The Prevalence of Nephrogenic Systemic Fibrosis in Patients with Renal Failure Who Have Received Gadopentetate Dimeglumine

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INTRODUCTION: Nephrogenic systemic fibrosis (NSF) or nephrogenic fibrosing dermopathy was first reported in 2000 in patients with end-state renal disease (1). It presents as a thickening and hardening of the skin similar to scleroderma, and has systemic manifestations. In 2006, NSF was first associated with the administration of gadolinium contrast agents in patients with renal disease (2). There are four reports of prevalence, all in patients who have received primarily gadodiamide: in dialysis dependent patients a prevalence between 2.3 to 4.0% has been reported, and in patients with decreased renal function a prevalence of 1.5% has been reported (3-6). This study intends to determine the risk of developing this disease in dialysis dependent patients and those with elevated creatinines who have received gadopentetate dimeglumine. No previous studies have reported a prevalence in patients receiving gadopentetate dimeglumine. This abstract describes preliminary results.

MATERIALS AND METHODS: This study was approved by the local institutional review board. Utilizing the Northern California Kaiser database, all dialysis dependent patients or those with a creatinine level higher than 1.8 mg/dl, who received gadolinium contrast between January 1st 2004 and May 31st 2007, were selected for this study. Gadopentetate dimeglumine (Magnevist, Berlex laboratories) was the only gadolinium based contrast agent used at all hospitals in the Kaiser medical system. Information on contrast dose and race was not available. In order to determine the number of patients who developed NSF, all nephrologists, rheumatologists and dermatologists in the Northern California region were surveyed. Additionally the database was searched for all patients with the diagnosis of NSF, NFD, scleroderma or scleroderma type disease, and searched for all patients who were referred to a dermatologist or rheumatologist, or who received a skin biopsy within one year of each scan.

RESULTS: All magnetic resonance angiograms (MRAs) performed in the Northern California Kaiser region between January 1st 2004 and May 31st 2007 were included. 115,252 MRAs were performed in 84,659 patients. There were 6,789 patients who had been on dialysis during the study period, and there were 1,272 MRAs in 940 dialysis patients. In dialysis patients, 423 scans in 338 patients were before patients went on dialysis, 624 scans in 442 patients were while patients were on dialysis, and 225 scans in 160 patients were after patients stopped dialysis. Of patients not on dialysis, 7,732 patients had a creatinine ≥ 1.8 within one year of 9,772 MRAs. 3,640 scans in 3,065 patients were included. The table below describes the inclusion and exclusion criteria for patients not on dialysis:

Inclusion criteria: 3,640 scans in 3,065 patients		*Exclusion criteria*: 6,132 scans in 4,667 patients	
Criteria	Scans	Criteria	Scans
all creatinines were ≥ 1.8 within one week	1,293	all creatinines were < 1.8 within one week	2,714
all creatinines were ≥ 1.8 within one month	885	all creatinines were < 1.8 within one month	1,459
all creatinines were ≥ 1.8 within six months	394	all creatinines were < 1.8 within six months	576
all creatinines ≥ 1.8 seven days prior to the scan but < 1.8 seven days after	236	all creatinines < 1.8 seven days prior to the scan but ≥ 1.8 seven days after	287
all creatinines ≥ 1.8 thirty days prior to the scan but < 1.8 thirty days after	68	all creatinines < 1.8 thirty days prior to the scan but ≥ 1.8 thirty days after	379
nearest creatinine ≥ 1.8	360	nearest creatinine < 1.8	717
single creatinine ≥ 1.8 within two days of the scan	396		
only 1 creatinine measured and it was ≥ 1.8	8		

From the survey, to date, 98% of nephrologists (54/55), 70% of rheumatologists (26/37) and 49% of dermatologists (46/97) have responded to the survey. At total of 15 patients were singled out as possibly having NSF. 11 of the patients did not receive an MRA during our study period. 4 patients received an MRA included in our study: 3 were dialysis dependent patients and 1 had an increased creatinine. Results from our database search of diagnoses, referrals, pathology samples, as well as a chart review of patients is still pending at this time.

CONCLUSIONS: Our preliminary results show a significantly lower risk of developing NSF in patients with renal disease who have received gadolinium based contrast agents than has previously been reported. Note that this does not include results from our pending database search, which may result in the discovery of more patients who have developed NSF. Another reason for this lower risk may be the type of contrast administered as higher rates of NSF have been reported in patients who have received gadodiamide. No previous study has published a prevalence using gadopentetate dimeglumine. Further database searches and chart reviews are still pending at this time.

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