

MULTICENTER CASE REGISTRY STUDY OF LECANEMAB IN EARLY ALZHEIMER'S DISEASE IN NORTHWEST CHINA

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Background

Lecanemab is the first drug approved by the FDA for the treatment of early Alzheimer's disease (AD) with confirmed brain amyloid pathology. However, the long-term efficacy and safety of Lecanemab in China had not been reported.

Methods

- **Study design & participants:** Multicenter case registry study across 13 hospitals in Northwest China; enrolled all AD patients receiving Lecanemab.
- **Clinical efficacy assessment:** Evaluated every 3 months using Clinical Dementia Rating-Sum of Boxes (CDR-SB), Alzheimer's Disease Assessment Scale (ADAS-cog), Alzheimer's Disease Cooperative Study-Activities of Daily Living Scale (ADCS-ADL), and Minimal-Mental State Examination (MMSE).
- **Safety monitoring:** Detected amyloid-related imaging abnormalities (ARIA) via MRI-T2-FLAIR and MRI-SWI.
- **Plasma biomarker detection:** Collected blood samples to test A β 42, A β 40, A β 42/40 ratio, p-tau181, p-tau217, GFAP and NfL.

Conclusion

- This real-world study suggested that lecanemab was well-tolerated with no severe adverse events. Neuropsychological function remained stable at 6 months, and plasma biomarkers improved significantly. Longer follow-up and larger studies are warranted.

Results

- **Baseline (n=189):** Mean age 67.1 years; 65.1% female; ApoE ϵ 4 heterozygotes 47.1%, homozygotes 10.6%. Baseline CDR-SB 4.3 ± 2.4 , MMSE 18.7 ± 6.2 , ADAS-cog 19.0 ± 10.7 , ADCS-ADL 56.6 ± 17.8 .

- **Changes in clinical efficacy (6-month vs baseline):** ADCS-ADL showed significant improvement (-4.35 , 95%CI -6.88 to -1.81 , $P=0.002$). CDR-SB (0.36 , 95%CI -0.19 to 0.91 , $P=0.193$), MMSE (0.36 , 95%CI -0.50 to 1.22 , $P=0.400$), ADAS-cog (0.77 , 95%CI -0.86 to 2.41 , $P=0.343$) showed no significant change (**Figure 1**).

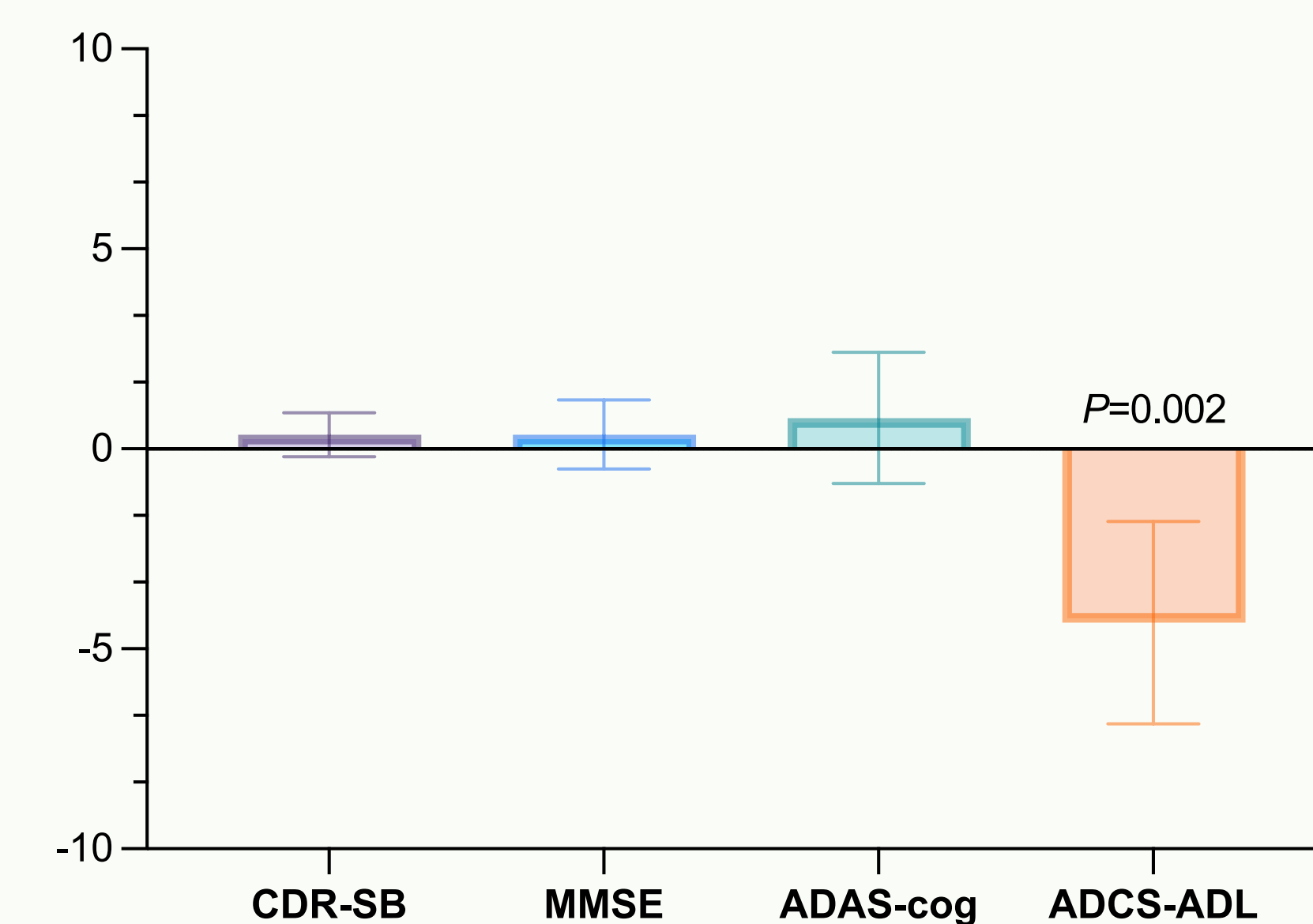


Figure 1 Cognitive and Functional Scores at 6 months compared to baseline.

- **Changes in plasma biomarkers (6-month vs baseline):** Significant decreases were observed in A β 42/40 ratio (0.004 , 95%CI 0.001 to 0.007 , $P=0.011$), p-Tau181 (1.21 , 95%CI 0.65 to 1.77 , $P<0.001$), and GFAP (42.44 , 95%CI 24.51 to 60.37 , $P<0.001$); A β 40 increased significantly (12.66 , 95%CI 3.02 to 22.30 , $P=0.012$) (**Figure 2**).

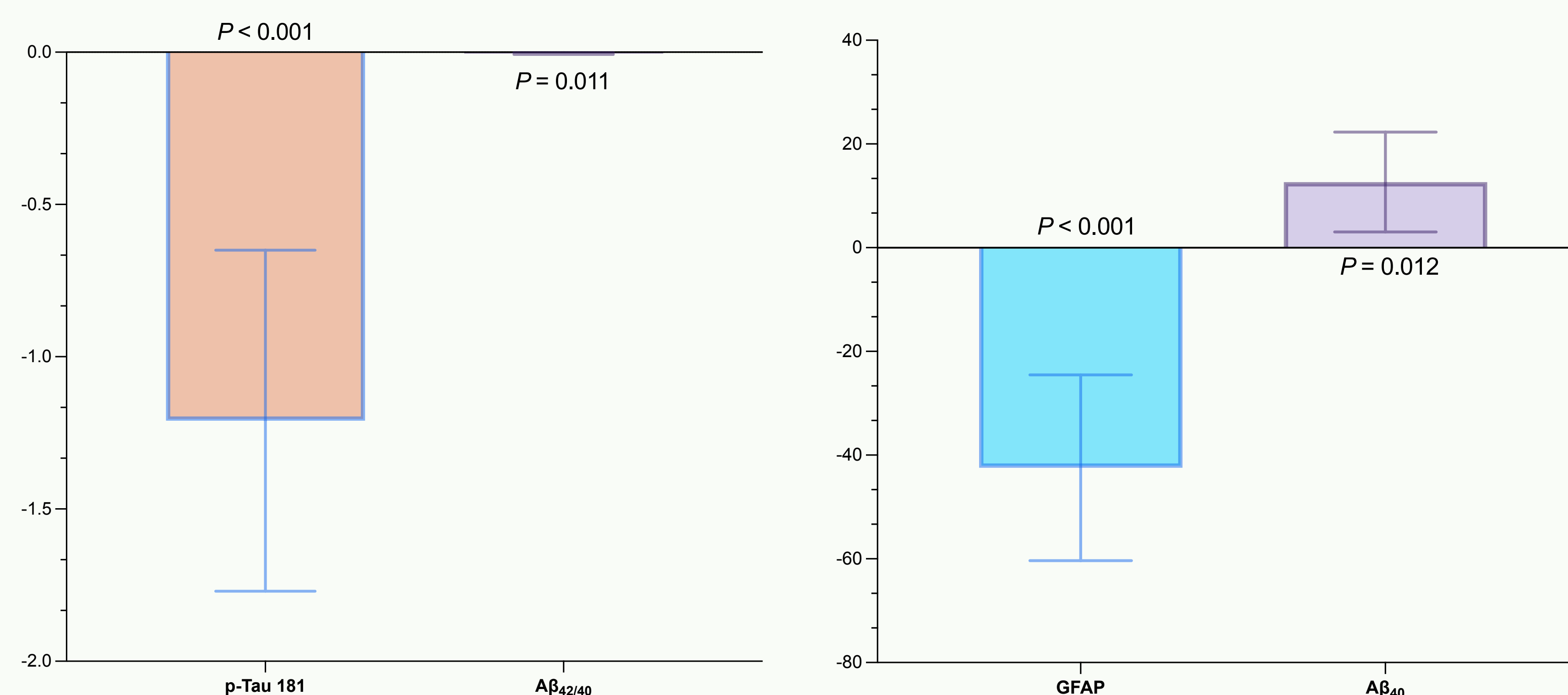


Figure 2 Plasma biomarkers change from baseline.

- **Safety:** Asymptomatic ARIA occurred in 4 patients (2.56%; 1 ARIA-E, 3 ARIA-H). Treatment-related adverse events (~20%) were mainly infusion-related reactions (fever, chills) occurring within 24 hours of the first infusion, resolving with symptomatic treatment.