Equity in Efficacy: Patient-Intrinsic Disparities in Non-Small Cell Lung Cancer Immunotherapy

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Abstract

While immune checkpoint inhibitors (ICIs) have transformed non-small cell lung cancer (NSCLC) treatment, patient responses can vary widely. This suggests that patient-intrinsic factors may play a critical role in determining therapeutic outcomes. This review will examine how patient-intrinsic factors, such as obesity and biological sex, can influence the effectiveness of ICI efficacy in NSCLC. Data on NSCLC patient characteristics, treatment type, and outcomes were extracted and synthesised by categorizing the data into themes of obesity or biological sex. Findings indicate that obesity may enhance ICI efficacy in patients with preserved skeletal muscle mass, demonstrating the “obesity paradox.” At the same time, biological sex influences tumour characteristics and drug metabolism through sex-specific hormones, contributing to differences in treatment response. These insights suggest that both obesity and biological sex are critical determinants of ICI outcomes. Incorporating these factors into clinical trial design and personalised treatment strategies may improve patient survival, reduce treatment disparities, and lead to equitable healthcare.

Introduction

Lung cancer remains the leading cause of cancer-related deaths worldwide, accounting for nearly 1.8 million deaths in 2022 (Zhou, 2024). There are two main types of lung cancer, non-small cell lung cancer (NSCLC) and small-cell lung cancer, with NSCLC accounting for approximately 85% of all cases (Figure 1). As such, NSCLC represents a major focus for treatment innovation (Tee-Melegrito, 2021). However, despite advances in early detection and therapy, survival rates for NSCLC remain low, at around 20%, particularly at advanced stages (Guo, 2021; American Cancer Society, 2025).

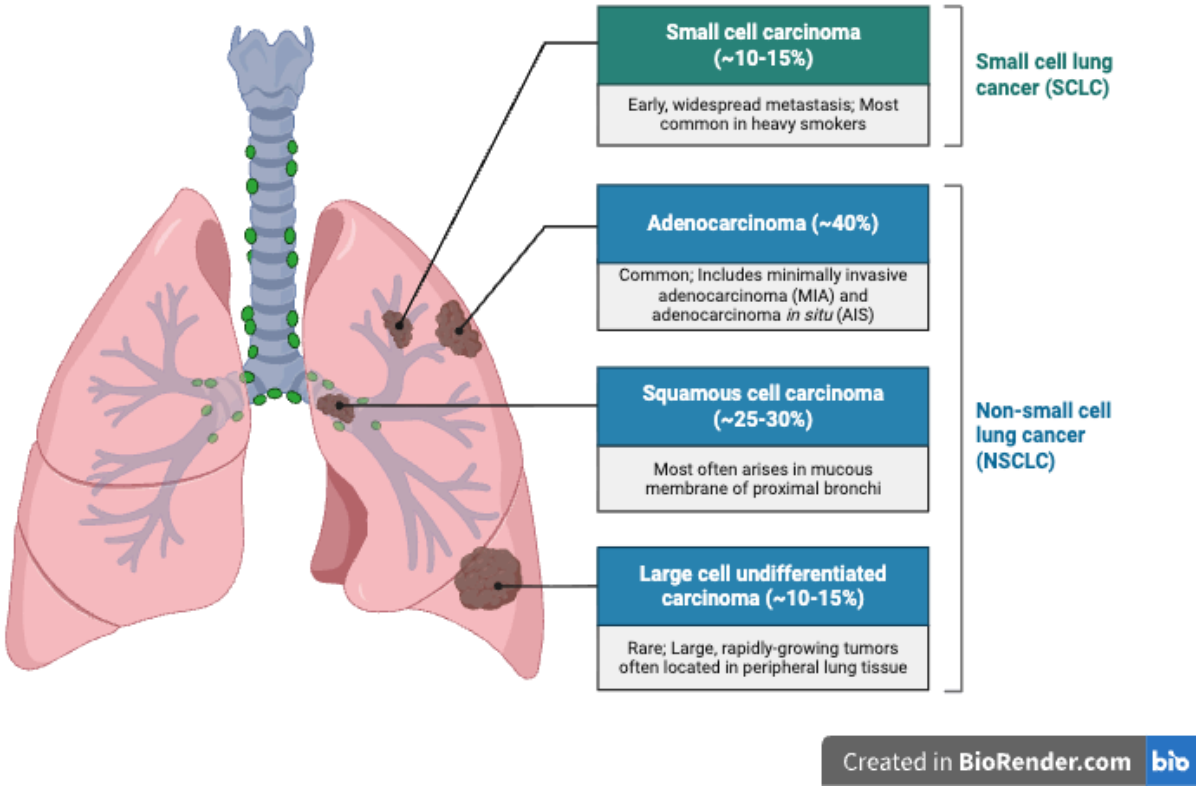

Figure 1. Types of lung cancer. (BioRender, 2025)

In recent years, immunotherapies such as immune checkpoint inhibitors (ICIs) have improved the management of NSCLC. ICIs work to reactivate T-cell anti-tumour activity by blocking inhibitory immune pathways such as programmed death-1 (PD-1/PD-L1) and cytotoxic T-lymphocyte antigen-4 (CTLA-4). T-cells are a group of lymphocytes that play a vital role in active immunity. However, responses to ICIs vary between patients, with only specific patient groups, such as those with greater tumor mutational burden or immune activity, experiencing benefit. This highlights a massive gap in understanding the factors that impact immunotherapeutic efficacy (Lai, 2021).

Emerging evidence suggests that patient-intrinsic factors, such as biological sex and obesity, may significantly influence ICI efficacy (Xu, 2024). Biological sex influences tumor biology, immune regulation, and drug metabolism, while obesity is more strongly associated with inflammation, as excess adipose tissue promotes chronic low-grade inflammatory signalling through cytokine release, all of which alter treatment outcomes (Vick, 2024). Despite these insights, a major challenge remains: historical bias and ongoing underrepresentation in clinical trials (Arias, 2022). Systemic and social factors play an important role in shaping cancer treatment outcomes. For example, men receive earlier diagnoses, which generally prevents

more extreme mortality rates. Patients with obesity frequently experience weight-related stigma in healthcare, which contributes to delayed diagnosis, undertreatment, and reduced access to enrollment in clinical trials. Women also remain underrepresented in oncology research, limiting the generalisability of findings and obscuring sex-specific differences in treatment response (Bae, 2023). These disparities underscore the importance of evaluating immunotherapy through an equity and patient diversity lens.

This review synthesises current literature on how biological sex and obesity, both independently and in overlapping patient populations, affect immune checkpoint inhibitor efficacy in NSCLC. By examining the underlying mechanisms of these characteristics, along with clinical outcome data, the goal is to enhance our understanding of these patient-intrinsic factors to create more personalized and equitable immunotherapy strategies in lung cancer.

Methods

Search and Inclusion Criteria

A systematic literature search was conducted using PubMed, Google Scholar, and ResearchGate to identify primary research articles published between 2010 and 2025 to ensure that the data collected were recent. Search query keywords included: “obesity”, “body mass index”, “NSCLC”, “non-small cell lung cancer”, “immune checkpoint inhibitors”, “immunotherapy”, and “biological sex”.

Studies published between 2010 and 2025 were included if they met the following criteria:

1. Focused on treating NSCLC with immune checkpoint inhibitors
2. Investigated the role of obesity/BMI/body composition in treatment outcomes
3. Examined biological sex differences in NSCLC incidence or ICI efficacy

Data Extraction and Synthesis

From each selected study, the following information was extracted:

1. Author(s) and year of publication
2. Study sample size
3. Patient characteristics such as age, sex, BMI, and muscle mass.
4. Treatment type
5. Outcomes measured
6. Key findings related to obesity or biological sex

The extracted data were synthesised by grouping studies by key themes:

1. Effects of obesity on ICI efficacy in NSCLC
2. Influence of biological sex on NSCLC incidence and ICI efficacy
3. Interaction between obesity, muscle mass, and sex-specific treatment outcomes

The quality of included studies was evaluated based on:

1. Sample size
2. Characteristics of the sample size
3. Reporting of patient characteristics (BMI and sex)

Beyond BMI: The Obesity Paradox and NSCLC Immunotherapeutic Efficacy

Obesity, a chronic and increasingly prevalent global health condition, has complex effects on cancer biology and treatment outcomes (Pati, 2023). Traditionally, obesity has been considered a negative risk factor in oncology, associated with higher risks of cancer incidence, recurrence, and mortality. It is commonly defined by Body Mass Index (BMI), with the World Health Organisation (WHO) defining obesity as a BMI ≥30 kg/m² in Western populations and a BMI ≥25 kg/m² in Asia-Pacific cohorts due to differences in body composition (Georgakopoulou, 2024). However, BMI is not a perfect measure as it does not account for visceral (fat under the skin) versus subcutaneous (fat under the muscle) fat distribution or quality (strength per unit of mass) of skeletal muscle (American Medical Association, 2023). As a result, individuals may be classified as obese without considering metabolic differences, which has implications for research and treatment.

Epidemiological evidence often links obesity with an increased risk of cancer incidence and worse outcomes across cancers, including lung cancer (Georgakopoulou, 2024). In a recent 2024 review, researchers emphasised that obesity is associated with higher cancer-related mortality rates, largely due to chronic low-grade inflammation (Georgakopoulou, 2024). Chronic inflammation is a well-established indicator of cancer, as persistent inflammatory signalling can promote DNA damage, support tumour initiation, and enhance cancer cell survival and proliferation (Hanahan & Weinberg, 2011).

Similarly, analyses of NSCLC patient cohorts have found that obese patients are often diagnosed at later stages of disease and face higher risks of recurrence after treatment. These findings support the traditional view of obesity as a negative prognostic factor in oncology. However, recent data challenge this paradigm, showing that in the context of immunotherapy, obesity may in fact improve survival in certain patients (Farag et al., 2021). This dichotomy between obesity as both a risk factor for cancer development and, paradoxically, a protective factor in immunotherapy response showcases its complexity in the role of determining NSCLC outcomes.

The obesity paradox is one of the most intriguing observations in this field. This phenomenon explores the dual role of obesity in oncology, specifically NSCLC, wherein obese patients who were treated with ICIs experienced improved survival rates compared to non-obese patients. A 2024 study conducted by Yasutaka Ihara et al. found that obesity was associated with longer overall (20.7 vs 11.3 months (Nie, Run-Cong, 2021)) survival among those receiving ICIs. Similarly, a large Korean study conducted with over 7,000 NSCLC patients who underwent curative surgical treatment reported that obese patients with preserved skeletal muscle mass (simply having enough healthy muscle mass tissue in the body) had a 21% lower risk of mortality and 13% lower risk of recurrence or death compared to non-obese patients (Ihara,

2024). However, these advantages are not found in patients with low muscle mass, showing that muscle quality is a key factor in the obesity paradox (Caan, 2018).

The mechanisms underlying the obesity paradox have not yet been fully explored, exposing a gap in scientific research. Obesity is characterised by chronic low-grade inflammation driven by adipose (fat) tissue secretion of small signalling molecules known as cytokines (Lee, 2025). While long-term inflammation typically promotes cancer progression, for immunotherapy, it might help prime or "prepare" the immune system for a more effective ICI response. Additionally, adipose tissue also secretes leptin, a hormone that regulates appetite but also activates effector T-cells. In NSCLC, leptin has been suggested to increase T-cell division and strengthen immune responses, which may contribute to improved outcomes for obese NSCLC patients. Patients with higher muscle mass may tolerate treatment better and sustain longer immune responses, which could explain why people with sarcopenic obesity (Khanna, 2022), low muscle mass but excess body weight, have higher death rates while on ICIs (Figure 2).

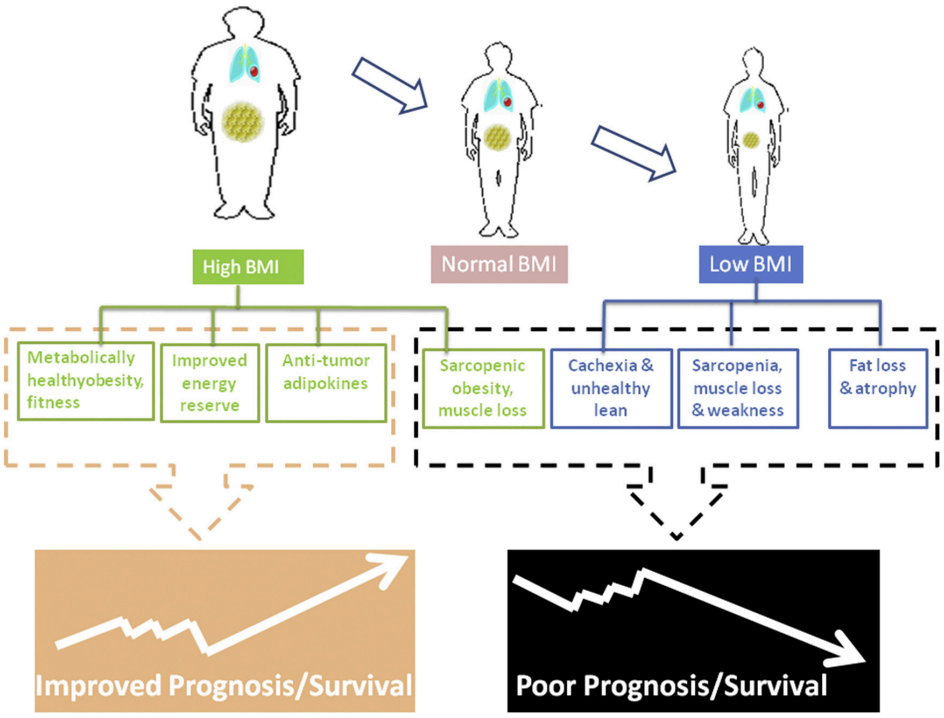

Figure 2. Obesity paradox in lung cancer prognosis: Evolving biological insights and clinical implications. (Zhang, 2017)

Societal Implications

Beyond the biological mechanisms, obesity's role in cancer has both social and systemic implications. Patients with obesity often encounter stigmas attached to their weight in healthcare settings, resulting in delayed diagnoses, undertreatment, and assumptions about their

compliance (Ryan, 2023). Importantly, clinical trials for cancer therapies often exclude obese patients, which narrows the generalizability of the findings. This is due to a variety of factors, including restrictive eligibility criteria, comorbid conditions, and social determinants of health such as limited access to specialised care (Abdullah, 2025). Additionally, reliance on BMI as a universal indicator of obesity oversimplifies it, as this ignores factors such as muscle mass and fat distribution that have proven to critically alter cancer therapy outcomes (Shachar & Williams, 2017). This demonstrates how scientific oversights can reinforce inequalities in the real world, aligning obesity with not only biology but also with social determinants of health.

Sex-Specific Biology: Hormonal Impact on NSCLC Immunotherapy

Biological sex significantly influences both the incidence of NSCLC and the outcomes of immunotherapy (Liang, 2022). Epidemiological studies consistently show that adenocarcinoma is more common in women, whereas squamous cell carcinoma is more prevalent in men (Barrera-Rodríguez, 2012). These patterns cannot be fully explained by smoking behaviors alone, suggesting that underlying biological factors contribute to sex-specific vulnerabilities in lung cancer development (Fuentes, 2021).

A central element in this disparity is the role of sex hormones, such as estrogen and progesterone. Estrogen regulates multiple cellular and immune processes, such as cell proliferation, apoptosis, inflammatory signalling, and immune cell activation (Fuentes, 2021). In lung cancer, this translates to stimulation of tumor cell proliferation, interference with DNA repair, and cross-talk with estrogen receptors such as epidermal growth factor (EGFR) (Fuentes, 2021). EGFR is a transmembrane receptor that receives growth signals and activates intracellular pathways to prompt cellular growth, division, or survival (Ramoni, 2025).

Beyond tumor biology, aberrant expression of estrogen receptors has been identified in lung cancer cells, further linking hormonal signaling to tumour progression. On the other hand, androgens, hormones that assist in controlling the development of male-associated traits, and androgen receptors are involved in shaping tumor-associated immune responses, influencing macrophage (cells that digest pathogens) activity and tumor growth (Fuentes, 2021).

Hormones also have a powerful influence on immune cell function, which directly affects responsiveness to ICIs. A 2022 study in NSCLC patients found that serum soluble PD-1 (sPD-1, a circulating form of the immune checkpoint inhibitor) levels were higher in women than in men, and membrane-bound PD-1 expression on CD4+ helper T cells was also elevated in female patients (Gu, 2022). This would indicate greater levels of T-cell exhaustion in females, limiting effector functions such as the release of cytokines. These findings suggest that sex-specific differences exist in regulating immune checkpoints. Furthermore, testosterone was found to downregulate PD-1 expression on T-cells (Gu, 2022). This could reduce the effect of PD-1 blockade by limiting the amount of antigen present on cells (Gu, 2022). These insights from

Yong Gu et al. indicate that hormonal regulation of immune checkpoints could be a potential explanation for the differential clinical outcomes between men and women with NSCLC.

Additionally, sex-specific drug metabolism plays a significant role. Biological men and women handle medications differently, as their bodies vary in fat distribution, how the liver breaks down drugs, and how hormones affect these processes (Canzian, 2025). For example, biological women generally exhibit higher drug plasma concentrations at equal doses due to the differences in fat distribution and lower cytochrome P450 enzyme expression (Fuentes, 2021). These differences in how drugs are systemically processed can affect not only how well the treatment works but also the severity of the side effects. In fact, premenopausal women appear to be at a higher risk of experiencing immune-related complications when receiving ICIs.

Societal Implications

The findings of this review highlight the historical and ongoing underrepresentation of women in NSCLC clinical trials. This imbalance stems from a long history of excluding women from clinical research due to concerns about hormonal variation or not wanting to impact a potential pregnancy, practices that have left modern medicine with large gaps in data. Underrepresentation has direct consequences in today's world: treatments are often optimized based on predominantly male data, meaning that the applications may not accurately reflect responses in women (Bae, 2023). In the context of ICIs, this raises concern because women have distinct immune activation patterns, different tumour biology, and therefore unique risk factors. When clinical trials fail to include women, the resulting data risks being less effective or even dangerous when applied broadly. Improving representation is therefore not just a scientific requirement but a matter of ethical and equitable cancer care.

Across NSCLC immunotherapy trials, women make up less than 40% of the participants (Balch, 2024). This underrepresentation presents limitations to the generalizability and applicability of the data collected. For example, a 2024 study conducted by Sara Frida Cohen et al. suggested that biological women respond better to chemo-immunotherapy combinations, whereas biological men respond better to ICI immunotherapy. However, the caveat to this is that, given the uneven participant distribution, this data may not be as applicable. Concurrently, women with lung cancer face systemic barriers to making a timely diagnosis. With cancer, a disease where time is of the essence, delays in prognosis can make a vast difference. These barriers include but are not limited to: physician bias, restrictive screening criteria, and psychological burdens (Florez, 2025).

In conclusion, the evidence shows that sex hormones, their effects on immune cells, sex-specific differences in drug metabolism, as further seen in Figure 3, and the misrepresentation of women all shape how NSCLC patients respond to ICIs. Failure to account for these factors risks reinforcing treatment disparities and designing therapies that optimise

outcomes for only a select group of the population. Addressing these gaps in available options requires integrating sex-based analysis in both trial design and prescribing treatments. In short, biological sex matters in NSCLC treatment. Hormones, immune differences, and drug metabolism all shape how patients respond to treatment. The lack of female representation in trials only makes these disparities worse. Therefore, by highlighting these differences and mechanisms, this review directly addresses the research question by showing that biological sex is a critical determinant of ICI efficacy in NSCLC, and one that must be considered in both clinical practice and future research.

Discussion

The goal of this review was to explore overlooked patient-intrinsic factors that may influence therapeutic outcome. The literature indicates that both biological sex and obesity significantly influence the efficacy of ICIs in NSCLC, though the underlying mechanisms remain complicated.

Obesity introduces an additional layer of complexity when considering clinical trial enrollment and design. The “obesity paradox” describes the observation that overweight and moderately obese patients sometimes exhibit improved ICI responses compared to non-obese patients (Hahn, 2023). This paradox may be due to low-grade inflammation, which keeps the immune system alert by increasing pro-inflammatory signals and PD-1 expression on the T-cells, making them more responsive to ICIs (Georgakopoulou, 2024). However, the benefit appears contingent on preserved skeletal muscle mass, as sarcopenic obesity correlates with poorer outcomes and diminished drug tolerance (Golban, 2025).

Furthermore, both of these factors –sex and obesity– can synergize impact treatment outcomes (Figure 3). For instance, biological men and women differ in both fat distribution and metabolic responses; men typically accumulate more visceral fat, which activates inflammation, while women accumulate more subcutaneous fat, which is less metabolically active (Ramoni, D, 2025). These differences may contribute to why studies have found the survival benefit of obesity during ICI treatment is more prevalent in men than women (Lee, 2025). Since sex hormones regulate both fat deposition and immune function, the impact of obesity on immunotherapy is intertwined with biological sex. This intersection re-emphasises the need to account for patient intrinsic factors to design more equitable and effective cancer care.

The intersection between biological sex and obesity is an emerging field. Sex-specific fat distribution, hormonal regulation, and metabolic differences may modulate ICI outcomes in various ways (Figure 3). For example, postmenopausal women with central adiposity may exhibit immune activation patterns that are similar to those of obese men, potentially reducing differences between the two biological sexes (Lee, 2023). Several studies suggest that women generally exhibit stronger innate and adaptive immune responses than men, potentially enhancing responsiveness to ICIs. However, this also exposes women to greater

immune-related adverse events, creating a clinical dilemma (Conforti, 2021). Conversely, men may benefit from a higher tumor mutational burden and distinct PD-L1 expression profiles, contributing to different treatment outcomes across the sexes (Rodriguez-Lara, 2023).

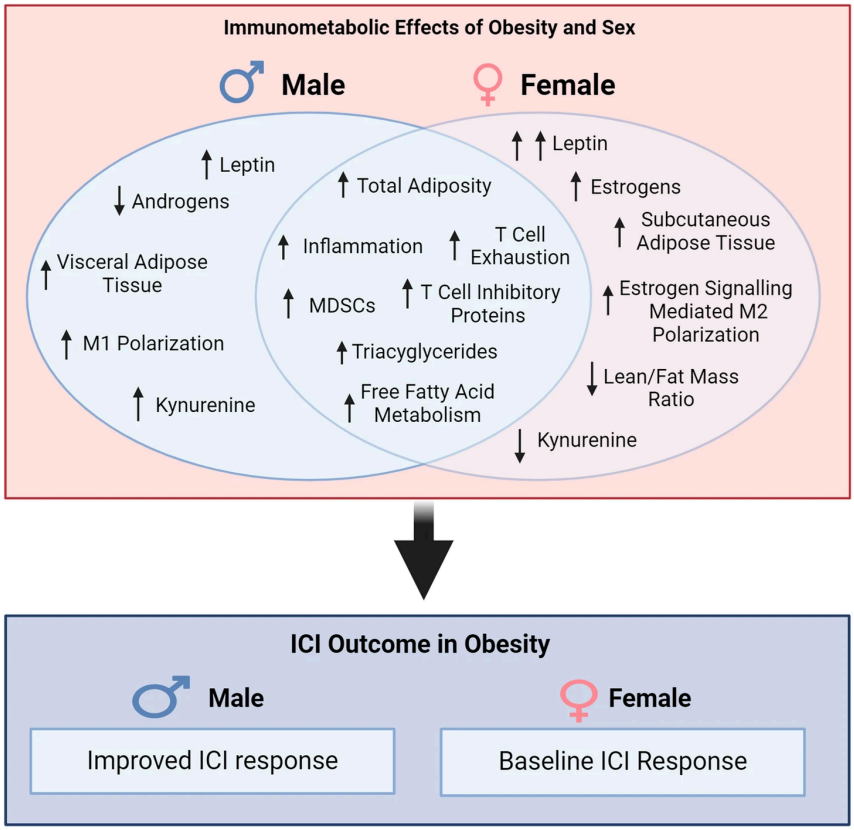

Figure 3. Immunometabolic effects of obesity and sex. (Vick, 2024)

These findings carry important implications for health equity and the ethics of medical research. If biological sex and body composition meaningfully alter ICI efficacy, then failing to measure, report, or control for these variables creates evidence that benefits some groups of people more than others. This reinforces inequalities in treatment access, clinical expectations, and survival outcomes. Ethically, this raises concerns about justice and fairness in clinical research, as marginalized groups, particularly women with obesity, are systematically overlooked. Ensuring that research accurately reflects patient diversity– particularly in groups where the disease is most prevalent– is therefore not just a scientific necessity but a matter of responsible and equitable medical practice.

Together, these nuances illustrate that biological sex and body composition do not operate independently but instead shape immunotherapy outcomes through overlapping biological pathways. Recognizing these interactions is essential for understanding who benefits from ICIs

and whose needs may be overlooked, providing a necessary foundation for examining the broader clinical and societal implications of these findings.

Given these findings, current studies on immunotherapeutic efficacy face several limitations. A lot of existing analysis is retrospective, relying on previously collected medical records and historic patient datasets rather than data collected specifically for the study. Because these records and datasets weren't designed to answer today's research questions, they can often lack key information and make it harder to detect the impacts of patient-intrinsic patterns (Mullins, 2023). Many clinical trials lack sufficient representation of women or do not categorize findings by sex or obesity category. Additionally, obesity is frequently measured by BMI, a system that does not account for fat distribution or skeletal muscle mass.

These limitations are not unique to non-small cell lung cancer but reflect a broader pattern across cancer research. Similar reliance on retrospective analyses, inadequate categorisation by sex, and oversimplified measures of obesity have been observed in studies of melanoma, renal cell carcinoma, and colorectal cancer, particularly in the context of immunotherapy. As immune checkpoint inhibitors are increasingly approved across multiple tumour types, failing to address these gaps risks propagating the same biases and inequities throughout cancer care. Addressing patient-intrinsic factors such as biological sex and body composition should therefore be prioritised across cancer research fields to ensure that emerging therapies are effective, safe, and equitable for diverse patient populations.

Addressing these gaps requires coordinated action across clinical practice, research institutions, pharmaceutical companies, and policymakers. Future trials should implement mandatory sex-based and body composition-based reporting, using other tools like CT-derived skeletal muscle index, waist-to-hip ratio, or visceral fat area instead of BMI alone, as recommended in recent oncology body composition guidelines (Pekar, 2025). Governments and policymakers could establish inclusion quotas to ensure adequate representation of niche demographics, specifically biological women and obese patients, reinforcing more equitable cancer care. Additionally, pharmaceutical companies should prioritize designing protocols that organize datasets by muscle mass, given the findings that this significantly influences immunotherapy tolerance and therefore influences mortality rates. Ultimately, by embedding sex-specific data and muscle mass indicators, clinical research could yield more accurate predictions of ICI efficacy, reduce treatment disparities, and support the development of more personalized and efficient cancer therapies. Diversity in clinical trial enrollment is not optional but is foundational to producing valid, relevant, and fruitful data, ensuring that advances in immunotherapy benefit all patients, not just a subset.

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