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FDA approves first ever contrast agent for cardiac MRI

The U.S. Food and Drug Administration (FDA) has approved Gadavist®(gadobutrol) injection for use in cardiac magnetic resonance (MR) imaging to assess myocardial perfusion (stress, rest) and late gadolinium enhancement in adult patients with known or suspected coronary artery disease (CAD). Gadavist is now the first and only contrast agent FDA approved for use in cardiac MR – an important diagnostic tool for patients with CAD.

The Society for Cardiovascular Magnetic Resonance recognizes cardiac Medical Resonance imaging as a non-invasive tool that provides relevant and actionable information to healthcare professionals.

"Gadobutrol-enhanced cardiac MR demonstrated efficacy in a large global multicenter clinical trial," said Daniel S. Berman, MD, FACC, Chief of Cardiac Imaging and Nuclear Cardiology at the Cedars-Sinai Heart Institute and the S. Mark Taper Foundation Imaging Center. "The FDA approval is a landmark for making this validated, non-invasive method available to healthcare professionals to evaluate their patients for the most common form of heart disease in the world."

The approval was based on two multinational, non-randomized, blinded-read Phase 3 studies of almost 1,000 adults with suspected or known CAD based on signs and symptoms. Nearly 800 of those patients were evaluated for efficacy. First approved in 2011, cardiac MR is now the fourth FDA approved indication for Gadavist.

"We now have an approved contrast agent for use in cardiac MR to assess perfusion and late gadolinium enhancement in less than one hour," said Scott Flamm, MD, MBA, Head of Cardiovascular Imaging, Cleveland Clinic. "A Gadavist-enhanced cardiac MR is a key diagnostic tool, providing additional important clinical information, which can help physicians manage their patients with known or suspected CAD."

A disease that affects approximately 16.5 million Americans, CAD develops when the major blood vessels that supply the heart with blood, oxygen and nutrients (coronary arteries) become damaged or diseased.1,5 Cholesterol-containing deposits (plaque) in the arteries and inflammation are usually the cause of CAD. When plaque builds up, it narrows the coronary arteries, decreasing blood flow to the heart. Eventually, the decreased blood flow may cause chest pain (angina), shortness of breath, or other coronary artery disease signs and symptoms. A complete blockage can cause a heart attack.

"This latest FDA approval represents another first from Bayer, as Gadavist is the first and only contrast agent approved for cardiac MR," said Dennis Durmis, SVP and Head of Americas Region at Bayer Radiology. "Not only does this approval add to our existing indications for Gadavist, expanding scientific knowledge, but also underscores our dedication to research and provides radiologists and cardiologists with another diagnostic option as they manage their patients with known or suspected CAD."

For more information about Gadavist, please visit www.radiologysolutions.bayer.com/products/mr/contrast/gadavist/

About Gadavist

Gadavist® (gadobutrol) injection was first approved in the U.S. in 2011 for intravenous use in magnetic resonance (MR) imaging in adults and children (2 years of age and older) to detect and visualize areas with disrupted blood brain barrier and/or abnormal vascularity of the central nervous system. Gadavist was further approved in the U.S. in 2014 for MR of the breast in adult patients to assess the presence and extent of malignant breast disease and for pediatric patients less than 2 years of age, including term neonates, to detect and visualize areas with disrupted blood brain barrier and/or abnormal vascularity of the central nervous system. In 2016, it was approved in the U.S. for use with magnetic resonance angiography (MRA) to evaluate known or suspected supra-aortic or renal artery disease in adult and pediatric patients including term neonates.

Gadavist, also known as Gadovist® and Gadovist® 1.0 in other regions, is the U.S. brand name of the aqueous 1.0M solution of gadobutrol, a gadolinium (Gd)-based extracellular contrast agent for MRI with a macrocyclic structure. The safety profile of Gadavist has been established in clinical trials involving 7,713 patients (including 184 pediatric patients ages 0-17). The safety and effectiveness of Gadavist have not been established in preterm neonates for any indication or in pediatric patients of any age for use with MR to assess the presence and extent of malignant breast disease, or for use in cardiac MR to assess myocardial perfusion (stress, rest) and late gadolinium enhancement in patients with known or suspected coronary artery disease (CAD). Please see Important Safety Information, including Boxed Warning below.

INDICATIONS and IMPORTANT SAFETY INFORMATION

INDICATIONS

Gadavist® (gadobutrol) injection is a gadolinium-based contrast agent indicated for use with magnetic resonance imaging (MRI):

- To detect and visualize areas with disrupted blood brain barrier (BBB) and/or abnormal vascularity of the central nervous system in adult and pediatric patients including term neonates.
- To assess the presence and extent of malignant breast disease in adult patients.
- To assess myocardial perfusion (stress, rest) and late gadolinium enhancement in adult patients with known or suspected coronary artery disease (CAD).

Gadavist® is indicated for use in magnetic resonance angiography (MRA):

- To evaluate known or suspected supra-aortic or renal artery disease in adult and pediatric patients including term neonates.

IMPORTANT SAFETY INFORMATION

WARNING: NEPHROGENIC SYSTEMIC FIBROSIS (NSF)

Gadolinium-based contrast agents (GBCAs) increase the risk for NSF among patients with impaired elimination of the drugs. Avoid use of GBCAs in these patients unless the diagnostic information is essential and not available with non-contrasted MRI or other modalities. NSF may result in fatal or debilitating fibrosis affecting the skin, muscle and internal organs.

- The risk of NSF appears highest among patients with:
- - Chronic, severe kidney disease (GFR <30 mL/min/1.73m2), or
  - Acute kidney injury
- Screen patients for acute kidney injury and other conditions that may reduce renal function. For patients at risk for chronically reduced renal function (for example, age >60 years, hypertension or diabetes), estimate the glomerular filtration rate (GFR) through laboratory testing.
- For patients at highest risk for NSF, do not exceed the recommended GADAVIST dose and allow a sufficient period of time for elimination of the drug from the body prior to any re-administration.

Contraindication and Important Information about Hypersensitivity Reactions:

Gadavist® is contraindicated in patients with history of severe hypersensitivity reactions to Gadavist®. Anaphylactic and other hypersensitivity reactions with cardiovascular, respiratory, or cutaneous manifestations, ranging from mild to severe, including death, have uncommonly occurred following Gadavist® administration. Before Gadavist® administration, assess all patients for any history of a reaction to contrast media, bronchial asthma and/or allergic disorders. These patients may have an increased risk for a hypersensitivity reaction to Gadavist®.

Gadolinium Retention: Gadolinium is retained for months or years in several organs. Linear GBCAs cause more retention than macrocyclic GBCAs. At equivalent doses, retention varies among the linear agents. Retention is lowest and similar among the macrocyclic GBCAs. Consequences of gadolinium retention in the brain have not been established, but they have been established in the skin and other organs in patients with impaired renal function. While clinical consequences of gadolinium retention have not been established in patients with normal renal function, certain patients might be at higher risk. These include patients requiring multiple lifetime doses, pregnant and pediatric patients, and patients with inflammatory conditions. Consider the retention characteristics of the agent and minimize repetitive GBCA studies, when possible.

Acute Kidney Injury: In patients with chronic renal impairment, acute kidney injury sometimes requiring dialysis has been observed with the use of GBCAs. Do not exceed the recommended dose in these patients.

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Extravasation and Injection Site Reactions: Ensure catheter and venous patency before the injection of Gadavist®. Extravasation into tissues during Gadavist® administration may result in moderate irritation.

Overestimation of Extent of Malignant Disease in MRI of the Breast: Gadavist®MRI of the breast overestimated the histologically confirmed extent of malignancy in the diseased breast in up to 50% of the patients.

Low Sensitivity for Significant Arterial Stenosis: The performance of Gadavist®MRA for detecting arterial segments with significant stenosis (>50% renal, >70% supra-aortic) has not been shown to exceed 55%. Therefore, a negative MRA study alone should not be used to rule out significant stenosis.

Adverse Reactions: The most frequent (≥0.5%) adverse reactions associated with Gadavist® in clinical studies were headache (1.7%), nausea (1.2%) and dizziness (0.5%).

Source: https://speciality.medicaldialogues.in/fda-approves-first-ever-contrast-agent-for-cardiac-mri/