

M143

FROM FIRST VISIT TO DISCLOSURE: HOW CONFIRMATORY BLOOD-BASED BIOMARKERS ARE CHANGING DIAGNOSTIC TIMING IN ALZHEIMER’S DISEASE

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Introduction

- Clinical Practice Guidelines from the Alzheimer’s Association recommend use of high-performing BBM tests as triage tools (to determine need for confirmatory testing) and as alternatives to amyloid PET or CSF testing when diagnostic performance thresholds are met.¹
- Optimal integration of BBM testing into routine clinical workflows is not well defined and real-world evidence on BBM utilization in diagnostic pathways is still emerging.²
- This study aimed to characterize real-world BBM utilization and its impact on diagnostic pathways and timelines in patients undergoing evaluation for cognitive decline across diverse US clinical settings.

Methods

- This prospective, multi-site, observational study was conducted across 3 US clinical settings (rural private practice, academic medical center, and private neurology clinic), representing diverse practice types. All had experience using BBMs for triage and/or confirmatory purposes.
- Eligible patient cases included adults aged ≥55 years undergoing evaluation for cognitive decline with possible AD. Data were collected from EMRs via eCRFs over a 6-month observation period (between February 2025 and February 2026).
- Diagnostic pathways were characterized by capturing use of BBMs and other testing modalities, with timing relative to the initial general cognitive health assessment (CHA) and disclosure of results to patients, as well as diagnostic outcomes. All analyses were descriptive.

Results

Patient Demographics

- A total of 185 patient cases were included in the analysis. The mean (SD) age was 73 (9) years, and 61% were female; the cohort was predominantly white (78%), with representation across rural, suburban, and urban locations.

Biomarker Utilization

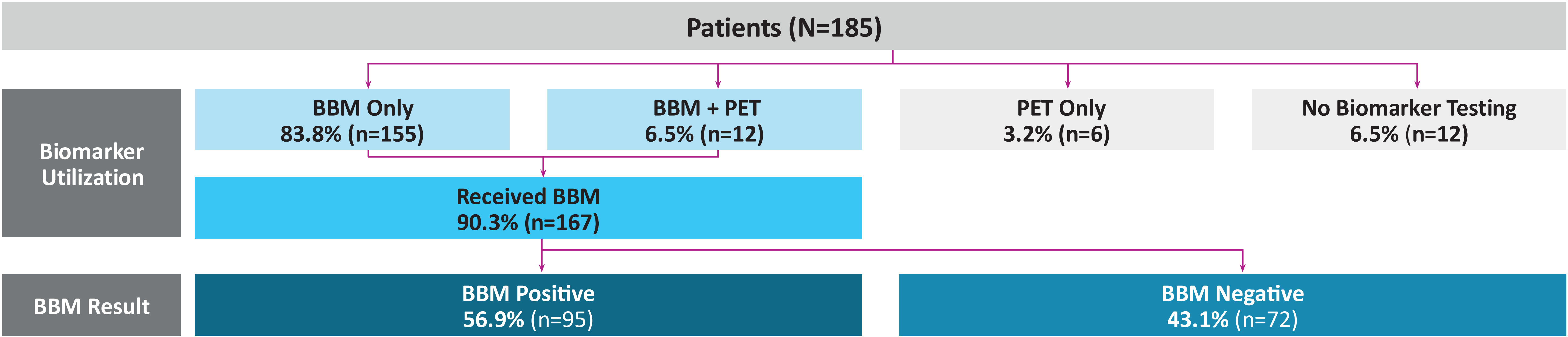
- BBM testing was widely implemented as part of the diagnostic workup for amyloid pathology and was predominantly used without additional confirmatory PET/CSF testing (Figure 1).
- PET imaging was utilized in a minority of cases, most often as a followup to BBM testing; no CSF testing was performed during the study period (Figure 1).
- Among patients receiving BBM testing, 56.9% were positive for amyloid pathology (Figure 1).
- Combination panels accounted for the majority of BBM use, with p-tau217 + Aβ42/40 representing the most frequently used assay, followed by single-analyte p-tau217 testing (Table 1).

Diagnostic Timing and Outcomes

- Median time from initial CHA to biomarker testing and result disclosure to patients was shorter with BBMs compared with PET imaging (Figure 2).
- Time from BBM test to patient disclosure varied across sites, with shorter and more consistent timelines observed at the private neurology clinic (with onsite laboratory testing) compared with the rural practice and academic medical center (Figure 3).
- At the end of the study period, almost half of patients were diagnosed with AD, most at the MCI stage (Figure 4), consistent with early use of biomarker testing in this cohort.

Results

Figure 1. Diagnostic Biomarker Utilization

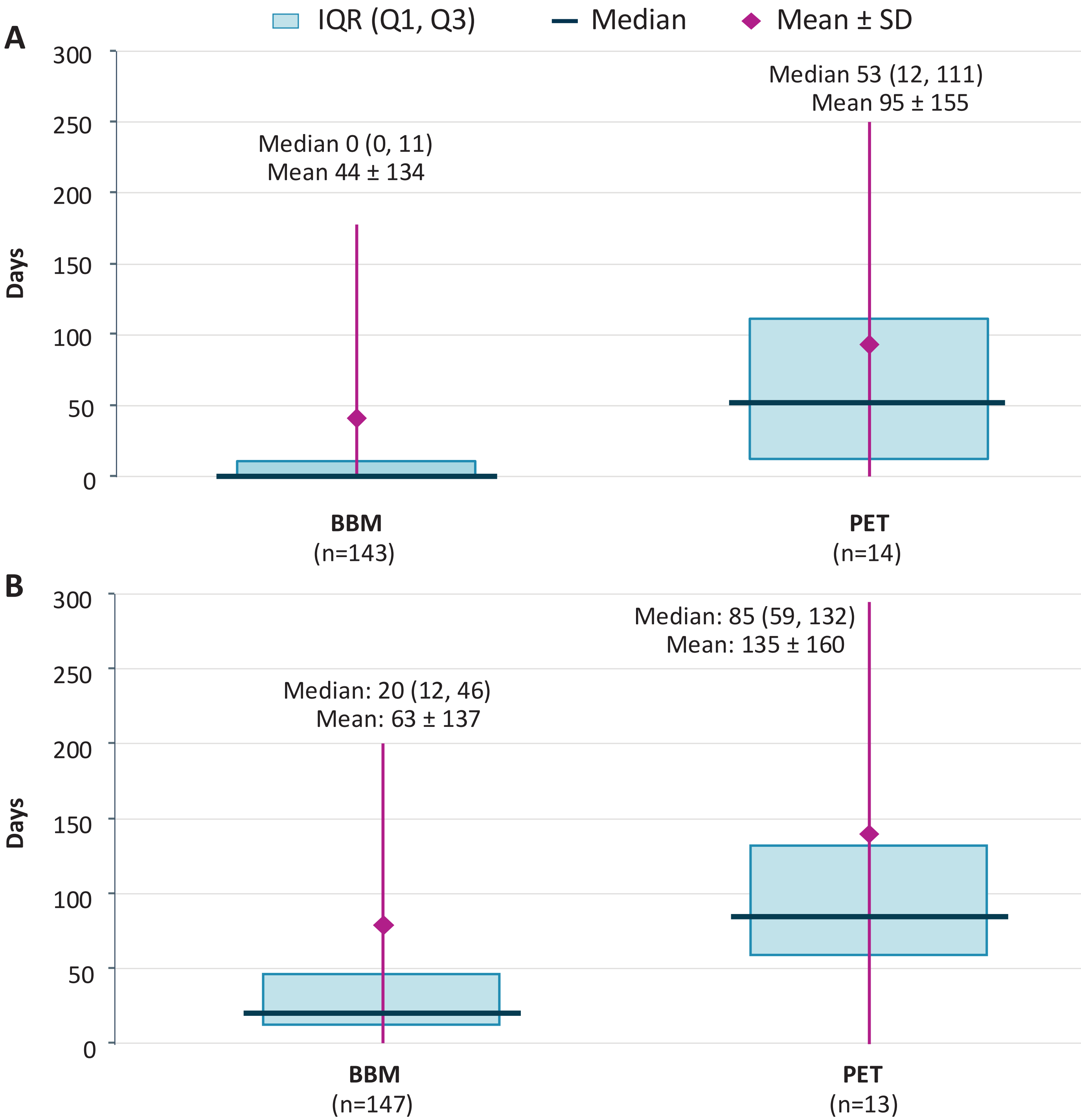


Biomarker utilization percentages are based on total cohort (N=185). BBM results are based on the number of patients receiving a BBM test (n=167). No participants received CSF biomarker testing during the study.

Table 2. BBM Assays Used (n=167)

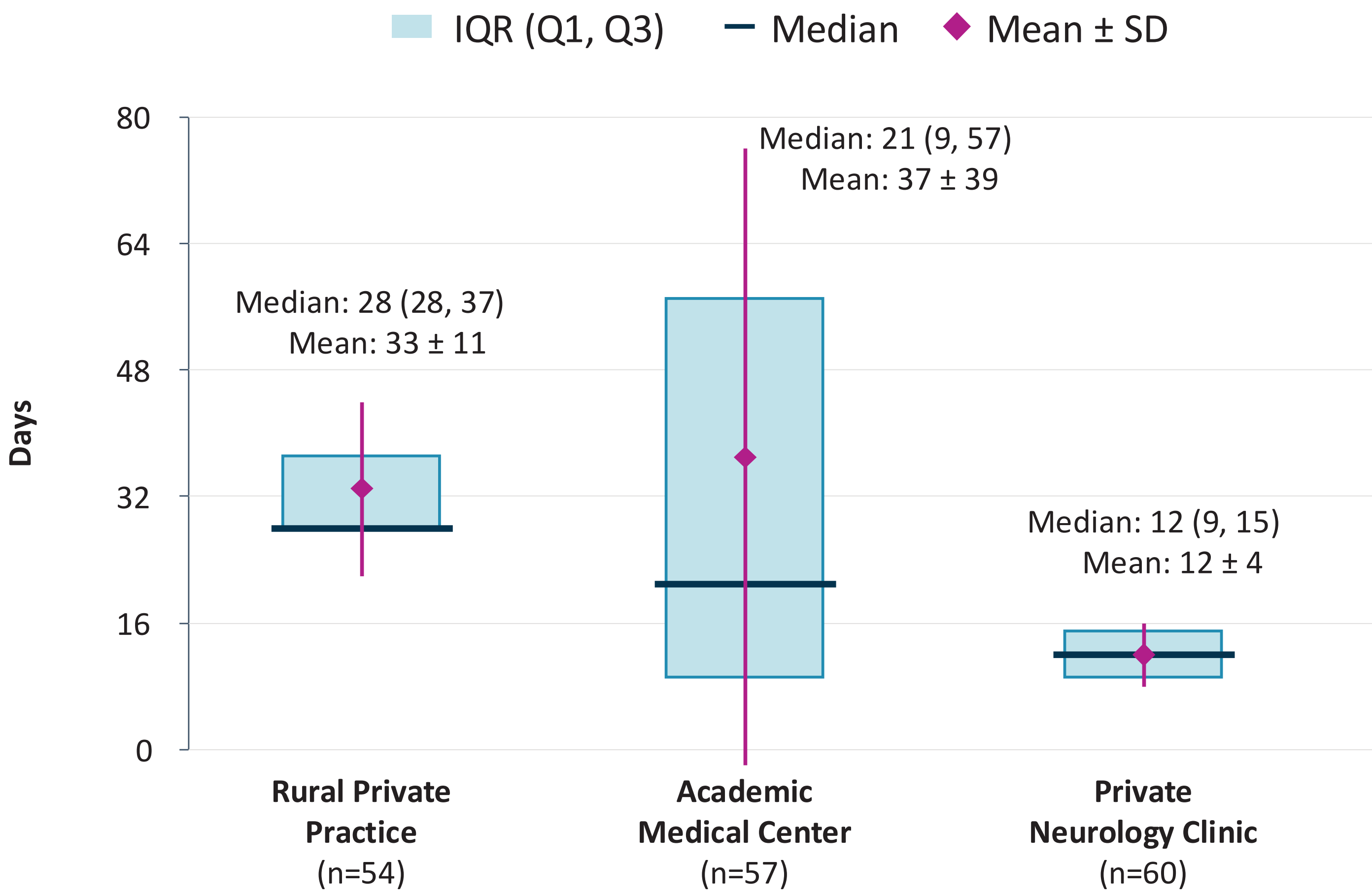
BBM Assay Combination	n
P-tau217 + Aβ42/40	79
P-tau217	61
P-tau217, p-tau181, Aβ42/40	9
P-tau217, p-tau181, Aβ42/40, GFAP, NfL	8
P-tau217/Aβ42	7
P-tau181, Aβ42/40, NfL	1
Missing or unknown data	2

Figure 2. Timing from CHA to Biomarker Test (A) and to Patient Test Results Disclosure (B)



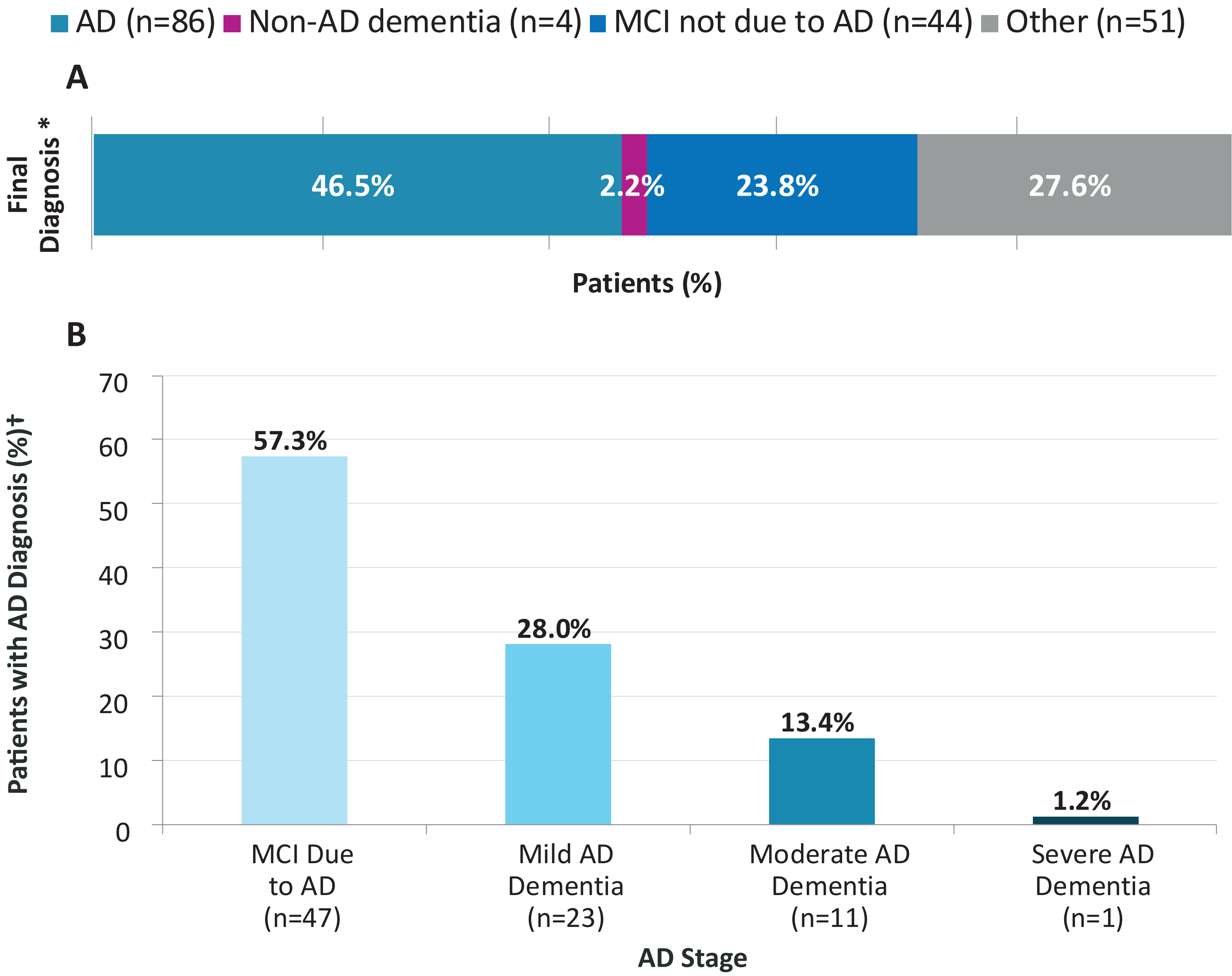
Time was calculated from date of patient CHA to date of biomarker test and to date of patient result disclosure. No patients received CSF testing during the study. Lower whiskers clipped at zero: interval is zero-bounded (no patient can have a negative time from initial assessment to test/disclosure).

Figure 3. Timing from BBM Test to Patient Disclosure by Site



Time was calculated from date of BBM test to date of patient result disclosure.

Figure 4. Final Diagnoses (A) and AD Disease Stages (B) at End of Study



* Final diagnoses reflect clinician-reported outcomes at the end of the study period for all patient cases (N=185). † Percentages are based on patients diagnosed with AD with non-missing data (n=82; AD stage data were missing for 4 patients); percentages may not sum to 100% due to rounding.

Conclusions

- In this real-world, multi-site, observational study, BBMs were widely adopted as confirmatory tools for amyloid pathology in patients undergoing evaluation for cognitive decline, with most testing performed using combination panels with p-tau217, as well as p-tau217 only.
- BBM testing was associated with shorter intervals from initial cognitive assessment to patient disclosure of results compared with PET imaging, indicating more efficient progression through clinical pathways.
- Time from BBM test to patient disclosure varied across settings, highlighting the influence of site-specific workflows and infrastructure, including choice of assay and reference laboratory on diagnostic timelines.
- The observed diagnostic profile, with a substantial proportion of patients diagnosed at the MCI stage, supports the use of BBMs within pathways targeting earlier stages of disease.
- These findings suggest that BBMs may support more streamlined diagnostic workflows and facilitate earlier confirmation of AD pathology in routine clinical practice.

References: 1. Palmqvist S, et al. *Alzheimers Dement*. 2025;21:e70535. 2. Prufert Q, et al. *Alzheimers Dement*. 2025;21:e70891. **Abbreviations:** Aβ, amyloid beta; AD, Alzheimer’s disease; BBM, blood-based biomarker; CHA, Cognitive Health Assessment; CSF, cerebrospinal fluid; eCRF, electronic case report form; EMR, electronic medical record; GFAP, glial fibrillary acidic protein; IQR, interquartile range; MCI, mild cognitive impairment; NfL, neurofilament light; p-tau, phosphorylated tau; PET, positron emission tomography; Q, quartile; SD, standard deviation; US, United States. **Acknowledgments:** The study was conducted by Premier Inc., funded by Eisai Inc. and Biogen. Medical writing support was provided by Panacea85, funded by Eisai Inc. and Biogen. **Disclosures:** Kimberly Petro is an employee of Eisai Inc. ABA is a principal investigator for Eisai Inc., Eli Lilly and Amgen; serves as a principal investigator for Abbvie, Alnylam, Ariobio, Biogen, Biohaven, Eisai, Eli Lilly, Olanzapine, and Vims. JES reports NIH research support and consulting relationships with Beckmann Coulter, Biogen, BMS, Cerevel, Cognition Therapeutics, Cognivue, Eisai, Eli Lilly, GE Healthcare, Genentech, Lobe, and Roche. MDV has no disclosures to report. LZ receives consulting fees from Novartis and Eisai Inc. DG serves as editor of *Alzheimer’s Disease Research and Treatment*; membership on data safety monitoring boards for Elan and Janssen; participation as an investigator in trials sponsored by Eli Lilly and Avid; and NIH research support (P50 AG05131 [PI] and U01 AG10483 [co-investigator]). SM serves on the board of directors of Sencio Systems and scientific advisory boards of Alzpath, BMS, and Boston Millennia Partners; receives consulting fees from Biogen, C2N, Eisai, Genentech, Novartis, Novo Nordisk, and Roche-Genentech; and is principal investigator on research contracts between USC and Biogen, Eisai, C2N, and Roche-Genentech. MMM receives research funding from NIH/NIA, the Department of Defense, the Alzheimer’s Association, and the Davos Alzheimer’s Consortium; serves as Senior Editor for *Alzheimer’s Research and Therapy* and *Alzheimer’s & Dementia*; and receives consulting/advisory fees from Althira, Biogen, Cognito Therapeutics, Eisai, LabCorp, Eli Lilly, Merck, Neurogen Biomarking, Novo Nordisk, Roche, and Siemens Healthineers. MNS holds stock/stock options in Alzheon and Lighthouse Pharmaceuticals, and receives consulting/speaker fees from AbbVie, Alzinova, Anavex, Cognito Therapeutics, Eisai, GSK, NeuroTherapia, Otsuka, Recall Therapeutics, and Signant. LLS and NJG are employees of Premier Applied Sciences, Premier Inc., which received funding from Eisai Inc. for the study. CA, FF, and DRJ are employees of Eisai Inc.