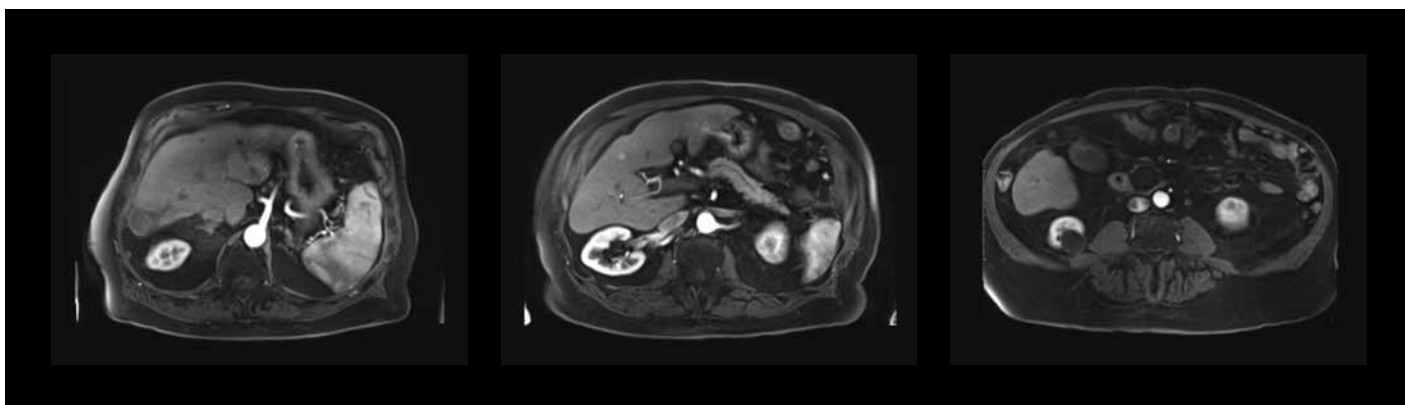


CASE STUDY

MRI of the liver



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.

macrocyclic
Pixxoscan[™]
gadobutrol

MRI of the liver

Medical history of the patient

80 year-old male patient with a history of liver cirrhosis and portal hypertension. The patient has known bifocal hepatocellular carcinoma located in segment 7 (right lobe) and segment 3 (left lobe). Both HCCs have previously been treated by trans-arterial chemoembolisation (TACE).

Preliminary diagnostics

The patient has undergone several contrast-enhanced abdominal CT before.

Indication for MRI

An MRI examination was requested to follow up both HCCs (in right lobe and left lobe) after chemoembolisation (TACE).

Scan protocol includes

MRI: 3T

1. 3D T1 Dixon for in-phase and out-of-phase
2. Axial 3D T1 GE Dixon
3. Coronal T2w SSTSE
4. Axial DWI with 3 b-values: 50, 400 and 800.
Reconstruction of the adc map
5. Axial T2w with FS and motion artefacts reduction
6. Axial 3D T1 GE with FS before contrast injection
7. Axial 3D T1 GE with FS after contrast injection at the arterial phase
8. Axial 3D T1 GE with FS after contrast injection at the venous phase
9. Axial 3D T1 GE with FS after contrast injection at a delayed phase
10. Coronal 3D T1 GE with FS after contrast injection at a delayed phase

Injection protocol

Patient weight 82 kg

GBCA injection

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



Findings of the MRI examination

In the right lobe (S7), there is a complete response after TACE. No residual tumour (no enhancement) can be seen.

In the left lobe (S3), a mass, measuring 4.7 cm and showing a hyper-enhancement at the arterial phase, can be seen after embolisation. It suggests residual/recurrent HCC, which must be embolised again.

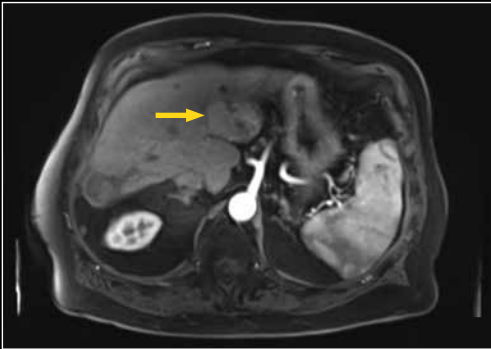
A new lesion is appearing on this MRI in the 4b/5 segments. It is a round-shape hyper-vascular lesion, measuring 0.7cm in diameter, without washout, which is suspicious for early HCC or dysplastic nodule.

A 1.5 cm cystic lesion can also be seen in the pancreatic head, most likely a branch-duct Intraductal Papillary Mucinous Neoplasm (IPMN).

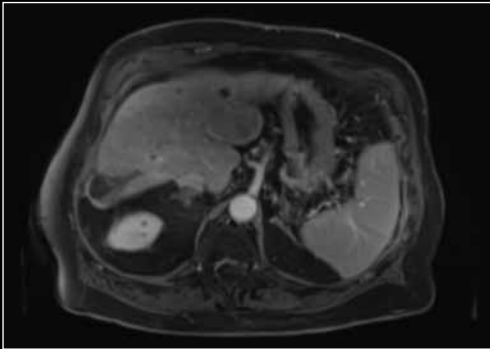
An incidental note is also made of a circumscribed adenomyomatosis of the fundus of the gallbladder.

Status post TACE with partial embolisation of a 4.7 cm HCC in left liver lobe (S3)

Axial 3D T1 GE at arterial phase



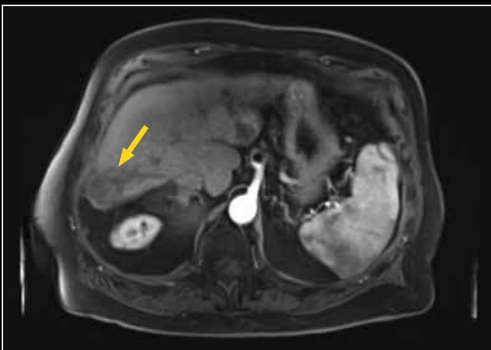
Axial 3D T1 GE at delayed phase



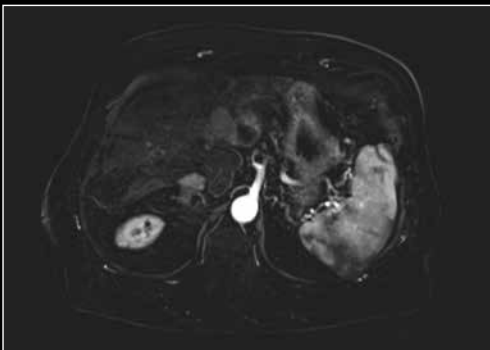
Status post TACE with partial embolisation of a 4.7 cm HCC in left liver lobe (S3)
Now moderately hyperintense enhancement at arterial phase, typical for tumour recurrence (yellow arrow). Wash-out of tumour (hypointense relative to liver parenchyma) is seen in the respective image in the delayed phase after 3 minutes, which is also typical for HCC.

Status post TACE of HCC in right lobe (S7)

Axial 3D T1 GE at arterial phase

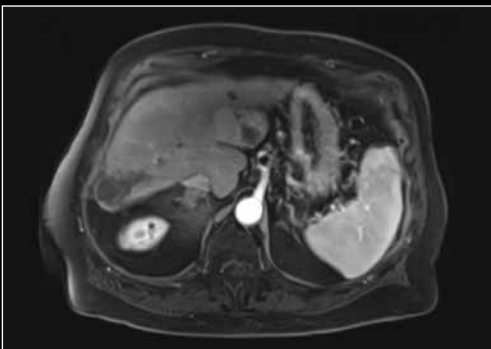


Subtraction of arterial phase

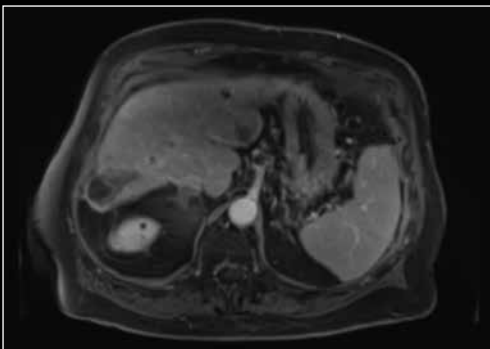


Status post TACE with partial embolisation of a 4.7 cm HCC in left liver lobe (S3)
Now moderately hyperintense enhancement at arterial phase, typical for tumour recurrence (yellow arrow). Wash-out of tumour (hypointense relative to liver parenchyma) is seen in the respective images in the delayed phase after 3 minutes, which is also typical for HCC.

Axial 3D T1 GE at venous phase

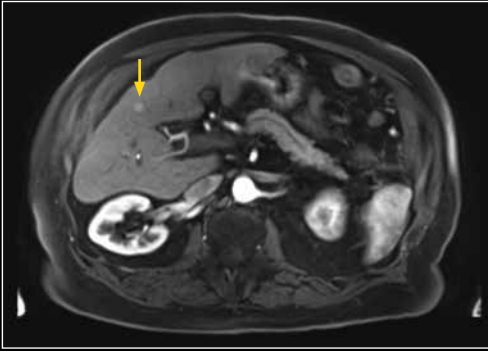


Axial 3D T1 GE at delayed phase

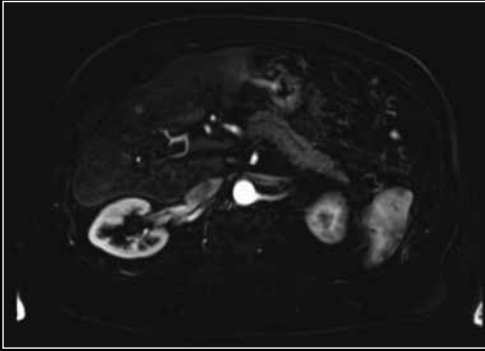


Lesion in S4b/5

Axial 3D T1 GE at arterial phase



Subtraction of arterial phase

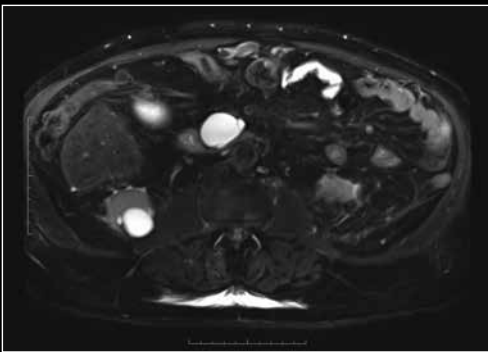


Lesion in S4b/5

Newly appearing round lesion, 0.7 cm large, hyperintense at arterial and portal/venous phases without washout (yellow arrow). Suspicious for early HCC or dysplastic nodule.

Cystic lesion

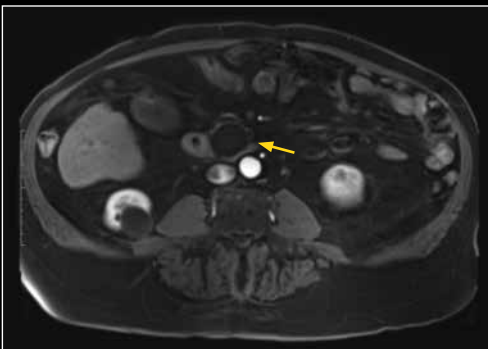
Axial T2w sequence with FS



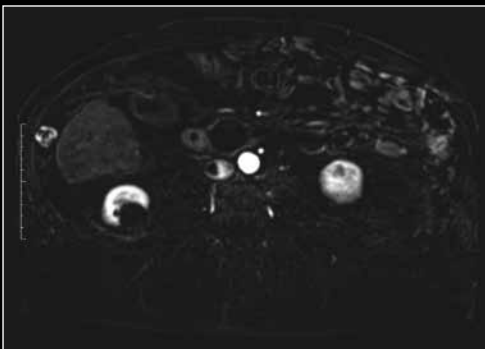
Cystic lesion

Cystic lesion of 3.5 cm in size in the pancreatic head (yellow arrow).

Axial 3D T1 GE at arterial phase



Subtraction of arterial phase



A good arterial phase enhancement is important for the assessment of patients with liver cirrhosis. Therefore, a standard-dose extracellular gadolinium is preferable to a liver-specific agent. Subtraction images of arterial phase help to find small hyper-enhancing nodules.



Diagnosis and therapy or follow-up:

Hepatic cirrhosis with portal hypertension.

According to the Liver Imaging Reporting and Data System (LI-RADS) and according to the Treatment Response (LR-TR) algorithm developed by (LI-RADS), the lesions can be classified:

- HCC post TACE in S7: LR-TR non-viable
- HCC post TACE in S3: LR-TR viable
- Lesion S4b/5 (under 1 cm diameter): LR-3

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

DWI: Diffusion-Weighted Imaging

FS: fat saturation

GE: gradient echo

HCC: hepatocellular carcinoma

MR: magnetic resonance

MRI: magnetic resonance imaging

SSTSE: Single Shot Turbo Spin Echo

TACE: trans-arterial chemoembolisation

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