

2026 World Conference on Lung Cancer

SEPTEMBER 12 – 15, 2026 | SEOUL, REPUBLIC OF KOREA

Noninvasive Metabolic Biomarker for Diagnosing and Predicting Outcomes in Checkpoint Inhibitor-Related Pneumonitis

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INTRODUCTION

- Checkpoint inhibitor-related pneumonitis (CIP) is a severe, potentially fatal immune-related adverse event.
- There is a lack of reliable diagnostic tools for CIP accurate identification.
- This study sought to characterize serum metabolic profiles to establish novel biomarkers for the early diagnosis and prognostic assessment of CIP.

METHODS

- Study groups: (1) ICI group: patients treated with PD-1/PD-L1 inhibitor and without CIP; (2) CIP group: patients treated with PD-1/PD-L1 inhibitor and with CIP.
- Serum metabolic and lipoprotein signatures were analyzed using ¹H-nuclear magnetic resonance (NMR) in lung cancer patients receiving immunotherapy (with and without CIP).
- Differentially expressed metabolites were identified using Least Absolute Shrinkage and Selection Operator (LASSO) regression.
- A diagnostic model was developed via logistic regression in a training cohort (n=58) and subsequently confirmed in a separate validation cohort (n=41).
- Univariate and multivariable Cox regression analysis were used to figure out the indicators independently related to CIP severity and overall survival.

RESULTS

- A total of 153 lipid metabolites were detected (39 metabolites and 114 lipoprotein-related indices).
- Analysis revealed ten differentially expressed metabolites and nine lipoprotein subfractions in the training set. (**Figure 1A, 1B**)
- An NMR-based combination signature (NCS) featuring six metabolic markers was developed. This model demonstrated high diagnostic accuracy, yielding an area under the curve (AUC) of 0.924 (95% CI: 0.857–0.991) in the training cohort and 0.911 (95% CI: 0.822–0.999) in the validation cohort. And the efficacy of NCS was better than the conventional clinical parameters. (**Figure 1C-F**)
- Elevated lysine levels were strongly linked to CIP severity (OR per SD: 3.873; 95% CI: 1.324–11.33; p=0.013). (**Table 1**)
- Increased glucose levels were a significant predictor of poorer overall survival (HR per SD: 1.478; 95% CI: 1.048–2.084; p=0.026). (**Figure 2**)

CONCLUSIONS

- CIP is characterized by distinct metabolic and lipoprotein alterations.
- A six-marker NMR signature demonstrated robust diagnostic performance for CIP (AUC 0.924–0.911).
- Elevated lysine was associated with increased CIP severity.
- Higher glucose levels predicted poorer overall survival.
- The results need further validation in large-scale prospective trials (NCT07340892).

Figure 1. Diagnosis efficacy of metabolic markers in training and validation cohort

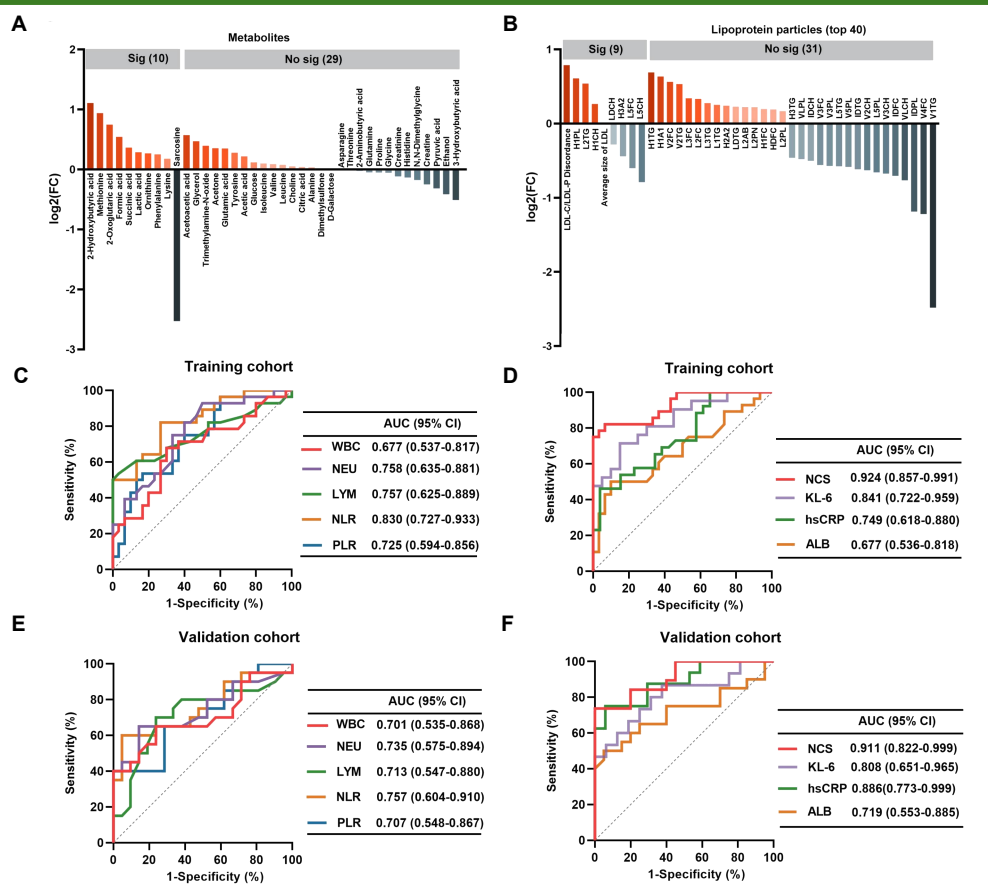
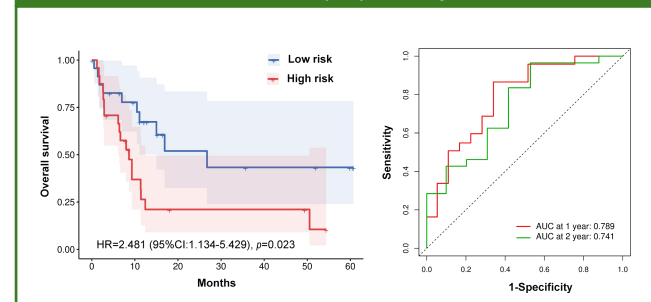


Table 1. NMR-derived biomarkers correlating with severity in CIP patients

Variables	Univariate Analysis			Multivariate Analysis		
	OR	95% CI	P-value	OR	95% CI	P-value
H1PL/SD	2.586	1.225-5.459	0.013	2.88	0.153-54.275	0.48
H1A1/SD	2.416	1.176-4.966	0.016	0.451	0.026-7.716	0.582
H1A2/SD	2.119	1.021-4.398	0.044	1.312	0.508-3.39	0.575
Isoleucine/SD	2.654	1.2-5.871	0.016	2.42	0.941-6.223	0.067
Lysine/SD	4.102	1.529-10.999	0.005	3.873	1.324-11.33	0.013

Figure 2. NMR indicators associated with overall survival (OS) in CIP patients



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