

A Prospective Study Following Patients with Chronic Kidney Disease Undergoing Contrast-Enhanced MRI

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Purpose: Nephrogenic systemic fibrosis (NSF) is a recently described debilitating disorder of the skin, connective tissues, and vital organs, which occurs in patients with renal disease. NSF was first identified in 1997 and formally described in 2000 by Shawn Cowper at Yale University. An international NSF registry at Yale maintains records on over 310 patients with NSF worldwide. In this database, gadobenate dimeglumine (MultiHance) has not yet been associated with any cases of NSF unless another gadolinium agent was also administered (confounded cases). The purpose of this study was to prospectively evaluate the incidence of NSF in patients with stages 3 to 5 chronic kidney disease (CKD) undergoing magnetic resonance imaging (MRI) with gadobenate dimeglumine.

Methods and Materials: As part of an ongoing prospective multi-center study, patients referred for MR neuroimaging with contrast were screened with a serum creatinine value obtained within 24 hours prior to MRI. Estimated glomerular filtration rate (eGFR; MDRD method) was calculated and, based on the results, patients were divided into 2 groups: cohort 1=eGFR 30–59 mL/min/1.73 m²; cohort 2=eGFR<30 mL/min/1.73 m². Patients with a history of gadolinium exposure within the previous year were excluded. After signing their informed consent, eligible patients received 0.1 mmol/kg gadobenate dimeglumine (MultiHance) intravenously. All patients are followed for up to 2 years with scheduled telephone calls and office visits to evaluate for any signs of NSF. For suspected cases, a skin biopsy is obtained and evaluated by a dermatologist.

Results: To date, 223 patients have been enrolled in this study, with 15 sites having enrolled one or more subjects. None of the patients with stages 3 to 5 CKD who have received gadobenate dimeglumine have developed NSF. Two patients have been lost to follow-up and one other patient died of unrelated causes.

Conclusions. No case of NSF has been reported to date. These findings are consistent with results from two recent studies, the first of which¹ found no cases of NSF following 180 gadobenate-dimeglumine-enhanced MRI examinations performed on 168 patients with stage 3 CKD. In the second study,² following a switch from gadodiamide to gadobenate dimeglumine or gadopentetate dimeglumine, the incidence of NSF changed from 37 of 65,240 in the preadoption period to 0 of 25,167 in the postadoption period ($P<0.0001$). The methodology of this prospective study may serve as a template for other institutions.

1. Bryant BJ, Im K, Broome DR. Clin Radiol. 2009;64:706-713.
2. Altun E, Martin DR, Wertman R, et al. Radiology. 2009 Oct 7.