MEDICAL IMAGING ASSOCIATES

2265 E. Sunnyside Road
Idaho Falls, ID 83404
Phone: (208) 542-5000
Fax: (208) 542-5151
www.miarad.com

Medical Imaging Associates (MIA) policy regarding GAD Contrast Agent for MRI Scans:

Assessment of Risk (See Table 1 for the classification of GBCAs)

Group II agents

Based on the most recent scientific and clinical evidence the ACR Committee on Drugs and Contrast Media considers the risk of Nephrogenic systemic fibrosis (NSF) among patients exposed to standard or lower than standard doses of group II Gadolinium-based contrast agent (GBCA) are sufficiently low or possibly nonexistent such that assessment of renal function with a questionnaire or laboratory testing is optional prior to intravenous administration. As in all instances, group II GBCAs should only be administered if they are deemed necessary by the supervising radiologist, and the lowest dose needed for diagnosis should be used as deemed necessary by the supervising radiologist.[1]

Group I and III agents

The ACR Committee on Drugs and Contrast Media concludes that patients receiving group I GBCAs should be considered at risk of developing Nephrogenic systemic fibrosis (NSF) if any of the following conditions apply to the patient:

- On dialysis (of any form)
- Severe or end-stage CKD (CKD 4 or 5, eGFR < 30 mL / min/1.73 m_2) without dialysis
- AKI

There is insufficient real-life data to determine the risk of NSF from administration of group III agents, despite an alternative excretion pathway for hepatobiliary agents. Thus, it is important to identify patients at risk of developing NSF, as defined above, prior to injection of group I and III GBCAs. The method used to identify such patients may differ for outpatients versus inpatients.

Identifying at-risk outpatients

Outpatients who may be receiving group I or group III agents should be screened for conditions and other factors that may be associated with renal function impairment. The following list of risk factors can be used to identify patients who have impaired renal function:

- History of renal disease, including:
  - Dialysis
  - Kidney transplant
  - Single kidney
  - Kidney surgery
  - History of known cancer involving the kidney(s)
  - History of Chronic Kidney Disease (CKD) or prior history of Acute Kidney Infection (AKI)
- History of diabetes mellitus (optional)

Once an outpatient is identified as being at risk for having reduced renal function based on screening, and group I or group III GBCA administration is contemplated, renal function should be assessed by laboratory testing (checking results of prior laboratory tests performed within an

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acceptable time window and ordering new laboratory tests only if necessary) and calculation of Glomerular filtration rate (eGFR). However, if the patient is on dialysis or has known AKI, laboratory testing and calculation of eGFR is not useful or necessary (i.e., eGFR is not accurate in this setting, and these patients would be considered at risk for NSF prior to group I or group III administration regardless of calculated eGFR).

Calculating eGFR

For adults, eGFR calculation is commonly performed using the Modification of Diet in Renal Disease (MDRD) equation or the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation.

Identifying at-risk inpatients

For all inpatients, an eGFR level should be obtained within 2 days prior to planned administration of a group I or group III GBCA. In addition, ordering health professionals should assess inpatients for the possibility of AKI, as eGFR calculation alone has limited accuracy for the detection of AKI.

Patients with CKD 4or5 (eGFR<30mL/min/1.73m$_2$) not on chronic dialysis

Group I agents are contraindicated in this setting. If a GBCA-enhanced MRI study is to be performed, a group II agent should be used.

Patients with CKD 3 (eGFR 30 to 59 mL / min/1.73 m$_2$)

NSF developing after GBCA administration to patients with stable eGFR 30-59 ml/min/1.73 m$_2$ is exceedingly rare. No special precautions are necessary in this group [48,49].

Patients with CKD 1or2 (eGFR60to119mlmin/1.73m$_2$)

There is no evidence that patients in these groups are at increased risk of developing NSF. Any GBCA can be administered safely to these patients.

TABLE 1. ACR Manual Classification of Gadolinium-Based Agents Relative to Nephrogenic Systemic Fibrosis

Group I: Agents associated with the greatest number of NSF cases:

Gadodiamide (Omniscan® – GE Healthcare)
Gadopentetate dimeglumine (Magnevist® – Bayer HealthCare Pharmaceuticals)
Gadoversetamide (OptiMARK® – Guerbet)

Group II: Agents associated with few, if any, unconfounded cases of NSF:

Gadobenate dimeglumine (MultiHance® – Bracco Diagnostics)
Gadobutrol (Gadavist® – Bayer HealthCare Pharmaceuticals; Gadovist in many countries) Gadoteric acid (Dotarem® – Guerbet, Clariscan – GE Healthcare)
Gadoteridol (ProHance® – Bracco Diagnostics)

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Group III: Agents for which data remains limited regarding NSF risk, but for which few, if any unconfounded cases of NSF have been reported:

Gadoxetate disodium (Eovist – Bayer HealthCare Pharmaceuticals; Primovist in many countries)

TABLE 2. eGFR Evaluation of Renal Function to Group I or Group III GBCA Administration

Patient Condition	eGFR Requirement
Patient on dialysis (any type)	No eGFR required — eGFR is not helpful in this situation.
Patient with AKI	No eGFR required — eGFR is not helpful in this situation.
Inpatient	Obtain eGFR within 2 days of the MRI study.
Outpatient/ED with no prior eGFR at the time the MR exam is scheduled	If NO risk factors [1], no eGFR required. WITH risk factors [1], obtain eGFR.*
Outpatient/ED with most recent prior eGFR of 45 or above	If NO risk factor [1] and eGFR of 60 or above, no new eGFR required. WITH risk factors [1] and/or eGFR 45-59, if most recent prior eGFR is within 6 weeks of the MRI, no new eGFR is needed; otherwise obtain a new eGFR.*
Outpatient/ED with most recent prior eGFR of 44 or below	Obtain eGFR within 2 days of the MRI study

* If the new eGFR is to be obtained expressly for evaluation of suitability for administration of GBCA, obtaining the eGFR within 2 days of the MRI exam would avoid the situation where the new eGFR might be less than 45 and require another eGFR within two days of the MRI exam, as per the last line in the table.