

Technology Readiness of Automated Microbleed Detection: A Systematic Review

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Background

Amyloid-targeting treatments require MRI-based safety monitoring for amyloid-related imaging abnormalities (ARIA), including cerebral microbleeds (CMB).

Visual CMB detection is prone to low inter-reader agreement and is a time-consuming task.

Automated CMB detection systems are getting regulatory approval for ARIA monitoring, but little is known about the clinical impact of this emerging technology.

Aim

To what extent have automated cerebral microbleed detection systems achieved technological readiness, and how have they been validated?

Methods

A systematic search was conducted in Embase, Web of Science, and MEDLINE on January 9, 2026.

- Strategy:** Broad search capturing variations in naming (e.g., “hemorrhage”) and clinical contexts like ARIA and Cerebral Small Vessel Disease.
- Screening:** 7,674 studies screened.
- Exclusion:** Non-MRI modalities and studies in which the microbleed tool was not evaluated on its own.
- Inclusion:** 68 studies met inclusion criteria.

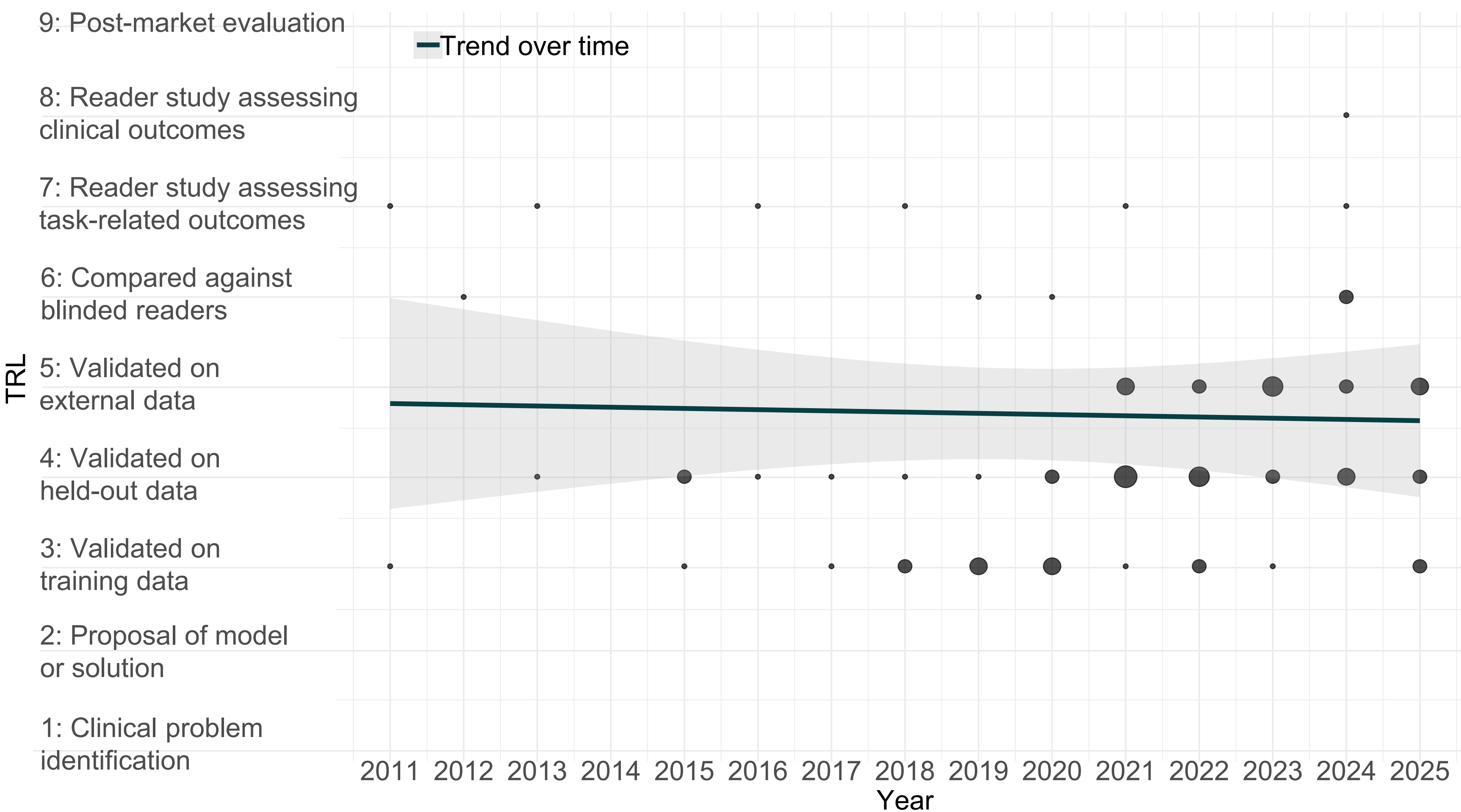
Studies were evaluated using the technology readiness level (TRL) framework adapted by Fleuren (2020) for clinical applications¹.

Data was systematically extracted using a template covering:

- MRI acquisition
- Ground truth establishment
- Outcomes assessed
- Validation method and performance stratification
- Number of clinicians involved

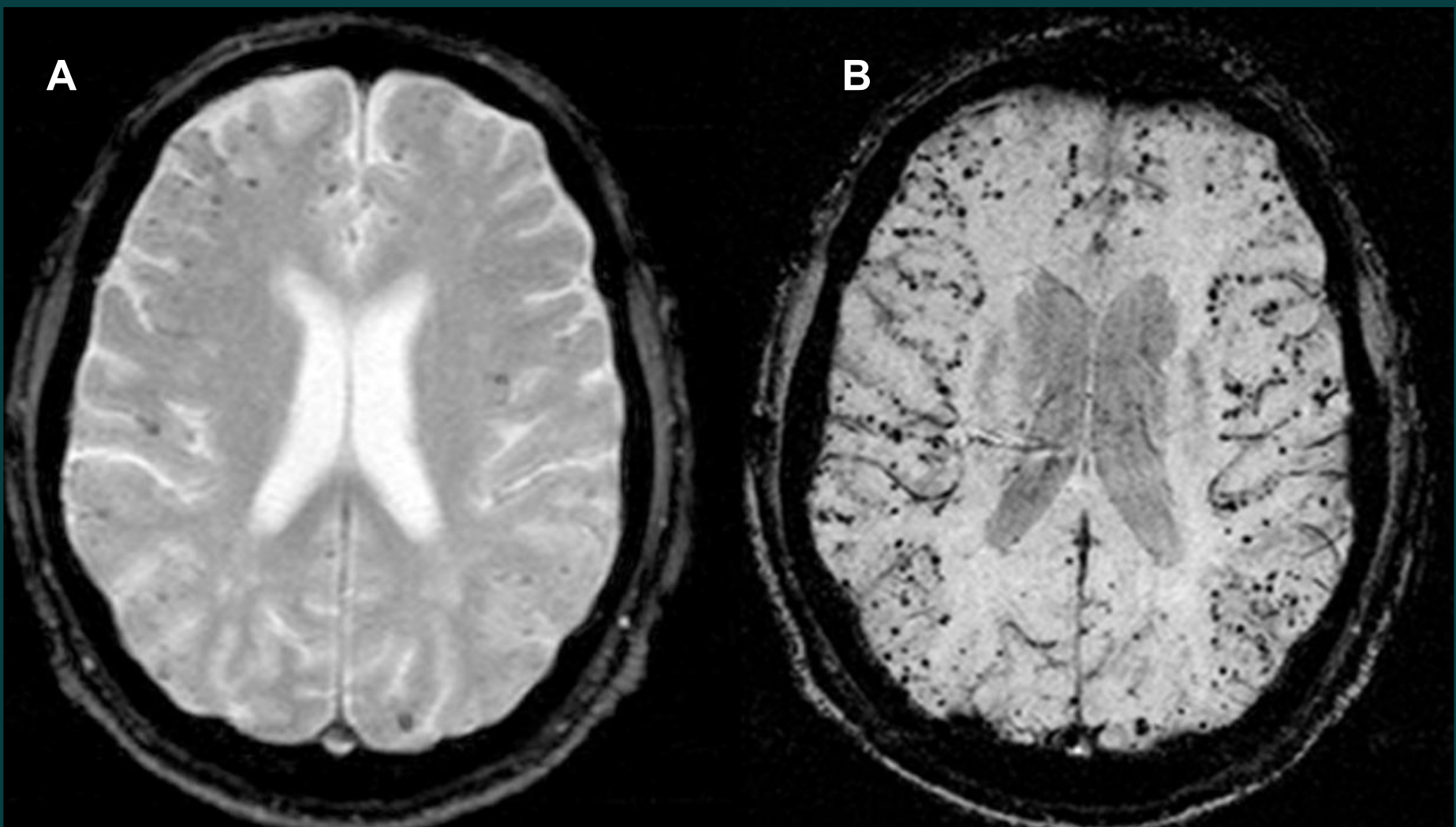
Bias was assessed using PROBAST-AI.

Technology Readiness Results



Research Gaps and Recommendations

Technical Robustness



Adapted from SBarnes (source: Zach Del Proposto), Wikimedia Commons, CC BY-SA 3.0.

CMB appearance varies by MRI acquisition (Patient with cerebral amyloid angiopathy scanned at 1.5 T using T2* (A) and SWI (B)).

Gap: Most detection systems are developed on homogeneous datasets.

Risk: Differences in MRI acquisition alter CMB appearance, reducing reliability across sites and over longitudinal follow-up.

Action: Assess performance across diverse MRI scanners, acquisition protocols, and repeated examinations.

Algorithmic Fairness

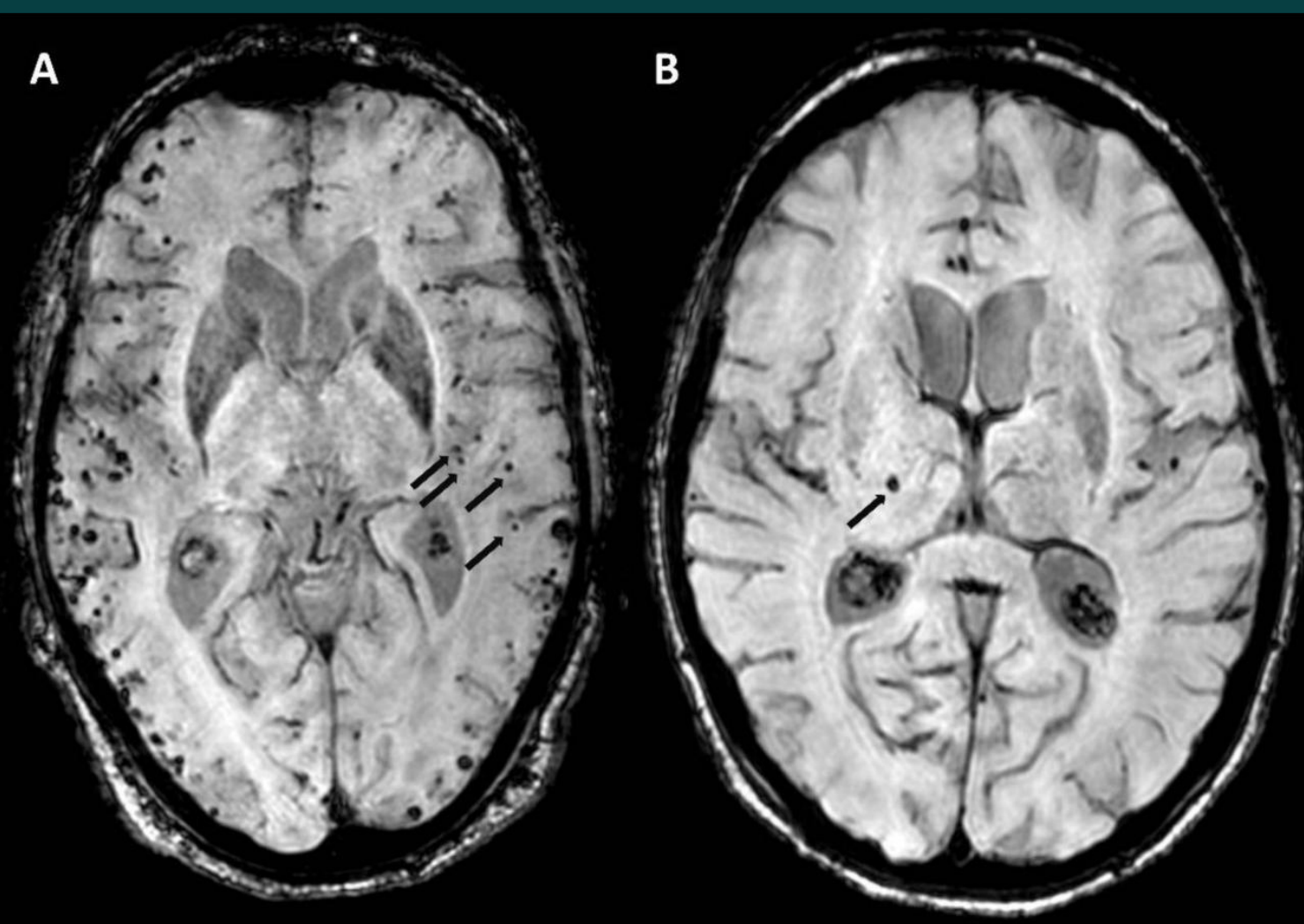


Figure from Jensen-Kondering et al., 2024, *Biomolecules*, 14(11):1459. Licensed under CC BY 4.0

CMB spatial distribution varies by etiology (A: cerebral amyloid angiopathy, B: Hypertension).

Gap: Limited evidence suggests non-uniform performance across the brain.

Risk: Automated detection systems may be biased towards specific presentations.

Action: Stratify performance by anatomical regions and clinical/demographic groups to uncover algorithmic bias.

Clinical Integration

User Diversity

Gap: We do not know if all clinicians benefit from automated CMB detection equally.

Risk: Inexperienced readers may unsafely over-rely on false positives or negatives.

Action: Include diverse readers (e.g., experience, specialty) to assess who benefits.

Post-market Evaluation

Gap: Zero studies have tracked long-term software impacts in actual clinics.

Risk: Hospitals risk adopting expensive tools that may fail to improve safety, speed, or costs.

Action: Evaluate post-market patient outcomes, workflow speeds, and cost-effectiveness.

Take Home Message

Automated CMB detection systems are stuck in technical validation. To achieve clinical readiness, future research must prioritize imaging robustness, algorithmic fairness, longitudinal tracking, and real-world utility.