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Pembrolizumab-Induced Pneumonitis in Esophageal Cancer: Three Clinical Scenarios and a Management Framework

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Data Interpretation D
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Case series
Patients: Male, 51-year-old • Male, 72-year-old • Male, 61-year-old
Final Diagnosis: Immune checkpoint inhibitor-associated pneumonitis • pneumonitis
Symptoms: Cough • dyspnea
Clinical Procedure: —
Specialty: Oncology
Objective: Unusual clinical course
Background: Pembrolizumab prolongs survival in advanced esophageal cancer but carries a risk of checkpoint inhibitor pneumonitis (CIP), a rare and potentially fatal immune-related adverse event. Real-world management of CIP is particularly complex in developing countries, where endemic tuberculosis and limited access to advanced diagnostic tools for infection create substantial diagnostic uncertainty, especially in patients with pre-existing pulmonary comorbidities.
Case Reports: We report 3 cases of stage IV esophageal squamous cell carcinoma that developed pembrolizumab-related CIP with distinct clinical trajectories. Case 1 was a 51-year-old man with multiple metastases, grade 3 steroid-refractory CIP, rapid disease progression, transitioned to best supportive care. Case 2 was a 72-year-old man with COPD and cisplatin-induced renal failure and CIP difficult to distinguish from acute exacerbation, who fully recovered with corticosteroids, but pembrolizumab was permanently discontinued due to high recurrence risk. Case 3 was a 61-year-old previously healthy man, grade 2 CIP after 6 cycles, with complete recovery, and successful pembrolizumab rechallenge without relapse.
Conclusions: Three clinical scenarios provide a practical framework for managing checkpoint inhibitor pneumonitis (CIP): (1) palliation for severe, steroid-refractory CIP accompanied by oncological progression; (2) permanent discontinuation for steroid-responsive CIP in patients with high-risk baseline features; and (3) safe rechallenge for mild CIP following complete resolution. Key decision determinants include CIP severity, steroid responsiveness, underlying lung function, and anticipated therapeutic benefit. Empiric antibiotics should be individualized. This is a hypothesis-generating single-institution observation, not a validated management guideline.
Keywords: Esophageal Squamous Cell Carcinoma • Immunotherapy • Drug-Related Side Effects and Adverse Reactions • Secondary Prevention • Pulmonary Disease, Chronic Obstructive
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Introduction

Pembrolizumab, a monoclonal antibody against PD-1, has been shown to improve overall survival in patients with advanced esophageal cancer in trials such as KEYNOTE-590 [1]. However, the immune-activating mechanism of the drug can cause immune-related adverse events (irAEs). Checkpoint inhibitor pneumonitis (CIP) is a rare but potentially life-threatening irAE. A systematic review reported that the incidence of CIP ranges from 1% to 7% and that PD-1 inhibitors (including pembrolizumab) are associated with higher risk than are PD-L1 inhibitors (OR = 3.56) [2]. In real-world clinical practice, the incidence may be even higher, especially in patients with pre-existing lung disease. CIP is also the most common cause of death related to PD-1/PD-L1 inhibitors, accounting for 35% of fatal irAEs [3].

Managing CIP in patients with esophageal cancer presents several specific challenges: differentiating CIP from infectious pneumonia, acute exacerbations of underlying lung disease such as COPD, progression of pulmonary metastases, pulmonary tuberculosis, and tumor invasion of the trachea. Furthermore, the high prevalence of smoking among patients with esophageal cancer increases the risk of pre-existing COPD and other chronic lung diseases, which may contribute to a higher observed frequency of CIP in this population compared with other cancers [4]. The primary aim of this case series is to describe 3 illustrative clinical courses observed in our practice and to highlight practical decision-making considerations that emerged from these cases: (1) steroid-refractory severe CIP with disease progression; (2) CIP with complete recovery but permanent discontinuation due to high recurrence risk; and (3) CIP with complete recovery enabling successful pembrolizumab rechallenge. To the best of our knowledge, no previous case series has synthesized pembrolizumab-related CIP management in Vietnamese patients with esophageal cancer into an explicit, 3-scenario framework tailored to settings where diagnostic resources (eg, procalcitonin, timely cultures) are often limited and the infection burden (eg, tuberculosis) is high. This series, therefore illustrates how such contextual factors influence the practical application of international CIP guidelines, particularly regarding empiric antibiotic use and the careful selection of candidates for pembrolizumab rechallenge.

Case Reports

All 3 patients were diagnosed with stage IV esophageal squamous cell carcinoma and treated with pembrolizumab combined with chemotherapy. CIP was diagnosed based on the following criteria: (1) the patient was receiving or had received pembrolizumab; (2) new respiratory symptoms appeared; (3) new lesions were found on chest CT; and (4) other causes

were excluded. CIP severity was graded according to Common Terminology Criteria for Adverse Events (CTCAE) version 5.0.

Case 1 (Severe, Steroid-Refractory CIP Leading to Palliative Care)

A 51-year-old man (ECOG PS 0; weight 60 kg; height 160 cm) was diagnosed with stage IV lower-third esophageal cancer (cT4bN3M1) with multiple pulmonary, liver, and splenic metastases. His history included pneumonia and liver failure. He had undergone percutaneous endoscopic gastrostomy for feeding. He received treatment with oxaliplatin + 5-FU + pembrolizumab for 4 cycles. Evaluation after 3 cycles showed stable disease (SD). On day 8 of cycle 4 he developed cough, dyspnea, and fever, rapidly requiring supplemental oxygen (grade 3 CIP). A chest CT scan obtained 2 days later revealed bilateral, patchy ground-glass opacities with lower-lobe predominance; no new pulmonary nodules were seen (Figure 1). Procalcitonin was mildly elevated (0.48 ng/mL), a nonspecific finding that did not reliably distinguish infection from CIP. Sputum Xpert MTB/RIF was negative, while sputum cultures were later reported as no growth. Bacterial infection could not be completely ruled out, yet the temporal relationship to pembrolizumab and the CT pattern favored CIP. Intravenous methylprednisolone (2 mg/kg/day) and empiric piperacillin-tazobactam were started immediately after CT. No clinical improvement was noted after 72 hours; repeat imaging on day 6 showed more extensive ground-glass opacities, and the patient remained oxygen dependent. Concurrently, liver and lung metastases progressed and new spinal bone lesions appeared. Because of steroid-refractory CIP and rapid disease progression, pembrolizumab was permanently discontinued and the patient was transitioned to palliative care.

Case 2 (CIP with Complete Recovery but Permanent Discontinuation)

A 72-year-old man, ECOG PS 1, weight 54 kg, height 150 cm, with a history of COPD and a gastrostomy tube for feeding, was diagnosed with middle-third esophageal cancer stage IV (cT3N3M1) with cervical lymph node metastases and a solitary right upper lobe lung metastasis. He received cisplatin + 5-FU + pembrolizumab for 3 cycles, achieving a partial response (PR), but then developed cisplatin-induced renal failure. The regimen was switched to oxaliplatin + 5FU + pembrolizumab for 3 additional cycles. Two weeks after the third cycle of this new regimen he presented with progressive cough and dyspnea that closely resembled his prior COPD exacerbations. Chest CT showed new multifocal ground-glass opacities superimposed on a background of emphysema, without lobar consolidation. Procalcitonin was normal (0.09 ng/mL), sputum cultures and Gram stain were negative, and an Xpert MTB/RIF test on sputum was also negative. Infection was considered unlikely, and a diagnosis of CIP was made. Oral prednisone (1 mg/kg/day)

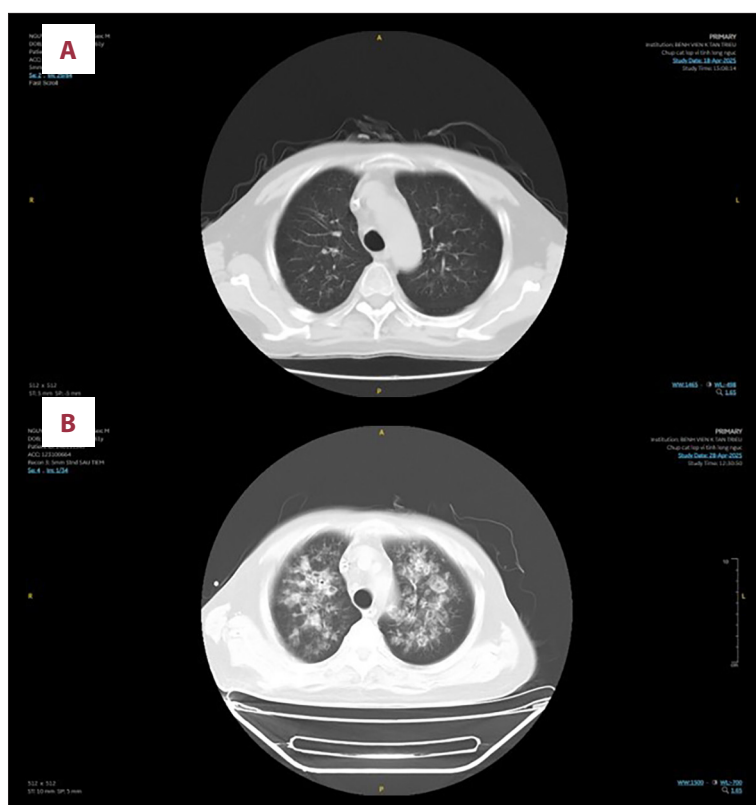


Figure 1. Serial axial chest CT images (lung window) obtained before and after pembrolizumab therapy in a patient with severe progressive checkpoint inhibitor pneumonitis (CIP). **(A)** Baseline chest CT image acquired prior to the initiation of pembrolizumab. The lung parenchyma appears relatively clear, with no significant focal consolidation, ground-glass opacities, or interstitial infiltrates. **(B)** Follow-up chest CT image obtained after the 4th cycle of pembrolizumab. Compared with **(A)**, this image demonstrates marked progression of pulmonary abnormalities, characterized by newly developed, extensive bilateral ground-glass opacities and patchy consolidations, predominantly involving the peripheral and mid-to-lower lung zones

was started, together with empiric levofloxacin for the first 7 days. His symptoms improved notably within 5 days, and a follow-up CT scan at 2 weeks showed marked regression of the ground-glass opacities. Prednisone was tapered slowly over 6 weeks without symptom recurrence. Despite the complete recovery, the multidisciplinary team decided to permanently discontinue pembrolizumab because of advanced age, severe COPD, renal impairment, and a perceived high risk of CIP recurrence. He was continued on maintenance 5-FU alone, and his disease remained stable.

Case 3 (Grade 2 CIP with Successful Pembrolizumab Rechallenge)

A 61-year-old man, previously healthy, ECOG PS 1, weight 60 kg, height 160 cm, was diagnosed with upper-third esophageal cancer stage IV (cT3N2M1) with cervical lymph node and liver metastases. He received cisplatin + 5-FU + pembrolizumab for 6 cycles, achieving a partial response (PR). Four weeks after cycle 6 he developed a dry cough and mild exertional dyspnea without fever (grade 2 CIP). High-resolution chest CT revealed a focal, well-defined area of ground-glass opacity in the right upper lobe, with no other parenchymal abnormalities. Procalcitonin was normal (0.06 ng/mL), and the white blood cell count was unremarkable, making bacterial infection unlikely. Sputum Xpert MTB/RIF was negative. He was started on oral prednisone (1 mg/kg/day) together with empiric amoxicillin-clavulanate for

5 days. His symptoms resolved completely within 1 week, and a repeat CT after 3 weeks showed complete disappearance of the ground-glass opacity. Prednisone was tapered and discontinued over 6 weeks. Given the grade 2 severity, full recovery, absence of underlying lung disease, and favorable tumor response, the multidisciplinary team decided to rechallenge with pembrolizumab. He subsequently received 3 additional cycles of 5-FU plus pembrolizumab, maintained a partial response, and experienced no recurrence of CIP. The clinical characteristics, treatment courses, and outcomes of the 3 patients are summarized in **Table 1**.

Discussion

CIP is an important irAE that requires attention when using pembrolizumab. A recent systematic review summarizing data from 35 studies found that the incidence of CIP ranges from 1% to 7%, with pembrolizumab having a significantly higher risk than PD-L1 inhibitors [2,5]. The risk of CIP is higher in patients with squamous cell carcinoma, previous thoracic radiotherapy, pre-existing respiratory disease, high PD-L1 expression, and no prior treatment. In patients with esophageal cancer, the high prevalence of smoking leads to an increased risk of underlying lung diseases such as COPD, which can further increase the risk and severity of CIP [6].

Table 1. Comparison of key characteristics of the 3 cases of pembrolizumab-induced pneumonitis.

Characteristic	Case 1	Case 2	Case 3
Age	51	72	61
Sex	Male	Male	Male
History of lung disease	Pneumonia (unspecified)	COPD	Healthy
Cancer stage	IV (cT4bN3M1)	IV (cT3N3M1)	IV (cT3N2M1)
Metastasis sites	Lung (multiple), liver, spleen	Cervical lymph nodes, lung (solitary)	Cervical lymph nodes, liver
Treatment regimen	Oxaliplatin + 5FU + pembrolizumab (4 cycles)	CF + pembrolizumab (3 cycles) → Oxaliplatin + 5FU + pembrolizumab (3 cycles)	CF + pembrolizumab (6 cycles)
Tumor response before CIP	SD	PR	PR
CIP grade	Grade 3	Grade 2-3 (difficult to determine)	Grade 2
Time of onset	Cycle 4	After 3 cycles of the new regimen	After 6 cycles
Main symptoms	Cough, dyspnea, fever	Cough, dyspnea (mimicking COPD exacerbation)	Dry cough, mild dyspnea
Treatment	Empiric antibiotics + corticosteroids	Empiric antibiotics + corticosteroids	Empiric antibiotics + corticosteroids
Response to CIP treatment	No improvement	Complete improvement	Complete improvement
Decision after CIP	Transition to palliative care	Discontinue pembrolizumab, maintenance chemotherapy	Successful pembrolizumab rechallenge
Final outcome	Disease progression, death	Stable disease	PR, no CIP recurrence

Abbreviations: CIP, checkpoint inhibitor pneumonitis; COPD, chronic obstructive pulmonary disease; SD, stable disease; PR, partial response; CF, cisplatin + 5-fluorouracil.

Differentiating CIP from infectious pneumonia, acute exacerbations of underlying lung disease, and other pulmonary conditions is a key step but is not always straightforward. Clinical symptoms (eg, cough, dyspnea, fever) can overlap considerably, and laboratory markers such as CRP are nonspecific. Procalcitonin can be helpful (often elevated in bacterial infection and normal in CIP), but it is not always available and is not fully specific for distinguishing infection from CIP. A recent case report showed that pembrolizumab-induced pneumonitis can mimic infection or exacerbate concomitant conditions such as congestive heart failure, and the nonspecific respiratory symptoms together with imaging findings often lead to delays in diagnosis and appropriate treatment [7]. A narrative review also noted that the symptoms of CIP can be subtle or nonspecific, necessitating a thorough and systematic evaluation to exclude other causes [8,9]. In Case 2, the patient's underlying COPD made it extremely difficult to distinguish CIP from an acute COPD exacerbation, as both conditions can present with cough, dyspnea, increased sputum production, and elevated CRP. Chest CT findings can be suggestive (acute COPD exacerbation often shows bronchial wall thickening and

emphysema; CIP often shows ground-glass opacities or organizing pneumonia patterns), but the 2 patterns can overlap. In Case 2, the diagnosis of CIP was made after excluding infection (normal procalcitonin, negative sputum cultures) and observing a response to corticosteroids. Furthermore, other specific causes must be excluded: pulmonary tuberculosis (especially in Vietnam, where the prevalence of latent tuberculosis is high), progression of pulmonary metastases (Case 1 illustrates the complexity when CIP occurs against a background of pre-existing pulmonary metastases), and tumor invasion of the trachea. Therefore, a comprehensive evaluation including a detailed history, physical examination, microbiological tests, and imaging is necessary for every patient with suspected CIP.

Corticosteroids are the mainstay of treatment for CIP, with the dose and duration depending on severity. For grade 2 CIP, ICI should be withheld and prednisone 0.5-1 mg/kg/day administered. For grade 3-4 CIP, ICI should be permanently discontinued, the patient hospitalized, and high-dose methylprednisolone (1-4 mg/kg/day) given. A slow corticosteroid taper (for 4-6 weeks or longer) is essential to avoid recurrence. A

recent meta analysis showed that rapid tapering is associated with a higher recurrence rate [10-12]. For corticosteroid refractory CIP, second line immunosuppressive agents such as tocilizumab, mycophenolate mofetil (MMF), infliximab, or intravenous immunoglobulin (IVIg) can be used [13-15]. A recent case report of a patient with metastatic esophageal cancer documented a significant response to the combination of tocilizumab and MMF after failure of high dose corticosteroids [14]. Another study also showed that tocilizumab is effective in treating corticosteroid refractory CIP and is not associated with worse outcomes [13].

From our 3 cases, the course of CIP can be classified into 3 main scenarios. Scenario 1 (Case 1): severe CIP (grade 3-4) with poor response to corticosteroids, often accompanied by rapid disease progression; the patient is transitioned to palliative care. Poor prognostic factors include multiple organ metastases, liver failure, poor PS, and lack of response to corticosteroids after 48-72 hours. Scenario 2 (Case 2): CIP responds well to corticosteroids, but the patient has multiple high-risk factors (advanced age, severe COPD, renal failure) that lead the multidisciplinary team to permanently discontinue pembrolizumab to avoid the risk of recurrence. Scenario 3 (Case 3): grade 1-2 CIP, good response to corticosteroids, no severe underlying lung disease, and a good response to ICI, allowing successful pembrolizumab rechallenge.

In all 3 cases, antibiotics were given empirically together with corticosteroids. It is important to distinguish this approach from true prophylaxis: the intent was not to prevent infection in asymptomatic patients, but to provide empiric coverage because active bacterial or opportunistic infection could not be confidently ruled out at the time of CIP diagnosis. This distinction is clinically meaningful, as the rationale shifts from “prevention” to “early treatment of possible occult co-infection.” The use of empiric antibiotics in this series reflects several realities common to Vietnam and many other low- and middle-income countries. First, patients with advanced esophageal cancer are frequently malnourished, have feeding tubes, and have received myelosuppressive chemotherapy, making them vulnerable to bacterial, tuberculous, and fungal respiratory infections [16]. Second, access to rapid and sensitive microbiological diagnostics—such as prompt procalcitonin measurement, high-quality sputum cultures, pneumococcal urinary antigen testing, or bronchoscopy with bronchoalveolar lavage—is often limited or delayed in public hospitals outside major cities. In such settings, waiting for definitive microbiological results before starting antibiotics while simultaneously giving high-dose corticosteroids may substantially increase the risk of infection-related deterioration [17]. Third, Vietnam has a high background prevalence of latent tuberculosis, and corticosteroids can trigger reactivation; empiric antibiotic regimens occasionally include anti-tuberculosis coverage when clinical suspicion is high, although this was not required in

our 3 patients. Fourth, the risk of opportunistic infections (eg, nocardiosis, pneumocystis) during corticosteroid therapy for CIP is documented in the literature, and clinicians in settings where these infections are diagnosed late may have a lower threshold for administering empiric antimicrobials [16]. It must be emphasized, however, that empiric antibiotics are not endorsed as a routine component of CIP management by international guidelines (eg, ESMO, NCCN, ASCO) [11]. The practice is not without harm: it can promote antimicrobial resistance, increase costs, cause drug-related adverse effects, and give a false sense of security if the diagnosis of CIP is delayed. Therefore, the decision to use empiric antibiotics must be individualized, based on clinical likelihood of infection, local antimicrobial resistance patterns, and the availability of timely diagnostic tests. This practice should not be interpreted as a standard recommendation but as a context-dependent adaptation. Whenever feasible, a thorough microbiological work-up should be performed before or shortly after starting corticosteroids and antibiotics, and the antibiotic regimen should be de-escalated or discontinued once infection is reasonably excluded [10,18].

The decision to rechallenge with pembrolizumab after CIP is one of the greatest challenges in the management of CIP. A recent retrospective study of 2673 patients showed that patients who were rechallenged with ICI after CIP had significantly longer progression-free survival (median PFS 13.67 vs 7.90 months, $P < 0.001$) and longer overall survival (median OS 33.77 vs 13.23 months, $P = 0.002$) compared with those who permanently discontinued ICI. The recurrence rate of CIP upon ICI rechallenge is approximately 32%, and most recurrences are of mild to moderate severity and are manageable. A recent review also emphasized that ICI rechallenge after CIP is associated with a significant risk of recurrence and should be carefully considered, especially in patients with organizing pneumonia patterns or prolonged ICI exposure [19-22]. Factors favoring rechallenge include grade 1-2 CIP, complete response to corticosteroids, absence of severe underlying lung disease, good response to ICI (PR or CR), and good PS. Factors arguing against rechallenge include grade 3-4 CIP, corticosteroid refractoriness, severe COPD, poor PS, and the availability of effective alternative treatment options [11]. In our Case 3, the patient met all the favorable criteria, and rechallenge was performed successfully without recurrence of CIP.

We acknowledge that our report has several limitations. The descriptive nature and small sample size mean that we cannot draw causal or generalizable conclusions; rather, we hope our observations offer practical illustrations of how differential diagnosis and rechallenge decisions might be approached in resource-limited settings. The lack of bronchoalveolar lavage (BAL)—a procedure not always accessible in our context—may have limited diagnostic precision, although this constraint itself

reflects the real-world reality we sought to highlight. The follow-up period after rechallenge in Case 3 was relatively short, and while no recurrence was observed, the long-term safety of this approach remains to be determined. We also recognize that the decision to rechallenge involves a delicate balance between potential tumor control and the risk of recurrent, possibly more severe pneumonitis. Furthermore, the concurrent use of empiric antibiotics introduces some confounding, making it difficult to attribute clinical improvement to any single intervention. For these reasons, we view the 3 observed trajectories as hypothesis-generating; they may serve as useful reference points, but larger, prospective, multicenter studies are needed to validate our observations.

Conclusions

Pembrolizumab-induced pneumonitis is a rare but potentially life-threatening complication in esophageal cancer. Early and accurate diagnosis—differentiating CIP from infection, COPD exacerbation, metastasis progression, and tuberculosis—is essential for favorable outcomes. Corticosteroids remain the mainstay of treatment; empiric antibiotics, used in all 3 cases, should be individualized and context-dependent rather than routine. Rechallenge decisions require careful consideration of CIP grade, treatment response, underlying lung disease, and anticipated benefit. Importantly, the 3 clinical trajectories described here are observations at a single institution and should be considered hypothesis-generating, not a validated framework. They may serve as practical reference points

for clinicians in Vietnam and similar resource-limited settings, but larger prospective studies are needed for validation.

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Institution Where Work Was Done

Vietnam National Cancer Hospital, Hanoi, Vietnam.

Ethical Approval and Informed Consent Statements

All patients included in this study have been fully informed about the manuscript, have been asked for their permission, and have provided their written informed consent for publication.

Declaration of Figures' Authenticity

All figures submitted have been created by the authors who confirm that the images are original with no duplication and have not been previously published in whole or in part.

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