DaTSCAN™
IOFLUPANE (^{123}I)

CASE STUDY

Alison

77-year-old patient with a history of comorbidities. She has developed a bilateral tremor and is eager to receive appropriate treatment.*

Resolve to provide a timely, accurate diagnosis

History

- 77-year-old, right-handed female
- Tremor originated in her right hand, but is now present in both hands
- Increasing difficulty with precise motor tasks such as buttoning shirts
- Stiffness in her limbs, particularly on the right-hand side
- Handwriting is small, messy and cramped
- Posture is stooped, her stride is small and she walks slowly
- History of comorbidities including osteoporosis, osteoarthritis, depression and hypertension

Examination

- Normal mental status
- Mildly reduced facial expression
- Soft voice with a slight tremor
- Moderate kyphosis
- Reduced finger taps
- Bilaterally reduced hand movements, slightly more on the right side
- Increased tone in the wrists, elbows and knees
- Bilateral rest, postural and action tremor in her hands
- Normal deep-tendon reflexes
- Needs to push herself up from her chair
- Walks with small steps
- Reduced arm swing, predominantly on the right-hand side

Medications

- Risedronate
- Acetaminophen
- Lamotrigine
- Lisinopril
- Aspirin

*Image is not of the actual patient. The patient's name has been altered. Based on a real patient profile provided by Dr. David Russell, Director of Clinical Research at the Institute of Neurodegenerative Disease, Yale University School of Medicine, US.

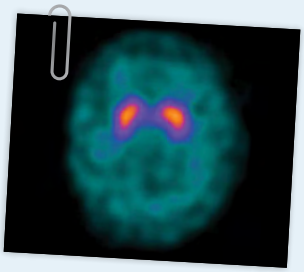
Discussion

Alison presents with symptoms that are common in many conditions associated with aging. She presents with tremors and her walking-pace has slowed, suggesting that she may have developed a PS. Diagnostic clarity is required in order to help move forward with her case and initiate an appropriate treatment plan.

Would you be concerned about initiating a levodopa trial with Alison's history of comorbidities?

Interpretation

The scan results revealed normal tracer-uptake, and therefore no deficits in dopaminergic function. The normal scan results indicate that a diagnosis of PS should be excluded.



How would this scan result affect your clinical diagnosis?

Impact of scan results

The normal scan results allowed the diagnosis of a PS to be excluded, leading to the avoidance of unnecessary follow-up visits. Alison was referred to orthopedics for further management of her skeletal disease.

PS: Parkinsonian syndrome

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CASE STUDY

Resolve to provide a timely, accurate diagnosis

Richard

72-year-old patient, retired due to disability 10 years ago. This patient, presenting with postural and action tremors, has shown no response to PD or ET medications.*

History

- 12-year history of tremor, suspected to have originated on the right side
- Postural, rest and action tremor is present
- Initially diagnosed with ET, then received a diagnosis of PD
- Unresponsive to both PD and ET medications
- Some stiffness in hands and fingers, but believes most of his disability is due to the severity of the tremor
- Tremor shakes the patient's trunk and head
- Presumptive diagnosis is PD; the patient is being considered for deep brain stimulator placement
- History of comorbidities, including hypertension, coronary artery disease, hyperlipidaemia and gastroesophageal reflux disease

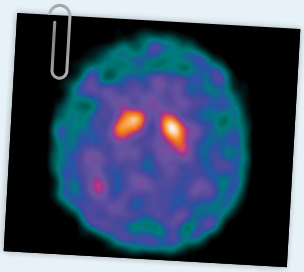
Examination

- Mental status, cranial nerves and fundi appeared to be normal
- Minimal hypomimia and vocal tremor
- Mildly increased tone in both upper extremities, more noticeably on the right
- Axial tone and tone in the lower extremities were also mildly increased
- Large amplitude, medium frequency tremor in his arms at rest and in action
- Moderate amplitude tremor in both legs
- Able to stand from a chair and walk with a good stride
- Presented with a bilaterally diminished arm swing with prominent tremor

Discussion

Discerning between severe ET and tremor-dominant PD is not an uncommon diagnostic dilemma. Patients with tremor-dominant PD are typically stable for many years with minimal rigidity or bradykinesia alongside variable, sometimes severe, mixed tremor. Furthermore, this type of PD tends to be resistant to levodopa therapy. An accurate diagnosis is needed to determine the disease course and select the optimal surgical targets.

Interpretation



How would this scan result affect your clinical diagnosis?

At first glance, this DaTSCAN image appears to show signal bilaterally in the putamen and caudate nuclei. However, it is clear from the high background signal throughout the other brain regions that the ratio of signal in the striata is quite low.

This scan reveals bilaterally reduced dopaminergic terminal density, consistent with a PS and, hence, with tremor-dominant PD.

Impact of scan results

The scan results helped confirm a diagnosis of tremor-dominant PD. Six months later, Richard underwent placement of bilateral subthalamic deep brain stimulator electrodes. This led to a significant reduction of his tremor, less exhaustion and improved function.

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ET: essential tremor
PD: Parkinson's disease
PS: Parkinsonian syndrome

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.

DaTSCAN images are interpreted visually, based upon the appearance of the striata. As an adjunct, visual interpretation may be assisted by semi-quantitative assessment. Semi-quantification should only be used an adjunct to visual assessment following the precautions described in the Summary of Product characteristics. Final assessment should always consider both visual appearance and semi-quantitative results.

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).

DATE OF REVISION OF TEXT 16 March 2021

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

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