Case Report

# A patient with advanced lung squamous cell carcinoma who failed to benefit from albumin bound paclitaxel plus pembrolizumab achieved partial response with second-line treatment of docetaxel plus pembrolizumab: a case report

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**Background:** Lung cancer, including squamous cell lung cancer and non-squamous non-small cell lung cancer (NSCLC), is the leading cause of cancer-related deaths. At present, for squamous cell lung cancer patients who have progressed on first-line chemotherapy plus immunotherapy, immunotherapy applied across the line is still inconclusive. Therefore, treatment for such patients is often challenging.

**Case Description:** We present a 53-year-old male patient who found lung mass in August 2021, without symptoms of cough, expectoration or hemoptysis. Through imaging examinations, we found he got tumor of upper lobe in right lung, with left lung metastasis and lymph node metastasis in the right hilar. Bronchoscopy biopsy showed poorly differentiated squamous cell carcinoma of the right lung. Gene screening showed *TP53* mutation. The patient was diagnosed as stage IVA (cT2aN1M1b) squamous cell carcinoma. He was administered four cycles of first-line albumin-binding paclitaxel + carboplatin combined with pembrolizumab. Reexamination of chest CT (2022-01-10) showed both right lung lesions and right hilar lymph nodes were progressed after progression free survival (PFS) of four months. After received two cycles of second-line therapy (docetaxel + carboplatin combined with pembrolizumab), the lung lesions shrunk significantly with efficacy of partial response (PR). As of 2022-05-18, he received a total of five cycles of second-line regimen. During this period, the disease was stable. No adverse events related to chemotherapy or immunotherapy were observed during the treatment. This is the first report of a successful case with an advanced lung squamous cell carcinoma patient who achieved disease remission after first-line progressed disease and second-line immunotherapy combined with chemotherapy. This case suggests that for such patients who fail to response to the first-line albumin-bound paclitaxel combined with immunotherapy, may get favorable response to docetaxel combined with immunotherapy. We need further investigations to validate that.

**Conclusions:** This case suggested advanced lung squamous cell carcinoma patients who have failed to respond to first-line albumin paclitaxel combined with immunotherapy may still benefit from second-line docetaxel combined with immunotherapy. In addition, presentation of the *TP53* mutation may be useful in predicting patients who may be responsive to docetaxel plus immunotherapy.

**Keywords:** Lung squamous cell carcinoma; docetaxel; pembrolizumab; *TP53*; case report

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Submitted Jul 29, 2022. Accepted for publication Sep 02, 2022.
doi: 10.21037/apm-22-960
**View this article at:** https://dx.doi.org/10.21037/apm-22-960

## Introduction

Lung cancer is the leading cause of cancer-related deaths in China and worldwide (1). Non-small cell lung cancer (NSCLC) is the most common type of lung cancer, with squamous cell lung cancer (SqCLC) being the second common pathological type of NSCLC, accounting for about 25–30% of NSCLC cases (2). More than 60% of SqCLC patients present at an advanced stage at the time of diagnosis (3). Combined chemotherapy and immunotherapy is currently the primary first-line treatment for advanced NSCLC patients without driver gene mutations (4). Chemotherapy monotherapy (including paclitaxel, docetaxel, gemcitabine, etc.) or immunotherapy (such as pembrolizumab) are the second-line recommendations, respectively (5). However, less than 20% of patients with NSCLC benefit from second-line therapy (6). For advanced NSCLC patients with disease progression after first-line treatment, selecting the appropriate second-line regimen to maximize survival benefit has become an urgent issue. At present, for patients who have progressed on first-line platinum-containing double-drug combination immunotherapy, whether immunotherapy is applied across the line is still inconclusive. Herein, we present a case of a 53-year-old man diagnosed with stage IVA right lung squamous cell lung cancer with left lung metastasis (cT2aN1M1b). After four cycles of first-line treatment with albumin-binding paclitaxel + carboplatin combined with pembrolizumab regimen, the patient presented with disease progression. He was subsequently administered four cycles of docetaxel + carboplatin combined with pembrolizumab. The lung lesions became significantly smaller with good efficacy [reaching partial response (PR)] and the patient only experienced mild adverse reactions. We present the following article in accordance with the CARE reporting checklist (available at https://apm.amegroups.com/article/view/10.21037/apm-22-960/rc).

## Case presentation

A 53-year-old man was diagnosed with a lung mass without cough, expectoration, nor hemoptysis, during his August 2021 health checkup. No family history or smoking history. Positron emission tomography/computed tomography (PET/CT) scans (performed on 2021-08-16) showed a massive soft tissue density shadow in the anterior segment of the upper lobe of the right lung, with a maximum cross-sectional diameter of 3.66 cm × 2.67 cm. A nodular high-density shadow was visible in the upper lobe of the left lung, with dimensions of 1.06 cm × 0.81 cm. High metabolic foci were found in both upper lobes. Considering the malignant lesions tended to be metastatic lesions in the left lung. There were multiple tiny nodules in both lungs without increased metabolism, and metastasis could not be excluded. Right hilar lymph node metastasis was detected. CT puncture biopsy of the upper tip bronchus of the right lung (performed on 2021-8-25) showed a medium-low differentiated squamous cell carcinoma. Genetic screening (performed on 2021-8-26) showed a *TP53* EXON6 C.641A>G P (H214R) change with mutation abundance of 59.86% and microsatellite stable (MSS). Immunohistochemistry (performed on 2021-9-2) showed poorly differentiated squamous cell carcinoma (in the upper tip bronchus of the right lung) with positive staining for P40(+), Ki-67(+60%), P63(+), programmed death ligand 1 (PD-L1; SP263) [tumor proportion score (TPS) <3%], and programmed death 1 (PD-1; lymphocytes +1%). There was no previous history of underlying medical conditions. History of alcohol abuse, smoking, and familial neoplasia were denied. The diagnosis at admission was stage IVA squamous cell carcinoma of the upper lobe of the right lung, with left lung metastasis (cT2aN1M1b). The patient received first-line albumin-binding paclitaxel + carboplatin combined with pembrolizumab regimen for four cycles from September 16, 2021. The regimen consisted of albumin-binding paclitaxel (260 mg/m$^2$) + carboplatin (AUC =6) d1 intravenous drip combined with pembrolizumab (200mg) d1 intravenous drip, q21d. The last cycle of chemotherapy was administered on December 9, 2021. Two-cycle chest enhancement CT showed stable disease (SD) and four-cycle chest enhancement CT showed anterior enlargement of the mediastinal soft tissue shadow in the upper lobe of the right lung. The efficacy evaluation was progressive disease (PD) (the mass in the anterior segment of the right lung upper lobe was 5.5 cm × 2.9 cm, larger than the anterior one) and progression free survival (PFS) was 4.0 months.

 

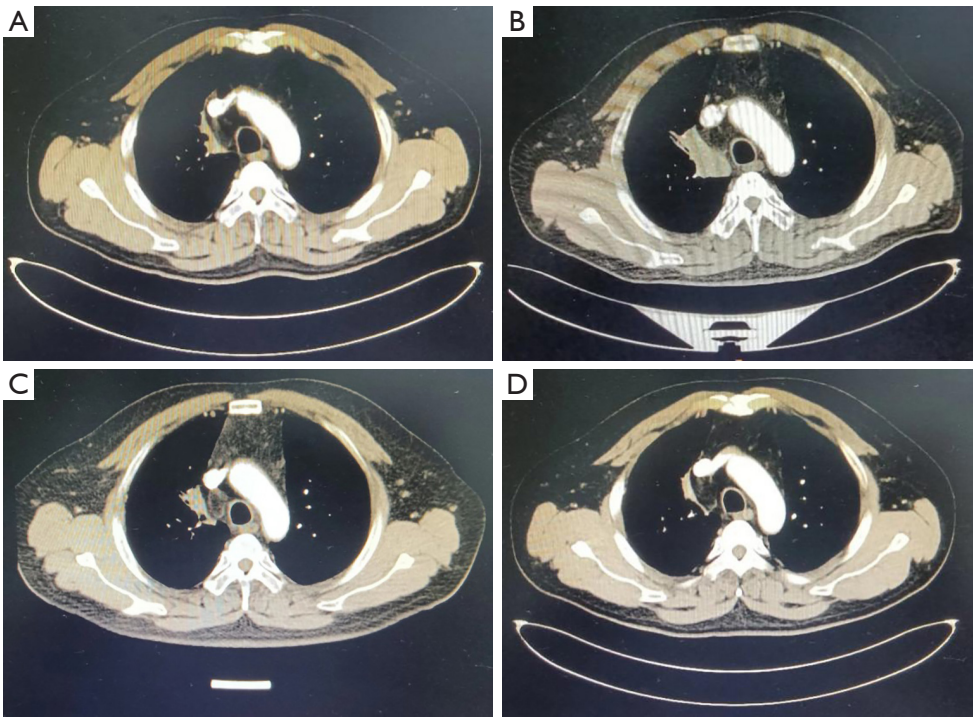


**Figure 1** Chest CT. (A) After 2 cycles of albumin-binding paclitaxel + carboplatin combined with pembrolizumab (2021-11-03). (B) After 4 cycles of albumin-binding paclitaxel + carboplatin combined with pembrolizumab (2022-01-11). (C) After 2 cycles of docetaxel + carboplatin combined with pembrolizumab (2022-03-15). (D) After 4 cycles of docetaxel + carboplatin combined with pembrolizumab (2022-05-17). CT, computed tomography.

The patient received second-line docetaxel + carboplatin combined with pembrolizumab regimen for four cycles from January 10, 2022. The regimen was as follows: docetaxel (75 mg/m$^2$) + carboplatin (AUC =6) d1 intravenous drip combined with pembrolizumab (200mg) d1 intravenous drip, q21d. The last treatment was administered on April 18, 2022. After two cycles, the evaluation was PR (43.6% reduction of the chest lesion, 3.1 cm × 1.1 cm) (*Figures 1*,*2*). During this period, myelosuppression accompanied with fever occurred after chemotherapy, and preventive leukocyte elevation therapy was given, with no other adverse events.

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee(s) and with the Declaration of Helsinki (as revised in 2013). Written informed consent was obtained from the patient for publication of this case report and accompanying images. A copy of the written consent is available for review by the editorial office of this journal.

## Discussion

At present, chemotherapy, targeted therapy, and immunotherapy are the three major treatment options for patients with advanced NSCLC, and these play an important role in the first-line setting. As the second most common pathological type of NSCLC, squamous cell lung cancer has unique molecular biological characteristics (including central tumor location, elderly patients, diagnosis with advanced disease, and more complications), with low epidermal growth factor receptor (*EGFR*) gene mutation rates and low anaplastic lymphoma kinase (ALK) gene fusiom rates, about 2.7% and 1.5–2.5%, respectively (7-9). Therefore, only a few patients can benefit from targeted therapy. For second-line treatment, there are far fewer options. While PD-1/PD-L1 inhibitor or docetaxel/gemcitabine chemotherapy is available, the actual efficacy is unsatisfactory. Clinically, more efficient regimens with lower toxicity are urgently needed to improve patients' survival and prognosis.

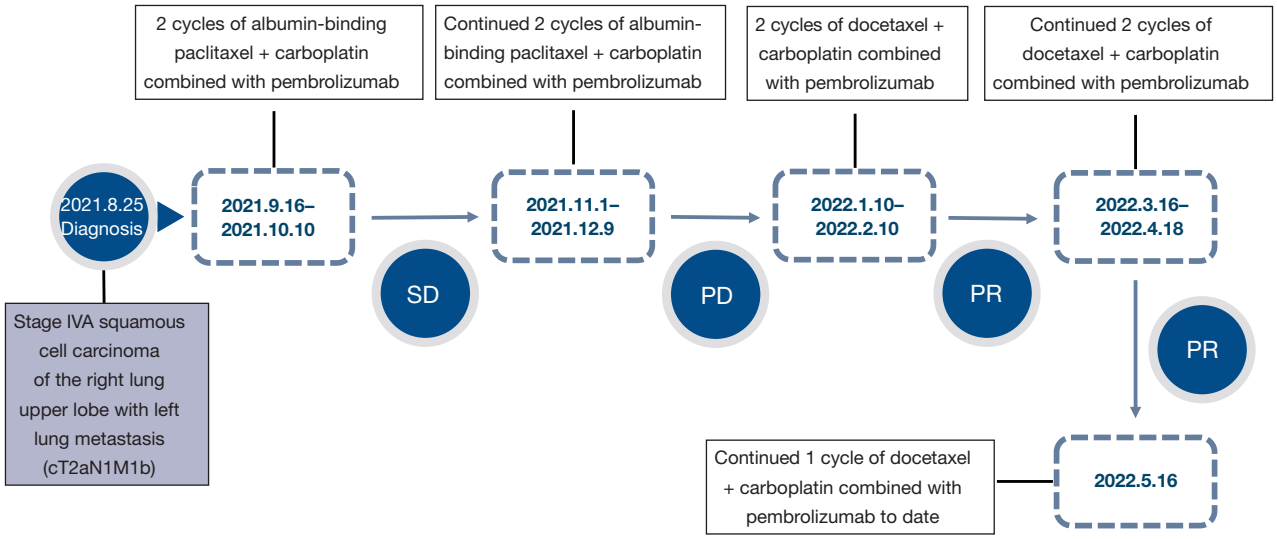


**Figure 2** The timeline of therapeutic process. This lung squamous cell cancer patient was diagnosed as advanced disease with left lung metastasis (cT2aN1M1b). After received 4 cycles of albumin-binding paclitaxel and carboplatin combined with pembrolizumab, the lung lesions progressed. Then the therapy was switched to docetaxel and carboplatin combined with pembrolizumab for 5 cycles, the best efficacy was PR during the treatment. SD, stable disease; PD, progressive disease; PR, partial remission.

Albumin-binding paclitaxel (hereinafter referred to as "albumin paclitaxel") and docetaxel are commonly used as first- and second-line chemotherapy drugs for advanced SqCLC, both of which belong to the taxane class of chemotherapy drugs. Taxanes can also include paclitaxel injection and paclitaxel liposome. Although the mechanisms are similar, a previous study has shown that they differ in their pharmaceutical properties and antitumor activities (10). Considering drug components and mechanisms, albumin paclitaxel is a novel paclitaxel antitumor agent, and the main active component is paclitaxel (11). It uses human albumin as a carrier and does not need polyoxyethylene castor oil as a cosolvent carrier. Tumor cells have a high metabolic uptake of albumin, which enters through the gp60 transcytosis pathway and the secreted protein acidic and rich in cysteine (SPARC) pathway. The cytotoxic drug is then released, allowing for a targeted effect. By using albumin, the allergic reaction associated with using castor oil as the paclitaxel cosolvent is avoided (12). Docetaxel is a second-generation high-efficiency taxane antitumor drug synthesized by modification of the basic structure of paclitaxel. The main active substance is a derivative of docetaxel, which blocks the cell cycle in stage M by inhibiting the normal recombination of intracellular microtubule network, thereby inhibiting the mitosis and cell proliferation of tumor cells to achieve its antitumor effect (13). Compared with traditional paclitaxel, docetaxel has a stronger affinity with tubulin at the same dose, and the combination of the two does not change the number of filaments. On the other hand, docetaxel has a longer retention time in cells, and a study has shown that docetaxel has a higher antitumor activity, which is about 2 times that of paclitaxel (14). In addition, it has been reported that docetaxel can also promote tumor cell apoptosis by down-regulating the expression of the *BCL-2* gene, thereby improving the survival rate of patients. In addition, a study *in vivo* and *in vitro* has found that docetaxel has a higher affinity for the beta subunit of tubulin compared with paclitaxel, so that a higher intracellular drug concentration can be achieved, resulting in a lower frequency of drug efflux pumps, and greater tumor growth inhibition (13).

In the present case, our patient developed lung lesions after receiving four cycles of the first-line albumin-binding paclitaxel + carboplatin combined with pembrolizumab regimen. The patient was then given four cycles of the second-line docetaxel + carboplatin combined with pembrolizumab regimen and the efficacy evaluation was PR. The above-mentioned characteristics of docetaxel may explain the lack of cross-resistance to docetaxel after previous paclitaxel treatment. Unfortunately, there is a

 

paucity of clinical studies evaluating the role of docetaxel as a second-line treatment for NSCLC patients, which limits our understanding of cross-resistance in the clinical setting (15-17). A prospective phase II study by Macedo-Pérez *et al.*, analyzing the response to docetaxel in advanced NSCLC patients after first-line paclitaxel treatment, found that the long-term PFS of first-line paclitaxel plus platinum was associated with the improvement of PFS after second-line docetaxel treatment (18). These findings suggested that previous treatment with paclitaxel does not exclude a favorable response to docetaxel. Therefore, some patients previously treated with paclitaxel may achieve a good response to the second-line taxane treatment, possibly due to the intrinsic sensitivity of the tumor to this series of drugs.

A report by Goto *et al.* (19) found that previous paclitaxel use had no effect on the response or survival of patients with subsequent docetaxel treatment. Rather, the response of advanced NSCLC patients to previous chemotherapy has predictive value for subsequent docetaxel treatment. Two phase III clinical trials (20,21) also indicated that the response to second-line docetaxel was not associated with prior paclitaxel treatment exposure or efficacy. However, none of these studies evaluated clinical pathology features nor molecular differences between patients who received first-line paclitaxel and those who received other taxanes (such as docetaxel) as the second-line treatment.

With the continuous development of therapeutic methods for the treatment of NSCLC, taxanes have often been combined with other drugs in clinical practice, and drug-drug interactions may affect the therapeutic effect to a certain extent. Recent data (22-26) emphasized that chemotherapy can enhance the immunogenicity and destroy the immune resistance of the tumor and its microenvironment. In addition, chemotherapy can also induce the generation of subclone new antigen, which helps to increase tumor mutation, thus activating cellular immune responses and enhancing the sensitivity of immune checkpoint inhibitors (ICIs). Therefore, when the chemotherapy drugs kill the tumor cells, they also enable the patients to produce lymphocytes with improved function and enhance the anti-tumor immune response capability of the body (27,28). The potential synergistic antitumor effects of checkpoint inhibitors combined with chemotherapy represented by PD-1/PD-L1 have been demonstrated in multiple solid tumors (29-32). Similarly, in the PROLUNG phase II study (33), pembrolizumab plus docetaxel was shown to significantly prolong the PFS in patients with NSCLC compared to docetaxel alone. A retrospective study by Huang *et al.* (34) demonstrated that ICIs combined with chemotherapy or antiangiogenic agents can provide survival benefits for NSCLC patients who failed to respond to first-line therapy. A prospective phase II study in China (35) indicated that the combination of sintilimab and docetaxel significantly improved PFS and tumor response in previously treated patients with advanced NSCLC. These data support the feasibility and potential benefits of docetaxel combined with ICIs in the second-line treatment of advanced NSCLC. In the present case, on the basis of disease progression after four cycles of first-line treatment with albumin paclitaxel and pembrolizumab, the chemotherapy drug was replaced with docetaxel as second-line treatment and the disease showed a partial response trend. Whether docetaxel may exert a superior synergistic anti-tumor efficacy compared to albumin paclitaxel warrants further investigation.

Notably, genetic testing in our patient revealed the presence of a *TP53* mutation with a high mutation abundance of 59.86%. Potential survival benefits have been observed with ICI therapy in patients with NSCLC harboring the *KRAS/TP53* mutation or co-mutations, and thus, the *TP53* mutation may be considered a potential predictive biomarker of ICI therapy outcomes (34,36). Indeed, it may provide potential evidence for showing the efficacy of PR in our patient after 8 cycles of treatment with pembrolizumab. ICIs combined with chemotherapy may be a novel treatment strategy for patients with *TP53* mutations and future studies are warranted.

Second-line ICIs combined with chemotherapy may have potential clinical benefits for NSCLC patients who have failed first-line treatment. As shown in this case study, the combination of pembrolizumab and docetaxel was beneficial in a patient who had previously failed to respond to albumin paclitaxel plus pembrolizumab. This suggested that patients with advanced lung squamous cell carcinoma who fail first-line immunotherapy with paclitaxel may achieve a good response to docetaxel combined with immunotherapy, and this may be related to the differences between the pharmacological properties of albumin paclitaxel and docetaxel and their antitumor activities. Alternatively, it may be related to the different cross-resistance ranges between the two drugs. In addition, due to the presence of ICIs, the drug-drug interaction between chemotherapy and immunotherapy may also affect the therapeutic outcome.

 

Further studies should be conducted to determine whether docetaxel may exert a superior synergistic antitumor effect compared to albumin paclitaxel. In addition, the *TP53* mutation may be a promising biomarker for predicting the therapeutic effect of clinical ICIs. This may be useful in identifying the beneficiary population for chemotherapy, especially docetaxel combined with immunotherapy. However, due to the limited sample size, insufficient data, and the possible combination of various other factors, a larger patient population and specialized pharmacological and clinical studies are required in the future to confirm the potential benefits, mechanisms, and beneficiary population identified herein.

## Acknowledgments

*Funding:* None.

## Footnote

*Reporting Checklist*: The authors have completed the CARE reporting checklist. Available at https://apm.amegroups.com/article/view/10.21037/apm-22-960/rc

*Conflicts of Interest:* All authors have completed the ICMJE uniform disclosure form (available at https://apm.amegroups.com/article/view/10.21037/apm-22-960/coif). The authors have no conflicts of interest to declare.

*Ethical Statement:* The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee(s) and with the Declaration of Helsinki (as revised in 2013). Written informed consent was obtained from the patient for publication of this case report and accompanying images. A copy of the written consent is available for review by the editorial office of this journal.



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(English Language Editor: J. Teoh)

**Cite this article as:** Zhang F, Xu Y, Guo S, Li S, Ma K, Wang J, Wei S. A patient with advanced lung squamous cell carcinoma who failed to benefit from albumin bound paclitaxel plus pembrolizumab achieved partial response with second-line treatment of docetaxel plus pembrolizumab: a case report. Ann Palliat Med 2022;11(9):3020-3027. doi: 10.21037/apm-22-960

 