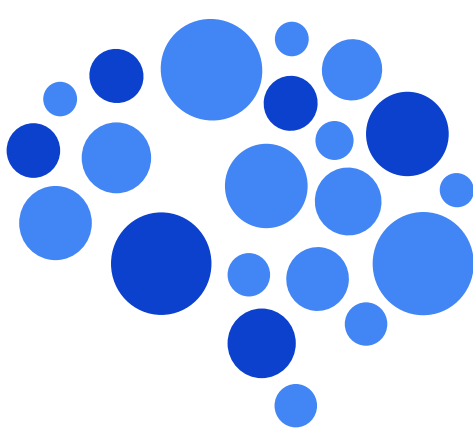


Elecsys cerebrospinal fluid biomarker ratio concordance with amyloid-positron emission tomography in a Chinese population

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What does this mean for the Alzheimer’s community?

- The Elecsys® CSF pTau181/Aβ42 and tTau/Aβ42 ratios are reliable biomarkers for detecting amyloid pathology in the Chinese population, providing a scalable alternative or adjunct to amyloid-PET testing within the AD diagnosis pathway.

Conclusions

- Predefined cutoffs for the Elecsys CSF pTau181/Aβ42 and tTau/Aβ42 ratios are applicable and robust in a Chinese cohort.
- These findings support the clinical utility of CSF biomarker ratios as a reliable alternative or adjunct to amyloid-PET in the AD diagnostic pathway in the Chinese population.

Background

- The CSF biomarker ratios pTau181/Aβ42 and tTau/Aβ42 show high concordance with amyloid-PET for detecting amyloid pathology.^{1–3}
- The Elecsys CSF immunoassays (Roche Diagnostics International Ltd) are FDA- and CE-approved for AD-related cognitive impairment assessment, with results concordant with amyloid-PET.^{4,5}
- Most CSF biomarker ratio validation studies are conducted in Western populations, with limited data in the Chinese population, despite evidence that biomarker levels can vary by ethnicity.⁶

Aim: To evaluate the concordance of established Elecsys CSF pTau181/Aβ42 and tTau/Aβ42 ratio cutoffs against amyloid-PET status in a Chinese cohort.

Methodology

- The prospective, observational COMPASS study (RD005711) enrolled adults (50–80 years) with physician-confirmed subjective or objective cognitive impairment across 13 hospitals in China.
- CSF samples collected in accordance with recommended pre-analytical procedures⁷ were used to measure CSF pTau181, tTau and Aβ42 using the Elecsys Phospho-Tau (181P) CSF, Total-Tau CSF and β-Amyloid (1-42) CSF II immunoassays (Roche Diagnostics International Ltd).
- CSF pTau181/Aβ42 and tTau/Aβ42 ratios were derived, and binary outcomes determined using predefined ratio cutoffs (pTau181/Aβ42, 0.023; tTau/Aβ42, 0.28).
- Diagnostic performance was assessed against amyloid-PET VR status using ROC-AUC analysis. PPA and NPA were calculated and evaluated against prespecified acceptance criteria.

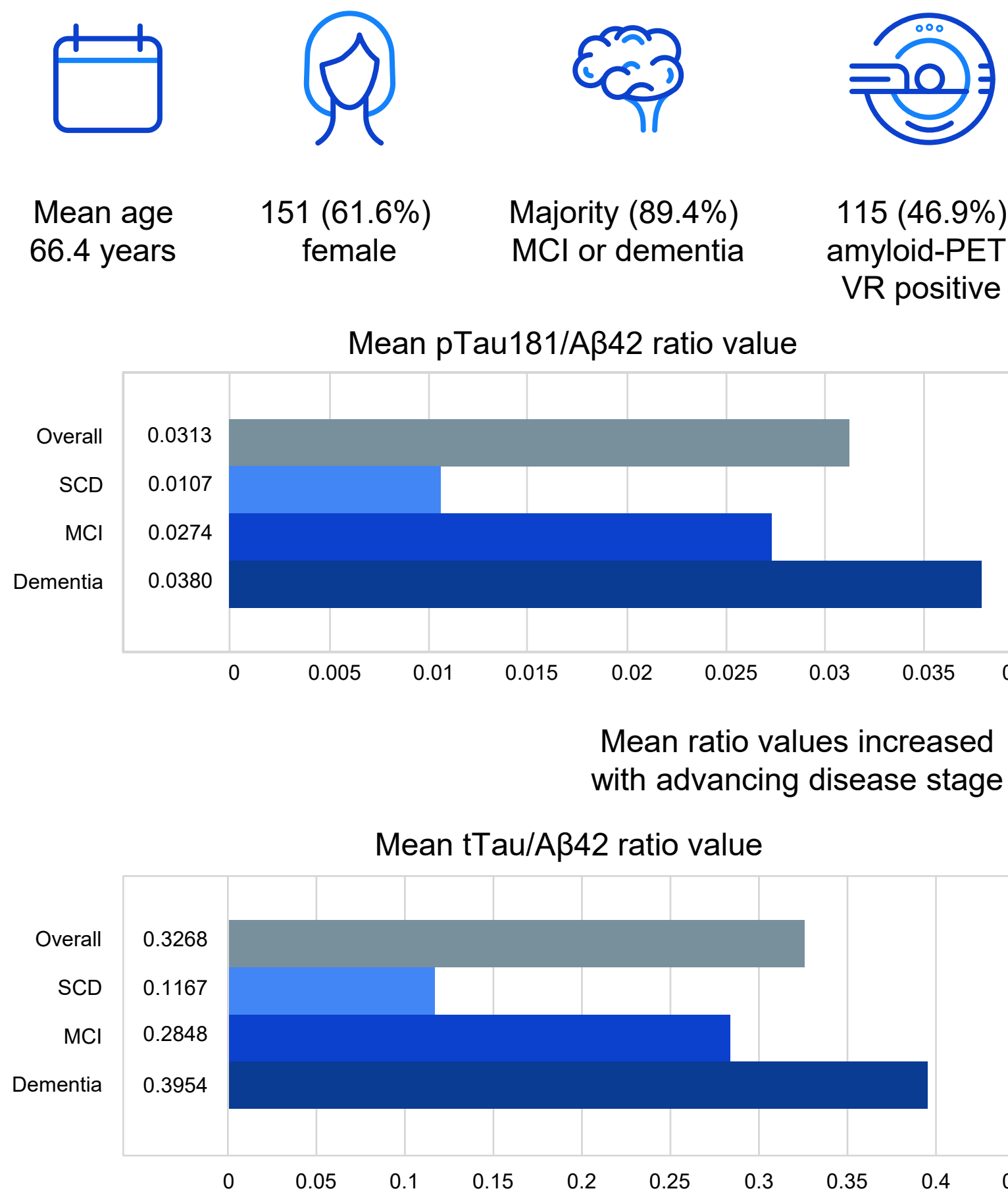
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- ELECSYS is a trademark of Roche. Elecsys Phospho-Tau (181P) CSF, Elecsys Total-Tau CSF and Elecsys β-Amyloid (1-42) CSF II immunoassays are approved for clinical use.

Results

- CSF and amyloid-PET VR measurements were available for 245 participants.
- Participant demographics and clinical characteristics are summarised in **Figure 1**.

Figure 1. Participant demographics and clinical characteristics (n=245*).



- The predefined CSF biomarker ratio cutoffs provided good discrimination between positive and negative amyloid-PET VR status (**Figure 2**).
- Both CSF biomarker ratios demonstrated robust discriminative ability (AUC >0.95; **Figure 3**) and outperformed Aβ42 as a single biomarker.

Figure 2. CSF biomarker ratio classification versus amyloid-PET VR classification.

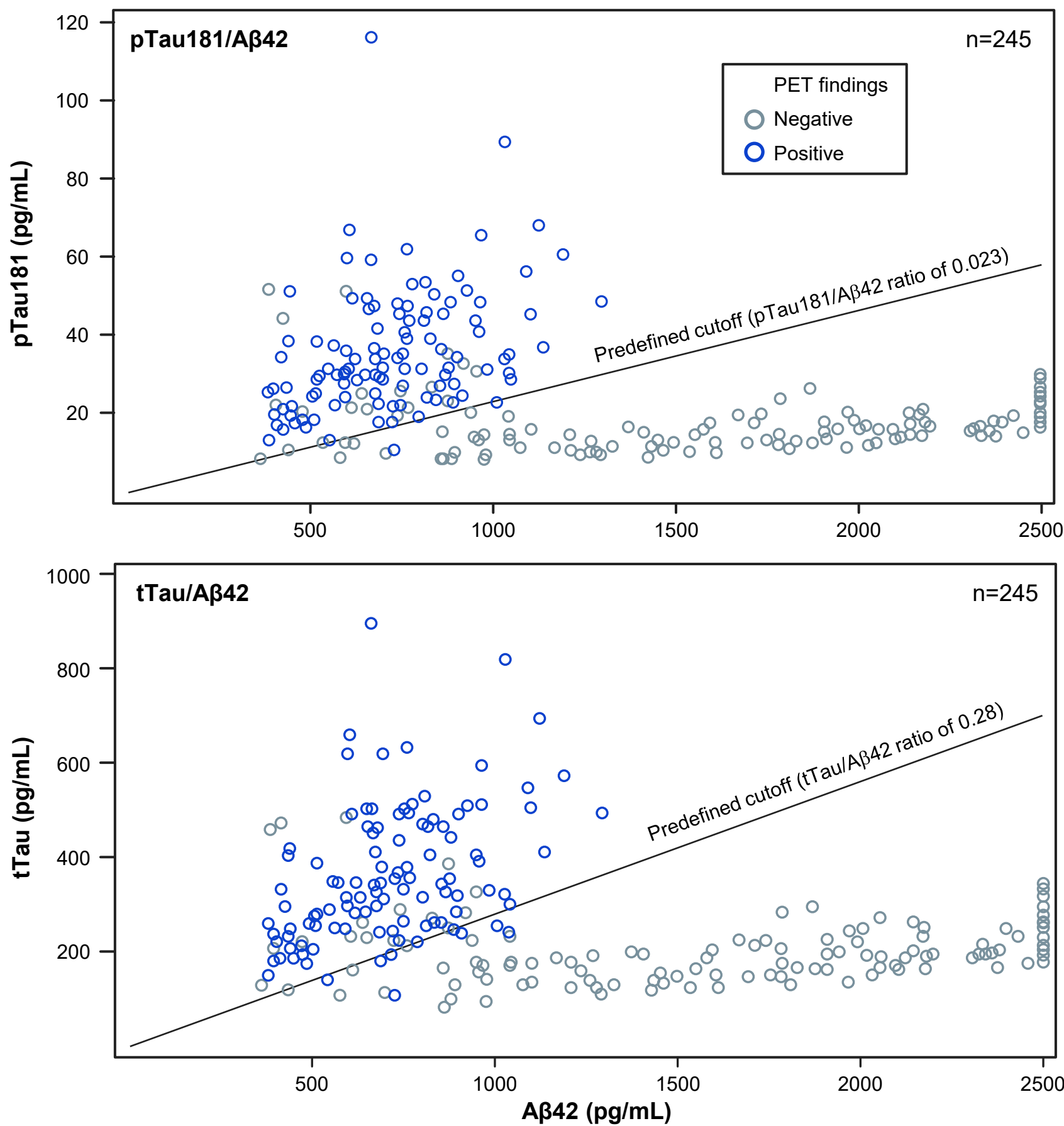
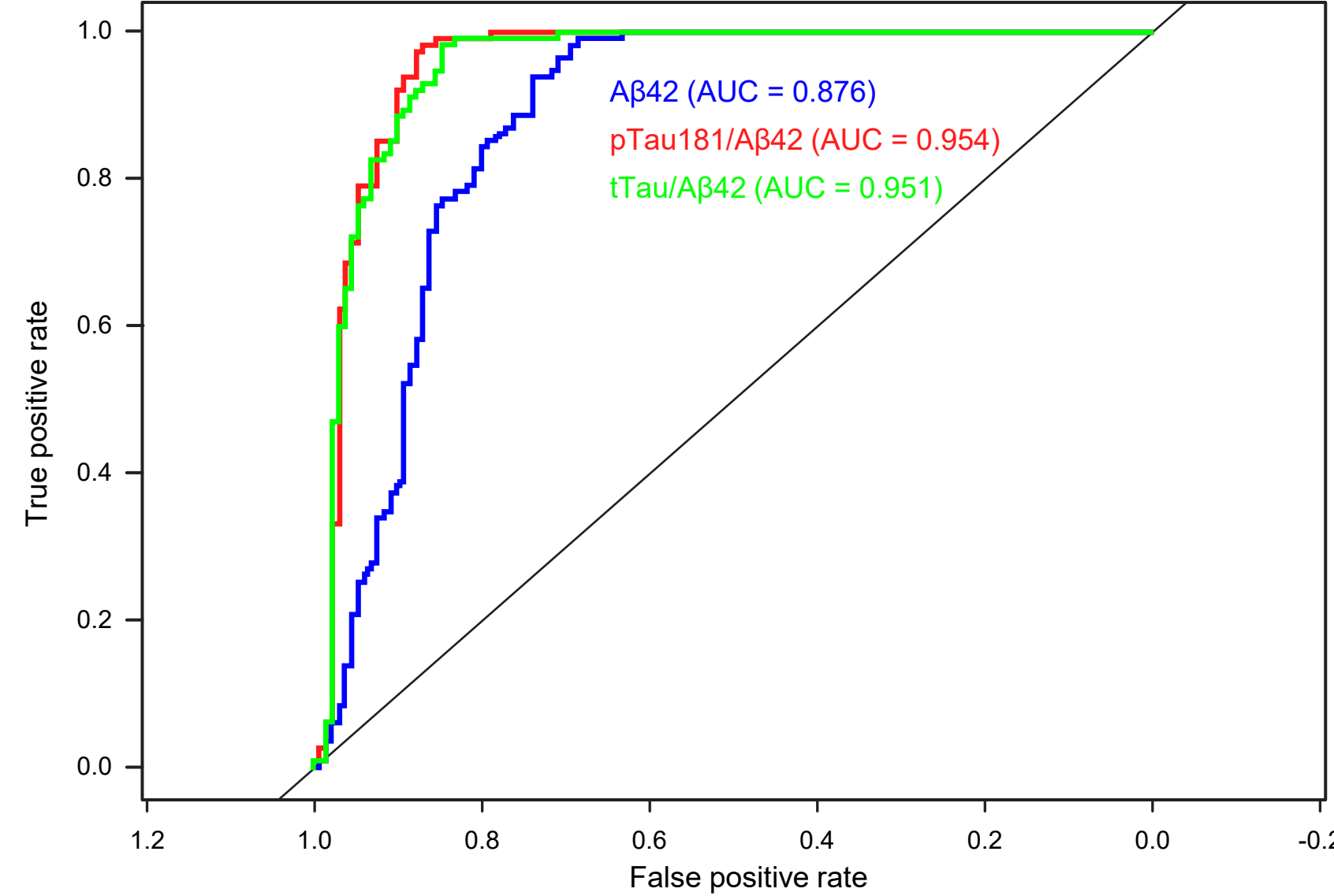


Figure 3. Overall diagnostic performance of the CSF ratios, pTau181/Aβ42 and tTau/Aβ42.



Results cont.

- CSF biomarker ratios at the predefined cutoffs were highly concordant with amyloid pathology status determined by amyloid-PET VR (**Table 1**).

Table 1. Concordance of CSF biomarker ratio classification with amyloid-PET VR status.

CSF biomarker ratio classification*		Amyloid-PET VR status		Percent agreement (95% CI†)
		Positive	Negative	
pTau181/Aβ42	Positive	112	17	PPA: 97.39 (92.57, 99.46)
	Negative	3	113	
tTau/Aβ42	Positive	105	16	PPA: 91.30 (84.59, 95.75)
	Negative	10	114	

*Determined using the respective established ratio cutoffs (pTau181/Aβ42 ratio: positive >0.023, negative ≤0.023; tTau/Aβ42 ratio: positive >0.28, negative ≤0.28). †Clopper-Pearson method.

Discussion

- This study achieved its objective of validating the predefined cutoff values for the Elecsys CSF pTau181/Aβ42 and tTau/Aβ42 biomarker ratios for concordance with PET VR in a Chinese cohort.
- Findings are consistent with studies conducted evaluating Elecsys CSF biomarker ratios against amyloid-PET in Western populations,^{1–3,6} supporting their applicability and use in the Chinese population.
- Scaling up CSF biomarkers for use across various healthcare settings could provide a viable solution to the growing demand for AD diagnostic testing in the era of disease-modifying therapies.^{3,8,9}

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