Update on Imaging Dementia-Evidence for Amyloid Scanning (IDEAS)

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Disclosures

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- Alzheimer’s Association, American College of Radiology
- Avid Radiopharmaceuticals/Eli Lilly, GE Healthcare, Life Molecular Imaging

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- Associate Editor, JAMA Neurology
Outline

• Overview of IDEAS study design and objectives
• Brief recap of Aim 1 results (patient management)
• Aim 2 analysis timeline (health outcomes)
• Secondary analyses
  • Predictors of amyloid positivity
  • Demographics and outcomes in racial/ethnic minorities
  • Add-on studies
Outline (Cont.)

• New IDEAS study approved by CMS 4/23/2020!
  • Study design & aims
Single arm, multi-site, longitudinal study evaluating the clinical utility of amyloid PET in 18,295 Medicare beneficiaries with MCI or dementia meeting amyloid PET Appropriate Use Criteria (Johnson et al. 2013)

- Eligible patients referred for PET by dementia specialists
- PET performed with FDA-approved Aβ PET ligand
  - $^{18}$F-florbetaben, $^{18}$F-florbetapir, $^{18}$F-flutametamol
- **Aim 1**: Impact of scan on management plan at 3 months
- **Aim 2**: Impact on major medical outcomes at 12 months
- *The primary hypothesis is that, in diagnostically uncertain cases, amyloid PET will lead to changes in patient management, and these will translate into improved outcomes*
Inclusion/Exclusion Criteria
For complete list see: www.ideas-study.org

• **Primary Inclusion Criteria**
  • Medicare beneficiary, age ≥ 65
  • English or Spanish speaking (for purposes of consent)
  • Meets Appropriate Use Criteria for amyloid PET
     • Objectively confirmed cognitive impairment (MCI/dementia)
     • Diagnosis uncertain after comprehensive evaluation by a dementia specialist (including labs and CT/MRI)
     • Knowledge of amyloid status expected to change management

• **Primary Exclusion Criteria**
  • Amyloid status known, previous enrollment in anti-Aβ trial
  • Knowledge of amyloid status expected to cause harm
  • Life expectancy < 24 months based on medical co-morbidities
  • Residence in a skilled nursing facility
Pre-PET visit:
Care plan assuming no access to amyloid PET

Scan completed with FDA-approved ligand:
Communicate results to patients
Recommend changes to care plan as appropriate

90 day post-PET visit:
Document implemented care plan following PET

12 months Medicare claims:
Hospitalizations, ED visits, aggregate utilization

Aim 1
≥30% change comparing pre-PET to post-PET?

Aim 2
≥10% reduction compared to matched cohort w/o amyloid PET
IDEAS Study Network

595 dementia practices
79% private/group practice
946 dementia specialists

343 PET facilities
733 imaging specialists

18,295 scans completed
Feb 2016 – Feb 2018

Median age 75 (65-105)
60.4% MCI
39.6% dementia

PET Aβ+:
MCI 55.2%
Dementia 69.6%

IDEAS-Study.org
Rabinovici et al., JAMA 2019
Association of Amyloid Positron Emission Tomography With Subsequent Change in Clinical Management Among Medicare Beneficiaries With Mild Cognitive Impairment or Dementia

Gil D. Rabinovici, MD; Constantine Gatsonis, PhD; Charles Apgar, MBA; Kiran Chaudhary, MS; Ilana Gareen, PhD; Lucy Hanna, MS; James Hendrix, PhD; Bruce E. Hillner, MD; Cynthia Olson, MBA; Orit H. Lesman-Segev, MD; Justin Romanoff, MA; Barry A. Siegel, MD; Rachel A. Whitmer, PhD; Maria C. Carrillo, PhD

JAMA 2019 321(13): 1286-1294
Amyloid PET Changes Patient Management (N=11,409)

Composite: AD drugs, non-AD drugs, counseling & referrals

Change in components:

AD drugs
- MCI 43.6%, dementia 44.9%
Non-AD drugs
- MCI 22.9%, dementia 25.4%
Counseling
- MCI 24.3%, dementia 20.7%

Change in diagnosis
- 25.1% AD to non-AD
- 10.5% Non-AD to AD

Pre-PET dx was AD in 71.5% of PET-neg patients -> 10.2% post-PET

Rabinovici et al., JAMA 2019
Aim 2: Approach and Endpoints

To assess the impact of brain amyloid PET on hospital admissions and emergency room visits in study patients (amyloid PET-known) compared to matched patients not in the study (amyloid PET-naïve) over 12 months.

Primary Endpoint: determine if amyloid PET is associated with ≥ 10% relative reduction in study patients compared to matched controls:
- Inpatient hospital admissions over 12 months
- Emergency room visits over 12 months

Secondary Endpoints:
- Preventable hospitalizations, aggregate resource utilization
- Associations between amyloid PET and health outcomes in:
  - Aβ-PET positive vs. Aβ-PET negative
  - MCI vs. dementia

Results expected in Summer 2020
Predictors of Amyloid Positivity

Lesman-Segev, La Joie et al. in prep
Minorities in IDEAS: Window into Disparities in Dementia Care

• Racial/ethnic minorities only 10.4% of participants
  • 4.8% Hispanic, 3.4% Black, 1.8% Asian

• Compared to Whites:
  • All minorities more likely to have dementia
    • 52% Blacks, 56% Hispanics, 47% Asian, 37% Whites
  • More likely to have Medicare Advantage plan
  • Higher prevalence of diabetes (all), hypertension (Blacks)
  • Lower prevalence of family history of dementia

Wilkins, Dilworth-Anderson et al., *in prep*
Lower Rates of PET-Positivity in Minorities vs. Whites

Wilkins, Dilworth-Anderson et al., *in prep*
Genetic testing
PI: Taitiana Foroud, Indiana
N=1,946

Online cognitive testing and questionnaires
PI: Mike Weiner, UCSF
N=853

Caregiver perspective
PI: Vince Mor, Brown
N=2,228

Plasma Aβ
N=697
New IDEAS: A Study to Improve Precision in Amyloid PET Coverage and Patient Care

- Recruit diverse cohort of 7,000 Medicare beneficiaries
  - At least 2,000 African-Americans/Blacks and 2,000 Latinx/Hispanics
  - Typical and atypical clinical presentations of AD
  - Early-onset and late-onset dementia
  - Biorepository (DNA and plasma) and image archive
- Study approved by CMS 4/23/2020
  - Hope to launch late summer/early fall 2020, COVID-19 permitting
  - Recruitment over 3 years
New IDEAS: Study Aims

• **AIM 1**: To compare 12-month claims-derived health outcomes in amyloid PET-positive versus amyloid PET-negative individuals presenting with MCI and dementia in the entire study cohort of diverse Medicare beneficiaries

• **AIM 2**: To describe the association of amyloid PET findings with changes in patient management and 12–month claims-derived health outcomes among Blacks/African Americans, Latinos/Hispanics and Whites/Caucasians presenting with MCI and dementia

• **AIM 3**: To describe the association of amyloid PET findings with changes in management and 12-month claims-derived health outcomes in individuals presenting with typical (progressive amnestic) versus atypical clinical presentations of MCI and AD dementia

• **ADDITIONAL OBJECTIVES**:
  • Establish biorepository of DNA, plasma
  • Collect and archive PET images
New IDEAS, New Leadership

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Vanderbilt University & Meharry Medical College

Peggye Dilworth-Anderson, PhD  
University of North Carolina Chapel-Hill

Sid O’Bryant, PhD  
University of N Texas

Robert Rissman, PhD  
UC San Diego
Conclusions and Next Steps

- IDEAS study provides strongest Phase IV data to date supporting the impact of amyloid PET on patient management
- Aim 2 results on health outcomes required for coverage reconsideration, expected Summer 2020
- New IDEAS: coming soon to a PET scanner near you
- IDEAS data as a resource to research community
  - Data sharing requests reviewed by Research & Publications Committee
  - Data and images to be placed on Global Alzheimer’s Association Interactive Network
Acknowledgments

IDEAS Steering Committee
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