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Levodopa-carbidopa intestinal gel may prove more effective for long-term treatment of PD

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Although levodopa remains the "gold standard" to effectively control motor deficits in the treatment of early stage Parkinson's disease (PD), it loses effectiveness as the disease progresses. After four to six years of treatment with oral medications for Parkinson's disease, about 40% of patients experience lack of muscle control (dyskinesias), end-of-dose wearing off, and fluctuations in "On/Off" states. By nine years of treatment, about 90% will suffer these effects.

Continuous dosing via a levodopa-carbidopa intestinal gel (LCIG, now carbidopa and levodopa enteral suspension in the U.S) directly into the small intestine may be the key to reducing the motor complications associated with long-term levodopa use. In the current issue of the *Journal of Parkinson's Disease*, researchers report on the safety and efficacy of LCIG therapy over a one-year period.

"This study demonstrated continued safety and tolerability as well as improvement in on time without troublesome dyskinesia in patients with advanced PD," explained lead investigator John T. Slevin, MD, MBA, Professor of Neurology and Vice Chair of Research, Department of Neurology, University of Kentucky. "Patients on long-term, open-label LCIG treatment sustain the efficacy and quality-of-life improvement achieved during the first 12 weeks of treatment. The safety profile of the LCIG system is stable over the longer-term and is acceptable to patients as evidenced by a low rate of discontinuation. LCIG has the potential to address a significant unmet need in this patient population with limited therapeutic options."

Prior to the one-year study, 66 patients completed a double-blind, double-dummy trial in which they were randomized to either LCIG or immediate-release oral levodopa-carbidopa (LC-IR), identified as continuing-LCIG vs. LCIG-naïve cohorts, respectively. The one-year phase 3, open-label LCIG, multicenter, continuation of treatment study enrolled 62 of the original 66 subjects.

LCIG system provided continuous levodopa infusion through a portable infusion pump directly into patients' proximal small intestine, largely bypassing issues of erratic gastric emptying and absorption; thus producing more stable plasma concentrations of levodopa.

At baseline, the continuing-LCIG group had both greater decreased "Off" time and increased "On" time without troublesome dyskinesia, compared to the LCIG-naïve group, reflecting improvement from treatment during the double-blind study. The continuing-LCIG group also had better scores using the Unified Parkinson's Disease Rating Scale (UPDRS), the 39-item Parkinson's Disease Questionnaire (PDQ39), and were judged to be less ill using the Clinical Global Impression-Severity scale (CGI-S).

At the end of the study a majority of patients in both groups were assessed as having improved on the Clinical Global Impression-Improvement scale (CGI-I). Mean CGI-I scores at the final assessment were statistically significant for both the continuing-LCIG and LCIG-naïve treatment groups (2.1 and 2.3, respectively). Quality-of-life measures showed sustained improvement for the continuing-LCIG group but not for the LCIG-naïve group from baseline to final visit.

Adverse effects (AEs) were rated as mild, moderate, or severe by the investigators, and evaluated for their potential relationship to the drug and device in the study. Forty-eight patients (77%) reported at least one AE assessed as possibly or probably related to treatment. Most AEs were

mild to moderate in severity. Only three subjects (4.8%) discontinued due to an AE. AE incidence gradually decreased over the year, from 52% to 24%, when examined in 30-day increments.

More information: iospress.metapress.com/content …1341251/fulltext.pdf

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