

# PARKINSON'S DISEASE IN 2021



## Updated Treatments

# INOVA PARKINSON'S & MOVEMENT DISORDERS CENTER



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## Alexandria

1500 N. Beauregard Street  
Suite 300  
Alexandria, VA 22311

## Fairfax

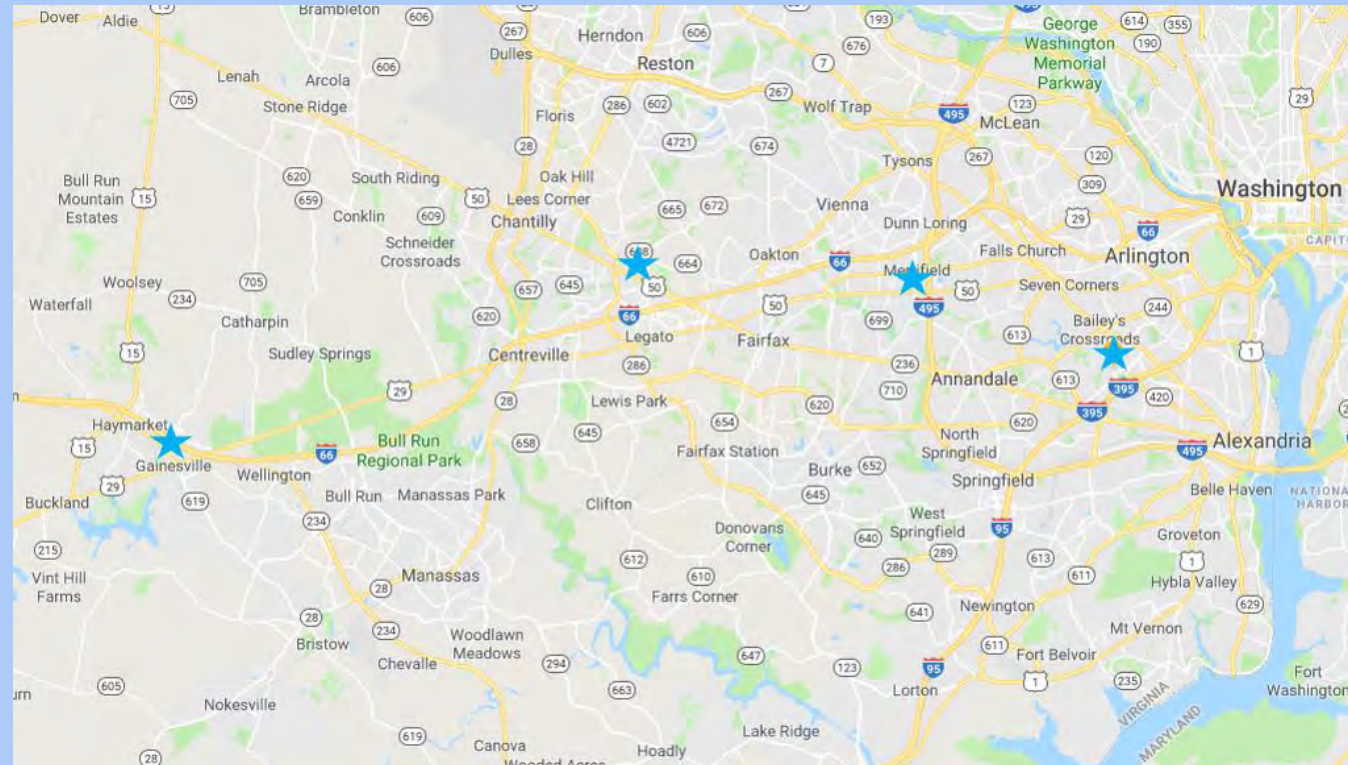
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Fairfax, VA 22031

## Fair Oaks

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## Gainesville

7051 Heathcote Village Way  
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- Telehealth = Access
- New patient appointment in 2 weeks or less
- Ability to accommodate follow-ups
- No time/distance/travel barriers

[Sonia.Gow@inova.org](mailto:Sonia.Gow@inova.org)



# WHAT IS PARKINSON'S?

PARKINSON'S DISEASE AFFECTS **ONE IN 100 PEOPLE OVER AGE 60**. IN THE UNITED STATES, 60,000 NEW CASES WILL BE DIAGNOSED THIS YEAR ALONE.

**1 / 100**  
OVER  
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**60,000**  
NEW

**1M** / US  **5M** / WORLD

TODAY, AN ESTIMATED **ONE MILLION** PEOPLE IN THE UNITED STATES AND MORE THAN **FIVE MILLION** WORLDWIDE ARE LIVING WITH PARKINSON'S DISEASE.

THERE IS  
**NO TEST**  
TO DIAGNOSE  
PARKINSON'S DISEASE.  
PEOPLE WITH PARKINSON'S  
VISIT MULTIPLE DOCTORS  
AND **CAN WAIT YEARS**  
BEFORE A CORRECT  
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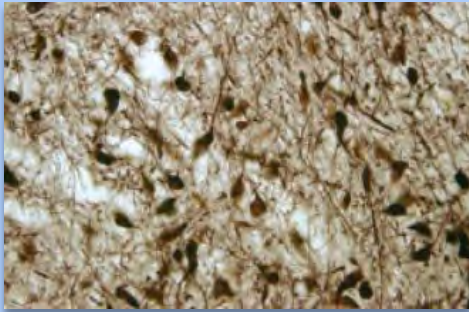
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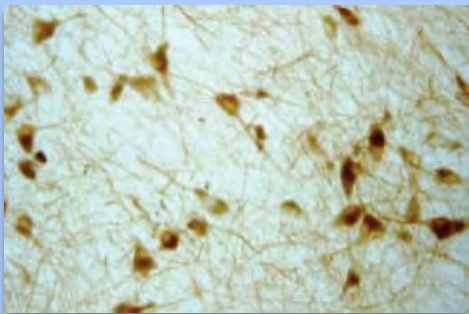


# THE CAUSE?

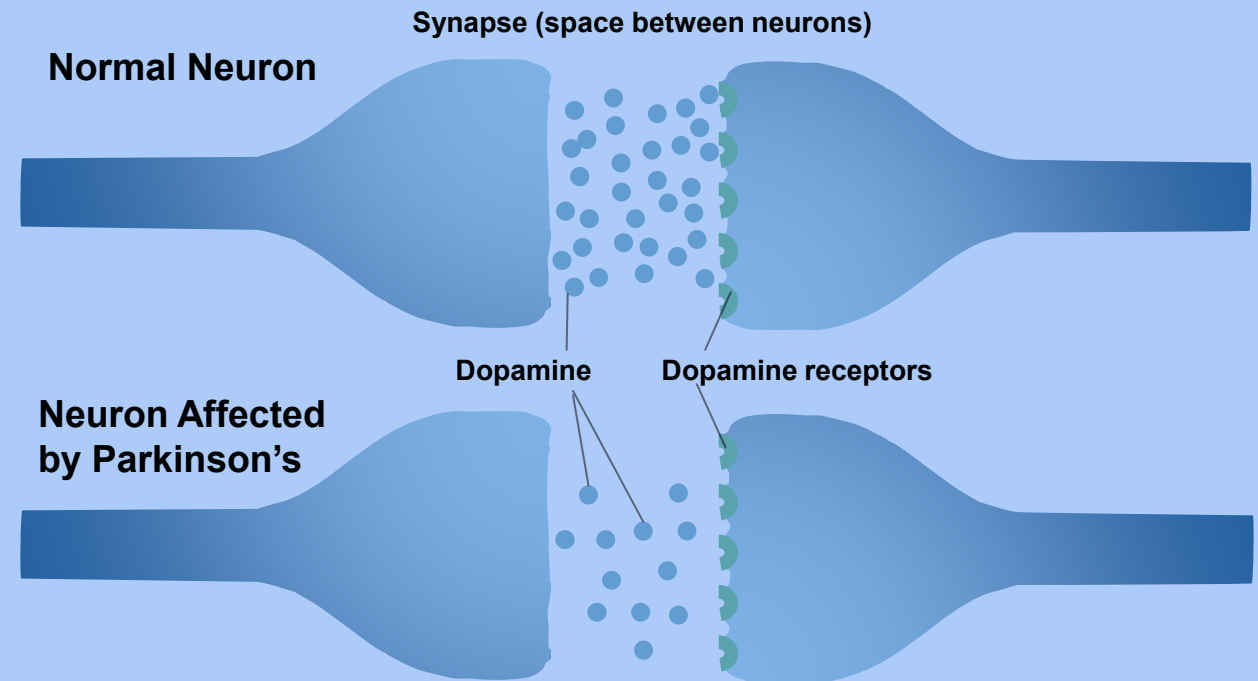
**PARKINSON'S DISEASE IS CAUSED BY A DECREASE IN DOPAMINE PRODUCTION IN THE BRAIN**



**Healthy Brain Cells (Neurons)**



**Brain Cells with  
Parkinson's Disease**



# THE CAUSE?

- Every Parkinson's is different
- Genetics
  - Classically NOT inherited
    - 15% of PD patients have 1<sup>st</sup> degree relative with PD
    - LRRK2
- Environmental factors
  - Pesticides including Agent Orange
  - Well water
  - Heavy metal exposure
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  - Head injury

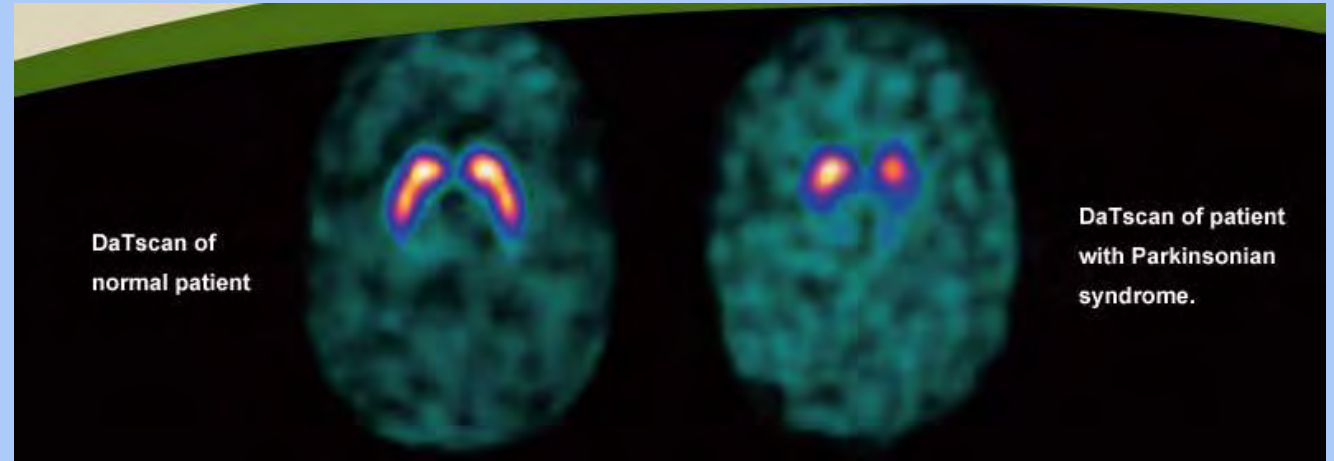


# DIAGNOSIS

- Symptoms/History/Exam + Response to Medications +/- DaTscan

- DaTscan

- Dopamine Active Transporter
- PET scan of brain highlighting dopamine transport system
- Tool to help with grey area
- FDA approved since 2010, covered by most insurers



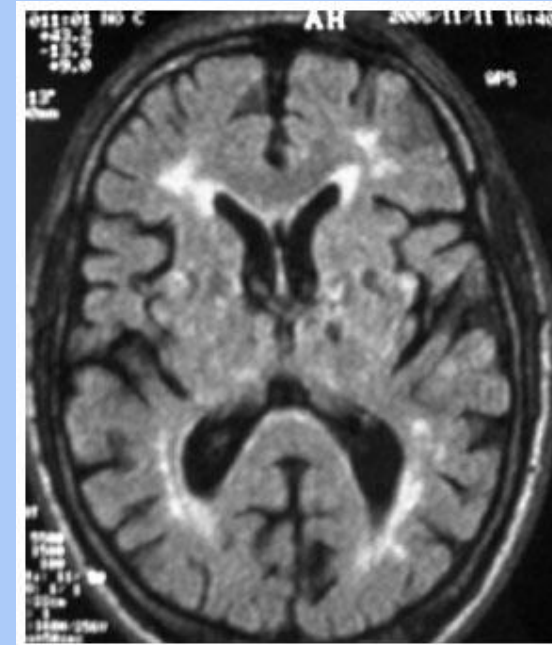
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  - Parkinson-isms, including the following:
    - Vascular Parkinson's
    - Medication-induced Parkinson's
    - Parkinson's Plus Syndromes
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**Proper diagnosis is key to proper treatment**

# WHAT HAPPENS IF YOU HAVE REDUCED DOPAMINE?

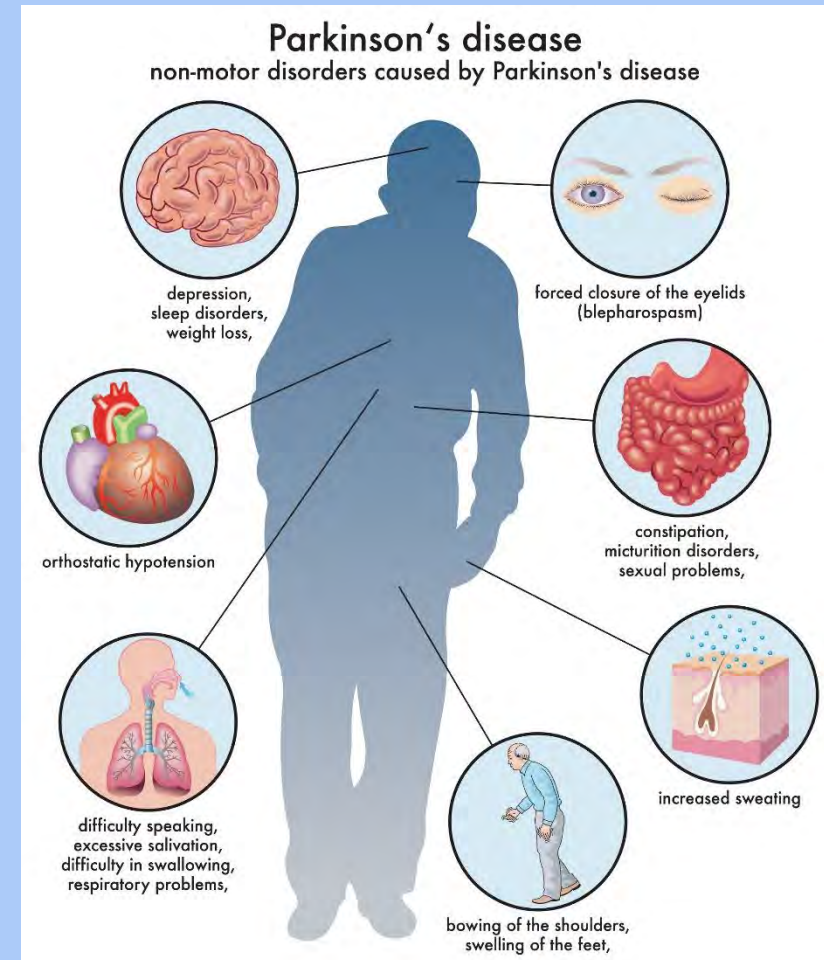
- **Motor and Non-motor Symptoms**
  - Systems which function inappropriately due to reduction in Dopamine or one of its byproducts
- **Motor Symptoms**
  - Resting tremor
  - Tremor with position
  - Bradykinesia (slowness)
  - Rigidity (stiffness)
  - Slow walking, shuffle, reduced arm swing
  - Balance issues
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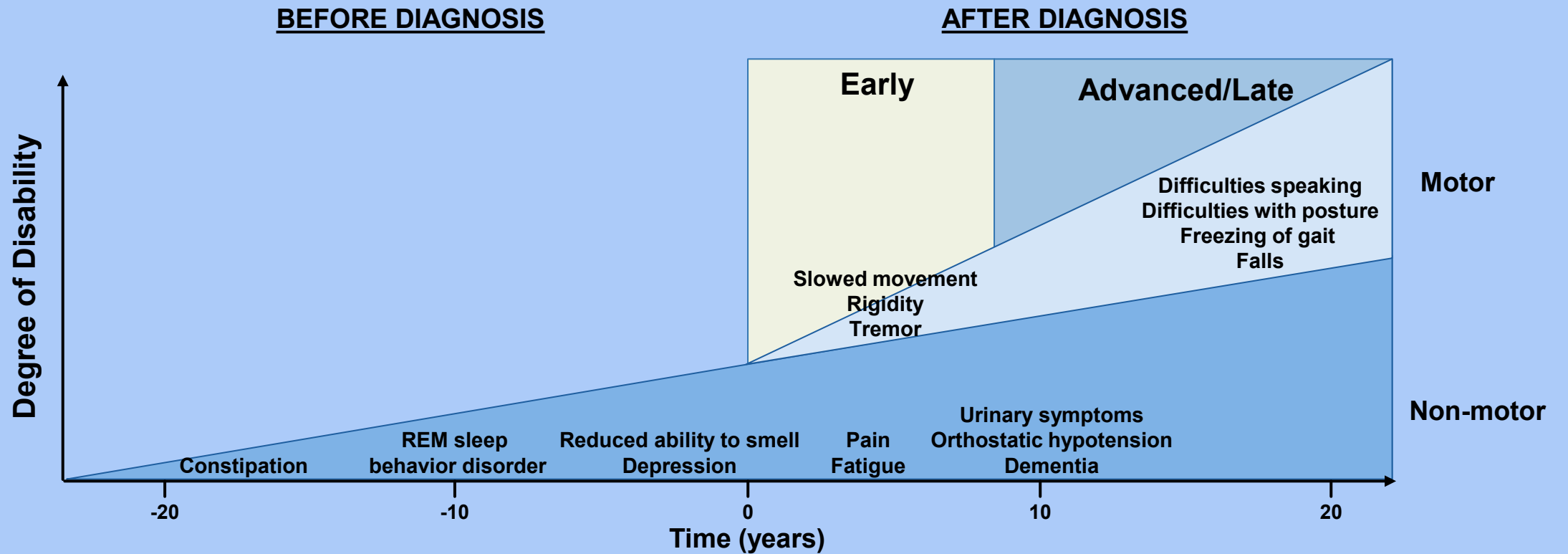
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**\*\*Can present years before diagnosis\*\***

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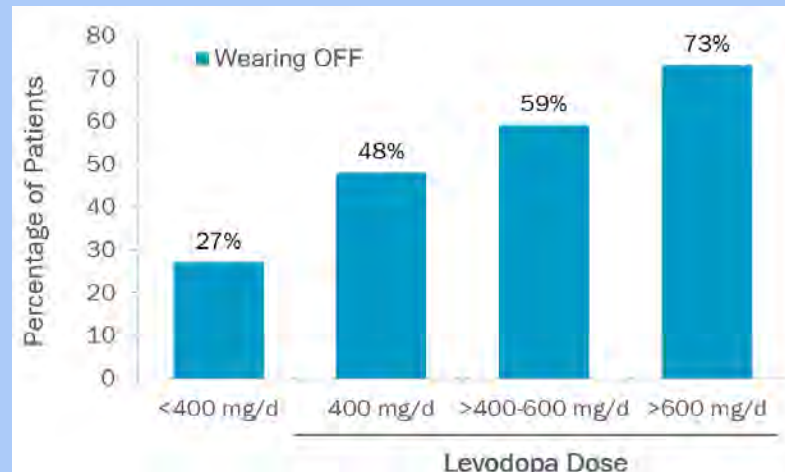
# PARKINSON'S CHANGES OVER TIME





# OFF TIME

- When medication is not doing what it is expected to or can do
- Many different types of OFF, sudden or subtle
  - First AM off
  - End of dose
  - Sub-optimal on
  - Sudden off
  - Dose failure
  - Exercise-induced
  - Food-induced
- Motor and non-motor OFF



Online survey of 3,000+

**70%** reported 2+ Off episodes a day.

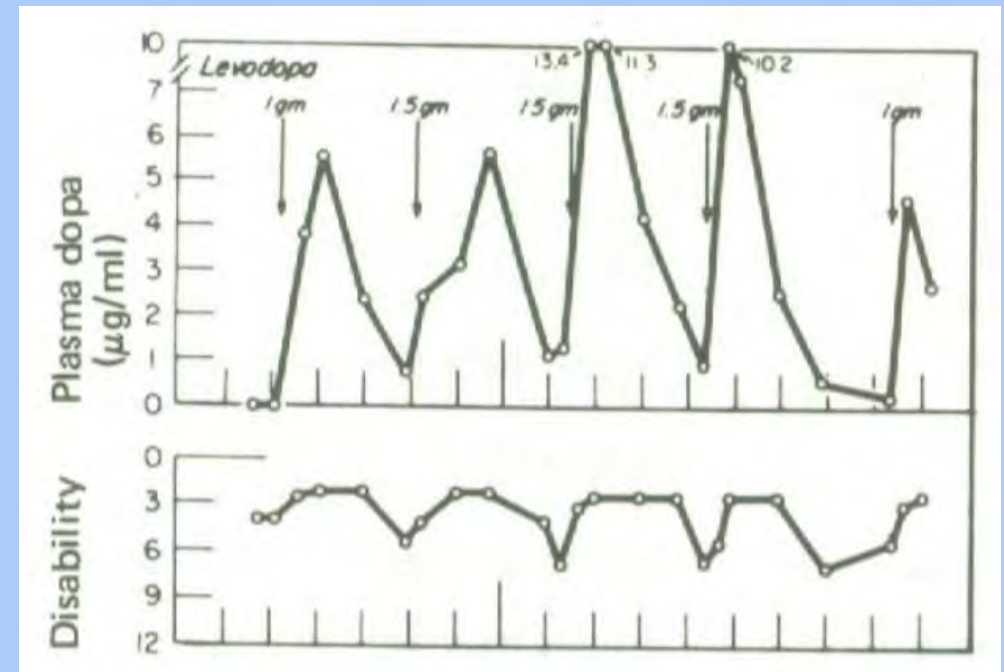
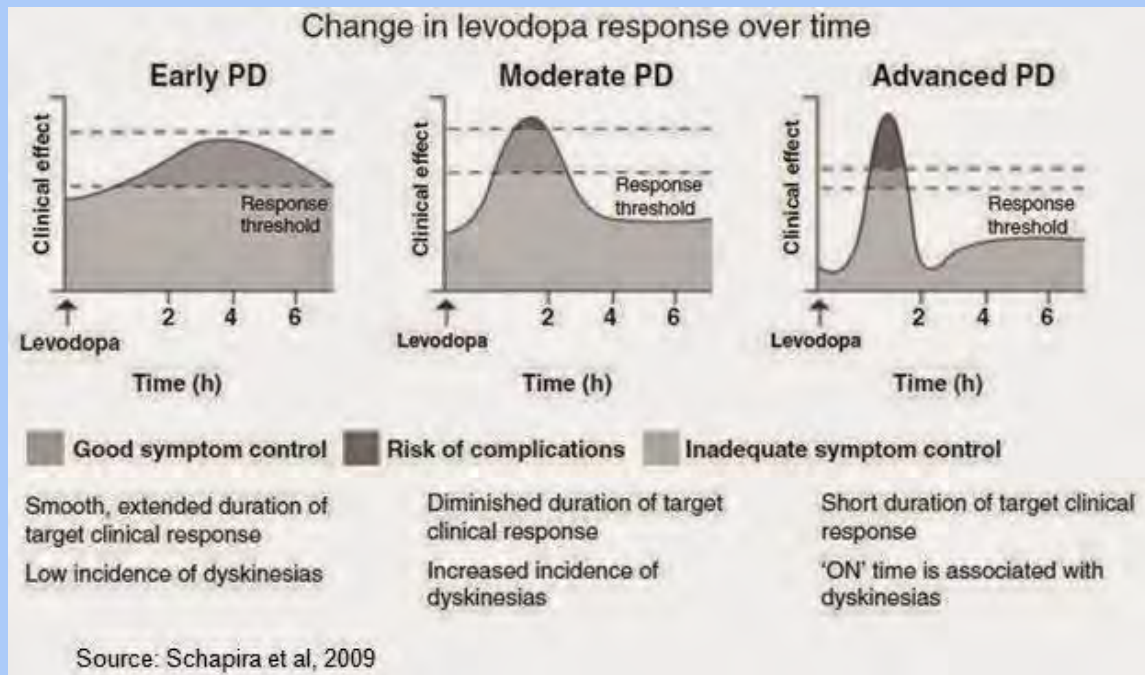
**65%** reported 2 or more hours a day

**50%** - moderate/severe, affected daily activities

**If we fix OFF, we fix Parkinson's Disease.**

# WHY DOES PD CHANGE OVER TIME?

## Current debate - the disease itself AND medications used?



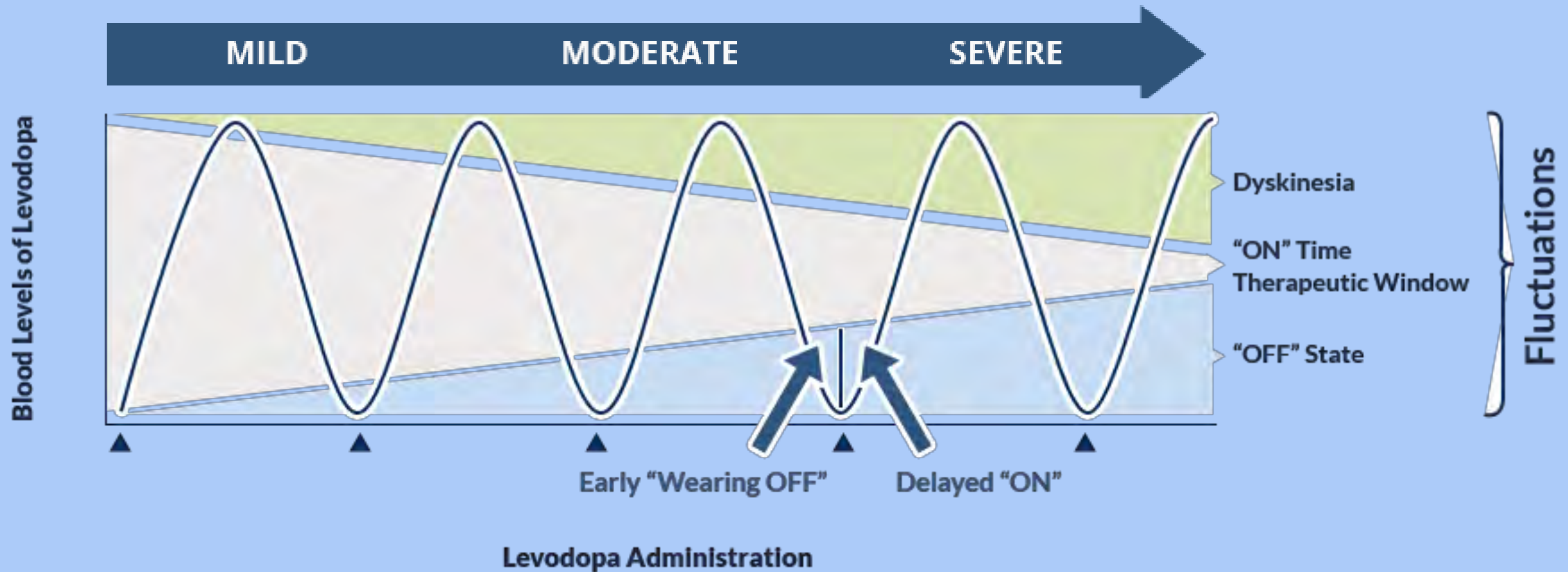
# WHY DOES PD CHANGE OVER TIME?

**Classic carbidopa/levodopa is great  
but need to understand its limitations**

- ELLDOPA trial 16.5% of patients randomized to 600 mg of LD daily developed dyskinesias after only 9 months of treatment versus 2.3% among those on 300 mg (2004)
- Worsening motor complications with doses  $\geq$  600mg per day at 6 months and 6 years (2005)
- Worsening PD motor symptoms in patients treated with lower (or no) levodopa dose compared to  $\geq$  600mg per day.

**Worsening on-off fluctuations throughout the day =  
Reliance on the tools used**

# CARBIDOPA – LEVODOPA OVER TIME





# DIFFERENT APPROACHES TO THERAPY

## Classic

- Pulsatile and frequent
- Higher and higher doses
- Fluctuations
- Early side effects
- Treatment horizon

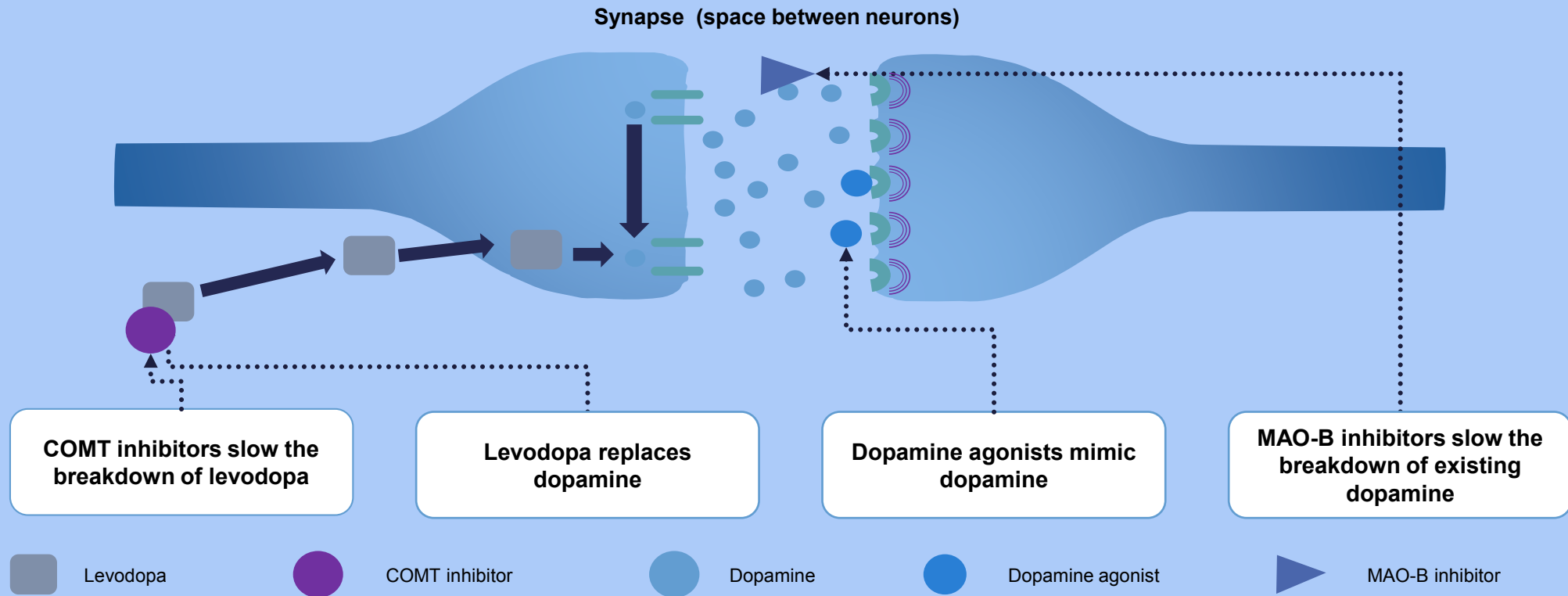
VS

## Contemporary

- Predictable and long acting
- Low doses, multiple targets
- “Rational polypharmacy”
- Employ technology earlier
- Smoother
- Reduced side effects
- Evergreen

# MEDICATION CATEGORIES FOR PD

## PARKINSON'S DISEASE MEDICINES WORK TO INCREASE DOPAMINE OR ACT LIKE DOPAMINE IN THE BRAIN



COMT = catechol-O-methyltransferase.

MAO-B = monoamine oxidase-B.

Kalia LV et al. *Lancet*. 2015;386:896–912

# EXPANDED TOOLBOX UP UNTIL 8 YEARS AGO

- Dopamine Agonist



- Carbidopa/Levodopa formulation



- MAOB inhibitor

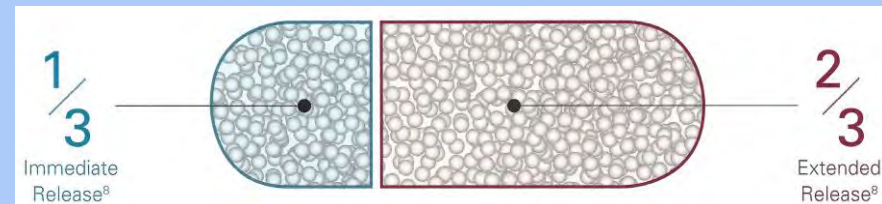
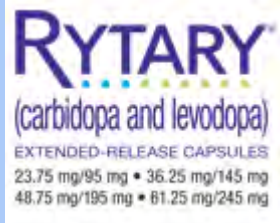
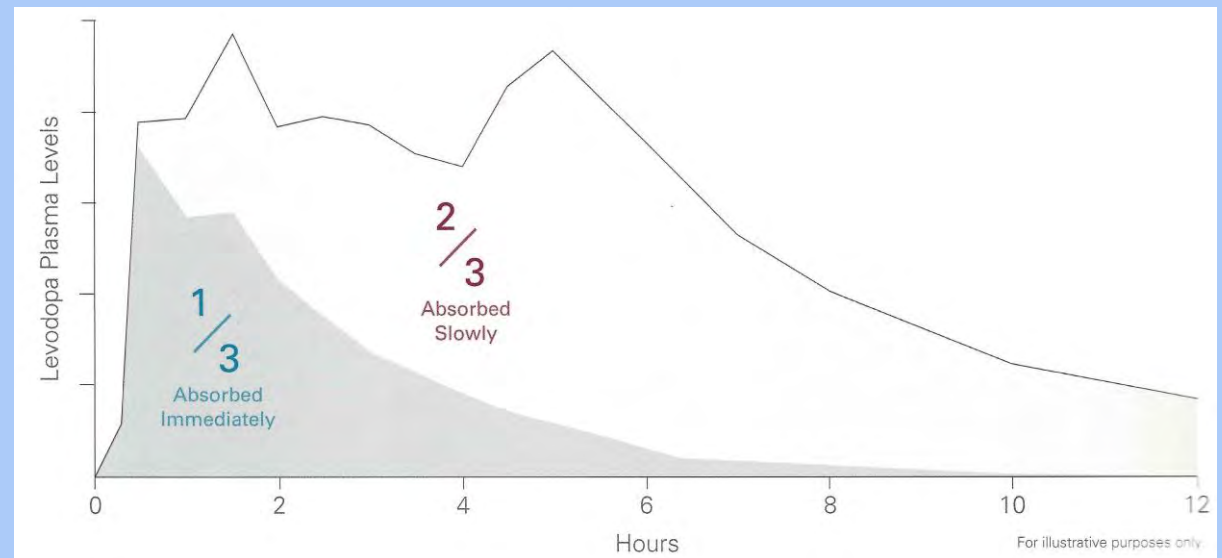
- COMT inhibitor



# NEW LEVODOPA FORMULATION

## Rytary™ (carbidopa/levodopa)

- Updated formulation to deliver Carbidopa-Levodopa.
- Can last from 5 to 8 hours compared to 2 to 3 hours for Sinemet.
  - 1 to 2 hours less off time, 2 hours more on time without dyskinesia.

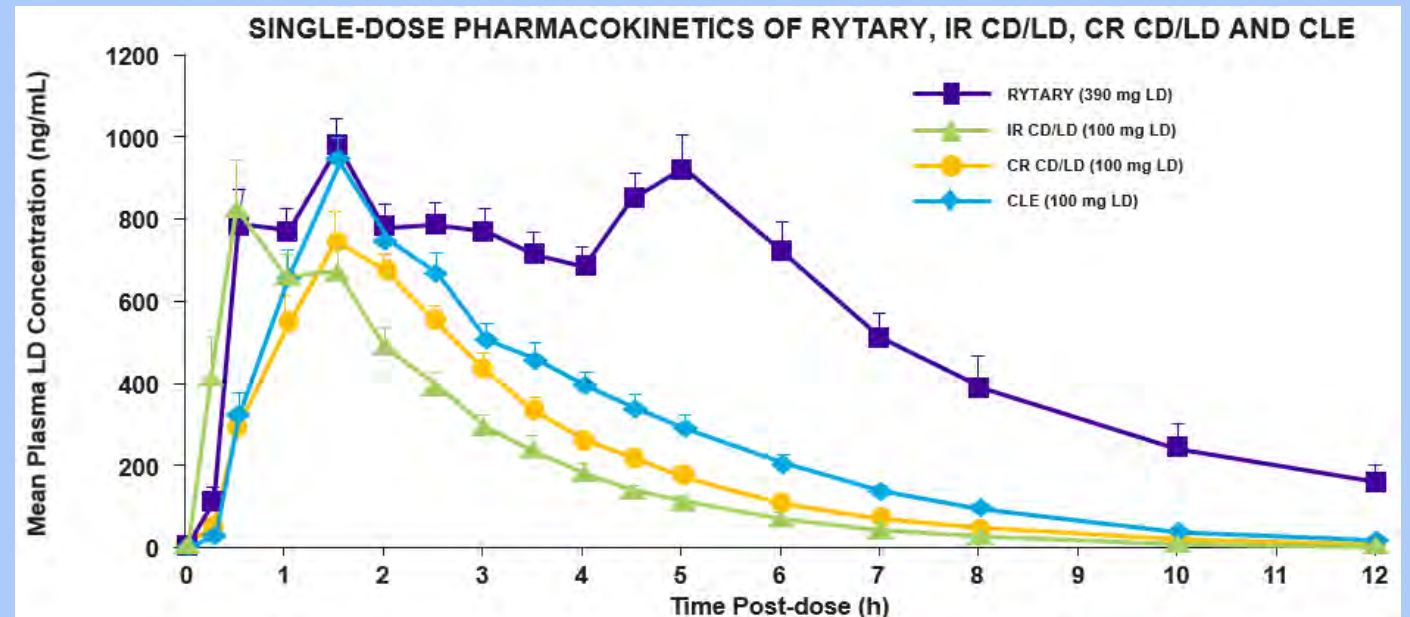
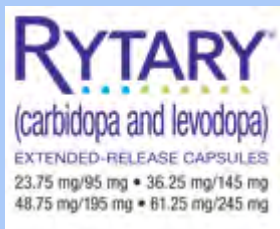




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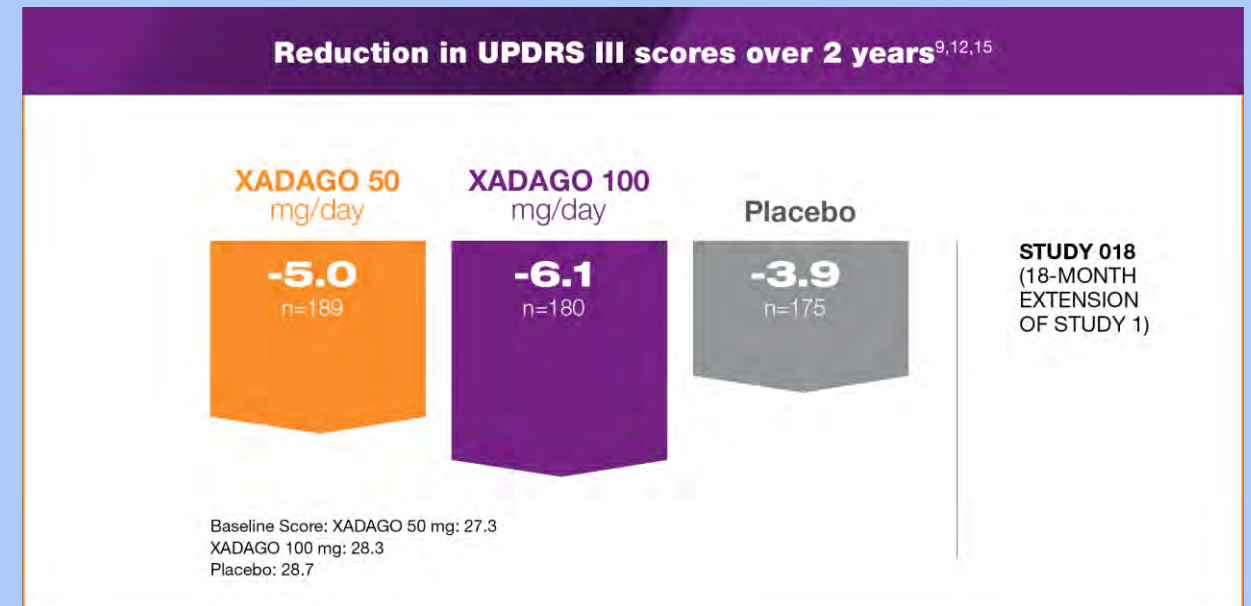


# MAO-B INHIBITOR, AUGMENTING THE SYSTEM

## Xadago™ (safinamide)

- Reversibly inhibits the MAO-B enzyme
- Boosts natural dopamine and potentiates artificial dopamine
- 1x daily
- Similarity to rasagiline (Azilect) which is now generic but still expensive to some

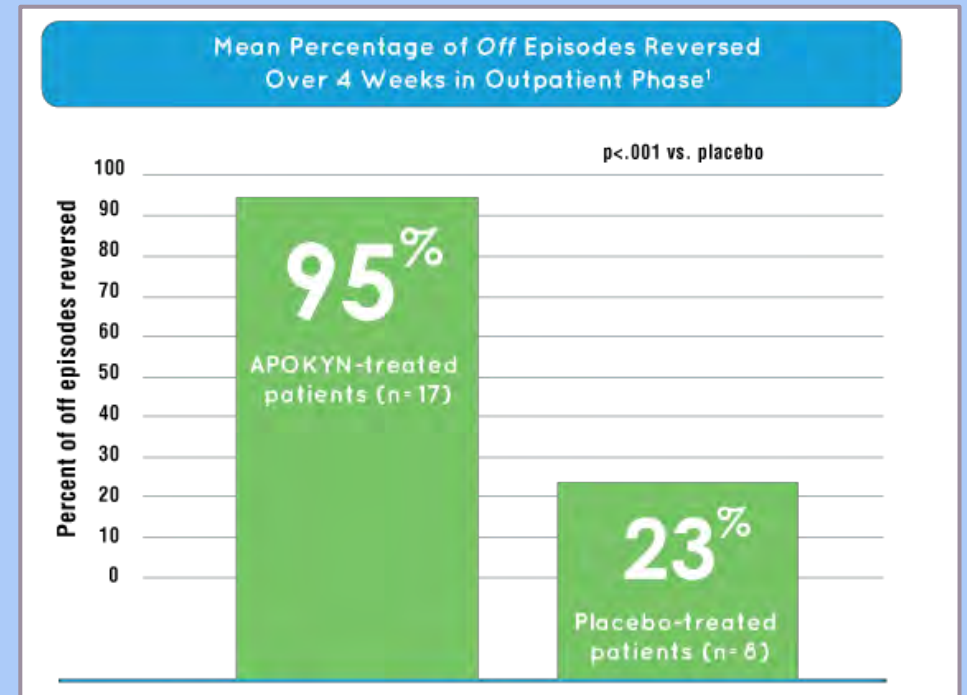
**XADAGO**<sup>®</sup>  
(safinamide) tablets



# RESCUE OPTION #1 - APOKYN

## Apokyn™ (apomorphine injection)

- Rapid onset Dopamine Agonist via injection
- For different types of OFF episodes:
  - Rapid off, wearing off
  - Dose failure / unexpected off
  - Delayed on
  - First AM symptoms or exercise intolerance
- Achieve ON within 10-20 minutes



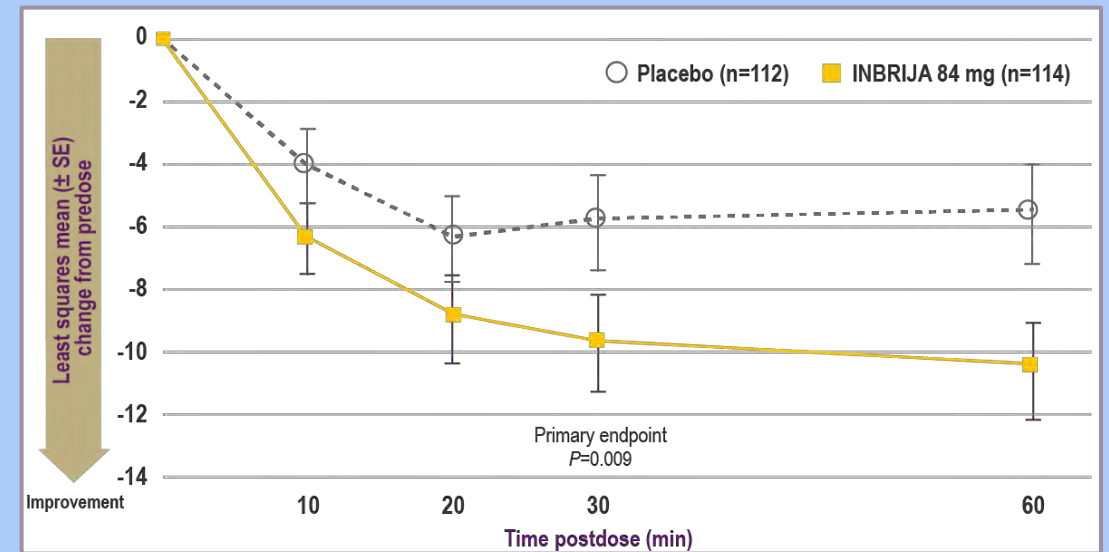
# RESCUE OPTION #2 - INBRIJA

## Inbrija™ (levodopa inhalation powder)

- Rapid onset levodopa through inhaler
- For different types of OFF episodes:
  - Rapid off, wearing off
  - Dose failure / unexpected off
  - Delayed on
  - First AM symptoms or exercise intolerance
- Achieve ON within 10 minutes, can take up to 5x daily



### UPDRS Part III Score Change From 0-60 Minutes Postdose at Week 12





# RESCUE OPTION #3 - KYNMOBI

## Kynmobi™ (apomorphine sublingual film)

- Sublingual dissolving film for “off” episodes.

- Improvement begins after 15 min

- For different types of OFF episodes:

- Rapid off, wearing off
- Dose failure / unexpected off
- Delayed on
- First AM symptoms or exercise intolerance

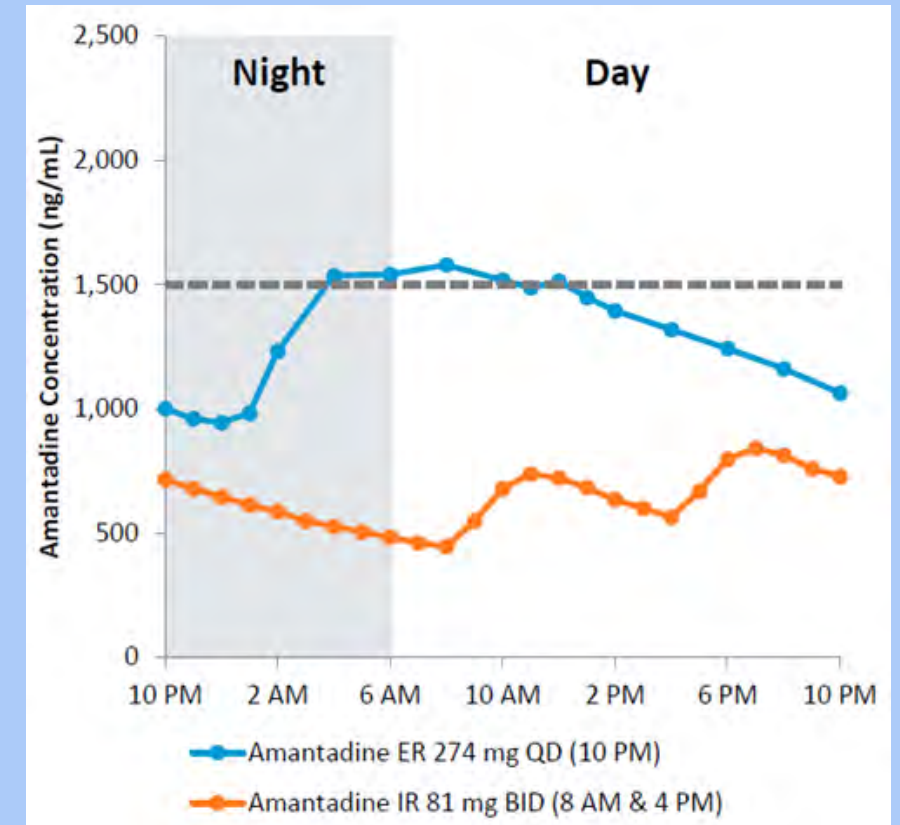
- Can be taken up to 5x daily.



# LONGER-ACTING AMANTADINE

## Gocovri™ (amantadine ER)

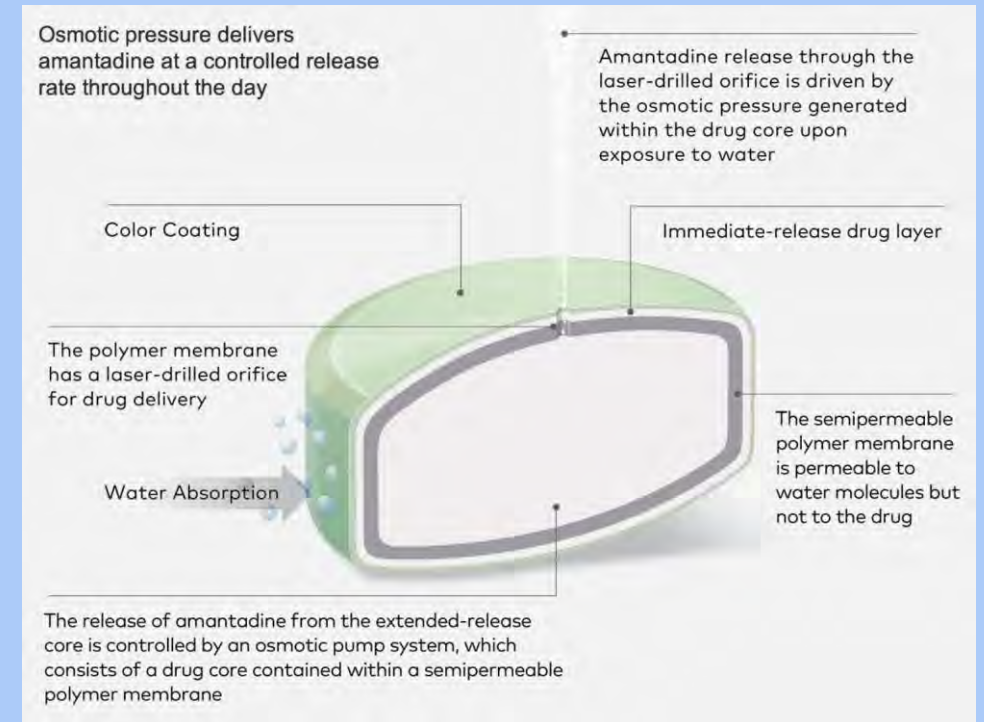
- 1x daily amantadine ER at bedtime
- First “FDA approved” therapy for dyskinesia AND off periods
- Used to reduce dyskinesia (37% reduction or elimination)
- Reduced OFF time by 45% during the day



# LONGER-ACTING AMANTADINE

## Osmolex ER™ (amantadine)

- 1x daily amantadine
- Another 1x daily option, more for classic amantadine use without 'off time' reduction

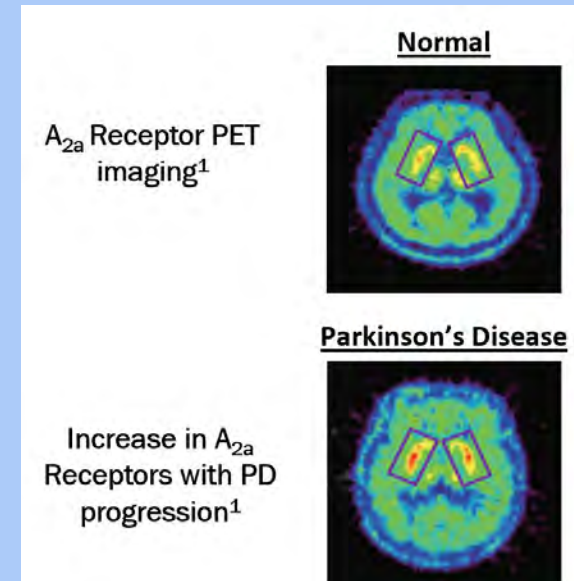


# NON-DOPAMINE APPROACH

## Nourianz™ (istradefylline)

- **INDIRECT pathway** – activation reduces motor activity
  - Direct pathway increases activity (dopamine, etc.)
  - Indirect pathway inhibits motor activity (adenosine, GABA)
- **Adenosine A<sub>2a</sub> receptor antagonist**
  - Double negative, blocks the block
- Improves off time, releasing the ‘brake’ on the system.

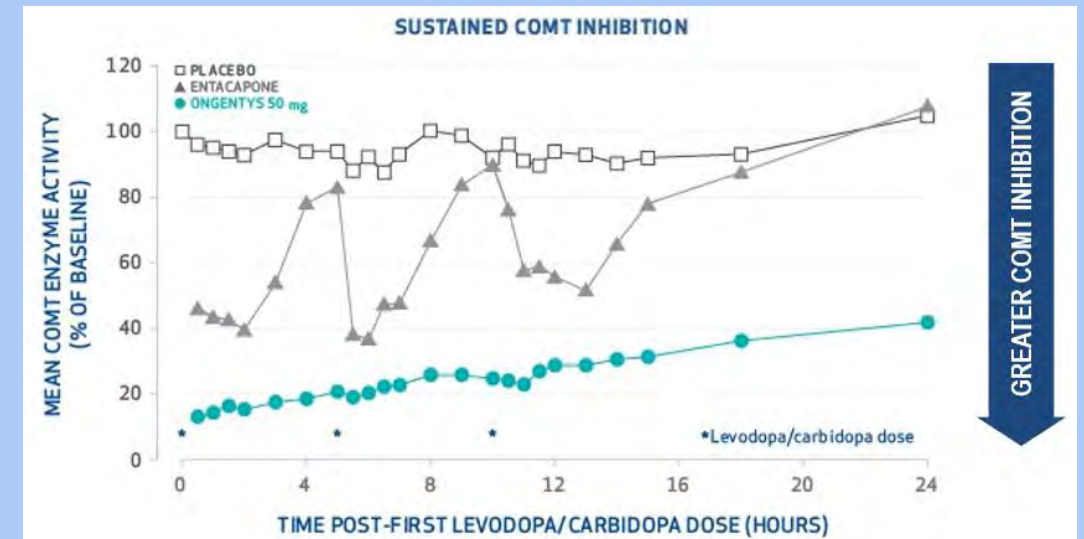
**NOURIANZ™**  
(istradefylline) tablets  
20mg | 40mg



# ONCE DAILY COMT INHIBITOR

## Ongentys™ (opicapone)

- 1x daily inhibitor of COMT enzyme.
- Boosts levodopa for 24 hours
- Blocks breakdown of levodopa in the periphery, making more available to the brain
- In use in Europe since 2016
- Once daily at bedtime away from food

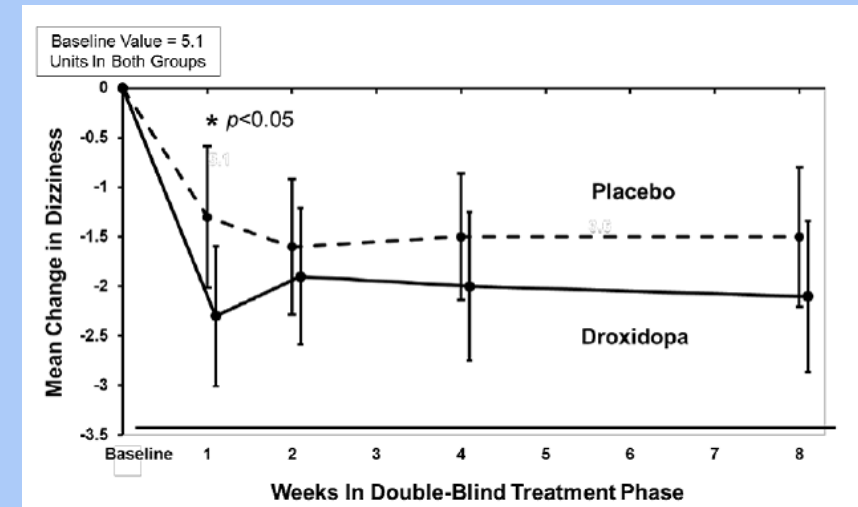




# ORTHOSTATIC HYPOTENSION

## Northera™ (droxidopa)

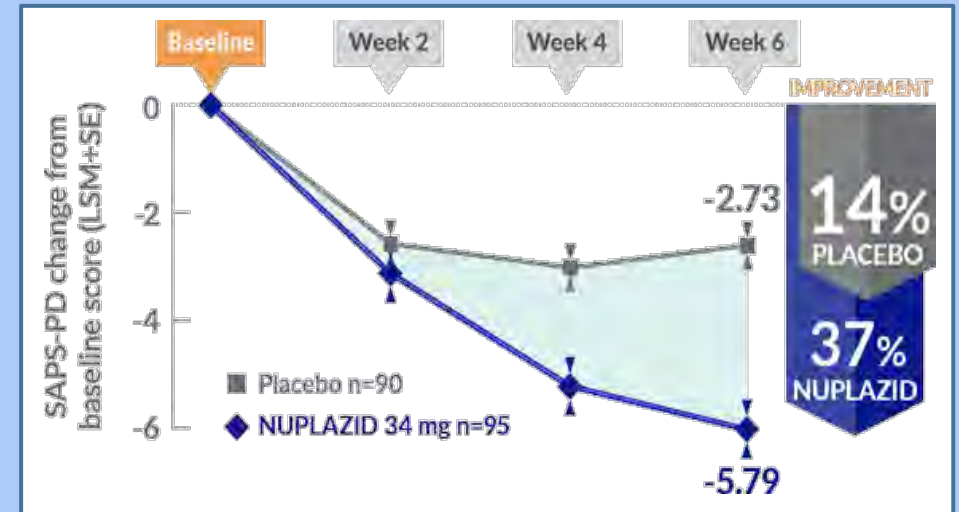
- OH is common symptom of Parkinson's Disease
- Can be worsened by dopamine supplementation
- Prodrug for Norepinephrine, crosses BBB



# HALLUCINATIONS AND PSYCHOSIS

## Nuplazid™ (pimavanserin)

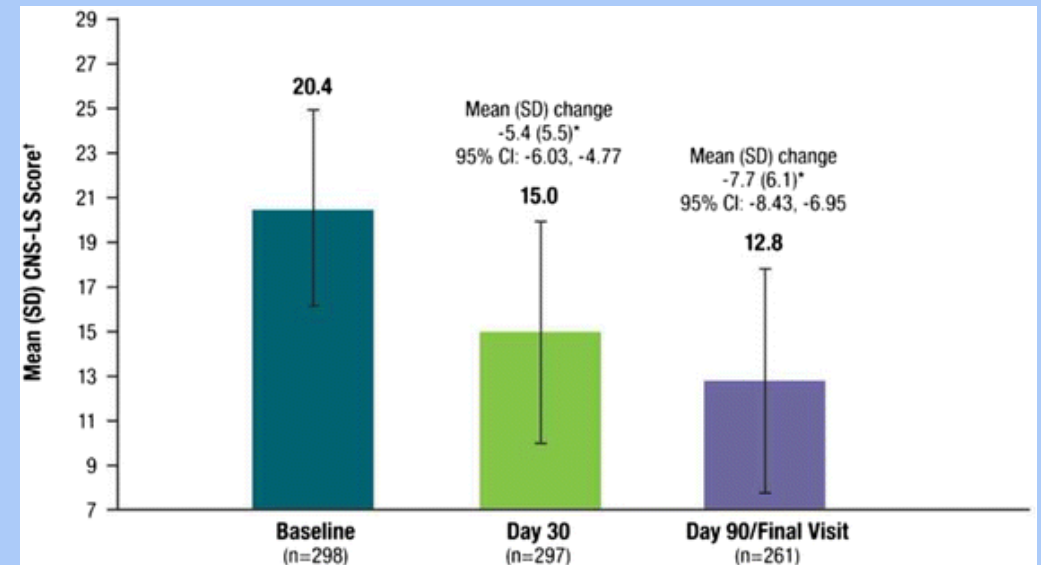
- First antipsychotic medication specifically designed for hallucinations and 'psychosis' associated with Parkinson's Dementia and Lewy Body Dementia.
- Serotonin Agonist with no impact on dopamine receptors
- + SAPS-PD improvement with no change in UPDRS



# PSEUDOBULBAR AFFECT

## Nuedexta™

- “Uncontrollable episodes of crying and/or laughing, or other emotional displays.”
- Disconnect between emotion and display, or inappropriate display
- PRISM study – 26%, though up to 40% in PD
- CNS-LS Screening reflects symptoms
- Reduction in episodes at 90 days was 72.3% if not fully resolved.



# PHYSICAL/OCCUPATIONAL/SPEECH THERAPY

*LSVTBIG<sup>®</sup> and LSVTLOUD<sup>®</sup>*

But also, non-LSVT Therapy aimed at  
balance/gait and strengthening



# NEW TOOLBOX...AND GROWING

- Dopamine Agonist
- Carbidopa/Levodopa formulation
- MAOB inhibitor
- COMT inhibitor
- A2a agonists
- Amantadine derivatives
- Rescue Therapies
- Symptom specific therapies

**Neupro®**  
(Rotigotine Transdermal System)

**REQUIP®**  
ropinirole HCl

**XADAGO®**  
(safinamide) tablets  
**Mirapex®**  
pramipexole dihydrochloride tablets

**NOUBIANZ™**

## MOVEMENT DISORDERS SPECIALTY CENTER

23.75 mg / 95 mg • 36.25 mg / 145 mg  
48.75 mg / 195 mg • 61.25 mg / 245 mg  
Every Moment Counts  
**Stalevo®**  
(levodopa, carbidopa and entacapone) tablets

**Inbrija®**  
(levodopa inhalation powder)  
42 mg capsules

**Northera™**  
(droxidopa) Capsules  
100 mg • 200 mg • 300 mg

**COMTan®**  
(entacapone) tabl

(pimavanserin) tablets

**Ongentys 50 mg**  
cápsulas / cápsulas duras  
opicapona  
via oral/via oral

**NUDEXTA®**  
tromethorphan HBr and  
lidine sulfate) capsules  
20 mg  
10 mg

**APOKYN®** Be on.  
apomorphine hydrochloride injection Live life.



# TO THE FUTURE

- Longer-acting levodopa formulations (10 hours or greater)
- New inhibitors
- Pump-based and sub-cutaneous formulations
- Improved technology
- Targeted protein therapy
- Cure

All of this equals

**HOPE**

# THANK YOU!

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**Join our newsletter!**

**Stay up to date on all  
of our center's offerings!**

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## Advanced Therapies

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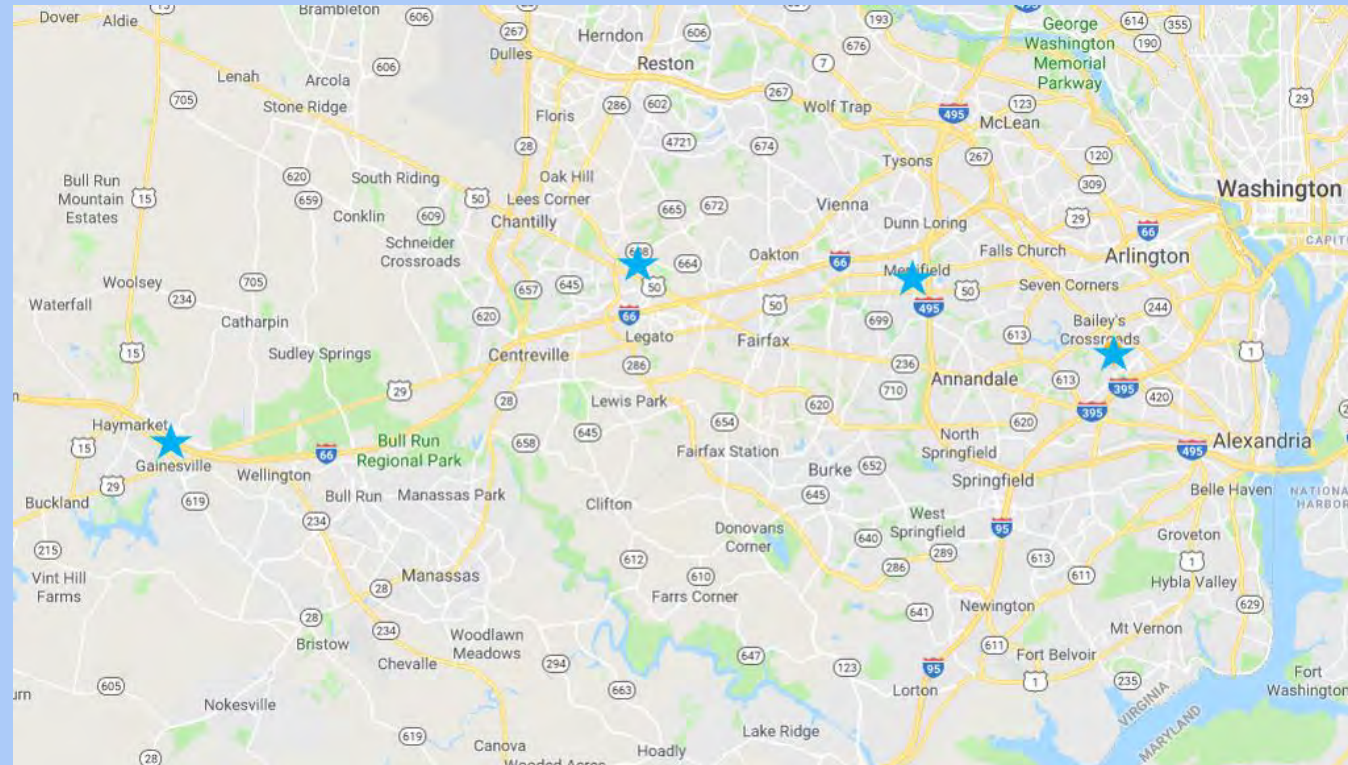
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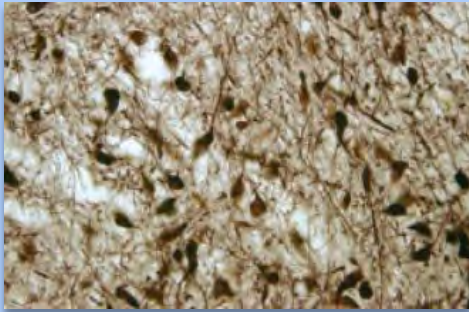
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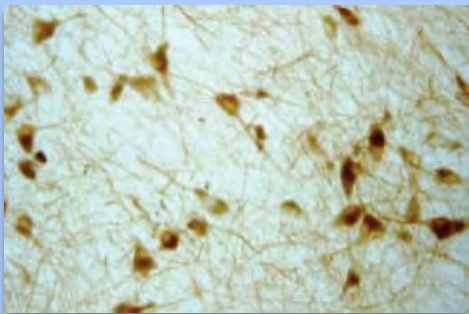


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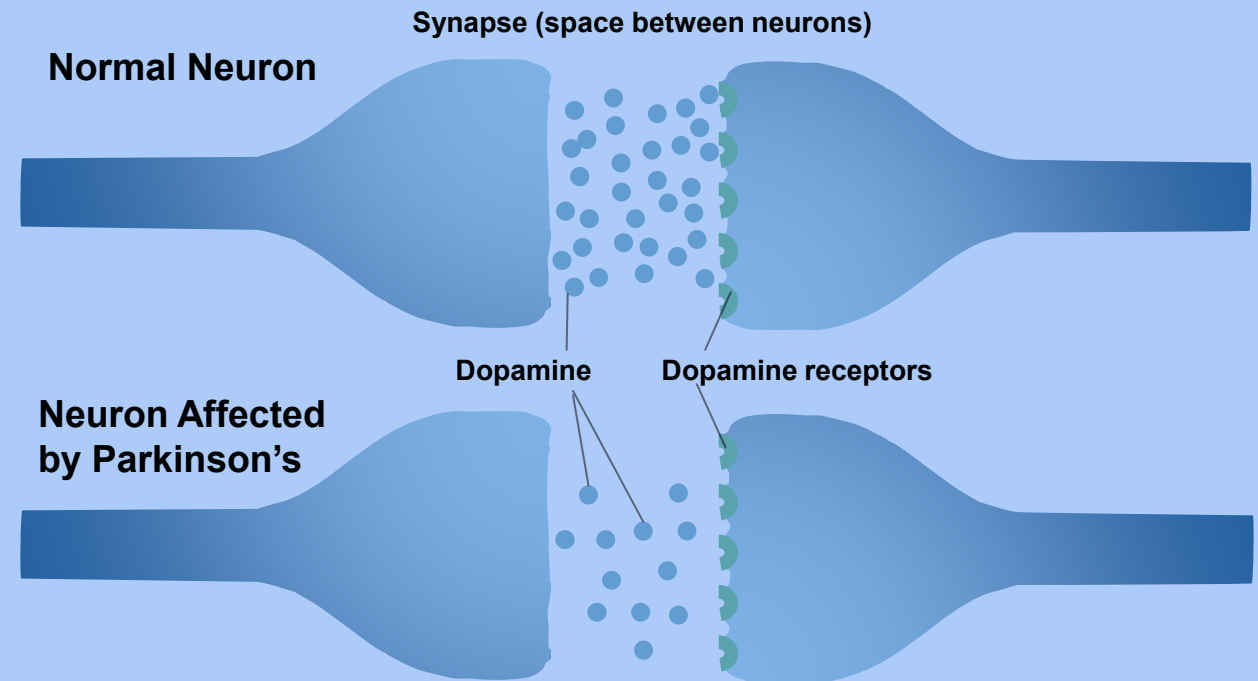
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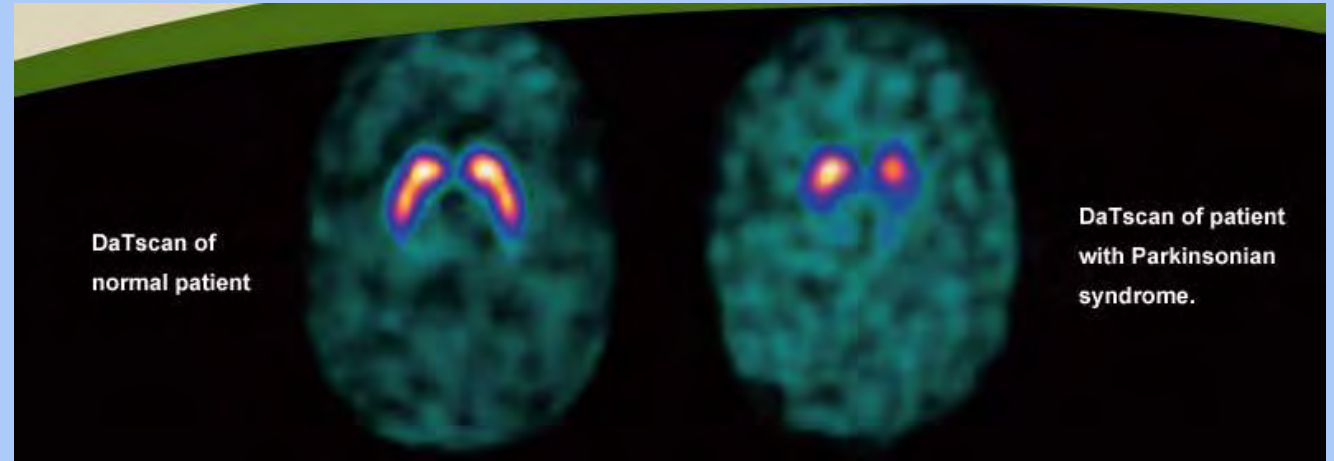


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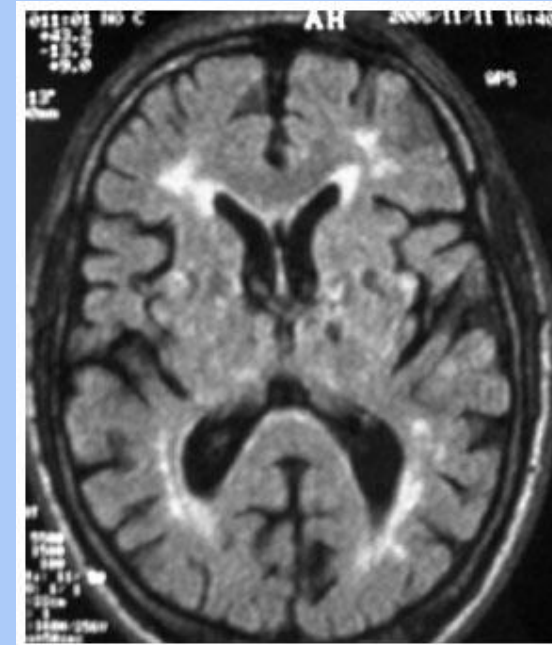
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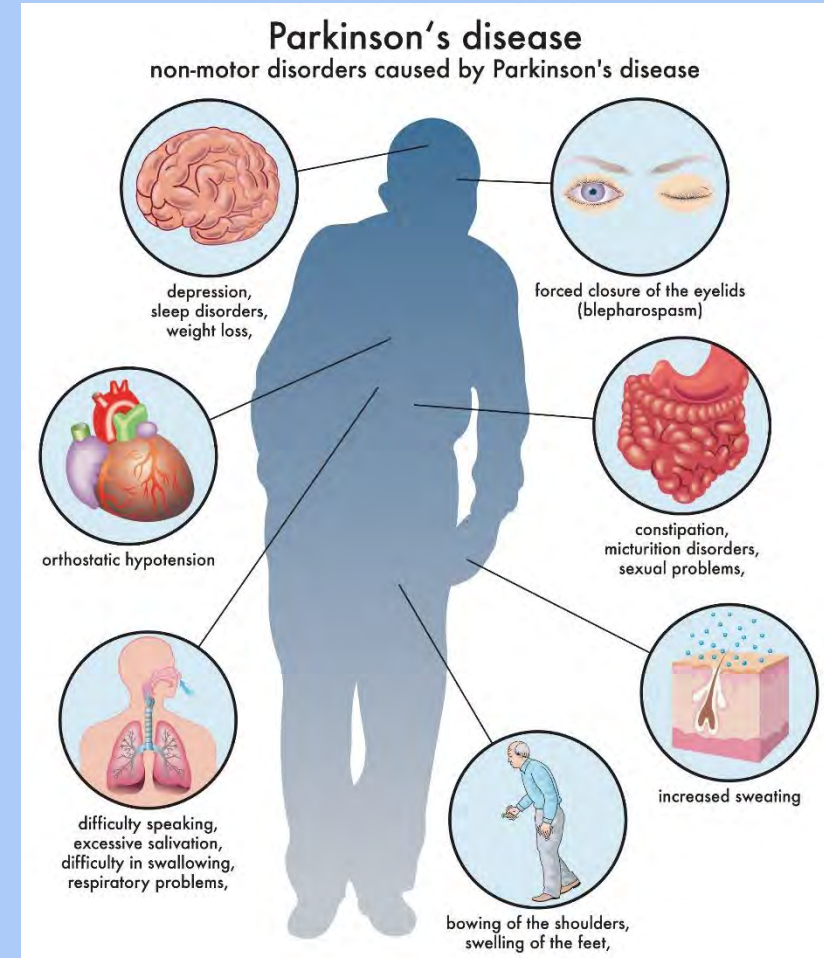
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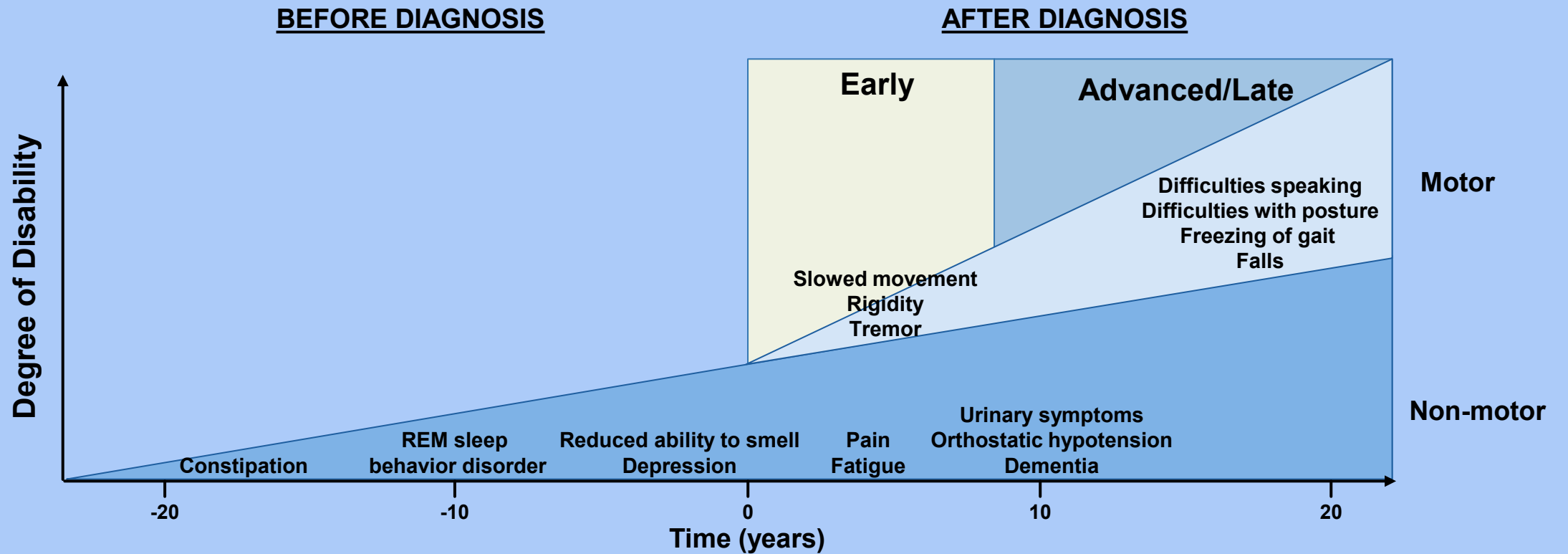
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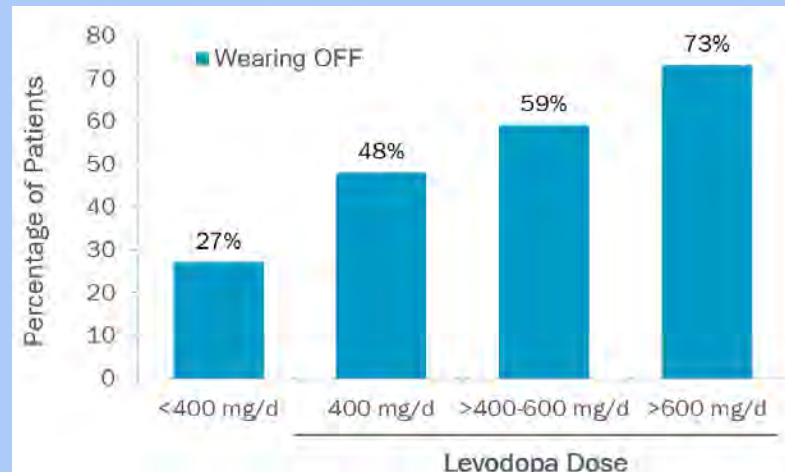


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Online survey of 3,000+

**70%** reported 2+ Off episodes a day.

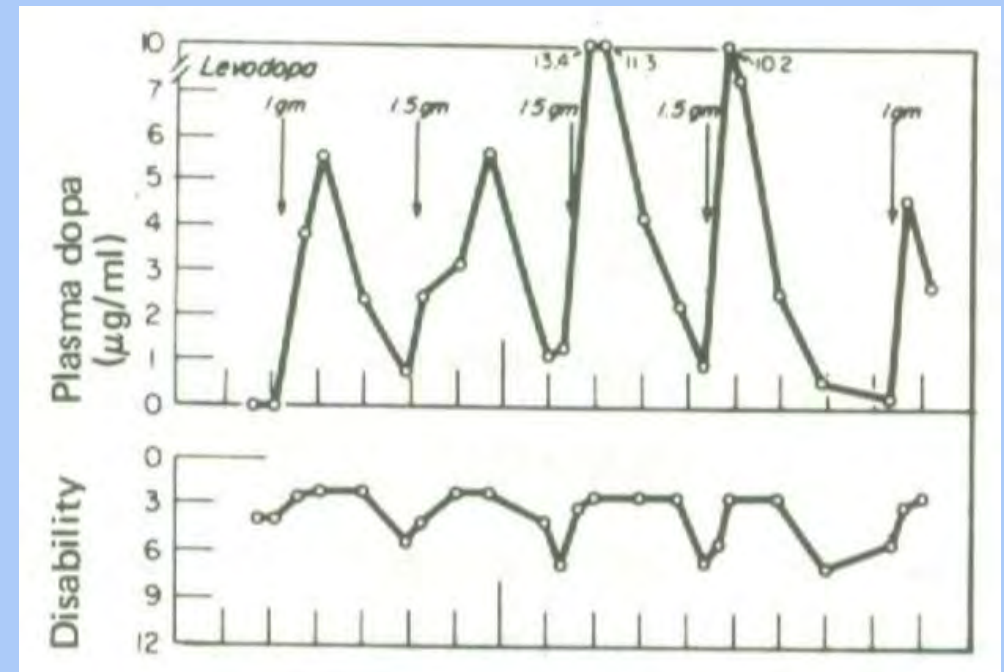
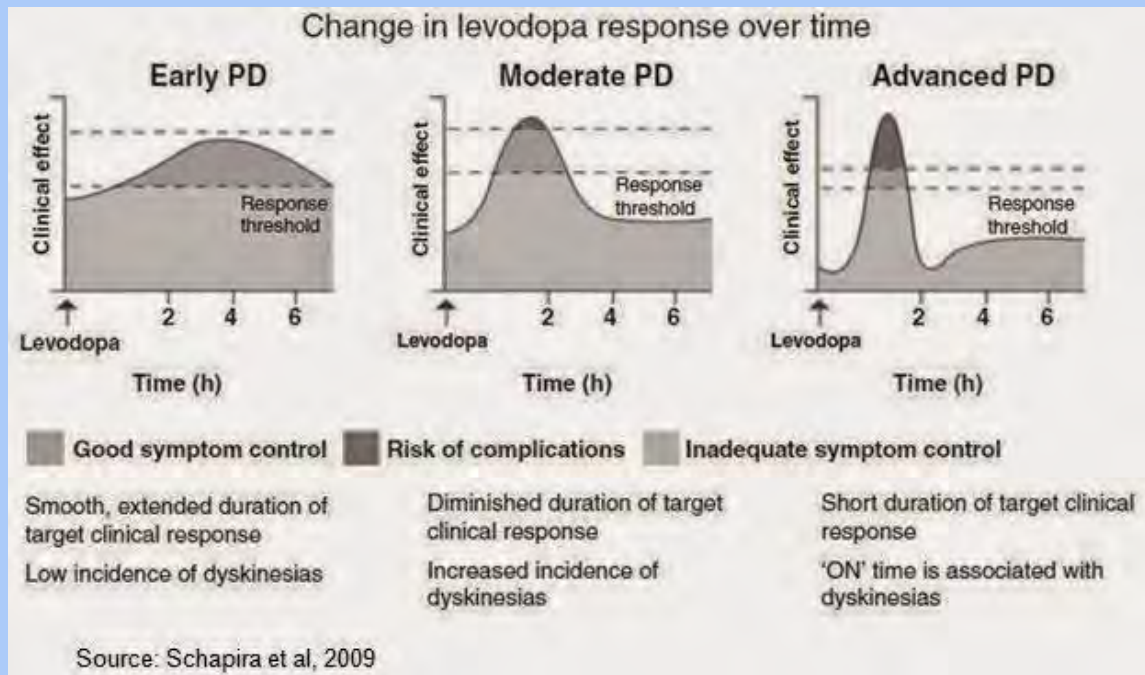
**65%** reported 2 or more hours a day

**50%** - moderate/severe, affected daily activities

**If we fix OFF, we fix Parkinson's Disease.**

# WHY DOES PD CHANGE OVER TIME?

## Current debate - the disease itself AND medications used?





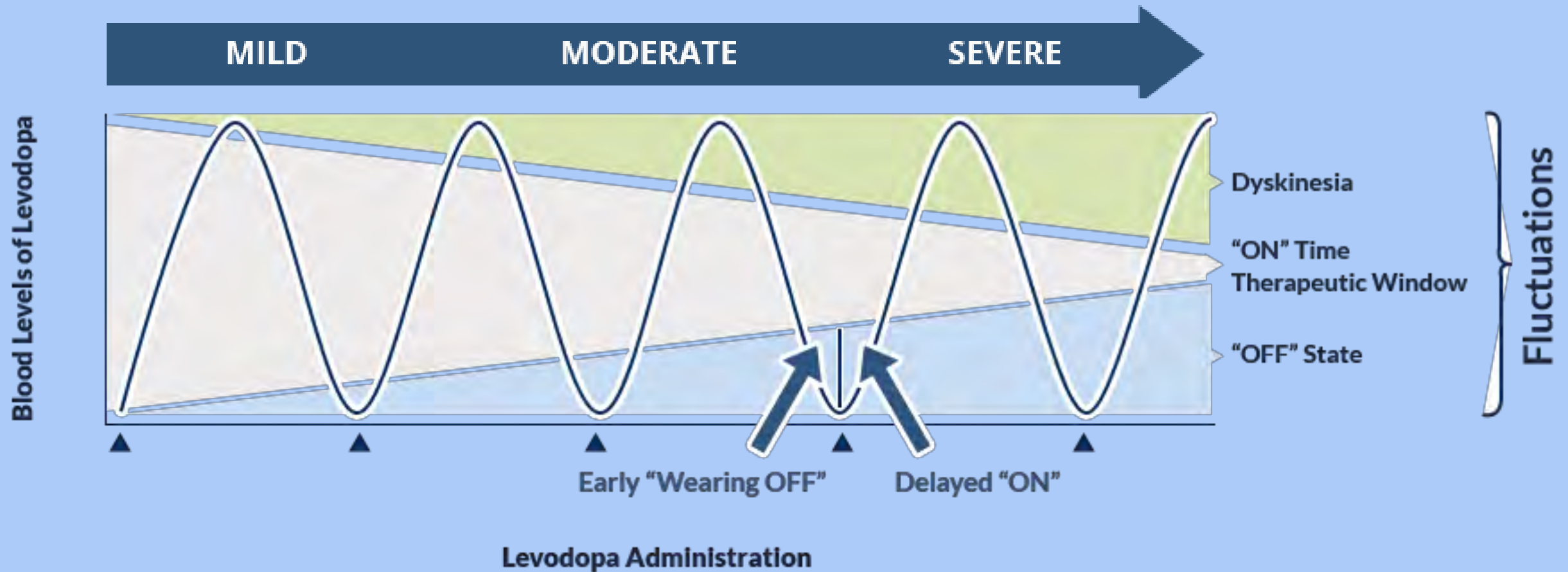
# WHY DOES PD CHANGE OVER TIME?

**Classic carbidopa/levodopa is great  
but need to understand its limitations**

- ELLDOPA trial 16.5% of patients randomized to 600 mg of LD daily developed dyskinesias after only 9 months of treatment versus 2.3% among those on 300 mg (2004)
- Worsening motor complications with doses  $\geq$  600mg per day at 6 months and 6 years (2005)
- Worsening PD motor symptoms in patients treated with lower (or no) levodopa dose compared to  $\geq$  600mg per day.

**Worsening on-off fluctuations throughout the day =  
Reliance on the tools used**

# CARBIDOPA – LEVODOPA OVER TIME



# DIFFERENT APPROACHES TO THERAPY

## Classic

- Pulsatile and frequent
- Higher and higher doses
- Fluctuations
- Early side effects
- Treatment horizon

VS

## Contemporary

- Predictable and long acting
- Low doses, multiple targets
- “Rational polypharmacy”
- Employ technology earlier
- Smoother
- Reduced side effects
- Evergreen

# NEW TOOLBOX...AND GROWING

- Dopamine Agonist
- Carbidopa/Levodopa formulation
- MAOB inhibitor
- COMT inhibitor
- A2a agonists
- Amantadine derivatives
- Rescue Therapies
- Symptom specific therapies

**Neupro®**  
(Ropinirole Transdermal System)

**REQUIP®**  
ropinirole HCl

**XADAGO®**  
(safinamide) tablets  
**Mirapex®**  
pramipexole dihydrochloride tablets

**GOCOVRI™**  
(amantadine) extended release capsules  
**AZILECT®**  
(lisdopa) tablets

**NOURIANZ™**  
(istradefylline) tablets  
20 mg | 40 mg

**PARCOLA®**  
(carbidopa and levodopa  
orally disintegrating tablets)  
**Osmolex ER™**  
(amantadine)  
Extended-release Tablets

**Rytary™**  
(Carbidopa and Levodopa)  
Extended-Release Capsules  
23.75 mg / 95 mg • 36.25 mg / 145 mg  
48.75 mg / 195 mg • 61.25 mg / 245 mg  
Every Moment Counts



**Stalevo®**  
(levodopa, carbidopa and entacapone) tablets

**Inbrija™**  
(levodopa inhalation powder)  
42 mg capsules

**COMTan®**  
(entacapone) tablets

**NUPLAZID™**  
(pimavanserin) tablets

**Ongentys 50 mg**  
capsules/capsules dures  
opicapone  
via oral/via oral

**NUDEXTA®**  
tromethorphan HBr and  
naltrexone hydrochloride capsules  
20 mg  
10 mg

**Northera™**  
(droxidopa) Capsules  
100 mg • 200 mg • 300 mg

**APOKYN®** Be on.  
apomorphine hydrochloride injection Live life.

# TECHNOLOGY

- DUOPA Intestinal Gel
- Focused Ultrasound
- Deep Brain Stimulation

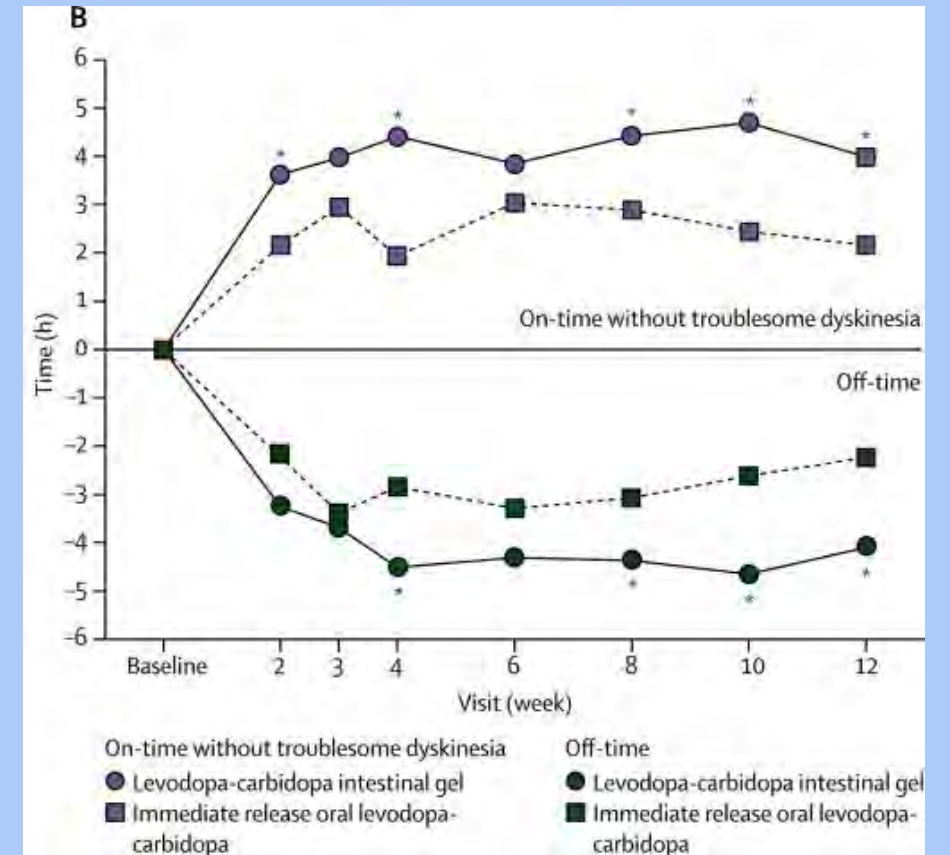




# CONSTANT DELIVERY OF LEVODOPA

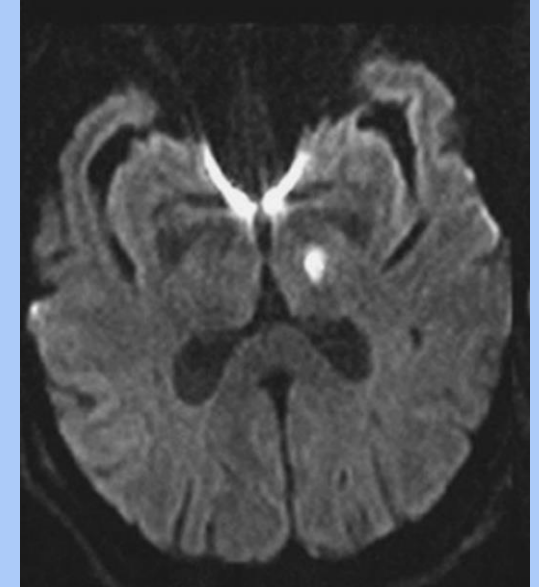
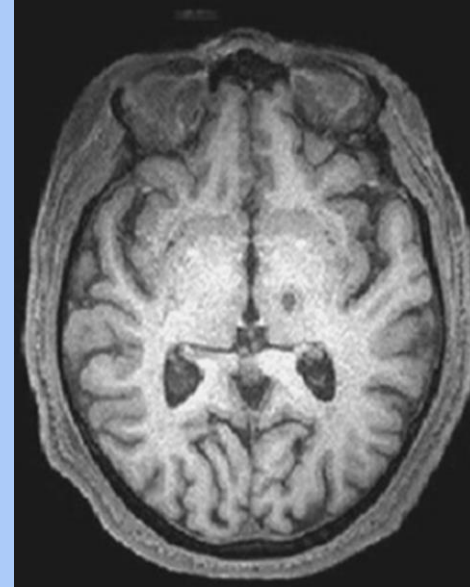
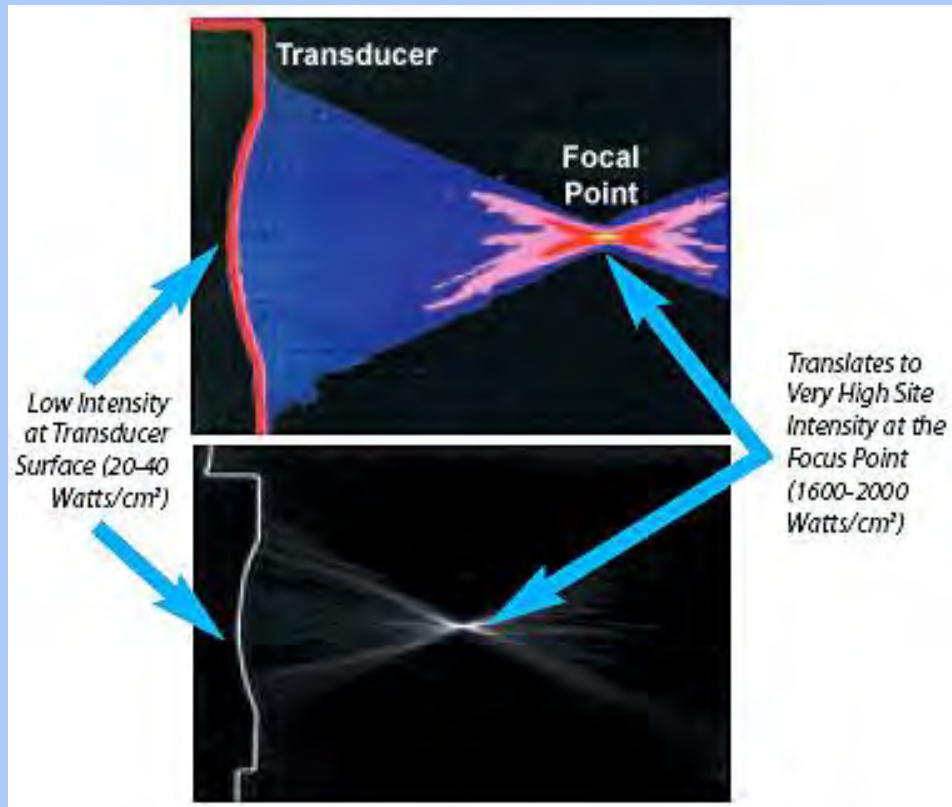
## Duopa

- Dopamine gel continuously administered via intra-intestinal pump
- Provides steady delivery of levodopa without the fluctuations of oral medication
- Off time decreased by 4h and on time increased by 4h<sup>1</sup>

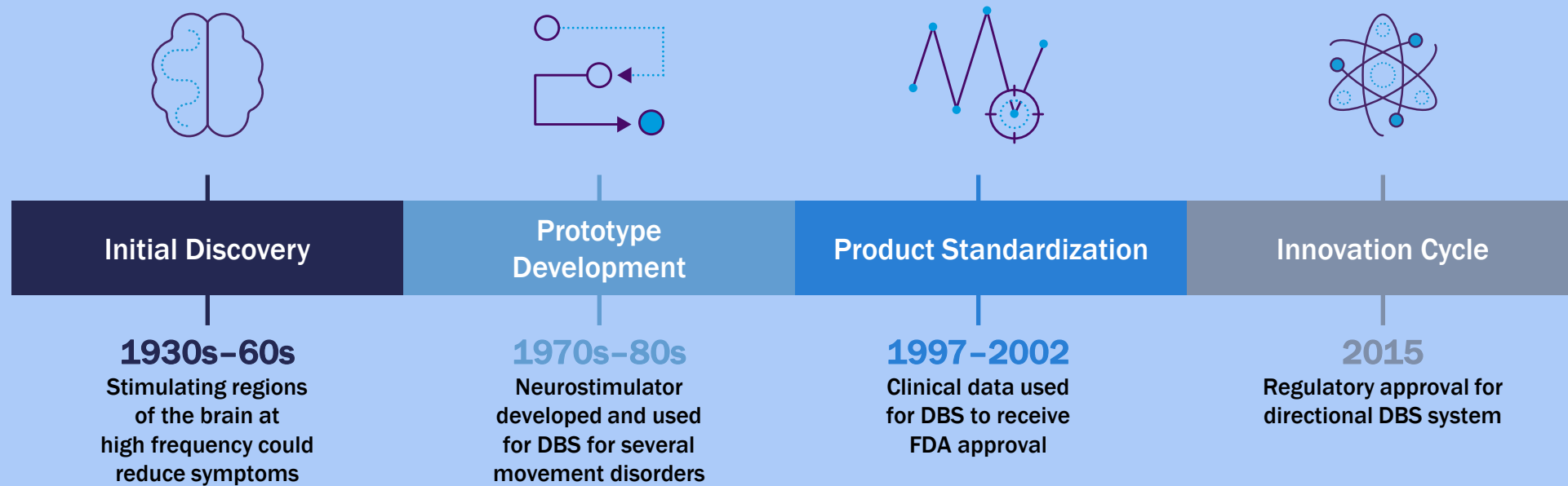


# FOCUSED ULTRASOUND (FUS)

- 1,000 ultrasound beams
- Non-invasive
- Creates focal lesion at target
- Approved unilateral ET, unilateral PD tremor



# DEEP BRAIN STIMULATION (DBS)

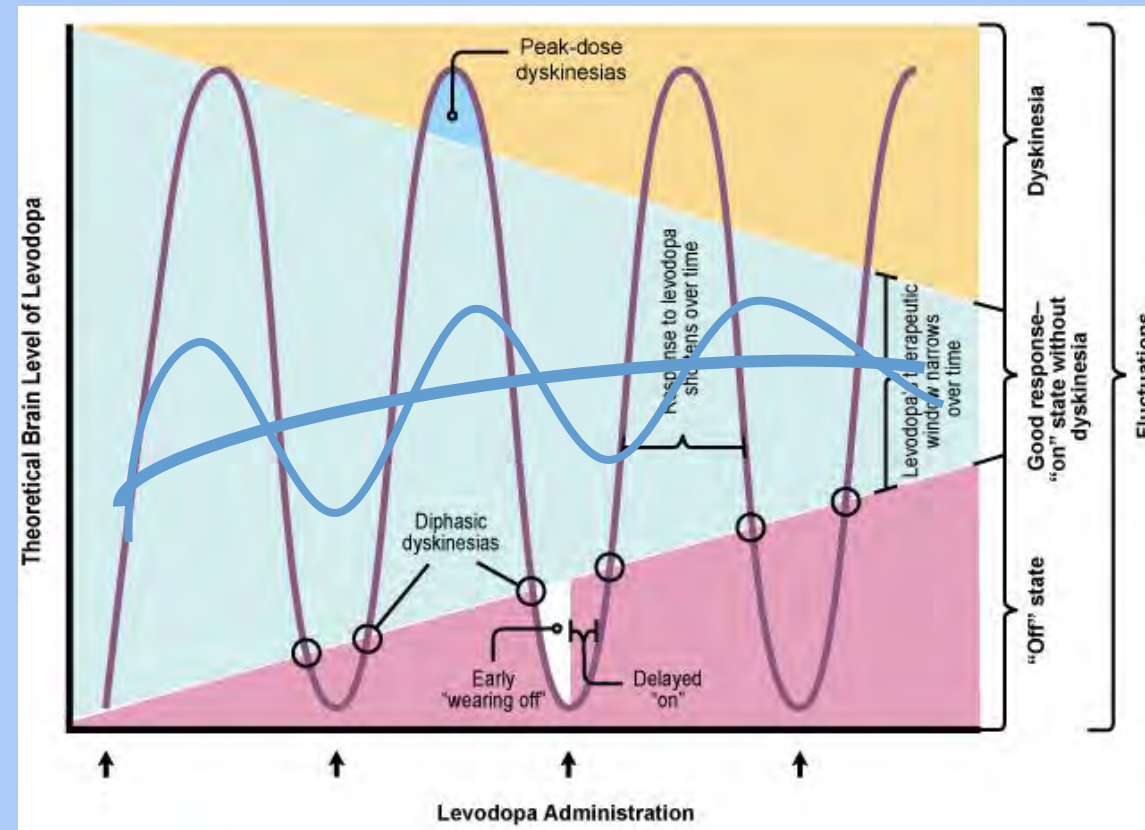


# HOW DOES IT WORK?

- Controlled stimulation of electricity to block electrical pathway.
- Surgeries for PD (pallidotomy or thalamotomy) and Focused Ultrasound destroys nerve cells, DBS does not.
- Programmable and adaptable, by MD and patient.
- Removable, if necessary, with little to no tissue damage.
- Standard of care.



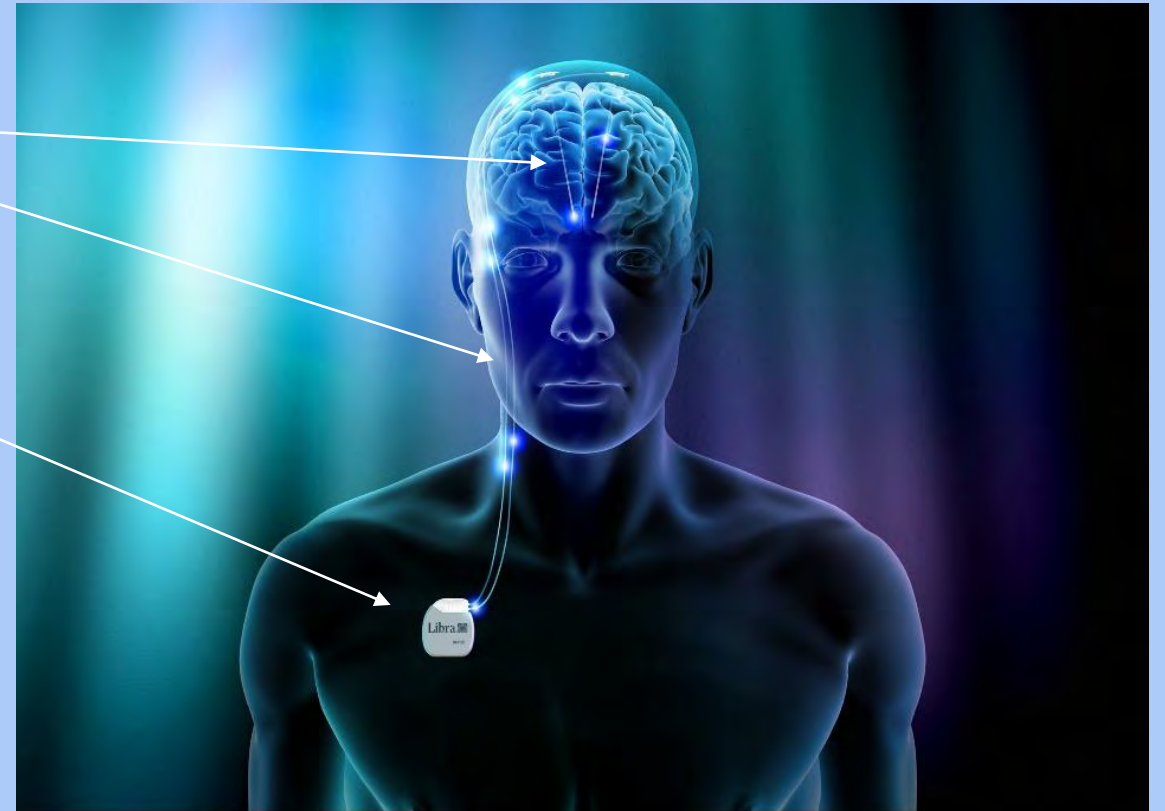
# HOW DOES IT WORK?





# COMPONENTS?

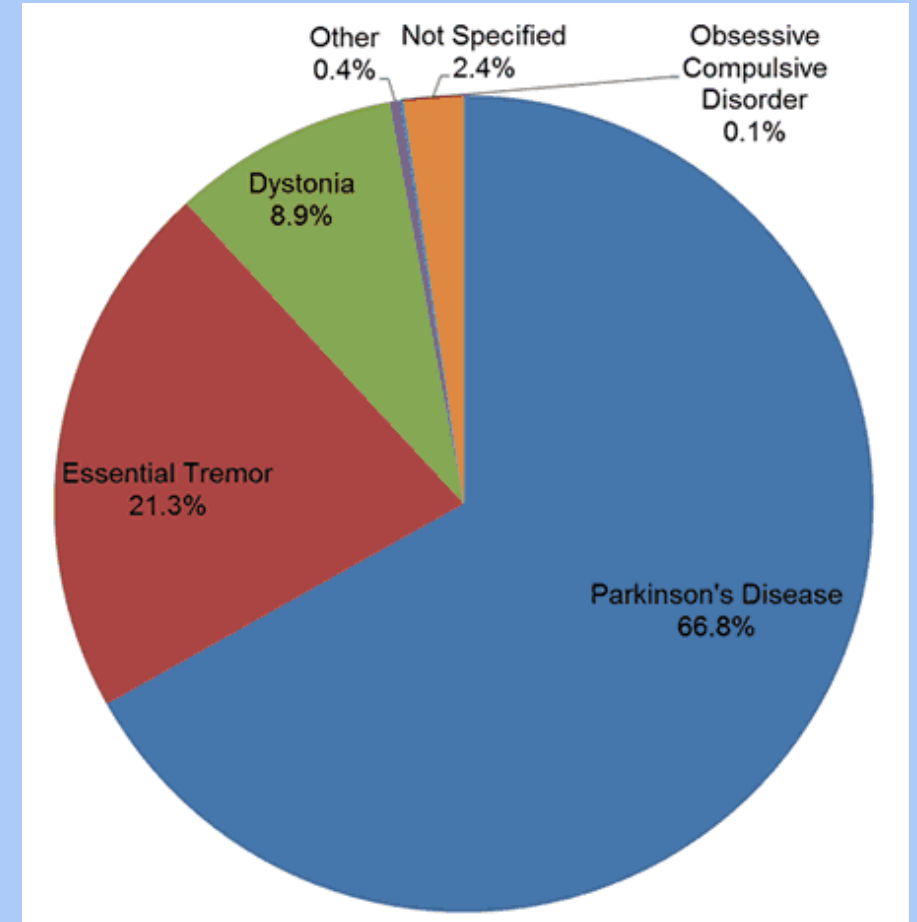
- The DBS system consists of three components:
  - Intracranial Lead
  - Extension connecting lead and generator
  - Implanted pulse generator (neurostimulator)
- Unilateral or bilateral leads
- Proper patient selection is key



# DBS INDICATIONS

- FDA indicated for:
  - Parkinson's Disease
  - Essential Tremor
  - Dystonia
- FDA approval:
  - Essential tremor - 1997
  - Parkinson's disease - 2002
  - Dystonia - 2003

Covered by all insurance providers.



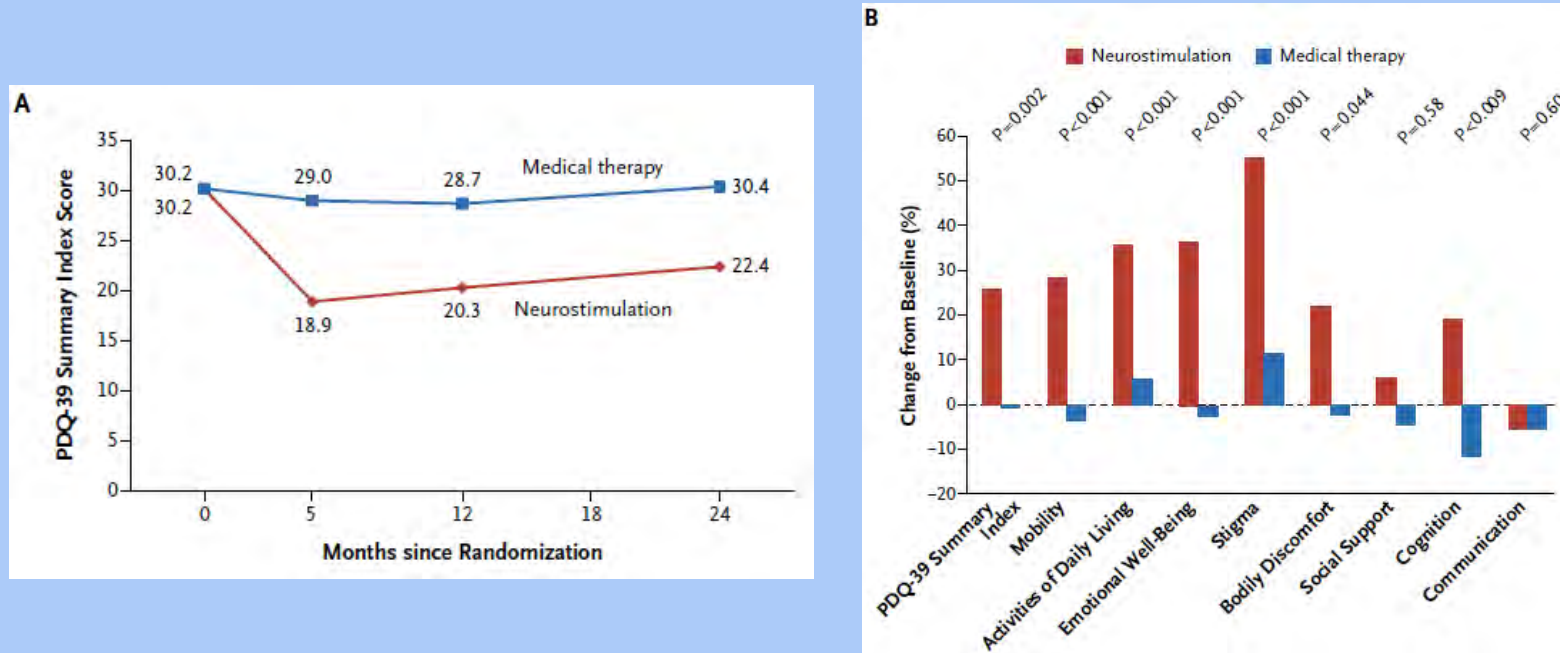
# BENEFIT FOR OUR PATIENTS

## Parkinson's Disease:

- **80-90%** subjective improvement
- **>60%** medication reduction
- **80%** improvement in “off” periods
- **10%** improvement in “on” periods
- **4.6 hours MORE** on time without dyskinesia
- Reduction in medications leads to decrease in the following:
  - Cost
  - Side effects (nausea, orthostasis, cognitive change, and downstream dyskinesia risk)



# EARLY-STIM STUDY



- **Conclusions:** DBS was found to be superior to medical therapy in patients with PD and early motor complications

# DBS, DISEASE MODIFYING THERAPY?

## Effects of deep brain stimulation on rest tremor progression in early stage Parkinson disease

Mallory L. Hacker, Mahlon R. DeLong, Maxim Turchan, Lauren E. Heusinkveld, Jill L. Ostrem, Anna L. Molinari, Amanda D. Currie, Peter E. Konrad, Thomas L. Davis, Fenna T. Phibbs, Peter Hedera, Kevin R. Cannard, Lea T. Drye, Alice L. Sternberg, David M. Shade, James Tonascia, David Charles

- **Classification of evidence** This study provides Class II evidence that for patients with early PD, DBS may slow the progression of rest tremor.

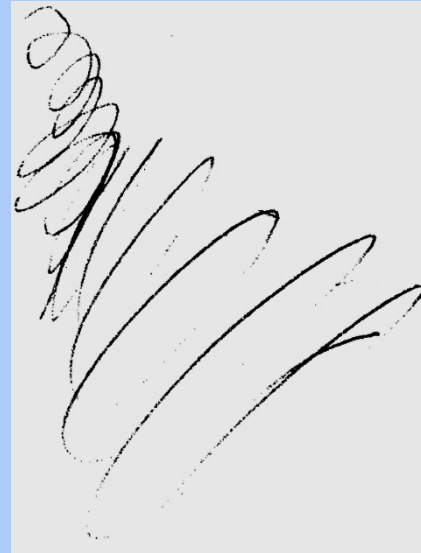
Neurology®



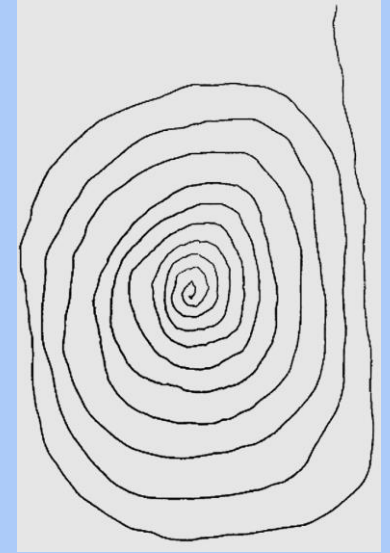
# BENEFIT FOR OUR PATIENTS

## Essential Tremor:

- **80% improvement in tremor.**
  - **70% improvement in handwriting.**
  - **Significant reduction in medications with possibility of stopping medication.**
- 
- **Reduction in medications leads to decrease in the following:**
    - Cost
    - Side effects (cognitive change, fatigue, lethargy, etc.)



Pre DBS on high dose  
Primidone



Post DBS on no  
medication

# WHO IS A CANDIDATE

- A good candidate for DBS per our center:

1. Parkinson's Disease at least 4 yrs (FDA indication)
2. Experiencing a response to medication
3. Experiencing the on-off fluctuation of medication
4. Able to participate in care
5. Good surgical candidate
6. No diagnosed dementia or severe psychiatric disorder

Also refractory  
tremor in  
Parkinson's  
disease



# EXPANDING FIELD: COMPETITION ONLY BENEFITS THE PATIENT

5 years ago



NOW



Boston  
Scientific

# AN EXPANDING FIELD

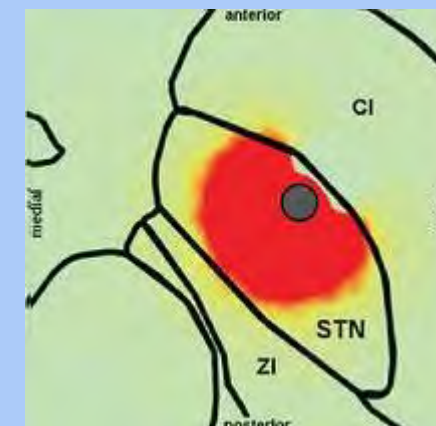
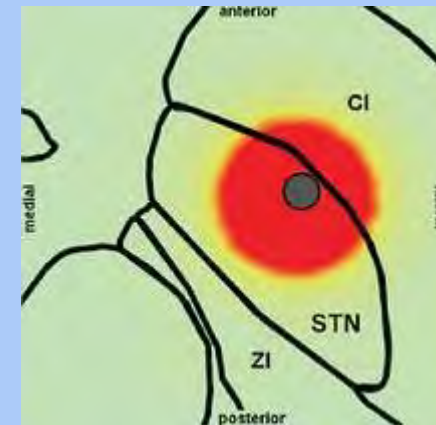
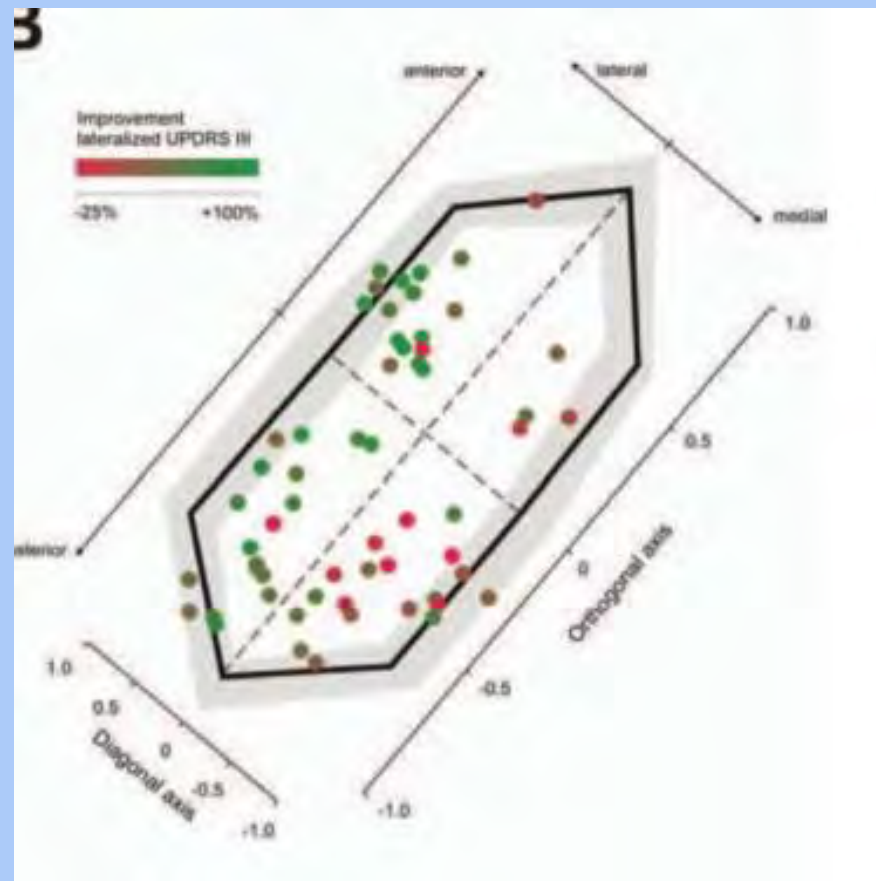
- Directional stimulation.
- Improved technology and wireless.
- Smaller technology, thinner.
- Longer battery life and rechargeable systems.
- Variety of rechargeable systems.



Boston  
Scientific

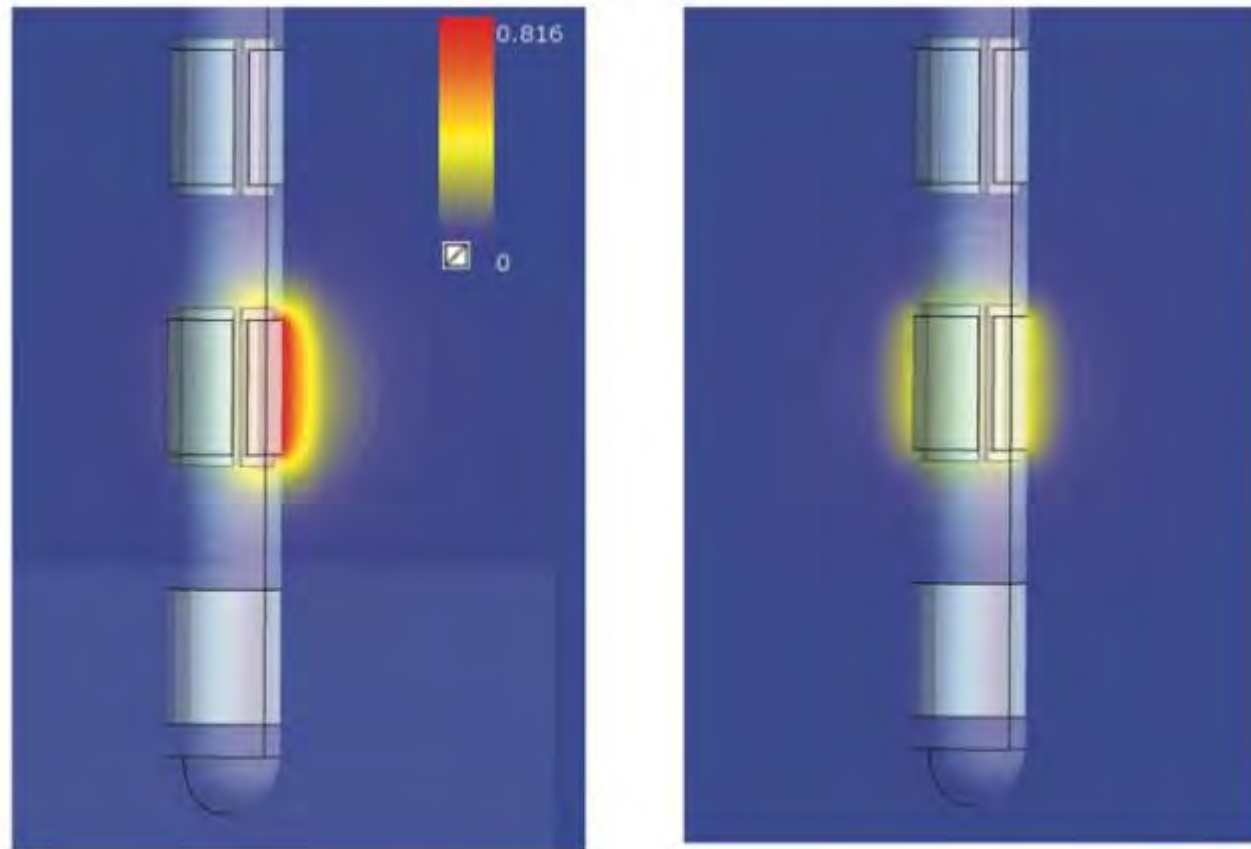


# DIRECTIONALITY, THE PRESENT AND FUTURE OF STIM





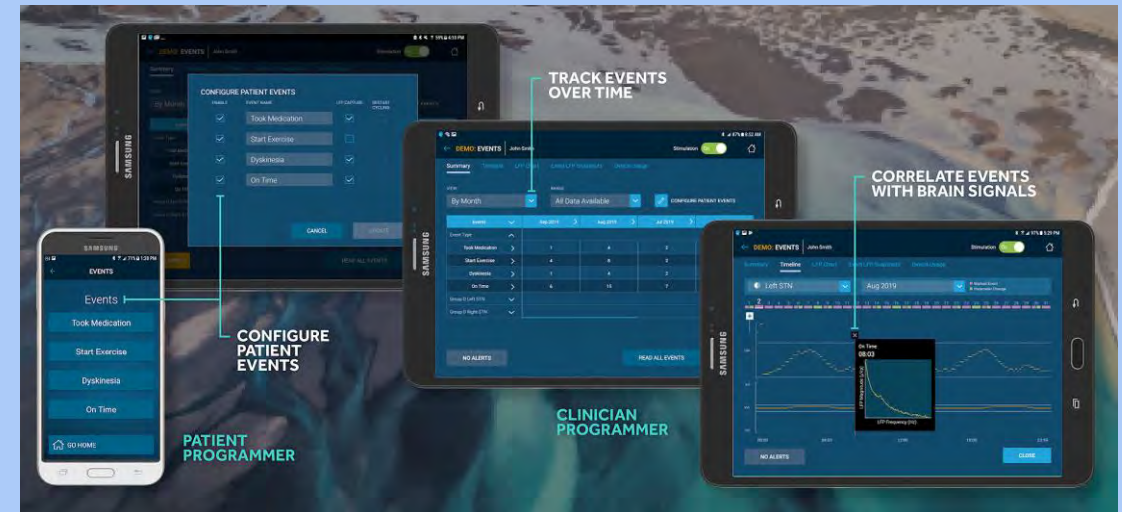
# DIRECTIONALITY, THE PRESENT AND FUTURE OF STIM



Reference: Poster: VTA Modelling studies- Cheeran, Venkatesan, Kent- WSSFN 2017

# THE FUTURE?

- Local field potential readings
- “Closed-loop” systems
- Longer batteries and better hardware
- Improved personalization and patient interaction
- Remote programming



Deep Brain Stimulation Systems - Percept PC | Medtronic

# MULTIDISCIPLINARY APPROACH

*A team approach is key to a successful outcome.*

- Cognitive evaluation
  - Full Neuropsychiatric testing
- Psychiatric evaluation, if necessary
- Physical therapy, occupational therapy and speech therapy
- Neurosurgical evaluation
  - Work together for pre-surgical planning
    - GPI vs STN, Unilateral vs Bilateral
  - Intra-operative cooperation
- Movement Disorders Specialist



# IN SUMMARY

- Longstanding, well-studied tool.
- Therapy at the source.
- Adaptable, adjustable with no treatment horizon.
- Average implant – 11 years from diagnosis.
- FDA approved – 4 years from diagnosis.
- The gap? Education, training and comfort.





# THANK YOU!

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**Join our newsletter!**

**Stay up to date on all  
of our center's offerings!**

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**703-375-9987**

