FDA Issues Alert on Gadolinium-Based Contrast Agent for Kidney Patients

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Review

ROCKVILLE, Md., Dec. 22 -- The FDA updated a public health advisory today about a serious new kidney disease that is apparently associated with a gadolinium-based contrast agent used with MRI or MR angiography.

The agency said that as of Dec. 21 it had received reports of 90 patients with moderate to end-stage kidney disease who developed the new disease, called nephrogenic systemic fibrosis or nephrogenic fibrosing dermopathy (NSF/NFD), after they had an MRI or MRA with a gadolinium-based contrast agent.

The FDA recommended that whenever possible patients with moderate to end-stage kidney disease who need an imaging study, be given imaging methods other than MRI or MRA with a gadolinium-based contrast agent.

NSF/NFD began from two days to 18 months after exposure to the contrast agent, said the FDA. Many, but not all of these patients, received a high dose of the contrast agent, yet some received only one dose.

The signs of NSF/NFD also 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.

The FDA notified physicians and patients that:

- Patients with moderate to end-stage kidney disease who receive an MRI or MRA with a gadolinium-based contrast agent may get NSF/NFD which is debilitating and may cause death.
- Patients who believe they may have NSF/NFD should get in touch with their doctor. Patients who develop NSF/NFD have areas of tight, rigid skin and may have scarring of their body organs.
- If these patients must receive a gadolinium-based contrast agent, prompt dialysis following the MRI or MRA should be considered.
- It is not clear why NSF/NFD occurs in patients with moderate to end-stage kidney disease who receive a gadolinium-based contrast agent.

There are five FDA-approved gadolinium-based contrast agents, Magnevist, MultiHance, Omniscan, OptiMARK, and ProHance. These contrast agents are FDA approved for use during an MRI scan, but not for use during an MRA scan. Although NSF/NFD has been reported for only three of the five gadolinium-based contrast agents, the FDA said it believes that there is a potential for NSF/NFD to occur with the use of any of the approved gadolinium-based contrast agents.

The advisory was an update to an alert last June when the FDA said it had

learned of 25 cases of NSF/NFD in patients with kidney failure who received Omniscan, and took the MRA test. "These reports provide more evidence for a causal relationship between gadolinium-based contrast agents and the development of NSF/NFD," the FDA said.

Worldwide, the re have been about 215 patients with NSF/NFD reported, said the FDA. The medical histories of 75 of these patients were reviewed in detail, and all of the patients had received a gadolinium-based contrast agent for an MRI or MRA. Researchers, the agency said, have identified gadolinium in skin biopsies of patients with NSF/NFD.

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