MCR MEDICAL CENTER RADIOLOGISTS

Prevention of Nephrogenic Systemic Fibrosis (NSF) with Gadolinium Based MRI Contrast Agents/Medications (GBCA)

- Group I agents: not currently approved for use.
- Group II agents: Dotarem® (gadoterate meglumine) is preferred. In case of shortage, Multihance® (gadobenate dimeglumine) and Gadavist® (gadobutrol) can be used.
- Group III agents: Eovist® (gadoxetate disodium)

NSF is a disease, primarily involving the skin and subcutaneous tissues but also known to involve other organs, such as the lungs, esophagus, heart, and skeletal muscles. Initial symptoms typically include skin thickening and/or pruritus. A skin biopsy is necessary to confirm the diagnosis. Symptoms may develop and progress rapidly, with some patients developing contractures and joint immobility. In some patients, the disease may be fatal.

Most patients who developed NSF had end-stage kidney disease and were on dialysis at the time of exposure. Among patients with severe chronic kidney disease (CKD) that developed NSF (~3%), most had an eGFR closer to 15mL/min/1.73m2 than to 30mL/min/1.73m2. There has only been one published case report of a patient with eGFR

>30mL/min/1.73m2 with NSF.

Pediatric patients at risk for NSF include those with known medical renal disease (CKD or acute kidney injury) or those with known renal/urinary tract structural abnormalities.

Adults with end-stage CKD (eGFR <15mL/min/1.73m2), and severe CKD (eGFR 15-29mL/min/1.73m2) have a 1% to 7% chance of developing NSF after one or more exposures to group I GBCAs. Between 12% and 20% of confirmed NSF cases occurred in patients with acute kidney insufficiency (AKI) with or without underlying CKD. Cases of NSF have occurred with single exposure to a GBCA, but most commonly in the setting of high doses of GBCA (single administration or cumulative multiple administrations over months to years.)

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 is contraindicated, and the ACR recommends the use of a group II agent. When using a group II agent, the risk of NSF is extremely low.

All patients receiving Group I or Group III GBCAs, and those with any risk factors listed below receiving Group II GBCAs shall have a Serum Creatinine (SCr) with eGFR calculations prior to GBCA administration. If a SCr is not available within guidelines/timeframes, an iSTAT SCr shall be done prior to administration of GBCA.

A. Within 48 hours for all patients receiving Group III agents
B. Within 48 hours for all inpatients (including ED patients) receiving Group II agents with the following risk factors
C. Within 6 weeks for outpatients receiving Group II agents with the following risk factors and eGFR result > or = 45 mL/min/1.73m2
D. Within 48 hours for outpatients receiving Group II agents with the following risk factors and eGFR within 6 weeks < or = 44 mL/min/1.73m2
    a. Age 60 years or older
    b. History of renal disease including:
        i. Prior dialysis
        ii. Renal transplant

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iii. Single kidney
iv. Renal cancer

c. Hypertension requiring medical therapy
d. Diabetes mellitus

eGFR shall be calculated in the electronic medical record, or by using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation, or the bedside Schwartz (pediatrics) prior to GBCA administration.

Pediatric Patients

Use of IV GBCA in children of all ages should be justified, and the benefit of administration should outweigh potential risks.

Caution should be used when administering these contrast agents to preterm neonates and infants due to renal immaturity and potential eGFR rates under 30mL/min/1.73m2. ACR recommends Group II GBCA be used for pediatric patients if feasible.

References

FDA Drug Safety Communication: New warnings for using gadolinium-based contrast agents in patients with kidney dysfunction - updated December 2010

FDA Drug Safety Communication: FDA evaluating the risk of brain deposits with repeated use of gadolinium-based contrast agents for magnetic resonance imaging (MRI) July 2015

ACR Contrast Media Manual 2021

FDA medication guides for GBCAs – https://www.fda.gov/Drugs/DrugSafety/ucm085729.htm

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