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Research Progress and Safety Evaluation of Immunotherapy for Cancer

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Abstract: As cancer remains a leading cause of death and morbidity worldwide, more effective immunotherapy strategies are urgently needed. Recent advances in immunotherapy, particularly through antibody-drug conjugates (ADCs), therapeutic vaccines, and immune checkpoint inhibitors (ICIs), show promising potential to improve patient outcomes. Still, there is significant debate about the long-term safety and effectiveness of these therapies, which are intended for different patient populations. This article analyzes recent studies of three different immunotherapies, adc, therapeutic vaccines, and ICIs, and makes the point that although these therapies improve survival and quality of life for many patients, there are still inconsistencies in treatment response and safety. The results emphasize the significance of tailored treatment strategies based on tumor biology and unique patient features. This study is significant because it adds to the expanding field of cancer treatment by offering some guidance on how to best use immunotherapy techniques. However, issues such as treatment resistance and individual differences in response to different patients remain unresolved. Future research will focus on this area, particularly in identifying biomarkers for better patient stratification and improved combination therapy approaches.

Keywords: Immunotherapy, antibody-drug conjugates (ADCs), immune checkpoint inhibitors (ICIs), therapeutic vaccines, immunotherapy for prostate cancer

1. Introduction

Ten million deaths from cancer are anticipated in 2020, making it one of the world's major sources of morbidity and mortality [1]. There are drawbacks to conventional therapies including radiation, chemotherapy, and surgery, such as systemic toxicity and poor effectiveness against advanced or metastatic cancer. [2] In recent years, immunotherapy has become an important tool in oncology, use the immune system to identify and eliminate cancerous cells, leading to the development of new therapies such as ICIs, antibody-drug coupling (ADC) therapies, and therapeutic vaccines.

The introduction of ICIs such as pembrolizumab and opdivo has significantly altered the way that bladder cancer, lung cancer, and melanoma are treated [2,3]. Relevant research indicates that within five years, the survival percentage for melanoma patients treated with pembrolizumab can approach 44% [4]. Furthermore, ADC treatment has demonstrated beneficial outcomes as well. For example, patients with HER2-positive breast cancer who receive trastuzumab emtansine have a progression-free survival (PFS) that is superior to that of conventional treatment [5].

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While the efficacy of immunotherapy is encouraging, safety concerns remain. Immune-related adverse events (irAEs) are a major risk for immunotherapy and can lead to colitis, pneumonia, and endocrine diseases. Studies have shown that approximately 30% of patients treated with ICIs develop irae, making it all the more important to conduct a comprehensive evaluation of the safety of these treatments [6]. Early detection and treatment of irAEs is believed to significantly improve the prognosis of patients, and relevant studies have shown that timely intervention of irAEs can reduce the incidence of severe cases by 50% [7].

Research on immunotherapy is currently primarily concerned with striking a balance between safety and efficacy. Specifically, biosignature studies are used to predict treatment response and toxicity to enable more personalized treatment. For example, when there is a higher level of PD-L1 expression on tumor cells, patients generally respond better to ICIs, resulting in improved treatment effectiveness. By measuring the amount of PD-L1 expression in a patient's tumor, doctors can more accurately decide if ICIs are necessary. This approach can help select the most appropriate treatment, improve efficacy and reduce unwanted side effects [8].

This study aims to improve the efficacy and safety of immunotherapy in clinical applications. By examining the balanced relationship between safety and effectiveness, research will optimize treatment protocols and patient management. Focus on the latest advances in antibody drug conjugates (ADCs), therapeutic vaccines, and immune checkpoint inhibitors (ICIs), evaluate current approaches to safety assessment, and explore future research directions to improve the therapeutic index of immunotherapy. Ultimately, research will advance a greater comprehension of immunotherapy's function in cancer treatment and how it affects patient care.

2. ADCs

2.1. Principle

ADC therapy is a therapeutic approach to targeting cancer using ADCs. ADC drugs have three main components: antibody, cytotoxic drug, and linker. The antibody portion can specifically target antigens on the external surface of malignant cells, thereby directing the drug directly into cancer cells. The cytotoxic drug portion is the direct active ingredient of ADC, which is capable of causing cell death by acting upon entry into the cell. The role of the linker is to connect the antibody portion and cytotoxic drug portion and keep the complex stable [9].

ADC drugs are characterized by high targeting and cell specificity. When the ADC drug enters the body, the antibody portion is able to target the cancer cells, allowing the drug to work mostly at the site of the cancer. In this way, compared with traditional chemotherapy, the drugs are focused on the site of action rather than scattered around, making the drug effect more precise and efficient. In addition, it reduces the side effects of toxicity that may harm healthy cells [9].

2.2. Current situation

A variety of ADC drugs have been authorized for application in clinical settings and have shown successful in treating a range of cancers. Trastuzumab emtansine is based on an IgG1 monoclonal antibody and is effective in the treatment of HER2-positive breast cancer. Its toxic drug component, Emtansine (DM1), disrupts microtubule function, leading to cell cycle arrest and apoptosis. A human-specific monoclonal antibody called daratumumab (anti-human CD38) targets the CD38 protein. It works quite well for treating multiple myeloma. Daratumumab impairs MM cell adhesion and results in an increased sensitivity of multiple myeloma to proteasome inhibition. Tissue factor (TF) is the target of the human IgG1 monoclonal antibody tisotumab (anti-human F3 recombinant antibody). Solid tumor research can benefit from the usage of tisotumab. It is effective in treating recurrent or metastatic cervical cancer. In the clinical trial KATHERINE, trastuzumab emtansine was used as an

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adjunct therapy for HER2 early-stage breast cancer. The trial showed disease-free survival (DFS) results for patients receiving Trastuzumab emtansine compared to standard treatment (trastuzumab + chemical), with DFS of 88.0% for trastuzumab emtansine [10]

There are also a number of ADC drugs that show good therapeutic potential and are still in lead trials. Enfortumab vedotin targets Nectin-4 [11]. It is primarily used to treat metastatic uroepithelial cancer (mUC). A bispecific T-cell ligand molecule (BiTE) that targets CD19/CD3 bispecific antibodies is called blinatumomab. It is mostly used to treat acute lymphoblastic leukemia (ALL) that has relapsed or is refractory. Blinatumomab connects T cells and B cells by binding to both CD19 on the surface of B cells and CD3 on the surface of T cells. Cell killing is then achieved by activating T cells and inducing them to attack CD19-expressing leukemia cells. ABBV-181 targets PD-1. It is primarily used in the treatment of a variety of tumors, including melanoma and non-small cell lung cancer (NSCLC). By blocking PD-1 from attaching to its own ligands (PD-L1 and PD-L2), ABBV-181 reverses immunological suppression and increases T-cell activation, which results in an enhanced immune attack against the tumor. In a multicenter clinical trial called TOWER, Blinatumomab was used to treat relapsed or refractory ALL. According to the study's findings, Blinatumomab considerably increased overall survival (OS) when compared to conventional chemotherapy. The median survival for the Blinatumomab group was 7.7 months, while the control group's was 4.0 months, and had a higher complete response rate (CR) of 44% [11].

There are also a number of ADCs that are still being studied. Zynlonta (Loncastuximab tesirine) is used primarily in the treatment of B-cell lymphoma. His target is CD19. A B-cell-specific antigen called CD19 is highly expressed in a range of B-cell cancers. CD37 is the target of the dual-specific ADC medication DuoHexaBody-CD37. The drug enhances T-cell activity and induces cancer cell death by simultaneously binding two CD37 molecules. The drug is still undergoing in vitro studies. If the results are positive, it may be further used in the clinical therapy for individuals with B-cell cancers that are CD37-positive. DuoHexaBody-CD37 is a bi-specific antibody drug whose effectiveness against CD37-positive B-cell tumors has been evaluated in vitro. The study showed that the drug significantly enhanced the activity of T cells by binding two CD37 molecules at the same time, leading to apoptosis of cancer cells. In experiments with CD37-positive B-cell lymphoma cell lines, such as the Ramos cell line, DuoHexaBody-CD37 reduced cell survival by more than 70%, and flow cytometry analysis showed a significant increase in the production of T cell cytokines, such as IFN-γ and TNF-α, demonstrating its ability to effectively activate T cells.

Clinical trials for Zynlonta (Loncastuximab tesirine), a medication used to treat relapsed or refractory B-cell lymphoma, have shown positive outcomes. In the pivotal clinical trial, called LOTIS-2, Zynlonta obtained a complete response rate (CR) of 24% and an overall response rate (ORR) of 48% [12].

2.3. Problems and optimizations of ADCs

ADCs targeted therapies show promising efficacy and unique benefits in cancer treatment, but they also have some defects and side effects. First, target expression on the outer layers of malignant cells may vary from person to person, resulting in ADCs being less effective in some patients. Even, some patients may have an allergic reaction to the antibody portion. In addition, some drug targets may also be expressed in normal cells, causing damage to healthy tissues. cytotoxic drugs in ADCs may also cause side effects such as myelosuppression and neurotoxicity. On the other hand, prolonged drug use may cause tumor cells to become resistant to drugs. Tumor cells may develop resistance to ADCs through multiple mechanisms (e.g., target downregulation, drug efflux, etc.). For example, the effects of trastuzumab emtansine (Kadcyla) on patients with HER2-positive breast cancer revealed that each person's target HER2 expression level differed and relatively low expression of HER2 makes some patients less responsive to the treatment. In the KATHERINE trial, patients with strong

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HER2 positivity had a disease-free survival (DFS) of 88%, while patients with low expression levels were significantly below that level. In addition, some patients also reported allergic reactions to Trastuzumab, further indicating the impact of individual differences on treatment safety. At the same time, tumor cells may develop resistance to ADCs through down-regulated target expression or drug efflux mechanisms, which limits therapeutic effectiveness. These challenges highlight the need for future studies to focus on patient characteristics and resistance mechanisms to optimize the use of ADCs. [10]

To address these problems and shortcomings, future research on ADC development can focus on several areas. First, the selection and validation of targets are crucial. Select a target with high specificity and analyze the target expression level to minimize the effect on normal cells. In addition, optimizing the linker's design to ensure the ADC drug's stability in the blood circulation and the circulation cycle will help to improve the effect. Meanwhile, combining ADC therapy with other immunotherapy or targeted therapy strategies may further enhance the efficacy of ADC. What's more, achieving a personalized treatment regimen tailored to a patient's genomic profile is also important for improving the effectiveness of ADC therapy. By monitoring patients' response to ADC in real time and optimizing side effect management, patients' treatment experience and quality of life can be effectively enhanced.

Overall, although ADCs have shown good development and application in cancer therapy, their defects and side effects still need attention and improvement. Through improvements in target selection, linker optimization, combination therapy and individualized treatment, the safety and efficacy of ADCs will be improved, thus promoting their development in clinical applications.

3. Therapeutical vaccine

3.1. Principle

Therapeutic vaccine is mainly used to treat cancer or chronic diseases. Therapeutic vaccines introduce specific antigens to activate the immune system belongs to some patient, enhancing the immune response to specific pathogens or tumor cells. For instance, therapeutic vaccines for cancer may use tumor-specific antigens to induce the production of T cells that attack tumor cells. Immune vaccines also can destroy immune resistance, and in some cases, the patient's immune system may develop resistance to self-antigens such as tumor antigens. Therapeutic vaccines, for example, can bind to heat shock proteins to break this resistance and activate immune responses [13].

Therapeutic vaccinations aim to do more than just stimulate the immune system in the short term but also to quickly respond and create long-term immune memory when exposed to pathogens again in the future. The formation of such memories is particularly important for chronic viral infections such as HIV and certain types of cancer. The development of therapeutic vaccines is not limited to cancer but also includes research on chronic viral infections (such as HIV, and hepatitis B) and autoimmune diseases (such as multiple sclerosis). Therapeutic vaccines could help develop the condition of patients or delay the development of diseases by stimulating specific immune responses. [13-15]

3.2. Current situation

Therapeutic vaccines are gradually becoming a highly anticipated innovative technology in cancer treatment. Unlike traditional vaccines developed for disease prevention, therapeutic vaccines have the purpose of strengthening the immune system of the patient to identify and combat cancerous cells that are already present. Sipuleucel-T is the first FDA approved therapeutic vaccine specifically designed for castration resistant prostate cancer (mCRPC). Sipuleucel-T works by targeting patient specific antigens, such as prostate acid phosphatase (PAP), which helps stimulate a strong immune

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response. The clinical trial results showed that the median survival of patients who received the vaccine was extended by 4.1 months (from 21.7 months to 25.8 months). In addition, their side effects are usually mild, with most patients only experiencing injection site reactions and fever. This demonstrates a promising progress in the human body's use of its own immune defense to combat cancer [16-18].

3.3. Problems/side-effects/optimizations

Therapeutic vaccinations have the power to alter the way we treat many diseases, which is incredibly exciting. However, there are important issues we need to consider. For one, since these vaccines are often tailored to target specific cancers or chronic illnesses, they can sometimes trigger an overly strong immune response in some patients. This can lead to uncomfortable side effects, like fever, fatigue, and muscle aches. For example, during a trial for a melanoma vaccine, some patients experienced severe autoimmune reactions that affected their healthy cells, which was really concerning.

Another point to keep in mind is that not everyone responds to these vaccines in the same way. Depending on the tumor's properties and the patient's immune system, the efficacy can vary significantly. Take prostate cancer vaccine, Sipuleucel-T [19], for instance; research showed that it was much more effective for those in the early stages of cancer compared to those with later-stage disease.

Finally, producing these vaccines is a complex and costly process. This complexity and expense can limit how widely they can be used, which is a significant barrier to making these promising treatments more accessible to everyone who might need them. It's a pretty mixed picture, full of hope but also challenges that need to be addressed.

4. ICIs

4.1. Principle

The immune system is essential for identifying as well as destroying foreign bodies such as tumor cells. Tumor cells, however, have evolved a number of ways to avoid this immune monitoring. One significant mechanism they use is the activation of immune checkpoints, which inhibit the immune response and allow the tumor cells to thrive. Major immune checkpoints include CTLA-4 (cytotoxic T lymphocyte antigen 4) and PD-1 (programmed death protein 1). CTLA-4 is essential in the initial activation of T cells and inhibits T cell activity by binding to the B7 protein. PD-1 mainly plays a role in the late activation of T cells, mainly through binding to its ligand PD-L1, resulting in the inactivation of T cells. The function of these checkpoints is to prevent the immune system from overreacting, but by upregating the expression of these checkpoints, tumor cells are able to effectively inhibit T cell attack on them. ICIs restore T cell function by specifically blocking the signaling of these immune checkpoints. For example, CTLA-4 inhibitors, such as Ipilimumab, enhance T cell activity and proliferation by binding to CTLA-4 and preventing its interaction with B7, promoting a primary immune response that enhances T lymphocytes' ability to identify and combat cancerous cells. Meanwhile, PD-1/PD-L1 inhibitors relieve the inhibition of T cells by prevent the binding of PD-1 to PD-L1, develop the persistence and function of T cells so that they can continue to attack tumor cells.

4.2. Current situation

Numerous ICIs have been approved for clinical usage and have shown promise in treating a range of cancer types. For example, A monoclonal antibody against PD-1 is called nivolumab which is widely

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used to treat a variety of cancers, melanoma, renal cell carcinoma, and non-small cell lung cancer. The mechanism is to restore the activity of T cells by blocking the binding between PD-1 and its ligand, thereby enhancing the immune response to tumor cells. In a pivotal clinical trial (CheckMate 017), Nivolumab was used to treat individuals with squamous non-small cell lung cancer that has progressed. The results showed that the median survival (OS) in the Nivolumab group was 9.2 months compared to 6.0 months in the chemotherapy group, and Nivolumab significantly reduced the risk of death in patients (hazard ratio 0.62). In addition, the objective response rate (ORR) was 20% in the Nivolumab group compared to 9% in the chemotherapy group (Brahmer et al., 2015). This result shows that Nivolumab has a significant advantage in improving patient survival [20].

There are also a number of ICIs that show good therapeutic potential and are still in lead trials. Another PD-1 inhibitor, pembrolizumab is mostly used to treat head and neck cancer, some forms of lung cancer, and melanoma. By blocking the action of PD-1, Pembrolizumab enhances the attack of T cells on tumor cells. In the KEYNOTE-001 trial, later period melanoma patients were treated with pembrolizumab. The study showed that Pembrolizumab achieved an ORR of 33% and a median survival (OS) of 23.5 months, significantly higher than the results of conventional therapies. In continued follow-up, about 39% of patients maintained a response after receiving Pembrolizumab. This data suggests that Pembrolizumab is not only effective, but also able to induce a long-lasting immune response [21].

There are also a number of ADCs that are still being studied. The main indications for atezolizumab, a monoclonal antibody against programmed death ligand-1 (PD-L1), are urothelial carcinoma and non-small cell lung cancer. By preventing PD-L1 from interacting with T cells, it increases the anticancer activity of T cells. In the IMvigor210 trial, Atezolizumab was evaluated for the treatment of patients who suffer from metastatic urothelial carcinoma. Results showed that Atezolizumab had an ORR of 23% and a median PFS of 2.7 months, which increased to 39% in PD-L1-positive patients. These results suggest that Atezolizumab has good efficacy in specific patient populations, especially those with positive PD-L1 expression. [22]

4.3. Problems/side effects/optimizations

The effectiveness of ICIs varies from patient to patient. Studies have shown that about 20% to 30% of patients do not recover well after ICIs treatment [23]. These individual differences may be related to patients' genomic characteristics, tumor microenvironment, and immune system status. Tumor cells may also develop resistance to ICIs through a variety of mechanisms. Immune escape is one of the types of resistance to ICIs that tumors may develop. For example, one study showed that some patients initially respond well to PD-1 inhibitors, but as treatment progresses, tumor cells may evade immune surveillance by altering the expression of their surface antigens [24].

ICIs may also trigger a variety of negative immune-related responses. According to one large-scale study, about 66% of individuals treated with PD-1 or PD-L1 inhibitors had some sort of adverse event [25]. Although most irAEs are mild and reversible, about 10% of patients may experience severe or life-threatening symptoms. For example, the incidence of immune-associated pneumonia has reached 20% in NSCLC patients treated with ICIs [26].

5. Evaluation of immunotherapy for prostate cancer

5.1. ADC

ADC therapy for prostate cancer has received a lot of attention in medical community in recent years. Prostate cancer is generally manageable in its early stages, but requires more specific treatments as it metastasizes and becomes more aggressive. By Combining the cytotoxicity of chemotherapeutic medications with the specificity of monoclonal antibodies, ADCs can use the principle of specificity

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to deliver drugs directly to cancer cells, thereby minimizing damage to surrounding healthy host tissue. Recent studies have shown that ADCs have potential in targeting prostate-specific antigens such as prostate-specific membrane antigen (PSMA). By linking cytotoxic drugs to antibodies that specifically bind to PSMA, these couplings can effectively deliver lethal drugs to tumor cells. In this clinical trial of PSMA-targeted ADCs, such as PSMA-ADC, an ORR of approximately 40% was accomplished in individuals undergoing therapy for metastatic castration-resistant prostate cancer, with tumor shrinkage of more than 50% in some patients [27].

5.2. Therapeutical vaccine

Immunotherapy for prostate cancer has also received a lot of attention in recent years, especially a therapeutic vaccine called Sipuleucel-T (Provenge®), which is the only FDA-approved therapeutic vaccination for prostate cancer. In a clinical trial, IMPACT (NCT00065442), Patients receiving Sipuleucel-T experienced a median survival of 25.8 months, up 4.1 months and a 22% decrease in mortality risk, as opposed to 21.7 months in the placebo group. (hazard ratio 0.78, 95% CI: 0.61~0.98, P=0.03) [28].

At the same time, in the same study, Sipuleucel-T was found to be well tolerated, with the most common adverse reactions being only mild fever and flu-like symptoms, and there was a minimal frequency of severe adverse events [28]. However, other prostate cancer vaccines have failed to show significant clinical benefits in extensive phase II and phase III randomized trials, and more scientific research is needed to optimize vaccine use [28].

5.3. ICIs

In addition to the two immunotherapies mentioned above, ICIs therapy for prostate cancer has become a popular research topic in recent years, especially in castration-resistant prostate cancer (CRPC) patients. The study showed that the anti-PD-1 antibody pembrolizumab showed good efficacy in prostate cancer patients with microsatellite instability (MSI) or mismatch repair defects (dMMR). Pembrolizumab-treated participants in a clinical trial had a median PFS of 5.5 months and an ORR of 29%, showing significant antitumor activity [28].

In addition, another study evaluating the effect of the anti-CTLA-4 antibody ipilimumab in combination with other therapies showed that the median survival in the combination treatment group was 22.5 months, which was significantly higher than the 15.7 months in the treatment group alone [29].

6. Conclusion

This article provides a conceptual summary of the research progress and safety evaluation of cancer immunotherapy, focusing on three immunotherapy approaches: ADC, therapeutic vaccine, and ICIs. By analyzing the mechanisms, clinical applications, and potential benefits of these emerging therapies, this paper highlights the importance of immunotherapy in cancer treatment, and uses prostate cancer as an example to analyze three therapies for safety assessment, while pointing out the potential ability of these three therapies to develop patient survival and improve patient quality of life.

However, there are some limitations in this paper. First, although three different immunotherapy approaches were analyzed, the individual differences in different patient populations and the underlying mechanisms of drug resistance were relatively insufficiently explored. In addition, the evaluation process in this article lacks a comprehensive assessment of long-term efficacy and adverse effects, which may limit readers' understanding of the long-term safety of immunotherapy.

Future research should focus on continuing to delve deeper into the individual characteristics of different cancer types and their patients, optimizing combination strategies for immunotherapy,

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especially in the identification and management of resistance mechanisms. At the same time, multi-center, long-term clinical trials are needed to obtain more precise and comprehensive data to improve the efficacy and safety of immunotherapy.

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