Alzheimer's disease:
Simple blood test, diagnostic clarity

PODCAST 50 - Part 2

00:17
Dr. Jane Caldwell
Hi, I'm your host Jane Caldwell. Welcome to the *On Medical Grounds* podcast, your source for engaging, relevant, evidence-based medical information. Today is part two of our series on early detection of Alzheimer's disease using plasma biomarkers in assays recently approved by the FDA. As a recap from part one, you'll remember that Alzheimer's disease, or AD, is the most common cause of dementia and accounts for an estimated 60 to 80% of dementia cases. It is now known that changes in brain physiology and function may begin 20 years or more before symptoms appear. Even though the need for an early diagnosis has been established, AD remains a diagnostically challenging disease for providers. Just a little over two decades ago, the diagnosis of AD was made through autopsy.

Today the pathology is much better understood, and diagnosis is often made through a combination of clinical signs, biomarkers in cerebrospinal fluid, and amyloid PET scans. However, many of these tests have their own challenges and may be costly for patients. Multiple companies have filed for FDA approval for plasma biomarkers for AD and two have received breakthrough device designation.

Recently, the FDA approved Lumipulse G pTau 217 /beta amyloid 1-42 plasma ratio as a blood-based test for the detection of Alzheimer's in patients with mild cognitive impairment.

Our guest today is Dr. Francesca De Simone.

02:04
Dr. Jane Caldwell
Dr. Francesca De Simone is Scientific Affairs Manager for Fujirebio Diagnostics. Formerly a post-doctoral clinical research associate at Temple University, Dr. De Simone studied and assessed potential biomarkers in both plasma and cerebrospinal fluid. She also served as clinical research coordinator for Thomas Jefferson University Hospitals in Philadelphia. At Fujirebio Diagnostics, Dr. Simone provides scientific support for immunoassay product development and coordinates study startup activities. She leads the neurodegenerative disease program, managing protocols to develop clinical evidence for Fujirebio's biomarker portfolio and expanding indications of use. Additionally, she evaluates new technologies and assesses the clinical utility of novel biomarkers in relevant diagnostic areas.

Hello, Dr. De Simone, welcome to *On Medical Grounds*.

Dr. Francesca De Simone
Hello and thank you so much for having me.

03:12

Dr. Jane Caldwell

First question, how do biomarkers work in disease diagnoses and what are blood-based biomarkers advantages over tests which may use imaging or cerebrospinal fluid?

Dr. Francesca De Simone

So biomarkers serve as measurable indicators of things happening in our bodies, whether that's biological processes, stage or severity of disease, or even how treatment works. In Alzheimer's disease, biomarkers like phosphorylated tau, so p-tau for short, or amyloid, better, provide molecular level insight that can detect disease long before clinical symptoms emerge and really help pinpoint where a patient lies within the disease continuum.

So compared to imaging like PET or cerebral spinal fluid or CSF analysis, plasma biomarkers are far less invasive, more scalable and cost effective, making them better suited for early detection in broader populations.

While biomarkers for screening AD in asymptomatic patients are not yet fully validated for routine use, research and clinical trials are currently exploring their potential to detect the disease before the cognitive impairment is apparent and help identify where a patient is within the disease continuum and assess therapeutic responses more effectively.

And additionally, blood-based biomarkers also enable repeat testing over time, which is critical for monitoring disease progression or therapeutic response. And lastly, plasma biomarkers hold the potential to revolutionize personalized medicine by enabling tailored treatment strategies based on an individual-specific biomarker profile.

05:00

Dr. Jane Caldwell

Thank you for that explanation. Could you please share your insights on clinical needs in the areas of cognitive impairment and Alzheimer's disease?

Dr. Francesca De Simone

Sure. Across cognitive impairment and Alzheimer's disease, several key clinical needs remain. So for patients with cognitive impairment, clinicians need earlier and more accessible tools to identify and characterize deficits, ideally in primary care settings where patients first present. So this includes better ways to assess the core symptoms, such as memory loss, executive dysfunction, language difficulties, and changes in behavior or mood. So standardized reliable methods to distinguish between normal aging, cognitive impairment and different underlying pathologies are essential. In Alzheimer's specifically, clinical needs center on confirming pathology, stratifying risk and monitoring patients on new disease modifying therapies or DMTs.

Standardization across assays and imaging methods is indeed critical to ensure consistent diagnosis, treatment eligibility, and response assessment.

And another major need is the ability to differentiate Alzheimer's from other contributors to cognitive decline, such as Lewy body disease or vascular causes. But beyond diagnostics, the field also requires more treatment options, better caregiver support, a clearer understanding of disease progression, as well as harmonized clinical protocol so that care teams are aligned and patients consistently receive the best possible care.

06:44
Dr. Jane Caldwell
How are these needs being addressed today?

Dr. Francesca De Simone
So we're seeing rapid progress in addressing key clinical needs for cognitive impairment and Alzheimer's. So plasma biomarkers are now FDA cleared, really helping to support earlier and more accessible diagnosis. And then major trials are also incorporating blood-based assays to screen and monitor patients, which advances risk stratification and treatment tracking.

Payers are also beginning to recognize their utility, really helping to enable broader access. And efforts like the Global Biomarker Standardization Consortium, or GPSC, and the FNIH Biomarker Consortium are driving harmonization across assays, truly ensuring consistent and reliable results.

And finally, the integration into electronic medical records and decision support tools is starting to take shape, which could help bring these biomarkers closer to routine clinical practice and support more standardized, evidence-based care.

07:52
Dr. Jane Caldwell
What do you personally find most rewarding in your work in this area?

Dr. Francesca De Simone
Wonderful question. So it's incredibly rewarding to be part of a field that's transforming how we understand, detect and even manage Alzheimer's disease. The ability to detect disease earlier and potentially change its course is really no longer theoretical. So contributing to the science that brings these tools from bench to bedside and ultimately improves patient outcomes and quality of life is deeply fulfilling. It's especially meaningful to work on solutions that can improve access and equity by making diagnostics more scalable and less invasive for all patients.

08:36
Dr. Jane Caldwell
Dr. De Simone, thank you so much for sharing your expertise with us.

Dr. Francesca De Simone
Thank you.

Dr. Jane Caldwell
And thank you for listening to the *On Medical Grounds* podcast. OMG is your source for engaging relevant, evidence-based medical information.

This podcast was sponsored by Fujirebio Diagnostics, makers of the Lumipulse G Beta-Amyloid Ratio Test, the first FDA approved test for CSF, and the Lumipulse G pTau 217 /Beta-Amyloid 1-42 Plasma Ratio Test, the first FDA approved blood test for early detection of AD.

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