
Resolve to move forward
A guide to reporting the image
DaTSCAN™
IOFLUPANE (123I)
Guiding by insight

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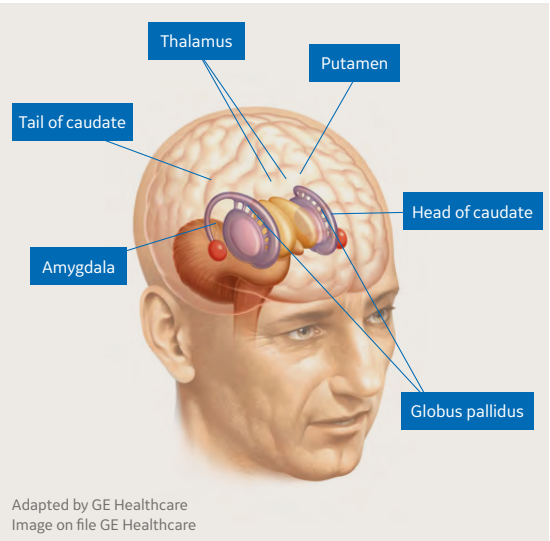
Introduction[1]

DaTSCAN contains a dopamine transporter radioligand and is used to assess the pre-synaptic striatal uptake in the basal ganglia of the brain

DaTSCAN is indicated for detecting loss of functional dopaminergic neuron terminals in the striatum:

- In adult patients with clinically uncertain Parkinsonian Syndromes, for example those with early symptoms, in order to help differentiate Essential Tremor from Parkinsonian Syndromes related to idiopathic Parkinson's disease, Multiple System Atrophy and Progressive Supranuclear Palsy.
- DaTSCAN is unable to discriminate between Parkinson's disease, Multiple System Atrophy and Progressive Supranuclear Palsy.
- In adult patients, to help differentiate probable dementia with Lewy bodies from Alzheimer's disease.
- DaTSCAN is unable to discriminate between dementia with Lewy bodies and Parkinson's disease dementia.

DaTSCAN is supplied in a ready to administer single dose vial.



Adapted by GE Healthcare
Image on file GE Healthcare

Imaging protocol[1]

1-day imaging protocol[1]

Slow injection via venflon (15 to 20 seconds) of 185 MBq/patient

Patient lying down with head in headrest

Image taken 3-6 hours after injection

Imaging time should be no longer than 45 minutes (30 minutes on average)

Contraindication

DaTSCAN is contraindicated in pregnancy and in patients with hypersensitivity to the active substance or to any of the excipients.[1]

MBq: megabecquerel
Image on file GE Healthcare (not actual patient).

The “Normal” DaTSCAN

All images are tomographic SPECT transverse slices and obey the radiographic convention of the right side of the brain displayed on the reader’s left.

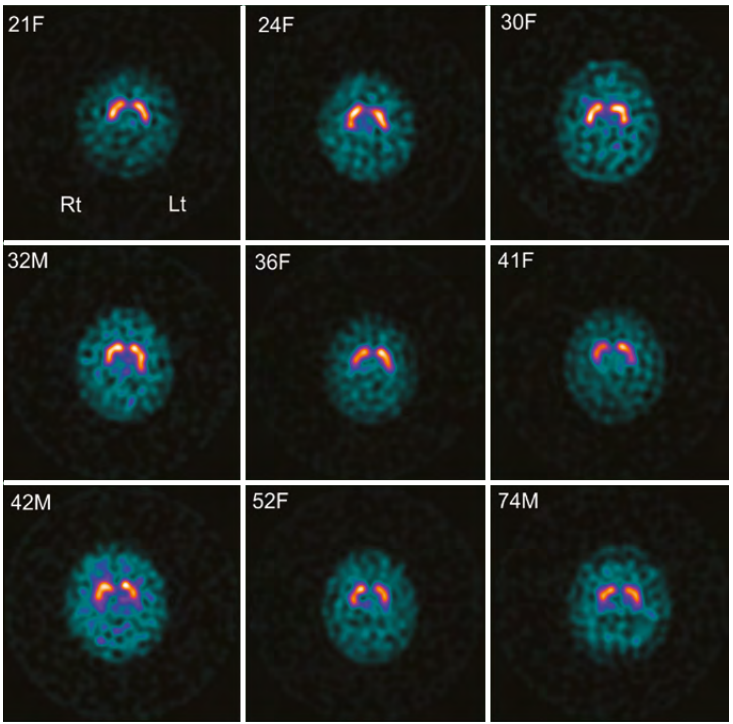
The tracer targets the dopamine transporter mechanism located on the pre-synaptic terminals in the caudate and lentiform nuclei (putamen and globus pallidus) giving rise to the appearance of two-mirror imaged commas.

It is important to note parkinsonian patients have to lose approximately 50% of their nigral dopaminergic neurones before clinical presentation.

Consequently, imaging the striata at clinical presentation should reveal marked abnormalities in the earliest stages of disease manifestation.[2]

Figure 1 shows variation across true normal images and emphasizes that subtle changes in comma shape can be seen in normal studies.

Figure 1:
True normal subjects across age ranges imaged on GE Infinia



Images on file GE Healthcare

Template reports

1. Normal

Normal images are characterised by two symmetrical crescent-shaped areas of equal intensity.[1]

This DaTSCAN demonstrates normal uptake of tracer throughout the striata.

Consequently there is no evidence of loss of the pre-synaptic dopaminergic terminals on this investigation.

In movement disorders

This normal appearance is against a diagnosis of idiopathic Parkinson's disease (PD) or a Parkinsonian Syndrome (PS) and is seen in healthy individuals and also in patients with Essential Tremor (ET).

In dementia

This normal appearance is against a diagnosis of DLB and is seen in healthy individuals and also patients with AD.

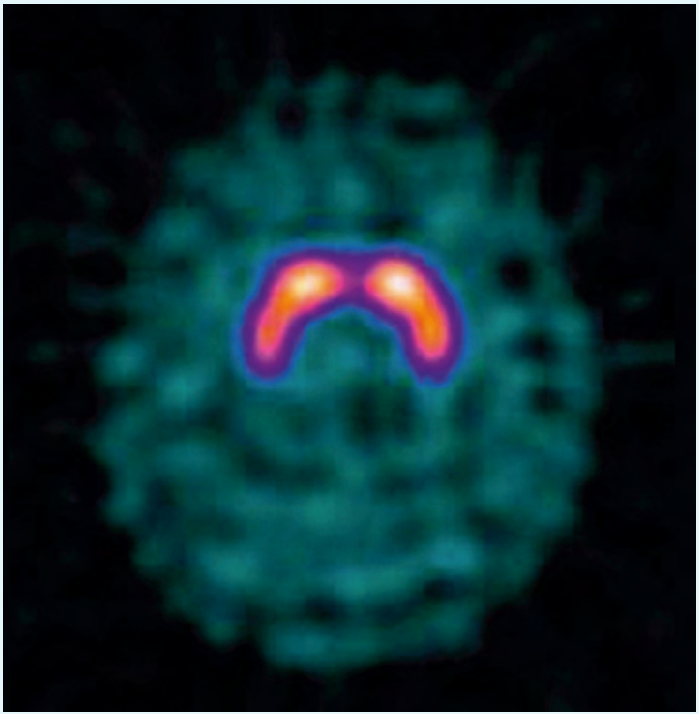


Image courtesy of Birmingham City Hospital, UK

2. Unilateral reduction*

Abnormal images are characterized by asymmetric or symmetric uptakes with an unequal intensity and / or loss of crescent.[1]

This DaTSCAN demonstrates significantly reduced uptake of tracer to the left striatum and possibly a minor reduction to the right. This indicates the loss of the pre-synaptic dopaminergic terminals and is usually supportive of a clinical diagnosis of probable DLB, idiopathic PD or PS.

However, given the marked asymmetry of the two sides, an MRI is recommended to ensure that this appearance is not due to a vascular aetiology.

*Only an example, affected sides may vary

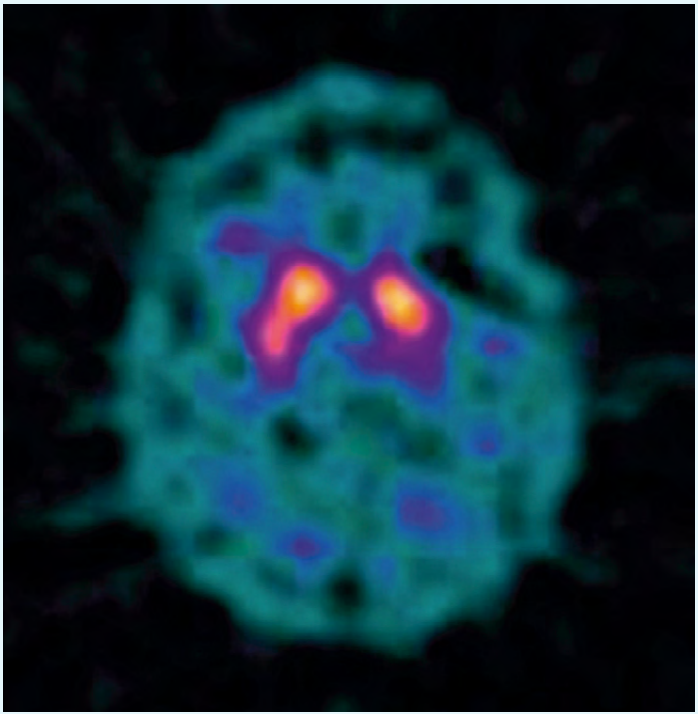


Image courtesy of Birmingham City Hospital, UK

3. Bilateral reduction

Abnormal images are characterized by asymmetric or symmetric uptakes with an unequal intensity and / or loss of crescent.[1]

This DaTSCAN demonstrates reduced uptake of tracer throughout the striata.

This appearance is consistent with the bilateral loss of the pre-synaptic dopaminergic terminals.

In movement disorders
This abnormal appearance is consistent with a diagnosis of iodiopathic PD or PS.

In dementia
This abnormal appearance is consistent with a diagnosis of probable DLB.

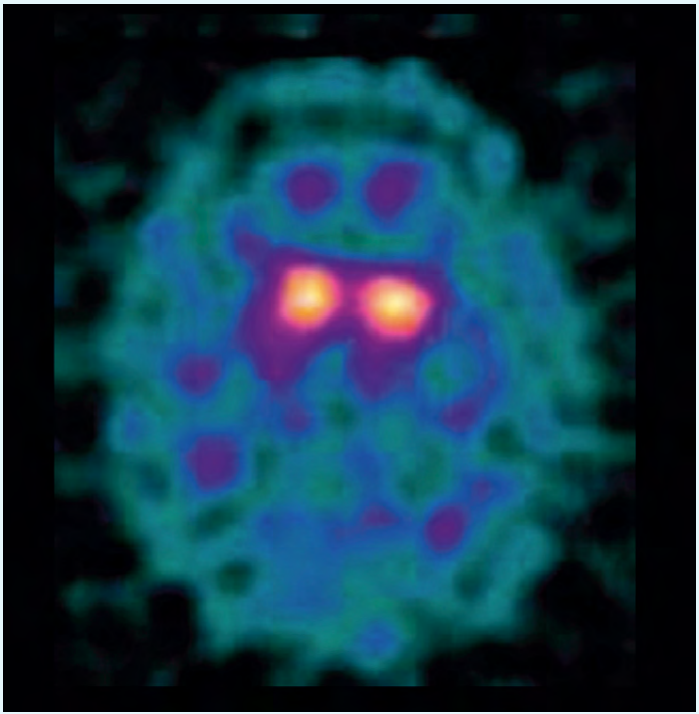


Image courtesy of Birmingham City Hospital, UK

4. Balanced striatal loss

Abnormal images are characterized by asymmetric or symmetric uptakes with an unequal intensity and / or loss of crescent.[1]

This DaTSCAN demonstrates balanced striatal loss to the caudate and putamina nuclei in the stirata.

This appearance is consistent with the loss of the pre-synaptic dopaminergic terminals.

This abnormal appearance is consistent with a diagnosis of probable DLB, idiopathic PD or PS.

A balanced loss of tracer uptake to the caudate and putamen gives rise to a “weak comma”-shaped appearance with high levels of background activity.[3]

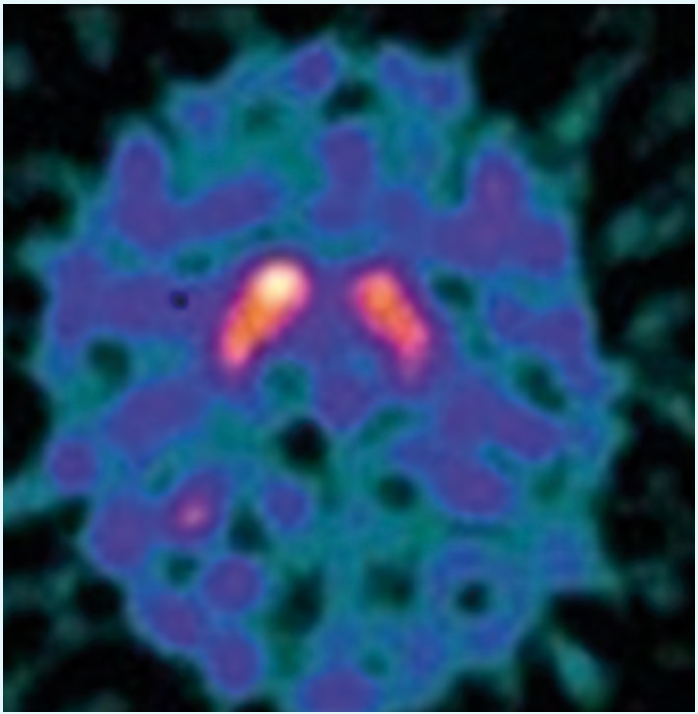


Image courtesy of Birmingham City Hospital, UK

5. Very low uptake*

Abnormal images are characterized by asymmetric or symmetric uptakes with an unequal intensity and / or loss of crescent.[1]

This DaTSCAN image demonstrates significantly reduced uptake of tracer bilaterally to the striata could be due to the severe loss of functional dopaminergic neurons.

This abnormal appearance would be supportive of a clinical diagnosis of probable DLB, idiopathic PD or PS.

*Check for any contraindicating medication including cocaine

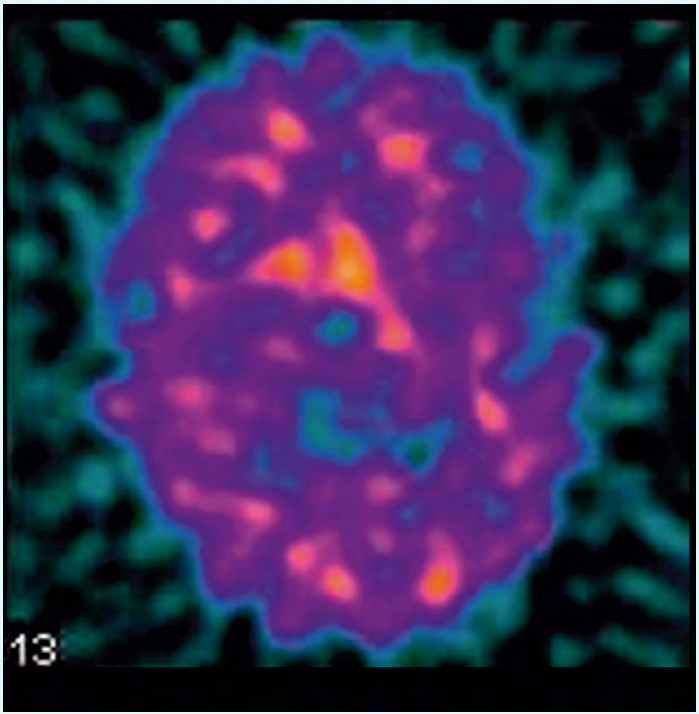


Image courtesy of Birmingham City Hospital, UK

Medication[1]

Ioflupane binds to the dopamine transporter. Dopamine agonists and antagonists acting on the postsynaptic dopamine receptors are not expected to interfere with DaTSCAN imaging and can therefore be continued if desired.

Medicines shown during clinical trials not to interfere with DaTSCAN imaging include:

- Amantadine
- Trihexyphenidyl
- Budipine
- Levodopa
- Metoprolol
- Primidone
- Propranolol
- Selegiline

Medicinal products shown in animal studies not to interfere with DaTSCAN imaging include pergolide.[1]

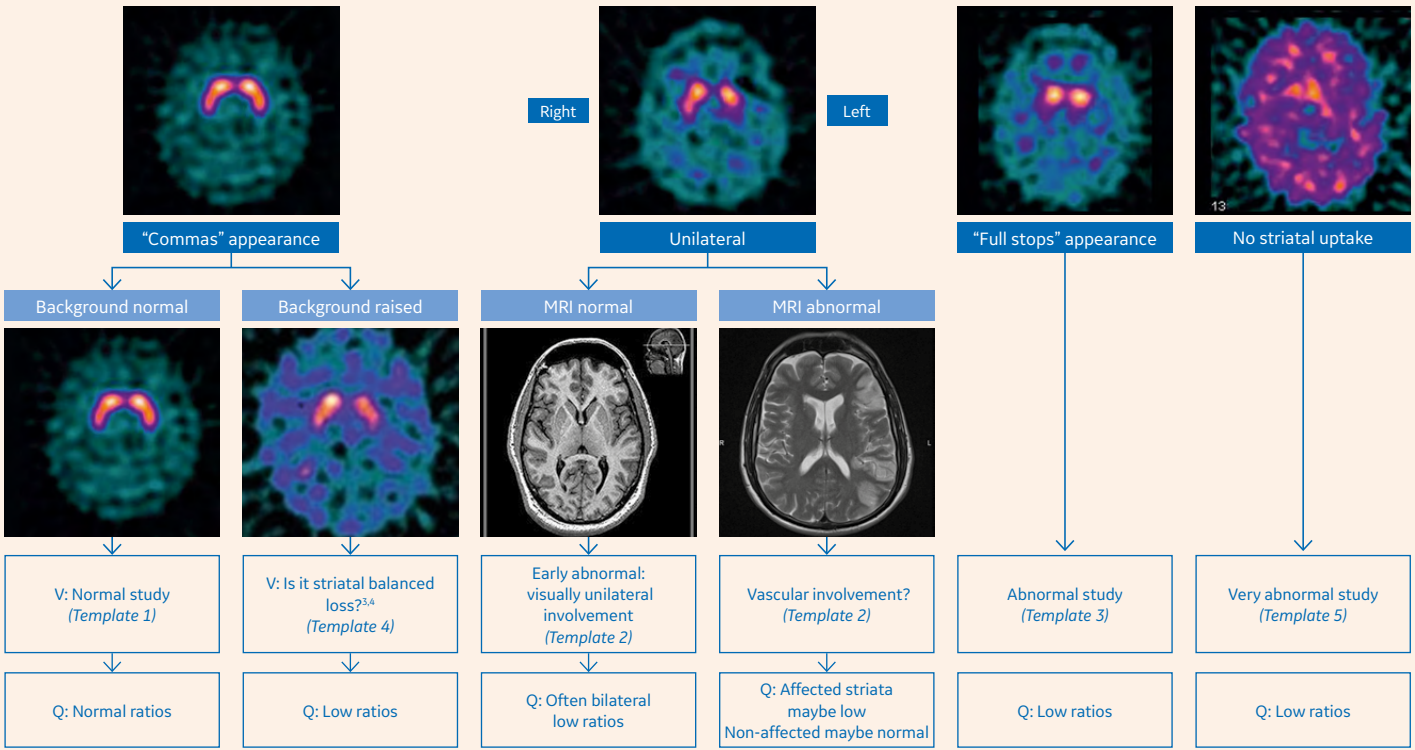
Medication[1]

Ioflupane binds to the dopamine transporter. Medicines that bind to the dopamine transporter with high affinity may therefore interfere with DaTSCAN diagnosis.

STOP use of the following treatments in routine clinical practice:[1]

- All dopaminergic CNS stimulants
  – Cocaine, amfetamine, methamphetamine
- Dopaminergic stimulants for anorexia and obesity
  – Mazindol, phentermine
- Dopaminergic stimulants for ADHD, narcolepsy and other sleeping disorders
  – Methylphenidate
- One dopaminergic stimulant / antidepressant / anti-smoking drug
  – Buproprion
- One anticholinergic
  – Benzatropine
- Selective Serotinin Reuptake Inhibitors (SSRI)
  – Sertraline

Reporting algorithm



Q= Quantification V= Visual assessment

Algorithm followed at Birmingham City Hospital, UK. Images courtesy of Birmingham City Hospital, UK

Quantification

Visual assessment should always be the primary form of reporting.

Quantification may be an important adjunct in helping interpret more difficult scans and is recommended in guidelines.[5]

Various software quantification packages are available which may assist with this.

As with visualisation, consistency of image acquisition, protocol and assessment of patient's medication should be ensured.

Ratios are produced comparing striatal uptake to a background region.

If actual ratio's are included in the report always state a normal range for the particular quantification package that has been used.

There is a variation in normal ranges across the available software packages.

Re-orientation of images

Figure 1

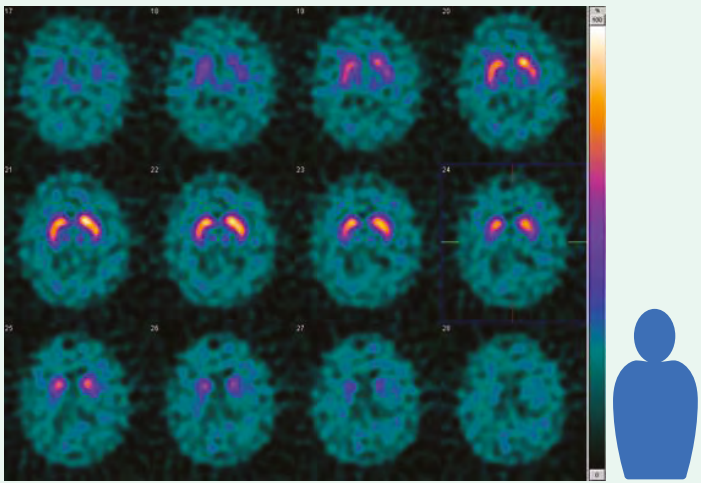
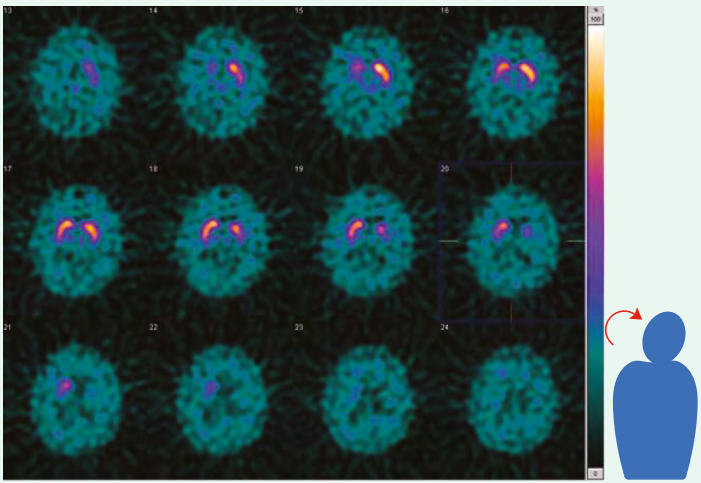


Figure 2



Re-orientation images courtesy of Russells Hall Hospital, Dudley, UK

All 3 planes need to be corrected for any tilt using reorientation software.

If the patient's head is rotated during the acquisition this can result in asymmetry on the processed scan which may give a normal study an abnormal appearance (Figure 2). This can be easily corrected by re-orientationg the reconstructed data (Figure 1). See above.

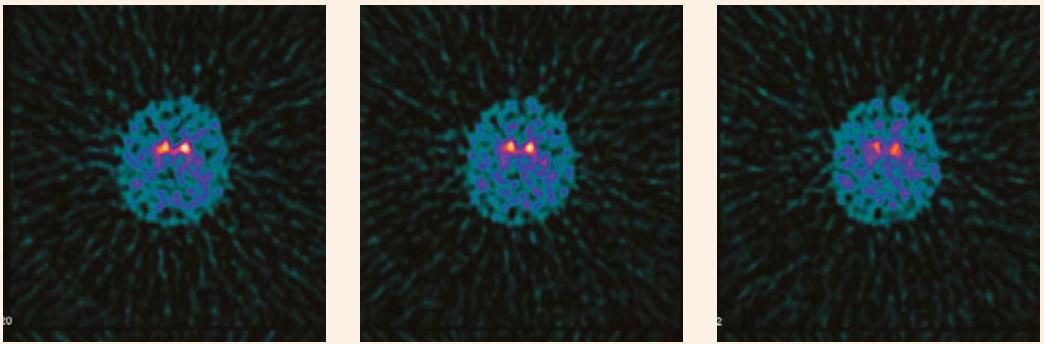
Patient movement

DaTSCAN is very difficult to motion-correct, so raw data should be checked for any evidence of movement before the patient leaves the department. This can be done by viewing the cine or quickly processing the data.

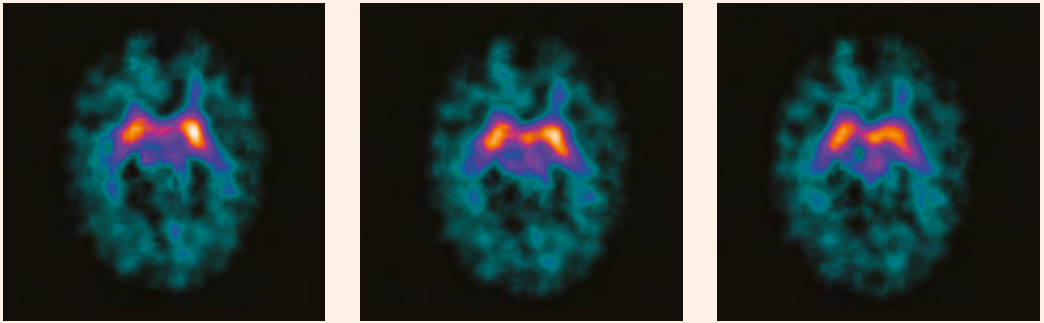
Motion correction software does not usually give satisfactory images so a repeat acquisition will be required.

Movement can be identified by the caudates joining together on the transverse slices; “kissing caudates” (Please refer to Movement 1).

Movement 1



Movement 2

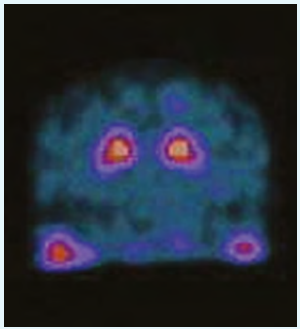


Images on file GE Healthcare

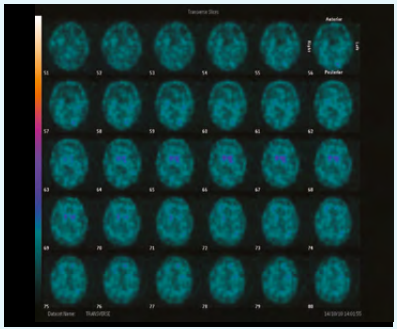
Incorrect scaling

The study will be scaled from the hottest pixel in the data set. If the patient had "hot" salivary glands and these were included in the reconstruction limits, the scaling of the whole study will be affected resulting in poorly resolved striata.

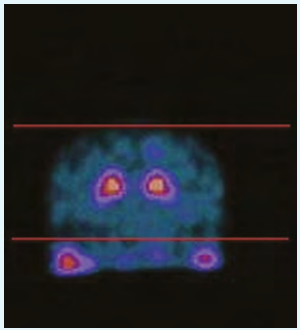
Salivary glands open



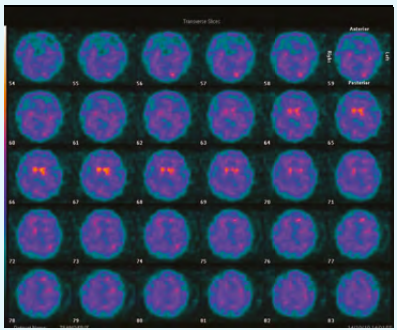
Salivary glands poor scaling



Salivary glands corrected



Salivary glands correct scaling



Images on file GE Healthcare

Case study 1: Normal case

Request

Differential diagnosis between Essential Tremor and Parkinsonian Syndrome.

Clinical history

79-year-old male presented with a 2 year history of tremor of the hands (right more than left), especially noted when trying to lift a cup to drink.

Asymmetrical tremor and head tremor are suggestive of dystonic tremor, other features suggestive of PD.

The clinical impression is that the features are suggestive of either PD or dystonic tremor, although it is more likely to be Parkinson's.

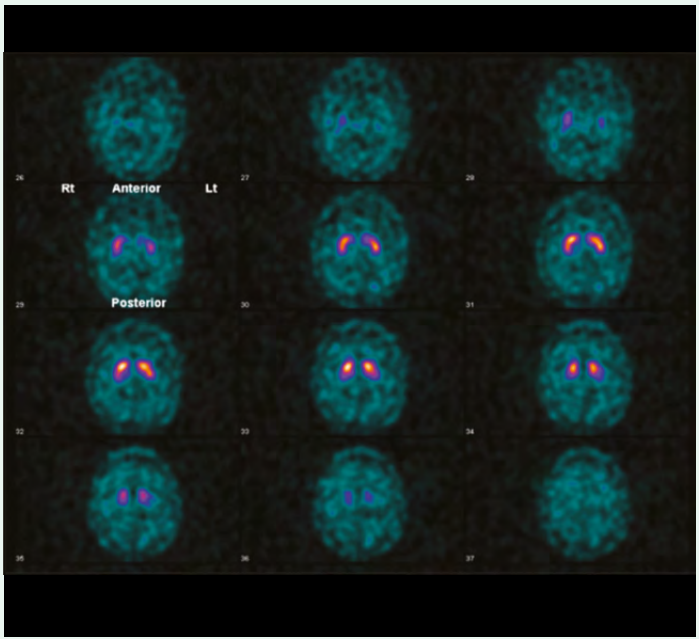


Image courtesy of Birmingham City Hospital, UK

Clinical case from Birmingham City Hospital, UK. Report from Doctor Alp Notghi.

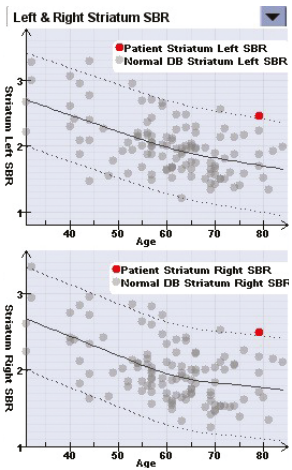
Case study 1: Report

DaT imaging analyze

The DaTSCAN (^{123}I-FP-CIT study) demonstrates normal uptake of tracer throughout the striata. Quantification confirms this showing high normal values of the striatal specific uptake (striatal background ratios). There is no evidence of loss of the pre-synaptic dopaminergic terminals.

Report conclusion

The ratios are in high normal range. This report is against the diagnosis of idiopathic Parkinson's disease or a Parkinsonian Syndrome and is seen in healthy individuals and also patients with Essential Tremor.



Quantification software showing comparison to age matched normal database.

Different quantification packages are available.

Normal DB: GE OSE...	Data: IRNC	Gender: Male	Counts(Counts): 1739301.0	Reconstruction OSEM	Collimator	LEHR
GE normals databa...	Camera: INFINIA	Age(Years): 79	Dose(MDq): 113.0	Corrections: No Correction	Collimator	Parallel

	Striatum Right SBR	Striatum Left SBR	Putamen Right SBR	Putamen Left SBR	Caudatus Right SBR	Caudatus Left SBR	Putamen to Caudatus Right Ratio	Putamen to Caudatus Left Ratio
Measured	+2.49	+2.45	+2.36	+2.35	+2.78	+2.66	+0.89	+0.91
Mean (±1 SD)	+1.78 (±0.33)	+1.71 (±0.36)	+1.68 (±0.33)	+1.61 (±0.35)	+2.00 (±0.40)	+1.91 (±0.42)	+0.91 (±0.06)	+0.90 (±0.07)
Deviation	+40%	+43%	+40%	+46%	+39%	+39%	-2%	+2%
Z-Score	+2.12	+2.10	+2.08	+2.14	+1.96	+1.78	-0.33	+0.22

Simple Advanced Ratios Asymmetry

Image and report generated at Birmingham City Hospital, UK

Case study 2: Abnormal case

Request

Differential diagnosis between Essential Tremor and Parkinsonian Syndrome.

Clinical history

65-year-old male

History of bilateral upper limb intentional tremors for 3 years now present at rest.

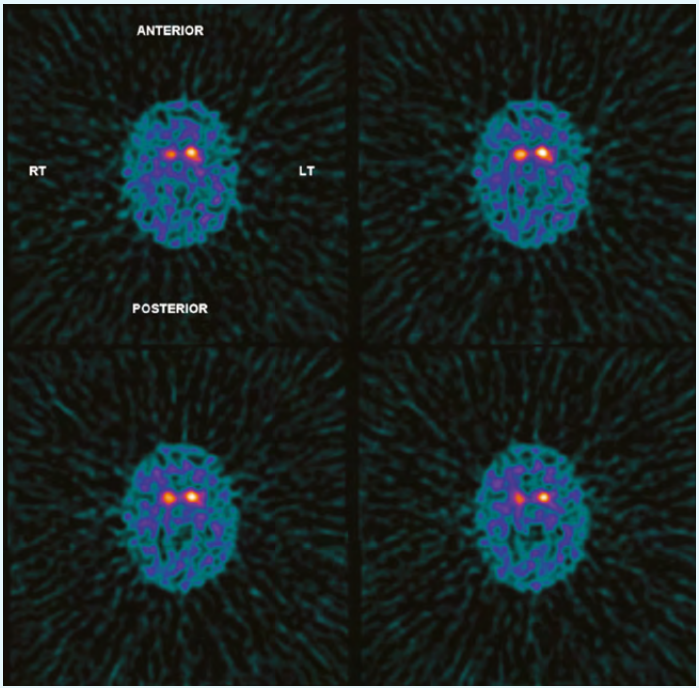


Image courtesy of Birmingham City Hospital, UK

Clinical case from Birmingham City Hospital, UK. Report from Doctor Alp Notghi.

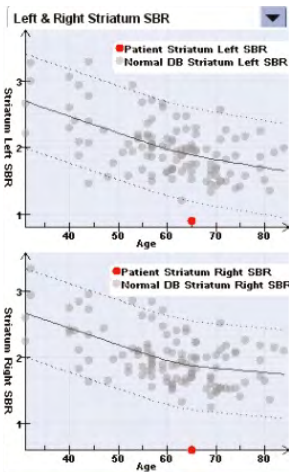
Case study 2: Report

DaT imaging analyze

The DaTSCAN (^{123}I-FP-CIT study) demonstrates reduced uptake of tracer throughout the both striata. Quantification confirms this showing reduced striatal to background ratios. This appearance is consistent with the loss of the pre-synaptic dopaminergic terminals.

Report conclusion

This abnormal appearance is consistent with the diagnosis of idiopathic Parkinson's disease or other parkinsonian syndroms.



Normal DB: GE OSEM NC ...	Data: IRNC	Gender: Male	Counts(Counts) 1914081.0	Reconstruction OSEM	Collimator LEHR
GE normals database for ...	Camera: INFINIA	Age(Years): 65	Dose(MBq): 0.0	Corrections: No Correction	Collimator Parallel
	Striatum Right SBR	Striatum Left SBR	Putamen Right SBR	Putamen Left SBR	Caudatus Right SBR	Caudatus Left SBR
Measured	+0.60	+0.90	+0.38	+0.59	+1.12	+1.50
Mean (±1 SD)	+1.88 (±0.33)	+1.89 (±0.35)	+1.79 (±0.33)	+1.78 (±0.35)	+2.08 (±0.40)	+2.11 (±0.42)
Deviation	-68%	-63%	-79%	-67%	-46%	-29%
Z-Score	-3.81	-2.80	-4.34	-3.41	-2.41	-1.46

Image and report generated at Birmingham City Hospital, UK

Quantification software showing comparison to age matched normal database.

Different quantification packages are available.

Case study 3: Balanced loss

Request

Differential diagnosis between Essential Tremor and Parkinsonian Syndrome.

Clinical history

49-year-old male presenting an atypical tremor.

Evidence of basal ganglia dysfunction?

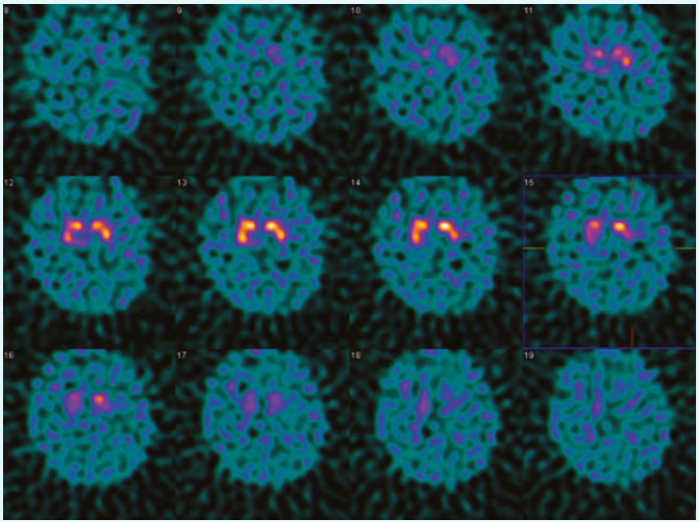


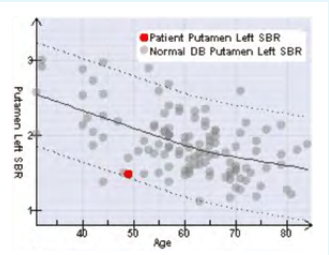
Image courtesy of Birmingham City Hospital, UK

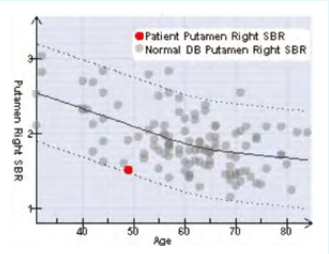
Clinical case from Birmingham City Hospital, UK. Report from Doctor Alp Notghi.

Case study 3: Report

DaT imaging analyze

Both striata have preserved comma shape appearance, with somewhat high background. Quantification was performed using the raw data. It shows bilateral reduced striatal uptake which is consistent with the visual findings. The findings indicate bilateral balanced loss of dopaminergic nerve terminals.





Report conclusion:

This is seen in Parkinson's disease, and more commonly with atypical parkinsonism, and in right clinical setting of dementia in DLB.

How ever if clinically indicated suggest a repeat scan in a year or two for comparison, as with PD/DLB one would expect further deterioration in the appearance and quantification with time.

	Striatum Right SBR	Striatum Left SBR	Putamen Right SBR	Putamen Left SBR	Caudatus Right SBR	Caudatus Left SBR	Putamen to Caudatus Right Ratio	Putamen to Caudatus Left Ratio
Measured	+1.58	+1.54	+1.52	+1.48	+1.71	+1.64	+0.93	+0.94
Mean (±1 SD)	+2.22 (±0.33)	+2.25 (±0.35)	+2.12 (±0.33)	+2.12 (±0.35)	+2.44 (±0.40)	+2.50 (±0.42)	+0.91 (±0.06)	+0.90 (±0.07)
Deviation	-29%	-32%	-28%	-30%	-30%	-34%	+2%	+5%
Z-Score	-1.91	-2.01	-1.85	-1.84	-1.82	-2.03	+0.31	+0.61

Image and report generated at Birmingham City Hospital, UK

Quantification software showing comparison to age matched normal database.

Different quantification packages are available.

DaTSCAN checklist

- 1 dose / 1 vial crucial to maintain image quality
- Thyroid blocking pre-injection only
- Difficult patients require adapted techniques – 180 degree
- Be aware of movement and scaling artefacts
- Process using consistent established parameters
- Check for raised background levels
- Consider quantification in difficult cases[2]
- Always check for asymmetry resulting from patient tilt

Image on file GE Healthcare
(permission sought)

Notes

Notes

Your DaTSCAN sales representative:

Name:

Contact information:

References:

1. DaTSCAN Summary of Product Characteristics (EN), GE Healthcare, December 2018.
2. Kemp PM. Nucl Med Comm 2005; 26: 87–96.
3. Shepherd B *et al.* Eur J Nucl Med Mol Imaging 2011; 38 (Suppl 2): S260–S441. Abstract (P287)
4. Walker Z *et al*. Neurology 2004; 62: 1568-72.
5. Darcourt J *et al*. Eur J Nucl Med Mol Imaging 2010; 37: 443–50.

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12-2019 JB8347/JB73844GB/PRT/OS UK

PRESCRIBING INFORMATION

DaTSCAN™ ioflupane (^{123}I) 74 MBq/ml solution for injection

Please refer to full Summary of Product Characteristics (SPC) before prescribing. Further information available on request.

PRESENTATION Single dose vials containing 185 MBq or 370 MBq ioflupane (^{123}I) at reference time.

INDICATIONS Detecting loss of functional dopaminergic neuron terminals in the striatum. **i)** in adult patients with clinically uncertain Parkinsonian Syndromes, for example those with early symptoms in order to help differentiate Essential Tremor from Parkinsonian Syndromes related to idiopathic Parkinson's Disease (PD), Multiple System Atrophy (MSA) and Progressive Supranuclear Palsy (PSP). DaTSCAN is unable to discriminate between PD, MSA and PSP. **ii)** in adult patients to help differentiate probable dementia with Lewy bodies (DLB) from Alzheimer's disease. DaTSCAN is unable to discriminate between DLB and Parkinson's Disease dementia.

DOSAGE AND METHOD OF ADMINISTRATION Prior to administration appropriate resuscitation equipment should be available. For use in patients referred by physicians experienced in the management of movement disorders/dementia. Clinical efficiency has been demonstrated across the range of 111-185 MBq; do not use outside this range. Appropriate thyroid blocking treatment must be given prior to injection of DaTSCAN. The safety and efficacy of DaTSCAN in children 0 to 18 years has not been established. No data are available in patients with significant renal or hepatic impairment. DaTSCAN should be used without dilution. Slow intravenous injection (15-20 seconds) via an arm vein is recommended. SPECT imaging should take place 3-6 hours after injection of DaTSCAN.

CONTRAINDICATIONS Pregnancy and hypersensitivity to the active substance or any of the excipients.

WARNINGS AND PRECAUTIONS If hypersensitivity reactions occur, the administration of the medicinal product must be discontinued immediately and, if necessary, intravenous treatment initiated. Resuscitative medicinal products and equipment (e.g. endotracheal tube and ventilator) have to be readily available. This radiopharmaceutical may be received, used and administered only by authorised persons in designated clinical settings. Its receipt, storage, use, transfer and disposal are subject to the regulations and the appropriate licences of the local competent official organisations. For each patient, exposure to ionising radiation must be justifiable on the basis of likely benefit. The activity administered must be such that the resulting dose is as low as reasonably achievable bearing in mind the need to obtain the intended diagnostic result. DaTSCAN is not recommended in cases of moderate to severe renal or hepatic impairment. Contains 39.5 g/l (5% volume) ethanol, up to 197mg per dose, harmful for those suffering from alcoholism. To be taken into account in high-risk groups such as patients with liver disease or epilepsy.

INTERACTIONS Consider current medication. Medicines that bind to the dopamine transporter with high affinity may interfere with diagnosis; these include amfetamine, benzatropine, buproprion, cocaine, mazindol, methylphenidate, phentermine and sertraline. Medicines shown during clinical trials not to interfere with DaTSCAN imaging include amantadine, trihexyphenidyl, budipine, levodopa, metoprolol, primidone, propranolol and selegiline. Dopamine agonists and antagonists acting on the postsynaptic dopamine receptors are not expected to interfere with DaTSCAN imaging and can therefore be continued if desired. In animal studies pergolide does not interfere with DaTSCAN imaging.

PREGNANCY AND LACTATION Contraindicated in pregnancy. Information should be sought about pregnancy from women of child bearing potential. A woman who has missed her period should be assumed to be pregnant. If uncertain, radiation exposure should be the minimum needed for satisfactory imaging. Consider alternative techniques. If administration to a breast feeding woman is necessary, substitute formula feeding for breast feeding for 3 days.

UNDESIRABLE EFFECTS The following undesirable effects are recognised for DaTSCAN: Common side effects include headache. Uncommon side effects include vertigo, increased appetite, formication, dizziness, dysgeusia, nausea and dry mouth. Intense pain or burning sensation on injection has been reported uncommonly following administration into small veins. Hypersensitivity occurs with unknown frequency, as well as erythema, pruritus, rash, urticaria, hyperhidrosis, dyspnea, vomiting, decreased blood pressure and feeling hot. Exposure to ionising radiation is linked with cancer induction and a potential for hereditary defects. Because of the low radiation dose incurred these adverse events are expected to occur with a low probability.

DOSIMETRY Effective dose from 185 MBq is 4.63 mSv.

OVERDOSE Encourage frequent micturition and defecation.

MARKETING AUTHORISATION HOLDER GE Healthcare B.V., De Rondom 8, 5612 AP, Eindhoven, The Netherlands.

CLASSIFICATION FOR SUPPLY Subject to medical prescription.

MARKETING AUTHORISATION NUMBERS EU/1/00/135/001 (2.5ml) and EU/1/00/135/002 (5.0ml).

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UK PRICE £525.00/185MBq.

Adverse events should be reported.
Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/.
Adverse events should also be reported to GE Healthcare at gpv.drugsafety@ge.com.