

Team develops blood test that detects early Alzheimer's disease

June 8 2016

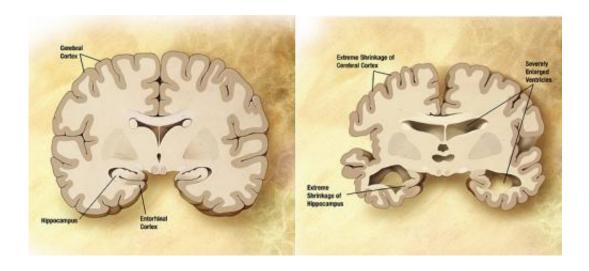


Diagram of the brain of a person with Alzheimer's Disease. Credit: Wikipedia/public domain.

A research team, led by Dr. Robert Nagele from Rowan University School of Osteopathic Medicine and Durin Technologies, Inc., has announced the development of a blood test that leverages the body's immune response system to detect an early stage of Alzheimer's disease referred to as the mild cognitive impairment (MCI) stage - with unparalleled accuracy. In a "proof of concept" study involving 236 subjects, the test demonstrated an overall accuracy, sensitivity and specificity rate of 100 percent in identifying subjects whose MCI was actually caused by an early stage of Alzheimer's disease.



"About 60 percent of all MCI patients have MCI caused by an early stage of Alzheimer's disease. The remaining 40 percent of cases are caused by other factors, including vascular issues, drug side-effects and depression. To provide proper care, physicians need to know which cases of MCI are due to early Alzheimer's and which are not," said Cassandra DeMarshall, the study's lead author, and a PhD candidate at the Rowan University Graduate School of Biomedical Sciences. "Our results show that it is possible to use a small number of blood-borne autoantibodies to accurately diagnose early-stage Alzheimer's. These findings could eventually lead to the development of a simple, inexpensive and relatively noninvasive way to diagnose this devastating disease in its earliest stages."

"It is now generally believed that Alzheimer's-related changes begin in the brain at least a decade before the emergence of telltale symptoms," Nagele explained. "To the best of our knowledge, this is the first blood test using autoantibody biomarkers that can accurately detect Alzheimer's at an early point in the course of the disease when treatments are more likely to be beneficial - that is, before too much brain devastation has occurred." Nagele is the study's corresponding author and the director of the Biomarker Discovery Center at Rowan's New Jersey Institute for Successful Aging. He is also the co-founder and chief scientific officer of Durin Technologies, Inc.

The researchers presented their results in an article published in *Alzheimer's & Dementia*: Diagnosis, Assessment & Disease Monitoring that also reported the test's ability to accurately "stage the disease," meaning it can distinguish early-stage Alzheimer's at MCI from later, more advanced stages. The test was also disease-specific. It readily distinguished early Alzheimer's at the MCI stage from other diseases including Parkinson's disease, multiple sclerosis, and early stage breast cancer.



For the study, the Rowan University researchers analyzed blood samples from 236 subjects, including 50 MCI subjects with low levels of amyloid-beta 42 peptide in their cerebrospinal fluid. The latter is a reliable indicator of ongoing Alzheimer's pathology in the brain and predicts a likely rapid progression to Alzheimer's.

Employing human protein microarrays, each containing 9,486 unique human proteins that are used as bait to attract blood-borne autoantibodies, the researchers identified the top 50 autoantibody biomarkers capable of detecting ongoing early-stage Alzheimer's pathology in patients with MCI. In multiple tests, the 50 biomarkers were 100 percent accurate in distinguishing patients with MCI due to Alzheimer's from healthy age- and gender-matched controls. Further testing of the selected MCI biomarker panel demonstrated similar high overall accuracy rates in differentiating patients with early Alzheimer's at the MCI stage from those with more advance, mild-moderate Alzheimer's (98.7 percent), early-stage Parkinson's disease (98.0 percent), multiple sclerosis (100 percent) and breast cancer (100 percent).

In their report, the researchers acknowledge that the utility of their MCI biomarker panel as a blood test for early detection of Alzheimer's disease will hinge on a successful larger replication study using an independent patient cohort. However, they also point out that, because this blood-based diagnostic strategy is dependent on the presence of Alzheimer's pathology which can be underway many years before symptoms emerge, this approach could open the door to even earlier presymptomatic detection of Alzheimer's disease.

According to the authors, early diagnosis of Alzheimer's disease and the ability to stage the disease through a simple blood test would offer many potential benefits. Patients could possibly delay disease progression through lifestyle adjustments, begin treatment sooner and plan future



medical care. Clinicians would have a way to measure the effectiveness of therapeutic intervention and clinical trials could enroll patients who were truly at the earliest stage of their disease.

More information: Cassandra A. DeMarshall et al, Detection of Alzheimer's disease at mild cognitive impairment and disease progression using autoantibodies as blood-based biomarkers, *Alzheimer's & Dementia: Diagnosis, Assessment & Disease Monitoring* (2016). DOI: 10.1016/j.dadm.2016.03.002

Provided by American Osteopathic Association

Citation: Team develops blood test that detects early Alzheimer's disease (2016, June 8) retrieved 27 April 2024 from

https://medicalxpress.com/news/2016-06-team-blood-early-alzheimer-disease.html

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