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Responder analyses on memantine in Alzheimer's disease¹

Executive Summary

¹Translation of the executive summary of the rapid report “Responderanalysen zu Memantin bei Alzheimer Demenz” (Version 1.0; Status: 28.03.2011). Please note: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

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Background

In its letter of 04 November 2010, the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to assess the responder analyses submitted by the pharmaceutical company Merz in October 2010. This assessment was conducted as a supplement to the final report A05-19C and to the working paper "Memantine in Alzheimer's disease".

Research question

The research question of the present investigation is as follows:

- What is the impact of the responder analyses calculated post hoc by Merz and submitted to the G-BA in the fourth quarter of 2010 on the conclusions of the final report A05-19C ("Memantine in Alzheimer's disease")?

Methods

The responder analyses submitted were assessed with the methods specified in the final report A05-19C and in the working paper "Memantine in Alzheimer's disease".

An additional literature search was not performed.

Results

The documents submitted by Merz included responder analyses on the 2 patient-relevant outcomes "activities of daily living" and "cognitive function". In addition, data were provided on the outcome "disease stage according to global clinical impression", which was classified as not being patient-relevant in the final report A05-19C and presented there as supplementary information. In each case the proportion of patients was investigated who experienced an at most irrelevant deterioration of their condition.

Overall, all of the 9 studies were considered in the assessment that had already been classified as relevant both in the final report A05-19C and in the working paper "Memantine in Alzheimer's disease". Seven of these studies compared memantine monotherapy with placebo. The other 2 studies compared memantine in combination with a cholinesterase inhibitor versus a cholinesterase inhibitor plus placebo.

The meta-analysis of the studies showed a statistically significant effect in favour of memantine, both for the 2 patient-relevant outcomes "activities of daily living" and "cognitive function", as well as for "disease stage according to global clinical impression". As a result, for the outcome "cognitive function", the data provide proof of benefit of memantine regarding the proportion of patients who experienced an at most irrelevant deterioration of their condition. In the analysis of the outcome "activities of daily living" solely response criteria were used that were characterized by a relatively high degree of uncertainty. While

also taking the small size of the effect into account, this results in an indication of a benefit of memantine.

Conclusions

The findings of the responder analyses calculated post hoc by Merz and submitted to the Federal Joint Committee lead to the following change to the conclusions of the final report A05-19C.

The data provide proof of a benefit of memantine in patients with Alzheimer's disease with regard to the prevention of a relevant deterioration in cognitive function. For activities of daily living, taking into account the uncertain response criteria, as well as the concurrent minor size of the effect, the data provide an indication of a benefit of memantine.

Keywords: memantine, Alzheimer's disease, dementia, benefit assessment, health technology assessment, systematic review

The full report (German version) is available under www.iqwig.de