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[Neuropsychiatr Dis Treat](#). 2017 Apr 19;13:1115-1124. doi: 10.2147/NDT.S133145. eCollection 2017.

Long-term effect of galantamine on cognitive function in patients with Alzheimer's disease versus a simulated disease trajectory: an observational study in the clinical setting

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Abstract

Background: Long-term maintenance of cognitive function is an important goal of treatment for Alzheimer's disease (AD), but evidence about the long-term efficacy of cholinesterase inhibitors is sparse. To evaluate the long-term efficacy and safety of galantamine for AD in routine clinical practice, we conducted a 72-week post-marketing surveillance study. The effect of galantamine on cognitive function was estimated in comparison with a simulated disease trajectory.

Patients and methods: Patients with mild-to-moderate AD received flexible dosing of galantamine (16-24 mg/day) during this study. Cognitive function was assessed by the mini mental state examination (MMSE) and the clinical status was determined by the Clinical Global Impression-Improvement (CGI-I). Changes of the MMSE score without treatment were estimated in each patient using Mendiondo's model. Generalized linear mixed model analysis was performed to compare the simulated MMSE scores with the actual scores.

Results: Of the 661 patients who were enrolled, 642 were evaluable for safety and 554 were assessed for efficacy. The discontinuation rate was 46.73%. Cognitive decline indicated by the mean change of actual MMSE scores was significantly smaller than the simulated decline. Individual analysis demonstrated that >70% of patients had better actual MMSE scores than their simulated scores. Significant improvement of CGI-I was also observed during the observation period. Adverse events occurred in 28.5% of patients and were serious in 8.41%. The reported events generally corresponded with the safety profile of galantamine in previous studies.

Conclusion: These findings support the long-term efficacy of galantamine for maintaining cognitive function and the clinical state in AD patients. Treatment with galantamine was generally safe. Importantly, this study revealed that galantamine improved cognitive function above the predicted level in >70% of the patients.

Keywords: Alzheimer's disease; cholinesterase inhibitor; cognitive function; disease progression; real-world evidence.

Figures



Figure 1 Flow chart of subject disposition...



Figure 2 Kaplan-Meier curves for discontinuation during...

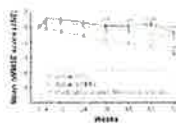


Figure 3 Mean actual changes of MMSE...

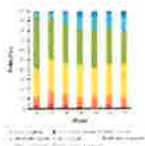


Figure 4 Clinical Global Impression-Improvement score over...

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