

Blood tests for Alzheimer disease: a game changer in dementia diagnosis



22nd Brain Health Forum
Tuesday, April 26, 2022
10:00 a.m.–12:30 p.m.



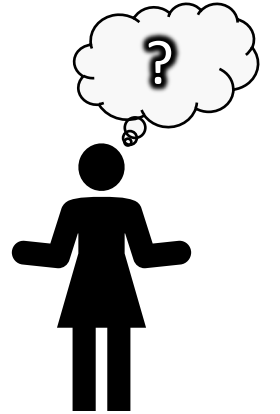
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Disclosures

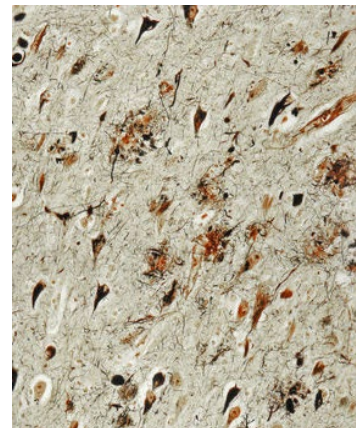
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- **Plasma A β 42/A β 40 data were provided to Washington University by C2N Diagnostics at no cost. No financial incentives or additional research funding were provided to Washington University or Dr. Schindler in return for analyzing the data. Washington University has a financial interest in C2N.**
- Stock/Equity: None
- Consulting/Employment: None
- Speakers Bureau/Honoraria: Dr. Schindler receives honoraria as a member of the biorepository review committee for the National Centralized Repository for Alzheimer's Disease (NCRAD); she has received honoraria for presentations, participating in expert panels and reviewing grants (only from non-profit organizations). She has not received personal compensation of any kind from C2N Diagnostics or any other diagnostics or pharmaceutical companies.
- Other: Dr. Schindler previously served as a sub-PI for the A4, DIAN-TU, and ENGAGE trials. Dr. Schindler participated in the IDEAS trial.

Dementia, Alzheimer disease, and biomarkers

- Dementia is a decline in memory and thinking that impairs functional abilities
- There are many causes of dementia
- Alzheimer disease (AD) is defined by the presence of amyloid plaques and tau tangles in the brain, not by the cognitive symptoms or the severity of dementia
- Alzheimer disease is the most common cause of dementia
- Tests that reflect Alzheimer disease brain pathology are referred to as Alzheimer disease biomarkers



Dementia



Alzheimer disease

Diagnosing dementia

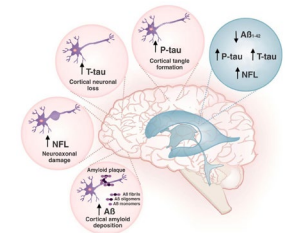
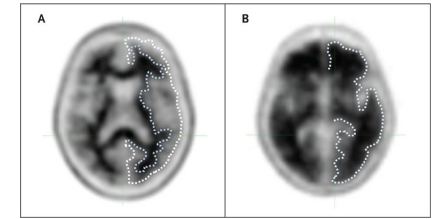
- **Comprehensive clinical evaluation**

- **Clinical history**- Was there an insidious onset, slow progression, and early impairment of memory?
- **Medical history**- Does the patient have medical conditions that can cause cognitive impairment?
- **Family history**- Did family members have dementia symptoms at approximately the patient's age?
- **Medication history**- Is the patient taking medications that impair cognition?
- **Neurological exam**- Are there signs of language dysfunction, visuospatial dysfunction, stroke or parkinsonism?
- **Psychometric testing**- Are there impairments on tasks of memory, orientation, attention/concentration, language, executive function, visuospatial function, etc.?
- **Blood work**- Are there metabolic issues that could cause cognitive impairment (blood chemistries, blood cell counts, thyroid function tests and vitamin B12 levels)
- **Brain imaging**- Is there evidence of strokes or an atypical degree of brain atrophy?
- **Other testing**- Does the patient have a sleep disorder or abnormal brain waves?

- **At the end of the evaluation, Alzheimer disease biomarkers are used in occasional cases (~<5% of cases)**

Why haven't we used biomarkers more often?

- **No specific treatments for Alzheimer disease: “There is nothing we can do about it anyway”**
- **Drawbacks of traditional Alzheimer disease biomarkers**
 - A specialized brain scan costs ~\$6,000, is not covered by insurance, involves radiation, and is only available in specialized centers
 - Spinal fluid testing costs ~\$2,000, is typically covered by insurance, but requires a spinal tap
- **Alzheimer disease blood tests**
 - Patients tolerate blood collection well and blood tests may be less expensive to perform
 - Currently only one blood tests available that is not covered by insurance, but this is expected to change
- **AD blood tests may allow for much broader diagnostic testing for Alzheimer disease**



Moving into a new era

- “There is nothing we can do about it anyway” — but what if/when we can?
- One drug (aducamumab/Aduhelm) that specifically treats Alzheimer disease was approved in 2021, but it is controversial and most patients don’t have access to it
- At least three other drugs are in late stages of clinical trials and could be approved in the next 2-3 years
- Needs in the era of disease-modifying treatments for Alzheimer disease
 - Rapid diagnosis- treatments are likely to be most effective in the very earliest stages of dementia
 - Biomarker testing- positive biomarkers will be required to start treatment
 - Monitoring- biomarkers may be used to monitor the effects of treatment
- Blood tests are likely the only type of Alzheimer disease biomarkers that will enable large numbers of individuals to be rapidly diagnosed and monitored

The future of dementia diagnosis?

- **Within 5 years?**

- Patients with cognitive impairment undergo an Alzheimer disease blood test as part of their initial evaluation
- Patients who may be candidates for specific Alzheimer disease treatments will be rapidly identified
- Non-Alzheimer disease causes of cognitive impairment will continue to be considered, even in patients with a positive blood test

- **Within 10 years?**

- Older cognitively normal individuals will undergo screening for Alzheimer disease with a blood test
- Those with a positive test will be started on a preventative treatment