Beth Israel Deaconess Medical Center

A teaching hospital of Harvard Medical School

Neil M. Rofsky, M.D.
Department of Radiology

Associate Professor of Radiology

Director, Magnetic Resonance Imaging

October 12, 2006

Dear Colleagues:

Re: Gadolinium and Nephrogenic Fibrosing Dermopathy

The Division of MRI is investigating a possible association between gadolinium contrast agents and Nephrogenic Systemic Fibrosis, also called Nephrogenic Fibrosing Dermopathy (NFS/NFD). I am writing to raise awareness of this possible association, and to enlist your help in identifying suspected cases of NFS/NFD. You are receiving this letter because you are ideally positioned to detect the clinical manifestations of NFS/NFD.

The FDA issued a Public Health Advisory in June 2006 about the possible link between NFS/NFD and exposure to gadolinium-containing contrast agents.
http://www.fda.gov/cder/drug/advisory/gadolinium_agents.htm
This was in response to 25 cases of NFS/NFD at two European hospitals over a four-year period. These cases occurred in patients with pre-existing renal insufficiency, who received a high dose of the Omniscan® contrast agent for Magnetic Resonance Angiography (MRA). The patients developed NFS/NFD at least two weeks after, but within 3 months, of receiving gadolinium. There are now approximately 200 cases recorded in the international NSF Registry.

To date, a causal relationship between gadolinium contrast agents and NFS/NFD has not been established, and the pathophysiology is unknown. NFS/NFD seems to occur only in the setting of pre-existing renal insufficiency. It is characterized by proliferation of connective tissue, and resembles scleroderma and eosinophilic fasciitis clinically. Prominent complaints are swelling and tightening of the skin, usually limited to the extremities, which can limit range of motion and result in contractures. Skin changes also include reddened or darkened macules, papules, or plaques, commonly leading to suspicion of cellulitis. More information about NFS/NFD is available online through the International Center for Nephrogenic Fibrosing Dermopathy Research (http://www.icnfdr.org/).

Please note that at BIDMC we do NOT use Omniscan® contrast, but I am wondering whether other gadolinium contrast products that we do use at BIDMC might have some association with NFS/NFD. Let me emphasize to you that, to the best of our current knowledge, NFS/NFD is an extremely rare disorder with only a miniscule percentage of the millions of doses of gadolinium given annually showing any kind of possible association; to date there is no causal relationship. However, I thought it prudent to initiate a proactive inquiry in response to the FDA Public Health Advisory so that we may evaluate our local experience.

330 Brookline Avenue
Boston, MA 02215

tel (617) 667-2721
fax (617) 667-2531
email: nrofsky@bidmc.harvard.edu

Re: Gadolinium and Nephrogenic Fibrosing Dermopathy

If you have reason to suspect a case of NFS/NFD, please contact *Shannon Bisbee, Nurse Practitioner for Clinical MRI*, so that the association with gadolinium may be investigated further. Shannon may be reached by telephone at (617) 754-2092, or by email at sbisbee@bidmc.harvard.edu.

Thank you in advance for your efforts.

Sincerely,

Neil M. Rofsky, MD

/nmr