

Attention Individuals who have had MRI or MRA within the past 2 years

Re: GADOLINIUM NSF/NSD ALERT

Nephrogenic Systemic Fibrosis or Nephrogenic Fibrosing Dermopathy (NSF/NFD) occurs in patients, particularly persons with moderate to end-stage kidney disease, after they have had a Magnetic Resonance Imaging (MRI) or Magnetic Resonance Angiography (MRA) scan with a gadolinium-based contrast agent. Recent reports and studies have strongly correlated the development of NSF with exposure to gadolinium-containing MRI contrast agents. Significantly, Researchers have identified gadolinium in skin biopsies of patients with NSF/NFD. NSF/NFD is debilitating and, with no effective treatment or cure, most often cause death in those suffering from the condition.

The United States Food and Drug Administration (FDA) has recommended that, whenever possible, when a patient with moderate to end-stage kidney disease needs an imaging study, imaging methods other than MRI or MRA with a gadolinium-based contrast agent should be used for the study. There are currently five FDA approved gadolinium-based contrast agents: Magnevist, MultiHance, Omniscan, OptiMARK, and ProHance.

In addition to kidney disease, conditions that may be associated with NSF include blood-clotting abnormalities and deep venous thrombosis (DVT), recent surgery (particularly vascular surgery), recent failure of a transplanted kidney, and sudden onset kidney disease with severe swelling of the extremities. It is very common for the NSF patient to have undergone a vascular surgical procedure (such as revision of an AV fistula or angioplasty of a blood vessel) or to have experienced a thrombotic episode (thrombotic loss of a transplant or deep venous thrombosis) within a few weeks before the onset of skin changes.

Patients with NSF describe swelling and tightening of the skin, usually limited to the arms and legs, but sometimes involving the remainder of the body. The condition may develop over a period of days to several weeks. In many cases, the skin thickening inhibits the flexion and extension of joints, resulting in contractures. Severely affected patients may be unable to walk, or fully extend the joints of their arms, hands, legs, and feet. Complaints of muscle weakness are common. Approximately 5% of patients rapidly progress to death.

The skin changes may start as reddened or darkened patches, papules, or plaques. In time, the skin may feel “woody” and the surface may resemble the texture of the peel of an orange. Patients may experience burning, itching, or severe sharp pains in the involved areas. Radiography may reveal calcifications of

the soft tissue. The skin lesions are commonly symmetrical, with zones between the ankles and thighs most commonly involved, followed by involvement between the wrist and upper arms. Hand and foot swelling with blister-like lesions has also been reported. Some patients have reported yellow papules or plaques on or near the eyes. Rapid, new onset fluctuating high blood pressure of unknown cause has been described prior to the onset of the skin lesions. Also, deep "bone pain" has been described in the hips and in the ribs.

NSF/NFD typically manifests from 2 days to 18 months after the MRI or MRA where the gadolinium-containing contrast agent was used. Many, but not all of the affected individuals, received a high dose of the contrast agent; **some received only one dose.** NSF appears to affect males and females in approximately equal numbers. NSF has been confirmed in children and the elderly, but tends to affect the middle-aged most commonly.