RSNA® Radiological Society of North America

820 Jorie Blvd
Oak Brook, IL 60523
TEL 1-630-571-2670
FAX 1-630-571-7837
RSNA.org

NEWS

RSNA Press Release

MRI Contrast Agent Linked to Rare Disease

Released: January 25, 2007

Media Contacts:

RSNA Media Relations: (630) 590-7762

Maureen Morley
(630) 590-7754
mmorley@rsna.org

At A Glance

- Gadolinium-based magnetic resonance imaging (MRI) contrast agents may be dangerous to patients with advanced kidney disease.
- Gadolinium has been associated with nephrogenic systemic fibrosis (NSF), a disorder characterized by thickening and hardening of the skin and immobility or tightening of the joints.
- Over 90 percent of NSF patients were previously exposed to gadodiamide (Omniscan).

OAK BROOK, Ill. (January 25, 2007) - New research has shown a possible association between a popular magnetic resonance imaging (MRI) contrast agent and the incidence of a rare disease called nephrogenic systemic fibrosis (NSF) in patients with kidney disease, according to an editorial appearing in the March issue of *Radiology*.

"We recommend avoiding the use of gadodiamide in patients with any degree of renal disease," said Phillip H. Kuo, M.D., Ph.D., assistant clinical professor of diagnostic radiology at Yale University School of Medicine in New Haven, Conn. "At this point, the data clearly show the vast majority of NSF cases are associated with the use of gadodiamide."

NSF, an emerging systemic disorder characterized by widespread tissue fibrosis, has been diagnosed in patients who were previously administered gadodiamide (Omniscan) and other gadolinium-based MRI contrast agents. While the precise cause of NSF is unknown, the disorder has only been observed in patients with kidney disease, especially those requiring dialysis.

"So far, NSF has only been reported in patients with renal failure," Dr. Kuo said. "Gadolinium contrast agents do not appear to cause NSF in patients with normal kidney function."

Patients with NSF experience an increase of collagen in the tissues, causing thickening and hardening of the skin of the extremities and often resulting in immobility and tightening or deformity of the joints. NSF can develop rapidly and may result in patients becoming wheelchair-bound within just a few weeks. In some cases, there is involvement of other tissues, including the lungs, heart, diaphragm, esophagus and skeletal muscle. No consistently effective therapy exists.

Approximately 400 cases of NSF have been reported worldwide. While gadolinium-based

Copyright © 2015 Radiological Society of North America (RSNA)

agents have not been definitively shown to cause NSF, as many as 90 percent of known NSF patients had previously received gadodiamide, and a recent survey of approximately 100 NSF patients revealed that more than 95 percent were exposed to a gadolinium agent within two to three months prior to disease onset. Other evidence linking gadolinium with NSF includes residual gadolinium in a skin biopsy of an NSF patient 11 months after the contrast agent was administered.

Studies investigating the relationship between NSF and gadolinium are currently underway at Yale, as well as the Centers for Disease Control, U.S. Food and Drug Administration (FDA) and the medical regulatory agencies of the European Union. In the meantime, the FDA advises cautionary use of all gadolinium-based contrast agents in patients with moderate to advanced renal disease.

"While I appreciate the conservative approach of the FDA," Dr. Kuo said, "my colleagues and I are concerned that expanding the warning to millions of patients with only moderate renal disease might have a negative impact on patient care."

Dr. Kuo noted that only three percent of patients with renal failure who are given gadolinium agents will develop NSF, and that an overwhelming majority of the reported cases of NSF are tied specifically to gadodiamide. "That leaves a large percentage of patients who can gain the benefits of a contrast-enhanced scan without developing NSF," he said.

Dr. Kuo and colleagues recommend not using gadodiamide in patients with kidney disease, but he pointed out that there are circumstances where the benefits of other gadolinium-based agents outweigh the risks.

"MRI with contrast is simply the best exam in many situations," Dr. Kuo said. "One has to wonder if excluding large numbers of patients with moderate renal failure from the best exam would do more harm than good."

The editorial is published online at
http://radiology.rsnajnls.org/cgi/content/full/2423061640v1.

# # #

Journal attribution required.

Radiology is a monthly scientific journal devoted to clinical radiology and allied sciences. The journal is edited by Anthony V. Proto, M.D., School of Medicine, Virginia Commonwealth University, Richmond, Va. *Radiology* is owned and published by the Radiological Society of North America, Inc. (radiology.rsna.org)

The Radiological Society of North America (RSNA) is an association of more than 40,000 radiologists, radiation oncologists, medical physicists and related scientists committed to promoting excellence in radiology through education and by fostering research, with the ultimate goal of improving patient care. The Society is based in Oak Brook, Ill. (RSNA.org)

"Gadolinium-based MRI Contrast Agents and Nephrogenic Systemic Fibrosis." Collaborating with Dr. Kuo on this report were Emanuel Kanal, M.D., Ali K. Abu-Alfa, M.D., and Shawn E. Cowper, M.D.

Copyright © 2015 Radiological Society of North America (RSNA)