Radiologists seek middle ground for policies to protect patients

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Most sources have suggested that NSF is extremely rare, occurring in less than 5% of patients with severe kidney disease exposed to gadolinium during contrast-enhanced MRI. One recent article published in *Arthritis and Rheumatism*, however, put the figure for dialysis patients much higher at 30%, based on a different testing method that did not require proof on biopsy.

Awareness is growing that cumulative or lifetime exposure plays an important role in disease development, said Dr. Emanuel Kanal, during a plenary session on contrast media at the very end of the RSNA meeting.

In one of the studies cited by Kanal, researchers at Massachusetts General Hospital found that patients who developed NSF received an average cumulative dose of Magnevist of 135.5 mL. Higher cumulative dose correlated with higher risk, according to results presented at RSNA 2007 and also at the American Roentgen Ray Society meeting last year. Similarly, a large Scottish study published in October found an association between higher cumulative dose of the agent Omniscan and NSF (Radiology 2007;245;1:168-175).

Since the majority of patients with chronic kidney disease are not aware of their condition, screening patients prior to contrast-enhanced imaging presents challenges, Kanal said in an interview with *Diagnostic Imaging* after the RSNA meeting. An estimated 97% of women and 82% of men with moderate chronic kidney disease do not know they have it.

Regardless of a patient's stated renal function status, the lowest dose of gadolinium necessary should be used, according to Kanal, a professor of radiology at the University of Pittsburgh Medical Center.

"As an industry, we are probably using more gadolinium-based contrast than is absolutely required for diagnosis," he said.

On the flipside, however, negative publicity related to NSF may lead to too much hesitancy to administer gadolinium when needed, and some patients may miss out on the benefits, said Kanal, who is also head of the American College of Radiology Blue Ribbon Panel on MR Safety.

"I personally almost never cancel administration of gadolinium-based MR contrast agents in renal disease patients. Rather, if I believe that the risks are outweighed by the potential benefits of receiving the agents, as I almost always believe that they are, I administer lower doses, such as half or quarter dose," he said.

Gadolinium agents have become indispensable to clinicians in helping to improve staging and the confidence level of imaging studies, said Dr. Jeffrey Weinreb, who moderated the RSNA plenary session on contrast media safety.

In the past, gadolinium contrast media were considered to be "extraordinarily safe," said Weinreb, a professor of diagnostic radiology at Yale University. Initially used in imaging the central nervous system, over time gadolinium agents were applied successfully to virtually every part of the body. Most recently, they have become a critical component of breast MRI, the modality's fastest growing application.

Gadolinium was once deemed so safe that experts around the world advocated using the media as a replacement for iodinated agents in patients with impaired renal function.

"We used to hear expressions like 'Gad is good' or 'gadolinium is holy water.' Gadolinium was used nondiscriminately for nonapproved applications and doses. All that came to screeching halt with the presumed association between gadolinium and NSF," he said.

The black box warning for all gadolinium agents announced in May 2007 by the FDA has led to considerable anxiety in the radiology community. Nowadays, if a cross-sectional imaging study is needed, the decision about using MR or CT often comes down to an assessment of whether the
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patient is at greater risk with iodinated contrast for contrast-induced nephropathy or gadolinium for getting NSF, Weinreb said.

Speaking during the same session, Yale University dermatopathologist Dr. Shawn Cowper said that so far he has collected 275 reports in his database of NSF cases, most of which have surfaced within two to three months of gadolinium exposure. (That is 36 more cases than Cowper had evaluated for his database as of May 2007.)

Though some cases of patients getting NSF without gadolinium exposure have occurred, these reports typically do not hold up under scrutiny. Sometimes, it turns out that a patient had actually received gadolinium but that the exposure had not been documented, Cowper said.

To help prevent the disease and to protect themselves legally, radiologists should be aware of American College of Radiology guidelines on NSF, including screening for renal function, said Dr. Leonard Berlin, radiology chair at Rush North Shore Medical Center in Skokie, IL, in an interview with Diagnostic Imaging.

The accepted means of measuring renal function is the estimated glomerular filtration rate (GFR). A GFR from 30 to 59 mL/min indicates stage 3 renal disease, while measurements from 15 to 29 mL/min reflect stage 4 or severe kidney disease.

These limits are not set in stone, however. Kanal points out that a patient with a GFR of 30 has a renal function markedly different from one with a GFR of 59. Even with appropriate patient GFR prescreening performed, it is still possible to miss some patients with acute renal failure, he said.

In a recently reported case, a 70-kg patient who was unknowingly suffering from severe acute renal injury was administered 35 mL (2.5 times the standard dose) of Omniscan during the transient episode of acute renal failure. Although he recovered from the acute kidney failure completely in a matter of days, he was subsequently diagnosed with biopsy-confirmed NSF. Gadolinium was detected in his biopsy specimens (Kalb et al. Br J Dermatol, published online Dec. 11, 2007).

Poor renal function is not an absolute contraindication to contrast media. In such cases, however, radiologists should be investigating imaging alternatives such as ultrasound prior to performing a contrast-enhanced MRI, Berlin said. The patient and physician then need to weigh the risks and benefits of a contrast-enhanced study, and informed consent should be secured.

Information has been lacking about how common NSF is and how many patients with severe renal disease have been getting contrast-enhanced exams since NSF warnings were first sounded, said Dr. Tim Leiner, vice chair of the NSF Working Group created by the International Society for Magnetic Resonance in Medicine. To help fill the knowledge gap, the committee will survey all of the association's members in January with questions about contrast use and screening protocols related to NSF.

Such information could help reestablish the safety profile of enhanced MRI with referring clinicians, said Leiner, an assistant professor of radiology at Maastricht University Hospital in the Netherlands. "Gadolinium-enhanced MRI is still a very safe and necessary examination in many people," he said.

Disclosures:

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