

Efficacy and Safety Analysis of Sintilimab Combined with Chemotherapy in the Treatment of Advanced Non-small Cell Lung Cancer

Fushuang Qiao

¹School of Clinical Medicine, Chengdu Medical College, Chengdu 610500, Sichuan, China.

²Department of Pulmonary and Critical Care Medicine, The First Affiliated Hospital of Chengdu Medical College, Chengdu 610500, Sichuan, China.

³Key Laboratory of Geriatric Respiratory Diseases of Sichuan Higher Education Institutes, Chengdu 610500, Sichuan, China.

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***Corresponding author:** Fushuang Qiao, School of Clinical Medicine, Chengdu Medical College, Chengdu 610500, Sichuan, China; Department of Pulmonary and Critical Care Medicine, The First Affiliated Hospital of Chengdu Medical College, Chengdu 610500, Sichuan, China; Key Laboratory of Geriatric Respiratory Diseases of Sichuan Higher Education Institutes, Chengdu 610500, Sichuan, China.

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Abstract

Objective: Taking the clinical treatment of advanced non-small cell lung cancer (NSCLC) as the research starting point, this study explores the practical application value of sintilimab combined with chemotherapy. **Methods:** The study was conducted from December 2024 to December 2025. A total of 86 NSCLC patients at stage IIIB-IV were selected from our hospital and randomly divided into two groups. The reference group (43 patients) received conventional chemotherapy, while the observation group (43 patients) received sintilimab in addition to the chemotherapy. After four treatment cycles, the clinical efficacy, serum tumor marker levels, and safety were compared between the two groups. **Results:** The objective response rate (ORR) and disease control rate (DCR) in the observation group were significantly higher than those in the reference group ($P < 0.05$). The levels of neuron-specific enolase (NSE), carbohydrate antigen 19-9 (CA19-9), and squamous cell carcinoma-related antigen (SCC-Ag) in the observation group were significantly lower than those in the reference group ($P < 0.05$). There was no significant difference in chemotherapy-related hematological and gastrointestinal adverse reactions between the two groups ($P > 0.05$). **Conclusion:** Based on the actual situation of patients with stage IIIB-IV advanced NSCLC, combining sintilimab with platinum-based double-drug chemotherapy can significantly improve clinical efficacy, reduce tumor marker levels, and has controllable safety, making it worthy of promotion.

Keywords

Sintilimab; chemotherapy; advanced non-small cell lung cancer; clinical efficacy; safety

Non-small cell lung cancer (NSCLC) is the most common pathological type of lung cancer. In advanced stages, it is prone to hematogenous and lymphatic metastasis, affecting vital organs throughout the body and endangering life safety [1]. Since advanced NSCLC has lost the opportunity for surgical radical treatment, chemotherapy is often used clinically to control tumor growth and prolong patients' survival. However, Monotherapy chemotherapy is prone to secondary drug resistance. It not only kills cancer cells but also damages rapidly proliferating normal cells such as bone marrow and gastrointestinal cells. Moreover, patients with poor physical condition and impaired organ function cannot tolerate double-drug chemotherapy. Sintilimab is a PD-1 inhibitor that can block the immune escape pathway of tumor cells. The combined application of the two can achieve long-term inhibition of tumor recurrence and

metastasis through the immune memory effect [2]. Based on this background, our hospital selected 86 patients with advanced NSCLC to conduct a combined trial, and the report is as follows.

1. Materials and Methods

1.1 General Information

The study was approved by the Medical Ethics Committee. From December 2024 to December 2025, 86 patients with advanced NSCLC were selected for a group trial. In the reference group, there were 25 males (58.14%) and 18 females (41.86%), with an average age of (59.27 ± 6.38) years and an average of (12.38 ± 2.92) years of education. Among them, 31 cases (72.09%) were adenocarcinoma, and 12 cases (27.91%) were squamous cell carcinoma. In the observation group, there were 26 males (60.47%) and 17 females (39.53%), with an average age of (59.46 ± 6.59) years and an average of (12.14 ± 2.46) years of education. Among them, 32 cases (74.42%) were adenocarcinoma, and 11 cases (25.58%) were squamous cell carcinoma.

1.1.1 Inclusion criteria

- (1) Diagnosed as stage IIIB-IV advanced NSCLC by cytological puncture examination;
- (2) No indication for surgical treatment;
- (3) Physical condition can tolerate chemotherapy and immuno-combined therapy;
- (4) Expected survival period ≥ 3 months;
- (5) Meet the indications for chemotherapy and immunotherapy drugs.

1.1.2 Exclusion criteria

- (1) Complicated with other primary malignant tumor diseases;
- (2) Already participating in similar trials during the same period;
- (3) Has a history of anti-tumor treatment with immune agents or a history of autoimmune diseases or congenital immune deficiency;
- (4) Complicated with vital organ failure;
- (5) Unable to cooperate with treatment and follow-up.

1.2 Methods

1.2.1 Reference Group: Simple platinum-based double-drug combined chemotherapy

- For adenocarcinoma patients: Pemetrexed 500 mg/m^2 + Cisplatin 75 mg/m^2 were administered by intravenous drip for chemotherapy.
- For squamous cell carcinoma patients: Gemcitabine 1250 mg/m^2 + Carboplatin (AUC = 5) were administered by intravenous drip for chemotherapy.

The doses of chemotherapy drugs for all patients were calculated according to body surface area. Three weeks constituted one treatment cycle, and all patients needed to complete four cycles of chemotherapy.

1.2.2 Observation Group: Sintilimab combined with the above treatment

200 mg of sintilimab was slowly infused intravenously in a conventional manner. The infusion speed was adjusted according to the patient's tolerance. The drug was administered once every three weeks, synchronously with chemotherapy.

1.3 Observation Indicators

- (1) **Efficacy evaluation:** According to the unified standard of Response Evaluation Criteria in Solid Tumors (RECIST 1.1), the treatment efficacy was divided into complete response (CR), partial response (PR), stable disease (SD), and progressive disease (PD). The objective response rate (ORR) and disease control rate (DCR) were compared [3].
- (2) **Evaluation of serum tumor marker levels:** Blood samples were collected to detect NSE, CA19-9, and SCC-Ag.
- (3) **Safety evaluation:** The occurrence of chemotherapy-related hematological and gastrointestinal adverse reactions in the two groups of patients was recorded in detail.

1.4 Statistical Methods

SPSS 28.0 statistical software was used to analyze the data. Measurement data were expressed as ($\bar{x} \pm s$) and analyzed using the t-test. Count data were expressed as [n (%)] and analyzed using the χ^2 test. A P-value < 0.05 indicated a statistically significant difference.

2. Results

2.1 Comparison of Clinical Treatment Efficacy Between the Two Groups

After treatment with simple platinum-based double-drug combined chemotherapy + sintilimab, the ORR and DCR in the observation group were significantly higher than those in the reference group ($P < 0.05$), as shown in Table 1.

Table 1. Comparison of Clinical Treatment Efficacy between the Two Groups [n (%)]

Group	Number of Cases	CR	PR	SD	PD	ORR	DCR
Observation group	43	0 (0.00)	23 (53.49)	16 (37.21)	4 (9.30)	23 (53.49)	39 (90.70)
Reference group	43	0 (0.00)	12 (27.91)	19 (44.19)	12 (27.91)	12 (27.91)	31 (72.09)
χ^2						5.793	4.198
<i>P</i>						0.015	0.042

2.2 Comparison of Serum Tumor Marker Levels Between the Two Groups

After treatment, the levels of NSE, CA19-9, and SCC-Ag in the observation group were lower than those in the reference group ($P < 0.05$), as shown in Table 2.

Table 2. Comparison of Serum Tumor Marker Levels between the Two Groups ($\bar{x} \pm s$)

Observation Indicator	Time Point	Observation Group (n = 43)	Reference Group (n = 43)	<i>t</i>	<i>P</i>
NSE (ng/mL)	Before Treatment	40.54 ± 6.42	40.81 ± 6.12	0.246	0.179
	After Treatment	19.72 ± 3.51	24.32 ± 4.46	7.193	<0.001
CA19-9 (U/mL)	Before Treatment	59.81 ± 7.96	59.03 ± 7.34	0.341	0.247
	After Treatment	21.93 ± 3.74	28.92 ± 4.17	8.372	<0.001
SCC-Ag (ng/mL)	Before Treatment	3.13 ± 0.62	3.09 ± 0.74	0.284	0.315
	After Treatment	1.23 ± 0.37	2.18 ± 0.53	8.092	<0.001

2.3 Comparison of the Incidence of Adverse Reactions Between the Two Groups

There was no significant difference in chemotherapy-related hematological and gastrointestinal adverse reactions between the two groups ($P > 0.05$), as shown in Table 3.

Table 3. Comparison of the Incidence of Adverse Reactions between the Two Groups [n (%)]

Observation Indicator	Observation Group (n=43)	Reference Group (n=43)	χ^2	<i>P</i>
Nausea and vomiting	13 (30.23)	14 (32.56)	0.274	0.594
Thrombocytopenia	12 (27.91)	13 (30.23)	0.287	0.615
Neutropenia	15 (34.88)	16 (37.21)	0.462	0.513
Anemia	23 (53.49)	24 (55.81)	0.385	0.735
Rash	22 (51.16)	21 (48.84)	0.763	0.282
Pneumonia	7 (16.28)	8 (18.60)	0.276	0.371
Hypoproteinemia	10 (23.26)	11 (25.58)	0.351	0.665

3. Discussion

The treatment goal for advanced NSCLC is to control tumor progression and prolong the long-term survival cycle. Although simple platinum-based combined chemotherapy can temporarily inhibit tumor proliferation and relieve clinical symptoms, long-term application is prone to tumor secondary drug resistance and cannot meet the actual diagnostic and treatment needs of patients [4]. Sintilimab is the first domestically approved fully humanized PD-1 monoclonal antibody in China. It can help patients' own T lymphocytes restore anti-tumor immune activity by blocking the PD-1/PD-L1 immune suppression pathway. In this study, the ORR and DCR in the observation group were significantly higher than those in the reference group ($P < 0.05$), and the tumor marker levels in the observation group were lower than those in the reference group ($P < 0.05$), indicating that the combined treatment can improve clinical efficacy and reduce tumor marker levels. Chemotherapy drugs can directly act on NSCLC cells, block cell mitosis by destroying tumor cell DNA synthesis, and achieve the goal of shrinking the primary tumor lesion. However, simple chemotherapy cannot clear circulating tumor cells and micrometastases. Sintilimab can help patients restore anti-tumor immune activity by relieving the immune suppression of tumor cells on T lymphocytes [5]. At the same time, advanced NSCLC is often in an immune-suppressive microenvironment. Chemotherapy drugs can reshape the tumor immune microenvironment by inducing immunogenic cell death of NSCLC cells, while sintilimab can restore T cell function by blocking immune escape [6]. In addition, the high level of tumor markers is often related to the fact that simple chemotherapy is difficult to effectively clear circulating tumor cells and micrometastases. Combining sintilimab can clear circulating tumor cells and micrometastases through activated immune cells, thereby blocking the ectopic synthesis and release of markers and achieving the goal of reducing marker levels [7].

The study found that there was no significant difference in chemotherapy-related hematological and gastrointestinal adverse reactions between the two groups ($P > 0.05$), indicating that the overall safety of the combined treatment is good, which is consistent with the research results of Zhu Xingzhou [8]. Platinum, pemetrexed, and other chemotherapy drugs mainly attack rapidly proliferating cells. They can cause neutropenia, anemia, thrombocytopenia and induce nausea, vomiting, and loss of appetite by damaging gastrointestinal mucosal epithelial cells while killing tumor cells. At the same time, chemotherapy drugs are metabolized by the liver and excreted by the kidneys, and patients may develop liver and kidney function damage due to an increased burden on these organs. Especially for patients with advanced NSCLC who often have problems such as malnutrition and low immunity, they may develop adverse reactions due to their weak organ reserve capacity. Sintilimab is an immune checkpoint inhibitor that only acts on the PD-1/PD-L1 immune pathway and thus does not aggravate adverse reactions such as neutropenia and anemia.

In conclusion, in the clinical treatment of advanced NSCLC, the combined application of chemotherapy and sintilimab can significantly improve clinical efficacy, reduce tumor marker levels, and has good overall safety, making it worthy of promotion.

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