CASE REPORT

Racotumomab Therapeutic Vaccine in the Treatment of Advanced Lung Cancer in the Elderly: A Case Report

Tatiana Hernández Casola*, Héctor Luis Salazar Ferrer, Isela Companioni de la Cruz

Hospital General Provincial Docente Capitán Roberto Rodríguez, Fernández, Cuba.

Abstract: We reported a clinical case of an 84-year-old smoker who was diagnosed with stage IV lung cancer and was included in the phase III clinical trial and treated with racotumomab. The patient had a an ECOG grade 0 according to the function scale. Therefore, it should be emphasized that this vaccine can improve the survival rate of patients with recurrent or advanced non-small cell lung cancer.

Keywords: Elderly, Non-small cell lung cancer, Therapeutic vaccine, Racotumomab, Phase III clinical trial, Survival rate

1. Introduction

Every year, 1.2 million new cases of lung cancer are diagnosed all over the world. This disease is the main cause of death in developed countries.

Cuba has an increasing incidence of lung cancer and is one of the tumors with the highest mortality. It is estimated that by 2020, there will be 9 million new cases in developing countries and 6 million in developed countries.

World Health Organization (WHO) predicts that 17 million people will die worldwide by 2030[1].

Non-small cell lung cancer is the most common subtype in the population, accounting for 75% of all lung tumors. Due to the poor treatment efficacy and the development of inherent and acquired tumor drug resistance, only 16% of patients survived within 5 years[2].

In addition, advances in understanding the cellular and molecular biology of cancer have enabled people to identify potential immunotherapy targets of these tumors. In addition, the development of safe, effective and affordable vaccines has become a global effort because of its huge impact on the overall health worldwide[3].

The incidence of this disease increases with age. Apart from that, smoking is the most important risk factor. Other risk factors include family history, chronic obstructive pulmonary disease, idiopathic pulmonary fibrosis, environmental inhalation of carcinogens and passive smoking[4].

2. Case presentation

We reported an 84-year-old healthy smoker who began to show respiratory symptoms and caused lung abscess. Sputum bacteriology was performed and Klebsiella pneumoniae was found growing in the culture. Therefore, he received antibiotic treatment and the treatment went well. The next month, he went to the department of Internal Medicine of Roberto Rodriguez Fernández de Morón Provincial Teaching General Hospital in Segovia because he occasionally had wet cough, high fever, dyspnea and physical discomfort.
During the trial, he showed anorexia, chest pain and marked decline.

1) Physical examination of patient showed
- Pale, sweating, moderate dyspnea
- Heart rate: 110 times per minute
- Blood pressure: 100/70 mm Hg

Respiratory rate was breathing 20 times per minute, retain blister murmur, slightly reduce the right half of the chest, accompanied by wet chest tightness.

2) His supplementary inspection was as follows:
   (i) Chest topographic map 1: the increase of heart area was observed, which was characterized by global myocardial enlargement, vascular mediastinum enlargement and adenosis, as well as right hilar lesions, in which the fiber bundle split to the subclavian area, which was consistent with the tumor process.
   (ii) Axial computed tomography (CT) of lung: the high-density image of the right half of the chest is 73 x 47 mm, accompanied by inflammatory infiltration around the lesion, increased bronchial permeability, bilateral large and medium-sized pleural effusion, and paratracheal adenosis with a small diameter of 18 mm.
   (iii) Head CT plain scan, abdominal ultrasound, respiratory function test and ECG: no abnormality. No hemolytic and vesicular lesions were found.
   (iv) Lung fine needle biopsy: non-small cell lung cancer, suggesting adenocarcinoma.

The case was analyzed by an oncologist who classified the cancer as stage IV (T3N0M1a). Therefore, the patient did not receive any first-line tumor specific treatments, but rather include him in the “multicenter, randomized, stratified, open label clinical trial” and compare with patients with advanced non-small cell lung cancer, which were not suitable for chemotherapy, and treated with racotumomab or CIMAvax-EGF® vaccine, or a combination of the two because he meets all the inclusion criteria. After signing the informed consent, he was included in the racotumomab treatment group.

Within 3 months after the start of racotumomab treatment, a 28 mm right half chest image was observed on CT. Compared with initial evaluation, some reactions were reduced by 37.77%; at 6 months, the image of the upper lobe of the right lung disappeared and was considered to be in complete remission, and the physical examination was normal; after 9 months, the 31 mm image of the right half of the chest was re-displayed. Partial response to the tumor, which results in 57.53% reduction compared with the initial evaluation was recorded, and the physical examination was normal again.

At 12, 15, 21 and 24 months, the image of the upper lobe of the right lung disappeared, which was considered a complete response. Normal physical examination was recorded.

It was observed that the overall clinical and general conditions of the patient had been improved, because the study ended with ECOG grade 0 and the quality of life was good. He received 40 doses of racotumomab vaccine.

The overall survival was 38 months after diagnosis and 37 months after inclusion in the clinical study. According to the general toxicity standard stipulated by the national cancer institute version 3.0, the overall toxicity of the vaccine is divided into grade 1 and grade 2. Treatment is mainly related to mild to moderate reactions, local erythema, induration and pain at the injection site. These reactions disappear within 24 to 48 hours without drug treatment.

3. Discussion

At present, clinical trials are the best tool to evaluate the efficacy and safety of new therapies, and have become a new paradigm of scientific research methods.

On the other hand, many studies and meta-analyses have confirmed the benefits of maintenance therapy for patients with non-small cell lung cancer and non-progressive lung cancer after first-line treatment[5]. New biological products are considered to be a tool to transform cancer into chronic non communicable diseases, which is suitable to improve quality of life for many years[6].

Appropriate patient selection and a combination chemotherapy, radiotherapy or control point inhibitors seem to be the key factors to maximize the effects of racotumomab vaccine on patients with lung cancer.

In a recent phase I clinical study of children with recurrent or drug-resistant neuroectodermal malignancies, racotumomab was well tolerated and immunogenic, and its evaluation as an immunotherapy for high-risk neuroblastoma is required[7]. A similar study in Japan showed that the survival rate was lower than that of the study subjects. The median survival time of gefitinib treatment group was 30.5 months and that of chemotherapy group was 23.6 milliseconds[8].

Similarly, a clinical study of patients with non-small cell lung cancer in Santiago, Cuba, found that the median survival time was 13 months regardless of the diagnosis stages of the disease[9].

In patients with melanoma, breast cancer and lung cancer, racotumab had been shown to induce specific immune response through tumor necrosis mechanism and directly recognize and kill tumor cells expressing new antigens. The specific expression of NGcGM3 in malignant cells reduces the potential risk of cross immune response that may cause serious side effects[10].

Considering the good development of this patient, racotumomab can improve the survival rate of patients with recurrent or advanced IIIB/IV non-small cell lung cancer compared with the best supportive treatment.
Conflicts of interest
The authors declare that they have no conflict of interest.

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