Research Confirms Patients with Essential Tremor and Parkinson's Disease Have Higher Comorbidities and Costs

Real-world claims data connects patients with essential tremor and Parkinson's disease with a higher prevalence of comorbidities, including psychiatric disorders, a greater number of falls, and rates of substance abuse

SAN MATEO, CA -- May 18, 2022 – <u>Cala Health</u>, the bioelectronic medicine leader setting a new standard of patient care for chronic disease, today announced new clinical research presented at <u>ISPOR 2022</u>.

The study, titled "Co-Morbidities and Mechanistic Similarities of Essential Tremor and Parkinson's Disease and Resulting Diagnostic Challenges," analyzed comorbidities among patients diagnosed with essential tremor and Parkinson's disease using claims data from Truven Health Analytics MarketScan® Commercial and Medicare Supplemental databases (2013-2019).

The results show that patients 65 years or older in the essential tremor (ET) and Parkinson's disease cohorts had a higher prevalence of the following disorders compared to those without ET or Parkinson's disease: accidental falls (14.1% vs. 24.5% vs. 2.0%); bradykinesia (14.9% vs. 10.0% vs. 0.3%); depression (22.4% vs. 25.1% vs. 14.4%); fatigue (28.1% vs. 35.7% vs. 17.4%); and sleep disorders (30.3% vs. 30.5% vs. 14.3%). These findings are consistent with Cala's earlier research, presented at The American Academy of Neurology Annual Meeting in April 2022, which shows that patients with ET (compared to those without ET) have a higher prevalence of depression (25.6% vs. 15.3%), anxiety (27.7% vs. 15.5%) and total psychiatric disorders (45.9% vs. 31.1%).

Additionally, of those patients who had pharmacy and medical records ≥12-months prior to and ≥24-months following the index date, only 10.7% of ET patients did not have a diagnosis claim at any point for Parkinson's disease in their history, and 20.4% of Parkinson's disease patients did not have a diagnosis claim at any point for ET in their history. These shared characteristics may explain why many patients often have a diagnosis of both ET and Parkinson's disease within two years of their index date and suggest that the similarities between these patients may contribute to misdiagnosis.

"These findings suggest that ET and Parkinson's disease action tremor may have similar central origins," said Dhira Khosla, DO, co-author of the abstract and medical director at Cala Health. "This builds upon our earlier research presented at ISPOR last year,² which found that the average patient with ET has 5.3 comorbidities, further demonstrating the need for better therapeutic offerings for this population."

On average, people living with ET have multiple comorbidities, traditionally requiring several medications that care teams need to consider when making clinical decisions. Prior to Cala TAPS therapy, 94% of patients in the study tried medication and 77% tried more than one.³ Available pharmacological treatments are often inadequate as they

¹ Increased Healthcare Cost and Mental Health Burden Among Patients with Essential Tremor: A Retrospective Observational Study in a Large U.S. Commercially Insured and Medicare Advantage Population. Dai, D. et al.

² Patient Characteristics and Comorbidities in Patients with Essential Tremor: A Retrospective Observational Study in a United States Commercially Insured and Medicare Advantage Population. Dai, D. et al. Value in Health, Volume 24, S167

³ Real-World Evidence for Symptomatic Relief in Essential Tremor Using Transcutaneous Afferent Patterned Stimulation Therapy. Rajagopal, A. et al. Value in Health, Volume 23, S642

frequently do not effectively reduce tremor severity and can cause adverse events leading to discontinuation. Based on clinical evidence and peer-recommended treatment guidelines, Cala TAPS therapy is a valid treatment option as an add-on or follow-up to first-line pharmacologic therapy prior to invasive surgical approaches.⁴

Disclaimer: Cala TAPS therapy is not currently indicated for treating hand tremor in Parkinson's Disease patients. Cala was granted breakthrough device designation for TAPS therapy in Parkinson's disease patients, and these data will be submitted for U.S. FDA review.

About Cala Health

Cala is a bioelectronic medicine company transforming the standard of care for chronic disease. The company's wearable neuromodulation therapies merge innovations in neuroscience and technology to deliver individualized peripheral nerve stimulation, and its vertically integrated commercial model is reshaping the delivery of prescription therapies. Cala's lead product, Cala TAPS therapy, is the only non-invasive prescription therapy for essential tremor. New therapies are under development in Parkinson's disease and other indications in neurology, as well as targets in psychiatry, cardiology, and autoimmune disorders. The company is headquartered in the San Francisco Bay Area and backed by leading investors in both healthcare and technology.

Indication: Cala therapy is indicated to aid in the temporary relief of hand tremors in the treated hand following stimulation in adults with essential tremor.

Caution: Federal law restricts this device to sale by or on the order of a physician.

Prior to use, refer to the product labeling for complete product instructions for use, contraindications, warnings, and precautions at https://calatrio.com/Safety.

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⁴ International Essential Tremor Foundation. Essential Tremor in Adult Patients. Accessed at http://eguideline.gui