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Body mass index as a predictor of the efficacy of immune checkpoint inhibitors in patients with non-small cell lung cancer and other solid tumors

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Body mass index (BMI) has been increasingly recognized as a potential predictor of response to immune checkpoint inhibitor (ICI) therapy across various malignancies. This study aimed to evaluate the association between BMI and clinical outcomes in patients with non-small cell lung cancer (NSCLC) and other solid tumors receiving ICIs. In this retrospective cohort study, 158 patients were included and analyzed. Clinicopathological characteristics such as BMI, Eastern Cooperative Oncology Group (ECOG) performance status, PD-L1 expression level, tumor histology, and the presence of distant metastases, including central nervous system (CNS) involvement, were comprehensively assessed. Survival outcomes, including progression-free survival (PFS) and overall survival (OS), were estimated using Kaplan–Meier survival curves, while independent prognostic factors were identified through multivariate Cox proportional hazards regression analysis. Patients with obesity (BMI > 30) demonstrated significantly improved survival outcomes compared with patients of normal weight, overweight, and underweight categories. Specifically, the median PFS was 11.2 months in obese patients versus 6.8 months in normal-weight individuals, while the median OS reached 22.2 months compared with 12.2 months, respectively. These findings remained statistically significant after adjustment for other clinicopathological variables. Multivariate analysis confirmed BMI, ECOG performance status, PD-L1 expression, tumor histology, and CNS metastases as independent predictors of both PFS and OS. The observed association between higher BMI and improved response to ICIs may be explained by immunometabolic mechanisms, including chronic low-grade inflammation, altered cytokine profiles, and leptin-mediated modulation of the PD-1/PD-L1 axis, potentially enhancing antitumor immune responses. These results suggest that BMI represents a simple, accessible, and cost-effective biomarker that can be readily incorporated into routine clinical practice. Therefore, patient selection for immunotherapy should consider BMI in conjunction with established prognostic factors such as ECOG performance status, PD-L1 expression, tumor histology, and metastatic burden, particularly CNS involvement. Overall, these findings support the prognostic and predictive value of BMI and highlight its potential role in optimizing individualized treatment strategies in patients receiving immune checkpoint inhibitors.

Keywords: obesity; body mass index; immune checkpoint inhibitors; progression-free survival; overall survival; PD-L1; solid tumors; immunotherapy.

Introduction

Over the past decade, immune checkpoint inhibitors (ICIs) have led to revolutionary changes in the treatment of patients with malignant neoplasms. By improving both progression-free and overall survival, this type of therapy is considered one of the most promising approaches in systemic cancer treatment (Li et al., 2023; Daste et al., 2024; Holder et al., 2024). However, a proportion of patients derive only limited benefit from ICIs, and in some cases, no therapeutic effect is observed. Therefore, it is crucial to identify patients who are most likely to benefit from immunotherapy, given its high cost and the risk of autoimmune and allergic adverse events.

The main biological markers influencing the decision to initiate ICI therapy include programmed cell death ligand 1 (PD-L1), tumor mutational burden, and microsatellite instability. It should be noted that, in most cases, clinicians rely primarily on the assessment of PD-L1 expression. However, the effectiveness of immunotherapy may also be influenced by patient age (Moskalenko et al., 2025a), corticosteroid use (Moskalenko et al., 2025b), smoking status (Moskalenko et al., 2025c), muscle condition (Moskalenko et al., 2025d), and other factors (Moskalenko & Moskalenko, 2025e; Moskalenko, 2025f).

Body mass index (BMI) remains a controversial prognostic factor. Traditionally, obesity has been considered a negative factor in oncology, contributing to the development and progression of malignancies and worsening patient outcomes (Jin et al., 2024). However, emerging evidence suggests the opposite, indicating that the efficacy of ICIs may be significantly higher in overweight and obese patients (Vithayathil et al., 2023). Studies in gastric (Deng et al., 2024), renal (De Giorgi et al., 2019), and lung cancer (Ichihara et al., 2020) have demonstrated that patients receiving ICIs have improved progression-free survival (PFS) and overall survival (OS) compared with those with underweight status.

Unlike chemotherapy dosing, which is calculated based on body weight and height, ICI dosing is typically fixed. Despite the lower drug dose per kilogram of body weight in overweight patients, treatment outcomes appear to be superior compared with those in underweight individuals. In our study, we analyzed the association between BMI and survival outcomes in patients with solid tumors receiving ICIs.

Materials and methods

The study was approved by the Commission on Bioethics of Sumy State University (№ 2/04, date of approval January 19, 2026) and conducted in accordance with the Declaration of Helsinki. Informed consent was obtained from all subjects involved in the study.

The study was conducted at the Sumy Regional Clinical Oncology Center. We evaluated the association between body mass index (BMI) and survival outcomes in patients with stage IV non-small cell lung cancer (NSCLC), head and neck cancers, breast cancer, kidney

cancer, esophageal cancer, and melanoma. All patients received either first-line immunotherapy or chemoimmunotherapy. The study was retrospective, analyzing data from patients who received immune checkpoint inhibitors (ICIs) between August, 2016, and September, 2022.

The primary clinical endpoints were progression-free survival (PFS) and overall survival (OS). Imaging assessments were performed every 6–8 weeks according to local practice. All responses were evaluated according to the iRECIST criteria for solid tumors. The parameters PFS and OS were defined as the time from initiation of ICI therapy to disease progression or patient death, respectively.

Following WHO recommendations, individuals with BMI <18.5 were classified as underweight, 18.5 ≤ BMI <24.9 as normal weight, 25 ≤ BMI <29.9 as overweight, and BMI ≥30 as obese. Body mass index was calculated using the formula weight/height² (kg/m²). Height and weight data were obtained from patients' medical records prior to ICI therapy.

Patients' clinicopathological characteristics were categorized according to BMI. Univariate analysis was used to explore associations between BMI and clinicopathological features. Multivariate Cox regression analysis with the Breslow method was applied to the intermediate results. Selected characteristics were chosen based on clinical relevance and applicability across major solid tumor types, including: age (<60 versus ≥60 years), sex (male versus female), ECOG performance status (0–1 versus ≥2), smoking status (current/former versus never), tumor type (lung versus other), histology of primary tumor (adenocarcinoma versus squamous cell carcinoma versus other), presence of metastases in the lungs, liver, or bones (present versus absent), PD-L1 expression level (≥50% versus 1–49%), and administered ICI (pembrolizumab versus atezolizumab).

Pearson's chi-square test and Fisher's exact test were used to compare clinicopathological characteristics across the groups. The Kaplan–Meier method was employed to estimate PFS and OS. The log-rank test and trend test in survival functions were applied to test the null hypothesis of no difference in recurrence or death probability between the groups at any time point. Hazard ratios (HRs) with 95% confidence intervals (CIs) and associations between clinicopathological characteristics were determined using multivariate Cox regression analysis. A two-sided P value of < 0.05 was considered statistically significant. The standard database was created in Excel, and the analytical model was implemented in Stata V.19.5 (StataCorp, Texas, USA; www.stata.com; 2025).

Results

A total of 158 patients receiving ICI therapy were included in the study. All patients and their clinicopathological characteristics prior to the initiation of immunotherapy were stratified into subgroups according to WHO criteria (Table 1).

Table 1
Clinicopathological characteristics of patients with solid tumors prior to ICI therapy stratified by BMI (n = 158)

Clinicopathological characteristics	Total number of patients, % (N = 158)	Underweight, % (N = 7)	Normal weight, % (N = 76)	Overweight, % (N = 49)	Obesity, % (N = 26)	P-value
Age (years), n (%)						
Mean	61	63	61	62	60	
Range	34–95	55–73	34–95	36–86	34–74	0.440
<60	67 (42.4)	2 (28.6)	32 (42.1)	22 (44.9)	11 (42.3)	
≥60	91 (57.6)	5 (71.4)	44 (57.9)	27 (55.1)	15 (57.7)	
Sex, n (%)						
Female	36 (22.8)	0 (0)	16 (21.1)	11 (22.4)	9 (34.6)	0.001
Male	122 (77.2)	7 (100)	60 (78.9)	38 (77.6)	17 (65.4)	
ECOG, n (%)						
0–1	150 (94.9)	4 (57.1)	74 (97.4)	48 (98.0)	24 (92.3)	0.0001
≥2	8 (5.1)	3 (42.9)	2 (2.6)	1 (2.0)	2 (7.7)	
Smoking status						
Never smokers	50 (31.6)	1 (14.3)	23 (30.3)	14 (28.6)	12 (46.2)	0.002
Former and current smokers	108 (68.4)	6 (85.7)	53 (69.7)	35 (71.4)	14 (53.8)	
Tumor type						
Lung	105 (66.5)	5 (71.4)	52 (68.4)	31 (63.3)	17 (65.4)	0.618
Other	53 (33.5)	2 (28.6)	24 (31.6)	18 (36.7)	9 (34.6)	
Histological type of tumor						
Adenocarcinoma	58 (36.7)	3 (42.9)	27 (35.5)	15 (30.6)	13 (50.0)	0.022
Squamous cell carcinoma	84 (53.2)	4 (57.1)	41 (53.9)	28 (57.1)	11 (42.3)	
Other type	16 (10.1)	0 (0)	8 (10.5)	6 (12.2)	2 (7.7)	
Lung metastases						
Yes	76 (48.1)	5 (71.4)	31 (40.8)	29 (59.2)	11 (42.3)	0.0001
No	82 (51.9)	2 (28.6)	45 (59.2)	20 (40.8)	15 (57.7)	
Liver metastases						
Yes	36 (22.8)	2 (28.6)	19 (25.0)	8 (16.3)	7 (26.9)	0.071
No	122 (77.2)	5 (71.4)	57 (75.0)	41 (83.7)	19 (73.1)	
Bone metastases						
Yes	37 (23.4)	2 (28.6)	17 (22.4)	10 (20.4)	8 (30.8)	0.193
No	121 (76.6)	5 (71.4)	59 (77.6)	39 (79.6)	18 (69.2)	
PD-L1 expression level						
≥50%	33 (20.9)	2 (28.6)	14 (18.4)	10 (20.4)	7 (26.9)	0.218
1–49%	125 (79.1)	5 (71.4)	62 (81.6)	39 (79.6)	19 (73.1)	
ICI therapy						
Pembrolizumab	99 (62.7)	5 (71.4)	51 (67.1)	28 (57.1)	15 (57.7)	0.068
Atezolizumab	59 (37.3)	2 (28.6)	25 (32.9)	21 (42.9)	11 (42.3)	

Note. The chi-square test and Fisher exact test were used for statistical analysis.

A total of 7 patients (4.4%) were classified as underweight, 76 (48.1%) as normal weight, 49 (31.0%) as overweight, and 26 (16.5%) as obese. The study cohort included 36 (22.8%) women and 122 (77.2%) men. Most patients were aged 60 years or older – 91 individuals (57.6%). In 8 patients (5.1%), ECOG performance status ≥2 was observed. Among the cohort, 108 patients (68.4%) were current or former smokers. The majority of the cohort consisted of patients with NSCLC – 105 (66.5%). Tumors of the head and neck, breast, kidney, esophagus, or melanoma were reported in 53 patients (33.5%) and were combined into a single group due to the small sample size. Additionally, 76 patients (48.1%) had lung metastases, 36 (22.8%) had liver metastases, and 37 (23.4%) had bone metastases. High PD-L1 expression (≥50%) was observed in 33 patients (20.9%), while moderate expression (1–49%) was noted in 125 patients (79.1%). No

patients had PD-L1 expression <1%. The cohort received two types of ICIs approved in Ukraine: Pembrolizumab was administered to 99 patients (62.7%) and atezolizumab to 59 patients (37.3%).

Some clinicopathological characteristics differed significantly across the BMI subgroups. In the normal-weight group, most patients were men (P = 0.001) and current or former smokers (P = 0.002). They had better ECOG performance status (P = 0.0001) and a lower frequency of lung metastases (P = 0.0001). Squamous cell carcinoma was the predominant histological type (P = 0.022).

The obese subgroup exhibited a slightly different pattern. Most patients in this group were women (P = 0.001) with better ECOG status (P = 0.0001). The majority were never smokers, had adenocarcinoma, and lower frequency of lung metastases. However, no statistically significant differences were observed within the obesity subgroup.

The median follow-up period was 20.7 months (95% CI: 1.1–101.2). Median PFS was 7 months (95% CI: 4–16.149 events), and median OS was 16.8 months (95% CI: 7.3–29.151 events). Median PFS for underweight, normal weight, overweight, and obese patients was 4.3 months (6 events), 6.8 months (73 events), 5.6 months (47 events), and 11.2 months (23 events), respectively (log-rank test: P = 0.0432; trend test in survival functions: P = 0.0284; Figure 1).

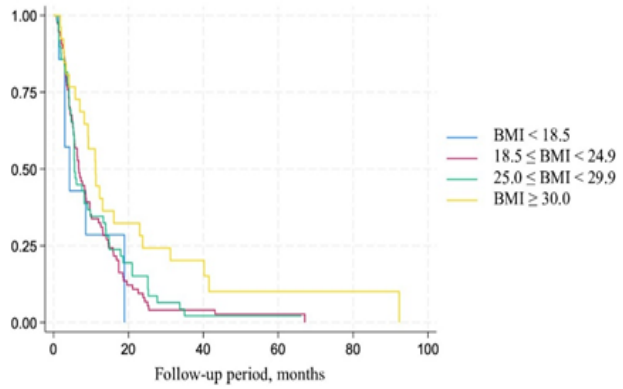

Fig. 1. Progression-free survival curves in patients receiving immunotherapy stratified by underweight, normal weight, overweight, or obesity (n = 158)

The median overall survival (OS) for patients who were underweight, normal weight, overweight, and obese was 17.6 months (6 events), 12.2 months (73 events), 17.7 months (48 events), and 22.2 months (24 events), respectively (log-rank test: P = 0.0283; trend test in survival functions: P = 0.0382; Figure 2).

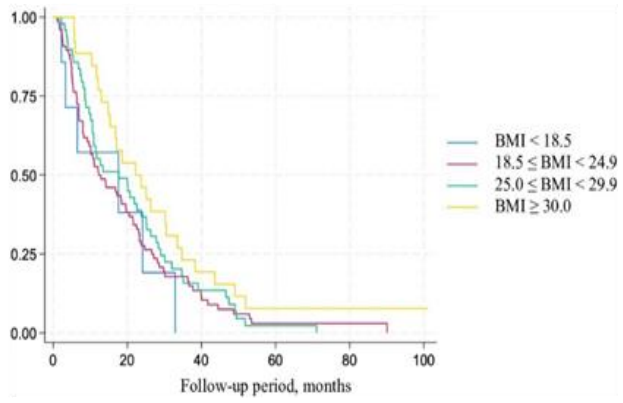

Fig. 2. Overall survival curves in patients receiving immunotherapy stratified by underweight, normal weight, overweight, or obesity (n = 158)

Multivariate analysis confirmed the association among baseline BMI, progression-free survival (PFS), and overall survival (OS). The patients with obesity had a statistically significantly longer survival period compared with those who were underweight, normal weight, or overweight. Additionally, ECOG performance status, tumor histology, and PD-L1 expression level were identified as significant determinants of PFS and OS (Table 2).

Table 2
Multivariate analysis of risk for disease progression and death in patients with solid tumors receiving ICIs (n = 158)

Clinicopathological characteristics	Progression-free survival (PFS) HR (95% CI), P-value	Overall survival (OS) HR (95% CI), P-value
Patient BMI	0.85 (0.73–1.00), 0.049	0.84 (0.71–1.01), 0.048
Age	1.16 (0.90–1.50), 0.224	1.22 (0.96–1.56), 0.098
Sex	0.77 (0.50–1.18), 0.234	0.80 (0.52–1.24), 0.332
Smoking status	0.82 (0.54–1.22), 0.328	0.72 (0.49–1.07), 0.108
ECOG status	5.78 (3.21–10.40), 0.0001	12.46 (6.57–23.63), 0.0001
Tumor type	1.05 (0.78–1.41), 0.36	0.92 (0.68–1.24), 0.597
Histological type of tumor	0.74 (0.59–0.93), 0.010	0.69 (0.56–0.86), 0.001
Lung metastases	0.99 (0.77–1.25), 0.939	0.87 (0.68–1.10), 0.257
Liver metastases	0.95 (0.70–1.29), 0.770	1.04 (0.77–1.40), 0.763
Bone metastases	1.01 (0.74–1.39), 0.906	0.95 (0.69–1.31), 0.789
PD-L1 expression level	0.33 (0.24–0.45), 0.0001	0.32 (0.23–0.44), 0.0001
ICI therapy	1.11 (0.90–1.50), 0.446	1.22 (0.94–1.59), 0.134

Discussion

In this retrospective study, we analyzed the association between BMI and the efficacy of immune checkpoint inhibitor (ICI) therapy in patients with solid tumors. The results demonstrated that the patients with obesity had significantly better progression-free survival (PFS) and overall survival (OS) compared with individuals with normal, overweight, or underweight status. Multivariate analysis confirmed the independent effect of BMI on clinical outcomes, alongside ECOG performance status, PD-L1 expression level, tumor histology, and the presence of central nervous system (CNS) metastases.

Increasingly, the literature reports a positive association between immunotherapy outcomes and obesity, a phenomenon termed the "obesity paradox." A plausible explanation involves the favorable impact of chronic inflammation. Adipose tissue functions as an endocrine organ influencing the immune system by producing pro-inflammatory hormones such as tumor necrosis factor (TNF)-α, leptin, and interleukin (IL)-6 (Mojibi et al., 2022). Each of these factors affects specific components of immunity. For example, leptin can induce CD8+ T-cell dysfunction and PD-1 receptor overexpression, with higher leptin levels correlating with a more pronounced effect. Consequently, these patients exhibit a better response to immunotherapy (Wang et al., 2019). Bu et al. (2017) demonstrated that elevated leptin levels activate PD-1 receptors on T cells via signal transducer and activator of transcription 3, with higher PD-1 expression intensifying T-cell exhaustion, thereby enhancing the therapeutic effect of ICIs in obese patients (Woodall et al., 2020).

Kraakman et al. (2014) investigated the tumor microenvironment, finding that obesity can cause an imbalance between pro-inflammatory (M1) and anti-inflammatory (M2) macrophages. Excess adipose tissue stimulates pro-inflammatory macrophages and maintains chronic systemic inflammation.

Recently, researchers have focused on the effects of visceral and subcutaneous fat on PFS and OS. Analyses of adipose tissue characteristics, including radiodensity parameters, underscore the significance of immunometabolic interactions in ICI therapy. Some studies assessed visceral fat radiodensity in patients with metastatic non-small cell lung cancer (NSCLC) receiving ICIs. While no independent association with survival was observed, a significant interaction with PD-L1 expression was noted, suggesting a potential modulatory role of metabolic factors in immunotherapy response. Specifically, high PD-L1 expression remained an independent predictor of reduced mortality risk, and the nonlinear relationship between visceral fat density and death risk highlighted complex immunometabolic interactions (Moskalenko et al., 2025g). Similar findings were reported for subcutaneous fat. One study demonstrated a U-shaped relationship between subcutaneous fat radiodensity and mortality in patients with metastat-

ic NSCLC receiving ICIs. Optimal survival was observed in patients with moderate subcutaneous fat density, reflecting a balance between metabolic activity and inflammatory status. Expression of PD-L1 further modified this relationship, supporting the interplay between immune and metabolic mechanisms in determining immunotherapy efficacy (Moskalenko et al., 2025h).

It is believed that subcutaneous and visceral adipose tissue differently influence the immune microenvironment and can have divergent effects on survival in patients receiving ICIs. Xiao et al. (2022) reported that visceral obesity is a predictor of better outcomes in patients with liver cancer, potentially due to increased expression of PD-L2, adenosine A2a receptors, CD160, and T-cell immunoglobulin, all of which are inhibitory immune checkpoints on T lymphocytes and potential targets of ICIs (Davern et al., 2023).

Other studies demonstrated an association between subcutaneous fat quantity and survival. A higher amount of subcutaneous fat reflects a favorable nutritional status, which is important given the high energy demands of malignant tumors. Additionally, subcutaneous fat secretes leptin, stimulating PD-1 expression on T lymphocytes (Baldessari et al., 2021; Ged et al., 2022). Together, these mechanisms help explain the positive impact of adipose tissue on immunotherapy outcomes.

Body mass index, as a predictive factor for immunotherapy, is particularly attractive because it does not require additional investigations or economic resources. Recent findings supporting a favorable effect of obesity on immunotherapy are reshaping oncologists' perspectives on treatment prospects. Our study results corroborate the positive association between obesity and improved survival. Kaplan-Meier curves clearly show significantly higher survival among patients with obesity. Compared with normal-weight patients, the median PFS for obese individuals was 11.2 versus 6.8 months, while OS was 22.2 versus 12.2 months.

Before analyzing PFS and OS, the most favorable subgroup appeared to be normal-weight male patients with better ECOG status and a low frequency of lung metastases. However, Kaplan-Meier analysis demonstrated the best survival in the obese subgroup, which was predominantly female. Evidence for the positive effect of adipose tissue on the prognosis in patients receiving ICIs is gradually increasing. For example, Huang et al. (2024), reported an association between better OS and obesity in metastatic urothelial carcinoma, Zhang et al. (2023) in NSCLC, Roccuzzo et al. (2023) in melanoma, and Ged et al. (2022) in clear cell renal carcinoma.

Multivariate regression analysis allowed us to assess the effects of various clinicopathological characteristics in patients receiving ICIs. According to our results, PFS and OS were influenced by baseline BMI, ECOG performance status, PD-L1 expression, tumor histology, and CNS metastases. The effect of ECOG status has been confirmed across multiple cancer types; better overall patient condition is a significant predictor of survival in individuals receiving both monotherapy and chemoimmunotherapy (Rosellini et al., 2023; Yang et al., 2020).

Expression of PD-L1 is a well-established biomarker used to identify candidates for immunotherapy. Higher receptor expression is associated with greater ICI efficacy (Yoneda et al., 2022). Obesity helps maintain elevated leptin levels and PD-L1 hyperexpression, which likely underlies the improved immunotherapy response in this patient group. Vallejo et al. (2024) recently demonstrated the positive effect of elevated PD-L1 levels on the outcomes of PD-1/PD-L1 inhibition in NSCLC patients.

The association of CNS metastases with survival is less clear. Generally, brain involvement is linked to poor prognosis. However, some studies show that ICIs substantially improve OS in NSCLC, melanoma, and triple-negative breast cancer patients with brain metastases, though this pattern was not observed in renal cancer (Du et al., 2021). In our study, CNS metastases were rare and only occurred in normal-weight patients. No CNS metastases were observed among the obese patients, who had the best survival outcomes.

Tumor histology also emerged as a prognostic factor for PFS and OS. In our cohort, adenocarcinoma was more frequent in obese patients. No statistically significant difference between squamous cell carcinoma and adenocarcinoma was observed, suggesting that the better immunotherapy response in this subgroup may be related to higher tumor mutational burden (Zheng et al., 2022; Quintanilha et al., 2023).

It should be noted that our study has limitations. A larger patient cohort is needed for BMI analysis. The study population was heterogeneous, including different cancer types, and molecular-genetic tumor profiling data were unavailable.

Conclusions

Better progression-free survival (PFS) and overall survival (OS) were observed in patients receiving immune checkpoint inhibitor (ICI) therapy with a BMI >30. When selecting candidates for immunotherapy, patient BMI, ECOG performance status, PD-L1 expression, tumor histology, and the presence of CNS metastases should be considered.

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The authors declare no conflict of interest.

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