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Cemiplimab in oncology: a review of the literature

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Abstract

Background. Cemiplimab, a fully human antibody that blocks programmed cell death 1 (PD-1), plays a key role in the treatment of patients with advanced cancers, including non-small cell lung cancer, cutaneous squamous cell carcinoma and cervical cancer, which typically have a poor prognosis under standard therapies.

Aim. The aim of this narrative review is to analyze the use of cemiplimab in the treatment of advanced cancers: non-small cell lung cancer, squamous cell carcinoma of the skin and cervical cancer.

Material and methods. A literature search was conducted in the PubMed and Google Scholar databases using the following keywords: "cemiplimab", "PD-1 receptor inhibitor", "non-small cell lung cancer", "cervical cancer", and "cutaneous squamous cell carcinoma". The review included original studies, systematic reviews and clinical trials without specific time restrictions. The reference lists of the retrieved articles were also cross-referenced to obtain additional valuable information.

Results. Current studies provide strong evidence supporting the efficacy of cemiplimab in the treatment of advanced cancers, including non-small cell lung cancer (NSCLC), cervical cancer and squamous cell skin cancer (CSCC).

Conclusions. Cemiplimab demonstrates significant clinical benefits in treating advanced cancers such as cervical cancer, non-small cell lung cancer (NSCLC) and squamous cell skin cancer (CSCC). Further clinical investigations are warranted to fully establish its therapeutic role in oncology.

Keywords: cemiplimab, non-small cell lung cancer, cervical cancer, cutaneous squamous cell carcinoma, PD-1 receptor inhibitor.

1. Introduction

Cemiplimab is a fully human immunoglobulin G4 (IgG4) monoclonal antibody that binds to the programmed cell death protein 1 (PD-1) receptor, thereby blocking its interaction with the PD-L1 and PD-L2 ligands.¹ By inhibiting the PD-1/PD-L1 pathway, cemiplimab eliminates the suppression of the immune response, subsequently enhancing the body's antitumor activity¹. Currently, this antibody is utilized to treat several malignancies, including metastatic cutaneous squamous cell carcinoma, non-small cell lung cancer, and recurrent cervical cancer. This literature review aims to summarize current evidence regarding the therapeutic benefits of cemiplimab in these patient populations¹.

2. Research materials and methods.

To prepare this review, electronic databases, including PubMed and Google Scholar, were systematically searched. The following keywords were utilized: "cemiplimab", "PD-1 receptor inhibitor", "non-small cell lung cancer", "cervical cancer", and "cutaneous squamous cell carcinoma". The review included English-language original studies, systematic reviews, and clinical trials, regardless of their publication date. Article selection specifically focused on clinical trials conducted involving oncology patients.

3. Research results

Recent studies suggest that cemiplimab acts as a potent PD-1 checkpoint inhibitor, enabling the patient's immune system to recognize and destroy cancer cells. Cancer cells often evade immune detection by reducing T-cell activity via the activation of the PD-1/PD-L1 pathway¹. By blocking this interaction, cemiplimab reactivates the patient's immune system to fight the malignancy.¹ These pharmacological characteristics have led to its use in treating locally advanced or metastatic squamous cell carcinoma of the skin, metastatic or recurrent cervical cancer, and metastatic or locally advanced non-small cell lung cancer.¹

3.1 Non-Small Cell Lung Cancer

Cemiplimab is a fully human immune PD-1 checkpoint inhibitor approved as the first-line treatment of patients with advanced Non-Small Cell Lung Cancer, both as a monotherapy and in combination with chemotherapy^{15,16}.

A recent study by Gogishvili et al. demonstrated that the use of cemiplimab as a first-line treatment for patients diagnosed with advanced non-small cell lung cancer significantly improved outcomes for these patients. Specifically, cemiplimab therapy significantly improved overall survival (OS) and prolonged progression-free survival (PFS). This study compared patients in the chemotherapy-only group with those receiving the combination of cemiplimab and chemotherapy in patients with advanced non-small cell lung cancer (aNSCLC) and PD-L1 expression $\geq 50\%$. The double-blind, placebo-controlled EMPOWER-Lung 3 study (NCT03409614) evaluated the benefit of cemiplimab in combination with a platinum doublet as first-line treatment for advanced non-small cell lung cancer, regardless of histological grade or PD-L1 expression. The study enrolled 466 patients with stage III/IV non-small cell lung cancer without EGFR, ALK, or ROS1 genomic aberrations. Patients were randomized (2:1) to receive cemiplimab 350 mg (n = 312) or placebo (n = 154). The antibody/placebo was administered every 3 weeks for up to 108 weeks. Therapy was continued in combination with four cycles of platinum-based doublet chemotherapy in both groups of patients. Pemetrexed-based maintenance therapy was initiated in each group when indicated. The study conducted by the above authors was stopped prematurely due to a statement issued by an independent data monitoring committee. The recommendation of this committee was based on the significant efficacy of cemiplimab in the treatment of advanced non-small cell lung cancer. The results in the individual groups were: median OS was 21.9 months (95% confidence interval (CI)) for the cemiplimab plus chemotherapy group versus 13.0 months (95% confidence interval CI) for the placebo plus chemotherapy group⁵.

Cemiplimab is the second anti-PD-1/PD-L1 drug to demonstrate efficacy in the treatment of advanced non-small cell lung cancer (NSCLC). Cemiplimab's efficacy is evident both in combination with platinum-based chemotherapy for both squamous and non-squamous cell lung cancer, and as a single agent. Its effectiveness is evident both as a single agent and in combination with platinum-based chemotherapy for squamous and non-squamous NSCLC. This option is particularly valuable for patients who experience severe chemotherapy-related side effects and exhibit high PD-L1 expression⁵.

Furthermore, a five-year follow-up study by Kiliçkap et al. comparing cemiplimab monotherapy with prior chemotherapy showed a durable benefit in overall survival (OS) and progression-free survival (PFS) compared with the OS and progression-free survival (PFS) benefits in patients receiving chemotherapy. The researchers found that the therapeutic benefits of cemiplimab increased alongside PD-L1 expression levels, with the greatest clinical benefit observed in patients exhibiting a PD-L1 expression of 90% or higher. These long-term data firmly support cemiplimab as a highly effective first-line therapeutic option for advanced NSCLC patients with a PD-L1 expression of $\geq 50\%$ ⁸.

3.2 Cutaneous Squamous-Cell Carcinoma

CSCC is the second most common skin cancer, following basal cell carcinoma^{11,12} Risk factors include chronic sun exposure, advanced age, UV-sensitive skin, and immunosuppression¹³. While surgery is an effective and standalone treatment for over 95% of patients, a small percentage develop an incurable, advanced neoplastic process that metastasizes to other organs.¹⁴ Such disseminated conditions often disqualify patients from radical surgery and local radiotherapy. Historically, no effective systemic therapy existed for advanced CSCC. However, immunotherapy has proven highly effective due to the high mutational burden of these tumors, which is closely linked to immunosuppression⁶.

In phase I trials, patients with metastatic cutaneous squamous cell carcinoma demonstrated a profound and durable response to therapy based on the antibody Cemiplimab.⁶

Furthermore, a randomized phase III trial by Rischin et al. revealed that adjuvant cemiplimab therapy significantly improved survival, induced tumor regression, and extended relapse-free survival. The cemiplimab group had a lower risk of recurrence of cutaneous squamous cell carcinoma compared to the placebo group. A total of 415 patients were enrolled in the study and then assigned to two groups. There were 209 patients in the cemiplimab group and 206 in the placebo group. The median follow-up period was 24 months. Cemiplimab proved to be an effective treatment compared to placebo. In this study, relapse-free survival was significantly higher in the cemiplimab group. In the first group, the hazard ratio for disease recurrence or death was 0.32; 95% confidence interval [CI], 0.20 to 0.51; $p < 0.001$). The estimated 24-month disease-free survival was 87.1% (95% CI, 80.3–91.6) in the cemiplimab group and 64.1% (95% CI, 55.9–71.1) in the placebo group. Cemiplimab therapy also led to a lower risk of locoregional

recurrence compared with placebo. Local recurrence was reported in 9 cases in the cemiplimab group compared with 40 cases in the placebo group (hazard ratio, 0.20; 95% CI, 0.09–0.40). Distant disease recurrence was observed in 10 patients in the cemiplimab group compared to 26 patients in the placebo group (hazard ratio 0.35; 95% CI, 0.17–0.72)³.

Additionally, phase I and II studies by Migden et al. showed that in patients with advanced cutaneous squamous cell carcinoma, cemiplimab induced a positive treatment response in approximately half of the patients. This response was associated with a benefit in terms of prolonged patient survival. In the phase I trial, 50% of patients responded (13 of 26 patients; 95% CI, 30–70), while the phase II metastatic cohort showed a 47% response rate (28 of 59 patients; 95% CI, 34–61) over a 7.9-month median follow-up. Impressively, of the 28 responding patients, approximately 82% maintained their response at the study's conclusion. However, typical immune-related adverse effects, such as diarrhea, fatigue, nausea, constipation, and rash, were noted in at least 15% of patients, with severe adverse events causing 7% of patients to discontinue treatment⁶.

Finally, a study by Rischin et al. confirmed that a fixed intravenous dose of 350 mg every three weeks yielded durable responses and a safety profile comparable to weight-based dosing. Further long-term follow-up of these patients is ongoing⁷.

3.3 Recurrent Cervical Cancer

Cervical cancer is the fourth most frequently diagnosed cancer and the fourth leading cause of cancer-related death in women globally, with approximately 570,000 cases and 311,000 deaths reported annually¹⁷. Evidence indicates that approximately 95% of these cases are linked to chronic human papillomavirus (HPV) infection.^{9, 18}

A study by Tewari et al. encompassing 608 women with recurrent cervical cancer, who had previously progressed on first-line platinum-based chemotherapy, compared cemiplimab therapy directly against chemotherapy alone. The median overall survival (OS) was significantly longer in the cemiplimab group (12.0 months) than in the chemotherapy group (8.5 months; HR = 0.69; 95% CI, 0.56–0.84; $p < 0.001$). Progression-free survival was similarly improved for women receiving the antibody. Objective response rates were 16.4% (95% CI, 12.5–21.1%) in the cemiplimab group versus 6.3% (95% CI, 3.8–9.6%) in the chemotherapy group. Although effective treatment responses were higher in cemiplimab-treated patients with

a PD-L1 expression $\geq 1\%$ (18%) compared to those with $<1\%$ (11%), the data suggests that even PD-L1 negative patients can derive clinical benefit from the therapy².

A study by Tewari et al. demonstrated that cemiplimab not only prolonged survival in patients with recurrent cervical cancer but also improved their quality of life. In this study, objective responses were also observed in patients with PD-L1 expression less than 1%. Unfortunately, not all patients could be accurately assessed for PD-L1 expression, making it difficult to interpret the role of PD-L1 expression in response to cemiplimab treatment. However, these results suggest that some patients with PD-L1 negative status may still respond to cemiplimab therapy. In this randomized trial of patients with recurrent cervical cancer whose disease had progressed following prior treatment with platinum-based chemotherapy alone, cemiplimab demonstrated a clinically significant benefit in overall survival. These findings suggest that many women with recurrent cervical cancer after unsuccessful chemotherapy may benefit from regular therapy with the antibody cemiplimab².

Research by Rischin, Gil-Martin, et al. reinforced these findings, showing that cemiplimab provides significant clinical benefits for patients resistant or intolerant to conventional platinum- and taxane-based chemotherapies, with an adverse event profile similar to other PD-1 inhibitors⁹.

The final overall survival analysis from the phase III trial, presented by Oaknin et al., definitively confirmed cemiplimab's sustained survival benefit regardless of PD-L1 status. These results robustly support cemiplimab as a standard second-line systemic treatment for patients with recurrent cervical cancer who have previously received platinum-based chemotherapy but no prior immunotherapy¹⁰.

4. Discussion:

This review highlights the important role of cemiplimab in the immunotherapeutic treatment of advanced cancers, including squamous cell carcinoma of the skin (CSCC), non-small cell lung cancer (NSCLC) and recurrent cervical cancer.

As observed in Migden et al.'s 2018 study, the efficacy of immune checkpoint blockades in advanced CSCC is likely driven by the tumor's high mutational burden and subsequent sensitivity to effector T cells, particularly given the strong link between CSCC and immunosuppression⁶.

Similarly, long-term studies have highlighted cemiplimab's superiority over chemotherapy in NSCLC. This is especially noteworthy for patients with squamous cell lung cancer, a notoriously difficult-to-treat population that typically faces a poorer prognosis and fewer treatment options than those with non-squamous subtypes^{19,20}. In the largest reported cohort of squamous cell lung cancer patients treated with monotherapy, Kiliçkap et al. demonstrated a sustained stabilization of the survival curve at five years, indicating a long-lasting survival benefit⁸.

5. Conclusions

This review of the available literature provides important insights into cemiplimab treatment for oncology patients. The administration of this antibody has been consistently associated with improved survival in patients with advanced cancers, including recurrent cervical cancer, CSCC and NSCLC. However, further studies are necessary to continually assess and confirm the long-term efficacy and safety of cemiplimab in oncology.

Disclosure

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The authors declare no conflict of interest.

Declaration of Artificial Intelligence Use

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