

Comparison of amyloid positivity and global cortical SUVR between black and white non-Hispanic participants in the GAP Bio-Hermes study

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Background

- Improved **enrolment of traditionally under-represented racial and ethnic groups** is critical for Alzheimer's disease (AD) clinical trials [1].
- The GAP Bio-Hermes study collected **Florbetapir (18F) PET (Amyvid)** from **398 cognitively normal, 293 MCI and 254 mild AD** participants across 16 US sites, recruiting 24% participants from traditionally underrepresented communities.
- Previously presented Bio-Hermes results show a **significantly lower amyloid positive (Aβ⁺) rate in Black (N=103, 26% Aβ⁺) compared to White (N=727, 37% Aβ⁺)**, Non-Hispanic or Latino participants, despite comparable mix in diagnostic groups and increased cognitive impairment in the Black population [2]. No significant differences in global cortical SUVR were observed between the two racial groups [2].

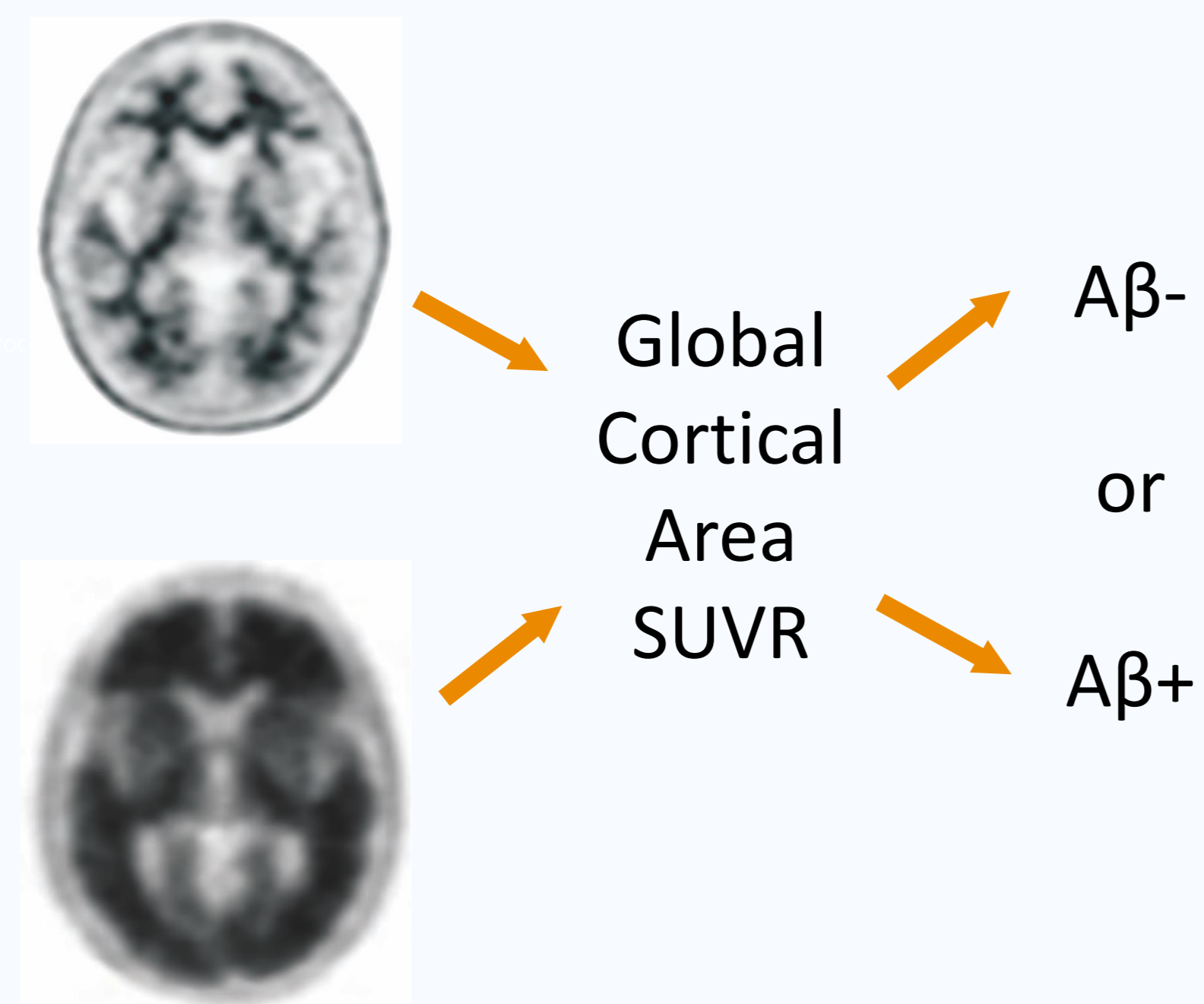
Objective

- Further investigate **amyloid PET differences between Black and White participants in Bio-Hermes**
- Better understand **relationship between Aβ⁺ status from visual read and quantitative SUVR**.

Methods

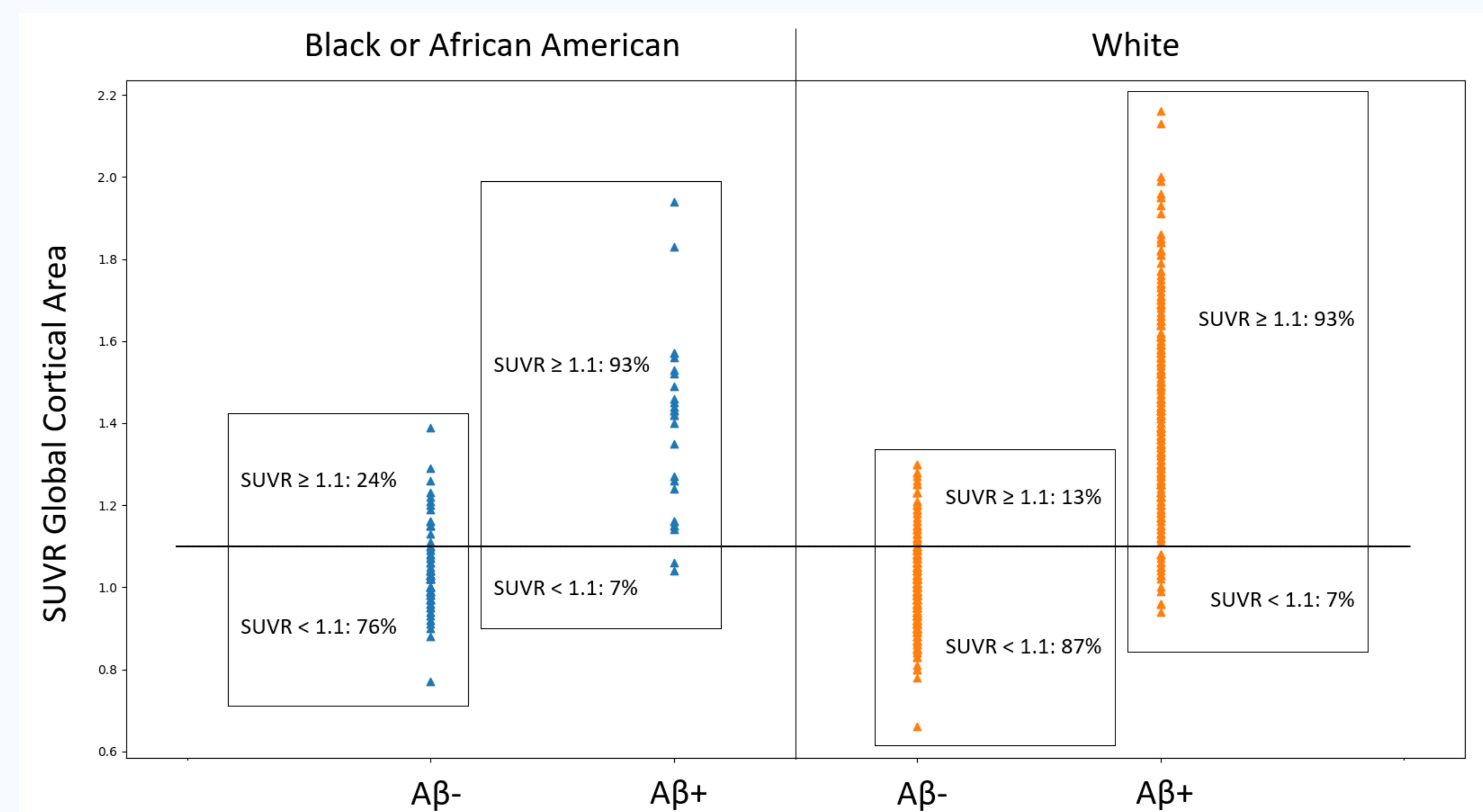
- Visual read** was performed centrally through the **VisQ process** [3] in the MIM Software [4], where visual inspection and **global cortical area SUVR** is considered by a reader to perform classification into Aβ⁺ or Aβ⁻.
- We compare agreement between the visual reader and the previously proposed cut-off for Aβ⁺ from global cortical SUVR of 1.10 [5] across the two racial groups.

Visual inspection + Quantification = VisQ read



Results

- Results are presented in both sub-populations, **93% of Aβ⁺ participants** (per visual read), also **exhibit SUVR ≥ 1.10**.
- In Aβ⁻ participants, **76% of Black participants** and **87% of White participants** also **exhibit SUVR < 1.10**.



Conclusion

- A substantially **higher disagreement of SUVR cut-off with visual read in Aβ⁻ Black participants compared to White participants** was observed, suggesting a potential difference in amyloid uptake patterns between the two populations is driving differences in Aβ⁺ rates in the absence of differences in mean SUVR.
- In future work, **regional SUVR analysis will be performed** to further qualify these findings.

References

- [1] FDA Guidance for Industry, 2022. <https://www.fda.gov/media/157635/download>
- [2] Wolz et al, Symposium 1, CTAD 2023
- [3] Harn et al; Clin Nucl Med. 2017 Aug;42(8):577-581.
- [4] MIM Software Package [<https://www.mimsoftware.com/>]
- [5] https://www.ema.europa.eu/en/documents/assessment-report/amyvid-epar-public-assessment-report_en.pdf