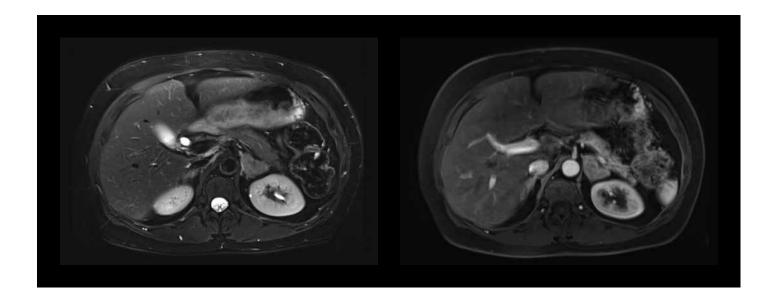


CASE STUDY

MRI of the adrenal gland



Images and content are courtesy of:

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All clinical protocols and decisions remain the responsibility of the healthcare provider. Information contained in this booklet may be abridged and should be used in alignment with institutional protocols and good clinical judgment.



CASE STUDY

MRI of the adrenal gland

Medical history of the patient

56 year-old female with history of type 2 diabetes.

Preliminary diagnostics

The patient has undergone an abdominal ultrasound and a CT scan which have revealed equivocal left adrenal mass with small amount of fat.

Indication for MRI

An MRI examination was requested to investigate the large nodule lesion seen on the abdominal CT scan.

MRI: 3T

Scan protocol includes

1. 3D T1 Dixon for in-phase and out-of-phase

- 2. Axial 3D T1 GE Dixon
- 3. Coronal T2w SSTSE
- 4. Axial T2w SSTSE
- 5. Axial DWI with 3 b-values : 50, 400 and 800. Reconstruction of the adc map
- 6. Axial T2w with FS and motion artefacts reduction
- 7. Axial 3D T1 GE with FS before contrast injection
- 8. Axial 3D T1 GE with FS after contrast injection at the arterial phase

Injection protocol

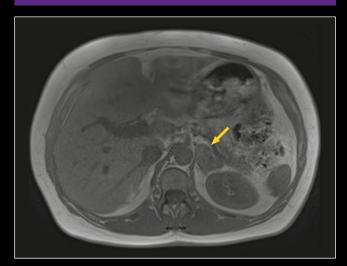
Patient weight 65 kg

GBCA injection	
Pixxoscan™ (gadobutrol) 0.1 mmol/kg	7.5 mL – 2 mL/sec
0.9 % NaCl	40mL
Administration mode	With injector

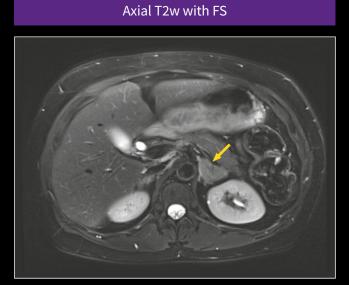
Findings of the MRI examination

A left adrenal mass with signal intensity loss in out-of-phase sequence and moderate contrast enhancement was seen on the MRI.

Axial 3D Dixon in-phase imaging



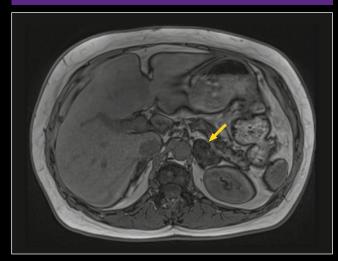
3D Dixon in-phase imaging: Showing a left adrenal mass measuring 3.8 cm (yellow arrow).



Axial T2w with FS and motion correction: The mass is showing low signal intensity (yellow arrow), which is consistent with an adenoma (pheochromocytoma would be high signal intensity).

Axial 3D T1 GE at arterial phase

Axial 3D Dixon out-of-phase imaging



3D Dixon out-of-phase imaging: Showing a signal intensity drop, indicative of fat content (yellow arrow).



3D T1 arterial phase: Showing a moderate, homogeneous enhancement of left adrenal mass (yellow arrow).



Diagnosis and therapy or follow-up:

This is a typical adrenal adenoma. No follow-up 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: adc: apparent diffusion coefficient; CT: computed tomography; DWI: Diffusion-Weighted Imaging; FS: fat saturation; GBCA: gadolinium-based contrast agent; GE: gradient echo; MR: magnetic resonance; MRI: magnetic resonance imaging; SSTSE: Single Shot Turbo Spin Echo; US: ultrasound

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