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Efficacy of Opicapone and Levodopa with Different Levodopa Daily Doses in Parkinson's Disease Patients with Early Motor Fluctuations: Findings from the Korean ADOPTION Study

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Abstract : The effective management of wearing-off is a key driver of medication changes for patients with Parkinson's disease (PD) treated with levodopa (L-DOPA). While L-DOPA is well tolerated and efficacious, its clinical utility over time is often limited by the development of complications such as dyskinesia. Still, common first-line option includes adjusting the daily L-DOPA dose followed by adjunctive therapies usually counting for the L-DOPA equivalent daily dose (LEDD). The LEDD conversion formulae are a tool used to compare the equivalence of anti-PD medications. The aim of this work is to compare the effects of opicapone (OPC) 50 mg, a catechol-O-methyltransferase (COMT) inhibitor, and an additional 100 mg dose of L-DOPA in reducing the off time in PD patients with early motor fluctuations receiving different daily L-DOPA doses. OPC was found to be well tolerated and efficacious in advanced PD population. This work utilized patients' home diary data from a 4-week Phase 2 pharmacokinetics clinical study. The Korean ADOPTION study randomized (1:1) patients with PD and early motor fluctuations treated with up to 600 mg of L-DOPA given 3–4 times daily. The main endpoint was change from baseline in off time in the subgroup of patients receiving 300–400 mg/day L-DOPA at baseline plus OPC 50 mg and in the subgroup receiving >300 mg/day L-DOPA at baseline plus an additional dose of L-DOPA 100 mg. Of the 86 patients included in this subgroup analysis, 39 received OPC 50 mg and 47 L-DOPA 100 mg. At baseline, both L-DOPA total daily dose and LEDD were lower in the L-DOPA 300–400 mg/day plus OPC 50 mg group than in the L-DOPA >300 mg/day plus L-DOPA 100 mg. However, at Week 4, LEDD was similar between the two groups. The mean (±standard error) reduction in off time was approximately three-fold greater for the OPC 50 mg than for the L-DOPA 100 mg group, being -63.0 (14.6) minutes for patients treated with L-DOPA 300–400 mg/day plus OPC 50 mg, and -22.1 (9.3) minutes for those receiving L-DOPA >300 mg/day plus L-DOPA 100 mg. In conclusion, despite similar LEDD, OPC demonstrated a significantly greater reduction in off time when compared to an additional 100 mg L-DOPA dose. The effect of OPC appears to be LEDD independent, suggesting that caution should be exercised when employing LEDD to guide treatment decisions as this does not take into account the timing of each dose, onset, duration of therapeutic effect and individual responsiveness. Additionally, OPC could be used for keeping the L-DOPA dose as low as possible for as long as possible to avoid the development of motor complications which are a significant source of disability.

Keywords : opicapone, levodopa, pharmacokinetics, off-time
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