

Clinical complexity in MCI and AD: a real-world study of comorbidities and medication use in the US (Medicare)

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Background

Clinical trials and patient registries often exclude individuals with certain comorbid conditions or on specific medications, thereby limiting generalisability to broader real-world patient populations.¹ As a result, trial participants may differ substantially from individuals seen in routine clinical practice in terms of age, comorbidity burden, concomitant medication use and disease severity.

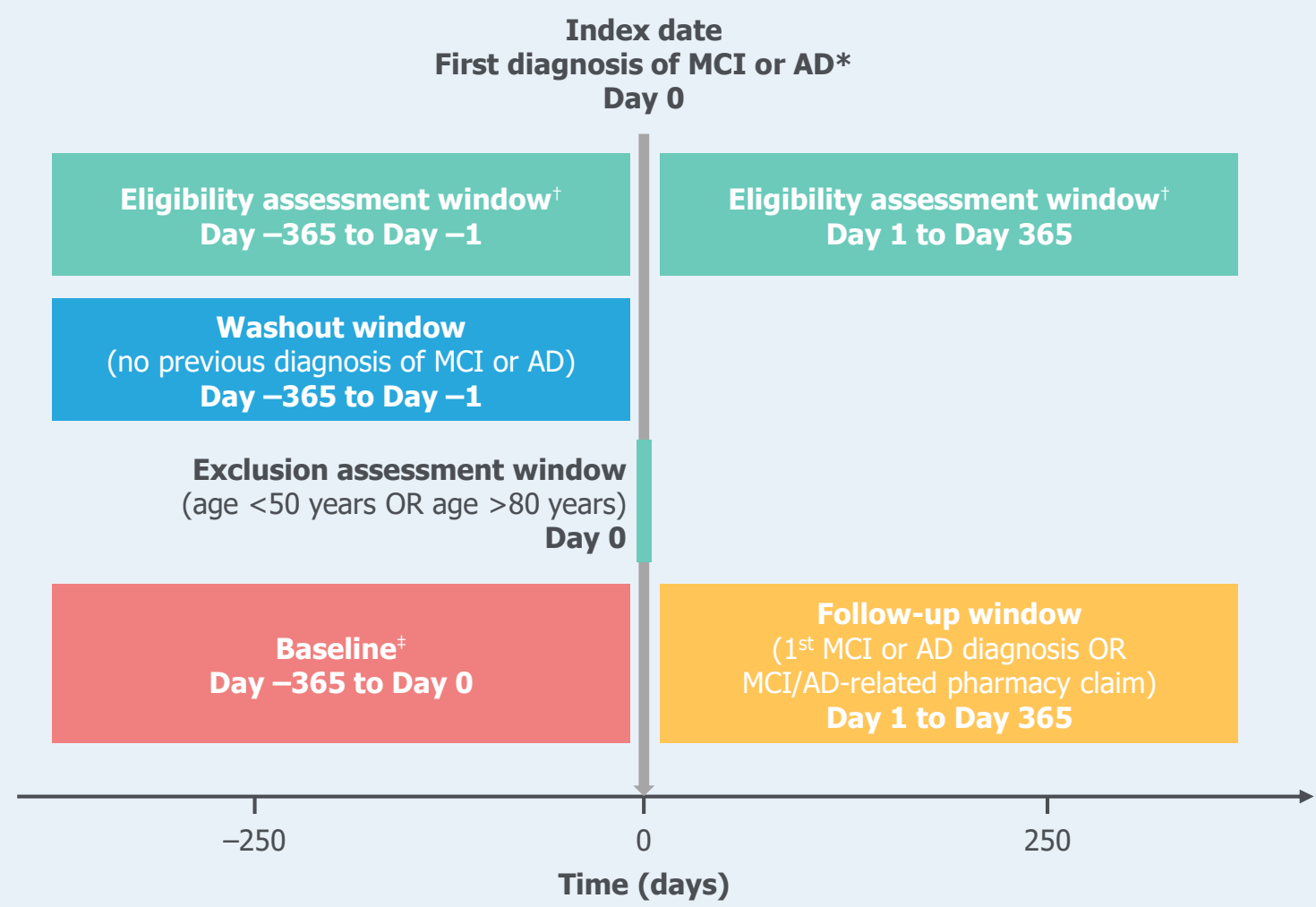
Objective

To **estimate** the **prevalence of selected comorbid conditions** and **medication use*** that are commonly applied as exclusion criteria in clinical trials and disease registries, in individuals newly diagnosed with mild cognitive impairment/Alzheimer's disease (MCI/AD), in the 12 months prior to, and including, the diagnosis date of MCI or AD.

Methods

- This retrospective, observational cohort study used US CMS Medicare Fee-for-Service claims data, covering individuals aged ≥65 years and younger individuals with disabilities. The data source represents the US population covered by Medicare Fee-for-Service across all states.
- Individuals aged 50–80 years with a first recorded MCI or AD diagnosis between 1 January 2019 and 31 December 2022 were eligible (**Figure 1**).
- Selected comorbidities (defined as ≥1 relevant ICD-10-CM code) and treatments of interest were ascertained over the Baseline period (**Figure 2**).
- For inclusion, all individuals required ≥12 months of continuous medical and pharmacy enrolment before and after the index date, with no prior MCI/AD diagnosis during the washout window.
- A sensitivity analysis with an extended Baseline period to include all prior data between enrolment and the index date was conducted to verify comorbidity estimates and minimise misclassification of prevalent cases.

Figure 1 Study design



Study period: US Medicare: 01/2018–12/2023.
Selection period: 01/2019–12/2022.
*Individuals were required to have ≥2 records supporting a diagnosis of MCI or AD, defined as two diagnostic codes using ICD-10-CM on separate dates and within 12 months prior to the first record of MCI or AD.
†Up to 2-month gaps in medical or pharmacy enrolment were allowed (as Medicare enrolment is recorded on a monthly basis).
*Baseline characteristics included sex, age at index, comorbidities, co-medications and ethnicity/race.

*Comorbidities were grouped into four categories: psychiatric (major depressive disorder, generalised anxiety disorder, bipolar disorder, schizophrenia, obsessive-compulsive disorder); neurological (epilepsy, Parkinson's, multiple sclerosis, Huntington's disease); cardiovascular (stroke, heart failure, myocardial infarction) and other conditions (malignant neoplasms, chronic kidney disease, hepatic failure, chronic hepatitis, fibrosis and cirrhosis of liver). Medication included anticoagulant and antiplatelet treatments.
AD, Alzheimer's disease; CMS, Centers for Medicare and Medicaid Services; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; MCI, mild cognitive impairment; Q, quartile; SD, standard deviation; US, United States.

References: ¹Franzen et al. *Alzheimers Dement* 2022;18:810–823.

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Overview



Research question

What is the prevalence of selected comorbidities and medication use amongst US individuals newly diagnosed with MCI or AD?

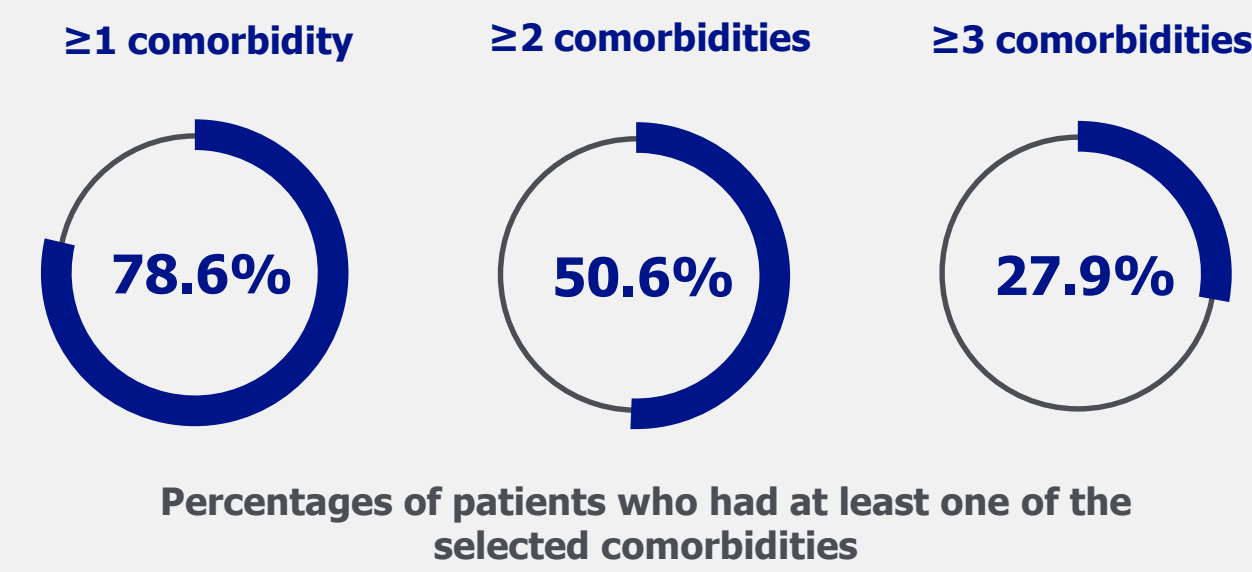


Data source and study population

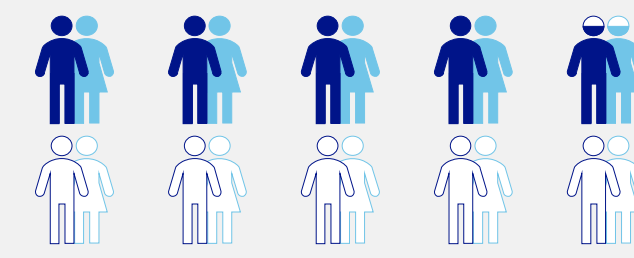
Data were drawn from US Medicare Fee-for-Service claims data for individuals aged 50–80 years with a first recorded MCI or AD diagnosis between 2019 and 2022. Selected comorbidities and medication use (commonly applied as exclusion criteria in clinical trials and disease registries) were assessed over the 12 months prior to diagnosis.



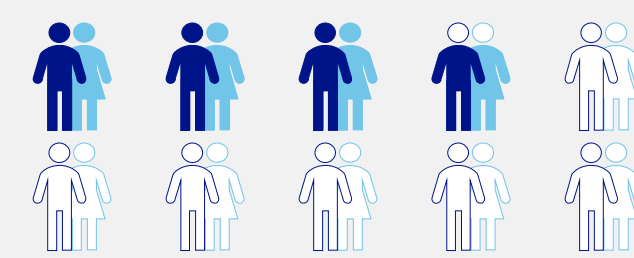
Results across selected comorbidities*



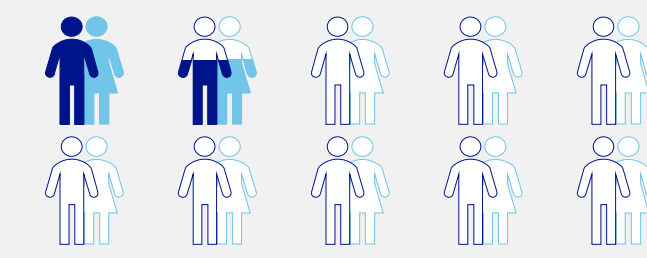
Psychiatric disorders: 49.1%



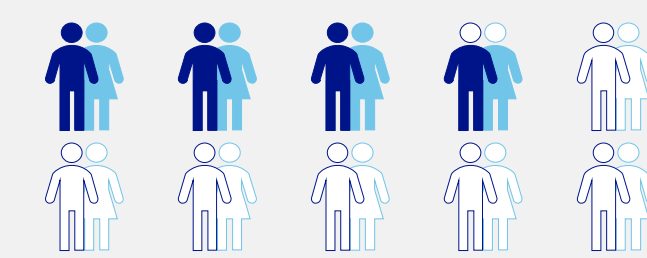
Cardiovascular conditions: 38.1%



Neurological disorders: 16.0%



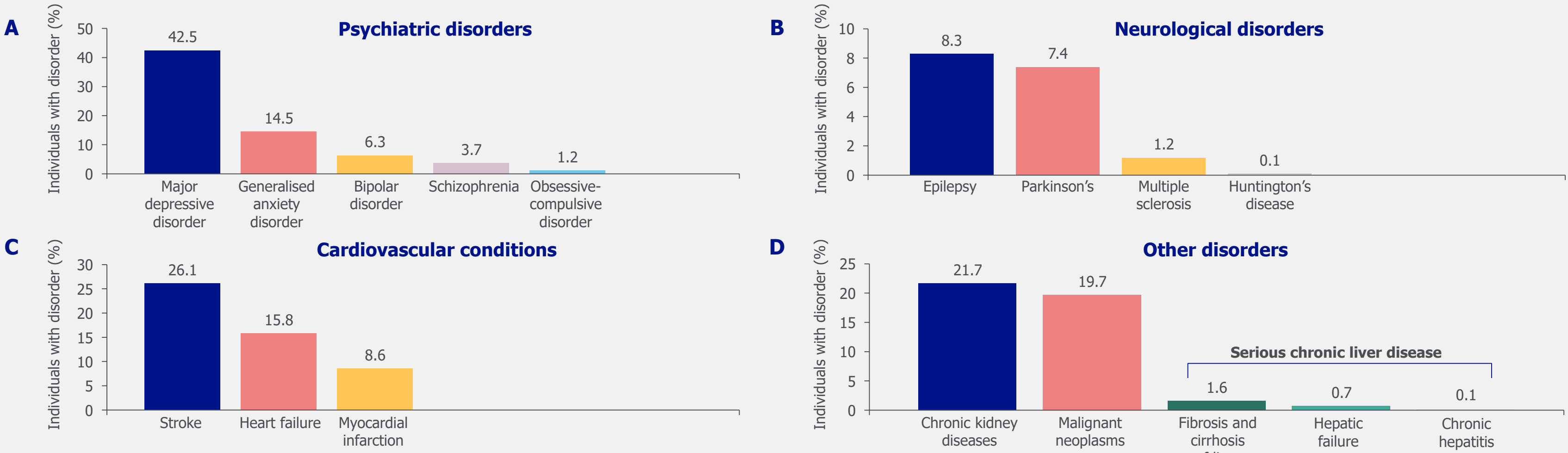
Other disorders: 37.4%



Results

- A total of 460,775 individuals with newly diagnosed MCI/AD (62.5% MCI; 36.9% AD; 0.6% both MCI and AD) met the eligibility criteria (58.3% female; 41.7% male); Baseline demographics and clinical characteristics are in **Table 1**.
- Overall, 78.6% of individuals had ≥1 of the comorbidities investigated; 50.6% had two or more and 27.9% had three or more.
- At Baseline, 49.1% of individuals had ≥1 psychiatric disorder (**Figure 2A**), 16.0% had ≥1 neurological disorder (**Figure 2B**), 38.1% had ≥1 cardiovascular condition (**Figure 2C**) and 37.4% had ≥1 other disorders (**Figure 2D**).
- At Baseline, 23.5% of individuals were receiving anticoagulant and/or antiplatelet therapy (**Figure 3**).
- Sensitivity analyses demonstrated that comorbidity prevalence estimates were broadly consistent across specifications, except for malignancy, where some variation was observed.

Figure 2 Selected comorbidities at Baseline



Baseline comorbidities were defined as the presence of at least one diagnosis code in the 12 months prior to and including index date. Patients may have had more than one comorbidity at Baseline.

Study limitations

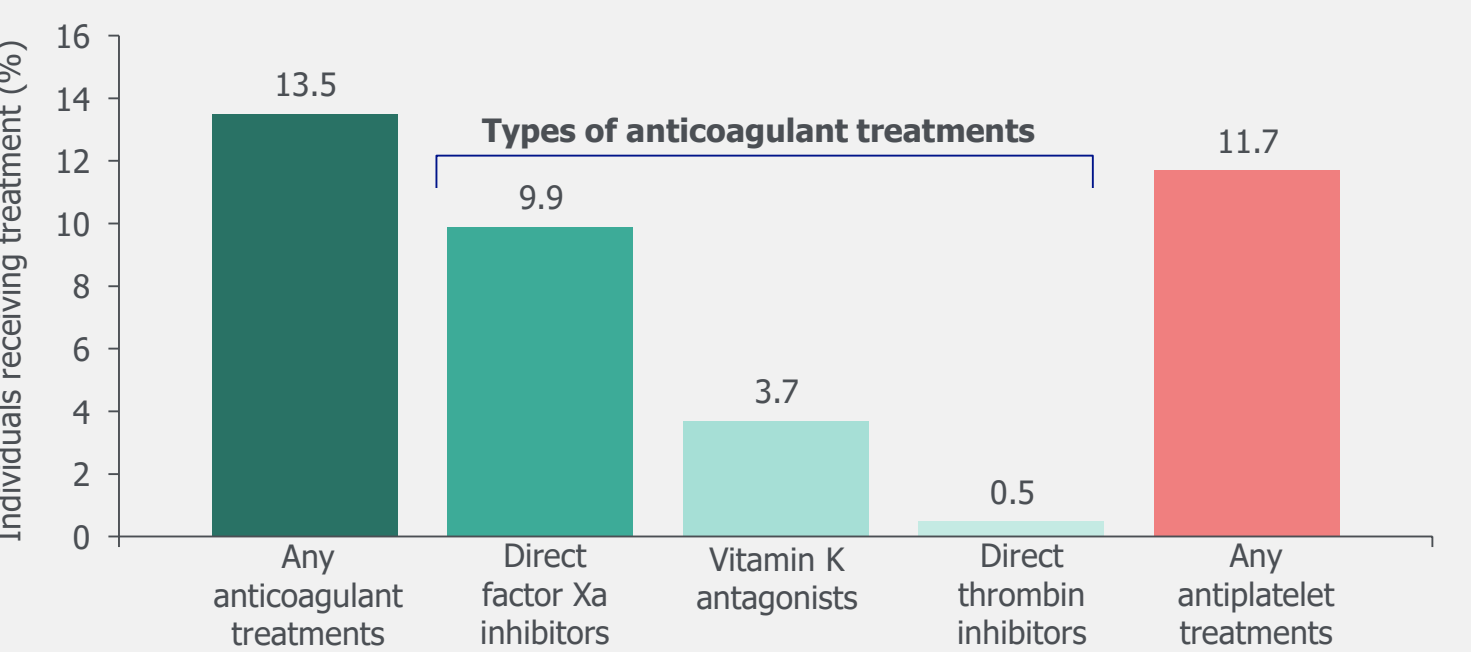
- Analyses using real-world data rely on predefined algorithms and definitions to identify MCI/AD cases and comorbidities. Although consistent definitions were applied throughout the study, the sensitivity of the claims-based algorithm is unlikely to be 100% due to the inherent limitations of claims data, which may result in some cases or comorbidities being missed or misclassified.
- Diagnosis codes did not allow differentiation between uncontrolled comorbidities, which are typically used as trial and disease registry exclusion criteria, and well-controlled comorbidities.

Table 1 Baseline demographics and characteristics

Characteristic	Overall MCI/AD cohort (N=460,775)
Age at index, years	
Mean (SD)	73.0 (5.7)
Median (Q1–Q3)	74.0 (70.0–77.0)
Min–max	50.0–80.0
Gender, n (%)	
Female	268,600 (58.3)
Male	192,175 (41.7)
Index diagnosis, n (%)	
MCI	287,909 (62.5)
AD	170,193 (36.9)
Both MCI and AD	2,673 (0.6)
Race/ethnicity—self-reported, n (%)	
White	389,287 (84.5)
Black	35,261 (7.7)
Unknown	9,573 (2.1)
Asian	8,567 (1.9)
Other	8,301 (1.8)
Hispanic	8,084 (1.8)
North American Native	1,702 (0.4)
Duration of Baseline period, months	
Mean (SD)	32.0 (13.7)
Median (Q1–Q3)	30.2 (19.8–43.1)
Min–max	12.0–60.0

Index date was defined as the date of first record of MCI or AD during the study period.
Duration of Baseline period was defined as the time from enrolment to the index date.

Figure 3 Selected treatments at Baseline



Receiving these treatments is commonly applied as exclusion criteria in clinical trials and disease registries. Patients may have received multiple classes of anticoagulants and/or antiplatelet treatments.

Conclusions

The **majority** of individuals with **MCI/AD** (78.6%; mean age 73 years) had **≥1 major selected comorbidity—often a condition that would exclude them from clinical trials or disease registries**. This finding reflects the complex, multi-morbid profile of MCI/AD in routine care, and it underscores the need for caution when generalising trial results to everyday practice.