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Update on Parkinson's Disease Treatment

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  - TRI Pilot award (PI)

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Learning Objectives

- Apply the diagnostic criteria for Parkinson's disease and Parkinson's disease dementia
- Recognize the motor and non-motor features of Parkinson's disease
- Employ treatment options for the motor and cognitive features of Parkinson's disease

UK Brain Bank Criteria for the diagnosis of Parkinson's Disease

- Bradykinesia (slowness and taper in amplitude of repetitive movements)

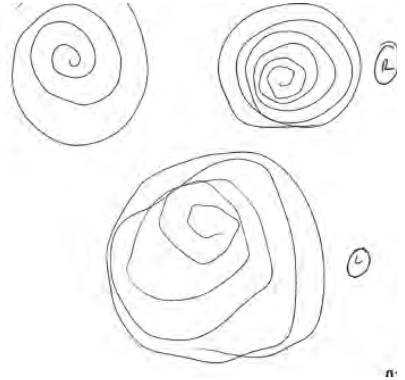
  AND

- At least one of the following
  - Muscular rigidity
  - 4-6 Hz rest tremor
  - postural instability (not caused by primary visual, vestibular, cerebellar, or proprioceptive dysfunction)

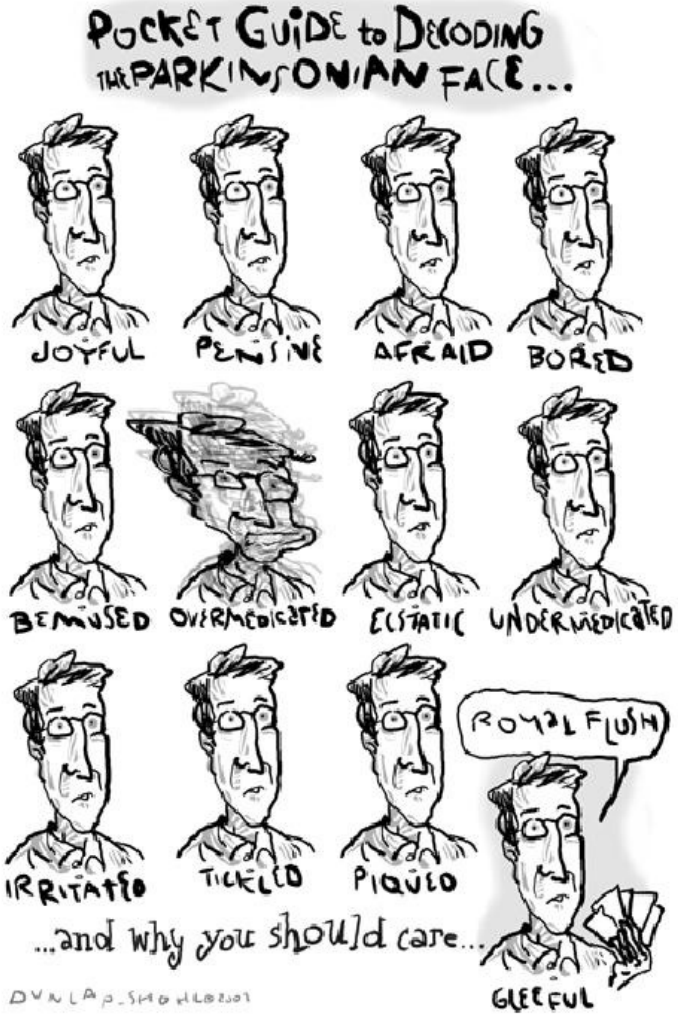
Note: tremor need not be present!

Supportive features for Parkinson's disease

- Meyerson's sign (glabellar tap)
- Rest tremor
- Unilateral onset, persistent asymmetry
- Sustained response to levodopa (>5 years)
- Progressive disorder, long clinical course (>10 years)
- Levodopa induced dyskinesias
- Other: hypophonia, hypomimia, micrographia, small spirals



Exclude: concurrent or recent antipsychotic use (haloperidol, ziprasidone, olanzapine, risperdone, perphenazine, aripiprazole etc.)



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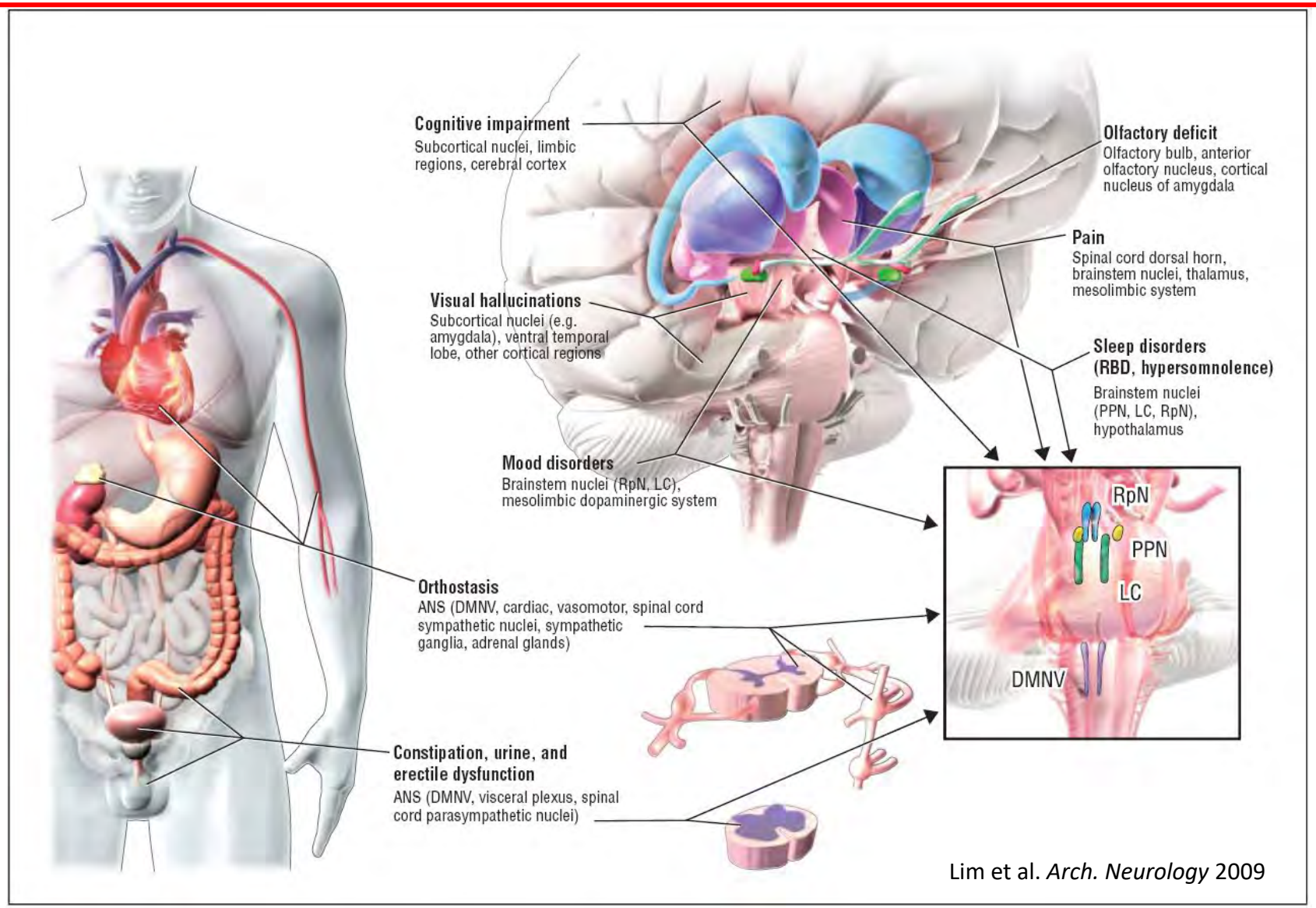
Parkinson's disease: Non-motor features



Lim et al. *Arch. Neurology* 2009

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Disease Course and Progression

From *Neuropathology Illustrated* by Townsend & Klatt

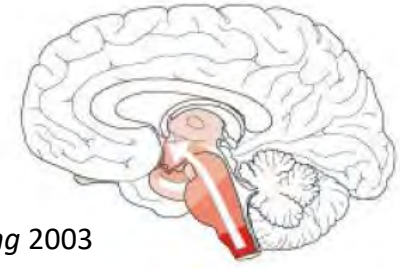
Motor Onset
Diagnosis
Treatment
Honeymoon period

Non-motor phase	Early motor phase	Motor complications	Resistant Symptoms	Cognitive decline
Years ?	0	3	8	15
Olfactory loss, RBD, Constipation, Anxiety, Depression, Impaired color vision, Urinary changes	Bradykinesia Rigidity Rest-tremor	Motor fluctuations Dyskinesias	Postural instability Gait freezing Dysarthria Dysphagia	Dementia Psychosis Sleep-wake dysregulation

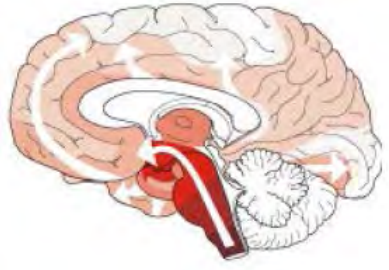
Braak Stage

Stage 1-2

Stage 3-4

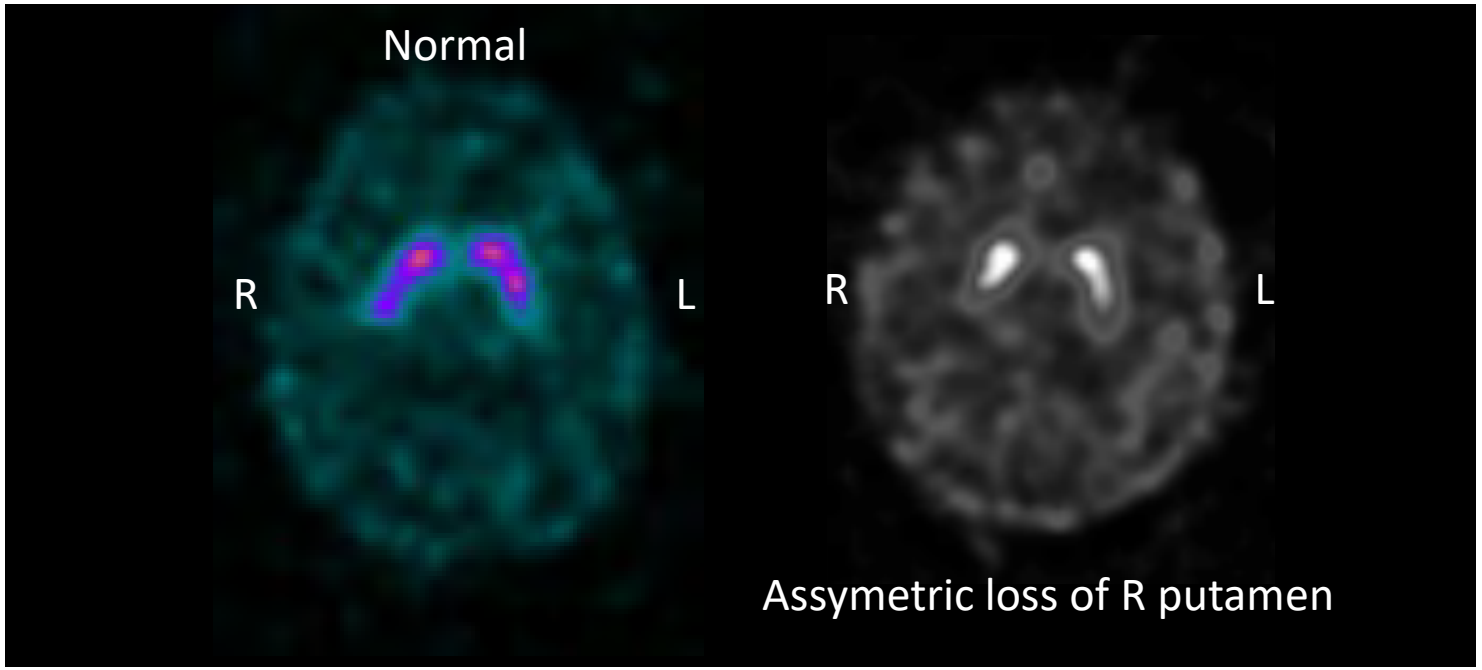


Stage 5-6



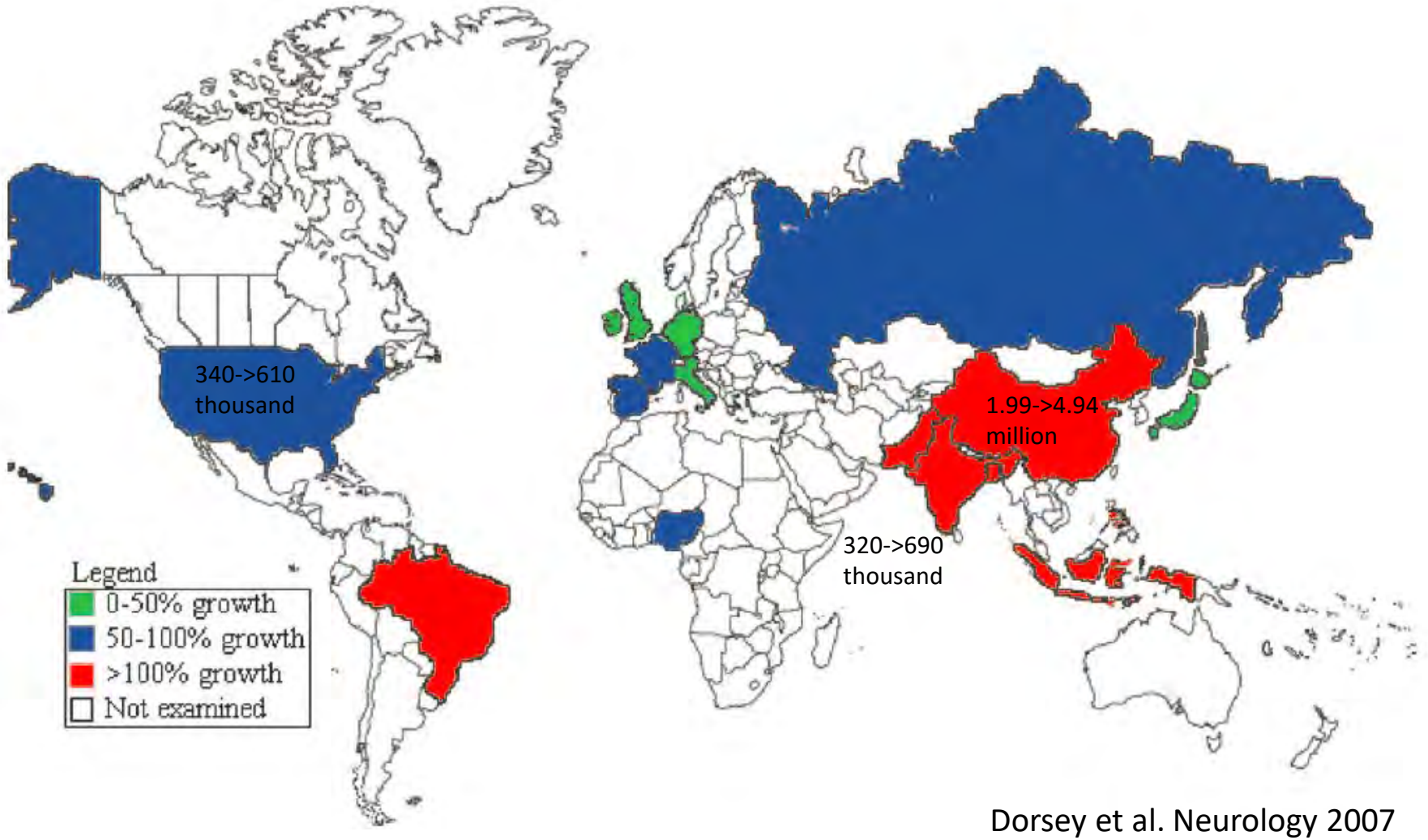
Braak et al. *Neurobiol. Aging* 2003

Dopamine transporter (DAT) SPECT Scan



- DAT SPECT scan is FDA approved for question of "Essential Tremor vs PD" (Benamer Mov do 2000).
- Reportedly also can help differentiate drug induced parkinsonism from degenerative parkinsonism (Tolosa et al. Mov do 2003)
- Cannot differentiate between atypical parkinsonism and idiopathic PD (Bajaj et al. JNNP 2013).

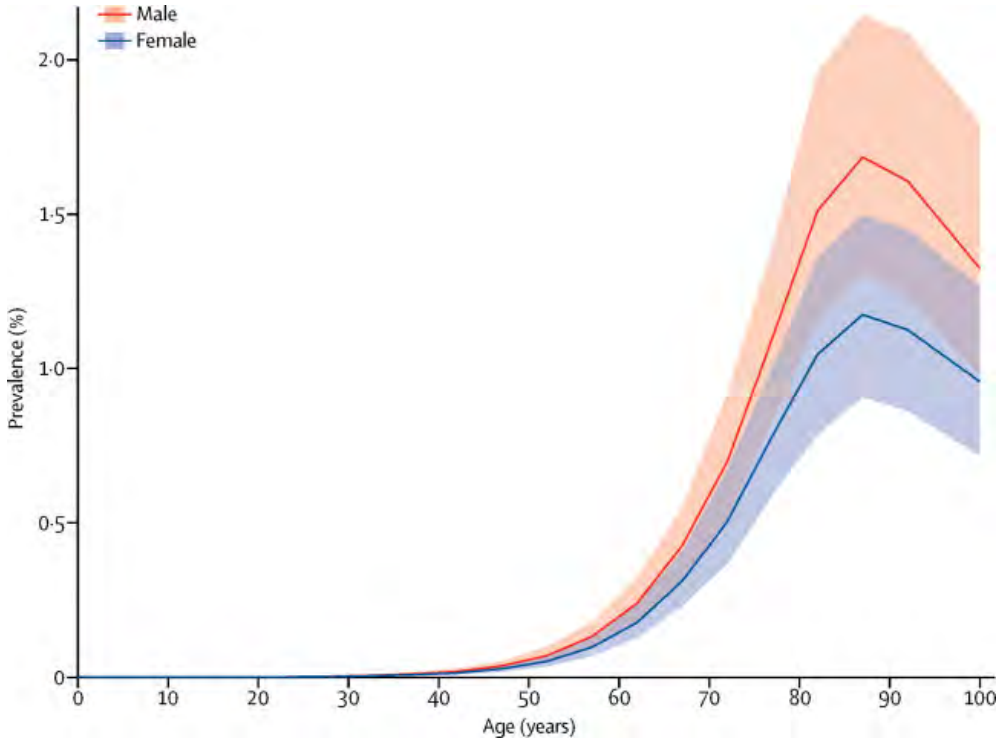
Projected growth rates in individuals over 50 with PD by 2030



Dorsey et al. Neurology 2007

Risk factors for PD

- Age: greatest risk factor, increases exponentially with age and peak after 80 yrs
- Gender: male:female 3:2
- Ethnicity: Hispanic>non-Hispanic Whites, Asians, Blacks



Dorsey et al. Lancet Neurol. 2018

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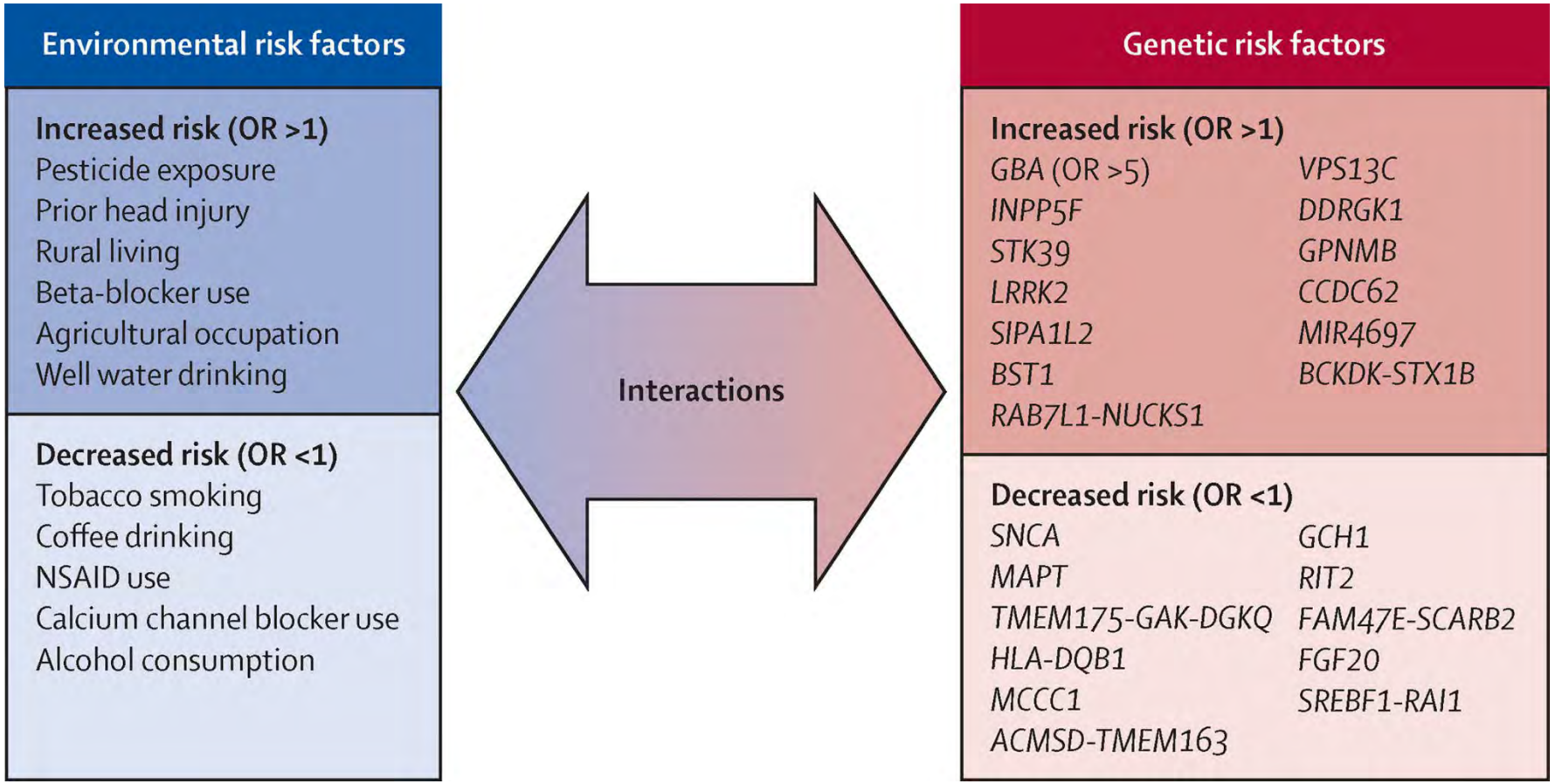
Risk factors for PD cont…



Kalia & Lang, *Lancet* 2015

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When to treat?

- You want to provide patients with the best quality of life at an age when they can enjoy that quality of life.
  - Evidence argues against withholding therapy to prevent future side effects. If a patient is symptomatic and ADLs are impacted then treat.
  - There are currently no neuroprotective agents for PD, so if symptoms are not bothersome can continue to monitor clinically.
- I almost always start levodopa if the patient is falling or there is postural instability on examination.

Commonly used medications for motor symptoms

Symptomatic:

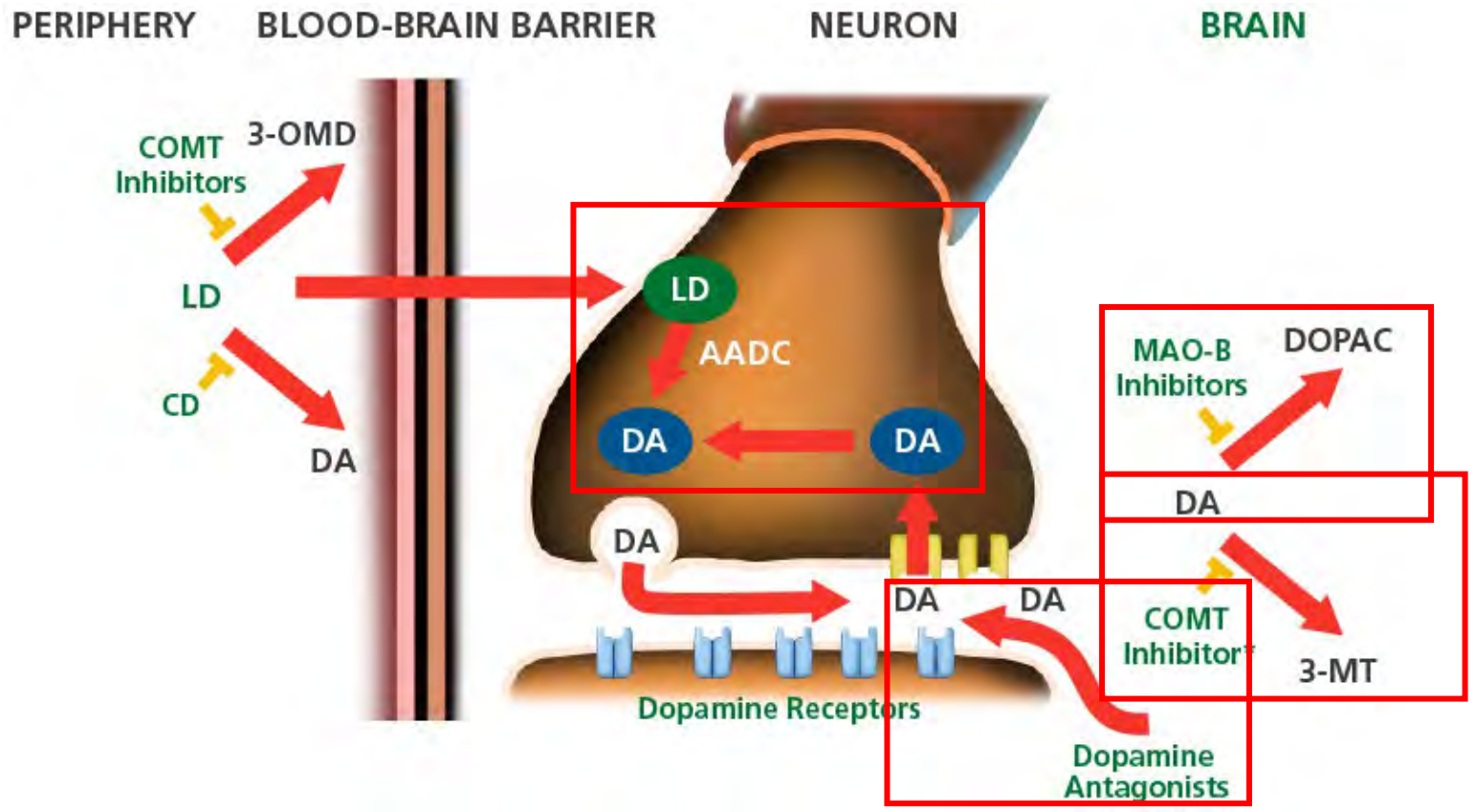
- Levodopa (gold standard)
- Dopamine agonists (ropinirole, pramipexole, rotigotine patch)
- Non-dopaminergic (may benefit tremor in young):
  - Anticholinergics (trihexyphenidyl, benztropine)
  - Amantadine

Mild symptomatic, unclear neuroprotection:

- MAO-B Inhibitors (selegiline, rasagiline, safinamide)

Levodopa extenders:

- COMT inhibitors (entacapone, tolcapone and opicapone)



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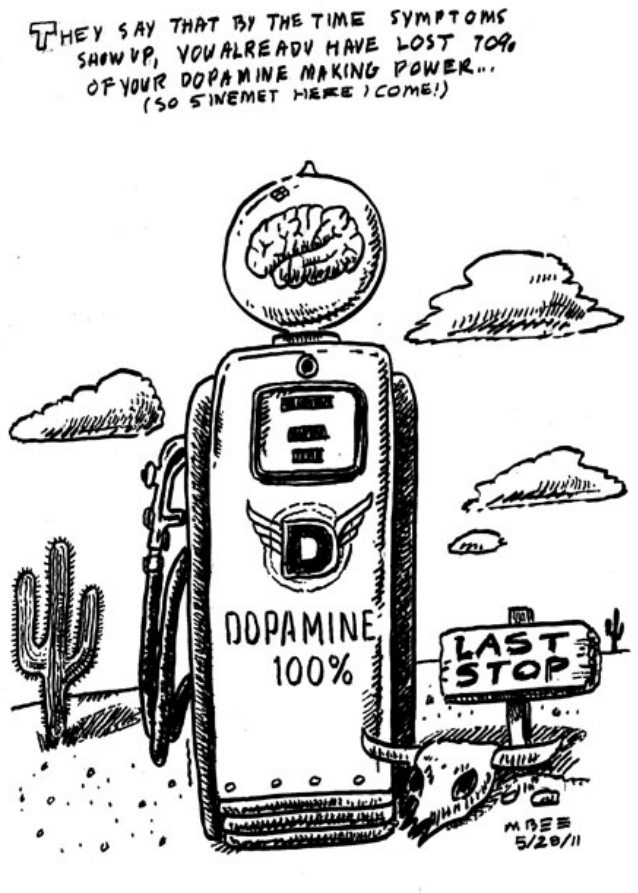
carbidopa/levodopa (Sinemet)

- Gold standard treatment for motor symptoms: rigidity/bradykinesia>tremor
- Start low go slow: 25/100 ½-1 tablet daily and increase weekly by ½-1 tablet up to 1 tablet three times daily initially but higher if needed.
- Ratio of 1:4 more effective in levodopa induced nausea than 1:10 (ie. 25/100 formulations not 10/100 or 25/250.
- Meals are a reasonable starting point during the honeymoon period.



Levodopa early-side effects

- Nausea:
  - Meals, extra carbidopa (Lodosyn), domperidone (from other countries), trimethobenzamide helps in some.
  - Avoid promethazine (Phenergan), prochlorperazine (Compazine) or metoclopramide (Reglan) as these are dopamine receptor blockers.
- Orthostasis: check orthostatics in all PD patients at each visit.
  - Over time BP trends down so patients may require weaning of anti-hypertensives.
  - If conservative treatments fail: midodrine 5-10 mg 2-3 times per day or fludrocortisone 0.1 mg 1-2 times daily
- Somnolence (rare but dose limiting): occurs at peak dose.

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Levodopa late side effects: dyskinesias

- "wiggly" movements resembling chorea, usually at peak dose (30-60 min) but can occur at end dose.
- Levodopa excess state
- Most patients prefer to be dyskinetic rather than slow and stiff
- Not dangerous unless:
  - frequent neck movements that can lead to mechanical issues
  - Involve walking leading to increased risk of falls
- Treatment:
  - amantadine IR, ER
  - Levetiracetam
  - DBS

Levodopa late side effects: psychosis

- "benign" hallucinations that can progress to paranoia.
- Treatment:
  - Lower levodopa dose if possible
  - Quetiapine (Seroquel) 25 mg (up to 100 mg) at bedtime (higher doses non-selectively block dopamine receptor)
  - Clozapine (Clozapine)
    - Better drug but requires WBC checks due to low risk of agranulocytosis.
  - Pimavanserin (Nuplazid)
    - Care with CYP3A inhibitors or inducers and other drugs that prolong QT.

ALL OTHER ANTIPSYCHOTICS ARE CONTRAINDICATED IN PD

An artists rendition of their hallucinations

Frucht & Bernsohn Neurology 2002

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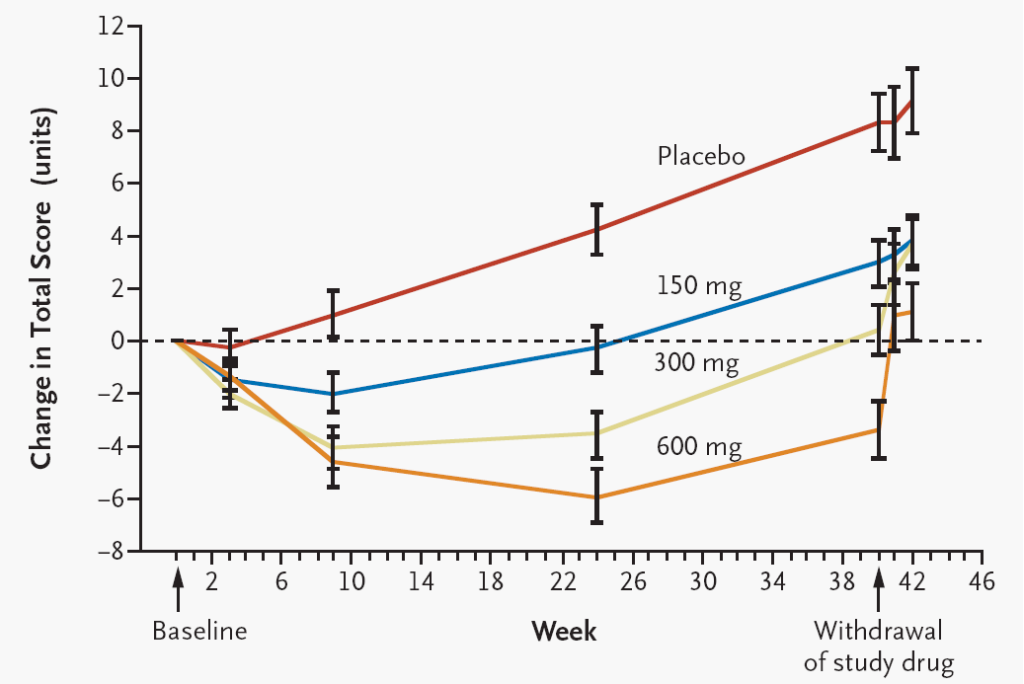
Some popular myths about levodopa

Levodopa is toxic:

- ELLDOPA trial suggested potential neuroprotective effect although hotly debated still. (PSG *NEJM* 2004;351:2498-508)
- Autopsy study reported no statistically significant damage from long term levodopa use. (Parkkinen et. al. *Neurology* 2011;77:1420 –1426)
- But are dyskinesias side effects? Non-PD patient will not get dyskinesias with levodopa.



Parkinson Study Group. *NEJM* 2004;351:2498-508

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Some popular myths about levodopa

The effect of levodopa wears off (or levodopa only works for a certain number of years):

- Levodopa (ie. dopamine) always continues to work.
- As the disease progresses more neurons die -> less endogenous dopamine is present -> more levodopa is required; both in absolute amount and frequency of dosing.
- Late developing side effects such as dyskinesias and hallucinations can limit the dose a patient can tolerate.

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Some popular myths about levodopa

- If a patient does not respond to 300 mg/day of levodopa then they do not have idiopathic Parkinson Disease.
  - Some PD patients require much higher doses of levodopa to get symptomatic improvement (up to 1500-2000 mg/day).
  - About 30% of patients do not show improved tremor with levodopa. Bradykinesia and rigidity almost always improve.

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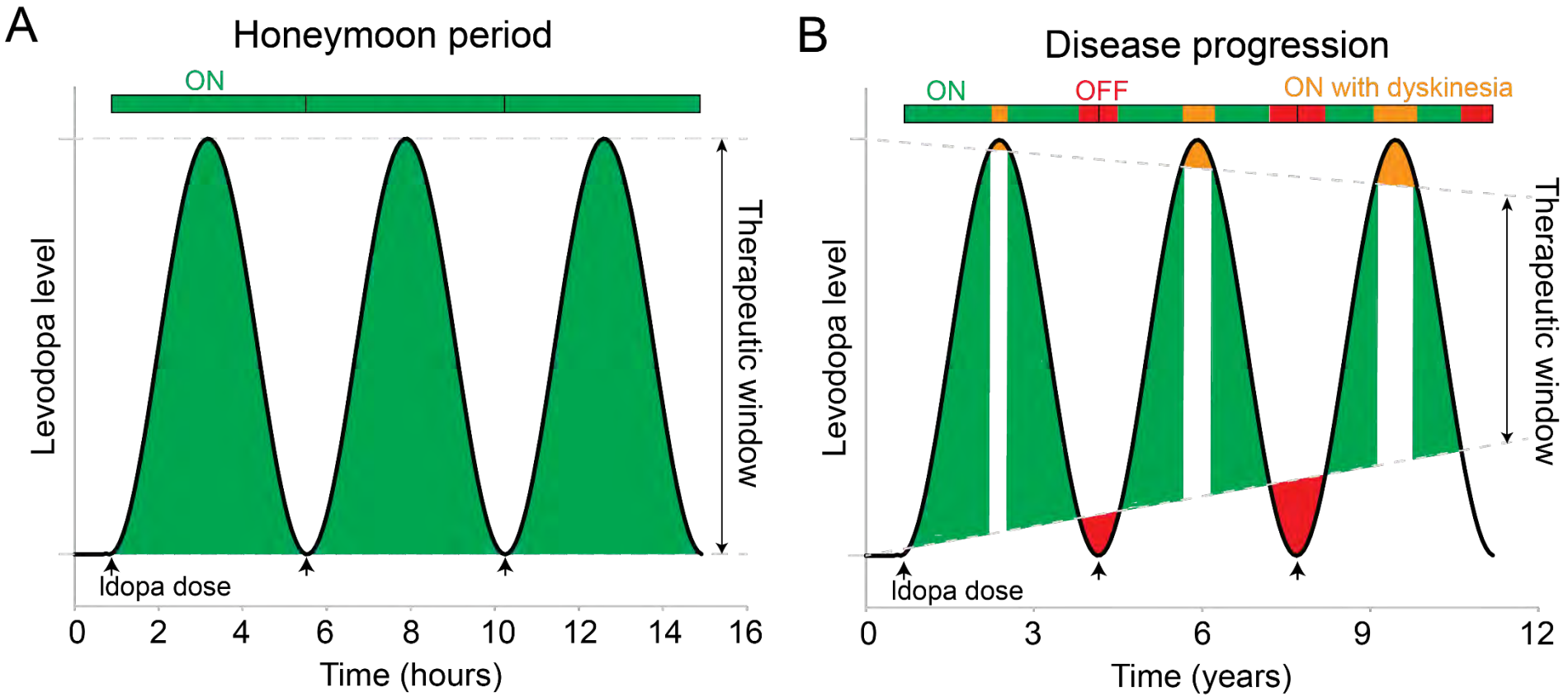
Dopamine agonists

- Available in oral (ropinirole and pramipexole), transdermal patch (rotigotine) and injectable/sublingual (apomorphine SC/SL) formulations.
- Weaker binding to the dopamine receptor than levodopa
- Can be used as a levodopa sparing strategy in young patients (30s-50s) who are more susceptible to early onset, more violent dyskinesias.
- Side effects:
  - Impulse control disorders:
    - More common in patients with prior smoking, drug abuse or other obsessions.
    - Estimated in up to 40% within 4 years (Mov. Disord. 2013;28(3):327-33)
    - Important to talk to patients **and family** about these if starting an agonist.
  - Daytime somnolence/sleep attacks: can fall asleep at the wheel
  - Edema: commonly incorrectly attributed to heart failure. Improves with a delay (sometimes long) after weaning off.
  - Cognitive impairment: especially in people over 65

Dopamine Agonist Withdrawal Syndrome (DAWS)

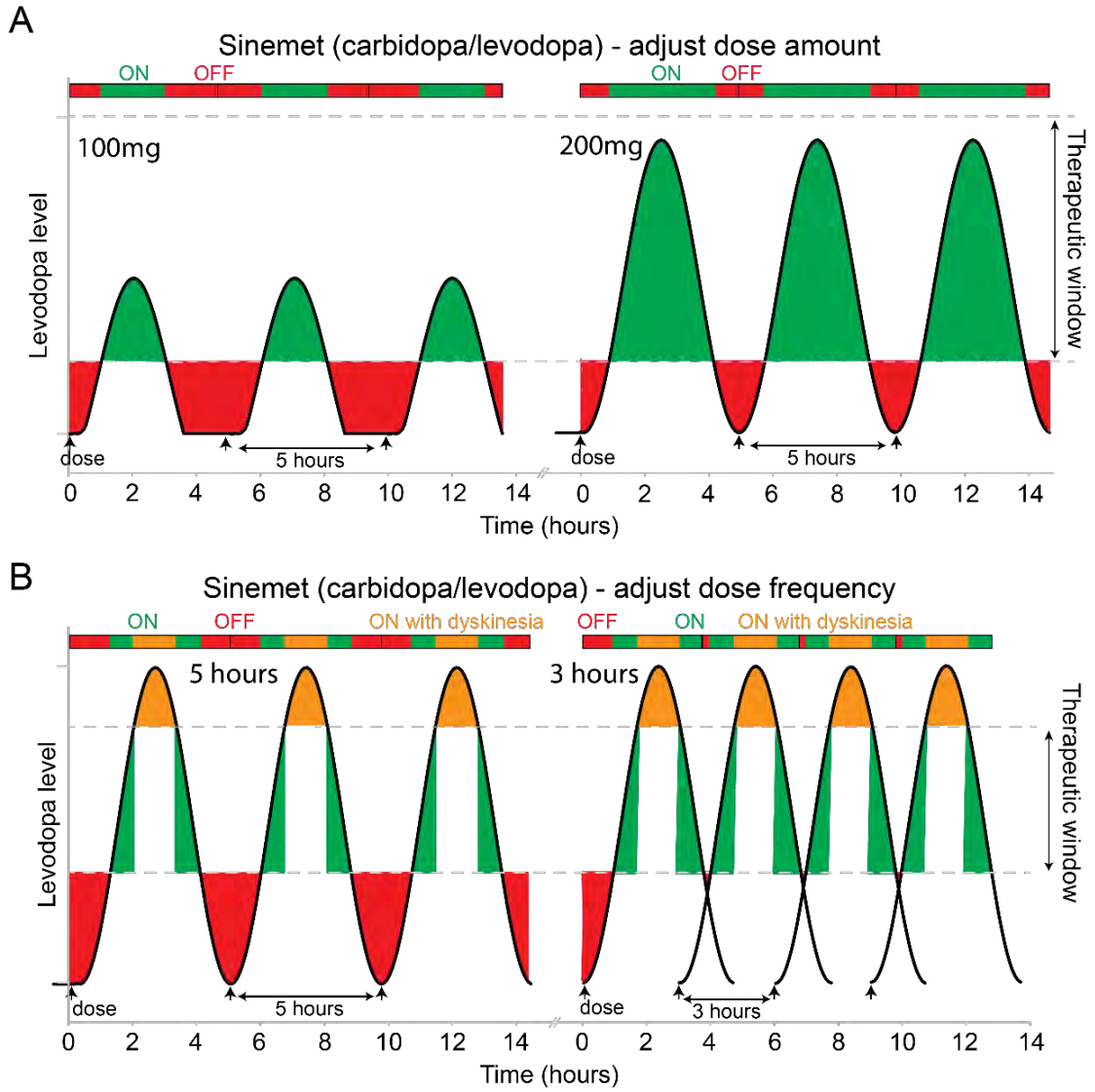
- Occurs when agonists are withdrawn abruptly but can also occur in some individuals when slowly tapered.
- Severe depression, anxiety, panic attacks, agitation, irritability, suicidal ideation, fatigue, orthostatic hypotension, nausea, vomiting, diaphoresis, generalized pain, and drug cravings.
- Self limited in most but can take weeks to several months to improve. In some never improves and only option is to resume agonists
- No known treatment other than continued low dose.
- To avoid wean agonists off very slowly especially in older adults and with long-term use.

Advanced disease: Motor fluctuations and OFF-states



Sinemet® (carbidopa/levodopa)

- Adjust absolute dose
- Adjust dosing frequency
- Main side effects:
  - Early:
    - Nausea: take with meals
    - Othostatic hypotension: check each visit
  - Late:
    - Dyskinesias
    - Hallucinations: only low dose Seroquel (<100mg/day), clozapine or pimavanserin safe to use in PD.



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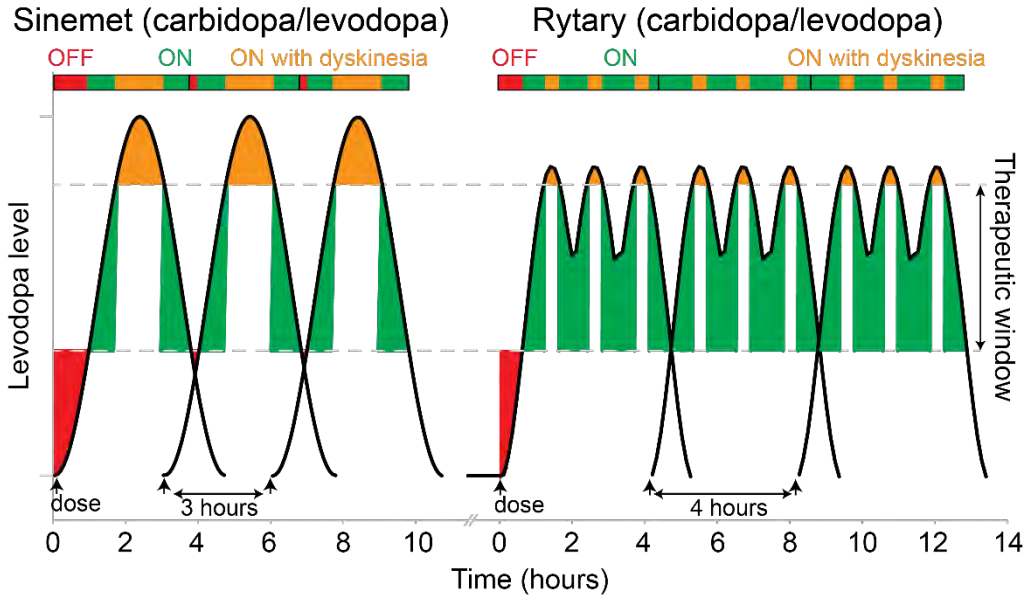
Rytary® (carbidopa/levodopa)

- Capsule with beads of carbidopa/levodopa that release at differential rates
- Same side effects as other oral carbidopa/ levodopa
- Benefits
  - Decreased dose frequency
  - Improved dyskinesias



Hauser et al. *Lancet Neuro.* 2013

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Nurianz® (istradefylline)

- Adenosine A2A antagonist
  - Dopamine is the GO signal
  - Adenosine is the STOP signal
  - Blocking Adenosine releases the STOP signal
- Pros:
  - Once daily
  - Decreased OFF time when added to carbidopa/levodopa

Cons:

- Can boost levodopa side effects
  - Dyskinesias
  - Hallucinations
  - Lightheadedness
  - nausea
- Can cause insomnia

Rescue for motor OFF states

Inbrijia®: inhaled levodopa

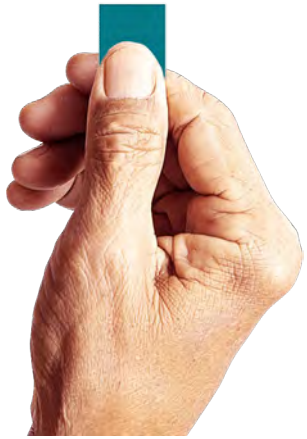
- Benefits:
- Rapid ON time

•Cons:

- Cough, nausea, dizziness in 7%.
- Needs to be primed before use which is in the OFF state

Lewitt et al. *Mov. Disord.* 2016

Kynmobi®: Sublingual apomorphine film



- Benefits:
- Rapid ON time
- Easy to use

•Cons:

- Mouth/throat side effects led to 17% of the 28% who withdrew from study
- Nausea, sleepiness and dizziness were other main side effects.

Olanow et al. *Lancet.* 2019

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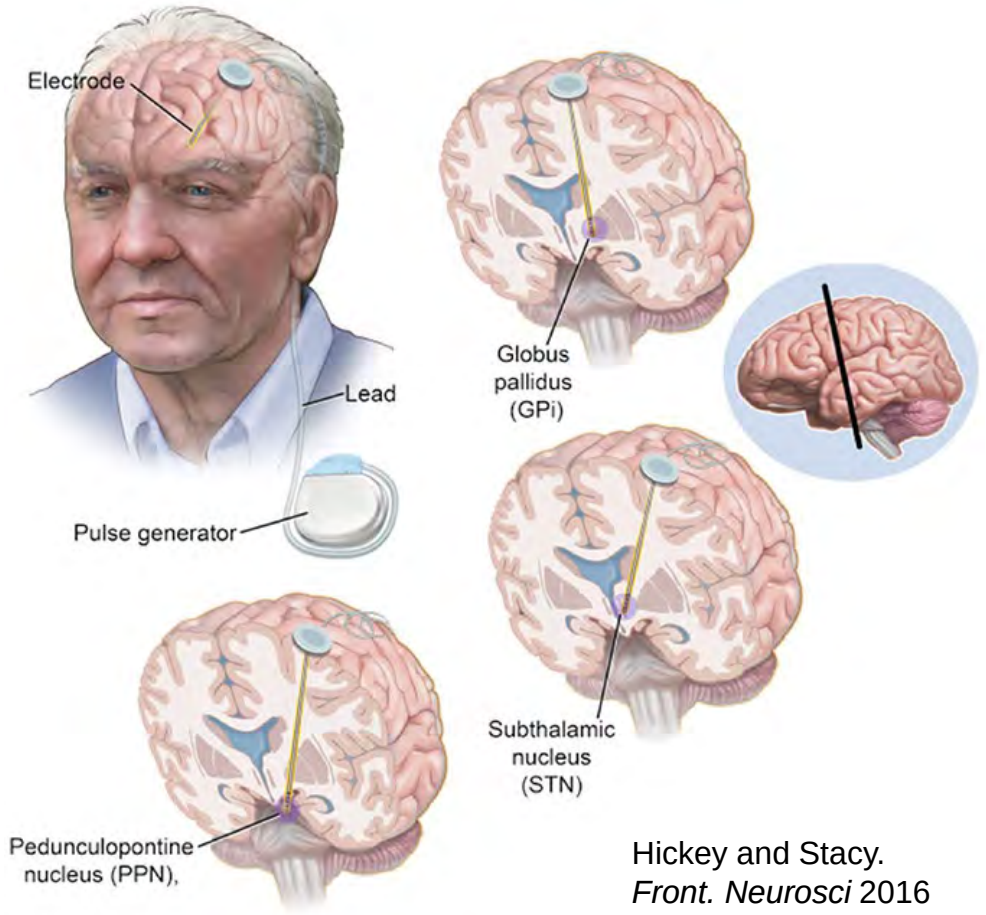
Deep Brain Stimulator (DBS) Surgery

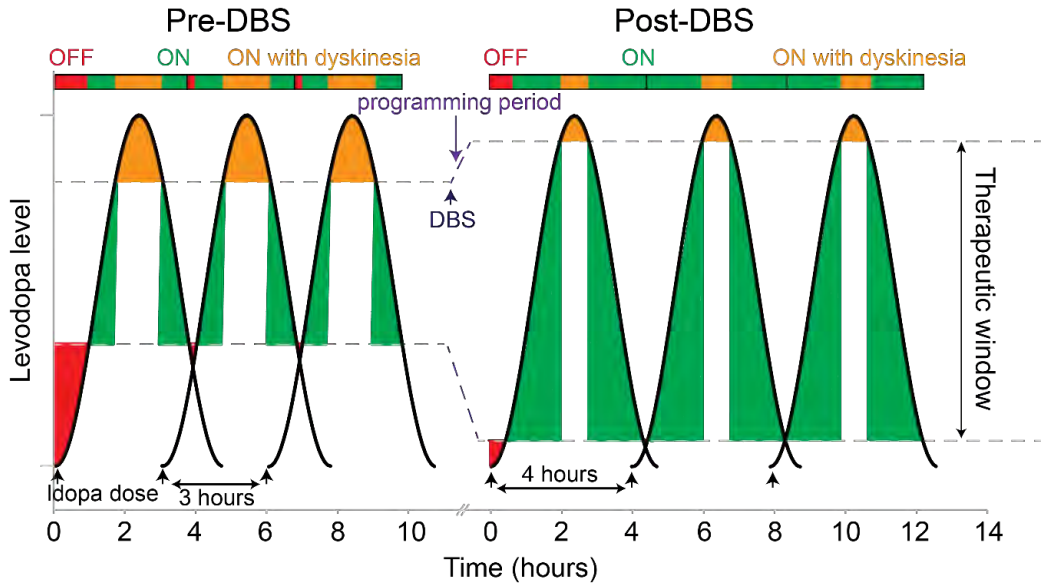
- Approved indications:
  - Motor fluctuations
  - Medication side effects limiting dose
  - Tremor not responsive to levodopa
- Not a cure
- Not a substitute for levodopa
- Does have surgical risks (bleeding, infection) and stimulation side effects.



Hickey and Stacy.
Front. Neurosci 2016

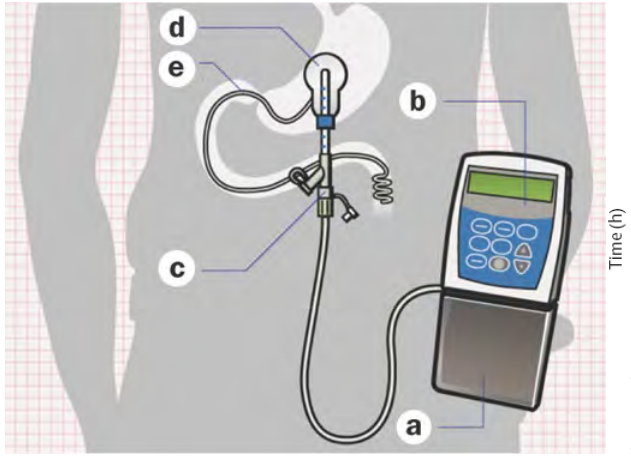
DBS benefits

- Typically helps levodopa responsive symptoms
  - Widens back therapeutic window.
- Postural instability and levodopa unresponsive freezing of gait do not typically improve
- Can help some non-motor features

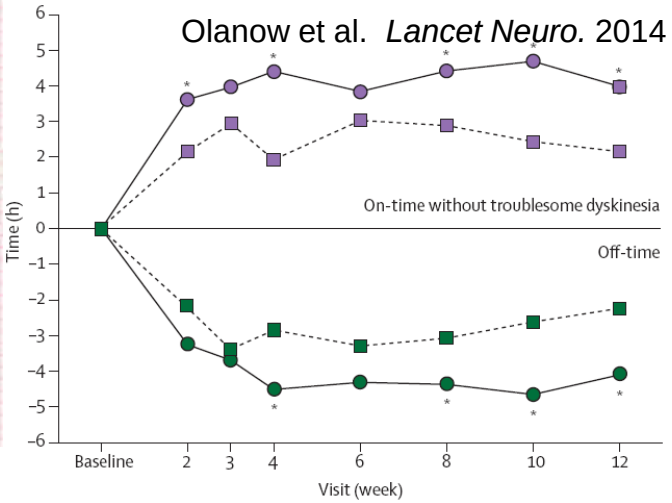


DUOPA® (carbidopa/levodopa intestinal gel infusion)

- Approved in the US in February 2015
- Improved OFF time, dyskinesias and motor fluctuations with continuous infusion
- Same side effects as other carbidopa/levodopa formulations
- Potential procedural/ device related side effects such as infection, tube leakage, dislocation, and occlusion



Richards *Nat. Rev. Neurol.* 2009



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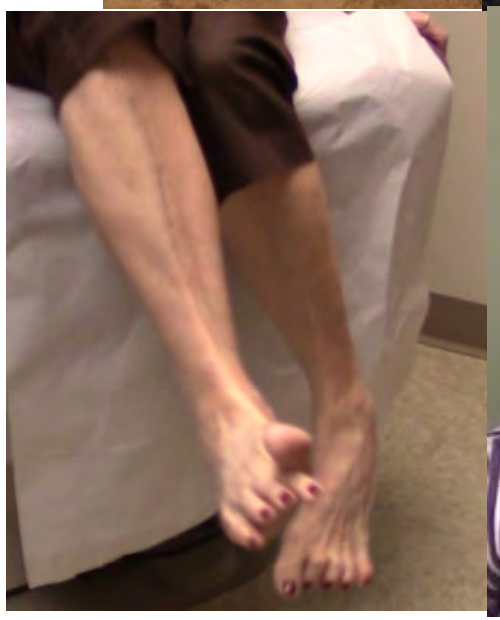
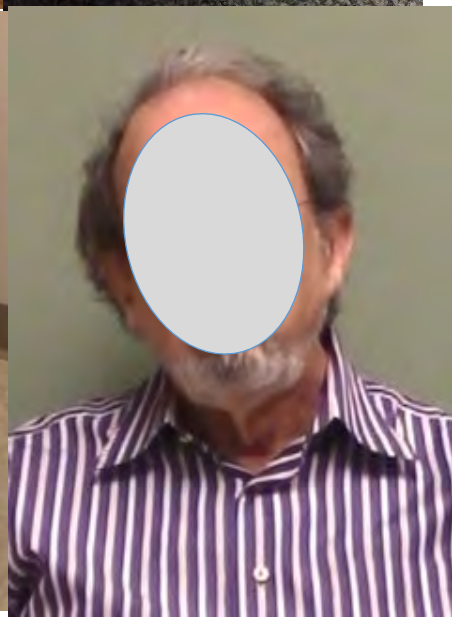
Dystonia in Parkinson's Disease

- Dystonia is common as PD progresses
  - Cervical dystonia
  - Foot dystonia (toe curling, foot turning)
- Can cause significant pain that may not respond to levodopa.
- Can impair gait and balance if feet are involved
- Treatment options:
  - Adjustment of levodopa dose timing if wearing OFF symptom.
  - Botulinum toxin injections





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Freezing of gait

- Exercise/Physical therapy: LSVT BIG is very beneficial to retrain automaticity of gait.
- Motor cuing: metronome, music, target, laser guide (USTEP-II walker)
- Experimental: modafinil, amantadine, donepezil, selegiline?

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Mild Cognitive Impairment (MCI)

- Different definitions of MCI in PD over time have led to different estimates of 20-50% at diagnosis of motor PD
- Criteria:
  - Diagnosis of PD based on UK brain bank criteria
  - Gradual decline of cognitive ability by either patient or informant or observed by clinician
  - Cognitive deficits on formal testing or a scale of global cognitive abilities
  - Cognitive deficits **are not** sufficient to interfere significantly with functional independence, although subtle difficulties on complex tasks may be present
  - Exclude: PD-dementia, other primary explanation for cognitive impairment, other co-morbid condition that can mimic cognitive impairment such as excessive daytime sleepiness or depression.
- Treatments: Investigational/insufficient evidence (Acetycholinesterase inhibitors, MAO-B inhibitors, transcranial direct current stimulation)

Litvan et al. Mov do 2011
Seppi et al. Mov disord. 2019

PD-D diagnosis criteria

- Estimates of up 60% within 12 years of motor disease
- Risk factors include older age, disease severity and earlier MCI?
- Core features:
  - Diagnosis of Parkinson's disease by UK brain bank criteria
  - A dementia syndrome with insidious onset and slow progression, developing in context of established PD
    - Impairment in more than one cognitive domain
    - Decline from premorbid level
    - Deficits severe enough to impair daily life (social, occupational, or personal care) independent of motor or autonomic symptoms.

Emre et al. Mov do 2007

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PD-D Associated clinical features

- Cognitive features:
  - Attention: impairment in spontaneous and focused attention, may fluctuate during the day and from day to day.
  - Executive function: impairment in tasks requiring initiation, planning, concept formation, rule finding, set shifting and impaired mental speed (bradyphrenia)
  - Visuo-spatial: impairment in tasks requiring visuo-spatial orientation, perception or construction
  - Memory: Impairment in free recal of recent events, improves with cueing.
  - Language: Core functions are largely preserved. Word finding difficulties may be present

Emre et al. Mov do 2007

PD-D Associated clinical features

- Behavioral features:
  - Apathy: decreaed spontaneity, loss of motivation and interest.
  - Changes in personality and mood including depression and anxiety
  - Hallucinations: mostly visual, usually complex formed people or animals
  - Delusions: Usually paranoid such as infidelity or phantom boarder (unwelcome guests living in home)
  - Excessive daytime sleepiness
- Exclusions:
  - Cognitive and behavioral symptoms appearing solely in the context of other conditions such as acute confusion from systemic disease or drug intoxication
  - Major depression according to DSM diagnosis
  - Vascular dementia

Emre et al. Mov do 2007

Treatment of PD-Dementia

Drug class/ intervention strategy	Drug/ intervention	Efficacy	Safety	Practice implications
Acetyl-cholinesterase inhibitors	Donepezil	Insufficient evidence	Acc. risk w/o spec. monitor.	Possibly useful
	rivastigmine	Efficacious	Acc. risk w/o spec. monitor.	Clinically useful
	galantamine	Insufficient evidence	Acc. risk w/o spec. monitor.	Possibly useful
NMDA antagonists	Memantine	Insufficient evidence	Acc. risk w/o spec. monitor.	Investigational

Seppi et al. Mov disord. 2019

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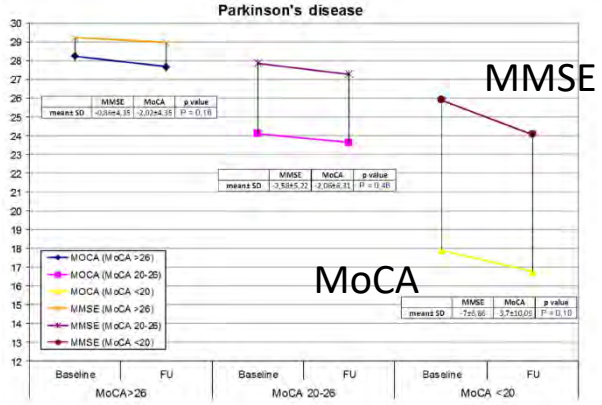
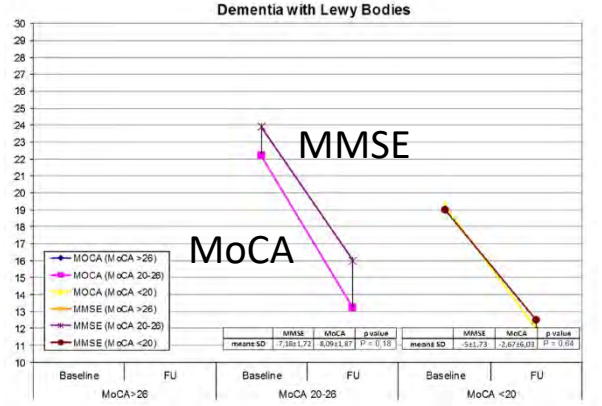
Dementia with Lewy Bodies

- Accounts for 4-8% of patients with dementia in clinic-based studies
- Essential:
  - presence of a progressive cognitive decline of sufficient magnitude to interfere with normal social or occupational functions, or with usual daily activities.
  - Prominent or persistent memory impairment may not occur in early stages but is usually evident with progression.
  - Deficits in attention, executive function, and visuoperceptual ability may be prominent and occur early
- Core features:
  - Fluctuating cognition with pronounce variations in attention and alertness
  - Recurrent visual hallucinations that are typically well formed and detailed
  - REM sleep behavior disorder, which may precede cognitive decline
  - One or more features of parkinsonism (bradykinesia, rest tremor or rigidity)

Parkinson's disease



Dementia with Lewy Bodies



McKeith et al. Neurology 2017
Taylor et al. Lancet Neurology 2020

Healthy Lifestyle

- Exercise Benefits:
  - improves overall motor function – especially gait and balance
  - improves apathy (decreased interest)
  - potentially neuroprotective
- Intensive cardio-exercise better:
  - LSVT BIG®: many trained therapists around the state including at UAMS.
  - Rock Steady Boxing®: multiple centers now in Arkansas
  - PWR!Moves®: classes in Reynolds Center at UAMS
  - Bicycling: recumbent bike
- Healthy diet: no clear indication for one diet over another, other than possibly the Mediterranean diet

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Active PD Research at UAMS

- Clinical and translational research (Virmani PI – TVirmani@uams.edu)
  - Longitudinal study of gait, cognition and mood in Parkinson's disease and other neurodegenerative disorders.
  - Developing predictive algorithms for freezing of gait in PD
  - Developing remote monitoring techniques for PD in rural Arkansas
- Active clinical trials (Dhall PI – RDhall@uams.edu):
  - Newly diagnosed Parkinson's Disease patients (therapy naïve) – Dr. Dhall will get apt in 4wks.
    - Exenatide (incretin mimic) SC injections vs placebo (diabetics excluded)
    - Tavapadon (D1/D5 partial agonist) vs placebo (TEMPO 1)
    - Upcoming:
      - c-ABL inhibitors for slowing disease progression (PROSEEK & INHIBIKASE)
      - Alpha-synuclein aggregation inhibitor (ORCHESTRA)
  - Parkinson's Disease motor-fluctuators:
    - Tavapadon as adjunct to oral levodopa (TEMPO 3, TEMPO 4)
    - Subcutaneous levodopa infusion (Neuroderm®: OFF time >3hrs per day)
  - All Parkinson's Disease:
    - Genetic testing for PD risk markers (PDGENEration)
    - Zolendronic acid to reduce fall related fractures (>60 yo, not on bisphosphonate) (TOPAZ)

https://is.gd/uamsmdclinicresearch

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When to refer to Movement disorders?

- Treatment naïve patients for clinical trial participation – please do not start medications, contact us and we can get them in quickly if needed.
- Whenever you are unclear about the diagnosis or management.
- Young-onset patients (<50 at sx onset)
- Mild-moderate disease for consideration of advanced therapies (>200mg/dose, dosing more than 3 times per day).
- For participation in patient-oriented research or clinical trials
- Patient has a movement disorder

"I already diagnosed myself on the Internet. I'm only here for a second opinion."

Multidisciplinary team

Neurology:
Tuhin Virmani, MD, PhD, FAAN
Rohit Dhall, MD, MSPH, CPE
Aditya Boddu, MD
Hillary Williams, MD
Shannon Doerhoff, ARPN
Rachel Sloan, APRN
Kathy Stafford, RN
Delores Chandler, RN
Kristie Cervantes, LPN

Psychiatry:
Jennifer Kleiner, PhD
Jennifer Gess, PhD
Crystal Fullen, PhD

Neurosurgery:
Erika Petersen, MD

Tiffany Reckling, RN

Social Work:
Kuganes Collins, LCSW
Liz New, LCSW

Speech Language Pathology:
Hannah Petersen, SLP
Amanda Davis, SLP
Rachel Beckham, SLP
Hylan Pickett, SLP

Physical Therapy:
Chris Oholendt, OTR\L, MHSA
Darrell Gray, DPT

Nutrition:
Dana McClendon, MSc

Genetics:
Andrew Burrow, MD
Jill Kelsay, MS, CGC

Education:
Suzanne Dhall

Research:
Lakshmi Pillai, MS
Aliyah Glover, BS
TRI research coordinators

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Questions?

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People with Parkinson's disease

https://redcap.link/patient_voices

Participate in a research study today!

We are collecting voice samples from people with Parkinson's disease and healthy people of all ages to develop better tools for earlier diagnosis of Parkinson's disease.

To participate scan the correct QR code with your devices' camera and click on the link or button that pops up on your devices screen.

You can also enter the internet address provided below the QR code

People without neurologic disease

https://redcap.link/voices