

This project was made possible by support from Dent Family Foundation, Inc.

## BACKGROUND

- Parkinson's disease (PD)** is a neurodegenerative disorder characterized by motor dysfunction including **bradykinesia, rigidity, tremor, dyskinesia** and **dystonia**. **Non-motor symptoms** including mood and cognitive disorders, sleep disruption, and autonomic dysfunction are also common.
- Because the **endocannabinoid system** modulates neurotransmission involved in **motor function** and may provide **neuroprotective effects**, it has attracted interest as a possible target for treatment of PD.<sup>1,2</sup>
- New York State (NYS) approved the use of **medical cannabis (MC)** on July 5<sup>th</sup> 2014. **PD is a qualifying medical condition** under NYS guidelines if accompanied by one of the following conditions: cachexia or wasting syndrome, severe or chronic pain, severe nausea, seizures, severe or persistent muscle spasms, PTSD or opioid use disorder.
- Preclinical data and anecdotal/observational reports have suggested **potential for MC to provide benefit in treating some PD motor and non-motor symptoms**; however, data from controlled studies is scarce and mixed, and concerns exist regarding possible adverse effects (AEs).<sup>1,3,4</sup>
- Due in part to regulatory barriers restricting clinical research on cannabis, robust efficacy and safety data- as well as long-term real world and outcomes data- are lacking.

## PURPOSE

- This study aims to **evaluate the impact of MC treatment on PD symptoms and adverse effects (AEs)** associated with MC treatment in PD patients.
- The impact of medical cannabis treatment on other patient outcomes, including concomitant medication use, was also explored.

## METHODS

- A **retrospective chart review** of patients (ages 18+) diagnosed with idiopathic PD and receiving treatment with medical cannabis was conducted.
- Objective and subjective data pertaining to Parkinson's Disease symptoms, medical cannabis treatment, and concomitant medications were collected following initiation of medical cannabis.
- Adverse events considered related to medical cannabis and reason for discontinuation were also recorded.

## REFERENCES

- Kluger B, Triolo P, Jones W, Jankovic J. The therapeutic potential of cannabinoids for movement disorders. *Mov Disord*. 2015;30(3):313-327.
- Pacher P, Bálkai S, Kúnos G. The endocannabinoid system as an emerging target of pharmacotherapy. *Pharmacol Rev*. 2006;58(3):389-462.
- Barbara S, Koppel, John G.M, Brust, Terry Fife, Jeff Bronstein, Sarah Youssef, Gary Gronseth, David Gloss. Systematic review: Efficacy and safety of medical marijuana in selected neurologic disorders. *Neurology* Apr 2014, 82 (17) 1556-1563
- National Academies of Sciences, Engineering, and Medicine. 2017. The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research. Washington, DC: The National Academies Press

## DISCLOSURES

**Disclosures:** Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation: Bennett Myers, MD: received compensation from Biogen, Teva, Novartis, and Genentech. Michelle Rainka, PharmD: Nothing to disclose. Traci Aladeen, PharmD: Nothing to disclose. Erica Westphal: Nothing to disclose. Alexandra Begley: Nothing to disclose. Stefania Florea: Nothing to disclose. Kory Zelen: Nothing to disclose. Laszlo Mechtler, MD FAAN, FASN: Dr. Mechtler is the medical director of Jushi Co. Dr. Mechtler has received personal compensation for consulting, serving on a scientific advisory board, speaking, or other activities with Teva, Promius, Allergan, Avanir, and Amgen. Dr. Mechtler has received research support from DENT Family Foundation.

## RESULTS

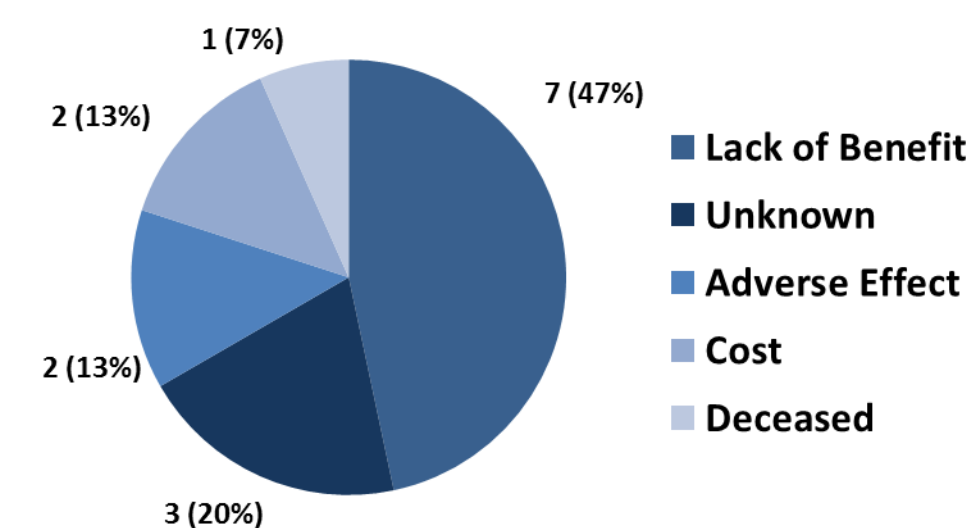
Table 1. Inclusion Overview

MC patients screened	138
Never initiated MC	2
No idiopathic PD Diagnosis	15
Never attended followup	52
Patients Included	69

Table 3. Cannabis Treatment

Starting Ratio (THC:CBD)	1:20	2
	1:6	1
	1:4	3
	1:1	64
	2:1	2
Starting Formulation	20:1	3
	Oral Tincture	68
	Oral Capsule	1
	Inhaled Vaporizer	3
# of Formulations (Mean)		1.06

Figure 1. Reason for Discontinuation (N=14)



**N=55 (80%) remained on MC at end of study period. Mean duration of treatment was 353 (+/-216) days.**

Table 5. Adverse Events

Somnolence or Fatigue	15 (22%)	Sleep Disturbance	1 (1%)
Confusion or Cognitive Impairment	8 (12%)	Irritability	1 (1%)
Dizziness	6 (9%)	Parasomnia	1 (1%)
Anxiety	4 (6%)	Shortness of Breath	1 (1%)
Euphoria or Feeling "High"	3 (4%)	Cough (Vapor)	1 (1%)
Vision Changes	2 (3%)	Airway Irritation (Vapor)	1 (1%)
Worsening Motor Function	2 (3%)	Nausea and Vomiting	1 (1%)
Hallucinations or Delusions	2 (3%)	Bad Taste (Tincture)	1 (1%)
Depression	1 (1%)	Burning Sensation in Eyes	1 (1%)
Decreased Appetite	1(1%)	Increased Appetite	1 (1%)

**32 patients (46%) experienced at least 1 AE. Adverse events lead to discontinuation in 2 patients (fatigue; confusion, anxiety and mood change). 1 patient death was reported. Cause of death is unknown (was not recorded in patient chart); patient was in hospice care due to progression of PD symptoms at the time of death. This was considered unrelated to MC.**

Table 2. Population Characteristics

Mean Age at Treatment Start, Years	72 (±9)	
Male	46 (66%)	
Female	23 (33%)	
History of Recreational Cannabis Use	14 (20%)	
Primary Condition	Parkinson's Disease	67 (97%)
	Cancer	1(1%)
	Chronic Pain	1(1%)
Complicating Condition	Chronic Pain	43 (62%)
	Spasticity	31 (45%)
	Nausea	2 (3%)

Table 4. Concomitant Medications

Patients on Opioid at Baseline	25
Decrease in opioid	10
Discontinuation of opioid	4
Increase in Opioid	2
Patients on Muscle Relaxer at BL	4
Decrease in muscle relaxer	0
Discontinuation of muscle relaxer	2
Increase in muscle relaxer	0
Patients on Benzodiazepine at BL	20
Decrease in benzodiazepine	3
Discontinuation of benzodiazepine	3
Increase in benzodiazepine	0
Patients on PD medication at BL	62
Decrease in PD medications	5
Discontinuation of PD medications	1
Increase in PD medications	9

Figure 2. Selected PD Symptoms Reported at Baseline

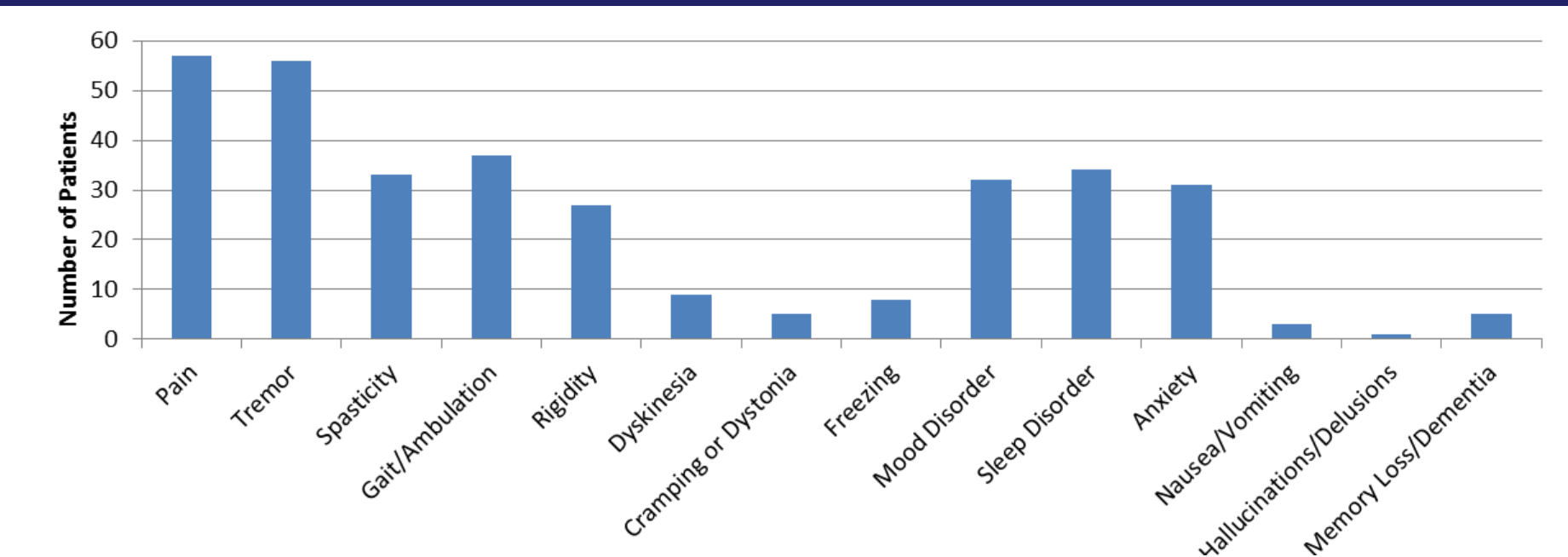
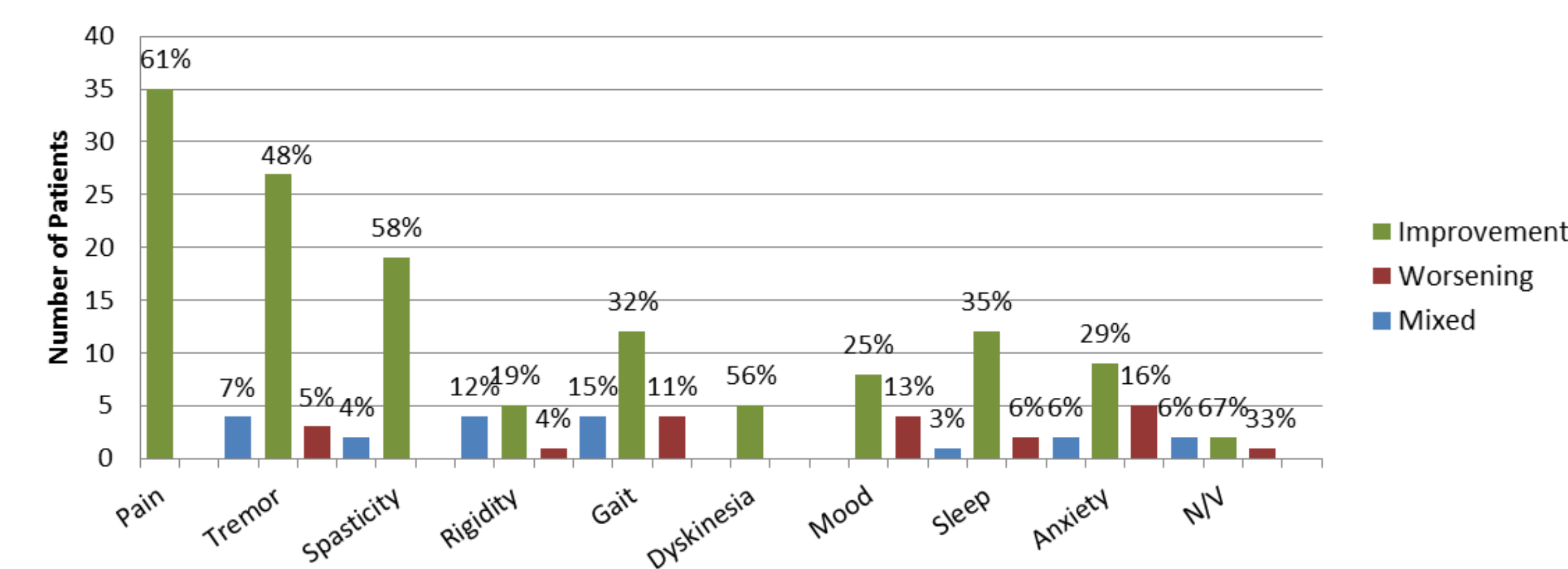


Figure 3. Selected Domains of Symptom Improvement or Decline Reported During MC Treatment



## DISCUSSION AND CONCLUSIONS

- Most patients reported benefit from medical cannabis, with **61 patients (88%) reporting improvement** in at least 1 symptom domain.
- Patients were able to **decrease and discontinue other medications** including opioids, benzodiazepines and muscle relaxants.
- Over 50% of patients on treatment with opioid pain medications were able to reduce their dose or discontinue treatment while on MC (p<0.001).**
- Low rate of discontinuation due to adverse effects was observed (2 patients).** The most common AE was **somnolence/fatigue (22%)**.
- High cost of MC treatment** is a significant barrier to treatment in many cases, and may have contributed to high rate of loss of follow-up after initial consult (N=52 patients).
- Neuropsychiatric AEs** (including confusion/cognitive impairment, anxiety, euphoria, and perceptual disturbances) were noted in multiple patients. Clinicians should be aware of this risk when considering MC for PD patients, who are at elevated risk of neuropsychiatric symptoms at baseline.
- Many classic PD symptoms, including bradykinesia and tremor, are not among the qualifying complicating conditions for MC in NY.** Most patients in this study sought MC treatment for chronic pain or spasticity. This may limit the generalizability of our cohort to the wider PD population.
- Limitations of this study include its **retrospective, open-label design**. Lack of followup for some patients may have precluded capturing complete information about efficacy and adverse events.