Contrast-Enhanced Ultrasound

An Idea Whose Time Has Come

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Contrast-enhanced ultrasound is used effectively throughout the world, especially in the diagnosis and characterization of focal liver lesions. Currently, heart chamber opacification and delineation of endocardial borders are the only clinical applications approved by the US Food and Drug Administration (FDA). As a result, contrast-enhanced ultrasound use in the United States lags behind the rest of the world and has yet to become approved by the FDA for a broad range of applications that are currently available and contributing valuable diagnostic and management information in other countries. The lack of ultrasound contrast availability potentially hinders the delivery of optimal diagnostic imaging, resulting in an adverse impact on clinical care to our society.

Under the leadership of Lennard Greenbaum, MD, immediate past president of the American Institute of Ultrasound in Medicine (AIUM), a dialog has been established with the FDA to encourage the review and approval for clinical use of ultrasound contrast agents. To enhance the exchange of information among interested groups, a series of educational seminars have been presented to the FDA over the past year. At the request of the FDA, the AIUM wrote a protocol for the performance of clinical trials, "American Institute of Ultrasound in Medicine Recommendations for Contrast-Enhanced Liver Ultrasound Imaging Clinical Trials," which appears in this issue of the *Journal of Ultrasound in Medicine* (*JUM*), to facilitate increasing awareness of designing proper clinical trials.

This document and the joint sessions have been well received, with the result that the FDA has requested recommendations for ultrasound contrast agent clinical trials as a step toward approval of broader clinical applications. Initial focus will be on the liver, with other organs and applications to follow, with the goal of decreasing variance among clinical sites and increasing the likelihood of successful clinical trials. These trials should help establish clinical efficacy in addition to standardizing clinical protocols to ensure that high-quality studies are performed at all sites.

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Meanwhile, the clinical use of contrast agents continues to expand worldwide. As experience is gained, there has been a growing recognition and appreciation that standardization of concepts and terminology is essential to further facilitate clinical use of ultrasound contrast agents and exchange information.

This issue of the *JUM* includes a Special Report, "Terminology for Contrast-Enhanced Sonography: A Practical Glossary," by Catalano and colleagues from the Ultrasound Section of the Italian Association of Medical Radiology. The glossary is indicative of the scope and maturity of contrast-enhanced ultrasound clinical applications in the global community.

We at the *JUM* strongly support and encourage endeavors working toward more rapid approval of ultrasound contrast agent clinical applications as part of continuing improvements in providing optimal diagnostic imaging and patient care. Under the leadership of the FDA, the AIUM, and other interested parties, the *JUM* and the AIUM look forward to successful approval of ultrasound contrast agents for clinical use in the United States in the near future.

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