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EFFECTIVENESS OF STALEVO DRUG USAGE IN PARKINSON'S PATIENTS

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Abstract: Parkinson's disease (PD) is a neurodegenerative disorder that affects patients' quality of life, with primary motor symptoms such as tremor, muscle rigidity, and bradykinesia. Levodopa is the mainstay of PD therapy, but approximately 80% of patients experience motor complications, such as motor fluctuations and "wearing-off" after several years of therapy. This study aimed to evaluate the effectiveness of Stalevo, a combination of carbidopa, levodopa, and entacapone, in managing long-term motor complications in PD patients. Methods included a search of articles in PUBMED and Google Scholar using the keywords "Stalevo" and "Parkinson's disease." The study revealed that Stalevo was effective in prolonging the duration of levodopa's effect, reducing the required levodopa dose, and improving patients' quality of life, particularly in patients with motor fluctuations. Although side effects such as dyskinesia and diarrhea may occur, Stalevo's overall safety profile is well-received. This study provides important insights into the management of motor complications in PD patients, but also emphasizes the need for monitoring for side effects and evaluating therapy in the early stages of the disease.

Keywords: Parkinson's Disease, Levodopa, Stalevo, Motor Complications, Patients

Introduction

Parkinson's disease (PD) is a neurodegenerative disorder characterized by three main motor symptoms: resting tremor, muscle rigidity, and bradykinesia, affecting approximately 1% of the population over the age of 60. PD is the second leading cause of neurodegenerative disorders after Alzheimer's disease in the elderly. Since its introduction 40 years ago, levodopa has become the most effective and acceptable symptomatic therapy for dopaminergic stimulation in patients with PD. Levodopa is commonly used in combination with a dopa-decarboxylase inhibitor (DDCI), such as carbidopa or benserazide, to prevent the conversion of levodopa to dopamine in the peripheral circulation, allowing more levodopa to reach the brain through active transport across the blood-brain barrier (Solla et al., 2010a). However, as the disease progresses, approximately 80% of patients who continue to receive levodopa experience disruptive motor complications, such as "wearing-off" symptoms, dyskinesias, and "on-off" mobility patterns. Approximately 10% of PD patients develop motor complications each year after starting levodopa treatment, and nearly 100% of patients experience these complications after 10 years of levodopa treatment (Reichmann, 2023). The exact cause of these motor fluctuations is not fully understood, but it is believed to be related to the short half-life of levodopa, which may cause atypical and pulsatile dopaminergic stimulation of dopamine receptors.

Levodopa remains the mainstay of pharmacological treatment for Parkinson's disease (PD) more than 50 years after its initial use. The continued use of levodopa in PD treatment underscores the importance of dopamine in the pathogenesis of the disease and the difficulty in finding alternative therapeutic targets. However, the use of levodopa is not without challenges. Most patients who use levodopa long-term eventually develop fluctuating motor responses to repeated oral doses (Jenner, 2023). The therapeutic benefit of each dose of levodopa becomes increasingly short-lived, leading patients to experience relapses of their Parkinson's symptoms before the next dose is administered. This

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"wearing-off" phenomenon is due to the pharmacokinetics of levodopa and can initially be controlled by adjusting the dose or dosing interval, using a sustained-release formulation, or adding a dopamine agonist. However, once developed, these wearing-off fluctuations often increase in duration and severity, leading to significant PD-related disability that can negatively impact patients' quality of life. These wearing-off fluctuations also negatively impact a number of non-motor symptoms of PD, including dysphagia, anxiety, depression, fatigue, excessive sweating, restlessness, pain, impaired concentration, dizziness, and bladder urgency. Furthermore, wearing-off fluctuations are often accompanied by the appearance of levodopa-induced dyskinesias, which can progress to involuntary movements indicative of severe motor impairment or dystonia. Dystonia often occurs at the peak of each therapeutic dose, although other patterns, including diphasic dyskinesias occurring at the beginning and end of the dosing cycle, can also be observed. These side effects highlight the importance of managing levodopa pharmacokinetics to reduce the risk of levodopa deficiency leading to wearing-off (too low levodopa levels) or dyskinesias (too high levodopa levels) (Solla et al., 2010b). The use of Stalevo, which combines levodopa with carbidopa and entacapon, aims to address these pharmacokinetic issues by increasing the duration of levodopa's therapeutic effect and reducing motor fluctuations. Entacapon, as a COMT inhibitor, helps prolong the duration of levodopa's action in the body by inhibiting dopamine degradation, thereby reducing symptoms of wearing-off and dyskinesia in PD patients (Sethi et al., 2009). Therefore, evaluating the effectiveness of Stalevo in managing long-term motor complications of levodopa therapy is crucial to improving the quality of life of Parkinson's patients and reducing the impairment caused by motor fluctuations and associated non-motor symptoms. Levodopa, despite its potential, has had a challenging clinical development journey. With suboptimal pharmacokinetics and pharmacodynamics—including poor absorption, rapid metabolism, a short plasma half-life, and an unacceptable side effect profile due to peripheral dopamine formation—levodopa nearly failed as a PD treatment. However, recognition of levodopa's peripheral and central metabolism, as well as the development of enzyme inhibitors that regulate key metabolic pathways, have helped optimize levodopa's use. These inhibitors, such as dopa-decarboxylase and COMT inhibitors, have become important adjunctive therapies that enhance levodopa's clinical effectiveness (Männistö et al., 2024). To address this issue, various therapeutic strategies have been developed to delay or prevent levodopa-induced complications, one of which is the use of Stalevo. Stalevo is a combination of levodopa, carbidopa, and entacapon, designed to enhance the effectiveness of levodopa treatment and reduce motor fluctuations associated with long-term treatment. Although Stalevo has been shown to be effective in reducing some motor symptoms and improving patients' quality of life, its effectiveness and impact on long-term complications remain important areas of research in the management of Parkinson's disease. Stalevo is a combination of levodopa, carbidopa, and entacapone (a COMT inhibitor) used to increase the stability of levodopa levels in plasma and improve motor symptoms in Parkinson's patients, especially those experiencing motor fluctuations such aswearing-offThis combination is in line with therapeutic guidelines, particularly in advanced Parkinson's disease, as entacapone can prolong the effects of levodopa and reduce the "off" time. Although considered "unique" in the context of pharmacotherapy, its use is tailored to the individual patient's clinical needs and should be monitored to prevent side effects such as orange urine discoloration or diarrhea. A multinational phase IIIb study published by Brooks et al. (2005) showed that Stalevo provided comparable results to the combination of levodopa/DDCI (a dopa-decarboxylase inhibitor) and entacapone given alone. This study involved 177 patients with Parkinson's disease who were experiencing "wearing-off." This study aimed to evaluate the effectiveness of Stalevo in Parkinson's patients in addressing motor complications that develop as a result of long-term levodopa therapy.

Method

Research Design

The search was conducted using the PUBMED, ScienceDirect, Google Scholar, and government websites databases from 2004 to 2024. The keywords used in this study were "Stalevo" and "Parkinson's Disease" with the Boolean operator "AND." All articles published up to the search date that met the research requirements were included in this review study. Articles included in this analysis met the following inclusion criteria: 1) The study design was randomized or observational, 2) The study subjects were patients diagnosed with Parkinson's disease, 3) The treatment intervention involved oral Stalevo (levodopa, carbidopa, and entacapon), with or without combination with other drug classes, and the control therapy was placebo with or without combination with other drug classes. The analysis in this study was conducted using a descriptive narrative approach. Initially, research articles were selected to avoid duplication through title and abstract screening. Next, eligible articles were extracted by reviewing the full text according to the predetermined inclusion criteria. Data extracted from each research article included: 1) Research article identity (year of

publication, study design, researcher name, year of study), 2) Disease severity, 3) Population, 4) Patient demographic characteristics (age, gender, height, and weight), 5) Intervention details (drug name, dose, frequency of administration, route of administration, duration of treatment, follow-up), 6) Outcome measures (motor symptoms, quality of life, and side effects), and 7) Study results (efficacy, safety, and tolerability).

Results

Seventeen articles were identified during the electronic database search. After screening based on the inclusion criteria, 10 articles were randomly selected to meet the requirements. Furthermore, after reviewing the titles and abstracts of these 17 articles, five were found to be identical, resulting in only 10 articles being used in this study. Thus, 10 articles were used as primary references in this paper, while the remaining five articles were used as supporting references.

Discussion

Stalevo Mechanism of Action

Stalevo® is a combination of three active ingredients: levodopa, carbidopa, and entacapon. Each of these components plays a role in enhancing the effectiveness of PD treatment through complementary mechanisms (Novataris, 2010):

1. Levodopa: Levodopa, a precursor to dopamine, can cross the blood-brain barrier and is converted to dopamine in the brain. Dopamine is a neurotransmitter that regulates body movement, and its deficiency in PD patients causes characteristic motor symptoms. Levodopa administration can reduce PD symptoms by increasing dopamine levels in the brain, thereby relieving the tremors, rigidity, and bradykinesia associated with the disease (Sethi et al., 2009).
2. Carbidopa: Carbidopa is a peripheral dopamine decarboxylase inhibitor that prevents the conversion of levodopa to dopamine outside the brain. This ensures that more levodopa reaches the brain, thereby increasing the effectiveness of treatment. Carbidopa also prolongs the half-life of levodopa from 50 minutes to 1.5 hours and reduces peripheral levels of dopamine and its main metabolite, homovanillic acid, which can cause side effects.
3. Entacapone: Entacapone is a selective and reversible inhibitor of the enzyme catechol-O-methyltransferase (COMT). COMT plays a role in the metabolism of levodopa to inactive metabolites. When entacapon is co-administered with levodopa and carbidopa, the effect of COMT on levodopa metabolism can be minimized, thereby increasing levodopa plasma concentrations and prolonging its therapeutic effect. Co-administration of entacapon with levodopa and carbidopa can increase levodopa plasma exposure by 35%-40% and prolong the elimination half-life of levodopa, which may result in more persistent dopaminergic stimulation in the brain.

Stalevo® (carbidopa, levodopa, and entakapon) has been studied in clinical trials in healthy subjects aged 45–75 years. The results showed that mean plasma concentrations of levodopa, carbidopa, and entakapon were similar after administration of Stalevo® or the combination of carbidopa/levodopa with Comtan® (entakapon) tablets. Stalevo® consistently increased levodopa plasma concentrations, contributing to better control of PD symptoms (Hauser, 2022).

"Wearing Off" and OFF Periods in Parkinson's Disease

"Wearing off" is a common complication of long-term therapy in Parkinson's disease (PD) patients, falling under the category of motor fluctuations. This term refers to the decreasing duration of effect of each dose of levodopa, as the disease progresses and treatment lengthens. This condition affects nearly all PD patients and has a significant impact on their quality of life. Although often associated with advanced disease stages, "wearing off" can appear earlier than anticipated and is often not recognized or properly treated. In addition to motor symptoms, "wearing off" also includes non-motor symptoms, such as changes in cognition, attention, anxiety, depression, and apathy. These symptoms are often the first sign of the "off" period and are difficult to manage (Srinivasa, 2023).

The causes and mechanisms underlying "wearing off" remain a matter of debate. The classic explanation suggests that in the early stages of PD, remaining dopaminergic neurons retain the ability to store levodopa/dopamine, which acts as a "buffer" against fluctuations in plasma levodopa levels. However, as the disease progresses, the number of dopaminergic neurons decreases, resulting in the loss of this buffering ability (Männistö et al., 2024). Consequently, the duration of levodopa's therapeutic effect shortens, reflecting fluctuations in plasma levodopa levels. The levodopa response becomes more unstable, no longer able to compensate for the loss of sustained dopamine receptor stimulation. This contributes to worsening of the "wearing off" period and triggers the onset of dyskinesias.

Treatment for "wearing off" can be achieved by improving the delivery and plasma profile of levodopa. The primary goal is to maintain stable levodopa plasma levels throughout the day to reduce the off period. One important step is to increase levodopa bioavailability to more quickly reach the levels needed to activate the patient (on time) and prolong its duration of effect. Furthermore, slowing the decline in plasma levodopa levels can increase the on duration and reduce the off period. Another possible approach is to reduce peak and trough fluctuations in levodopa plasma levels (Skelly et al., 2017).

Several strategies have been developed to achieve this goal. One is increasing the levodopa dose, although this carries the risk of causing larger peak and trough fluctuations. Another alternative is increasing the frequency of levodopa dosing. This approach can reduce large fluctuations but adds complexity to therapy. Another, more attractive option is the use of controlled-release or extended-release levodopa formulations. However, the development of these formulations has been hampered by the fact that levodopa is only absorbed in the upper small intestine through active transport, which limits drug retention in the absorption zone. One effective way to optimize levodopa therapy is to inhibit its enzymatic metabolism. The use of enzyme inhibitors such as entacapone (a COMT inhibitor) and carbidopa (a dopa decarboxylase inhibitor) has been shown to prolong the duration of levodopa's effects, reduce motor fluctuations, and improve patients' quality of life (Xie et al., 2021). This approach allows for better control of the pharmacokinetic profile of levodopa in the plasma and brain, resulting in a more stable and consistent therapeutic response.

Use of the Carbidopa/Levodopa/Entacapone (Stalevo®) Combination in Parkinson's Disease (PD)

In 2003, the FDA approved the triple combination tablet Stalevo, containing carbidopa, levodopa, and entacapone, for the treatment of Parkinson's disease (PD) patients experiencing "wearing-off" symptoms (a decrease in the drug's effect before the next dose). Stalevo was designed to help reduce the motor fluctuations that often occur in PD patients, especially in those who require more frequent doses of levodopa or who are already showing signs of the drug's waning effectiveness (Jenner, 2013). The combination of carbidopa, levodopa, and entacapone works by improving the uptake and utilization of levodopa in the brain. Levodopa is a precursor of dopamine, which is needed for motor function in PD patients. Carbidopa helps reduce the side effects of levodopa by preventing its breakdown outside the brain. Entacapone, which is a COMT (catechol-O-methyltransferase) inhibitor, prolongs the duration of action of levodopa in the body by inhibiting the breakdown of levodopa, thus providing a more stable and longer-lasting therapeutic effect (Jenner, 2023).

Several studies have shown that Stalevo has an effect equivalent to that of levodopa/carbidopa and entacapone administered separately. A randomized, crossover study in 132 healthy subjects showed that the pharmacokinetics of levodopa in Stalevo tablets were similar to those of the individual drugs. This study also showed that PD patients taking Stalevo experienced a better quality of life and preferred the combination tablet to taking several tablets separately. This suggests that Stalevo is not only effective in reducing PD symptoms but also makes daily medication easier for patients (Männistö et al., 2024).

Further studies, such as FIRST-STEP, a 39-week randomized trial, compared Stalevo with levodopa/carbidopa alone in early-stage PD patients. Results showed that Stalevo provided superior therapeutic benefit in reducing PD symptoms, as demonstrated by improvements in Unified Parkinson's Disease Rating Scale (UPDRS) and Clinical Global Impression (CGI) scores. While there were no significant differences in other clinical measures, such as the Hoehn-Yahr score or PDQ-39 (patient quality of life), Stalevo was found to be more effective in reducing motor fluctuations in early-stage PD patients (Hauser, 2022).

One of the goals of Stalevo is to reduce dyskinesia (involuntary movements) that often occur in PD patients who have been on levodopa therapy for a long time. Some preliminary studies suggest that therapy with levodopa/carbidopa/entacapone may reduce the risk of dyskinesia if given early, but the STRIDE-PD study failed to provide strong evidence that Stalevo reduces the incidence of dyskinesia better than standard levodopa/carbidopa (Jenner, 2023). Furthermore, some research suggests that entacapone can reduce blood homocysteine levels. High homocysteine levels are associated with an increased risk of cardiovascular disease and cognitive decline in PD patients. Several studies suggest that the use of levodopa/carbidopa/entacapone may help lower homocysteine levels, which in turn may reduce the risk of heart disease and cognitive impairment in PD patients (Reichmann, 2023). incorporate simple animations and voice narration. Intuitive navigation buttons enable easy page movement, animation playback, and quiz access, making the media user-friendly and aligned with elementary students' characteristics. Stalevo is a combination of levodopa, carbidopa, and entacapone (a COMT inhibitor) designed to treat motor fluctuations in Parkinson's patients. This combination is considered "unique" because it combines therapy with a direct COMT inhibitor in a single tablet, unlike raditional therapy that separates entacapone. This formulation

offers convenience for patients with Parkinson's phenomena.end-of-dose wearing-off, thereby improving adherence to therapy and significantly reducing symptoms of motor fluctuations. By reducing the number of tablets required, Stalevo is a practical solution for patients who need more efficient symptom management.

Based on therapy guidelines (Tunjungsari et al., 2024), Stalevo is recommended for advanced Parkinson's patients who experience motor fluctuations, especially to prolong the duration ofon-timeand stabilizes levodopa levels in the blood. Its effectiveness in reducing the timeoffSeveral clinical studies have supported its effectiveness and improved quality of life for patients. However, its use is less appropriate for patients with early-stage Parkinson's disease who do not exhibit motor fluctuations, as it may carry the risk of side effects without providing significant clinical benefit in these conditions. Therefore, Stalevo therapy should be tailored to the patient's clinical needs. Although Stalevo offers unique advantages in formulation and effective management of Parkinson's symptoms, its use should be based on clear clinical indications and in accordance with treatment guidelines. Close monitoring is necessary to prevent side effects such as diarrhea or orange urine discoloration, which frequently occur in patients taking entacapone. An individualized approach to therapy is essential to ensure optimal benefit from Stalevo.

A multinational phase IIIb study by Brooks et al., 2005, demonstrated that Stalevo provided comparable results to the combination of levodopa/DDCI (a dopamine decarboxylase inhibitor) and entacapone given alone. The study, involving 177 Parkinson's patients experiencing wear-off, showed that 87% of patients in the Stalevo group reported significant improvement in motor symptoms after 6 weeks, compared with 81% in the levodopa/DDCI and entacapone group. Most patients (81%) preferred Stalevo over the combination alone due to its ease of administration. Furthermore, patients using Stalevo also reported a significant improvement in quality of life compared with the combination alone. Although dopaminergic side effects such as nausea and dyskinesia were noted, most were mild to moderate, with no significant difference in the side effect profile between the Stalevo and levodopa/DDCI plus entacapone groups.

Stalevo therapy is sometimes used outside of guidelines in certain situations, such as in patients with poor tolerance to entacapone, where the dose may need to be adjusted or changed. An individualized approach is often applied in cases with comorbidities or differing clinical responses, although standard therapy is usually the reference. This study demonstrated that Stalevo provided clinical improvement comparable to separate tablet combination therapy, particularly in reducing the duration of "off-time" and extending "on-time." However, despite its convenience and good efficacy, its use needs to be tailored to the patient's clinical condition to ensure optimal results, while still considering existing therapy guidelines.

European studies have shown that Stalevo® is effective in prolonging "ON" time and reducing "OFF" time in Parkinson's patients. One of the main studies cited is STRIDE-PD, which aimed to assess Stalevo®'s ability to delay the progression of dyskinesia compared to standard levodopa/carbidopa (Warren Olanow et al., 2013). However, the results of this study showed that the time to development of dyskinesia was shorter in patients treated with Stalevo® compared to those receiving standard levodopa/carbidopa. Nevertheless, Stalevo® remains an effective therapy in managing motor symptoms in patients with motor fluctuations (Sierra et al., 2019).

In the United States, Stalevo® is widely used as an adjunctive therapy for patients experiencing motor fluctuations due to long-term medication. Research shows that the combination of levodopa, carbidopa, and entacapone in Stalevo® has been the standard treatment for more than two decades. This therapy has been shown to help overcome "off" periods in Parkinson's patients by stabilizing levodopa levels in the body, thereby reducing motor symptoms. The use of Stalevo® in the United States continues to grow, supported by recommendations from the American Academy of Neurology and clinical studies showing significant improvements in patients' quality of life (Jenner, 2023).

In Asian countries such as Japan, South Korea, and Taiwan, levodopa-carbidopa intestinal gel (LCIG) infusion therapy is becoming increasingly used to treat motor and non-motor complications in patients with advanced Parkinson's disease. Clinical studies in these regions have shown that LCIG is highly effective in prolonging the "ON" time while reducing motor fluctuations that occur during the "OFF" period. Furthermore, this therapy is reportedly well tolerated by patients, making it a very important alternative for managing Parkinson's symptoms that are difficult to manage with conventional oral therapy (Murata et al., 2016).

Several research trials and studies in several countries have shown that Stalevo®, a combination of carbidopa, levodopa, and entacapone, is effective in managing Parkinson's symptoms, particularly in patients with "wearing-off" and motor fluctuations. These three active ingredients work synergistically to prolong the duration of levodopa's effects, reduce levodopa dose requirements, and improve patients' quality of life. This combination tablet offers practical advantages for

patients on long-term therapy, as it reduces the number of pills required. Although side effects such as dyskinesia and diarrhea can occur, the overall safety profile of Stalevo® is acceptable. Early studies have shown some limitations, such as the lack of a placebo comparison and the lack of impact on early-stage Parkinson's symptoms, but Stalevo remains an important and viable therapeutic option, particularly for patients with inconsistent levodopa dosing or experiencing "wearing-off."

Cover

The use of Stalevo®, a combination of carbidopa, levodopa, and entacapone, provides important lessons in the management of Parkinson's disease, particularly in patients with motor fluctuations and the "wearing-off" phenomenon. This combination has demonstrated significant effectiveness in prolonging the duration of levodopa effects, reducing dosage requirements, and improving patients' quality of life, particularly through a more practical and stable therapeutic approach. However, studies also highlight the need to monitor side effects such as dyskinesia and diarrhea, and evaluate its effectiveness in the early stages of the disease. Clinical experience from various countries suggests that the selection of appropriate therapy should consider the individual patient's needs, prioritizing stable levodopa levels and reducing motor fluctuations, while also considering the long-term safety profile.

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Author Contributions

All authors made substantial contributions to this study. A.P. was responsible for developing the learning materials, collecting and validating field data, conducting the formal analysis, and drafting the manuscript. A.P. contributed to the preparation of the research methodology and ensured consistency between the analysis and the methodological framework. F.H. managed data curation, provided research supervision, and assisted with project administration. All authors have reviewed and approved the final version of the manuscript.

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Conflicts of Interest

The authors declare no conflict of interest.

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