intrahepatic cholangiocarcinoma. Surgical resection is preferred over transplantation and is considered potentially curative in patients with resectable HCC and normal liver function (3). Transplantation is considered the gold standard for patients with unresectable HCC and whose disease is within the Milan criteria (4). Resection and transplantation have limited roles, given advanced disease (chronic liver disease and/or tumor extent) at presentation and limited organ availability (5–7). Chemoembolization and radiofrequency ablation represent standard therapies in treating patients and serve as a bridge to transplantation in selected patients (8,9). Radioembolization has an emerging role in “bridging” patients within criteria by delaying tumor progression. It has also been shown to downstage disease beyond the Milan, to within, transplant criteria (10–12). A recent study has demonstrated that radioembolization leads to longer time-to-progression and better toxicity profile when compared with chemoembolization (13). Patients with macrovascular tumor involvement have also exhibited evidence of clinical benefit after radioembolization (14).

Secondary (Metastatic) Liver Tumors

Worldwide, secondary liver tumors are more common than primary liver tumors (15). Secondary liver tumors are man-

aged by both surgical and nonsurgical methods. The role of radioembolization for secondary liver tumors is promising and it has been shown to be safe and efficacious in patients with secondary liver tumors from colorectal carcinoma, neuroendocrine tumors, and other primary tumors (16–23).

Requirement for Research Reporting Standards for Radioembolization of Hepatic Malignancies

The International Working Group on Image-guided Tumor Ablation published a document entitled “Image-guided tumor ablation: standardization of terminology and reporting criteria” (24). The main objective was “improved precision and communication in this field that leads to more accurate comparison of technologies and results and ultimately to improved patient outcomes” (24). The publication of this document led to the publication of a document focused on catheter-directed therapies entitled “Transcatheter therapy for hepatic malignancy: standardization of terminology and reporting criteria” (25). A transcatheter therapy that is believed to have potential benefit from standardization of terminology and reporting criteria is radioembolization. This therapy is commonly used for patients diagnosed with primary and secondary liver malignancies. A comprehensive document standardizing the indications, techniques, multimodality treatment approaches, and dosimetry has been presented previously by the Radioembolization Brachytherapy Oncology Consortium (26).

The initial goals of the Working Group’s proposal for standardization fall in line with the initiative of the Society of Interventional Radiology (SIR), which promotes interventional oncology. Along these lines, SIR’s Technology Assessment Committee has been charged with reviewing and commenting on the standardization of terminology and reporting criteria. Accordingly, the document has been modified in an attempt to align its contents with prior SIR standards and to address additional issues that have been raised by the Technology Assessment Committee. In essence, this independent review and ratification by the SIR Technology Assessment Committee of the previous reports represents a continuation of the collaborative initiative to consolidate and unite all investigators and clinicians practicing interventional oncology by providing a common language to describe therapies and outcomes (24,25). Recognizing that the management of patients with liver tumors requires a multidisciplinary approach, it is recommended to use terms that are in accordance with all disciplines in-

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