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Prediction Model for PD-1 Inhibitor -Related irAEs: From Mechanisms to Clinical Applications

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Abstract. Immune checkpoint inhibitors (ICIs) can substantially improve the treatment outcome of patients with diverse cancers, but they may also cause immune-related adverse events (irAEs). The mechanisms of these events mainly include T-cell overactivation, cytokine storms, and disruption of immune tolerance. At present, there is still a lack of an effective early warning and risk classification method. Consequently, establishing a reliable irAEs prediction model has become an important requirement for the precise management of immunotherapy. Previous studies mostly relied on single clinical indicators or serum factor testing, and they were difficult to comprehensively evaluate individual differences in immune responses. This paper systematically reviews the existing PD-1 inhibitor-related irAE prediction models, integrating genomic, immunome, clinical and microbiome features. It reviews the performance, pointing out the limitations, and highlights representative achievements, including the multi-omics nomogram models. These findings indicate that multi-variable integration will greatly enhance the model generalization and clinical understandability. This review provides comprehensive insights, detailed discussion and references for the clinical translation and future improvement of irAE prediction models.

Keywords: PD-1 inhibitors, Immune-related adverse events (irAEs), Predictive models, Biomarkers, Clinical translation.

1. Introduction

Programmed death protein-1 (PD-1) inhibitors have become a key treatment for tumors since they can block immunosuppressive signals and restore the anti-tumor activity of T cells. However, while it disrupts tumor immune tolerance, it often leads to immune-related adverse reactions (iAES), which can affect multiple organs, including the skin, gut, endocrine glands, lungs, and heart. In severe cases, it can be life-threatening, and its occurrence shows significant individual differences and it is hard to predict [1]. At present, most irAEs in clinical practice are managed only after they appear. This not only may affect the anti-tumor effects, but also, may cause immune side effects. Therefore, if the risk of irAEs can be predicted before treatment, individualized plans can be better formulated, which is important for people's safety. In recent years, there has been growing interest among researchers in developing predictive models for early warning of immune-related adverse

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events (irAEs), with these models leveraging readily available clinical features and laboratory test results. Clinical studies have demonstrated that predictive tools incorporating inflammatory markers, blood cell ratio parameters, and patient baseline characteristics exhibit promising predictive efficacy across multiple tumor types—including advanced gastric cancer, esophageal squamous cell carcinoma (ESCC), and non-small cell lung cancer (NSCLC) [1-3]. As a notable example, the prediction model for ESCC developed by Wu Shanshan et al. achieved an area under the curve (AUC) of 0.831 [3]. Such models offer valuable practical support for enhancing the safety monitoring of immunotherapy regimens. The present study aims to synthesize the current state of research regarding the immune mechanisms underlying PD-1 inhibitor-related irAEs and the corresponding predictive models. It will first elaborate on the core mechanisms driving irAE occurrence, followed by a systematic review of diverse predictive models constructed using clinical features, laboratory biomarkers, and multi-omics data.

Additionally, the study will compare these models in terms of their construction methodologies and predictive performance, with a specific focus on AUC values as the key evaluation metric. Finally, this paper will discuss the limitations of current models in terms of sample size and generalization ability, and look forward to future research directions, including multi-omics integration and artificial intelligence. The goal is to provide theoretical guidance and practical ideas for the precise prevention, control and clinical translation of irAEs.

2. Immunological mechanisms and risk factors of irAEs

2.1. Immunological mechanisms

PD-1 and its ligand PH-L1 constitute a critical immune checkpoint pathway, primarily regulating negative feedback following T cell activation to prevent excessive immune responses. When the PD-1/PD-L1 pathway is blocked by inhibitors, T cell anti-tumor function is restored, but this may also disrupt immune homeostasis and induce irAEs. At the mechanistic level, T cell overactivation is the core component. Studies indicate that PD-1 inhibitors promote sustained proliferation and enhanced cytotoxicity of effector CD8+T cells and Th1-type CD4+ T cells, leading them to attack normal tissue antigens that cross-react with tumor antigens [4]. Additionally, cytokine storms are another important cause of irAEs. The proinflammatory factors, such as lFN-γ, IL-6, and TNF-α, trigger systemic inflammatory responses and multi-organ damage. Also, reduced regulatory T cell (Treg), B-cell activation, increased production of autoantibodies, and changes in gut bacteria may amplify irAEs development. Overall, these immune mechanisms show that irAEs can affect the human body and vary between individuals.

2.2. Classification of risk factors

The development of irAEs caused by PD-1inhibitors is not only due to a single factor. It happens because of many combined different factors, including the patient's clinical characteristics, laboratory indicators, and molecular omics features. Based on current research, the risk factors for irAEs can be divided into three categories: clinical characteristics, laboratory biomarkers, and omics features.

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2.2.1. Host clinical characteristics

Many previous studies consistently demonstrate that immune checkpoint inhibitor(lCl)-related adverse events exhibit distinct clinical characteristics and identifiable risk factors. First, gender differences have been repeatedly observed across multiple studies in male patients, showing a higher risk of developing irAEs, which suggests that gender should be a possible variable considered in risk assessment [5, 6]. Second, age is another significant risk factor. Multiple data indicate that elderly patients experience irAEs more frequently, potentially related to age-related changes in immune regulatory function [5, 7]. Patients with a history of autoimmune diseases usually have a higher risk of immune-mediated adverse events (irAE). This indicates that the pre-existing autoimmune state may increase the side effects caused by immune activation. Therefore, in clinical practice, such patients require closer follow-up and treatment tailored to their individual conditions in order to strike a balance between effectiveness and risk [5, 6]. Furthermore, studies have shown that people with a high body mass index (BMI) are more likely to experience immune-mediated skin side effects (cirAEs). It indicates that both metabolic and immune factors are involved in the formation of these reactions. Therefore, when creating a predictive model, BMI should be taken into consideration [5]. Meanwhile, the data indicate that many patients who have experienced immune-mediated side effects have a history of smoking. This further indicates that the environment and lifestyle can influence the state of organs by altering the response patterns of the immune system (Table 1) [5]. In conclusion, the above examples support the establishment of a comprehensive risk assessment model, including factors such as gender, age, autoimmune history, body mass index, and smoking history. This model can help us manage individual monitoring, early intervention and risk communication more effectively, thereby ensuring the success of treatment while minimizing the associated risks of side effects [5-7].

Table 1. Clinical characteristics

Clinical Characteristics/Indicators	Research Findings	Source
Gender	Higher risk in men	[5,6]
Age	Predominantly elderly patients	[5,7]
Autoimmune Conditions	Significantly increased risk of irAEs	[5-7]
BMI	Elevated BMI associated with increased cirAE risk	[5]
Smoking History	Most patients with immune hepatitis have a history of smoking	[5]

2.2.2. Laboratory biomarker risk factors

Blood biomarkers in peripheral blood are useful in predicting the occurrence, severity and prognosis of PD-1 inhibitor-related irAEs. As shown in Table 2, these markers can be divided into three categories. Among blood routine indicators, the systemic immune inflammation index (SII) is a strong tool for predicting severe immune pneumonia (CIP). Changes in SII, such as the decrease in absolute lymphocyte count (ALC) and the increase in platelet-lymphocyte ratio (PLR), can help identify high-risk patients [8]. Inflammation and nutritional indicators show the body's inflammatory and nutritional state. A decrease in albumin (ALB) levels is an independent risk factor for poor outcomes in CIP patients, while an increase in lactate dehydrogenase (LDH) indicates damage to lung tissue. Meanwhile, as an immunomodulatory factor, the elevated level of interleukin-10 (IL-10) is associated with an increased risk of severe CIP [8]. Most importantly, some cytokines are not only indicators but also therapeutic targets. The level of interleukin-6 (IL-6) is a key factor in predicting

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severe CIP and its poor prognosis. Tocilizumab targeting this pathway has been proven to effectively manage hormone-refractory irAEs, achieving a leap from prediction to treatment [8,9]. Similarly, therapeutic strategies targeting TNF-α and the intestinal-specific target α4β7 integrin also provide a new direction for the management of refractory irAEs [9]. These findings collectively highlight the core role of laboratory biomarkers in the precise management of irAES.

Table 2. Laboratory prediction and prognostic biomarkers of PD-1 inhibitor-related irAEs

Biomarker type	Specific indicators	Main clinical significance	sources
Blood routine derivative indicator	Systemic immune inflammation index (SII)	Predicts the risk of severe immune (CIP) pneumonia. (OR=3.12).	[8]
	Absolute lymphocyte count (ALC)	A dynamic decrease at a low level is associated with an increased risk of severe CIP. (OR=0.19).	[8]
	Platelet-lymphocyte ratio (PLR)	Dynamic elevation is associated with the risk of ICU admission in patients with CIP. (AUC=0.701).	[8]
Inflammation and nutritional indicators	albumin (ALB)	A significant decrease is an independent risk factor for poor prognosis in CIP patients. (HR=0.28).	[8]
	Lactate dehydrogenase (LDH)	Elevated LDH indicates lung tissue damage and is associated with a reduced remission rate of CIP.	[8]
Cytokine	Interleukin-10(IL-10)	Elevated IL-10 is associated with an increased risk of severe CIP (OR=2.62).	[8]
	interleukin-6(IL-6)	An independent predictor (OR=5.23) of severe CIP and an indicator of poor prognosis (HR=0.17); its receptor inhibitor is effective for hormone-refractory irAEs.	[8, 9]
	TNF-α/α4β7 integrins	Anti-TNF-α preparations and vedolizumab are respectively effective in treating refractory colitis and reducing its recurrence risk, indicating their potential as predictive and therapeutic targets.	[9]

2.2.3. Omics characteristic risk factors

At the genomic level, HLA genes are located on the short arm of chromosome 6and encode the human leukocyte antigen system. They are the core regulatory factors of immune responses, and the consequences of their variations involve multi-system disease mechanisms such as autoimmune diseases. Genetic variations of the BRCA1/BRCA3 genes are significantly associated with the risk of malignant tumors such as breast cancer and ovarian cancer. In terms of transcriptomic characteristics. The single-nucleotide polymorphism (SNP) at the rs1800872 locus of the IL10 gene plays a key role in autoimmune diseases. Frameshift mutations in the BRCA1 protein significantly increase the genetic risk of breast and ovarian cancer by disrupting the DNA damage repair mechanism. Abnormal expression levels of TNF-α protein are associated with chronic inflammatory responses and the pathological process of metabolic syndrome. From the perspective of metabolomics, the decreased activity of the UGT1A1 enzyme leads to bilirubin metabolic disorders, which are directly related to hereditary liver diseases such as Gilbert syndrome. Abnormal lipid metabolism of APOE protein is an important risk factor for Alzheimer's disease and cardiovascular

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diseases, while the abnormal glycolytic pathway of lactate dehydrogenase has been confirmed to be involved in the energy metabolism reprogramming of tumor cells (Table 3).

Table 3. Multi-omics indicators

Characteristic type C Specific gene	Specific genes/markers	variation type	origin
Genomic variation	HLA genes	—	[10]
Genomic variation	BRCA1/BRCA3genes	—	[11]
Transcriptomic characteristics	The rs1800872 locus of the IL10 gene	SNP	[12]
Proteomic characteristics	TP53 protein	missense mutation	[13]
Proteomic characteristics	BRCA1protein	Frameshift mutation	[14]
Proteomic characteristics	TNF-αprotein	Abnormal expression level	[15]
Metabolomics characteristics	UGT1A1Enzyme	Abnormal expression level	[16]
Metabolomics characteristics	APOE protein	Abnormal lipid metabolism	[17]
Metabolomics characteristics	APOE protein	abnormal lipid metabolism	[17]
Metabolomics characteristics	LDH	Abnormal glycolytic pathways	[18]

3. Progress of predictive models

With the wide application of ICIs in the treatment of various malignant tumors, while significantly improving patient survival, it has also brought about the important challenge of irAEs [19-21]. To achieve early risk identification and precise intervention, researchers have carried out a large number of construction and verification works of irAEs prediction models in recent years, making remarkable progress.

In multi-cancer studies, Jing and colleagues used a bivariate linear regression model to screen out two key genes LCP1 and ADPGK, and constructed a joint prediction model (AUC=0.80). This model demonstrated high stability in an independent validation cohort [22]. Subsequently, Yi Wang and colleagues integrated clinical and multi-omics data to establish a machine learning model for predicting the risk of irAEs. As can be seen from Figure 1, the AUC of the test set reaches 0.81. From this, it can be known that multi-omics integration can help us improve the prediction accuracy of the model [23]. However, although multi-omics models have relatively good predictive effects, their data processing is rather complex. Therefore, more standardization and validation should be implemented in clinical applications to ensure the accuracy of the data and facilitate subsequent data processing.

The team led by Xie Hongmei developed an irAEs risk prediction model of the non-small cell lung cancer (NSCLC) through the application of Logistic regression and a nomogram. The training and validation set AUC were 0.863 and 0.851 respectively, and the results suggest a good performance. The variables of the clinic utility included BMI and blood indicators in the model [1]. In ESCC, the team by Wu Shanshan created a lexogram model with an AUC of 0.831 with the assistance of LASSO and multivariate Logistic regression, and the most important predictors were LMR, ALB, BMI and treatment plan. This model might be useful in determining patients who might get long-lasting clinical benefits (DCB) [3]. Also, Su Hang built a predictive model for PD-1 inhibitor therapy in gastric cancer by Cox regression. The C-index was 0.932 with good accuracy, which could guide treatment that is personalized treatment [2].

Due to their ease of use and low cost, blood and inflammatory indicators are commonly used in the study of irAEs prediction. Based on age, BMI, and SII, Qiu's team created a risk prediction

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model. The standard of the training set of 6 months was 0.76 and the standard of the validation set of 6 months was 0.61. However, the AUC was comparatively lower within 12 months. The training data set and validation data were 0.77 and 0.57 respectively. This indicates that inflammatory indicators have a certain predictive effect on short-term irAEs risk [24]. Yunyi Du and colleagues established a multi-factor model using dynamic blood indicators such as NLR, PLR and AEC. The internal verification showed AUC was 0.783, which could predict severe irAEs [25]. Lu Peiyu and colleagues constructed a specific prediction model for immunotherapy-related renal injury, with a validation set AUC of 0.791, expanding the organ-specific prediction research of irAEs [26].

In the field of radiomics, Zhang Lan's team established a prediction model for pathological complete response (pCR) in patients with locally advanced rectal cancer (LARC) after PD-1/PD-L1 combined with TNT treatment based on MRl image features using LASSO regression. The AUCs of the training set, test set and external validation set were 0.920, 0.885 and 0.875 respectively, indicating that radiomics has great potential in predicting immune efficacy [27]. However, its repeatability under different devices, parameters and image resolutions still needs further confirmation.

Overall, the current research on irAEs risk prediction models shows a trend of moving from a single clinical variable to multi-dimensional integration. Clinical and laboratory indicator models, such as BM, NLR, PLR, LMR, and ALB, are easy to operate and suitable for promotion, while radiomics and multi-omics models can provide higher accuracy and potential mechanism explanatory power [1,3,22,23,25]. However, most studies are still done at a single center with small-sample designs and limited external validity. Future research should be based on large samples and multi-center cohort studies, integrating artificial intelligence and machine learning algorithms to further optimize model performance, providing precise toxicity risk assessment and individualized treatment decision support for immunotherapy patients [4-9, 28-31].

4. Clinical applicability and validation

As can be seen from Figure 1, the models established based on Cox regression and Logistic regression and nomogram methods in different studies have shown high AUC values, which are mostly above 0.75 in both the training set and the validation set, indicating that these models have good discriminative ability in distinguishing between high-risk and low-risk patients. Especially for some nomogram models based on Logistic regression, if the AUC of the training set reaches above 0.85, it indicates that the fitting effect of the model in the modeling stage is ideal. However, from the AUC results of the validation set, it can be seen that the performance of some models has declined to a certain extent, indicating that there may be a certain degree of overfitting problem with the models. Further validation is still needed through larger sample sizes or external multi-center data (Figure 1). At the clinical application level, this type of nomogram predictive model has good interpretability and visualization features, which can visually present the contribution of different clinical variables to irAEs or efficacy prediction, providing references for clinical risk assessment and individualized intervention. However, as most of the current models are derived from single-center studies, there is heterogeneity in sample composition and tumor types. The differences in clinical characteristics and detection standards among different populations may affect the generalization performance of the models. Therefore, future research should attach importance to the external validation of multi-center cohorts and reduce the risk of overfitting through cross-validation or regularization methods, thereby enhancing the reliability and applicability of the model in actual clinical decision-making. The establishment of these predictive models provides new ideas and tools for the early identification of irAEs and their therapeutic effects, and has higher potential for clinical

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transformation. For instance, through a nomogram, the contribution of different clinical variables (such as BMI, laboratory indicators, levels of inflammatory factors, etc.) to risk can be intuitively quantified, which helps doctors conduct individualized risk stratification and dynamic management for patients before treatment, thereby achieving precise monitoring and intervention. Furthermore, the high AUC performance of the model also indicates its potential practical value in assisting clinical decision-making. However, the existing models still have certain limitations. Most studies are single-center retrospective designs with limited sample sizes, and there is significant heterogeneity in patient sources, cancer types, and detection methods, which may affect the robustness and external generalizability of the model. Meanwhile, some models lack independent validation or multi-center external validation, posing a risk of overfitting.

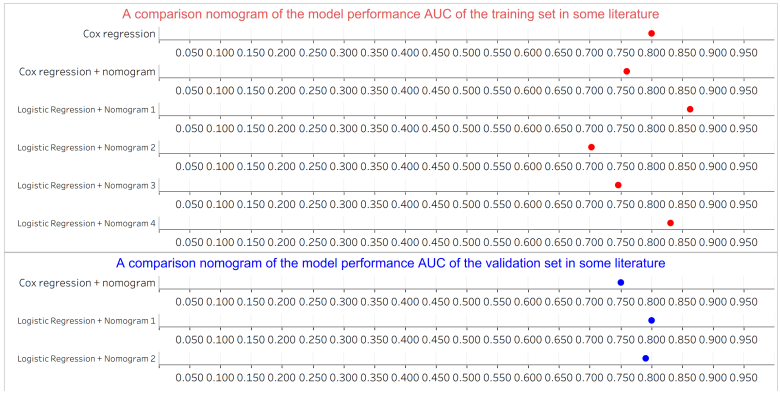

Figure 1. The nomogram compares the performance AUC of some existing models (data from [1-3, 22, 24-27])

5. Conclusions

The wide application of immune checkpoint inhibitors, especially PD-1/PD-L1inhibitors, has ushered in a new era of tumor immunotherapy. However, the emergence of irAEs has also brought safety and management challenges. Its occurrence is influenced by multiple factors such as immune genetic background, tumor microenvironment, cytokines and drug exposure, reflecting the imbalance between immune tolerance and activation. Current research is dedicated to constructing irAEs prediction models, integrating multi-dimensional information from clinical features, laboratory indicators, immunomes, to gut microbiomes, to promote the model's development from univariate to multimodal integration. Traditional statistical models are interpretable, while machine learning and deep learning models perform outstandingly in high-dimensional nonlinear data processing and show potential in multi-omics fusion. However, the existing models have limited sample sizes, insufficient validation, inconsistent variable standards, and poor interpretability. In the future, a multi-center prospective validation system should be established to promote the standardized integration of multi-omics and clinical data. By combining the features of scRNA-seq and radiomics, a multimodal AI model should be constructed. Strengthen interpretability and clinical visualization, achieve dynamic monitoring and real-time risk assessment, and promote the prediction of irAEs from research to clinical practice.

Authors contribution

All the authors contributed equally and their names were listed in alphabetical order.

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