Journal of Clinical and Nursing Research, 2025, Volume 9, Issue 11
http://ojs.bbwpublisher.com/index.php/JCNR
Online ISSN: 2208-3693
Print ISSN: 2208-3685

Efficacy and Safety Study of Rasagiline Tablets in the Treatment of Parkinson's Disease

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Abstract: *Objective:* To evaluate the efficacy and safety of rasagiline tablets in the treatment of Parkinson's disease, in order to provide a more scientific basis for the application of the drug in Parkinson's disease. *Methods:* This study is a single-arm, prospective, observational study. The trial collected patients with primary Parkinson's disease who met the inclusion and exclusion criteria after being assessed by the investigator to evaluate the efficacy and safety of rasagiline tablets in the treatment of Parkinson's disease patients through UPDRSIII and UPDRSII scales, and evaluated the efficacy and safety of rasagiline tablets in the treatment of Parkinson's disease patients. *Results:* A total of 3560 patients were included in this study. 44.1% of patients had early Parkinson's disease, 52.4% had intermediate Parkinson's disease, and 3.5% had advanced Parkinson's disease. The UPDRSIII (exercise capacity) score was 26.76 at baseline, 25.47 at 1 month, 24.18 at 2 months, and 23.39 at 3 months after treatment, and scores significantly improved over time ($P < 0.001$). The UPDRSII (ability to perform daily living) score was an average of 23.60 at baseline, 22.49 at 1 month, 21.53 at 2 months, and 21.09 at 3 months after treatment, with statistically significant differences in scores between months ($P < 0.001$). A total of 18 adverse events/reactions occurred in this study, and adverse symptoms eventually disappeared or resolved, without termination due to adverse events/reactions or patient discharge. *Conclusion:* Rasagiline tablets have significant efficacy in improving daily exercise capacity and living ability in patients with Parkinson's disease, and have a certain safety, which supports the effectiveness of rasagiline as a treatment for Parkinson's disease and provides new evidence for its clinical application.

Keywords: Parkinson's disease; Rasagiline tablets; UPDRS score

Online publication: Dec 16, 2025

1. Introduction

Parkinson's Disease (PD) is a common degenerative disease of the central nervous system, mainly manifested by symptoms such as resting tremor, muscle rigidity, bradykinesia and postural instability. The pathogenesis of PD is closely related to the gradual loss of dopaminergic neurons in the substantia nigra and the imbalance of related neurotransmitters. Epidemiological surveys show that the prevalence of PD in Europe and the United States reaches 1% for people over 60 years old, more than 4% for those over 80 years old, and the prevalence rate for people aged 65 and above in our country is 1700/100,000. With the progression of the disease, these motor and non-motor symptoms of PD gradually appear and worsen, which, on the one hand, will damage the patient's own daily activities, seriously reduce the patient's quality of life, and, on the other hand, it will also bring a huge economic and care burden to the family and society.

At present, the treatment of PD mainly includes drug therapy, surgical treatment, and rehabilitation treatment, of which drug treatment is the most commonly used method. With the deepening of research on the pathogenesis of PD, monoamine oxidase B (MAO-B) inhibitors can selectively inhibit endogenous and exogenous dopamine breakdown, prolong the action time of dopamine, and improve the clinical symptoms of PD. Rasagiline is a novel, irreversible MAO-B inhibitor that can improve motor and non-motor symptoms in patients. In addition, rasagiline has potential neuroprotective effects, which opens up new possibilities for early intervention in PD.

Studies have shown that rasagiline has shown good efficacy in both monotherapy and combination therapy, but its safety and long-term application effect in different populations still need to be further verified. Therefore, this study aims to evaluate the efficacy and safety of rasagiline tablets in the treatment of PD through a prospective, observational study, to provide more scientific basis for the application of the drug in PD and explore its potential in delaying disease progression. This not only helps optimize the treatment strategy for PD, but also has important implications for improving the quality of life of patients.

2. Data and methods

2.1. Study design

This study is a single-arm, prospective, observational study that collects patients with primary PD who met the inclusion criteria after being assessed by the investigator between January 2023 and June 2024, and evaluated the efficacy and safety of rasagiline in the treatment of PD patients through UPDRSIII, UPDRSII, and adverse reactions [1,2]. Rasagiline mesylate tablets were administered at a dose of 1 mg once daily orally. The treatment duration was 3 months for all enrolled patients. Medication adherence was assessed through patient diaries and pill counts at each follow-up visit.

2.2. Study population

The target population of this study is PD patients who are seen between January 2023 and June 2024 and who can be treated with rasagiline tablets after being evaluated by the investigator in the case of basic treatment. Inclusion criteria: (1) Patients with a clinical diagnosis of primary PD; (2) Receiving a relatively stable dose of antiparkinsonian drugs during the study period; (3) Age ≥ 18 years old; (4) Patients or their legal representatives sign the informed consent form and are willing to participate in this study and complete the survey as required. Exclusion criteria: (1) PD caused by encephalitis or metabolic diseases; (2) Accompanied by severe mental illness; (3) Patients with severe heart, liver, and kidney function impairment; (4) Patients with severe cognitive

dysfunction; (5) Patients with allergy to rasagiline tablets; (6) Unable to cooperate and complete the researcher.

2.3. Research indicators

(1) Evaluation of patients' motor function: UPDRSIII (Unified Parkinson's Disease Rating Scale Part III) is the third part of the Unified PD rating scale to evaluate the motor function of patients. The evaluation of this part includes limb resting tremor, limb stiffness, bradykinesia, standing balance, and gait [3,4].

(2) Evaluation of patients' ability to perform daily living: UPDRSII (Unified Parkinson's Disease Rating Scale Part II) is the second part of the Unified PD rating scale to evaluate patients' ability to live in daily living. This score mainly examines the patient's ability to perform activities in daily life, such as eating, writing, dressing, washing, walking, and getting up. The higher the score, the greater the difficulty the patient encounters in daily life.

(3) Adverse reaction evaluation: Adverse reaction evaluation is used to monitor various adverse reactions that patients have during rasagiline, including but not limited to nausea, headache, insomnia, hypotension, hallucinations, etc. [5,6]

2.4. Statistical analysis

Statistical analysis was performed using SAS 9.4 software. The quantitative data were described as the number of cases, mean, standard deviation, median and interquartile range according to whether they conformed to or were approximately normally distributed. For continuous variables, the changes from baseline to post-treatment were analyzed using a paired t-test (after confirming normality of the differences with the Shapiro-Wilk test). For categorical variables, changes in function status were assessed using the Wilcoxon signed-rank test. The frequency and rate were described by qualitative data, and the chi-square test was used for comparison between groups. The difference in hypothesis testing with a $P < 0.05$ was statistically significant [7,8].

3. Results

3.1. Demographic characteristics and disease diagnosis of patients

A total of 3560 patients with primary PD who attended the clinic between January 2023 and June 2024 and met the inclusion exclusion criteria after being assessed by the investigator were collected in this study. 44.1% of patients had early PD, 52.4% had intermediate PD, and 3.5% had late PD. The results are shown in **Table 1**.

3.2. Changes in UPDRSIII (Motor Examination) score before and after treatment

The UPDRSIII (Motor Examination) score was 26.76 at baseline, 25.47 at 1 month, 24.18 at 2 months, and 23.39 at 3 months after treatment, with statistically significant differences in scores between months ($P < 0.001$). The results are shown in **Table 2**.

3.3. Changes in UPDRSII (ability of daily living) before and after treatment

The UPDRSII (ability to perform daily living) score was an average of 23.60 at baseline, 22.49 at 1 month, 21.53 at 2 months, and 21.09 at 3 months after treatment, with statistically significant differences in scores between months ($P < 0.001$). The results are shown in **Table 3**.

Table 1. Demographic characteristics and disease diagnosis of patients

Variable	Statistics [Mean ± SD,n(%)] (N = 3560)
Age	64.0 ± 9.8
Gender	
Male	2016 (56.6)
Female	1544 (43.4)
Clinical staging diagnosis	
Early-stage (Hoehn-Yahr 1-2 stage)	1569 (44.1)
Mid-stage (Hoehn-Yahr 2.5-3stage)	1865 (52.4)
Advanced-stage (Hoehn-Yahr 4-5stage)	126 (3.5)
The duration of the disease from illness to this visit	
Less than 1 year	769 (21.6)
1–5 years	2226 (62.5)
5–10 years	516 (14.5)
More than 10 years	49 (1.4)

Table 2. Changes in UPDRSIII (Motor Examination) score before and after treatment

	Before treatment	Treatment for 1 month	Treatment for 2 months	Treatment for 3 months	*P*
The mean ± standard deviation	26.76 ± 13.92	25.47 ± 13.03	24.18 ± 12.02	23.39 ± 11.82	< 0.001
Median (Q1–Q3)	25 (16–38)	24 (15–36)	23 (15–33)	23 (14–33)	

Table 3. Changes in UPDRSII (ability of daily living) before and after treatment

	Before treatment	Treatment for 1 month	Treatment for 2 months	Treatment for 3 months	*P*
The mean ± standard deviation	23.60 ± 11.36	22.49 ± 10.90	21.53 ± 10.22	21.09 ± 10.46	< 0.001
Median (Q1–Q3)	23 (15–34)	22 (14–32)	21 (14–30)	21 (13–29)	

3.4. Evaluation of adverse reactions of patients

A total of 18 adverse events/reactions occurred in this study, including neurologic abnormalities, digestive system abnormalities, metabolic and nutritional abnormalities, ocular, ear, and labyrinth abnormalities, cardiac or vascular abnormalities, and muscular, skeletal, and connective tissue abnormalities of mild severity. Among them, 6 cases were in the first cycle, 3 cases in the second cycle, 5 cases in the third cycle, and 4 cases in the fourth cycle. Adverse symptoms eventually disappeared or resolved without termination of adverse events/reactions or discharge of the patient.

4. Discussion

The results of the study showed that rasagiline tablets had significant efficacy in improving motor function (UPDRS III score) and daily living ability (UPDRS II score) in PD patients. Compared with baseline, patients experienced significant reductions in both scores after receiving rasagiline, indicating effective improvements in patients' quality of life and motor function. This is similar to the results of a study in Taizhou, Jiangsu Province, where the UPDRSII score and UPDRSIII score of PD patients were significantly reduced after 12 weeks of treatment with levodopa preparations combined with rasagiline [9]. Our findings further support the effectiveness of rasagiline as a treatment for PD and provide new evidence for its clinical application.

In addition, the results of this trial showed that only 18 adverse events/reactions occurred in 3560 patients treated with rasagiline for PD, with mild severity and good outcomes. A meta-analysis published in 2013 found that the most commonly reported adverse events/reactions of rasagiline as monotherapy were headache, dizziness, and insomnia by searching the literature from 1990-2012; When treated in combination with other drugs, depression, dizziness, drowsiness, and other sleep disturbances can occur [10].

As a progressive neurodegenerative disease, PD not only seriously affects the quality of life of patients but also brings a heavy economic and nursing burden to society and families. The core pathological mechanism of PD is the loss of dopaminergic neurons in the substantia nigra, leading to a decrease in dopamine levels in the brain. Rasagiline tablets, as a selective and irreversible monoamine oxidase B (MAO-B) inhibitor, reduce the degradation of dopamine in the brain by inhibiting the activity of MAO-B, thereby increasing dopamine levels and improving motor symptoms in patients [11]. In addition, rasagiline also has antioxidant and anti-apoptotic effects, which may provide some protection to neurons and help delay disease progression. Therefore, rasagiline tablets can not only improve the clinical symptoms of PD but also reduce the long-term burden of the disease.

5. Conclusion

In summary, this study verified the effectiveness and safety of the drug in improving daily living ability and motor function by evaluating the effect of rasagiline tablets on the UPDRSII and UPDRSIII scores of PD patients. Future studies should further explore its long-term effects and potential neuroprotective mechanisms to provide a more comprehensive plan for the treatment of PD.

Disclosure statement

The authors declare no conflict of interest.

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