FROM THE ALZHEIMER’S ASSOCIATION INTERNATIONAL CONFERENCE 2017

UNDERUTILIZATION OF BRAIN AMYLOID SCANS DRIVES COST AND HURTS ALZHEIMER’S DISEASE CARE

- Clinical trials show brain PET imaging improves dementia diagnosis –
- More than 80 percent of Alzheimer’s patients and caregivers receptive to PET scanning –

Disclosure: The IDEAS Study is following more than 18,000 Medicare beneficiaries to determine the clinical value of a brain amyloid PET scan in diagnosing and managing treatment of patients 65 and older with MCI or dementia of uncertain cause. The IDEAS Study is funded, in part, by the Alzheimer's Association, who also provide study leadership, and managed by the American College of Radiology/American College of Radiology Imaging Network.

LONDON, July 16, 2017 – Research reported at the Alzheimer’s Association International Conference (AAIC) 2017 in London highlighted the clinical value of amyloid-β PET scans, which detect the presence of amyloid-beta plaques in the brain - one of the hallmarks of Alzheimer’s disease. Studies also revealed an underutilization of amyloid-β PET imaging in clinical care, contributing to misdiagnosis of dementia.

Two studies at AAIC 2017 reported that brain PET imaging allows for more accurate detection or exclusion of Alzheimer’s in a larger proportion of individuals than standard clinical assessment supported by structural and metabolic imaging, and cerebrospinal fluid (CSF), and that use of amyloid PET scans may lead to a change in diagnosis in up to two-thirds of cases. A meta-analysis of data in a large population of participants found that brain amyloid PET scans led to a change in diagnosis in approximately 20 percent of these individuals.

Other PET-related research reported at AAIC 2017 included the following findings:

- A survey of individuals with cognitive impairment and their caregivers found that more than 80 percent were receptive to undergoing a PET imaging study if it was recommended by their doctor, and clinicians would base decisions about future patient care on brain PET scan findings. Many study participants were frustrated by the lack of availability of brain amyloid PET scans in clinical practice.
- An analysis of Medicare claims data found that approximately 60 percent of dementia cases are missed in clinical practice, particularly cases of early dementia.

“A negative brain PET scan indicating sparse to no amyloid plaques rules out Alzheimer’s disease as the cause of dementia symptoms. This makes it a valuable tool to clarify an uncertain or difficult diagnosis,” said James A. Hendrix, PhD, Alzheimer’s Association Director of Global Science Initiatives. “Misdiagnosis is costly to health systems, and expensive and distressing to persons with dementia and their families.”
“Beyond the data reported at AAIC 2017, the IDEAS Study will provide further evidence to demonstrate the utility of amyloid PET imaging in a clinical setting,” said Hendrix. “A swift and accurate diagnosis has a huge impact on access to Alzheimer’s treatments, eligibility for research trials, plus much-needed support and information services.” The IDEAS Study is led by the Alzheimer’s Association and managed by the American College of Radiology and American College of Radiology Imaging Network.

Utilization of PET Scanning Greatly Enhanced Diagnosis of Alzheimer’s Disease

Identification of amyloid-β in clinical practice has relied largely on CSF testing and the administration of cognitive and psychiatric tests that are not specific to Alzheimer’s disease. The emergence of PET imaging has been instrumental in advancing Alzheimer’s research, but despite the high rate of misdiagnosis in this disease, the prevailing wisdom has been that PET imaging does not provide sufficient additional diagnostic accuracy to justify its cost. Two small studies and a meta-analysis presented at AAIC are challenging that view.

In an ongoing study of individuals with cognitive complaints performed at Oslo University Hospital by Nenad Bogdanovic, MD, PhD, of the University of Oslo in Norway, amyloid PET imaging was found to be a key contributor to either diagnosing or excluding a diagnosis of Alzheimer’s disease in all 50 (100 percent) of participants. In contrast, CSF amyloid testing allowed for diagnosis or exclusion in 44 of 50 individuals (88 percent) using a higher detection cutoff and in only 21 individuals (42 percent) using traditional cutoffs.

As part of a 135-person study, doctoral student Antoine Leuzy, MSc, of Karolinska Institute in Stockholm and colleagues presented PET imaging results for 61 individuals diagnosed with mild cognitive impairment (n=38), Alzheimer’s disease (n=13), other types of dementia (n=8) or severe cognitive impairment (n=2). PET imaging studies led to a change in diagnosis in 68 percent of these participants. Agreement between CSF testing and PET imaging was only 53–57 percent, depending on the approach used to read the PET scan. Where results disagreed, 75–77 percent of individuals were amyloid-β positive on PET scanning. Results from these small studies highlight not only the diagnostic value of PET but also the potential for misdiagnosis using traditional assessments.

Enrico Fantoni, PhD, of GE Healthcare in Amersham, UK, is performing an ongoing meta-analysis of four clinical trials conducted between 2000 and 2017 to evaluate the value of amyloid PET (aPET) in a large population of individuals with cognitive impairment. A preliminary evaluation of four studies with more than 1,100 clinical cases revealed that the use of aPET led to a change in diagnosis in over 20 percent of people independent of PET scan outcome.

- In those individuals with a prescan Alzheimer’s diagnosis and a positive aPET scan, the diagnosis was subsequently confirmed in 99 percent. Conversely, an Alzheimer’s diagnosis was ruled out in the majority of cases with a negative aPET scan (similarly, 99% of cases).
- If the prescan diagnosis was non-Alzheimer’s, however, a positive aPET scan led to reassessment as Alzheimer’s in 60 percent of cases.
- If the prescan diagnosis was Alzheimer’s, a negative aPET scan led to exclusion of Alzheimer’s in 54 percent of cases.

Thus, aPET was valuable for excluding and confirming diagnoses of Alzheimer’s disease.

Limited Access Leads to Underutilization of PET Scanning

While research supports the value of PET scans for clarifying a diagnosis of Alzheimer’s disease, Liana Apostolova, MD, of Indiana University School of Medicine in Indianapolis and colleagues presented a study at AAIC 2017 that indicates that limited access to PET imaging is proving frustrating to individuals and their caregivers, and it leads to continued frequent misdiagnoses of people who would benefit from early intervention.
The team surveyed 510 participants and caregivers (predominantly in the U.S.) to gauge their attitudes about PET imaging as a part of patient care. Between 85 percent and 91 percent of respondents indicated they were dissatisfied with the availability of PET scans, supported additional research on PET imaging and were willing to undergo PET scans if they were recommended by their physician.

**Medicare Claims Frequently Misidentify Dementia**

Carolyn Zhu, PhD, of Icahn School of Medicine at Mount Sinai in New York and colleagues analyzed data from 2,144 participants in the Washington Heights-Inwood Columbia Aging Project and found that Medicare claims frequently misidentified dementia cases. The sample included 1,689 individuals not diagnosed with dementia and 455 with a clinical diagnosis of dementia based on a rigorous clinical assessment performed at study enrollment. Medicare claims prior to study enrollment allowed for successful identification of 1808 subjects (85 percent), suggesting moderate agreement between claims data and subsequent clinical diagnoses. However, 281 subjects (62 percent) diagnosed with dementia at study enrollment were not identified as such based on prior treatment reported in Medicare claims. These people were younger and had better general health and cognitive function than those identified as having dementia based on Medicare claims.

While the U.S. Congress has recently provided additional funding for Alzheimer’s research at the National Institutes of Health (NIH), the commitment falls far short of the need. In 2017, for every $100 the NIH spends on Alzheimer’s research, Medicare and Medicaid will spend $12,500 caring for those with the disease. Congress must continue its commitment to the fight against Alzheimer’s and other dementias by increasing funding for Alzheimer’s research by at least an additional $414 million in fiscal year 2018.

**About Alzheimer’s Association International Conference**

The Alzheimer’s Association International Conference (AAIC) is the world’s largest gathering of researchers from around the world focused on Alzheimer’s and other dementias. As a part of the Alzheimer’s Association’s research program, AAIC serves as a catalyst for generating new knowledge about dementia and fostering a vital, collegial research community.

AAIC 2017 home page: [www.alz.org/aaic/](http://www.alz.org/aaic/)

**About the Alzheimer’s Association**

The Alzheimer’s Association is the leading voluntary health organization in Alzheimer's care, support and research. Our mission is to eliminate Alzheimer’s disease through the advancement of research, to provide and enhance care and support for all affected, and to reduce the risk of dementia through the promotion of brain health. Our vision is a world without Alzheimer’s. Visit alz.org or call +1 800.272.3900.

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- Antoine Leuzy, MSc, et al. Investigating the Clinical Impact of [18F]flutemetamol PET in a Tertiary Memory Clinic Setting in Patients with Uncertain Diagnosis. (Funder: Vinnova, Swedish Research Council; Swedish Foundation for Strategic Research (SSF); Regional Agreement on Medical Training and Clinical Research (ALF) for Stockholm County Council; Swedish Brain Foundation; Swedish Alzheimer’s Foundation; Gun and Bertil Stohne's Foundation; Demensfonden)
- Enrico Fantoni, PhD, et al. Amyloid PET Utility in Clinical Practice: A Systematic Review and MetaAnalysis. (Funder(s): GE Healthcare)
- Liana Apostolova, MD, MS, et al. Patient and Caregiver Assessment of the Benefits from the Clinical Use of Amyloid PET Imaging (Weds). (Funder(s): U.S. National Institute on Aging)
- Carolyn Zhu, PhD, et al. The Accuracy of Dementia Diagnosis in Medicare Claim.

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