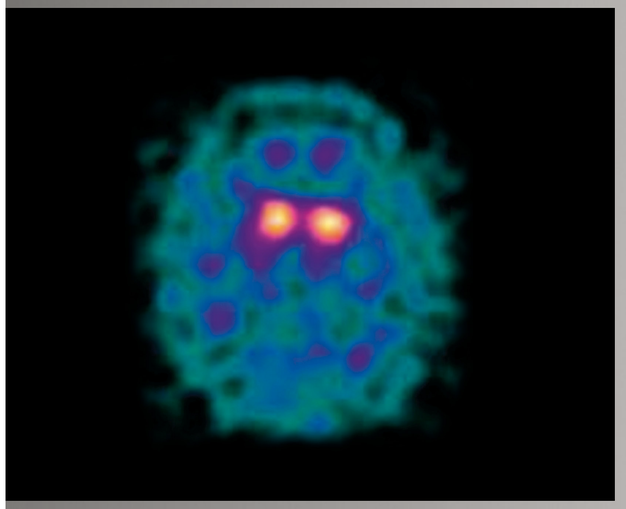
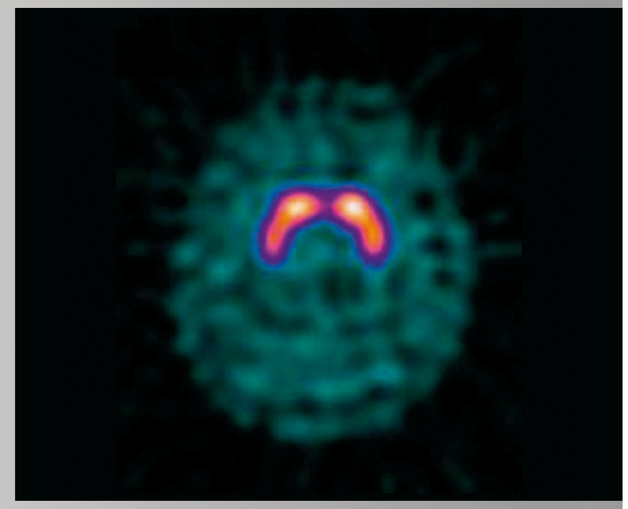
Possible
Dementia with
Lewy Bodies?



Or not?



The more you know about an individual case, the greater the opportunity for individual care

GE HealthCare

Please see Important Safety Information on the following page.
Click here for full Prescribing Information

DaTscan™
Ioflupane I 123 Injection

PRODUCT INDICATIONS AND USE

DATSCAN is indicated as an adjunct to other diagnostic evaluations for striatal dopamine transporter visualization using single photon emission computed tomography (SPECT) brain imaging in adult patients with:

- suspected Parkinsonian syndromes (PS) or
- suspected dementia with Lewy bodies (DLB).

Important Safety Information About DaTscan™ (ioflupane I 123 injection)

CONTRAINDICATIONS

- DaTscan is contraindicated in patients with known serious hypersensitivity to ioflupane I 123.

WARNINGS AND PRECAUTIONS

- **Hypersensitivity Reactions:** Hypersensitivity reactions, including dyspnea, edema, rash, erythema, and pruritus, have been reported following DATSCAN administration.
- **Thyroid Accumulation:** DaTscan may contain up to 6% of free iodide (iodine-123). Thyroid uptake of iodine-123 may result in an increased long-term risk for thyroid neoplasia. To decrease thyroid accumulation of iodine-123, block the thyroid gland before administration of DaTscan.

ADVERSE REACTIONS

- In clinical trials, headache, nausea, vertigo, dry mouth, or dizziness of mild to moderate severity were reported. In postmarketing experience, hypersensitivity reactions and injection-site pain have been reported.

DRUG INTERACTIONS

- Drugs that bind to the dopamine transporter with high affinity may interfere with the DaTscan image. The impact of dopamine agonists and antagonists on DaTscan imaging results has not been established.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** Radioactive iodine products cross the placenta and can permanently impair fetal thyroid function. Administration of a thyroid blocking agent is recommended before the use of DaTscan in a pregnant woman. All radiopharmaceuticals have potential to cause fetal harm. There are no available data on DaTscan use in pregnant women to evaluate for a drug- associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. Advise pregnant woman of the potential risks of fetal exposure to radiation with the administration of DaTscan.
- **Lactation:** Iodine 123 (I 123), the radionuclide in DaTscan, is present in human milk. There is no information on the effects on breastfed infants or on milk. Advise a lactating woman to interrupt breastfeeding and pump and discard breast milk for at least 6 days after DaTscan administration to minimize radiation exposure to a breastfeeding infant.
- **Pediatric Use:** The safety and efficacy of DaTscan have not been established in pediatric patients.
- **Geriatric Use:** There were no differences in responses between elderly patients and younger patients that would require a dose adjustment observed in the parkinsonian syndrome studies.
- **Renal Impairment:** DaTscan is excreted by the kidney and patients with severe renal impairment may have increased radiation exposure and altered DaTscan images.

OVERDOSAGE

- The risks of overdose relate predominantly to increased radiation exposure, with the long-term risks for neoplasia. In case of overdosage of radioactivity, frequent urination and defecation should be encouraged to minimize radiation exposure to the patient.

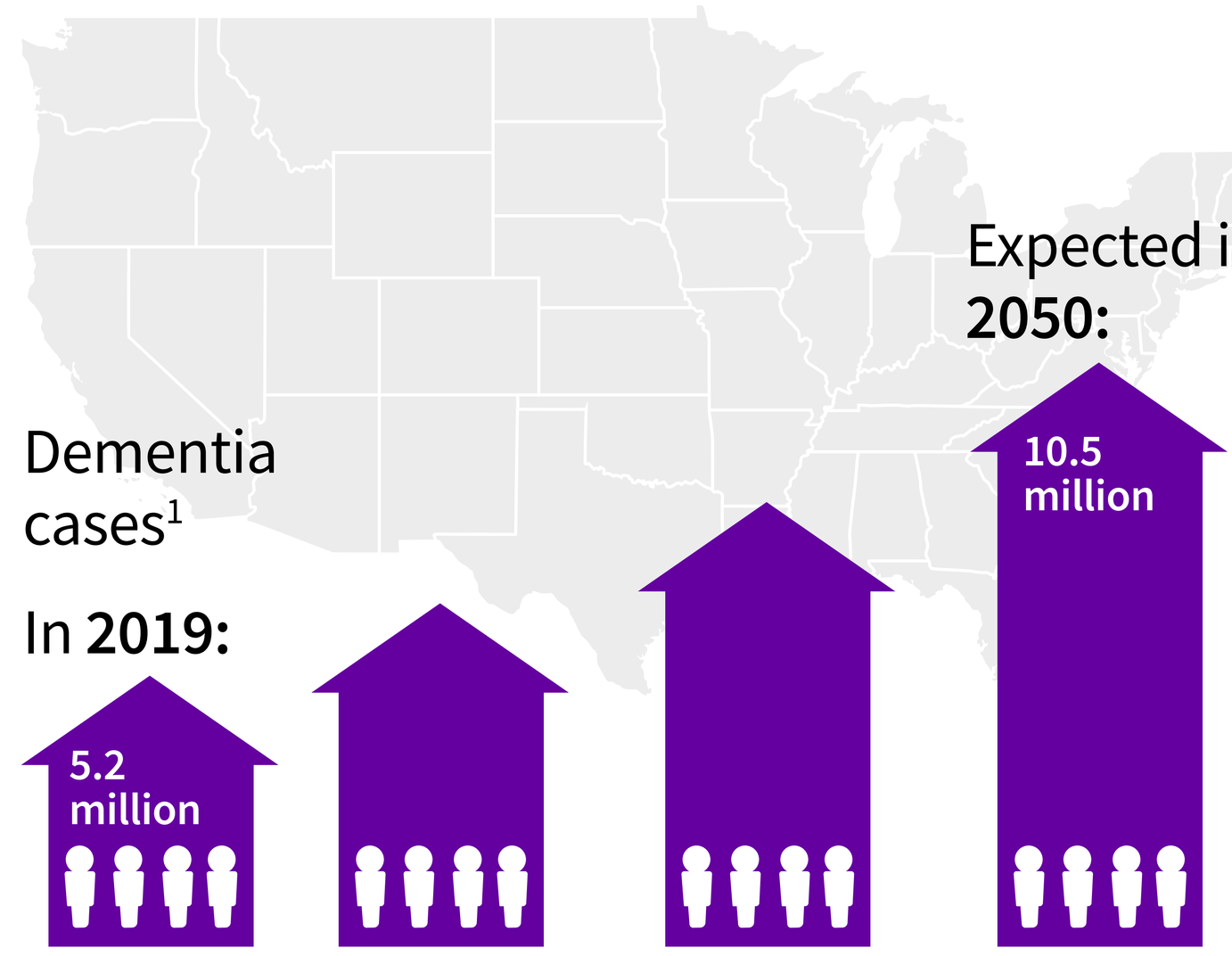
PROCEDURE — Radiation Safety

- DaTscan emits radiation and must be handled with safety measures to minimize radiation exposure to clinical personnel and patients.

Prior to DaTscan administration, please read the full Prescribing Information, here, for additional Important Safety Information.

To report SUSPECTED ADVERSE REACTIONS, contact GE Healthcare at 800 654 0118 (option 2, then option 1) or the FDA at 800 FDA 1088 or www.fda.gov/medwatch.

The dementia picture in the USA



LBD

(Lewy body dementia)

is the second-most-common neurodegenerative dementia after AD estimated to affect 1.4 million adults in the US[2,3]

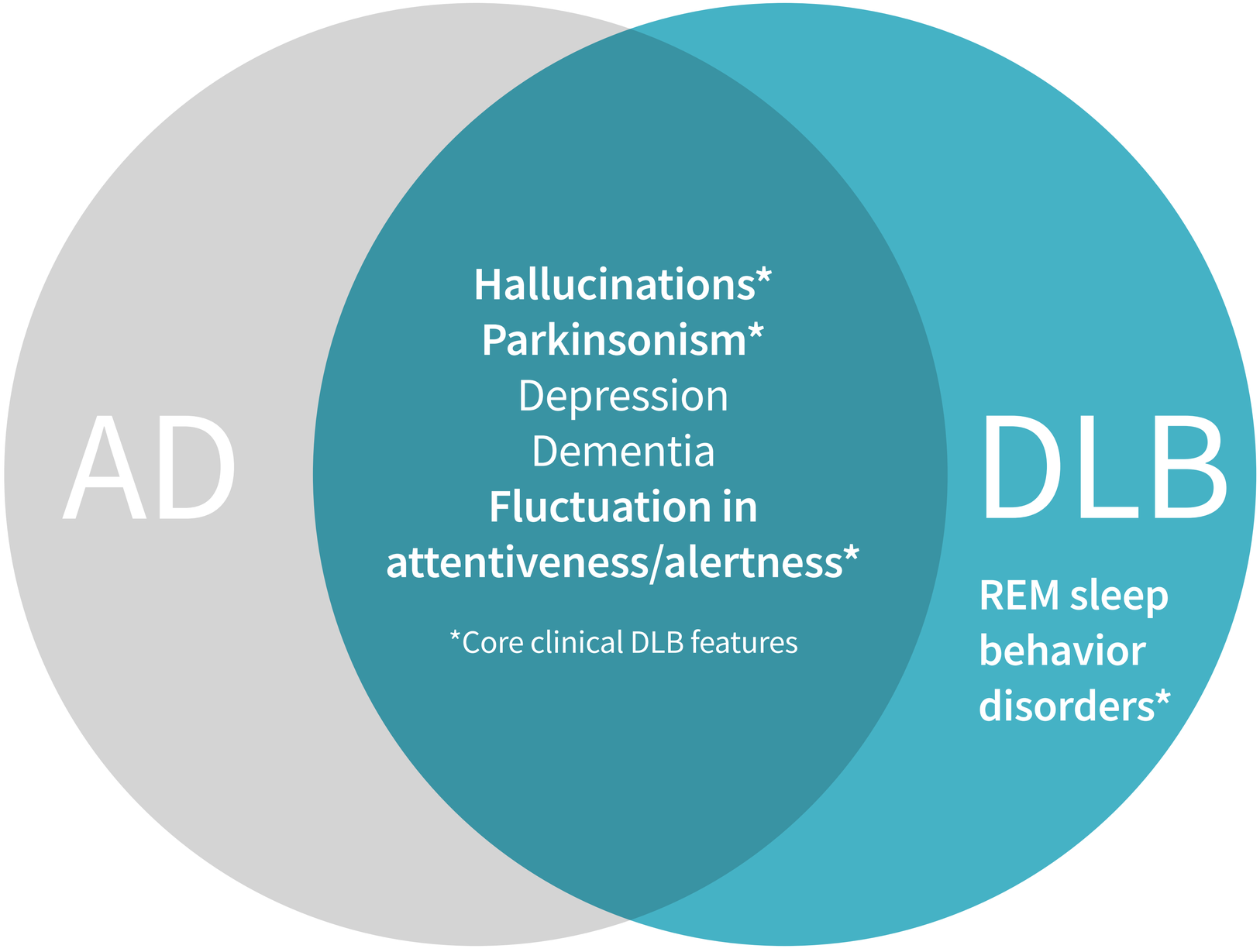
LBD includes DLB (Dementia with Lewy Bodies) and PDD (Parkinson's Disease Dementia)[2]

AD, Alzheimer's disease

The challenges of overlapping symptoms

“…individuals with DLB often see multiple physicians over several years before receiving the correct diagnosis[4]”

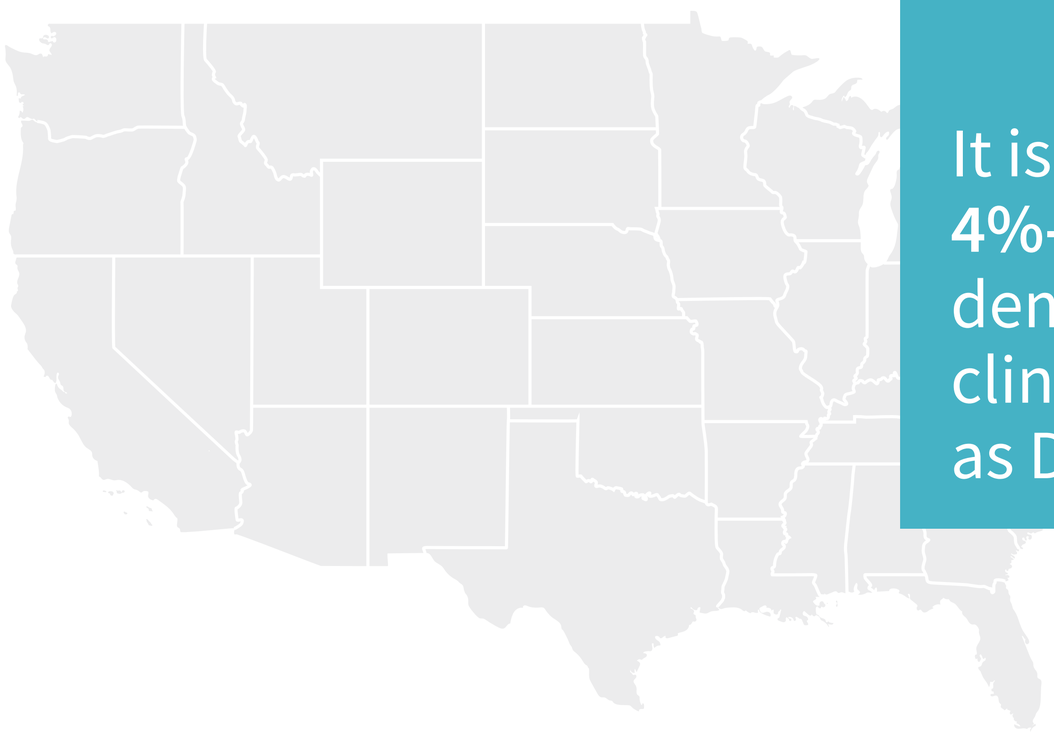
In particular, patients with DLB symptoms are **frequently misdiagnosed with AD**[5-7]

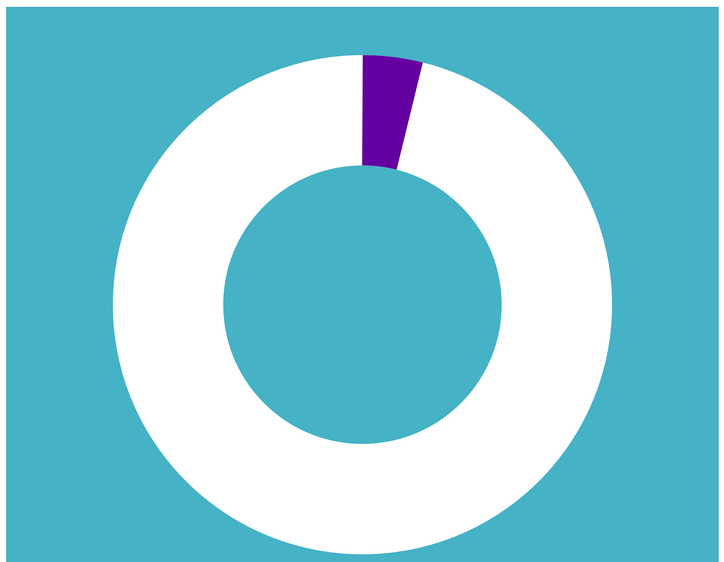


AD, Alzheimer’s disease; **DLB,** dementia with Lewy bodies; **REM,** rapid eye movement

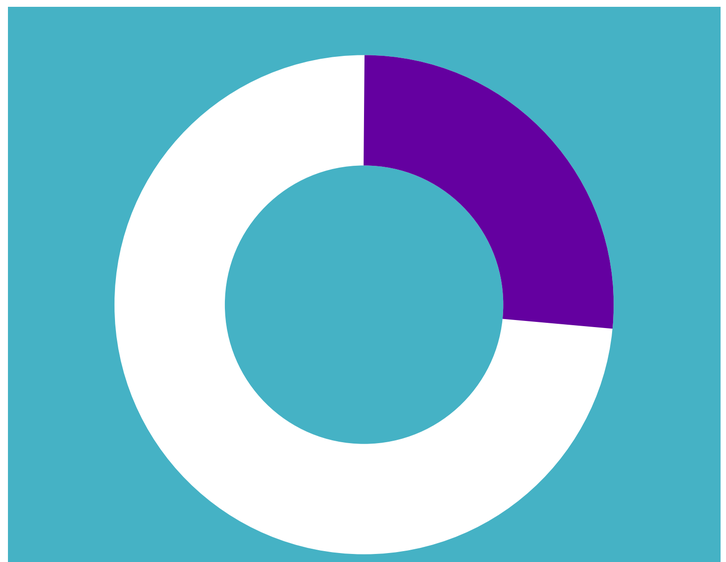
The challenges of the DLB diagnosis

"…detection rates in clinical practice remain suboptimal, with many cases missed[7]"





It is estimated **4%-5%** of all dementias are clinically confirmed as DLB[5]



However 26% of post-mortem dementia cases were found to have Lewy body pathology[3]

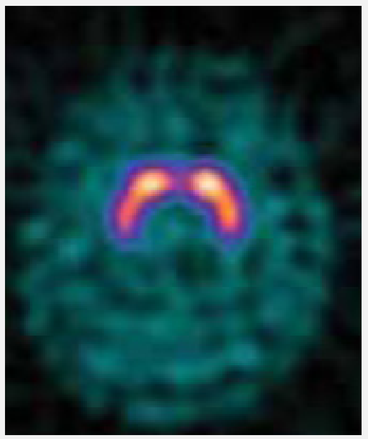
DLB, dementia with Lewy bodies

The value of DATSCAN

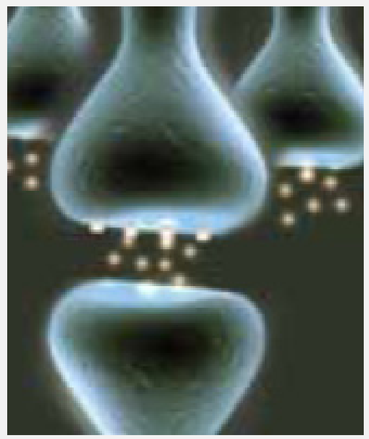
> “ . . . striatal binding is usually normal or only mildly diminished in AD and is significantly decreased in DLB[8] ”

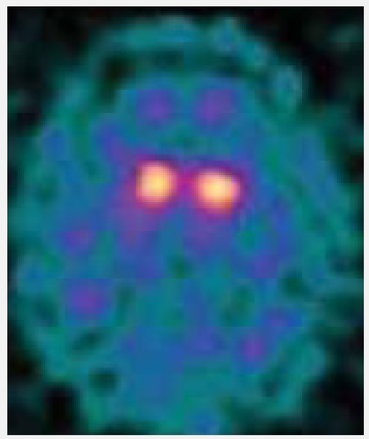
DaTscan provides a **visualization** of **underlying** brain function[9]

DaTscan binds selectively to **dopamine transporters** in the striatum, acting as a biomarker for functional dopaminergic neurons[9]



With intact dopaminergic neurons, DaTscan typically appears in distinctive “comma” shapes





With dopaminergic neuronal degeneration, DaTscan typically appears in “period” shapes

Diagnostic Criteria Guideline:

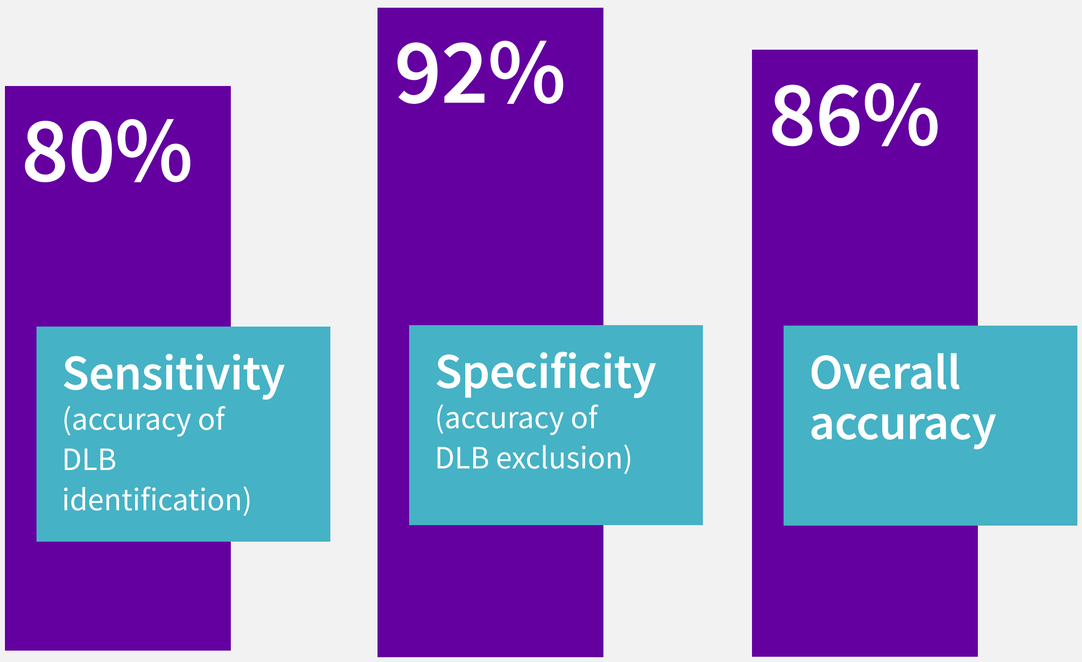
Low dopamine transporter uptake in the basal ganglia is an **indicative biomarker** for DLB[7]

Fourth consensus report of the DLB Consortium

AD, Alzheimer’s disease; **DLB,** dementia with Lewy bodies

The accuracy of DaTscan in DLB

DaTscan *is* **closely aligned** with **post-mortem** diagnosis:[10]



After death, 55 patients with dementia who had undergone DaTscan imaging and been reviewed in prospective studies underwent detailed autopsy assessment; neuropathologic diagnoses were applied with the use of standard international criteria[10]

SNMMI Procedure Standard/EANM Practice Guideline

DAT SPECT is an **accurate way to differentiate** between AD and DLB[8]

ACR Appropriateness Criteria® Dementia

DAT SPECT results in **lower relative radiation levels** compared with FDG-PET[11]

Figure adapted from Thomas AJ et al. 2017.[10]

ACR, American College of Radiology; **AD,** Alzheimer's disease; **DAT,** dopamine active transporter; **DLB,** dementia with Lewy bodies; **EANM,** European Association of Nuclear Medicine; **FDG,** fluorodeoxyglucose; **PET,** positron emission tomography; **SNMMI,** Society of Nuclear Medicine and Molecular Imaging; **SPECT,** single-photon emission computed tomography

The difference DaTscan makes in DLB diagnosis

170 people with a clinical diagnosis of possible DLB[12]

114 received imaging with DaTscan, 56 were a control group[12]

Multicenter, randomized, open-label trial conducted in 6 European countries[12]

Those who underwent imaging were far more likely to receive a change in diagnosis[12]

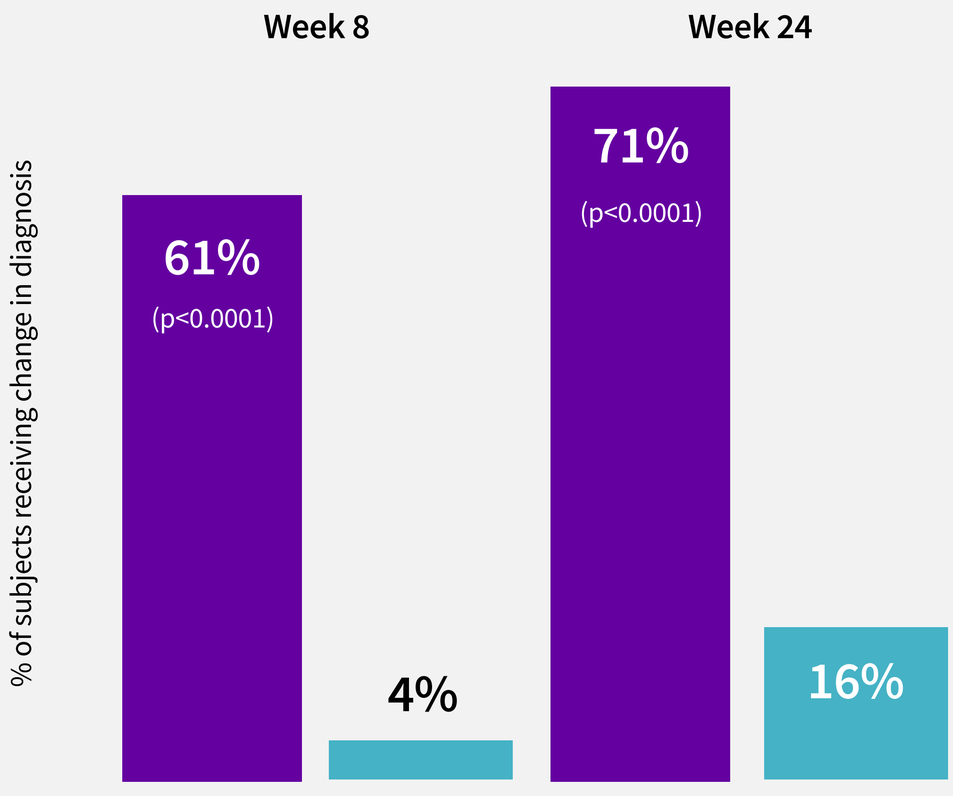


Figure adapted from Walker Z et al. 2015.[12]

In this study, only 25% of patients had parkinsonian features, but 43% had abnormal scans[12]

> “DaTscan imaging significantly contributed to a more certain diagnosis, proving to be a useful adjunct in the work-up of patients with possible DLB[12]”

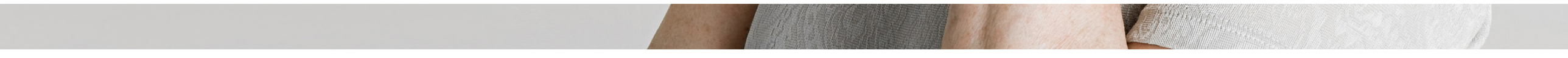
DLB, dementia with Lewy bodies

The greater opportunity for individual care

An **early** and **accurate diagnosis** of DLB can help:[5,13-15]

- prompt discussion and guide appropriate treatment and access to resources
- prevent use of potentially harmful medication
- enable timely financial planning
- support quality of life

> “As a result of a delay in diagnosis and misdiagnosis, people with LBD and their caregivers endure daily challenges and uncertainty[16]”



DLB, dementia with Lewy bodies; **LBD,** Lewy body dementia

Diagnosis with purpose

The number of individuals affected by dementia, including DLB, is on the rise in the US [1-3]

– however, it is often misdiagnosed as AD due to overlapping symptoms [5-7]

DAT SPECT is an accurate way to differentiate between AD and DLB[8]

DaTscan provides a visualization of underlying brain function[9]

– it binds selectively to dopamine transporters in the striatum, acting as a biomarker for functional dopaminergic neurons[9]

With 92% specificity and 80% sensitivity, DaTscan is closely aligned with post-mortem diagnosis[10]

DaTscan can significantly contribute to a more certain diagnosis, proving to be a useful adjunct in the work-up of patients with possible DLB[12]

An early and accurate diagnosis of DLB can help patients and caregivers plan their future [5, 13-15]

AD, Alzheimer's disease; **DAT,** dopamine active transporter; **DLB,** dementia with Lewy bodies; **SPECT,** single-photon emission computed tomography

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RESOURCES

Customer Service: 800 292 8514
Reimbursement Hotline: 800 767 6664
Medical Affairs for Clinical and Scientific Support:
800 654 0118. (option 2, then option 3) or medical.affairs@ge.com

gehealthcare.com

GE HealthCare

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