SUNY DOWNSTATE MEDICAL CENTER
UNIVERSITY HOSPITAL OF BROOKLYN
POLICY AND PROCEDURE

No: MRI-8

Subject: USE OF GADOLINIUM-BASE CONTRAST IN MRI

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TJC Standards: NPSG 03.02.01 EP.2 Implement the procedures for managing the critical results of tests and diagnostic procedures
PC.01.02.01 (EP.2) The hospital defines, in writing, criteria that identify when additional, specialized, or more in-depth assessments are performed.

MM.04.01.01 medication orders are clear and accurate
UP.01.03.01 A time-out is performed before procedure

RAD-12 Medication Orders for Contrast Media Imaging Procedures

Issued by: Radiology Department

I. PURPOSE

To minimize risk of "*Gadolinium Induced Pathology"* in patients receiving MRI studies.

The FDA has issued an alert about a new disease known as Nephrogenic Systemic Fibrosis or Nephrogenic Fibrosing Dermopathy (NSF/ NFD) which may occur in patients with moderate to end-stage kidney disease after they have had a MRI or MRA scan With a Gadolinium-Based Contrast Agent.

II. DEFINITION

Nephrogenic Systemic Fibrosis (NFS) is a rear condition that leads to excessive formation of connective tissue in the skin and internal organs. NSF is a progressive and may be debilitating or fatal.

III. POLICY

Patient receiving gadolinium-based contrast will be screened for renal disease.

IV. RESPONSIBILITIES

Radiologist and Ordering Physician, Nursing

V. PROCEDURES/GUIDELINES

A. Procedure Assessment

1. ***The association occurs under the following combination of conditions:***
2. Renal Failure of insufficiency, GFR<30 mg/di. FDA warning specifies creatinine clearance < 30mimin/1.73m. This may be relevant for patients who are smaller than the body surface for the average adult, which is 1.73m
3. Renal Acidosis.
4. Double and triple doses of contrast sometimes used for MRA

B. Patients are to be assessed to identify RISK FACTORS FOR CONTRAST NEPHROTOXICITY, which includes the following:

1. Renal Failure, Renal Insufficiency, Dialysis
2. Diabetes Mellitus
3. Dehydration – vomiting, diarrhea decreased p.c. intake.
4. Cardiovascular Disease and the use of diuretics
5. Fifty years or older
6. Myeloma
7. Hypertension
8. Hyperuriema

C. Other Risk Factors have also been correlated with NSF in the literature

- *Vascular injury, hypercoagulability*
- *Recent surgery*
- *Pro-inflammatory process*
- *Acidosis*
- *Increased serum calcium, phosphate, iron, zinc, copper, and lanthanum.*

VI. *I. SPECIFIC MEDICATIONS*

Serum Creatinine to be obtained on patients who meet the following*:*

1. A history of kidney disease including transplant
2. Family history of kidney failure
3. Diabetes medically treated
4. Paraprotenteinemia syndromes such a myeloma

II. MEDICATIONS

1. NSAIDS (chronic use or recent large doses)
2. Metformin of metformin containing combinations such as Advandamet, Glucophage, Glocovance and metaglip
3. Regular use of nephrotoxic antibiotics, such as aminoglycosides.

Note: *Some data exists about potential (actual or theoretical) risk for drug interactions and greater risk of NSF reported with these medications. Data is not very strong at this point, so the clinicians should decide how much a warning they would like to place of any.*

I. Erythropoietin(Epogen- used for dialysis and non-dialysis patients*)*

II. Divalent/trivalent cation sources: iron ,calcium and/ or lanthanum products-may increase risk of transmetallation
III. Medications that can cause / Aggravated acidosis are:
- Documented: Sevenlamer (Rena gel –used in dialysis and pre- dialysis patients)
- Theoretical: Metformin, nucleoside analogs.

VII. SCREENING

All patients having an MR will be screened and the following implemented.

A. Serium Creatinine for All of the following patients:

1. Age fifty years or greater (50 years or >)
2. Two or more risk factors
3. Any indication from the above list

B. Convert the serum cratinine to an estimated GFR using the following accepted methodology

1. This takes into account the gender, the race and the age of the patient.
2. www.nkdep.nih.gov/professionals/gfr_calculator or www.kidney.org/professionals *MDRD GFR* Calculator

C. Creatinine Results are Valid

1. Stable Out patients 30 days
2. Diabetic patients 1 week
3. Inpatients Current hospital stay
4. Sick out patients (vomiting, diarrhea, decreased p. o. intake)

D. Gadolinium to be used with caution in patients with a GFR < 30 mg/dl.

1. A radiologist and ordering physician will review the medical necessity for contrast in patients who have a GFR < 30mg/dl.
2. If the benefit of the test using gadolinium is identified, the risk, benefit and alternates will be explained to the patient by a physician. This discussion will be documented in the patient's medical record.
3. For end stage renal disease patients , prompt dialysis should be considered after the procedure. The utility of this measure for preventing or treating NSF/NSD in patients with impaired renal function has not been established. Average excretory rates of gadolinium during consecutive hemodialysis sessions are 78%, 96% and 99% respectively. Suggestion that hemodialysis within hours is recommended and (clarification that peritoneal dialysis does not appear to remove gadolinium significantly).

E. Contrast is contra-indicated in patients with previous allegoric reaction and in patients with or awaiting liver transplant

F. Use single dose only. 0.1. mmlk/kg for standard studies. Any multiple doses must be discussed with the Radiologist prior to procedure. Dose recommended is 0.1 mMol /kg (or 0.2. mLkg).

Note: *Provide patients is cleared for examination based on the above mentioned indicators the technologist will perform a compete (**Time-Out**) prior to the start of the procedure. The **Time Out** includes:*

- verification of PT. name (first/ Last & DOB)
- Patient Medical Record (MR#)
- correct procedure
- correct site/ Body part
- correct laterality,
- correct contrast(if applicable)
- correct agent, dose & route (if applicable

VIII. ATTACHMENTS:

None

IX. REASON FOR REVISION

Review

VII. REFERENCES:

ACRC guidelines 5.0
Below, Mary, MD, Radiologist, MR Medical Director, St. Francis Hospital & Health centers, December 2006
Clark, Steven, A MD. Pathologist, Medical Director of St. Francis Hospital Health centers Pathology. December 2006
Dorulla, Georgia MD, Radiologist, St. Francis Hospital & Health centers, December 2006
Johnston, Douglas MD, Nephrologist Medical Center Director of Patient safety and Performance improvement December 2006
Diagnostic Imaging.co : Gadolinium contrast may link to life threating condition. August 2006.
FDA Public Health Advisory: Gadolinium –containing Contrast Agent Magnetic Resonance Imaging, June 8, 2006
Medscape Medical news: Use of Gadolinium in MRI and MRA Linked to NSF/NFD in Patients with Renal Failure January 2, 2007

- *RAD-12 Medication Orders for Contrast Media Imaging Procedures http://www.downstate.edu/regulatory/pdf/policies/RAD-12.pdf*

Date Revie	Revision Required (Check One)		Responsible Staff Name and Title
1/2001	**Yes**		James Shanahan Director Radiology Department
12/2010	**(Yes)**		James Shanahan Director Radiology Department
2/2016		**No**	Vincent Monte, Associate Director Radiology Departmen
11/2018		**No**	Vincent Monte, Associate Director Radiology Departmen