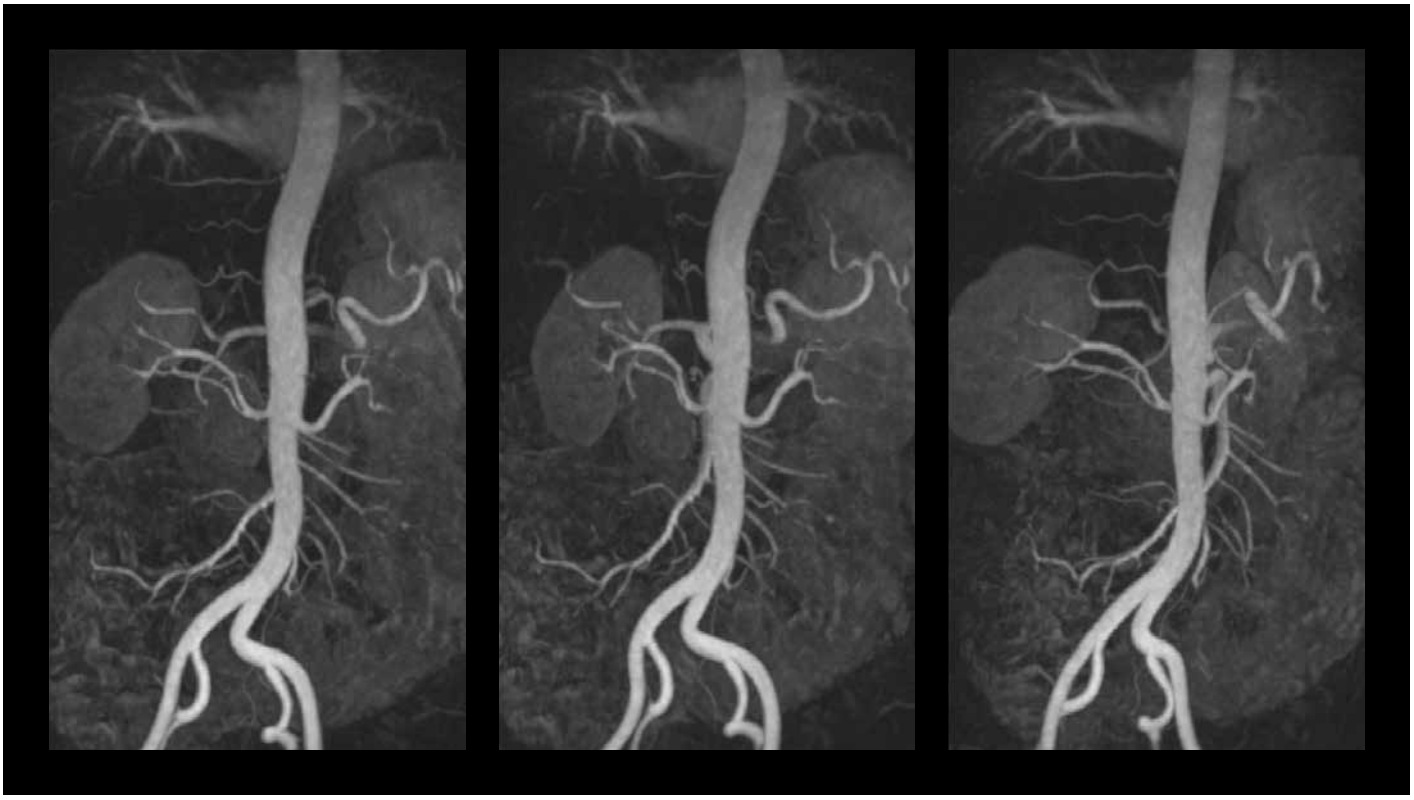
GE HealthCare

CASE STUDY

MRI of the renal arteries



Images and content are courtesy of:

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macrocyclic
Pixxoscan™
gadobutrol

CASE STUDY

MRI of the renal arteries

Medical history of the patient

41-year-old male patient presenting with suspected malignant hypertension. “Malignant” in this condition means that this type of hypertension has a “malignant” clinical course with severe hypertension, which is refractory to medication.

Preliminary diagnostics

Renal artery stenosis may be one cause of hypertension.
No imaging has been done so far.

Indication for MRI

An MRI examination was requested to investigate the renal arteries and rule out stenosis of the artery. Colour-coded ultrasound, in general, is not as sensitive as MRA to detect renal artery stenosis and in this particular case it is not an option (because of patient weight).

Scan protocol includes **MRI: 3T**

1. Coronal balanced SSFP (T2/T1 weighted)
2. Axial 3D T1 GE Dixon
3. MRA of the renal arteries with MIP reconstruction
4. Axial 3D T1 GE Dixon after contrast injection

Injection protocol

Patient weight 115 kg

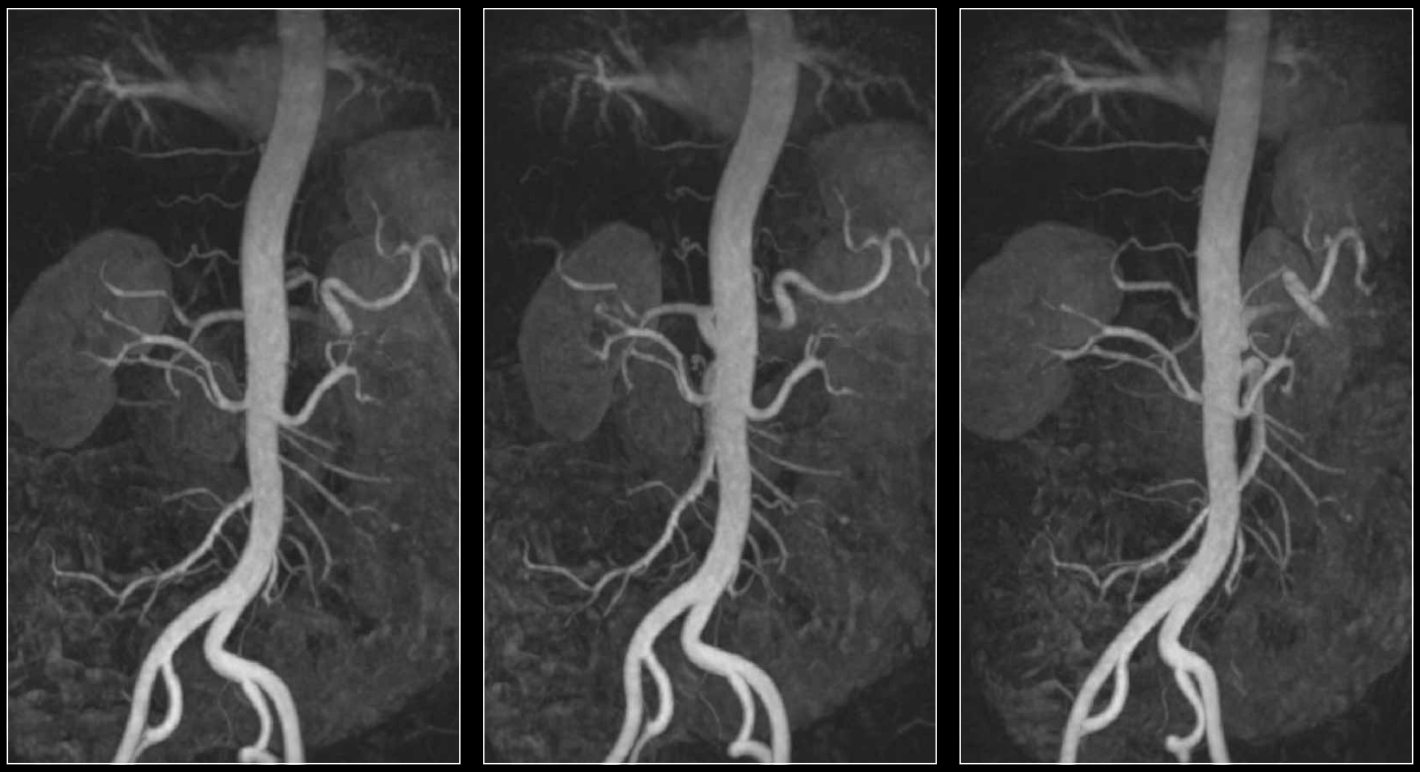
GBCA injection	
Pixxoscan™ (gadobutrol) 0.1 mmol/kg	9 mL – 2 mL/sec
0.9 % NaCl	40 mL
Administration mode	With injector

Please refer to the full Product Monograph before prescribing.

Findings of the MRI examination

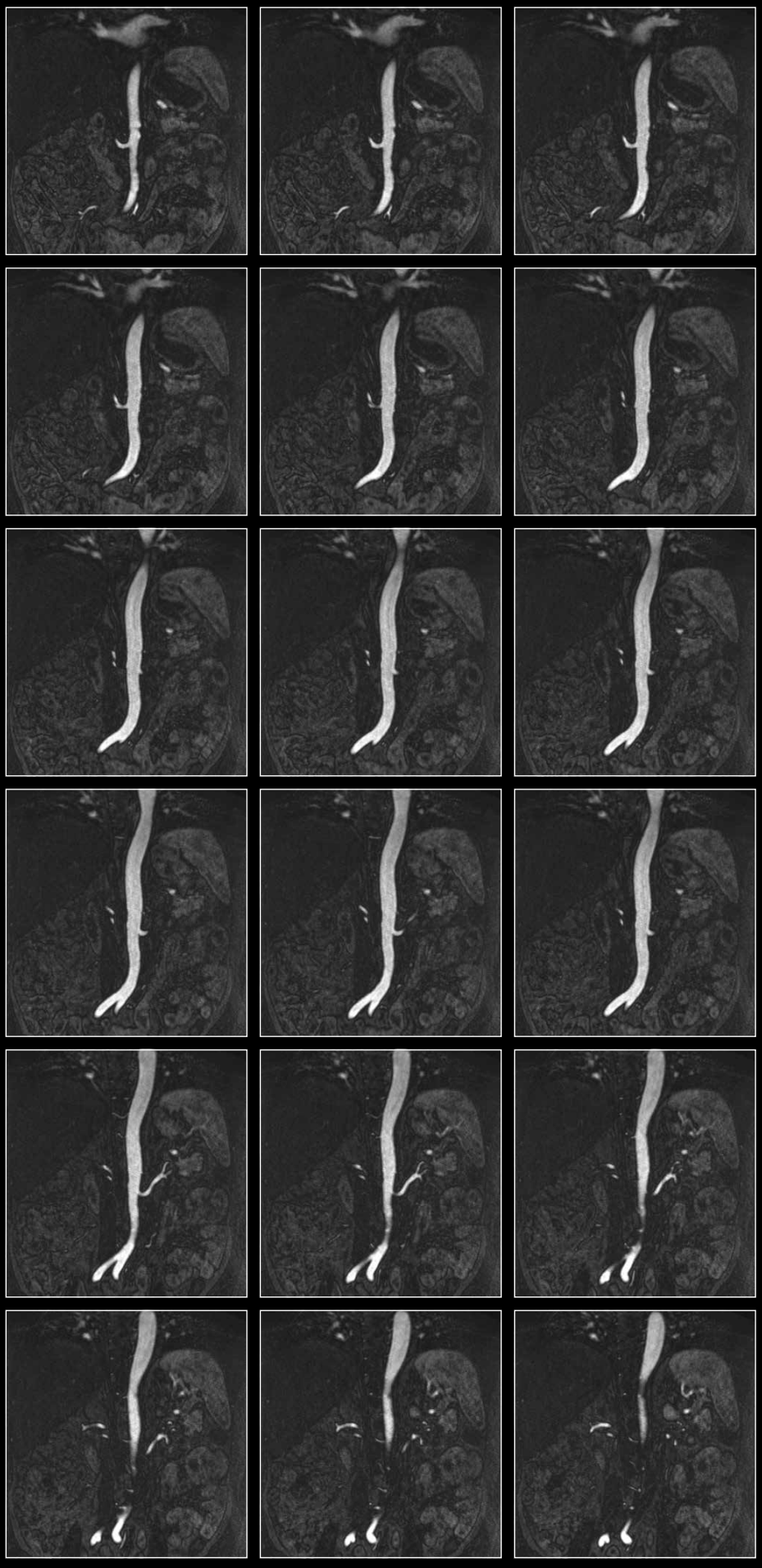
The MRA is showing normal arteries.

3D T1 MRA sequence acquired in coronal plane



MIP reconstruction of the MRA sequence:
Showing normal renal arteries

Raw images of the 3D MRA sequence acquired in coronal plane



MRA raw data:
MRA nicely shows the normal renal arteries, no stenoses, no accessory (supernumerary) renal arteries present.

Diagnosis and therapy or follow-up:

Patient with malignant hypertension and normal renal arteries (no stenosis).
Intensive medical therapy for hypertension is suggested, no intervention is needed.

Product Indications and Clinical Use – Pixxoscan™ (Gadobutrol injection)

Indications

Pixxoscan (gadobutrol injection) is a medicinal product for diagnostic use only. Pixxoscan (gadobutrol injection) is indicated in adults and children of all ages including term newborns for:

Contrast enhancement during cranial and spinal MRI investigations and for contrast-enhanced magnetic resonance angiography (CE-MRA).

- Contrast enhanced MRI of the breast to assess the presence and extent of malignant breast disease, and MRI of the kidney.
- Pixxoscan is particularly suited for cases where the exclusion or demonstration of additional pathology may influence the choice of therapy or patient management, for detection of very small lesions and for visualization of tumors that do not readily take up contrast media.
- Pixxoscan is also suited for perfusion studies for the diagnosis of stroke, detection of focal cerebral ischemia and tumor perfusion.

Contraindications

Gadobutrol injection should not be administered to patients who have experienced a life-threatening reaction to gadobutrol injection previously.

SERIOUS WARNINGS AND PRECAUTIONS BOX

Serious Warnings and Precautions
Nephrogenic Systemic Fibrosis (NSF)

Gadolinium-based contrast agents (GBCAs) increase the risk for NSF in patients with:

- chronic severe renal insufficiency (glomerular filtration rate <30 mL / min / 1.73m2), or
- acute renal failure / acute kidney injury

In these patients, avoid use of GBCAs unless the diagnostic information is essential and not available with noncontrast-enhanced magnetic resonance imaging (MRI). NSF may result in fatal or debilitating systemic fibrosis affecting the skin, muscle, and internal organs. Screen all patients for renal dysfunction by obtaining a history and / or laboratory tests. When administering a GBCA, do not exceed the recommended dose and allow a sufficient period of time for elimination of the agent from the body prior to any readministration.

- Pixxoscan is intended for intravenous administration only and may cause tissue irritation and pain if administered extravascularly.
- Pronounced states of excitement, anxiety and pain may increase the risk of adverse reactions or intensify contrast medium-related reactions.
- Gadolinium has been detected in brain tissue after multiple exposures to GBCAs, particularly in the dentate nucleus and globus pallidus. In order to minimize potential risks associated with gadolinium accumulation in the brain, it is recommended to use the lowest effective dose and perform a careful benefit risk assessment before administering repeated doses.
- Extravasation into tissues during Pixxoscan administration may result in moderate irritation
- Gadobutrol injection can be associated with anaphylactoid / hypersensitivity or other idiosyncratic reactions, characterized by cardiovascular, respiratory or cutaneous manifestations, and ranging to severe reactions including shock.
- Careful evaluation of the risk-benefit ratio in patients with a history of previous reaction to contrast media, allergic disorders, or bronchial asthma should be made.
- Precautionary measures should be taken with patients predisposed to seizure, eg, close monitoring and availability of injectable anticonvulsants.
- In patients with severely impaired renal function, the benefits of gadobutrol must be weighed carefully against the risks, since elimination will be delayed in such patients.
- Pixxoscan can be removed from the body by hemodialysis. For patients already receiving hemodialysis at the time of Pixxoscan administration, prompt initiation of hemodialysis following the administration of Pixxoscan should be considered, in order to enhance the contrast agent's elimination.
- The safe use of gadobutrol injection during pregnancy has not been established. Pixxoscan should be used during pregnancy only if the benefit justifies the potential risk to the fetus.
- Transfer of gadobutrol into the milk of lactating mothers has not been investigated in humans.
- The cautious utilization of the lowest possible dose of Pixxoscan (0.1 mL / kg body weight) is recommended in the pediatric population under 2 years of age; the recommended dose should not be exceeded and a sufficient period of time for elimination of the agent from the body (at least 7 days) should be allowed prior to re-administration.
- No special precautions are required in elderly patients unless renal function is impaired

Prior to administration, please read the Product Monograph for Pixxoscan and the Important Safety Information About Gadobutrol Based Agents, which is available by calling Customer Service 1 800 387 7146 or through an email request to canadainfo@gehealthcare.com.

Reporting Side Effects

To report SUSPECTED ADVERSE REACTIONS, contact GE HealthCare at 1 800 654 0118 (option 2, then option 1), or email canadainfo@gehealthcare.com to request an adverse events form, or fax to 905 847 5849 to request an adverse events form.

Adverse reactions can also be reported to Health Canada as follows:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health- canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or

  Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Abbreviations:
GE: gradient echo
MIP: maximum intensity projection
MRA: MR angiography
MRI: magnetic resonance imaging
SSFP: Steady-State Free Precession

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04-2025 JB01417CA