Standards of Practice

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

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The field of interventional oncology includes tumor ablation as well as the use of transcatheter therapies such as embolization, chemoembolization, and radioembolization. Terminology and reporting standards for tumor ablation have been developed. The development of standardization of terminology and reporting criteria for transcatheter therapies should provide a similar framework to facilitate the clearest communication among investigators and provide the greatest flexibility in comparing established and emerging technologies. An appropriate vehicle for reporting the various aspects of catheter directed therapy is outlined, including classification of therapies and procedure terms, appropriate descriptors of imaging guidance, and terminology to define imaging and pathologic findings. Methods for standardizing the reporting of outcomes toxicities, complications, and other important aspects that require attention when reporting clinical results are addressed. It is the intention of the group that adherence to the recommendations will facilitate achievement of the group's main objective: improved precision and communication for reporting the various aspects of transcatheter management of hepatic malignancy that will translate to more accurate comparison of technologies and results and, ultimately, to improved patient outcomes.

J Vasc Interv Radiol 2007; 18:1469–1478

Abbreviations: HCC = hepatocellular carcinoma, RECIST = Response Evaluation Criteria In Solid Tumors, WHO = World Health Organization

RECENTLY, the International Working Group on Image-guided Tumor Ablation published a document entitled "Image-guided tumor ablation: standardization of terminology and reporting criteria" (1). 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" (1). Another branch of interventional oncology that was believed could benefit from such standardization of terminology and reporting criteria is catheter-directed treatment of malignancy. This includes chemoembolization, chemotherapeutic infusion, embolization, and radioembolization, which are the most commonly performed procedures by interventional radiologists for patients diagnosed with unresectable hepatic tumors. Accordingly, a panel of experts was convened to develop standard terminology for transcatheter therapy in parallel with the ablation document (1).

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, the Technology Assessment Committee of SIR 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 the

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None of the authors have identified a conflict of interest.

DOI: 10.1016/j.jvir.2007.08.027

contents with previous 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 report 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.

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. Currently, various agents such as chemotherapeutic agents, embolic particles, or radioactive materials are injected via feeding vessels to tumor(s) in an attempt to achieve cytoreduction by enabling more focused delivery or deposition of higher concentrations within the tumor (2–9). Therapeutic material may eventually include drug-eluting microspheres, biologically active agents, chemical mediators of cell function and/or the tumor microenvironment, viral vectors, genetic material, nanoparticles, or other as yet undescribed agents. The term "transcatheter" aims to distinguish these therapies from others that are applied orally or via a systemic, peripheral venous route as well as from direct ablative therapies. We stress the concept of image guidance in the title of this discipline to reflect our radiologic perspective and to highlight that image guidance is critical to the success of these therapies (2–9). Additionally, the term "image guidance" separates these therapies from chemotherapy administered via an implanted hepatic arterial chemotherapy port. Percutaneous placement and management of hepatic arterial infusion ports is beyond the scope of the current work. Currently, transcatheter therapies are performed with the use of fluoroscopy. Given current research into use of complimentary imaging modalities for delivery/monitoring of therapies (particularly magnetic resonance [MR] imaging), the more general term "image guidance" is preferred to accommodate future technical developments (10,11).

Individual procedures and therapies have often been given multiple different names by various investigators, which may result in confusion. Hence, we propose and recommend a unified approach to the terminology regarding these therapies. The primary aim of this classification is to provide simplicity and clarity, most notably by eliminating extraneous detail and many acronyms. Therefore terms such as "HACE" for hepatic arterial chemoembolization and "TACE" for transhepatic arterial chemoembolization should be avoided. 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 (1).

The methods of image-guided transcatheter tumor therapy most commonly used in current practice are divided into three main categories: (i) chemoembolization, (ii) embolization, and (iii) radioembolization. These categories require further definition and standardization of terminology as outlined later. Chemoembolization, embolization, and radioembolization are performed after catheterization of the common, proper, lobar, or segmental 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 (12). Other interventional oncologic therapeutic approaches, including the transcatheter and percutaneous delivery of genetic material or growth inhibitors, will likely ultimately require better consensus definition. Yet, they are beyond the scope of this article as they require further maturation of the technique and/or technology before description and standardization of terminology. Nevertheless, many of the issues discussed concerning reporting criteria will likely be equally appropriate for clinical trials of those therapies.

Chemoembolization

Chemoembolization is defined as the infusion of a mixture of chemotherapeutic agents with or without iodized oil followed by embolization with particles such as polyvinyl alcohol, calibrated microspheres, or Gelfoam (Pharmacia & Upjohn, Kalamazoo, Mich) (12). When results with chemoembolization are reported, the dose and method of reconstitution of chemotherapy (empiric or weight-based), the use of iodized oil, the method of mixing the chemoembolic solution or emulsion, 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 Materials and Methods section.

Embolization

Embolization is defined as blockade of hepatic arterial flow with a vascular occlusion agent. Most commonly, particulate agents such as Gelfoam, polyvinyl alcohol, or calibrated microspheres have been used, although use of other agents including glue and herbal agents such as bletilla striata have been described (12). When results with embolization are reported, the type, size(s), and volume of particles used should be specified. Additionally, arteriographic criteria used to determine the selection of particle size(s) and the embolization endpoints should be described

Radioembolization

Radioembolization is defined as the infusion of radioactive substances including. microspheres containing yttrium Y 90, iodine I 131 iodized oil, and similar agents (12). Outcomes from preprocedural hepatic artery/pulmonary shunt studies should be reported. Pretreatment embolization of nontarget vessels (eg, gastroduodenal and right gastric arteries) should be documented. The method used to calculate activity for the individual patient population should be consistent and reported in the Materials and Methods section. Activity of the agent should be reported in gigabecquerels (GBq) and dose should be reported in Grays (Gy). The disparity between the prescribed and the delivered activity (if any) should be documented.