Contrast Agents May Pose Danger in Renal Disease

BY BRUCE K. DIXON
Chicago Bureau

Gadolinium-based contrast agents, when given to patients with renal disease, have been linked to a rare, potentially fatal, sclerodermalike skin disease called nephrogenic systemic fibrosis or nephrogenic fibrosing dermopathy. In December, the Food and Drug Administration issued a public health advisory stating that the agency has received reports of 90 patients with moderate to end-stage kidney disease who developed the new disease within 2 to 18 months after they had magnetic resonance imaging (MRI) or magnetic resonance angiography (MRA) with a gadolinium-based contrast agent. Many—but not all—of these patients received a high dose of the contrast agent; some received only one dose, according to the FDA.

Nephrogenic fibrosing dermopathy (NFD) is marked by areas of tight, rigid skin and may progress to nephrogenic systemic fibrosis (NSF), which is associated with scarring of internal organs. Symptoms may include burning, itching, swelling; hardening and tightening of the skin; red or dark patches on the skin; yellow spots on the whites of the eyes; stiffness in joints, with trouble moving or straightening the arms, hands, legs, or feet; pain deep in the hip bones or ribs; and muscle weakness.

Further, about 215 cases of NSF/NFD have been reported. The medical histories of 75 of these patients have been reviewed in detail, and all had received gadolinium-based contrast agents.

The advisory recommends alternative imaging studies for patients with renal disease. When patients with renal disease must receive a gadolinium-based contrast agent, prompt dialysis following the MRI or MRA should be considered, the FDA statement said.

Reports of the new disease have been steadily increasing since April 2006, when two European hospitals reported 25 cases following Omniscan injection. These cases had accumulated over a period of 4 to 6 months. In June 2006, the FDA issued an initial advisory about the disorder. In its December advisory, the FDA said that cases have been associated with three of the five approved gadolinium-based contrast agents, but there is reason to believe that any of the approved agents could cause the disease. Currently, there are five FDA-approved gadolinium-based contrast agents: Magnevist, Multilin, Omniscan, OptiMARK, and ProFiance. These contrast agents are FDA approved for use during an MRI scan, but not for use during an MRA scan.

Dr. Emanuel Kanal, professor of radiology and neuroradiology at the University of Pittsburgh Medical Center, was one of several radiologists who reviewed concerns about the emerging disease at the annual meeting of the Radiological Society of North America in Chicago.

“Nearly 100% of the patients with known NSF were confirmed to have received a gadolinium-based MR contrast agent prior to the diagnosis being made. Of those, over 90% had received Omniscan, which is way out of proportion to Omniscan’s market share,” said Dr. Kanal, who also is director of MR services at the medical center.

Fewer cases of NSF have been reported in patients who had been scanned using OptiMARK or Magnevist, and no cases have been linked to the remaining licensed agents, ProFiance and Multilin.

In a statement, GE Healthcare said the company is “concerned by this trend of a higher incidence of NSF concurrent with gadodiamide use, and we continue to urge caution in using Omniscan in really compromised patients, consistent with our prescribing information.”

A revised guidance document for safe MRI practices is slated for publication early this year in the American Journal of Roentgenology and on the American College of Radiology Web site.

Tissue Characterization Key

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Multislice CT and MPI Both Useful for Detecting CAD

BY JOHN R. BELL
Associate Editor

The information offered by multislice CT and myocardial perfusion imaging is sufficiently different that both tools are meaningful to the diagnosis of coronary artery disease—but evidence may predispose MSCT to becoming the first-line test. A normal MSCT allows the urgent emphasis from inducible ischemia to atherosclerosis,” said Dr. Schuijf and colleagues.

“Based on the discrepancy between MSCT and MPI, one can argue that MSCT could be used as the first-line test. A normal MSCT excludes CAD, and the patient can be reassured.”

In an accompanying editorial, Dr. Sharmila Dorbala of Brigham and Women’s Hospital, Boston, and colleagues noted that although the consistency between the findings via MSCT and those via invasive coronary angiography was “excellent,” the study—like its predecessors in the literature—showed a diagnostic inconsistency between MSCT and MPI.

However, their ultimate assessment of the study’s findings seemed to indicate a diagnostic advantage to MSCT. “Except in patients with high-risk scan features, combined testing with [MSCT and MPI] may be an effective strategy to both diagnose extent of CAD and guide management to the appropriate vessel,” they wrote.