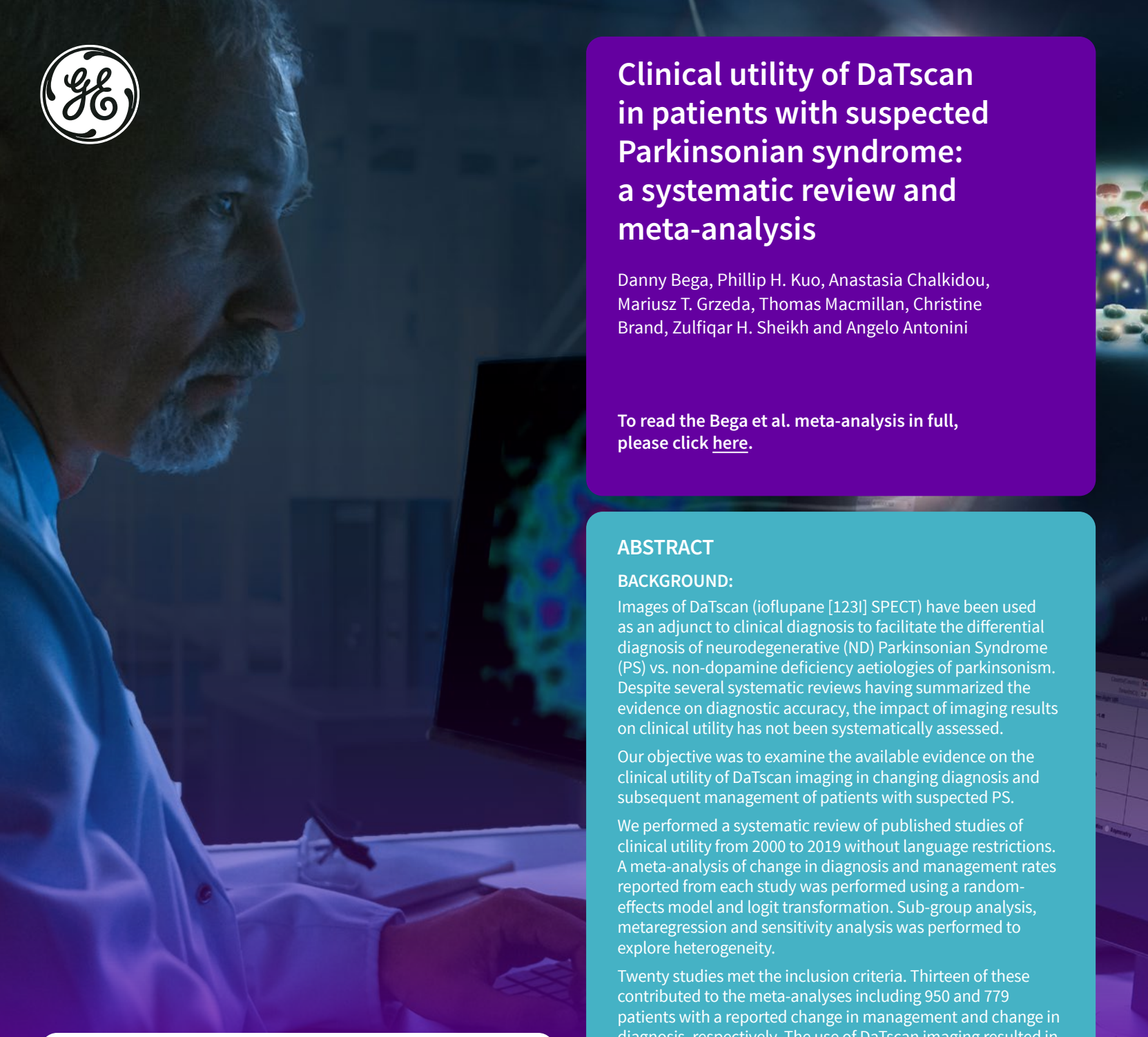

Clinical utility of DaTscan in patients with suspected Parkinsonian syndrome: a systematic review and meta-analysis

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To read the Bega et al. meta-analysis in full, please click here.

ABSTRACT

BACKGROUND:

Images of DaTscan (ioflupane [123I] SPECT) have been used as an adjunct to clinical diagnosis to facilitate the differential diagnosis of neurodegenerative (ND) Parkinsonian Syndrome (PS) vs. non-dopamine deficiency aetiologies of parkinsonism. Despite several systematic reviews having summarized the evidence on diagnostic accuracy, the impact of imaging results on clinical utility has not been systematically assessed.

Our objective was to examine the available evidence on the clinical utility of DaTscan imaging in changing diagnosis and subsequent management of patients with suspected PS.

We performed a systematic review of published studies of clinical utility from 2000 to 2019 without language restrictions. A meta-analysis of change in diagnosis and management rates reported from each study was performed using a random-effects model and logit transformation. Sub-group analysis, metaregression and sensitivity analysis was performed to explore heterogeneity.

Twenty studies met the inclusion criteria. Thirteen of these contributed to the meta-analyses including 950 and 779 patients with a reported change in management and change in diagnosis, respectively. The use of DaTscan imaging resulted in a change in management in 54% (95% CI: 47–61%) of patients. Change in diagnosis occurred in 31% (95% CI: 22–42%) of patients. The two pooled analyses were characterized by high levels of heterogeneity.

Our systematic review and meta-analysis show that imaging with DaTscan was associated with a change in management in approximately half the patients tested and the diagnosis was modified in one third. Regardless of time from symptom onset to scan results, these changes were consistent. Further research focusing on specific patient subgroups could provide additional evidence on the impact on clinical outcomes.

PRODUCT INDICATION 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™

CONTRAINDICATIONS

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

Please see Important Safety Information on back page and the full Prescribing Information here.

DaTscan™ Ioflupane I 123 Injection

DaTscan™
Ioflupane I 123 Injection

Background

Clinically uncertain Parkinsonian syndromes (CUPS) may be an important challenge for physicians as they may delay an accurate diagnosis needed to provide patients with the appropriate clinical care.

For over 10 years, physicians have used DaTscan to assess the presence of nigrostriatal dopaminergic degeneration (NSDD) in patients with CUPS, helping to differentiate PS with NSDD from disorders without NSDD.

PS with NSDD	Disorders without NSDD
Parkinson's disease	Essential tremor
Multiple system atrophy	Other disorders
Progressive supranuclear palsy	No disorder

For the first time, the impact of DaTscan imaging on clinical utility has been systematically assessed.

Objective

To examine the available evidence on the clinical utility of DaTscan imaging in changing diagnosis and subsequent management of patients with suspected PS.

Method

3,916

Unique records were identified in a literature search

335

Full-text articles were screened for eligibility by two independent reviewers

20

Studies met the inclusion criteria and were selected for meta-analysis

- ✓ Reported clinical utility analysis of imaging with DaTscan
- ✓ Used clinical examination to establish the diagnosis prior to DaTscan imaging
- ✓ Published in a peer-reviewed scientific journal
- ✓ Did not combine DaTscan imaging with other imaging tests to establish the diagnosis
- ✓ Included a patient population ≥10

Meta-analysis results

Primary endpoint

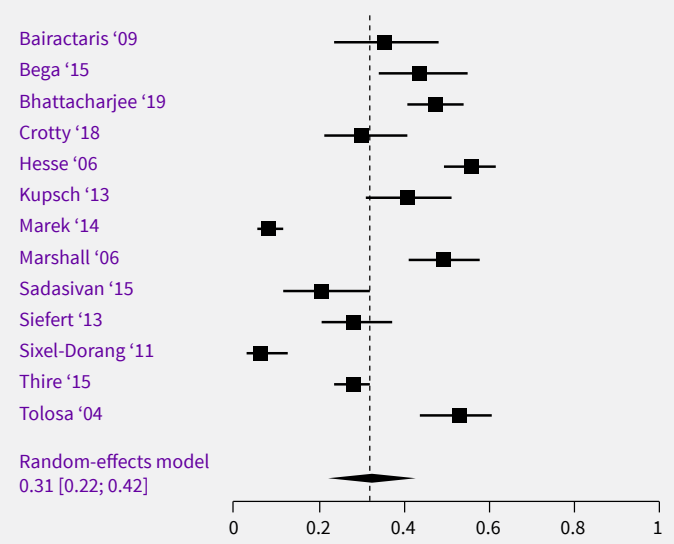
Change in diagnosis and management was pooled with a random-effects model to account for clinical and study design heterogeneity.

Change in diagnosis

13
studies reported change in diagnosis

n=779/2659
patients with a change in diagnosis

31%
of patients had a change in diagnosis associated with DaTscan imaging (95% CI: 22-42%)

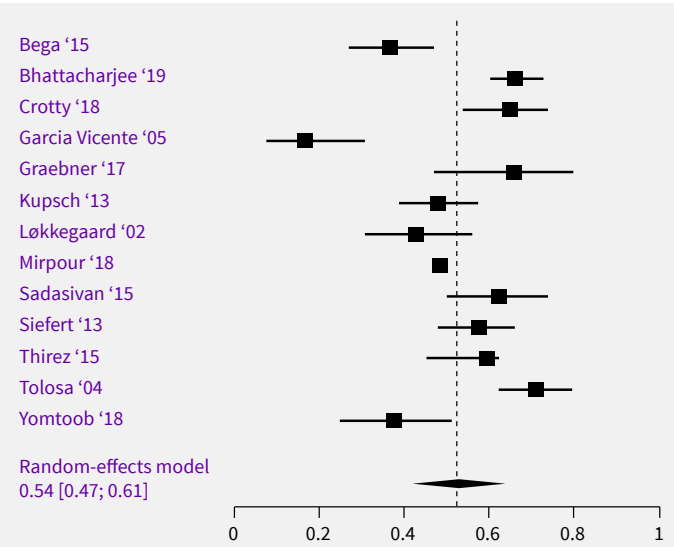


Change in management

13
studies reported change in management

n=950/1660
patients with a change in management

54%
of patients had a change in management associated with DaTscan imaging (95% CI: 47-61%)



Secondary endpoint

The impact of DaTscan imaging results on clinical management included changes to patients' medication.*

*Significant heterogeneity for all outcomes ($p<0.01$)

Starting a new drug treatment
10 studies
26% of patients
(95% CI: 21–32%)

Stopping a drug treatment
12 studies
14% of patients
(95% CI: 10–20%)

Changing the dose of a drug treatment
6 studies
6% of patients
(95% CI: 2–19%)

Conclusion

The results of imaging with DaTscan may be associated with an impact on clinical utility; changing diagnosis in one third of patients and changing management in over half.

Regardless of time from symptom onset to scan results, these changes were consistent and suggest that imaging with DaTscan may improve diagnostic confidence in uncertain cases.

GE HealthCare

PRODUCT INDICATION AND USE

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

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CONTRAINDICATIONS

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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.

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

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