

# PARKINSON'S DISEASE IN 2020



Parkinson's Fundamentals and  
Applying Updated Medical Options

# INOVA PARKINSON'S & MOVEMENT DISORDERS CENTER



# INOVA MOVEMENT DISORDERS CENTER

## Alexandria

1500 N. Beauregard Street  
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Alexandria, VA 22311

## Fairfax

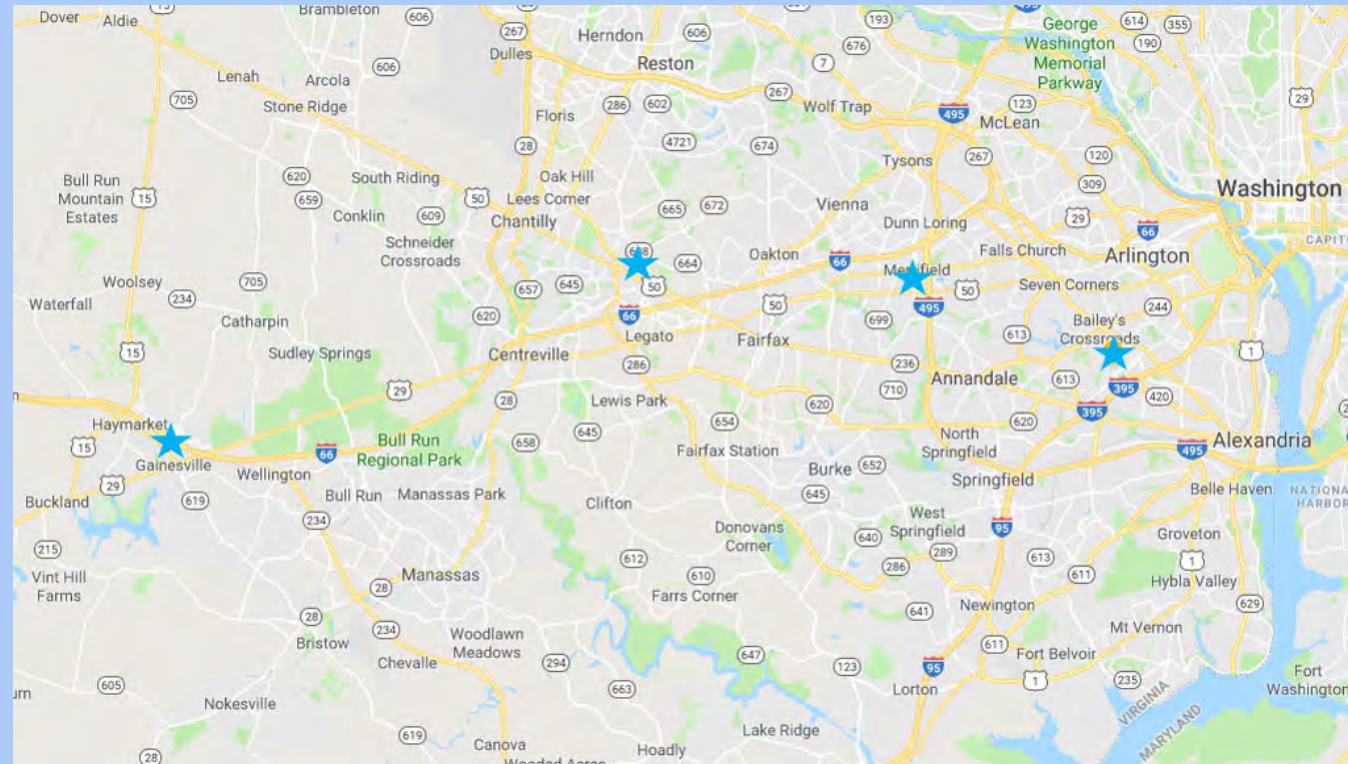
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Fairfax, VA 22031

## Fair Oaks

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Suite 206  
Fairfax, VA 22033

## Gainesville

7051 Heathcote Village Way  
Suite 230  
Gainesville, VA 20155



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# WHAT IS PARKINSON'S?

**1**/100  
OVER AGE  
OF 60



**60,000**  
NEW

**1M**/US



**5M**/WORLD

There is

**NO TEST**  
and no  
**PROGRESSION  
MARKER**



**NO CURE,**  
MEDICATION ONLY HELPS WITH  
SYMPTOMS

PARKINSON'S DISEASE IS CAUSED BY THE DEATH  
OF DOPAMINE CELLS.

**60 TO 80%**

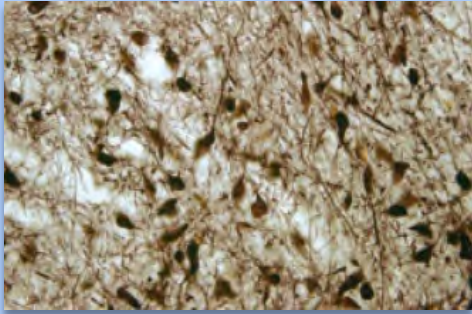
OF THESE CELLS ARE ALREADY LOST BY THE TIME  
MOTOR SYMPTOMS APPEAR.



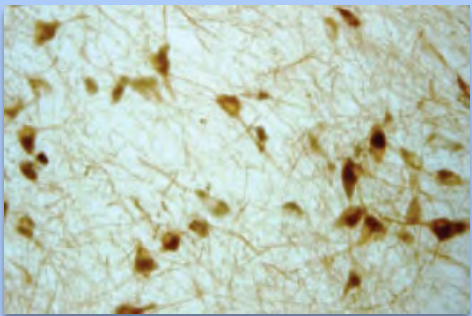


# WHAT CAUSE PARKINSON'S DISEASE?

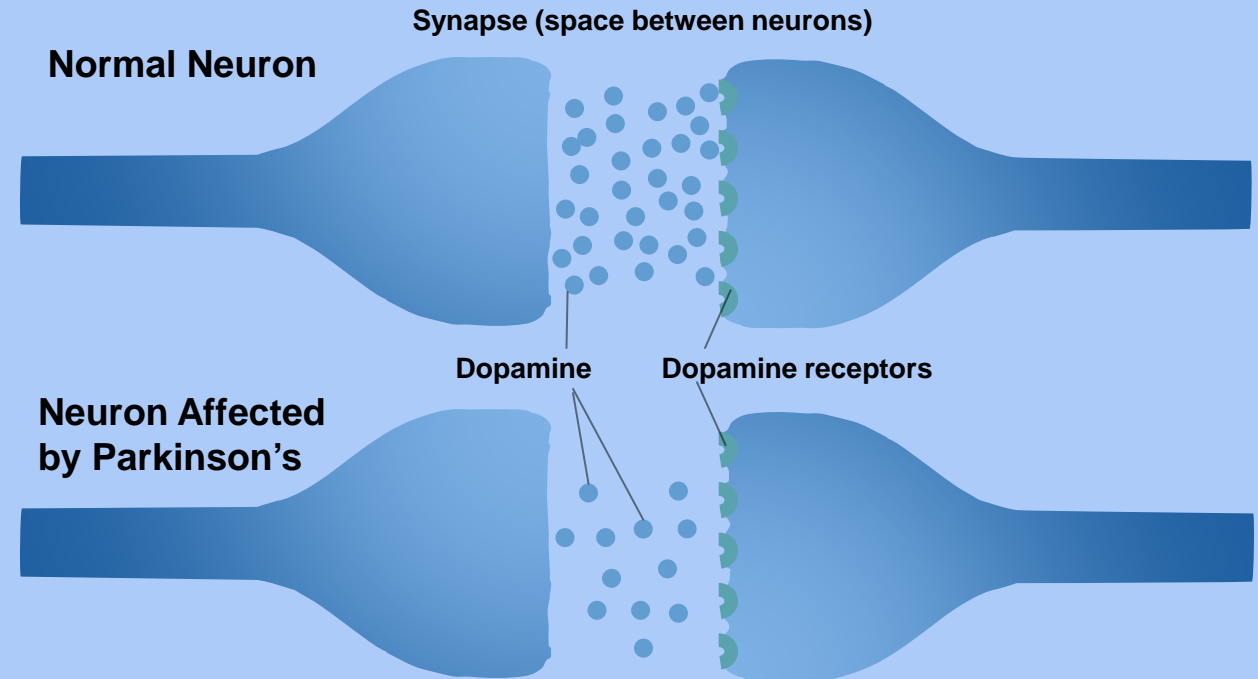
**PARKINSON'S DISEASE IS CAUSED BY A DECREASE IN DOPAMINE PRODUCTION IN THE BRAIN**



**Healthy Brain Cells (Neurons)**



**Brain Cells with Parkinson's Disease**



# WHAT HAPPENS IF YOU HAVE REDUCED DOPAMINE?

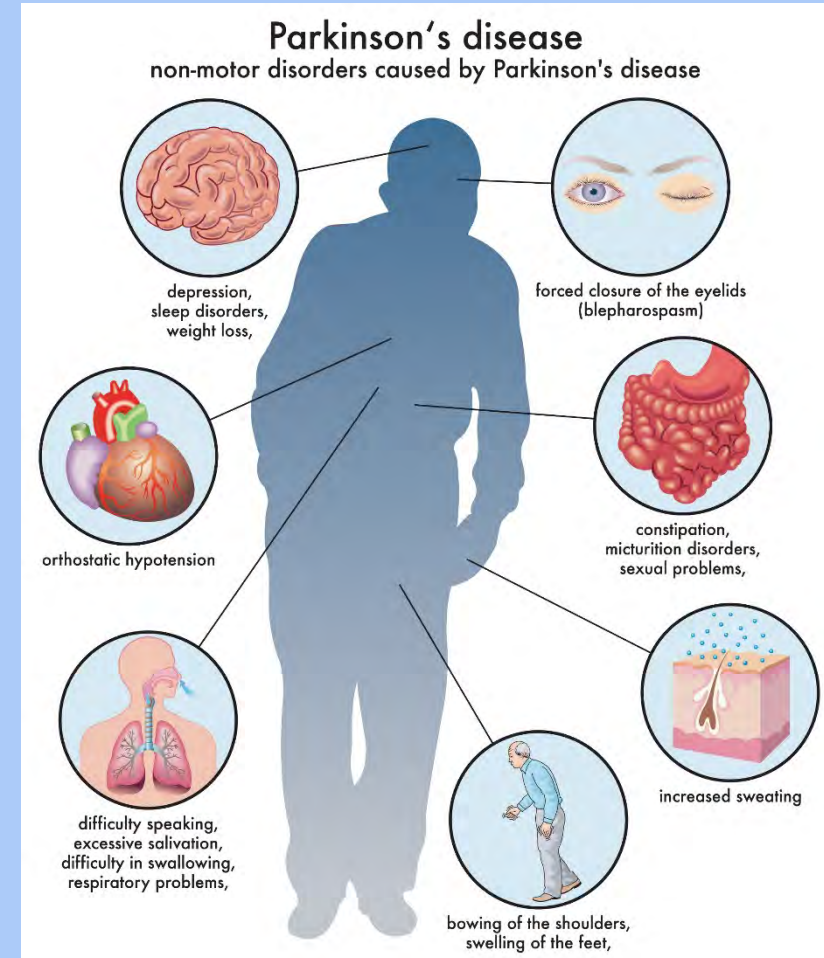
- **Motor and Non-motor Symptoms**
  - Systems which function inappropriately due to reduction in Dopamine or one of its byproducts
- **Motor Symptoms**
  - Resting tremor
  - Tremor with position
  - Bradykinesia (slowness)
  - Rigidity (stiffness)
  - Slow walking, shuffle, reduced arm swing
  - Balance issues
  - Reduced facial expression (flat affect)
  - Speech changes (hypophonia)



# NON-MOTOR SYMPTOMS

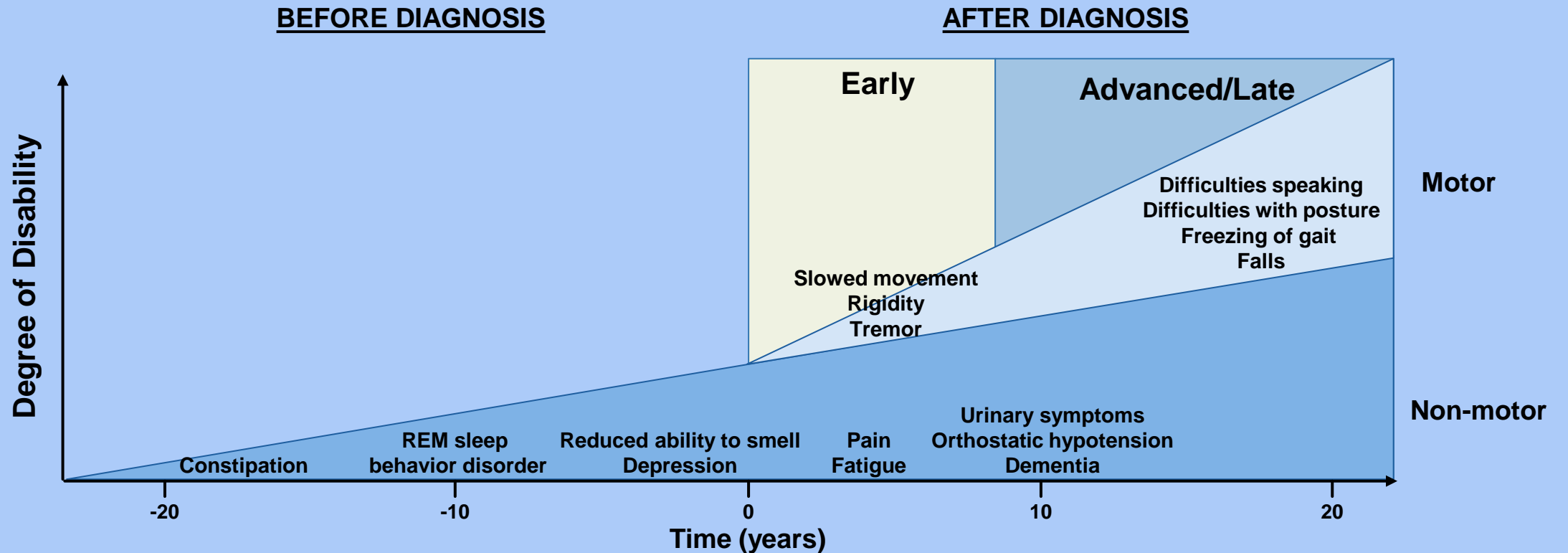
**\*\*Can present years before diagnosis\*\***

- Loss of sense of smell
- Constipation
- Talking in sleep or acting out dreams
- Anxiety/Depression
- Bladder issues
- Excessive saliva/drooling
- Vision changes
- Problems sweating
- Lightheadedness/Dizziness on standing
- Fatigue
- Skin problems
- Cognitive changes



# PARKINSON'S CHANGES OVER TIME

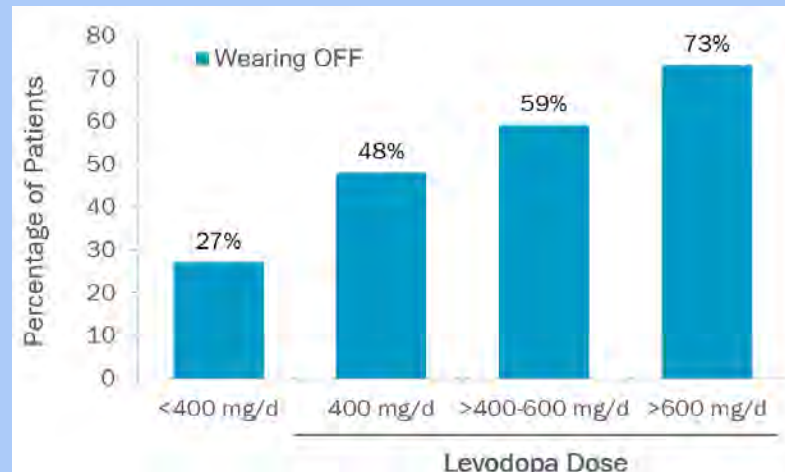
THE SYMPTOMS OF PARKINSON'S DISEASE VARY FROM PERSON TO PERSON, BUT MAY INCLUDE BOTH MOTOR AND NON-MOTOR SYMPTOMS





# 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.

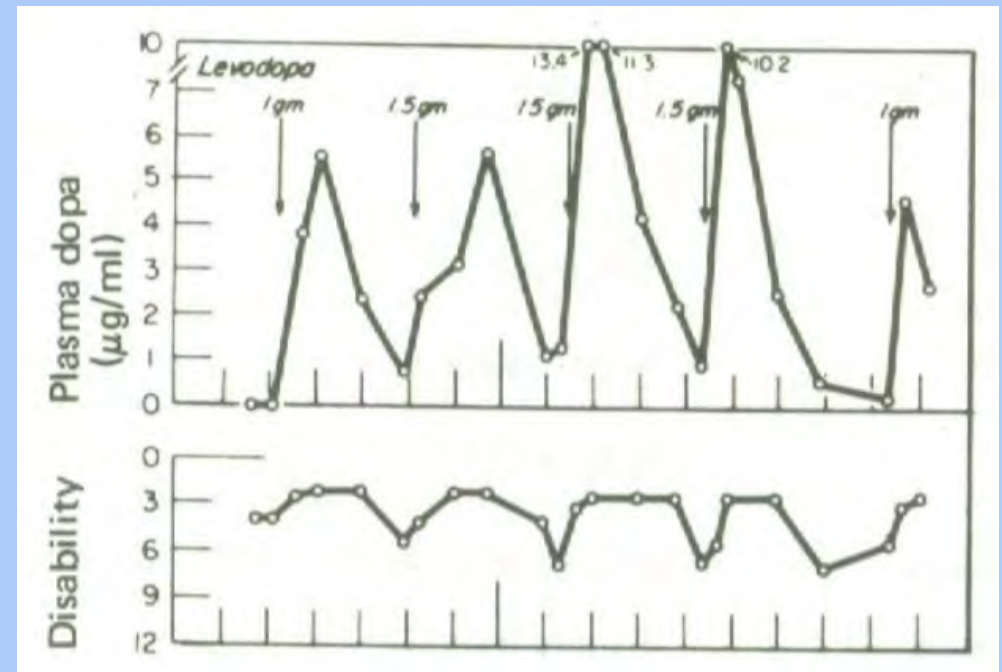
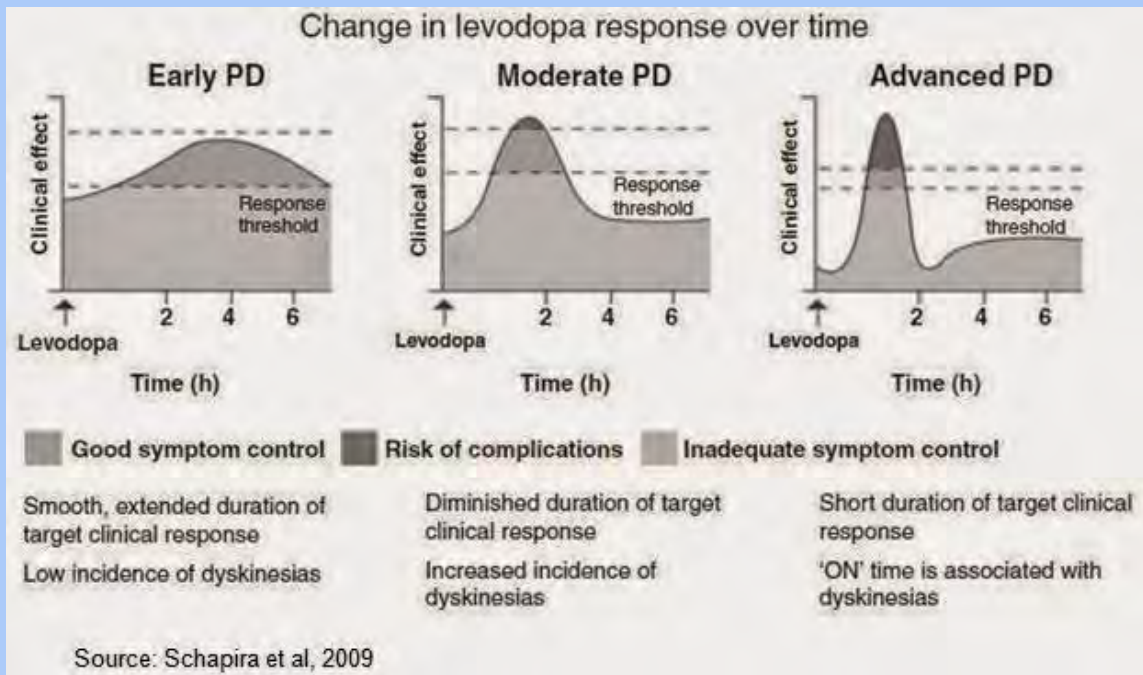
**65%** reported 2 or more hours a day

**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?

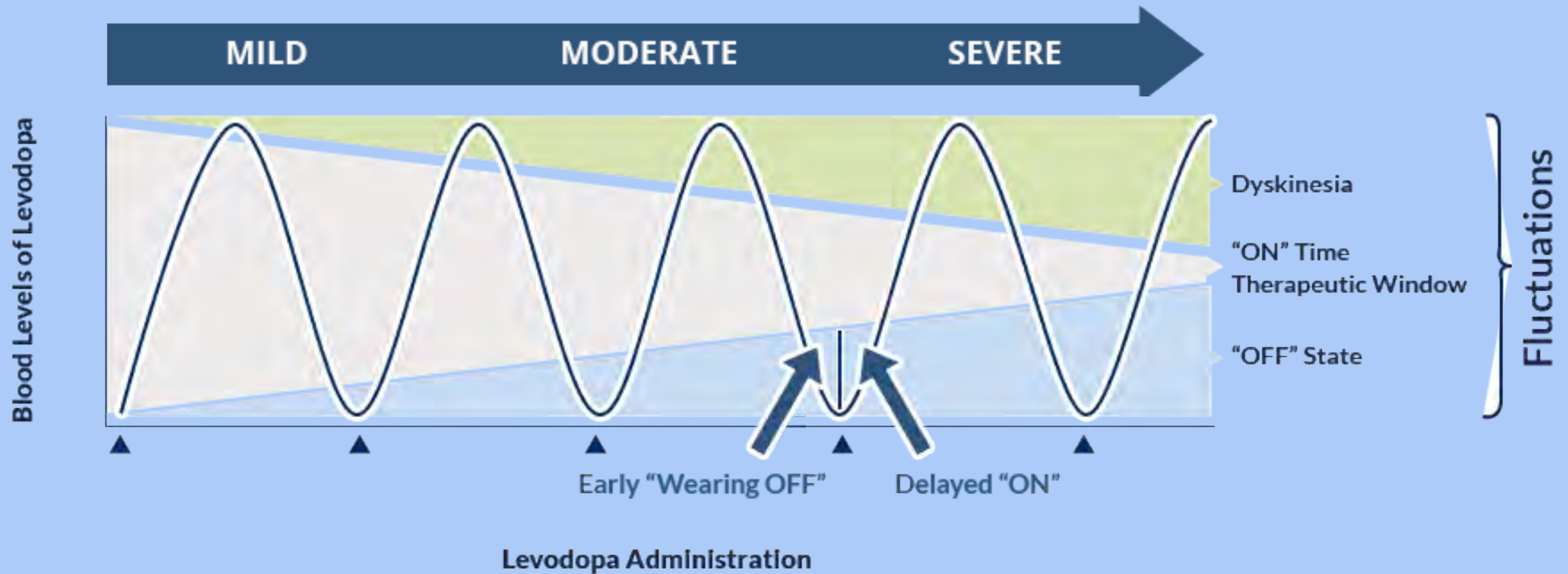
## Classic carbidopa/levodopa

- 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)
- STRIDE-PD trial showed increased motor fluctuations and dyskinesia  $\geq$  500mg per day at 6 years (2013)

Combination of disease progression and pulsatile medication dosing impacts the number of dopamine receptors present among other things.

**Result = Worsening on-off fluctuations throughout the day**

# CARBIDOPA – LEVODOPA



# APPROACH TO THERAPY

## Classic

vs

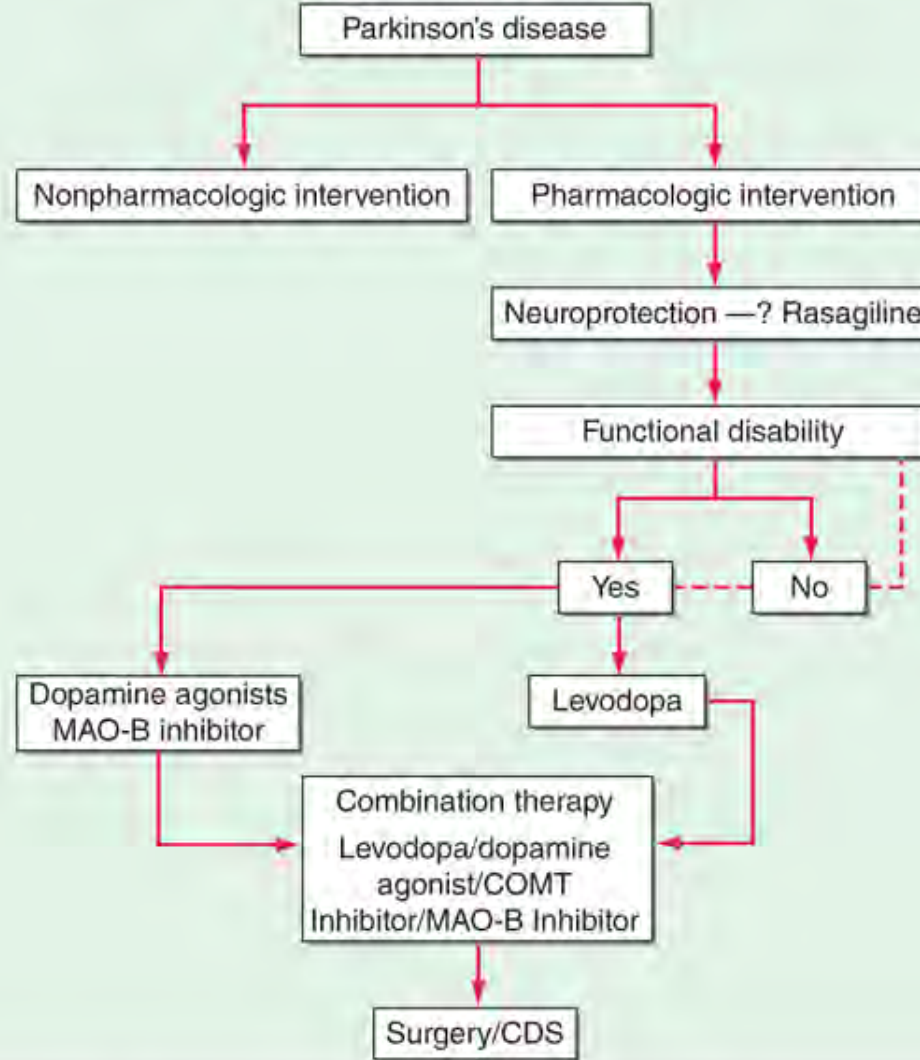
## Contemporary

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

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



## TREATMENT ALGORITHM FOR THE MANAGEMENT OF PARKINSON'S DISEASE



Source: J.L. Jameson, A.S. Fauci, D.L. Kasper, S.L. Hauser, D.L. Longo, J. Loscalzo: Harrison's Principles of Internal Medicine, 20th Edition Copyright © McGraw-Hill Education. All rights reserved.

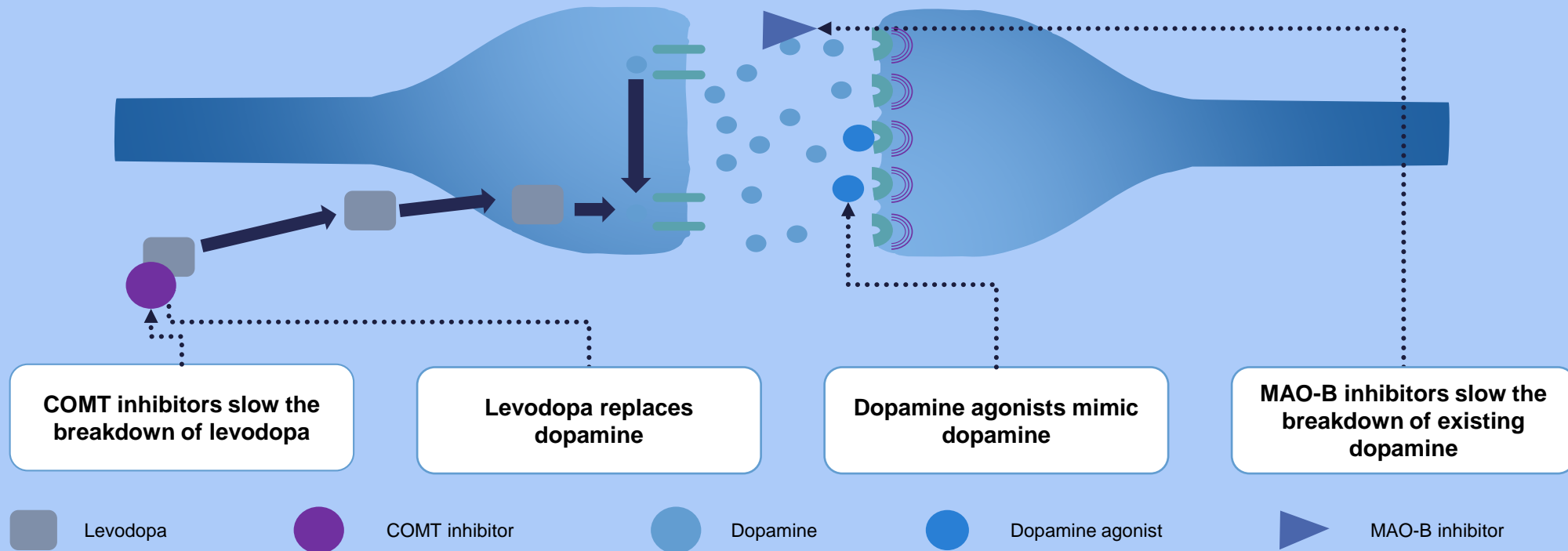
## GENERAL TREATMENT ALGORITHM

Varies based on:  
Experience  
Comfort  
Place of training  
Industry interaction  
Clinic structure and time

# MEDICATION CATEGORIES FOR PD

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

Synapse (space between neurons)



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

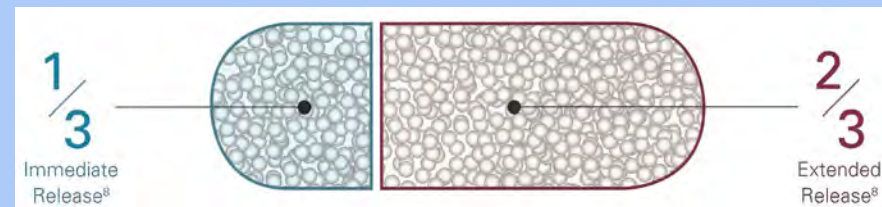
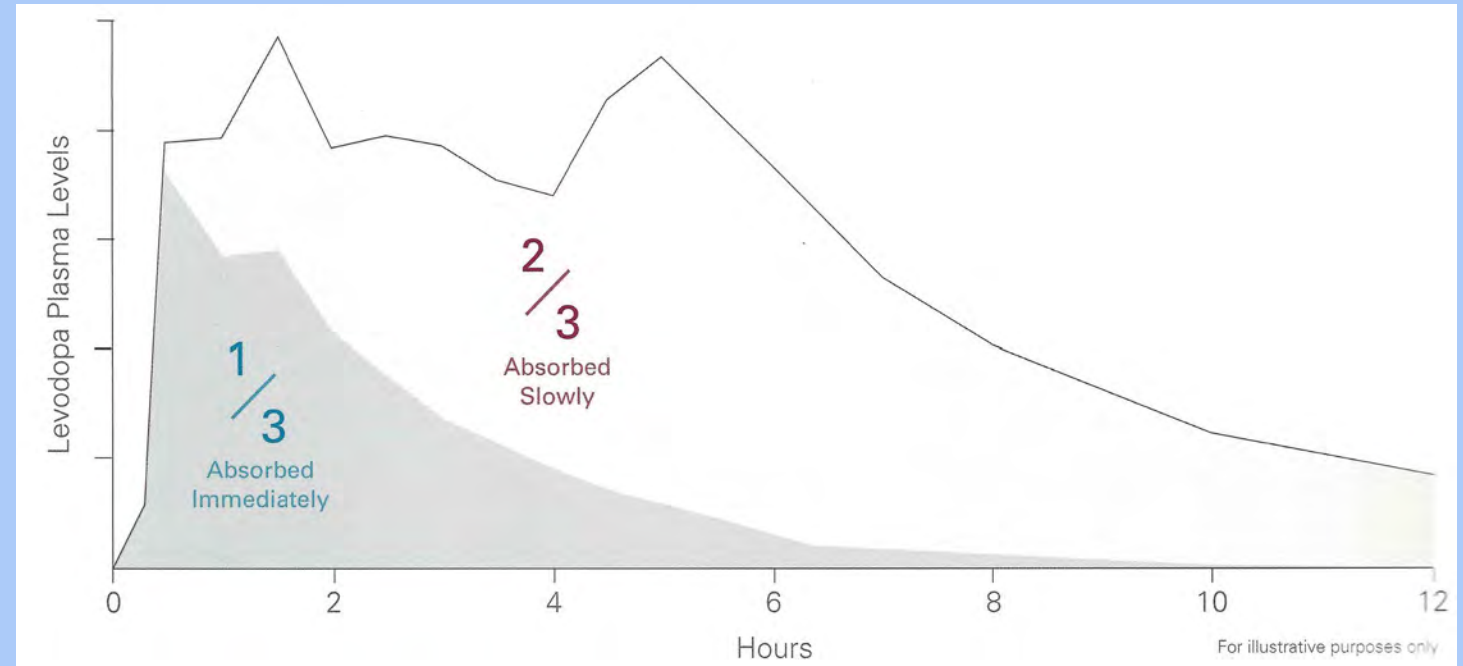
- COMT inhibitor



# NEW LEVODOPA FORMULATION

## Rytary

- New 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

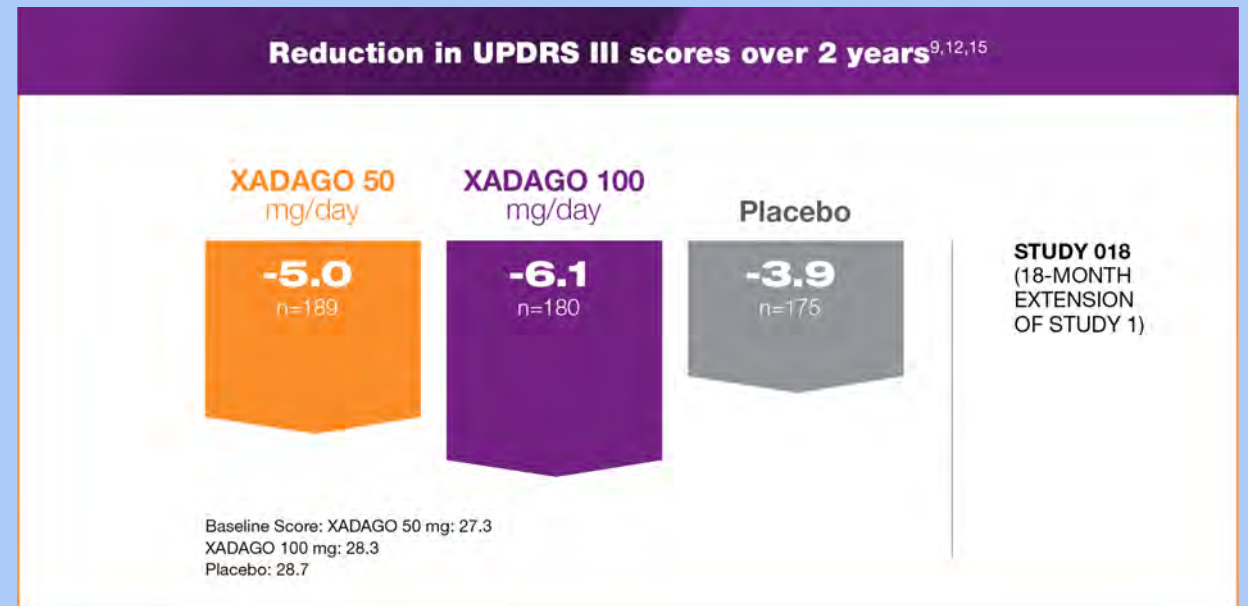


# NEW MAO-B INHIBITOR, AUGMENTING THE SYSTEM

## Safinamide (Xadago)

- 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

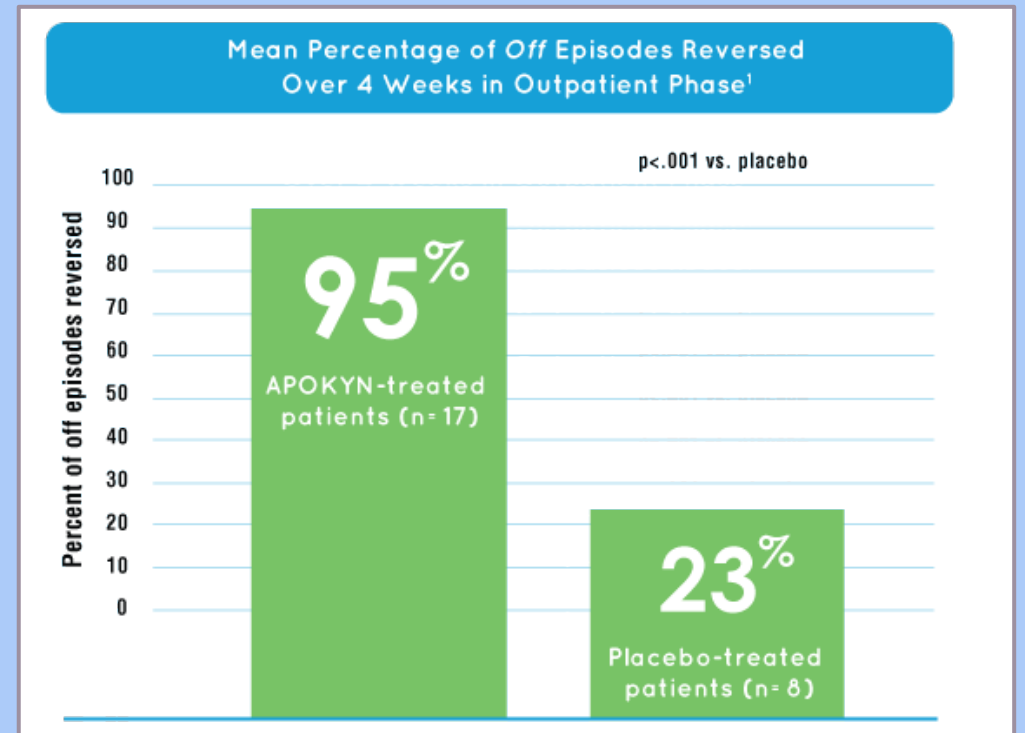




# RESCUE OPTION #1 - APOKYN

## 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



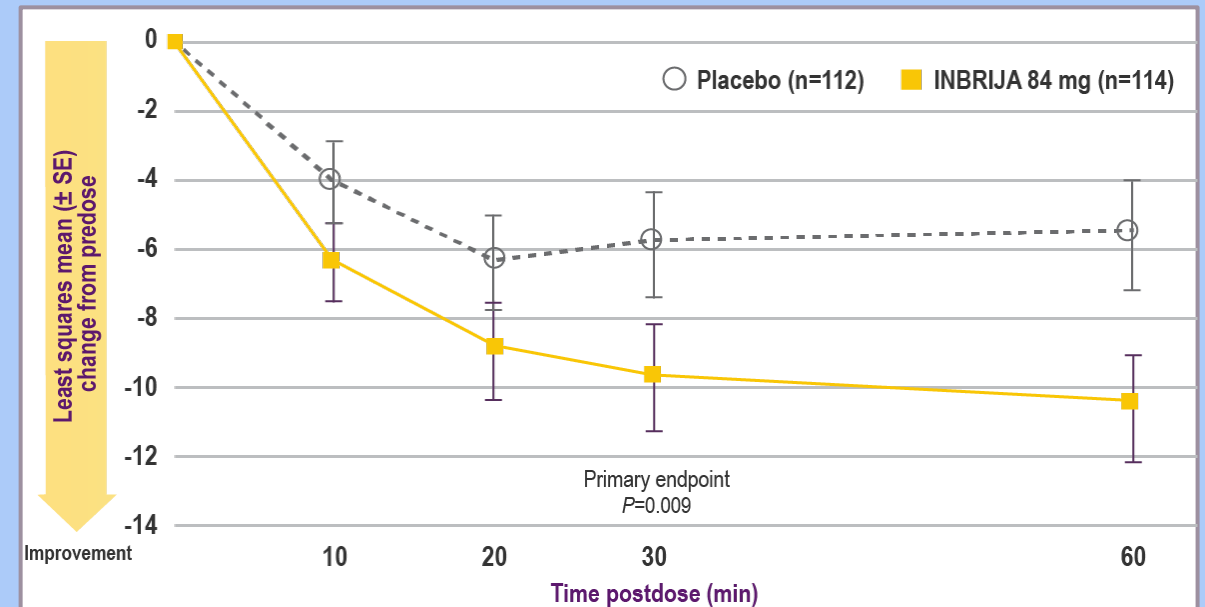
# RESCUE OPTION #2 - INBRIJA

## 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

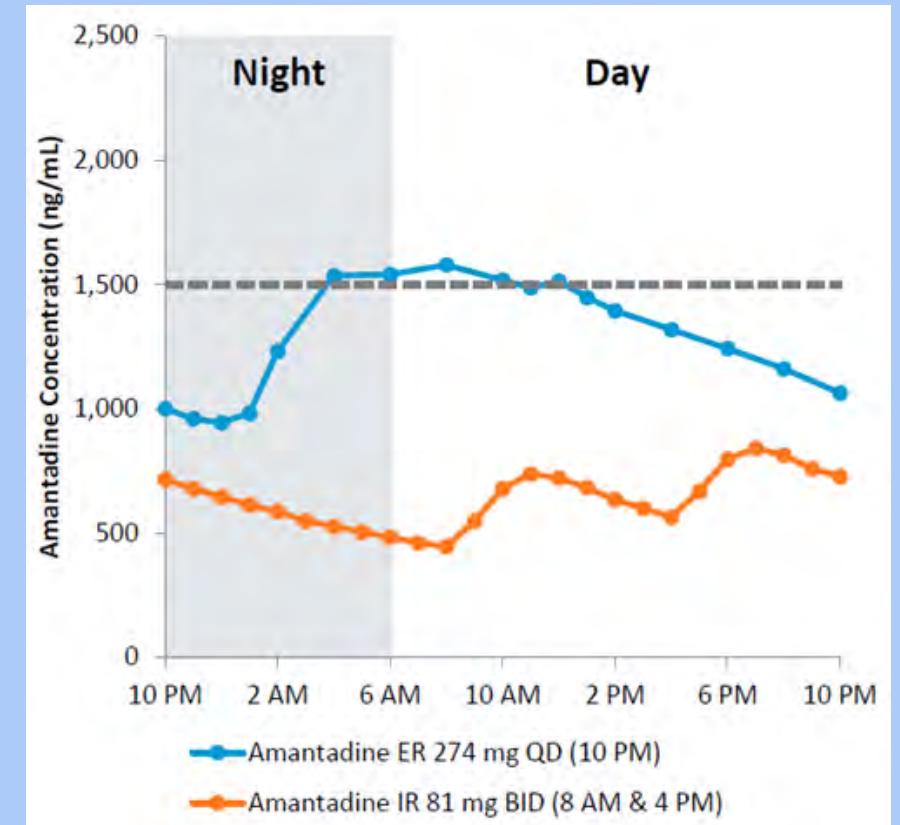


# LONGER-ACTING AMANTADINE

## Amantadine ER (Gocovri)

- 1x daily amantadine
- First “FDA approved” therapy for dyskinesia
  - Classic amantadine is ‘off label’
- Used to reduce dyskinesia (37% reduction)
- Reduced OFF time by 45%
- Available in 2 doses

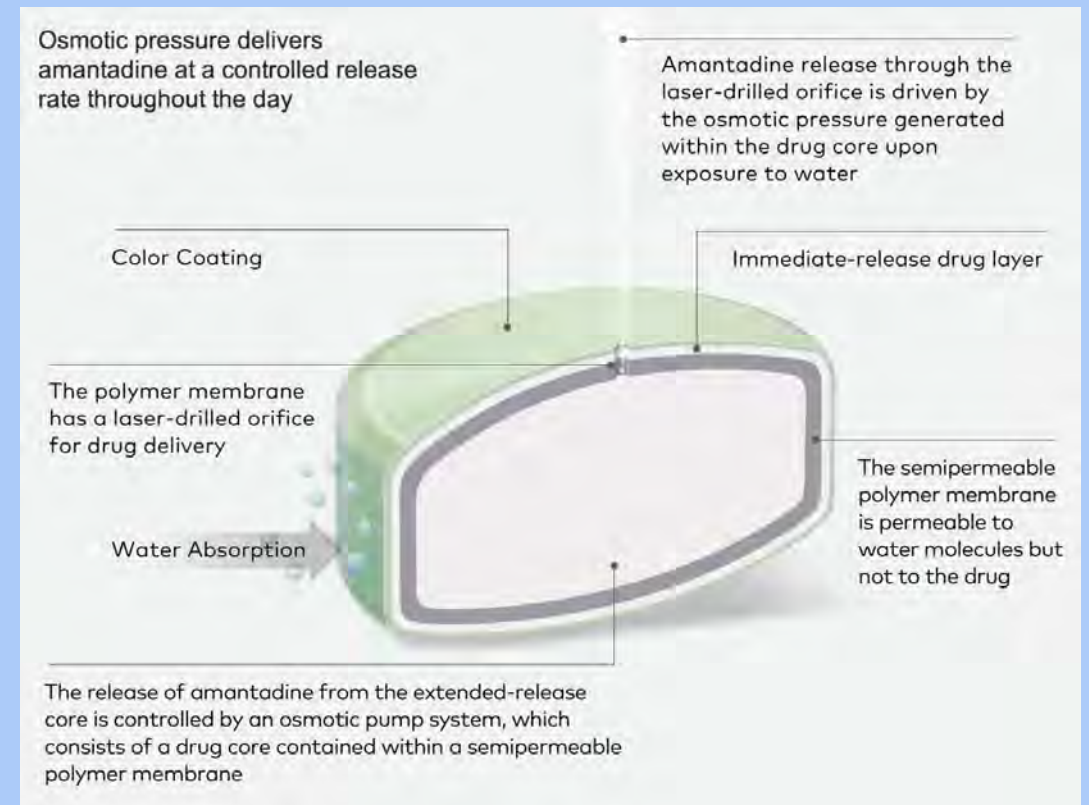
**GOCOVRI™**  
(amantadine) extended release capsules  
68.5 mg | 137 mg



# LONGER-ACTING AMANTADINE

## Osmolex ER (Amantadine)

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



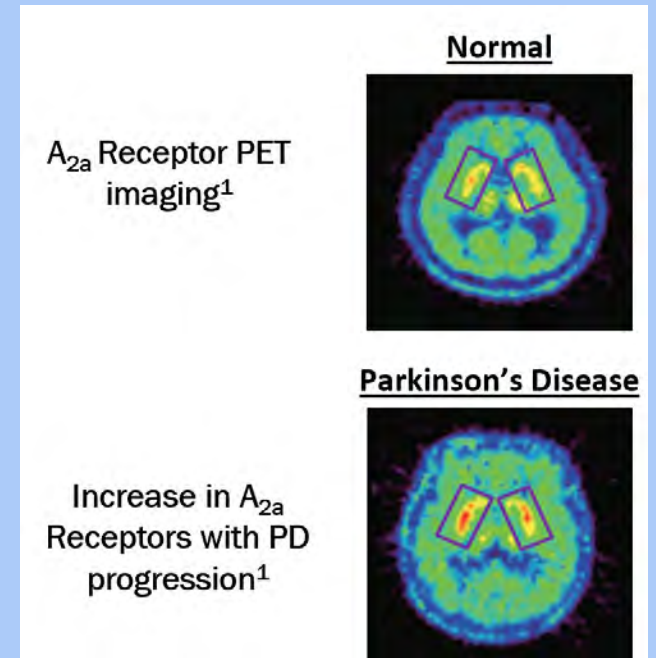
**Osmolex ER™**  
(amantadine)  
*Extended-release Tablets*

# BLOCK THE INDIRECT PATHWAY

## Nourianz

- INDIRECT pathway – activation reduces motor activity
  - Direct pathway increases activity (dopamine, etc.)
  - Indirect pathway inhibits motor activity (adenosine, GABA)
- Adenosine A2a receptor antagonist
  - Double negative, blocks the block
- Improves off time, releasing the ‘brake’ on the system.

**NOURIANZ**<sup>™</sup>  
(istradefylline) tablets  
20mg | 40mg





# ONCE DAILY COMT INHIBITOR

## Opicapone

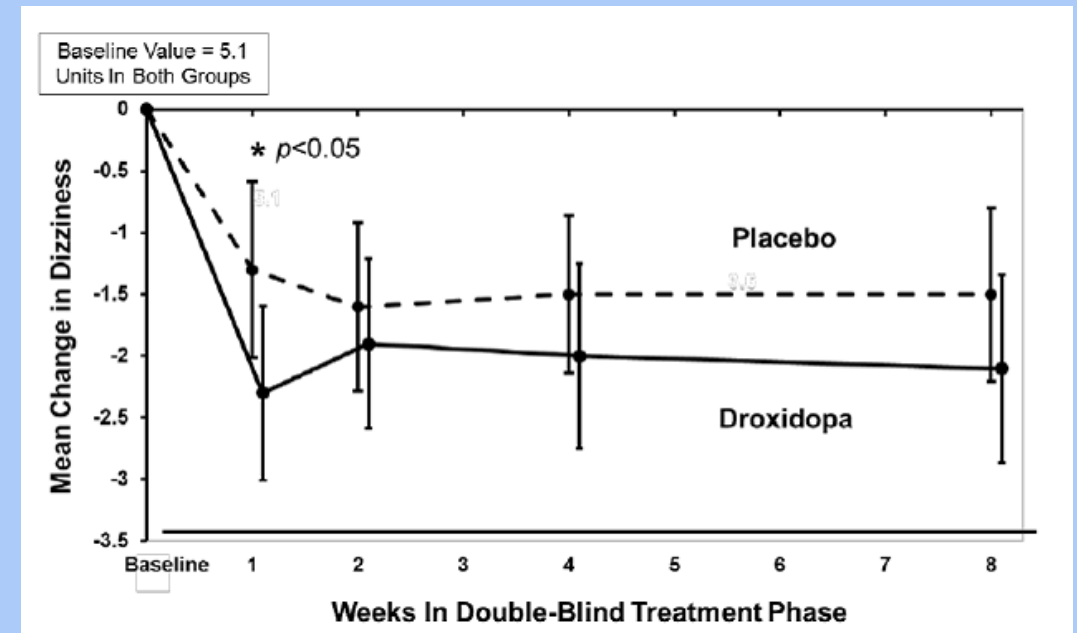
- JUST APPROVED BY FDA
- “Add on” therapy to treat “off” episodes.
- Peripherally acting COMT-inhibitor
- 1x daily (instead of 4-5 daily)
  - Half life of 94 hours.
- Blocks breakdown of levodopa in the periphery, making more available to the brain.
- In use in Europe since 2016.



# ORTHOSTATIC HYPOTENSION

## Northera

- OH is common symptom of Parkinson's Disease
- Can be worsened by dopamine supplementation
- Prodrug for Norepinephrine, crosses BBB
- Peripheral Nervous system – increased BP, improved Neurogenic Orthostatic Hypotension
- Central Nervous system – attention? Gait? Falls?

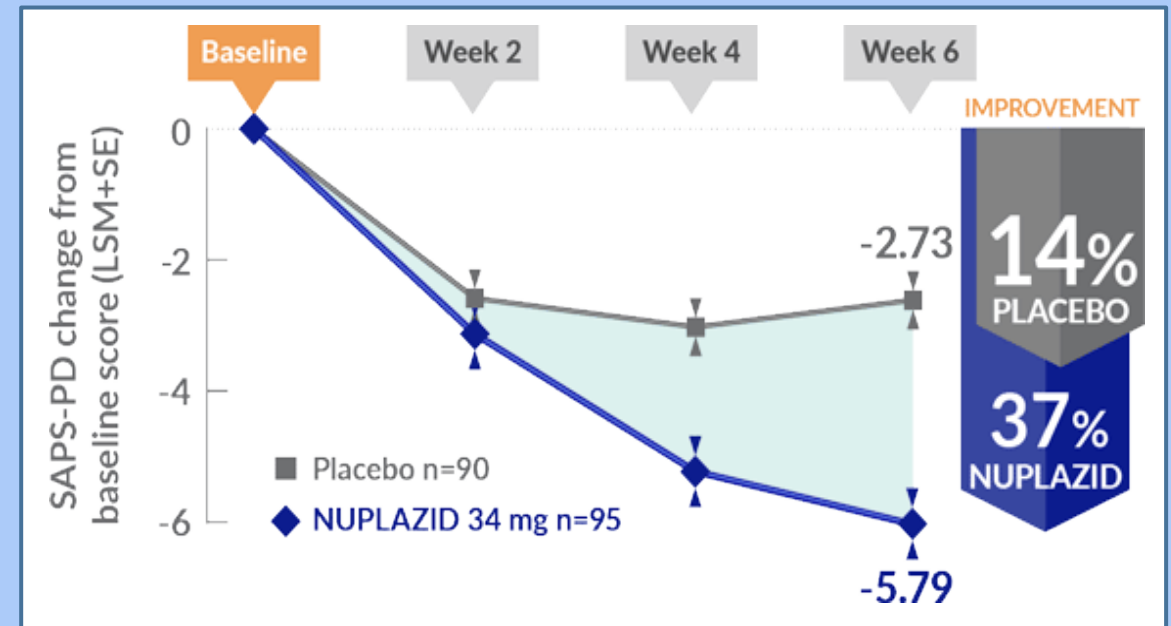


# HALLUCINATIONS AND PSYCHOSIS

## 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
- Novel drug status
- + SAPS-PD improvement with no change in UPDRS

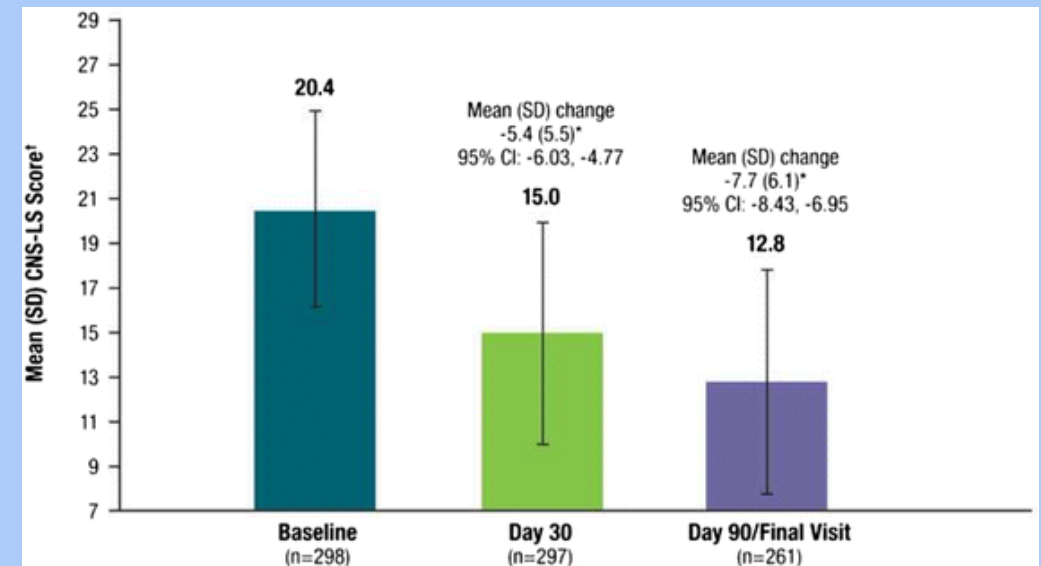
**NUPLAZID™**  
(pimavanserin) tablets



# 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%.



# 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**<sup>®</sup>  
(Rotigotine Transdermal System)

**REQUIP**<sup>®</sup>  
ropinirole HCl

**XADAGO**<sup>®</sup>  
(safinamide) tablets  
**Mirapex**<sup>®</sup>  
pramipexole dihydrochloride tablets

## 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**<sup>®</sup>  
(levodopa, carbidopa and entacapone) tablets

**Inbrija**<sup>®</sup>  
(levodopa inhalation powder)  
42 mg capsules

**Northera**<sup>™</sup>  
(droxidopa) Capsules  
100 mg • 200 mg • 300 mg

**COMTan**<sup>®</sup>  
(entacapone) tabl

(pimavanserin) tablets

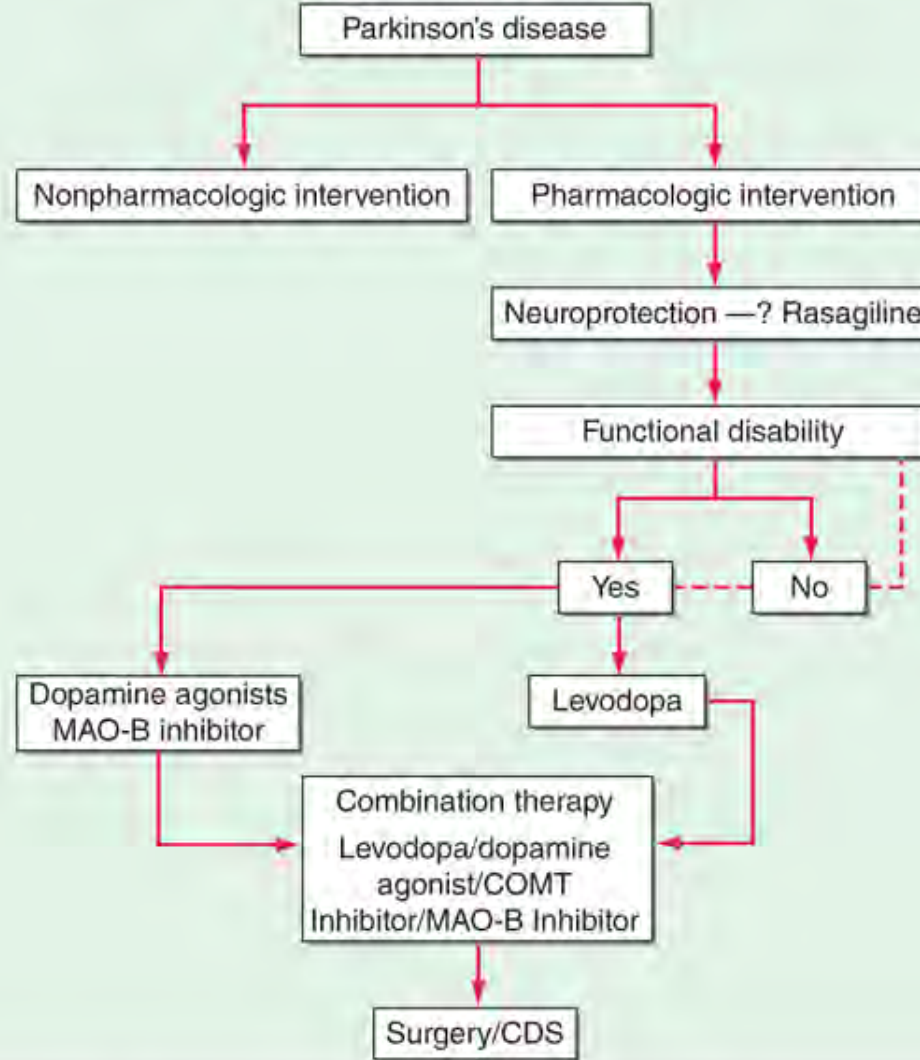
**Ongentys 50 mg**  
cápsulas / cápsulas duras  
opicapona  
via oral / via oral

**NUEDEXTA**<sup>®</sup>  
tromethorphan HBr and  
tidine sulfate) capsules  
20 mg  
10 mg

**APOKYN**<sup>®</sup> Be on.  
apomorphine hydrochloride injection Live life.



## TREATMENT ALGORITHM FOR THE MANAGEMENT OF PARKINSON'S DISEASE



Source: J.L. Jameson, A.S. Fauci, D.L. Kasper, S.L. Hauser, D.L. Longo, J. Loscalzo: Harrison's Principles of Internal Medicine, 20th Edition Copyright © McGraw-Hill Education. All rights reserved.

## GENERAL TREATMENT ALGORITHM

Now more complex.  
Two MUSTS to navigate:

1) NEED MOVEMENT DISORDERS TEAM

2) TAKE CLINICAL DECISION FROM BASICS OF DOPAMINE DEFICIENCY AND TARGET SPECIFIC SYMPTOMS/ LIMITATIONS

# TO THE FUTURE

- Longer-acting levodopa formulations (10 hours or greater)
- New inhibitors
- Inhaled, sublingual, pump-based formulations
- Improved technology
- Targeted protein therapy
- Cure

All of this equals

**HOPE**

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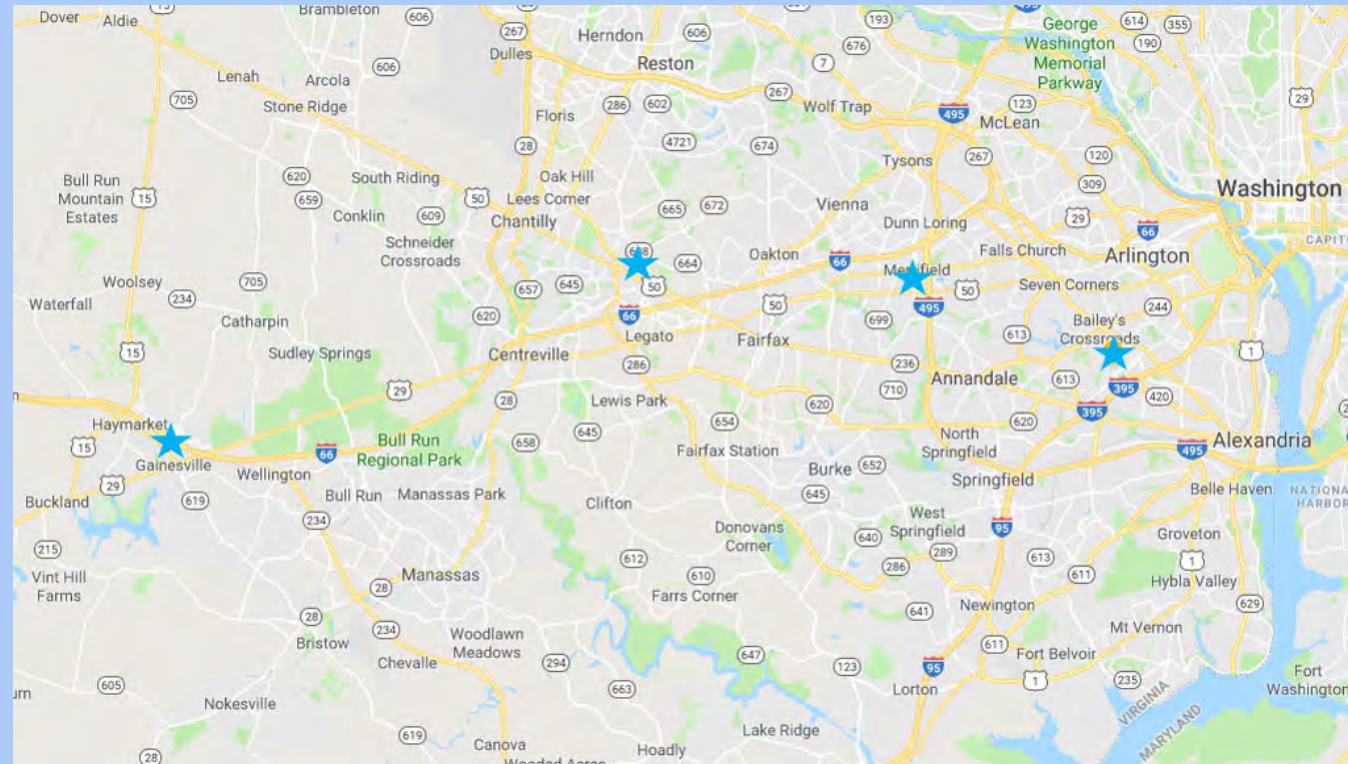
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# THANK YOU – Q&A WITH OUR TEAM

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[www.inova.org/move](http://www.inova.org/move)

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

Find us on Facebook!





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Advanced Therapies: DBS, Duopa and more

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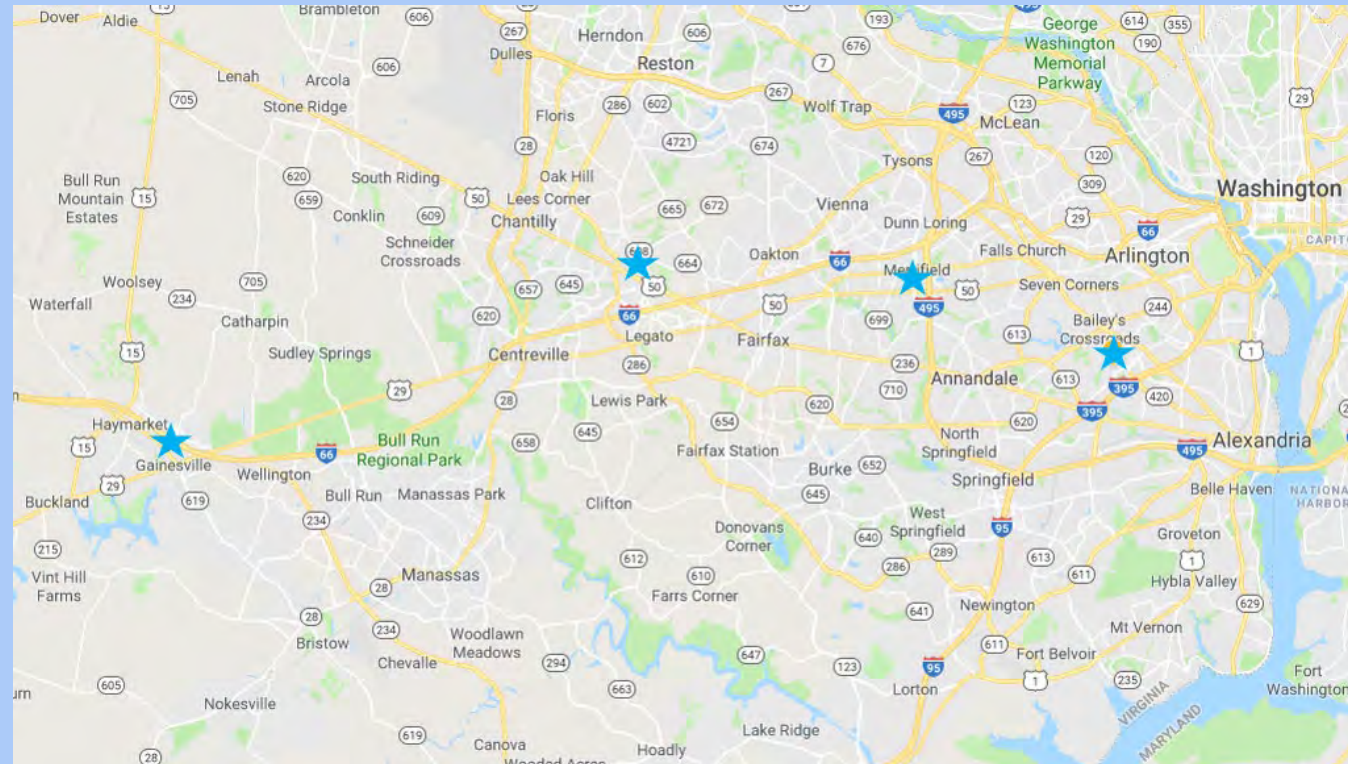
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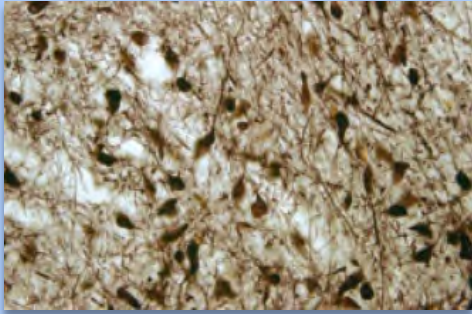


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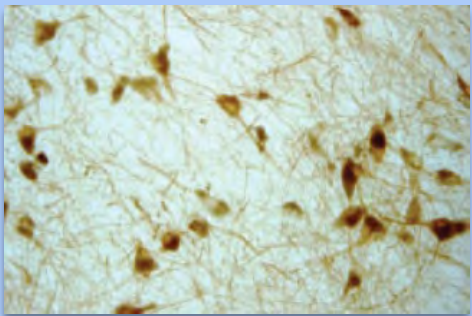
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# WHAT CAUSE PARKINSON'S DISEASE?

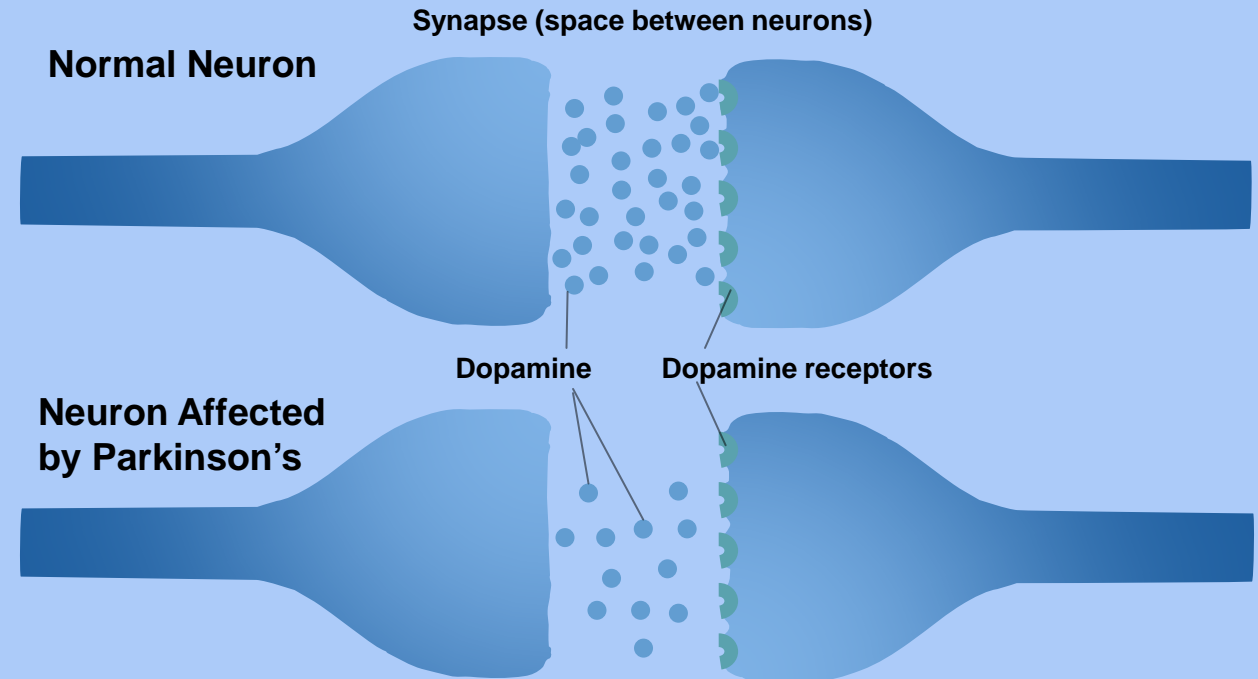
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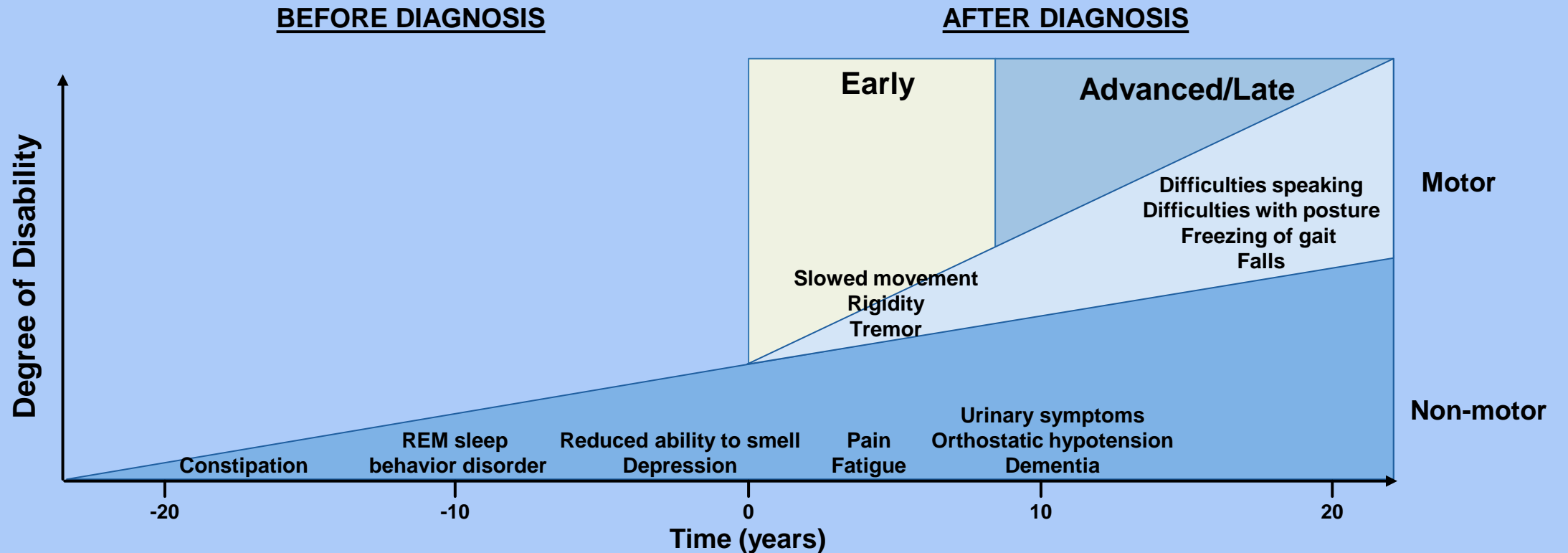


**Brain Cells with Parkinson's Disease**



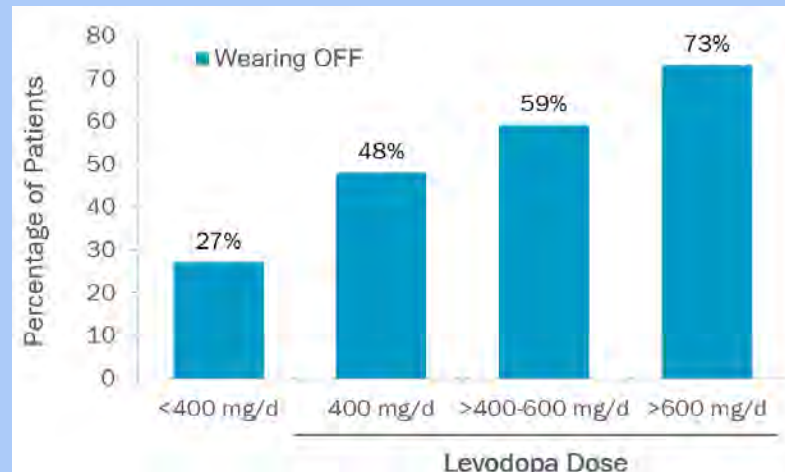
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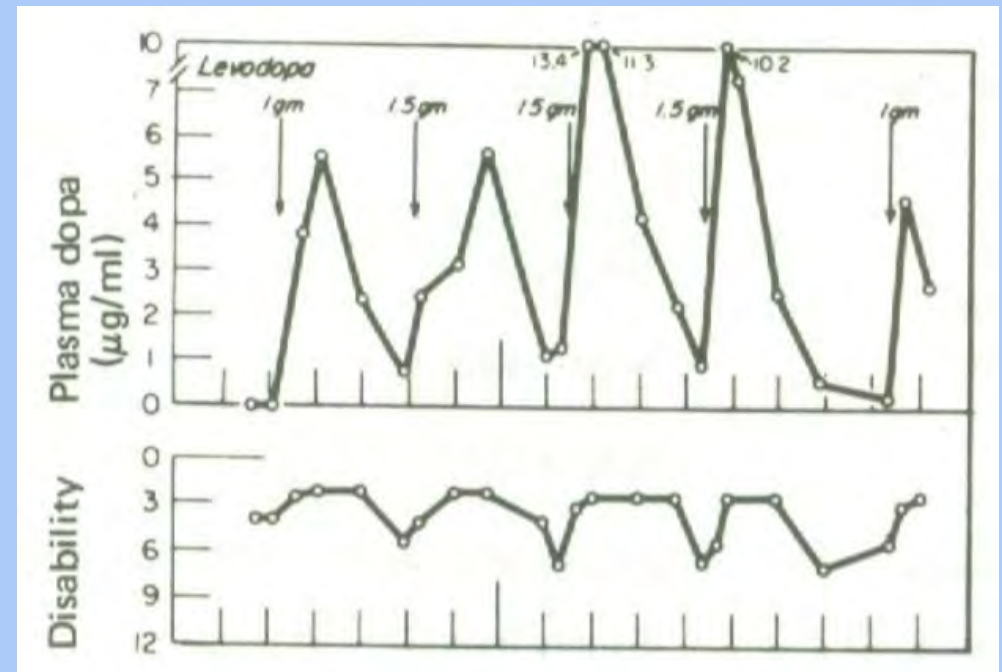
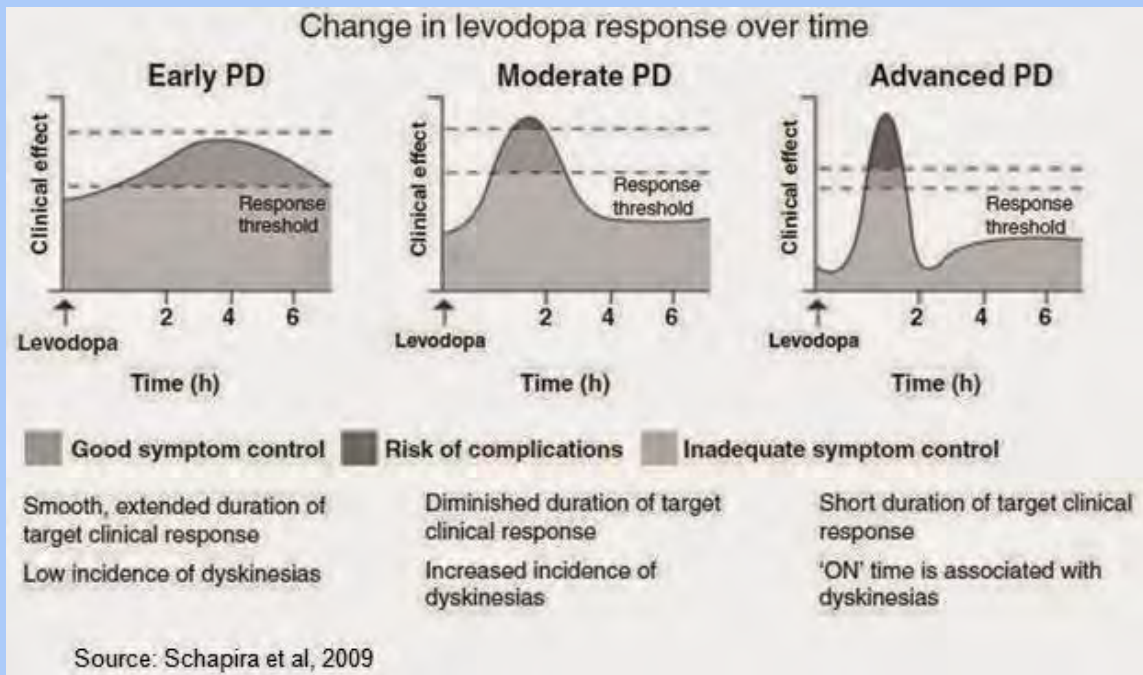
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# WHY DOES PD CHANGE OVER TIME?

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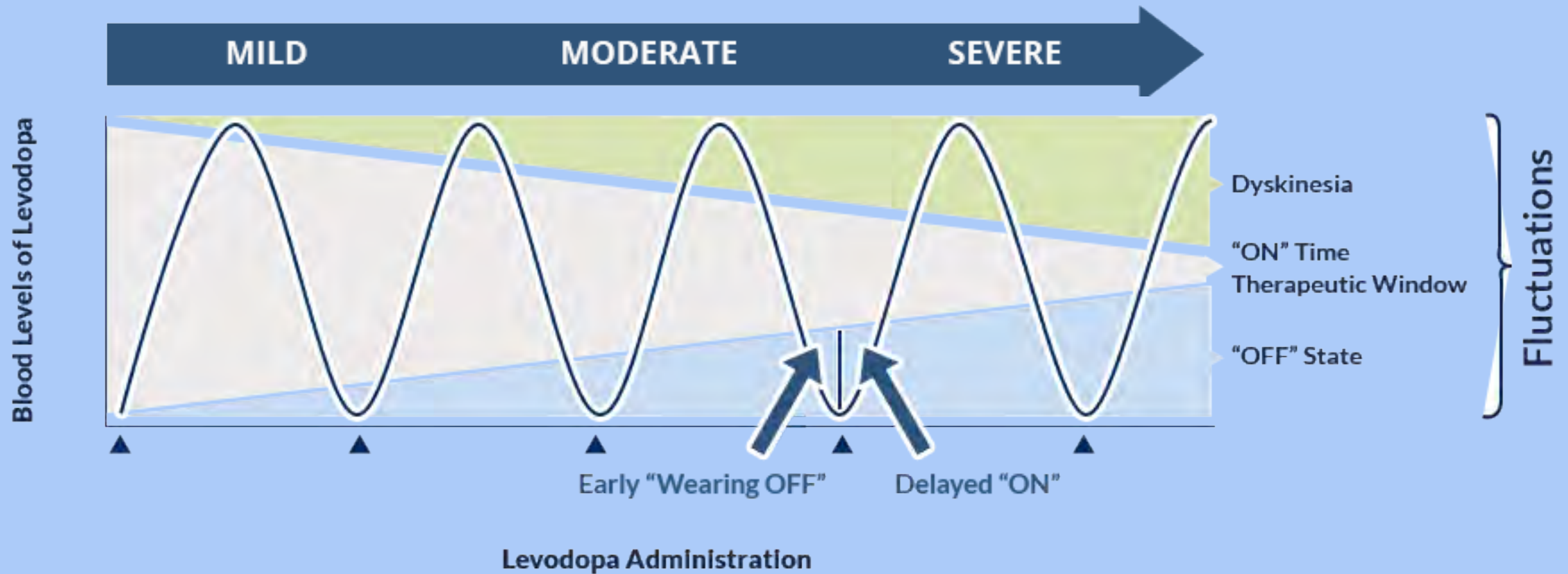
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# CARBIDOPA – LEVODOPA



# APPROACH TO THERAPY

## Classic

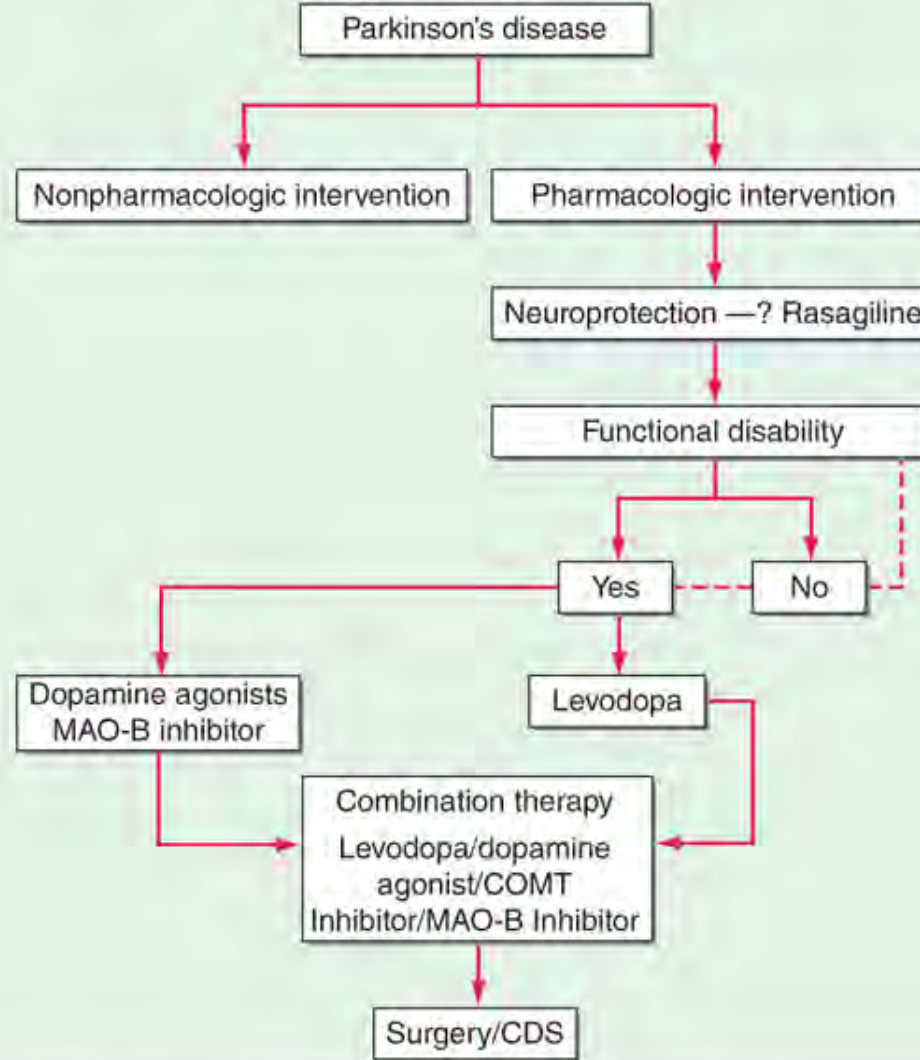
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## GENERAL TREATMENT ALGORITHM

Varies based on:  
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Comfort  
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Industry interaction  
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# TECHNOLOGY

- **DUOPA Intestinal Gel**
- **Focused Ultrasound**
- **Deep Brain Stimulation**

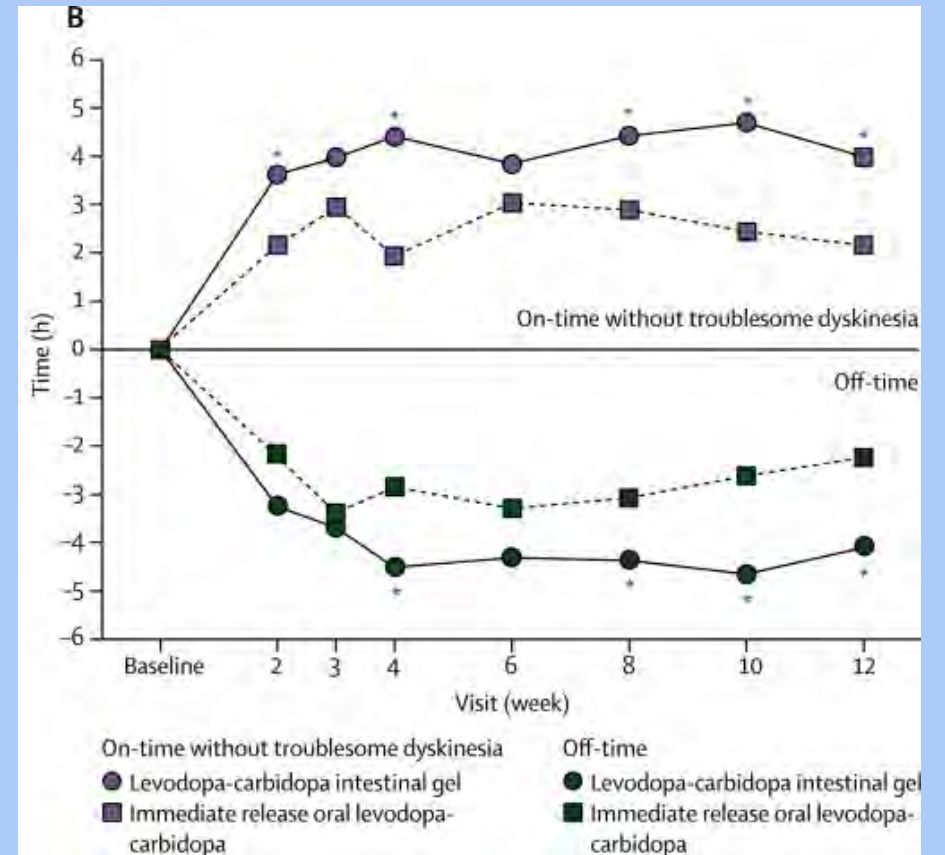


# CONSTANT DELIVERY OF LEVODOPA

## Duopa

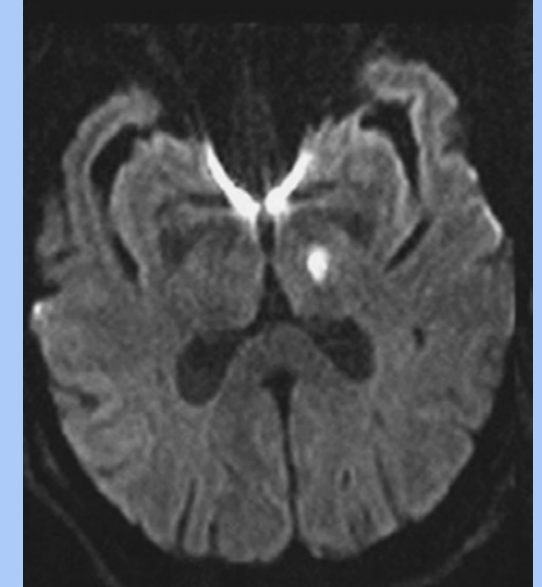
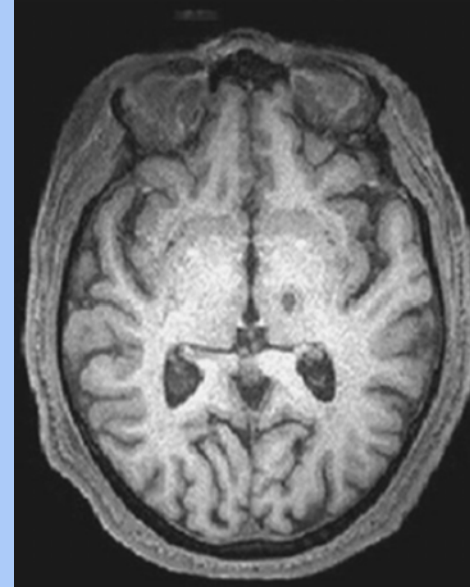
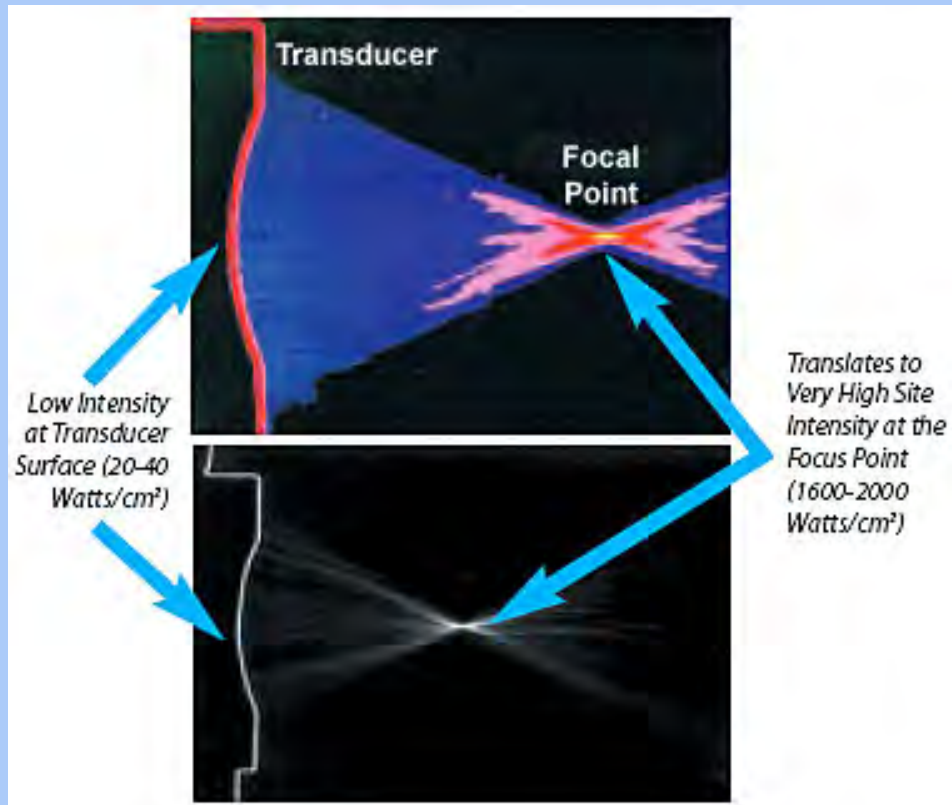
- Dopamine gel continuously administered via intra-intestinal pump
- Provides steady delivery of levodopa without the fluctuations of oral medication
- Off time decreased by 4h and on time increased by 4h<sup>1</sup>

**Duopa**  
carbidopa/levodopa  
enteral suspension  
4.63 mg/20 mg per mL



# FOCUSED ULTRASOUND (FUS)

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





# DEEP BRAIN STIMULATION (DBS)

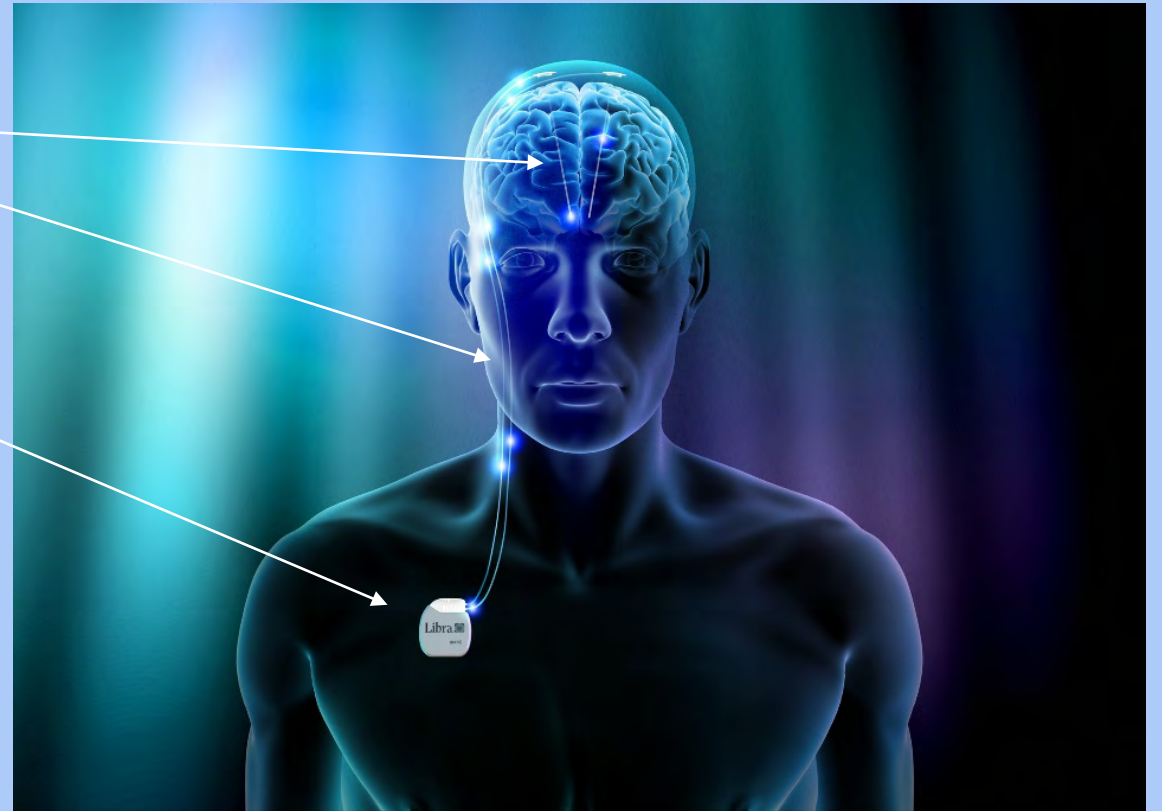
**1990s – DBS emerged as safer treatment with significantly longer duration of action compared to lesioning; no ‘burnout’.**

- Surgically implanted device to deliver a controlled stimulation of electricity to a specific region of the brain.
- Implanted in 2 step procedure, then programmed as outpatient.
- Unlike previous surgeries for PD (pallidotomy or thalamotomy), DBS does not damage healthy brain tissue by destroying nerve cells.
- Removable, if necessary, with little to no tissue damage.\*



# DEEP BRAIN STIMULATION (DBS)

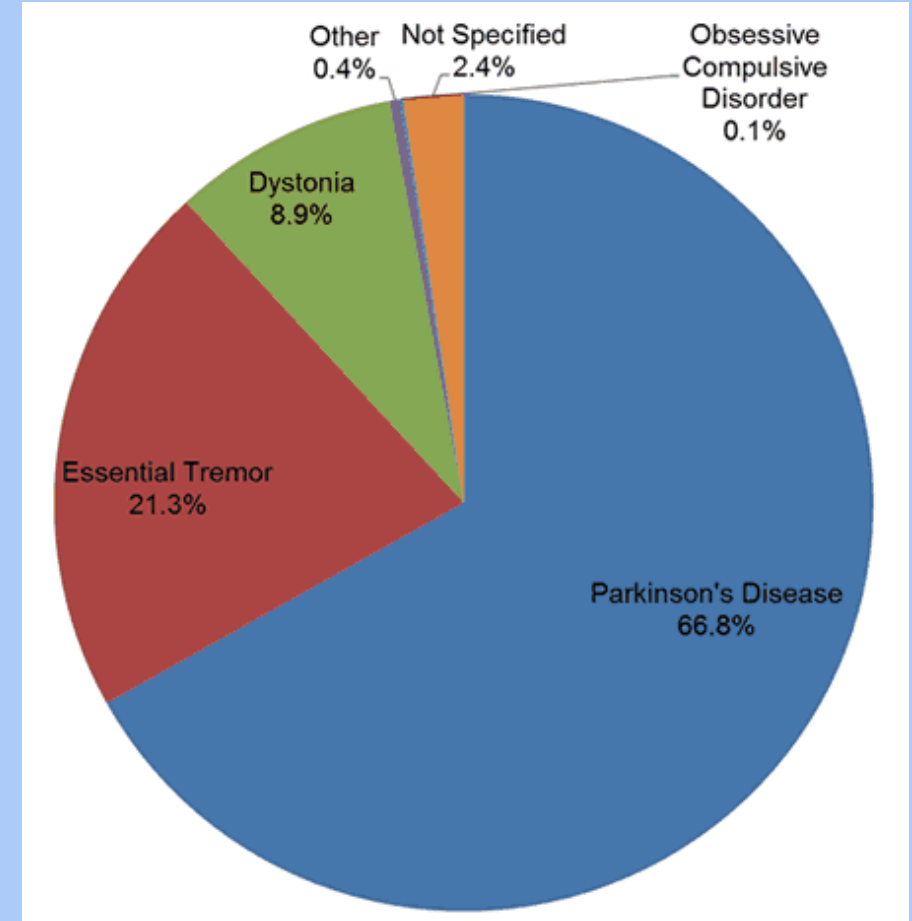
- The DBS system consists of three components:
  - Intracranial Lead
  - Extension connecting lead and generator
  - Implanted pulse generator (neurostimulator)
- Unilateral or bilateral leads
- Proper patient selection is key



# DBS INDICATIONS

- DBS is an FDA indicated surgical procedure for the treatment of movement disorders, such as:
  - Parkinson's Disease
  - Essential Tremor
  - Dystonia
- FDA approved:
  - Essential tremor in 1997
  - Parkinson's disease in 2002
  - Dystonia in 2003

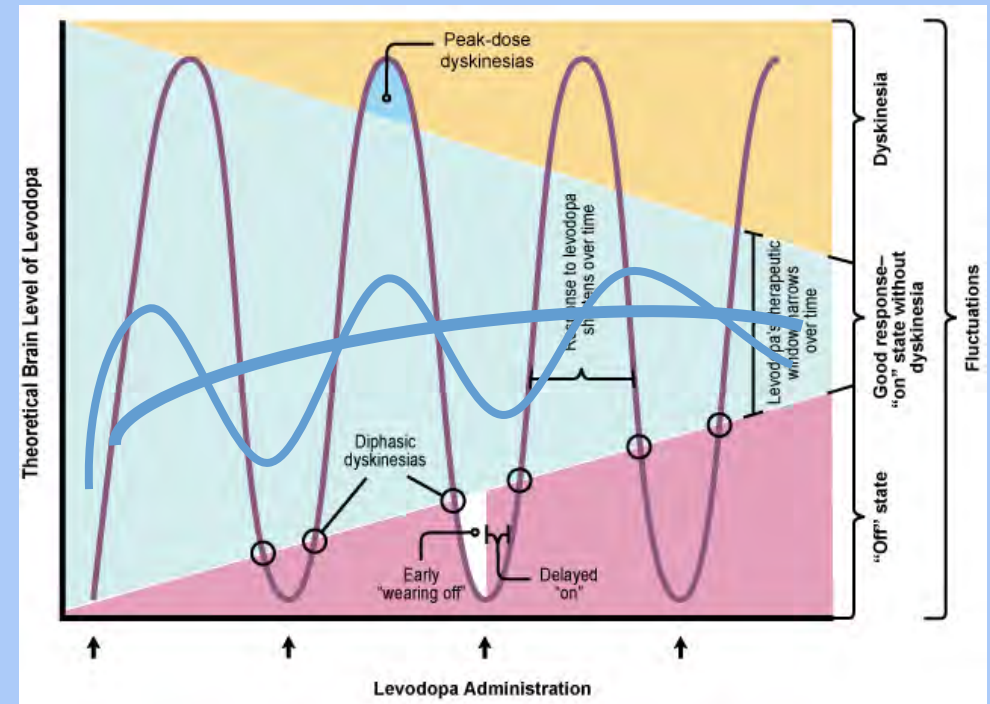
Covered by all insurance providers.



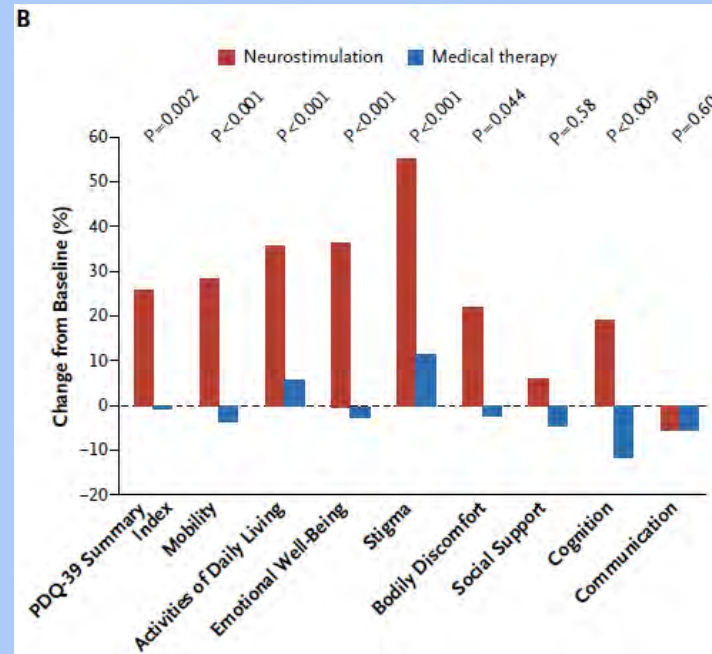
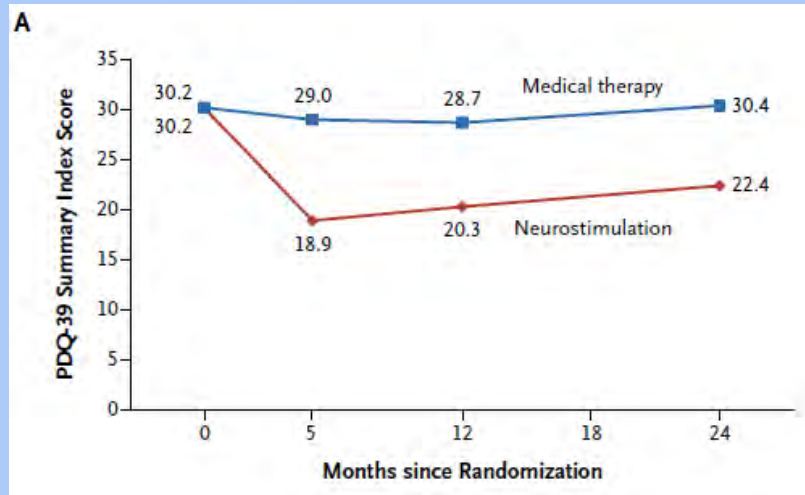
# BENEFIT FOR OUR PATIENTS

## Parkinson's Disease:

- 80-90% of patients note improvement
- 60% reduction in medications
- 60% reduction in dyskinesias
- 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



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

## Neurostimulation for Parkinson's Disease with Early Motor Complications

W.M.M. Schuepbach, J. Rau, K. Knudsen, J. Volkmann, P. Krack, L. Timmermann, T.D. Hälbig, H. Hesekamp, S.M. Navarro, N. Meier, D. Falk, M. Mehdorn, S. Paschen, M. Maarouf, M.T. Barbe, G.R. Fink, A. Kupsch, D. Gruber, G.-H. Schneider, E. Seigneure, A. Kistner, P. Chaynes, F. Ory-Magne, C. Brefel Courbon, J. Vesper, A. Schnitzler, L. Wojtecki, J.-L. Houeto, B. Bataille, D. Maltête, P. Damier, S. Raoul, F. Sixel-Doering, D. Hellwig, A. Gharabaghi, R. Krüger, M.O. Pinsker, F. Amtage, J.-M. Régis, T. Witjas, S. Thobois, P. Mertens, M. Kloss, A. Hartmann, W.H. Oertel, B. Post, H. Speelman, Y. Agid, C. Schade-Brittinger, and G. Deuschl, for the EARLYSTIM Study Group\*

- **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

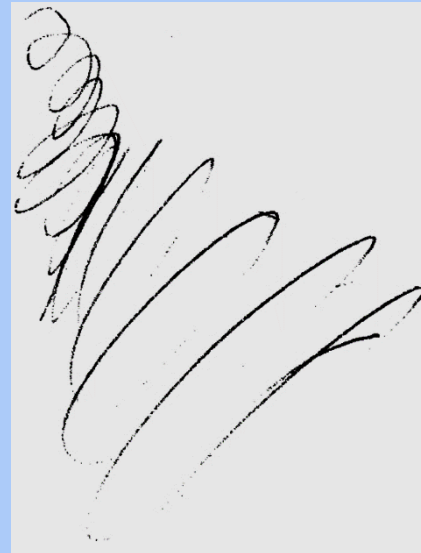
- **Results** UPDRS-III “off” rest tremor score change from baseline to 24 months was worse in patients receiving ODT vs DBS + ODT ( $p = 0.002$ ). Rest tremor slopes from baseline to 24 months favored DBS + ODT both “off” and “on” therapy ( $p < 0.001$ ,  $p = 0.003$ , respectively). More ODT patients developed new rest tremor in previously unaffected limbs than those receiving DBS + ODT ( $p = 0.001$ ).
- **Conclusions** These results suggest the possibility that DBS in early PD may slow rest tremor progression. Future investigation in a larger cohort is needed, and these findings will be tested in the Food and Drug Administration–approved, phase III, pivotal, multicenter clinical trial evaluating DBS in early PD.
- **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

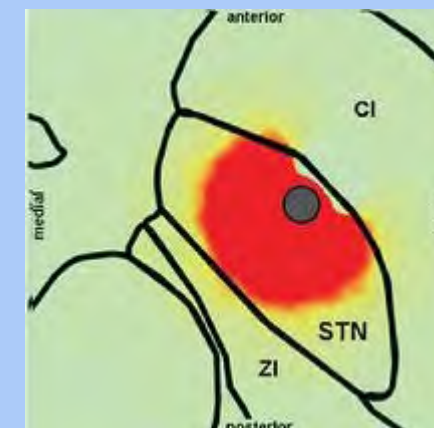
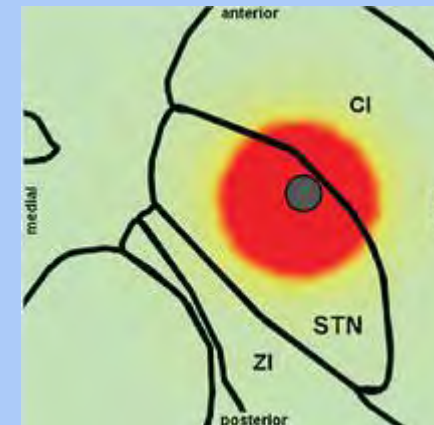
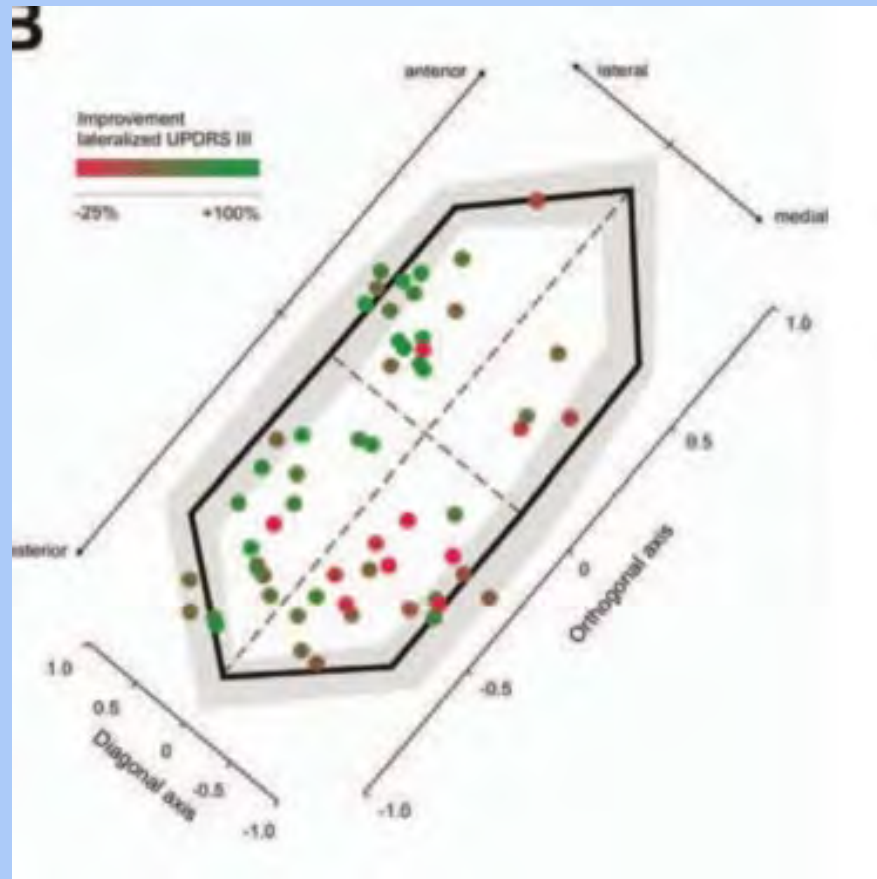
# AN EXPANDING FIELD

- Directional stimulation
- Improved technology
- Smaller technology, thinner
- Longer battery life



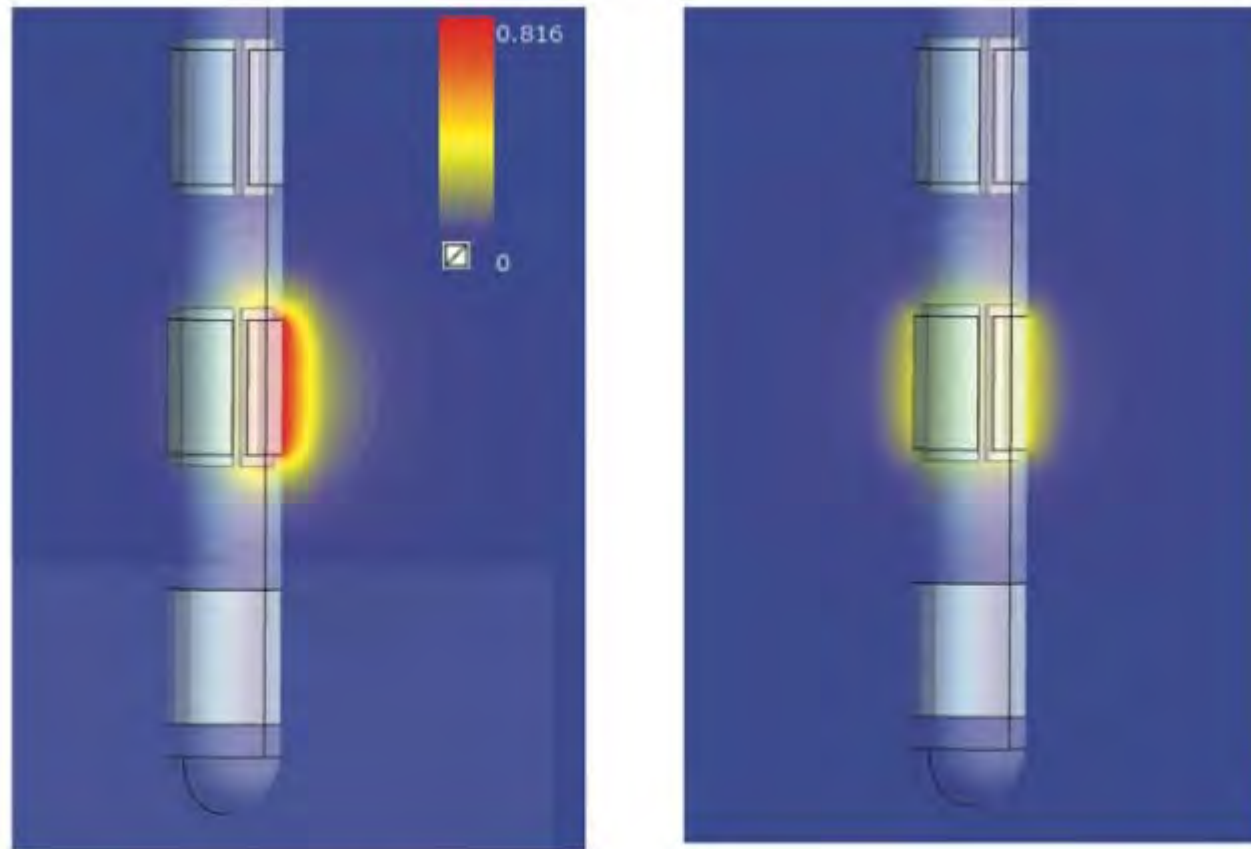
Boston  
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# DIRECTIONALITY, THE PRESENT AND FUTURE OF STIM





# DIRECTIONALITY, THE PRESENT AND FUTURE OF STIM



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

# COMPETITION ONLY BENEFITS THE PATIENT

3 years ago



NOW



Boston  
Scientific

# 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



# TO THE FUTURE

- Longer-acting levodopa formulations (10 hours or greater)
- New inhibitors
- Sublingual, pump-based formulations
- Improved technology
- Targeted protein therapy
- Cure

All of this equals

**HOPE**

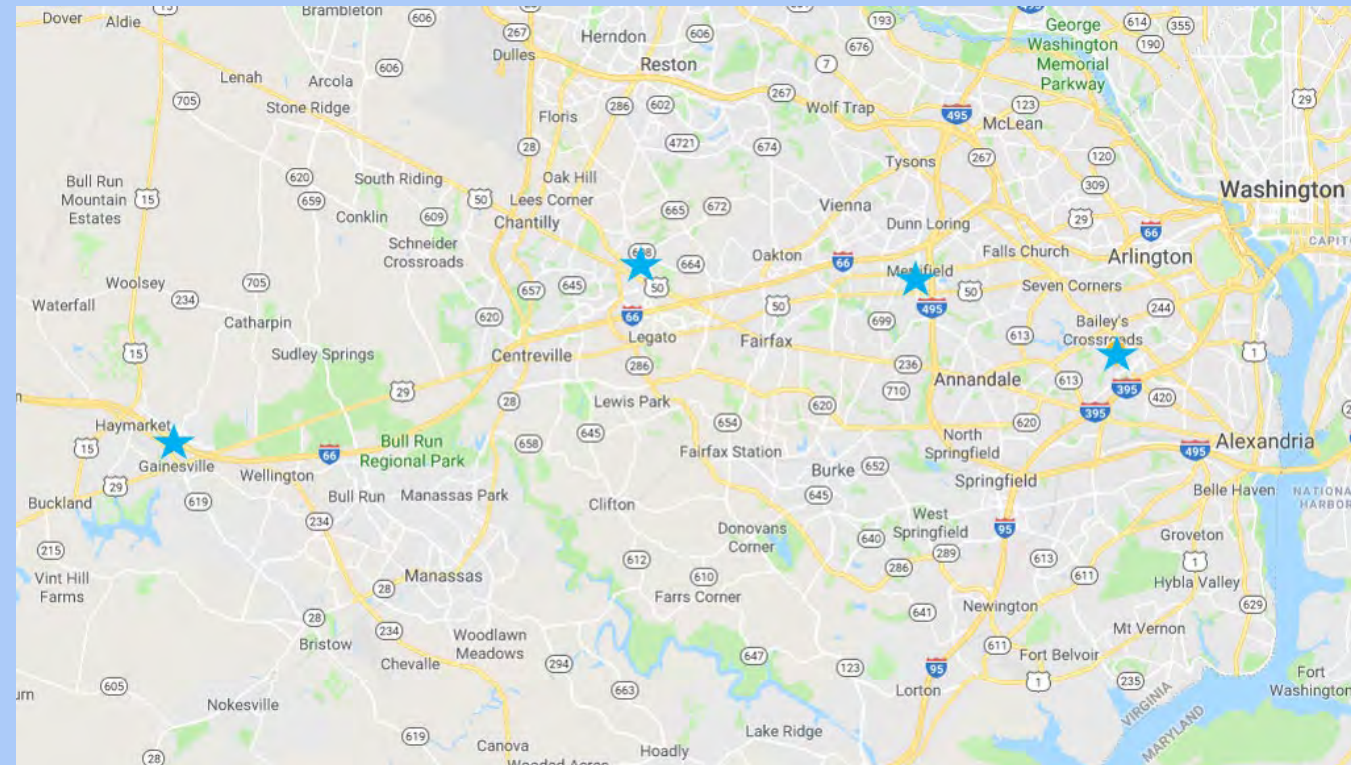
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# THANK YOU – Q&A WITH OUR TEAM

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