Study questions benefit of new Alzheimer's drug

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Last summer, the U.S. Food and Drug Administration fully approved the first drug shown to slow the progress of Alzheimer's. But new research from the University of Georgia suggests that patients and caregivers may not experience any benefit from the drug in their daily lives.

The drug, Leqembi, became eligible for coverage through Medicare, making it more affordable for the millions of Americans in the early stages of the disease. But experts remained skeptical that the drug provided enough benefit to justify the cost and potential harms of the drug.

A new study from UGA's Mark Ebell systematically reviewed 19 publications with more than 23,000 participants that evaluated eight monoclonal antibodies, including Leqembi. The paper, "Clinically Important Benefits and Harms of Monoclonal Antibodies Targeting Amyloid for Treatment of Alzheimer Disease: A systematic Review and Meta-Analysis," is published in *The Annals of Family Medicine*.

"We focused very clearly on patient-centered outcomes," said Ebell, who is a physician and professor of epidemiology and biostatistics in UGA's College of Public Health. "We found that even after 18 to 24 months of treatment, the differences in function and cognition between treated and untreated patients were so small that a patient or their caregiver generally wouldn't notice the difference," said Ebell.

"For example, the Mini-Mental State test has 30 possible points, but the difference seen in the studies was less than a third of a point. To be noticeable to a patient or their family, that difference would have to be at least 1 to 3 points."

Ebell and his co-authors examined the drugs' effects on memory and life skills, such as the ability to dress and feed yourself, as well as reported side effects.

Overall, the researchers found that most studies showed that monoclonal antibody drugs led to statistically significant improvements in cognitive function, but none of the drugs showed clinically significant improvements in memory or behaviors.

The study suggests the drug's hefty cost, time burden, and potential side effects, which include brain swelling and brain bleeds, may not be worth the minimal benefit for most patients.

Doctors and patients are being sold the promise of new breakthrough

treatment for Alzheimer's, Ebell said. But understanding the potential risks in contrast to limited benefits is critical for patients and their doctors to make informed decisions.

"The potential benefit always has to be weighed against any potential harms," said Ebell. "And it's not by any means a clear-cut choice."

More information: Mark H. Ebell et al, Clinically Important Benefits and Harms of Monoclonal Antibodies Targeting Amyloid for the Treatment of Alzheimer Disease: A Systematic Review and Meta-Analysis, *The Annals of Family Medicine* (2024). DOI: 10.1370/afm.3050

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