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Review Article

The potential of mRNA vaccine in HCC treatment

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Abstract

Neoantigen mRNA vaccines are a potential form of immunotherapy for Hepatocellular Carcinoma (HCC). These neoantigens can be targeted with personalized mRNA vaccines, which are designed to stimulate the patient's immune system to recognize and destroy cancer cells. Neoantigen mRNA vaccines are developed using RNA sequences that are synthesized based on the genetic mutations found in HCC patients. These RNA sequences are formulated into a vaccine and administered to the patient, typically in combination with other cancer treatments for enhancing the anti-cancer effect. Several preclinical and clinical studies have shown promising results for neoantigen mRNA vaccines in HCC immunotherapy. Early results suggest that they may be a valuable addition to the treatment options available for HCC patients. However, more research is needed to determine the safety and efficacy of these vaccines.

Introduction

Hepatocellular Carcinoma (HCC) is the most common type of primary liver cancer. It develops in the hepatocytes, the main type of liver cells responsible for filtering toxins from the blood and producing bile. HCC usually develops in individuals with underlying liver disease, such as cirrhosis or hepatitis B or C infection. HCC typically grows slowly over time and may not cause symptoms in its early stages. However, as the tumor grows, it can cause abdominal pain, swelling, and weight loss. In advanced stages, it can spread to other parts of the body, such as the lungs and bones, and cause additional symptoms. Risk factors for developing HCC include chronic liver disease, excessive alcohol consumption, obesity, exposure to aflatoxins (a type of mold commonly found in improperly stored grains and nuts), and certain genetic conditions. Diagnosis of HCC usually involves imaging tests such as ultrasound, Computed Tomography (CT) scans, or Magnetic Resonance Imaging (MRI). A biopsy may also be performed to confirm the diagnosis. Treatment options for HCC depend on the stage and severity of the cancer. Treatment may include surgery to remove the tumor, radiation therapy, chemotherapy, targeted therapy, or a combination of these approaches. Liver transplantation may also be an option for some patients with early-stage HCC [1,2].

Cancer mRNA vaccines are designed to search genes (DNA or RNA) that can encode the amino acid sequence of tumor cell antigen proteins. RNA tumor vaccines generally use template messenger RNA (mRNA) of translated proteins to prepare and inject them into the body on this basis. Specific antigen proteins are synthesized through the protein synthesis system of human cells and used as "targets" to induce the body to generate an immune response to "targets", then targeted attack on tumor cells [3-8]. Therapeutic tumor vaccine is different from immune checkpoint inhibitors and adoptive Cell therapy (such as CAR-T therapy). It can use the whole immune system of patients to stimulate stronger and more targeted immune responses. Among them, the advantages of mRNA tumor vaccine are prominent, and it has very promising anti-cancer strength and prospects [3-21].

Neoantigen mRNA vaccine offers new hope for HCC patients

A neoantigen mRNA vaccine is a type of vaccine that is designed to help the immune system recognize and attack

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cancer cells based on the unique genetic mutations or neoantigens present in those cells [22]. Neoantigens are proteins that are generated by mutations in cancer cells and are not present in normal cells, making them a specific target for the immune system. The neoantigen mRNA vaccine is created by synthesizing small pieces of RNA that code for the neoantigens found in a patient's tumor. The RNA is then formulated into a vaccine and administered to the patient. When the vaccine is injected, the RNA enters the patient's cells and instructs them to produce the neoantigens, which are then presented to the immune system as foreign and targeted for destruction. This approach is personalized and specific to each patient's tumor, as the neoantigens in each tumor can vary from person to person. The vaccine can be designed to target multiple neoantigens, which may increase its effectiveness and decrease the likelihood of cancer cells developing resistance. Neoantigen mRNA vaccines are still in the early stages of development and clinical trials are ongoing to determine their safety and efficacy. However, early results have been promising, with some studies suggesting that the vaccines can elicit strong immune responses and improve survival in patients with certain types of cancer.

Under investigation are several clinical trials on neoantigen mRNA vaccines in human cancer [23, 24]. A stage progress report was recently released by the KEYNOTE-942 trial (NCT03897881), demonstrating that combining neoantigen mRNA vaccines with ICIs enhances patient survival in human solid tumors [25]. This phase II clinical trial, KEYNOTE-942, evaluates the safety and efficacy of mRNA-4157-P201 along with pembrolizumab for treating patients with unresectable melanoma. A previous clinical trial (KEYNOT-603) implemented the same study design and already exhibited an acceptable safety profile, as well as observed clinical responses when combining mRNA-4157 and pembrolizumab in patients with various cancer types, including HCC [25-27]. Encouragingly, the trial yielded promising results, with an overall response rate (ORR) of 33% and a disease control rate (DCR) of 67%. Moreover, the combination therapy exhibited good tolerability without any new safety signals detected. These promising findings are driving the expansion of individualized neoantigen mRNA vaccines to other solid cancers. Notably, an ongoing clinical trial (NCT05738447) is investigating the use of an HBV mRNA vaccine for HCC treatment.

Concurrently, the trial NCT05192460 is assessing the safety and tolerability of the neoantigen tumor vaccine (PGV002 mRNA Vaccine), either alone or in combination with programmed death receptor-1/ligand 1 (PD-1/L1) inhibitors, in patients with advanced liver, esophageal, or gastric cancer. This investigator-initiated, single-center, open-label, single-arm exploratory study comprises both a dose escalation phase and a dose expansion phase. Based on the safety and efficacy data observed during the dose escalation phase, the intended clinical dose is determined by the investigator's judgment for the subsequent dose expansion phase. During the dose escalation phase, subjects exclusively receive the neoantigen tumor vaccine. In the dose expansion phase, patients receive the neoantigen vaccine in combination with PD-1/L1 inhibitors to further assess the efficacy and safety profile of the neoantigen tumor vaccine at a specific dose [28].

Potential mRNA vaccine for treating HCC

The development of mRNA vaccines for HCC immunotherapy is an active area of research, and there are several potential targets that are currently being investigated. Here are some of the potential mRNA vaccines that may be used in HCC immunotherapy:

a) **Alpha-Fetoprotein (AFP) mRNA vaccine:** AFP is a protein that is often overexpressed in HCC, and targeting it with a vaccine may help the immune system recognize and destroy cancer cells. AFP mRNA vaccines have shown promise in preclinical studies and are currently being tested in clinical trials [29,30].

b) **Cancer-Testis Antigen (CTA) mRNA vaccine:** CTAs are a group of proteins that are normally expressed only in the testes but are often overexpressed in various types of cancer, including HCC. Targeting CTAs with a vaccine may help the immune system recognize and destroy cancer cells. Several CTAs, including MAGE-A3, NY-ESO-1, and LAGE-1, are currently being investigated as potential targets for mRNA vaccines in HCC [31,32].

c) **Neoantigen mRNA vaccine:** As mentioned earlier, neoantigens are proteins that are generated by mutations in cancer cells and are not present in normal cells. Targeting neoantigens with a vaccine may help the immune system recognize and destroy cancer cells. Neoantigen mRNA vaccines are personalized to each patient's tumor and are currently being tested in clinical trials for various types of cancer, including HCC [22].

d) **Immune checkpoint inhibitor mRNA vaccine:** Immune checkpoint inhibitors are drugs that help the immune system recognize and attack cancer cells. Targeting immune checkpoint proteins, such as PD-1 or CTLA-4, with an mRNA vaccine may help enhance the immune system's ability to recognize and attack HCC cells. mRNA vaccines targeting immune checkpoints are currently being investigated in preclinical studies[33-35].

It is important to note that these potential mRNA vaccines are still in the early stages of development, and more research is needed to determine their safety and efficacy in HCC immunotherapy.

The future direction of mRNA vaccine in HCC treatment

The future direction of studying mRNA vaccines in HCC treatment involves several key aspects. Targeting Tumor-Specific Antigens: Researchers are exploring the identification of specific antigens present in HCC cells. By developing mRNA vaccines that target these tumor-specific antigens, they aim to elicit a potent immune response against cancer cells while minimizing damage to healthy tissues. Combination Therapies: Future studies are likely to focus on combining mRNA vaccines

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with other treatment modalities, such as immune checkpoint inhibitors or targeted therapies. The goal is to enhance the efficacy of mRNA vaccines by leveraging the complementary mechanisms of action of different therapies, leading to improved outcomes for HCC patients. Personalized Vaccines: HCC is a heterogeneous disease, meaning it varies among individuals. Future research may concentrate on developing personalized mRNA vaccines tailored to each patient's specific tumor characteristics. This approach could optimize the immune response and increase treatment effectiveness. Overcoming Immune Evasion: HCC has mechanisms that enable it to evade immune detection and destruction. Future studies will aim to design mRNA vaccines that can overcome these immunosuppressive mechanisms, thereby enhancing the immune response against cancer cells and improving treatment outcomes. Optimization of Delivery Systems: Researchers are actively exploring different delivery systems to enhance the efficiency of mRNA vaccines. This includes lipid nanoparticles, electroporation, and other innovative techniques. Developing more effective delivery methods can improve vaccine stability, cellular uptake, and immune response. Clinical Trials and Safety Evaluation: As mRNA vaccines for HCC treatment progress, future research will involve rigorous clinical trials to evaluate safety, efficacy, and long-term outcomes. These trials will assess the effectiveness of mRNA vaccines in larger patient populations, helping to establish their role in standard HCC treatment protocols.

Overall, the future direction of studying mRNA vaccines in HCC treatment involves a multidisciplinary approach combining personalized medicine, innovative delivery systems, and combination therapies. By addressing the challenges of tumor heterogeneity and immune evasion, researchers aim to harness the potential of mRNA vaccines to provide more effective and targeted treatments for HCC patients [36-41].

Conclusion

To sum up, the novelty and significance of neoantigen mRNA vaccines in liver cancer treatment lie in their personalized nature, utilization of mRNA technology, potential for precision medicine, ability to enhance immune responses, potential for combination therapies, and ongoing clinical trials exploring their safety and efficacy. These factors highlight the current excitement and potential breakthroughs in liver cancer treatment using neoantigen mRNA vaccines.

Neoantigen mRNA vaccines represent a promising approach to HCC immunotherapy, as they offer a personalized and specific way to target the unique genetic mutations present in each patient's tumor. More research is strongly recommended to explore such a field for retrieving more potential clinical benefits for patients with HCC.

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