

Dear Health Care Provider,

The purpose of this newsletter is to inform you of MDR's screening protocol for gadolinium contrast for MRA and MRI. We believe that, like those who receive iodinated contrast, patients who undergo MRA and MRI require screening with renal function tests including BUN and Creatinine. It has been shown that while most of the contrast passes through the liver, some is excreted through the kidneys.

After 18 years of use and more than 200 million doses worldwide, MRI contrast agents have an excellent overall safety profile. However, recent reports have described a correlation between certain gadolinium-based MR contrast agents and a rare, but serious, medical condition called Nephrogenic Systemic Fibrosis (NSF) or Nephrogenic Fibrosing Dermopathy (NFD).

NSF/NFD was first described in 1997 and has only been observed as a side effect in patients with chronic kidney disease. There are only 250-400 cases currently reported.

NSF/NFD causes thickening and hardening of the skin and may also affect the internal organs. The disease is progressive and can be fatal, and current medicine lacks an effective treatment. There have been reports suggesting a relationship between the use of Gadolinium contrast agents and NSF/NFD, but at this time, the majority of cases have been associated with certain preparations of gadolinium. Although we do not use these brands of gadolinium, the risk of NSF/NFD is not entirely eliminated. The FDA has issued an alert regarding use of gadolinium in patients with renal disease or who are on dialysis.

To prevent delays in obtaining imaging studies, MDR's radiologists can order the renal function tests in patients who do not have recent labs. Coding for medical necessity, whenever possible, should be based on the disease that places the patient at risk; e.g., hypertension or diabetes. Where there is no known disease or the only risk factor is age, the code V 81.5 (screening for nephropathy) should be used.

As always, MDR is committed to providing the highest standard of medical care for your patients.

Sincerely,
Your colleagues at MDR

SCREENING PROTOCOL FOR GADOLINIUM CONTRAST FOR MRA AND MRI

1. Screening for GFR will be done for patients with any of the following risk factors:

- History of renal disorder including acute renal failure and hepatorenal syndrome
- History of diabetes mellitus
- History of vascular disease
- Patients \geq 60 years of age
- Severe liver disease*
- Recent vascular surgery including renal or liver transplantation, arteriovenous graft or revision and acute venous thrombosis

Patients currently on dialysis (peritoneal dialysis and hemodialysis) are excluded from requiring renal function tests.

Lab data is valid for 60 days for outpatients and 30 days for inpatients with stable medical status.

If lab information is not available and the patient is 60 years of age or older and has no other risk factor(s) as above, default to the CKD 3b protocol, 1/2 dose for MRI and up to full dose for MRA.

2. Prohance will be available as a backup gadolinium agent for Multihance. Omniscan will be available for pediatric patients less than 2 years of age. (Of the five gadolinium agents, Multihance and Prohance appear to have the best safety profiles at the present time).

*overestimates GFR so use 40 ml/min/1.73 m² as lower limit of CKD 3b in these patients. (MDR - 04/23/2008)



GADOLINIUM CONTRAST GUIDELINES FOR PATIENTS WITH RENAL DISEASE

RENAL STATUS	DOSAGE OF MULTIHANCE OR PROHANCE	
	MRI	MRA
Normal renal function	full dose	up to full dose
Chronic Kidney Disease (CKD) presence of kidney damage with GFR		
CKD 1 $>$ 90 ml/min/1.73 m ²	full dose	up to full dose
CKD 2 60-89 ml/min/1.73 m ²	full dose	up to full dose
CKD 3a $>$ 45-59 ml/min/1.73 m ²	full dose	up to full dose
CKD 3b 30-45 ml/min/1.73 m ²	1/2 dose	up to full dose
CKD 4 15-29 ml/min/1.73 m ² CKD 5 14 or less ml/min/1.73 m ² }	restricted to lowest possible dose with maximum 1/2 dose with documented medical necessity by referring attending and radiologist and nephrology consult or with dialysis to follow study.	

A standard full dose of Multihance is 0.1 mmol/kg

Patients with any stage of kidney disease should not receive Omniscan.

For all patients with CKD 3b, 4 or 5 kidney disease (moderate (3b) to end stage) or those with acute kidney injury, it is recommended that one consider refraining from administering any GBMCAs unless a risk-benefit assessment for that particular patient indicates that the benefit of doing so clearly outweighs the potential risk(s).

1. The indication for the contrast MR study will be reviewed by the covering MR or oncall radiologist to see if a non-contrast MRI/MRA or another test would provide the information required for patient care.

Patient should not receive a second dose of gadolinium contrast within 24 hours unless there is a documented medical emergency.

2. All patients with CKD 3b, 4 & 5 renal disease who are to undergo contrast-enhanced MR imaging examination of any kind must have a written order to this effect for this agent from the radiologist approving the examination. This should include the name of the patient, the name and specific brand of GBMCA, dose, route and rate of administration should all be explicitly specified on the order, along with the date and signature of the requesting radiologist.
3. Informed consent should be obtained for CKD 3b, 4 & 5.
4. If the patient is on CAPD (chronic ambulatory peritoneal dialysis), the patient should be advised to begin an "extra" dialysis treatment as soon as they complete the MR examination.
5. If the patient is on continuous peritoneal dialysis, no additional intervention/dialysis treatment is required.

6. If the patient is on hemodialysis, the patient should proceed to hemodialysis as soon as possible after the MRI/MRA. The ACR guidance document recommends no later than 2 hours.
7. If the patient is CKD 1, 2 or 3a, no special treatment or handling is recommended. If the patient is CKD 4 or 5 the patient should be referred to a nephrologist prior to the study. If the patient is CKD 3b, direct discussion with the attending physician is recommended.
8. If the patient has protected regions in which gadolinium might not be readily cleared, i.e., amniotic fluid, pleural effusion or ascites, consider refraining from administering any GBMCAs unless a risk-benefit assessment for that particular patients indicates that the benefit of doing so clearly outweighs the potential risk.

(MDR - 04/11/2008)