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ORIGINAL ARTICLE

Association Between Prognostic Nutritional Index and Clinical Outcomes in Advanced Non-Small Cell Lung Cancer Treated with Immune Checkpoint Inhibitors

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What is already known on this topic?

- *The PNI is a biomarker derived from serum albumin and lymphocyte count that reflects a patient's nutritional and immune status.*
- *Progression-free survival has been studied as a prognostic marker in various solid tumors, especially gastrointestinal malignancies.*
- *Previous evidence suggests that low PNI may be associated with worse outcomes in patients receiving systemic therapies, including ICIs, but its role in NSCLC remains underexplored.*

What this study adds on this topic?

- *This study demonstrates that a low pretreatment PNI is independently associated with significantly shorter OS in advanced NSCLC patients treated with immune checkpoint inhibitors.*
- *Radiologic response rates were also more favorable in the high PNI group, suggesting a potential predictive value of PNI beyond survival endpoints.*
- *The findings support the integration of PNI, a simple and cost-effective tool derived from routine lab tests, into clinical practice to refine risk stratification in NSCLC patients undergoing immunotherapy.*

Abstract

Objective: The Prognostic Nutritional Index (PNI), an inflammation-based biomarker derived from serum albumin and lymphocyte count, reflects both nutritional and immunological status. Although widely studied in gastrointestinal malignancies, its prognostic value in non-small cell lung cancer (NSCLC) patients receiving immune checkpoint inhibitors (ICIs) remains insufficiently explored.

Methods: A retrospective cohort of 263 patients diagnosed with stage IV non-small-cell lung cancer (NSCLC) who received ICIs (ICIs) between March 2018 and May 2024 at a single tertiary institution was evaluated. The PNI was computed using pre-treatment laboratory data obtained prior to immunotherapy initiation. Patients were categorized into high (≥45.32) and low (<45.32) PNI groups, with the cut-off value determined through receiver operating characteristic (ROC) curve analysis. Survival outcomes were assessed using Kaplan–Meier and Cox regression analyses. Radiological responses were also compared between groups.

Results: Patients in the high PNI group demonstrated a markedly prolonged median overall survival (OS) compared to those in the low PNI group (14.17 vs. 6.07 months; log-rank test, $P < .001$). In multivariate Cox regression analysis, a high PNI was identified as an independent predictor of improved OS (hazard ratio [HR] = 0.48; 95% CI: 0.34-0.67; $P < .001$). While patients with elevated PNI also exhibited a trend toward longer progression-free survival (6.80 vs. 5.03 months), this finding did not reach statistical significance ($P = .14$). Radiologic response rates were more favorable in the high PNI group, with higher rates of partial and complete response.

Conclusion: Pretreatment PNI is an independent prognostic factor for OS in patients with advanced NSCLC treated with ICIs. Its ease of calculation, low cost, and reflection of host immune-nutritional status support its potential integration into routine clinical practice to refine risk stratification and guide supportive interventions.

Keywords: Prognostic nutritional index, non-small-cell lung cancer, immunotherapy, overall survival, inflammation, nutritional status

Introduction

Non-small-cell lung cancer, representing approximately 85% of all lung cancer cases, remains the leading cause of cancer-related mortality worldwide. Despite advances in targeted therapies and ICIs, including anti-PD-1 and anti-PD-L1 agents, the prognosis for advanced-stage NSCLC remains poor for many patients.[1,2] Immune checkpoint inhibitors have become a cornerstone of treatment but only a subset of patients derives long-term benefit, highlighting the need for effective and accessible prognostic biomarkers.[2]

The tumor microenvironment, particularly host immunity and systemic inflammation, plays a crucial role in determining response to immunotherapy.[4] Inflammatory cytokines can promote immune evasion, tumor progression, and resistance to therapy.[4] Consequently, systemic markers that shows

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the inflammation situation and nutritional status have gained importance in recent years.

Prognostic nutritional index, derived from serum albumin concentration and peripheral lymphocyte count, serves as a straightforward and economic indicator that captures a patient's nutritional condition as well as immune competence. In the beginning of research about this, it is developed to evaluate surgical risk and has been shown to be associated with treatment outcomes in several malignancies, including gastrointestinal and thoracic cancers. Low PNI values are often linked to increased postoperative complications and worse survival outcomes.[3]

In the era of immunotherapy, where intact immune function is paramount, the relevance of PNI as a predictor of clinical outcome in NSCLC is biologically reasonable but has not been extensively studied. Prior studies have demonstrated that markers of systemic inflammation, such as red blood cell distribution width, are independently associated with poor survival in lung cancer.[5] Furthermore, large-scale population data suggest that cancer patients with impaired immune function or chronic inflammation may be at higher risk for developing secondary malignancies, including lung cancer.[6]

Accordingly, this study aimed to explore the prognostic relevance of PNI in patients with metastatic NSCLC undergoing immunotherapy. The authors postulated that lower baseline PNI scores would be independently linked to reduced progression-free and overall survival (PFS and OS), thereby highlighting the potential role of PNI as a practical tool in therapeutic decision-making.

Methods

Study Design and Patients

This retrospective analysis encompassed 263 patients that are confirmed at advanced stage NSCLC. Eligible patients treated with immune checkpoint inhibitors (ICIs) between March 2018 and May 2024 were recruited through hospital electronic medical records.

In Türkiye, due to national reimbursement policies, ICIs are approved for use only in the second-line or later settings for patients with metastatic disease. Therefore, all included patients had previously received at least one line of systemic therapy before initiating immunotherapy. Eligible patients were required to be 18 years or older, have a histologically has diagnosis of stage IV NSCLC according to the eighth edition of the American Joint Committee on Cancer (AJCC) staging system, and have complete clinical and laboratory data available prior to the initiation of immunotherapy.

This retrospective study was approved by the Instutitional Ethics Committee of Dr. Lütfi Kırdar City Hospital (Approval No: 2024/010.99/8/8; Date: 25.09.2024). The need for informed consent was waived by the Ethics Committee in accordance with national regulations, as stipulated in the Regulation on Clinical Research (published on April 13, 2013, Official Gazette No. 28617, Article 2.2), which permits the use of retrospective data without informed consent.

Data Collection and Definitions

Demographic, clinical, pathological, and laboratory data were retrospectively collected from the hospital's medical records. Collected variables included age at diagnosis, sex, smoking history, Eastern Cooperative Oncology Group (ECOG) performance status, histological subtype (adenocarcinoma, squamous cell carcinoma, or other), de novo metastatic status, treatment details (immunotherapy regimen and line of therapy), and PD-L1 expression levels. Programmed death-ligand 1 expression was categorized as <1%, ≥1%, or unknown. Programmed death-ligand 1 expression was assessed by immunohistochemistry as part of routine clinical practice. Due to the retrospective nature of the study, information regarding the specific assay or clone used for PD-L1 testing was not consistently available. Therefore, potential variability in testing methodology across patients could not be excluded.

Baseline laboratory values, including serum albumin (g/dL) and absolute lymphocyte count (per mm^3), measured within 1 week prior to the initiation of immunotherapy, were used to calculate the PNI. Prognostic nutritional index was calculated using the following formula:

PNI = [10 × serum albumin (g/dL)] + [0.005 × total lymphocyte count (per mm^3)]

Patients were divided into high and low PNI groups according to the threshold value of 45.32 determined by ROC curve analysis to optimize the prediction of OS. Individuals with a PNI ≥45.32 were allocated to the high PNI cohort, whereas those with values below this threshold were placed in the low PNI group.[7]

Tumor response to immunotherapy was assessed based on RECIST version 1.1 criteria.[8]

Statistical Analysis

Survival analyses were conducted with 95% CIs, calculated using the exact method. Comparisons of categorical variables between high and low PNI groups were made using Pearson's chi-square test or Fisher's exact test. It was considered statistically significant if *P*-value < .05.

Kaplan–Meier methodology was employed to evaluate PFS and OS, with group differences assessed via the log-rank test. To determine prognostic factors, Cox proportional hazards regression analyses were performed. Variables yielding a *P*-value below .10 in univariate analysis, alongside clinically meaningful covariates, were incorporated into the multivariate model.

Survival analyses excluded cases with incomplete data. All statistical procedures were carried out using IBM SPSS Statistics version 26.0 (IBM Corp., Armonk, NY, USA). The authors acknowledge the use of generative AI tools such as DeepL Translate and Grammarly solely for linguistic editing and grammatical improvements. All conceptual contributions, data analyses, and interpretations contained in this manuscript are entirely the work of the authors.

Results

Baseline Patient Characteristics Stratified by Prognostic Nutritional Index Status

A total of 263 patients with NSCLC were included in the study. The median age at diagnosis was 63 years (range: 24-88 years). Most patients were male (n = 223, 84.8%), while 15.2% (n = 40) were female. At initial diagnosis, 159 patients (60.5%) presented with metastatic disease, whereas 104 patients (39.5%) had early-stage disease.

Histopathological evaluation revealed that 41.8% (n = 110) of the cases were adenocarcinoma, 41.1% (n = 108) were squamous cell carcinoma, and 17.1% (n = 45) were of mixed histology.

Eastern Cooperative Oncology Group performance status (PS) at the time of treatment initiation was available for all patients. Among those with low PNI, 90.0% had ECOG 0, and 10.0% had ECOG 2. In contrast, among those with high PNI, 95.8% had ECOG 0, and 4.2% had ECOG 2, indicating that patients with high PNI tended to have better functional status.

Programmed death-ligand 1 expression data was available for 120 patients. Among them, 62 (23.6%) had a tumor proportion

score (TPS) <1%, 58 (22.1%) had TPS >1%, while PD-L1 status was unknown in 143 patients (54.4%).

Comparative analysis using the chi-square test revealed no statistically significant association between baseline PNI status (high vs. low) and sex (P = .484), ECOG performance status (P = .263), PD-L1 expression (P = .333), or initial disease stage at diagnosis (P = .797). Similarly, histological subtype (adenocarcinoma vs. squamous cell carcinoma vs. mixed histology) did not show a significant difference between PNI groups (P = .333).

However, a significant association was observed between PNI group and histological subtype when histology was categorized more granularly. In this comparison, squamous cell carcinoma was more frequently observed in the low PNI group, while adenocarcinoma was more common in the high PNI group (P < .001).

The optimal cut-off value of PNI was used to predict survival outcomes by ROC curve analysis. The area under the curve (AUC) for PNI was calculated as 0.651 (95% CI: 0.586-0.717), with a standard error of 0.033. It was statistically significant (P < .001) that PNI had a modest but statistically significant discriminatory capacity (Figure 1).

A PNI cut-off value of 45.32 was identified as the most predictive threshold, providing a sensitivity of 86.5% and a specificity of 41.4% in estimating clinical outcomes. This value was subsequently used to classify patients into 2 categories, those with high PNI (≥ 45.32) and those with low PNI (< 45.32)—for subsequent survival analyses.

Impact of Pretreatment Prognostic Nutritional Index on Progression-Free and Overall Survival

Progression-free and overall survival were analyzed according to the baseline PNI groups defined by the ROC-derived cut-off value of 45.32.

Median PFS was 5.03 months (95% CI: 2.17-7.90) in patients with low PNI, whereas it was 6.80 months (95% CI: 5.53-8.07) in the high PNI group. However, this difference was not statistically significant (P = .14) (Figure 2). In univariate Cox regression analysis, high PNI was associated with a non-significant trend toward improved PFS (HR = 0.789; 95% CI: 0.573-1.086; P = .145).

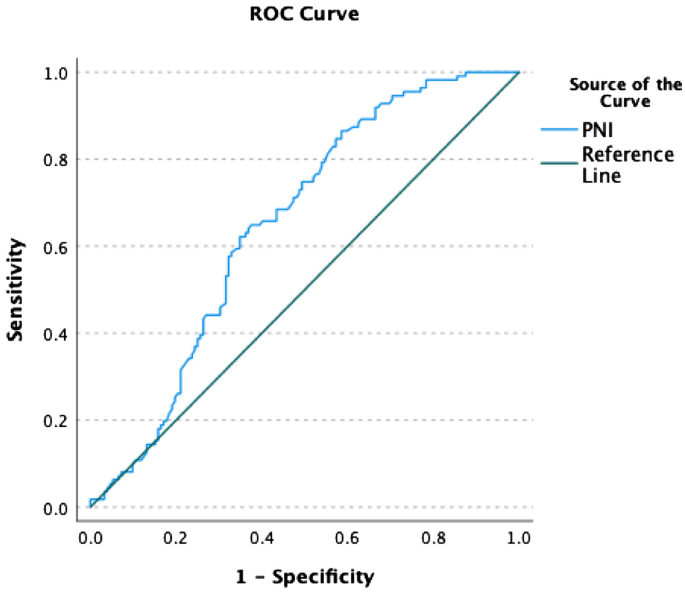

Figure 1. Time-dependent receiver operating characteristic curve for determining the optimal cut-off value of the prognostic nutritional index in predicting overall survival.

Patients classified within the high PNI group demonstrated a significantly extended median OS of 14.17 months (95% CI: 9.41-18.93), in contrast to 6.07 months (95% CI: 3.14-8.99) observed in the low PNI group. The survival advantage associated with a higher PNI was statistically significant (log-rank test, P < .001) (Figure 3). Furthermore, univariate Cox regression analysis identified elevated PNI as an independent protective factor against mortality (HR = 0.489; 95% CI: 0.354-0.675; P < .001).

Univariate and Multivariate Assessments of Progression-Free Survival Determinants

Univariate Cox regression analysis revealed that none of the evaluated clinical or pathological parameters demonstrated a statistically significant relationship with PFS. While patients in the high PNI group exhibited a numerically prolonged PFS, this difference did not attain statistical significance. Additionally, factors such as sex, ECOG performance status, tumor histology, PD-L1 expression levels, and initial stage at diagnosis were not significantly correlated with PFS.

Similarly, in multivariate Cox regression analysis, none of the variables retained independent prognostic value for PFS. The trend toward better PFS in the high PNI group persisted, but without statistical significance.

All univariate and multivariate analyses for PFS are summarized in Table 1.

Univariate and Multivariate Assessments of Overall Survival Determinants

In the univariate Cox regression analysis, poor performance status (ECOG ≥2) and low PNI (<45.32) were significantly associated with shorter OS. Specifically, patients with low PNI had a significantly higher risk of death compared to those with high PNI. Similarly, ECOG ≥2 was associated with markedly inferior OS. Other clinical variables including age, sex, smoking history, de novo metastatic presentation, histological subtype, and PD-L1 expression were not significantly associated with OS (all P > .05).

Multivariate analysis confirmed that both low PNI and ECOG ≥2 were independent predictors of worse OS. Low PNI remained significantly associated with reduced OS (HR = 0.48, 95% CI: 0.34-0.67; P < .001), while ECOG ≥2 was independently associated with more than 4-fold increased mortality risk (HR = 4.07, 95% CI: 1.66-8.60; P < .001).

All results from the univariate and multivariate analyses for OS are summarized in Table 2.

Association between Prognostic Nutritional Index and Radiologic Response

Radiologic response was evaluated according to baseline PNI groups. Patients with high PNI had more favorable response rates compared to those with low PNI. Among the 7 patients who achieved CR, 5 (71.4%) were in the high PNI group, and 2 (28.6%) in the low PNI group. Similarly, PR was observed in 63 high PNI patients (74.1%) and 22 low PNI patients (25.9%). SD was reported in 35 patients with high PNI (74.5%) and 12 with low PNI (25.5%). In contrast, PD was more prevalent among low PNI patients, with 42 cases (33.9%) compared to 82 cases (66.1%) in the high PNI group.

Although statistical significance was not formally tested in this comparison, the trend suggests that a higher baseline PNI may be associated with better radiological tumor control.

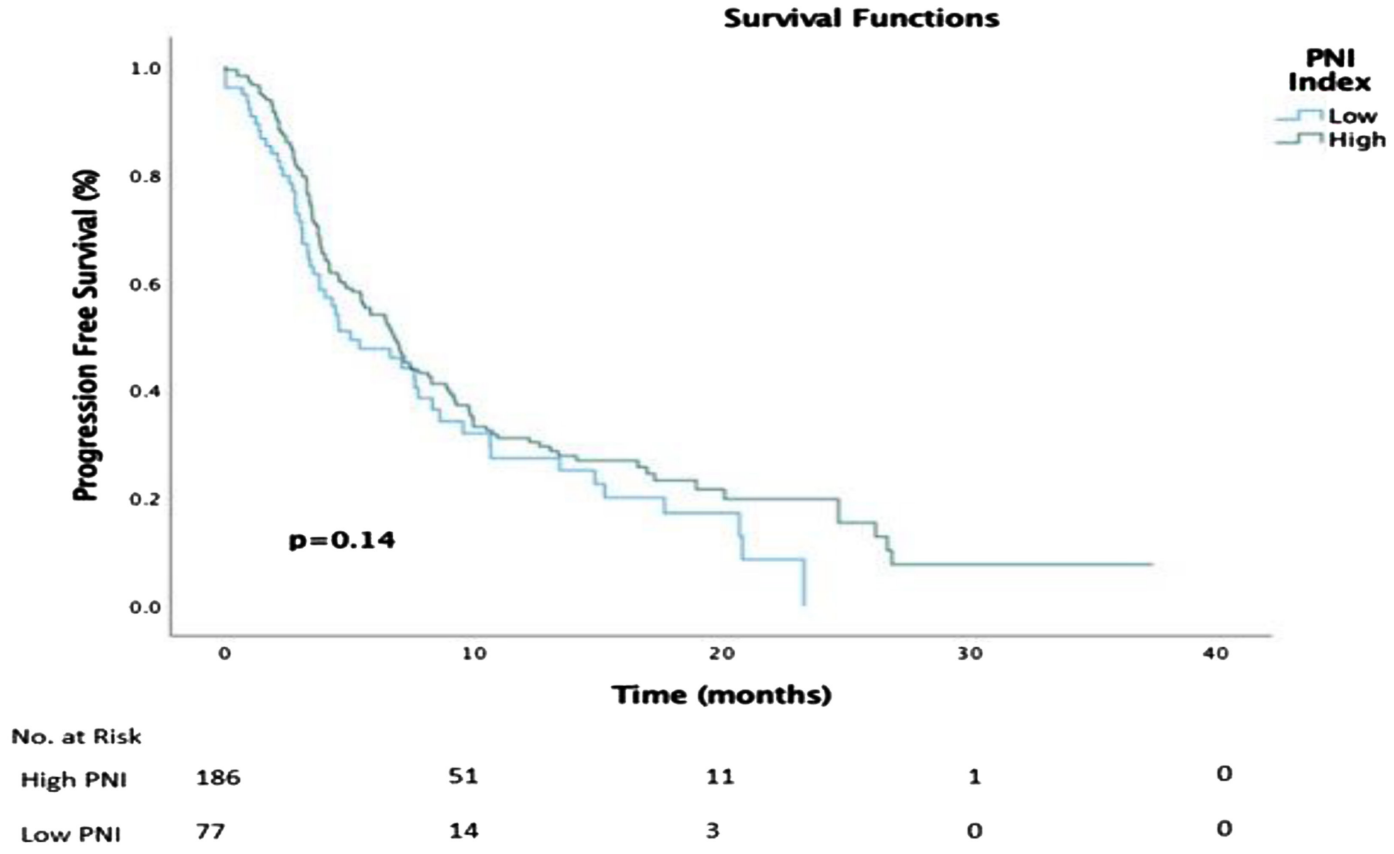

Figure 2. Kaplan–Meier curve for progression-free survival according to baseline prognostic nutritional index status.

Response distributions according to PNI status are illustrated in Figure 4.

Discussion

The authors' findings indicate that a lower baseline PNI is significantly associated with inferior OS in advanced NSCLC patients undergoing treatment with ICIs. Moreover, PNI retained its status as an independent prognostic marker in multivariate analysis. Although PFS tended to be shorter among patients with low PNI, the difference did not reach statistical significance. These results are consistent with an expanding body of literature underscoring the prognostic relevance of systemic immune-nutritional biomarkers in the context of immunotherapy.

The PNI, derived from serum albumin levels and peripheral lymphocyte counts, serves as a composite marker that reflects both the patient's nutritional status and overall systemic immune function.

Prognostic nutritional index is calculated by using serum albumin and peripheral lymphocyte count, it shows both nutritional status and systemic immune competence. Malnutrition and chronic inflammation are frequently observed in cancer patients, and both have been shown to impair immune mediated tumor control, which is critical for the efficacy of ICIs.[3,9] McMillan et al[10] reported that in cancer patients hypoalbuminemia is a result of systemic inflammation and strongly associated with reduced body cell mass and survival.

Our findings are consistent with previous studies reporting that lower baseline PNI is associated with shorter OS and poorer response to ICIs in lung cancer. A recent meta-analysis including over 800 patients demonstrated that NSCLC patients treated with ICIs, low PNI significantly correlated with inferior OS and PFS (HR: 2.50 and 1.94, respectively).[11] Oku et al[12] similarly found that PNI was an independent prognostic marker in patients receiving first line chemoimmunotherapy or monotherapy, particularly underline its prediction in the chemoimmunotherapy subgroup (HR = 2.49, *P* = .0006).

In this study, ECOG performance status and PNI were both independently provides prediction of OS. This supports the concept that systemic physiological status, beyond tumor burden and molecular biomarkers, plays a critical role in immunotherapy outcomes.[12,13] Mezquita et al[14] had previously proposed the Lung Immune Prognostic Index (LIPI), integrating derived neutrophil lymphocyte ratio and LDH, as a prognostic tool in NSCLC treated with ICIs. Similarly, PNI incorporates immune and nutritional status and may offer additional granularity in patient stratification.

The immune functional rationale for PNI's predictive value is supported by emerging evidence linking nutritional and inflammatory status with tumor-infiltrating lymphocytes (TILs) and immune cell profiles in the tumor microenvironment.[15] Kitahara et al[16] showed that higher PNI was associated with increased CD8+ T-cell infiltration proves that systemic immune nutritional health may correlate with local anti-tumor immune activation.

In addition, several studies have shown that patients with higher PNI not only survive longer but are more likely to experience favorable radiological responses, such as partial or complete response.[11,12] Although not statistically tested in the authors' cohort, the distribution of response types according to PNI status appeared to follow a similar trend.

The most valuable advantages of PNI is its one of the advantages of PNI is simplicity and accessibility. Unlike PD-L1 testing

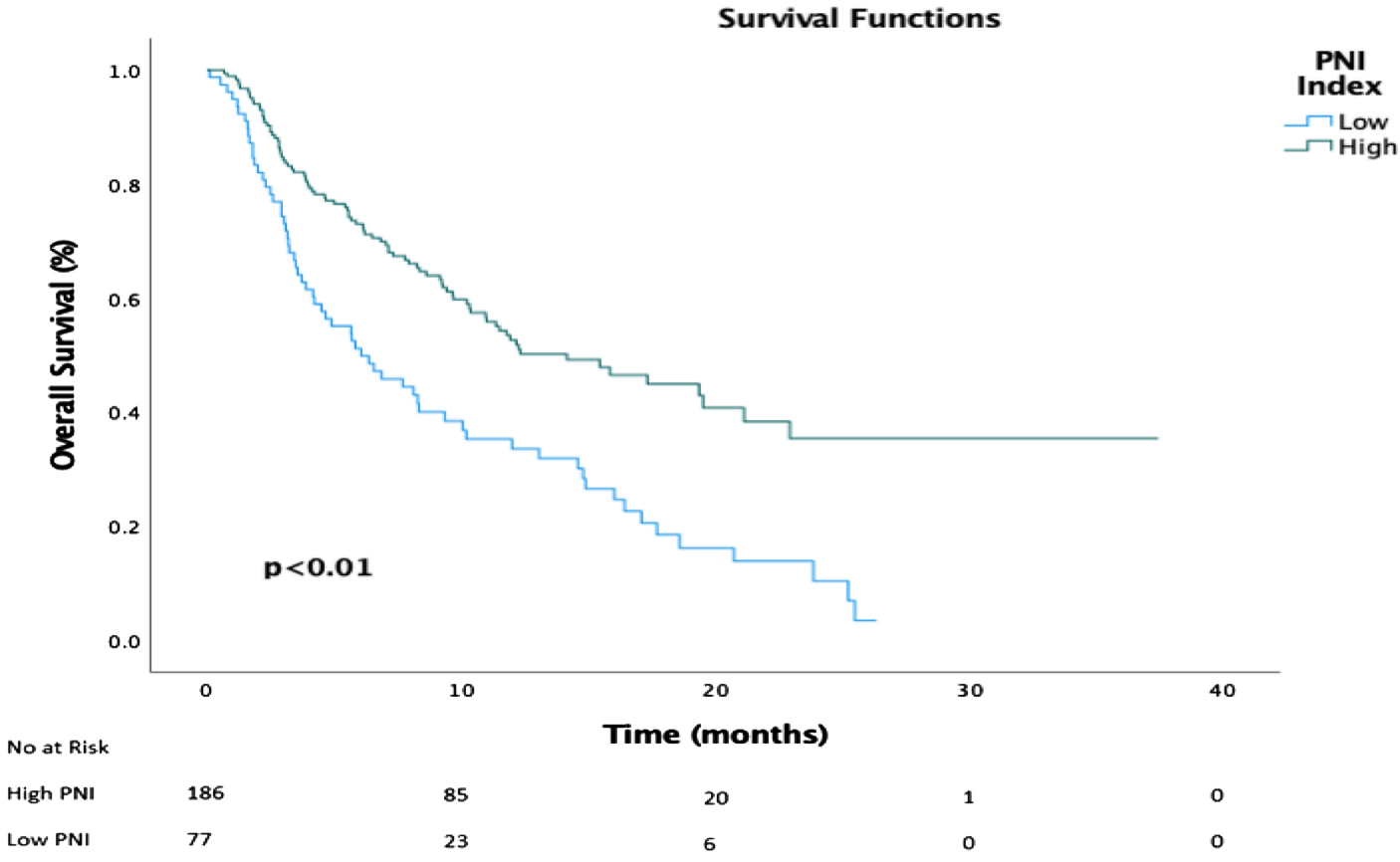

Figure 3. Kaplan–Meier curve for overall survival according to baseline prognostic nutritional index status.

or next-generation sequencing, PNI is calculated from routine laboratory data, making it an attractive adjunct in settings where biomarker testing is not available.[17] Due to limitations of PD-L1 as a predictive marker, PNI may serve as a complementary prognostic indicator to help refine treatment decisions.[14]

Taken together, the authors' findings support the growing recognition of host-related immune-nutritional status in influencing immunotherapy outcomes. Prognostic nutritional index is a non-invasive, cost-effective, and reproducible index and may serve as a practical tool for risk stratification in clinical oncology, particularly for NSCLC patients receiving ICIs. Moreover, it is plausible that targeted nutritional interventions, such as protein-rich diets, nutritional supplements, or early dietitian consultation, might help improve PNI and potentially enhance immunotherapy efficacy by restoring immune competence. Prospective, large-scale studies are needed to investigate whether nutritional or immunological status can increase the effectiveness of immunotherapy. Prospective, large-scale studies are needed to investigate whether nutritional or immunological status can increase the effectiveness of immunotherapy.

Table 1. Univariate and Multivariate Analyses of Progression-Free Survival

		Univariate Analysis			Multivariate Analysis		
Characteristics		**PFS HR**	**95% CI**	***P***	**PFS HR**	**95% CI**	***P***
Age, years	≥65	0.98	0.79-1.49	.923	1.35	0.86-3.13	.468
Sex	Male	1.18	0.78-1.78	.431	1.14	0.75-1.73	.271
Smoking	Current or ex	0.91	0.63-1.39	.449	0.91	0.59-1.65	.436
De nova met.	Yes	1.04	0.77-1.39	.797	1.04	0.77-1.40	.793
PS	≥2	2.54	1.89-6.02	.001	3.10	1.38-6.74	.016
Histology	Squamous	1.07	0.96-1.18	.178	1.06	0.96-1.18	.213
PD-L1	<1%	0.99	0.83-1.18	.979	0.99	0.83-1.18	.902
PNI	<45.32	0.79	0.57-1.09	.145	0.79	0.57-1.09	.144

HR, hazard ratio; PD-L1, programmed death-ligand 1; PFS, progression-free survival; PNI, prognostic nutritional index; PS, performance status.

Table 2. Univariate and Multivariate Analyses of Overall Survival

		Univariate Analysis			Multivariate Analysis		
Characteristics		**OS HR**	**95% CI**	***P***	**OS HR**	**95% CI**	***P***
Age, years	≥65	0.98	0.79-1.49	.92	1.56	0.86-3.13	.26
Sex	Male	1.072	0.682-1.68	.76	0.97	0.61-1.53	.90
Smoking	Current or ex	0.91	0.63-1.39	.44	0.89	0.49-2.01	.63
De Nova met.	Yes	1.274	0.917-1.76	.14	1.28	0.92-1.78	.14
PS	≥2	2.54	1.89-6.02	< .001	4.07	1.66-8.60	< .001
Histology	Squamous	1.07	0.96-1.18	.17	1.11	0.99-1.24	.71
PD-L1	<1%	1.05	0.87-1.28	.57	1.04	0.85-1.26	.70
PNI	<45.32	0.48	0.35-0.67	< .001	0.48	0.34-0.67	< .001

HR, hazard ratio; OS, overall survival; PD-L1, programmed death-ligand 1; PNI, Prognostic Nutritional Index; PS, performance status.

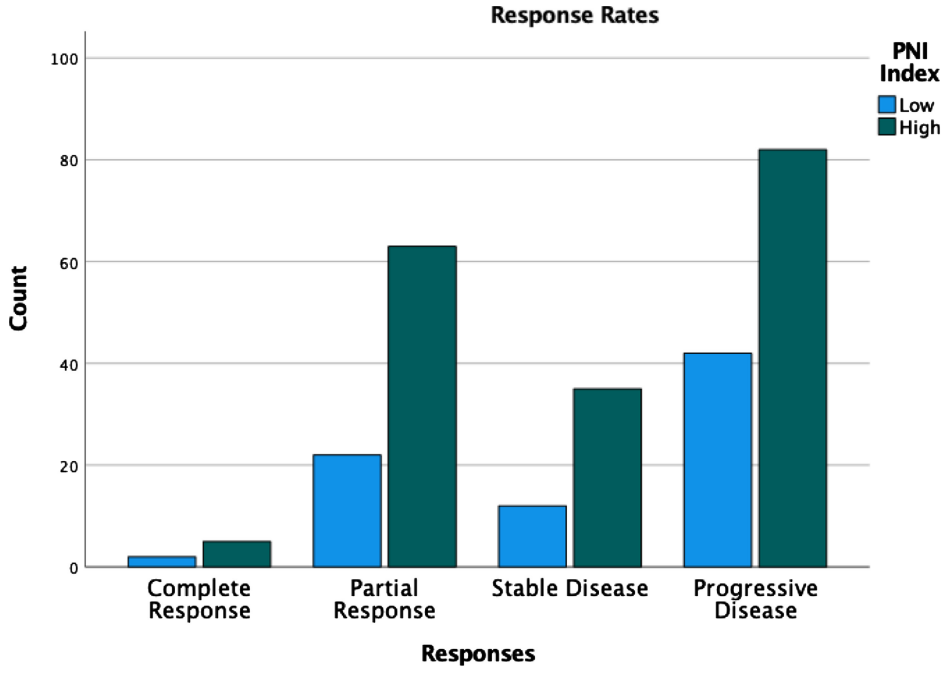

Figure 4. Distribution of radiologic responses (complete response, partial response, stable disease, and progressive disease) according to baseline prognostic nutritional index groups.

The first most important factor limiting this study is that it may create selection bias due to its retrospective design. Secondly, since it is a single-center study, access to large patient populations was limited. Third, due to national reimbursement constraints in Türkiye, only nivolumab was available for use in the second-line treatment of advanced NSCLC during the study period. As a result, the prognostic value of PNI could not be evaluated in the context of other ICIs such as pembrolizumab or atezolizumab. Additionally, the lack of standardized PD-L1 testing across all cases represents a potential limitation. As the study was retrospective, the authors were unable to verify whether a uniform assay was used for PD-L1 evaluation, which may have introduced variability. These factors should be considered when interpreting the results, and future prospective, multi-center studies involving various ICI regimens are warranted to validate the authors' findings.

This study highlights the prognostic value of baseline PNI in patients with advanced NSCLC receiving ICI therapy. The findings suggest that a lower pretreatment PNI is associated with significantly shorter OS and a tendency toward poorer radiologic treatment response. Notably, even after controlling clinical variables such as ECOG performance status, PNI retained its role as an independent predictor of OS.

Given its simplicity, low cost, and accessibility from routine laboratory parameters, PNI represents a practical and reproducible biomarker for risk stratification in the immunotherapy setting. Integration of PNI into clinical decision-making may enhance the identification of patients who would benefit from additional nutritional or immunological support. Future prospective studies are needed to confirm these observations and to investigate whether strategies targeting the improvement of PNI may contribute to enhanced clinical outcomes.

Data Availability Statement: The data that support the findings of this study are available on request from the corresponding author.

Ethics Committee Approval: This study was received for this study from the Ethics Committee of the Kartal Dr. Lütfi Kırdar City Hospital (Date: 25.09.2024, Approval No: 2024/010.99/8/8).

Informed Consent: The requirement for informed consent was waived by the Ethics Committee of Dr. Lütfi Kırdar City Hospital due to the retrospective nature of the study.

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Declaration of Interests: The authors have no conflict of interest to declare.

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