ESTIMATING THE ELIGIBLE POPULATION FOR ANTI-AMYLOID THERAPY IN FINLAND

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Introduction

- Alzheimer's Disease (AD) is a chronic, progressive, and irreversible neurodegenerative disorder that is the leading cause of cognitive impairment and dementia in individuals aged ≥65 years worldwide [1] and accounted for almost a fifth of all deaths in Finland in 2020 [2].
- As AD progresses, individuals with AD lose their ability to live independently, slowly losing their identity and independence, and become completely dependent on others for their care [3].
- Anti-amyloid therapies that slow the progression of AD have received regulatory approval for early-stages of AD (MCI due to AD and mild AD) in several countries, including within the European Union [4].
- Recent publications have expressed concern regarding the potential impact of these therapies on healthcare systems, primarily due to the financial burden associated with treating a large population of eligible patients.
- An estimate is presented of the eligible, treatable population in Finland, based on a detailed analysis of the patient journey.

Methods

- The patient journey was modelled on the diagnostic and treatment pathway for early-stage AD in Finland, which is presented in **Figure 1**.
- The clinical setting for AD diagnosis is dependent on age, where it is usually diagnosed either in secondary care, neurology memory clinics (patients <65 – 70 years of age) or in geriatric memory clinics (≥65 – 70 years of age) with a different diagnostic workup [5];
  - as the age limit differs between counties, 70 years of age is presented as the average threshold, i.e., patients under 70 receive diagnostic workup in neurological memory clinics.
- Patients were considered eligible for anti-amyloid therapy if they fulfilled the following criteria:
  - Diagnosed with early AD;
  - Have confirmed amyloid pathology;
  - Are apolipoprotein E ε4 (Apo E4) non-carriers or heterozygotes; current anti-amyloid treatments are not indicated for Apo E4 homozygous patients in the EU;
  - Do not have one of the following contraindications: taking anticoagulants; have comorbid vascular dementia, previous infarcts, recent history of transient ischemic attacks, or other brain pathologies that contribute to cognitive decline [4].
- Literature searches, including Finnish and internal studies as well as local registry data, were conducted to identify epidemiological inputs and estimate the proportion of patients likely to progress through each stage of the pathway.
- A Finnish clinical expert was also consulted to review input and results [6].

Assumptions

- **Figure 2** shows the step-by-step inclusion considerations and respective references identified to inform the percent of the patient population that would meet the criteria.
- In Finland, the number of newly diagnosed (incident) patients with any memory diseases was 23 263 in 2021 [7];
  - It was deemed more applicable to base the eligible patient population on incident patients, since data for prevalence in Finland had limited information about the proportion of biomarker-confirmed AD as well as disease diagnosis.

MRI

- In the neurology clinics, practically all patients (99%) with a suspected memory disease receive an MRI as a part of the diagnostic workup; In contrast, it is estimated that only 80% of patients in geriatric memory clinics receive an MRI, largely due to the increased prevalence of contraindications among elderly patients and limited MRI availability in certain wellbeing service regions, where CT scans are often used as an alternative [6, 8].

Cerebrospinal fluid (CSF) analysis

- Similarly, CSF biomarkers are routinely assessed in most patients diagnosed in neurological memory clinics. However, their use is limited in geriatric memory clinics due to insufficient infrastructure and logistical challenges associated with CSF sample collection [6, 8].

Assumptions *(continued)*

Amyloid-positivity

- In the absence of Finnish data, Swedish sources were used to estimate the proportion of patients with MCI and mild AD impairment whose CSF Aβ levels exceeded the laboratory-defined positivity threshold, estimated at 32% [9].

Apo E4 status

- The 15% of patients ineligible due to being Apo E4 homozygotes was based on data from Emrani et al., 2020 [10] and the CLARITY AD Phase 3 study [11].

Stage at diagnosis

- A Finnish study assessing the severity of cognitive problems at the time of diagnosis both in primary and secondary care indicates that as many as 21% of patients receive AD diagnosis in moderate or severe dementia stages and are thus ineligible for treatment [12].

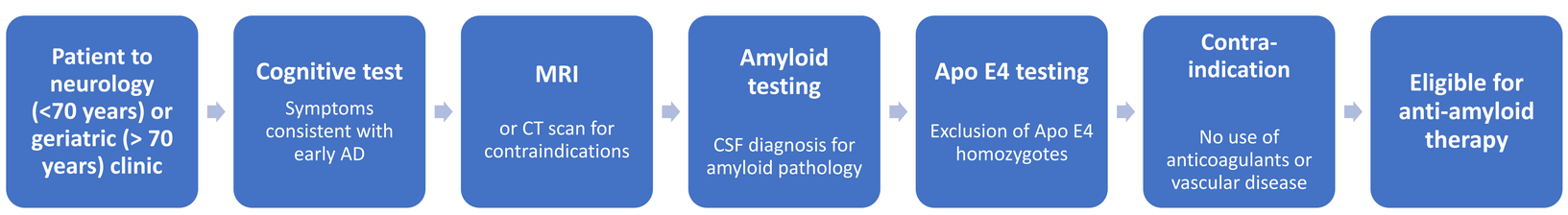
Anticoagulant use

- According to data from the national health insurance prescription database (KELA) [13], the use of anticoagulants is common and increases significantly by age, reaching 44% in patients over 85 years of age. The accessible data lacks sufficient granularity to accurately determine the proportion of patients aged 70 and above who are receiving anticoagulant therapy. Therefore, conservative estimates of 90% and 75% were used for MCI and mild AD, respectively.

Vascular disease

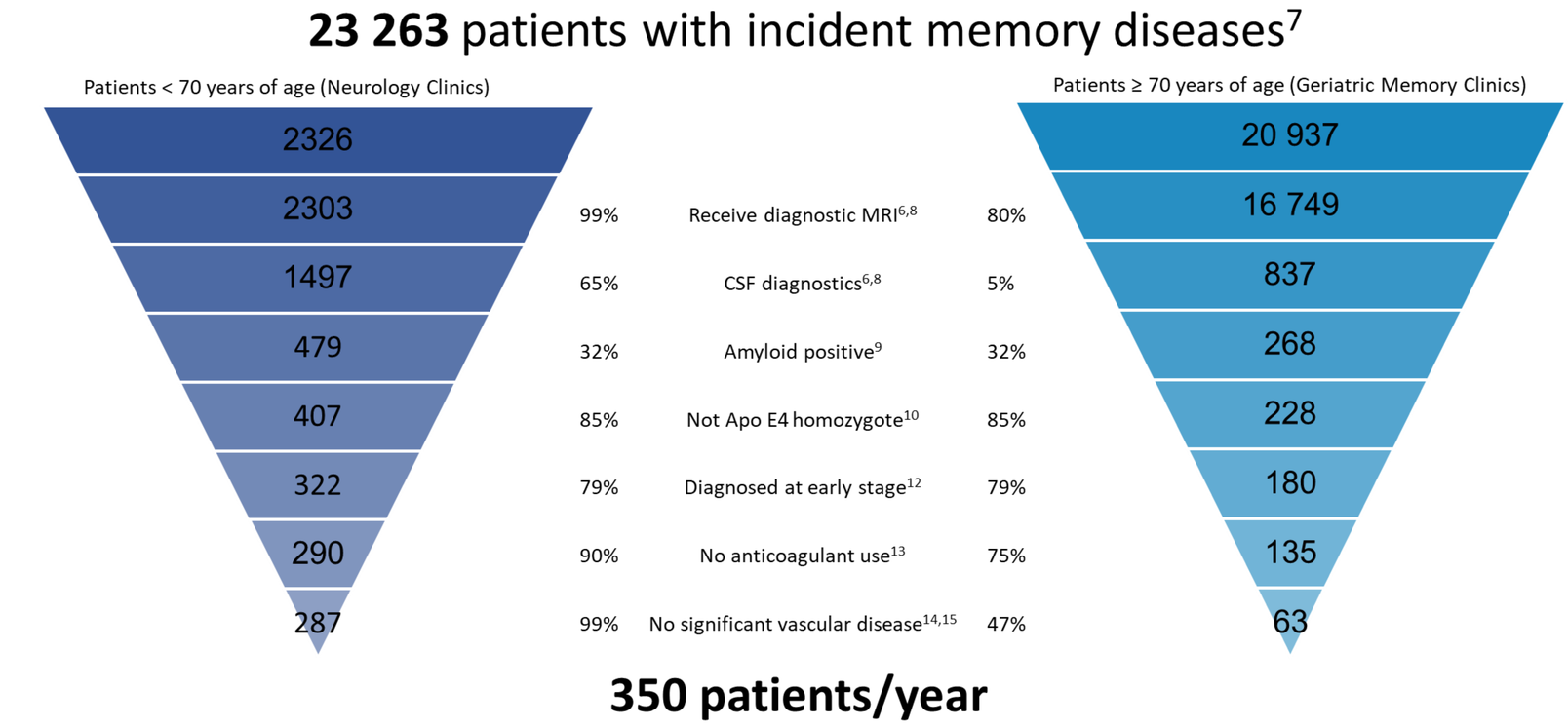
- Study estimated that at least 53% of patients over 70 years have a further significant vascular disease that would be contraindicated for anti-amyloid therapy [14]; these conditions were not considered as significant exclusion factors for patients under 70 years.

Figure 1. Simplified treatment pathway for patients with AD who may become eligible for anti-amyloid treatment



Results

Figure 2. Estimated eligible patient population for anti-amyloid therapy in Finland, early AD patients who are Apo E4 heterozygotes or non-carriers



Discussion and limitations

- Overall, approximately 350 incident AD patients eligible for anti-amyloid treatment are estimated to be identified in the Finnish healthcare system in the first year of anti-amyloid therapy availability; this is approximately 1.5% of the incident cases of any memory disorder.
- The main limitations and uncertainties in the analysis come from lack of local data relevant to Finnish patients with early AD and lack of consideration of the healthcare system's current (e.g., diagnostic) capacity in terms of infrastructure and resources.
- There is also a lack of data to accurately estimate the prevalence and severity of vascular comorbidities in this patient population.
- The number of patients receiving treatment may be further limited by patients unwilling to receive treatment or patients who do not have a care partner, which is generally required for the treatment [16].
- However, the number of eligible patients is likely to increase over the next years due to improving diagnostics, adaptations of healthcare capacity and patients seeking care earlier in the upcoming years.

Conclusions

- Relative to the overall incidence of memory disorders, the number of patients eligible for anti-amyloid therapy is limited (approximately 1.5% of the incident cases of any memory disorder).
- As healthcare systems adapt to the clinical and operational demands of anti-amyloid therapies, this population is expected to gradually expand over time.
- Strategic evaluation of diagnostic infrastructure, care pathways, and workforce readiness will be critical to realizing the full potential of these therapies.

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