STANDARDS OF PRACTICE

Transcatheter Therapy for Hepatic Malignancy: Standardization of Terminology and Reporting Criteria

Ron C. Gaba, MD, Robert J. Lewandowski, MD, Ryan Hickey, MD, Mark O. Baerlocher, MD, Emil I. Cohen, MD, Sean R. Dariushnia, MD, Bertrand Janne d'Othée, MD, MPH, MBA, Siddharth A. Padia, MD, Riad Salem, MD, MBA, David S. Wang, MD, Boris Nikolic, MD, MBA, and Daniel B. Brown, MD, for the Society of Interventional Radiology Technology Assessment Committee

ABBREVIATIONS

CR = complete response, EASL = European Association for the Study of the Liver, HCC = hepatocellular carcinoma, MAA = macroaggregated albumin, mRECIST = modified Response Evaluation Criteria In Solid Tumors, PET = positron emission tomography, PFS = progression-free survival, PD = progressive disease, PR = partial response, RECIST = Response Evaluation Criteria In Solid Tumors, SD = stable disease, TTP = time to progression, WHO = World Health Organization

Transcatheter liver-directed intraarterial therapies—such as embolization, chemoembolization, and radioembolization—represent fundamental interventional oncology procedures that have gained international acceptance for the treatment of primary and secondary hepatic malignancies. The growing use of these interventions mandates objective and formalized criteria for the consistent reporting of research outcomes to optimize accurate communication in the field and to facilitate valid comparison of technologies and results across clinical studies. Accordingly, a panel of experts was convened in 2007 and again in 2009 to develop standard terminology for transcatheter therapy (1,2). The evolution and advancement of the field of transcatheter therapy for hepatic malignancy since that time has seen the introduction of new delivery vehicles (3,4), expanded use of novel targeting technologies (5), and development of improved response assessment criteria (6), all of which must be incorporated into updated Research Reporting Standards to ensure that standard definitions, terms, principles, and benchmarks properly align with current interventional oncologic clinical practice. Thus, the present independent review, revision, and ratification of the previous report by the Society of Interventional Radiology (SIR) Interventional Oncology Service Line and Technology Assessment Committee (1,2) 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 transcatheter therapies and outcomes.

From the Department of Radiology, Division of Interventional Radiology (R.C.G.), University of Illinois Hospital and Health Sciences System, Chicago, Illinois; Department of Radiology, Section of Interventional Radiology (R.J.L., R.H., R.S.), Northwestern Memorial Hospital, Chicago, Illinois; Department of Radiology (E.I.C.), Medstar Washington Hospital Center, Washington, DC; Department of Radiology and Imaging Sciences, Division of Interventional Radiology and Image-Guided Medicine (S.R.D.), Emory University School of Medicine, Atlanta, Georgia; Department of Diagnostic Radiology and Nuclear Medicine, Division of Vascular and Interventional Radiology (B.J.d.O.), University of Maryland School of Medicine, Baltimore, Maryland; Department of Radiology, Section of Interventional Radiology (S.A.P.), University of Washington, Seattle, Washington; Division of Interventional Radiology (D.S.W.), Stanford University Medical Center, Stanford, California; Department of Radiology (B.N.), Stratton Medical Center, Albany, New York; Department of Radiology, Division of Interventional Oncology (D.B.B.), Vanderbilt University Medical Center, Nashville, Tennessee; and Department of Radiology (M.O.B.), Royal Victoria Hospital, Barrie, Ontario, Canada. Received December 18, 2015; final revision received and accepted December 21, 2015. **Address correspondence to** R.C.G., Department of Radiology, Division of Interventional Radiology, University of Illinois Hospital and Health Sciences System, 1740 W. Taylor St., MC 931, Chicago, IL 60612; E-mail: rgaba@uic.edu

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CLASSIFICATION OF THERAPIES

Image-Guided Transcatheter Tumor Therapy

The term "image-guided transcatheter tumor therapy" is defined as the intravascular delivery of therapeutic agents via selective catheter placement with imaging guidance for the treatment of malignancy. Currently, various devices—such as embolic or drug-eluting particles, chemotherapeutic medications, or radioactive materials—are injected via tumor-feeding vessels with intent to achieve cytoreduction through focused delivery and deposition of high concentrations of therapeutic agent as well as ischemic devascularization (7–14). Therapeutic material may eventually include biologically active agents, chemical mediators of cell function and/or the tumor microenvironment, viral vectors, genetic material, nanoparticles, or other agents not yet developed or described. The term "transcatheter" aims to distinguish these therapies from other treatments that are applied orally or via a systemic intravenous route, direct ablative therapies, percutaneous intratumoral injections, or external-beam radiation therapies. The concept of "image guidance" is stressed in the title of this discipline to highlight the radiologic targeting that is critical to the success of

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these therapies (7–14), and this term differentiates these therapies from targeted treatments not administered with the direction of real-time radiologic imaging, such as chemotherapy administered via an implanted hepatic arterial chemotherapy port. Presently, transcatheter therapies are predominantly performed with the use of fluoroscopy. However, given current research into the use of complementary imaging modalities for delivery and monitoring of therapies, including magnetic resonance (MR) imaging (15), contrast-enhanced ultrasound (US) (16,17), and potentially optical or near-infrared imaging, the more general term "image guidance" is preferred to accommodate future technical developments.

The methods of image-guided transcatheter tumor therapy most commonly used in current practice include (*i*) embolization, (*ii*) chemoembolization, and (*iii*) radioembolization. These individual procedures and therapies have often been given multiple names by various investigators, which may result in confusion. Hence, a unified approach to the terminology describing these therapies is proposed and recommended. The primary aim of the present classification is to provide simplicity and clarity, most notably by eliminating extraneous detail and unnecessary acronyms. To this end, the previously noted terms—"embolization," "chemoembolization," and "radioembolization"—are the most acceptable procedure descriptors. By virtue of wide recognition and acknowledgement as a designation for transarterial chemoembolization/transcatheter arterial chemoembolization, the acronym "TACE" is also acceptable nomenclature. In contrast, nonstandard terms such as "HACE" for hepatic arterial chemoembolization should be avoided. Similarly, while the terms "bland embolization" or "bland particle embolization" have been used in lieu of "embolization" to distinguish this procedure from those embolization procedures using drug- or radioactive agent–loaded embolic materials, this nomenclature does not enhance the procedure description in any meaningful way (in contrast to a term such as "radioembolization," in which the descriptor "radio-" describes a therapeutic mechanism of action), and is therefore superfluous. Finally, the term "infusion" for the direct delivery of pharmacologic agents is preferred, rather than "instillation," which may refer to administration of an agent for chemical ablation (18).

Embolization, chemoembolization, and radioembolization are performed after catheterization of the common, proper, lobar, segmental, and/or subsegmental (ie, direct tumor-feeding) hepatic arteries according to standard angiographic principles as described in the SIR Quality Improvement Guidelines for Transhepatic Arterial Chemoembolization, Embolization, and Chemotherapeutic Infusion for Hepatic Malignancy (19). Other interventional oncologic therapeutic approaches currently in development (eg, injection of growth inhibitors and genetic material) will require further standardization of terminology as these technologies mature and are further refined. Nevertheless, many of the reporting criteria issues discussed herein will likely be equally appropriate for clinical trials of those therapies.

Embolization

Embolization is defined as blockade of hepatic arterial flow with a vascular occlusive agent. Most commonly, particulate agents such as gelatin sponge, polyvinyl alcohol, or calibrated microspheres have been used. When results with embolization are reported, the type, size, and volume of particles used should be specified, and the rationale for selection of the particular embolic device characteristics should be explained (such as arteriographic criteria used to determine the selection of particle size). The embolization endpoints and/or arteriographic benchmarks used for delineation of the procedure conclusion should be reported and explained. Techniques used to delineate the angiographic endpoints of transcatheter therapies are discussed later.

Chemoembolization

Chemoembolization may be performed by using conventional or drug-eluting embolic approaches. Conventional chemoembolization is defined as the infusion of single or multiple chemotherapeutic agents with or without ethiodized oil and with or without concurrent (as a component of the chemoembolic emulsion) or tandem embolization with particles such as gelatin sponge, polyvinyl alcohol, or calibrated microspheres (19). The term "conventional chemoembolization" is favored over other descriptors such as "oily chemoembolization." Drug-eluting embolic chemoembolization is defined as the administration of microspheres onto which chemotherapeutic medication is loaded or adsorbed with the intention of sustained in vivo drug release. In identifying chemoembolization with the use of drug-loaded microspheres, the designation "drug-eluting embolic chemoembolization" is preferred over other descriptors in view of its nonspecific and generic nature as well as eschewal of terminology with potential proprietary connotation.

Results with conventional chemoembolization should aim to report the type of chemotherapy regimen and rationale for agent selection, the dose (empiric or weight-based) and method of reconstitution of chemotherapy drugs, the use or omission of ethiodized oil, the method of mixing the chemoembolic solution or emulsion, and the timing of addition of the embolic agents to the chemotherapeutic mixture, and the type, size, and volume of embolic particles used should be included in the description of procedure methodology. Results with drug-eluting embolic chemoembolization should aim to report particle type and material composition, manufacturer, embolic particle size, number of microsphere vials, chemotherapeutic agent regimen used, drug dose and dosing rationale, and chemotherapeutic agent loading methodology and time, with appropriate references to relevant supporting preclinical studies (20,21) and/or technical guidelines (22,23). Investigations reporting on drug-eluting embolic chemoembolization also need to consider reporting parameters of embolic injection technique, including suspension media and degree of dilution as well as rate or duration of injection. The application of other embolic materials in addition to drug-eluting embolic agents (eg, particle embolization for tumors not completely devascularized by drug-eluting embolic agents) should be noted. Actual dose of chemotherapy administered should ideally be reported for both types of chemoembolization. Adjunctive use of intraarterial anesthetic agents or vasodilators before therapy should be reported for conventional and drug-eluting embolic agent chemoembolization.

Various simple and innovative methods have been described to objectively determine the angiographic endpoints of chemoembolization procedures (24–28). Although it is not feasible to describe advanced endpoint measures in all chemoembolization studies, the standard criteria used to determine the technical, fluoroscopic, and/or arteriographic endpoint of chemoembolization procedures (eg, entire prescribed chemotherapy dose administered, dense chemotherapy mixture staining of tumor on fluoroscopy, no further tumor vascular enhancement) in a given study should nonetheless be objectively defined and reported. If assessed, a description of any cross-sectional imaging endpoints or postprocedure measures, such as pattern and degree of intratumoral ethiodized oil deposition (29,30) or iodinated contrast agent retention (31), should be included.

Radioembolization

Radioembolization is defined as the infusion of radioactive substances such as microspheres containing yttrium-90 (^{90}Y), iodine-131 (^{131}I) ethiodized oil, and similar agents (19). Guidelines for reporting the outcomes of radioembolization studies are outlined in detail in the SIR Research Reporting Standards for Radioembolization of Hepatic Malignancies (32). Briefly, the radioisotope delivered and radioembolic device (eg, glass or resin ^{90}Y-labeled microspheres) used should be described. Outcomes from preprocedural hepatic arteriography and hepatopulmonary shunt studies (ie, lung shunt fraction) should be reported. Pretreatment embolization of nontarget vessels (eg, gastroduodenal and right gastric arteries) should be documented. The method used to calculate activity and/or prescribed dose for the individual patient population should be consistent and reported in the description of procedure methodology. Activity and dose of the

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