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Sysmex Corporation

【Overview presentation】

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Increasing plasma Abeta42/40 accuracy by combining p-tau181 levels that are measured by fully automated immunoassay platform

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Overview presentation	**Objectives** Confirming amyloid pathology in the brain is necessary for determining the eligibility for Alzheimer's disease treatment with disease-modifying therapeutics. Blood-based biomarkers have attracted attention for invasiveness and accessibility, including the plasma β-amyloid1-40, 1-42 ratio (Aβ42/40) and phosphorylated tau (p-tau). We have previously shown that plasma Aβ42/40 measured by an Automated Immunoassay System HISCLTM-5000 / HISCL-800 can predict amyloid pathology with high accuracy. In this study, clinical performance was evaluated in combination with prototype p-tau181 assay to investigate the additional potential of blood biomarkers in predicting amyloid pathology. **Methods** Plasma Aβ42/40 and p-tau181 were measured in 25 samples collected at Tokyo Metropolitan Geriatric Hospital and Institute of gerontology to assess their ability to predict amyloid pathology. Amyloid pathology in the brain was determined by amyloid PET scans as assessed by visual read method. The distribution of each biomarker level in the PET-positive and PET-negative groups was compared by Mann-Whitney U test. The predictive performance of amyloid pathology was evaluated by ROC analysis.

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	Results The samples were classified into 8 amyloid PET positive and 17 negative groups. Both Aβ42/40 and p-tau181 showed significant differences between two groups ($p<0.005$, $p<0.05$, respectively). Furthermore, ROC analysis showed that the area under the curve (AUC) value was increased when combining p-tau181 with Aβ42/40 (AUC: 0.890) compared to Aβ42/40 alone (AUC: 0.857). **Conclusion** Our study has demonstrated that the plasma p-tau181 assay increased the predictive accuracy of plasma Aβ42/40 for amyloid PET status. In the future, we would increase the number of clinical samples to confirm the reliability of this specific combination. Through the expanding of our research, our goal is to contribute to the advancement of AD diagnosis using blood-based biomarkers.
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