United Radiology Group Consensus REGARDING GADOLINIUM-BASED CONTRAST MEDIA(GBCM):

GROUP II and GROUP III GADOLINIUM-BASED CONTRAST MEDIA(GBCM) should be utilized for all MRI examinations that require the use of IV contrast agents. Due to the potential detrimental long-term effects (i.e. the potential long term toxicity, nephrogenic systemic fibrosis, neuronal deposition) GROUP I GBCM are not recommended at this time.

Usage of IV Gadolinium Based Contrast Media in patients with Kidney Disease:

The American College of Radiology (ACR) and National Kidney Foundation (NKF) 2021 consensus statement to improve and standardize the care of patients with kidney disease, who have indication(s) to receive ACR designated GROUP II OR GROUP III GADOLINIUM-BASED CONTRAST MEDIA(GBCM) indicated the following:

1. The risk of NSF from GROUP II GBCM in patients with advanced kidney disease is thought to be very low: eGFR<30mL/min per 1.73 m2 0.07%overall and 0.2% for stage 5 chronic kidney disease, 0.5% for stage 5 CKD /no dialysis

2. Depending on the clinical indication, the potential harms of delaying or withholding GROUP II or GROUP III GBCM for an MRI in a patient with acute kidney injury or eGFR less than 30mL/min per 1.73m2 should be balanced against and may outweigh the risk of NSF.

3. Dialysis initiation or alteration is likely unnecessary based on group II or group III GBCM administration

ACR Manual on Contrast Media 2021

General Recommendations for Imaging Patients at Risk for NSF

Group II agents are strongly preferred in patients at risk for NSF. Given the very low, if any, risk of NSF development with group II agents, regardless of renal function or dialysis status, informed consent is not recommended prior to GBCA group II injection, but deference is made to local practice preferences.

If use of a group I or group III agent is being considered in a patient with a risk of NSF, the potential benefit of a GBCA-enhanced MRI exam are felt to outweigh the risk of NSF in an individual patient, and there is no suitable alternative, the referring physician and patient should be informed of the risks of GBCA administration, and both should agree with the decision to proceed with GBCA injection.

Group I agents (see Table 1), the GBCAs that have been most often associated with NSF, have been contraindicated by the FDA for use in these patients [24].

The lowest dose of GBCA required to obtain the needed clinical information should be used in at-risk patients, and it should generally not exceed the recommended single dose. (Note: the lowest diagnostic dose has not been thoroughly investigated for many indications; be careful not to minimize dose below diagnostic quality).

Exceptions to the above recommendations may be made at the discretion of the supervising radiologist, such as in the rare instance of an acute, life-threatening condition, and after consultation with the referring health care professional. Documentation of the rationale for the exception is recommended.

Limiting use of GBCAs in at-risk patients has already had a dramatic effect in reducing or even eliminating the

number of new cases of NSF [43]. It must be remembered that the risks of administering a GBCA to a high- risk patient must always be balanced against the often substantial risks of not performing a needed contrast- enhanced imaging procedure.

Multiple doses of GBCA
In unusual circumstances, it may be necessary to administer multiple doses of a GBCA within a relatively short time frame. Examples include a rapid change in patient condition for which an additional enhanced MR exam may be of benefit or when the initial MR exam indicates an acute need for a more sophisticated enhanced MR exam. In patients not at risk of NSF, there is no contraindication if the examination(s) are determined to be necessary. In patients at risk of NSF, the committee recommends the use of group II agent(s).

Additional Specific Recommendations for Specific Groups of Patients:

Patients with end-stage renal disease on chronic dialysis
If a contrast-enhanced cross-sectional imaging study is required in an anuric patient with no residual renal function, it would be reasonable to consider administering iodinated contrast media and performing a CT rather than an MRI, assuming the anticipated diagnostic yield is similar.

If a contrast-enhanced MR examination is to be performed in a patient with end-stage renal disease on chronic dialysis, injection of GROUP I agents (see Table 1) is contraindicated, and the committee recommends the use of a GROUP II agent. When using a GROUP II agent, the risk of NSF is extremely low. The ACR Committee on Drugs and Contrast Media also recommends that elective GBCA-enhanced MRI examinations be performed as closely before hemodialysis as is possible, as prompt postprocedural hemodialysis, although unproven to date, may reduce the likelihood that NSF will develop. Some experts recommend multiple dialysis sessions following GBCA administration, with use of prolonged dialysis times and increased flow rates and volumes to facilitate GBCA clearance, but the incremental benefits remain speculative. When using a GROUP II agent, the risk of NSF is so low that the ACR Committee on Drugs and Contrast Media believes that the risk-benefit equation does not favor repeated dialysis sessions.

Peritoneal dialysis may provide less NSF risk reduction compared to hemodialysis, but this has not been adequately studied.
Patients with CKD 4or5 (eGFR<30mL/min/1.73m2) 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 m2). NSF developing after GBCA administration to patients with stable eGFR 30-59 ml/min/1.73 m2 is exceedingly rare. No special precautions are necessary in this group [44,45].

Patients with CKD 1or2 (eGFR60to119mlmin/1.73m2). 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.

Patients with acute kidney injury (AKI)
Patients with AKI who have been exposed to GBCA are at risk for developing NSF [17]. Due to the temporal lag between eGFR (which is calculated using serum creatinine values) and actual glomerular filtration rates, it is not possible to determine whether a given patient has AKI based on a single eGFR determination. Accordingly, GROUP I agents should be avoided in patients with known or suspected AKI. If GBCA is to be administered in this setting, a group II agent is preferred.

Children
A systematic search of databases published in 2014 [46] found only 23 reported pediatric cases of NSF, and no cases in children under the age of 6 years. Nevertheless, there is not enough data to demonstrate that NSF is less likely to occur in children than in adults with similarly significant renal disease. Therefore, it is prudent to follow the same guidelines for adult and pediatric patients as described in the remainder of this document. However, eGFR values in certain premature infants and neonates may be <30 ml/min/1.73 m2 simply due to immature renal function (and not due to pathologic renal impairment). In these individuals, the ACR Committee on Drugs and Contrast Media believes that caution should still be used when administering GBCAs, and GROUP II agents should be used in this setting if feasible.

Caveat

Information on NSF and its relationship to GBCA administration continues to evolve, and the summary included here represents only the most recent opinions of the ACR Committee on Drugs and Contrast Media. If additional information becomes available, our understanding of causative events leading to NSF and recommendations for preventing it may change, leading to further revisions of this document.

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)

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.

Risk Factors:
1. History of renal disease, including:
a. Prior dialysis
b. Renal transplant
c. Single kidney
d. Kidney surgery
e. Renal cancer
2. Hypertension requiring medical therapy
3. Diabetes mellitus