

REAL-WORLD DIAGNOSTIC PATHWAYS FOR ALZHEIMER’S DISEASE IN U.S. CLINICAL PRACTICE USING CLAIMS AND INTEGRATED EHR DATA

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Introduction

- Timely diagnosis of early stages of Alzheimer’s disease (AD) remains a challenge in clinical practice¹⁻²
- Diagnostic delays increase healthcare cost and utilization, limit access to anti-amyloid therapies (AAT), and reduce opportunities for patients and their care partners to make informed decisions about care³⁻⁵
- Understanding real-world diagnostic pathways and inefficiencies is critical to identify opportunities for earlier detection and intervention⁶⁻⁷
- The objective of this analysis was to estimate the time from initial cognitive complaint (CC) to first diagnosis of AD and to describe demographic characteristics and elements of the real-world diagnostic journey

Methods

- This retrospective study uses de-identified claims and electronic health record (EHR) data from the Optum Market Clarity Integrated Clinical+Claims database linked to the Optum Alzheimer’s Enriched Clinical Data
- The study period spans 01/01/2020-12/31/2025. Subjects aged ≥50 years with ≥12 months of baseline and follow-up enrollment and an initial CC documented via ICD-10 codes related to cognitive, orientation and behavioral symptoms on a nondiagnostic medical claim
- The primary endpoint is time (days) from index CC to first diagnosis of AD or mild cognitive impairment (MCI) due to AD. Analysis includes Kaplan-Meier estimate for time-to event outcomes
- Secondary endpoints include number and types of providers involved and diagnostic work-up (cognitive assessments, diagnostic tests, laboratory tests, and neuroimaging) and are summarized descriptively

Results

- More than 14 million subjects were identified with a CC during the ID period. A total of 163,439 subjects had an AD diagnosis and met inclusion/exclusion for this study.
- A full summary of the patient identification and attrition from this study can be found here: 
- The mean age was 74.9 years (SD 8.6); 60% were female, 68% White, and 86% covered by Medicare (**Table 1**)

Table 1. Patient Demographic Characteristics

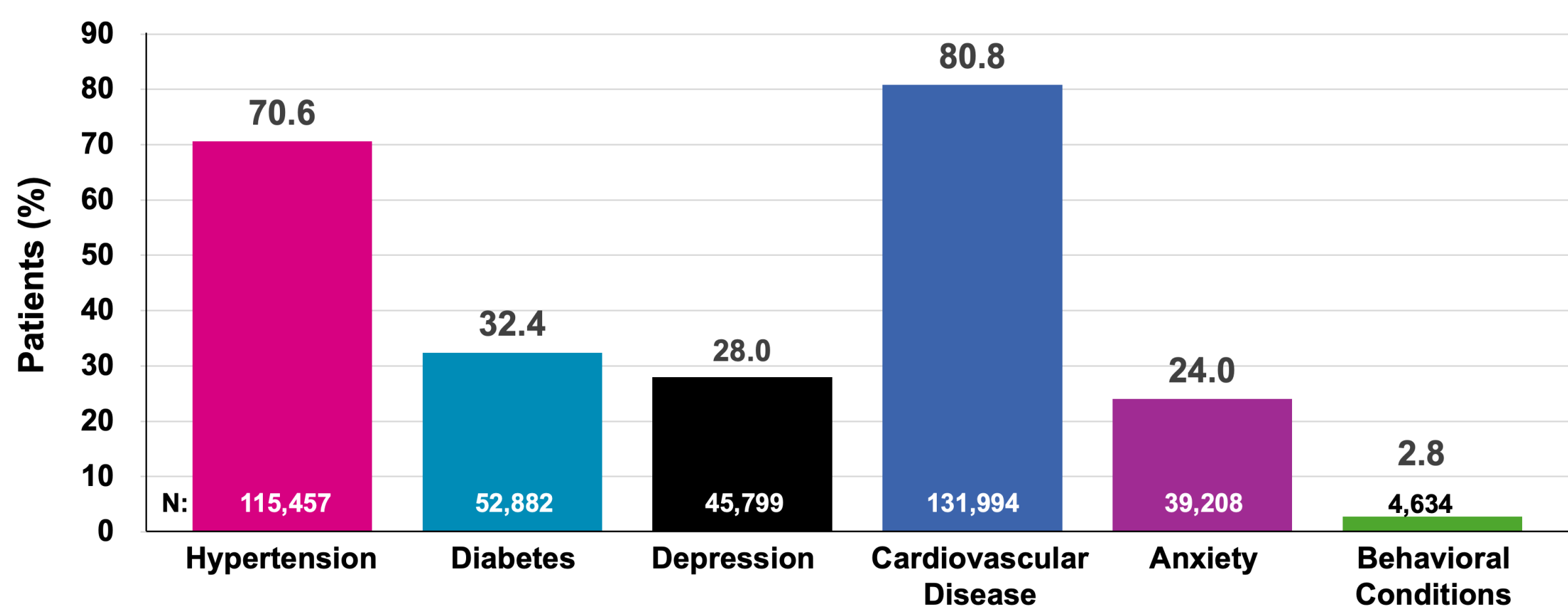
Demographics	AD or MCI due to AD (N=163,439)
Age (continuous), mean years (SD)	74.9 (8.6)
Age group, n (%)	
50-64	21,973 (13.4)
65-74	47,334 (29.0)
75+	94,132 (57.6)
Sex, n (%)	
Female	98,693 (60.4)
Male	64,746 (39.6)
Race and ethnicity, n (%)	
Hispanic	15,007 (9.2)
White	111,049 (68.0)
Black	14,511 (8.9)
Asian	4,717 (2.9)
Other/unknown	18,155 (11.1)
Insurance type, n (%)	
Commercial only	14,338 (8.8)
Medicare only	140,712 (86.1)
Medicaid only	5,284 (3.2)
Multiple known	2,985 (1.8)
None of these/unknown	120 (0.1)
US Census Region, n (%)	
Northeast	31,296 (19.2)
Midwest	43,624 (26.7)
South	53,512 (32.7)
West	29,829 (18.3)
Other	5,178 (3.2)

Abbreviations: AD, Alzheimer’s disease; BBM, blood-based biomarker; CSF, cerebrospinal fluid; MCI, mild cognitive impairment; PET, positron emission tomography

Results (continued)

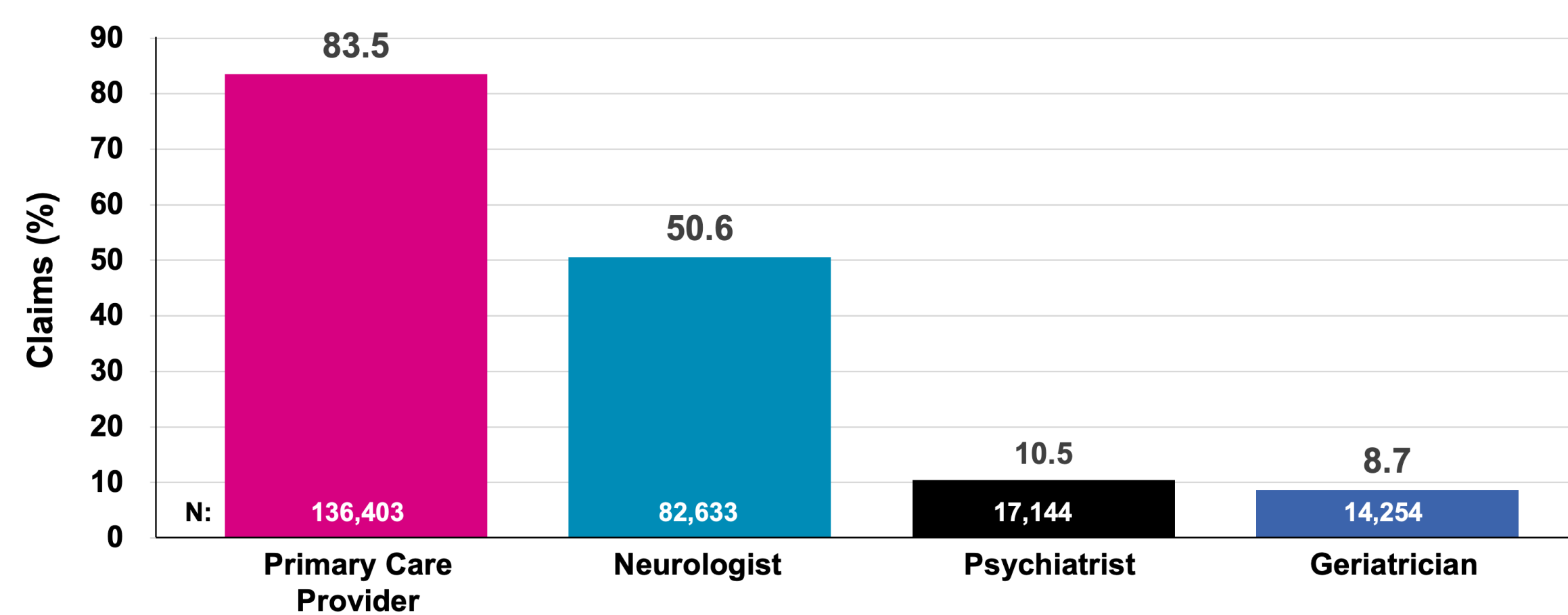
- The most common comorbid conditions were cardiovascular disease (81%) and hypertension (71%) (**Figure 1**)

Figure 1. Baseline Clinical Characteristics



- Follow-up visits were most often with primary care providers (83%) (**Figure 2**)

Figure 2. Follow-up Provider Visits



The mean number of provider visits during the diagnostic process was 8.93

- Cognitive and biomarker tests were uncommon, but over 50% of patients had an MRI and CT scan (**Table 2**)

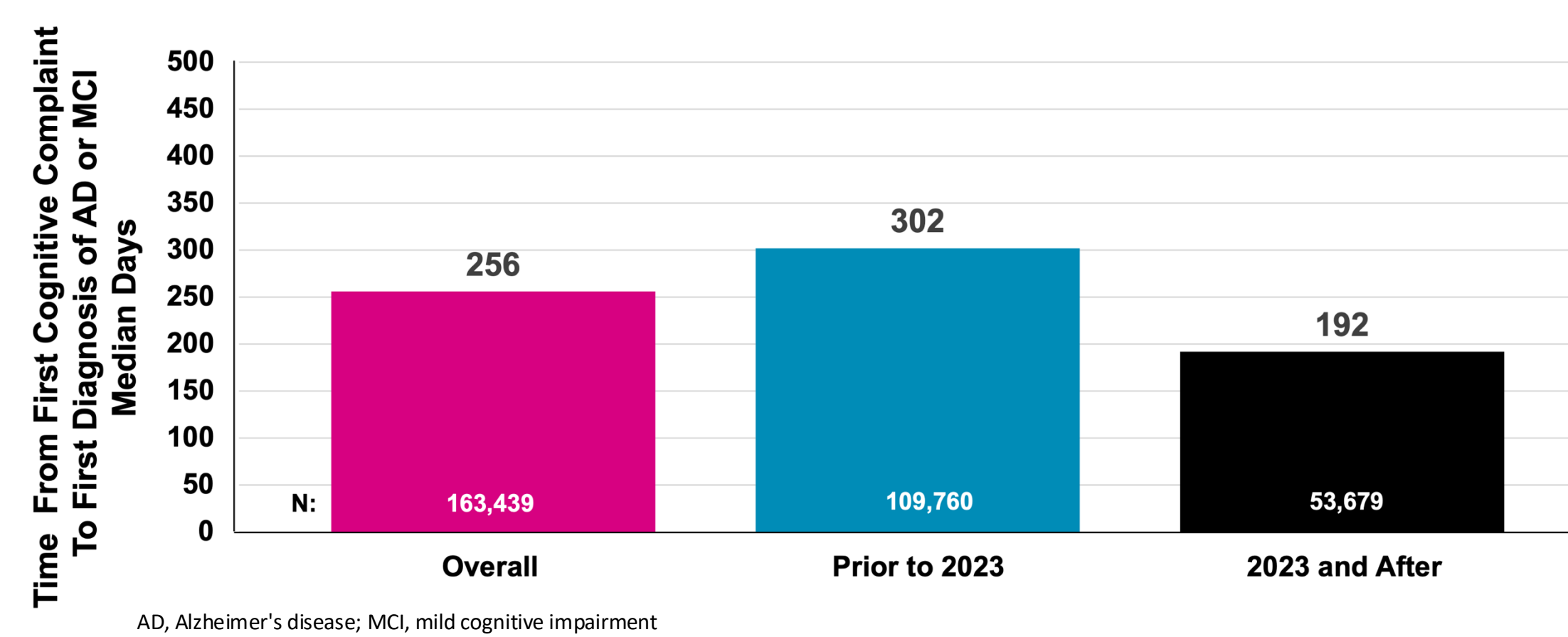
Table 2. Follow-up Cognitive Assessments, Diagnostic Testing, and Diagnostic Imaging Procedures

Diagnostic Work-up	AD or MCI due to AD (N=163,439)
Cognitive assessments (Alzheimer's enriched data), n (%)	
6CIT	334 (0.2)
AD8	12 (0.01)
MMSE	1,538 (0.9)
MoCA	1,679 (1.0)
Mini-Cog	1,083 (0.7)
SLUMS	940 (0.6)
Diagnostic tests, n (%)	
BBM analysis (claims)	5,425 (3.3)
CSF biomarker analysis (claims)	7,662 (4.7)
BBM or CSF test (Alzheimer's enriched data)	113 (0.1)
Diagnostic imaging procedures (claims or Alzheimer's enriched data), n (%)	
MRI	93,113 (57.0)
MRS	50 (0.03)
CT scan	93,376 (57.1)
PET scan	14,075 (8.6)
SPECT	3 (0.0)

Abbreviations: 6CIT, Six-Item Cognitive Impairment Test; AD, Alzheimer’s disease; AD8, Ascertain Dementia 8; BBM, blood-based biomarker; CSF, cerebrospinal fluid; CT, computed tomography; MCI, mild cognitive impairment; MMSE, Mini-Mental State Examination; MoCA, Montreal Cognitive Assessment; MRI, magnetic resonance image; MRS, magnetic resonance spectroscopy; PET, positron emission tomography; SLUMS, Saint Louis University Mental Status Exam; SPECT, single-photon emission computed tomography

- Median time from first cognitive complaint to first diagnosis of AD or MCI due to AD was 371.24 days (**Figure 3**)
- These results improve over time (i.e., 425.86 and 259.54 mean days if first complaint is prior or after 1/1/2023, respectively)

Figure 3. Median Time from First Cognitive Complaint to First Diagnosis of AD or MCI due to AD



- All-cause health care resource utilization during the diagnostic journey is summarized in **Table 3**

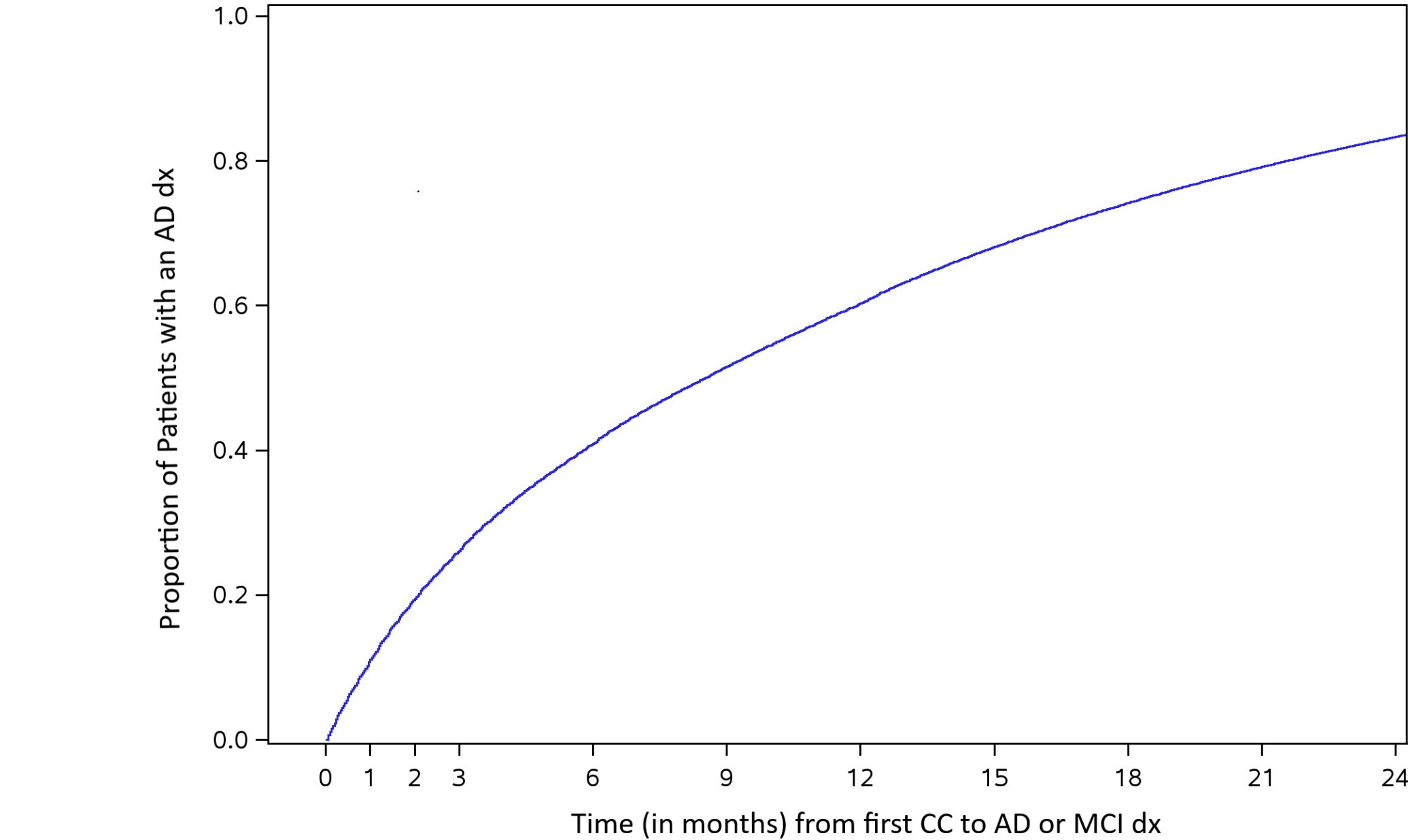
Table 3. Follow-up Per Patient Per Year (PPPY) All-Cause HCRU

PPPY All-Cause HCRU	AD or MCI due to AD (N=163,439)
All-cause utilization counts, mean (SD)	
Office visits	16.2 (16.5)
Outpatient visits	10.9 (17.7)
Emergency room visits	2.0 (3.8)
Inpatient stays	0.6 (1.2)
Inpatient stay length (days)	9.4 (29.0)
Pharmacy fills	41.4 (39.4)

Abbreviations: AD, Alzheimer’s disease; HCRU, healthcare resource utilization; MCI, mild cognitive impairment; PPPY, per patient per year; SD, standard deviation

- Median time from initial CC to diagnosis was 8.53 months (95% CI: 8.43, 8.60) (**Figure 4**)

Figure 4. Kaplan-Meier Analysis of the Time to AD or MCI due to AD Diagnosis from the Index Date



Conclusions

- This study provides real-world evidence on diagnostic timelines and patterns of care from first CC to first diagnosis of AD or MCI due to AD
- Median time from initial cognitive complaint to diagnosis of AD or MCI is 9 months
- These findings may inform strategies to streamline diagnostic pathways and support earlier identification and diagnosis, enabling patients and care partners to make well-informed care decisions

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